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Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Any medical history	9598 (73.4)	9726 (74.3)
Blood and lymphatic system disorders	165 (1.3)	172 (1.3)
Anaemia	98 (0.7)	114 (0.9)
Anaemia of pregnancy	0	1 (0.0)
Antiphospholipid syndrome	3 (0.0)	3 (0.0)
Blood loss anaemia	1 (0.0)	0
Coagulopathy	2 (0.0)	1 (0.0)
Eosinophilia	1 (0.0)	0
Haemolytic anaemia	0	1 (0.0)
Haemolytic uraemic syndrome	1 (0.0)	0
Hypercoagulation	2 (0.0)	0
Hypersplenism	1 (0.0)	0
Hypochromic anaemia	1 (0.0)	0
Immune thrombocytopenia	1 (0.0)	7 (0.1)
Increased tendency to bruise	2 (0.0)	0
Iron deficiency anaemia	33 (0.3)	31 (0.2)
Leukopenia	2 (0.0)	2 (0.0)
Lymphadenitis	0	1 (0.0)
Lymphadenopathy	5 (0.0)	2 (0.0)
Macrocytosis	1 (0.0)	0
Mast cell activation syndrome	1 (0.0)	0

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Mastocytosis	2 (0.0)	0
Microcytic anaemia	1 (0.0)	1 (0.0)
Microcytosis	0	1 (0.0)
Neutropenia	0	3 (0.0)
Normocytic anaemia	1 (0.0)	0
Pernicious anaemia	3 (0.0)	0
Polycythaemia	2 (0.0)	0
Spherocytic anaemia	0	1 (0.0)
Splenomegaly	1 (0.0)	1 (0.0)
Thrombocytopenia	5 (0.0)	5 (0.0)
Thrombocytosis	0	1 (0.0)
Cardiac disorders	250 (1.9)	234 (1.8)
Acute coronary syndrome	0	1 (0.0)
Acute myocardial infarction	12 (0.1)	0
Adams-Stokes syndrome	1 (0.0)	0
Angina pectoris	2 (0.0)	8 (0.1)
Angina unstable	1 (0.0)	0
Aortic valve incompetence	2 (0.0)	1 (0.0)
Aortic valve stenosis	0	1 (0.0)
Arrhythmia	12 (0.1)	19 (0.1)
Arteriosclerosis coronary artery	2 (0.0)	0
Arteriospasm coronary	1 (0.0)	3 (0.0)

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	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Atrial fibrillation	22 (0.2)	20 (0.2)
Atrial flutter	0	1 (0.0)
Atrial tachycardia	3 (0.0)	1 (0.0)
Atrioventricular block complete	0	2 (0.0)
Atrioventricular block first degree	1 (0.0)	1 (0.0)
Bradycardia	6 (0.0)	3 (0.0)
Bradycardia neonatal	0	1 (0.0)
Bundle branch block left	2 (0.0)	3 (0.0)
Bundle branch block right	2 (0.0)	4 (0.0)
Cardiac arrest	1 (0.0)	1 (0.0)
Cardiac disorder	1 (0.0)	0
Cardiac failure	4 (0.0)	4 (0.0)
Cardiac failure chronic	1 (0.0)	1 (0.0)
Cardiac failure congestive	12 (0.1)	8 (0.1)
Cardiac ventricular thrombosis	1 (0.0)	0
Cardiomegaly	1 (0.0)	0
Cardiomyopathy	3 (0.0)	3 (0.0)
Cardiovascular disorder	1 (0.0)	2 (0.0)
Congestive cardiomyopathy	1 (0.0)	0
Coronary artery aneurysm	0	1 (0.0)
Coronary artery disease	21 (0.2)	22 (0.2)
Coronary artery insufficiency	1 (0.0)	0
Coronary artery occlusion	2 (0.0)	2 (0.0)

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Diastolic dysfunction	0	1 (0.0)
Extrasystoles	1 (0.0)	1 (0.0)
Ischaemic cardiomyopathy	1 (0.0)	0
Left ventricular failure	0	2 (0.0)
Left ventricular hypertrophy	2 (0.0)	1 (0.0)
Long QT syndrome	1 (0.0)	0
Mitral valve disease	1 (0.0)	1 (0.0)
Mitral valve incompetence	7 (0.1)	5 (0.0)
Mitral valve prolapse	19 (0.1)	17 (0.1)
Mitral valve stenosis	1 (0.0)	0
Myocardial infarction	21 (0.2)	26 (0.2)
Myocardial ischaemia	0	1 (0.0)
Myocarditis	1 (0.0)	0
Palpitations	24 (0.2)	18 (0.1)
Pericardial effusion	1 (0.0)	0
Pericarditis	3 (0.0)	3 (0.0)
Postural orthostatic tachycardia syndrome	3 (0.0)	2 (0.0)
Prinzmetal angina	1 (0.0)	0
Pulmonary valve incompetence	1 (0.0)	0
Pulmonary valve stenosis	2 (0.0)	2 (0.0)
Right atrial enlargement	0	1 (0.0)
Right ventricular failure	1 (0.0)	0
Sinus arrhythmia	0	3 (0.0)

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Sinus bradycardia	0	2 (0.0)
Sinus node dysfunction	2 (0.0)	0
Sinus tachycardia	7 (0.1)	6 (0.0)
Stress cardiomyopathy	0	1 (0.0)
Supraventricular extrasystoles	1 (0.0)	3 (0.0)
Supraventricular tachycardia	24 (0.2)	13 (0.1)
Tachyarrhythmia	1 (0.0)	0
Tachycardia	18 (0.1)	16 (0.1)
Tachycardia paroxysmal	0	1 (0.0)
Tricuspid valve disease	1 (0.0)	0
Ventricular extrasystoles	10 (0.1)	14 (0.1)
Ventricular tachycardia	3 (0.0)	2 (0.0)
Wolff-Parkinson-White syndrome	4 (0.0)	6 (0.0)
Congenital, familial and genetic disorders	216 (1.7)	262 (2.0)
Acrocephalosyndactyly	1 (0.0)	0
Adrenogenital syndrome	1 (0.0)	0
Albinism	1 (0.0)	0
Alpha-1 antitrypsin deficiency	2 (0.0)	0
Anal atresia	1 (0.0)	0
Aniridia	0	1 (0.0)
Ankyloglossia congenital	0	1 (0.0)
Anomalous pulmonary venous connection	1 (0.0)	1 (0.0)

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Anomaly of external ear congenital	0	1 (0.0)
Antithrombin III deficiency	0	1 (0.0)
Arnold-Chiari malformation	5 (0.0)	3 (0.0)
Arteriovenous malformation	2 (0.0)	1 (0.0)
Asplenia	1 (0.0)	0
Ataxia telangiectasia	0	1 (0.0)
Atrial septal defect	3 (0.0)	9 (0.1)
BRCA1 gene mutation	0	1 (0.0)
BRCA2 gene mutation	0	2 (0.0)
Benign familial pemphigus	1 (0.0)	0
Bicuspid aortic valve	5 (0.0)	4 (0.0)
Bicuspid pulmonary valve	0	1 (0.0)
Brachymetatarsia	0	1 (0.0)
Branchial cyst	1 (0.0)	0
Cancer gene carrier	0	3 (0.0)
Cataract congenital	2 (0.0)	1 (0.0)
Cerebral palsy	1 (0.0)	8 (0.1)
Cerebrovascular arteriovenous malformation	0	2 (0.0)
Checkpoint kinase 2 gene mutation	1 (0.0)	0
Cleft lip	0	2 (0.0)
Cleft palate	2 (0.0)	4 (0.0)
Coarctation of the aorta	1 (0.0)	1 (0.0)
Colour blindness	2 (0.0)	1 (0.0)

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Congenital anomaly	0	1 (0.0)
Congenital aortic anomaly	0	1 (0.0)
Congenital aortic stenosis	2 (0.0)	1 (0.0)
Congenital cerebrovascular anomaly	1 (0.0)	0
Congenital coronary artery malformation	0	1 (0.0)
Congenital cystic kidney disease	5 (0.0)	1 (0.0)
Congenital cystic lung	2 (0.0)	0
Congenital ectodermal dysplasia	0	1 (0.0)
Congenital eye disorder	1 (0.0)	0
Congenital flat feet	3 (0.0)	0
Congenital foot malformation	0	2 (0.0)
Congenital hand malformation	0	1 (0.0)
Congenital hearing disorder	2 (0.0)	0
Congenital heart valve disorder	0	2 (0.0)
Congenital hydronephrosis	0	1 (0.0)
Congenital hypothyroidism	1 (0.0)	1 (0.0)
Congenital intestinal malformation	0	2 (0.0)
Congenital jaw malformation	2 (0.0)	2 (0.0)
Congenital joint malformation	1 (0.0)	0
Congenital lymphoedema	0	1 (0.0)
Congenital multiplex arthrogryposis	2 (0.0)	0
Congenital myopathy	0	1 (0.0)
Congenital neoplasm	0	1 (0.0)

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	n ^b (%)	n ^b (%)
Congenital osteodystrophy	1 (0.0)	0
Congenital skin disorder	0	1 (0.0)
Congenital small intestinal atresia	0	1 (0.0)
Congenital spinal stenosis	1 (0.0)	0
Congenital toxoplasmosis	1 (0.0)	0
Congenital ureteric anomaly	0	1 (0.0)
Congenital uterine anomaly	1 (0.0)	2 (0.0)
Corneal dystrophy	1 (0.0)	2 (0.0)
Cornelia de Lange syndrome	0	1 (0.0)
Craniosynostosis	0	1 (0.0)
Cryptorchism	3 (0.0)	2 (0.0)
Cystic fibrosis	0	2 (0.0)
Deafness congenital	2 (0.0)	2 (0.0)
Dermoid cyst	1 (0.0)	0
Developmental glaucoma	0	1 (0.0)
Developmental hip dysplasia	1 (0.0)	6 (0.0)
Dextrocardia	0	1 (0.0)
Diverticulitis Meckel's	1 (0.0)	0
Dolichocolon	0	1 (0.0)
Dysmorphism	1 (0.0)	1 (0.0)
Eagle Barrett syndrome	1 (0.0)	0
Ear malformation	1 (0.0)	0
Ectopic kidney	1 (0.0)	0

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	n ^b (%)	n ^b (%)
Ehlers-Danlos syndrome	12 (0.1)	7 (0.1)
Factor II deficiency	0	1 (0.0)
Factor V Leiden carrier	1 (0.0)	1 (0.0)
Factor V Leiden mutation	7 (0.1)	11 (0.1)
Factor V deficiency	3 (0.0)	0
Factor VII deficiency	0	2 (0.0)
Factor VIII deficiency	1 (0.0)	1 (0.0)
Factor XI deficiency	1 (0.0)	1 (0.0)
Factor XII deficiency	1 (0.0)	0
Fallot's tetralogy	2 (0.0)	2 (0.0)
Familial mediterranean fever	1 (0.0)	2 (0.0)
Familial tremor	0	1 (0.0)
Femoral anteversion	1 (0.0)	0
Gaucher's disease	0	1 (0.0)
Gene mutation	1 (0.0)	1 (0.0)
Gilbert's syndrome	10 (0.1)	7 (0.1)
Glucose-6-phosphate dehydrogenase deficiency	2 (0.0)	5 (0.0)
Haemangioma congenital	1 (0.0)	0
Haemoglobin C trait	0	1 (0.0)
Haemoglobinopathy	2 (0.0)	3 (0.0)
Heart disease congenital	1 (0.0)	1 (0.0)
Hepato-lenticular degeneration	0	1 (0.0)
Hereditary motor and sensory neuropathy	1 (0.0)	0

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	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.0)
Hereditary pancreatitis	0	1 (0.0)
Hereditary spherocytosis	1 (0.0)	0
Hydrocele	2 (0.0)	2 (0.0)
Hypertrophic cardiomyopathy	1 (0.0)	4 (0.0)
Hypochondroplasia	0	1 (0.0)
Hypospadias	1 (0.0)	1 (0.0)
Imperforate hymen	0	1 (0.0)
Keratosis follicular	1 (0.0)	0
Kidney malformation	0	1 (0.0)
Klinefelter's syndrome	2 (0.0)	0
Klippel-Feil syndrome	1 (0.0)	2 (0.0)
Kyphosis congenital	1 (0.0)	0
Leptin receptor deficiency	0	1 (0.0)
Limb reduction defect	1 (0.0)	0
Marfan's syndrome	2 (0.0)	1 (0.0)
Methylenetetrahydrofolate reductase gene mutation	0	4 (0.0)
Micrognathia	0	2 (0.0)
Microphthalmos	1 (0.0)	0
Muscular dystrophy	1 (0.0)	0
Myocardial bridging	0	1 (0.0)
Myotonia congenita	0	1 (0.0)
Myotonic dystrophy	0	1 (0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Naevus flammeus	1 (0.0)	0
Neurofibromatosis	5 (0.0)	6 (0.0)
Non-compaction cardiomyopathy	1 (0.0)	0
Oesophageal cyst	0	1 (0.0)
Olfacto genital dysplasia	0	1 (0.0)
Osteogenesis imperfecta	0	1 (0.0)
Otospondylomegaepiphyseal dysplasia	1 (0.0)	0
PTEN gene mutation	0	1 (0.0)
Pancreas divisum	1 (0.0)	0
Patent ductus arteriosus	0	1 (0.0)
Pectus carinatum	0	1 (0.0)
Pectus excavatum	3 (0.0)	3 (0.0)
Pelvic kidney	0	1 (0.0)
Phenylketonuria	0	1 (0.0)
Phimosis	3 (0.0)	5 (0.0)
Poland's syndrome	1 (0.0)	0
Polycystic liver disease	0	1 (0.0)
Polydactyly	0	1 (0.0)
Protein C deficiency	0	1 (0.0)
Protein S deficiency	3 (0.0)	2 (0.0)
Pulmonary hypoplasia	1 (0.0)	0
Pulmonary malformation	1 (0.0)	0
Pyloric stenosis	2 (0.0)	7 (0.1)

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	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Renal aplasia	3 (0.0)	3 (0.0)
Renal dysplasia	1 (0.0)	0
Renal fusion anomaly	2 (0.0)	1 (0.0)
Retinitis pigmentosa	1 (0.0)	2 (0.0)
Schizencephaly	0	1 (0.0)
Schmid Fraccaro syndrome	1 (0.0)	0
Scimitar syndrome	0	1 (0.0)
Sebaceous naevus	0	1 (0.0)
Sickle cell anaemia	1 (0.0)	1 (0.0)
Sickle cell trait	4 (0.0)	6 (0.0)
Spina bifida	2 (0.0)	1 (0.0)
Spina bifida occulta	0	2 (0.0)
Spine malformation	1 (0.0)	0
Stargardt's disease	0	1 (0.0)
Supernumerary nipple	1 (0.0)	0
Syndactyly	1 (0.0)	1 (0.0)
Syringomyelia	1 (0.0)	0
Talipes	3 (0.0)	3 (0.0)
Thalassaemia	8 (0.1)	4 (0.0)
Thalassaemia alpha	1 (0.0)	2 (0.0)
Thalassaemia beta	2 (0.0)	6 (0.0)
Thalassaemia minor	5 (0.0)	5 (0.0)
Thyroglossal cyst	1 (0.0)	1 (0.0)

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	n ^b (%)	n ^b (%)
Tourette's disorder	4 (0.0)	2 (0.0)
Tracheo-oesophageal fistula	1 (0.0)	0
Transitional vertebrae	1 (0.0)	0
Tuberous sclerosis complex	1 (0.0)	2 (0.0)
Type IIa hyperlipidaemia	6 (0.0)	5 (0.0)
Type V hyperlipidaemia	9 (0.1)	9 (0.1)
Umbilical malformation	0	1 (0.0)
Urethral valves	1 (0.0)	0
VACTERL syndrome	0	1 (0.0)
Ventricular septal defect	2 (0.0)	9 (0.1)
Vitello-intestinal duct remnant	1 (0.0)	1 (0.0)
Von Willebrand's disease	1 (0.0)	2 (0.0)
Wolff-Parkinson-White syndrome congenital	1 (0.0)	0
Ear and labyrinth disorders	169 (1.3)	180 (1.4)
Auditory disorder	0	1 (0.0)
Aural polyp	0	1 (0.0)
Cerumen impaction	3 (0.0)	2 (0.0)
Conductive deafness	1 (0.0)	0
Deafness	14 (0.1)	23 (0.2)
Deafness bilateral	17 (0.1)	14 (0.1)
Deafness neurosensory	4 (0.0)	3 (0.0)
Deafness unilateral	18 (0.1)	17 (0.1)

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	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ear deformity acquired	1 (0.0)	0
Ear disorder	1 (0.0)	3 (0.0)
Ear pain	1 (0.0)	3 (0.0)
Ear pruritus	0	1 (0.0)
Eustachian tube dysfunction	1 (0.0)	5 (0.0)
Eustachian tube patulous	1 (0.0)	0
Eustachian tube stenosis	0	1 (0.0)
Excessive cerumen production	0	1 (0.0)
Exostosis of external ear canal	1 (0.0)	1 (0.0)
Hypoacusis	15 (0.1)	16 (0.1)
Inner ear disorder	1 (0.0)	0
Meniere's disease	10 (0.1)	11 (0.1)
Middle ear effusion	1 (0.0)	0
Motion sickness	5 (0.0)	1 (0.0)
Otosclerosis	3 (0.0)	3 (0.0)
Sudden hearing loss	1 (0.0)	0
Tinnitus	46 (0.4)	51 (0.4)
Tympanic membrane perforation	7 (0.1)	6 (0.0)
Vertigo	20 (0.2)	30 (0.2)
Vertigo positional	3 (0.0)	3 (0.0)
Vestibular disorder	1 (0.0)	1 (0.0)
Endocrine disorders	765 (5.9)	810 (6.2)

