

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
12-15	C4591001 1005 10051328	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1005 10051410	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1005 10051412	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
	C4591001 1005 10051414	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Autism spectrum disorder	01JAN2010		Y
	C4591001 1005 10051418	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1005 10051419	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1005 10051420	Immune system disorders	Hypersensitivity	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1005 10051422	Immune system disorders	Food allergy	01JAN2014		Y
		Nervous system disorders	Migraine without aura	01JAN2018		Y
	C4591001 1005 10051425	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051429	Musculoskeletal and connective tissue disorders	Short stature	01OCT2019		Y
	C4591001 1005 10051431	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1005 10051436	Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1005 10051437	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1005 10051438	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
	C4591001 1005 10051439	Endocrine disorders	Hypothyroidism	01JAN2017		Y
	C4591001 1005 10051440	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2011	31DEC2011	N
	C4591001 1005 10051441	Immune system disorders	Hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N
	C4591001 1005 10051444	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1005 10051445	Psychiatric disorders	Anxiety	01OCT2020		Y
	C4591001 1005 10051449	Immune system disorders	Hypersensitivity	01JAN2010		Y
	C4591001 1005 10051451	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1006 10061183	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1006 10061184	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1006 10061188	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1006 10061189	Immune system disorders	Hypersensitivity	01JAN2011		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Investigations	Blood pressure increased	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2009		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1006 10061190	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1006 10061191	Immune system disorders	Seasonal allergy	19MAR2012		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	07MAR2017		Y
		Nervous system disorders	Migraine	04NOV2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	27FEB2013		Y
			Depression	06JUN2019		Y
			Insomnia	02JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	21NOV2016		Y
	C4591001 1006 10061196	Gastrointestinal disorders	Toothache	01OCT2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1006 10061200	Skin and subcutaneous tissue disorders	Acne	19JUN2019		Y
	C4591001 1006 10061201	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JUL2020		Y
	C4591001 1006 10061203	Immune system disorders	Allergy to animal	01JAN2013		Y
			Hypersensitivity	01FEB2013		Y
			Seasonal allergy	01FEB2013		Y
		Nervous system disorders	Headache	01AUG2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1006 10061206	Immune system disorders	Perennial allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
			Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
	C4591001 1006 10061207	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1006 10061209	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
	C4591001 1006 10061212	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1006 10061214	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	27MAR2013		Y
	C4591001 1006 10061219	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1006 10061220	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Muscle strain	01NOV2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1006 10061221	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	20JUL2018		Y
			Temporomandibular joint syndrome	12SEP2019		Y

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstruation irregular	03JAN2019		Y
	C4591001 1006 10061223	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1006 10061224	Immune system disorders	Allergy to animal	01JAN2015		Y
		Infections and infestations	Chronic sinusitis	13NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	13NOV2019		Y
			Nasal turbinate hypertrophy	13NOV2019		Y
			Rhinitis allergic	01JAN2015		Y
	C4591001 1006 10061227	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1006 10061228	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01DEC2019		Y
	C4591001 1006 10061229	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01APR2017		Y
	C4591001 1006 10061230	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1006 10061231	Psychiatric disorders	Anxiety	01JAN2012		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2013		Y
			Obsessive-compulsive disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012	08AUG2014	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Adenoidectomy	08AUG2014	08AUG2014	N
			Turbinectomy	08AUG2014	08AUG2014	N
	C4591001 1006 10061232	Surgical and medical procedures	Bone operation	06OCT2019	06OCT2019	N
	C4591001 1006 10061234	Musculoskeletal and connective tissue disorders	Scoliosis	05FEB2019		Y
	C4591001 1006 10061235	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1006 10061236	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1006 10061237	Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01SEP2020		Y
		Injury, poisoning and procedural complications	Facial bones fracture	04AUG2013	08AUG2013	N
			Jaw fracture	04AUG2013	08AUG2013	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
			Major depression	01NOV2019		Y
		Surgical and medical procedures	Fracture treatment	08AUG2013	08AUG2013	N

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061239	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1006 10061241	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1006 10061242	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1006 10061248	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1006 10061249	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1006 10061250	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1006 10061252	Immune system disorders	Allergy to animal	01JAN2008		Y
			Hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1006 10061253	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Wrist fracture	01MAY2020	31JUL2020	N
	C4591001 1006 10061254	Gastrointestinal disorders	Abdominal pain upper	06JUN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JUN2020		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JUL2020		Y
	C4591001 1006 10061256	Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Adjustment disorder with depressed mood	01APR2020	31JUL2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1006 10061257	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
	C4591001 1006 10061258	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1006 10061259	Injury, poisoning and procedural complications	Ligament sprain	24AUG2020		Y
		Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1006 10061260	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1006 10061261	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 2006		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1006 10061262	Skin and subcutaneous tissue disorders	Acne cystic	01JUL2020		Y
	C4591001 1006 10061263	Nervous system disorders	Headache	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061265	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Growth retardation	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1006 10061266	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1006 10061269	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Knee deformity	01JAN2008		Y
		Surgical and medical procedures	Epiphysiodesis	01DEC2020	01DEC2020	N
	C4591001 1006 10061270	Immune system disorders	Allergy to plants	01JAN2017		Y
			Rubber sensitivity	(b) (6) 2005		Y
	C4591001 1006 10061271	Infections and infestations	Meningitis	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01NOV2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1006 10061272	Psychiatric disorders	Aggression	01JAN2017	31DEC2017	N
			Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2014		Y
			Disruptive mood dysregulation disorder	01JAN2012		Y
			Insomnia	01JAN2014		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nightmare	01JAN2015		Y
			Post-traumatic stress disorder	06NOV2015		Y
			Separation anxiety disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1006 10061273	Nervous system disorders	Headache	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1006 10061274	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Insomnia	01AUG2019		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1006 10061276	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1006 10061277	Eye disorders	Hypermetropia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1006 10061279	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2007	29DEC2020	N
	C4591001 1006 10061280	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1006 10061282	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1006 10061283	Infections and infestations	Appendicitis	30SEP2009	30SEP2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1006 10061286	Surgical and medical procedures	Appendicectomy	30SEP2009	30SEP2009	N
		Eye disorders	Eyelid ptosis	01JAN2007		Y
		Immune system disorders	Allergy to animal	01JAN2015		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1006 10061287	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1006 10061288	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Osteomyelitis	01NOV2007	31DEC2007	N
			Paronychia	01JAN2017		Y
			Pharyngitis	01JAN2006	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N

16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1006 10061289	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1006 10061290	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Contusion	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1006 10061291	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01JAN2011	31DEC2018	N
		Surgical and medical procedures	Ear operation	01JAN2018	31DEC2018	N
	C4591001 1006 10061292	Injury, poisoning and procedural complications	Nasal injury	01JUN2020	04JUN2020	N
		Metabolism and nutrition disorders	Dairy intolerance	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01AUG2019	14OCT2019	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	04JUN2020	04JUN2020	N
			Spinal fusion surgery	14OCT2019	14OCT2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061293	Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1006 10061294	Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1006 10061295	Immune system disorders	Allergy to animal	01JAN2015		Y
			Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1006 10061296	Infections and infestations	Appendicitis	18NOV2016	18NOV2016	N
		Surgical and medical procedures	Appendicectomy	18NOV2016	18NOV2016	N
	C4591001 1006 10061298	Immune system disorders	Food allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1006 10061299	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1006 10061300	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1007 10071409	Nervous system disorders	Febrile convulsion	(b) (6) 2007	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2009	N
	C4591001 1007 10071417	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1007 10071429	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1007 10071469	Congenital, familial and genetic disorders	Chondrodystrophy	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071471	Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2006	31DEC2011	N
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1007 10071472	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1007 10071480	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN2006		Y
	C4591001 1007 10071483	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1007 10071484	Immune system disorders	Drug hypersensitivity	(b) (6) 2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071485	Immune system disorders	Serum sickness	01JAN2013		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
	C4591001 1007 10071488	Eye disorders	Blepharitis	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071492	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2020		Y
		Ear and labyrinth disorders	Vestibular disorder	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1007 10071495	Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1007 10071497	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071499	Immune system disorders	Drug hypersensitivity	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071500	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1007 10071504	Immune system disorders	Drug hypersensitivity	(b) (6) 2005		Y
	C4591001 1007 10071505	Congenital, familial and genetic disorders	Cerebral palsy	(b) (6) 2008		Y
		Nervous system disorders	Hydrocephalus	(b) (6) 2008		Y
			Migraine	01JAN2015		Y
			Seizure	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
		Surgical and medical procedures	Portal shunt procedure	01JAN2019		Y
	C4591001 1007 10071511	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
			Chronic tonsillitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Appendicectomy	01JAN2011	31DEC2011	N
	C4591001 1007 10071512	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1007 10071514	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071515	Immune system disorders	Drug hypersensitivity	(b) (6) 2008		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1007 10071516	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071517	Immune system disorders	Drug hypersensitivity	01JAN2010		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071518	Nervous system disorders	Headache	12OCT2020		Y
	C4591001 1007 10071520	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1007 10071521	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1007 10071522	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1007 10071524	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN2015		Y
	C4591001 1007 10071525	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN2012		Y
	C4591001 1007 10071527	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1007 10071531	Ear and labyrinth disorders	Ear pain	05DEC2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1007 10071533	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071535	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1007 10071536	Nervous system disorders	Migraine	01JAN2011		Y
	C4591001 1007 10071537	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1007 10071539	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2006		Y
			Milk allergy	01JAN2006		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071541	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071542	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1007 10071543	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nephroblastoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Nephrectomy	01JAN2007		Y
	C4591001 1007 10071544	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1007 10071546	Immune system disorders	Drug hypersensitivity	(b) (6) 2005		Y
			Seasonal allergy	(b) (6) 2005		Y
		Infections and infestations	Sinusitis	09NOV2020	13NOV2020	N
	C4591001 1007 10071547	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1007 10071550	Immune system disorders	Seasonal allergy	(b) (6) 2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1007 10071551	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1007 10071552	Immune system disorders	Allergy to animal	01JAN2008		Y
			Drug hypersensitivity	01JAN2007		Y
			Hypersensitivity	01JAN2008		Y
	C4591001 1007 10071557	Skin and subcutaneous tissue disorders	Acne cosmetica	01JAN2019		Y
	C4591001 1007 10071558	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071560	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2019		Y
	C4591001 1007 10071561	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1007 10071563	Immune system disorders	Food allergy	01JAN2011		Y
	C4591001 1007 10071567	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1007 10071570	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2019		Y
			Impulsive behaviour	01AUG2019		Y
			Insomnia	01MAR2019		Y
	C4591001 1007 10071573	Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
	C4591001 1007 10071574	Injury, poisoning and procedural complications	Lower limb fracture	01AUG2020	30SEP2020	N
	C4591001 1007 10071575	Immune system disorders	Food allergy	01JAN2008		Y
	C4591001 1007 10071577	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1007 10071581	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071583	Immune system disorders	Seasonal allergy	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071584	Immune system disorders	Allergy to animal	01JAN2010		Y
	C4591001 1007 10071585	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1007 10071586	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1007 10071587	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1007 10071590	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2017		Y
		Endocrine disorders	Precocious puberty	01JAN2017		Y
	C4591001 1007 10071591	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2017		Y
	C4591001 1007 10071592	Ear and labyrinth disorders	Deafness	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1007 10071593	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2011		Y
	C4591001 1007 10071594	Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1007 10071596	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1007 10071599	Immune system disorders	Allergy to animal	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2018		Y
	C4591001 1007 10071600	Renal and urinary disorders	Renal cyst	01JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071601	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071603	Endocrine disorders	Hypothyroidism	30NOV2020		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	17DEC2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1007 10071605	Immune system disorders	Food allergy	01JAN2012		Y
				01MAR2020		Y
	C4591001 1007 10071606	Psychiatric disorders	Anxiety	01SEP2020		Y
	C4591001 1007 10071608	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1007 10071609	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1007 10071613	Renal and urinary disorders	Single functional kidney	(b) (6) 2007		Y
	C4591001 1007 10071617	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1007 10071618	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071619	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1007 10071620	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1007 10071621	Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071622	Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2015		Y
	C4591001 1007 10071624	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1007 10071625	Immune system disorders	Drug hypersensitivity	01NOV2007		Y
	C4591001 1007 10071627	Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2008		Y
	C4591001 1007 10071629	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1007 10071630	Immune system disorders	Seasonal allergy	01DEC2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2014		Y
	C4591001 1007 10071634	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1007 10071635	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1007 10071638	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1007 10071641	Immune system disorders	Milk allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071642	Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1007 10071647	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1007 10071650	Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1007 10071651	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1007 10071653	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1007 10071654	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1007 10071656	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1007 10071658	Immune system disorders	Allergy to animal	01APR2020		Y
		Psychiatric disorders	Depression	24DEC2020		Y
	C4591001 1008 10081751	Gastrointestinal disorders	Gastroesophageal reflux disease	(b) (6) 2007		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Hyperhidrosis	01JUN2020		Y
	C4591001 1008 10081752	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081753	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1008 10081755	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
			Depression	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2019		Y
	C4591001 1008 10081756	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1008 10081757	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1008 10081758	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081761	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081763	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1008 10081764	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081767	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081768	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2016		Y
	C4591001 1008 10081769	Immune system disorders	Obsessive-compulsive disorder	01JAN2015		Y
			Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2009		Y
			Asthma	01JAN2006		Y
	C4591001 1008 10081770	Respiratory, thoracic and mediastinal disorders				
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1008 10081771	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1008 10081777	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1008 10081780	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081781	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1008 10081785	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1008 10081788	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1008 10081789	Immune system disorders	Drug hypersensitivity	01JAN2014		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081790	Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081791	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1008 10081792	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1008 10081794	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081795	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Investigations	Body height decreased	01JAN2019		Y
			Weight decreased	01JAN2019		Y
	C4591001 1008 10081798	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1008 10081799	Skin and subcutaneous tissue disorders	Acne	01SEP2020		Y
		Social circumstances	Premenarche	(b) (6) 2007	11MAR2021	N
	C4591001 1008 10081800	Psychiatric disorders	Anxiety	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081801	Cardiac disorders	Supraventricular tachycardia	01JAN2014	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
	C4591001 1008 10081803	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1008 10081804	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1008 10081805	Social circumstances	Premenarche	(b) (6) 2008	04FEB2021	N
	C4591001 1008 10081806	Nervous system disorders	Migraine	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081807	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1008 10081809	Gastrointestinal disorders	Constipation	01OCT2020		Y
			Gastroesophageal reflux disease	01OCT2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081810	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2020		Y
	C4591001 1008 10081812	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1008 10081814	Congenital, familial and genetic disorders	Metabolic myopathy	01JAN2019		Y
		Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Nervous system disorders	Syncope	01OCT2020		Y
	C4591001 1008 10081816	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1008 10081818	Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1008 10081819	Immune system disorders	Seasonal allergy	01MAR2020		Y
	C4591001 1008 10081820	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1008 10081821	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081822	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1008 10081823	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1008 10081824	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081825	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081826	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1008 10081827	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1008 10081828	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2010		Y
	C4591001 1008 10081830	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1008 10081831	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1008 10081832	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1008 10081836	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081837	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1008 10081838	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Autism spectrum disorder	01JAN2013		Y
			Depression	01JAN2013		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081839	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1008 10081841	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1008 10081842	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081843	Immune system disorders	Food allergy	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1008 10081846	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081847	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Tic	01OCT2020		Y
	C4591001 1008 10081850	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1008 10081851	Psychiatric disorders	Anxiety	01OCT2018		Y
			Autism spectrum disorder	01JAN2009		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081852	Psychiatric disorders	Autism spectrum disorder	01JAN2007		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081853	Congenital, familial and genetic disorders	Gilbert's syndrome	01MAR2019		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1008 10081854	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1008 10081855	Nervous system disorders	Migraine	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
			Psoriasis	01JAN2015		Y
	C4591001 1008 10081856	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN2015		Y
	C4591001 1008 10081857	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1008 10081858	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1008 10081860	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1008 10081864	Social circumstances	Premenarche	(b) (6) 2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081865	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
			Hand dermatitis	01JAN2008		Y
	C4591001 1008 10081866	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1008 10081867	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081869	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
				01JUN2020		Y
	C4591001 1008 10081870	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1008 10081871	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1008 10081872	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1008 10081873	Immune system disorders	Seasonal allergy	01JAN2015		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081875	Infections and infestations	Appendicitis	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Appendicectomy	01JUL2020	31JUL2020	N
	C4591001 1008 10081877	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
	C4591001 1008 10081878	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081879	Endocrine disorders	Growth hormone deficiency	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JUN2020		Y
	C4591001 1008 10081880	Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1008 10081881	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081883	Endocrine disorders	Hypothyroidism	01AUG2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01AUG2010		Y
			Autism spectrum disorder	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081884	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y
	C4591001 1008 10081886	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081887	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081889	Musculoskeletal and connective tissue disorders	Scoliosis	01JUN2020		Y
	C4591001 1008 10081890	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
			Hand dermatitis	01JAN2012		Y
	C4591001 1008 10081891	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1008 10081892	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2014		Y
	C4591001 1008 10081893	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2007		Y
	C4591001 1008 10081894	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1008 10081895	Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1008 10081897	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1008 10081898	Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081901	Immune system disorders	Drug hypersensitivity	(b) (6) 2005		Y
	C4591001 1008 10081902	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081903	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 2008		Y
	C4591001 1008 10081904	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1008 10081905	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081906	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081907	Reproductive system and breast disorders	Dysmenorrhoea	01SEP2020		Y
	C4591001 1008 10081908	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081910	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081911	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1008 10081912	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1008 10081913	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2016		Y
	C4591001 1008 10081914	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	01JUL2020		Y
	C4591001 1008 10081915	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1008 10081916	Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1008 10081917	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1008 10081918	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081919	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1008 10081920	Psychiatric disorders	Enuresis	01JAN2016		Y
	C4591001 1008 10081921	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2017		Y
	C4591001 1008 10081922	Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1008 10081923	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081924	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1008 10081928	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1008 10081929	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081930	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081931	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1008 10081932	Psychiatric disorders	Anxiety	01FEB2019		Y
	C4591001 1008 10081934	Gastrointestinal disorders	Coeliac disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Alopecia areata	01JAN2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1008 10081935	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1008 10081937	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081938	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2009		Y
	C4591001 1008 10081940	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1008 10081941	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1008 10081942	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1008 10081943	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1009 10091204	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1009 10091208	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1009 10091209	Psychiatric disorders	Anxiety	01SEP2018		Y
			Attention deficit hyperactivity disorder	01SEP2017		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091212	Infections and infestations	Tinea infection	06SEP2020		Y
	C4591001 1009 10091218	Eye disorders	Amblyopia	(b) (6) 2007		Y
			Strabismus	(b) (6) 2007		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16SEP2011		Y
			Rhinitis allergic	01JAN2009		Y
	C4591001 1009 10091220	Immune system disorders	Seasonal allergy	12JUN2017		Y
		Injury, poisoning and procedural complications	Post concussion syndrome	01JUN2019		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	05MAY2017		Y
			Migraine	05MAY2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1009 10091221	Infections and infestations	Tonsillitis	10AUG2017	30APR2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2020		Y
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1009 10091223	Nervous system disorders	Benign rolandic epilepsy	01JAN2014	31DEC2016	N
	C4591001 1009 10091226	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1009 10091227	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2018		Y
	C4591001 1009 10091229	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Ear infection	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	19AUG2020		Y
	C4591001 1009 10091233	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1009 10091234	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1009 10091237	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2007		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091238	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091247	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2019		Y
	C4591001 1009 10091249	Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1009 10091265	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1009 10091266	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1009 10091267	Immune system disorders	Allergy to plants	21AUG2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1009 10091272	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JUL2020		Y
	C4591001 1009 10091273	Respiratory, thoracic and mediastinal disorders	Tracheomalacia	01DEC2005		Y
	C4591001 1009 10091274	Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091277	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	19FEB2020		Y
	C4591001 1009 10091280	Psychiatric disorders	Enuresis	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091282	Skin and subcutaneous tissue disorders	Acne	01JUN2019		Y
	C4591001 1009 10091283	Immune system disorders	Allergy to animal	01JAN2015		Y
			Milk allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Shoulder deformity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1009 10091287	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
			Eczema	(b) (6) 2005		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091288	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1009 10091289	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1009 10091292	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091293	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1009 10091294	Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
			Dermatitis atopic	01JAN2018		Y
	C4591001 1009 10091295	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091297	Immune system disorders	Food allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1009 10091300	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1009 10091301	Immune system disorders	Allergy to animal	01JAN2016		Y
			Food allergy	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oral allergy syndrome	01JAN2016		Y
			Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1009 10091304	Investigations	Cardiac murmur	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1009 10091305	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1009 10091307	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2015		Y
	C4591001 1009 10091308	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1009 10091309	Nervous system disorders	Arachnoid cyst	01JAN2006		Y
			Febrile convulsion	01JUL2008	31JUL2008	N
		Surgical and medical procedures	Cerebral cyst excision	01OCT2018	01OCT2018	N
	C4591001 1009 10091310	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2011		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091311	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 2007		Y
		Renal and urinary disorders	Dysuria	20NOV2020	23NOV2020	N
	C4591001 1009 10091312	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis allergic	01JAN2011		Y
	C4591001 1009 10091314	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2013		Y
	C4591001 1009 10091315	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2020		Y
	C4591001 1009 10091316	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2008		Y
			Insomnia	01DEC2010		Y
	C4591001 1009 10091318	Immune system disorders	Hypersensitivity	01JAN2012		Y
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1009 10091319	Immune system disorders	Food allergy	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
	C4591001 1009 10091320	Psychiatric disorders	Depression	01SEP2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Suicidal ideation	01SEP2020		Y
	C4591001 1009 10091321	Investigations	Cardiac murmur	10DEC2020		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Nail psoriasis	01JAN2016		Y
	C4591001 1009 10091323	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2015		Y
	C4591001 1009 10091324	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1009 10091326	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 2008		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091328	Congenital, familial and genetic disorders	Pectus excavatum	(b) (6) 2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091330	Metabolism and nutrition disorders	Food intolerance	01JAN2015		Y
			Lactose intolerance	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091331	Musculoskeletal and connective tissue disorders	Pain in jaw	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091333	Cardiac disorders	Aortic valve disease	01JAN2008		Y
	C4591001 1009 10091334	General disorders and administration site conditions	Drug intolerance	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091335	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091336	Immune system disorders	Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1009 10091338	Cardiac disorders	Ventricular extrasystoles	30OCT2019		Y
	C4591001 1009 10091340	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1009 10091341	Psychiatric disorders	Anxiety	01DEC2019		Y
	C4591001 1009 10091342	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091343	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091344	Reproductive system and breast disorders	Varicocele	01JAN2019		Y
	C4591001 1009 10091345	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1009 10091346	Eye disorders	Strabismus	01JAN2010		Y
		Immune system disorders	Allergy to animal	01FEB2020		Y
			Oral allergy syndrome	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01FEB2020		Y
	C4591001 1009 10091347	Investigations	Cardiac murmur	15DEC2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091349	Congenital, familial and genetic disorders	Imperforate hymen	06JUL2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01AUG2019		Y
	C4591001 1009 10091350	Immune system disorders	Allergy to animal	(b) (6) 2006		Y
	C4591001 1009 10091351	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091353	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091354	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1009 10091355	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2017		Y
			Oppositional defiant disorder	01JAN2019		Y
	C4591001 1009 10091356	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091357	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Back pain	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1009 10091358	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1009 10091359	Congenital, familial and genetic disorders	Transposition of the great vessels	(b) (6) 2007	(b) (6) 2007	N
		Investigations	Cardiac murmur	(b) (6) 2007		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Arterial switch operation	(b) (6) 2007	(b) (6) 2007	N
	C4591001 1009 10091360	Musculoskeletal and connective tissue disorders	Scoliosis	01MAY2019	31JUL2019	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JUL2019	31JUL2019	N
	C4591001 1009 10091361	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1009 10091362	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 2008		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2016		Y
	C4591001 1009 10091363	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1009 10091364	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1009 10091365	Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1009 10091366	Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 2006	31AUG2009	N
		Immune system disorders	Food allergy	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Atrial septal defect repair	01AUG2009	31AUG2009	N
	C4591001 1009 10091369	Immune system disorders	Perennial allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091370	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091371	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1009 10091372	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUN2019		Y
	C4591001 1009 10091376	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Insomnia	01JAN2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091380	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1009 10091381	Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2012		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091382	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1009 10091383	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Nystagmus	(b) (6) 2005		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091384	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091386	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1009 10091387	Injury, poisoning and procedural complications	Wrist fracture	01JAN2021		Y
	C4591001 1009 10091388	Immune system disorders	Drug hypersensitivity	01DEC2018		Y
			Seasonal allergy	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Radius fracture	26DEC2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1009 10091391	Immune system disorders	Anaphylactic reaction	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091392	Immune system disorders	Food allergy	01FEB2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091396	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091398	Injury, poisoning and procedural complications	Meniscus injury	31DEC2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01SEP2020		Y
	C4591001 1009 10091399	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091400	Infections and infestations	Otitis media	01JAN2008	31DEC2017	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ear tube insertion	01JAN2014	31DEC2014	N
	C4591001 1009 10091402	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1009 10091403	Immune system disorders	Hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091404	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091405	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1009 10091406	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091407	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01SEP2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1009 10091408	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091409	Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1009 10091410	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1009 10091412	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	30OCT2018		Y
			Autism spectrum disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1009 10091413	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1009 10091414	Immune system disorders	Allergy to animal	01JAN2017		Y
			Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1013 10131821	Hepatobiliary disorders	Cholelithiasis	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Cholecystectomy	01SEP2020	30SEP2020	N
	C4591001 1013 10131823	Congenital, familial and genetic disorders	Sickle cell trait	(b) (6) 2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1013 10131824	Congenital, familial and genetic disorders	Sickle cell anaemia	01JAN2007		Y
		Surgical and medical procedures	Central venous catheterisation	01JAN2018		Y
	C4591001 1013 10131826	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
	C4591001 1013 10131828	Immune system disorders	Drug hypersensitivity	01JAN2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2008		Y
	C4591001 1013 10131830	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1013 10131839	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1013 10131841	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1013 10131842	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1013 10131843	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Decreased appetite	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	02DEC2016		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1013 10131844	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Decreased appetite	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131845	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1013 10131846	Immune system disorders	Hypersensitivity	01JAN2007		Y
	C4591001 1013 10131850	Eye disorders	Myopia	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1013 10131852	Nervous system disorders	Headache	01JAN2016		Y
			Migraine	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131855	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2019		Y
	C4591001 1013 10131858	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1013 10131859	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y
	C4591001 1013 10131860	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1013 10131861	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131867	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1013 10131868	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JUL2018		Y
	C4591001 1013 10131869	Immune system disorders	Seasonal allergy	(b) (6) 2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2016		Y
	C4591001 1013 10131870	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1013 10131871	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1013 10131872	Immune system disorders	Food allergy	01JAN2010		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1013 10131873	Eye disorders	Myopia	01JAN2014		Y
	C4591001 1013 10131874	Eye disorders	Myopia	01JAN2016		Y
		Surgical and medical procedures	Myringotomy	01JAN2009	31DEC2009	N
	C4591001 1013 10131875	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2019		Y
	C4591001 1013 10131876	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1013 10131877	Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2013		Y
	C4591001 1013 10131879	Endocrine disorders	Growth hormone deficiency	01JAN2019		Y
	C4591001 1013 10131881	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1016 10161307	Immune system disorders	Seasonal allergy	04FEB2016		Y
		Psychiatric disorders	Depression	15JUN2020		Y
	C4591001 1016 10161308	Immune system disorders	Seasonal allergy	30MAR2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30MAR2010		Y
		Skin and subcutaneous tissue disorders	Eczema	08JAN2013		Y
			Psoriasis	16DEC2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161310	Immune system disorders	Seasonal allergy	01APR2016		Y
	C4591001 1016 10161311	Immune system disorders	Seasonal allergy	18DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07MAR2012		Y
	C4591001 1016 10161314	Immune system disorders	Seasonal allergy	01JUN2007		Y
	C4591001 1016 10161315	Immune system disorders	Seasonal allergy	01APR2014		Y
	C4591001 1016 10161316	Immune system disorders	Seasonal allergy	08MAR2007		Y
	C4591001 1016 10161318	Gastrointestinal disorders	Constipation	01FEB2009		Y
		Immune system disorders	Seasonal allergy	01MAR2008		Y
	C4591001 1016 10161319	Immune system disorders	Seasonal allergy	01OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2015	30NOV2017	N
			Oropharyngeal pain	12OCT2020	15OCT2020	N
	C4591001 1016 10161320	Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2012		Y
	C4591001 1016 10161322	Gastrointestinal disorders	Abdominal pain	01OCT2019		Y
		Nervous system disorders	Febrile convulsion	08APR2008	08APR2008	N
				20AUG2010	20AUG2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	26JUN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	06JAN2020		Y
	C4591001 1016 10161323	Psychiatric disorders	Attention deficit hyperactivity disorder	18SEP2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161324	Immune system disorders	Seasonal allergy	01MAY2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2015	31DEC2015	N
	C4591001 1016 10161326	Immune system disorders	Seasonal allergy	24APR2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11MAY2007		Y
	C4591001 1016 10161327	Immune system disorders	Seasonal allergy	24APR2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	24APR2009		Y
	C4591001 1016 10161329	Gastrointestinal disorders	Constipation	01FEB2013		Y
		Immune system disorders	Seasonal allergy	01MAY2012		Y
		Psychiatric disorders	Anxiety	01AUG2019		Y
			Attention deficit hyperactivity disorder	01MAR2018		Y
			Chronic tic disorder	01SEP2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2010		Y
	C4591001 1016 10161330	Nervous system disorders	Migraine	01JUN2009		Y
		Psychiatric disorders	Anxiety	01AUG2019		Y
	C4591001 1016 10161331	Immune system disorders	Seasonal allergy	01AUG2016		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01AUG2018	31OCT2018	N
		Nervous system disorders	Migraine	01APR2016		Y
	C4591001 1016 10161332	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2011		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161334	Respiratory, thoracic and mediastinal disorders	Asthma	23OCT2009		Y
	C4591001 1016 10161335	Immune system disorders	Seasonal allergy	01AUG2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	28AUG2015	30SEP2018	N
			Insomnia	01JUN2017		Y
		Surgical and medical procedures	Adenoidectomy	28MAY2020	28MAY2020	N
			Tonsillectomy	28MAY2020	28MAY2020	N
	C4591001 1016 10161336	Nervous system disorders	Headache	01APR2015		Y
		Psychiatric disorders	Aggression	23JUL2012		Y
			Anxiety	01APR2012		Y
			Attention deficit hyperactivity disorder	24APR2014		Y
			Behaviour disorder	07AUG2007		Y
			Post-traumatic stress disorder	27JUL2020		Y
	C4591001 1016 10161338	Immune system disorders	Drug hypersensitivity	20NOV2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2015		Y
	C4591001 1016 10161339	Gastrointestinal disorders	Constipation	01APR2020		Y
		Immune system disorders	Seasonal allergy	01APR2016		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01SEP2020	09SEP2020	N
		Nervous system disorders	Headache	11FEB2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	10NOV2016		Y
			Insomnia	12FEB2020		Y
	C4591001 1016 10161340	Immune system disorders	Seasonal allergy	01MAY2019		Y
		Infections and infestations	Infectious mononucleosis	01SEP2017	31OCT2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Disruptive mood dysregulation disorder	10SEP2020		Y
			Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2010		Y
	C4591001 1016 10161343	Psychiatric disorders	Attention deficit hyperactivity disorder	30JAN2012		Y
			Oppositional defiant disorder	30MAR2017		Y
			Tic	14JUN2017	05JUL2017	N
	C4591001 1016 10161344	Immune system disorders	Seasonal allergy	01FEB2010		Y
		Psychiatric disorders	Anger	01NOV2018	30JUN2019	N
			Anxiety	01AUG2017		Y
			Attention deficit hyperactivity disorder	01SEP2014		Y
			Chronic tic disorder	01MAY2020		Y
			Depression	01MAY2019		Y
			Oppositional defiant disorder	01NOV2018	30JUN2019	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2017		Y
		Vascular disorders	Hypotension	01MAY2017		Y
	C4591001 1016 10161350	Ear and labyrinth disorders	Deafness unilateral	24MAY2010		Y
		Immune system disorders	Seasonal allergy	31AUG2007		Y
		Reproductive system and breast disorders	Varicocele	24SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06SEP2012	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	17SEP2020		Y
	C4591001 1016 10161351	Immune system disorders	Seasonal allergy	01OCT2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Oppositional defiant disorder	01MAY2009	31MAY2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2012	31JUL2017	N
	C4591001 1016 10161352	Immune system disorders	Seasonal allergy	01OCT2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	04OCT2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14APR2017		Y
	C4591001 1016 10161353	Immune system disorders	Seasonal allergy	01MAY2011		Y
	C4591001 1016 10161354	Renal and urinary disorders	Vesicoureteric reflux	01SEP2006	31JAN2011	N
	C4591001 1016 10161356	Psychiatric disorders	Attention deficit hyperactivity disorder	18SEP2012		Y
			Impulse-control disorder	20APR2016		Y
	C4591001 1016 10161358	Immune system disorders	Seasonal allergy	01MAR2017		Y
	C4591001 1016 10161361	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Abscess limb	01JUN2015	30JUN2015	N
	C4591001 1016 10161362	Immune system disorders	Seasonal allergy	01MAY2013	31OCT2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	09AUG2011	31MAR2016	N
	C4591001 1016 10161363	Immune system disorders	Seasonal allergy	01MAY2009		Y
	C4591001 1016 10161364	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	06MAR2012		Y
			Bipolar disorder	24JUL2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	03AUG2020		Y
	C4591001 1016 10161365	Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	06JAN2009	30APR2016	N
	C4591001 1016 10161366	Nervous system disorders	Headache	01DEC2018		Y
	C4591001 1016 10161367	Gastrointestinal disorders	Gastrooesophageal reflux disease	01SEP2008		Y
		Immune system disorders	Seasonal allergy	01NOV2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2014		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JUL2020		Y
	C4591001 1016 10161368	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1016 10161369	Immune system disorders	Seasonal allergy	01JUN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2015		Y
		Skin and subcutaneous tissue disorders	Miliaria	01JUN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1016 10161372	Immune system disorders	Seasonal allergy	01APR2019		Y
	C4591001 1016 10161373	Congenital, familial and genetic disorders	Spina bifida occulta	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01FEB2020		Y
			Lordosis	01FEB2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161374	Immune system disorders	Seasonal allergy	01APR2013		Y
	C4591001 1016 10161375	Immune system disorders	Seasonal allergy	01APR2010		Y
		Nervous system disorders	Migraine	01JUN2019		Y
	C4591001 1016 10161376	Skin and subcutaneous tissue disorders	Acne	01MAR2019		Y
		Surgical and medical procedures	Chondroplasty	01FEB2020	14FEB2020	N
	C4591001 1016 10161377	Immune system disorders	Seasonal allergy	01APR2016		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01FEB2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2019		Y
	C4591001 1016 10161378	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAY2018		Y
		Skin and subcutaneous tissue disorders	Eczema	03MAR2010		Y
	C4591001 1016 10161379	Immune system disorders	Seasonal allergy	01APR2012		Y
	C4591001 1016 10161381	Immune system disorders	Seasonal allergy	01APR2006		Y
	C4591001 1016 10161382	Immune system disorders	Seasonal allergy	01AUG2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01NOV2010		Y
	C4591001 1016 10161383	Immune system disorders	Seasonal allergy	01APR2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01DEC2010		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161384	Immune system disorders	Food allergy	01MAY2009		Y
			Seasonal allergy	01OCT2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2016		Y
	C4591001 1016 10161385	Psychiatric disorders	Attention deficit hyperactivity disorder	15AUG2011		Y
		Skin and subcutaneous tissue disorders	Eczema	14NOV2006		Y
	C4591001 1016 10161386	Immune system disorders	Seasonal allergy	01APR2011		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01APR2011		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1016 10161387	Immune system disorders	Seasonal allergy	01APR2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01MAY2019		Y
		Psychiatric disorders	Gender dysphoria	01SEP2016		Y
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1016 10161388	Immune system disorders	Seasonal allergy	01APR2006		Y
		Nervous system disorders	Headache	01MAY2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JUN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR2006		Y
	C4591001 1039 10391246	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2011		Y
	C4591001 1039 10391247	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1039 10391250	General disorders and administration site conditions	Cyst	01JAN2015	31DEC2015	N
		Psychiatric disorders	Tic	01JAN2019		Y
		Social circumstances	Menarche	01JAN2018		Y
	C4591001 1039 10391251	Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2020		Y
		Social circumstances	Menarche	01JAN2016		Y
			Vegetarian	(b) (6) 2005		Y
	C4591001 1039 10391252	Eye disorders	Strabismus	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
	C4591001 1039 10391253	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1039 10391255	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Social circumstances	Vegan	01JUN2020		Y
	C4591001 1039 10391256	Nervous system disorders	Epilepsy	01JAN2017	30SEP2020	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391258	Social circumstances	Vegetarian	(b) (6) 2008		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1039 10391259	Social circumstances	Menarche	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2013	31DEC2013	N
		Eye disorders	Amblyopia	01JAN2011		Y
			Myopia	01JAN2011		Y
	C4591001 1039 10391260	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2011		Y
		Surgical and medical procedures	Circumcision	(b) (6) 2007	31DEC2007	N
			Myringotomy	01APR2008	30APR2008	N
		Eye disorders	Myopia	01JAN2019		Y
	C4591001 1039 10391262	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
		Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
			Premenarche	(b) (6) 2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391263	Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2007		Y
	C4591001 1039 10391264	Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1039 10391265	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
		Infections and infestations	Ear infection	01JAN2010	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2011		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N
			Myringotomy	01JAN2010	31DEC2010	N
	C4591001 1039 10391266	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2019		Y
		Surgical and medical procedures	Circumcision	01JAN2008	31DEC2008	N
			Ear tube insertion	01JAN2009	31DEC2009	N
				01JAN2013	31DEC2013	N
	C4591001 1039 10391267	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Social circumstances	Menarche	01JAN2018		Y
			Vegetarian	01JAN2019		Y
	C4591001 1039 10391268	Social circumstances	Menarche	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391269	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Ear infection	(b) (6) 2008	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01APR2009	30APR2009	N
			Ear tube insertion	01JAN2010	31DEC2010	N
			Myringotomy	01JAN2010	31DEC2010	N
	C4591001 1039 10391270	Eye disorders	Astigmatism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Infections and infestations	Ear infection	01JAN2008	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Menarche	01APR2020		Y
		Surgical and medical procedures	Myringotomy	01JAN2011	31DEC2011	N
	C4591001 1039 10391271	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Social circumstances	Menarche	01MAR2020		Y
	C4591001 1039 10391272	Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Surgical and medical procedures	Myringotomy	01JAN2010	31DEC2010	N
	C4591001 1039 10391273	Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2020		Y
		Social circumstances	Menarche	01JAN2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391274	Immune system disorders	Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1039 10391276	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Idiopathic urticaria	01JAN2018		Y
	C4591001 1039 10391277	Social circumstances	Menarche	01JAN2019		Y
			Vegetarian	(b) (6) 2006		Y
	C4591001 1039 10391278	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2010	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1039 10391279	Social circumstances	Menarche	01FEB2019		Y
	C4591001 1039 10391280	Eye disorders	Blindness unilateral	01JAN2014		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rash	01MAR2020		Y
		Social circumstances	Menarche	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitrectomy	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
	C4591001 1039 10391281	Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
	C4591001 1039 10391282	Immune system disorders	Food allergy	01JAN2012		Y
	C4591001 1039 10391283	Eye disorders	Myopia	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Asthma exercise induced	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Drug eruption	01JAN2005		Y
	C4591001 1039 10391284	Surgical and medical procedures	Dacryocystorhinostomy	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Reproductive system and breast disorders	Epididymal cyst	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Eczema	01JAN2013		Y
			Hand dermatitis	01JAN2013		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391285	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
			Vegetarian	01JAN2019		Y
	C4591001 1039 10391286	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1039 10391287	Gastrointestinal disorders	Umbilical hernia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1039 10391289	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Social circumstances	Premenarche	(b) (6) 2005		Y
	C4591001 1039 10391290	Eye disorders	Myopia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
			Menarche	30JUN2020		Y
	C4591001 1039 10391291	Eye disorders	Hypermetropia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2019		Y
			Vegetarian	01JAN2004		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2019		Y
	C4591001 1039 10391292	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Social circumstances	Menarche	01JUN2018		Y
	C4591001 1039 10391293	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1039 10391294	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1039 10391295	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01NOV2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Social circumstances	Menarche	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JUL2020	31JUL2020	N
	C4591001 1039 10391296	Nervous system disorders	Dyslexia	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1039 10391298	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1039 10391299	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
	C4591001 1039 10391300	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1039 10391301	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2016		Y
	C4591001 1039 10391302	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1039 10391303	Congenital, familial and genetic disorders	Developmental hip dysplasia	01APR2008	30APR2008	N
		Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1039 10391304	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Dehydration	01JUN2020	30JUN2020	N
		Psychiatric disorders	Depression	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Haematuria	01JUN2020	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1039 10391306	Immune system disorders	Drug hypersensitivity	(b) (6) 2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1039 10391307	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Social circumstances	Menarche	01SEP2019		Y
	C4591001 1039 10391308	Congenital, familial and genetic disorders	Pectus excavatum	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2015		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1039 10391309	Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
		Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
	C4591001 1039 10391310	Immune system disorders	Seasonal allergy	(b) (6) 2007		Y
	C4591001 1039 10391314	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
			Menorrhagia	01JAN2018		Y
		Social circumstances	Menarche	01JAN2018		Y
	C4591001 1039 10391315	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1039 10391316	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391317	Eye disorders	Astigmatism	01JAN2013		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN2013		Y
	C4591001 1039 10391318	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN2018		Y
		Social circumstances	Menarche	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1039 10391319	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Social circumstances	Vegetarian	01JAN2018		Y
	C4591001 1039 10391320	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Social circumstances	Menarche	01SEP2020		Y
	C4591001 1039 10391321	Social circumstances	Menarche	01SEP2020		Y
	C4591001 1039 10391322	Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 2005		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Social circumstances	Menarche	01JAN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391323	Gastrointestinal disorders	Abdominal hernia	(b) (6) 2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1039 10391324	Social circumstances	Corrective lens user	01OCT2020		Y
			Menarche	02SEP2020		Y
	C4591001 1039 10391325	Social circumstances	Corrective lens user	01JAN2013		Y
			Menarche	01SEP2020		Y
	C4591001 1039 10391326	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006	31DEC2018	N
		Social circumstances	Corrective lens user	01JAN2012		Y
	C4591001 1039 10391327	Eye disorders	Myopia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01NOV2020		Y
			Depression	01NOV2020		Y
		Surgical and medical procedures	Limb reconstructive surgery	31JUL2020	31JUL2020	N
	C4591001 1039 10391328	Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Menarche	01JAN2017		Y
	C4591001 1039 10391329	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391330	Eye disorders	Presbyopia	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1039 10391331	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2016		Y
	C4591001 1039 10391332	Nervous system disorders	Migraine	01SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
				01NOV2020	30NOV2020	N
			Post-traumatic stress disorder	01NOV2020	30NOV2020	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Social circumstances	Menarche	01JAN2018		Y
	C4591001 1039 10391333	Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2019	31DEC2020	N
	C4591001 1039 10391334	Endocrine disorders	Growth hormone deficiency	01JAN2010		Y
		Surgical and medical procedures	Lipoma excision	01JAN2012		Y
	C4591001 1039 10391336	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391337	Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Eczema	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1039 10391338	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Social circumstances	Menarche	01DEC2016		Y
			Vegetarian	01JAN2018		Y
	C4591001 1039 10391339	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1044 10441256	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1044 10441260	Immune system disorders	Drug hypersensitivity	01FEB2020		Y
				01JAN2008		Y
	C4591001 1044 10441263	Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2019		Y
	C4591001 1044 10441266	Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1044 10441267	Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1044 10441268	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441273	Gastrointestinal disorders	Gastroesophageal reflux disease	(b) (6) 2008		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1044 10441274	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1044 10441276	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1044 10441279	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1044 10441280	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUL2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1044 10441281	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1044 10441282	General disorders and administration site conditions	Drug intolerance	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
			Rhinitis allergic	01JAN2008		Y
	C4591001 1044 10441284	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1044 10441285	Psychiatric disorders	Anxiety	01AUG2019		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441286	Reproductive system and breast disorders	Menstruation irregular	01MAR2018		Y
	C4591001 1044 10441288	Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1044 10441289	Immune system disorders	Allergy to animal	01JAN2009		Y
			Food allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1044 10441290	Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1044 10441292	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1044 10441293	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1044 10441294	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1044 10441295	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2015		Y
	C4591001 1044 10441296	Injury, poisoning and procedural complications	Radius fracture	01SEP2020	18SEP2020	N
	C4591001 1044 10441297	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1044 10441298	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Social circumstances	Premenarche	01NOV2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441299	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1044 10441300	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
				01JAN2007		Y
	C4591001 1044 10441302	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1044 10441303	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1044 10441304	Immune system disorders	Drug hypersensitivity	01AUG2018		Y
	C4591001 1044 10441306	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1044 10441308	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1044 10441309	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1044 10441310	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL2020		Y
	C4591001 1044 10441311	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
	C4591001 1044 10441312	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1044 10441313	Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441316	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1044 10441317	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1044 10441319	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1044 10441321	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2007	30SEP2007	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2007	30SEP2007	N
	C4591001 1044 10441322	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2020		Y
	C4591001 1044 10441324	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1044 10441326	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1044 10441327	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1044 10441330	Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2020		Y
	C4591001 1044 10441331	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1044 10441332	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441333	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1044 10441334	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1044 10441335	Musculoskeletal and connective tissue disorders	Osteochondrosis	01OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Dry skin	01JAN2020		Y
	C4591001 1044 10441338	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1044 10441341	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2018		Y
	C4591001 1044 10441343	Eye disorders	Punctate keratitis	15AUG2013		Y
	C4591001 1044 10441345	Immune system disorders	Food allergy	01JAN2017		Y
			Seasonal allergy	01JAN2016		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1044 10441347	Psychiatric disorders	Depression	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1044 10441348	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1044 10441349	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1044 10441350	Congenital, familial and genetic disorders	Von Willebrand's disease	01FEB2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1044 10441352	Reproductive system and breast disorders	Dysmenorrhoea	01APR2017		Y
	C4591001 1044 10441353	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1044 10441354	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1044 10441355	Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Rhinitis allergic	01JAN2012		Y
	C4591001 1044 10441356	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01DEC2020		Y
	C4591001 1044 10441357	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2020		Y
		Psychiatric disorders	Depression	01MAR2019		Y
			Obsessive-compulsive disorder	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441358	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
	C4591001 1044 10441361	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2007		Y
	C4591001 1044 10441362	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1044 10441366	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Stress fracture	21DEC2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1044 10441367	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1044 10441368	Nervous system disorders	Migraine with aura	01JAN2014		Y
	C4591001 1044 10441371	Reproductive system and breast disorders	Menstruation irregular	17NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441372	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1044 10441373	Gastrointestinal disorders	Gastroesophageal reflux disease	(b) (6) 2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1044 10441375	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1044 10441376	Immune system disorders	Food allergy	01JAN2009		Y
			Hypersensitivity	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1044 10441377	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Injury, poisoning and procedural complications	Foot fracture	08JAN2021		Y
		Nervous system disorders	Dizziness	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	12JAN2021	22JAN2021	N
			Vasomotor rhinitis	01JAN2015		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1044 10441378	Psychiatric disorders	Anxiety	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441379	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1044 10441380	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1044 10441381	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1044 10441382	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1044 10441383	Injury, poisoning and procedural complications	Limb fracture	30SEP2020		Y
	C4591001 1044 10441384	Endocrine disorders	Autoimmune thyroiditis	01JUN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Milk allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1057 10571377	Immune system disorders	Hypersensitivity	01JAN2008		Y
		Infections and infestations	Adenoiditis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
	C4591001 1057 10571378	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Adenoiditis	01JAN2009	31DEC2009	N
			Tonsillitis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2011	31DEC2011	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571379	Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2014		Y
	C4591001 1057 10571380	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2013		Y
	C4591001 1057 10571382	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2012	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2007		Y
	C4591001 1057 10571383	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1057 10571385	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Major depression	01JAN2016	31DEC2017	N
	C4591001 1057 10571386	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1057 10571388	Immune system disorders	Allergy to animal	01JAN2016		Y
	C4591001 1057 10571389	Immune system disorders	Allergy to animal	01JAN2016		Y
	C4591001 1057 10571390	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Major depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1057 10571391	Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571393	Psychiatric disorders	Major depression	01JUN2018		Y
	C4591001 1057 10571394	Infections and infestations	Adenoiditis	01JAN2011	31MAR2011	N
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	01JUN2020		Y
		Surgical and medical procedures	Adenoidectomy	01MAR2011	31MAR2011	N
	C4591001 1057 10571395	Immune system disorders	Food allergy	01JAN2009		Y
			Seasonal allergy	01JAN2009		Y
				01JAN2013		Y
	C4591001 1057 10571396	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
	C4591001 1057 10571397	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1057 10571398	Gastrointestinal disorders	Constipation	01JAN2007		Y
	C4591001 1057 10571399	Infections and infestations	Adenoiditis	01JAN2013	31DEC2013	N
		Psychiatric disorders	Bipolar disorder	01JUN2019		Y
			Obsessive-compulsive disorder	01JUN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2013	31DEC2013	N
	C4591001 1057 10571400	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1057 10571401	Musculoskeletal and connective tissue disorders	Knee deformity	01JAN2016	31DEC2018	N
		Surgical and medical procedures	Knee operation	01DEC2018	31DEC2018	N
	C4591001 1057 10571402	Metabolism and nutrition disorders	Obesity	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571404	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
			Major depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2008		Y
	C4591001 1057 10571405	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2013		Y
	C4591001 1057 10571406	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1057 10571408	Immune system disorders	Mycotic allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Adenoiditis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
	C4591001 1057 10571411	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1057 10571413	Infections and infestations	Tonsillitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1057 10571414	Immune system disorders	Rubber sensitivity	01JAN2018		Y
	C4591001 1057 10571415	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1057 10571417	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571418	Metabolism and nutrition disorders	Obesity	01APR2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	27MAR2018		Y
		Reproductive system and breast disorders	Menorrhagia	01DEC2019		Y
	C4591001 1057 10571419	Immune system disorders	Drug hypersensitivity	01APR2011		Y
		Infections and infestations	Adenoiditis	01JAN2010	31JAN2010	N
		Psychiatric disorders	Autism spectrum disorder	01MAR2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31JAN2010	N
	C4591001 1057 10571420	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013	31DEC2014	N
	C4591001 1057 10571421	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2017	31MAR2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1057 10571422	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1057 10571423	Immune system disorders	Seasonal allergy	(b) (6) 2005		Y
		Infections and infestations	Adenoiditis	01JAN2011	31DEC2011	N
			Tonsillitis	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2005		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2011	31DEC2011	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571424	Immune system disorders	Seasonal allergy	(b) (6) 2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2008		Y
	C4591001 1057 10571425	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1057 10571426	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1057 10571427	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1057 10571428	Congenital, familial and genetic disorders	Hereditary spherocytosis	01JAN2010		Y
	C4591001 1057 10571431	Infections and infestations	Tonsillitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1057 10571432	Eye disorders	Optic atrophy	01NOV2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1057 10571433	Musculoskeletal and connective tissue disorders	Scoliosis	15OCT2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2014		Y
		Surgical and medical procedures	Scoliosis surgery	15OCT2020	15OCT2020	N
	C4591001 1057 10571434	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571435	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571436	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1057 10571437	Infections and infestations	Adenoiditis	01JAN2008	31DEC2008	N
			Tonsillitis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Autism spectrum disorder	01JAN2011		Y
			Generalised anxiety disorder	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1057 10571438	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1057 10571439	Reproductive system and breast disorders	Metrorrhagia	01JAN2020		Y
	C4591001 1057 10571440	Immune system disorders	Drug hypersensitivity	(b) (6) 2008		Y
	C4591001 1057 10571441	Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
	C4591001 1057 10571442	Gastrointestinal disorders	Umbilical hernia	01JAN2014	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2014	31DEC2014	N
	C4591001 1057 10571443	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1057 10571446	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2015		Y
	C4591001 1057 10571447	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571448	Eye disorders	Strabismus	01JAN2008	31DEC2018	N
		Infections and infestations	Adenoiditis	01JAN2016	31DEC2016	N
			Tonsillitis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2016	31DEC2016	N
			Eye operation	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1057 10571449	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
	C4591001 1057 10571450	Injury, poisoning and procedural complications	Foot fracture	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1057 10571451	Infections and infestations	Vulvovaginal mycotic infection	01JAN2012		Y
	C4591001 1066 10661394	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Pharyngeal abscess	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Abscess drainage	01JAN2008	31DEC2008	N
	C4591001 1066 10661395	Nervous system disorders	Mental impairment	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Autism spectrum disorder	01JAN2019		Y
	C4591001 1066 10661397	Nervous system disorders	Headache	01NOV2018		Y
		Psychiatric disorders	Anxiety	01DEC2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01DEC2018		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1066 10661401	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1066 10661402	Psychiatric disorders	Anxiety	01JAN2018		Y
			Eating disorder	01FEB2019		Y
	C4591001 1066 10661404	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Turbinoplasty	01JAN2012	31DEC2012	N
	C4591001 1066 10661405	Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2018		Y
			Sleep disorder	01JAN2013		Y
	C4591001 1066 10661407	Infections and infestations	Oral herpes	01JAN2017		Y
	C4591001 1066 10661408	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Ingrowing nail	01JAN2019	31DEC2019	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nail operation	01JAN2019	31DEC2019	N
	C4591001 1066 10661409	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1066 10661410	Infections and infestations	Pharyngitis streptococcal	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1066 10661411	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1066 10661412	Infections and infestations	Pharyngitis streptococcal	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2014		Y
			Migraine	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1066 10661414	Psychiatric disorders	Autism spectrum disorder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1066 10661415	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2006	(b) (6) 2006	N
		Psychiatric disorders	Depression	01OCT2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2019		Y
	C4591001 1066 10661416	Injury, poisoning and procedural complications	Tibia fracture	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661417	Immune system disorders	Hypersensitivity	01JAN2010		Y
	C4591001 1066 10661418	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1066 10661419	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Concussion	01AUG2019	30SEP2019	N
		Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	01JAN2018		Y
	C4591001 1066 10661420	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Appendicitis	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Appendicectomy	01MAR2020	31MAR2020	N
	C4591001 1066 10661421	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Enuresis	01JAN2010		Y
			Reactive attachment disorder of infancy or early childhood	01JAN2008		Y
	C4591001 1066 10661422	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Autism spectrum disorder	01JAN2011		Y
	C4591001 1066 10661423	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1066 10661424	Gastrointestinal disorders	Cyclic vomiting syndrome	01JAN2010	31DEC2018	N
			Eosinophilic oesophagitis	01JAN2008	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Hypersensitivity	01JAN2008	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chronic tonsillitis	(b) (6) 2006	31JUL2006	N
		Investigations	Endoscopy	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JUL2006	31DEC2006	N
	C4591001 1066 10661425	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Rosacea	01JAN2018		Y
	C4591001 1066 10661426	Congenital, familial and genetic disorders	Hypospadias	(b) (6) 2005	30APR2006	N
		Immune system disorders	Hypersensitivity	01JAN2017		Y
		Surgical and medical procedures	Urethral repair	01APR2006	30APR2006	N
	C4591001 1066 10661428	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2020		Y
	C4591001 1066 10661430	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1066 10661431	Nervous system disorders	Headache	(b) (6) 2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1066 10661432	Infections and infestations	Appendicitis	01MAY2018	31MAY2018	N
			Tonsillitis	01JAN2009	31DEC2011	N
		Social circumstances	Premenarche	(b) (6) 2006		Y
		Surgical and medical procedures	Appendicectomy	01MAY2018	31MAY2018	N
			Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1066 10661433	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661434	Psychiatric disorders	Attention deficit hyperactivity disorder	12JAN2015		Y
			Insomnia	12JAN2019		Y
	C4591001 1066 10661435	Congenital, familial and genetic disorders	Talipes	(b) (6) 2007	(b) (6) 2007	N
		Nervous system disorders	Mental impairment	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Hallucination, auditory	01JAN2017		Y
			Neurodevelopmental disorder	(b) (6) 2007		Y
	C4591001 1077 10771274	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Radius fracture	01JAN2011	31DEC2011	N
	C4591001 1077 10771277	Congenital, familial and genetic disorders	Hemivertebra	(b) (6) 2007		Y
			Oculoauriculovertebral dysplasia	(b) (6) 2007		Y
		Ear and labyrinth disorders	Deafness unilateral	(b) (6) 2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2013		Y
		Surgical and medical procedures	Temporomandibular joint surgery	01JAN2014	31DEC2014	N
	C4591001 1077 10771279	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
	C4591001 1077 10771280	Immune system disorders	Rubber sensitivity	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1077 10771281	Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771282	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1077 10771283	Infections and infestations	Sinusitis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
	C4591001 1077 10771286	Immune system disorders	Reaction to colouring	01JAN2014		Y
			Seasonal allergy	01JAN2011		Y
		Infections and infestations	Tonsillitis	01JAN2017	31DEC2017	N
		Nervous system disorders	Epilepsy	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2018	31JAN2018	N
			Strabismus correction	01JAN2009	31DEC2009	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2018	31JAN2018	N
	C4591001 1077 10771287	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
	C4591001 1077 10771288	Psychiatric disorders	Attention deficit hyperactivity disorder	30OCT2020		Y
	C4591001 1077 10771290	Psychiatric disorders	Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1077 10771293	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1077 10771294	Psychiatric disorders	Anxiety	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771295	Immune system disorders	Hypersensitivity	01JAN2012		Y
	C4591001 1077 10771300	Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1084 10841541	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Ear infection	01JAN2009	31DEC2010	N
			Pharyngitis	01JAN2009	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011	31DEC2019	N
	C4591001 1084 10841542	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Reproductive system and breast disorders	Menstruation irregular	01SEP2019		Y
	C4591001 1084 10841543	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N
			Tibia fracture	01JAN2009	31DEC2009	N
	C4591001 1084 10841544	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1084 10841545	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Ear infection	01JAN2016	31JAN2019	N
		Surgical and medical procedures	Myringotomy	01JAN2019	31JAN2019	N
	C4591001 1084 10841546	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1084 10841547	Immune system disorders	Seasonal allergy	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1084 10841548	Surgical and medical procedures	Myringotomy	01JAN2006	31DEC2006	N
		Eye disorders	Visual acuity reduced	01JAN2014		Y
	C4591001 1084 10841549	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2018	31DEC2018	N
			Wrist fracture	01JAN2012	31DEC2012	N
				01JUL2019	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Myringotomy	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841550	Congenital, familial and genetic disorders	Renal dysplasia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2013		Y
	C4591001 1084 10841551	Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
			Umbilical hernia	01JAN2009	31DEC2009	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Ear infection	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Inguinal hernia repair	01JAN2009	31DEC2009	N
			Myringotomy	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2009	31DEC2009	N
	C4591001 1084 10841552	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Injury, poisoning and procedural complications	Torus fracture	01JAN2015		Y
	C4591001 1084 10841553	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1084 10841555	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1084 10841556	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Kidney infection	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1084 10841557	Immune system disorders	Allergy to animal	01JAN2014		Y
	C4591001 1084 10841558	Eye disorders	Visual acuity reduced	01JAN2016		Y
		Gastrointestinal disorders	Diarrhoea	(b) (6) 2005		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1084 10841559	Eye disorders	Visual acuity reduced	01JAN2016		Y
		Immune system disorders	Allergy to arthropod bite	01JAN2007		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Respiratory syncytial virus infection	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Growing pains	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1084 10841560	Eye disorders	Visual acuity reduced	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Infections and infestations	Ear infection	01JAN2005	31DEC2008	N
			Molluscum contagiosum	01JAN2008	31DEC2009	N
			Tonsillitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Torus fracture	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01AUG2020		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Myringotomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841561	Eye disorders	Visual acuity reduced	01JAN2013		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1084 10841562	General disorders and administration site conditions	Pain	01JAN2008		Y
	C4591001 1084 10841563	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1084 10841564	Congenital, familial and genetic disorders	Sickle cell trait	01JAN2008		Y
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Cardiac murmur	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1084 10841565	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	10SEP2020		Y
	C4591001 1084 10841566	Eye disorders	Visual acuity reduced	01JAN2015		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2012	31DEC2012	N
			Upper limb fracture	01JAN2009	31DEC2009	N
	C4591001 1084 10841567	Immune system disorders	Seasonal allergy	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1084 10841568	Eye disorders	Visual acuity reduced	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Stress fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1084 10841569	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y
	C4591001 1084 10841570	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Hypersensitivity	01JAN2016		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1084 10841571	Eye disorders	Visual acuity reduced	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Autism spectrum disorder	01MAY2020		Y
			Depression	01JAN2016		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01DEC2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1084 10841572	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01NOV2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01OCT2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1084 10841573	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	(b) (6) 2008	31DEC2011	N
	C4591001 1084 10841574	Eye disorders	Visual acuity reduced	01JAN2017		Y
		Infections and infestations	Gastrointestinal viral infection	01JAN2015	31DEC2015	N
			Otitis media	01JAN2010		Y
			Viral infection	01JAN2009	31DEC2009	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2017		Y
	C4591001 1084 10841576	Eye disorders	Visual acuity reduced	01JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1084 10841577	Eye disorders	Visual acuity reduced	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2013	31DEC2013	N
	C4591001 1084 10841578	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1084 10841581	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
	C4591001 1084 10841582	Immune system disorders	Hypersensitivity	01JAN2019		Y
	C4591001 1084 10841583	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841584	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2018		Y
		Nervous system disorders	Dyslexia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1084 10841586	Eye disorders	Chalazion	01JAN2014	31DEC2014	N
			Visual acuity reduced	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Eye operation	01JAN2014	31DEC2014	N
	C4591001 1084 10841587	Eye disorders	Visual acuity reduced	01JAN2012		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841588	Nervous system disorders	Headache	01JAN2012		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1084 10841590	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
		Eye disorders	Visual acuity reduced	01JAN2013		Y
		Gastrointestinal disorders	Dysphagia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1084 10841591	Infections and infestations	Ear infection	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Ear infection	01JAN2009	31DEC2009	N
	C4591001 1084 10841592	Nervous system disorders	Headache	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2020	30APR2020	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Myringotomy	01JAN2009	31DEC2009	N
		Eye disorders	Visual acuity reduced	01JAN2016		Y
		Infections and infestations	Adenoiditis	01JAN2012	31DEC2012	N
			Tonsillitis	01JAN2012	31DEC2012	N
		Nervous system disorders	Headache	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1084 10841593	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1084 10841594	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1084 10841595	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2012	31DEC2012	N
	C4591001 1084 10841596	Eye disorders	Visual acuity reduced	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1084 10841597	Eye disorders	Visual acuity reduced	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016	31DEC2018	N
	C4591001 1091 10911394	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1091 10911395	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911396	Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1091 10911399	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1091 10911400	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
	C4591001 1091 10911402	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1091 10911403	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2017		Y
	C4591001 1091 10911404	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1091 10911406	Immune system disorders	Allergy to animal	(b) (6) 2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Testes exploration	01DEC2019		Y
	C4591001 1091 10911407	Immune system disorders	Seasonal allergy	01JAN2012		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Hand fracture	01AUG2020	31OCT2020	N
			Upper limb fracture	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1091 10911408	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1091 10911409	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1091 10911410	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Lyme disease	01JAN2017	31DEC2017	N
			Scarlet fever	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Ankle fracture	05NOV2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	05NOV2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1091 10911411	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Scarlet fever	01JAN2010	31DEC2010	N
	C4591001 1091 10911412	Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2007	31DEC2007	N
			Tonsillar hypertrophy	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2007	31DEC2007	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1091 10911413	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Hypersensitivity	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1091 10911414	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2008	31DEC2008	N
		Immune system disorders	Hypersensitivity	01JAN2009		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1091 10911415	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1091 10911417	Immune system disorders	Food allergy	(b) (6) 2007		Y
	C4591001 1091 10911418	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1091 10911422	Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
		Surgical and medical procedures	Mastoidectomy	01NOV2019	30NOV2019	N
			Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1091 10911423	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1091 10911424	Surgical and medical procedures	Myringotomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2011	31DEC2011	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911425	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01OCT2019		Y
	C4591001 1091 10911427	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1091 10911428	Gastrointestinal disorders	Coeliac disease	01JUN2020		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01AUG2020		Y
	C4591001 1091 10911429	Skin and subcutaneous tissue disorders	Acne	01JUN2019		Y
	C4591001 1091 10911430	Immune system disorders	Seasonal allergy	01APR2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1091 10911431	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1091 10911432	Infections and infestations	Sinusitis	01JAN2015		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1091 10911433	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2006		Y
			Rhinitis allergic	01JAN2008		Y
	C4591001 1091 10911434	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2008		Y
	C4591001 1091 10911435	Surgical and medical procedures	Tonsillectomy	01JAN2018	31DEC2018	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911436	Injury, poisoning and procedural complications	Wrist fracture	01JUL2020	31JUL2020	N
		Investigations	Cardiac murmur	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1091 10911437	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2015	31DEC2015	N
	C4591001 1091 10911438	Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
			Wrist fracture	01JAN2014	31DEC2014	N
	C4591001 1091 10911439	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1091 10911440	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1091 10911441	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1091 10911442	Immune system disorders	Food allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
	C4591001 1091 10911443	Surgical and medical procedures	Hydrocele operation	01JAN2010	31DEC2010	N
	C4591001 1091 10911444	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Infections and infestations	Histoplasmosis	01JAN2015	31DEC2015	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2020		Y
	C4591001 1091 10911446	Nervous system disorders	Headache	01JAN2015		Y
			Migraine	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Myringotomy	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
			Tympanoplasty	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
	C4591001 1091 10911448	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN2011		Y
		Surgical and medical procedures	Eye operation	01JAN2015	31DEC2015	N
	C4591001 1091 10911449	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1091 10911451	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2018		Y
	C4591001 1091 10911452	Infections and infestations	Appendicitis	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Appendicectomy	01MAY2019	31MAY2019	N
	C4591001 1091 10911453	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Lactose intolerance	01MAR2020		Y
		Surgical and medical procedures	Knee operation	01JAN2008	31DEC2008	N
	C4591001 1091 10911454	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2008	31DEC2008	N
	C4591001 1091 10911455	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1091 10911456	Congenital, familial and genetic disorders	Anorectal malformation	(b) (6) 2007	(b) (6) 2007	N
		Musculoskeletal and connective tissue disorders	Scoliosis	21DEC2018		Y
		Nervous system disorders	Sensory processing disorder	12DEC2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUL2020		Y
			Depression	21DEC2018		Y
			Generalised anxiety disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Adenotonsillectomy	01NOV2018	30NOV2018	N
			Anorectal operation	(b) (6) 2007		Y
			Scoliosis surgery	20OCT2020	20OCT2020	N
	C4591001 1091 10911457	Congenital, familial and genetic disorders	Congenital nystagmus	04MAR2019		Y
		Eye disorders	Amblyopia strabismic	04MAR2019		Y
		General disorders and administration site conditions	Pain	11DEC2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	27NOV2018		Y
		Nervous system disorders	Migraine with aura	17APR2019		Y
			Retinal migraine	17APR2019		Y
			Sensory processing disorder	29NOV2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	29NOV2018		Y
			Autism spectrum disorder	02APR2019		Y
			Disruptive mood dysregulation disorder	29NOV2018		Y
			Gender dysphoria	13OCT2019		Y
			Suicidal ideation	11SEP2018	13OCT2018	N
		Surgical and medical procedures	Intrauterine contraception	17FEB2019	17FEB2020	N
	C4591001 1091 10911458	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1091 10911459	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1091 10911460	Immune system disorders	Drug hypersensitivity	(b) (6) 2007		Y
		Surgical and medical procedures	Myringotomy	01JAN2012	31DEC2012	N
	C4591001 1091 10911461	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 2006	31DEC2010	N
		Surgical and medical procedures	Pharyngeal reconstruction	01JAN2010	31DEC2010	N
	C4591001 1091 10911462	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2018		Y
	C4591001 1091 10911463	Injury, poisoning and procedural complications	Stress fracture	01SEP2020	30NOV2020	N
			Tibia fracture	01SEP2020	30NOV2020	N
		Investigations	Blood pressure increased	01JAN2019		Y
	C4591001 1091 10911464	Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911466	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1123 11231422	Musculoskeletal and connective tissue disorders	Pain in extremity	01SEP2020		Y
	C4591001 1123 11231434	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1123 11231438	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1123 11231439	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1123 11231441	Infections and infestations	Appendicitis	01JUN2020	31JUL2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01SEP2020		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2020		Y
		Surgical and medical procedures	Appendicectomy	01JUL2020	31JUL2020	N
	C4591001 1123 11231442	Infections and infestations	Pharyngitis streptococcal	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2017	31DEC2017	N



16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231443	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1123 11231446	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Food allergy	01JAN2006		Y
			Hypersensitivity	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1123 11231447	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01MAR2020		Y
		Infections and infestations	Adenoiditis	01JAN2009	31DEC2009	N
			Otitis media acute	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
			Bronchial hyperreactivity	01MAR2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Myringotomy	01JAN2009	31DEC2009	N
	C4591001 1123 11231448	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1123 11231449	Immune system disorders	Food allergy	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2020		Y
	C4591001 1123 11231450	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1123 11231451	Eye disorders	Strabismus	01JAN2009	31JAN2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Surgical and medical procedures	Strabismus correction	01DEC2020	01DEC2020	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231452	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1123 11231453	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2019	31DEC2019	N
	C4591001 1123 11231454	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1123 11231455	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Keratosis pilaris	01JAN2018		Y
	C4591001 1123 11231456	Psychiatric disorders	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	01JAN2015		Y
	C4591001 1123 11231457	Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1123 11231458	Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1123 11231459	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1123 11231460	Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1123 11231461	Injury, poisoning and procedural complications	Tibia fracture	15MAY2020	15MAY2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	15MAY2020		Y
		Surgical and medical procedures	Open reduction of fracture	15MAY2020	15MAY2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231465	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1123 11231467	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1123 11231468	Congenital, familial and genetic disorders	Ankyloglossia congenital	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1123 11231469	Skin and subcutaneous tissue disorders	Seborrhoea	01JAN2015		Y
	C4591001 1123 11231470	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231472	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231473	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1123 11231474	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231475	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1123 11231477	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231478	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231479	Blood and lymphatic system disorders	Lymphadenopathy	01MAY2019	31MAY2019	N
		Immune system disorders	Seasonal allergy	(b) (6) 2006		Y
		Surgical and medical procedures	Lymphadenectomy	01MAY2019	31MAY2019	N
	C4591001 1123 11231482	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	20DEC2020		Y
	C4591001 1123 11231483	Immune system disorders	Seasonal allergy	01AUG2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231485	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1123 11231486	Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1123 11231488	Infections and infestations	Ear infection	01JAN2013	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Myringotomy	01JAN2014	31DEC2015	N
	C4591001 1123 11231489	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	(b) (6) 2007		Y
	C4591001 1123 11231491	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231493	Gastrointestinal disorders	Abdominal migraine	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Finger amputation	01JUL2020	31JUL2020	N
	C4591001 1123 11231494	Respiratory, thoracic and mediastinal disorders	Asthma	29JAN2020		Y
	C4591001 1123 11231495	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231497	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231500	Immune system disorders	Seasonal allergy	01JAN2012	31JAN2020	N
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1123 11231501	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1123 11231502	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1123 11231503	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231506	Immune system disorders	Seasonal allergy	01MAR2015		Y
		Nervous system disorders	Headache	01AUG2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2016		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2018		Y
			Eczema	01JAN2009		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231507	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01OCT2018		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01OCT2018		Y
	C4591001 1123 11231508	Immune system disorders	Hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
	C4591001 1123 11231509	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231510	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1123 11231511	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1123 11231512	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1123 11231513	Surgical and medical procedures	Abscess drainage	(b) (6) 2008	31JAN2009	N
	C4591001 1123 11231514	Congenital, familial and genetic disorders	Naevus flammeus	(b) (6) 2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231515	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2008		Y
	C4591001 1123 11231516	Immune system disorders	Food allergy	01JUL2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	16DEC2020		Y
	C4591001 1123 11231517	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1123 11231518	Injury, poisoning and procedural complications	Radius fracture	01OCT2017	31OCT2017	N
		Skin and subcutaneous tissue disorders	Eczema	01MAR2007		Y
		Surgical and medical procedures	Fracture treatment	01OCT2017	31OCT2017	N
	C4591001 1123 11231519	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2019		Y
	C4591001 1123 11231520	Gastrointestinal disorders	Constipation	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1123 11231521	Gastrointestinal disorders	Constipation	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1123 11231522	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2016		Y
		Investigations	Endoscopy upper gastrointestinal tract	01JAN2018	31DEC2018	N
	C4591001 1123 11231523	Congenital, familial and genetic disorders	Congenital megacolon	(b) (6) 2008	(b) (6) 2008	N
		Surgical and medical procedures	Colon operation	(b) (6) 2008	(b) (6) 2008	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231524	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01MAR2018	31MAR2018	N
		Surgical and medical procedures	Appendicectomy	01MAR2018	31MAR2018	N
	C4591001 1123 11231525	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2017		Y
	C4591001 1123 11231526	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01FEB2020		Y
	C4591001 1124 11241236	Immune system disorders	Allergy to arthropod sting	01SEP2020		Y
	C4591001 1124 11241239	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2008		Y
	C4591001 1124 11241240	Skin and subcutaneous tissue disorders	Acne	01JAN2018	31JAN2020	N
	C4591001 1124 11241241	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1124 11241242	Surgical and medical procedures	Scrotal cystectomy	01JAN2009	31DEC2009	N
				01JAN2013	31DEC2013	N
	C4591001 1124 11241243	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Autism spectrum disorder	01JAN2010		Y
	C4591001 1124 11241244	Gastrointestinal disorders	Constipation	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241245	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1124 11241246	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1124 11241248	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2010		Y
		Injury, poisoning and procedural complications	Upper limb fracture	18NOV2020	18NOV2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1124 11241249	Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2006	31DEC2006	N
	C4591001 1124 11241250	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1124 11241253	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1124 11241254	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1124 11241255	Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N
			Umbilical hernia repair	01JAN2009	31DEC2009	N
	C4591001 1124 11241257	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01MAY2020	31AUG2020	N
	C4591001 1124 11241259	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
	C4591001 1124 11241260	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015	31DEC2019	N
	C4591001 1124 11241261	Immune system disorders	Seasonal allergy	01SEP2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1124 11241262	Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Dermatitis	01JAN2017		Y
			Eczema	01JAN2005		Y
	C4591001 1124 11241268	Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01APR2020		Y
			Depression	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241269	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2013		Y
			Insomnia	01JUN2020		Y
	C4591001 1124 11241270	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1124 11241271	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1124 11241272	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
	C4591001 1124 11241273	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1125 11251241	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1125 11251244	Infections and infestations	Otitis media chronic	01JAN2007	31DEC2007	N
			Tonsillitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Sinuplasty	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1125 11251246	Infections and infestations	Otitis media chronic	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Ear tube insertion	01JAN2009	31DEC2010	N
	C4591001 1125 11251249	Nervous system disorders	Migraine	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251250	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1125 11251252	Surgical and medical procedures	Ear tube insertion	01JAN2016	31DEC2016	N
	C4591001 1125 11251254	Immune system disorders	Drug hypersensitivity	01DEC2008		Y
	C4591001 1125 11251255	Immune system disorders	Allergy to plants	01JAN2018		Y
	C4591001 1126 11261235	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	10DEC2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis	14AUG2015		Y
	C4591001 1126 11261239	Immune system disorders	Allergy to arthropod sting	03MAY2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25APR2012	17MAY2019	N
	C4591001 1126 11261240	Musculoskeletal and connective tissue disorders	Foot deformity	27JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	11APR2014		Y
			Autism spectrum disorder	27FEB2008		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2020		Y
	C4591001 1126 11261241	Nervous system disorders	Headache	09OCT2018		Y
	C4591001 1126 11261243	Gastrointestinal disorders	Constipation	21OCT2016		Y
		Psychiatric disorders	Enuresis	01OCT2016		Y
	C4591001 1126 11261246	Respiratory, thoracic and mediastinal disorders	Vocal cord thickening	06JUL2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	27MAY2009		Y
	C4591001 1126 11261253	Immune system disorders	Food allergy	23JAN2020		Y
			Oral allergy syndrome	01APR2019		Y
			Seasonal allergy	17MAY2013		Y
			Selective IgA immunodeficiency	20SEP2012	09JUN2016	N
		Investigations	Blood pressure increased	12NOV2020		Y
	C4591001 1126 11261254	Eye disorders	Recession of chamber angle of eye	28DEC2018		Y
		Immune system disorders	Food allergy	12SEP2014		Y
	C4591001 1126 11261255	Skin and subcutaneous tissue disorders	Acne	24APR2019		Y
	C4591001 1126 11261258	Skin and subcutaneous tissue disorders	Acne	04JUN2019		Y
	C4591001 1126 11261263	Infections and infestations	Appendicitis	26OCT2016	26OCT2016	N
		Surgical and medical procedures	Appendectomy	26OCT2016	26OCT2016	N
	C4591001 1126 11261264	Immune system disorders	Drug hypersensitivity	29MAR2010		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1126 11261265	Immune system disorders	Allergy to arthropod sting	28AUG2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06OCT2017		Y
	C4591001 1126 11261268	Immune system disorders	Allergy to arthropod sting	07OCT2010		Y
		Injury, poisoning and procedural complications	Muscle strain	12NOV2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Radius fracture	27JUL2012	22AUG2012	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	25JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	09NOV2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	07OCT2010		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1126 11261269	Immune system disorders	Drug hypersensitivity	25NOV2019		Y
			Food allergy	20NOV2018		Y
		Injury, poisoning and procedural complications	Foot fracture	01DEC2020		Y
				06MAR2019	03OCT2019	N
		Musculoskeletal and connective tissue disorders	Foot deformity	15NOV2016		Y
			Tendonitis	19SEP2019	03OCT2019	N
		Nervous system disorders	Migraine with aura	25NOV2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01JUN2020		Y
			Major depression	01JUN2020		Y
		Reproductive system and breast disorders	Uterine haemorrhage	25NOV2019	25NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	29SEP2008		Y
			Rhinitis allergic	20AUG2008		Y
		Skin and subcutaneous tissue disorders	Urticaria	13JUL2006		Y
		Surgical and medical procedures	Ostectomy	03OCT2019	03OCT2019	N
	C4591001 1126 11261271	Respiratory, thoracic and mediastinal disorders	Asthma	02JUL2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261275	Immune system disorders	Rubber sensitivity	15JAN2010		Y
	C4591001 1126 11261277	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06APR2010		Y
	C4591001 1126 11261278	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Injury, poisoning and procedural complications	Hand fracture	09SEP2020	09SEP2020	N
	C4591001 1126 11261279	Musculoskeletal and connective tissue disorders	Osteitis	15AUG2018		Y
			Tendonitis	15AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16JAN2008	09APR2015	N
	C4591001 1126 11261282	Infections and infestations	Appendicitis	16JUL2019	16JUL2019	N
		Reproductive system and breast disorders	Ovulation disorder	27OCT2020		Y
		Surgical and medical procedures	Appendicectomy	16JUL2019	16JUL2019	N
	C4591001 1126 11261284	Infections and infestations	Chronic tonsillitis	04APR2011	20JUN2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Spider naevus	17JUN2013	21JUN2018	N
		Surgical and medical procedures	Adenotonsillectomy	20JUN2012	20JUN2012	N
	C4591001 1126 11261290	Congenital, familial and genetic disorders	Phimosis	26JUN2013		Y
		Psychiatric disorders	Autism spectrum disorder	24JUL2014		Y
		Skin and subcutaneous tissue disorders	Pityriasis rosea	14DEC2020		Y
			Psoriasis	10DEC2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261292	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2016	15JUL2019	N
	C4591001 1126 11261293	Congenital, familial and genetic disorders	Thalassaemia beta	06AUG2007		Y
		Immune system disorders	Drug hypersensitivity	23SEP2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25SEP2008		Y
	C4591001 1126 11261294	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1126 11261295	Respiratory, thoracic and mediastinal disorders	Asthma	15MAR2019		Y
	C4591001 1126 11261297	Skin and subcutaneous tissue disorders	Vitiligo	30JUL2019		Y
	C4591001 1126 11261298	Congenital, familial and genetic disorders	Cryptorchism	(b) (6) 2006	01DEC2017	N
			Phimosis	19JUL2019	08AUG2019	N
		Immune system disorders	Drug hypersensitivity	30MAY2020		Y
		Surgical and medical procedures	Circumcision	08AUG2019	08AUG2019	N
			Orchidopexy	01DEC2017	01DEC2017	N
	C4591001 1126 11261301	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1126 11261302	Musculoskeletal and connective tissue disorders	Scoliosis	23FEB2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	12NOV2014		Y
	C4591001 1126 11261303	Immune system disorders	Drug hypersensitivity	05JAN2009		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	05AUG2020		Y
			Hypertriglyceridaemia	05AUG2020		Y
	C4591001 1126 11261304	Ear and labyrinth disorders	Eustachian tube dysfunction	16JAN2018	20FEB2018	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Nervous system disorders	Migraine	06SEP2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16DEC2008		Y
		Surgical and medical procedures	Ear tube insertion	20FEB2018	20FEB2018	N
	C4591001 1126 11261307	Ear and labyrinth disorders	Eustachian tube dysfunction	02NOV2020	15DEC2020	N
		Nervous system disorders	Migraine	23SEP2020		Y
	C4591001 1126 11261310	Congenital, familial and genetic disorders	Colour blindness	09SEP2013		Y
	C4591001 1126 11261312	Immune system disorders	Drug hypersensitivity	01MAY2017		Y
		Infections and infestations	Urinary tract infection	03JAN2021		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23JUN2015		Y
	C4591001 1126 11261313	General disorders and administration site conditions	Peripheral swelling	07DEC2020	31DEC2020	N
		Immune system disorders	Food allergy	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02DEC2014		Y
	C4591001 1126 11261314	Musculoskeletal and connective tissue disorders	Short stature	21MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20NOV2012		Y
	C4591001 1126 11261316	Psychiatric disorders	Anxiety disorder	01JAN2018		Y
	C4591001 1126 11261317	Metabolism and nutrition disorders	Type 1 diabetes mellitus	14JUN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	22JUN2020		Y
			Major depression	12MAY2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1126 11261318	Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	30DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	11DEC2019		Y
	C4591001 1126 11261319	Immune system disorders	Food allergy	01JAN2014		Y
	C4591001 1126 11261320	Immune system disorders	Drug hypersensitivity	09SEP2019		Y
	C4591001 1126 11261321	Eye disorders	Conjunctivitis allergic	01MAY2018		Y
		Musculoskeletal and connective tissue disorders	Short stature	11OCT2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12JUN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	13NOV2008		Y
	C4591001 1126 11261322	Ear and labyrinth disorders	Motion sickness	14SEP2017		Y
		Musculoskeletal and connective tissue disorders	Short stature	11OCT2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	02MAR2011		Y
			Rhinitis allergic	12JUN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	13NOV2008		Y
	C4591001 1126 11261325	Immune system disorders	Seasonal allergy	10APR2018		Y
	C4591001 1131 11311275	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Rubber sensitivity	01JAN2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1131 11311277	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Surgical and medical procedures	Cautery to nose	01JAN2018	31DEC2018	N
	C4591001 1131 11311278	Hepatobiliary disorders	Cholelithiasis	29AUG2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
		Surgical and medical procedures	Medical diet	01JAN2017		Y
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1131 11311280	Eye disorders	Hypermetropia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2013		Y
			Woman of childbearing potential	01JAN2019		Y
	C4591001 1131 11311281	Eye disorders	Hypermetropia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
			Menorrhagia	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
			Menarche	01JAN2016		Y
		Surgical and medical procedures	Intrauterine contraception	01FEB2020		Y
			Jaw operation	01MAR2006	31MAR2006	N
	C4591001 1131 11311282	Social circumstances	Menarche	01JAN2017		Y
	C4591001 1131 11311283	Injury, poisoning and procedural complications	Concussion	01JAN2019	31DEC2019	N
	C4591001 1131 11311285	Investigations	Menstruation normal	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1131 11311286	Eye disorders	Hypermetropia	01JAN2014		Y
		Nervous system disorders	Dizziness	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1131 11311287	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depressive symptom	01OCT2020		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
			Eczema	01JAN2019		Y
	C4591001 1131 11311288	Eye disorders	Hypermetropia	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311289	Investigations	Menstruation normal	01JAN2017		Y
	C4591001 1131 11311290	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1131 11311291	Eye disorders	Hypermetropia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2015		Y
	C4591001 1131 11311292	Infections and infestations	Pneumonia	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013		Y
			Premenstrual dysphoric disorder	01OCT2020		Y
	C4591001 1131 11311293	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1131 11311294	Musculoskeletal and connective tissue disorders	Scoliosis	31MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Generalised anxiety disorder	01JAN2016		Y
	C4591001 1131 11311295	Eye disorders	Hypermetropia	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2011	31DEC2011	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311296	Blood and lymphatic system disorders	Anaemia	01SEP2020		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2020	31JUL2020	N
	C4591001 1131 11311299	Congenital, familial and genetic disorders	Cystic fibrosis	(b) (6) 2005		Y
		Eye disorders	Myopia	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	07JAN2021		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1131 11311300	Congenital, familial and genetic disorders	Cystic fibrosis	(b) (6) 2007		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2019	31DEC2019	N
		Social circumstances	Premenarche	(b) (6) 2007		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1131 11311301	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Fall	01JAN2015	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2015	31DEC2015	N
			Suture insertion	01JAN2015	31DEC2015	N
	C4591001 1131 11311302	Congenital, familial and genetic disorders	Malformation venous	01JAN2012		Y
		Psychiatric disorders	Anxiety	31AUG2020		Y
			Depression	01AUG2020		Y
	C4591001 1139 11391144	Immune system disorders	Seasonal allergy	30JUN2009		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391145	Immune system disorders	Seasonal allergy	30NOV2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	15MAR2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Facial lesion excision	30NOV2014	30NOV2014	N
			Limb operation	30NOV2009	30NOV2009	N
	C4591001 1139 11391151	Skin and subcutaneous tissue disorders	Acne	30JUN2017		Y
	C4591001 1139 11391152	Eye disorders	Myopia	30JUN2016		Y
		Injury, poisoning and procedural complications	Wrist fracture	30JUN2015	30JUN2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2012		Y
	C4591001 1139 11391154	Gastrointestinal disorders	Coeliac disease	30JUN2012		Y
	C4591001 1139 11391157	Immune system disorders	Food allergy	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	30JUN2014	30JUN2014	N
	C4591001 1139 11391158	Musculoskeletal and connective tissue disorders	Myalgia	30JUN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2013		Y
	C4591001 1139 11391159	Eye disorders	Myopia	30JUN2019		Y
		Injury, poisoning and procedural complications	Femur fracture	30JUN2009	30JUN2009	N
			Wrist fracture	30JUN2013	30JUN2013	N
	C4591001 1139 11391161	Injury, poisoning and procedural complications	Upper limb fracture	30JUN2010	30JUN2010	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				30JUN2015	30JUN2015	N
		Nervous system disorders	Headache	30JUN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2017		Y
	C4591001 1139 11391162	Surgical and medical procedures	Adenoidectomy	15AUG2017	15AUG2017	N
	C4591001 1139 11391163	Surgical and medical procedures	Finger amputation	30JUN2008	30JUN2008	N
	C4591001 1139 11391165	Skin and subcutaneous tissue disorders	Acne	01OCT2020		Y
	C4591001 1139 11391166	Respiratory, thoracic and mediastinal disorders	Epistaxis	30JUN2013		Y
	C4591001 1139 11391168	Musculoskeletal and connective tissue disorders	Myalgia	30JUN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2017		Y
	C4591001 1139 11391169	Immune system disorders	Food allergy	30JUN2017		Y
		Psychiatric disorders	Post-traumatic stress disorder	30JUN2015		Y
	C4591001 1139 11391170	Metabolism and nutrition disorders	Lactose intolerance	30JUN2007		Y
		Psychiatric disorders	Post-traumatic stress disorder	30JUN2017		Y
	C4591001 1139 11391171	Immune system disorders	Seasonal allergy	(b) (6) 2005		Y
	C4591001 1139 11391172	Injury, poisoning and procedural complications	Epiphyseal fracture	15SEP2020	15NOV2020	N
		Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1139 11391173	Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2013		Y
			Autism spectrum disorder	31MAY2018		Y
			Depression	30JUN2018		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Disruptive mood dysregulation disorder	31MAY2018		Y
			Generalised anxiety disorder	30JUN2015		Y
	C4591001 1139 11391174	Immune system disorders	Allergy to animal	30JUN2007		Y
			Food allergy	30JUN2020		Y
			Milk allergy	30JUN2007		Y
			Mite allergy	30JUN2007		Y
			Seasonal allergy	30JUN2018		Y
		Metabolism and nutrition disorders	Calcium deficiency	30NOV2019		Y
			Iron deficiency	02NOV2020		Y
			Vitamin D deficiency	30NOV2019		Y
		Psychiatric disorders	Depression	30JUN2018		Y
			Generalised anxiety disorder	30JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2017		Y
	C4591001 1139 11391175	Injury, poisoning and procedural complications	Joint dislocation	30JUN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2017		Y
		Surgical and medical procedures	Mole excision	30JUN2015	30JUN2015	N
	C4591001 1139 11391177	Congenital, familial and genetic disorders	Congenital nystagmus	30JUN2008		Y
		Metabolism and nutrition disorders	Lactose intolerance	30JUN2015		Y
	C4591001 1139 11391178	General disorders and administration site conditions	Medical device pain	15JUN2019		Y
		Immune system disorders	Drug hypersensitivity	15JUN2015		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1139 11391179	Immune system disorders	Seasonal allergy	15AUG2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	30JUN2010	30JUN2010	N
		Nervous system disorders	Epilepsy	15AUG2014		Y
			Tension headache	30JUN2015		Y
	C4591001 1139 11391180	Reproductive system and breast disorders	Menorrhagia	30JUN2019		Y
	C4591001 1139 11391181	Immune system disorders	Seasonal allergy	15JUN2010		Y
		Injury, poisoning and procedural complications	Hand fracture	15JUN2012	15JUN2012	N
				15JUN2014	15JUN2014	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	15JUN2017	15JUN2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	15JUN2010		Y
	C4591001 1139 11391182	Immune system disorders	Seasonal allergy	30JUN2012		Y
		Injury, poisoning and procedural complications	Facial bones fracture	15JAN2017	15JAN2017	N
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2018		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1139 11391185	Injury, poisoning and procedural complications	Hand fracture	15JUN2018	15JUN2018	N
			Upper limb fracture	15JUN2017	15JUN2017	N
		Nervous system disorders	Headache	15JUN2020		Y
	C4591001 1139 11391186	Gastrointestinal disorders	Intussusception	15JUN2015	15JUN2015	N
		Surgical and medical procedures	Appendicectomy	15JUN2015	15JUN2015	N
	C4591001 1139 11391187	Injury, poisoning and procedural complications	Hand fracture	30JUN2018	30JUN2018	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391188	Immune system disorders	Drug hypersensitivity	30JUN2006		Y
		Infections and infestations	Tonsillitis	30JUN2010	30JUN2010	N
		Musculoskeletal and connective tissue disorders	Exostosis	15NOV2018	15NOV2018	N
			Scoliosis	30JUN2015		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
	C4591001 1139 11391189	Eye disorders	Myopia	15JUN2015		Y
		Psychiatric disorders	Anxiety	15JUN2018		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1139 11391190	Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2017		Y
	C4591001 1139 11391191	Immune system disorders	Drug hypersensitivity	30JUN2015	30JUN2015	N
	C4591001 1139 11391192	Immune system disorders	Seasonal allergy	30JUN2015		Y
		Injury, poisoning and procedural complications	Hand fracture	30JUN2014	30JUN2014	N
			Upper limb fracture	15JUN2009	15JUN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	15AUG2020		Y
	C4591001 1139 11391193	Psychiatric disorders	Anxiety	15JUN2013		Y
			Attention deficit hyperactivity disorder	15JUN2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1139 11391195	Skin and subcutaneous tissue disorders	Psoriasis	30JUN2008	30JUN2008	N
	C4591001 1139 11391196	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391197	Immune system disorders	Seasonal allergy	30JUN2018		Y
		Injury, poisoning and procedural complications	Ankle fracture	30JUN2017	31DEC2017	N
			Clavicle fracture	30JUN2013	31DEC2013	N
	C4591001 1139 11391198	Eye disorders	Myopia	15JAN2017		Y
		Injury, poisoning and procedural complications	Upper limb fracture	15JUN2016	15JUN2016	N
	C4591001 1139 11391199	Immune system disorders	Seasonal allergy	30JUN2008		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
			Eczema	30JUN2018		Y
	C4591001 1139 11391200	Immune system disorders	Allergy to animal	30JUN2010		Y
			Seasonal allergy	30JUN2015		Y
		Nervous system disorders	Migraine	30JUN2019		Y
	C4591001 1139 11391201	Eye disorders	Myopia	30JUN2013		Y
		Immune system disorders	Seasonal allergy	30JUN2015		Y
		Psychiatric disorders	Anxiety	30JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2020		Y
	C4591001 1139 11391202	Eye disorders	Myopia	15JUN2016		Y
		Immune system disorders	Drug hypersensitivity	15JUN2009		Y
			Seasonal allergy	15JUN2009		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391204	Injury, poisoning and procedural complications	Hand fracture	01SEP2019	30NOV2019	N
	C4591001 1139 11391205	Eye disorders	Myopia	15JUN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUN2017		Y
			Scoliosis	30JUN2017		Y
	C4591001 1139 11391206	Surgical and medical procedures	Appendicectomy	30APR2020	30APR2020	N
	C4591001 1139 11391207	Infections and infestations	Respiratory syncytial virus bronchiolitis	(b) (6) 2008	31DEC2009	N
	C4591001 1139 11391208	General disorders and administration site conditions	Medical device pain	15AUG2020		Y
		Immune system disorders	Seasonal allergy	30JUN2008		Y
		Injury, poisoning and procedural complications	Upper limb fracture	30MAY2020	30MAY2020	N
		Social circumstances	Premenarche	(b) (6) 2006		Y
		Surgical and medical procedures	Tonsillectomy	30DEC2010	30DEC2010	N
	C4591001 1139 11391209	Investigations	Cardiac murmur	30JUN2011	30JUN2014	N
		Surgical and medical procedures	Adenoidectomy	15MAY2012	15MAY2012	N
			Tonsillectomy	15MAY2012	15MAY2012	N
	C4591001 1139 11391210	Immune system disorders	Drug hypersensitivity	15JUN2009		Y
		Injury, poisoning and procedural complications	Ankle fracture	15JUN2016	15JUN2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	15OCT2019		Y
	C4591001 1139 11391211	Gastrointestinal disorders	Coeliac disease	30JUN2015		Y
			Irritable bowel syndrome	30JUN2016		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	(b) (6) 2005		Y
		Infections and infestations	Meningitis viral	(b) (6) 2005	30AUG2005	N
		Injury, poisoning and procedural complications	Foot fracture	30JUN2016	30JUN2016	N
		Psychiatric disorders	Anxiety	30JUN2015		Y
			Attention deficit hyperactivity disorder	30JUN2015		Y
	C4591001 1139 11391212	Immune system disorders	Food allergy	30JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15JUN2010	15JUN2015	N
	C4591001 1139 11391213	Injury, poisoning and procedural complications	Hand fracture	30JUN2019	30JUN2019	N
			Muscle strain	23DEC2020	23DEC2020	N
		Investigations	Cardiac murmur	(b) (6) 2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2010		Y
	C4591001 1139 11391214	Ear and labyrinth disorders	Tympanic membrane perforation	30JUN2015	30JUN2015	N
		Immune system disorders	Drug hypersensitivity	15JAN2020	15JAN2020	N
		Injury, poisoning and procedural complications	Facial bones fracture	30JUN2016	30JUN2016	N
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUN2018	30JUN2018	N
			Osteochondrosis	30JUN2017	30JUN2017	N
		Psychiatric disorders	Anxiety	30JUN2018		Y
		Skin and subcutaneous tissue disorders	Acne	15FEB2020	15AUG2020	N
	C4591001 1139 11391215	Musculoskeletal and connective tissue disorders	Discoid meniscus	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391216	Immune system disorders	Drug hypersensitivity	30JUN2006		Y
		Infections and infestations	Ear infection	30JUN2006	15JUL2006	N
		Injury, poisoning and procedural complications	Clavicle fracture	30JUN2017	30JUN2017	N
			Concussion	30JUN2017	30JUN2017	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	30JUN2013	30JUN2013	N
		Psychiatric disorders	Anxiety	30JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal inflammation	30JUN2006		Y
	C4591001 1139 11391217	Immune system disorders	Seasonal allergy	30JUN2015		Y
		Nervous system disorders	Headache	30JUN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2014		Y
		Skin and subcutaneous tissue disorders	Drug eruption	30JUN2010		Y
	C4591001 1139 11391219	Injury, poisoning and procedural complications	Concussion	01NOV2019	29FEB2020	N
			Wrist fracture	01NOV2020	31DEC2020	N
				01SEP2018	30NOV2020	N
		Surgical and medical procedures	Wisdom teeth removal	01OCT2020	31OCT2020	N
	C4591001 1139 11391220	Injury, poisoning and procedural complications	Joint injury	01APR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2010		Y
		Surgical and medical procedures	Ankle operation	01APR2020	30APR2020	N
	C4591001 1139 11391221	Reproductive system and breast disorders	Dysmenorrhoea	30JUN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2015		Y
	C4591001 1139 11391222	Gastrointestinal disorders	Gastrooesophageal reflux disease	(b) (6) 2007		Y
	C4591001 1139 11391223	Immune system disorders	Seasonal allergy	30JUN2016		Y
		Injury, poisoning and procedural complications	Upper limb fracture	15NOV2008	15NOV2008	N
	C4591001 1139 11391224	Gastrointestinal disorders	Gastrooesophageal reflux disease	30JUN2007		Y
			Hiatus hernia	15AUG2020	15AUG2020	N
		Immune system disorders	Seasonal allergy	30JUN2010		Y
		Nervous system disorders	Dyslexia	30JUN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2013		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2008	30JUN2011	N
			Oesophagogastric fundoplasty	15AUG2020	15AUG2020	N
	C4591001 1139 11391225	Eye disorders	Myopia	30JUN2014		Y
		Nervous system disorders	Headache	30JUN2015		Y
	C4591001 1139 11391226	Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391227	Eye disorders	Hypermetropia	30JUN2009		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 2007		Y
		Skin and subcutaneous tissue disorders	Acne	15JAN2019		Y
	C4591001 1139 11391228	Psychiatric disorders	Attention deficit hyperactivity disorder	15JUN2017		Y
	C4591001 1139 11391229	Eye disorders	Myopia	30JUN2015		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1139 11391230	Eye disorders	Myopia	30JUN2009		Y
		Injury, poisoning and procedural complications	Wrist fracture	30JUN2016	30JUN2016	N
		Reproductive system and breast disorders	Vaginal disorder	01JUL2020	28SEP2020	N
		Surgical and medical procedures	Hymenectomy	28SEP2020	28SEP2020	N
	C4591001 1139 11391231	Immune system disorders	Allergy to plants	30JUN2008		Y
			Seasonal allergy	30JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	30JUN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2007		Y
	C4591001 1139 11391232	Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	30JUN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01NOV2020		Y
			Eczema	30JUN2007		Y
		Surgical and medical procedures	Wisdom teeth removal	30JUN2015	30JUN2015	N
	C4591001 1139 11391233	Reproductive system and breast disorders	Dysmenorrhoea	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	30JUN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2007		Y
		Surgical and medical procedures	Tonsillectomy	15JUL2018	15JUL2018	N
	C4591001 1139 11391235	Eye disorders	Myopia	30JUN2015		Y
		Nervous system disorders	Headache	30JUN2019		Y