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	n^b (%)	n^b (%)
Adrenal insufficiency	1 (0.0)	0
Adrenal mass	0	1 (0.0)
Androgen deficiency	2 (0.0)	3 (0.0)
Anovulatory cycle	1 (0.0)	1 (0.0)
Autoimmune hypothyroidism	0	1 (0.0)
Autoimmune thyroiditis	47 (0.4)	40 (0.3)
Basedow's disease	11 (0.1)	10 (0.1)
Diabetes insipidus	0	1 (0.0)
Endocrine disorder	1 (0.0)	0
Goitre	17 (0.1)	22 (0.2)
Gonadotrophin deficiency	0	1 (0.0)
Growth hormone deficiency	1 (0.0)	2 (0.0)
Hyperaldosteronism	1 (0.0)	0
Hyperandrogenism	0	1 (0.0)
Hyperparathyroidism	2 (0.0)	0
Hyperprolactinaemia	3 (0.0)	1 (0.0)
Hyperthyroidism	29 (0.2)	32 (0.2)
Hypogonadism	24 (0.2)	30 (0.2)
Hypogonadism male	7 (0.1)	4 (0.0)
Hypoparathyroidism	3 (0.0)	1 (0.0)
Hypopituitarism	1 (0.0)	0
Hypothalamo-pituitary disorder	0	1 (0.0)
Hypothyroidism	616 (4.7)	654 (5.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Oestrogen deficiency	1 (0.0)	3 (0.0)
Pituitary-dependent Cushing's syndrome	1 (0.0)	0
Primary hypogonadism	0	1 (0.0)
Secondary hypogonadism	2 (0.0)	0
Secondary hypothyroidism	0	1 (0.0)
Testicular failure	3 (0.0)	2 (0.0)
Thyroid calcification	1 (0.0)	0
Thyroid cyst	6 (0.0)	3 (0.0)
Thyroid disorder	3 (0.0)	1 (0.0)
Thyroid mass	23 (0.2)	20 (0.2)
Thyroid stimulating hormone deficiency	0	1 (0.0)
Thyroiditis	1 (0.0)	0
Thyroiditis subacute	0	1 (0.0)
Eye disorders	831 (6.4)	880 (6.7)
Amaurosis	1 (0.0)	1 (0.0)
Amblyopia	11 (0.1)	6 (0.0)
Angle closure glaucoma	1 (0.0)	0
Anisometropia	0	1 (0.0)
Astigmatism	42 (0.3)	49 (0.4)
Binocular eye movement disorder	1 (0.0)	0
Blepharitis	1 (0.0)	0
Blepharospasm	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Blindness	2 (0.0)	1 (0.0)
Blindness unilateral	11 (0.1)	10 (0.1)
Borderline glaucoma	1 (0.0)	2 (0.0)
Cataract	21 (0.2)	23 (0.2)
Chalazion	0	1 (0.0)
Chorioretinopathy	7 (0.1)	2 (0.0)
Conjunctival haemorrhage	0	1 (0.0)
Conjunctivitis allergic	9 (0.1)	5 (0.0)
Corneal degeneration	1 (0.0)	1 (0.0)
Corneal disorder	0	1 (0.0)
Corneal scar	0	1 (0.0)
Dacryostenosis acquired	2 (0.0)	2 (0.0)
Diabetic eye disease	1 (0.0)	0
Diabetic retinopathy	5 (0.0)	5 (0.0)
Diplopia	0	1 (0.0)
Dry eye	20 (0.2)	20 (0.2)
Entropion	0	1 (0.0)
Exophthalmos	0	1 (0.0)
Extraocular muscle paresis	0	1 (0.0)
Eye allergy	1 (0.0)	1 (0.0)
Eye disorder	0	1 (0.0)
Eye haemorrhage	1 (0.0)	0
Eye irritation	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Eye movement disorder	0	1 (0.0)
Eye pruritus	1 (0.0)	0
Eye swelling	0	1 (0.0)
Eyelid cyst	0	1 (0.0)
Eyelid ptosis	4 (0.0)	2 (0.0)
Giant papillary conjunctivitis	0	1 (0.0)
Glaucoma	29 (0.2)	42 (0.3)
Heterophoria	0	1 (0.0)
Hypermetropia	111 (0.8)	107 (0.8)
Iridocyclitis	0	1 (0.0)
Iridodialysis	0	1 (0.0)
Iris disorder	0	1 (0.0)
Iritis	1 (0.0)	3 (0.0)
Keratitis	1 (0.0)	1 (0.0)
Keratoconus	8 (0.1)	5 (0.0)
Lacrimal disorder	0	1 (0.0)
Macular degeneration	1 (0.0)	0
Maculopathy	2 (0.0)	2 (0.0)
Meibomian gland dysfunction	1 (0.0)	0
Mydriasis	2 (0.0)	0
Myopia	457 (3.5)	445 (3.4)
Necrotising retinitis	1 (0.0)	0
Ocular hypertension	2 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ocular rosacea	0	1 (0.0)
Open angle glaucoma	0	4 (0.0)
Optic disc drusen	1 (0.0)	0
Optic ischaemic neuropathy	0	1 (0.0)
Optic nerve cupping	0	1 (0.0)
Optic neuropathy	1 (0.0)	0
Pinguecula	1 (0.0)	0
Presbyopia	90 (0.7)	98 (0.7)
Pterygium	3 (0.0)	4 (0.0)
Punctate keratitis	2 (0.0)	0
Pupils unequal	0	1 (0.0)
Refraction disorder	1 (0.0)	5 (0.0)
Refractive amblyopia	0	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0
Retinal degeneration	2 (0.0)	0
Retinal detachment	11 (0.1)	9 (0.1)
Retinal disorder	1 (0.0)	0
Retinal scar	0	1 (0.0)
Retinal tear	3 (0.0)	2 (0.0)
Retinal vein occlusion	0	1 (0.0)
Retinopathy	1 (0.0)	0
Retinoschisis	0	1 (0.0)
Strabismus	14 (0.1)	21 (0.2)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Uveitis	2 (0.0)	2 (0.0)
Vision blurred	2 (0.0)	3 (0.0)
Visual acuity reduced	49 (0.4)	65 (0.5)
Visual impairment	7 (0.1)	20 (0.2)
Vitreous degeneration	1 (0.0)	0
Vitreous detachment	2 (0.0)	0
Vitreous floaters	2 (0.0)	1 (0.0)
Gastrointestinal disorders	1573 (12.0)	1561 (11.9)
Abdominal adhesions	0	1 (0.0)
Abdominal distension	2 (0.0)	5 (0.0)
Abdominal fat apron	1 (0.0)	0
Abdominal hernia	19 (0.1)	22 (0.2)
Abdominal mass	1 (0.0)	0
Abdominal migraine	1 (0.0)	1 (0.0)
Abdominal pain	15 (0.1)	11 (0.1)
Abdominal pain lower	1 (0.0)	2 (0.0)
Abdominal pain upper	8 (0.1)	4 (0.0)
Abdominal tenderness	1 (0.0)	0
Acquired oesophageal web	1 (0.0)	2 (0.0)
Anal fissure	3 (0.0)	4 (0.0)
Anal fistula	3 (0.0)	8 (0.1)
Anal prolapse	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Anal skin tags	1 (0.0)	0
Anogenital dysplasia	1 (0.0)	1 (0.0)
Aphthous ulcer	5 (0.0)	3 (0.0)
Appendicitis noninfective	0	1 (0.0)
Barrett's oesophagus	8 (0.1)	11 (0.1)
Bile acid malabsorption	1 (0.0)	1 (0.0)
Cannabinoid hyperemesis syndrome	0	1 (0.0)
Chronic gastritis	8 (0.1)	10 (0.1)
Coeliac disease	27 (0.2)	32 (0.2)
Colitis	5 (0.0)	3 (0.0)
Colitis ischaemic	0	1 (0.0)
Colitis microscopic	1 (0.0)	2 (0.0)
Colitis ulcerative	12 (0.1)	16 (0.1)
Constipation	78 (0.6)	72 (0.5)
Crohn's disease	8 (0.1)	9 (0.1)
Dental caries	4 (0.0)	9 (0.1)
Diaphragmatic hernia	3 (0.0)	1 (0.0)
Diarrhoea	26 (0.2)	24 (0.2)
Diverticulum	23 (0.2)	16 (0.1)
Diverticulum intestinal	3 (0.0)	4 (0.0)
Dry mouth	2 (0.0)	0
Dumping syndrome	0	1 (0.0)
Duodenal ulcer	2 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Duodenogastric reflux	2 (0.0)	2 (0.0)
Dyspepsia	150 (1.1)	142 (1.1)
Dysphagia	8 (0.1)	6 (0.0)
Enlarged uvula	0	1 (0.0)
Enterovesical fistula	1 (0.0)	0
Eosinophilic oesophagitis	7 (0.1)	9 (0.1)
Epigastric discomfort	1 (0.0)	0
Epiploic appendagitis	0	1 (0.0)
Erosive oesophagitis	1 (0.0)	0
Femoral hernia	2 (0.0)	1 (0.0)
Flatulence	2 (0.0)	1 (0.0)
Food poisoning	1 (0.0)	4 (0.0)
Functional gastrointestinal disorder	1 (0.0)	0
Gastric disorder	3 (0.0)	1 (0.0)
Gastric haemorrhage	0	1 (0.0)
Gastric ileus	1 (0.0)	0
Gastric mucosal lesion	1 (0.0)	0
Gastric polyps	0	1 (0.0)
Gastric ulcer	17 (0.1)	18 (0.1)
Gastric ulcer perforation	0	1 (0.0)
Gastritis	43 (0.3)	45 (0.3)
Gastritis erosive	1 (0.0)	1 (0.0)
Gastroenteritis eosinophilic	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Gastrointestinal disorder	2 (0.0)	2 (0.0)
Gastrointestinal haemorrhage	4 (0.0)	4 (0.0)
Gastrointestinal hypomotility	1 (0.0)	1 (0.0)
Gastrointestinal inflammation	0	1 (0.0)
Gastrointestinal necrosis	1 (0.0)	0
Gastrointestinal pain	2 (0.0)	2 (0.0)
Gastrointestinal scarring	0	1 (0.0)
Gastroesophageal reflux disease	781 (6.0)	775 (5.9)
Gingival discomfort	0	1 (0.0)
Gingival recession	1 (0.0)	3 (0.0)
Haematochezia	2 (0.0)	0
Haemorrhoids	57 (0.4)	67 (0.5)
Haemorrhoids thrombosed	1 (0.0)	0
Hiatus hernia	27 (0.2)	46 (0.4)
Hyperaesthesia teeth	1 (0.0)	0
Impaired gastric emptying	10 (0.1)	9 (0.1)
Inflammatory bowel disease	1 (0.0)	1 (0.0)
Inguinal hernia	83 (0.6)	93 (0.7)
Intestinal cyst	1 (0.0)	0
Intestinal obstruction	5 (0.0)	4 (0.0)
Intestinal perforation	1 (0.0)	2 (0.0)
Intestinal polyp	1 (0.0)	0
Intestinal prolapse	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Intestinal strangulation	1 (0.0)	0
Intussusception	0	1 (0.0)
Irritable bowel syndrome	164 (1.3)	152 (1.2)
Large intestinal obstruction	1 (0.0)	1 (0.0)
Large intestine perforation	2 (0.0)	0
Large intestine polyp	16 (0.1)	16 (0.1)
Lumbar hernia	3 (0.0)	4 (0.0)
Malabsorption	2 (0.0)	0
Malocclusion	4 (0.0)	3 (0.0)
Mouth ulceration	2 (0.0)	3 (0.0)
Nausea	11 (0.1)	15 (0.1)
Necrotising colitis	1 (0.0)	0
Noninfective sialoadenitis	2 (0.0)	0
Obstruction gastric	0	1 (0.0)
Oesophageal achalasia	2 (0.0)	2 (0.0)
Oesophageal disorder	1 (0.0)	0
Oesophageal perforation	0	1 (0.0)
Oesophageal spasm	1 (0.0)	1 (0.0)
Oesophageal stenosis	3 (0.0)	2 (0.0)
Oesophageal ulcer	2 (0.0)	0
Oesophagitis	9 (0.1)	11 (0.1)
Pancreatic failure	0	2 (0.0)
Pancreatitis	14 (0.1)	7 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Pancreatitis acute	3 (0.0)	0
Pancreatitis chronic	3 (0.0)	4 (0.0)
Pancreatitis necrotising	0	1 (0.0)
Pelvic floor dysfunction	2 (0.0)	1 (0.0)
Peptic ulcer	4 (0.0)	9 (0.1)
Periodontal disease	0	1 (0.0)
Peritoneal cyst	0	1 (0.0)
Proctitis ulcerative	1 (0.0)	2 (0.0)
Rectal fissure	2 (0.0)	1 (0.0)
Rectal haemorrhage	4 (0.0)	3 (0.0)
Rectal polyp	0	1 (0.0)
Rectal prolapse	1 (0.0)	2 (0.0)
Reflux gastritis	1 (0.0)	0
Salivary gland calculus	0	1 (0.0)
Salivary gland cyst	1 (0.0)	0
Salivary gland disorder	0	1 (0.0)
Short-bowel syndrome	2 (0.0)	0
Small intestinal obstruction	3 (0.0)	0
Stomatitis	1 (0.0)	1 (0.0)
Superior mesenteric artery syndrome	0	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tooth impacted	30 (0.2)	19 (0.1)
Tooth loss	2 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Toothache	5 (0.0)	9 (0.1)
Umbilical hernia	52 (0.4)	59 (0.5)
Upper gastrointestinal haemorrhage	1 (0.0)	0
Volvulus	1 (0.0)	3 (0.0)
Vomiting	4 (0.0)	1 (0.0)
General disorders and administration site conditions	161 (1.2)	161 (1.2)
Adverse drug reaction	7 (0.1)	5 (0.0)
Application site vesicles	0	1 (0.0)
Asthenia	0	1 (0.0)
Calcinosis	0	1 (0.0)
Chest discomfort	0	1 (0.0)
Chest pain	8 (0.1)	8 (0.1)
Chronic fatigue syndrome	1 (0.0)	3 (0.0)
Cyst	9 (0.1)	11 (0.1)
Cyst rupture	1 (0.0)	0
Discomfort	0	2 (0.0)
Disease susceptibility	0	1 (0.0)
Drug intolerance	23 (0.2)	24 (0.2)
Dysplasia	1 (0.0)	0
Face oedema	1 (0.0)	0
Fat tissue increased	0	1 (0.0)
Fatigue	17 (0.1)	19 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Feeling abnormal	1 (0.0)	0
Generalised oedema	1 (0.0)	0
Hernia	21 (0.2)	17 (0.1)
Hyperplasia	2 (0.0)	0
Inflammation	2 (0.0)	0
Injection site erythema	0	1 (0.0)
Injection site swelling	0	1 (0.0)
Injury associated with device	1 (0.0)	0
Lithiasis	0	1 (0.0)
Localised oedema	0	1 (0.0)
Medical device site scar	0	1 (0.0)
Nodule	0	1 (0.0)
Oedema	5 (0.0)	6 (0.0)
Oedema peripheral	17 (0.1)	21 (0.2)
Pain	32 (0.2)	30 (0.2)
Perforated ulcer	2 (0.0)	0
Peripheral swelling	4 (0.0)	0
Polyp	1 (0.0)	1 (0.0)
Precancerous condition	2 (0.0)	1 (0.0)
Pyrexia	1 (0.0)	0
Surgical failure	0	1 (0.0)
Temperature intolerance	1 (0.0)	0
Treatment noncompliance	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ulcer	1 (0.0)	0
Vaccination site reaction	0	1 (0.0)
Vaccination site swelling	1 (0.0)	0
Vascular stent occlusion	0	1 (0.0)
Xerosis	1 (0.0)	0
Hepatobiliary disorders	348 (2.7)	369 (2.8)
Bile duct stone	2 (0.0)	2 (0.0)
Biliary colic	5 (0.0)	0
Biliary cyst	0	1 (0.0)
Biliary dyskinesia	2 (0.0)	1 (0.0)
Biliary polyp	0	1 (0.0)
Biliary tract disorder	2 (0.0)	0
Cholecystitis	74 (0.6)	88 (0.7)
Cholecystitis acute	2 (0.0)	1 (0.0)
Cholelithiasis	178 (1.4)	191 (1.5)
Cholelithiasis obstructive	1 (0.0)	0
Cholestasis	1 (0.0)	1 (0.0)
Cirrhosis alcoholic	0	1 (0.0)
Gallbladder disorder	28 (0.2)	27 (0.2)
Gallbladder hypofunction	4 (0.0)	2 (0.0)
Gallbladder obstruction	0	1 (0.0)
Gallbladder oedema	2 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Gallbladder polyp	1 (0.0)	4 (0.0)
Hepatic cirrhosis	5 (0.0)	1 (0.0)
Hepatic cyst	0	1 (0.0)
Hepatic function abnormal	0	1 (0.0)
Hepatic lesion	1 (0.0)	0
Hepatic mass	0	3 (0.0)
Hepatic steatosis	40 (0.3)	36 (0.3)
Hepatitis	0	1 (0.0)
Hepatitis alcoholic	0	1 (0.0)
Hepatomegaly	2 (0.0)	1 (0.0)
Hepatorenal syndrome	0	1 (0.0)
Hyperbilirubinaemia	1 (0.0)	1 (0.0)
Jaundice	0	1 (0.0)
Liver disorder	1 (0.0)	3 (0.0)
Non-alcoholic steatohepatitis	3 (0.0)	3 (0.0)
Nonalcoholic fatty liver disease	7 (0.1)	7 (0.1)
Immune system disorders	3238 (24.8)	3285 (25.1)
Allergic oedema	5 (0.0)	2 (0.0)
Allergy to animal	87 (0.7)	90 (0.7)
Allergy to arthropod bite	0	3 (0.0)
Allergy to arthropod sting	32 (0.2)	36 (0.3)
Allergy to chemicals	10 (0.1)	11 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Allergy to metals	12 (0.1)	15 (0.1)
Allergy to plants	14 (0.1)	18 (0.1)
Allergy to surgical sutures	0	2 (0.0)
Allergy to synthetic fabric	1 (0.0)	0
Allergy to vaccine	6 (0.0)	4 (0.0)
Amyloidosis	1 (0.0)	0
Anaphylactic reaction	10 (0.1)	8 (0.1)
Anaphylactic shock	1 (0.0)	0
Atopy	1 (0.0)	2 (0.0)
Cockroach allergy	1 (0.0)	0
Contrast media allergy	13 (0.1)	12 (0.1)
Contrast media reaction	0	1 (0.0)
Drug hypersensitivity	1360 (10.4)	1310 (10.0)
Dust allergy	21 (0.2)	31 (0.2)
Flour sensitivity	0	1 (0.0)
Food allergy	244 (1.9)	259 (2.0)
Hypersensitivity	118 (0.9)	117 (0.9)
Iodine allergy	21 (0.2)	29 (0.2)
Milk allergy	9 (0.1)	18 (0.1)
Mite allergy	19 (0.1)	15 (0.1)
Multiple allergies	13 (0.1)	14 (0.1)
Mycotic allergy	16 (0.1)	12 (0.1)
Oral allergy syndrome	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Perennial allergy	17 (0.1)	20 (0.2)
Perfume sensitivity	1 (0.0)	2 (0.0)
Reaction to colouring	3 (0.0)	4 (0.0)
Reaction to food additive	4 (0.0)	4 (0.0)
Reaction to preservatives	0	1 (0.0)
Rubber sensitivity	60 (0.5)	75 (0.6)
Sarcoidosis	7 (0.1)	4 (0.0)
Seasonal allergy	1888 (14.4)	1931 (14.7)
Smoke sensitivity	1 (0.0)	0
Sunscreen sensitivity	0	1 (0.0)
Infections and infestations	1173 (9.0)	1072 (8.2)
Abscess limb	1 (0.0)	0
Abscess neck	1 (0.0)	0
Abscess soft tissue	0	1 (0.0)
Acarodermatitis	0	1 (0.0)
Actinomycosis	0	1 (0.0)
Acute sinusitis	1 (0.0)	3 (0.0)
Adenoiditis	9 (0.1)	11 (0.1)
American trypanosomiasis	2 (0.0)	1 (0.0)
Anorectal human papilloma virus infection	0	1 (0.0)
Appendicitis	221 (1.7)	197 (1.5)
Appendicitis perforated	4 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Arthritis bacterial	1 (0.0)	3 (0.0)
Arthritis infective	0	2 (0.0)
Asymptomatic HIV infection	1 (0.0)	1 (0.0)
Atypical pneumonia	1 (0.0)	0
Babesiosis	0	1 (0.0)
Bacterial allergy	0	1 (0.0)
Bacterial infection	1 (0.0)	0
Bacterial tracheitis	1 (0.0)	0
Bacterial vaginosis	3 (0.0)	3 (0.0)
Bacterial vulvovaginitis	1 (0.0)	0
Bartonellosis	0	1 (0.0)
Body tinea	0	1 (0.0)
Bone abscess	1 (0.0)	0
Brain abscess	0	1 (0.0)
Breast abscess	2 (0.0)	0
Bronchitis	19 (0.1)	14 (0.1)
COVID-19	1 (0.0)	0
Candida infection	1 (0.0)	2 (0.0)
Cat scratch disease	3 (0.0)	2 (0.0)
Cellulitis	6 (0.0)	5 (0.0)
Cellulitis orbital	0	1 (0.0)
Cervicitis human papilloma virus	2 (0.0)	1 (0.0)
Chikungunya virus infection	5 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
System Organ Class Preferred Term		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
		n ^b (%)	n ^b (%)
Chlamydial infection		12 (0.1)	9 (0.1)
Cholecystitis infective		0	1 (0.0)
Chronic hepatitis B		1 (0.0)	0
Chronic sinusitis		40 (0.3)	35 (0.3)
Chronic tonsillitis		5 (0.0)	6 (0.0)
Clostridial infection		1 (0.0)	0
Clostridium difficile colitis		3 (0.0)	1 (0.0)
Clostridium difficile infection		1 (0.0)	1 (0.0)
Coccidioidomycosis		2 (0.0)	0
Conjunctivitis		2 (0.0)	0
Conjunctivitis viral		0	1 (0.0)
Croup infectious		0	1 (0.0)
Cyclosporidium infection		0	1 (0.0)
Cystitis		1 (0.0)	2 (0.0)
Cytomegalovirus hepatitis		0	1 (0.0)
Dengue fever		4 (0.0)	7 (0.1)
Dermatophytosis		0	1 (0.0)
Device related infection		1 (0.0)	0
Diverticulitis		26 (0.2)	24 (0.2)
Ear infection		31 (0.2)	25 (0.2)
Eczema infected		1 (0.0)	0
Encephalitis		0	1 (0.0)
Encephalomyelitis		1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Endocarditis	1 (0.0)	1 (0.0)
Enterobiasis	1 (0.0)	0
Epididymitis	2 (0.0)	0
Epstein-Barr virus infection	0	1 (0.0)
Escherichia infection	0	1 (0.0)
Escherichia sepsis	0	1 (0.0)
Eye infection	0	1 (0.0)
Eye infection toxoplasmal	0	1 (0.0)
Eyelid infection	1 (0.0)	0
Folliculitis	5 (0.0)	6 (0.0)
Fracture infection	1 (0.0)	0
Fungal infection	6 (0.0)	2 (0.0)
Fungal skin infection	2 (0.0)	4 (0.0)
Furuncle	1 (0.0)	2 (0.0)
Gastroenteritis	2 (0.0)	4 (0.0)
Gastroenteritis norovirus	1 (0.0)	0
Gastroenteritis viral	0	1 (0.0)
Gastrointestinal bacterial overgrowth	0	1 (0.0)
Gastrointestinal infection	0	2 (0.0)
Genital herpes	29 (0.2)	27 (0.2)
Genital herpes simplex	11 (0.1)	7 (0.1)
Genitourinary chlamydia infection	0	1 (0.0)
Giardiasis	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Gingivitis	0	2 (0.0)
Gonorrhoea	2 (0.0)	1 (0.0)
Groin infection	1 (0.0)	0
HIV infection	13 (0.1)	16 (0.1)
Hand-foot-and-mouth disease	0	1 (0.0)
Helicobacter gastritis	5 (0.0)	1 (0.0)
Helicobacter infection	2 (0.0)	6 (0.0)
Hepatitis A	13 (0.1)	13 (0.1)
Hepatitis B	5 (0.0)	4 (0.0)
Hepatitis C	8 (0.1)	9 (0.1)
Herpes dermatitis	1 (0.0)	0
Herpes ophthalmic	0	1 (0.0)
Herpes simplex	73 (0.6)	77 (0.6)
Herpes virus infection	12 (0.1)	6 (0.0)
Herpes zoster	44 (0.3)	39 (0.3)
Histoplasmosis	1 (0.0)	0
Hordeolum	2 (0.0)	2 (0.0)
Human ehrlichiosis	0	1 (0.0)
Impetigo	0	1 (0.0)
Infected cyst	0	2 (0.0)
Infected dermal cyst	1 (0.0)	0
Infectious mononucleosis	5 (0.0)	5 (0.0)
Infective myositis	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Infective tenosynovitis	1 (0.0)	0
Influenza	2 (0.0)	3 (0.0)
Joint abscess	0	1 (0.0)
Kidney infection	2 (0.0)	5 (0.0)
Labyrinthitis	4 (0.0)	5 (0.0)
Laryngitis	1 (0.0)	0
Latent tuberculosis	7 (0.1)	5 (0.0)
Localised infection	1 (0.0)	2 (0.0)
Lyme disease	4 (0.0)	12 (0.1)
Lymph gland infection	0	1 (0.0)
Lymph node abscess	1 (0.0)	0
Mastitis	0	4 (0.0)
Mastoiditis	0	2 (0.0)
Mediastinitis	1 (0.0)	0
Meningitis	3 (0.0)	5 (0.0)
Meningitis aseptic	1 (0.0)	0
Meningitis herpes	0	1 (0.0)
Meningitis viral	3 (0.0)	2 (0.0)
Myringitis	1 (0.0)	1 (0.0)
Nasopharyngitis	2 (0.0)	2 (0.0)
Oesophagitis bacterial	1 (0.0)	0
Onychomycosis	20 (0.2)	25 (0.2)
Ophthalmic herpes simplex	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ophthalmic herpes zoster	0	1 (0.0)
Oral candidiasis	0	1 (0.0)
Oral herpes	58 (0.4)	52 (0.4)
Oral infection	1 (0.0)	0
Osteomyelitis	4 (0.0)	3 (0.0)
Otitis externa	2 (0.0)	2 (0.0)
Otitis media	7 (0.1)	8 (0.1)
Otitis media acute	1 (0.0)	1 (0.0)
Otitis media chronic	4 (0.0)	3 (0.0)
Overgrowth bacterial	0	1 (0.0)
Papilloma viral infection	9 (0.1)	5 (0.0)
Parasite allergy	1 (0.0)	0
Paronychia	0	2 (0.0)
Parotitis	0	1 (0.0)
Pelvic infection	0	1 (0.0)
Pelvic inflammatory disease	1 (0.0)	2 (0.0)
Periodontal destruction	1 (0.0)	0
Perirectal abscess	0	1 (0.0)
Peritonitis	3 (0.0)	2 (0.0)
Peritonsillar abscess	2 (0.0)	0
Pertussis	1 (0.0)	2 (0.0)
Pharyngitis	4 (0.0)	4 (0.0)
Pharyngitis streptococcal	16 (0.1)	12 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Pharyngotonsillitis	0	1 (0.0)
Pilonidal cyst	9 (0.1)	10 (0.1)
Pleurisy viral	0	1 (0.0)
Pneumonia	41 (0.3)	29 (0.2)
Pneumonia adenoviral	0	1 (0.0)
Pneumonia bacterial	1 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0
Pneumonia viral	1 (0.0)	0
Post procedural sepsis	0	1 (0.0)
Postoperative abscess	1 (0.0)	0
Presumed ocular histoplasmosis syndrome	0	1 (0.0)
Pulmonary tuberculosis	4 (0.0)	2 (0.0)
Pyelonephritis	3 (0.0)	3 (0.0)
Rectal abscess	1 (0.0)	0
Respiratory syncytial virus infection	1 (0.0)	1 (0.0)
Respiratory tract infection	1 (0.0)	0
Rhinitis	21 (0.2)	11 (0.1)
Rocky mountain spotted fever	1 (0.0)	0
Root canal infection	0	1 (0.0)
Rubella	0	1 (0.0)
Salpingitis	2 (0.0)	1 (0.0)
Scarlet fever	2 (0.0)	2 (0.0)
Scrotal infection	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Sepsis	3 (0.0)	2 (0.0)
Sepsis syndrome	1 (0.0)	0
Septic arthritis staphylococcal	2 (0.0)	0
Septic shock	0	1 (0.0)
Sinusitis	57 (0.4)	50 (0.4)
Sinusitis fungal	1 (0.0)	1 (0.0)
Skin bacterial infection	2 (0.0)	0
Skin infection	0	2 (0.0)
Staphylococcal infection	10 (0.1)	11 (0.1)
Staphylococcal skin infection	1 (0.0)	1 (0.0)
Streptococcal infection	6 (0.0)	1 (0.0)
Subcutaneous abscess	2 (0.0)	0
Syphilis	5 (0.0)	5 (0.0)
Tinea pedis	9 (0.1)	3 (0.0)
Tinea versicolour	15 (0.1)	10 (0.1)
Tonsillitis	209 (1.6)	192 (1.5)
Tonsillitis streptococcal	1 (0.0)	0
Tooth abscess	1 (0.0)	3 (0.0)
Tooth infection	2 (0.0)	3 (0.0)
Toxic shock syndrome	1 (0.0)	1 (0.0)
Trichomoniasis	2 (0.0)	0
Tuberculosis	7 (0.1)	3 (0.0)
Tuberculous pleurisy	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Typhoid fever	1 (0.0)	0
Typhus	0	1 (0.0)
Upper respiratory tract infection	5 (0.0)	3 (0.0)
Urinary tract infection	43 (0.3)	51 (0.4)
Urinary tract infection bacterial	1 (0.0)	1 (0.0)
Urosepsis	1 (0.0)	0
Vaginal infection	2 (0.0)	2 (0.0)
Vaginitis chlamydial	0	2 (0.0)
Vaginitis gardnerella	1 (0.0)	0
Varicella	6 (0.0)	4 (0.0)
Varicella zoster virus infection	1 (0.0)	0
Viral infection	3 (0.0)	0
Viral myocarditis	0	1 (0.0)
Vulval abscess	1 (0.0)	0
Vulvitis	1 (0.0)	0
Vulvovaginal candidiasis	1 (0.0)	5 (0.0)
Vulvovaginal mycotic infection	4 (0.0)	2 (0.0)
West Nile viral infection	0	1 (0.0)
Injury, poisoning and procedural complications	745 (5.7)	752 (5.7)
Abdominal injury	2 (0.0)	1 (0.0)
Accident	0	1 (0.0)
Accidental poisoning	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Acetabulum fracture	0	1 (0.0)
Alcohol poisoning	0	1 (0.0)
Animal bite	0	1 (0.0)
Animal scratch	1 (0.0)	0
Ankle fracture	44 (0.3)	49 (0.4)
Arterial injury	0	2 (0.0)
Arthropod bite	3 (0.0)	4 (0.0)
Avulsion fracture	0	1 (0.0)
Back injury	11 (0.1)	8 (0.1)
Bladder injury	0	1 (0.0)
Blindness traumatic	0	1 (0.0)
Brachial plexus injury	1 (0.0)	0
Burns second degree	2 (0.0)	0
Burns third degree	0	2 (0.0)
Bursa injury	0	1 (0.0)
Cartilage injury	27 (0.2)	30 (0.2)
Cataract traumatic	0	1 (0.0)
Cervical vertebral fracture	6 (0.0)	2 (0.0)
Clavicle fracture	21 (0.2)	25 (0.2)
Concussion	18 (0.1)	10 (0.1)
Contusion	0	2 (0.0)
Corneal abrasion	0	2 (0.0)
Craniocerebral injury	6 (0.0)	7 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Dislocation of vertebra	1 (0.0)	0
Epicondylitis	6 (0.0)	8 (0.1)
Epiphyseal fracture	0	1 (0.0)
Exposure to communicable disease	1 (0.0)	3 (0.0)
Eye injury	2 (0.0)	4 (0.0)
Face injury	2 (0.0)	1 (0.0)
Facial bones fracture	21 (0.2)	27 (0.2)
Fall	2 (0.0)	2 (0.0)
Fascial rupture	1 (0.0)	0
Femoral neck fracture	0	1 (0.0)
Femur fracture	16 (0.1)	15 (0.1)
Fibula fracture	11 (0.1)	10 (0.1)
Foot fracture	36 (0.3)	29 (0.2)
Forearm fracture	7 (0.1)	5 (0.0)
Foreign body	1 (0.0)	1 (0.0)
Foreign body in ear	0	1 (0.0)
Foreign body in eye	0	1 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0
Fracture	0	1 (0.0)
Fractured coccyx	2 (0.0)	4 (0.0)
Gastrointestinal injury	0	1 (0.0)
Gastrointestinal procedural complication	0	1 (0.0)
Gun shot wound	5 (0.0)	6 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Hand fracture	44 (0.3)	47 (0.4)
Head injury	5 (0.0)	13 (0.1)
Hip fracture	4 (0.0)	6 (0.0)
Humerus fracture	6 (0.0)	6 (0.0)
Hyphaema	0	1 (0.0)
Iliotibial band syndrome	0	3 (0.0)
Ilium fracture	0	1 (0.0)
Incisional hernia	4 (0.0)	3 (0.0)
Injury	0	1 (0.0)
Injury to brachial plexus due to birth trauma	0	1 (0.0)
Intentional overdose	0	1 (0.0)
Intentional product misuse	0	1 (0.0)
Intervertebral disc injury	3 (0.0)	1 (0.0)
Jaw fracture	7 (0.1)	6 (0.0)
Joint dislocation	20 (0.2)	22 (0.2)
Joint injury	16 (0.1)	30 (0.2)
Ligament injury	6 (0.0)	9 (0.1)
Ligament rupture	85 (0.7)	78 (0.6)
Ligament sprain	7 (0.1)	8 (0.1)
Limb fracture	1 (0.0)	1 (0.0)
Limb injury	25 (0.2)	20 (0.2)
Limb traumatic amputation	1 (0.0)	1 (0.0)
Lisfranc fracture	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Lower limb fracture	28 (0.2)	16 (0.1)
Lumbar vertebral fracture	7 (0.1)	3 (0.0)
Mallet finger	0	1 (0.0)
Maternal drugs affecting foetus	1 (0.0)	0
Meniscus injury	87 (0.7)	78 (0.6)
Multiple fractures	0	1 (0.0)
Multiple injuries	1 (0.0)	0
Muscle injury	1 (0.0)	4 (0.0)
Muscle rupture	10 (0.1)	5 (0.0)
Muscle strain	13 (0.1)	9 (0.1)
Musculoskeletal foreign body	1 (0.0)	1 (0.0)
Nail injury	0	1 (0.0)
Nasal injury	2 (0.0)	3 (0.0)
Neck injury	4 (0.0)	4 (0.0)
Nerve injury	2 (0.0)	4 (0.0)
Overdose	2 (0.0)	0
Pancreatic injury	1 (0.0)	0
Patella fracture	7 (0.1)	1 (0.0)
Pelvic fracture	5 (0.0)	2 (0.0)
Penetrating abdominal trauma	1 (0.0)	0
Penis injury	0	1 (0.0)
Peripheral nerve injury	1 (0.0)	6 (0.0)
Persistent corneal epithelial defect	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Pneumothorax traumatic	1 (0.0)	0
Post ablation tubal sterilisation syndrome	1 (0.0)	0
Post concussion syndrome	1 (0.0)	0
Post laminectomy syndrome	0	1 (0.0)
Post procedural complication	1 (0.0)	0
Post procedural diarrhoea	0	1 (0.0)
Post procedural hypothyroidism	6 (0.0)	2 (0.0)
Post procedural pulmonary embolism	0	1 (0.0)
Post-traumatic neck syndrome	2 (0.0)	0
Post-traumatic pain	1 (0.0)	0
Postoperative adhesion	1 (0.0)	0
Procedural pain	3 (0.0)	3 (0.0)
Procedural pneumothorax	1 (0.0)	0
Radius fracture	10 (0.1)	9 (0.1)
Repetitive strain injury	2 (0.0)	1 (0.0)
Respiratory fume inhalation disorder	0	1 (0.0)
Retinal injury	0	1 (0.0)
Rib fracture	6 (0.0)	5 (0.0)
Road traffic accident	16 (0.1)	21 (0.2)
Scar	32 (0.2)	35 (0.3)
Sciatic nerve injury	2 (0.0)	0
Sinus barotrauma	0	1 (0.0)
Skeletal injury	4 (0.0)	5 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Skin injury	0	2 (0.0)
Skin laceration	8 (0.1)	11 (0.1)
Skull fracture	1 (0.0)	4 (0.0)
Skull fractured base	1 (0.0)	1 (0.0)
Snake bite	1 (0.0)	0
Spinal column injury	1 (0.0)	1 (0.0)
Spinal compression fracture	3 (0.0)	2 (0.0)
Spinal cord injury	1 (0.0)	1 (0.0)
Spinal cord injury cervical	1 (0.0)	0
Spinal cord injury thoracic	0	1 (0.0)
Spinal fracture	4 (0.0)	5 (0.0)
Splenic rupture	3 (0.0)	1 (0.0)
Sports injury	1 (0.0)	0
Stab wound	1 (0.0)	0
Sternal fracture	1 (0.0)	1 (0.0)
Stress fracture	0	6 (0.0)
Subarachnoid haematoma	1 (0.0)	0
Subdural haematoma	1 (0.0)	2 (0.0)
Suture rupture	1 (0.0)	0
Tendon injury	5 (0.0)	3 (0.0)
Tendon rupture	27 (0.2)	31 (0.2)
Testicular injury	1 (0.0)	1 (0.0)
Thermal burn	3 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Thermal burns of eye	0	1 (0.0)
Thoracic vertebral fracture	1 (0.0)	1 (0.0)
Tibia fracture	19 (0.1)	18 (0.1)
Tooth fracture	1 (0.0)	1 (0.0)
Traumatic arthritis	3 (0.0)	1 (0.0)
Traumatic ear amputation	1 (0.0)	0
Traumatic haematoma	1 (0.0)	1 (0.0)
Traumatic lung injury	0	3 (0.0)
Traumatic renal injury	2 (0.0)	0
Ulna fracture	3 (0.0)	10 (0.1)
Ulnar nerve injury	0	1 (0.0)
Upper limb fracture	36 (0.3)	45 (0.3)
Uterine perforation	1 (0.0)	0
Uterine rupture	1 (0.0)	0
Wrist fracture	39 (0.3)	46 (0.4)
Investigations	587 (4.5)	563 (4.3)
Alanine aminotransferase increased	2 (0.0)	0
Angiocardigram	0	1 (0.0)
Angiogram	1 (0.0)	2 (0.0)
Anti-platelet antibody positive	1 (0.0)	0
Anti-thyroid antibody positive	1 (0.0)	0
Antinuclear antibody positive	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Aortic bruit	0	1 (0.0)
Apolipoprotein E	1 (0.0)	0
Arthroscopy	47 (0.4)	59 (0.5)
Aspiration bone marrow	1 (0.0)	0
Aspiration breast	1 (0.0)	0
Aspiration joint	0	2 (0.0)
Aspiration pleural cavity	0	2 (0.0)
Biopsy	1 (0.0)	3 (0.0)
Biopsy bone marrow	0	1 (0.0)
Biopsy breast	5 (0.0)	10 (0.1)
Biopsy breast normal	5 (0.0)	3 (0.0)
Biopsy cervix	1 (0.0)	5 (0.0)
Biopsy cervix abnormal	1 (0.0)	0
Biopsy cervix normal	2 (0.0)	0
Biopsy colon	2 (0.0)	2 (0.0)
Biopsy endometrium normal	1 (0.0)	1 (0.0)
Biopsy liver	1 (0.0)	2 (0.0)
Biopsy liver normal	1 (0.0)	0
Biopsy lung	0	1 (0.0)
Biopsy lymph gland	2 (0.0)	1 (0.0)
Biopsy pharynx normal	1 (0.0)	0
Biopsy prostate	0	3 (0.0)
Biopsy site unspecified normal	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Biopsy skin	2 (0.0)	4 (0.0)
Biopsy thyroid gland	0	1 (0.0)
Biopsy uterus	1 (0.0)	0
Blood bilirubin increased	1 (0.0)	1 (0.0)
Blood cholesterol	0	1 (0.0)
Blood cholesterol increased	160 (1.2)	154 (1.2)
Blood cholinesterase decreased	0	1 (0.0)
Blood creatine phosphokinase increased	0	1 (0.0)
Blood glucose	1 (0.0)	0
Blood glucose abnormal	1 (0.0)	0
Blood glucose increased	4 (0.0)	2 (0.0)
Blood iron decreased	2 (0.0)	2 (0.0)
Blood oestrogen	0	1 (0.0)
Blood oestrogen decreased	2 (0.0)	0
Blood oestrogen increased	2 (0.0)	0
Blood potassium decreased	2 (0.0)	1 (0.0)
Blood pressure diastolic increased	1 (0.0)	1 (0.0)
Blood pressure increased	10 (0.1)	8 (0.1)
Blood prolactin increased	1 (0.0)	1 (0.0)
Blood testosterone	0	1 (0.0)
Blood testosterone decreased	54 (0.4)	57 (0.4)
Blood thyroid stimulating hormone abnormal	1 (0.0)	0
Blood thyroid stimulating hormone decreased	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Blood thyroid stimulating hormone increased	0	1 (0.0)
Blood triglycerides	1 (0.0)	0
Blood triglycerides increased	16 (0.1)	10 (0.1)
Blood uric acid increased	1 (0.0)	1 (0.0)
Blood zinc decreased	1 (0.0)	0
Body mass index decreased	0	1 (0.0)
Body mass index increased	0	1 (0.0)
Bronchoscopy	2 (0.0)	3 (0.0)
Cardiac murmur	42 (0.3)	28 (0.2)
Cardiac murmur functional	0	2 (0.0)
Cardiac stress test	0	1 (0.0)
Catheterisation cardiac	3 (0.0)	3 (0.0)
Chlamydia test positive	0	1 (0.0)
Coagulation factor V level	1 (0.0)	1 (0.0)
Coagulation factor VIII level decreased	0	1 (0.0)
Colonoscopy	42 (0.3)	29 (0.2)
Colonoscopy normal	1 (0.0)	1 (0.0)
Colposcopy	3 (0.0)	2 (0.0)
Colposcopy normal	0	1 (0.0)
Cystoscopy	1 (0.0)	4 (0.0)
Cystoscopy normal	0	1 (0.0)
Dehydroepiandrosterone increased	1 (0.0)	0
Diagnostic aspiration	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Diagnostic procedure	2 (0.0)	0
Discogram	1 (0.0)	0
Ejection fraction decreased	1 (0.0)	0
Electrocardiogram QT prolonged	1 (0.0)	1 (0.0)
Electrocardiogram ST segment depression	1 (0.0)	0
Electrocardiogram abnormal	1 (0.0)	0
Endoscopy	6 (0.0)	4 (0.0)
Endoscopy upper gastrointestinal tract	6 (0.0)	4 (0.0)
Epstein-Barr virus test positive	0	1 (0.0)
False positive investigation result	0	1 (0.0)
Gene mutation identification test positive	0	1 (0.0)
Glycosylated haemoglobin increased	1 (0.0)	0
HIV test positive	60 (0.5)	52 (0.4)
HLA marker study	0	2 (0.0)
HLA-B*27 positive	1 (0.0)	1 (0.0)
Haemoglobin decreased	0	1 (0.0)
Heart rate increased	1 (0.0)	2 (0.0)
Heart rate irregular	9 (0.1)	9 (0.1)
Helicobacter test positive	1 (0.0)	0
Hepatic enzyme abnormal	1 (0.0)	0
Hepatic enzyme increased	8 (0.1)	2 (0.0)
Hepatitis A antibody positive	1 (0.0)	0
Hepatitis B antibody positive	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Hepatitis B surface antibody positive	0	1 (0.0)
Hepatitis B test negative	0	1 (0.0)
Hepatitis C core antibody negative	0	1 (0.0)
Hepatitis C test negative	0	1 (0.0)
High density lipoprotein decreased	4 (0.0)	1 (0.0)
Hormone level abnormal	0	3 (0.0)
Human papilloma virus test	0	1 (0.0)
Human papilloma virus test positive	24 (0.2)	23 (0.2)
Hysteroscopy	5 (0.0)	4 (0.0)
Intraocular pressure increased	0	1 (0.0)
Laparoscopy	15 (0.1)	11 (0.1)
Lipids increased	2 (0.0)	3 (0.0)
Lipoprotein (a) increased	0	1 (0.0)
Liver function test abnormal	0	1 (0.0)
Liver function test increased	8 (0.1)	2 (0.0)
Low density lipoprotein increased	0	1 (0.0)
Lumbar puncture	0	1 (0.0)
Lumbar puncture normal	1 (0.0)	0
Magnetic resonance imaging	0	1 (0.0)
Mammogram abnormal	3 (0.0)	0
Mean cell volume increased	0	1 (0.0)
Mediastinoscopy	0	2 (0.0)
Mumps antibody test positive	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Mycobacterium tuberculosis complex test negative	1 (0.0)	0
Mycobacterium tuberculosis complex test positive	2 (0.0)	0
Nasoendoscopy	1 (0.0)	1 (0.0)
Oesophagogastrroduodenoscopy	2 (0.0)	2 (0.0)
Oesophagoscopy	1 (0.0)	0
Pelvic laparoscopy	2 (0.0)	0
Precancerous cells present	4 (0.0)	8 (0.1)
Progesterone decreased	0	3 (0.0)
Prostatic specific antigen increased	2 (0.0)	1 (0.0)
Pulmonary function test decreased	0	1 (0.0)
Red blood cell count increased	0	1 (0.0)
Serum ferritin decreased	1 (0.0)	1 (0.0)
Serum ferritin increased	0	1 (0.0)
Sigmoidoscopy	0	1 (0.0)
Sleep study	1 (0.0)	0
Smear cervix abnormal	19 (0.1)	10 (0.1)
Streptococcus test positive	0	1 (0.0)
Thyroid function test abnormal	0	1 (0.0)
Transaminases increased	2 (0.0)	0
Tuberculin test	0	1 (0.0)
Tuberculin test positive	3 (0.0)	3 (0.0)
Vitamin B12 decreased	1 (0.0)	0
Vitamin D abnormal	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Vitamin D decreased	4 (0.0)	9 (0.1)
Weight decreased	3 (0.0)	1 (0.0)
Weight increased	3 (0.0)	0
White blood cell count decreased	1 (0.0)	1 (0.0)
White blood cell count increased	1 (0.0)	0
X-ray	1 (0.0)	0
Metabolism and nutrition disorders	2414 (18.5)	2357 (18.0)
Abnormal loss of weight	0	1 (0.0)
Abnormal weight gain	0	1 (0.0)
Calcium deficiency	0	2 (0.0)
Central obesity	2 (0.0)	0
Cholesterosis	1 (0.0)	0
Dairy intolerance	2 (0.0)	0
Decreased appetite	1 (0.0)	2 (0.0)
Dehydration	1 (0.0)	2 (0.0)
Diabetes mellitus	13 (0.1)	10 (0.1)
Diabetes mellitus inadequate control	1 (0.0)	0
Diabetic ketoacidosis	1 (0.0)	1 (0.0)
Disaccharide metabolism disorder	1 (0.0)	0
Dyslipidaemia	158 (1.2)	121 (0.9)
Fluid retention	8 (0.1)	5 (0.0)
Folate deficiency	0	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
System Organ Class Preferred Term	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)	
	n ^b (%)	n ^b (%)	
Food intolerance	1 (0.0)	2 (0.0)	
Fructose intolerance	1 (0.0)	0	
Glucose tolerance impaired	80 (0.6)	74 (0.6)	
Gluten sensitivity	17 (0.1)	15 (0.1)	
Gout	54 (0.4)	59 (0.5)	
Haemochromatosis	7 (0.1)	0	
Histamine intolerance	0	1 (0.0)	
Hypercalcaemia	2 (0.0)	0	
Hypercholesterolaemia	322 (2.5)	320 (2.4)	
Hyperglycaemia	10 (0.1)	9 (0.1)	
Hyperhomocysteinaemia	1 (0.0)	0	
Hyperinsulinaemia	0	1 (0.0)	
Hyperinsulinism	1 (0.0)	0	
Hyperkalaemia	1 (0.0)	0	
Hyperlactacidaemia	0	1 (0.0)	
Hyperlipidaemia	322 (2.5)	311 (2.4)	
Hypernatraemia	1 (0.0)	0	
Hyperphagia	1 (0.0)	0	
Hypertriglyceridaemia	40 (0.3)	30 (0.2)	
Hyperuricaemia	7 (0.1)	8 (0.1)	
Hypocalcaemia	0	1 (0.0)	
Hypocholesterolaemia	5 (0.0)	2 (0.0)	
Hypoglycaemia	9 (0.1)	3 (0.0)	

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Hypokalaemia	6 (0.0)	9 (0.1)
Hypolipidaemia	0	1 (0.0)
Hypomagnesaemia	0	1 (0.0)
Hyponatraemia	1 (0.0)	0
Hypovitaminosis	1 (0.0)	2 (0.0)
Impaired fasting glucose	11 (0.1)	3 (0.0)
Insulin resistance	7 (0.1)	9 (0.1)
Insulin resistant diabetes	0	1 (0.0)
Iron deficiency	10 (0.1)	19 (0.1)
Iron metabolism disorder	0	1 (0.0)
Lactose intolerance	43 (0.3)	50 (0.4)
Latent autoimmune diabetes in adults	1 (0.0)	0
Lipid metabolism disorder	0	1 (0.0)
Lipoedema	1 (0.0)	0
Lipomatosis	0	1 (0.0)
Malnutrition	1 (0.0)	0
Metabolic acidosis	1 (0.0)	0
Metabolic disorder	1 (0.0)	0
Metabolic syndrome	12 (0.1)	2 (0.0)
Monogenic diabetes	0	1 (0.0)
Obesity	1013 (7.8)	1001 (7.6)
Overweight	180 (1.4)	200 (1.5)
Refeeding syndrome	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Type 1 diabetes mellitus	63 (0.5)	53 (0.4)
Type 2 diabetes mellitus	405 (3.1)	419 (3.2)
Underweight	2 (0.0)	6 (0.0)
Vitamin A deficiency	2 (0.0)	0
Vitamin B complex deficiency	3 (0.0)	2 (0.0)
Vitamin B12 deficiency	24 (0.2)	21 (0.2)
Vitamin D deficiency	152 (1.2)	138 (1.1)
Vitamin E deficiency	1 (0.0)	0
Musculoskeletal and connective tissue disorders	1382 (10.6)	1355 (10.3)
Ankle impingement	0	1 (0.0)
Ankylosing spondylitis	2 (0.0)	2 (0.0)
Arthralgia	168 (1.3)	195 (1.5)
Arthritis	60 (0.5)	49 (0.4)
Arthritis reactive	1 (0.0)	1 (0.0)
Arthropathy	5 (0.0)	5 (0.0)
Articular calcification	0	1 (0.0)
Back disorder	1 (0.0)	1 (0.0)
Back pain	374 (2.9)	360 (2.7)
Bone cyst	3 (0.0)	3 (0.0)
Bone deformity	0	1 (0.0)
Bone disorder	0	1 (0.0)
Bone hypertrophy	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Bone lesion	1 (0.0)	0
Bursitis	14 (0.1)	14 (0.1)
CREST syndrome	0	1 (0.0)
Cervical spinal stenosis	1 (0.0)	2 (0.0)
Chondromalacia	2 (0.0)	0
Chondropathy	3 (0.0)	2 (0.0)
Coccydynia	1 (0.0)	0
Compartment syndrome	3 (0.0)	3 (0.0)
Connective tissue disorder	0	1 (0.0)
Costochondritis	2 (0.0)	1 (0.0)
Deformity thorax	1 (0.0)	0
Diastasis recti abdominis	1 (0.0)	0
Diffuse idiopathic skeletal hyperostosis	1 (0.0)	0
Dupuytren's contracture	1 (0.0)	2 (0.0)
Dwarfism	1 (0.0)	0
Eagle's syndrome	1 (0.0)	0
Epiphysiolysis	1 (0.0)	0
Exostosis	25 (0.2)	16 (0.1)
Facet joint syndrome	3 (0.0)	0
Femoroacetabular impingement	1 (0.0)	2 (0.0)
Fibromyalgia	70 (0.5)	47 (0.4)
Fistula	1 (0.0)	0
Flank pain	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Floating patella	0	1 (0.0)
Foot deformity	32 (0.2)	36 (0.3)
Fracture nonunion	0	1 (0.0)
Growth retardation	0	1 (0.0)
Hypermobility syndrome	4 (0.0)	3 (0.0)
Intervertebral disc compression	2 (0.0)	6 (0.0)
Intervertebral disc degeneration	56 (0.4)	38 (0.3)
Intervertebral disc disorder	6 (0.0)	1 (0.0)
Intervertebral disc displacement	0	1 (0.0)
Intervertebral disc protrusion	140 (1.1)	108 (0.8)
Jaw cyst	1 (0.0)	0
Jaw disorder	2 (0.0)	2 (0.0)
Joint effusion	0	1 (0.0)
Joint instability	2 (0.0)	2 (0.0)
Joint range of motion decreased	0	1 (0.0)
Joint stiffness	1 (0.0)	0
Joint swelling	2 (0.0)	4 (0.0)
Juvenile idiopathic arthritis	2 (0.0)	1 (0.0)
Knee deformity	0	1 (0.0)
Kyphosis	1 (0.0)	2 (0.0)
Ligament disorder	1 (0.0)	1 (0.0)
Ligament laxity	1 (0.0)	1 (0.0)
Limb asymmetry	3 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Limb deformity	0	1 (0.0)
Limb mass	1 (0.0)	1 (0.0)
Lordosis	0	1 (0.0)
Lumbar spinal stenosis	6 (0.0)	3 (0.0)
Metatarsalgia	0	1 (0.0)
Mobility decreased	0	2 (0.0)
Morphoea	1 (0.0)	0
Muscle atrophy	1 (0.0)	1 (0.0)
Muscle contracture	0	1 (0.0)
Muscle disorder	0	1 (0.0)
Muscle spasms	40 (0.3)	54 (0.4)
Muscle tightness	2 (0.0)	2 (0.0)
Muscle twitching	1 (0.0)	0
Muscular weakness	2 (0.0)	1 (0.0)
Musculoskeletal chest pain	3 (0.0)	1 (0.0)
Musculoskeletal disorder	1 (0.0)	0
Musculoskeletal pain	1 (0.0)	1 (0.0)
Musculoskeletal stiffness	1 (0.0)	1 (0.0)
Myalgia	42 (0.3)	58 (0.4)
Myalgia intercostal	0	1 (0.0)
Myofascial pain syndrome	3 (0.0)	3 (0.0)
Myositis	0	1 (0.0)
Neck mass	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Neck pain	47 (0.4)	53 (0.4)
Neuropathic arthropathy	1 (0.0)	0
Os trigonum syndrome	1 (0.0)	0
Osteitis	1 (0.0)	0
Osteitis deformans	0	1 (0.0)
Osteoarthritis	245 (1.9)	234 (1.8)
Osteochondritis	1 (0.0)	2 (0.0)
Osteochondrosis	11 (0.1)	6 (0.0)
Osteolysis	0	1 (0.0)
Osteonecrosis	4 (0.0)	4 (0.0)
Osteopenia	12 (0.1)	14 (0.1)
Osteoporosis	15 (0.1)	20 (0.2)
Pain in extremity	22 (0.2)	28 (0.2)
Pain in jaw	1 (0.0)	4 (0.0)
Patellofemoral pain syndrome	8 (0.1)	3 (0.0)
Periarthritis	5 (0.0)	5 (0.0)
Perthes disease	1 (0.0)	0
Plantar fascial fibromatosis	0	1 (0.0)
Plantar fasciitis	21 (0.2)	25 (0.2)
Plica syndrome	0	2 (0.0)
Polyarthritis	2 (0.0)	1 (0.0)
Posterior tibial tendon dysfunction	1 (0.0)	0
Prognathism	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Psoriatic arthropathy	1 (0.0)	4 (0.0)
Retrognathia	1 (0.0)	0
Reynold's syndrome	1 (0.0)	0
Rhabdomyolysis	2 (0.0)	3 (0.0)
Rheumatic fever	1 (0.0)	1 (0.0)
Rheumatoid arthritis	15 (0.1)	12 (0.1)
Rotator cuff syndrome	59 (0.5)	40 (0.3)
Sacroiliac joint dysfunction	1 (0.0)	0
Sacroiliitis	2 (0.0)	2 (0.0)
Scapular dyskinesis	1 (0.0)	0
Scleroderma	1 (0.0)	1 (0.0)
Scoliosis	44 (0.3)	48 (0.4)
Seronegative arthritis	1 (0.0)	1 (0.0)
Sjogren's syndrome	1 (0.0)	2 (0.0)
Soft tissue mass	0	1 (0.0)
Spinal deformity	0	2 (0.0)
Spinal disorder	8 (0.1)	4 (0.0)
Spinal flattening	0	1 (0.0)
Spinal osteoarthritis	44 (0.3)	39 (0.3)
Spinal pain	5 (0.0)	6 (0.0)
Spinal stenosis	9 (0.1)	8 (0.1)
Spondylitis	5 (0.0)	9 (0.1)
Spondyloarthropathy	2 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Spondylolisthesis	6 (0.0)	6 (0.0)
Spondylolysis	4 (0.0)	0
Symphysiolysis	0	1 (0.0)
Synovial cyst	13 (0.1)	13 (0.1)
Synovitis	0	1 (0.0)
Systemic lupus erythematosus	2 (0.0)	1 (0.0)
Temporomandibular joint syndrome	26 (0.2)	21 (0.2)
Tendon disorder	3 (0.0)	2 (0.0)
Tendon laxity	0	2 (0.0)
Tendon pain	2 (0.0)	1 (0.0)
Tendonitis	27 (0.2)	29 (0.2)
Tenosynovitis	2 (0.0)	1 (0.0)
Tenosynovitis stenosans	1 (0.0)	3 (0.0)
Torticollis	1 (0.0)	2 (0.0)
Trigger finger	10 (0.1)	7 (0.1)
Vertebral foraminal stenosis	0	1 (0.0)
Vertebral osteophyte	0	2 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	487 (3.7)	492 (3.8)
Abdominal neoplasm	1 (0.0)	0
Abdominal wall neoplasm	0	1 (0.0)
Acoustic neuroma	2 (0.0)	1 (0.0)
Acute lymphocytic leukaemia	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Adenocarcinoma of the cervix	0	1 (0.0)
Adenoid cystic carcinoma	1 (0.0)	0
Adenoma benign	3 (0.0)	2 (0.0)
Adrenal adenoma	2 (0.0)	2 (0.0)
Adrenal neoplasm	0	1 (0.0)
Angiomyolipoma	0	1 (0.0)
Anogenital warts	1 (0.0)	3 (0.0)
Appendix cancer	1 (0.0)	0
Astrocytoma	1 (0.0)	0
B-cell lymphoma	1 (0.0)	0
Basal cell carcinoma	41 (0.3)	41 (0.3)
Basosquamous carcinoma	0	1 (0.0)
Basosquamous carcinoma of skin	0	1 (0.0)
Benign bone neoplasm	1 (0.0)	2 (0.0)
Benign breast neoplasm	10 (0.1)	10 (0.1)
Benign cardiac neoplasm	0	1 (0.0)
Benign hydatidiform mole	1 (0.0)	0
Benign lung neoplasm	0	2 (0.0)
Benign muscle neoplasm	1 (0.0)	0
Benign neoplasm	3 (0.0)	3 (0.0)
Benign neoplasm of adrenal gland	0	1 (0.0)
Benign neoplasm of bladder	1 (0.0)	0
Benign neoplasm of eye	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Benign neoplasm of skin	3 (0.0)	3 (0.0)
Benign neoplasm of thyroid gland	11 (0.1)	15 (0.1)
Benign ovarian tumour	2 (0.0)	1 (0.0)
Benign uterine neoplasm	1 (0.0)	1 (0.0)
Benign vascular neoplasm	0	1 (0.0)
Bladder cancer	1 (0.0)	0
Bowen's disease	0	1 (0.0)
Brain neoplasm	1 (0.0)	0
Brain neoplasm benign	1 (0.0)	1 (0.0)
Brain neoplasm malignant	1 (0.0)	0
Breast cancer	31 (0.2)	29 (0.2)
Breast cancer metastatic	1 (0.0)	0
Breast cancer stage I	1 (0.0)	1 (0.0)
Breast fibroma	2 (0.0)	0
Breast neoplasm	1 (0.0)	2 (0.0)
Carcinoid tumour	1 (0.0)	0
Carcinoid tumour of the gastrointestinal tract	1 (0.0)	0
Cervix carcinoma	6 (0.0)	6 (0.0)
Cervix carcinoma stage 0	1 (0.0)	0
Cholesteatoma	2 (0.0)	3 (0.0)
Chronic lymphocytic leukaemia	1 (0.0)	0
Colon adenoma	3 (0.0)	1 (0.0)
Colon cancer	3 (0.0)	4 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Colon cancer stage II	0	1 (0.0)
Colon cancer stage III	1 (0.0)	0
Cutaneous T-cell lymphoma	0	1 (0.0)
Desmoplastic melanoma	0	1 (0.0)
Dysplastic naevus	1 (0.0)	2 (0.0)
Ear neoplasm malignant	0	1 (0.0)
Elastofibroma	1 (0.0)	0
Enchondromatosis	0	1 (0.0)
Endometrial cancer	0	1 (0.0)
Essential thrombocythaemia	2 (0.0)	0
Ewing's sarcoma	0	1 (0.0)
Extragenital primary seminoma (pure)	0	1 (0.0)
Eye naevus	0	1 (0.0)
Eyelid haemangioma	1 (0.0)	0
Fibroadenoma of breast	3 (0.0)	8 (0.1)
Fibroma	4 (0.0)	3 (0.0)
Fibrosarcoma	1 (0.0)	0
Fibrous histiocyoma	1 (0.0)	1 (0.0)
Ganglioneuroblastoma	0	1 (0.0)
Gastric neoplasm	1 (0.0)	0
Gastrointestinal melanoma	1 (0.0)	0
Gastrointestinal tract adenoma	1 (0.0)	0
Gestational trophoblastic tumour	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Haemangioma	1 (0.0)	5 (0.0)
Haemangioma of spleen	1 (0.0)	0
Hepatic adenoma	1 (0.0)	1 (0.0)
Hodgkin's disease	4 (0.0)	6 (0.0)
Intraductal proliferative breast lesion	0	3 (0.0)
Intraocular melanoma	1 (0.0)	0
Iris melanoma	0	1 (0.0)
Langerhans' cell histiocytosis	1 (0.0)	0
Laryngeal papilloma	1 (0.0)	0
Leiomyoma	2 (0.0)	3 (0.0)
Leukaemia	3 (0.0)	2 (0.0)
Lip and/or oral cavity cancer	1 (0.0)	0
Lip squamous cell carcinoma	1 (0.0)	0
Lipoma	14 (0.1)	16 (0.1)
Lipoma of breast	1 (0.0)	0
Lobular breast carcinoma in situ	1 (0.0)	0
Lung adenocarcinoma	1 (0.0)	0
Lung neoplasm malignant	0	1 (0.0)
Lymphangioma	1 (0.0)	0
Lymphoma	0	3 (0.0)
Malignant melanoma	26 (0.2)	10 (0.1)
Malignant melanoma in situ	2 (0.0)	1 (0.0)
Malignant melanoma stage I	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Melanocytic naevus	9 (0.1)	12 (0.1)
Meningioma	3 (0.0)	5 (0.0)
Meningioma benign	2 (0.0)	1 (0.0)
Nasopharyngeal cancer	1 (0.0)	0
Neoplasm	0	3 (0.0)
Neoplasm malignant	0	2 (0.0)
Neoplasm of appendix	1 (0.0)	0
Nephroblastoma	1 (0.0)	1 (0.0)
Nervous system neoplasm benign	0	1 (0.0)
Neurilemmoma benign	0	1 (0.0)
Neurofibroma	1 (0.0)	0
Neuroma	5 (0.0)	4 (0.0)
Non-Hodgkin's lymphoma	2 (0.0)	2 (0.0)
Oesophageal adenocarcinoma	1 (0.0)	0
Osteochondroma	0	3 (0.0)
Osteoma	0	1 (0.0)
Osteosarcoma	0	2 (0.0)
Ovarian cancer	1 (0.0)	4 (0.0)
Ovarian cancer stage III	0	1 (0.0)
Ovarian cancer stage IV	1 (0.0)	0
Ovarian fibroma	2 (0.0)	0
Ovarian germ cell teratoma	1 (0.0)	0
Ovarian germ cell teratoma benign	0	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ovarian neoplasm	1 (0.0)	1 (0.0)
Papillary thyroid cancer	5 (0.0)	8 (0.1)
Parathyroid tumour benign	1 (0.0)	2 (0.0)
Phaeochromocytoma	0	1 (0.0)
Phyllodes tumour	1 (0.0)	0
Pineal germinoma	0	1 (0.0)
Pituitary tumour	0	2 (0.0)
Pituitary tumour benign	8 (0.1)	9 (0.1)
Pleural neoplasm	0	1 (0.0)
Prolactin-producing pituitary tumour	1 (0.0)	2 (0.0)
Prostate cancer	5 (0.0)	8 (0.1)
Rectal cancer	0	1 (0.0)
Renal cancer	3 (0.0)	1 (0.0)
Renal cell carcinoma	1 (0.0)	0
Renal hamartoma	1 (0.0)	1 (0.0)
Renal neoplasm	1 (0.0)	0
Retinoblastoma	1 (0.0)	1 (0.0)
Salivary gland neoplasm	0	1 (0.0)
Sarcoma	0	1 (0.0)
Schwannoma	0	1 (0.0)
Seborrhoeic keratosis	0	2 (0.0)
Skin cancer	2 (0.0)	2 (0.0)
Skin papilloma	10 (0.1)	5 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Soft tissue sarcoma	0	1 (0.0)
Spinal cord neoplasm	0	1 (0.0)
Squamous cell carcinoma	9 (0.1)	4 (0.0)
Squamous cell carcinoma of lung	1 (0.0)	0
Squamous cell carcinoma of skin	3 (0.0)	4 (0.0)
Sweat gland tumour	0	1 (0.0)
Synovial sarcoma	0	1 (0.0)
Testis cancer	11 (0.1)	9 (0.1)
Thymoma	1 (0.0)	0
Thyroid cancer	19 (0.1)	22 (0.2)
Thyroid neoplasm	0	2 (0.0)
Tongue neoplasm	0	1 (0.0)
Uterine cancer	4 (0.0)	2 (0.0)
Uterine leiomyoma	159 (1.2)	161 (1.2)
Uterine neoplasm	1 (0.0)	0
Vulval cancer	2 (0.0)	1 (0.0)
Vulvovaginal warts	1 (0.0)	0
Xanthogranuloma	1 (0.0)	0
Nervous system disorders	1466 (11.2)	1450 (11.1)
Akathisia	1 (0.0)	0
Amnesia	2 (0.0)	5 (0.0)
Anosmia	2 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Arachnoid cyst	5 (0.0)	1 (0.0)
Arachnoiditis	0	1 (0.0)
Autonomic nervous system imbalance	0	1 (0.0)
Balance disorder	0	1 (0.0)
Brachial plexopathy	1 (0.0)	0
Brain injury	2 (0.0)	1 (0.0)
Brain stem stroke	1 (0.0)	0
Carotid arterial embolus	0	1 (0.0)
Carotid arteriosclerosis	1 (0.0)	1 (0.0)
Carotid artery dissection	3 (0.0)	1 (0.0)
Carotid artery stenosis	3 (0.0)	0
Carpal tunnel syndrome	62 (0.5)	64 (0.5)
Central auditory processing disorder	2 (0.0)	0
Cerebellar infarction	1 (0.0)	0
Cerebellar stroke	2 (0.0)	0
Cerebral atrophy	1 (0.0)	0
Cerebral cyst	1 (0.0)	0
Cerebral haemorrhage	1 (0.0)	1 (0.0)
Cerebral venous sinus thrombosis	0	1 (0.0)
Cerebral venous thrombosis	1 (0.0)	0
Cerebrospinal fluid leakage	0	1 (0.0)
Cerebrovascular accident	22 (0.2)	18 (0.1)
Cervical radiculopathy	6 (0.0)	7 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Cervicobrachial syndrome	1 (0.0)	0
Cervicogenic headache	0	1 (0.0)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	2 (0.0)
Circadian rhythm sleep disorder	1 (0.0)	0
Cluster headache	8 (0.1)	4 (0.0)
Cognitive disorder	0	1 (0.0)
Colloid brain cyst	0	1 (0.0)
Complex regional pain syndrome	1 (0.0)	2 (0.0)
Convulsive threshold lowered	0	1 (0.0)
Cramp-fasciculation syndrome	0	1 (0.0)
Cranial nerve disorder	0	1 (0.0)
Cubital tunnel syndrome	0	1 (0.0)
Diabetic neuropathy	16 (0.1)	14 (0.1)
Disturbance in attention	2 (0.0)	3 (0.0)
Dizziness	11 (0.1)	6 (0.0)
Drug withdrawal headache	1 (0.0)	0
Dyslexia	4 (0.0)	3 (0.0)
Dystonia	2 (0.0)	0
Encephalopathy	0	2 (0.0)
Epilepsy	32 (0.2)	35 (0.3)
Essential tremor	6 (0.0)	9 (0.1)
Extrapyramidal disorder	1 (0.0)	2 (0.0)
Facial nerve disorder	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Facial neuralgia	1 (0.0)	0
Facial paralysis	7 (0.1)	7 (0.1)
Febrile convulsion	4 (0.0)	2 (0.0)
Fine motor skill dysfunction	1 (0.0)	0
Focal dyscognitive seizures	0	1 (0.0)
Generalised tonic-clonic seizure	0	3 (0.0)
Glossopharyngeal neuralgia	1 (0.0)	0
Haemorrhagic stroke	1 (0.0)	3 (0.0)
Headache	352 (2.7)	366 (2.8)
Hemiparesis	1 (0.0)	3 (0.0)
Hemiplegia	0	2 (0.0)
Hemiplegic migraine	1 (0.0)	1 (0.0)
Hydrocephalus	2 (0.0)	6 (0.0)
Hypersomnia	7 (0.1)	7 (0.1)
Hypoaesthesia	4 (0.0)	6 (0.0)
Hyposmia	0	2 (0.0)
IVth nerve paralysis	1 (0.0)	0
Idiopathic generalised epilepsy	0	1 (0.0)
Idiopathic intracranial hypertension	1 (0.0)	3 (0.0)
Intention tremor	0	1 (0.0)
Intercostal neuralgia	0	1 (0.0)
Intracranial aneurysm	3 (0.0)	4 (0.0)
Intracranial mass	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Intracranial pressure increased	1 (0.0)	2 (0.0)
Irlen syndrome	1 (0.0)	0
Ischaemic stroke	2 (0.0)	1 (0.0)
Juvenile myoclonic epilepsy	0	1 (0.0)
Lumbar radiculopathy	8 (0.1)	10 (0.1)
Lumbosacral radiculopathy	0	1 (0.0)
Medication overuse headache	1 (0.0)	0
Memory impairment	1 (0.0)	0
Mental impairment	1 (0.0)	0
Migraine	631 (4.8)	666 (5.1)
Migraine with aura	16 (0.1)	15 (0.1)
Migraine without aura	19 (0.1)	14 (0.1)
Monoplegia	1 (0.0)	0
Morton's neuralgia	2 (0.0)	3 (0.0)
Multiple sclerosis	1 (0.0)	2 (0.0)
Muscle contractions involuntary	1 (0.0)	3 (0.0)
Myasthenia gravis	1 (0.0)	1 (0.0)
Narcolepsy	5 (0.0)	11 (0.1)
Nerve compression	13 (0.1)	8 (0.1)
Nervous system disorder	1 (0.0)	1 (0.0)
Neuralgia	19 (0.1)	7 (0.1)
Neuritis	1 (0.0)	1 (0.0)
Neuropathy peripheral	52 (0.4)	43 (0.3)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Nystagmus	2 (0.0)	2 (0.0)
Occipital neuralgia	2 (0.0)	1 (0.0)
Optic neuritis	2 (0.0)	1 (0.0)
Paraesthesia	4 (0.0)	6 (0.0)
Paraparesis	0	1 (0.0)
Paraplegia	0	1 (0.0)
Parkinson's disease	2 (0.0)	0
Paroxysmal choreoathetosis	0	1 (0.0)
Perineurial cyst	1 (0.0)	0
Periodic limb movement disorder	1 (0.0)	2 (0.0)
Peripheral nerve lesion	1 (0.0)	0
Peroneal nerve palsy	1 (0.0)	2 (0.0)
Petit mal epilepsy	0	2 (0.0)
Piriformis syndrome	2 (0.0)	0
Polyneuropathy	1 (0.0)	0
Post herpetic neuralgia	1 (0.0)	2 (0.0)
Post-traumatic epilepsy	0	1 (0.0)
Post-traumatic headache	1 (0.0)	2 (0.0)
Posterior reversible encephalopathy syndrome	0	1 (0.0)
Postural tremor	1 (0.0)	0
Presyncope	1 (0.0)	2 (0.0)
Psychomotor hyperactivity	0	3 (0.0)
Radial nerve compression	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Radiculopathy	5 (0.0)	3 (0.0)
Restless legs syndrome	38 (0.3)	46 (0.4)
Ruptured cerebral aneurysm	0	1 (0.0)
Sciatica	41 (0.3)	41 (0.3)
Seizure	25 (0.2)	21 (0.2)
Serotonin syndrome	1 (0.0)	1 (0.0)
Shift work disorder	3 (0.0)	1 (0.0)
Sinus headache	24 (0.2)	18 (0.1)
Sleep deficit	1 (0.0)	1 (0.0)
Somnolence	1 (0.0)	0
Spasmodic dysphonia	0	1 (0.0)
Speech disorder	0	1 (0.0)
Spinal cord disorder	1 (0.0)	0
Syncope	16 (0.1)	12 (0.1)
Tardive dyskinesia	2 (0.0)	1 (0.0)
Tarsal tunnel syndrome	4 (0.0)	1 (0.0)
Temporal lobe epilepsy	1 (0.0)	0
Tension headache	92 (0.7)	53 (0.4)
Thoracic outlet syndrome	0	3 (0.0)
Transient ischaemic attack	9 (0.1)	12 (0.1)
Tremor	6 (0.0)	3 (0.0)
Trigeminal nerve disorder	0	1 (0.0)
Trigeminal neuralgia	5 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Vertebral artery dissection	1 (0.0)	0
Vestibular migraine	1 (0.0)	3 (0.0)
Visual field defect	0	1 (0.0)
Vocal cord paralysis	0	1 (0.0)
Pregnancy, puerperium and perinatal conditions	93 (0.7)	103 (0.8)
Abnormal cord insertion	1 (0.0)	0
Abortion	5 (0.0)	2 (0.0)
Abortion incomplete	0	1 (0.0)
Abortion spontaneous	15 (0.1)	17 (0.1)
Breech presentation	1 (0.0)	1 (0.0)
Cephalo-pelvic disproportion	0	1 (0.0)
Complication of pregnancy	1 (0.0)	0
Delivery	33 (0.3)	32 (0.2)
Eclampsia	1 (0.0)	0
Ectopic pregnancy	12 (0.1)	16 (0.1)
Foetal death	0	1 (0.0)
Foetal distress syndrome	0	1 (0.0)
Gestational diabetes	10 (0.1)	14 (0.1)
Gestational hypertension	1 (0.0)	4 (0.0)
Habitual abortion	0	1 (0.0)
Intrapartum haemorrhage	0	1 (0.0)
Morning sickness	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Peripartum cardiomyopathy	1 (0.0)	0
Placenta accreta	1 (0.0)	1 (0.0)
Post abortion haemorrhage	0	1 (0.0)
Postpartum haemorrhage	2 (0.0)	3 (0.0)
Pre-eclampsia	8 (0.1)	5 (0.0)
Pregnancy	3 (0.0)	7 (0.1)
Premature baby	1 (0.0)	2 (0.0)
Premature labour	1 (0.0)	0
Premature separation of placenta	0	1 (0.0)
Stillbirth	0	1 (0.0)
Unintended pregnancy	0	1 (0.0)
Product issues	0	1 (0.0)
Device malfunction	0	1 (0.0)
Psychiatric disorders	2695 (20.6)	2819 (21.5)
Adjustment disorder	3 (0.0)	7 (0.1)
Adjustment disorder with depressed mood	6 (0.0)	5 (0.0)
Adjustment disorder with mixed anxiety and depressed mood	3 (0.0)	3 (0.0)
Aerophobia	0	1 (0.0)
Affect lability	0	1 (0.0)
Affective disorder	9 (0.1)	4 (0.0)
Aggression	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Alcohol abuse	8 (0.1)	9 (0.1)
Alcohol problem	0	1 (0.0)
Alcohol use disorder	1 (0.0)	2 (0.0)
Alcoholism	8 (0.1)	10 (0.1)
Anger	1 (0.0)	3 (0.0)
Anorexia nervosa	2 (0.0)	3 (0.0)
Anxiety	1208 (9.2)	1264 (9.7)
Anxiety disorder	94 (0.7)	87 (0.7)
Attention deficit hyperactivity disorder	486 (3.7)	458 (3.5)
Autism spectrum disorder	19 (0.1)	18 (0.1)
Behaviour disorder	1 (0.0)	1 (0.0)
Binge eating	3 (0.0)	7 (0.1)
Bipolar I disorder	4 (0.0)	5 (0.0)
Bipolar II disorder	15 (0.1)	9 (0.1)
Bipolar disorder	116 (0.9)	119 (0.9)
Borderline personality disorder	4 (0.0)	1 (0.0)
Bruxism	0	3 (0.0)
Bulimia nervosa	2 (0.0)	4 (0.0)
Chronic tic disorder	1 (0.0)	0
Cyclothymic disorder	1 (0.0)	2 (0.0)
Dependence	1 (0.0)	1 (0.0)
Depressed mood	2 (0.0)	0
Depression	1114 (8.5)	1133 (8.7)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Depression suicidal	0	1 (0.0)
Depressive symptom	1 (0.0)	0
Dissociative disorder	0	1 (0.0)
Drug abuse	12 (0.1)	14 (0.1)
Drug dependence	7 (0.1)	7 (0.1)
Drug use disorder	0	1 (0.0)
Dysphemia	0	2 (0.0)
Eating disorder	4 (0.0)	3 (0.0)
Encopresis	1 (0.0)	0
Enuresis	0	1 (0.0)
Gambling disorder	0	1 (0.0)
Gastrointestinal somatic symptom disorder	1 (0.0)	0
Gender dysphoria	5 (0.0)	2 (0.0)
Generalised anxiety disorder	71 (0.5)	81 (0.6)
Grief reaction	0	1 (0.0)
Hallucination	0	1 (0.0)
Initial insomnia	0	2 (0.0)
Insomnia	475 (3.6)	501 (3.8)
Intentional self-injury	1 (0.0)	0
Intermittent explosive disorder	0	1 (0.0)
Irritability	1 (0.0)	3 (0.0)
Libido decreased	7 (0.1)	4 (0.0)
Major depression	69 (0.5)	91 (0.7)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Mania	0	2 (0.0)
Mental disorder	3 (0.0)	3 (0.0)
Mood swings	1 (0.0)	1 (0.0)
Nicotine dependence	16 (0.1)	11 (0.1)
Nightmare	1 (0.0)	1 (0.0)
Obsessive-compulsive disorder	34 (0.3)	37 (0.3)
Obsessive-compulsive personality disorder	0	1 (0.0)
Obsessive-compulsive symptom	1 (0.0)	0
Oppositional defiant disorder	0	4 (0.0)
Panic attack	22 (0.2)	21 (0.2)
Panic disorder	13 (0.1)	7 (0.1)
Panic reaction	2 (0.0)	2 (0.0)
Parasomnia	0	1 (0.0)
Performance fear	1 (0.0)	0
Perinatal depression	14 (0.1)	16 (0.1)
Persistent depressive disorder	1 (0.0)	10 (0.1)
Personality disorder	0	1 (0.0)
Post-traumatic amnesic disorder	0	1 (0.0)
Post-traumatic stress disorder	82 (0.6)	83 (0.6)
Postpartum anxiety	2 (0.0)	0
Premature ejaculation	1 (0.0)	5 (0.0)
Psychotic disorder	2 (0.0)	2 (0.0)
Rapid eye movements sleep abnormal	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Restlessness	0	2 (0.0)
Schizoaffective disorder	5 (0.0)	2 (0.0)
Schizophrenia	17 (0.1)	19 (0.1)
Seasonal affective disorder	7 (0.1)	4 (0.0)
Selective eating disorder	1 (0.0)	1 (0.0)
Sleep disorder	12 (0.1)	19 (0.1)
Sleep disorder due to general medical condition, insomnia type	1 (0.0)	0
Sleep terror	2 (0.0)	1 (0.0)
Social anxiety disorder	7 (0.1)	1 (0.0)
Somatic symptom disorder	1 (0.0)	1 (0.0)
Somnambulism	0	1 (0.0)
Stress	2 (0.0)	2 (0.0)
Substance abuse	4 (0.0)	1 (0.0)
Substance dependence	1 (0.0)	1 (0.0)
Substance use disorder	1 (0.0)	0
Suicidal behaviour	1 (0.0)	0
Suicidal ideation	4 (0.0)	4 (0.0)
Suicide attempt	4 (0.0)	2 (0.0)
Tachyphrenia	0	1 (0.0)
Tic	2 (0.0)	2 (0.0)
Tobacco abuse	8 (0.1)	4 (0.0)
Trichotillomania	2 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Renal and urinary disorders	311 (2.4)	313 (2.4)
Acute kidney injury	2 (0.0)	1 (0.0)
Bladder disorder	0	1 (0.0)
Bladder diverticulum	1 (0.0)	0
Bladder dysfunction	0	1 (0.0)
Bladder irritation	0	1 (0.0)
Bladder malposition acquired	1 (0.0)	0
Bladder obstruction	1 (0.0)	1 (0.0)
Bladder perforation	0	1 (0.0)
Bladder prolapse	5 (0.0)	5 (0.0)
Bladder spasm	4 (0.0)	2 (0.0)
Bladder stenosis	1 (0.0)	0
Calculus bladder	0	2 (0.0)
Calculus urinary	0	3 (0.0)
Chronic kidney disease	13 (0.1)	12 (0.1)
Cystitis glandularis	0	1 (0.0)
Cystitis interstitial	7 (0.1)	2 (0.0)
Dysuria	3 (0.0)	4 (0.0)
End stage renal disease	1 (0.0)	0
Glomerulonephritis membranous	0	1 (0.0)
Haematuria	4 (0.0)	10 (0.1)
Hydronephrosis	3 (0.0)	1 (0.0)
Hypercalciuria	3 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Hypertonic bladder	35 (0.3)	33 (0.3)
IgA nephropathy	0	1 (0.0)
Incontinence	3 (0.0)	3 (0.0)
Lupus nephritis	0	1 (0.0)
Microalbuminuria	5 (0.0)	1 (0.0)
Micturition disorder	0	1 (0.0)
Micturition urgency	3 (0.0)	2 (0.0)
Mixed incontinence	1 (0.0)	0
Nephritis	0	1 (0.0)
Nephrolithiasis	163 (1.2)	162 (1.2)
Nephropathy	2 (0.0)	2 (0.0)
Nephrotic syndrome	1 (0.0)	2 (0.0)
Neurogenic bladder	0	2 (0.0)
Nocturia	11 (0.1)	10 (0.1)
Pollakiuria	4 (0.0)	6 (0.0)
Polyuria	0	1 (0.0)
Post streptococcal glomerulonephritis	1 (0.0)	0
Proteinuria	0	2 (0.0)
Reflux nephropathy	1 (0.0)	0
Renal atrophy	0	1 (0.0)
Renal colic	2 (0.0)	0
Renal cyst	4 (0.0)	6 (0.0)
Renal disorder	2 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Renal failure	1 (0.0)	3 (0.0)
Renal impairment	1 (0.0)	2 (0.0)
Renal necrosis	0	1 (0.0)
Single functional kidney	1 (0.0)	0
Stress urinary incontinence	13 (0.1)	9 (0.1)
Trigonitis	1 (0.0)	0
Ureteral disorder	1 (0.0)	0
Ureteric stenosis	1 (0.0)	2 (0.0)
Urethral dilatation	0	1 (0.0)
Urethral disorder	0	2 (0.0)
Urethral prolapse	0	1 (0.0)
Urethral stenosis	3 (0.0)	2 (0.0)
Urge incontinence	4 (0.0)	1 (0.0)
Urinary hesitation	2 (0.0)	0
Urinary incontinence	17 (0.1)	14 (0.1)
Urinary retention	2 (0.0)	6 (0.0)
Urogenital fistula	0	2 (0.0)
Urogenital haemorrhage	0	1 (0.0)
Vesicoureteric reflux	1 (0.0)	2 (0.0)
Reproductive system and breast disorders	754 (5.8)	749 (5.7)
Adenomyosis	7 (0.1)	9 (0.1)
Adnexa uteri cyst	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Amenorrhoea	15 (0.1)	8 (0.1)
Anisomastia	1 (0.0)	1 (0.0)
Atrophic vulvovaginitis	4 (0.0)	3 (0.0)
Azoospermia	1 (0.0)	1 (0.0)
Bartholin's cyst	1 (0.0)	1 (0.0)
Benign prostatic hyperplasia	31 (0.2)	39 (0.3)
Breast calcifications	1 (0.0)	0
Breast cyst	6 (0.0)	6 (0.0)
Breast enlargement	5 (0.0)	4 (0.0)
Breast mass	8 (0.1)	7 (0.1)
Breast pain	3 (0.0)	1 (0.0)
Breast swelling	1 (0.0)	0
Cervical cyst	2 (0.0)	0
Cervical dysplasia	13 (0.1)	12 (0.1)
Cervix disorder	0	1 (0.0)
Cystocele	0	1 (0.0)
Dysfunctional uterine bleeding	8 (0.1)	2 (0.0)
Dysmenorrhoea	66 (0.5)	79 (0.6)
Dyspareunia	4 (0.0)	2 (0.0)
Ectropion of cervix	1 (0.0)	0
Endometrial disorder	0	1 (0.0)
Endometrial hyperplasia	4 (0.0)	2 (0.0)
Endometrial thickening	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Endometriosis	108 (0.8)	91 (0.7)
Epididymal cyst	1 (0.0)	2 (0.0)
Erectile dysfunction	56 (0.4)	80 (0.6)
Fallopian tube adhesion	0	1 (0.0)
Fallopian tube cyst	0	1 (0.0)
Fallopian tube disorder	0	1 (0.0)
Fallopian tube obstruction	1 (0.0)	5 (0.0)
Female genital tract fistula	0	1 (0.0)
Fibrocystic breast disease	14 (0.1)	9 (0.1)
Genital lesion	0	1 (0.0)
Genital rash	1 (0.0)	0
Gynaecomastia	5 (0.0)	7 (0.1)
Infertility	10 (0.1)	9 (0.1)
Infertility female	4 (0.0)	7 (0.1)
Infertility male	2 (0.0)	1 (0.0)
Lactation puerperal increased	0	1 (0.0)
Mastoptosis	0	1 (0.0)
Menometrorrhagia	3 (0.0)	1 (0.0)
Menopausal symptoms	13 (0.1)	21 (0.2)
Menorrhagia	109 (0.8)	94 (0.7)
Menstrual discomfort	1 (0.0)	0
Menstrual disorder	12 (0.1)	17 (0.1)
Menstruation irregular	32 (0.2)	23 (0.2)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Metrorrhagia	3 (0.0)	4 (0.0)
Micromastia	1 (0.0)	0
Oligomenorrhoea	2 (0.0)	2 (0.0)
Oligospermia	1 (0.0)	0
Ovarian cyst	61 (0.5)	67 (0.5)
Ovarian cyst ruptured	2 (0.0)	1 (0.0)
Ovarian failure	0	3 (0.0)
Ovarian haemorrhage	1 (0.0)	0
Ovarian mass	1 (0.0)	1 (0.0)
Ovarian rupture	1 (0.0)	1 (0.0)
Ovulation pain	0	1 (0.0)
Pelvic pain	4 (0.0)	1 (0.0)
Perineal cyst	0	1 (0.0)
Peyronie's disease	0	1 (0.0)
Polycystic ovaries	103 (0.8)	92 (0.7)
Polymenorrhoea	1 (0.0)	0
Postmenopausal haemorrhage	0	1 (0.0)
Premature menopause	9 (0.1)	4 (0.0)
Premenstrual dysphoric disorder	8 (0.1)	8 (0.1)
Premenstrual headache	0	1 (0.0)
Premenstrual syndrome	5 (0.0)	5 (0.0)
Prostatic calcification	0	1 (0.0)
Prostatic disorder	2 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Prostatism	2 (0.0)	0
Prostatitis	4 (0.0)	2 (0.0)
Prostatomegaly	9 (0.1)	10 (0.1)
Rectocele	2 (0.0)	2 (0.0)
Sexual dysfunction	0	2 (0.0)
Testicular cyst	1 (0.0)	1 (0.0)
Testicular pain	2 (0.0)	0
Testicular swelling	0	1 (0.0)
Testicular torsion	4 (0.0)	5 (0.0)
Uterine adhesions	0	1 (0.0)
Uterine cyst	2 (0.0)	1 (0.0)
Uterine disorder	2 (0.0)	1 (0.0)
Uterine enlargement	1 (0.0)	1 (0.0)
Uterine haemorrhage	7 (0.1)	8 (0.1)
Uterine malposition	1 (0.0)	2 (0.0)
Uterine mass	0	1 (0.0)
Uterine polyp	10 (0.1)	11 (0.1)
Uterine prolapse	11 (0.1)	6 (0.0)
Vaginal cyst	0	1 (0.0)
Vaginal discharge	0	1 (0.0)
Vaginal haemorrhage	3 (0.0)	2 (0.0)
Varicocele	11 (0.1)	9 (0.1)
Varicose veins pelvic	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Vulval disorder	1 (0.0)	0
Vulvovaginal dryness	5 (0.0)	1 (0.0)
Vulvovaginal pain	1 (0.0)	0
Respiratory, thoracic and mediastinal disorders	1785 (13.7)	1818 (13.9)
Adenoidal hypertrophy	10 (0.1)	13 (0.1)
Allergic bronchitis	3 (0.0)	0
Allergic cough	1 (0.0)	3 (0.0)
Allergic pharyngitis	1 (0.0)	0
Allergic sinusitis	23 (0.2)	27 (0.2)
Apnoea	0	2 (0.0)
Asthma	860 (6.6)	853 (6.5)
Asthma exercise induced	61 (0.5)	34 (0.3)
Bronchial hyperreactivity	12 (0.1)	14 (0.1)
Bronchiectasis	1 (0.0)	2 (0.0)
Bronchitis chronic	13 (0.1)	7 (0.1)
Bronchospasm	7 (0.1)	5 (0.0)
Childhood asthma	10 (0.1)	16 (0.1)
Chronic obstructive pulmonary disease	36 (0.3)	36 (0.3)
Chronic respiratory failure	0	1 (0.0)
Cough	8 (0.1)	18 (0.1)
Cough variant asthma	0	2 (0.0)
Cystic lung disease	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Dysphonia	0	2 (0.0)
Dyspnoea	14 (0.1)	11 (0.1)
Dyspnoea exertional	0	2 (0.0)
Emphysema	4 (0.0)	8 (0.1)
Epistaxis	7 (0.1)	7 (0.1)
Glottal incompetence	0	1 (0.0)
Haemothorax	0	1 (0.0)
Hypoxia	0	1 (0.0)
Infantile apnoea	0	1 (0.0)
Laryngeal oedema	0	1 (0.0)
Laryngeal polyp	0	1 (0.0)
Laryngospasm	0	1 (0.0)
Nasal congestion	7 (0.1)	15 (0.1)
Nasal cyst	1 (0.0)	0
Nasal discomfort	1 (0.0)	0
Nasal obstruction	1 (0.0)	1 (0.0)
Nasal polyps	16 (0.1)	13 (0.1)
Nasal septum deviation	73 (0.6)	80 (0.6)
Nasal turbinate hypertrophy	1 (0.0)	5 (0.0)
Obliterative bronchiolitis	0	1 (0.0)
Oropharyngeal pain	4 (0.0)	5 (0.0)
Paranasal cyst	1 (0.0)	2 (0.0)