16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	30JUN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2019		Y
	C4591001 1139 11391236	Immune system disorders	Seasonal allergy	30JUN2010		Y
		Injury, poisoning and procedural complications	Chest injury	17DEC2020	19DEC2020	N
		Reproductive system and breast disorders	Menorrhagia	30JUN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN2006		Y
	C4591001 1139 11391237	Eye disorders	Myopia	23SEP2020		Y
		Immune system disorders	Seasonal allergy	30JUN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	15FEB2019	15MAY2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	15FEB2019		Y
			Post-traumatic stress disorder	30JUN2010		Y
	C4591001 1139 11391238	Immune system disorders	Food allergy	30JUN2009		Y
		Injury, poisoning and procedural complications	Ankle fracture	15APR2017	15APR2017	N
		Nervous system disorders	Headache	30JUN2014	30OCT2020	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391239	Injury, poisoning and procedural complications	Concussion	30JUN2018	30JUN2018	N
			Tibia fracture	30JUN2012	30JUN2012	N
		Psychiatric disorders	Anxiety	30JUN2017		Y
			Attention deficit hyperactivity disorder	30JUN2012		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	30JUN2019		Y
	C4591001 1139 11391240	Infections and infestations	Ear infection	30JUN2014	30JUN2014	N
		Injury, poisoning and procedural complications	Foot fracture	30JUN2015	30JUN2015	N
			Tibia fracture	30JUN2015	30JUN2015	N
			Upper limb fracture	30JUN2014	30JUN2014	N
				30JUN2019	30JUN2019	N
			Wrist fracture	30JUN2017	30JUN2017	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2014	30JUN2014	N
	C4591001 1139 11391241	Respiratory, thoracic and mediastinal disorders	Epistaxis	30JUN2015		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	30JUN2012		Y
	C4591001 1139 11391242	Endocrine disorders	Growth hormone deficiency	30JUN2018		Y
		Eye disorders	Myopia	30JUN2013		Y
		Immune system disorders	Drug hypersensitivity	30JUN2011		Y
		Infections and infestations	Ear infection	(b) (6) 2005	15FEB2017	N
		Nervous system disorders	Headache	30JUN2019		Y
		Social circumstances	Premenarche	(b) (6) 2005		Y
		Surgical and medical procedures	Ear tube insertion	15FEB2007	15FEB2007	N
	C4591001 1139 11391243	Immune system disorders	Seasonal allergy	01SEP2019		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1139 11391244	Social circumstances	Premenarche	(b) (6) 2006		Y
	C4591001 1139 11391245	Congenital, familial and genetic disorders	Strabismus congenital	(b) (6) 2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	30JUN2011		Y
		Immune system disorders	Seasonal allergy	30JUN2015		Y
		Nervous system disorders	Headache	30JUN2015		Y
	C4591001 1139 11391246	Injury, poisoning and procedural complications	Muscle strain	30JUN2018		Y
		Nervous system disorders	Dyslexia	01JAN2005		Y
		Psychiatric disorders	Sleep disorder	30JUN2015		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391247	Eye disorders	Myopia	30JUN2016		Y
		Gastrointestinal disorders	Eosinophilic oesophagitis	30DEC2017		Y
		Immune system disorders	Milk allergy	30DEC2011		Y
			Seasonal allergy	30JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2005	31DEC2014	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391248	Injury, poisoning and procedural complications	Concussion	15MAR2020	15MAR2020	N
			Muscle strain	16DEC2020	16DEC2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2017		Y
	C4591001 1139 11391249	Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2015		Y
		Immune system disorders	Seasonal allergy	30JUN2010		Y
		Injury, poisoning and procedural complications	Upper limb fracture	15DEC2012	15DEC2012	N
			Wrist fracture	31DEC2013	31DEC2013	N
		Nervous system disorders	Headache	30JUN2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391250	Psychiatric disorders	Anxiety	30JUN2018		Y
			Attention deficit hyperactivity disorder	30JUN2015		Y
			Depression	30JUN2018		Y
	C4591001 1139 11391251	Gastrointestinal disorders	Constipation	04NOV2020		Y
		Immune system disorders	Allergy to animal	30JUN2007		Y
			Seasonal allergy	30JUN2008		Y
		Infections and infestations	Chronic sinusitis	(b) (6) 2007	30JUN2008	N
		Reproductive system and breast disorders	Menorrhagia	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2007		Y
		Surgical and medical procedures	Adenoidectomy	30JUN2008	30JUN2008	N
	C4591001 1139 11391252	Infections and infestations	Ear infection	15DEC2008	15DEC2008	N
		Psychiatric disorders	Anxiety	30JUN2010		Y
			Attention deficit hyperactivity disorder	30JUN2014		Y
		Reproductive system and breast disorders	Dysmenorrhoea	27DEC2020		Y
		Skin and subcutaneous tissue disorders	Eczema	15NOV2008		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2009	30JUN2009	N
	C4591001 1139 11391253	Nervous system disorders	Headache	30JUN2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	10JAN2021		Y
	C4591001 1139 11391254	Immune system disorders	Seasonal allergy	30JUN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391255	Injury, poisoning and procedural complications	Foot fracture	15JUL2019		Y
			Ligament rupture	15MAR2019	15MAR2020	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391256	Immune system disorders	Seasonal allergy	30JUN2011		Y
		Infections and infestations	Sinusitis	01MAY2018	31MAY2018	N
		Injury, poisoning and procedural complications	Hand fracture	01APR2016	30APR2016	N
				20NOV2019	30NOV2019	N
			Radius fracture	03JUN2017	30JUN2017	N
			Upper limb fracture	01APR2014	31AUG2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2012		Y
	C4591001 1139 11391257	Infections and infestations	Urinary tract infection	01SEP2008	30SEP2008	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1139 11391258	Reproductive system and breast disorders	Gynaecomastia	01JAN2018		Y
	C4591001 1139 11391259	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1139 11391260	Infections and infestations	Croup infectious	(b) (6) 2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391261	Congenital, familial and genetic disorders	Congenital diaphragmatic hernia	(b) (6) 2005	(b) (6) 2005	N
		Eye disorders	Myopia	30JUN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	15JUN2006		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2018	31DEC2019	N
		Nervous system disorders	Headache	30JUN2020		Y
		Surgical and medical procedures	Hernia diaphragmatic repair	(b) (6) 2005	(b) (6) 2005	N
	C4591001 1139 11391262	Musculoskeletal and connective tissue disorders	Short stature	30JUN2007		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2005	(b) (6) 2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2010		Y
	C4591001 1139 11391263	Nervous system disorders	Dyslexia	30JUN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2015		Y
	C4591001 1140 11401323	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y
	C4591001 1140 11401324	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Autism spectrum disorder	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01FEB2012		Y
	C4591001 1140 11401325	Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1140 11401326	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1140 11401328	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
	C4591001 1140 11401329	Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401330	Surgical and medical procedures	Fracture treatment	01FEB2020	29FEB2020	N
		Immune system disorders	Food allergy	01OCT2008		Y
	C4591001 1140 11401332	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1140 11401333	Musculoskeletal and connective tissue disorders	Seasonal allergy	01APR2019		Y
		Immune system disorders	Arthralgia	01SEP2019		Y
	C4591001 1140 11401334	Musculoskeletal and connective tissue disorders	Seasonal allergy	01MAY2020		Y
		Immune system disorders	Scoliosis	01SEP2010		Y
	C4591001 1140 11401336	Skin and subcutaneous tissue disorders	Acne	01OCT2019		Y
		Surgical and medical procedures	Adenoidectomy	01JUL2008	31JUL2008	N
	C4591001 1140 11401337	Immune system disorders	Seasonal allergy	01AUG2018		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01SEP2012		Y
	C4591001 1140 11401338	Skin and subcutaneous tissue disorders	Acne	01OCT2019		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
	C4591001 1140 11401339	Psychiatric disorders	Anxiety	01OCT2020	30NOV2020	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1140 11401337	Skin and subcutaneous tissue disorders	Acne	21NOV2020		Y



16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401338	Psychiatric disorders	Obsessive-compulsive disorder	01JUL2019		Y
	C4591001 1140 11401340	Immune system disorders	Seasonal allergy	01MAR2012		Y
	C4591001 1140 11401344	Metabolism and nutrition disorders	Fructose intolerance	01JAN2017		Y
	C4591001 1140 11401345	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2018	31MAY2020	N
			Post-traumatic stress disorder	01JAN2018	31MAY2020	N
		Renal and urinary disorders	Urinary retention	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1140 11401347	Congenital, familial and genetic disorders	Hereditary motor and sensory neuropathy	01JAN2017		Y
		Immune system disorders	Allergy to metals	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1140 11401354	Immune system disorders	Drug hypersensitivity	(b) (6) 2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR2019		Y
	C4591001 1140 11401357	Congenital, familial and genetic disorders	Hypoplastic left heart syndrome	(b) (6) 2005		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01AUG2018		Y
		Surgical and medical procedures	Cardiac operation	01MAR2011	31MAR2011	N
				(b) (6) 2005	(b) (6) 2005	N
			Hernia diaphragmatic repair	01FEB2006	28FEB2006	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401358	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1140 11401361	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1140 11401362	Gastrointestinal disorders	Irritable bowel syndrome	01JUN2012	30JUN2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JUN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JUN2011		Y
	C4591001 1140 11401363	Immune system disorders	Food allergy	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
	C4591001 1140 11401365	Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
	C4591001 1140 11401367	Metabolism and nutrition disorders	Decreased appetite	(b) (6) 2008		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1140 11401369	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2019	31DEC2019	N
			Upper limb fracture	01JAN2015	31DEC2015	N
	C4591001 1140 11401370	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401372	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1140 11401373	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1140 11401375	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1140 11401378	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Wrist fracture	01SEP2020	31OCT2020	N
	C4591001 1140 11401379	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2015		Y
	C4591001 1140 11401380	Injury, poisoning and procedural complications	Concussion	01JAN2018	31DEC2018	N
			Foot fracture	01JAN2017	31DEC2017	N
			Limb fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01NOV2020		Y
			Depression	01NOV2020		Y
	C4591001 1140 11401381	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2018	31DEC2018	N
			Wrist fracture	01FEB2020	31MAR2020	N
				01JAN2014	31DEC2014	N
	C4591001 1140 11401383	Immune system disorders	Hypersensitivity	01JAN2008		Y
	C4591001 1140 11401386	Immune system disorders	Seasonal allergy	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401387	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Limb operation	22MAY2019	22MAY2019	N
	C4591001 1140 11401388	Eye disorders	Amblyopia	01MAR2008		Y
		Skin and subcutaneous tissue disorders	Acne	16DEC2020		Y
		Surgical and medical procedures	Ear tube insertion	01APR2008	30APR2008	N
			Eye operation	01APR2010	30APR2010	N
				01JUN2009	30JUN2009	N
			Tonsillectomy	01MAR2011	31MAR2011	N
	C4591001 1140 11401389	Psychiatric disorders	Insomnia	16DEC2020		Y
		Surgical and medical procedures	Adenoidectomy	01SEP2011	30SEP2011	N
	C4591001 1140 11401390	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2015	N
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1140 11401391	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1140 11401393	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2008	30JUN2008	N
	C4591001 1140 11401394	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT2020		Y
		Psychiatric disorders	Anxiety	01OCT2010		Y
			Attention deficit hyperactivity disorder	01OCT2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive disorder	01MAR2018		Y
	C4591001 1140 11401396	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018		Y
		Nervous system disorders	Headache	01JUN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1140 11401397	Gastrointestinal disorders	Coeliac disease	01MAY2013		Y
		Immune system disorders	Seasonal allergy	01MAY2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAY2016		Y
	C4591001 1140 11401398	Skin and subcutaneous tissue disorders	Acne	01MAY2020		Y
	C4591001 1140 11401399	Nervous system disorders	Migraine	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2008		Y
	C4591001 1140 11401400	Nervous system disorders	Migraine	01MAY2018		Y
		Surgical and medical procedures	Ear tube insertion	01DEC2009	31DEC2009	N
	C4591001 1140 11401401	Immune system disorders	Food allergy	01DEC2019		Y
	C4591001 1140 11401402	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1140 11401403	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2019		Y
	C4591001 1142 11421318	Infections and infestations	Conjunctivitis	04DEC2019	07DEC2019	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015	30SEP2019	N
		Surgical and medical procedures	Pilonidal sinus repair	27JAN2020	27JAN2020	N
	C4591001 1142 11421321	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1142 11421323	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1142 11421324	Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Post-traumatic stress disorder	01JAN2012		Y
	C4591001 1142 11421325	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1142 11421326	Surgical and medical procedures	Eye operation	01JAN2013	31DEC2013	N
			Foot operation	01JAN2019	31DEC2019	N
	C4591001 1142 11421333	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1142 11421340	Nervous system disorders	Seizure	01JAN2012		Y
	C4591001 1142 11421341	Investigations	Cardiac murmur	(b) (6) 2005		Y
		Surgical and medical procedures	Hernia repair	01APR2019	30APR2019	N
				01JUN2019	30JUN2019	N
			Mass excision	01APR2019	30APR2019	N
			Urethral repair	01JUN2019	30JUN2019	N
	C4591001 1142 11421345	Surgical and medical procedures	Elbow operation	01JAN2006	31DEC2006	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421346	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1142 11421348	Gastrointestinal disorders	Oesophagitis	01JAN2017	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1142 11421350	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1142 11421351	Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1142 11421354	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2006	31DEC2006	N
	C4591001 1142 11421355	Injury, poisoning and procedural complications	Clavicle fracture	(b) (6) 2008	(b) (6) 2008	N
			Hand fracture	01JAN2017	31DEC2017	N
	C4591001 1142 11421358	Cardiac disorders	Pulmonary valve stenosis	30AUG2019		Y
	C4591001 1142 11421359	Blood and lymphatic system disorders	Thrombocytopenia	(b) (6) 2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2013	31DEC2013	N
	C4591001 1142 11421361	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Circumcision	01JAN2011	31DEC2011	N
	C4591001 1142 11421362	Psychiatric disorders	Attention deficit hyperactivity disorder	22DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19APR2013		Y
	C4591001 1142 11421364	Metabolism and nutrition disorders	Type 1 diabetes mellitus	11DEC2018		Y
	C4591001 1142 11421366	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1142 11421367	Surgical and medical procedures	Eye operation	01JAN2012	31DEC2012	N
			Hernia repair	01JAN2009	31DEC2009	N
	C4591001 1142 11421369	Psychiatric disorders	Anxiety disorder	01NOV2013		Y
			Attention deficit hyperactivity disorder	18NOV2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	18JUN2019		Y
	C4591001 1142 11421371	Immune system disorders	Food allergy	01JAN2011		Y
	C4591001 1142 11421372	Immune system disorders	Food allergy	01JAN2008		Y
	C4591001 1142 11421377	Psychiatric disorders	Attention deficit hyperactivity disorder	25MAR2015		Y
	C4591001 1142 11421379	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2010		Y
	C4591001 1142 11421383	Infections and infestations	Otitis media	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Ear tube insertion	01JAN2013	31DEC2013	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421385	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1142 11421391	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2007		Y
			Ventricular septal defect	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Hypersensitivity	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1142 11421392	Immune system disorders	Allergy to plants	01JAN2016		Y
		Injury, poisoning and procedural complications	Fibula fracture	26NOV2017	26NOV2017	N
			Tibia fracture	26NOV2017	26NOV2017	N
		Surgical and medical procedures	Bone operation	26NOV2017	26NOV2017	N
			Epiphyseal surgery	01JUN2020	30JUN2020	N
	C4591001 1142 11421394	Immune system disorders	Drug hypersensitivity	14DEC2007		Y
		Infections and infestations	Otitis media	01JAN2008	31DEC2015	N
		Injury, poisoning and procedural complications	Wrist fracture	23DEC2013	23DEC2013	N
		Renal and urinary disorders	Hydronephrosis	(b) (6) 2007		Y
			Renal disorder	(b) (6) 2007	31JAN2008	N
		Surgical and medical procedures	Adenoidectomy	02JUN2010	02JUN2010	N
			Ear tube insertion	01JUL2011		Y
			Myringotomy	01JUL2010	01JUL2010	N
			Tonsillectomy	02JUN2010	02JUN2010	N
	C4591001 1142 11421395	Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypotension	01JAN2017		Y
	C4591001 1147 11471262	Psychiatric disorders	Generalised anxiety disorder	01JAN2020		Y
	C4591001 1147 11471268	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1147 11471269	Metabolism and nutrition disorders	Gluten sensitivity	09APR2018		Y
	C4591001 1147 11471270	Immune system disorders	Seasonal allergy	01OCT2020		Y
	C4591001 1147 11471271	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1147 11471274	Immune system disorders	Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1147 11471278	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1147 11471281	Blood and lymphatic system disorders	Iron deficiency anaemia	27MAY2020		Y
		Ear and labyrinth disorders	Tympanic membrane perforation	02JUL2014		Y
		Gastrointestinal disorders	Constipation	02JUL2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
	C4591001 1147 11471282	Eye disorders	Cataract	(b) (6) 2006		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Childhood depression	01JAN2018		Y
	C4591001 1147 11471283	Immune system disorders	Drug hypersensitivity	26NOV2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471284	Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y
	C4591001 1147 11471285	Immune system disorders	Drug hypersensitivity	01APR2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1147 11471286	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Migraine	01APR2018		Y
	C4591001 1147 11471288	Immune system disorders	Seasonal allergy	(b) (6) 2006		Y
		Nervous system disorders	Dysgraphia	01JAN2013		Y
			Idiopathic intracranial hypertension	01MAR2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1147 11471289	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAY2016		Y
	C4591001 1147 11471290	Immune system disorders	Allergy to animal	01JAN2020		Y
			Cockroach allergy	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1147 11471294	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2018		Y
	C4591001 1147 11471296	Psychiatric disorders	Anxiety	01JAN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471301	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1147 11471302	Immune system disorders	Allergy to animal	01JAN2005		Y
		Seasonal allergy		01JAN2006		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2005		Y
	C4591001 1147 11471303	Skin and subcutaneous tissue disorders	Acne	01OCT2019		Y
	C4591001 1147 11471308	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2019		Y
	C4591001 1147 11471310	Immune system disorders	Allergy to chemicals	01JAN2019		Y
			Perfume sensitivity	01JAN2019		Y
			Rubber sensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1147 11471311	Immune system disorders	Allergy to animal	01JAN2015		Y
	C4591001 1147 11471317	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1147 11471319	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1147 11471320	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Rubber sensitivity	01JAN2005		Y
	C4591001 1147 11471321	Metabolism and nutrition disorders	Obesity	12MAY2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471322	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1147 11471323	Congenital, familial and genetic disorders	Multiple epiphyseal dysplasia	04APR2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Rubber sensitivity	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
			Disruptive mood dysregulation disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Dermatitis contact	01JAN2013		Y
		Surgical and medical procedures	Hip surgery	01JAN2017	31JAN2017	N
	C4591001 1147 11471325	Immune system disorders	Allergy to animal	01JAN2011		Y
			Cockroach allergy	01JAN2011		Y
			Mite allergy	01JAN2011		Y
	C4591001 1147 11471328	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Otitis media chronic	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Umbilical hernia repair	01JAN2006	31DEC2006	N
	C4591001 1147 11471329	Immune system disorders	Multiple allergies	01JAN2015	31DEC2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tooth extraction	03SEP2020	03SEP2020	N
	C4591001 1147 11471331	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Bronchial hyperreactivity	01JAN2015		Y
	C4591001 1147 11471333	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Surgical and medical procedures	Adenoidectomy	14NOV2019	14NOV2019	N
			Tonsillectomy	14NOV2019	14NOV2019	N
	C4591001 1147 11471334	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1147 11471337	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1147 11471338	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1147 11471339	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1147 11471340	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1147 11471341	Immune system disorders	Drug hypersensitivity	01JAN2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1147 11471344	Immune system disorders	Allergy to plants	01JAN2014		Y
			Food allergy	01JAN2014		Y
				01JAN2016		Y
			Hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1147 11471347	Immune system disorders	Rubber sensitivity	01JAN2010		Y
	C4591001 1150 11501118	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Dermatophytosis of nail	31JUL2019		Y
	C4591001 1150 11501119	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Milk allergy	01JAN2012		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Appendicitis	01OCT2018	30NOV2018	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2017	N
			Bronchial hyperreactivity	01JAN2007	31DEC2017	N
			Snoring	01JAN2008	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1150 11501120	Eye disorders	Pupils unequal	12NOV2019	31DEC2020	N
		Immune system disorders	Food allergy	01JAN2006		Y
		Renal and urinary disorders	Haematuria	01JAN2018	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501121	Metabolism and nutrition disorders	Overweight	01AUG2017	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01AUG2017	31DEC2017	N
		Psychiatric disorders	Eating disorder	01APR2020		Y
			Generalised anxiety disorder	01APR2020		Y
	C4591001 1150 11501123	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Plantar fascial fibromatosis	01AUG2020	30SEP2020	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1150 11501124	Psychiatric disorders	Anxiety disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1150 11501125	Immune system disorders	Food allergy	01JAN2007		Y
				01JAN2017		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1150 11501126	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2018		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1150 11501127	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1150 11501128	Immune system disorders	Allergy to animal	01JAN2007		Y
	C4591001 1150 11501129	Gastrointestinal disorders	Constipation	01JAN2017	31DEC2019	N
			Gastrooesophageal reflux disease	01JAN2017	31DEC2018	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2018	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2017	31DEC2018	N
		Psychiatric disorders	Anxiety disorder	01FEB2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1150 11501130	Eye disorders	Anisometropia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Impetigo	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
	C4591001 1150 11501131	General disorders and administration site conditions	Developmental delay	01JAN2017		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety disorder	01JAN2019	31DEC2020	N
			Attention deficit hyperactivity disorder	01JAN2016	31DEC2019	N
			Oppositional defiant disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1150 11501132	Ear and labyrinth disorders	Eustachian tube disorder	01JAN2016	31DEC2017	N
		Metabolism and nutrition disorders	Overweight	01JAN2016	31DEC2017	N
		Nervous system disorders	Disturbance in attention	01JAN2019		Y
	C4591001 1150 11501133	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1150 11501134	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Sleep disorder	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501135	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Short stature	01JAN2020		Y
	C4591001 1150 11501136	Gastrointestinal disorders	Abdominal pain	01JAN2020		Y
			Constipation	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2017	31DEC2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1150 11501166	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Eating disorder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2014		Y
	C4591001 1150 11501168	Gastrointestinal disorders	Malabsorption	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1150 11501171	Skin and subcutaneous tissue disorders	Acne	01FEB2019		Y
	C4591001 1150 11501176	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	18APR2018	31MAY2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1150 11501178	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1150 11501179	Metabolism and nutrition disorders	Fructose intolerance	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1150 11501180	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2019		Y
	C4591001 1150 11501183	Immune system disorders	Allergy to animal	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1150 11501185	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2007		Y
	C4591001 1150 11501186	Immune system disorders	Food allergy	01JAN2007		Y
			Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015	31DEC2016	N
	C4591001 1150 11501187	Immune system disorders	Allergy to animal	01JAN2016		Y
		Infections and infestations	Cellulitis	01JAN2019	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501189	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Nervous system disorders	Dysgraphia	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501190	Eye disorders	Myopia	01JAN2016	31DEC2017	N
		Gastrointestinal disorders	Abdominal pain	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Nervous system disorders	Migraine without aura	01JAN2015	31DEC2016	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2017		Y
		Reproductive system and breast disorders	Menstruation irregular	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1150 11501191	Congenital, familial and genetic disorders	Congenital anomaly	(b) (6) 2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
	C4591001 1150 11501192	Immune system disorders	Allergy to animal	01JAN2008		Y
			Mite allergy	01JAN2008		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Enuresis	01JAN2015	31DEC2016	N
			Tic	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
			Sleep apnoea syndrome	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2015		Y
	C4591001 1150 11501193	Immune system disorders	Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN2016		Y
	C4591001 1150 11501195	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1150 11501196	General disorders and administration site conditions	Pyrexia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Chronic sinusitis	01JAN2017		Y
	C4591001 1150 11501197	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1150 11501198	Musculoskeletal and connective tissue disorders	Short stature	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Persistent depressive disorder	01JAN2018		Y
	C4591001 1150 11501199	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1150 11501202	Immune system disorders	Food allergy	01MAR2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dairy intolerance	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
	C4591001 1150 11501203	Ear and labyrinth disorders	Deafness	01JAN2012	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012	31DEC2013	N
			Epistaxis	01JAN2019	31DEC2019	N
	C4591001 1150 11501204	Endocrine disorders	Precocious puberty	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014	31DEC2020	N
		Psychiatric disorders	Social anxiety disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1150 11501205	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1150 11501206	Musculoskeletal and connective tissue disorders	Scoliosis	13SEP2016	30SEP2017	N
	C4591001 1150 11501208	Social circumstances	Premenarche	01JAN2008		Y
	C4591001 1150 11501209	Immune system disorders	Allergy to animal	01JAN2010		Y
		Injury, poisoning and procedural complications	VIIth nerve injury	01JAN2017		Y
		Nervous system disorders	Speech disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501210	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501211	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Food allergy	01JAN2009		Y
					31DEC2016	N
			Seasonal allergy	01JAN2009		Y
	C4591001 1150 11501212	Nervous system disorders	Dyslexia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501213	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01MAY2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2008		Y
	C4591001 1150 11501214	Immune system disorders	Food allergy	(b) (6) 2008		Y
	C4591001 1150 11501215	Psychiatric disorders	Anxiety	01OCT2020		Y
	C4591001 1150 11501216	Eye disorders	Blepharitis	01FEB2018	31MAR2018	N
		Injury, poisoning and procedural complications	Ankle fracture	03DEC2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2018	31DEC2019	N
			Vitamin D deficiency	01FEB2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501218	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1150 11501219	Gastrointestinal disorders	Constipation	01JAN2015	31DEC2018	N
		Nervous system disorders	Disturbance in attention	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Blister	01JAN2019		Y
	C4591001 1150 11501220	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1150 11501221	Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1150 11501222	Metabolism and nutrition disorders	Overweight	01JAN2015	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501224	Gastrointestinal disorders	Constipation	01JAN2019	30JUN2020	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Reading disorder	01JAN2019		Y
	C4591001 1150 11501225	Investigations	Cardiac murmur	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	01AUG2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501226	Nervous system disorders	Apraxia	(b) (6) 2004		Y
		Psychiatric disorders	Speech sound disorder	01JAN2009		Y
	C4591001 1150 11501227	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2015		Y
	C4591001 1150 11501228	Immune system disorders	Allergy to animal	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1150 11501229	Gastrointestinal disorders	Constipation	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2016		Y
	C4591001 1150 11501230	Surgical and medical procedures	Ear tube insertion	01JAN2009		Y
	C4591001 1150 11501232	Immune system disorders	Drug hypersensitivity	(b) (6) 2006		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1150 11501233	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1150 11501234	Immune system disorders	Food allergy	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501235	Immune system disorders	Food allergy	01JAN2005		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1150 11501237	Nervous system disorders	Dyslexia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1150 11501238	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Food allergy	01JAN2009		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
			Attention deficit hyperactivity disorder	01AUG2020		Y
		Social circumstances	Premenarche	01JAN2008		Y
	C4591001 1150 11501239	Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2020		Y
	C4591001 1150 11501240	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501241	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Depression	01MAR2020		Y
	C4591001 1150 11501242	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2019		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Tendon disorder	01JUL2019	31JAN2020	N
	C4591001 1150 11501243	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1150 11501244	Ear and labyrinth disorders	Middle ear adhesions	01MAR2020		Y
		Endocrine disorders	Precocious puberty	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Food allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1150 11501246	Gastrointestinal disorders	Constipation	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Short stature	01NOV2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2005		Y
		Nervous system disorders	Disturbance in attention	01NOV2020		Y
		Psychiatric disorders	Anxiety disorder	01NOV2020		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2017		Y
			Eczema	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501247	Psychiatric disorders	Depression	01DEC2020		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2018		Y
	C4591001 1150 11501248	Immune system disorders	Food allergy	01JUN2020		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Overweight	01JAN2014	31DEC2017	N
	C4591001 1150 11501249	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1150 11501250	Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1150 11501251	Investigations	Cardiac murmur	01JAN2016		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2016	31DEC2017	N
		Psychiatric disorders	Tic	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1150 11501252	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1150 11501253	Immune system disorders	Allergy to animal	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Surgical and medical procedures	Adenoidectomy	01OCT2010	31OCT2010	N
			Skin lesion removal	01JAN2007	31JAN2007	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501254	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01NOV2020		Y
		Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501255	Gastrointestinal disorders	Enterocolitis	01JAN2007		Y
		Immune system disorders	Rubber sensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2007		Y
	C4591001 1150 11501256	Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1150 11501257	Immune system disorders	Food allergy	01JAN2009		Y
			Reaction to food additive	01JAN2015		Y
			Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2015		Y
	C4591001 1150 11501258	Immune system disorders	Allergy to arthropod bite	01JAN2008		Y
	C4591001 1150 11501259	Immune system disorders	Allergy to animal	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
	C4591001 1150 11501260	Nervous system disorders	Disturbance in attention	01NOV2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501262	Social circumstances	Premenarche	01NOV2020		Y
	C4591001 1150 11501263	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1150 11501264	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1150 11501266	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1150 11501267	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1150 11501268	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
	C4591001 1150 11501269	Cardiac disorders	Arrhythmia	01DEC2019	31JAN2020	N
		General disorders and administration site conditions	Adverse food reaction	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1150 11501270	Social circumstances	Premenarche	01DEC2020		Y
	C4591001 1150 11501271	Congenital, familial and genetic disorders	Birth mark	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501272	Skin and subcutaneous tissue disorders	Hirsutism	01JAN2010		Y
	C4591001 1150 11501273	Metabolism and nutrition disorders	Underweight	01JAN2018	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Impulse-control disorder	01JAN2018		Y
	C4591001 1150 11501274	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
			Obsessive-compulsive disorder	01JAN2020		Y
	C4591001 1150 11501275	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
	C4591001 1150 11501276	Investigations	Cardiac murmur	01DEC2017		Y
		Nervous system disorders	Headache	01OCT2017	31DEC2019	N
	C4591001 1150 11501277	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501278	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		General disorders and administration site conditions	Developmental delay	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Nervous system disorders	Sensory disturbance	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
			Eczema	01JAN2016		Y
	C4591001 1150 11501279	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2016	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Autism spectrum disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
	C4591001 1150 11501281	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1150 11501282	Skin and subcutaneous tissue disorders	Acne	01SEP2020		Y
	C4591001 1150 11501283	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y
	C4591001 1150 11501284	Nervous system disorders	Migraine	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501285	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1150 11501286	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2013		Y
	C4591001 1150 11501287	Musculoskeletal and connective tissue disorders	Scoliosis	01FEB2016		Y
	C4591001 1150 11501288	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1150 11501289	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1150 11501290	Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1150 11501291	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1150 11501292	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1150 11501293	Infections and infestations	Lyme disease	01JAN2008	31DEC2009	N
	C4591001 1150 11501294	Immune system disorders	Oral allergy syndrome	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2020		Y
		Psychiatric disorders	Major depression	01JAN2020	01JAN2021	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2015		Y
	C4591001 1150 11501297	Congenital, familial and genetic disorders	Thalassaemia beta	01JAN2008		Y
		Immune system disorders	Allergy to animal	01JAN2020		Y
	C4591001 1150 11501298	Immune system disorders	Food allergy	01JAN2010		Y
				01JAN2014		Y
	C4591001 1150 11501299	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2014		Y
	C4591001 1150 11501301	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01AUG2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
		Social circumstances	Premenarche	(b) (6) 2005	29JAN2021	N
	C4591001 1152 11521605	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	(b) (6) 2005		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1152 11521612	Eye disorders	Myopia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521614	Immune system disorders	Seasonal allergy	(b) (6) 2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2006		Y
	C4591001 1152 11521617	Immune system disorders	Allergy to animal	01JAN2018		Y
		Infections and infestations	Conjunctivitis	01JAN2019	31DEC2019	N
			Ear infection	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011	31DEC2012	N
	C4591001 1152 11521625	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Croup infectious	01JAN2016	31DEC2016	N
			Osteomyelitis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2018	N
	C4591001 1152 11521628	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1152 11521629	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1152 11521633	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1152 11521635	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Pneumonia	01JAN2013	31DEC2013	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1152 11521637	Congenital, familial and genetic disorders	Birth mark	(b) (6) 2007	(b) (6) 2007	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1152 11521639	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Rotavirus infection	01JAN2009	31DEC2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1152 11521640	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1152 11521641	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1152 11521642	Eye disorders	Astigmatism	01JAN2016		Y
	C4591001 1152 11521644	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 2007		Y
	C4591001 1152 11521645	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011	31DEC2017	N
	C4591001 1152 11521646	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1152 11521647	Surgical and medical procedures	Circumcision	01JAN2016	31DEC2016	N
	C4591001 1152 11521649	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521650	Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2007	31DEC2007	N
	C4591001 1152 11521651	Eye disorders	Myopia	01JAN2012		Y
	C4591001 1152 11521653	Eye disorders	Myopia	01JAN2012		Y
	C4591001 1152 11521654	Eye disorders	Astigmatism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Foreign body in ear	01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Removal of foreign body from external ear	01JAN2011	31DEC2011	N
	C4591001 1152 11521655	Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
	C4591001 1152 11521656	Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN2015	31DEC2015	N
			Tooth extraction	01JAN2015	31DEC2015	N
	C4591001 1152 11521659	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Ear infection	01JAN2010	31DEC2017	N
		Product issues	Device breakage	01JUN2020	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Ear tube insertion	01JAN2010	31DEC2010	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Medical device change	01JUN2020	30JUN2020	N
			Tonsillectomy	01JAN2011	31DEC2011	N
			Cyst	01JUL2018	31JUL2018	N
	C4591001 1152 11521661	General disorders and administration site conditions				
		Surgical and medical procedures	Facial lesion excision	01JUL2018	31JUL2018	N
	C4591001 1152 11521662	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1152 11521663	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1152 11521665	Hepatobiliary disorders	Hepatic steatosis	01JUN2020		Y
	C4591001 1152 11521667	Immune system disorders	Allergy to metals	01JAN2016		Y
	C4591001 1152 11521668	Ear and labyrinth disorders	Auditory disorder	01JAN2011	31DEC2011	N
		Nervous system disorders	Speech disorder	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Ear tube insertion	01JAN2011	31DEC2011	N
			Ear tube removal	01JAN2012	31DEC2012	N
	C4591001 1152 11521669	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Ear infection	01JAN2005	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N
			Ear tube removal	01JAN2012	31DEC2012	N
			Myringotomy	01JAN2012	31DEC2012	N
			Epilepsy	01JAN2013	31DEC2017	N
	C4591001 1152 11521670	Nervous system disorders				
	C4591001 1152 11521671	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1152 11521672	Eye disorders	Strabismus	01JAN2011	31DEC2015	N
		Surgical and medical procedures	Strabismus correction	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
	C4591001 1152 11521673	Reproductive system and breast disorders	Testicular torsion	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Testicular operation	01JUL2020	31JUL2020	N
	C4591001 1152 11521674	Psychiatric disorders	Depression	01AUG2020		Y
	C4591001 1152 11521679	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1152 11521680	Skin and subcutaneous tissue disorders	Urticaria	01NOV2020	05DEC2020	N
	C4591001 1152 11521681	Gastrointestinal disorders	Coeliac disease	01JAN2015		Y
	C4591001 1152 11521682	Immune system disorders	Allergy to animal	01JUL2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1152 11521683	Eye disorders	Myopia	01JAN2015		Y
	C4591001 1152 11521684	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521685	Immune system disorders	Milk allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
			Tonsillolith	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008	31DEC2015	N
	C4591001 1152 11521688	Eye disorders	Strabismus	01JAN2015	31DEC2015	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Strabismus correction	01JAN2015	31DEC2015	N
	C4591001 1152 11521689	Eye disorders	Hypermetropia	01JAN2018		Y
		Infections and infestations	Ear infection	01OCT2008	30JUN2009	N
		Surgical and medical procedures	Ear tube insertion	01JUN2009	30JUN2009	N
	C4591001 1152 11521690	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2013	31DEC2013	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Fracture treatment	01JAN2013	31DEC2013	N
	C4591001 1152 11521691	Eye disorders	Myopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1152 11521692	Infections and infestations	Adenoiditis	01JAN2014	31DEC2014	N
		Nervous system disorders	Convulsion in childhood	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521693	Immune system disorders	Allergy to arthropod sting	01JAN2012		Y
	C4591001 1152 11521697	Skin and subcutaneous tissue disorders	Eczema	01JAN2008	31DEC2018	N
	C4591001 1152 11521699	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1152 11521700	Immune system disorders	Allergy to animal	01JUN2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1152 11521701	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1152 11521702	Cardiac disorders	Aortic valve disease	01JAN2009		Y
		Infections and infestations	Staphylococcal scalded skin syndrome	01JAN2011	31DEC2011	N
		Investigations	Cardiac murmur	21DEC2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2009		Y
	C4591001 1152 11521703	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1152 11521704	Immune system disorders	Allergy to arthropod sting	01JAN2016		Y
	C4591001 1152 11521705	Psychiatric disorders	Depression	01AUG2020		Y
	C4591001 1152 11521706	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1152 11521707	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1152 11521708	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament injury	01AUG2020	31AUG2020	N
			Meniscus injury	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2015	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
			Eczema	01JAN2015		Y
			Urticaria	01SEP2020	30SEP2020	N
		Surgical and medical procedures	Ligament operation	01AUG2020	31AUG2020	N
			Meniscus operation	01JAN2015	31DEC2015	N
	C4591001 1152 11521709	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1152 11521710	Immune system disorders	Mite allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2018	N
	C4591001 1152 11521713	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1152 11521715	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1152 11521716	Immune system disorders	Allergy to animal	01JAN2011		Y
			Seasonal allergy	01JAN2019		Y
	C4591001 1152 11521717	Injury, poisoning and procedural complications	Skin laceration	01JAN2017	31DEC2017	N
			Upper limb fracture	01MAR2020	31MAR2020	N
		Skin and subcutaneous tissue disorders	Ingrowing nail	01DEC2020	01DEC2020	N
		Surgical and medical procedures	Fracture treatment	01MAR2020	31MAR2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Joint stabilisation	01DEC2020	01DEC2020	N
	C4591001 1152 11521718	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1152 11521720	Gastrointestinal disorders	Constipation	01JAN2019	30SEP2019	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Pneumonia	01JAN2016	31DEC2016	N
	C4591001 1152 11521722	Blood and lymphatic system disorders	Immune thrombocytopenia	01SEP2006	31JAN2007	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1152 11521723	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Adenoiditis	01JAN2009	31DEC2009	N
			Appendicitis	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1152 11521724	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Perennial allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2019	31JAN2019	N
		Nervous system disorders	Headache	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2016		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521727	Surgical and medical procedures	Toe operation	01JAN2019	31JAN2019	N
		Gastrointestinal disorders	Intussusception	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2012	31DEC2012	N
	C4591001 1152 11521730	Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cautery to nose	01JAN2012	31DEC2012	N
			Circumcision	01JAN2007	31DEC2007	N
			Intestinal operation	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ear neoplasm	01JAN2010	31DEC2010	N
	C4591001 1152 11521731	Nervous system disorders	Migraine	01APR2020		Y
		Surgical and medical procedures	Middle ear operation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015	31DEC2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1152 11521732		Insomnia	01JAN2015		Y
		Surgical and medical procedures	Liposuction	01JUL2020	31JUL2020	N
			Wisdom teeth removal	01JAN2020	31JAN2020	N
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1152 11521733	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2018		Y
		Eye disorders	Dacryostenosis acquired	01JAN2009	31DEC2009	N
			Hypermetropia	01JAN2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1152 11521734	Surgical and medical procedures	Lacrimal duct procedure	01JAN2009	31DEC2009	N
		Immune system disorders	Perennial allergy	01JAN2015		Y
		Infections and infestations	Adenoiditis	01JAN2010	31DEC2010	N
			Ear infection	01JAN2008	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Ear tube insertion	01JAN2008	31DEC2011	N
	C4591001 1152 11521736	Eye disorders	Myopia	01JAN2017		Y
	C4591001 1152 11521737	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
			Open reduction of fracture	01JAN2016	31DEC2016	N
	C4591001 1152 11521738	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1152 11521740	Immune system disorders	Mite allergy	01JAN2016		Y
			Perennial allergy	01JAN2016		Y
		Renal and urinary disorders	Vesicoureteric reflux	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Urinary tract operation	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521743	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1152 11521744	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Pneumonia	01JAN2009	31DEC2009	N
	C4591001 1152 11521746	Ear and labyrinth disorders	Hypoacusis	01DEC2020		Y
	C4591001 1152 11521747	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010	31DEC2014	N
	C4591001 1152 11521748	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1152 11521749	Immune system disorders	Food allergy	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009	31DEC2014	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1152 11521751	Immune system disorders	Allergy to animal	01JAN2016		Y
			Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1152 11521752	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1152 11521753	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2016		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1152 11521756	Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1152 11521757	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1156 11561243	Infections and infestations	Body tinea	11MAY2019		Y
	C4591001 1156 11561244	Blood and lymphatic system disorders	Iron deficiency anaemia	01MAY2019		Y
	C4591001 1156 11561245	Infections and infestations	Rhinitis	04NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	02DEC2015		Y
	C4591001 1156 11561246	Respiratory, thoracic and mediastinal disorders	Asthma	11AUG2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1156 11561247	Immune system disorders	Food allergy	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1156 11561249	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1156 11561253	Metabolism and nutrition disorders	Dyslipidaemia	05JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	26FEB2020		Y
	C4591001 1156 11561254	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1156 11561255	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1156 11561257	Psychiatric disorders	Behaviour disorder	27APR2017		Y
	C4591001 1156 11561260	Reproductive system and breast disorders	Dysmenorrhoea	24JAN2019		Y
	C4591001 1156 11561262	Respiratory, thoracic and mediastinal disorders	Asthma	05APR2010		Y
	C4591001 1156 11561263	Metabolism and nutrition disorders	Hypertriglyceridaemia	14NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2019		Y
	C4591001 1156 11561264	Psychiatric disorders	Behaviour disorder	02OCT2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2017		Y
	C4591001 1156 11561265	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2020		Y
	C4591001 1156 11561304	Metabolism and nutrition disorders	Dyslipidaemia	26OCT2020		Y
			Obesity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	03MAR2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561308	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1156 11561311	Infections and infestations	Chronic tonsillitis	01JAN2010	31DEC2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	01OCT2020		Y
			Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Rhinitis allergic	10JUN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1156 11561312	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1156 11561313	Metabolism and nutrition disorders	Hyperlipidaemia	15AUG2019		Y
	C4591001 1156 11561314	Reproductive system and breast disorders	Menstruation irregular	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561317	Metabolism and nutrition disorders	Obesity	26JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1156 11561319	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	30OCT2020		Y
	C4591001 1156 11561322	Psychiatric disorders	Insomnia	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561324	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1156 11561325	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561328	Infections and infestations	Adenoiditis	01JAN2010	31DEC2012	N
			Chronic tonsillitis	01JAN2009	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2013	N
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561334	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1156 11561335	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1156 11561337	Musculoskeletal and connective tissue disorders	Scoliosis	14MAR2018		Y
		Reproductive system and breast disorders	Breast cyst	11MAR2019		Y
	C4591001 1156 11561338	Endocrine disorders	Hypopituitarism	01JUN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	22JAN2015		Y
	C4591001 1156 11561339	Congenital, familial and genetic disorders	Sickle cell trait	(b) (6) 2008		Y
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	20MAY2019	29FEB2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
	C4591001 1156 11561340	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
		Vascular disorders	Peripheral venous disease	01JAN2017		Y
	C4591001 1156 11561343	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1156 11561344	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Adenoiditis	01JAN2010	31MAR2010	N
		Surgical and medical procedures	Adenoidectomy	01MAR2010	31MAR2010	N
	C4591001 1156 11561346	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1156 11561351	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1156 11561353	Congenital, familial and genetic disorders	Pectus excavatum	(b) (6) 2008		Y
		Infections and infestations	Adenoiditis	01JAN2011	31DEC2012	N
		Social circumstances	Premenarche	(b) (6) 2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561356	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
	C4591001 1156 11561357	Eye disorders	Refractive amblyopia	01JAN2014		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1156 11561359	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009	31DEC2017	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561360	Hepatobiliary disorders	Non-alcoholic steatohepatitis	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2018		Y
			Obesity	01JAN2017	08JAN2021	N
	C4591001 1156 11561363	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1156 11561367	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1156 11561371	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
	C4591001 1156 11561372	Endocrine disorders	Precocious puberty	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1156 11561373	Gastrointestinal disorders	Inguinal hernia	(b) (6) 2007	(b) (6) 2007	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2011		Y
		Surgical and medical procedures	Inguinal hernia repair	(b) (6) 2007	(b) (6) 2007	N
	C4591001 1156 11561374	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1223 12231267	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1223 12231268	Congenital, familial and genetic disorders	Cerebral cavernous malformation	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231271	Immune system disorders	Allergy to animal	01JAN2016	31DEC2018	N
	C4591001 1223 12231272	Immune system disorders	Food allergy	01JAN2007		Y
			Hypersensitivity	01JAN2007		Y
	C4591001 1223 12231273	Immune system disorders	Seasonal allergy	(b) (6) 2005		Y
	C4591001 1223 12231278	Psychiatric disorders	Anxiety	01DEC2019		Y
			Depression	01JAN2019		Y
	C4591001 1223 12231283	Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1223 12231284	Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1223 12231285	Nervous system disorders	Epilepsy	01JAN2011		Y
	C4591001 1235 12351235	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1235 12351236	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
	C4591001 1235 12351239	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1235 12351242	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2011		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2011		Y
	C4591001 1235 12351244	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1235 12351245	Infections and infestations	Sinusitis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1235 12351246	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1235 12351247	Congenital, familial and genetic disorders	Cleft lip and palate	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1235 12351249	Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1235 12351250	Infections and infestations	Nail infection	01NOV2020		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351251	Immune system disorders	Allergy to arthropod bite	01JAN2009		Y
	C4591001 1235 12351252	Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1235 12351253	Renal and urinary disorders	Urinary tract disorder	01JAN2008	31DEC2008	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	01JAN2017	31DEC2017	N
	C4591001 1235 12351254	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017	31DEC2017	N
	C4591001 1270 12701173	Musculoskeletal and connective tissue disorders	Scoliosis	02NOV2017		Y
		Nervous system disorders	Syncope	07JAN2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	02JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	07MAY2018		Y
	C4591001 1270 12701174	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	21MAY2009		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	20NOV2009		Y
	C4591001 1270 12701184	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eyelid haemangioma	13AUG2019		Y
		Skin and subcutaneous tissue disorders	Acne	13DEC2019		Y
	C4591001 1270 12701187	Immune system disorders	Drug hypersensitivity	24MAY2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	27SEP2019		Y
			Osteitis	30SEP2014		Y
	C4591001 1270 12701188	Immune system disorders	Food allergy	28NOV2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	04FEB2020		Y
	C4591001 1270 12701189	Respiratory, thoracic and mediastinal disorders	Asthma	06MAR2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701191	Respiratory, thoracic and mediastinal disorders	Snoring	05APR2011		Y
			Wheezing	16SEP2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01SEP2016	01DEC2018	N
	C4591001 1270 12701194	Congenital, familial and genetic disorders	Congenital skin dimples	(b) (6) 2007		Y
		Immune system disorders	Drug hypersensitivity	22SEP2008		Y
				31JAN2016		Y
		Skin and subcutaneous tissue disorders	Pityriasis alba	01AUG2012		Y
	C4591001 1270 12701198	Immune system disorders	Drug hypersensitivity	03AUG2011		Y
			Food allergy	07MAR2009		Y
				11AUG2009		Y
	C4591001 1270 12701199	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	10JAN2020		Y
		Reproductive system and breast disorders	Menstruation irregular	01SEP2019		Y
	C4591001 1270 12701200	Immune system disorders	Drug hypersensitivity	16NOV2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13FEB2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	20DEC2007		Y
	C4591001 1270 12701201	Eye disorders	Astigmatism	19JUN2019		Y
			Myopia	17JUN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	29JUN2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	13FEB2020		Y
	C4591001 1270 12701202	Metabolism and nutrition disorders	Lactose intolerance	29MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29MAY2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis	07AUG2018		Y
	C4591001 1270 12701203	Congenital, familial and genetic disorders	Congenital flat feet	17JUN2020		Y
	C4591001 1270 12701204	Psychiatric disorders	Generalised anxiety disorder	11FEB2016		Y
			Obsessive-compulsive disorder	07JAN2019		Y
	C4591001 1270 12701205	Immune system disorders	Drug hypersensitivity	07FEB2014		Y
				12AUG2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	04JUN2013		Y
	C4591001 1270 12701206	Injury, poisoning and procedural complications	Joint injury	08NOV2020	08NOV2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	10NOV2020		Y
		Nervous system disorders	Migraine with aura	15JAN2019		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	20JUN2018		Y
	C4591001 1270 12701207	Congenital, familial and genetic disorders	Thyroglossal cyst	27MAR2019	06MAY2019	N
		Gastrointestinal disorders	Abdominal migraine	21APR2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	20AUG2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	06AUG2018		Y
	C4591001 1270 12701208	Surgical and medical procedures	Thyroglossal cyst excision	06MAY2019	06MAY2019	N
		Infections and infestations	Rhinitis	10JUL2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	30SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30SEP2020		Y
	C4591001 1270 12701209	Eye disorders	Myopia	11JUN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	08JAN2016		Y
		Investigations	Serum ferritin decreased	22AUG2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	22AUG2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	10JAN2014		Y
		Nervous system disorders	Headache	02DEC2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	22MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25JAN2013		Y
	C4591001 1270 12701210	Eye disorders	Myopia	20JUL2020		Y
		Musculoskeletal and connective tissue disorders	Toe walking	22MAR2018		Y
		Psychiatric disorders	Anxiety	03JUL2019		Y
	C4591001 1270 12701211	Eye disorders	Astigmatism	20JUL2020		Y
			Myopia	20JUL2020		Y
		Immune system disorders	Drug hypersensitivity	20JUL2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701212	Immune system disorders	Drug hypersensitivity	24FEB2016		Y
	C4591001 1270 12701213	Musculoskeletal and connective tissue disorders	Arthralgia	23JUL2019		Y
		Psychiatric disorders	Anxiety disorder	02DEC2020		Y
			Obsessive-compulsive disorder	02DEC2020		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1270 12701214	Injury, poisoning and procedural complications	Limb injury	11DEC2020		Y
		Skin and subcutaneous tissue disorders	Acne	20OCT2017		Y
	C4591001 1270 12701215	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03APR2015		Y
	C4591001 1270 12701216	Musculoskeletal and connective tissue disorders	Synovial cyst	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Eczema	08OCT2015		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1270 12701217	Metabolism and nutrition disorders	Vitamin D deficiency	05DEC2020		Y
		Psychiatric disorders	Autism spectrum disorder	14APR2014		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1270 12701218	Musculoskeletal and connective tissue disorders	Arthralgia	24NOV2020		Y
	C4591001 1270 12701221	Musculoskeletal and connective tissue disorders	Scoliosis	03JUL2017		Y
	C4591001 1270 12701222	Musculoskeletal and connective tissue disorders	Arthralgia	19JUN2020		Y
			Pain in extremity	19JUN2020		Y
		Psychiatric disorders	Anxiety	31AUG2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	08DEC2020		Y
	C4591001 1270 12701223	Gastrointestinal disorders	Abdominal migraine	08AUG2018		Y
		Immune system disorders	Food allergy	10FEB2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	15APR2015		Y
	C4591001 1270 12701224	Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1270 12701225	Eye disorders	Myopia	08DEC2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	12SEP2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	02FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	15JUN2020		Y
	C4591001 1270 12701226	Immune system disorders	Food allergy	03SEP2009		Y
			Seasonal allergy	17MAR2017		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	24JUL2017		Y
		Skin and subcutaneous tissue disorders	Acne	19AUG2018		Y
			Dermatitis atopic	24JUL2017		Y
	C4591001 1270 12701227	Eye disorders	Astigmatism	31DEC2019		Y
			Myopia	31DEC2019		Y
			Optic nerve cupping	31DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03AUG2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	06SEP2020		Y
	C4591001 1270 12701228	Immune system disorders	Drug hypersensitivity	25JUN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	05FEB2020		Y
			Epistaxis	29JAN2014		Y
		Social circumstances	Premenarche	(b) (6) 2008		Y
	C4591001 1270 12701230	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08JUN2011		Y
	C4591001 1270 12701233	Immune system disorders	Drug hypersensitivity	17APR2015		Y
		Injury, poisoning and procedural complications	Chillblains	12SEP2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	18JAN2020		Y
		Nervous system disorders	Tethered cord syndrome	12SEP2016		Y
		Psychiatric disorders	Anxiety	27FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19MAR2019		Y
		Skin and subcutaneous tissue disorders	Acne	19NOV2020		Y
			Psoriasis	30NOV2020		Y
		Vascular disorders	Raynaud's phenomenon	22JAN2019		Y
	C4591001 1270 12701234	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 2005		Y
			Otospondylomegaepiphyseal dysplasia	(b) (6) 2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	08AUG2019		Y
	C4591001 1270 12701235	Psychiatric disorders	Attention deficit hyperactivity disorder	18MAY2018		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701236	Psychiatric disorders	Learning disorder	08AUG2017		Y
	C4591001 1270 12701237	Congenital, familial and genetic disorders	Pectus carinatum	30DEC2020		Y
		Immune system disorders	Drug hypersensitivity	30DEC2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	22JUN2020		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	18DEC2020		Y
			Temporomandibular joint syndrome	16NOV2020		Y
		Psychiatric disorders	Anxiety	23AUG2019		Y
			Depression	02DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2016		Y
	C4591001 1270 12701238	Congenital, familial and genetic disorders	Adenomatous polyposis coli	09NOV2016		Y
		Immune system disorders	Drug hypersensitivity	12FEB2020		Y
	C4591001 1270 12701239	Eye disorders	Strabismus	21JAN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	19AUG2020		Y
		Social circumstances	Premenarche	(b) (6) 2007		Y
	C4591001 1270 12701240	Psychiatric disorders	Attention deficit hyperactivity disorder	23MAY2012		Y
	C4591001 1270 12701241	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	31AUG2017		Y
	C4591001 1270 12701242	Metabolism and nutrition disorders	Lactose intolerance	29AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	26OCT2012		Y
	C4591001 1270 12701243	Respiratory, thoracic and mediastinal disorders	Asthma	12APR2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
16-25	C4591001 1270 12701244		Rhinitis allergic	12APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04SEP2019		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2019		Y
	C4591001 1001 10011085	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Reproductive system and breast disorders	Amenorrhoea	01FEB2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1003 10031111	Nervous system disorders	Migraine	01JAN2005	31DEC2007	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1005 10051024	Immune system disorders	Hypersensitivity	01FEB2008		Y
		Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2008		Y
		Surgical and medical procedures	Orchidectomy	01JAN1998	31DEC1998	N
	C4591001 1005 10051052	Immune system disorders	Hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051147	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1005 10051198	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1005 10051216	Nervous system disorders	Migraine without aura	01JAN2006		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1005 10051217	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1005 10051236	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1005 10051238	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01MAR2020	31MAR2020	N
		Investigations	Arthroscopy	01MAR2020	31MAR2020	N
		Nervous system disorders	Migraine without aura	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1005 10051264	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1005 10051283	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1005 10051295	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Nervous system disorders	Migraine without aura	01JAN2011		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Eczema	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012		Y
	C4591001 1005 10051341	Gastrointestinal disorders	Irritable bowel syndrome	01DEC2019		Y
		Immune system disorders	Hypersensitivity	01OCT2019		Y
		Metabolism and nutrition disorders	Overweight	01DEC2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1005 10051343	Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Internal fixation of fracture	01JAN2018	31DEC2018	N
	C4591001 1005 10051394	Psychiatric disorders	Anxiety	01NOV2019		Y
			Depression	01NOV2019		Y
			Insomnia	01OCT2010		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2016		Y
	C4591001 1005 10051398	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1005 10051409	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1005 10051411	Congenital, familial and genetic disorders	Anal atresia	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Constipation	01JAN2013		Y
			Short-bowel syndrome	01JAN2003		Y
			Volvulus	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2003	31DEC2003	N
			Enterostomy	01JAN2003	31DEC2003	N
			Intestinal resection	01JAN2003	31DEC2003	N
			Stoma closure	01JAN2003	31DEC2003	N
	C4591001 1005 10051416	Immune system disorders	Hypersensitivity	01JAN2015		Y
	C4591001 1005 10051432	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1005 10051433	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1005 10051435	Blood and lymphatic system disorders	Anaemia	01SEP2019		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1005 10051442	Immune system disorders	Hypersensitivity	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2014		Y
			Migraine without aura	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1005 10051446	Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1006 10061013	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Urinary tract infection	01MAY2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	19OCT2019	19OCT2019	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
	C4591001 1006 10061031	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	(b) (6) 2000		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	(b) (6) 2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1006 10061033	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1999		Y