Paranasal sinus discomfort	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Paranasal sinus haemorrhage	1 (0.0)	0
Pharyngeal cyst	0	1 (0.0)
Pharyngeal polyp	1 (0.0)	1 (0.0)
Pleural effusion	1 (0.0)	2 (0.0)
Pleurisy	1 (0.0)	3 (0.0)
Pneumonitis	0	1 (0.0)
Pneumothorax	8 (0.1)	9 (0.1)
Pneumothorax spontaneous	8 (0.1)	4 (0.0)
Pulmonary calcification	1 (0.0)	0
Pulmonary embolism	10 (0.1)	14 (0.1)
Pulmonary fibrosis	0	1 (0.0)
Pulmonary hypertension	1 (0.0)	1 (0.0)
Pulmonary mass	0	1 (0.0)
Pulmonary oedema	0	2 (0.0)
Reflux laryngitis	0	4 (0.0)
Respiratory disorder	0	1 (0.0)
Respiratory failure	0	1 (0.0)
Respiratory tract congestion	0	1 (0.0)
Rhinitis allergic	540 (4.1)	530 (4.0)
Rhinitis perennial	17 (0.1)	18 (0.1)
Rhinorrhoea	4 (0.0)	1 (0.0)
Sinus congestion	14 (0.1)	9 (0.1)
Sinus disorder	1 (0.0)	7 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Sinus pain	0	1 (0.0)
Sinus polyp	3 (0.0)	5 (0.0)
Sleep apnoea syndrome	216 (1.7)	222 (1.7)
Sneezing	0	1 (0.0)
Snoring	3 (0.0)	2 (0.0)
Thoracic insufficiency syndrome	1 (0.0)	0
Throat clearing	0	1 (0.0)
Throat irritation	0	1 (0.0)
Throat tightness	0	1 (0.0)
Tonsillar disorder	1 (0.0)	0
Tonsillar hypertrophy	9 (0.1)	11 (0.1)
Tonsillar inflammation	1 (0.0)	3 (0.0)
Tonsillolith	3 (0.0)	1 (0.0)
Upper airway resistance syndrome	1 (0.0)	0
Upper-airway cough syndrome	1 (0.0)	4 (0.0)
Vocal cord dysfunction	0	1 (0.0)
Vocal cord polyp	1 (0.0)	2 (0.0)
Vocal cord thickening	1 (0.0)	1 (0.0)
Wheezing	4 (0.0)	3 (0.0)
Skin and subcutaneous tissue disorders	903 (6.9)	968 (7.4)
Acanthosis	1 (0.0)	0
Acanthosis nigricans	2 (0.0)	2 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Acne	281 (2.2)	273 (2.1)
Acne cystic	6 (0.0)	7 (0.1)
Actinic cheilitis	0	1 (0.0)
Actinic keratosis	3 (0.0)	9 (0.1)
Alopecia	64 (0.5)	66 (0.5)
Alopecia areata	2 (0.0)	4 (0.0)
Androgenetic alopecia	8 (0.1)	23 (0.2)
Angioedema	1 (0.0)	1 (0.0)
Angiokeratoma	0	1 (0.0)
Cafe au lait spots	1 (0.0)	0
Chloasma	1 (0.0)	3 (0.0)
Chronic spontaneous urticaria	2 (0.0)	5 (0.0)
Cold urticaria	2 (0.0)	1 (0.0)
Cutaneous lupus erythematosus	0	1 (0.0)
Dandruff	3 (0.0)	4 (0.0)
Decubitus ulcer	0	1 (0.0)
Dermal cyst	14 (0.1)	10 (0.1)
Dermatitis	13 (0.1)	11 (0.1)
Dermatitis acneiform	0	1 (0.0)
Dermatitis allergic	4 (0.0)	6 (0.0)
Dermatitis atopic	35 (0.3)	29 (0.2)
Dermatitis contact	30 (0.2)	52 (0.4)
Dermatomyositis	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Diabetic dermopathy	0	1 (0.0)
Diabetic foot	1 (0.0)	1 (0.0)
Diffuse alopecia	0	1 (0.0)
Drug eruption	18 (0.1)	20 (0.2)
Dry skin	5 (0.0)	4 (0.0)
Dyshidrotic eczema	1 (0.0)	5 (0.0)
Eczema	167 (1.3)	197 (1.5)
Eczema asteatotic	0	1 (0.0)
Eczema nummular	0	1 (0.0)
Erythema annulare	1 (0.0)	0
Granuloma annulare	1 (0.0)	2 (0.0)
Guttate psoriasis	0	1 (0.0)
Hand dermatitis	10 (0.1)	17 (0.1)
Henoch-Schonlein purpura	1 (0.0)	0
Hidradenitis	7 (0.1)	8 (0.1)
Hirsutism	6 (0.0)	3 (0.0)
Hyperhidrosis	16 (0.1)	7 (0.1)
Hyperkeratosis	6 (0.0)	1 (0.0)
Hypertrophic scar	1 (0.0)	0
Hypohidrosis	0	1 (0.0)
Hypotrichosis	0	1 (0.0)
Idiopathic urticaria	5 (0.0)	0
Ingrowing nail	4 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Ingrown hair	2 (0.0)	1 (0.0)
Intertrigo	1 (0.0)	0
Keloid scar	3 (0.0)	5 (0.0)
Keratosis pilaris	7 (0.1)	8 (0.1)
Lentigo	1 (0.0)	1 (0.0)
Lichen planus	1 (0.0)	1 (0.0)
Lichen sclerosus	2 (0.0)	3 (0.0)
Lichenification	0	1 (0.0)
Lichenoid keratosis	0	1 (0.0)
Madarosis	0	1 (0.0)
Mechanical urticaria	1 (0.0)	6 (0.0)
Miliaria	2 (0.0)	2 (0.0)
Nail bed disorder	0	1 (0.0)
Nail discolouration	1 (0.0)	0
Neurodermatitis	4 (0.0)	1 (0.0)
Night sweats	2 (0.0)	3 (0.0)
Palmoplantar keratoderma	1 (0.0)	0
Peau d'orange	0	1 (0.0)
Perioral dermatitis	1 (0.0)	1 (0.0)
Photodermatosis	1 (0.0)	2 (0.0)
Pityriasis	1 (0.0)	0
Pityriasis lichenoides et varioliformis acuta	0	1 (0.0)
Pityriasis rosea	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Polymorphic light eruption	1 (0.0)	0
Precancerous skin lesion	2 (0.0)	0
Pruritus	3 (0.0)	3 (0.0)
Pruritus allergic	5 (0.0)	2 (0.0)
Pseudofolliculitis	0	1 (0.0)
Psoriasis	79 (0.6)	75 (0.6)
Rash	11 (0.1)	11 (0.1)
Rash pruritic	0	1 (0.0)
Rosacea	51 (0.4)	57 (0.4)
Seborrhoea	1 (0.0)	1 (0.0)
Seborrhoeic dermatitis	19 (0.1)	12 (0.1)
Sensitive skin	1 (0.0)	1 (0.0)
Skin atrophy	1 (0.0)	0
Skin discolouration	2 (0.0)	1 (0.0)
Skin disorder	1 (0.0)	1 (0.0)
Skin exfoliation	1 (0.0)	0
Skin hyperpigmentation	0	1 (0.0)
Skin hypertrophy	1 (0.0)	0
Skin irritation	1 (0.0)	0
Skin lesion	1 (0.0)	3 (0.0)
Skin maceration	0	1 (0.0)
Skin mass	1 (0.0)	0
Skin ulcer	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Solar lentigo	2 (0.0)	0
Stevens-Johnson syndrome	1 (0.0)	0
Transient acantholytic dermatosis	1 (0.0)	0
Urticaria	33 (0.3)	50 (0.4)
Urticaria cholinergic	0	1 (0.0)
Urticaria chronic	0	3 (0.0)
Urticaria thermal	1 (0.0)	0
Vitiligo	11 (0.1)	11 (0.1)
Social circumstances	748 (5.7)	726 (5.5)
Alcohol use	13 (0.1)	9 (0.1)
Andropause	1 (0.0)	1 (0.0)
Bereavement	1 (0.0)	0
Blood donor	11 (0.1)	13 (0.1)
Celibacy	5 (0.0)	5 (0.0)
Corrective lens user	113 (0.9)	102 (0.8)
Denture wearer	2 (0.0)	0
Drug abuser	1 (0.0)	0
Electronic cigarette user	5 (0.0)	1 (0.0)
Ex-tobacco user	32 (0.2)	33 (0.3)
Eye prosthesis user	0	1 (0.0)
Familial risk factor	2 (0.0)	2 (0.0)
Hearing aid user	2 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
High risk sexual behaviour	0	2 (0.0)
Inadequate diet	0	1 (0.0)
Menarche	0	2 (0.0)
Menopause	138 (1.1)	137 (1.0)
Multigravida	0	1 (0.0)
Multiparous	0	1 (0.0)
Organ donor	5 (0.0)	6 (0.0)
Orthodontic appliance user	1 (0.0)	0
Postmenopause	328 (2.5)	342 (2.6)
Social alcohol drinker	5 (0.0)	2 (0.0)
Substance use	21 (0.2)	13 (0.1)
Tobacco user	107 (0.8)	82 (0.6)
Trans-sexualism	4 (0.0)	1 (0.0)
Vegan	0	1 (0.0)
Woman of childbearing potential	1 (0.0)	1 (0.0)
Surgical and medical procedures	3976 (30.4)	3993 (30.5)
Abdominal exploration	2 (0.0)	0
Abdominal hernia repair	16 (0.1)	21 (0.2)
Abdominal operation	9 (0.1)	1 (0.0)
Abdominal panniculectomy	2 (0.0)	2 (0.0)
Abdominal wall operation	1 (0.0)	2 (0.0)
Abdominoplasty	38 (0.3)	38 (0.3)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Abortion induced	2 (0.0)	3 (0.0)
Abscess drainage	7 (0.1)	9 (0.1)
Acoustic neuroma removal	0	1 (0.0)
Adenoidectomy	69 (0.5)	65 (0.5)
Adenotonsillectomy	15 (0.1)	15 (0.1)
Adhesiolysis	0	1 (0.0)
Adrenalectomy	0	2 (0.0)
Alcohol rehabilitation	0	1 (0.0)
Amblyopia therapy	1 (0.0)	1 (0.0)
Amputation	0	1 (0.0)
Anal fissure excision	1 (0.0)	0
Anal fistula repair	4 (0.0)	4 (0.0)
Anal sphincterotomy	0	1 (0.0)
Angioplasty	3 (0.0)	3 (0.0)
Ankle arthroplasty	5 (0.0)	6 (0.0)
Ankle operation	31 (0.2)	38 (0.3)
Anorectal operation	4 (0.0)	3 (0.0)
Antibiotic prophylaxis	1 (0.0)	1 (0.0)
Antibiotic therapy	1 (0.0)	0
Antidepressant therapy	1 (0.0)	0
Antiviral prophylaxis	1 (0.0)	0
Aorta coarctation repair	0	1 (0.0)
Aortic aneurysm repair	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Aortic valve repair	0	1 (0.0)
Aortic valve replacement	3 (0.0)	4 (0.0)
Apicectomy	0	1 (0.0)
Appendicectomy	328 (2.5)	309 (2.4)
Arm amputation	1 (0.0)	0
Arterial bypass operation	1 (0.0)	0
Arterial repair	0	1 (0.0)
Arterial therapeutic procedure	1 (0.0)	0
Arteriovenous fistula operation	2 (0.0)	0
Arthrodesis	5 (0.0)	5 (0.0)
Arthroscopic surgery	0	1 (0.0)
Arthrotomy	0	1 (0.0)
Artificial crown procedure	0	2 (0.0)
Artificial insemination	1 (0.0)	0
Astrocytoma surgery	1 (0.0)	0
Atrial septal defect repair	5 (0.0)	6 (0.0)
Axillary lymphadenectomy	2 (0.0)	2 (0.0)
Bartholin's cyst removal	3 (0.0)	1 (0.0)
Benign breast lump removal	14 (0.1)	9 (0.1)
Benign tumour excision	2 (0.0)	2 (0.0)
Bilateral orchidectomy	2 (0.0)	1 (0.0)
Bile duct stent insertion	1 (0.0)	0
Bile duct stent removal	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Biliary stent placement	1 (0.0)	0
Bladder lesion excision	0	1 (0.0)
Bladder neoplasm surgery	1 (0.0)	0
Bladder operation	1 (0.0)	1 (0.0)
Bladder repair	4 (0.0)	5 (0.0)
Blepharoplasty	2 (0.0)	2 (0.0)
Blood donation	1 (0.0)	5 (0.0)
Bone cyst excision	5 (0.0)	3 (0.0)
Bone debridement	1 (0.0)	0
Bone graft	3 (0.0)	2 (0.0)
Bone lesion excision	14 (0.1)	14 (0.1)
Bone marrow donation	1 (0.0)	1 (0.0)
Bone operation	27 (0.2)	21 (0.2)
Botulinum toxin injection	0	2 (0.0)
Brain lobectomy	2 (0.0)	0
Brain operation	4 (0.0)	4 (0.0)
Brain tumour operation	1 (0.0)	0
Breast conserving surgery	22 (0.2)	27 (0.2)
Breast cyst excision	3 (0.0)	6 (0.0)
Breast operation	4 (0.0)	2 (0.0)
Breast prosthesis removal	4 (0.0)	0
Breast reconstruction	6 (0.0)	7 (0.1)
Breast tumour excision	2 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Bunion operation	36 (0.3)	34 (0.3)
Burn operation	1 (0.0)	0
Bursa removal	0	2 (0.0)
Bursal operation	0	2 (0.0)
Caecopexy	0	1 (0.0)
Caesarean section	392 (3.0)	421 (3.2)
Cancer surgery	12 (0.1)	8 (0.1)
Capsulorrhaphy	1 (0.0)	0
Cardiac ablation	23 (0.2)	12 (0.1)
Cardiac operation	4 (0.0)	7 (0.1)
Cardiac pacemaker insertion	8 (0.1)	5 (0.0)
Cardiac pacemaker removal	0	2 (0.0)
Cardiac pacemaker replacement	0	1 (0.0)
Carotid endarterectomy	0	2 (0.0)
Carpal tunnel decompression	36 (0.3)	38 (0.3)
Cartilage operation	1 (0.0)	0
Cataract operation	11 (0.1)	13 (0.1)
Catheter placement	0	1 (0.0)
Central venous catheterisation	1 (0.0)	0
Cerebral cyst excision	0	1 (0.0)
Cerebral endovascular aneurysm repair	0	1 (0.0)
Cervical conisation	0	1 (0.0)
Cervical laser therapy	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Cervical polypectomy	2 (0.0)	0
Cervicectomy	0	2 (0.0)
Cervix cautery	1 (0.0)	0
Cervix cryotherapy	3 (0.0)	0
Chemical contraception	0	1 (0.0)
Chemotherapy	2 (0.0)	4 (0.0)
Chest tube insertion	3 (0.0)	3 (0.0)
Chest wall operation	0	1 (0.0)
Cholecystectomy	348 (2.7)	371 (2.8)
Cholecystostomy	0	1 (0.0)
Choledocholithotomy	0	1 (0.0)
Cholelithotomy	1 (0.0)	3 (0.0)
Cholesteatoma removal	0	3 (0.0)
Chondrectomy	1 (0.0)	1 (0.0)
Chondroplasty	25 (0.2)	28 (0.2)
Circumcision	7 (0.1)	10 (0.1)
Cleft lip repair	1 (0.0)	1 (0.0)
Cleft palate repair	3 (0.0)	2 (0.0)
Closed fracture manipulation	1 (0.0)	0
Coccygectomy	0	1 (0.0)
Cochlea implant	4 (0.0)	3 (0.0)
Colectomy	12 (0.1)	14 (0.1)
Colectomy total	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Colon operation	3 (0.0)	2 (0.0)
Colostomy	1 (0.0)	0
Commissurotomy of pulmonary valve	1 (0.0)	0
Contact lens therapy	1 (0.0)	1 (0.0)
Continuous positive airway pressure	9 (0.1)	5 (0.0)
Contraception	14 (0.1)	17 (0.1)
Contraceptive implant	5 (0.0)	7 (0.1)
Corneal operation	0	1 (0.0)
Corneal transplant	4 (0.0)	4 (0.0)
Coronary angioplasty	1 (0.0)	1 (0.0)
Coronary arterial stent insertion	16 (0.1)	19 (0.1)
Coronary artery bypass	6 (0.0)	3 (0.0)
Coronary artery surgery	1 (0.0)	1 (0.0)
Coronary revascularisation	0	1 (0.0)
Cranial nerve decompression	1 (0.0)	0
Cranial operation	4 (0.0)	4 (0.0)
Craniectomy	0	1 (0.0)
Cranioplasty	1 (0.0)	1 (0.0)
Craniotomy	3 (0.0)	1 (0.0)
Cryotherapy	2 (0.0)	1 (0.0)
Cyst drainage	1 (0.0)	0
Cyst removal	10 (0.1)	10 (0.1)
Cystocele repair	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Dacryocystorhinostomy	1 (0.0)	0
Debridement	4 (0.0)	5 (0.0)
Decompressive craniectomy	0	1 (0.0)
Dental care	0	1 (0.0)
Dental implantation	3 (0.0)	8 (0.1)
Dental operation	4 (0.0)	2 (0.0)
Dental prosthesis placement	1 (0.0)	1 (0.0)
Detoxification	0	1 (0.0)
Diplopia correction	1 (0.0)	0
Diverticulectomy	1 (0.0)	2 (0.0)
Drug delivery device placement	1 (0.0)	0
Drug rehabilitation	1 (0.0)	1 (0.0)
Duodenal switch	0	2 (0.0)
Dupuytren's contracture operation	1 (0.0)	0
Ear operation	7 (0.1)	3 (0.0)
Ear tube insertion	23 (0.2)	27 (0.2)
Ear tube removal	1 (0.0)	3 (0.0)
Ectopic pregnancy termination	1 (0.0)	1 (0.0)
Elbow operation	10 (0.1)	10 (0.1)
Electrodesiccation	1 (0.0)	0
Endocervical curettage	1 (0.0)	0
Endodontic procedure	1 (0.0)	4 (0.0)
Endometrial ablation	74 (0.6)	77 (0.6)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Endometriosis ablation	2 (0.0)	7 (0.1)
Endoscopic sleeve gastropasty	0	1 (0.0)
Enterorrhaphy	0	1 (0.0)
Enterostomy	2 (0.0)	0
Epidermoid cyst excision	1 (0.0)	0
Epididymal cyst removal	1 (0.0)	0
Epididymal operation	1 (0.0)	0
Epiphysiodesis	1 (0.0)	0
Eustachian tube operation	1 (0.0)	2 (0.0)
Exeresis	5 (0.0)	2 (0.0)
Explorative laparotomy	2 (0.0)	1 (0.0)
External fixation of fracture	2 (0.0)	1 (0.0)
External nose lesion excision	1 (0.0)	0
Eye excision	2 (0.0)	1 (0.0)
Eye laser surgery	24 (0.2)	13 (0.1)
Eye muscle operation	3 (0.0)	5 (0.0)
Eye operation	10 (0.1)	14 (0.1)
Eyelid cyst removal	1 (0.0)	1 (0.0)
Eyelid operation	1 (0.0)	2 (0.0)
Face lift	2 (0.0)	1 (0.0)
Facet joint block	0	2 (0.0)
Facial lesion excision	0	1 (0.0)
Facial operation	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Fallopian tube operation	0	1 (0.0)
Fascia release	2 (0.0)	2 (0.0)
Fascial operation	1 (0.0)	2 (0.0)
Fasciotomy	7 (0.1)	2 (0.0)
Female genital operation	1 (0.0)	0
Female sterilisation	424 (3.2)	468 (3.6)
Femoral derotation osteotomy	0	1 (0.0)
Femoral hernia repair	1 (0.0)	1 (0.0)
Finger amputation	3 (0.0)	7 (0.1)
Finger repair operation	3 (0.0)	2 (0.0)
Fistula repair	1 (0.0)	1 (0.0)
Foetal surgery	0	1 (0.0)
Foot amputation	1 (0.0)	1 (0.0)
Foot operation	23 (0.2)	16 (0.1)
Foraminotomy	1 (0.0)	0
Fracture reduction	2 (0.0)	2 (0.0)
Fracture treatment	72 (0.6)	74 (0.6)
Frontal sinus operation	1 (0.0)	0
Functional endoscopic sinus surgery	2 (0.0)	4 (0.0)
Gallbladder operation	4 (0.0)	3 (0.0)
Gastrectomy	58 (0.4)	71 (0.5)
Gastric banding	16 (0.1)	13 (0.1)
Gastric banding reversal	2 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Gastric bypass	68 (0.5)	67 (0.5)
Gastric operation	2 (0.0)	5 (0.0)
Gastric stapling	0	1 (0.0)
Gastric ulcer surgery	0	1 (0.0)
Gastroenterostomy	1 (0.0)	0
Gastrointestinal surgery	2 (0.0)	1 (0.0)
Gastrointestinal ulcer management	1 (0.0)	0
Gastroplasty	0	3 (0.0)
Gastrostomy	1 (0.0)	0
Gastrostomy tube removal	1 (0.0)	0
Gender reassignment therapy	1 (0.0)	0
Gingival graft	2 (0.0)	6 (0.0)
Gingival operation	0	1 (0.0)
Glaucoma surgery	0	1 (0.0)
Haemangioma removal	2 (0.0)	3 (0.0)
Haematoma evacuation	0	1 (0.0)
Haemorrhoid operation	16 (0.1)	11 (0.1)
Haemostasis	1 (0.0)	0
Hair transplant	2 (0.0)	4 (0.0)
Hand repair operation	1 (0.0)	3 (0.0)
Heart valve replacement	2 (0.0)	0
Hepatectomy	0	1 (0.0)
Hepatitis B immunisation	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Hernia diaphragmatic repair	2 (0.0)	0
Hernia hiatus repair	5 (0.0)	15 (0.1)
Hernia repair	55 (0.4)	52 (0.4)
High frequency ablation	2 (0.0)	1 (0.0)
Hip arthroplasty	21 (0.2)	21 (0.2)
Hip surgery	7 (0.1)	11 (0.1)
Hormone replacement therapy	4 (0.0)	2 (0.0)
Hospitalisation	1 (0.0)	0
Hydrocele operation	1 (0.0)	4 (0.0)
Hysterectomy	521 (4.0)	498 (3.8)
Hysteropexy	0	1 (0.0)
Hysterosalpingectomy	0	1 (0.0)
Hysterosalpingo-oophorectomy	6 (0.0)	4 (0.0)
Hysterotomy	0	1 (0.0)
Ileectomy	0	1 (0.0)
Ileostomy	0	2 (0.0)
Immune tolerance induction	1 (0.0)	1 (0.0)
Immunoglobulin therapy	1 (0.0)	0
Implantable cardiac monitor insertion	0	3 (0.0)
Implantable defibrillator insertion	1 (0.0)	4 (0.0)
In vitro fertilisation	1 (0.0)	3 (0.0)
Incisional drainage	2 (0.0)	5 (0.0)
Incisional hernia repair	1 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Influenza immunisation	0	1 (0.0)
Inguinal hernia repair	86 (0.7)	94 (0.7)
Injection	0	1 (0.0)
Inner ear operation	1 (0.0)	0
Internal fixation of fracture	6 (0.0)	6 (0.0)
Intervertebral disc operation	52 (0.4)	45 (0.3)
Intestinal operation	5 (0.0)	4 (0.0)
Intestinal resection	10 (0.1)	5 (0.0)
Intra-cerebral aneurysm operation	2 (0.0)	1 (0.0)
Intra-uterine contraceptive device insertion	29 (0.2)	31 (0.2)
Intramedullary rod insertion	1 (0.0)	1 (0.0)
Intraocular lens implant	3 (0.0)	3 (0.0)
Intrauterine contraception	26 (0.2)	34 (0.3)
Iridotomy	0	1 (0.0)
Jaw operation	15 (0.1)	18 (0.1)
Jejunostomy	0	1 (0.0)
Joint arthroplasty	2 (0.0)	4 (0.0)
Joint debridement	4 (0.0)	2 (0.0)
Joint dislocation reduction	4 (0.0)	6 (0.0)
Joint fluid drainage	1 (0.0)	0
Joint manipulation	0	1 (0.0)
Joint resurfacing surgery	2 (0.0)	0
Joint stabilisation	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Joint surgery	3 (0.0)	5 (0.0)
Keratomileusis	80 (0.6)	71 (0.5)
Keratotomy	0	1 (0.0)
Knee arthroplasty	32 (0.2)	34 (0.3)
Knee operation	72 (0.6)	73 (0.6)
Lacrimal duct procedure	1 (0.0)	3 (0.0)
Lacrimal gland operation	0	1 (0.0)
Laminaplasty	0	1 (0.0)
Laparoscopic surgery	4 (0.0)	2 (0.0)
Laparotomy	2 (0.0)	2 (0.0)
Large intestinal polypectomy	11 (0.1)	10 (0.1)
Large intestine operation	1 (0.0)	0
Laryngeal operation	1 (0.0)	0
Laryngeal polypectomy	0	1 (0.0)
Laryngoplasty	0	1 (0.0)
Laser therapy	1 (0.0)	0
Leg amputation	3 (0.0)	2 (0.0)
Lesion excision	1 (0.0)	1 (0.0)
Ligament operation	110 (0.8)	106 (0.8)
Limb operation	40 (0.3)	47 (0.4)
Limb reattachment surgery	1 (0.0)	0
Limb reconstructive surgery	0	1 (0.0)
Lipectomy	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Lipoma excision	11 (0.1)	12 (0.1)
Liposuction	9 (0.1)	13 (0.1)
Lithotripsy	17 (0.1)	14 (0.1)
Liver transplant	0	1 (0.0)
Loop electrosurgical excision procedure	14 (0.1)	11 (0.1)
Lower oesophageal sphincter magnetic augmentation	1 (0.0)	0
Lung assist device therapy	1 (0.0)	0
Lung cyst removal	1 (0.0)	0
Lung lobectomy	2 (0.0)	3 (0.0)
Lung operation	0	2 (0.0)
Lymphadenectomy	4 (0.0)	6 (0.0)
Lymphoid tissue operation	1 (0.0)	0
Lymphoma operation	1 (0.0)	2 (0.0)
Mammary ductectomy	0	1 (0.0)
Mammoplasty	163 (1.2)	147 (1.1)
Mass excision	2 (0.0)	1 (0.0)
Mastectomy	21 (0.2)	31 (0.2)
Mastoidectomy	1 (0.0)	4 (0.0)
Maxillofacial operation	4 (0.0)	1 (0.0)
Medical cannabis therapy	0	1 (0.0)
Medical device battery replacement	1 (0.0)	0
Medical device implantation	2 (0.0)	1 (0.0)
Medical device removal	5 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Meningioma surgery	3 (0.0)	2 (0.0)
Meniscus operation	57 (0.4)	52 (0.4)
Meniscus removal	9 (0.1)	8 (0.1)
Metabolic surgery	34 (0.3)	34 (0.3)
Metatarsal excision	1 (0.0)	0
Micrographic skin surgery	5 (0.0)	13 (0.1)
Middle ear operation	1 (0.0)	0
Middle ear prosthesis insertion	0	1 (0.0)
Mitral valve repair	0	1 (0.0)
Mitral valve replacement	1 (0.0)	2 (0.0)
Mole excision	13 (0.1)	8 (0.1)
Muscle graft	0	1 (0.0)
Muscle operation	5 (0.0)	9 (0.1)
Myectomy	0	2 (0.0)
Myomectomy	17 (0.1)	18 (0.1)
Myopia correction	2 (0.0)	5 (0.0)
Myringotomy	7 (0.1)	10 (0.1)
Nail operation	5 (0.0)	1 (0.0)
Nasal operation	7 (0.1)	9 (0.1)
Nasal polypectomy	11 (0.1)	5 (0.0)
Nasal septal operation	82 (0.6)	75 (0.6)
Nasal sinus irrigation	0	1 (0.0)
Neck dissection	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Neck surgery	8 (0.1)	3 (0.0)
Nephrectomy	8 (0.1)	10 (0.1)
Nephrostomy	0	2 (0.0)
Nerve block	3 (0.0)	2 (0.0)
Nervous system neoplasm surgery	2 (0.0)	0
Neurectomy	5 (0.0)	7 (0.1)
Neuroprosthesis implantation	0	1 (0.0)
Neurosurgery	0	1 (0.0)
Oesophageal dilation procedure	2 (0.0)	3 (0.0)
Oesophageal lesion excision	0	1 (0.0)
Oesophagocardiomyotomy	0	2 (0.0)
Oesophagogastrrectomy	1 (0.0)	0
Oesophagogastric fundoplasty	6 (0.0)	6 (0.0)
Oocyte harvest	2 (0.0)	1 (0.0)
Oophorectomy	25 (0.2)	34 (0.3)
Oophorectomy bilateral	23 (0.2)	18 (0.1)
Open reduction of fracture	32 (0.2)	29 (0.2)
Oral cavity neoplasm surgery	0	1 (0.0)
Oral contraception	1 (0.0)	0
Oral surgery	2 (0.0)	1 (0.0)
Orchidectomy	10 (0.1)	8 (0.1)
Orchidopexy	4 (0.0)	3 (0.0)
Orthognathic surgery	9 (0.1)	9 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Orthopaedic procedure	3 (0.0)	4 (0.0)
Ossiculoplasty	0	1 (0.0)
Ostectomy	5 (0.0)	8 (0.1)
Osteotomy	6 (0.0)	6 (0.0)
Otoplasty	4 (0.0)	4 (0.0)
Ovarian cystectomy	17 (0.1)	23 (0.2)
Ovarian lesion excision	2 (0.0)	1 (0.0)
Ovarian neoplasm surgery	2 (0.0)	1 (0.0)
Ovarian operation	1 (0.0)	3 (0.0)
Ovariocentesis	0	1 (0.0)
Pancreatic stent placement	0	1 (0.0)
Pancreatic stent removal	0	1 (0.0)
Papilloma excision	5 (0.0)	1 (0.0)
Paranasal sinus polypectomy	2 (0.0)	7 (0.1)
Parathyroidectomy	3 (0.0)	1 (0.0)
Parotidectomy	3 (0.0)	2 (0.0)
Penis frenulectomy	1 (0.0)	0
Percutaneous coronary intervention	2 (0.0)	0
Peripheral nerve decompression	7 (0.1)	5 (0.0)
Peripheral nerve destruction	0	2 (0.0)
Peripheral nerve neurostimulation	0	1 (0.0)
Peripheral nerve operation	2 (0.0)	10 (0.1)
Peripheral nerve transposition	2 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Permanent contraceptive tubal implant	1 (0.0)	2 (0.0)
Pharyngeal operation	0	2 (0.0)
Pharyngeal polypectomy	1 (0.0)	0
Phlebectomy	2 (0.0)	4 (0.0)
Photorefractive keratectomy	5 (0.0)	7 (0.1)
Physiotherapy	0	2 (0.0)
Pilonidal sinus repair	11 (0.1)	15 (0.1)
Pituitary tumour removal	2 (0.0)	2 (0.0)
Plastic surgery	2 (0.0)	2 (0.0)
Plastic surgery to the face	5 (0.0)	3 (0.0)
Platelet rich plasma therapy	1 (0.0)	0
Pleural operation	0	2 (0.0)
Pleurectomy	0	1 (0.0)
Pleurodesis	1 (0.0)	0
Pneumocentesis	0	1 (0.0)
Polypectomy	3 (0.0)	4 (0.0)
Precancerous lesion excision	1 (0.0)	0
Preventive surgery	1 (0.0)	0
Prophylaxis against HIV infection	6 (0.0)	2 (0.0)
Prostatectomy	6 (0.0)	3 (0.0)
Prostatic urethral lift procedure	1 (0.0)	0
Prosthesis implantation	1 (0.0)	1 (0.0)
Psychotherapy	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Pterygium operation	1 (0.0)	2 (0.0)
Ptosis repair	1 (0.0)	0
Pulmonary bullectomy	1 (0.0)	0
Pulmonary resection	2 (0.0)	0
Pulmonary valve replacement	0	1 (0.0)
Pyeloplasty	0	1 (0.0)
Pyloromyotomy	2 (0.0)	2 (0.0)
Pyloroplasty	2 (0.0)	5 (0.0)
Pylorus dilation procedure	0	1 (0.0)
Radical hysterectomy	1 (0.0)	6 (0.0)
Radical prostatectomy	1 (0.0)	0
Radiculotomy	0	1 (0.0)
Radioactive iodine therapy	1 (0.0)	2 (0.0)
Radiotherapy	2 (0.0)	1 (0.0)
Radiotherapy to breast	1 (0.0)	2 (0.0)
Radiotherapy to thyroid	0	1 (0.0)
Rectal fistula repair	1 (0.0)	3 (0.0)
Rectal lesion excision	1 (0.0)	0
Rectal prolapse repair	1 (0.0)	1 (0.0)
Rectocele repair	2 (0.0)	0
Reduction of increased intracranial pressure	1 (0.0)	0
Removal of foreign body	3 (0.0)	9 (0.1)
Removal of foreign body from eye	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Removal of foreign body from gastrointestinal tract	1 (0.0)	1 (0.0)
Removal of foreign body from joint	1 (0.0)	0
Removal of foreign body from rectum	1 (0.0)	0
Renal artery stent placement	0	1 (0.0)
Renal cyst excision	0	1 (0.0)
Renal stone removal	19 (0.1)	22 (0.2)
Renal surgery	1 (0.0)	7 (0.1)
Retinal operation	4 (0.0)	5 (0.0)
Retinopexy	7 (0.1)	3 (0.0)
Rhinoplasty	35 (0.3)	42 (0.3)
Rib excision	1 (0.0)	1 (0.0)
Rotator cuff repair	41 (0.3)	41 (0.3)
Salivary gland operation	0	4 (0.0)
Salivary gland resection	2 (0.0)	1 (0.0)
Salpingectomy	77 (0.6)	77 (0.6)
Salpingo-oophorectomy	1 (0.0)	2 (0.0)
Salpingo-oophorectomy bilateral	2 (0.0)	2 (0.0)
Salpingo-oophorectomy unilateral	3 (0.0)	0
Salpingoplasty	1 (0.0)	0
Salpingostomy	3 (0.0)	1 (0.0)
Sarcoma excision	0	2 (0.0)
Scar excision	1 (0.0)	7 (0.1)
Scleral buckling surgery	0	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Sclerotherapy	1 (0.0)	0
Scoliosis surgery	5 (0.0)	3 (0.0)
Sebaceous cyst excision	0	3 (0.0)
Seizure prophylaxis	1 (0.0)	0
Sesamoidectomy	1 (0.0)	1 (0.0)
Shoulder arthroplasty	6 (0.0)	3 (0.0)
Shoulder operation	58 (0.4)	30 (0.2)
Sigmoidectomy	1 (0.0)	2 (0.0)
Sinuplasty	2 (0.0)	5 (0.0)
Sinus antrostomy	1 (0.0)	0
Sinus operation	40 (0.3)	36 (0.3)
Skin cosmetic procedure	2 (0.0)	4 (0.0)
Skin cyst excision	4 (0.0)	1 (0.0)
Skin graft	8 (0.1)	8 (0.1)
Skin lesion removal	6 (0.0)	3 (0.0)
Skin neoplasm excision	29 (0.2)	35 (0.3)
Skin operation	5 (0.0)	2 (0.0)
Skull fracture treatment	0	2 (0.0)
Small intestinal resection	1 (0.0)	3 (0.0)
Small intestine operation	1 (0.0)	0
Soft tissue flap operation	0	1 (0.0)
Spermatic cord operation	1 (0.0)	0
Spinal cord operation	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Spinal decompression	4 (0.0)	0
Spinal fracture treatment	3 (0.0)	0
Spinal fusion surgery	56 (0.4)	53 (0.4)
Spinal laminectomy	19 (0.1)	26 (0.2)
Spinal nerve stimulator implantation	5 (0.0)	5 (0.0)
Spinal operation	33 (0.3)	26 (0.2)
Splenectomy	8 (0.1)	9 (0.1)
Splenorrhaphy	1 (0.0)	0
Stapedectomy	2 (0.0)	0
Stem cell therapy	1 (0.0)	1 (0.0)
Stent placement	4 (0.0)	3 (0.0)
Sterilisation	13 (0.1)	6 (0.0)
Sterilisation reversal	3 (0.0)	1 (0.0)
Stoma closure	1 (0.0)	0
Stomach lesion excision	1 (0.0)	0
Strabismus correction	13 (0.1)	16 (0.1)
Subdural haematoma evacuation	1 (0.0)	0
Surgery	4 (0.0)	7 (0.1)
Surgical fixation of rib fracture	1 (0.0)	0
Suture insertion	2 (0.0)	2 (0.0)
Sympathectomy	0	1 (0.0)
Synovectomy	1 (0.0)	1 (0.0)
Synovial cyst removal	13 (0.1)	11 (0.1)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Talipes correction	1 (0.0)	4 (0.0)
Tarsal tunnel decompression	0	1 (0.0)
Temporomandibular joint surgery	6 (0.0)	1 (0.0)
Tendon graft	1 (0.0)	0
Tendon operation	3 (0.0)	6 (0.0)
Tendon sheath incision	7 (0.1)	6 (0.0)
Tendon transfer	3 (0.0)	3 (0.0)
Tenolysis	1 (0.0)	1 (0.0)
Tenectomy	1 (0.0)	0
Tenoplasty	38 (0.3)	37 (0.3)
Tenotomy	6 (0.0)	7 (0.1)
Testes exploration	1 (0.0)	3 (0.0)
Testicular operation	1 (0.0)	1 (0.0)
Tetralogy of Fallot repair	2 (0.0)	1 (0.0)
Therapeutic aspiration	0	1 (0.0)
Therapeutic embolisation	1 (0.0)	0
Therapeutic nerve ablation	4 (0.0)	1 (0.0)
Therapeutic procedure	2 (0.0)	0
Thermal ablation	1 (0.0)	0
Thoracic operation	4 (0.0)	1 (0.0)
Thoracic outlet surgery	1 (0.0)	0
Thoracoplasty	2 (0.0)	2 (0.0)
Thoracotomy	1 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Thrombectomy	2 (0.0)	0
Thymectomy	1 (0.0)	1 (0.0)
Thyroglossal cyst excision	1 (0.0)	0
Thyroid nodule removal	1 (0.0)	3 (0.0)
Thyroid operation	2 (0.0)	1 (0.0)
Thyroidectomy	71 (0.5)	79 (0.6)
Toe amputation	4 (0.0)	8 (0.1)
Toe operation	4 (0.0)	10 (0.1)
Tongue tie operation	1 (0.0)	2 (0.0)
Tonsillectomy	399 (3.1)	361 (2.8)
Tooth extraction	8 (0.1)	12 (0.1)
Tooth repair	0	1 (0.0)
Trabeculectomy	0	1 (0.0)
Trabeculoplasty	0	1 (0.0)
Tracheal fistula repair	1 (0.0)	0
Tracheostomy	1 (0.0)	1 (0.0)
Transfusion	5 (0.0)	4 (0.0)
Transgender hormonal therapy	2 (0.0)	1 (0.0)
Transgender operation	2 (0.0)	0
Transplant	1 (0.0)	0
Transurethral incision of prostate	1 (0.0)	0
Transurethral prostatectomy	0	1 (0.0)
Tumour excision	3 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =13069)	Placebo (N ^a =13095)
	n ^b (%)	n ^b (%)
Turbinectomy	5 (0.0)	8 (0.1)
Turbinoplasty	1 (0.0)	1 (0.0)
Tympanoplasty	11 (0.1)	13 (0.1)
Umbilical hernia repair	39 (0.3)	60 (0.5)
Umbilicoplasty	0	1 (0.0)
Ureteral stent insertion	2 (0.0)	6 (0.0)
Ureteral stent removal	0	1 (0.0)
Ureteric operation	2 (0.0)	2 (0.0)
Ureteric repair	0	2 (0.0)
Urethral dilation procedure	0	1 (0.0)
Urethral operation	4 (0.0)	3 (0.0)
Urethral repair	2 (0.0)	5 (0.0)
Urethral stent insertion	0	1 (0.0)
Urethrectomy	0	1 (0.0)
Urinary bladder suspension	15 (0.1)	15 (0.1)
Urinary tract operation	1 (0.0)	1 (0.0)
Urogenital fistula repair	0	1 (0.0)
Urostomy	1 (0.0)	0
Uterine cystectomy	1 (0.0)	1 (0.0)
Uterine dilation and curettage	28 (0.2)	43 (0.3)
Uterine leiomyoma embolisation	1 (0.0)	0
Uterine operation	1 (0.0)	1 (0.0)
Uterine polypectomy	7 (0.1)	4 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Uterine repair	1 (0.0)	0
Uterine tumour excision	1 (0.0)	0
Uvulectomy	1 (0.0)	1 (0.0)
Uvulopalatopharyngoplasty	6 (0.0)	4 (0.0)
Uvuloplasty	1 (0.0)	0
Vaginal fistula repair	0	1 (0.0)
Vaginal operation	2 (0.0)	2 (0.0)
Vaginal prolapse repair	1 (0.0)	0
Vaginal ring	1 (0.0)	0
Valvuloplasty cardiac	1 (0.0)	0
Varicocele repair	6 (0.0)	12 (0.1)
Varicose vein operation	5 (0.0)	6 (0.0)
Vascular graft	1 (0.0)	2 (0.0)
Vascular operation	1 (0.0)	2 (0.0)
Vascular stent insertion	2 (0.0)	3 (0.0)
Vasectomy	348 (2.7)	307 (2.3)
Vasectomy reversal	2 (0.0)	1 (0.0)
Venous reconstruction	0	1 (0.0)
Venous stent insertion	1 (0.0)	0
Ventricular drainage	1 (0.0)	0
Ventricular septal defect repair	1 (0.0)	1 (0.0)
Ventriculo-peritoneal shunt	1 (0.0)	3 (0.0)
Vertebroplasty	2 (0.0)	1 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Vesicoureteral reflux surgery	0	1 (0.0)
Vestibular apparatus operation	0	1 (0.0)
Vision correction operation	4 (0.0)	1 (0.0)
Vitamin supplementation	1 (0.0)	0
Vitrectomy	0	2 (0.0)
Vocal cord nodule removal	1 (0.0)	1 (0.0)
Vocal cord operation	0	1 (0.0)
Vocal cord polypectomy	0	1 (0.0)
Vulval operation	1 (0.0)	1 (0.0)
Vulvectomy	2 (0.0)	1 (0.0)
Weight control	2 (0.0)	0
Wisdom teeth removal	136 (1.0)	142 (1.1)
Wound closure	3 (0.0)	6 (0.0)
Wound treatment	2 (0.0)	0
Wrist surgery	15 (0.1)	24 (0.2)
Vascular disorders	1641 (12.6)	1673 (12.8)
Aortic aneurysm	2 (0.0)	1 (0.0)
Aortic arteriosclerosis	0	2 (0.0)
Aortic dilatation	2 (0.0)	1 (0.0)
Aortic disorder	0	1 (0.0)
Aortic stenosis	1 (0.0)	1 (0.0)
Arteriosclerosis	1 (0.0)	3 (0.0)

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Arteriovenous fistula	1 (0.0)	0
Capillary fragility	0	1 (0.0)
Collateral circulation	0	1 (0.0)
Deep vein thrombosis	18 (0.1)	23 (0.2)
Embolism	1 (0.0)	1 (0.0)
Embolism venous	1 (0.0)	1 (0.0)
Erythromelalgia	1 (0.0)	0
Essential hypertension	24 (0.2)	16 (0.1)
Extremity necrosis	1 (0.0)	0
Fibromuscular dysplasia	0	1 (0.0)
Giant cell arteritis	0	1 (0.0)
Haematoma	1 (0.0)	1 (0.0)
Haemorrhage	0	1 (0.0)
Hot flush	48 (0.4)	60 (0.5)
Hypertension	1495 (11.4)	1507 (11.5)
Hypotension	5 (0.0)	6 (0.0)
Kawasaki's disease	1 (0.0)	0
Lymphoedema	3 (0.0)	0
May-Thurner syndrome	2 (0.0)	2 (0.0)
Orthostatic hypertension	1 (0.0)	0
Orthostatic hypotension	0	3 (0.0)
Peripheral arterial occlusive disease	1 (0.0)	1 (0.0)
Peripheral artery thrombosis	1 (0.0)	0

Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=13069)	Placebo (N^a=13095)
	n^b (%)	n^b (%)
Peripheral vascular disorder	0	1 (0.0)
Peripheral venous disease	4 (0.0)	9 (0.1)
Phlebosclerosis	1 (0.0)	0
Prehypertension	2 (0.0)	1 (0.0)
Raynaud's phenomenon	17 (0.1)	14 (0.1)
Subclavian artery aneurysm	1 (0.0)	0
Subclavian vein thrombosis	1 (0.0)	1 (0.0)
Thrombosis	7 (0.1)	10 (0.1)
Varicose vein	21 (0.2)	32 (0.2)
Vena cava thrombosis	1 (0.0)	0
Venous thrombosis	2 (0.0)	0
Venous thrombosis limb	0	2 (0.0)
White coat hypertension	8 (0.1)	2 (0.0)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 28MAR2021 (14:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .\nda2_unblinded\C4591001_EUA_1655\admh_s002_all_1655_saf