16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061071	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1006 10061081	Immune system disorders	Allergy to animal	01JAN2007		Y
			Hypersensitivity	01JAN2007		Y
		Infections and infestations	Staphylococcal infection	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1006 10061088	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Generalised anxiety disorder	11SEP2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1006 10061091	Metabolism and nutrition disorders	Obesity	25JUL2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1006 10061104	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1006 10061114	Gastrointestinal disorders	Enlarged uvula	01JUN2016		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23DEC2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2016		Y
			Nasal septum deviation	01JUN2016	15DEC2016	N
			Nasal turbinate hypertrophy	01JUN2016		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Nasal septal operation	15DEC2016	15DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1006 10061130	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2017		Y
	C4591001 1006 10061131	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1006 10061136	Gastrointestinal disorders	Volvulus	27JUL2015		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1006 10061141	Immune system disorders	Perennial allergy	01OCT2019		Y
		Metabolism and nutrition disorders	Underweight	01JAN2015		Y
		Vascular disorders	Hypotension	01JAN2012		Y
	C4591001 1006 10061153	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Fructose intolerance	09AUG2010		Y
		Psychiatric disorders	Anxiety	26JUL2019		Y
			Depression	12SEP2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061154	Ear and labyrinth disorders	Deafness unilateral	01JAN2006		Y
		Psychiatric disorders	Autism spectrum disorder	01MAR2010		Y
	C4591001 1006 10061155	Skin and subcutaneous tissue disorders	Acne cystic	02DEC2019		Y
	C4591001 1006 10061156	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
			Back pain	01JUL2019		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1006 10061159	General disorders and administration site conditions	Drug intolerance	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Connective tissue disorder	01MAY2018	01JUN2018	N
			Femoroacetabular impingement	01APR2019	31MAR2020	N
		Surgical and medical procedures	Bone operation	01JAN2020	31MAR2020	N
			Chondroplasty	01JAN2020	31MAR2020	N
			Fascial operation	01JUN2018	01JUN2018	N
	C4591001 1006 10061162	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061164	Immune system disorders	Allergy to animal	01JAN2017		Y
			Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
	C4591001 1006 10061167	Blood and lymphatic system disorders	Iron deficiency anaemia	26FEB2016		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061169	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1006 10061170	Immune system disorders	Perennial allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	01JAN2007		Y
	C4591001 1006 10061171	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	03APR2013		Y
	C4591001 1006 10061173	Reproductive system and breast disorders	Menstruation irregular	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061176	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1006 10061180	Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1006 10061181	Eye disorders	Myopia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1006 10061182	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1006 10061185	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
	C4591001 1006 10061186	Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
		Immune system disorders	Food allergy	01OCT2020		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2009		Y
	C4591001 1006 10061187	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	16JAN2019		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	08SEP2020	N
		Surgical and medical procedures	Nasal septal operation	08SEP2020	08SEP2020	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1006 10061192	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1006 10061193	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061194	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1006 10061195	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1006 10061197	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1006 10061199	Gastrointestinal disorders	Abdominal pain lower	01JAN2017		Y
	C4591001 1006 10061202	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01AUG2020		Y
	C4591001 1006 10061204	Infections and infestations	Pharyngitis	01MAY2007	31DEC2008	N
		Nervous system disorders	Migraine	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
		Surgical and medical procedures	Adenoidectomy	01MAY2008	31MAY2008	N
			Tonsillectomy	01MAY2008	31MAY2008	N
	C4591001 1006 10061205	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1006 10061208	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1006 10061210	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061215	Congenital, familial and genetic disorders	Hypospadias	(b) (6) 2004	31DEC2005	N
		Gastrointestinal disorders	Inguinal hernia	(b) (6) 2004	31DEC2005	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
			Urethral repair	01JAN2005	31DEC2005	N
	C4591001 1006 10061216	Infections and infestations	Oral herpes	01JAN2011		Y
		Nervous system disorders	Facial paralysis	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Granuloma annulare	22NOV2020	23DEC2020	N
	C4591001 1006 10061217	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1006 10061222	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Injury, poisoning and procedural complications	Concussion	01OCT2017	31OCT2017	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1006 10061225	Blood and lymphatic system disorders	Iron deficiency anaemia	05AUG2020		Y
	C4591001 1006 10061238	Injury, poisoning and procedural complications	Back injury	06JUN2018		Y
	C4591001 1006 10061240	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061246	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Suicidal ideation	01JUN2020	01NOV2020	N
	C4591001 1006 10061255	Cardiac disorders	Palpitations	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Pneumonia viral	10NOV2012	20NOV2012	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
			Menorrhagia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1007 10071082	Immune system disorders	Hypersensitivity	03JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071123	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1007 10071154	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2018		Y
	C4591001 1007 10071289	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
			Nasal turbinate hypertrophy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Nasal septal operation	01JAN2012	31DEC2012	N
			Turbinectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071341	Immune system disorders	Allergy to metals	01JAN2016		Y
			Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1007 10071353	Immune system disorders	Food allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive symptom	01JAN2015		Y
	C4591001 1007 10071378	Immune system disorders	Rubber sensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1007 10071385	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1007 10071399	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1007 10071403	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1007 10071404	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1007 10071408	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1007 10071422	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071423	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1007 10071433	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Depression	01MAY2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1007 10071434	Surgical and medical procedures	Appendicectomy	01FEB2019	28FEB2019	N
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2006		Y
		Infections and infestations	Ear infection	01JAN2004	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2017		Y
		Renal and urinary disorders	Hypercalciuria	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1007 10071435	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071436	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2012		Y
	C4591001 1007 10071437	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1007 10071443	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1007 10071444	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Decreased appetite	01JAN2019		Y
		Psychiatric disorders	Depression suicidal	01JAN2019	30JUL2019	N
	C4591001 1007 10071446	Cardiac disorders	Sinus tachycardia	01AUG2020		Y
	C4591001 1007 10071448	Immune system disorders	Allergy to animal	01JAN2011		Y
			Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1007 10071449	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2010		Y
	C4591001 1007 10071450	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071451	Immune system disorders	Allergy to animal	01JAN2007		Y
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Autism spectrum disorder	01JAN2005		Y
			Insomnia	01JAN2013		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071452	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2018		Y
	C4591001 1007 10071455	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1007 10071456	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Investigations	Blood iron decreased	01JAN2015	31DEC2018	N
	C4591001 1007 10071457	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071458	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1007 10071461	Psychiatric disorders	Anxiety	01OCT2019		Y
			Attention deficit hyperactivity disorder	01MAR2016		Y
	C4591001 1007 10071462	Psychiatric disorders	Depression	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1007 10071464	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1007 10071465	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071468	Metabolism and nutrition disorders	Gluten sensitivity	01AUG2020		Y
		Psychiatric disorders	Insomnia	01AUG2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1007 10071473	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Spondylolysis	01DEC2020		Y
	C4591001 1007 10071474	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	16MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1007 10071477	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1007 10071479	Surgical and medical procedures	Ankle operation	15JAN2019	15JAN2019	N
	C4591001 1007 10071487	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1007 10071489	Immune system disorders	Hypersensitivity	01JAN2003		Y
	C4591001 1007 10071491	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2017		Y
	C4591001 1007 10071498	Immune system disorders	Food allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1007 10071501	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071502	Congenital, familial and genetic disorders	Fallot's tetralogy	(b) (6) 2004		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Heart valve replacement	05AUG2020	05AUG2020	N
			Lung assist device therapy	(b) (6) 2004	(b) (6) 2004	N
			Tetralogy of Fallot repair	(b) (6) 2004	(b) (6) 2004	N
	C4591001 1007 10071503	Congenital, familial and genetic disorders	Cataract congenital	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Scapular dyskinesis	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Erythema annulare	01JAN2019		Y
	C4591001 1007 10071510	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01SEP2020	30SEP2020	N
	C4591001 1007 10071513	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN2004		Y
	C4591001 1007 10071532	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Surgical and medical procedures	Adenotonsillectomy	30JAN2018	30JAN2018	N
	C4591001 1007 10071534	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1007 10071548	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071553	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1008 10081160	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1008 10081191	Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1008 10081281	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081290	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1008 10081310	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2019		Y
	C4591001 1008 10081333	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1008 10081365	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2014		Y
	C4591001 1008 10081419	Blood and lymphatic system disorders	Anaemia	26AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081420	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar II disorder	01JAN2012		Y
			Gender dysphoria	01JAN2014		Y
	C4591001 1008 10081435	Gastrointestinal disorders	Toothache	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JUN2020		Y
	C4591001 1008 10081444	Psychiatric disorders	Depression	01DEC2019		Y
	C4591001 1008 10081499	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1008 10081551	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081553	Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1008 10081554	Eye disorders	Strabismus	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Insomnia	01JAN2009		Y
	C4591001 1008 10081558	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081559	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081577	Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081583	Immune system disorders	Rubber sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081598	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081607	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1999		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1008 10081630	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1008 10081632	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
			Hand dermatitis	01JAN2009		Y
	C4591001 1008 10081633	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081638	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
		Surgical and medical procedures	Vascular stent insertion	01JAN1997	31DEC1997	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081647	Vascular disorders	Aortic stenosis	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN2020		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Genital herpes	01JAN2015		Y
			Herpes simplex	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2010		Y
	C4591001 1008 10081673	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1008 10081678	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1008 10081736	Gastrointestinal disorders	Gastritis	01MAR2020		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081741	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081742	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1008 10081743	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081744	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081746	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081747	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081748	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1008 10081749	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081750	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01SEP2020		Y
	C4591001 1008 10081762	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1008 10081765	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1008 10081766	Nervous system disorders	Migraine	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081776	Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
	C4591001 1008 10081778	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081779	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Eczema	01JAN2009		Y
	C4591001 1008 10081782	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1008 10081783	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1008 10081784	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081786	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1009 10091028	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
	C4591001 1009 10091053	Blood and lymphatic system disorders	Anaemia	01AUG2017		Y
		Ear and labyrinth disorders	Meniere's disease	01OCT2019		Y
		Endocrine disorders	Hyperthyroidism	11AUG2020		Y
		Infections and infestations	Pharyngitis	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1009 10091066	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1009 10091070	Psychiatric disorders	Anxiety	01DEC2019		Y
	C4591001 1009 10091134	Immune system disorders	Allergy to animal	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tenosynovitis	29JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1009 10091174	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2014		Y
		Nervous system disorders	Tension headache	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1009 10091198	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Urticaria	27JUL2020		Y
	C4591001 1009 10091200	Psychiatric disorders	Depression	01JAN2020		Y
			Insomnia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1009 10091201	Metabolism and nutrition disorders	Underweight	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2020		Y
			Limb asymmetry	01JAN2018		Y
		Surgical and medical procedures	Bone operation	01JUL2020	31JUL2020	N
				01SEP2019	30SEP2019	N
	C4591001 1009 10091207	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1009 10091210	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1009 10091224	Psychiatric disorders	Attention deficit hyperactivity disorder	13SEP2016		Y
	C4591001 1009 10091235	Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091242	Psychiatric disorders	Attention deficit hyperactivity disorder	26JUL2011		Y
	C4591001 1009 10091243	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1009 10091256	Ear and labyrinth disorders	Deafness neurosensory	01JAN2005		Y
		Surgical and medical procedures	Cochlea implant	01JUN2020	30JUN2020	N
	C4591001 1009 10091257	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091260	Skin and subcutaneous tissue disorders	Acne	01NOV2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091261	Infections and infestations	Ear infection	01JAN2015	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2017		Y
	C4591001 1009 10091262	Surgical and medical procedures	Ear tube insertion	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2007		Y
	C4591001 1009 10091263	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN2012		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1009 10091264	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1009 10091271	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091276	Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1009 10091278	Immune system disorders	Hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2019		Y
	C4591001 1009 10091279	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1009 10091285	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Eczema	01JAN2017		Y
	C4591001 1009 10091286	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1009 10091290	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01NOV2017		Y
	C4591001 1009 10091291	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091299	Immune system disorders	Allergy to animal	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1011 10111005	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1011 10111043	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111116	Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1011 10111118	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1011 10111124	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1011 10111164	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2019		Y
	C4591001 1011 10111174	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1011 10111215	Endocrine disorders	Hyperthyroidism	01JAN2009		Y
	C4591001 1012 10121144	Cardiac disorders	Arrhythmia	01JAN2009		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1013 10131002	General disorders and administration site conditions	Peripheral swelling	01DEC2013		Y
	C4591001 1013 10131005	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1013 10131020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JUN2004		Y
			Hypersensitivity	01JUN2016		Y
	C4591001 1013 10131059	Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
	C4591001 1013 10131060	Infections and infestations	Gingivitis	30JUL2020		Y
	C4591001 1013 10131077	Eye disorders	Myopia	01SEP2007		Y
		Infections and infestations	Chronic tonsillitis	01JAN2003	30JUN2003	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2003	30JUN2003	N
	C4591001 1013 10131121	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1013 10131174	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1013 10131200	Hepatobiliary disorders	Hepatic steatosis	01JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Hypersensitivity	01JAN2004		Y
		Investigations	Biopsy liver	01JUL2019	31JUL2019	N
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01MAR2020		Y
	C4591001 1013 10131229	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JUN2020	30JUN2020	N
	C4591001 1013 10131276	Nervous system disorders	Migraine without aura	01JAN2007		Y
		Psychiatric disorders	Major depression	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131353	Endocrine disorders	Hypothyroidism	01MAY2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y
			Irritable bowel syndrome	01JAN2016		Y
		Psychiatric disorders	Anxiety	01SEP2018		Y
			Depression	01OCT2018		Y
	C4591001 1013 10131366	Psychiatric disorders	Autism spectrum disorder	01JAN2004		Y
	C4591001 1013 10131371	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1013 10131394	General disorders and administration site conditions	Cyst	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Surgical and medical procedures	Thoracic operation	01JAN2017	31DEC2017	N
	C4591001 1013 10131395	Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2019	03AUG2020	N
		Surgical and medical procedures	Tonsillectomy	03AUG2020	03AUG2020	N
	C4591001 1013 10131413	Metabolism and nutrition disorders	Obesity	01AUG2010		Y
	C4591001 1013 10131421	Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Meniscus injury	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2016		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131424	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Tonsillitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1013 10131425	Immune system disorders	Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1013 10131427	Psychiatric disorders	Anxiety	01NOV2017		Y
			Depression	01NOV2017		Y
	C4591001 1013 10131437	Gastrointestinal disorders	Tooth impacted	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1013 10131463	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
	C4591001 1013 10131470	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1013 10131471	Injury, poisoning and procedural complications	Cartilage injury	01JAN2019	31JUL2020	N
		Investigations	Arthroscopy	01JUL2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131486	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JUN2019		Y
	C4591001 1013 10131499	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2011	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Ear infection	01JAN2011	31AUG2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2017		Y
		Surgical and medical procedures	Ear tube insertion	01AUG2013		Y
			Ear tube removal	01AUG2013	31AUG2013	N
			Myringotomy	01JAN2012	31AUG2013	N
	C4591001 1013 10131533	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2012		Y
	C4591001 1013 10131541	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2008		Y
	C4591001 1013 10131556	Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
			Ligament rupture	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN2014	31DEC2014	N
	C4591001 1013 10131559	Nervous system disorders	Essential tremor	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Bipolar II disorder	01JAN2020		Y
	C4591001 1013 10131563	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131587	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131592	Congenital, familial and genetic disorders	Congenital hand malformation	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Surgical and medical procedures	Hand repair operation	01JAN1997	31DEC1997	N
	C4591001 1013 10131599	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131611	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
			Insomnia	01APR2020		Y
			Major depression	01APR2020		Y
	C4591001 1013 10131624	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131633	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001	31DEC2016	N
	C4591001 1013 10131634	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131638	Reproductive system and breast disorders	Gynaecomastia	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Dermatitis	01MAY2020		Y
	C4591001 1013 10131653	Congenital, familial and genetic disorders	Hereditary motor and sensory neuropathy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	11SEP2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Tenoplasty	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
	C4591001 1013 10131697	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN2010		Y
	C4591001 1013 10131740	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1013 10131749	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
	C4591001 1013 10131761	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1013 10131763	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Otitis media	09OCT2020	18OCT2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1013 10131817	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01MAY2019		Y
	C4591001 1013 10131818	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Scleral buckling surgery	01MAR2019	31MAR2019	N
	C4591001 1013 10131819	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1013 10131820	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
	C4591001 1013 10131825	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1013 10131829	Immune system disorders	Food allergy	01JAN2003		Y
	C4591001 1013 10131831	Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1013 10131832	Immune system disorders	Hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131833	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Autism spectrum disorder	01NOV2020		Y
			Encopresis	01JAN2008		Y
			Generalised anxiety disorder	01JAN2016		Y
			Major depression	01JAN2016		Y
	C4591001 1013 10131837	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2012		Y
	C4591001 1013 10131838	Psychiatric disorders	Depression	01JUL2020		Y
			Generalised anxiety disorder	01JUL2020		Y
	C4591001 1013 10131840	Immune system disorders	Food allergy	01JAN2004		Y
	C4591001 1013 10131847	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
	C4591001 1013 10131854	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1013 10131857	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1015 10151029	Nervous system disorders	Migraine	01JAN2008		Y
			Narcolepsy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
	C4591001 1015 10151038	Psychiatric disorders	Depression	01JAN2013		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151044	Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
	C4591001 1015 10151049	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Food allergy	30JUN2020		Y
			Seasonal allergy	30JUN2020		Y
	C4591001 1015 10151050	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1015 10151075	Immune system disorders	Food allergy	01JAN2018		Y
			Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1015 10151081	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Obsessive-compulsive disorder	01JAN2014		Y
	C4591001 1015 10151082	Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1015 10151099	Congenital, familial and genetic disorders	Congenital hypothyroidism	(b) (6) 1997		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1015 10151133	Ear and labyrinth disorders	Eustachian tube patulous	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1015 10151147	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151170	Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1015 10151189	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1015 10151191	Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1015 10151225	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1016 10161003	Immune system disorders	Seasonal allergy	01MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian neoplasm	01JUN2016	30JUN2016	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2010		Y
	C4591001 1016 10161010	Psychiatric disorders	Bipolar disorder	01DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01APR2017		Y
	C4591001 1016 10161028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JUL2017	31JUL2017	N
	C4591001 1016 10161047	Immune system disorders	Seasonal allergy	01APR2010		Y
	C4591001 1016 10161114	Immune system disorders	Seasonal allergy	01AUG2004		Y
		Surgical and medical procedures	Ligament operation	01MAR2016	31MAR2016	N
			Meniscus operation	01MAR2016	31MAR2016	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161125	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2015		Y
	C4591001 1016 10161154	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JUL2009		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2009	31JUL2009	N
	C4591001 1016 10161155	Immune system disorders	Seasonal allergy	01APR2005		Y
		Nervous system disorders	Migraine	01JUN2016		Y
	C4591001 1016 10161170	Immune system disorders	Seasonal allergy	01MAR2005		Y
		Psychiatric disorders	Social anxiety disorder	01JUN2010		Y
	C4591001 1016 10161171	Skin and subcutaneous tissue disorders	Acne	20JUN2019		Y
	C4591001 1016 10161206	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	22APR2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	07JAN2020		Y
			Obesity	29DEC2008		Y
		Psychiatric disorders	Anxiety	12JAN2017		Y
			Attention deficit hyperactivity disorder	18DEC2009		Y
			Bipolar I disorder	21JUN2007		Y
			Major depression	21DEC2016		Y
	C4591001 1016 10161210	Surgical and medical procedures	Female sterilisation	01AUG2019	31AUG2019	N
	C4591001 1016 10161245	Immune system disorders	Seasonal allergy	09JUN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	15APR2019		Y
		Psychiatric disorders	Anxiety	10DEC2019		Y
			Attention deficit hyperactivity disorder	30JAN2020		Y
			Depression	10DEC2019		Y
			Insomnia	03JAN2020		Y
	C4591001 1016 10161273	Surgical and medical procedures	Mammoplasty	01JUN2016	30JUN2016	N
		Cardiac disorders	Pulmonary valve stenosis	27MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01AUG2020		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
	C4591001 1016 10161284	Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01FEB2017	28FEB2017	N
	C4591001 1016 10161285	Gastrointestinal disorders	Constipation	12MAY2014		Y
			Gastrooesophageal reflux disease	01JUN2019		Y
			Irritable bowel syndrome	24SEP2018		Y
		Hepatobiliary disorders	Gallbladder disorder	06MAR2018	29MAR2018	N
		Immune system disorders	Seasonal allergy	20NOV2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
		Psychiatric disorders	Anger	13AUG2013		Y
			Attention deficit hyperactivity disorder	08MAY2013		Y
			Depression	11DEC2018		Y
			Oppositional defiant disorder	22SEP2015	30JUN2020	N
		Reproductive system and breast disorders	Ovarian cyst	10JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	30NOV2015		Y
		Surgical and medical procedures	Cholecystectomy	29MAR2018	29MAR2018	N
			Umbilical hernia repair	01SEP2003	30SEP2003	N
	C4591001 1016 10161286	Immune system disorders	Seasonal allergy	01MAR2006		Y
	C4591001 1016 10161287	Immune system disorders	Hypersensitivity	01OCT2008		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01NOV2016		Y
		Psychiatric disorders	Anxiety	01JUL2018	31MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2016	31JAN2017	N
		Skin and subcutaneous tissue disorders	Acne	14JAN2019		Y
	C4591001 1016 10161288	Gastrointestinal disorders	Gastrooesophageal reflux disease	15MAY2017		Y
		Nervous system disorders	Migraine	18SEP2019		Y
	C4591001 1016 10161289	Immune system disorders	Seasonal allergy	01MAY2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2010		Y
	C4591001 1016 10161290	Congenital, familial and genetic disorders	Cerebral palsy	01JAN2005		Y
			Schizencephaly	04JUN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01APR2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	03MAY2012		Y
			Binge eating	17JUN2019		Y
			Depression	13MAR2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oppositional defiant disorder	29AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26MAR2007	30APR2007	N
		Skin and subcutaneous tissue disorders	Eczema	31MAR2010	31DEC2012	N
	C4591001 1016 10161291	Immune system disorders	Seasonal allergy	29AUG2009		Y
		Psychiatric disorders	Obsessive-compulsive disorder	25MAR2019	31AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	18DEC2008		Y
		Vascular disorders	Orthostatic hypotension	01JUL2019	01JUL2019	N
	C4591001 1016 10161292	Gastrointestinal disorders	Abdominal pain	08APR2013		Y
		Hepatobiliary disorders	Cholecystitis	20AUG2019	28AUG2019	N
		Psychiatric disorders	Anxiety	08APR2013		Y
		Surgical and medical procedures	Cholecystectomy	28AUG2019	28AUG2019	N
	C4591001 1016 10161293	Immune system disorders	Seasonal allergy	01APR2006		Y
	C4591001 1016 10161294	Injury, poisoning and procedural complications	Meniscus injury	01MAR2018		Y
		Metabolism and nutrition disorders	Obesity	14AUG2013		Y
	C4591001 1016 10161295	Hepatobiliary disorders	Cholecystitis	09DEC2013	06FEB2015	N
		Immune system disorders	Seasonal allergy	01MAY2007		Y
		Surgical and medical procedures	Cholecystectomy	06FEB2015	06FEB2015	N
	C4591001 1016 10161296	Immune system disorders	Seasonal allergy	01APR2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2006	30JUN2010	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161297	Metabolism and nutrition disorders	Hyperlipidaemia	28MAR2013		Y
		Nervous system disorders	Migraine	24FEB2016		Y
		Psychiatric disorders	Anxiety	05FEB2015		Y
			Attention deficit hyperactivity disorder	28MAR2013		Y
			Bipolar disorder	05FEB2015		Y
			Depression	05FEB2015		Y
			Insomnia	27AUG2009		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1016 10161298	Cardiac disorders	Mitral valve incompetence	22APR2016		Y
		Congenital, familial and genetic disorders	Neurofibromatosis	16JAN2014		Y
		Immune system disorders	Seasonal allergy	01MAR2008		Y
		Investigations	Cardiac murmur	23JAN2007		Y
		Psychiatric disorders	Anxiety disorder	17AUG2016		Y
			Attention deficit hyperactivity disorder	23NOV2011		Y
			Depression	17AUG2016		Y
			Insomnia	27AUG2018		Y
		Skin and subcutaneous tissue disorders	Cafe au lait spots	12JAN2007		Y
	C4591001 1016 10161299	Immune system disorders	Seasonal allergy	05JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07OCT2010		Y
	C4591001 1016 10161300	Musculoskeletal and connective tissue disorders	Scoliosis	12JUN2012		Y
	C4591001 1016 10161301	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01MAR2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161302	Gastrointestinal disorders	Constipation	27JUN2017		Y
		Infections and infestations	Pilonidal cyst	10JUN2019	11JUN2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	16SEP2010		Y
		Skin and subcutaneous tissue disorders	Acne	14NOV2016		Y
		Surgical and medical procedures	Cyst removal	10JUN2019	11JUN2019	N
	C4591001 1016 10161305	Musculoskeletal and connective tissue disorders	Pain in extremity	10OCT2020		Y
	C4591001 1016 10161306	Immune system disorders	Seasonal allergy	01APR2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	06DEC2019		Y
		Psychiatric disorders	Anxiety	29NOV2017		Y
			Attention deficit hyperactivity disorder	01SEP2012		Y
			Tic	19AUG2013	30JUN2018	N
		Skin and subcutaneous tissue disorders	Acne	23SEP2019		Y
	C4591001 1016 10161317	Immune system disorders	Seasonal allergy	29JUL2008		Y
	C4591001 1016 10161328	Gastrointestinal disorders	Gastroesophageal reflux disease	19OCT2010		Y
		Immune system disorders	Seasonal allergy	06MAR2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	29FEB2012		Y
			Behaviour disorder	27MAR2012		Y
			Oppositional defiant disorder	13MAY2016		Y
	C4591001 1016 10161342	Ear and labyrinth disorders	Cerumen impaction	14OCT2020		Y
		Gastrointestinal disorders	Abdominal pain	12NOV2019		Y
		Immune system disorders	Seasonal allergy	01APR2005		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161345	Psychiatric disorders	Anxiety	12NOV2019		Y
		Hepatobiliary disorders	Cholelithiasis	22NOV2017	22NOV2017	N
		Immune system disorders	Drug hypersensitivity	01JUN2006		Y
			Hypersensitivity	01APR2014		Y
			Rubber sensitivity	01JUN2006		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUN2017	31JUL2017	N
		Nervous system disorders	Hemiplegic migraine	24JUL2018		Y
			Seizure	01JUN2004	30JUN2016	N
		Psychiatric disorders	Behaviour disorder	05AUG2014		Y
			Bipolar disorder	24JUL2018		Y
	Insomnia		01JUN2007		Y	
	Respiratory, thoracic and mediastinal disorders	Asthma	15JUL2020		Y	
	C4591001 1016 10161346	Surgical and medical procedures	Cholecystectomy	22NOV2017	22NOV2017	N
		Metabolism and nutrition disorders	Obesity	19SEP2011		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	25AUG2020		Y
			Plantar fascial fibromatosis	23SEP2020		Y
	C4591001 1016 10161347	Infections and infestations	Pyelonephritis	01APR2020	30APR2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2013		Y
			Back pain	01MAY2013		Y
		Psychiatric disorders	Anxiety	13MAR2019		Y
Depression			13MAR2019		Y	
Reproductive system and breast disorders		Menstruation irregular	23FEB2018		Y	

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161348	Endocrine disorders	Hyperthyroidism	23JUL2019		Y
			Hypothalamo-pituitary disorder	01DEC2003		Y
		Immune system disorders	Hypersensitivity	07JUL2015		Y
		Metabolism and nutrition disorders	Obesity	13FEB2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01APR2015		Y
		Vascular disorders	Essential hypertension	13FEB2019	30NOV2019	N
	C4591001 1016 10161349	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 2003		Y
			Seasonal allergy	01AUG2013		Y
		Vascular disorders	Orthostatic hypertension	01AUG2013		Y
	C4591001 1016 10161355	Immune system disorders	Seasonal allergy	01APR2016		Y
	C4591001 1016 10161359	Immune system disorders	Seasonal allergy	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2019		Y
	C4591001 1016 10161360	Immune system disorders	Seasonal allergy	01APR2010		Y
		Injury, poisoning and procedural complications	Joint dislocation	01SEP2019	30SEP2019	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Renal and urinary disorders	Nephrolithiasis	01SEP2012	30SEP2012	N
	C4591001 1018 10181015	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2014		Y
	C4591001 1018 10181022	Immune system disorders	Seasonal allergy	01JAN2000		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181032	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2018		Y
			Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Sinus congestion	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2017	31OCT2017	N
	C4591001 1018 10181042	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2013	31DEC2013	N
			Radius fracture	01JAN2007	31DEC2007	N
			Ulna fracture	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1018 10181046	Musculoskeletal and connective tissue disorders	Back pain	01AUG2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2014		Y
			Generalised anxiety disorder	01MAR2017		Y
			Panic attack	01JAN2015		Y
	C4591001 1018 10181054	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	04JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181091	Infections and infestations	Tinea pedis	06JUN2020		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N
	C4591001 1018 10181133	Infections and infestations	Infectious mononucleosis	01MAR2020	31MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2018		Y
	C4591001 1018 10181166	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2011		Y
	C4591001 1018 10181195	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Onychomycosis	01DEC2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
	C4591001 1018 10181197	Gastrointestinal disorders	Constipation	01JUN2019	31OCT2019	N
		General disorders and administration site conditions	Precancerous condition	01SEP2019	30SEP2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Large intestinal polypectomy	01SEP2019	30SEP2019	N
			Polypectomy	01SEP2019	30SEP2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181224	Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Immune system disorders	Allergy to metals	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1018 10181228	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1018 10181288	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Trans-sexualism	01SEP2019		Y
		Surgical and medical procedures	Breast prosthesis removal	12JUL2020		Y
			Mammoplasty	04JUN2020	04JUN2020	N
	C4591001 1018 10181298	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma benign	01JUN2020	15JUL2020	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Oophorectomy	15JUL2020	15JUL2020	N
	C4591001 1018 10181315	Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1018 10181316	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2003	31DEC2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
			Eczema	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1018 10181324	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015	31DEC2019	N
	C4591001 1018 10181335	Immune system disorders	Hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01SEP2018	30SEP2018	N
	C4591001 1018 10181341	Immune system disorders	Allergy to animal	01JAN2000		Y
			Allergy to arthropod sting	01JAN2000		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Eye laser surgery	01JAN2016	31JAN2016	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1018 10181347	Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Dermatitis allergic	01JAN2016		Y
	C4591001 1018 10181351	Eye disorders	Hypermetropia	01JAN2002	31DEC2002	N
	C4591001 1019 10191032	Gastrointestinal disorders	Constipation	01JAN2020	29FEB2020	N
			Dyspepsia	01JAN2012		Y
			Haemorrhoids	01JAN2014	31DEC2014	N
		Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y

16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Scoliosis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2011		Y
			Tension headache	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2010	N
			Rhinitis allergic	01JAN2000		Y
		Social circumstances	Substance use	01JAN2012	31DEC2015	N
	C4591001 1019 10191041	Eye disorders	Myopia	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1019 10191125	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1019 10191171	Eye disorders	Myopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2018	31DEC2018	N
		Nervous system disorders	Sinus headache	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1019 10191175	Eye disorders	Myopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
			Radius fracture	01JAN2013	31DEC2013	N
		Nervous system disorders	Sinus headache	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1019 10191194	Endocrine disorders	Rhinitis allergic	01JAN2012		Y
			Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1019 10191197	Psychiatric disorders	Depression	01NOV2019	29FEB2020	N
		Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Peripheral nerve injury	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1019 10191218	Surgical and medical procedures	Peripheral nerve operation	01JAN2019	31DEC2019	N
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Food allergy	01JAN2003		Y
		Infections and infestations	Pneumonia	01JAN2004	31DEC2004	N
			Sinusitis	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1019 10191246	Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tension headache	01JAN2015		Y
	C4591001 1019 10191251	Metabolism and nutrition disorders	Vitamin D deficiency	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2010		Y
	C4591001 1019 10191265	Injury, poisoning and procedural complications	Accidental poisoning	01JAN2018	31DEC2018	N
			Ulna fracture	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Substance use	01JAN2018	31JUL2020	N
	C4591001 1019 10191273	Metabolism and nutrition disorders	Vitamin A deficiency	01AUG2020		Y
			Vitamin E deficiency	01AUG2000		Y
	C4591001 1019 10191321	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN1997		Y
	C4591001 1021 10211083	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Insomnia	01JAN2019		Y
	C4591001 1021 10211142	Respiratory, thoracic and mediastinal disorders	Pleurisy	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211230	Surgical and medical procedures	Dental implantation	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillolith	01JAN2014	31DEC2014	N
	C4591001 1021 10211240	Surgical and medical procedures	Dental operation	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
	C4591001 1021 10211245	Surgical and medical procedures	Tenoplasty	01JAN2015	31DEC2015	N
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1022 10221111	Metabolism and nutrition disorders	Obesity	06AUG2008		Y
		Reproductive system and breast disorders	Amenorrhoea	01OCT2011		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	20JUL2012		Y
			Sleep apnoea syndrome	27AUG2002		Y
	C4591001 1022 10221122		Tonsillar hypertrophy	27AUG2002		Y
		Cardiac disorders	Pulmonary valve stenosis	01JAN2011		Y
		Endocrine disorders	Hypothyroidism	01MAY2011		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG2003		Y
	C4591001 1022 10221147	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12DEC2012		Y
		Metabolism and nutrition disorders	Lactose intolerance	03JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2019		Y
	C4591001 1027 10271129	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
	C4591001 1028 10281009	Psychiatric disorders	Anxiety	01NOV2019		Y
			Depression	01NOV2019		Y
			Insomnia	01FEB2020		Y
	C4591001 1028 10281029	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Sinusitis	01JAN2002		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2017	31DEC2017	N
		Nervous system disorders	Febrile convulsion	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
			Sinus operation	30JUN2016	30JUN2016	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1028 10281053	Immune system disorders	Food allergy	01JAN2002		Y
			Multiple allergies	01JAN2002		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2011	N
	C4591001 1028 10281065	Immune system disorders	Allergy to metals	01JAN2019		Y
			Drug hypersensitivity	01JAN2000		Y
			Milk allergy	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Investigations	Smear cervix abnormal	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	26AUG2020		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1028 10281090	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2004	31DEC2004	N
			Nasal operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1028 10281094	Metabolism and nutrition disorders	Lactose intolerance	01JUL2020		Y
		Renal and urinary disorders	Dysuria	07MAR2019	30APR2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281120	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1028 10281131	Gastrointestinal disorders	Aphthous ulcer	29MAY2020	05JUN2020	N
			Eosinophilic oesophagitis	20JUN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Urinary tract infection	24MAR2020	28MAR2020	N
		Investigations	Endoscopy upper gastrointestinal tract	20JUN2018	20JUN2018	N
				24OCT2018	24OCT2018	N
		Renal and urinary disorders	Dysuria	24MAR2020	28MAR2020	N
			Haematuria	24MAR2020	28MAR2020	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2020	31JUL2020	N
	C4591001 1028 10281135	Gastrointestinal disorders	Inguinal hernia	01JAN2010	07AUG2010	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2017	01JAN2017	N
			Tonsillectomy	01JAN2017	01JAN2017	N
	C4591001 1028 10281154	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
			Upper limb fracture	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
			Menorrhagia	01JAN2013		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281184	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2011	31DEC2011	N
			Foot fracture	01JAN2010	31DEC2010	N
		Investigations	Colposcopy normal	21APR2020	21APR2020	N
			Smear cervix abnormal	01APR2020	30APR2020	N
				01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	27AUG2015	10DEC2015	N
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2019	31DEC2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1028 10281191	Surgical and medical procedures	Tenotomy	11DEC2015	11DEC2015	N
		Gastrointestinal disorders	Abdominal pain	31JUL2020	01AUG2020	N
		Musculoskeletal and connective tissue disorders	Back pain	31JUL2020		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
			Menorrhagia	01JAN2015		Y
	C4591001 1028 10281198	Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01DEC2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2013		Y
			Migraine	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009		Y
		Surgical and medical procedures	Brain operation	01DEC2018	31DEC2018	N
	C4591001 1028 10281200	Ear and labyrinth disorders	Aural polyp	01JAN2004	31DEC2004	N
		Eye disorders	Anisometropia	01JAN2001		Y
			Astigmatism	01JAN2001		Y
			Hypermetropia	01JAN2001		Y
			Refractive amblyopia	01JAN2001		Y
		Gastrointestinal disorders	Abdominal pain lower	01JAN2012	31DEC2012	N
			Constipation	01JAN2010		Y
		General disorders and administration site conditions	Fatigue	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2016		Y
			Drug hypersensitivity	01JAN2016		Y
			Dust allergy	01JAN2016		Y
			Food allergy	01JAN2016		Y
			Milk allergy	01JAN2016		Y
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
			Ovulation pain	01JAN2018		Y
			Vaginal discharge	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
			Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Eustachian tube operation	01JAN2004	31DEC2004	N
	C4591001 1028 10281211	Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Epididymal cyst	27JUN2020		Y
		Surgical and medical procedures	Wisdom teeth removal	01DEC2016	31DEC2016	N
	C4591001 1028 10281213	Infections and infestations	Tonsillitis	10SEP2020	22SEP2020	N
		Investigations	Cardiac murmur	01JAN1998		Y
	C4591001 1028 10281240	Musculoskeletal and connective tissue disorders	Osteochondrosis	17MAY2018		Y
			Posterior tibial tendon dysfunction	20FEB2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1028 10281242	Musculoskeletal and connective tissue disorders	Back pain	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug abuse	01JAN2018	31DEC2018	N
			Nicotine dependence	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUL2019		Y
	C4591001 1028 10281248	Gastrointestinal disorders	Haemorrhoids	17AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1028 10281249	Eye disorders	Conjunctivitis allergic	01JAN2012		Y
		Immune system disorders	Food allergy	13MAR2017	13MAR2017	N
			Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Rotator cuff syndrome	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1028 10281250	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1028 10281258	Injury, poisoning and procedural complications	Clavicle fracture	(b) (6) 1995	(b) (6) 1995	N
			Hand fracture	01JAN2009	31DEC2009	N
			Wrist fracture	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281284	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Dysuria	25SEP2020	28SEP2020	N
	C4591001 1028 10281286	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Orthognathic surgery	03DEC2019	03DEC2019	N
			Osteotomy	03DEC2019	03DEC2019	N
	C4591001 1028 10281294	Blood and lymphatic system disorders	Anaemia	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2014		Y
			Reaction to food additive	01JAN2016		Y
			Rubber sensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2003	31DEC2003	N
			Wrist fracture	01JAN2013	31DEC2013	N



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Post-traumatic stress disorder	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2017		Y
			Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1030 10301145	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1036 10361032	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1036 10361047	Ear and labyrinth disorders	Vertigo	22OCT2018		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Injury, poisoning and procedural complications	Head injury	22OCT2018	22OCT2018	N
		Nervous system disorders	Headache	22OCT2018		Y
	C4591001 1036 10361048	Investigations	Cardiac murmur	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
		Nervous system disorders	Nystagmus	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361061	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Scoliosis	(b) (6) 1998		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1036 10361073	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1036 10361084	Immune system disorders	Allergy to animal	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1036 10361093	Surgical and medical procedures	Intrauterine contraception	01JUN2020		Y
	C4591001 1036 10361104	Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01FEB2020		Y
	C4591001 1037 10371043	Immune system disorders	Food allergy	01JAN2006		Y
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
		Surgical and medical procedures	Oophorectomy	01JAN2014	31DEC2014	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1037 10371054	Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1037 10371074	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1037 10371140	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	Blood iron decreased	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2001	31DEC2005	N
	C4591001 1037 10371152	Congenital, familial and genetic disorders	Congenital myopathy	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1037 10371180	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
	C4591001 1037 10371198	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01SEP2020		Y
	C4591001 1037 10371214	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1037 10371240	Psychiatric disorders	Anxiety	01MAY2019		Y
			Depression	01MAY2019		Y
	C4591001 1037 10371241	Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
	C4591001 1037 10371271	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1037 10371288	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371302	Congenital, familial and genetic disorders	Pectus carinatum	01MAR2019		Y
		Psychiatric disorders	Depression	01FEB2020		Y
	C4591001 1037 10371315	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1037 10371316	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1037 10371328	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1037 10371344	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1038 10381038	Infections and infestations	Onychomycosis	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01NOV2013		Y
	C4591001 1038 10381075	Musculoskeletal and connective tissue disorders	Back pain	07OCT2015		Y
		Psychiatric disorders	Anxiety	17JUN2020		Y
			Major depression	17JUN2020		Y
	C4591001 1038 10381079	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	11FEB2020		Y
			Insomnia	01APR2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Limb operation	12NOV2013	12NOV2013	N
	C4591001 1038 10381098	Immune system disorders	Drug hypersensitivity	31MAR2013		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2010		Y
	C4591001 1038 10381117	Musculoskeletal and connective tissue disorders	Scoliosis	29JUL2010		Y
		Psychiatric disorders	Anxiety disorder	17JUN2011		Y
			Attention deficit hyperactivity disorder	26APR2005		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2010		Y
	C4591001 1039 10391016	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	07DEC2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cranial operation	01JAN1997	31DEC1997	N
	C4591001 1039 10391017	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
	C4591001 1039 10391065	Eye disorders	Myopia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1039 10391093	Social circumstances	Corrective lens user	01JAN2013		Y
	C4591001 1039 10391198	Injury, poisoning and procedural complications	Radius fracture	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31JUL2020	N
	C4591001 1039 10391220	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Presyncope	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN2006		Y
	C4591001 1039 10391235	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2013		Y
		Social circumstances	Corrective lens user	01JAN2004		Y
	C4591001 1039 10391241	Gastrointestinal disorders	Colitis ulcerative	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Colectomy	01JAN2005	31DEC2005	N
	C4591001 1039 10391242	Immune system disorders	Seasonal allergy	01JAN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1039 10391243	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
			Chronic spontaneous urticaria	01JAN2004		Y
	C4591001 1039 10391244	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1039 10391245	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
	C4591001 1039 10391248	Congenital, familial and genetic disorders	Hypospadias	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Circumcision	01JAN2005	31DEC2005	N
	C4591001 1039 10391249	Eye disorders	Myopia	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Oesophagitis	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Autism spectrum disorder	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2014	31DEC2014	N
	C4591001 1039 10391254	Social circumstances	Vegan	01APR2020		Y
	C4591001 1039 10391257	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
			Menorrhagia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Tenoplasty	01MAY2020	31MAY2020	N
	C4591001 1039 10391261	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Splenorrhaphy	01JAN2015	31DEC2015	N
	C4591001 1042 10421003	Infections and infestations	Tonsillitis	01JAN2005	01JAN2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005		Y
	C4591001 1042 10421020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Rubber sensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Otitis media chronic	01JAN1997	31DEC1999	N
		Nervous system disorders	Tension headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016	31DEC2020	N
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31DEC2000	N
	C4591001 1042 10421111	Immune system disorders	Food allergy	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1042 10421155	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1042 10421177	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Abortion induced	05DEC2019	05DEC2019	N
	C4591001 1042 10421181	General disorders and administration site conditions	Application site vesicles	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1042 10421206	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1042 10421228	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1042 10421253	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Arthritis bacterial	01JUN2016	30JUN2016	N
			Tonsillitis	01JUN2020	30JUN2020	N
		Investigations	Arthroscopy	01JUN2016	30JUN2016	N
			Laparoscopy	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2020	31DEC2020	N
	C4591001 1044 10441034	Immune system disorders	Drug hypersensitivity	30DEC2019		Y
	C4591001 1044 10441129	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1044 10441171	Reproductive system and breast disorders	Erectile dysfunction	01SEP2020		Y
	C4591001 1044 10441193	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1044 10441229	Reproductive system and breast disorders	Erectile dysfunction	01OCT2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441230	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1044 10441232	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1044 10441234	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1044 10441237	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
	C4591001 1044 10441238	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2004		Y
	C4591001 1044 10441239	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1044 10441241	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1044 10441242	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1044 10441243	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1044 10441244	General disorders and administration site conditions	Drug intolerance	01SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441245	Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	01JAN2018		Y
	C4591001 1044 10441246	Psychiatric disorders	Autism spectrum disorder	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1044 10441249	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1044 10441250	Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1044 10441254	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1044 10441269	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1044 10441287	Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1046 10461034	Gastrointestinal disorders	Tooth impacted	01JAN2018	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Ear infection	01JAN1999	31DEC1999	N
			Tonsillitis	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
			Tooth impacted	01JAN2014	31DEC2014	N
	C4591001 1046 10461055	Gastrointestinal disorders				
		Nervous system disorders	Tremor	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N
	C4591001 1046 10461071	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	25APR2020	25APR2020	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Lymphadenectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	25APR2020	25APR2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461104	Eye disorders	Amblyopia	01JAN1999	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Ureteral disorder	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Amblyopia therapy	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
			Caesarean section	30OCT2017	30OCT2017	N
			Tonsillectomy	01JAN2005	31DEC2005	N
			Ureteric operation	01JAN2015	31DEC2015	N
	C4591001 1046 10461118	Gastrointestinal disorders	Pancreatitis	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1046 10461119	Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
	C4591001 1046 10461125	Infections and infestations	Pilonidal cyst	20OCT2017	20OCT2017	N
		Surgical and medical procedures	Pilonidal sinus repair	20OCT2017	20OCT2017	N
	C4591001 1046 10461134	Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
	C4591001 1046 10461148	Infections and infestations	Otitis media	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Cholesteatoma removal	01JAN2003	31DEC2003	N
	C4591001 1046 10461164	Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
			Menstrual disorder	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Drug rehabilitation	01JAN2019	31DEC2019	N
			Endometrial ablation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461171	Skin and subcutaneous tissue disorders	Urticaria	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	08JUN2020	08JUN2020	N
	C4591001 1046 10461172	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Chest tube insertion	01JAN2018	31DEC2018	N
	C4591001 1046 10461194	Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1046 10461227	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1046 10461291	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1046 10461292	Eye disorders	Dacryostenosis acquired	01JAN1999	31DEC1999	N
		Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Lacrimal duct procedure	01JAN1999	31DEC1999	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461303	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Food allergy	01JAN1997		Y
			Seasonal allergy	01JAN1997		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461319	Gastrointestinal disorders	Tooth impacted	01JAN2017	31JAN2017	N
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31JAN2017	N
	C4591001 1046 10461327	Infections and infestations	Appendicitis perforated	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
	C4591001 1046 10461336	Psychiatric disorders	Bipolar disorder	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
			Major depression	01JAN2019		Y
			Panic disorder	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUN2020	30JUN2020	N
	C4591001 1046 10461338	Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1046 10461341	Infections and infestations	Adenoiditis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
	C4591001 1046 10461342	Immune system disorders	Seasonal allergy	01JAN2019		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1046 10461343	Congenital, familial and genetic disorders	Sleep apnoea syndrome	01JAN2019		Y
			Albinism	(b) (6) 2003		Y
		Eye disorders	Blindness	(b) (6) 2003		Y
	C4591001 1046 10461344	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1046 10461346	Infections and infestations	Tonsillitis	01MAR2017	31MAR2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01MAR2017	31MAR2017	N
	C4591001 1046 10461347	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1046 10461348	Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2017		Y
	C4591001 1047 10471061	Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1047 10471079	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1047 10471089	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1047 10471115	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Lipoma excision	01JAN2014	31DEC2014	N
	C4591001 1047 10471124	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Obsessive-compulsive disorder	01JAN2016		Y
	C4591001 1047 10471151	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Orthognathic surgery	01JAN2016	31DEC2016	N
	C4591001 1047 10471155	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAY2020	31DEC2020	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
			Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1047 10471163	Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
			Major depression	01JAN2014		Y
	C4591001 1047 10471232	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Pneumothorax spontaneous	10AUG2014	10AUG2014	N
	C4591001 1047 10471243	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2006		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Impaired gastric emptying	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1047 10471275	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
					31DEC2008	N
		Infections and infestations	Pharyngitis streptococcal	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2002	31DEC2002	N
			Tonsillar hypertrophy	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1047 10471284	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1047 10471291	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1047 10471306	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1047 10471310	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Epilepsy	14JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471312	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1047 10471317	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1048 10481021	Immune system disorders	Drug hypersensitivity	01SEP2012		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Headache	01OCT2008		Y
	C4591001 1048 10481092	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Depression	01FEB2020		Y
	C4591001 1052 10521013	Respiratory, thoracic and mediastinal disorders	Asthma	01APR2020		Y
	C4591001 1052 10521109	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1999		Y
	C4591001 1052 10521117	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
	C4591001 1054 10541012	Psychiatric disorders	Anxiety	01JUL2019		Y
	C4591001 1054 10541022	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Injury, poisoning and procedural complications	Scar	08MAY2018		Y
		Surgical and medical procedures	Caesarean section	08MAY2018	08MAY2018	N
	C4591001 1054 10541043	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Testicular pain	02DEC2019	02DEC2019	N
	C4591001 1054 10541125	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016	31DEC2019	N
		Psychiatric disorders	Depression	01JUN2020	31AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2020		Y
	C4591001 1054 10541135	Congenital, familial and genetic disorders	Pyloric stenosis	(b) (6) 1996	(b) (6) 1996	N
		Injury, poisoning and procedural complications	Scar	(b) (6) 1996		Y
		Surgical and medical procedures	Pyloromyotomy	(b) (6) 1996	(b) (6) 1996	N
	C4591001 1054 10541200	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 2003	30JUN2005	N
		Gastrointestinal disorders	Mouth ulceration	01MAR2020	31MAR2020	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
			Scar	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2019	30SEP2019	N
		Surgical and medical procedures	Cleft palate repair	01JUN2005	30JUN2005	N
			Knee operation	01JAN2016	31DEC2016	N
	C4591001 1054 10541208	Gastrointestinal disorders	Constipation	01JAN2003		Y
			Diarrhoea	01JAN2005		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia	01JAN1997	31DEC1997	N
		General disorders and administration site conditions	Cyst	28SEP2020	28SEP2020	N
		Infections and infestations	Infectious mononucleosis	01NOV2014	30NOV2014	N
		Injury, poisoning and procedural complications	Scar	28SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Ingrown hair	28SEP2020	28SEP2020	N
		Surgical and medical procedures	Limb operation	28SEP2020	28SEP2020	N
			Umbilical hernia repair	01JAN1997	31DEC1997	N
		Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
	C4591001 1054 10541215	Gastrointestinal disorders	Diaphragmatic hernia	12OCT2020		Y
			Gastritis	12OCT2020		Y
			Gastrooesophageal reflux disease	12OCT2020		Y
			Irritable bowel syndrome	01JAN2008		Y
			Oesophagitis	12OCT2020		Y
		Infections and infestations	Gastrointestinal bacterial overgrowth	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2013		Y
	C4591001 1055 10551021	Nervous system disorders	Migraine	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1055 10551232	Immune system disorders	Seasonal allergy	01JAN1998		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1055 10551243	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	04JAN2009		Y
	C4591001 1056 10561061	Surgical and medical procedures	Caesarean section	01MAR2017	01MAR2017	N
	C4591001 1056 10561116	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561171	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561194	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1056 10561397	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561405	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561475	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561476	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561529	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561554	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561559	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561560	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561592	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1057 10571014	Nervous system disorders	Migraine	01JUL2015		Y
	C4591001 1057 10571044	Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1057 10571103	Psychiatric disorders	Major depression	01AUG2018		Y
	C4591001 1057 10571109	Psychiatric disorders	Major depression	01JAN2013		Y
	C4591001 1057 10571195	Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Salpingo-oophorectomy unilateral	01JAN2018	31DEC2018	N
	C4591001 1057 10571204	Ear and labyrinth disorders	Deafness unilateral	(b) (6) 1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1057 10571211	Endocrine disorders	Autoimmune thyroiditis	01OCT2019		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
			Rhinitis allergic	01JAN2018		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571217	Infections and infestations	Herpes simplex	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2000		Y
	C4591001 1057 10571218	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01APR2018		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1057 10571230	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1057 10571235	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1057 10571239	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01FEB2013	28FEB2013	N
	C4591001 1057 10571248	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01FEB2017	28FEB2017	N
	C4591001 1057 10571249	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2010		Y
			Major depression	01FEB2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01APR2016		Y
	C4591001 1057 10571252	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571267	Psychiatric disorders	Depression	01OCT2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571273	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010		Y
		Congenital, familial and genetic disorders	Thalassaemia beta	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1057 10571277	Skin and subcutaneous tissue disorders	Keloid scar	01JAN2018		Y
	C4591001 1057 10571298	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01OCT2019		Y
	C4591001 1057 10571304	Endocrine disorders	Autoimmune thyroiditis	01OCT2019		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1057 10571314	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2018		Y
	C4591001 1057 10571319	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1057 10571336	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2010		Y
			Major depression	01FEB2019		Y
	C4591001 1057 10571363	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rhinoplasty	01JUN2020	01JUN2020	N
	C4591001 1057 10571366	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2019		Y
	C4591001 1057 10571367	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1057 10571368	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
	C4591001 1057 10571369	Immune system disorders	Food allergy	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2020		Y
			Depression	01NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1057 10571370	Eye disorders	Strabismus	01JAN2005	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Strabismus correction	01JAN2007	31DEC2007	N
	C4591001 1057 10571371	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571372	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571373	Immune system disorders	Food allergy	01FEB2006		Y
			Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2004		Y
	C4591001 1057 10571381	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1066 10661142	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Chronic tonsillitis	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1066 10661290	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2006	31DEC2010	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1066 10661293	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2019		Y
	C4591001 1066 10661317	Immune system disorders	Seasonal allergy	01SEP2015		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2019	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1066 10661324	Immune system disorders	Hypersensitivity	01JAN2009		Y
		Nervous system disorders	Migraine	01JUN2010		Y
		Psychiatric disorders	Anxiety	01FEB2009	31AUG2009	N
	C4591001 1066 10661336	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1066 10661340	Immune system disorders	Food allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1066 10661391	Infections and infestations	Ear infection	01JAN2004	31DEC2007	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2006	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2009		Y
	C4591001 1066 10661392	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019	31DEC2020	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1066 10661393	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2013	31DEC2019	N
			Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1066 10661396	Nervous system disorders	Headache	01DEC2019		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01DEC2017		Y
			Attention deficit hyperactivity disorder	01DEC2019		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2017		Y
	C4591001 1066 10661398	Gastrointestinal disorders	Salivary gland disorder	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Injury, poisoning and procedural complications	Epiphyseal fracture	01JAN2018	31DEC2018	N
			Joint injury	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1066 10661399	Surgical and medical procedures	Salivary gland resection	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Escherichia infection	05OCT2018	16OCT2018	N
			Kidney infection	05OCT2018	16OCT2018	N
			Tonsillitis	01JAN2004	31DEC2005	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661400	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2011		Y
			Insomnia	01JAN2011		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661406	Gastrointestinal disorders	Diaphragmatic hernia	(b) (6) 2003	31DEC2005	N
		Infections and infestations	Oral herpes	01JAN2016		Y
		Surgical and medical procedures	Hernia diaphragmatic repair	01JAN2005	31DEC2005	N
	C4591001 1066 10661413	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1068 10681002	Nervous system disorders	Syncope	01SEP2018		Y
	C4591001 1068 10681010	Infections and infestations	Appendicitis	17MAY2018	17MAY2018	N
	C4591001 1068 10681037	Investigations	Hepatic enzyme increased	15JAN2020	15AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12SEP1998	31DEC2007	N
		Social circumstances	Alcohol use	01JAN2010		Y
			Tobacco user	01JAN2010		Y
	C4591001 1068 10681047	Investigations	Chlamydia test positive	21AUG2020	22AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1068 10681098	Immune system disorders	Food allergy	01JAN2001		Y
	C4591001 1068 10681099	Injury, poisoning and procedural complications	Joint dislocation	01JAN2006		Y
		Investigations	Diagnostic procedure	11FEB2020	11FEB2020	N
	C4591001 1068 10681100	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1068 10681119	Infections and infestations	Pilonidal cyst	30DEC2017	10JAN2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	16MAY2017	08AUG2017	N
		Nervous system disorders	Dizziness	18JAN2018	31OCT2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	08MAY2017	28FEB2018	N
	C4591001 1071 10711039	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1071 10711080	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Facial neuralgia	01JAN2013		Y
			Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	12AUG2015		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	20SEP2013		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01AUG2018	31AUG2018	N
	C4591001 1071 10711138	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1071 10711206	Gastrointestinal disorders	Nausea	01FEB2020		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2010		Y
	C4591001 1071 10711231	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01FEB2000		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2004		Y
	C4591001 1071 10711233	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1072 10721049	Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1072 10721089	Metabolism and nutrition disorders	Folate deficiency	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1072 10721093	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1073 10731038	Immune system disorders	Drug hypersensitivity	(b) (6) 1998		Y
	C4591001 1073 10731048	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN2001		Y
			Reaction to colouring	01JAN2001		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Urinary tract infection	15MAR2020	22MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01OCT2016		Y
		Surgical and medical procedures	Ankle arthroplasty	01JUN2019	01JUN2019	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731064	Infections and infestations	Bacterial vulvovaginitis	01JAN2018	21JUL2020	N
			Herpes simplex	01JAN2017		Y
		Investigations	Human papilloma virus test positive	22JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2007	31DEC2015	N
	C4591001 1073 10731067	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1996		Y
		Infections and infestations	Cholecystitis infective	01JAN2015	31DEC2015	N
			Herpes simplex	(b) (6) 1996		Y
		Investigations	Progesterone decreased	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1073 10731083	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1999		Y
	C4591001 1073 10731101	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Panic attack	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1073 10731114	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Food allergy	(b) (6) 1999		Y
			Seasonal allergy	(b) (6) 1999		Y
		Infections and infestations	Sinusitis	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1077 10771008	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1077 10771010	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
	C4591001 1077 10771058	Psychiatric disorders	Anxiety	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2013		Y
	C4591001 1077 10771079	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1077 10771198	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
	C4591001 1077 10771240	Immune system disorders	Allergy to animal	01JAN2014		Y
	C4591001 1077 10771247	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Autism spectrum disorder	01JAN2015		Y
	C4591001 1077 10771250	Immune system disorders	Drug hypersensitivity	01JAN2001		Y

16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	15JUN2020		Y
			Depression	01JAN2016		Y
	C4591001 1077 10771258	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1077 10771262	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1077 10771269	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1077 10771272	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1077 10771273	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1079 10791013	Investigations	Heart rate increased	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1079 10791059	Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN2019	31DEC2019	N
	C4591001 1079 10791162	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1079 10791170	Psychiatric disorders	Anxiety	01SEP2019		Y
			Major depression	01SEP2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791186	Gastrointestinal disorders	Gastroesophageal reflux disease	19AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Appendectomy	01JAN2006	31DEC2006	N
	C4591001 1079 10791230	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
	C4591001 1079 10791238	Congenital, familial and genetic disorders	Cerebral palsy	01JAN2004		Y
		Eye disorders	Strabismus	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Hydrocephalus	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014		Y
			Spinal operation	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
				01JAN2014	31DEC2014	N
			Ventriculo-peritoneal shunt	01JAN2001		Y
	C4591001 1079 10791288	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1080 10801009	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Psychiatric disorders	Bipolar disorder	01APR2020		Y
			Depression	01JAN2018		Y
			Generalised anxiety disorder	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2018		Y
			Obsessive-compulsive disorder	01FEB2020		Y
			Panic disorder	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y
	C4591001 1080 10801019	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1080 10801054	Nervous system disorders	Syncope	01JAN2010	31DEC2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1080 10801055	Infections and infestations	Infectious mononucleosis	01OCT2019	01NOV2019	N
	C4591001 1080 10801079	Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1080 10801087	Cardiac disorders	Supraventricular tachycardia	01DEC2018		Y
	C4591001 1080 10801108	Infections and infestations	Pneumonia	01JAN2009	31DEC2009	N
	C4591001 1080 10801119	Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1080 10801153	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Sleep disorder	01JAN2016		Y
	C4591001 1080 10801179	Surgical and medical procedures	Wisdom teeth removal	13JUL2020	13JUL2020	N
	C4591001 1080 10801193	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1080 10801201	Injury, poisoning and procedural complications	Muscle rupture	01JAN2011	31DEC2012	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801219	Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Eye disorders	Glaucoma	01AUG2020		Y
		Injury, poisoning and procedural complications	Foreign body in eye	01JAN2010	31DEC2010	N
	C4591001 1080 10801221	Surgical and medical procedures	Removal of foreign body from eye	01JAN2010	31DEC2010	N
		Immune system disorders	Milk allergy	01JAN2015		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1081 10811012	Infections and infestations	Appendicitis	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Appendectomy	01OCT2018	31OCT2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Folliculitis	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2017		Y
	C4591001 1081 10811075	Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1082 10821014	Injury, poisoning and procedural complications	Joint dislocation	01JAN2006	31DEC2006	N
			Upper limb fracture	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Elbow operation	01JAN2006	31DEC2006	N
			Rhinoplasty	01JAN2017	31DEC2017	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
			Insomnia	01JAN2020		Y
	C4591001 1082 10821036	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2011		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1082 10821044	Eye disorders	Astigmatism	01JAN2008		Y
	C4591001 1082 10821054	Injury, poisoning and procedural complications	Tibia fracture	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Surgical and medical procedures	Bone operation	01JAN2015	31DEC2015	N