Vaccine as Administered by Vaccine Group – Phase 2/3 Subjects 16-55 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N ^a =13104) n ^b (%)	Placebo (N ^a =13132) n ^b (%)
Vaccinated	13073 (99.8)	13100 (99.8)
Not vaccinated	31 (0.2)	32 (0.2)
Dose 1		
BNT162b2 (30 µg)	13071 (99.7)	2 (0.0)
Placebo	1 (0.0)	13098 (99.7)
Indeterminate vaccine ^c	1 (0.0)	0
Dose 2		
BNT162b2 (30 µg)	12860 (98.1)	1 (0.0)
Placebo	2 (0.0)	12824 (97.7)
Indeterminate vaccine ^c	0	0
Dose 3		
First dose BNT162b2 (30 µg)		11405 (86.8)
Indeterminate vaccine ^c		0
Dose 4		
Second dose BNT162b2 (30 µg)		8586 (65.4)
Indeterminate vaccine ^c		0

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects with the specified characteristic.

c. "Indeterminate vaccine" refers to subjects whose vaccine (as administered) could not be determined.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 28MAR2021 (12:39)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/advx_s002_adm_1655_rand

Vaccine Administration Timing – Phase 2/3 Subjects 16-55 Years of Age – All Randomized Subjects		
	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)
Randomized	13104 (100.0)	13132 (100.0)
Not vaccinated	31 (0.2)	32 (0.2)
Dose 1	13073 (99.8)	13100 (99.8)
Dose 2 ^c	12862 (98.2)	12825 (97.7)
<14 Days	0	1 (0.0)
14 to 20 Days	4280 (32.7)	4245 (32.3)
21 to 27 Days	8221 (62.7)	8239 (62.7)
28 to 34 Days	158 (1.2)	200 (1.5)
35 to 41 Days	62 (0.5)	61 (0.5)
42 to 48 Days	43 (0.3)	34 (0.3)
49 to 55 Days	23 (0.2)	20 (0.2)
>55 Days	75 (0.6)	25 (0.2)
Dose 3 (first dose of BNT162b2 [30 µg])		11405 (86.8)
Dose 4 (second dose of BNT162b2 [30 µg]) ^d		8586 (65.4)
<14 Days		1 (0.0)
14 to 20 Days		2564 (19.5)
21 to 27 Days		5788 (44.1)
28 to 34 Days		152 (1.2)
35 to 41 Days		56 (0.4)
42 to 48 Days		18 (0.1)
49 to 55 Days		6 (0.0)
>55 Days		1 (0.0)

Vaccine Administration Timing – Phase 2/3 Subjects 16-55 Years of Age – All Randomized Subjects		
Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N ^a =13104) n ^b (%)	Placebo (N ^a =13132) n ^b (%)
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.		
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.		
b. n = Number of subjects with the specified characteristic.		
c. Days calculated since Dose 1.		
d. Days calculated since Dose 3.		
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 28MAR2021 (14:23)		
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/advx_s002_time_1655_rand		

Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
Vaccine^b	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=12995)	Placebo (N^a=13026)
	n^c (%)	n^c (%)
Any concomitant vaccine	1291 (9.9)	1562 (12.0)
ANTHRAX VACCINE	0	1 (0.0)
CHOLERA VACCINE	0	1 (0.0)
COVID-19 VACCINE	3 (0.0)	56 (0.4)
COVID-19 VACCINE INACT (VERO)	4 (0.0)	6 (0.0)
COVID-19 VACCINE INACT (VERO) HB02	1 (0.0)	1 (0.0)
COVID-19 VACCINE MRNA (MRNA 1273)	8 (0.1)	71 (0.5)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	0	3 (0.0)
DIPHtheria VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	2 (0.0)
DIPHtheria VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	15 (0.1)	16 (0.1)
DIPHtheria VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0	1 (0.0)
DIPHtheria VACCINE TOXOID;TETANUS VACCINE TOXOID	4 (0.0)	1 (0.0)
DIPHtheria VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0.0)	4 (0.0)
DIPHtheria VACCINE;TETANUS VACCINE	0	1 (0.0)
HEPATITIS A VACCINE	4 (0.0)	4 (0.0)
HEPATITIS A VACCINE;HEPATITIS B VACCINE	1 (0.0)	0
HEPATITIS B VACCINE	10 (0.1)	13 (0.1)
HEPATITIS VACCINES	1 (0.0)	0
HIB VACCINE CONJ	1 (0.0)	0
HPV VACCINE	7 (0.1)	4 (0.0)

Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
Vaccine^b	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=12995)	Placebo (N^a=13026)
	n^c (%)	n^c (%)
HPV VACCINE VLP RL1 2V (BACULOVIRUS)	0	1 (0.0)
HPV VACCINE VLP RL1 4V (YEAST)	5 (0.0)	3 (0.0)
HPV VACCINE VLP RL1 9V (YEAST)	1 (0.0)	1 (0.0)
INFLUENZA VACCINE	1053 (8.1)	1195 (9.2)
INFLUENZA VACCINE INACT SAG 3V	19 (0.1)	17 (0.1)
INFLUENZA VACCINE INACT SAG 4V	17 (0.1)	13 (0.1)
INFLUENZA VACCINE INACT SPLIT 3V	25 (0.2)	22 (0.2)
INFLUENZA VACCINE INACT SPLIT 4V	99 (0.8)	117 (0.9)
INFLUENZA VACCINE LIVE REASSORT 4V	0	1 (0.0)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	1 (0.0)	0
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	10 (0.1)	10 (0.1)
INFLUENZA VACCINES	0	1 (0.0)
MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR)	0	1 (0.0)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	8 (0.1)	5 (0.0)
MENINGOCOCCAL VACCINE	2 (0.0)	5 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W	1 (0.0)	0
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	1 (0.0)	3 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (0.0)	1 (0.0)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	1 (0.0)	2 (0.0)
MENINGOCOCCAL VACCINE B RFHBPA/FHBPB	0	1 (0.0)
PNEUMOCOCCAL VACCINE	5 (0.0)	10 (0.1)

Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
Vaccine ^b	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =12995)	Placebo (N ^a =13026)
	n ^c (%)	n ^c (%)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	0	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	2 (0.0)	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (0.0)	0
POLIO VACCINE	0	1 (0.0)
RABIES VACCINE	1 (0.0)	1 (0.0)
RUBELLA VACCINE	0	1 (0.0)
TETANUS VACCINE	15 (0.1)	16 (0.1)
TETANUS VACCINE TOXOID	4 (0.0)	0
TYPHOID VACCINE	1 (0.0)	2 (0.0)
VARICELLA ZOSTER VACCINE	19 (0.1)	13 (0.1)
VARICELLA ZOSTER VACCINE LIVE (OKA/MERCK)	0	1 (0.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	9 (0.1)	16 (0.1)
YELLOW FEVER VACCINE	0	2 (0.0)
YELLOW FEVER VACCINE LIVE (17D-204)	1 (0.0)	0
Note: WHO DDE v202003 coding dictionary applied. a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations. b. Subjects are counted only once for each preferred term. c. n = Number of subjects with the specified characteristic. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adcm Table Generation: 28MAR2021 (14:47) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adsl_fu_1655_saf		

E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
	n^a (%)	n^a (%)
Vaccinated at Dose 1 ^b	2982	2997
E-diary		
Not transmitted ^c	46 (1.5)	50 (1.7)
Transmitted ^d		
Day 1	2812 (94.3)	2775 (92.6)
Day 2	2804 (94.0)	2770 (92.4)
Day 3	2716 (91.1)	2771 (92.5)
Day 4	2685 (90.0)	2707 (90.3)
Day 5	2658 (89.1)	2705 (90.3)
Day 6	2665 (89.4)	2662 (88.8)
Day 7	2657 (89.1)	2676 (89.3)
All 7 days ^c	2005 (67.2)	2005 (66.9)
Vaccinated at Dose 2 ^b	2924	2923
E-diary		
Not transmitted ^c	201 (6.9)	199 (6.8)
Transmitted ^d		
Day 1	2245 (76.8)	2120 (72.5)
Day 2	2511 (85.9)	2324 (79.5)
Day 3	2445 (83.6)	2390 (81.8)
Day 4	2426 (83.0)	2415 (82.6)
Day 5	2429 (83.1)	2419 (82.8)
Day 6	2446 (83.7)	2425 (83.0)
Day 7	2414 (82.6)	2442 (83.5)

E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population		
	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n^a (%)	Placebo n^a (%)
All 7 days ^e	1517 (51.9)	1376 (47.1)
<p>Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.</p> <p>a. n = Number of subjects with the specified characteristic.</p> <p>b. These values are the denominators for the percentage calculations.</p> <p>c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 through Day 7), the e-diary is considered not transmitted.</p> <p>d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.</p> <p>e. "All 7 days" includes Day 1 through Day 7 after vaccination. Day 1 is the day of vaccination.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 28MAR2021 (12:24) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s200_trns_1655_saf</p>		