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821139	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2007		Y
			Tobacco abuse	01JAN2016		Y
	C4591001 1082 10821171	Gastrointestinal disorders	Tooth impacted	01JAN2013	31DEC2013	N
		Infections and infestations	Adenoiditis	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N
			Nasal septal operation	01JAN2014	31DEC2014	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1082 10821196	Infections and infestations	Tonsillitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1999	31DEC1999	N
			Fibula fracture	01JAN1999	31DEC1999	N
			Tibia fracture	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Bone operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1082 10821201	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821211	Gastrointestinal disorders	Diarrhoea	01JAN2014		Y
			Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
			Papilloma viral infection	15SEP2020		Y
			Tonsillitis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JUN2020		Y
			Depression	01JAN2019		Y
			Post-traumatic stress disorder	01JAN2019		Y
		Reproductive system and breast disorders	Varicocele	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Varicocele repair	01JAN2017	31DEC2017	N
	C4591001 1083 10831001	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1083 10831062	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Generalised anxiety disorder	01JAN2015		Y
			Insomnia	01JAN2015		Y
	C4591001 1083 10831082	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1083 10831084	Injury, poisoning and procedural complications	Epicondylitis	01JAN2019		Y
	C4591001 1083 10831094	Psychiatric disorders	Insomnia	01JAN2011		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive disorder	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1083 10831105	Skin and subcutaneous tissue disorders	Acne	01JUL2019		Y
	C4591001 1083 10831113	Gastrointestinal disorders	Peritoneal cyst	01NOV2018	09NOV2019	N
		Surgical and medical procedures	Cyst removal	09NOV2018	09NOV2018	N
	C4591001 1083 10831124	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1083 10831127	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831132	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1083 10831145	Infections and infestations	Tonsillitis	01JAN2019	31JAN2020	N
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Social circumstances	Electronic cigarette user	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2020	31JAN2020	N
			Wisdom teeth removal	01JAN2020	31JAN2020	N
	C4591001 1083 10831163	Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
	C4591001 1083 10831174	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1083 10831191	Gastrointestinal disorders	Dyspepsia	01SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1083 10831205	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1083 10831227	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1083 10831253	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1084 10841029	Eye disorders	Visual acuity reduced	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Investigations	Endoscopy	01JAN2016	31DEC2016	N
	C4591001 1084 10841031	Eye disorders	Myopia	01NOV2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
			Hyperhidrosis	01MAY2020		Y
		Surgical and medical procedures	Contraceptive implant	01NOV2018		Y
			Synovial cyst removal	01JAN2009	31DEC2009	N
	C4591001 1084 10841069	Eye disorders	Visual acuity reduced	01JAN2011		Y
	C4591001 1084 10841101	Eye disorders	Myopia	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1084 10841214	Eye disorders	Visual acuity reduced	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
	C4591001 1084 10841228	Eye disorders	Visual acuity reduced	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1084 10841280	Surgical and medical procedures	Ankle operation	02APR2020	02APR2020	N
			Open reduction of fracture	02APR2020	02APR2020	N
	C4591001 1084 10841393	Eye disorders	Visual acuity reduced	01JUL2019		Y
	C4591001 1084 10841409	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2009	N
	C4591001 1084 10841410	Immune system disorders	Allergy to animal	01JAN2003		Y
			Seasonal allergy	01JAN2003		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Nervous system disorders	Epilepsy	01JAN2016		Y
			Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841423	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Bacterial vaginosis	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2014	31DEC2016	N
	C4591001 1084 10841492	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2017		Y
		Surgical and medical procedures	Eye operation	01JAN2015	31DEC2015	N
	C4591001 1084 10841495	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Nasal septum deviation	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1084 10841512	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Immune system disorders	Allergy to plants	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015	31DEC2016	N
	C4591001 1084 10841517	Eye disorders	Visual acuity reduced	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001	31DEC2005	N
	C4591001 1084 10841530	General disorders and administration site conditions	Pain	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1084 10841533	Infections and infestations	Adenoiditis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014	31DEC2014	N
			Radius fracture	01JAN2018	31DEC2018	N
	C4591001 1084 10841535	Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Ear infection	01OCT2003	31MAY2004	N
	C4591001 1084 10841536	Surgical and medical procedures	Ear tube insertion	01MAY2004	31MAY2004	N
		Eye disorders	Visual acuity reduced	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN2007		Y
			Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2014	31DEC2014	N
			Hand fracture	01JAN2014	31DEC2014	N
			Limb fracture	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2019		Y
			Major depression	01JAN2018	31DEC2018	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Varicocele	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2008	31DEC2008	N
			Varicocele repair	01JAN2019	31DEC2019	N
			Seasonal allergy	01JAN2014		Y
	C4591001 1084 10841537	Immune system disorders				
	C4591001 1084 10841538	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Kidney infection	01AUG2010		Y
			Tonsillitis	01JAN2004	30NOV2006	N
			Urinary tract infection	01SEP2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1084 10841539	Eye disorders	Visual acuity reduced	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01MAR2011		Y
		Investigations	Arthroscopy	30JUN2020	30JUN2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2004	31DEC2005	N
				01JAN2005	31DEC2006	N
	C4591001 1084 10841540	Nervous system disorders	Headache	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851003	Immune system disorders	Seasonal allergy	01APR2011		Y
		Psychiatric disorders	Anxiety	01DEC2015		Y
			Insomnia	01MAY2020		Y
	C4591001 1085 10851019	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1085 10851049	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01JAN1998	31DEC2014	N
		Surgical and medical procedures	Cholesteatoma removal	01JAN2014	31DEC2014	N
			Cochlea implant	01MAY2018		Y
	C4591001 1085 10851050	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01SEP2018	30SEP2018	N
		Surgical and medical procedures	Intervertebral disc operation	01SEP2018	30SEP2018	N
	C4591001 1085 10851079	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1997		Y
	C4591001 1085 10851081	Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1085 10851165	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1085 10851281	Psychiatric disorders	Depression	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01AUG2020		Y
	C4591001 1085 10851299	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1085 10851373	Immune system disorders	Seasonal allergy	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851374	Psychiatric disorders	Depression	01SEP2020		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
	C4591001 1085 10851375	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
			Depression	01APR2020		Y
	C4591001 1087 10871021	Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01MAY2019		Y
	C4591001 1087 10871062	Psychiatric disorders	Anxiety	01DEC2019		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1087 10871064	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1087 10871078	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1087 10871087	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Onychomycosis	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1087 10871089	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1087 10871108	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
	C4591001 1087 10871182	Psychiatric disorders	Depression	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871214	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1087 10871243	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1087 10871279	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
	C4591001 1087 10871325	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
	C4591001 1087 10871343	Injury, poisoning and procedural complications	Muscle strain	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1087 10871356	Immune system disorders	Food allergy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1087 10871363	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1087 10871473	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1087 10871490	Infections and infestations	Bacterial vaginosis	09SEP2020	16SEP2020	N
		Psychiatric disorders	Anxiety	11SEP2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871491	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1087 10871593	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2010	31DEC2010	N
	C4591001 1088 10881054	Infections and infestations	Paronychia	14AUG2020		Y
	C4591001 1088 10881130	Musculoskeletal and connective tissue disorders	Spinal deformity	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2004		Y
	C4591001 1088 10881200	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1088 10881239	Psychiatric disorders	Affective disorder	01JAN2003		Y
			Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2015		Y
	C4591001 1088 10881256	Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1089 10891015	Endocrine disorders	Hypothyroidism	01MAY2019		Y
		Immune system disorders	Allergy to chemicals	01JAN2001		Y
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01SEP2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01SEP2018		Y
			Insomnia	01SEP2018		Y
	C4591001 1089 10891120	Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2001		Y
	C4591001 1089 10891179	Surgical and medical procedures	Bone operation	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1089 10891181	Nervous system disorders	Seizure	01JAN2009		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
	C4591001 1089 10891192	Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
	C4591001 1089 10891225	Injury, poisoning and procedural complications	Ligament rupture	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Lithotripsy	01JAN2018	31DEC2018	N
	C4591001 1089 10891273	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1089 10891306	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2016	31DEC2016	N
	C4591001 1089 10891318	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901031	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1090 10901038	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1999	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
		Surgical and medical procedures	Hip surgery	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1090 10901043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1090 10901044	Blood and lymphatic system disorders	Anaemia	01JAN2008	31DEC2010	N
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2018		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Nervous system disorders	Idiopathic intracranial hypertension	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Contraceptive implant	01JAN2019		Y
			Tonsillectomy	01JAN2013	31DEC2013	N
			Tooth extraction	01JAN2014	31DEC2014	N
	C4591001 1090 10901090	Psychiatric disorders	Anxiety	01DEC2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2012		Y
	C4591001 1090 10901197	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Petit mal epilepsy	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1090 10901201	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Dyspepsia	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN2002		Y
			Milk allergy	01JUN2020		Y
		Infections and infestations	Tinea versicolour	01JAN2011	31DEC2016	N
		Metabolism and nutrition disorders	Gluten sensitivity	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1090 10901314	Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Dyspepsia	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2001		Y
			Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Dairy intolerance	01JAN2010		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2008		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Wisdom teeth removal	01DEC2016	31DEC2016	N
	C4591001 1090 10901315	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2015	N
	C4591001 1090 10901328	Immune system disorders	Food allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1090 10901369	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1090 10901377	Immune system disorders	Allergy to animal	01JAN2004		Y
			Food allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
	C4591001 1090 10901416	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1090 10901424	Infections and infestations	Lyme disease	01JAN2002	31DEC2002	N
		Psychiatric disorders	Insomnia	01OCT2012	31MAY2014	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31MAR2016	N
		Surgical and medical procedures	Ear tube insertion	01MAY1995	31MAY1996	N
			Shoulder operation	01DEC2014	31DEC2014	N
	C4591001 1090 10901443	Psychiatric disorders	Anxiety disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2013	31JUL2013	N
	C4591001 1090 10901517	Endocrine disorders	Hypothyroidism	01JAN1997		Y
	C4591001 1090 10901540	Investigations	Serum ferritin decreased	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2019	31DEC2019	N
			Ear tube insertion	01JAN2001	31DEC2001	N
			Limb operation	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1090 10901550	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 109010901559	Gastrointestinal disorders	Pelvic floor dysfunction	01JAN2016		Y
		Investigations	Pelvic laparoscopy	04AUG2020	31DEC2020	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 109110911019	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2011		Y
		Investigations	Cardiac murmur	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 109110911067	General disorders and administration site conditions	Pain	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 109110911088	Immune system disorders	Hypersensitivity	01JAN2010		Y
	C4591001 109110911095	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2019		Y
	C4591001 109110911106	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
	C4591001 1091 10911111	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1091 10911120	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
	C4591001 1091 10911122	General disorders and administration site conditions	Cyst	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JUL2019		Y
		Surgical and medical procedures	Foot operation	01JAN2014	31DEC2014	N
	C4591001 1091 10911125	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Ear infection	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2010	31DEC2010	N
			Tympanoplasty	01JAN2010	31DEC2010	N
	C4591001 1091 10911149	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911160	Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2005		Y
	C4591001 1091 10911233	Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1091 10911238	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1091 10911270	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
			Cold urticaria	01JAN2014		Y
	C4591001 1091 10911297	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
			Depression	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
	C4591001 1091 10911322	Congenital, familial and genetic disorders	Micrognathia	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Orthognathic surgery	01JAN2015	31DEC2015	N
	C4591001 1091 10911328	Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2002	31DEC2002	N
			Rhinitis allergic	01JAN2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
	C4591001 1091 10911331	Investigations	Cardiac murmur	01JAN2005		Y
	C4591001 1091 10911334	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1091 10911341	Psychiatric disorders	Anxiety	01AUG2019		Y
	C4591001 1091 10911342	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1091 10911344	Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Autism spectrum disorder	01JAN2015		Y
			Insomnia	01JAN2019		Y
	C4591001 1091 10911379	Endocrine disorders	Autoimmune thyroiditis	01JAN2011		Y
	C4591001 1091 10911380	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01AUG2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911381	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1091 10911382	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2018		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2018		Y
	C4591001 1091 10911383	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1091 10911384	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1091 10911385	Surgical and medical procedures	Meniscus operation	03JAN2020	03JAN2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911386	Injury, poisoning and procedural complications	Ligament rupture	01AUG2020	30SEP2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Rhinitis allergic	01FEB2005		Y
	C4591001 1091 10911387	Surgical and medical procedures	Ligament operation	01JAN2020	31DEC2020	N
		Immune system disorders	Food allergy	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	05AUG2020		Y
		Reproductive system and breast disorders	Menorrhagia	01AUG2013		Y
	C4591001 1091 10911389	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2017		Y
	C4591001 1091 10911392	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1091 10911393	Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1091 10911398	Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1092 10921002	Eye disorders	Myopia	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2018	01OCT2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1092 10921055	Metabolism and nutrition disorders	Obesity	01JAN2018		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1092 10921083	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1092 10921098	Congenital, familial and genetic disorders	Cornelia de Lange syndrome	(b) (6) 1998		Y
		Nervous system disorders	Migraine	(b) (6) 1998		Y
	C4591001 1092 10921109	Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC2014	N
		Surgical and medical procedures	Gastric bypass	01JAN2014	31DEC2014	N
	C4591001 1092 10921127	Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2016		Y
	C4591001 1092 10921128	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1092 10921144	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1092 10921157	Nervous system disorders	Headache	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921177	Endocrine disorders	Hypothyroidism	19FEB2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1092 10921189	Metabolism and nutrition disorders	Obesity	05FEB2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
			Hirsutism	19JUN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1092 10921197	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1092 10921227	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
	C4591001 1092 10921260	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007		Y
		Reproductive system and breast disorders	Ovarian cyst	08JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1093 10931041	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN2019		Y
	C4591001 1093 10931055	Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2013		Y
	C4591001 1093 10931087	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1093 10931088	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Food allergy	01JAN2018		Y
			Milk allergy	01JAN2018		Y
	C4591001 1093 10931126	Psychiatric disorders	Depression	01JAN2019		Y
		Renal and urinary disorders	Micturition urgency	01JAN2018		Y
	C4591001 1093 10931133	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1093 10931168	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1093 10931203	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1093 10931204	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1093 10931210	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1093 10931218	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931219	Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
	C4591001 1094 10941075	Metabolism and nutrition disorders	Vitamin D deficiency	06AUG2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN2003	31DEC2003	N
	C4591001 1094 10941076	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2005		Y
			Autism spectrum disorder	01JAN2005		Y
	C4591001 1094 10941117	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Helicobacter infection	01JUN2020	30JUN2020	N
			Onychomycosis	01JUN2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2019		Y
		Nervous system disorders	Hypoaesthesia	16JUN2020		Y
			Migraine	01JAN2015	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
	C4591001 1094 10941156	Eye disorders	Strabismus	(b) (6) 2000	31AUG2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Strabismus correction	01AUG2018	31AUG2018	N
	C4591001 1094 10941169	Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	C4591001 1095 10951002	Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 1095 10951038	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1095 10951046	Immune system disorders	Seasonal allergy	15MAR2013		Y
		Nervous system disorders	Migraine	15OCT2019		Y
	C4591001 1095 10951055	Psychiatric disorders	Attention deficit hyperactivity disorder	15JUL2018		Y
	C4591001 1095 10951132	Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1095 10951170	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1095 10951217	Musculoskeletal and connective tissue disorders	Scoliosis	01JUN2006	07DEC2011	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1998	01JAN2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	01JAN2019	N
			Scoliosis surgery	01JAN2011	01JAN2011	N
			Tonsillectomy	01JAN2000	01JAN2000	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951225	Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1095 10951243	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1095 10951244	Immune system disorders	Rubber sensitivity	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
	C4591001 1095 10951260	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1095 10951271	Psychiatric disorders	Tobacco abuse	01JAN2010		Y
	C4591001 1095 10951278	Gastrointestinal disorders	Gastrointestinal pain	21AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2020		Y
			Depression	01JAN2016		Y
	C4591001 1095 10951308	Psychiatric disorders	Depression	01DEC2016		Y
	C4591001 1095 10951309	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1095 10951311	Ear and labyrinth disorders	Hypoacusis	(b) (6) 2003		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Renal and urinary disorders	Nephrotic syndrome	01JAN2007	31DEC2007	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951312	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1095 10951313	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1095 10951314	Nervous system disorders	Epilepsy	01JAN2012		Y
	C4591001 1095 10951315	Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1095 10951316	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2019		Y
	C4591001 1095 10951317	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
	C4591001 1095 10951319	Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1096 10961027	Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Psychiatric disorders	Depression	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2004	31DEC2004	N
	C4591001 1096 10961030	Skin and subcutaneous tissue disorders	Rash	01APR2020	30APR2020	N
	C4591001 1096 10961031	Immune system disorders	Allergy to animal	01JAN2000		Y
		Infections and infestations	Mastitis	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004	31DEC2008	N
		Surgical and medical procedures	Breast operation	01OCT2016	31OCT2016	N
			Caesarean section	08JUN2016	08JUN2016	N
	C4591001 1096 10961032	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
	C4591001 1096 10961053	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961057	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1096 10961096	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961141	Gastrointestinal disorders	Flatulence	25AUG2020	09SEP2020	N
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1096 10961168	Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1096 10961178	Infections and infestations	Herpes simplex	01DEC2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011	31DEC2013	N
				01JAN2014		Y
		Nervous system disorders	Headache	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2009	N
		Surgical and medical procedures	Caesarean section	14JUL2014	14JUL2014	N
				24JUL2019	24JUL2019	N
			Gastric bypass	01JAN2013	31DEC2013	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961195	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1096 10961205	Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
	C4591001 1096 10961213	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1096 10961219	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
			Chronic sinusitis	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ankle operation	01JAN2016	31DEC2016	N
			Appendicectomy	01JAN2014	31DEC2014	N
			Sinus operation	01JAN2018	31DEC2018	N
	C4591001 1096 10961220	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
	C4591001 1096 10961223	Reproductive system and breast disorders	Menorrhagia	01JAN2017	30SEP2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Metrorrhagia	01JAN2017	30SEP2020	N
	C4591001 1096 10961245	Infections and infestations	Arthritis bacterial	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
	C4591001 1096 10961313	Gastrointestinal disorders	Flatulence	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1096 10961319	Gastrointestinal disorders	Salivary gland cyst	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAY2018	31DEC2018	N
			Parotidectomy	01JAN2015	31DEC2015	N
	C4591001 1096 10961321	Gastrointestinal disorders	Hiatus hernia	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01MAR2019		Y
			Depression	01APR2020		Y
			Suicidal ideation	05SEP2020		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2004	31DEC2004	N
	C4591001 1096 10961335	Investigations	Hormone level abnormal	01AUG2019	31AUG2019	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
			Post-traumatic stress disorder	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01AUG2019	31AUG2019	N
	C4591001 1096 10961336	Eye disorders	Retinal detachment	01JAN2013	31DEC2013	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Depression	01MAR2019		Y
		Surgical and medical procedures	Eye operation	01JAN2013	31DEC2013	N
	C4591001 1096 10961341	Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1096 10961367	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961372	Injury, poisoning and procedural complications	Back injury	01JUL2019	31JUL2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2019		Y
			Intervertebral disc protrusion	01JUL2019	30JUN2020	N
		Surgical and medical procedures	Physiotherapy	01JUN2020		Y
			Spinal laminectomy	01JUN2020	30JUN2020	N
	C4591001 1096 10961373	Immune system disorders	Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2018		Y
	C4591001 1096 10961385	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Ear infection	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ear tube insertion	01JAN2007	31DEC2007	N
	C4591001 1096 10961387	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961388	Gastrointestinal disorders	Nausea	11SEP2020	13SEP2020	N
			Vomiting	11SEP2020	13SEP2020	N
		Infections and infestations	Gastroenteritis viral	11SEP2020	13SEP2020	N
		Injury, poisoning and procedural complications	Joint injury	01JUN2018	30JUN2018	N
		Surgical and medical procedures	Ligament operation	01JUN2018	30JUN2018	N
			Osteotomy	01JUN2018	30JUN2018	N
	C4591001 1096 10961390	Infections and infestations	Tonsillitis	01JAN2010	30JUN2019	N
		Surgical and medical procedures	Tonsillectomy	01JUN2019	30JUN2019	N
	C4591001 1096 10961392	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Bipolar disorder	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1096 10961393	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1097 10971096	Reproductive system and breast disorders	Polycystic ovaries	01JUL2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1098 10981177	Immune system disorders	Allergy to animal	01JAN2001		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Infectious mononucleosis	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01SEP2020		Y
			Depression	01SEP2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1098 10981187	Immune system disorders	Allergy to animal	01JAN2010		Y
	C4591001 1098 10981198	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1098 10981200	Nervous system disorders	Epilepsy	01JAN2002		Y
	C4591001 1098 10981252	Reproductive system and breast disorders	Polycystic ovaries	01JUL2020		Y
	C4591001 1098 10981254	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Bipolar disorder	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Adenoidectomy	01JAN2005	31DEC2005	N
			Circumcision	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1101 11011004	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1101 11011022	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1101 11011033	Infections and infestations	Bronchitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1101 11011038	Immune system disorders	Food allergy	01JAN2011		Y
	C4591001 1101 11011040	Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1101 11011052	Immune system disorders	Mycotic allergy	01JAN2015		Y
		Infections and infestations	Bronchitis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2013		Y
	C4591001 1101 11011056	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1101 11011062	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1101 11011069	Musculoskeletal and connective tissue disorders	Back pain	20JUN2014		Y
		Skin and subcutaneous tissue disorders	Acne	20JUL2020		Y
	C4591001 1101 11011073	Gastrointestinal disorders	Constipation	01JAN2000		Y
			Diarrhoea	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1101 11011075	Gastrointestinal disorders	Haemorrhoids	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011080	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1101 11011088	Skin and subcutaneous tissue disorders	Acne	01SEP2017		Y
	C4591001 1101 11011100	Skin and subcutaneous tissue disorders	Acne	01AUG2016		Y
	C4591001 1101 11011105	Psychiatric disorders	Anxiety	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
			Eczema	01JAN2000		Y
	C4591001 1101 11011107	Gastrointestinal disorders	Gastric ulcer	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Bipolar disorder	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1101 11011110	Immune system disorders	Food allergy	01JAN2006		Y
	C4591001 1101 11011118	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1107 11071025	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1107 11071055	Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071122	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1107 11071124	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1107 11071179	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
	C4591001 1109 11091020	Infections and infestations	Appendicitis	28JUN2013	28JUN2013	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	28JUN2013	28JUN2013	N
	C4591001 1109 11091030	Metabolism and nutrition disorders	Hypercholesterolaemia	(b) (6) 1994		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JAN2015	01JAN2015	N
	C4591001 1109 11091046	Surgical and medical procedures	Oral surgery	01JAN2016	31JAN2016	N
	C4591001 1109 11091092	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1109 11091132	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Cluster headache	01JAN2018		Y
			Migraine	28JAN2018		Y
			Narcolepsy	04JUN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2008		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2015		Y
	C4591001 1109 11091176	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1109 11091251	Surgical and medical procedures	Foot operation	01JAN2014	31DEC2014	N
	C4591001 1109 11091309	Immune system disorders	Seasonal allergy	01JAN2010		Y
				01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1109 11091332	Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N
	C4591001 1109 11091333	Congenital, familial and genetic disorders	Congenital multiplex arthrogryposis	(b) (6) 1998		Y
		Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
	C4591001 1109 11091335	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
	C4591001 1109 11091434	Surgical and medical procedures	Intra-uterine contraceptive device insertion	30APR2020	30APR2020	N
	C4591001 1109 11091457	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Alcohol abuse	01JAN2017	31DEC2019	N
			Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
			Drug abuse	01JAN2017	31DEC2019	N
	C4591001 1109 11091514	Immune system disorders	Hypersensitivity	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01MAY2020	31MAY2020	N
	C4591001 1109 11091522	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN2008		Y
	C4591001 1109 11091532	Psychiatric disorders	Post-traumatic stress disorder	01JAN2015		Y
	C4591001 1109 11091539	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1110 11101085	Surgical and medical procedures	Fracture treatment	01JAN2015	31JAN2015	N
	C4591001 1110 11101116	Psychiatric disorders	Insomnia	01JAN2004		Y
	C4591001 1110 11101156	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1110 11101316	Infections and infestations	Rhinitis	01JAN2006		Y
	C4591001 1110 11101320	Psychiatric disorders	Anxiety disorder	01JAN2010		Y
			Major depression	01JAN2010		Y
	C4591001 1110 11101338	Immune system disorders	Allergy to animal	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1110 11101379	Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2019		Y
	C4591001 1111 11111001	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1111 11111018	Gastrointestinal disorders	Constipation	01JAN2004	31DEC2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Psoriasis	01JAN2010		Y
	C4591001 1111 11111050	Infections and infestations	Urinary tract infection	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1111 11111053	Eye disorders	Myopia	01JAN2009		Y
		Investigations	Heart rate irregular	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1111 11111079	Eye disorders	Myopia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1111 11111143	Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015	31DEC2018	N
			Synovial cyst	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
			Dandruff	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111188	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2009		Y
	C4591001 1112 11121019	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Depression	01JAN2009		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	04SEP2018	04SEP2018	N
	C4591001 1112 11121031	Infections and infestations	Herpes simplex	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
		Surgical and medical procedures	Contraceptive implant	01JUN2019	30JUN2019	N
	C4591001 1112 11121045	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 2002		Y
	C4591001 1112 11121058	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAR2019	31MAR2019	N
	C4591001 1112 11121078	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1112 11121098	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1112 11121125	Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	06AUG2019	06AUG2019	N
	C4591001 1112 11121193	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1112 11121217	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1112 11121228	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2005		Y
	C4591001 1112 11121229	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1112 11121260	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1112 11121271	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1112 11121297	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	08MAY2019		Y
			Sinus headache	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JUL2019	31JUL2019	N
	C4591001 1112 11121298	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01APR2020		Y
	C4591001 1112 11121307	Surgical and medical procedures	Wisdom teeth removal	29SEP2020	29SEP2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121335	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
	C4591001 1112 11121345	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1114 11141009	Eye disorders	Presbyopia	01JUN2018		Y
		Immune system disorders	Seasonal allergy	01OCT2018		Y
	C4591001 1114 11141012	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1114 11141014	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01MAR2009		Y
		Nervous system disorders	Headache	01SEP2018		Y
			Migraine	01SEP2018		Y
		Psychiatric disorders	Anxiety	01OCT2004		Y
			Depression	01SEP2018		Y
		Renal and urinary disorders	Hypertonic bladder	01OCT2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2004		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2009		Y
			Eczema	(b) (6) 1999		Y
	C4591001 1114 11141021	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01AUG2016		Y
		Injury, poisoning and procedural complications	Ankle fracture	01MAR2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018	15DEC2018	N
	C4591001 1114 11141024	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1114 11141033	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Peptic ulcer	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menstruation irregular	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1114 11141038	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1114 11141041	Eye disorders	Astigmatism	01AUG2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
			Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm malignant	01JAN2008	18JAN2008	N
		Nervous system disorders	Cerebrovascular accident	01AUG2019	01AUG2019	N
			Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01AUG2017		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
			Polycystic ovaries	01JAN2013		Y
		Surgical and medical procedures	Arterial bypass operation	01JAN2019	01JAN2019	N
			Tumour excision	18JAN2008	18JAN2008	N
		Eye disorders	Myopia	01JAN2004		Y
	C4591001 1114 11141065	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1114 11141076	Hepatobiliary disorders	Cholecystitis	01OCT2016		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Product issues	Device malfunction	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Cough	18AUG2020		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2016	31DEC2020	N
			Female sterilisation	01JUN2019	30JUN2020	N
			Uterine dilation and curettage	01MAY2018	31MAY2018	N
	C4591001 1114 11141085	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1114 11141089	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1116 11161043	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161044	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1116 11161047	Infections and infestations	Folliculitis	01APR2020		Y
	C4591001 1116 11161059	Gastrointestinal disorders	Abdominal pain	01AUG2019	19SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1116 11161076	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2009		Y
		Nervous system disorders	Irlen syndrome	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Autism spectrum disorder	01JAN2009		Y
	C4591001 1116 11161099	Congenital, familial and genetic disorders	Sickle cell trait	28JAN2020		Y
	C4591001 1116 11161100	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
	C4591001 1116 11161119	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2007	N
	C4591001 1116 11161175	Psychiatric disorders	Anxiety	01JAN2003	31DEC2005	N
	C4591001 1116 11161196	Surgical and medical procedures	Female sterilisation	16SEP2019	16SEP2019	N
	C4591001 1116 11161256	Infections and infestations	Urinary tract infection	01JAN2010		Y
	C4591001 1116 11161292	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161320	Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1117 11171050	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1117 11171063	Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2013		Y
	C4591001 1117 11171068	Eye disorders	Myopia	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
			Depression	01JUN2016		Y
			Gender dysphoria	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2010		Y
		Social circumstances	Substance use	01JAN2013		Y
			Tobacco user	01JAN2017		Y
	C4591001 1117 11171070	Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	(b) (6) 1997		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2014	31DEC2014	N
			Ligament rupture	01JAN2017	31DEC2017	N
			Post-traumatic neck syndrome	01AUG2001		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01AUG2019		Y
		Psychiatric disorders	Anxiety	01JAN2011	31DEC2017	N
			Depression	01JAN2011	31DEC2017	N
			Insomnia	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1997		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Social alcohol drinker	01JAN2015		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Continuous positive airway pressure	01JAN2019		Y
			Ligament operation	01JAN2017	31DEC2017	N
			Renal stone removal	01JAN2017	31DEC2017	N
	C4591001 1117 11171084	Eye disorders	Visual impairment	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2014		Y
			Hypersensitivity	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2013		Y
		Surgical and medical procedures	Immune tolerance induction	01JUL2020		Y
	C4591001 1117 11171099	Eye disorders	Visual impairment	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
	C4591001 1117 11171107	Eye disorders	Visual impairment	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2012	31DEC2012	N
			Concussion	01JAN2010	31DEC2014	N
			Ligament rupture	01JAN2013	31DEC2013	N
		Investigations	Cardiac murmur	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2011	31DEC2015	N
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2001		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1117 11171113	Infections and infestations	Clostridium difficile infection	01JAN2009	31DEC2009	N
			Pharyngitis streptococcal	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2015		Y
			Ingrowing nail	01JAN2019	31DEC2019	N
		Social circumstances	Alcohol use	01JAN2015		Y
			Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Nail operation	01JAN2019	31DEC2019	N
	C4591001 1117 11171131	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Ear infection	01JAN2003	31DEC2005	N
		Social circumstances	Alcohol use	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N
	C4591001 1117 11171138	Eye disorders	Visual impairment	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01NOV2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171169	Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1117 11171178	Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2020		Y
		Social circumstances	Alcohol use	01JUL2020		Y
	C4591001 1117 11171187	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	22OCT2015	22OCT2015	N
	C4591001 1118 11181017	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1118 11181027	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2010		Y
		Nervous system disorders	Paroxysmal choreoathetosis	(b) (6) 1998		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1118 11181042	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1118 11181101	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2017		Y
	C4591001 1120 11201037	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1120 11201038	Congenital, familial and genetic disorders	Porokeratosis	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
	C4591001 1120 11201115	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Nervous system disorders	Hypersomnia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2012		Y
	C4591001 1120 11201130	Injury, poisoning and procedural complications	Ligament sprain	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1120 11201157	Immune system disorders	Allergy to animal	01JAN2015		Y
	C4591001 1120 11201172	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1120 11201223	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1120 11201237	Immune system disorders	Allergy to animal	01JAN2010		Y
			Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201240	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1120 11201250	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2003		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Ankle operation	01JAN2011	31DEC2011	N
			Brain operation	01JAN2006	31DEC2006	N
	C4591001 1120 11201259	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Traumatic arthritis	01JAN2011		Y
	C4591001 1120 11201279	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2014		Y
	C4591001 1121 11211060	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1121 11211067	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1121 11211118	Psychiatric disorders	Depression	12FEB2020		Y
	C4591001 1122 11221032	Musculoskeletal and connective tissue disorders	Arthralgia	08JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Lumbar radiculopathy	08JUN2020		Y
		Psychiatric disorders	Major depression	20FEB2020		Y
	C4591001 1123 11231045	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1123 11231051	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1123 11231057	Skin and subcutaneous tissue disorders	Pityriasis	01JAN2003		Y
	C4591001 1123 11231069	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1123 11231073	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018	30APR2019	N
		Psychiatric disorders	Depression	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Gastrectomy	01APR2019	30APR2019	N
	C4591001 1123 11231075	Psychiatric disorders	Depression	01JAN2013		Y
			Panic disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Rhinitis allergic	01JAN2001		Y
	C4591001 1123 11231085	Immune system disorders	Allergy to animal	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231115	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2017	N
	C4591001 1123 11231116	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1123 11231135	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1123 11231157	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1123 11231164	Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
	C4591001 1123 11231204	Psychiatric disorders	Anxiety	01DEC2018		Y
			Attention deficit hyperactivity disorder	01DEC2018		Y
			Depression	01DEC2018		Y
	C4591001 1123 11231229	Psychiatric disorders	Anxiety	01JAN2017		Y
			Major depression	01JAN2017		Y
	C4591001 1123 11231237	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231303	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231308	Psychiatric disorders	Anxiety	14DEC2019		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231336	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Surgical and medical procedures	Abscess drainage	01JAN2004	31DEC2004	N
			Maxillofacial operation	01DEC2018	31DEC2018	N
	C4591001 1123 11231381	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231383	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tinea pedis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1123 11231398	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1123 11231407	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1123 11231409	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Mastectomy	17OCT2019	17OCT2019	N
	C4591001 1123 11231411	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2020		Y
	C4591001 1123 11231413	Infections and infestations	Tonsillitis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1123 11231415	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1123 11231418	Investigations	Arthroscopy	01JAN2017		Y
	C4591001 1123 11231419	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
	C4591001 1123 11231421	Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Keloid scar	01JAN2017		Y
	C4591001 1123 11231423	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	28SEP2016	26NOV2016	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	26NOV2016	26NOV2016	N
	C4591001 1123 11231426	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2012		Y
	C4591001 1123 11231427	Congenital, familial and genetic disorders	Vitello-intestinal duct remnant	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Diverticulectomy	01JAN2005	31DEC2005	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231429	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2019		Y
		Investigations	Arthroscopy	01JAN2019	31DEC2019	N
	C4591001 1123 11231430	Infections and infestations	Ear infection	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Testicular torsion	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Orchidectomy	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1123 11231433	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1123 11231435	Metabolism and nutrition disorders	Iron deficiency	01DEC2018		Y
		Nervous system disorders	Headache	01DEC2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1123 11231436	Immune system disorders	Allergy to animal	01JAN2018		Y
			Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Deformity thorax	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tympanoplasty	01JAN2016	31DEC2016	N
	C4591001 1123 11231437	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231471	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1123 11231480	Reproductive system and breast disorders	Menstruation irregular	01DEC2019		Y
	C4591001 1123 11231490	Infections and infestations	Ear infection	01JAN2005	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Myringotomy	01JAN2006	31DEC2009	N
	C4591001 1123 11231498	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Dermatitis atopic	01JAN2015		Y
	C4591001 1124 11241018	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Eye disorders	Strabismus	01JAN2000	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Strabismus correction	01JAN2016	31DEC2016	N
	C4591001 1124 11241030	Infections and infestations	Mastoiditis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Mastoidectomy	01JAN2005	31DEC2005	N
			Rhinoplasty	01JAN2014	31DEC2014	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016	31DEC2016	N
	C4591001 1124 11241038	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
	C4591001 1124 11241049	Blood and lymphatic system disorders	Anaemia	01JAN2015	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2015	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
	C4591001 1124 11241068	Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1124 11241069	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1124 11241071	Gastrointestinal disorders	Dysphagia	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Investigations	Biopsy pharynx normal	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2010	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2012	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Menstruation irregular	01JAN2009	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Bone lesion excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
			Cholelithiasis	01JAN2014	31DEC2014	N
	C4591001 1124 11241081	Hepatobiliary disorders				
		Skin and subcutaneous tissue disorders	Acne	01JAN2010	31DEC2014	N
	C4591001 1124 11241122	Surgical and medical procedures	Wisdom teeth removal	01JAN2020	01JAN2020	N
	C4591001 1124 11241141	Psychiatric disorders	Anxiety disorder	01JAN2012		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2010		Y
	C4591001 1124 11241170	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN1995		Y
	C4591001 1124 11241219	Metabolism and nutrition disorders	Iron deficiency	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1124 11241223	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1124 11241227	Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1125 11251004	Hepatobiliary disorders	Cholelithiasis obstructive	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	28JUN2018	28JUN2018	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1125 11251050	Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1125 11251059	Surgical and medical procedures	Removal of foreign body	01JAN2019	31DEC2019	N
	C4591001 1125 11251096	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1125 11251134	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1125 11251140	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2016		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
		Surgical and medical procedures	Benign breast lump removal	01AUG2019	31AUG2019	N
	C4591001 1125 11251197	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1125 11251200	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1125 11251237	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1125 11251238	Immune system disorders	Allergy to animal	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
	C4591001 1125 11251243	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1126 11261194	Gastrointestinal disorders	Dyspepsia	25APR2019		Y
		Immune system disorders	Iodine allergy	09SEP2020		Y
		Metabolism and nutrition disorders	Obesity	13FEB2019		Y
		Nervous system disorders	Migraine	31JUL2006		Y
		Psychiatric disorders	Anxiety disorder	24DEC2013		Y
			Major depression	14MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14OCT2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	11NOV2016		Y
	C4591001 1126 11261201	Gastrointestinal disorders	Gastroesophageal reflux disease	09OCT2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	25MAR2020		Y
			Attention deficit hyperactivity disorder	09MAY2018		Y
			Selective eating disorder	15SEP2015	19APR2018	N
	C4591001 1126 11261202	Psychiatric disorders	Attention deficit hyperactivity disorder	12APR2017		Y
	C4591001 1126 11261208	Immune system disorders	Drug hypersensitivity	01JUL2005		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01SEP2005		Y
	C4591001 1126 11261209	Ear and labyrinth disorders	Motion sickness	02SEP2014		Y
		Nervous system disorders	Migraine	14JUL2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01OCT2019		Y
	C4591001 1126 11261210	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09APR2009		Y
			Asthma	30MAY2006		Y
	C4591001 1126 11261211	Infections and infestations	Cellulitis	19OCT2020	29OCT2020	N
	C4591001 1126 11261212	Skin and subcutaneous tissue disorders	Acne	01JUL2018		Y
	C4591001 1126 11261213	Immune system disorders	Seasonal allergy	01APR2011		Y
	C4591001 1126 11261216	Psychiatric disorders	Anxiety disorder	08JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	27APR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2016		Y
	C4591001 1126 11261217	Gastrointestinal disorders	Tooth impacted	01JAN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261218	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	15JUL2020		Y
		Surgical and medical procedures	Wisdom teeth removal	22JUL2020	22JUL2020	N
	C4591001 1126 11261221	Gastrointestinal disorders	Gastrooesophageal reflux disease	03APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	27MAR2014		Y
	C4591001 1126 11261222	Musculoskeletal and connective tissue disorders	Scoliosis	05FEB2020		Y
	C4591001 1126 11261223	Psychiatric disorders	Tic	01JUL2020		Y
	C4591001 1126 11261224	Psychiatric disorders	Attention deficit hyperactivity disorder	30MAR2013		Y
	C4591001 1126 11261226	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1126 11261227	Gastrointestinal disorders	Eosinophilic oesophagitis	09NOV2016	15MAY2020	N
		Immune system disorders	Flour sensitivity	17JAN2020		Y
			Seasonal allergy	16NOV2016		Y
	C4591001 1126 11261228	Congenital, familial and genetic disorders	Phimosis	17AUG2020		Y
		Immune system disorders	Seasonal allergy	10OCT2014		Y
		Nervous system disorders	Migraine	05MAR2014		Y
		Psychiatric disorders	Generalised anxiety disorder	06AUG2019		Y
			Major depression	21JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05MAR2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	10OCT2020		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261232	Psychiatric disorders	Depression	18JAN2019		Y
			Generalised anxiety disorder	18JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07MAY2008		Y
			Rhinitis allergic	19MAY2008		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	06DEC2017		Y
			Urticaria	24APR2008		Y
	C4591001 1126 11261234	Congenital, familial and genetic disorders	Urethral valves	(b) (6) 2003		Y
		Renal and urinary disorders	Hydronephrosis	28SEP2015	18JUN2019	N
		Reproductive system and breast disorders	Epididymal cyst	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	23NOV2016		Y
		Surgical and medical procedures	Urethral operation	(b) (6) 2003	(b) (6) 2003	N
				30APR2004	30APR2004	N
				30AUG2004	30AUG2004	N
	C4591001 1126 11261236	Immune system disorders	Food allergy	22FEB2010		Y
			Seasonal allergy	09JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11FEB2010		Y
	C4591001 1126 11261237	Gastrointestinal disorders	Gastrooesophageal reflux disease	29JUN2017		Y
		Investigations	Body mass index increased	22MAR2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29JUN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	15AUG2019		Y
	C4591001 1126 11261238	Psychiatric disorders	Attention deficit hyperactivity disorder	21DEC2015		Y
			Autism spectrum disorder	30NOV2005		Y
	C4591001 1126 11261242	Congenital, familial and genetic disorders	Congenital flat feet	10JUL2014		Y
			Femoral anteversion	10JUL2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02APR2013		Y
	C4591001 1126 11261244	Respiratory, thoracic and mediastinal disorders	Asthma	20APR2010		Y
		Skin and subcutaneous tissue disorders	Acne	22JAN2018		Y
	C4591001 1126 11261245	Injury, poisoning and procedural complications	Exposure to communicable disease	14JUL2016	31JUL2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	03FEB2012		Y
		Musculoskeletal and connective tissue disorders	Muscle tightness	09MAY2018		Y
	C4591001 1126 11261247	Respiratory, thoracic and mediastinal disorders	Asthma	16MAY2008		Y
	C4591001 1126 11261252	Psychiatric disorders	Attention deficit hyperactivity disorder	05MAR2012		Y
	C4591001 1126 11261256	Infections and infestations	Appendicitis	01NOV2020	01NOV2020	N
	C4591001 1126 11261257	Immune system disorders	Drug hypersensitivity	25APR2018		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	15MAY2018		Y
		Skin and subcutaneous tissue disorders	Acne	21JUL2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261259	Gastrointestinal disorders	Irritable bowel syndrome	09DEC2019		Y
		Injury, poisoning and procedural complications	Concussion	13NOV2016	28FEB2019	N
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2019		Y
			Scoliosis	08JUN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	26MAR2019		Y
			Menorrhagia	27DEC2018		Y
	C4591001 1126 11261260	Eye disorders	Iridodialysis	16JUN2008		Y
			Iritis	16JUN2008	23AUG2010	N
		Injury, poisoning and procedural complications	Cataract traumatic	31MAY2016		Y
			Hyphaema	16JUN2008	23AUG2010	N
		Metabolism and nutrition disorders	Iron deficiency	12JUL2019		Y
		Psychiatric disorders	Insomnia	15DEC2018		Y
		Skin and subcutaneous tissue disorders	Acne	07FEB2018		Y
	C4591001 1126 11261261	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08DEC2011		Y
	C4591001 1127 11271021	Gastrointestinal disorders	Dyspepsia	25JUL2020		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JUN2018	01DEC2018	N
	C4591001 1127 11271033	Eye disorders	Presbyopia	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2015		Y
	C4591001 1127 11271043	General disorders and administration site conditions	Fatigue	01JUL2020		Y
		Infections and infestations	Oral herpes	01JAN2006		Y
		Psychiatric disorders	Anxiety	01DEC2018		Y
	C4591001 1127 11271059	Eye disorders	Myopia	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1127 11271087	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2011		Y
	C4591001 1127 11271099	Eye disorders	Myopia	01JAN2016		Y
	C4591001 1128 11281050	Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1128 11281057	Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1128 11281098	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1128 11281176	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Rhinitis allergic	01JAN2001		Y
	C4591001 1128 11281177	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1128 11281196	Infections and infestations	Pharyngitis streptococcal	01JAN2000	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1128 11281210	Gastrointestinal disorders	Tooth impacted	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1128 11281216	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
	C4591001 1128 11281247	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Sinus headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1128 11281282	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1128 11281294	Nervous system disorders	Headache	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1128 11281299	Immune system disorders	Seasonal allergy	01JAN2007		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pharyngitis	01JAN2002	31DEC2002	N
		Nervous system disorders	Migraine	01AUG2014		Y
		Surgical and medical procedures	Debridement	01JAN2002	31DEC2002	N
			Tooth extraction	01SEP2014	30SEP2014	N
			Wisdom teeth removal	01NOV2015	30NOV2015	N
	C4591001 1128 11281338	Nervous system disorders	Headache	01DEC2019		Y
	C4591001 1128 11281339	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Vitamin D deficiency	01AUG2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01AUG2019		Y
	C4591001 1128 11281343	Infections and infestations	Ear infection	01JAN1998	31DEC2001	N
		Nervous system disorders	Headache	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
	C4591001 1128 11281359	Surgical and medical procedures	Myringotomy	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1128 11281384	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Meningitis	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1129 11291097	Infections and infestations	Papilloma viral infection	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Nervous system disorders	Headache	01FEB2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2001		Y
		Social circumstances	Tobacco user	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Papilloma excision	01JAN2017	31DEC2017	N
	C4591001 1129 11291143	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020	31JUL2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2019		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1129 11291168	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2013	31DEC2013	N
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2013	31DEC2013	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Appendicectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1129 11291171	Eye disorders	Myopia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1129 11291216	Surgical and medical procedures	Keratomileusis	01JAN2020	31JAN2020	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1129 11291223	Eye disorders	Myopia	01JAN2006		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Pilonidal cyst	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015	31DEC2017	N
			Overweight	01JAN2010	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Renal and urinary disorders	Micturition disorder	01JAN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
		Surgical and medical procedures	Spinal operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013	31DEC2017	N
	C4591001 1129 11291255	Eye disorders	Myopia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN2019	31DEC2019	N
	C4591001 1129 11291256	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
			Hand fracture	01JAN2017	31DEC2017	N
			Radius fracture	01JAN2008	31DEC2008	N
			Ulna fracture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N
	C4591001 1129 11291257	Injury, poisoning and procedural complications	Clavicle fracture	(b) (6) 2003	31OCT2003	N
			Concussion	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1129 11291258	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN2018	31DEC2018	N
	C4591001 1129 11291260	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
				01JAN2007		Y
		Investigations	Bronchoscopy	01JAN2016	31DEC2016	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
	C4591001 1129 11291261	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Injury, poisoning and procedural complications	Ankle fracture	01FEB2020	29FEB2020	N
				01JAN2018	31DEC2018	N
			Radius fracture	01JAN2006	31DEC2006	N
				01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Scoliosis surgery	12FEB2019	12FEB2019	N
	C4591001 1129 11291262	Congenital, familial and genetic disorders	Congenital flat feet	(b) (6) 2003	31DEC2017	N
		Gastrointestinal disorders	Aphthous ulcer	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Foot operation	01MAR2017	31MAR2017	N
				01MAY2017	31MAY2017	N
	C4591001 1129 11291263	Eye disorders	Myopia	01JAN2014		Y
	C4591001 1129 11291264	Eye disorders	Myopia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2007	31DEC2007	N
			Hand fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010	31DEC2010	N
			Insomnia	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1129 11291265	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1130 11301021	Gastrointestinal disorders	Gastroesophageal reflux disease	22MAY2017		Y
		Infections and infestations	Herpes simplex	15FEB2016		Y
			Staphylococcal infection	19SEP2012	31OCT2012	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	28JUL2017		Y
			Eating disorder	10JUL2013		Y
			Major depression	28JUL2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301089	Blood and lymphatic system disorders	Iron deficiency anaemia	05FEB2018		Y
		General disorders and administration site conditions	Fatigue	29MAY2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	06JUN2018		Y
			Generalised anxiety disorder	20MAR2018		Y
			Insomnia	11JUL2018		Y
			Major depression	08MAR2018		Y
			Social anxiety disorder	08MAR2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	26APR2018		Y
		Skin and subcutaneous tissue disorders	Acne	23MAY2018		Y
	C4591001 1131 11311061	Eye disorders	Presbyopia	01JAN2018		Y
		Surgical and medical procedures	Chondroplasty	01JAN2018	31DEC2018	N
	C4591001 1131 11311064	Eye disorders	Hypermetropia	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
	C4591001 1131 11311091	Eye disorders	Myopia	01JAN2009		Y
		Injury, poisoning and procedural complications	Road traffic accident	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Neck pain	01FEB2020	29FEB2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2009		Y
	C4591001 1131 11311102	Eye disorders	Hypermetropia	01JAN2018	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01DEC2018	30SEP2019	N
		Surgical and medical procedures	Mole excision	01JAN2015	31DEC2015	N
	C4591001 1131 11311107	Eye disorders	Myopia	01JAN2007		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
		Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
	C4591001 1131 11311221	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN2004	31DEC2004	N
		Nervous system disorders	Seizure	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1131 11311263	Cardiac disorders	Cardiomyopathy	01JAN2019		Y
		Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
			Snoring	01JAN2009		Y
		Surgical and medical procedures	Tongue tie operation	01JAN2003	31DEC2003	N
	C4591001 1131 11311264	Immune system disorders	Seasonal allergy	01JAN2004		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2014		Y
	C4591001 1131 11311265	Eye disorders	Myopia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
	C4591001 1131 11311266	Eye disorders	Hypermetropia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2020	31JAN2020	N
	C4591001 1131 11311267	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Generalised anxiety disorder	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
		Surgical and medical procedures	Orchidectomy	01JAN2004	31DEC2004	N
	C4591001 1131 11311268	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Panic disorder	01JAN2019		Y
			Sleep disorder	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1131 11311269	Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1131 11311270	Surgical and medical procedures	Tooth extraction	01JAN2013	31DEC2013	N
		Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
			Menorrhagia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Psoriasis	01JAN2017		Y
	C4591001 1131 11311271	Social circumstances	Corrective lens user	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1131 11311272	Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Tension headache	01SEP2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
			Menorrhagia	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N
	C4591001 1131 11311273	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
	C4591001 1131 11311274	Eye disorders	Hypermetropia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Dyslexia	01JAN2009		Y
			Migraine	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1131 11311276	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Cardiac murmur functional	01JAN2008		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2020	31JUL2020	N
	C4591001 1131 11311279	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1133 11331043	Eye disorders	Hypermetropia	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1133 11331047	Injury, poisoning and procedural complications	Humerus fracture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Bone operation	01JAN2007	31DEC2007	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331093	Social circumstances	Ex-tobacco user	01JAN2014	31DEC2020	N
	C4591001 1133 11331123	Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1133 11331135	Surgical and medical procedures	Mammoplasty	01APR2015	30APR2015	N
	C4591001 1133 11331273	Eye disorders	Myopia	01JAN2006		Y
	C4591001 1133 11331274	Eye disorders	Hypermetropia	01JAN2012		Y
	C4591001 1133 11331332	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1133 11331360	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Dust allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1133 11331428	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Aphthous ulcer	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Milk allergy	01JAN2010		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1133 11331473	Infections and infestations	Sinusitis	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2003	31DEC2003	N
	C4591001 1133 11331480	Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
			Upper limb fracture	01JAN2017	31DEC2017	N
			Wrist fracture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Elbow operation	01JAN2017	31DEC2017	N
			Limb operation	01JAN2017	31DEC2017	N
			Wrist surgery	01JAN2017	31DEC2017	N
	C4591001 1133 11331485	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1133 11331587	Eye disorders	Myopia	01JAN2005		Y
		Infections and infestations	Tooth infection	24FEB2020	24FEB2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Social circumstances	Substance use	01JAN2016		Y
		Surgical and medical procedures	Tongue tie operation	01JAN2006	31DEC2006	N
			Wisdom teeth removal	24FEB2020	24FEB2020	N
	C4591001 1133 11331602	Eye disorders	Myopia	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
			Depression	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1998	31DEC2012	N
	C4591001 1133 11331603	Eye disorders	Myopia	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1133 11331609	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Tobacco user	01JAN2019		Y
	C4591001 1133 11331640	Cardiac disorders	Palpitations	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JUN2017		Y
			Attention deficit hyperactivity disorder	01JUN2017		Y
	C4591001 1133 11331647	Surgical and medical procedures	Rhinoplasty	01AUG2016	31AUG2016	N
		Immune system disorders	Food allergy	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	08MAR2019	08MAR2019	N
	C4591001 1134 11341046	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1994		Y
		Injury, poisoning and procedural complications	Muscle strain	01AUG2020		Y
		Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1134 11341184	Injury, poisoning and procedural complications	Ligament rupture	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1134 11341203	Investigations	Cardiac murmur	01JAN1999		Y
	C4591001 1134 11341213	Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341268	Eye disorders	Myopia	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	03SEP2020	03SEP2020	N
	C4591001 1134 11341313	Injury, poisoning and procedural complications	Spinal cord injury	01JAN2011	31DEC2013	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
	C4591001 1134 11341324	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2011	31DEC2011	N
		Renal and urinary disorders	Urethral stenosis	01JAN1996	31DEC2006	N
		Surgical and medical procedures	Tenoplasty	01JAN2011	31DEC2011	N
			Urinary tract operation	01JAN2006	31DEC2006	N
	C4591001 1134 11341327	Surgical and medical procedures	Inguinal hernia repair	01JAN1999	31DEC1999	N
	C4591001 1134 11341328	Immune system disorders	Drug hypersensitivity	01OCT2017		Y
			Food allergy	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Investigations	Endoscopy	01DEC2017	31DEC2017	N
				01OCT2019	31OCT2019	N
				01SEP2018	30SEP2018	N
				11SEP2017	11SEP2017	N
			Lumbar puncture	11SEP2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	11SEP2017	09DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01AUG2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1134 11341332	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1134 11341379	Gastrointestinal disorders	Tooth impacted	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Oral surgery	01JAN2014	31DEC2014	N
	C4591001 1135 11351001	Eye disorders	Hypermetropia	01JAN2018		Y
	C4591001 1135 11351080	Gastrointestinal disorders	Umbilical hernia	01JAN1997	31DEC1997	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1997	31DEC1997	N
	C4591001 1135 11351083	Gastrointestinal disorders	Rectal prolapse	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
		Surgical and medical procedures	Otoplasty	01JAN2015	31DEC2015	N
			Rectal prolapse repair	01JAN2015	31DEC2015	N
	C4591001 1135 11351088	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1135 11351113	Immune system disorders	Food allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Limb operation	01JAN2017	31DEC2017	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351120	Gastrointestinal disorders	Tooth impacted	01JAN2019	30NOV2019	N
		Surgical and medical procedures	Wisdom teeth removal	01NOV2019	30NOV2019	N
	C4591001 1135 11351139	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1135 11351154	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1135 11351166	Eye disorders	Myopia	01JAN2005		Y
		Gastrointestinal disorders	Vomiting	01JAN1999	31DEC1999	N
		Immune system disorders	Food allergy	01JAN1997		Y
			Seasonal allergy	01JAN1997		Y
		Investigations	Oesophagoscopy	01JAN1999	31DEC1999	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351175	Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Allergy to metals	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351195	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
	C4591001 1135 11351199	Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Depression	01JAN2009		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351203	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
			Overweight	01JAN2012		Y
	C4591001 1135 11351234	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1135 11351239	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2018	23JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Overweight	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Nasal septal operation	23JUL2020	23JUL2020	N
	C4591001 1135 11351253	Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1135 11351285	Eye disorders	Hypermetropia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1135 11351301	Eye disorders	Myopia	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012	31DEC2012	N
	C4591001 1135 11351323	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1135 11351350	Skin and subcutaneous tissue disorders	Keloid scar	01JAN2015		Y
	C4591001 1135 11351361	Eye disorders	Myopia	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC2016	N
		Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1135 11351367	Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
			Localised infection	23AUG2020	30AUG2020	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Ankle operation	01JAN2013	31DEC2013	N
			Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351378	Investigations	Arthroscopy	01JUL2020	31JUL2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351410	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Skin lesion removal	01JAN2014	31DEC2014	N
	C4591001 1135 11351412	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
	C4591001 1135 11351414	Eye disorders	Myopia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1135 11351428	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1135 11351461	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Psychiatric disorders	Anxiety	01FEB2011		Y
			Depression	01FEB2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
	C4591001 1135 11351486	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2015	N
		Gastrointestinal disorders	Tooth impacted	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1135 11351488	Surgical and medical procedures	Wisdom teeth removal	01JAN2009	31DEC2009	N
		Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1135 11351489	Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
	C4591001 1135 11351491	Eye disorders	Overweight	01JAN2011		Y
			Myopia	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1135 11351492	Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2016		Y
	C4591001 1135 11351497	Nervous system disorders	Thoracic outlet syndrome	01JAN2016		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2019	31DEC2019	N
	C4591001 1135 11351498	Eye disorders	Hypermetropia	01JAN2014		Y
			Myopia	01JAN2014		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351513	Gastrointestinal disorders	Abdominal pain	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1135 11351522	Eye disorders	Myopia	01JAN2008		Y
	C4591001 1135 11351529	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1135 11351547	Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1135 11351549	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1135 11351552	Congenital, familial and genetic disorders	Developmental glaucoma	01JAN2014		Y
		Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
			Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JUN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Eczema	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1135 11351556	Eye disorders	Presbyopia	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1136 11361007	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1136 11361034	Blood and lymphatic system disorders	Increased tendency to bruise	01JAN2003		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	(b) (6) 2002		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1136 11361048	Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
	C4591001 1136 11361049	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361091	Eye disorders	Astigmatism	01JAN2006		Y
			Myopia	01JAN2006		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2005	31DEC2005	N
			Skin laceration	22NOV2001	22NOV2001	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Autism spectrum disorder	01JAN2011		Y
			Depression	01JAN2017		Y
			Obsessive-compulsive disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1998		Y
		Surgical and medical procedures	Tendon operation	22NOV2001	22NOV2001	N
	C4591001 1139 11391048	Eye disorders	Myopia	30JUN2014		Y
		Nervous system disorders	Tension headache	15NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	15NOV2019		Y
		Surgical and medical procedures	Scar excision	30JUN2019	30JUN2019	N
	C4591001 1139 11391049	Eye disorders	Presbyopia	30JUN2008		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1995		Y
		Injury, poisoning and procedural complications	Foot fracture	30JUN2001	30JUN2001	N
		Surgical and medical procedures	Tonsillectomy	30JUN2005	30JUN2005	N
	C4591001 1139 11391083	Eye disorders	Astigmatism	30JUN2018		Y
		Immune system disorders	Drug hypersensitivity	30JUN2008		Y
			Seasonal allergy	30JUN2006		Y
		Nervous system disorders	Cluster headache	30JUN2012		Y
			Tension headache	30JUN2010		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391089	Gastrointestinal disorders	Irritable bowel syndrome	30JUN2010	30JUN2014	N
		Immune system disorders	Seasonal allergy	30JUN2008		Y
		Nervous system disorders	Essential tremor	30JUN2012		Y
			Tension headache	30JUN2012		Y
	C4591001 1139 11391116	Nervous system disorders	Epilepsy	30JUN2009		Y
		Psychiatric disorders	Autism spectrum disorder	14MAR2020		Y
	C4591001 1139 11391117	Immune system disorders	Seasonal allergy	(b) (6) 2000		Y
	C4591001 1139 11391130	Infections and infestations	Tonsillitis	30JUN2013	30JUN2013	N
		Nervous system disorders	Tension headache	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2010		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2004		Y
	C4591001 1139 11391131	Nervous system disorders	Tension headache	30JUN2015		Y
	C4591001 1139 11391132	General disorders and administration site conditions	Pyrexia	30JUN2009	30JUN2009	N
		Injury, poisoning and procedural complications	Wrist fracture	30JUN2015	30JUN2015	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
		Surgical and medical procedures	Tonsillectomy	30JUN2009	30JUN2009	N
	C4591001 1139 11391133	Injury, poisoning and procedural complications	Hip fracture	10NOV2019	15JAN2020	N
			Upper limb fracture	30JUN2008	30JUN2008	N
		Surgical and medical procedures	Elbow operation	30JUN2008	30JUN2008	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391134	Cardiac disorders	Bradycardia neonatal	(b) (6) 2004	(b) (6) 2004	N
		Injury, poisoning and procedural complications	Clavicle fracture	30JUN2012	30JUN2012	N
			Concussion	30JUN2015	30JUN2019	N
		Nervous system disorders	Dyslexia	30JUN2009		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2004	(b) (6) 2004	N
		Respiratory, thoracic and mediastinal disorders	Infantile apnoea	(b) (6) 2004	(b) (6) 2004	N
		Surgical and medical procedures	Hernia repair	(b) (6) 2004	(b) (6) 2004	N
			Wound closure	30SEP2020	30SEP2020	N
			Concussion	30JUN2009	30JUN2017	N
	C4591001 1139 11391135	Injury, poisoning and procedural complications				
		Nervous system disorders	Dyslexia	30JUN2009		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2004	(b) (6) 2004	N
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	31AUG2020		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2008	30JUN2008	N
	C4591001 1139 11391138	Eye disorders	Myopia	30JUN2015		Y
		Immune system disorders	Drug hypersensitivity	30JUN2003		Y
		Injury, poisoning and procedural complications	Upper limb fracture	15JAN2020	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	30JUN2018		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2003	30JUN2004	N
	C4591001 1139 11391139	Injury, poisoning and procedural complications	Eye injury	06NOV2020	20NOV2020	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Foot fracture	15NOV2016	15FEB2018	N
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
		Surgical and medical procedures	Toe operation	15FEB2018	15FEB2018	N
	C4591001 1139 11391140	Immune system disorders	Seasonal allergy	30JUL2017		Y
		Infections and infestations	Otitis externa	16NOV2020	23NOV2020	N
		Injury, poisoning and procedural complications	Clavicle fracture	30JUN2008	30JUN2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020	30AUG2020	N
	C4591001 1139 11391141	Eye disorders	Dry eye	30JUN2020		Y
		Injury, poisoning and procedural complications	Limb injury	30JUN2016	30JUN2016	N
		Metabolism and nutrition disorders	Gluten sensitivity	15JUN2013		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
		Surgical and medical procedures	Foot operation	30JUN2016	30JUN2016	N
	C4591001 1139 11391142	Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391143	Ear and labyrinth disorders	Deafness bilateral	(b) (6) 2004		Y
		Immune system disorders	Seasonal allergy	30JUN2006		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391146	Injury, poisoning and procedural complications	Ligament sprain	30JUN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	30JUN2014		Y
	C4591001 1139 11391147	Gastrointestinal disorders	Coeliac disease	30JUN2019		Y
		Psychiatric disorders	Anxiety	30JUN2020		Y
			Attention deficit hyperactivity disorder	30JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2018		Y
	C4591001 1139 11391148	Injury, poisoning and procedural complications	Upper limb fracture	30JUN2016	30JUN2016	N
			Wrist fracture	30JUN2016	30JUN2016	N
		Psychiatric disorders	Insomnia	12AUG2020		Y
	C4591001 1139 11391149	Eye disorders	Myopia	30JUN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	30JUN2015		Y
		Immune system disorders	Food allergy	30JUN2004		Y
			Seasonal allergy	30JUN2015		Y
		Infections and infestations	Urinary tract infection	13NOV2020	19NOV2020	N
		Injury, poisoning and procedural complications	Pelvic fracture	30JUN2016	30JUN2016	N
			Wrist fracture	30JUN2014	30JUN2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis	15NOV2020		Y
	C4591001 1139 11391150	Immune system disorders	Dust allergy	30JUN2015		Y
		Injury, poisoning and procedural complications	Upper limb fracture	30JUN2009	30JUN2009	N
				30JUN2017	30JUN2017	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	30JUN2019		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391153	Eye disorders	Myopia	30JUN2018		Y
	C4591001 1139 11391160	Eye disorders	Myopia	30JUN2018		Y
		Immune system disorders	Allergy to arthropod sting	15JUN2020		Y
		Surgical and medical procedures	Wisdom teeth removal	15OCT2019	15OCT2019	N
	C4591001 1139 11391164	Reproductive system and breast disorders	Menorrhagia	15MAY2020		Y
		Skin and subcutaneous tissue disorders	Acne cystic	15JAN2019		Y
	C4591001 1139 11391167	Blood and lymphatic system disorders	Anaemia	01JAN2015	31DEC2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2017		Y
		Reproductive system and breast disorders	Menorrhagia	30JUN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1140 11401006	Injury, poisoning and procedural complications	Foot fracture	01OCT2012	15NOV2012	N
		Surgical and medical procedures	Pilonidal sinus repair	02FEB2015	01OCT2017	N
	C4591001 1140 11401030	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1140 11401046	Cardiac disorders	Supraventricular tachycardia	01JAN2011	30APR2016	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Infectious mononucleosis	25DEC2019	07JAN2020	N
		Surgical and medical procedures	Cardiac ablation	01APR2016	30APR2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401206	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2018		Y
		Surgical and medical procedures	Limb reconstructive surgery	01AUG1999	01AUG1999	N
	C4591001 1140 11401259	Injury, poisoning and procedural complications	Hip fracture	01JAN2016	31DEC2016	N
			Road traffic accident	01JAN2016	31DEC2016	N
			Wrist fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Autism spectrum disorder	01JAN2003		Y
			Generalised anxiety disorder	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN2003		Y
	C4591001 1140 11401262	Immune system disorders	Seasonal allergy	01APR2015		Y
	C4591001 1140 11401281	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Sinus operation	01JAN2019	31DEC2019	N
	C4591001 1140 11401314	Surgical and medical procedures	Hernia repair	01JAN2006	31DEC2006	N
	C4591001 1140 11401316	Reproductive system and breast disorders	Menorrhagia	01DEC2018		Y
	C4591001 1140 11401318	Psychiatric disorders	Anxiety	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1140 11401319	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1140 11401321	Gastrointestinal disorders	Tooth impacted	28JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord dysfunction	01NOV2018		Y
	C4591001 1141 11411006	Blood and lymphatic system disorders	Anaemia	01MAR2010	31MAR2018	N
		Infections and infestations	Tonsillitis	01JUN2004	30JUN2004	N
		Nervous system disorders	Headache	01JUN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2004	30JUN2004	N
	C4591001 1141 11411010	Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
	C4591001 1141 11411016	Eye disorders	Eyelid ptosis	01JAN1998		Y
			Myopia	01JAN2009		Y
		Gastrointestinal disorders	Gingival discomfort	01JAN2012	31DEC2013	N
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2014		Y
		Surgical and medical procedures	Gingival operation	01JAN2013	31DEC2013	N
	C4591001 1141 11411021	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01DEC2018		Y
	C4591001 1141 11411029	Eye disorders	Myopia	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2007		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
	C4591001 1141 11411032	Infections and infestations	Keratosis pilaris	01JAN2009		Y
			Bacterial vaginosis	31JUL2020		Y
		Nervous system disorders	Headache	01AUG2017		Y
		Psychiatric disorders	Anxiety	01JUN2018		Y
			Attention deficit hyperactivity disorder	01JUL2017		Y
			Depression	01JUN2018		Y
	C4591001 1141 11411053	Surgical and medical procedures	Contraception	01DEC2019		Y
		Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2018		Y
	C4591001 1141 11411056	Injury, poisoning and procedural complications	Limb traumatic amputation	01AUG2019	31DEC2019	N
	C4591001 1141 11411065	Nervous system disorders	Headache	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006	31DEC2006	N
	C4591001 1141 11411067	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2005		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411070	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Major depression	01JAN2008		Y
	C4591001 1141 11411072	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1141 11411074	Eye disorders	Astigmatism	01JAN2002		Y
			Myopia	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1141 11411077	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01DEC2019		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1141 11411081	General disorders and administration site conditions	Hernia	01DEC2016	01DEC2016	N
		Immune system disorders	Seasonal allergy	01DEC1998		Y
		Injury, poisoning and procedural complications	Hand fracture	01DEC2016	01DEC2016	N
			Meniscus injury	01DEC2019	01DEC2019	N
			Muscle injury	30JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01DEC2013		Y
		Surgical and medical procedures	Hernia repair	01DEC2016	01DEC2016	N
	C4591001 1141 11411092	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	27JAN2020		Y
		Nervous system disorders	Tension headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2017		Y
	C4591001 1141 11411110	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1141 11411122	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Injury	01JAN2017	31DEC2017	N
			Ligament injury	01JAN2013	31DEC2013	N
			Wrist fracture	25DEC2018	25DEC2018	N
		Nervous system disorders	Headache	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
	C4591001 1141 11411123	Nervous system disorders	Migraine	01JAN2010		Y
			Presyncope	01JAN2016		Y
	C4591001 1141 11411125	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Infections and infestations	Tinea versicolour	01JUL2012		Y
			Tonsillitis	01JAN2003	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteochondrosis	01DEC2006		Y
			Scoliosis	01FEB2016		Y
		Nervous system disorders	Headache	01OCT2006		Y
			Migraine	01SEP2004		Y
		Psychiatric disorders	Anxiety	01SEP2016		Y
			Depression	01SEP2016		Y
			Insomnia	01FEB2016		Y
		Surgical and medical procedures	Tonsillectomy	01APR2004	30APR2004	N
	C4591001 1141 11411127	Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
			Major depression	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1141 11411128	Injury, poisoning and procedural complications	Cartilage injury	01DEC2016	31DEC2016	N
			Humerus fracture	01JAN2016	31DEC2016	N
			Joint dislocation	01JAN2016	31DEC2016	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
			Major depression	01JAN2016		Y
		Surgical and medical procedures	Rotator cuff repair	01DEC2016	31DEC2016	N
	C4591001 1141 11411130	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Nervous system disorders	Migraine	01MAR2020		Y
	C4591001 1141 11411131	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Elbow operation	01JAN2014	31DEC2014	N
	C4591001 1141 11411133	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1141 11411135	Psychiatric disorders	Anxiety	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1141 11411139	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011		Y
	C4591001 1141 11411146	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1141 11411161	Musculoskeletal and connective tissue disorders	Back pain	01JAN2006	31DEC2020	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	14JUN2020	31DEC2020	N
	C4591001 1141 11411162	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
	C4591001 1141 11411167	Eye disorders	Myopia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2008	31DEC2008	N
			Rhinoplasty	01JAN2012	31DEC2012	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411174	Immune system disorders	Seasonal allergy	01JUN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUN2011	01JUN2012	N
	C4591001 1141 11411182	Eye disorders	Myopia	(b) (6) 1998	01MAY2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2018		Y
			Depression	01JUN2015		Y
		Surgical and medical procedures	Keratomileusis	01MAY2019	01MAY2019	N
	C4591001 1141 11411192	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1141 11411202	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
			Ligament rupture	01JAN2019	31DEC2019	N
			Meniscus injury	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
		Surgical and medical procedures	Ankle operation	01JUL2020	31DEC2020	N
			Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1141 11411203	Infections and infestations	Pharyngitis streptococcal	01JAN2014	31JUL2016	N
		Surgical and medical procedures	Tonsillectomy	01JUL2016	31JUL2016	N
	C4591001 1141 11411204	Injury, poisoning and procedural complications	Ligament rupture	15SEP2015	01OCT2015	N
		Metabolism and nutrition disorders	Lipomatosis	01AUG2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01SEP2019		Y
		Psychiatric disorders	Anxiety	09AUG2014	01JUN2019	N
			Depression	01AUG2014	01JUN2019	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2012		Y
		Surgical and medical procedures	Ligament operation	01OCT2015	01OCT2015	N
			Lipoma excision	01OCT2014		Y
	C4591001 1141 11411205	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1141 11411206	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1141 11411211	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1141 11411213	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2018		Y
	C4591001 1141 11411215	Eye disorders	Myopia	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1141 11411220	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411226	Investigations	Body mass index decreased	01JAN2016		Y
	C4591001 1141 11411227	Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
	C4591001 1141 11411228	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1141 11411235	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1141 11411236	Infections and infestations	Otitis media chronic	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Ear tube insertion	01JAN1997	31DEC1997	N
	C4591001 1141 11411238	Blood and lymphatic system disorders	Anaemia	30MAY2020	28AUG2020	N
		Immune system disorders	Seasonal allergy	01JUN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2006		Y
	C4591001 1141 11411239	Congenital, familial and genetic disorders	Deafness congenital	01JAN1998		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1141 11411242	Immune system disorders	Allergy to vaccine	01JAN2000		Y
			Seasonal allergy	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Floating patella	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1141 11411250	Immune system disorders	Food allergy	01APR2012		Y
		Infections and infestations	Gastroenteritis	01NOV2016	30NOV2016	N
		Injury, poisoning and procedural complications	Stress fracture	01DEC2017	31DEC2018	N
				01OCT2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01APR2017	31AUG2017	N
	C4591001 1141 11411254	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Muscle strain	01JAN2018	31DEC2018	N
			Upper limb fracture	01JAN2014	31DEC2014	N
	C4591001 1141 11411255	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1141 11411260	Investigations	Cystoscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Flank pain	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2013	31DEC2015	N



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ureteral stent removal	01JAN2015	31DEC2015	N
			Ureteric operation	01JUN2015	31DEC2015	N
	C4591001 1141 11411262	Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1141 11411263	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1141 11411267	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2012	31DEC2012	N
			Gun shot wound	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Surgical and medical procedures	Internal fixation of fracture	01JAN2012	31DEC2012	N
			Jaw operation	01JAN2007	31DEC2010	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
			Tracheostomy	01JAN2007	31DEC2010	N
	C4591001 1141 11411270	Congenital, familial and genetic disorders	Klippel-Feil syndrome	(b) (6) 1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Lisfranc fracture	01OCT2013	11OCT2013	N
			Meniscus injury	01JAN2016	28NOV2016	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	11OCT2013	11OCT2013	N
			Meniscus operation	28NOV2016	28NOV2016	N
			Wisdom teeth removal	01MAY2020	31MAY2020	N
	C4591001 1142 11421028	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01NOV2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421037	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01MAY2010	31DEC2010	N
	C4591001 1142 11421078	Gastrointestinal disorders	Colitis ulcerative	01JAN2015		Y
	C4591001 1142 11421100	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1142 11421149	Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
	C4591001 1142 11421188	Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31JAN2016	N
	C4591001 1142 11421233	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1142 11421261	Immune system disorders	Allergy to animal	01JAN2005		Y
			Milk allergy	01JAN2018		Y
			Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Pilonidal sinus repair	01MAR2020	31MAR2020	N
	C4591001 1142 11421269	Psychiatric disorders	Insomnia	01JAN2011		Y
	C4591001 1142 11421274	Surgical and medical procedures	Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1142 11421295	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1142 11421313	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421314	Endocrine disorders	Hyperthyroidism	01JUN2020		Y
	C4591001 1142 11421315	Immune system disorders	Allergy to arthropod sting	01JAN2008		Y
	C4591001 1142 11421317	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009	31DEC2015	N
	C4591001 1142 11421322	Immune system disorders	Seasonal allergy	15DEC2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	12OCT2020	12OCT2020	N
		Skin and subcutaneous tissue disorders	Acne	06DEC2017		Y
	C4591001 1142 11421328	Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N
	C4591001 1142 11421336	Cardiac disorders	Sinus arrhythmia	12JUN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Rubber sensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2007	31JAN2007	N
		Surgical and medical procedures	Adenoidectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1145 11451026	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Blood cholesterol increased	12AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	10JUL2020	10JUL2020	N
			Rhinitis allergic	10JUL2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451059	Hepatobiliary disorders	Gallbladder disorder	01JAN2019	31DEC2019	N
		Infections and infestations	Ear infection	01JAN2018		Y
		Investigations	Cardiac murmur	01JAN2000	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
			Hypermobility syndrome	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1145 11451071	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Surgical and medical procedures	Fasciotomy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1145 11451079	Skin and subcutaneous tissue disorders	Acne	01JAN2008	31DEC2010	N
			Eczema	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1145 11451080	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01MAR2020	31MAR2020	N
		Injury, poisoning and procedural complications	Ligament rupture	24JUL2020		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01MAR2020	31MAR2020	N
	C4591001 1146 11461077	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461083	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1146 11461096	Psychiatric disorders	Generalised anxiety disorder	01APR2020		Y
	C4591001 1146 11461100	Endocrine disorders	Hypothyroidism	01AUG2018		Y
		Gastrointestinal disorders	Coeliac disease	13AUG2003		Y
	C4591001 1146 11461119	Psychiatric disorders	Anxiety	01NOV2012		Y
			Bipolar disorder	01APR2014		Y
	C4591001 1146 11461140	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1146 11461142	Surgical and medical procedures	Eyelid operation	01OCT2015	31OCT2015	N
	C4591001 1146 11461199	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1146 11461243	Immune system disorders	Allergy to animal	01JAN2015		Y
		Psychiatric disorders	Depression	01APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2019		Y
	C4591001 1146 11461278	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1146 11461280	Immune system disorders	Food allergy	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Insulin resistant diabetes	01JAN2018		Y
		Psychiatric disorders	Anxiety	01SEP2013		Y
			Depression	01SEP2013		Y
	C4591001 1146 11461285	Gastrointestinal disorders	Coeliac disease	01JAN2005		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1146 11461289	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Autism spectrum disorder	01JAN2004		Y
			Depression	01JAN2018		Y
	C4591001 1146 11461292	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2013		Y
			Generalised anxiety disorder	01JAN2014		Y
	C4591001 1146 11461316	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1146 11461332	Psychiatric disorders	Anxiety	01AUG2020		Y
			Depression	01AUG2020		Y
	C4591001 1146 11461333	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2006	31DEC2006	N
				01JAN2010	31DEC2010	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Turbinectomy	01JAN2009	31DEC2009	N
	C4591001 1146 11461338	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1146 11461342	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1146 11461343	Nervous system disorders	Migraine	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2007		Y
	C4591001 1146 11461350	Infections and infestations	Lyme disease	01AUG2019	30SEP2019	N
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1146 11461351	Ear and labyrinth disorders	Motion sickness	01JAN2018		Y
		Gastrointestinal disorders	Dry mouth	01OCT2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1146 11461358	Psychiatric disorders	Anxiety	01FEB2020		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
	C4591001 1146 11461372	Skin and subcutaneous tissue disorders	Rash	01AUG2020		Y
	C4591001 1146 11461378	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
	C4591001 1147 11471166	Eye disorders	Conjunctivitis allergic	01JAN2010		Y
		Immune system disorders	Oral allergy syndrome	05JUN2020		Y
			Seasonal allergy	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1147 11471174	Gastrointestinal disorders	Pancreatitis chronic	01JAN2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2016		Y
	C4591001 1147 11471209	Immune system disorders	Allergy to animal	19DEC2019		Y
			Iodine allergy	20JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	09JUL2020		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2019		Y
	C4591001 1147 11471255	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Food allergy	01JAN2018		Y
	C4591001 1147 11471258	Injury, poisoning and procedural complications	Stress fracture	17NOV2020		Y
	C4591001 1147 11471259	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Chronic sinusitis	01JAN2009		Y
	C4591001 1147 11471260	Injury, poisoning and procedural complications	Fibula fracture	16SEP2020		Y
	C4591001 1147 11471265	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1147 11471266	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
	C4591001 1147 11471267	Eye disorders	Borderline glaucoma	01JAN2016		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2005		Y
	C4591001 1147 11471276	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1149 11491021	Gastrointestinal disorders	Umbilical hernia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1149 11491023	Social circumstances	Corrective lens user	01JAN2014		Y
	C4591001 1149 11491024	Social circumstances	Corrective lens user	01JAN2004		Y
	C4591001 1149 11491050	Eye disorders	Hypermetropia	01JAN1999		Y
	C4591001 1149 11491061	Reproductive system and breast disorders	Menstrual disorder	01JAN2005		Y
	C4591001 1149 11491154	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2008	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1149 11491173	Nervous system disorders	Headache	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01JAN2009	31DEC2009	N
			Wound closure	01JAN2014	31DEC2014	N
	C4591001 1149 11491203	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491218	Blood and lymphatic system disorders	Blood loss anaemia	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2009		Y
	C4591001 1149 11491263	Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1149 11491271	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1149 11491294	Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Reproductive system and breast disorders	Breast mass	01JAN2014	31DEC2014	N
	C4591001 1149 11491302	Immune system disorders	Food allergy	01APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
	C4591001 1149 11491303	Metabolism and nutrition disorders	Lactose intolerance	01JAN2007		Y
	C4591001 1149 11491315	Eye disorders	Myopia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1149 11491321	Nervous system disorders	Migraine	01JAN2014		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491328	Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1149 11491331	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2006		Y
	C4591001 1149 11491332	Surgical and medical procedures	Appendicectomy	01MAY2020	31MAY2020	N
		Eye disorders	Hypermetropia	01JAN2014		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
	C4591001 1149 11491335†	Investigations	HIV test positive	01JAN2017		Y
	C4591001 1150 11501020	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1150 11501031	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2018		Y
		Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1150 11501054	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501070	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Psychiatric disorders	Anorexia nervosa	01JAN2014	31DEC2020	N
	C4591001 1150 11501080	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
	C4591001 1150 11501090	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1150 11501096	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2009	31DEC2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1150 11501104	Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1150 11501117	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2003		Y
	C4591001 1150 11501122	Infections and infestations	Herpes dermatitis	01AUG2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017	31DEC2018	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501142	Gastrointestinal disorders	Coeliac disease	27AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2018		Y
			Panic disorder	01JAN2018		Y
	C4591001 1150 11501144	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1150 11501145	Gastrointestinal disorders	Constipation	01JAN2014	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Folliculitis	01JAN2018	31DEC2019	N
	C4591001 1150 11501146	Nervous system disorders	Tremor	01JUN2020	31AUG2020	N
		Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1150 11501147	Congenital, familial and genetic disorders	Phimosis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Nystagmus	01JAN2018		Y
	C4591001 1150 11501148	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2016	31DEC2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
	C4591001 1150 11501149	Gastrointestinal disorders	Abdominal migraine	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2002		Y
		Psychiatric disorders	Anger	01JAN2015	31DEC2018	N
			Irritability	01JAN2015	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Inadequate diet	01JAN2007		Y
	C4591001 1150 11501151	Metabolism and nutrition disorders	Underweight	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2011	31JUL2020	N
	C4591001 1150 11501152	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2019	31DEC2019	N
	C4591001 1150 11501153	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Adjustment disorder	01JAN2018		Y
			Anxiety disorder	01OCT2017		Y
			Major depression	01OCT2017		Y
			Persistent depressive disorder	01JAN2018		Y
	C4591001 1150 11501154	Immune system disorders	Allergy to animal	01JAN2003		Y
		Surgical and medical procedures	Penis frenulectomy	01APR2020	30APR2020	N
	C4591001 1150 11501155	Congenital, familial and genetic disorders	Factor VII deficiency	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2003		Y
		Psychiatric disorders	Anxiety disorder	01MAY2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Bronchospasm	01JAN2018		Y
			Rhinitis allergic	01JAN2017		Y
	C4591001 1150 11501156	Metabolism and nutrition disorders	Lactose intolerance	01JAN2018		Y
			Vitamin D deficiency	01APR2018	31DEC2020	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018	31DEC2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1150 11501158	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
	C4591001 1150 11501160	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1150 11501161	Injury, poisoning and procedural complications	Concussion	01OCT2020	01NOV2020	N
		Nervous system disorders	Dizziness	01JAN2020	31MAR2020	N
	C4591001 1150 11501162	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2018	31DEC2019	N
		Nervous system disorders	Headache	01JAN2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501163	Metabolism and nutrition disorders	Underweight	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01JUL2020	31JUL2020	N
	C4591001 1150 11501164	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2020		Y
	C4591001 1150 11501165	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2020		Y
	C4591001 1150 11501167	Infections and infestations	Lyme disease	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Tic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1150 11501169	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1150 11501170	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2005		Y
		Injury, poisoning and procedural complications	Stress fracture	01SEP2019	31OCT2019	N
		Investigations	Vitamin D decreased	01SEP2019	31OCT2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501174	Endocrine disorders	Growth hormone deficiency	01JAN2017		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1150 11501175	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2016		Y
	C4591001 1150 11501181	Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1150 11501184	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1150 11501188	Cardiac disorders	Tachycardia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2017		Y
	C4591001 1152 11521009	Immune system disorders	Food allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1152 11521019	Surgical and medical procedures	Wisdom teeth removal	01JUN2019	30JUN2019	N
	C4591001 1152 11521030	Hepatobiliary disorders	Cholelithiasis	01SEP2019	30SEP2019	N
		Surgical and medical procedures	Cholecystectomy	01SEP2019	30SEP2019	N
	C4591001 1152 11521032	Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521038	Eye disorders	Myopia	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1152 11521044	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N
	C4591001 1152 11521054	Gastrointestinal disorders	Abdominal hernia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2016	31DEC2016	N
	C4591001 1152 11521058	Infections and infestations	Chlamydial infection	01FEB2020	29FEB2020	N
	C4591001 1152 11521075	Blood and lymphatic system disorders	Anaemia	01JAN2019	31JAN2020	N
		Gastrointestinal disorders	Food poisoning	01JAN2014	31DEC2014	N
		Psychiatric disorders	Insomnia	01JAN2016	31DEC2017	N
	C4591001 1152 11521086	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1152 11521118	Eye disorders	Astigmatism	01JAN2005		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2007	31DEC2007	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2018	31JAN2020	N
			Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2007	31DEC2007	N
	C4591001 1152 11521131	Hepatobiliary disorders	Jaundice	01JAN2000	31DEC2000	N
		Investigations	Biopsy liver	01JAN2000	31DEC2000	N
			Liver function test abnormal	01JAN2000	31DEC2000	N
	C4591001 1152 11521149	Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2013	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1152 11521158	Immune system disorders	Food allergy	01JAN1997		Y
		Infections and infestations	Gingivitis	01JUN2020	31JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007	31DEC2009	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Gingival graft	01JUL2020	31JUL2020	N
				01JUN2020	30JUN2020	N
			Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1152 11521159	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2019	31DEC2019	N
		Investigations	Human papilloma virus test positive	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2013	31DEC2017	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Mental disorder	01JAN2012	31DEC2018	N
		Surgical and medical procedures	Fracture treatment	01JAN2019	31DEC2019	N
	C4591001 1152 11521164	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1152 11521189	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2008		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31JAN2019	N
	C4591001 1152 11521208	Eye disorders	Astigmatism	01JAN2000		Y
			Strabismus	01JAN1996		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
			Meniscus injury	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Adenoidectomy	01JAN2018	31DEC2018	N
			Ligament operation	01JAN2011	31DEC2011	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1152 11521220	Congenital, familial and genetic disorders	Cryptorchism	01JAN2000	31DEC2000	N
		Infections and infestations	Pharyngitis	01JAN2007		Y
		Surgical and medical procedures	Orchidopexy	01JAN2000	31DEC2000	N
	C4591001 1152 11521222	Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2011	N
			Clavicle fracture	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Ankle operation	01JAN2011	31DEC2011	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bone operation	01JAN2012	31DEC2012	N
	C4591001 1152 11521224	Eye disorders	Myopia	01JAN2007		Y
	C4591001 1152 11521255	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1152 11521296	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521312	Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2006		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1152 11521322	Immune system disorders	Food allergy	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
	C4591001 1152 11521355	Injury, poisoning and procedural complications	Ligament sprain	27AUG2020		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1152 11521357	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2014	31DEC2019	N
	C4591001 1152 11521362	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2004	31DEC2004	N
	C4591001 1152 11521363	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521384	Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31JAN2019	N
	C4591001 1152 11521402	Infections and infestations	Cellulitis orbital	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1152 11521403	Congenital, familial and genetic disorders	Anomaly of external ear congenital	01JAN1995		Y
			Congenital neoplasm	01JAN1995		Y
		General disorders and administration site conditions	Surgical failure	01DEC2011	31DEC2011	N
		Vascular disorders	Hypotension	01JAN2010	31DEC2014	N
	C4591001 1152 11521408	Surgical and medical procedures	Circumcision	01JUN2020	30JUN2020	N
	C4591001 1152 11521426	Eye disorders	Myopia	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1152 11521436	Congenital, familial and genetic disorders	Congenital foot malformation	(b) (6) 1994	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2013	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Foot operation	01JAN2005	31DEC2005	N
	C4591001 1152 11521439	Gastrointestinal disorders	Haemorrhoids	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2012		Y
			Perennial allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2003		Y
	C4591001 1152 11521441	Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
		Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2007	31DEC2019	N
			Depression	01JAN2007	31DEC2017	N
	C4591001 1152 11521443	Surgical and medical procedures	Osteotomy	01JAN2008	31DEC2008	N
		Eye disorders	Myopia	01JAN1999		Y
	C4591001 1152 11521451	Eye disorders	Myopia	01JAN2006		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Suicide attempt	01JAN2012	31DEC2012	N
	C4591001 1152 11521456	Renal and urinary disorders	Urge incontinence	01JAN2019		Y
		Immune system disorders	Allergy to animal	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1152 11521460	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009	31DEC2016	N
	C4591001 1152 11521474	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521489	Infections and infestations	Respiratory syncytial virus infection	01JAN2000	31DEC2000	N
					31DEC2002	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1152 11521505	Immune system disorders	Mite allergy	01JAN1999		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1152 11521519	Immune system disorders	Food allergy	01JAN2014		Y
			Perennial allergy	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Staphylococcal infection	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2014	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
			Ingrowing nail	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Urticaria	01JAN2012		Y
		Surgical and medical procedures	Nail operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1152 11521534	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Facial paralysis	01JAN2008	31DEC2008	N
			Headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1152 11521537	Surgical and medical procedures	Eye operation	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2011	N
	C4591001 1152 11521552	Gastrointestinal disorders	Constipation	01JAN2019	31JUL2020	N
		Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2010		Y
	C4591001 1152 11521571	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2005	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1152 11521583	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	30NOV2019	N
		Surgical and medical procedures	Joint arthroplasty	01NOV2019	30NOV2019	N
	C4591001 1152 11521588	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1152 11521590	Eye disorders	Myopia	01JAN2015		Y
	C4591001 1152 11521591	Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
			Insomnia	01JAN2018	29FEB2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521598	Immune system disorders	Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1152 11521600	Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
	C4591001 1152 11521601	Infections and infestations	Respiratory syncytial virus infection	01JAN2003	31DEC2003	N
	C4591001 1152 11521602	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1152 11521603	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2018		Y
			Mental disorder	01FEB2020	29FEB2020	N
	C4591001 1152 11521606	Infections and infestations	Ear infection	01JAN2004	31DEC2008	N
		Surgical and medical procedures	Ear tube insertion	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
	C4591001 1152 11521609	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004	31DEC2006	N
	C4591001 1152 11521610	Immune system disorders	Mite allergy	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521618	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1152 11521620	Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1152 11521621	Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521622	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
	C4591001 1152 11521623	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1152 11521624	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N
	C4591001 1152 11521627	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
	C4591001 1152 11521631	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Bone operation	01JAN2019	31DEC2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521632	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Reproductive system and breast disorders	Testicular torsion	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Testicular operation	01JAN2013	31DEC2013	N
	C4591001 1152 11521634	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	01JAN2006	31DEC2006	N
	C4591001 1152 11521643	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Investigations	Thyroid function test abnormal	02OCT2020		Y
	C4591001 1156 11561007	Metabolism and nutrition disorders	Obesity	06JUN2019		Y
		Reproductive system and breast disorders	Menorrhagia	03JAN2020	20JAN2020	N
		Surgical and medical procedures	Caesarean section	16MAY2019	16MAY2019	N
	C4591001 1156 11561009	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2018	31DEC2018	N
	C4591001 1156 11561012	Cardiac disorders	Tachycardia	20JAN2016		Y
		Immune system disorders	Iodine allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	02AUG2020		Y
	C4591001 1156 11561015	Immune system disorders	Food allergy	01JAN2010		Y
	C4591001 1156 11561039	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Surgical and medical procedures	Liposuction	01JAN2015	31JAN2015	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561040	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1156 11561056	Infections and infestations	Rhinitis	13JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	05MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16DEC2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	13SEP2011		Y
	C4591001 1156 11561057	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2015		Y
	C4591001 1156 11561064	Infections and infestations	Tonsillitis	01JAN2010	31DEC2012	N
		Injury, poisoning and procedural complications	Head injury	08AUG2020	11AUG2020	N
			Neck injury	08AUG2020	11AUG2020	N
		Surgical and medical procedures	Caesarean section	24SEP2019	24SEP2019	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561075	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Food allergy	01JAN2018		Y
	C4591001 1156 11561090	Gastrointestinal disorders	Gastroesophageal reflux disease	13DEC2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1156 11561097	Endocrine disorders	Thyroid cyst	26DEC2019		Y
		Investigations	Antinuclear antibody positive	20DEC2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1156 11561119	Immune system disorders	Food allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561120	Infections and infestations	Adenoiditis	01JAN2006	31DEC2006	N
			Tonsillitis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1156 11561126	Hepatobiliary disorders	Cholelithiasis	30JUN2019	12AUG2019	N
		Investigations	Blood thyroid stimulating hormone decreased	21JAN2019	28MAR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	21JAN2019	28MAR2020	N
			Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2010	N
			Sleep apnoea syndrome	18JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	12AUG2019	12AUG2019	N
	C4591001 1156 11561132	Eye disorders	Visual acuity reduced	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
	C4591001 1156 11561135	Injury, poisoning and procedural complications	Muscle strain	11SEP2020		Y
			Road traffic accident	01MAY2020	31MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2015	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	04SEP2019	04SEP2019	N
				29JUL2015	29JUL2015	N
	C4591001 1156 11561164	Metabolism and nutrition disorders	Overweight	29OCT2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	29OCT2013		Y
	C4591001 1156 11561170	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1156 11561175	Endocrine disorders	Goitre	01JAN2019		Y
		Reproductive system and breast disorders	Menstruation irregular	18JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1156 11561203	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2007	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1156 11561206	Blood and lymphatic system disorders	Iron deficiency anaemia	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1156 11561213	Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561226	Infections and infestations	Adenoiditis	01JAN2013	31DEC2014	N
		Nervous system disorders	Seizure	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561229	Nervous system disorders	Headache	19DEC2019		Y
	C4591001 1156 11561230	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
			Oppositional defiant disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561268	Skin and subcutaneous tissue disorders	Acne	23SEP2020		Y
	C4591001 1156 11561275	Metabolism and nutrition disorders	Obesity	18FEB2019		Y
			Type 2 diabetes mellitus	18FEB2019		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	18MAR2019		Y
	C4591001 1156 11561276	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1156 11561288	Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1156 11561291	Metabolism and nutrition disorders	Obesity	09MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	09JAN2020		Y
	C4591001 1156 11561294	Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1156 11561295	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561298	Injury, poisoning and procedural complications	Injury to brachial plexus due to birth trauma	(b) (6) 2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	04SEP2019		Y
		Surgical and medical procedures	Peripheral nerve operation	01JAN2005	31DEC2005	N
	C4591001 1156 11561299	Reproductive system and breast disorders	Dysmenorrhoea	18JUL2017		Y
			Menorrhagia	18JUL2017		Y
	C4591001 1156 11561300	Immune system disorders	Food allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2010	N
		Surgical and medical procedures	Tenotomy	01JAN2010	31DEC2010	N
	C4591001 1156 11561302	Metabolism and nutrition disorders	Obesity	08FEB2017	19NOV2020	N
	C4591001 1156 11561315	Infections and infestations	Oral herpes	20NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
			Rhinitis allergic	20NOV2018		Y
	C4591001 1156 11561329	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1157 11571113	Psychiatric disorders	Depression	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
	C4591001 1161 11611007	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1161 11611009	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1161 11611010	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1161 11611015	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
		Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1161 11611016	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1161 11611019	Immune system disorders	Drug hypersensitivity	01JAN1994		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1161 11611023	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01OCT2019		Y
			Panic attack	01JAN2018		Y
	C4591001 1161 11611028	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1162 11621001	Psychiatric disorders	Obsessive-compulsive disorder	01FEB2018		Y
	C4591001 1162 11621019	Psychiatric disorders	Anxiety	01SEP2019		Y
			Attention deficit hyperactivity disorder	01MAY2019		Y
			Depression	01JAN2019		Y
			Insomnia	01FEB2020		Y
		Surgical and medical procedures	Rhinoplasty	01JUN2018	30JUN2018	N
	C4591001 1162 11621043	Gastrointestinal disorders	Hiatus hernia	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
		Investigations	Heart rate irregular	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Obsessive-compulsive disorder	01JAN2017		Y
			Suicidal ideation	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2016	31DEC2016	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septum deviation	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2016	31DEC2016	N
			Cardiac operation	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
	C4591001 1162 11621051	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Social circumstances	Corrective lens user	01FEB2020		Y
	C4591001 1162 11621055	Injury, poisoning and procedural complications	Fibula fracture	01JAN2010	31DEC2010	N
	C4591001 1162 11621080	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1162 11621081	Surgical and medical procedures	Ear operation	01JAN2005	31DEC2005	N
	C4591001 1162 11621110	Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1162 11621130	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Adenoidectomy	01JUN2009	30JUN2009	N
	C4591001 1162 11621141	Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2010		Y
	C4591001 1162 11621145	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621169	Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1162 11621187	Eye disorders	Astigmatism	01JAN2010		Y
			Myopia	01JAN2010		Y
	C4591001 1162 11621217	Eye disorders	Hypermetropia	(b) (6) 1996		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sneezing	01JAN2010		Y
			Upper-airway cough syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Eye operation	01JAN1998	31DEC1998	N
	C4591001 1162 11621226	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1162 11621235	Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1162 11621249	Gastrointestinal disorders	Umbilical hernia	01JAN1999	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2013	31DEC2017	N
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2013	31DEC2017	N
	C4591001 1162 11621310	Immune system disorders	Drug hypersensitivity	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621320	Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Mental disorder	01JAN2018	31DEC2018	N
			Nightmare	01JAN2010		Y
	C4591001 1162 11621360	Eye disorders	Myopia	01DEC2011		Y
		Immune system disorders	Food allergy	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01MAR2020	31MAR2020	N
			Ear tube insertion	01JAN2006	31DEC2006	N
	C4591001 1162 11621374	Nervous system disorders	Headache	14SEP2020		Y
			Multiple sclerosis	19MAY2017		Y
		Psychiatric disorders	Anxiety	01MAR2000		Y
			Autism spectrum disorder	01JAN2000		Y
			Mental disorder	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	11JAN2000		Y
			Nasal septum deviation	15JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1162 11621388	Congenital, familial and genetic disorders	Thalassaemia beta	(b) (6) 1996		Y
		Ear and labyrinth disorders	Deafness	01JUN2018		Y
	C4591001 1162 11621405	Psychiatric disorders	Anxiety	01AUG2020		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01AUG2020		Y
	C4591001 1162 11621434	Eye disorders	Myopia	01JAN2006		Y
		Psychiatric disorders	Anxiety	31DEC2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1162 11621439	Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
	C4591001 1162 11621456	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1162 11621479	Renal and urinary disorders	Chronic kidney disease	01JAN1998	31DEC1999	N
	C4591001 1162 11621576	Eye disorders	Myopia	01JAN2019		Y
	C4591001 1162 11621583	Congenital, familial and genetic disorders	Colour blindness	01JAN2016		Y
		Eye disorders	Myopia	01JAN2016		Y
	C4591001 1162 11621587	Eye disorders	Myopia	01JUL2017		Y
	C4591001 1162 11621589	Surgical and medical procedures	Umbilical hernia repair	01JAN2004	31DEC2010	N
	C4591001 1163 11631048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003	31JAN2011	N
		Psychiatric disorders	Anxiety	31JAN2015		Y
			Depression	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1999	31JAN2010	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1163 11631106	Immune system disorders	Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1166 11661008	Nervous system disorders	Cluster headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01APR2020		Y
	C4591001 1166 11661032	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2016		Y
		Surgical and medical procedures	Tenoplasty	01JUL2019	01JUL2019	N
				01MAR2020	01MAR2020	N
	C4591001 1166 11661042	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1166 11661063	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1166 11661083	Surgical and medical procedures	Contraception	01JAN2017		Y
			Keratomileusis	24AUG2020	24AUG2020	N
	C4591001 1166 11661088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Hip surgery	01JAN2016	31DEC2016	N
	C4591001 1166 11661096	Immune system disorders	Drug hypersensitivity	01JAN2001		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01JAN2008	31DEC2008	N
	C4591001 1167 11671129	Psychiatric disorders	Attention deficit hyperactivity disorder	14JAN2014		Y
	C4591001 1167 11671132	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	29AUG2020		Y
	C4591001 1167 11671140	Cardiac disorders	Palpitations	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Autism spectrum disorder	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2019		Y
	C4591001 1167 11671142	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1167 11671178	Psychiatric disorders	Attention deficit hyperactivity disorder	25JUL2020		Y
	C4591001 1167 11671213	Investigations	Cardiac murmur	01JAN2019		Y
	C4591001 1168 11681014	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1168 11681026	Psychiatric disorders	Anxiety	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2012		Y
	C4591001 1168 11681034	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1168 11681035	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Tension headache	01JAN2015		Y
	C4591001 1168 11681052	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1168 11681058	Surgical and medical procedures	Sesamoidectomy	01JAN2013	31DEC2013	N
	C4591001 1168 11681064	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
	C4591001 1168 11681069	Eye disorders	Hypermetropia	01JAN1999		Y
			Myopia	01JAN1999		Y
		Nervous system disorders	Headache	01JAN2007		Y
	C4591001 1168 11681071	Eye disorders	Myopia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1168 11681078	Infections and infestations	Tonsillitis	01JUL2019	31JUL2019	N
		Nervous system disorders	Headache	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Surgical and medical procedures	Tonsillectomy	01JUL2019	31JUL2019	N
	C4591001 1168 11681088	Immune system disorders	Seasonal allergy	01JAN2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pharyngitis streptococcal	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
			Dermatitis contact	01OCT2017		Y
		Surgical and medical procedures	Bursal operation	01OCT2017	31OCT2017	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1168 11681090	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Surgical and medical procedures	Gastric operation	01JAN2012	31DEC2012	N
	C4591001 1168 11681096	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2014		Y
	C4591001 1168 11681098	Eye disorders	Myopia	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1168 11681103	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014	31DEC2017	N
		Surgical and medical procedures	Scoliosis surgery	01JAN2017	31DEC2017	N
	C4591001 1168 11681109	Eye disorders	Myopia	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1168 11681135	Cardiac disorders	Tachycardia	01JAN2020		Y
		Endocrine disorders	Hyperthyroidism	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	31MAY2019	31MAY2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2017		Y
			Post-traumatic stress disorder	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	31MAY2019	31MAY2019	N
			Tonsillectomy	01JAN2003	31DEC2003	N
			Seasonal allergy	01JAN2015		Y
	C4591001 1168 11681145	Immune system disorders				
	C4591001 1168 11681154	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2011		Y
			Tension headache	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
	C4591001 1168 11681164	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y
	C4591001 1168 11681176	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
	C4591001 1168 11681177	Congenital, familial and genetic disorders	Cleft palate	01JAN1995		Y
		Eye disorders	Myopia	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681184	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1168 11681195	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Migraine	01SEP2018		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Autism spectrum disorder	01JAN2016		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2020		Y
	C4591001 1168 11681198	Ear and labyrinth disorders	Tinnitus	01JAN2013		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Nervous system disorders	Sinus headache	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1168 11681202	Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1168 11681212	Eye disorders	Myopia	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1168 11681219	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2019		Y
	C4591001 1168 11681221	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1168 11681224	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1168 11681226	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1168 11681228	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1168 11681241	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2006		Y
			Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAY2000	31DEC2012	N
	C4591001 1169 11691014	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01OCT2016	07OCT2016	N
		Surgical and medical procedures	Thyroidectomy	07OCT2016	07OCT2016	N
	C4591001 1169 11691060	Psychiatric disorders	Anxiety	23MAY2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	23MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	11APR2019		Y
	C4591001 1170 11701009	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1170 11701022	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2015		Y
	C4591001 1170 11701043	Hepatobiliary disorders	Hepatic steatosis	01JAN2019	31MAY2020	N
		Infections and infestations	Folliculitis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1170 11701048	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1170 11701076	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1170 11701095	Immune system disorders	Seasonal allergy	01JAN1999		Y
	C4591001 1170 11701096	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
	C4591001 1170 11701111	Metabolism and nutrition disorders	Lactose intolerance	01AUG2019		Y
			Obesity	01JAN2005		Y
	C4591001 1170 11701164	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Autism spectrum disorder	01JAN2005		Y
			Obsessive-compulsive disorder	01JAN2005		Y
	C4591001 1170 11701191	Psychiatric disorders	Anxiety disorder	01JAN2020		Y
	C4591001 1170 11701261	Immune system disorders	Hypersensitivity	01FEB2019		Y
	C4591001 1170 11701279	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1170 11701311	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1170 11701373	Immune system disorders	Seasonal allergy	01OCT2008		Y
	C4591001 1170 11701407	Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2010		Y
	C4591001 1170 11701419	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1170 11701430	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701444	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1170 11701487	Congenital, familial and genetic disorders	Renal fusion anomaly	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2018		Y
	C4591001 1171 11711012	Ear and labyrinth disorders	Deafness	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
	C4591001 1171 11711027	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN2006	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1171 11711028	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1171 11711037	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1171 11711056	Endocrine disorders	Hypothyroidism	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711088	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1171 11711139	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2014		Y
	C4591001 1171 11711194	Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
	C4591001 1171 11711211	Gastrointestinal disorders	Gastrooesophageal reflux disease	07JUL2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017	06JUL2020	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Gastrectomy	06JUL2020	06JUL2020	N
	C4591001 1171 11711221	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
			Haemorrhoids	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
	C4591001 1171 11711223	Congenital, familial and genetic disorders	Gilbert's syndrome	01JUN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711252	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
	C4591001 1171 11711265	Eye disorders	Strabismus	01JAN2001	09AUG2006	N
		Surgical and medical procedures	Strabismus correction	09AUG2006	09AUG2006	N
	C4591001 1171 11711287	Renal and urinary disorders	Micturition urgency	01JUL2020	06AUG2020	N
	C4591001 1174 11741005	Immune system disorders	Food allergy	01JAN2016		Y
			Hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1174 11741006	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Toxic shock syndrome	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Chondroplasty	01AUG2015	31DEC2015	N
				01JAN2018	31DEC2018	N
				01OCT2015	31OCT2015	N
	C4591001 1174 11741053	Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1177 11771086	Immune system disorders	Food allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Suicidal ideation	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771101	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Contraception	01JAN2017		Y
	C4591001 1177 11771113	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1177 11771170	Immune system disorders	Allergy to animal	01AUG2018		Y
	C4591001 1177 11771234	Eye disorders	Astigmatism	29JUN2017		Y
			Myopia	29JUN2017		Y
		Immune system disorders	Dust allergy	01JAN2010		Y
		Infections and infestations	Rhinitis	19MAY2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	10AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	07NOV2014		Y
			Depression	01JAN2016		Y
			Insomnia	01AUG2019		Y
			Obsessive-compulsive disorder	07NOV2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1177 11771235	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008	31DEC2008	N
	C4591001 1177 11771312	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1177 11771342	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1177 11771345	Immune system disorders	Allergy to chemicals	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771347	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1177 11771348	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2016		Y
	C4591001 1177 11771351	Eye disorders	Dacryostenosis acquired	01JAN2010	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Lacrimal duct procedure	01JAN2012	31DEC2012	N
	C4591001 1177 11771368	Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1177 11771393	Gastrointestinal disorders	Hyperaesthesia teeth	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1177 11771400	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1177 11771404	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1177 11771428	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2009		Y
		Surgical and medical procedures	Wisdom teeth removal	01APR2017	30APR2017	N
	C4591001 1177 11771432	Injury, poisoning and procedural complications	Subdural haematoma	01JAN2011	31DEC2011	N
			Upper limb fracture	01JAN2006	31DEC2006	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1177 11771435	Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Mite allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Peripheral nerve injury	15MAY2019	15MAY2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1177 11771439	Surgical and medical procedures	Peripheral nerve operation	15MAY2019	15MAY2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1177 11771442	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1177 11771443	Immune system disorders	Food allergy	01JAN2005		Y
		Infections and infestations	Ear infection	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Myringotomy	01JAN2004	31DEC2004	N
	C4591001 1177 11771454	Infections and infestations	Genital herpes	01APR2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2011	31DEC2014	N
	C4591001 1177 11771466	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771479	General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Infections and infestations	Adenoiditis	01JAN2011	31DEC2011	N
			Tonsillitis	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1177 11771488	Gastrointestinal disorders	Gingival recession	01JAN2017	30APR2017	N
		Infections and infestations	Urinary tract infection	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
		Surgical and medical procedures	Gingival graft	01APR2017	30APR2017	N
			Wisdom teeth removal	01APR2018	30APR2018	N
	C4591001 1177 11771490	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1177 11771516	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771529	Immune system disorders	Food allergy	01JAN2001		Y
	C4591001 1177 11771539	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	(b) (6) 1998		Y
	C4591001 1177 11771540	Infections and infestations	Otitis media	01JAN2005	31DEC2005	N
		Investigations	Cardiac murmur	01JAN2014		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N
	C4591001 1177 11771550	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771565	Immune system disorders	Dust allergy	01JAN2014		Y
			Food allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1178 11781067	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2019		Y
		Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1178 11781074	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1178 11781098	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1178 11781154	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1178 11781156	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1178 11781161	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1178 11781162	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Oral herpes	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781170	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
	C4591001 1178 11781186	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1178 11781190	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1178 11781234	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01NOV2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007		Y
	C4591001 1178 11781239	Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1178 11781245	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Liver disorder	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781247	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
	C4591001 1178 11781284	Endocrine disorders	Basedow's disease	01JUL2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01DEC2014		Y
	C4591001 1178 11781296	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1178 11781309	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1179 11791030	Surgical and medical procedures	Contraceptive implant	01JAN2019		Y
	C4591001 1179 11791050	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1179 11791082	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1179 11791087	Congenital, familial and genetic disorders	Hereditary spherocytosis	(b) (6) 1998		Y
	C4591001 1179 11791100	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1996		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791117	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1179 11791161	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1185 11851060	Investigations	Human papilloma virus test positive	01MAR2020		Y
		Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1194 11941067	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1997		Y
	C4591001 1194 11941082	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1194 11941086	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y
	C4591001 1194 11941103	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1195 11951019	Blood and lymphatic system disorders	Iron deficiency anaemia	01FEB2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	16JAN2015		Y
	C4591001 1195 11951061	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1195 11951080	Psychiatric disorders	Bulimia nervosa	15OCT2010		Y
	C4591001 1195 11951100	Endocrine disorders	Hypothyroidism	01JUL2020		Y
	C4591001 1195 11951113	Gastrointestinal disorders	Crohn's disease	01JAN2015		Y
	C4591001 1195 11951148	Metabolism and nutrition disorders	Obesity	20OCT2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	31JAN2017		Y
	C4591001 1204 12041061	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Surgical and medical procedures	Chondroplasty	01JAN2013	31DEC2013	N
			Wrist surgery	01JAN2014	31DEC2014	N
	C4591001 1204 12041080	Investigations	Blood cholesterol increased	10SEP2018		Y
	C4591001 1204 12041098	Investigations	Cardiac murmur	11SEP2012		Y
	C4591001 1204 12041112	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1204 12041129	Gastrointestinal disorders	Colitis	18SEP2013		Y
		Nervous system disorders	Migraine	18SEP2008		Y
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1204 12041134	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1204 12041147	Immune system disorders	Food allergy	01JAN2002		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1204 12041192	Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1204 12041203	Gastrointestinal disorders	Epigastric discomfort	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN2002	31DEC2002	N
	C4591001 1204 12041220	Blood and lymphatic system disorders	Anaemia	24SEP2020		Y
	C4591001 1204 12041247	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
	C4591001 1204 12041252	Injury, poisoning and procedural complications	Wrist fracture	08AUG2019	11SEP2019	N
				28JUN2020	17AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2006	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	08AUG2019	08AUG2019	N
	C4591001 1204 12041268	Gastrointestinal disorders	Tooth impacted	01JAN2010	31DEC2010	N
		Infections and infestations	Ear infection	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1205 12051079	Endocrine disorders	Hypothyroidism	(b) (6) 2000		Y
	C4591001 1210 12101009	Cardiac disorders	Pericarditis	01MAY2020	31MAY2020	N
	C4591001 1210 12101020	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAR2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1210 12101021	Congenital, familial and genetic disorders	Familial mediterranean fever	01AUG2020		Y
	C4591001 1210 12101030	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2020		Y
	C4591001 1210 12101041	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
	C4591001 1210 12101059	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
	C4591001 1212 12121007	Psychiatric disorders	Post-traumatic stress disorder	01JAN2015		Y
			Selective eating disorder	01JAN2019		Y
	C4591001 1214 12141013	Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Affective disorder	01APR2019		Y
	C4591001 1217 12171041	Psychiatric disorders	Bipolar disorder	01JAN2016		Y
	C4591001 1217 12171047	Metabolism and nutrition disorders	Insulin resistance	25JAN2019		Y
	C4591001 1218 12181011	Renal and urinary disorders	Nephrolithiasis	01JUL2018	31JUL2018	N
	C4591001 1218 12181014	Immune system disorders	Allergic oedema	01JAN2010		Y
			Allergy to arthropod sting	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 1218 12181030	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	02JAN2008		Y
		Psychiatric disorders	Anxiety	29DEC2016	31DEC2018	N
	C4591001 1218 12181047	Immune system disorders	Allergy to animal	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1218 12181050	Immune system disorders	Seasonal allergy	25JAN2017		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Vascular disorders	Hypertension	09OCT2019		Y
	C4591001 1218 12181053	Immune system disorders	Drug hypersensitivity	16FEB2015		Y
	C4591001 1219 12191004	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN2016		Y
			Substance use	01JAN2015	31DEC2015	N
			Tobacco user	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2020	31DEC2020	N
	C4591001 1219 12191058	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1220 12201012	Immune system disorders	Allergy to animal	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2014	31DEC2017	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Tooth extraction	02JUL2019	02JUL2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201015	Hepatobiliary disorders	Hepatic steatosis	01JUL2018		Y
		Immune system disorders	Food allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2019		Y
			Obesity	01APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2016	31DEC2016	N
			Depression	01JAN2004	31AUG2018	N
			Major depression	01DEC2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	14NOV2019	14NOV2019	N
			Caesarean section	15NOV2018	15NOV2018	N
			Medical device removal	02NOV2017	02NOV2017	N
	C4591001 1220 12201017	Immune system disorders	Allergy to animal	01JAN2014		Y
			Seasonal allergy	01JAN2018		Y
	C4591001 1220 12201036	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31JAN2020	N
	C4591001 1220 12201048	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2006	31DEC2006	N
	C4591001 1220 12201057	Surgical and medical procedures	Ligament operation	01OCT2018	31OCT2018	N
	C4591001 1221 12211006	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1221 12211012	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Pneumonia	01JAN2000	31DEC2000	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2015	31DEC2018	N
	C4591001 1221 12211037	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1221 12211038	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1221 12211047	Blood and lymphatic system disorders	Anaemia of pregnancy	21OCT2020		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01MAY2005	31MAY2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1221 12211054	Surgical and medical procedures	Fracture treatment	28MAY2010	21JUN2010	N
	C4591001 1221 12211062	Metabolism and nutrition disorders	Overweight	01APR2016		Y
	C4591001 1221 12211087	Psychiatric disorders	Depression	01SEP2018	31DEC2018	N
	C4591001 1223 12231025	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1223 12231053	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
	C4591001 1223 12231057	Psychiatric disorders	Insomnia	01AUG2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01AUG2018		Y
	C4591001 1223 12231061	Infections and infestations	Herpes virus infection	01JAN2018		Y
	C4591001 1223 12231073	Cardiac disorders	Palpitations	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01SEP2017		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1223 12231082	Endocrine disorders	Autoimmune thyroiditis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1223 12231111	Metabolism and nutrition disorders	Vitamin D deficiency	02SEP2020		Y
	C4591001 1223 12231113	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1223 12231117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
	C4591001 1223 12231120	Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1223 12231164	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1223 12231172	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1223 12231184	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1223 12231186	Psychiatric disorders	Attention deficit hyperactivity disorder	(b) (6) 1999		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2019		Y
	C4591001 1223 12231187	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1223 12231197	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241009	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUN2012	01JUN2012	N
	C4591001 1224 12241165	Gastrointestinal disorders	Abdominal migraine	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2016	31DEC2018	N
					31DEC2019	N
		Surgical and medical procedures	Medical device removal	01NOV2000	01NOV2020	N
	C4591001 1224 12241167	Immune system disorders	Seasonal allergy	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1224 12241168	Gastrointestinal disorders	Abdominal pain upper	01JAN2016		Y
	C4591001 1224 12241169	Endocrine disorders	Growth hormone deficiency	01JAN2018		Y
	C4591001 1224 12241170	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1224 12241171	Injury, poisoning and procedural complications	Concussion	01JAN2017		Y
	C4591001 1224 12241173	Immune system disorders	Drug hypersensitivity	01AUG2015		Y
			Food allergy	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01AUG2015	31AUG2015	N
	C4591001 1224 12241174	Immune system disorders	Food allergy	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241175	Blood and lymphatic system disorders	Iron deficiency anaemia	01MAY2019		Y
		Psychiatric disorders	Anxiety	23NOV2020		Y
			Attention deficit hyperactivity disorder	01AUG2018		Y
			Depression	23NOV2020		Y
	C4591001 1224 12241177	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1224 12241180	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2004		Y
	C4591001 1224 12241181	Investigations	Vitamin D decreased	01JAN2018		Y
		Psychiatric disorders	Depression	01NOV2018		Y
	C4591001 1224 12241182	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1224 12241185	Psychiatric disorders	Anxiety	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
	C4591001 1224 12241186	Nervous system disorders	Migraine	01MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Ventricular septal defect repair	02FEB2005	02FEB2005	N
	C4591001 1224 12241187	Reproductive system and breast disorders	Testicular torsion	01JAN2019	31JAN2019	N
	C4591001 1226 12261001	Nervous system disorders	Migraine	01JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261007	Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1226 12261082	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1226 12261096	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1226 12261103	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261122	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
	C4591001 1226 12261124	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1226 12261144	Infections and infestations	Labyrinthitis	01JAN2014		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2004		Y
	C4591001 1226 12261230	Gastrointestinal disorders	Umbilical hernia	01JAN2018	30JUN2019	N
		Social circumstances	Tobacco user	01JAN2016		Y
		Surgical and medical procedures	Hernia repair	01JUN2019	30JUN2019	N
	C4591001 1226 12261270	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1226 12261275	Metabolism and nutrition disorders	Obesity	01JAN2005	31DEC2012	N
		Nervous system disorders	Headache	01JAN2008		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2012	31DEC2012	N
	C4591001 1226 12261285	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261292	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261332	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2008		Y
	C4591001 1226 12261343	Gastrointestinal disorders	Gastritis	01JAN2010		Y
	C4591001 1226 12261348	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1226 12261443	Respiratory, thoracic and mediastinal disorders	Asthma	01JUL2019		Y
	C4591001 1226 12261543	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261570	Nervous system disorders	Headache	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2007		Y
	C4591001 1226 12261579	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261603	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2018		Y
	C4591001 1226 12261631	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261643	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1226 12261649	Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
	C4591001 1226 12261669	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
	C4591001 1226 12261709	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
	C4591001 1226 12261818	Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1226 12261828	Infections and infestations	Bronchitis	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261831	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1226 12261840	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1226 12261844	Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1226 12261850	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1226 12261950	Gastrointestinal disorders	Gastritis	01JUL2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261960	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1226 12261973	Reproductive system and breast disorders	Polycystic ovaries	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01AUG2020	31AUG2020	N
				01JAN2001	31DEC2001	N
			Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1226 12261999	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12262001	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
	C4591001 1226 12262021	Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1226 12262063	Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
	C4591001 1226 12262068	Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12262099	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1226 12262115	Ear and labyrinth disorders	Meniere's disease	01SEP2020		Y
	C4591001 1226 12262122	Psychiatric disorders	Depression	01JAN2017		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262143	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN2014		Y
	C4591001 1226 12262189	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12262201	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2018	31DEC2018	N
			Turbineotomy	01JAN2018	31DEC2018	N
	C4591001 1226 12262245	Psychiatric disorders	Anxiety	01OCT2019		Y
	C4591001 1226 12262279	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1226 12262280	Nervous system disorders	Migraine	01JAN2007		Y
	C4591001 1226 12262290	Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1226 12262293	Infections and infestations	Herpes simplex	01JAN2017		Y
	C4591001 1226 12262299	Endocrine disorders	Hypothyroidism	17OCT2008		Y
	C4591001 1226 12262322	Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262329	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12262334	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN2015		Y
	C4591001 1226 12262353	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1229 12291065	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1229 12291077	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1229 12291079	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1229 12291169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1230 12301005	Eye disorders	Hypermetropia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2014	31DEC2017	N
	C4591001 1230 12301009	Injury, poisoning and procedural complications	Limb injury	15FEB2019	01MAR2019	N
			Scar	15FEB2019		Y
		Surgical and medical procedures	Tendon graft	15FEB2019	01MAR2019	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1230 12301010	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001	31DEC2011	N
		Surgical and medical procedures	Appendectomy	01NOV2018	30NOV2018	N
			Open reduction of fracture	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1230 12301018	Surgical and medical procedures	Circumcision	01AUG2015	31AUG2015	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301031	Pregnancy, puerperium and perinatal conditions	Delivery	09SEP2013	09SEP2013	N
	C4591001 1230 12301039	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Myopia	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1230 12301052	Pregnancy, puerperium and perinatal conditions	Delivery	16JAN2018	16JAN2018	N
		Surgical and medical procedures	Antibiotic therapy	01JAN2001	31DEC2001	N
	C4591001 1230 12301056	Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1230 12301057	Pregnancy, puerperium and perinatal conditions	Delivery	25FEB2018	25FEB2018	N
	C4591001 1230 12301078	Surgical and medical procedures	Tonsillectomy	01JUN2019	30JUN2019	N
	C4591001 1230 12301079	Surgical and medical procedures	Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1230 12301083	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1230 12301085	Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1230 12301094	Surgical and medical procedures	Open reduction of fracture	01NOV2017	31DEC2017	N
	C4591001 1230 12301114	Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1230 12301115	Gastrointestinal disorders	Chronic gastritis	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1230 12301132	Surgical and medical procedures	Circumcision	01JAN2018	31DEC2018	N
	C4591001 1230 12301136	Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Toe operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1230 12301151	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1230 12301157	Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1230 12301166	Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1230 12301186	Surgical and medical procedures	Caesarean section	27MAY2016	27MAY2016	N
	C4591001 1230 12301198	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1230 12301205	Social circumstances	Tobacco user	01MAR2019		Y
	C4591001 1230 12301208	Social circumstances	Tobacco user	01JAN2014		Y
	C4591001 1230 12301213	Social circumstances	Tobacco user	01JAN2017		Y
	C4591001 1230 12301216	Surgical and medical procedures	Circumcision	01JAN2015	31DEC2015	N
	C4591001 1230 12301224	Eye disorders	Hypermetropia	01JAN2012		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Open reduction of fracture	01JAN2008	31DEC2008	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311047	Surgical and medical procedures	Tonsillectomy	01JUL2007	02JUL2007	N
	C4591001 1231 12311088	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JUN2015		Y
		Vascular disorders	Raynaud's phenomenon	01JUN2015		Y
	C4591001 1231 12311141	Infections and infestations	Genital herpes	03APR2020		Y
	C4591001 1231 12311268	Infections and infestations	Cellulitis	24APR2019	06MAY2020	N
	C4591001 1231 12311281	Gastrointestinal disorders	Abdominal pain upper	01APR2020		Y
			Gastritis	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	04APR2019		Y
	C4591001 1231 12311283	Nervous system disorders	Migraine	01JUN2019		Y
	C4591001 1231 12311306	Nervous system disorders	Migraine	02AUG2018	01FEB2020	N
	C4591001 1231 12311360	Reproductive system and breast disorders	Ovarian cyst	01DEC2015	01DEC2015	N
		Surgical and medical procedures	Ovarian cystectomy	01DEC2015	01DEC2015	N
	C4591001 1231 12311366	Endocrine disorders	Hyperprolactinaemia	14SEP2017		Y
			Hypothyroidism	10APR2019		Y
	C4591001 1231 12311387	Psychiatric disorders	Bulimia nervosa	01APR2015	10DEC2015	N
	C4591001 1231 12311388	Gastrointestinal disorders	Pancreatitis	01AUG2014	09AUG2014	N
		Surgical and medical procedures	Gastric bypass	07JAN2019		Y
	C4591001 1231 12311392	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2004		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311436	Psychiatric disorders	Anxiety disorder	21MAY2019	01JAN2020	N
	C4591001 1231 12311447	Surgical and medical procedures	Varicocele repair	05AUG2013	01MAR2014	N
	C4591001 1231 12311503	Respiratory, thoracic and mediastinal disorders	Asthma	07NOV2019		Y
	C4591001 1231 12311567	Congenital, familial and genetic disorders	Congenital hearing disorder	(b) (6) 1995		Y
	C4591001 1231 12311570	Nervous system disorders	Epilepsy	20JAN2020		Y
	C4591001 1231 12311623	Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
	C4591001 1231 12311627	Surgical and medical procedures	Renal stone removal	17JAN2019	18JAN2019	N
	C4591001 1231 12311627	Surgical and medical procedures	Appendicectomy	05AUG2012	05AUG2012	N
	C4591001 1231 12311633	Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2010		Y
	C4591001 1231 12311652	Surgical and medical procedures	Tonsillectomy	21FEB2012	21FEB2012	N
	C4591001 1231 12311661	Nervous system disorders	Psychomotor hyperactivity	(b) (6) 1996		Y
	C4591001 1231 12311683	Infections and infestations	Parasite allergy	03SEP2019		Y
	C4591001 1231 12311765	Nervous system disorders	Migraine	07JUN2019		Y
	C4591001 1231 12311765	Gastrointestinal disorders	Chronic gastritis	15JAN2020		Y
	C4591001 1231 12311770	Metabolism and nutrition disorders	Type 2 diabetes mellitus	19MAY2019		Y
	C4591001 1231 12311841	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999	01JAN2012	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311866	Gastrointestinal disorders	Irritable bowel syndrome	01MAR2020		Y
	C4591001 1231 12311928	Gastrointestinal disorders	Dental caries	20JAN2016	23FEB2016	N
		Surgical and medical procedures	Artificial crown procedure	23FEB2016	23FEB2016	N
	C4591001 1231 12311947	Immune system disorders	Seasonal allergy	11AUG2010		Y
	C4591001 1231 12311998	Endocrine disorders	Hypothyroidism	23JUN2020		Y
	C4591001 1231 12312069	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2010		Y
	C4591001 1231 12312080	Immune system disorders	Seasonal allergy	01APR2010		Y
		Social circumstances	Tobacco user	01MAY2008		Y
	C4591001 1231 12312192	Infections and infestations	Atypical pneumonia	15NOV2005	10JAN2006	N
			Hepatitis A	10FEB1998	28FEB1998	N
			Varicella	10AUG1998	20AUG1998	N
	C4591001 1231 12312200	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2002		Y
	C4591001 1231 12312283	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1231 12312305	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y
	C4591001 1231 12312339	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23JUL2013		Y
	C4591001 1231 12312344	Surgical and medical procedures	Tonsillectomy	01JUN2005	01AUG2005	N
	C4591001 1231 12312346	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25SEP2013		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis allergic	25SEP2013		Y
			Dermatitis atopic	25SEP2013		Y
	C4591001 1231 12312359	Respiratory, thoracic and mediastinal disorders	Asthma	15FEB2020		Y
	C4591001 1231 12312376	Endocrine disorders	Hypothyroidism	26AUG2010		Y
	C4591001 1231 12312442	Immune system disorders	Drug hypersensitivity	02AUG2001		Y
	C4591001 1231 12312464	Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1995	01DEC2008	N
	C4591001 1231 12312545	Surgical and medical procedures	Cholecystectomy	01JAN2018	01JAN2018	N
	C4591001 1231 12312608	Reproductive system and breast disorders	Amenorrhoea	01APR2020		Y
	C4591001 1231 12312641	Psychiatric disorders	Depression	08AUG2019		Y
	C4591001 1231 12312674	Endocrine disorders	Hypothyroidism	01DEC2019		Y
	C4591001 1231 12312716	Blood and lymphatic system disorders	Hypochromic anaemia	12FEB2020		Y
	C4591001 1231 12312725	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y
	C4591001 1231 12312741	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JUN2006	01JUN2018	N
	C4591001 1231 12312762	Hepatobiliary disorders	Hepatic steatosis	01AUG2018		Y
	C4591001 1231 12312857	Infections and infestations	Sinusitis	01JAN2005		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2005	31DEC2005	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312874	Psychiatric disorders	Anxiety disorder	01MAR2016		Y
	C4591001 1231 12312895	Endocrine disorders	Hypothyroidism	01AUG2018		Y
	C4591001 1231 12312972	Skin and subcutaneous tissue disorders	Dermatitis atopic	15OCT2018		Y
	C4591001 1231 12312986	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1231 12312990	Infections and infestations	Chronic tonsillitis	01JAN2019		Y
	C4591001 1231 12312996	Psychiatric disorders	Generalised anxiety disorder	20NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	23AUG2004		Y
	C4591001 1231 12313117	Eye disorders	Myopia	01JAN2009		Y
	C4591001 1231 12313124	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09OCT2005		Y
		Endocrine disorders	Hypothyroidism	15MAR2015		Y
	C4591001 1231 12313177	Respiratory, thoracic and mediastinal disorders	Obliterative bronchiolitis	01JAN1996		Y
	C4591001 1231 12313229	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2015		Y
	C4591001 1231 12313231	Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2018		Y
	C4591001 1231 12313257	Reproductive system and breast disorders	Ovarian cyst	12SEP2014		Y
	C4591001 1231 12313288	Psychiatric disorders	Anxiety	06JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313308	Psychiatric disorders	Panic disorder	07JUL2017		Y
	C4591001 1231 12313381	Congenital, familial and genetic disorders	Dysmorphism	(b) (6) 1999	30OCT2020	N
	C4591001 1231 12313383	Endocrine disorders	Hypothyroidism	29MAY2011	07JAN2020	N
	C4591001 1231 12313409	Metabolism and nutrition disorders	Hyperuricaemia	02MAY2015		Y
	C4591001 1231 12313430	Surgical and medical procedures	Vesicoureteral reflux surgery	01DEC2009	04DEC2009	N
	C4591001 1231 12313432	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1996		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1231 12313434	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17AUG2010		Y
	C4591001 1231 12313467	Reproductive system and breast disorders	Varicocele	06FEB2019		Y
	C4591001 1231 12313722	Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2008		Y
	C4591001 1231 12313778	Psychiatric disorders	Depression	20AUG2013		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01MAR2007		Y
	C4591001 1231 12313854	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1231 12313889	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 1231 12313919	Congenital, familial and genetic disorders	Klinefelter's syndrome	10OCT2017		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314135	Injury, poisoning and procedural complications	Road traffic accident	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Spinal operation	01JAN2011		Y
	C4591001 1231 12314178	Infections and infestations	Dengue fever	09JUN2015	22JUN2020	N
	C4591001 1231 12314243	Congenital, familial and genetic disorders	Klippel-Feil syndrome	(b) (6) 1997		Y
		Renal and urinary disorders	Single functional kidney	(b) (6) 1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2013		Y
		Surgical and medical procedures	Spinal fusion surgery	10OCT2012		Y
	C4591001 1231 12314278	Congenital, familial and genetic disorders	Arteriovenous malformation	01MAY2019	01JUN2019	N
	C4591001 1231 12314396	Gastrointestinal disorders	Coeliac disease	28AUG2002		Y
	C4591001 1231 12314482	Infections and infestations	Syphilis	11JUL2019	25JUL2019	N
	C4591001 1231 12314489	Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2015		Y
	C4591001 1231 12314574	Psychiatric disorders	Autism spectrum disorder	01AUG2018		Y
			Sleep disorder	01AUG2018		Y
	C4591001 1231 12314582	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
	C4591001 1231 12314742	Congenital, familial and genetic disorders	Thalassaemia minor	29AUG2006		Y
	C4591001 1231 12314746	Psychiatric disorders	Anxiety	01DEC2018		Y
	C4591001 1231 12314800	Reproductive system and breast disorders	Menstrual disorder	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314845	Nervous system disorders	Headache	01JUN2010		Y
	C4591001 1231 12314862	Metabolism and nutrition disorders	Obesity	05MAR2005		Y
	C4591001 1231 12314870	Metabolism and nutrition disorders	Obesity	02AUG2017		Y
			Type 2 diabetes mellitus	01AUG2017		Y
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2010		Y
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12314894	Infections and infestations	Pneumonia	01JUN2005	15JUN2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2005	01JUN2006	N
	C4591001 1231 12314925	Skin and subcutaneous tissue disorders	Pityriasis rosea	12MAR2017		Y
	C4591001 1231 12314977	Gastrointestinal disorders	Gastritis	10MAY2009		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	26NOV2008		Y
	C4591001 1231 12315013	Respiratory, thoracic and mediastinal disorders	Bronchospasm	14JUN2006		Y
	C4591001 1231 12315039	Psychiatric disorders	Anxiety disorder	28AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01SEP2019		Y
	C4591001 1231 12315080	Endocrine disorders	Thyroid mass	06JUN2016		Y
	C4591001 1231 12315136	Respiratory, thoracic and mediastinal disorders	Asthma	10MAR2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315169	Congenital, familial and genetic disorders	Thalassaemia	01JAN2006		Y
	C4591001 1231 12315182	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1231 12315241	Renal and urinary disorders	Nephrolithiasis	01FEB2017		Y
	C4591001 1231 12315299	Skin and subcutaneous tissue disorders	Angioedema	11AUG2005	12AUG2015	N
	C4591001 1231 12315357	Nervous system disorders	Migraine	01JUN2018		Y
	C4591001 1231 12315371	Blood and lymphatic system disorders	Neutropenia	13SEP2019		Y
		Endocrine disorders	Hypothyroidism	01MAR2007		Y
	C4591001 1231 12315406	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
	C4591001 1231 12315446	Surgical and medical procedures	Thyroidectomy	28JUL2011	28JUL2011	N
	C4591001 1231 12315462	Skin and subcutaneous tissue disorders	Acne	10JAN2019		Y
	C4591001 1231 12315465	Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
	C4591001 1231 12315471	Skin and subcutaneous tissue disorders	Vitiligo	26MAY2020		Y
	C4591001 1231 12315527	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1231 12315529	Nervous system disorders	Epilepsy	01AUG2019		Y
	C4591001 1231 12315648	Surgical and medical procedures	Cholecystectomy	06JUN2016	06JUN2016	N
			Tonsillectomy	08AUG2014	08AUG2014	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315678	Nervous system disorders	Encephalopathy	18AUG1998		Y
	C4591001 1232 12321028	Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1232 12321056	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2020		Y
			Psoriasis	01JAN2020		Y
	C4591001 1232 12321101	Surgical and medical procedures	Caesarean section	30JUN2020	30JUN2020	N
	C4591001 1232 12321120	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01SEP2001		Y
		Psychiatric disorders	Depression	01JUN2019		Y
	C4591001 1232 12321141	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1232 12321146	Psychiatric disorders	Schizophrenia	01JAN2017		Y
	C4591001 1232 12321159	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1232 12321310	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1232 12321408	Investigations	Heart rate irregular	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Reynold's syndrome	01JAN2017		Y
		Vascular disorders	Erythromelalgia	01JAN2019		Y
	C4591001 1232 12321429	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1235 12351003	Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01NOV2019		Y
	C4591001 1235 12351004	Renal and urinary disorders	Bladder spasm	01JAN2015		Y
		Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1235 12351006	Infections and infestations	Oral herpes	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1235 12351009	Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1235 12351014	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1235 12351015	Psychiatric disorders	Chronic tic disorder	01JAN2003		Y
	C4591001 1235 12351016	Reproductive system and breast disorders	Polycystic ovaries	01FEB2016		Y
	C4591001 1235 12351036	Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	01JAN2014		Y
	C4591001 1235 12351040	Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351052	Cardiac disorders	Supraventricular tachycardia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1235 12351055	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351058	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351064	Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Contraception	01JAN2014		Y
	C4591001 1235 12351068	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1235 12351073	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1235 12351092	Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1235 12351105	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1235 12351108	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1235 12351112	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1235 12351124	Psychiatric disorders	Depression	01JAN2020		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351126	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1235 12351127	Surgical and medical procedures	Intrauterine contraception	01JAN2019		Y
	C4591001 1235 12351128	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1235 12351146	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1235 12351153	Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Intrauterine contraception	01JUL2020		Y
	C4591001 1235 12351156	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
	C4591001 1235 12351165	Infections and infestations	Furuncle	29SEP2020		Y
	C4591001 1235 12351166	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2004		Y
	C4591001 1235 12351171	Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1235 12351172	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1235 12351209	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1235 12351212	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Investigations	Vitamin D decreased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1235 12351228	Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1235 12351237	Cardiac disorders	Sinus tachycardia	01JAN2014		Y
		Congenital, familial and genetic disorders	Muscular dystrophy	01JAN2003		Y
		Gastrointestinal disorders	Diaphragmatic hernia	01JAN2003		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Thoracic insufficiency syndrome	01JAN2003		Y
	C4591001 1235 12351240	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1235 12351241	Psychiatric disorders	Depression	01SEP2020		Y
		Surgical and medical procedures	Wisdom teeth removal	04DEC2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411010	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL2020		Y
	C4591001 1241 12411011	Nervous system disorders	Migraine	01JAN2017	30JUN2018	N
		Reproductive system and breast disorders	Polycystic ovaries	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Benign breast lump removal	01NOV2016	30NOV2016	N
	C4591001 1241 12411028	Immune system disorders	Dust allergy	01JAN2017		Y
		Nervous system disorders	Tension headache	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
	C4591001 1241 12411034	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1241 12411036	Reproductive system and breast disorders	Endometriosis	08FEB2020		Y
	C4591001 1241 12411063	Psychiatric disorders	Anxiety disorder	01JAN2000		Y
	C4591001 1241 12411127	Gastrointestinal disorders	Flatulence	12AUG2020	12AUG2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1241 12411157	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1241 12411178	Gastrointestinal disorders	Toothache	01AUG2020	01AUG2020	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411215	Injury, poisoning and procedural complications	Rib fracture	01OCT2018	31DEC2018	N
	C4591001 1241 12411220	Infections and infestations	Pulmonary tuberculosis	01JAN1995	31DEC1995	N
	C4591001 1241 12411233	Surgical and medical procedures	Metabolic surgery	23MAR2017	23MAR2017	N
	C4591001 1241 12411303	Nervous system disorders	Tension headache	17AUG2020		Y
	C4591001 1241 12411347	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1241 12411366	Surgical and medical procedures	Eye operation	01AUG2016	31AUG2016	N
	C4591001 1241 12411372	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
	C4591001 1241 12411393	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2018	30JUN2020	N
	C4591001 1241 12411427	Infections and infestations	Subcutaneous abscess	01JUN2017	30JUN2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1241 12411450	Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
	C4591001 1241 12411461	Reproductive system and breast disorders	Breast mass	01FEB2020		Y
	C4591001 1241 12411476	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008	10AUG2020	N
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2008		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411509	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411539	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12411544	Injury, poisoning and procedural complications	Ligament injury	01MAR2020	31MAR2020	N
	C4591001 1241 12411556	Nervous system disorders	Tension headache	01JAN2014	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2019	31AUG2020	N
	C4591001 1241 12411600	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2020		Y
	C4591001 1241 12411624	Immune system disorders	Food allergy	01JAN2009		Y
	C4591001 1241 12411672	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Surgical and medical procedures	Physiotherapy	24AUG2020	31AUG2020	N
	C4591001 1241 12411674	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006	31AUG2020	N
	C4591001 1241 12411678	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2012		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2004		Y
	C4591001 1241 12411680	Infections and infestations	Genital herpes	01JAN2016	31JAN2016	N
				25AUG2020	30AUG2020	N
			Varicella	01JAN2004	31DEC2004	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1241 12411698	Surgical and medical procedures	Sympathectomy	01JAN2014	31DEC2014	N
	C4591001 1241 12411700	Psychiatric disorders	Anxiety	01MAR2019		Y
			Depression	01MAR2019		Y
			Insomnia	01MAR2019		Y
	C4591001 1241 12411729	Nervous system disorders	Epilepsy	01JAN2002		Y
	C4591001 1241 12411777	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12411791	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1241 12411827	Reproductive system and breast disorders	Polycystic ovaries	01JAN2019		Y
	C4591001 1241 12411833	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Myasthenia gravis	01JAN2007		Y
		Surgical and medical procedures	Thymectomy	01JAN2007	31JAN2007	N
	C4591001 1241 12411839	Metabolism and nutrition disorders	Lactose intolerance	01MAR2020		Y
	C4591001 1241 12411848	Surgical and medical procedures	Bone cyst excision	01JAN2006	31DEC2006	N
	C4591001 1241 12411850	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012	31JUL2020	N
	C4591001 1241 12411858	Immune system disorders	Drug hypersensitivity	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411860	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2016		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2018	31DEC2018	N
	C4591001 1241 12411865	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	05SEP2020	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JUN2020		Y
	C4591001 1241 12411871	Surgical and medical procedures	Bone operation	01JAN2017	31DEC2017	N
	C4591001 1241 12411880	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR2019	31MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411881	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1241 12411884	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1241 12411885	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411886	Nervous system disorders	Tension headache	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411888	Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411889	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	31DEC2018	N
	C4591001 1241 12411898	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Pneumothorax spontaneous	01JAN2017	31DEC2017	N
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411914	Cardiac disorders	Mitral valve prolapse	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12411917	Psychiatric disorders	Depression	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1241 12411960	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1241 12411974	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411975	Nervous system disorders	Tension headache	01JAN2011		Y
	C4591001 1241 12411985	Infections and infestations	Chronic sinusitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2003	31DEC2003	N
	C4591001 1241 12411996	Infections and infestations	Chronic sinusitis	01JAN2010		Y



## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
	C4591001 1241 12411997	Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12412002	Gastrointestinal disorders	Coeliac disease	01JAN1998		Y
		Psychiatric disorders	Anxiety disorder	01DEC2019		Y
		Surgical and medical procedures	Tympanoplasty	01JUN2019	30JUN2019	N
	C4591001 1241 12412014	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1241 12412027	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2009		Y
	C4591001 1241 12412072	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	30SEP2020		Y
	C4591001 1241 12412114	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2013		Y
				01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1241 12412135	Psychiatric disorders	Depression	01SEP2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1241 12412136	Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JUN2019		Y
	C4591001 1241 12412141	Surgical and medical procedures	Bone lesion excision	01AUG2020	31AUG2020	N
	C4591001 1241 12412159	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1241 12412165	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1241 12412172	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12412199	Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12412218	Nervous system disorders	Migraine	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412221	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12412227	Gastrointestinal disorders	Gastritis	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1241 12412232	Infections and infestations	Sinusitis	01JAN2013		Y
	C4591001 1241 12412257	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1241 12412262	Congenital, familial and genetic disorders	Sickle cell trait	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1241 12412267	Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412295	Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412327	Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
			Bone lesion excision	01JAN2015	31DEC2015	N
	C4591001 1241 12412329	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1241 12412339	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1241 12412351	Congenital, familial and genetic disorders	Thalassaemia	01JAN1997		Y
	C4591001 1241 12412352	Immune system disorders	Food allergy	01JAN2002		Y
			Iodine allergy	01JAN2002		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2002		Y
	C4591001 1241 12412373	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12412377	Metabolism and nutrition disorders	Lactose intolerance	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1241 12412383	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012	31DEC2014	N
	C4591001 1241 12412396	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12412397	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1241 12412398	Psychiatric disorders	Anxiety	01APR2019		Y
			Depression	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412399	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412421	Infections and infestations	Sinusitis	01JAN2008		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
	C4591001 1241 12412444	Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412482	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2017		Y
	C4591001 1241 12412485	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12412505	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412517	Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1241 12412527	Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2010		Y
		Nervous system disorders	Dyslexia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412534	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12412537	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412540	Gastrointestinal disorders	Gastritis	01JAN2016	31DEC2018	N
		Infections and infestations	Labyrinthitis	01JAN2016	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12412565	Gastrointestinal disorders	Gastritis	01SEP2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1246 12461018	Infections and infestations	Chronic sinusitis	01JAN2018		Y
	C4591001 1246 12461026	Cardiac disorders	Palpitations	01JAN2009		Y
	C4591001 1246 12461028	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1246 12461038	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01AUG2020		Y
	C4591001 1246 12461070	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1246 12461075	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1246 12461084	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1246 12461098	Surgical and medical procedures	Caesarean section	31JAN2019	31JAN2019	N
	C4591001 1246 12461108	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1246 12461109	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1246 12461112	Infections and infestations	Chronic sinusitis	01JAN2018		Y
	C4591001 1246 12461126	Gastrointestinal disorders	Peptic ulcer	01JAN2015		Y
	C4591001 1246 12461135	Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1247 12471010	Eye disorders	Refraction disorder	01OCT2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1247 12471087	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1247 12471174	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1247 12471185	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1247 12471197	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1247 12471244	Nervous system disorders	Facial paralysis	01FEB2018	30APR2018	N
				01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1247 12471245	Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1248 12481025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1248 12481038	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1248 12481055	Immune system disorders	Mite allergy	01JAN2018		Y
	C4591001 1248 12481062	Infections and infestations	Herpes virus infection	01JAN2013		Y
	C4591001 1248 12481099	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006	31DEC2012	N
	C4591001 1248 12481154	Reproductive system and breast disorders	Endometriosis	01NOV2017		Y
		Surgical and medical procedures	Endometriosis ablation	01JAN2018	31JAN2018	N
			Fracture treatment	01JAN2018	31DEC2018	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481165	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	06AUG2016	06AUG2016	N
	C4591001 1248 12481178	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1248 12481189	Immune system disorders	Multiple allergies	01JAN2003		Y
	C4591001 1248 12481193	Immune system disorders	Allergy to animal	01JAN2006		Y
			Seasonal allergy	01JAN2006		Y
		Surgical and medical procedures	Foot operation	01JAN2017	31DEC2017	N
	C4591001 1248 12481227	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1248 12481240	Psychiatric disorders	Bipolar disorder	15OCT2019		Y
			Depression	15OCT2019		Y
	C4591001 1248 12481246	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
			Gender dysphoria	01JAN2017		Y
	C4591001 1251 12511032	Nervous system disorders	Migraine	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	02APR2019	02APR2019	N
				25JUN2016	25JUN2016	N



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511061	Hepatobiliary disorders	Cholecystitis	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2020	29FEB2020	N
	C4591001 1251 12511115	Surgical and medical procedures	Female sterilisation	01JAN2018	01JAN2018	N
	C4591001 1251 12511128	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
	C4591001 1251 12511129	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1252 12521024	Renal and urinary disorders	Nephrolithiasis	01JUN2020	30JUN2020	N
	C4591001 1252 12521036	Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1254 12541035	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1254 12541057	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
	C4591001 1254 12541104	Injury, poisoning and procedural complications	Ligament sprain	01JAN2010	31DEC2019	N
	C4591001 1254 12541115	Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1254 12541117	Eye disorders	Astigmatism	01JAN2007	31AUG2019	N
			Myopia	01JAN2007	31AUG2019	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Genital herpes	01JAN2015		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1254 12541121	Surgical and medical procedures	Keratomileusis	01AUG2019	31AUG2019	N
		Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Gastritis	01JAN2013		Y
	C4591001 1254 12541133	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2015	31DEC2015	N
	C4591001 1254 12541142	Immune system disorders	Food allergy	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2016	31DEC2019	N
	C4591001 1254 12541151	Psychiatric disorders	Anxiety	01JAN2015		Y
		Ear and labyrinth disorders	Ear pain	01JAN2002	31DEC2002	N
	C4591001 1254 12541158	Surgical and medical procedures	Ear operation	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2016	N
	C4591001 1254 12541162	Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
		Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01SEP2019		Y
		Injury, poisoning and procedural complications	Arterial injury	13SEP2019	14SEP2019	N
			Muscle injury	13SEP2019	14SEP2019	N

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Peripheral nerve injury	14SEP2019	14SEP2019	N
			Ulnar nerve injury	13SEP2019	14SEP2019	N
		Psychiatric disorders	Alcoholism	01JAN2006	17AUG2020	N
			Anxiety	01JAN2014		Y
			Panic attack	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Pneumonitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Muscle operation	14SEP2019	14SEP2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541171	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Malocclusion	01JAN2013	31DEC2015	N
		Immune system disorders	Allergy to animal	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1254 12541193	Surgical and medical procedures	Jaw operation	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2014	31DEC2015	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y
	C4591001 1258 12581060	Surgical and medical procedures	Female sterilisation	13JAN2017	13JAN2017	N
	C4591001 1258 12581065	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1260 12601004	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601023	Musculoskeletal and connective tissue disorders	Compartment syndrome	01JAN2013	31JAN2013	N
		Nervous system disorders	Migraine with aura	01JAN2005		Y
	C4591001 1260 12601045	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2013		Y
	C4591001 1260 12601126	Psychiatric disorders	Sleep disorder	01JAN2014		Y
	C4591001 1261 12611047	Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1264 12641009	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	24JUN2020	24JUN2020	N
	C4591001 1264 12641037	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2013		Y
		Surgical and medical procedures	Jaw operation	01JAN2013	31DEC2013	N
	C4591001 1264 12641089	Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1264 12641095	Congenital, familial and genetic disorders	Renal dysplasia	01JAN1996		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019		Y
		Surgical and medical procedures	Limb operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1264 12641119	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1264 12641120	Immune system disorders	Food allergy	01JUL2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01MAR2013		Y
			Eczema	01JAN2012		Y
		Surgical and medical procedures	Contraceptive implant	01APR2013	30APR2013	N
				20JAN2020	20JAN2020	N
	C4591001 1264 12641215	Ear and labyrinth disorders	Tinnitus	01MAY2018		Y
		Psychiatric disorders	Depression	15SEP2015		Y
	C4591001 1264 12641227	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Vulvovaginal mycotic infection	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1265 12651013	Infections and infestations	Herpes simplex	23MAY2019		Y
		Metabolism and nutrition disorders	Obesity	07MAY2018		Y
		Psychiatric disorders	Borderline personality disorder	18DEC2015		Y
			Major depression	01FEB2013		Y
		Skin and subcutaneous tissue disorders	Acne	06OCT2014		Y
	C4591001 1265 12651082	Infections and infestations	Pneumonia	01JAN1995	31DEC1995	N

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	26NOV2019		Y
			Attention deficit hyperactivity disorder	02OCT2017		Y
			Depression	26NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	26JUL2011		Y
		Surgical and medical procedures	Appendicectomy	12SEP2017	12SEP2017	N
			Circumcision	01JAN1994	31DEC1994	N
	C4591001 1265 12651083	Metabolism and nutrition disorders	Obesity	22OCT2013		Y
	C4591001 1269 12691010	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2009		Y
	C4591001 1269 12691047	Infections and infestations	Vulvovaginal candidiasis	01SEP2019	30SEP2019	N
	C4591001 1269 12691106	Immune system disorders	Food allergy	01JAN2008		Y
			Seasonal allergy	01JAN2019		Y
	C4591001 1270 12701048	Reproductive system and breast disorders	Dysmenorrhoea	15MAY2020		Y
	C4591001 1270 12701146	Skin and subcutaneous tissue disorders	Acne	17NOV2016		Y
	C4591001 1270 12701148	Skin and subcutaneous tissue disorders	Acne	07MAY2020		Y
	C4591001 1270 12701149	Infections and infestations	Rhinitis	15FEB2020		Y
	C4591001 1270 12701150	Congenital, familial and genetic disorders	Imperforate hymen	27OCT2020		Y
		Immune system disorders	Food allergy	30MAR2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	31MAR2017		Y

## 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Cold urticaria	23JUL2018		Y
	C4591001 1270 12701151	Respiratory, thoracic and mediastinal disorders	Dermatitis atopic Pneumothorax spontaneous	17AUG2011 12MAR2019	12MAR2019	Y N
		Skin and subcutaneous tissue disorders	Acne	12MAY2017		Y
		Surgical and medical procedures	Dermatitis atopic Thoracic operation	04JUN2012 16MAR2019	16MAR2019	Y N
	C4591001 1270 12701154	Psychiatric disorders	Attention deficit hyperactivity disorder	04SEP2014		Y
	C4591001 1270 12701156	Endocrine disorders	Thyroid mass	04MAY2018	03JUL2018	N
	C4591001 1270 12701157	Surgical and medical procedures Infections and infestations	Thyroidectomy Oral herpes	03JUL2018 24MAY2011	03JUL2018	N Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	29OCT2020		Y
	C4591001 1270 12701158	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17JUL2015		Y
	C4591001 1270 12701159	Psychiatric disorders	Autism spectrum disorder	31JUL2018		Y
			Depression	15MAY2018		Y
			Generalised anxiety disorder	15MAY2018		Y
	C4591001 1270 12701160	Eye disorders	Astigmatism	28AUG2020		Y
			Myopia	10APR2019		Y
		Immune system disorders	Drug hypersensitivity	21OCT2018		Y
	C4591001 1270 12701162	Metabolism and nutrition disorders	Lactose intolerance	17JAN2012		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	25FEB2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	20MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19APR2010		Y
		Skin and subcutaneous tissue disorders	Acne	20AUG2020		Y
	C4591001 1270 12701164	Immune system disorders	Drug hypersensitivity	29MAY2020		Y
	C4591001 1270 12701165	Injury, poisoning and procedural complications	Cartilage injury	15JAN2019	29JAN2019	N
		Surgical and medical procedures	Chondroplasty	29JAN2019	29JAN2019	N
	C4591001 1270 12701166	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19MAY2020		Y
	C4591001 1270 12701167	Skin and subcutaneous tissue disorders	Acne	10MAR2016		Y
	C4591001 1270 12701168	Musculoskeletal and connective tissue disorders	Arthralgia	30SEP2020		Y
	C4591001 1270 12701169	Nervous system disorders	Central auditory processing disorder	02AUG2017		Y
			Migraine with aura	02AUG2020		Y
	C4591001 1270 12701170	Nervous system disorders	Migraine	07MAR2013		Y
	C4591001 1270 12701171	Immune system disorders	Drug hypersensitivity	04MAR2015		Y
		Infections and infestations	Folliculitis	12NOV2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03MAR2015		Y
			Rhinitis allergic	03MAR2015		Y
		Skin and subcutaneous tissue disorders	Acne	07FEB2019		Y



### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701172	Immune system disorders	Drug hypersensitivity	04MAR2015		Y
		Infections and infestations	Folliculitis	12NOV2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28OCT2019		Y
			Rhinitis allergic	04MAR2015		Y
		Skin and subcutaneous tissue disorders	Acne	14JUL2016		Y
	C4591001 1270 12701175	Musculoskeletal and connective tissue disorders	Arthralgia	18APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26OCT2007		Y
			Rhinitis allergic	26JAN2007		Y
	C4591001 1270 12701176	Respiratory, thoracic and mediastinal disorders	Asthma	28NOV2006		Y
			Rhinitis allergic	04DEC2013		Y
	C4591001 1270 12701178	Eye disorders	Refraction disorder	05MAR2019		Y
		Metabolism and nutrition disorders	Iron deficiency	24SEP2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	11JUN2008		Y
	C4591001 1270 12701179	Nervous system disorders	Headache	03OCT2019		Y
		Skin and subcutaneous tissue disorders	Acne	03OCT2019		Y
	C4591001 1270 12701182	Immune system disorders	Drug hypersensitivity	28FEB2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	09AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	29JAN2020		Y

### 16.2.5.3.1 Listing of Medical History – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701183	Psychiatric disorders	Social anxiety disorder	21JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	08AUG2017		Y
			Mechanical urticaria	26OCT2010		Y
	C4591001 1270 12701185	Nervous system disorders	Febrile convulsion	16JUL2006	31DEC2008	N
	C4591001 1270 12701186	Immune system disorders	Food allergy	01JUL2011		Y
				28NOV2012		Y
			Seasonal allergy	01JUL2011		Y
	C4591001 1270 12701190	Reproductive system and breast disorders	Dysmenorrhoea	23AUG2018		Y
	C4591001 1270 12701193	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	12NOV2015		Y
	C4591001 1270 12701196	Eye disorders	Retinoschisis	11AUG2014		Y
	C4591001 1270 12701197	Immune system disorders	Drug hypersensitivity	25OCT2013		Y
		Psychiatric disorders	Adjustment disorder	13OCT2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25OCT2013		Y
	C4591001 4444 44441065	Skin and subcutaneous tissue disorders	Acne	02JAN2013		Y
	C4591001 4444 44441147	Psychiatric disorders	Anorexia nervosa	09SEP2016		Y
			Major depression	09SEP2016		Y
	C4591001 4444 44441160	Injury, poisoning and procedural complications	Hand fracture	18DEC2017	18FEB2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016		Y

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01MAR2015		Y
	C4591001 4444 44441171	Endocrine disorders	Hypothyroidism	01JUN2006		Y
		Infections and infestations	Pulmonary tuberculosis	01JUL2018	01FEB2019	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 4444 44441284	Immune system disorders	Drug hypersensitivity	22AUG2005		Y
	C4591001 4444 44441334	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 4444 44441360	Gastrointestinal disorders	Haemorrhoids	01NOV2019		Y
		Surgical and medical procedures	Knee operation	10JAN2019	10JUN2019	N
			Ligament operation	10JAN2019	10JUN2019	N
			Meniscus operation	10JAN2019	10JUN2019	N
	C4591001 4444 44441388	Gastrointestinal disorders	Coeliac disease	11FEB2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	17MAY2017	24MAY2017	N
		Surgical and medical procedures	Knee operation	17MAY2017	24MAY2017	N
	C4591001 4444 44441395	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01SEP2011	01SEP2012	N
		Surgical and medical procedures	Cholesteatoma removal	01SEP2011	01SEP2012	N
	C4591001 4444 44441444	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 4444 44441446	Metabolism and nutrition disorders	Obesity	01JAN2020		Y

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441485	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 4444 44441498	Congenital, familial and genetic disorders	Microphthalmos	(b) (6) 2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 4444 44441510	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 4444 44441524	Surgical and medical procedures	Inguinal hernia repair	14SEP1995	14SEP1995	N
	C4591001 4444 44441593	Respiratory, thoracic and mediastinal disorders	Asthma	10JUL2018		Y
	C4591001 4444 44441612	Congenital, familial and genetic disorders	Arnold-Chiari malformation	16APR2017		Y
		Surgical and medical procedures	Ventriculo-peritoneal shunt	20JUL2017		Y
	C4591001 4444 44441654	Nervous system disorders	Hemiplegia	(b) (6) 1995		Y
	C4591001 4444 44441668	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
	C4591001 4444 44441721	Endocrine disorders	Hypothyroidism	01JUN2008		Y
	C4591001 4444 44441726	Psychiatric disorders	Depression	01AUG2019		Y
	C4591001 4444 44441779	Immune system disorders	Drug hypersensitivity	01SEP2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	02JUL2003		Y
	C4591001 4444 44441800	Metabolism and nutrition disorders	Obesity	01JUL2008		Y
		Surgical and medical procedures	Gastric bypass	23DEC2011	25DEC2011	N
	C4591001 4444 44441851	Eye disorders	Glaucoma	10JUN2012		Y

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441857	Respiratory, thoracic and mediastinal disorders	Asthma	15MAY2008		Y
	C4591001 4444 44441874	Eye disorders	Retinal disorder	20AUG2004	01SEP2018	N
		Surgical and medical procedures	Preventive surgery	01SEP2018	01SEP2018	N
	C4591001 4444 44441891	Endocrine disorders	Hypothyroidism	04JUN2014		Y
		Musculoskeletal and connective tissue disorders	Synovitis	15AUG2019		Y
		Surgical and medical procedures	Arthrotomy	10SEP2020	10SEP2020	N
			Synovectomy	10SEP2020	10SEP2020	N
	C4591001 4444 44441937	Gastrointestinal disorders	Coeliac disease	09SEP2018		Y
	C4591001 4444 44441956	Nervous system disorders	Migraine without aura	01FEB2017		Y
	C4591001 4444 44441965	Nervous system disorders	Migraine with aura	01JUN2012		Y
	C4591001 4444 44441973	Reproductive system and breast disorders	Menstruation irregular	01JAN2011		Y
			Ovarian cyst	01JUL2018		Y
	C4591001 4444 44441982	Nervous system disorders	Paraesthesia	01JUN2010	01MAR2017	N
	C4591001 4444 44441997	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 4444 44442025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 4444 44442135	Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	28MAR2020		Y
	C4591001 4444 44442155	Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	14SEP2010	27SEP2010	N
				22MAR2011	05APR2011	N

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Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442196	Musculoskeletal and connective tissue disorders	Scoliosis	01MAR2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 4444 44442217	Endocrine disorders	Hypothyroidism	27SEP2017		Y
	C4591001 4444 44442219	Surgical and medical procedures	Adenoidectomy	09JUL2002	09JUL2002	N
	C4591001 4444 44442236	Respiratory, thoracic and mediastinal disorders	Asthma	01APR2004		Y
	C4591001 4444 44442256	Musculoskeletal and connective tissue disorders	Scoliosis	15JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
<p>Note: MedDRA (v23.1) coding dictionary applied.</p> <p>Note: † = Human immunodeficiency virus (HIV)-positive subject.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:45)</p> <p>(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_l006_ped</p>						