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Vaccine Group (as Administered)							
Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
1	Redness ^d						
	Any	2899	156 (5.4)	(4.6, 6.3)	2908	28 (1.0)	(0.6, 1.4)
	Mild	2899	113 (3.9)	(3.2, 4.7)	2908	19 (0.7)	(0.4, 1.0)
	Moderate	2899	36 (1.2)	(0.9, 1.7)	2908	6 (0.2)	(0.1, 0.4)
	Severe	2899	7 (0.2)	(0.1, 0.5)	2908	3 (0.1)	(0.0, 0.3)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Swelling ^d						
	Any	2899	184 (6.3)	(5.5, 7.3)	2908	16 (0.6)	(0.3, 0.9)
	Mild	2899	124 (4.3)	(3.6, 5.1)	2908	6 (0.2)	(0.1, 0.4)
	Moderate	2899	54 (1.9)	(1.4, 2.4)	2908	8 (0.3)	(0.1, 0.5)
	Severe	2899	6 (0.2)	(0.1, 0.4)	2908	2 (0.1)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Pain at the injection site ^e						
	Any	2899	2426 (83.7)	(82.3, 85.0)	2908	414 (14.2)	(13.0, 15.6)
	Mild	2899	1464 (50.5)	(48.7, 52.3)	2908	391 (13.4)	(12.2, 14.7)
	Moderate	2899	923 (31.8)	(30.1, 33.6)	2908	20 (0.7)	(0.4, 1.1)
	Severe	2899	39 (1.3)	(1.0, 1.8)	2908	3 (0.1)	(0.0, 0.3)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Any local reaction ^f	2899	2444 (84.3)	(82.9, 85.6)	2908	432 (14.9)	(13.6, 16.2)
2	Redness ^d						
	Any	2682	151 (5.6)	(4.8, 6.6)	2684	18 (0.7)	(0.4, 1.1)
	Mild	2682	90 (3.4)	(2.7, 4.1)	2684	12 (0.4)	(0.2, 0.8)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Vaccine Group (as Administered)							
Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Moderate	2682	50 (1.9)	(1.4, 2.5)	2684	6 (0.2)	(0.1, 0.5)
	Severe	2682	11 (0.4)	(0.2, 0.7)	2684	0	(0.0, 0.1)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Swelling ^d						
	Any	2682	183 (6.8)	(5.9, 7.8)	2684	5 (0.2)	(0.1, 0.4)
	Mild	2682	110 (4.1)	(3.4, 4.9)	2684	3 (0.1)	(0.0, 0.3)
	Moderate	2682	66 (2.5)	(1.9, 3.1)	2684	2 (0.1)	(0.0, 0.3)
	Severe	2682	7 (0.3)	(0.1, 0.5)	2684	0	(0.0, 0.1)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Pain at the injection site ^e						
	Any	2682	2101 (78.3)	(76.7, 79.9)	2684	312 (11.6)	(10.4, 12.9)
	Mild	2682	1274 (47.5)	(45.6, 49.4)	2684	284 (10.6)	(9.4, 11.8)
	Moderate	2682	788 (29.4)	(27.7, 31.1)	2684	28 (1.0)	(0.7, 1.5)
	Severe	2682	39 (1.5)	(1.0, 2.0)	2684	0	(0.0, 0.1)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Any local reaction ^f	2682	2108 (78.6)	(77.0, 80.1)	2684	325 (12.1)	(10.9, 13.4)
	Any dose						
	Redness ^d						
	Any	2909	276 (9.5)	(8.4, 10.6)	2921	42 (1.4)	(1.0, 1.9)
	Mild	2909	180 (6.2)	(5.3, 7.1)	2921	27 (0.9)	(0.6, 1.3)
	Moderate	2909	78 (2.7)	(2.1, 3.3)	2921	12 (0.4)	(0.2, 0.7)
	Severe	2909	18 (0.6)	(0.4, 1.0)	2921	3 (0.1)	(0.0, 0.3)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Vaccine Group (as Administered)							
Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Swelling ^d						
	Any	2909	309 (10.6)	(9.5, 11.8)	2921	20 (0.7)	(0.4, 1.1)
	Mild	2909	195 (6.7)	(5.8, 7.7)	2921	9 (0.3)	(0.1, 0.6)
	Moderate	2909	101 (3.5)	(2.8, 4.2)	2921	9 (0.3)	(0.1, 0.6)
	Severe	2909	13 (0.4)	(0.2, 0.8)	2921	2 (0.1)	(0.0, 0.2)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Pain at the injection site ^e						
	Any	2909	2577 (88.6)	(87.4, 89.7)	2921	585 (20.0)	(18.6, 21.5)
	Mild	2909	1280 (44.0)	(42.2, 45.8)	2921	538 (18.4)	(17.0, 19.9)
	Moderate	2909	1223 (42.0)	(40.2, 43.9)	2921	44 (1.5)	(1.1, 2.0)
	Severe	2909	74 (2.5)	(2.0, 3.2)	2921	3 (0.1)	(0.0, 0.3)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Any local reaction ^f	2909	2590 (89.0)	(87.8, 90.1)	2921	609 (20.8)	(19.4, 22.4)
<p>Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.</p> <p>Note: Grade 4 reactions were classified by the investigator or medically qualified person.</p> <p>a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.</p> <p>b. n = Number of subjects with the specified characteristic.</p> <p>c. Exact 2-sided CI based on the Clopper and Pearson method.</p> <p>d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).</p> <p>e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.</p> <p>f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 28MAR2021 (14:46) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .nda2_unblinded/C4591001 EUA 1655/adce s010 lr 1655 saf</p>							

Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Local Reaction	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
1	Redness		
	n ^a	156	28
	Mean (SD)	2.2 (1.92)	1.7 (1.39)
	Median	1.0	1.0
	Min, max	(1, 14)	(1, 6)
	Swelling		
	n ^a	184	16
	Mean (SD)	2.0 (1.55)	2.2 (2.46)
	Median	1.0	1.0
	Min, max	(1, 12)	(1, 10)
	Pain at the injection site		
	n ^a	2426	414
	Mean (SD)	2.2 (1.49)	1.6 (1.51)
	Median	2.0	1.0
	Min, max	(1, 22)	(1, 17)
	Unknown ^b	2	1
2	Redness		
	n ^a	151	18
	Mean (SD)	2.2 (1.60)	1.2 (0.43)
	Median	2.0	1.0
	Min, max	(1, 9)	(1, 2)
	Swelling		
	n ^a	183	5

Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Local Reaction	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Mean (SD)	2.1 (1.50)	2.2 (0.84)
	Median	2.0	2.0
	Min, max	(1, 8)	(1, 3)
	Pain at the injection site		
	n ^a	2101	312
	Mean (SD)	2.5 (2.21)	1.9 (2.84)
	Median	2.0	1.0
	Min, max	(1, 70)	(1, 35)
	Unknown ^b	5	0

Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.

Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.

a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.

b. Includes those reactions where the resolution date is partial or missing.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 30MAR2021 (08:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .\nda2_unblinded\C4591001_EUA_1655/adce_s030_lr_dur_1655_saf

Onset Days for Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
1	Redness		
	n ^a	156	28
	Mean (SD)	2.3 (0.98)	1.9 (1.30)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 5)
	Swelling		
	n ^a	184	16
	Mean (SD)	2.0 (0.80)	1.8 (1.29)
	Median	2.0	1.0
	Min, max	(1, 5)	(1, 5)
	Pain at the injection site		
	n ^a	2426	414
	Mean (SD)	1.4 (0.55)	1.6 (1.16)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
	Any local reaction ^b		
	n ^a	2444	432
	Mean (SD)	1.4 (0.55)	1.6 (1.14)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
2	Redness		
	n ^a	151	18
	Mean (SD)	2.5 (0.97)	2.2 (1.50)
	Median	2.0	2.0

Onset Days for Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Min, max	(1, 6)	(1, 6)
	Swelling		
	n ^a	183	5
	Mean (SD)	2.0 (0.86)	2.0 (1.00)
	Median	2.0	2.0
	Min, max	(1, 5)	(1, 3)
	Pain at the injection site		
	n ^a	2101	312
	Mean (SD)	1.4 (0.59)	1.5 (0.96)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 7)
	Any local reaction ^b		
	n ^a	2108	325
	Mean (SD)	1.4 (0.59)	1.5 (1.01)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 7)

Note: Day of onset is the first day the specified reaction was reported.

a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.

b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 30MAR2021 (08:23)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adce s050 lr onset 1655 saf

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
1	Fever						
	≥38.0°C	2899	119 (4.1)	(3.4, 4.9)	2908	25 (0.9)	(0.6, 1.3)
	≥38.0°C to 38.4°C	2899	86 (3.0)	(2.4, 3.7)	2908	16 (0.6)	(0.3, 0.9)
	>38.4°C to 38.9°C	2899	25 (0.9)	(0.6, 1.3)	2908	5 (0.2)	(0.1, 0.4)
	>38.9°C to 40.0°C	2899	8 (0.3)	(0.1, 0.5)	2908	4 (0.1)	(0.0, 0.4)
	>40.0°C	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Fatigue ^d						
	Any	2899	1431 (49.4)	(47.5, 51.2)	2908	960 (33.0)	(31.3, 34.8)
	Mild	2899	760 (26.2)	(24.6, 27.9)	2908	570 (19.6)	(18.2, 21.1)
	Moderate	2899	630 (21.7)	(20.2, 23.3)	2908	372 (12.8)	(11.6, 14.1)
	Severe	2899	41 (1.4)	(1.0, 1.9)	2908	18 (0.6)	(0.4, 1.0)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Headache ^d						
	Any	2899	1262 (43.5)	(41.7, 45.4)	2908	975 (33.5)	(31.8, 35.3)
	Mild	2899	785 (27.1)	(25.5, 28.7)	2908	633 (21.8)	(20.3, 23.3)
	Moderate	2899	444 (15.3)	(14.0, 16.7)	2908	318 (10.9)	(9.8, 12.1)
	Severe	2899	33 (1.1)	(0.8, 1.6)	2908	24 (0.8)	(0.5, 1.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Chills ^d						
	Any	2899	479 (16.5)	(15.2, 17.9)	2908	199 (6.8)	(6.0, 7.8)
	Mild	2899	338 (11.7)	(10.5, 12.9)	2908	148 (5.1)	(4.3, 6.0)
	Moderate	2899	126 (4.3)	(3.6, 5.2)	2908	49 (1.7)	(1.2, 2.2)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Severe	2899	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Vomiting ^e						
	Any	2899	34 (1.2)	(0.8, 1.6)	2908	36 (1.2)	(0.9, 1.7)
	Mild	2899	29 (1.0)	(0.7, 1.4)	2908	30 (1.0)	(0.7, 1.5)
	Moderate	2899	5 (0.2)	(0.1, 0.4)	2908	5 (0.2)	(0.1, 0.4)
	Severe	2899	0	(0.0, 0.1)	2908	1 (0.0)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Diarrhea ^f						
	Any	2899	309 (10.7)	(9.6, 11.8)	2908	323 (11.1)	(10.0, 12.3)
	Mild	2899	251 (8.7)	(7.7, 9.7)	2908	264 (9.1)	(8.1, 10.2)
	Moderate	2899	55 (1.9)	(1.4, 2.5)	2908	58 (2.0)	(1.5, 2.6)
	Severe	2899	3 (0.1)	(0.0, 0.3)	2908	1 (0.0)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	New or worsened muscle pain ^d						
	Any	2899	664 (22.9)	(21.4, 24.5)	2908	329 (11.3)	(10.2, 12.5)
	Mild	2899	353 (12.2)	(11.0, 13.4)	2908	231 (7.9)	(7.0, 9.0)
	Moderate	2899	296 (10.2)	(9.1, 11.4)	2908	96 (3.3)	(2.7, 4.0)
	Severe	2899	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	New or worsened joint pain ^d						
	Any	2899	342 (11.8)	(10.6, 13.0)	2908	168 (5.8)	(5.0, 6.7)
	Mild	2899	200 (6.9)	(6.0, 7.9)	2908	112 (3.9)	(3.2, 4.6)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
2	Moderate	2899	137 (4.7)	(4.0, 5.6)	2908	55 (1.9)	(1.4, 2.5)
	Severe	2899	5 (0.2)	(0.1, 0.4)	2908	1 (0.0)	(0.0, 0.2)
	Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
	Any systemic event ^g	2899	1979 (68.3)	(66.5, 70.0)	2908	1559 (53.6)	(51.8, 55.4)
	Use of antipyretic or pain medication ^h	2899	805 (27.8)	(26.1, 29.4)	2908	398 (13.7)	(12.5, 15.0)
	Fever						
	≥38.0°C	2682	440 (16.4)	(15.0, 17.9)	2684	11 (0.4)	(0.2, 0.7)
	≥38.0°C to 38.4°C	2682	254 (9.5)	(8.4, 10.6)	2684	5 (0.2)	(0.1, 0.4)
	>38.4°C to 38.9°C	2682	146 (5.4)	(4.6, 6.4)	2684	4 (0.1)	(0.0, 0.4)
	>38.9°C to 40.0°C	2682	39 (1.5)	(1.0, 2.0)	2684	2 (0.1)	(0.0, 0.3)
	>40.0°C	2682	1 (0.0)	(0.0, 0.2)	2684	0	(0.0, 0.1)
	Fatigue ^d						
	Any	2682	1649 (61.5)	(59.6, 63.3)	2684	614 (22.9)	(21.3, 24.5)
	Mild	2682	558 (20.8)	(19.3, 22.4)	2684	317 (11.8)	(10.6, 13.1)
	Moderate	2682	949 (35.4)	(33.6, 37.2)	2684	283 (10.5)	(9.4, 11.8)
	Severe	2682	142 (5.3)	(4.5, 6.2)	2684	14 (0.5)	(0.3, 0.9)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Headache ^d						
	Any	2682	1448 (54.0)	(52.1, 55.9)	2684	652 (24.3)	(22.7, 26.0)
	Mild	2682	699 (26.1)	(24.4, 27.8)	2684	404 (15.1)	(13.7, 16.5)
	Moderate	2682	658 (24.5)	(22.9, 26.2)	2684	230 (8.6)	(7.5, 9.7)
	Severe	2682	91 (3.4)	(2.7, 4.1)	2684	18 (0.7)	(0.4, 1.1)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Chills ^d						
	Any	2682	1015 (37.8)	(36.0, 39.7)	2684	114 (4.2)	(3.5, 5.1)
	Mild	2682	477 (17.8)	(16.4, 19.3)	2684	89 (3.3)	(2.7, 4.1)
	Moderate	2682	469 (17.5)	(16.1, 19.0)	2684	23 (0.9)	(0.5, 1.3)
	Severe	2682	69 (2.6)	(2.0, 3.2)	2684	2 (0.1)	(0.0, 0.3)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Vomiting ^e						
	Any	2682	58 (2.2)	(1.6, 2.8)	2684	30 (1.1)	(0.8, 1.6)
	Mild	2682	42 (1.6)	(1.1, 2.1)	2684	20 (0.7)	(0.5, 1.1)
	Moderate	2682	12 (0.4)	(0.2, 0.8)	2684	10 (0.4)	(0.2, 0.7)
	Severe	2682	4 (0.1)	(0.0, 0.4)	2684	0	(0.0, 0.1)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Diarrhea ^f						
	Any	2682	269 (10.0)	(8.9, 11.2)	2684	205 (7.6)	(6.7, 8.7)
	Mild	2682	219 (8.2)	(7.2, 9.3)	2684	169 (6.3)	(5.4, 7.3)
	Moderate	2682	44 (1.6)	(1.2, 2.2)	2684	35 (1.3)	(0.9, 1.8)
	Severe	2682	6 (0.2)	(0.1, 0.5)	2684	1 (0.0)	(0.0, 0.2)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	New or worsened muscle pain ^d						
	Any	2682	1055 (39.3)	(37.5, 41.2)	2684	237 (8.8)	(7.8, 10.0)
	Mild	2682	441 (16.4)	(15.1, 17.9)	2684	150 (5.6)	(4.7, 6.5)
	Moderate	2682	552 (20.6)	(19.1, 22.2)	2684	84 (3.1)	(2.5, 3.9)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
Any dose	Severe	2682	62 (2.3)	(1.8, 3.0)	2684	3 (0.1)	(0.0, 0.3)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	New or worsened joint pain ^d						
	Any	2682	638 (23.8)	(22.2, 25.4)	2684	147 (5.5)	(4.6, 6.4)
	Mild	2682	291 (10.9)	(9.7, 12.1)	2684	82 (3.1)	(2.4, 3.8)
	Moderate	2682	320 (11.9)	(10.7, 13.2)	2684	61 (2.3)	(1.7, 2.9)
	Severe	2682	27 (1.0)	(0.7, 1.5)	2684	4 (0.1)	(0.0, 0.4)
	Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
	Any systemic event ^g	2682	2034 (75.8)	(74.2, 77.4)	2684	1026 (38.2)	(36.4, 40.1)
	Use of antipyretic or pain medication ^h	2682	1213 (45.2)	(43.3, 47.1)	2684	320 (11.9)	(10.7, 13.2)
	Fever						
	≥38.0°C	2909	517 (17.8)	(16.4, 19.2)	2921	34 (1.2)	(0.8, 1.6)
	≥38.0°C to 38.4°C	2909	310 (10.7)	(9.6, 11.8)	2921	20 (0.7)	(0.4, 1.1)
	>38.4°C to 38.9°C	2909	163 (5.6)	(4.8, 6.5)	2921	9 (0.3)	(0.1, 0.6)
	>38.9°C to 40.0°C	2909	43 (1.5)	(1.1, 2.0)	2921	5 (0.2)	(0.1, 0.4)
	>40.0°C	2909	1 (0.0)	(0.0, 0.2)	2921	0	(0.0, 0.1)
	Fatigue ^d						
	Any	2909	2038 (70.1)	(68.4, 71.7)	2921	1172 (40.1)	(38.3, 41.9)
	Mild	2909	672 (23.1)	(21.6, 24.7)	2921	615 (21.1)	(19.6, 22.6)
	Moderate	2909	1191 (40.9)	(39.1, 42.8)	2921	529 (18.1)	(16.7, 19.6)
	Severe	2909	175 (6.0)	(5.2, 6.9)	2921	28 (1.0)	(0.6, 1.4)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		N ^a	BNT162b2 (30 µg)		N ^a	Placebo	
			n ^b (%)	(95% CI) ^c		n ^b (%)	(95% CI) ^c
	Headache ^d						
	Any	2909	1889 (64.9)	(63.2, 66.7)	2921	1225 (41.9)	(40.1, 43.8)
	Mild	2909	870 (29.9)	(28.2, 31.6)	2921	730 (25.0)	(23.4, 26.6)
	Moderate	2909	901 (31.0)	(29.3, 32.7)	2921	454 (15.5)	(14.2, 16.9)
	Severe	2909	118 (4.1)	(3.4, 4.8)	2921	41 (1.4)	(1.0, 1.9)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Chills ^d						
	Any	2909	1208 (41.5)	(39.7, 43.3)	2921	270 (9.2)	(8.2, 10.4)
	Mild	2909	594 (20.4)	(19.0, 21.9)	2921	205 (7.0)	(6.1, 8.0)
	Moderate	2909	532 (18.3)	(16.9, 19.7)	2921	61 (2.1)	(1.6, 2.7)
	Severe	2909	82 (2.8)	(2.2, 3.5)	2921	4 (0.1)	(0.0, 0.4)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Vomiting ^e						
	Any	2909	87 (3.0)	(2.4, 3.7)	2921	60 (2.1)	(1.6, 2.6)
	Mild	2909	67 (2.3)	(1.8, 2.9)	2921	44 (1.5)	(1.1, 2.0)
	Moderate	2909	16 (0.6)	(0.3, 0.9)	2921	15 (0.5)	(0.3, 0.8)
	Severe	2909	4 (0.1)	(0.0, 0.4)	2921	1 (0.0)	(0.0, 0.2)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Diarrhea ^f						
	Any	2909	492 (16.9)	(15.6, 18.3)	2921	460 (15.7)	(14.4, 17.1)
	Mild	2909	393 (13.5)	(12.3, 14.8)	2921	369 (12.6)	(11.4, 13.9)
	Moderate	2909	90 (3.1)	(2.5, 3.8)	2921	89 (3.0)	(2.5, 3.7)
	Severe	2909	9 (0.3)	(0.1, 0.6)	2921	2 (0.1)	(0.0, 0.2)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
Dose	Systemic Event	Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
		N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	New or worsened muscle pain ^d						
	Any	2909	1325 (45.5)	(43.7, 47.4)	2921	471 (16.1)	(14.8, 17.5)
	Mild	2909	530 (18.2)	(16.8, 19.7)	2921	304 (10.4)	(9.3, 11.6)
	Moderate	2909	721 (24.8)	(23.2, 26.4)	2921	162 (5.5)	(4.7, 6.4)
	Severe	2909	74 (2.5)	(2.0, 3.2)	2921	5 (0.2)	(0.1, 0.4)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	New or worsened joint pain ^d						
	Any	2909	799 (27.5)	(25.9, 29.1)	2921	272 (9.3)	(8.3, 10.4)
	Mild	2909	359 (12.3)	(11.2, 13.6)	2921	161 (5.5)	(4.7, 6.4)
	Moderate	2909	408 (14.0)	(12.8, 15.3)	2921	106 (3.6)	(3.0, 4.4)
	Severe	2909	32 (1.1)	(0.8, 1.5)	2921	5 (0.2)	(0.1, 0.4)
	Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
	Any systemic event ^e	2909	2446 (84.1)	(82.7, 85.4)	2921	1797 (61.5)	(59.7, 63.3)
	Use of antipyretic or pain medication ^h	2909	1485 (51.0)	(49.2, 52.9)	2921	605 (20.7)	(19.3, 22.2)
<p>Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.</p> <p>a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.</p> <p>b. n = Number of subjects with the specified characteristic.</p> <p>c. Exact 2-sided CI based on the Clopper and Pearson method.</p> <p>d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.</p> <p>e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.</p> <p>f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room</p>							

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population							
		Vaccine Group (as Administered)					
Dose	Systemic Event	N ^a	BNT162b2 (30 µg)			Placebo	
			n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
visit or hospitalization for severe diarrhea.							
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.							
h. Severity was not collected for use of antipyretic or pain medication.							
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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
1	Fever ($\geq 38.0^{\circ}\text{C}$)		
	n ^a	119	25
	Mean (SD)	1.2 (0.87)	1.7 (1.52)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
	Unknown ^b	0	1
	Fatigue		
	n ^a	1431	960
	Mean (SD)	2.5 (2.50)	2.9 (2.89)
	Median	1.0	2.0
	Min, max	(1, 23)	(1, 23)
	Unknown ^b	6	5
	Headache		
	n ^a	1262	975
	Mean (SD)	2.4 (2.45)	2.6 (2.62)
	Median	1.0	1.0
	Min, max	(1, 25)	(1, 22)
	Unknown ^b	5	4
	Chills		
	n ^a	479	199
	Mean (SD)	1.6 (1.34)	2.1 (2.77)
	Median	1.0	1.0
	Min, max	(1, 9)	(1, 31)

Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Unknown ^b	1	2
	Vomiting		
	n ^a	34	36
	Mean (SD)	1.5 (1.13)	1.4 (0.91)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 4)
	Diarrhea		
	n ^a	309	323
	Mean (SD)	2.0 (2.97)	1.8 (1.91)
	Median	1.0	1.0
	Min, max	(1, 39)	(1, 23)
	Unknown ^b	1	0
	New or worsened muscle pain		
	n ^a	664	329
	Mean (SD)	1.7 (1.63)	2.0 (2.56)
	Median	1.0	1.0
	Min, max	(1, 17)	(1, 31)
	Unknown ^b	1	1
	New or worsened joint pain		
	n ^a	342	168
	Mean (SD)	1.6 (1.74)	2.2 (2.38)
	Median	1.0	1.0
	Min, max	(1, 24)	(1, 17)
	Unknown ^b	2	0

Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
2	Use of antipyretic or pain medication		
	n ^a	805	398
	Mean (SD)	1.9 (1.76)	2.2 (2.44)
	Median	1.0	1.0
	Min, max	(1, 16)	(1, 23)
	Unknown ^b	1	4
	Fever (≥38.0°C)		
	n ^a	440	11
	Mean (SD)	1.1 (0.51)	2.1 (2.08)
	Median	1.0	1.0
	Min, max	(1, 8)	(1, 6)
	Unknown ^b	0	1
	Fatigue		
	n ^a	1649	614
	Mean (SD)	2.2 (2.14)	2.8 (3.04)
	Median	1.0	2.0
	Min, max	(1, 35)	(1, 38)
	Unknown ^b	5	10
	Headache		
	n ^a	1448	652
	Mean (SD)	2.2 (2.01)	2.4 (3.00)
	Median	1.0	1.0
	Min, max	(1, 25)	(1, 35)
	Unknown ^b	5	10

Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Chills		
	n ^a	1015	114
	Mean (SD)	1.3 (0.81)	2.2 (1.99)
	Median	1.0	1.0
	Min, max	(1, 11)	(1, 10)
	Unknown ^b	3	2
	Vomiting		
	n ^a	58	30
	Mean (SD)	2.4 (5.27)	1.5 (1.15)
	Median	1.0	1.0
	Min, max	(1, 37)	(1, 6)
	Unknown ^b	1	1
	Diarrhea		
	n ^a	269	205
	Mean (SD)	1.8 (2.31)	2.1 (3.32)
	Median	1.0	1.0
	Min, max	(1, 31)	(1, 33)
	Unknown ^b	1	3
	New or worsened muscle pain		
	n ^a	1055	237
	Mean (SD)	1.5 (1.34)	2.3 (2.71)
	Median	1.0	1.0
	Min, max	(1, 23)	(1, 27)
	Unknown ^b	3	1

Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	New or worsened joint pain		
	n ^a	638	147
	Mean (SD)	1.6 (1.75)	2.2 (2.28)
	Median	1.0	1.0
	Min, max	(1, 28)	(1, 16)
	Unknown ^b	5	2
	Use of antipyretic or pain medication		
	n ^a	1213	320
	Mean (SD)	1.9 (2.00)	2.1 (2.83)
	Median	1.0	1.0
	Min, max	(1, 34)	(1, 38)
	Unknown ^b	6	9
<p>Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.</p> <p>Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.</p> <p>a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.</p> <p>b. Includes those events where the resolution date is partial or missing.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 28MAR2021 (18:13) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s040_se_dur_1655_saf</p>			

Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
1	Fever ($\geq 38.0^{\circ}\text{C}$)		
	n ^a	119	25
	Mean (SD)	2.5 (1.24)	3.7 (2.10)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n ^a	1431	960
	Mean (SD)	2.0 (1.23)	2.3 (1.62)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Headache		
	n ^a	1262	975
	Mean (SD)	2.4 (1.53)	2.6 (1.71)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n ^a	479	199
	Mean (SD)	2.2 (1.23)	2.9 (1.78)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Vomiting		
	n ^a	34	36
	Mean (SD)	3.8 (1.85)	3.6 (2.03)
	Median	4.0	4.0

Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Min, max	(1, 7)	(1, 7)
	Diarrhea		
	n ^a	309	323
	Mean (SD)	3.5 (1.68)	3.6 (1.77)
	Median	3.0	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n ^a	664	329
	Mean (SD)	2.3 (1.20)	3.1 (1.78)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	New or worsened joint pain		
	n ^a	342	168
	Mean (SD)	2.6 (1.43)	3.4 (1.61)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Any systemic event ^b		
	n ^a	1979	1559
	Mean (SD)	2.0 (1.22)	2.3 (1.59)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		
	n ^a	805	398
	Mean (SD)	2.4 (1.33)	3.4 (1.85)

Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
2	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Fever ($\geq 38.0^{\circ}\text{C}$)		
	n ^a	440	11
	Mean (SD)	2.0 (0.53)	3.6 (2.25)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n ^a	1649	614
	Mean (SD)	1.9 (0.76)	2.4 (1.60)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Headache		
	n ^a	1448	652
	Mean (SD)	2.1 (1.02)	2.8 (1.75)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n ^a	1015	114
	Mean (SD)	1.9 (0.54)	2.7 (1.63)
	Median	2.0	2.0
	Min, max	(1, 6)	(1, 7)
	Vomiting		
	n ^a	58	30

Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	Mean (SD)	2.6 (1.38)	3.8 (2.12)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Diarrhea		
	n ^a	269	205
	Mean (SD)	3.2 (1.71)	3.7 (1.92)
	Median	3.0	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n ^a	1055	237
	Mean (SD)	2.0 (0.66)	3.0 (1.83)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	New or worsened joint pain		
	n ^a	638	147
	Mean (SD)	2.1 (0.81)	3.3 (1.82)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Any systemic event ^b		
	n ^a	2034	1026
	Mean (SD)	1.8 (0.85)	2.4 (1.62)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		

Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	n ^a	1213	320
	Mean (SD)	2.0 (0.77)	3.4 (1.79)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
<p>Note: Day of onset is the first day the specified event was reported.</p> <p>a. n = Number of subjects reporting the specified event, with each subject counted only once per event.</p> <p>b. Any systemic event: any fever $\geq 38.0^{\circ}\text{C}$, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 30MAR2021 (08:28) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adce s060 se onset 1655 saf</p>			

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Any event	4233 (32.6)	(31.8, 33.4)	1871 (14.4)	(13.8, 15.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	80 (0.6)	(0.5, 0.8)	10 (0.1)	(0.0, 0.1)
Lymphadenopathy	67 (0.5)	(0.4, 0.7)	4 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lymph node pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	27 (0.2)	(0.1, 0.3)	24 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Tachycardia	10 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	36 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.2)
Vertigo	10 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Ear pain	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vertigo positional	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Autoimmune thyroiditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogonadism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	34 (0.3)	(0.2, 0.4)	22 (0.2)	(0.1, 0.3)
Eye pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	440 (3.4)	(3.1, 3.7)	288 (2.2)	(2.0, 2.5)
Diarrhoea	157 (1.2)	(1.0, 1.4)	117 (0.9)	(0.7, 1.1)
Nausea	184 (1.4)	(1.2, 1.6)	61 (0.5)	(0.4, 0.6)
Vomiting	54 (0.4)	(0.3, 0.5)	22 (0.2)	(0.1, 0.3)
Toothache	14 (0.1)	(0.1, 0.2)	16 (0.1)	(0.1, 0.2)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Abdominal pain upper	18 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Abdominal pain	11 (0.1)	(0.0, 0.2)	14 (0.1)	(0.1, 0.2)
Gastroesophageal reflux disease	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Dyspepsia	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Odynophagia	9 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Dental caries	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth impacted	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lip swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendix disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3161 (24.3)	(23.6, 25.1)	681 (5.2)	(4.9, 5.6)
Injection site pain	1929 (14.8)	(14.2, 15.5)	284 (2.2)	(1.9, 2.4)
Fatigue	1012 (7.8)	(7.3, 8.3)	270 (2.1)	(1.8, 2.3)
Pyrexia	1117 (8.6)	(8.1, 9.1)	54 (0.4)	(0.3, 0.5)
Chills	966 (7.4)	(7.0, 7.9)	77 (0.6)	(0.5, 0.7)
Pain	430 (3.3)	(3.0, 3.6)	40 (0.3)	(0.2, 0.4)
Injection site erythema	119 (0.9)	(0.8, 1.1)	18 (0.1)	(0.1, 0.2)
Injection site swelling	86 (0.7)	(0.5, 0.8)	12 (0.1)	(0.0, 0.2)
Malaise	86 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Asthenia	46 (0.4)	(0.3, 0.5)	18 (0.1)	(0.1, 0.2)
Injection site pruritus	23 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Chest pain	10 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site bruising	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Influenza like illness	15 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Axillary pain	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Injection site reaction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Medical device pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	19 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Drug hypersensitivity	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	190 (1.5)	(1.3, 1.7)	218 (1.7)	(1.5, 1.9)
Urinary tract infection	32 (0.2)	(0.2, 0.3)	25 (0.2)	(0.1, 0.3)
Tooth infection	9 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Sinusitis	8 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Cellulitis	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Ear infection	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Conjunctivitis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Otitis media	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Herpes zoster	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hordeolum	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticulitis	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastroenteritis	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth abscess	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Folliculitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinea versicolour	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Furuncle	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Herpes simplex	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Otitis media acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chronic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papilloma viral infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coxsackie viral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	113 (0.9)	(0.7, 1.0)	140 (1.1)	(0.9, 1.3)
Fall	17 (0.1)	(0.1, 0.2)	13 (0.1)	(0.1, 0.2)
Exposure during pregnancy	10 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.2)
Ligament sprain	10 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Contusion	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Road traffic accident	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Skin laceration	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Muscle strain	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Foot fracture	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Joint injury	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Procedural pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Arthropod bite	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Epicondylitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendon injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure to communicable disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	105 (0.8)	(0.7, 1.0)	21 (0.2)	(0.1, 0.2)
Body temperature increased	80 (0.6)	(0.5, 0.8)	10 (0.1)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	59 (0.5)	(0.3, 0.6)	42 (0.3)	(0.2, 0.4)
Decreased appetite	26 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Vitamin D deficiency	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyslipidaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folate deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1201 (9.2)	(8.7, 9.8)	303 (2.3)	(2.1, 2.6)
Myalgia	871 (6.7)	(6.3, 7.1)	104 (0.8)	(0.7, 1.0)
Arthralgia	176 (1.4)	(1.2, 1.6)	54 (0.4)	(0.3, 0.5)
Pain in extremity	98 (0.8)	(0.6, 0.9)	22 (0.2)	(0.1, 0.3)
Back pain	57 (0.4)	(0.3, 0.6)	56 (0.4)	(0.3, 0.6)
Neck pain	19 (0.1)	(0.1, 0.2)	21 (0.2)	(0.1, 0.2)
Muscle spasms	12 (0.1)	(0.0, 0.2)	6 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscle contracture	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscular weakness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Flank pain	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle fatigue	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Exostosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systemic lupus erythematosus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Lipoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1067 (8.2)	(7.7, 8.7)	393 (3.0)	(2.7, 3.3)
Headache	930 (7.2)	(6.7, 7.6)	290 (2.2)	(2.0, 2.5)
Dizziness	46 (0.4)	(0.3, 0.5)	33 (0.3)	(0.2, 0.4)
Paraesthesia	17 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)
Migraine	21 (0.2)	(0.1, 0.2)	9 (0.1)	(0.0, 0.1)
Sciatica	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Tension headache	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Syncope	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysgeusia	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical radiculopathy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Parosmia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	64 (0.5)	(0.4, 0.6)	55 (0.4)	(0.3, 0.5)
Anxiety	17 (0.1)	(0.1, 0.2)	20 (0.2)	(0.1, 0.2)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
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Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Insomnia	17 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Depression	13 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Depressed mood	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Panic attack	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	13 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	31 (0.2)	(0.2, 0.3)	31 (0.2)	(0.2, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

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	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Amenorrhoea	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Haemorrhagic ovarian cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Uterine haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	111 (0.9)	(0.7, 1.0)	121 (0.9)	(0.8, 1.1)
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)	23 (0.2)	(0.1, 0.3)
Nasal congestion	14 (0.1)	(0.1, 0.2)	28 (0.2)	(0.1, 0.3)
Cough	13 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.2)
Rhinitis allergic	11 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)
Rhinorrhoea	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Asthma	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Upper-airway cough syndrome	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	124 (1.0)	(0.8, 1.1)	88 (0.7)	(0.5, 0.8)
Rash	32 (0.2)	(0.2, 0.3)	23 (0.2)	(0.1, 0.3)
Hyperhidrosis	18 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Pruritus	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Night sweats	9 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash pruritic	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash papular	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	11 (0.1)	(0.0, 0.2)	14 (0.1)	(0.1, 0.2)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth extraction	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	42 (0.3)	(0.2, 0.4)	39 (0.3)	(0.2, 0.4)
Hypertension	19 (0.1)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Hot flush	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (15:30)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_all_pd2_1655_saf

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Any event	4396	88.4	(85.8, 91.0)	2136	43.5	(41.7, 45.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	84	1.7	(1.3, 2.1)	15	0.3	(0.2, 0.5)
Anaemia	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Blood loss anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency anaemia	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leukopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymph node pain	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	69	1.4	(1.1, 1.8)	5	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	30	0.6	(0.4, 0.9)	31	0.6	(0.4, 0.9)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina pectoris	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Atrial flutter	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left ventricular hypertrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mitral valve prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Palpitations	3	0.1	(0.0, 0.2)	13	0.3	(0.1, 0.5)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachycardia	10	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.2)
Tricuspid valve incompetence	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Arnold-Chiari malformation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	41	0.8	(0.6, 1.1)	29	0.6	(0.4, 0.8)
Allergic otitis media	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerumen impaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deafness unilateral	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear pain	9	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoacusis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tinnitus	4	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Tympanic membrane perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	14	0.3	(0.2, 0.5)	15	0.3	(0.2, 0.5)
Vertigo positional	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
ENDOCRINE DISORDERS	8	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.3)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypogonadism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypothyroidism	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Thyroid cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	39	0.8	(0.6, 1.1)	28	0.6	(0.4, 0.8)
Amaurosis fugax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenopia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Chalazion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Eye pain	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Keratitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Lacrimation increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	471	9.5	(8.6, 10.4)	307	6.3	(5.6, 7.0)
Abdominal discomfort	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Abdominal distension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abdominal pain	13	0.3	(0.1, 0.4)	16	0.3	(0.2, 0.5)
Abdominal pain lower	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain upper	19	0.4	(0.2, 0.6)	8	0.2	(0.1, 0.3)
Acute abdomen	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aphthous ulcer	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Colitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dental caries	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Diarrhoea	163	3.3	(2.8, 3.8)	117	2.4	(2.0, 2.9)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry mouth	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Dyspepsia	9	0.2	(0.1, 0.3)	10	0.2	(0.1, 0.4)
Dysphagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eructation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Food poisoning	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	3	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.4)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal disorder	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Gastroesophageal reflux disease	8	0.2	(0.1, 0.3)	15	0.3	(0.2, 0.5)
Gingival bleeding	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival pain	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematemesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematochezia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hiatus hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Large intestine polyp	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Lip swelling	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nausea	186	3.7	(3.2, 4.3)	61	1.2	(1.0, 1.6)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	9	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral mucosa haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Palatal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Proctalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Retching	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stomatitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Swollen tongue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	16	0.3	(0.2, 0.5)	17	0.3	(0.2, 0.6)
Umbilical hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vomiting	56	1.1	(0.9, 1.5)	23	0.5	(0.3, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3167	63.7	(61.5, 65.9)	693	14.1	(13.1, 15.2)
Adverse drug reaction	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site rash	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenia	46	0.9	(0.7, 1.2)	18	0.4	(0.2, 0.6)
Axillary pain	9	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest discomfort	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Chest pain	10	0.2	(0.1, 0.4)	15	0.3	(0.2, 0.5)
Chills	968	19.5	(18.3, 20.7)	77	1.6	(1.2, 2.0)
Chronic fatigue syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	1013	20.4	(19.1, 21.7)	270	5.5	(4.9, 6.2)
Feeling abnormal	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	6	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	16	0.3	(0.2, 0.5)	3	0.1	(0.0, 0.2)
Injection site bruising	8	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.4)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site erythema	119	2.4	(2.0, 2.9)	19	0.4	(0.2, 0.6)
Injection site haematoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Injection site induration	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site nodule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	10	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Injection site pain	1930	38.8	(37.1, 40.6)	286	5.8	(5.2, 6.5)
Injection site papule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	23	0.5	(0.3, 0.7)	5	0.1	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site reaction	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site swelling	86	1.7	(1.4, 2.1)	12	0.2	(0.1, 0.4)
Injection site warmth	8	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Injury associated with device	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Malaise	86	1.7	(1.4, 2.1)	11	0.2	(0.1, 0.4)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device site granuloma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Oedema peripheral	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pain	430	8.6	(7.8, 9.5)	41	0.8	(0.6, 1.1)
Peripheral swelling	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pyrexia	1118	22.5	(21.2, 23.8)	55	1.1	(0.8, 1.5)
Sensation of foreign body	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
HEPATOBIILIARY DISORDERS	9	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Hepatic steatosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	20	0.4	(0.2, 0.6)	20	0.4	(0.2, 0.6)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug hypersensitivity	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Food allergy	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hypersensitivity	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Milk allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seasonal allergy	7	0.1	(0.1, 0.3)	8	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	230	4.6	(4.0, 5.3)	290	5.9	(5.2, 6.6)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess jaw	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute sinusitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal fistula infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Appendicitis	12	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cellulitis	10	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.3)
Chlamydial infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis	6	0.1	(0.0, 0.3)	6	0.1	(0.0, 0.3)
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	3	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Dermatitis infected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	3	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Ear infection	7	0.1	(0.1, 0.3)	13	0.3	(0.1, 0.5)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Folliculitis	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Fungal infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Furuncle	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingivitis	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Gonorrhoea	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hepatitis A	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Herpes simplex	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Herpes zoster	9	0.2	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes zoster oticus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hordeolum	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Impetigo	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Infected bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Kidney infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Localised infection	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Onychomycosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Oral herpes	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Otitis media	7	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.3)
Otitis media acute	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paronychia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodontitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pharyngitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Pustule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rash pustular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinitis	6	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.3)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sialoadenitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	10	0.2	(0.1, 0.4)	17	0.3	(0.2, 0.6)
Sinusitis bacterial	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin infection	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Tinea versicolour	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth abscess	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Tooth infection	9	0.2	(0.1, 0.3)	21	0.4	(0.3, 0.7)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Trichomoniasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	7	0.1	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Ureaplasma infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	36	0.7	(0.5, 1.0)	39	0.8	(0.6, 1.1)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vulvovaginal candidiasis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	163	3.3	(2.8, 3.8)	202	4.1	(3.6, 4.7)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Ankle fracture	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropod bite	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropod sting	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Burns second degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Chillblains	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Contusion	10	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Corneal abrasion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Ear injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epicondylitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Exposure during pregnancy	30	0.6	(0.4, 0.9)	42	0.9	(0.6, 1.2)
Exposure to communicable disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fall	23	0.5	(0.3, 0.7)	20	0.4	(0.2, 0.6)
Fibula fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	4	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint dislocation	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Joint injury	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Ligament injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ligament rupture	1	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.3)
Ligament sprain	10	0.2	(0.1, 0.4)	18	0.4	(0.2, 0.6)
Limb injury	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lumbar vertebral fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Maternal exposure during pregnancy	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Meniscus injury	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscle strain	8	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.3)
Overdose	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural pain	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Radius fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Road traffic accident	11	0.2	(0.1, 0.4)	13	0.3	(0.1, 0.5)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin abrasion	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Skin injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	11	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.3)
Skull fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal compression fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thermal burn	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth fracture	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Vaccination complication	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	110	2.2	(1.8, 2.7)	27	0.5	(0.4, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood creatinine increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood iron decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	81	1.6	(1.3, 2.0)	10	0.2	(0.1, 0.4)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Serum ferritin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	73	1.5	(1.2, 1.8)	63	1.3	(1.0, 1.6)
Decreased appetite	26	0.5	(0.3, 0.8)	6	0.1	(0.0, 0.3)
Dehydration	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Gout	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypercholesterolaemia	5	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.4)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hyperlipidaemia	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperuricaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Insulin resistance	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	8	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitamin D deficiency	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1226	24.6	(23.3, 26.1)	346	7.0	(6.3, 7.8)
Arthralgia	182	3.7	(3.1, 4.2)	62	1.3	(1.0, 1.6)
Arthritis	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	61	1.2	(0.9, 1.6)	65	1.3	(1.0, 1.7)
Bone pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bursitis	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Coccydynia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Exostosis	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fibromyalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Flank pain	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Groin pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Intervertebral disc disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Limb discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscle contracture	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Muscle discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle fatigue	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle spasms	14	0.3	(0.2, 0.5)	6	0.1	(0.0, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Musculoskeletal chest pain	9	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Musculoskeletal discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Musculoskeletal stiffness	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Myalgia	873	17.5	(16.4, 18.8)	104	2.1	(1.7, 2.6)
Myalgia intercostal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Neck pain	23	0.5	(0.3, 0.7)	24	0.5	(0.3, 0.7)
Osteitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Osteochondrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoporosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pain in extremity	101	2.0	(1.7, 2.5)	27	0.5	(0.4, 0.8)
Pain in jaw	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periarthritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Plantar fasciitis	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Psoriatic arthropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhabdomyolysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff syndrome	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Scoliosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spondylitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Synovitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tendon disorder	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22	0.4	(0.3, 0.7)	23	0.5	(0.3, 0.7)
Acrochordon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1085	21.8	(20.5, 23.1)	407	8.3	(7.5, 9.1)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Aphasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Disturbance in attention	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	46	0.9	(0.7, 1.2)	34	0.7	(0.5, 1.0)
Dysgeusia	9	0.2	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Dystonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paralysis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	934	18.8	(17.6, 20.0)	293	6.0	(5.3, 6.7)
Hemiparaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypersomnia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lethargy	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine	23	0.5	(0.3, 0.7)	11	0.2	(0.1, 0.4)
Migraine with aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine without aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nerve compression	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	18	0.4	(0.2, 0.6)	15	0.3	(0.2, 0.5)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parosmia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	6	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.2)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

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Sciatica	9	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Somnolence	5	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.4)
Subarachnoid haemorrhage	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	10	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.2)
Taste disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tension headache	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Transient ischaemic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tremor	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	75	1.5	(1.2, 1.9)	81	1.6	(1.3, 2.1)
Abnormal dreams	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Anxiety	21	0.4	(0.3, 0.6)	26	0.5	(0.3, 0.8)
Anxiety disorder	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Attention deficit hyperactivity disorder	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Bipolar disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	17	0.3	(0.2, 0.5)	17	0.3	(0.2, 0.6)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Insomnia	17	0.3	(0.2, 0.5)	8	0.2	(0.1, 0.3)
Irritability	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic attack	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	20	0.4	(0.2, 0.6)	22	0.4	(0.3, 0.7)
Acute kidney injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic kidney disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysuria	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Haematuria	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	9	0.2	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Pollakiuria	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal colic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urethral discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Urinary retention	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	35	0.7	(0.5, 1.0)	43	0.9	(0.6, 1.2)
Adenomyosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Amenorrhoea	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Benign prostatic hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysmenorrhoea	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erectile dysfunction	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Genital erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Menstruation irregular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian cyst	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pelvic pain	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Penile vein thrombosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostatomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pruritus genital	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Testicular pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Uterine inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	127	2.6	(2.1, 3.0)	133	2.7	(2.3, 3.2)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Allergic respiratory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	8	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bronchospasm	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cough	13	0.3	(0.1, 0.4)	11	0.2	(0.1, 0.4)
Dry throat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysphonia	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Dyspnoea	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Dyspnoea exertional	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Epistaxis	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Haemoptysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Interstitial lung disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal congestion	18	0.4	(0.2, 0.6)	29	0.6	(0.4, 0.8)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oropharyngeal pain	24	0.5	(0.3, 0.7)	23	0.5	(0.3, 0.7)
Paranasal sinus discomfort	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pleuritic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary embolism	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinitis allergic	12	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Rhinorrhoea	12	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Sinus congestion	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Sleep apnoea syndrome	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sneezing	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Upper respiratory tract congestion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Wheezing	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	140	2.8	(2.4, 3.3)	107	2.2	(1.8, 2.6)
Acne	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alopecia	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Alopecia areata	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angioedema	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blister	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Dermatitis atopic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	7	0.1	(0.1, 0.3)	12	0.2	(0.1, 0.4)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ecchymosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eczema	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
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	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Erythema	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand dermatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	18	0.4	(0.2, 0.6)	5	0.1	(0.0, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Night sweats	9	0.2	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peau d'orange	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pruritus	9	0.2	(0.1, 0.3)	13	0.3	(0.1, 0.5)
Pruritus allergic	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Rash	37	0.7	(0.5, 1.0)	25	0.5	(0.3, 0.8)
Rash erythematous	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rash maculo-papular	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin lesion	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	12	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menopause	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	13	0.3	(0.1, 0.4)	18	0.4	(0.2, 0.6)
Abortion induced	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cataract operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Dental implantation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device implantation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinoplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vasectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
VASCULAR DISORDERS	56	1.1	(0.9, 1.5)	50	1.0	(0.8, 1.3)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriosclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Flushing	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Haematoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hot flush	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Hypertension	27	0.5	(0.4, 0.8)	27	0.5	(0.4, 0.8)
Hypertensive urgency	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group.

b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.

c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.

e. 2-sided CI based on Poisson distribution.

Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 28MAR2021 (13:27) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s131_all_exp_1655_saf						

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Any event	52 (0.4)	(0.3, 0.5)	49 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
GASTROINTESTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBIILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

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Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

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Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (15:02)
 (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_ser_all_pd2_1655_saf

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Any event	103	2.1	(1.7, 2.5)	117	2.4	(2.0, 2.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	9	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.4)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
EYE DISORDERS	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBIILIARY DISORDERS	6	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	26	0.5	(0.3, 0.8)	23	0.5	(0.3, 0.7)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Appendicitis	12	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.4)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meniscus injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	10	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	11	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cerebrovascular accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Transient ischaemic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	6	0.1	(0.0, 0.3)	6	0.1	(0.0, 0.3)
Nephrolithiasis	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population						
System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endometriosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Asthmatic crisis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Hypertensive urgency	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group.

b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.

c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.

e. 2-sided CI based on Poisson distribution.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (17:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s131_sae_exp_1655_saf

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Any event	3480 (26.8)	(26.0, 27.5)	882 (6.8)	(6.3, 7.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	56 (0.4)	(0.3, 0.6)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	52 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Lymph node pain	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tachycardia	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Eye irritation	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	322 (2.5)	(2.2, 2.8)	140 (1.1)	(0.9, 1.3)
Diarrhoea	135 (1.0)	(0.9, 1.2)	87 (0.7)	(0.5, 0.8)
Nausea	168 (1.3)	(1.1, 1.5)	41 (0.3)	(0.2, 0.4)
Vomiting	45 (0.3)	(0.3, 0.5)	9 (0.1)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Abdominal pain upper	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspepsia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3118 (24.0)	(23.3, 24.7)	608 (4.7)	(4.3, 5.0)
Injection site pain	1927 (14.8)	(14.2, 15.5)	280 (2.1)	(1.9, 2.4)
Fatigue	991 (7.6)	(7.2, 8.1)	254 (1.9)	(1.7, 2.2)
Pyrexia	1114 (8.6)	(8.1, 9.1)	50 (0.4)	(0.3, 0.5)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Chills	965 (7.4)	(7.0, 7.9)	71 (0.5)	(0.4, 0.7)
Pain	429 (3.3)	(3.0, 3.6)	36 (0.3)	(0.2, 0.4)
Injection site erythema	119 (0.9)	(0.8, 1.1)	17 (0.1)	(0.1, 0.2)
Injection site swelling	86 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Malaise	85 (0.7)	(0.5, 0.8)	7 (0.1)	(0.0, 0.1)
Asthenia	42 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	23 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Injection site bruising	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Influenza like illness	15 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site reaction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Application site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	87 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Body temperature increased	79 (0.6)	(0.5, 0.8)	8 (0.1)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	26 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Decreased appetite	24 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1053 (8.1)	(7.6, 8.6)	128 (1.0)	(0.8, 1.2)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Myalgia	858 (6.6)	(6.2, 7.0)	96 (0.7)	(0.6, 0.9)
Arthralgia	142 (1.1)	(0.9, 1.3)	23 (0.2)	(0.1, 0.3)
Pain in extremity	84 (0.6)	(0.5, 0.8)	4 (0.0)	(0.0, 0.1)
Back pain	18 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Neck pain	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle spasms	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendonitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	945 (7.3)	(6.8, 7.7)	262 (2.0)	(1.8, 2.3)
Headache	877 (6.7)	(6.3, 7.2)	221 (1.7)	(1.5, 1.9)
Dizziness	32 (0.2)	(0.2, 0.3)	19 (0.1)	(0.1, 0.2)
Paraesthesia	9 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysgeusia	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Migraine	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tension headache	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Insomnia	10 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Irritability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37 (0.3)	(0.2, 0.4)	27 (0.2)	(0.1, 0.3)
Oropharyngeal pain	11 (0.1)	(0.0, 0.2)	6 (0.0)	(0.0, 0.1)
Nasal congestion	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Cough	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinorrhoea	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	63 (0.5)	(0.4, 0.6)	28 (0.2)	(0.1, 0.3)
Rash	17 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Hyperhidrosis	15 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Pruritus	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Night sweats	9 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Dermatitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	10 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (17:36)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adae s130 1md2 rel 1655 saf

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Any event	154 (1.2)	(1.0, 1.4)	74 (0.6)	(0.4, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
EYE DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Abdominal pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	75 (0.6)	(0.5, 0.7)	4 (0.0)	(0.0, 0.1)
Pyrexia	34 (0.3)	(0.2, 0.4)	1 (0.0)	(0.0, 0.0)
Fatigue	16 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Injection site pain	13 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Chills	12 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Pain	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Injection site swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBIILIARY DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	10 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis externa	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	30 (0.2)	(0.2, 0.3)	11 (0.1)	(0.0, 0.2)
Myalgia	18 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Arthralgia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Back pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Pain in extremity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neck pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)
Headache	15 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Migraine	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (18:22)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_1md2_sev_1655_saf

**Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Any event	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

**Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2,
by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (18:35)

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Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI ^c)	n ^b (%)	(95% CI ^c)
Any event	19 (0.1)	(0.1, 0.2)	20 (0.2)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (18:52)

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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Any event	2093 (16.1)	(15.5, 16.7)	768 (5.9)	(5.5, 6.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	14 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	13 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Eye irritation	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	157 (1.2)	(1.0, 1.4)	117 (0.9)	(0.7, 1.1)
Diarrhoea	82 (0.6)	(0.5, 0.8)	64 (0.5)	(0.4, 0.6)
Nausea	42 (0.3)	(0.2, 0.4)	29 (0.2)	(0.1, 0.3)
Vomiting	16 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.2)
Abdominal pain upper	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Gastroesophageal reflux disease	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dental caries	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dyspepsia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toothache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1707 (13.1)	(12.6, 13.7)	402 (3.1)	(2.8, 3.4)
Injection site pain	1326 (10.2)	(9.7, 10.7)	169 (1.3)	(1.1, 1.5)
Fatigue	369 (2.8)	(2.6, 3.1)	162 (1.2)	(1.1, 1.4)
Chills	198 (1.5)	(1.3, 1.7)	43 (0.3)	(0.2, 0.4)
Pyrexia	209 (1.6)	(1.4, 1.8)	27 (0.2)	(0.1, 0.3)
Pain	88 (0.7)	(0.5, 0.8)	13 (0.1)	(0.1, 0.2)
Injection site erythema	57 (0.4)	(0.3, 0.6)	10 (0.1)	(0.0, 0.1)
Injection site swelling	49 (0.4)	(0.3, 0.5)	5 (0.0)	(0.0, 0.1)
Malaise	36 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Asthenia	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Injection site bruising	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Influenza like illness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site oedema	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Chest discomfort	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Feeling hot	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site warmth	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site induration	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBIILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	27 (0.2)	(0.1, 0.3)	45 (0.3)	(0.3, 0.5)
Urinary tract infection	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Ear infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinusitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Otitis media	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis externa	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hordeolum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	20 (0.2)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Fall	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle strain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination complication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	22 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Body temperature increased	17 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	15 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Decreased appetite	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperlipidaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	357 (2.7)	(2.5, 3.0)	102 (0.8)	(0.6, 0.9)
Myalgia	245 (1.9)	(1.7, 2.1)	55 (0.4)	(0.3, 0.5)
Arthralgia	56 (0.4)	(0.3, 0.6)	20 (0.2)	(0.1, 0.2)
Pain in extremity	47 (0.4)	(0.3, 0.5)	3 (0.0)	(0.0, 0.1)
Back pain	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Muscle spasms	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Neck pain	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tendonitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint stiffness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosaurs	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
NERVOUS SYSTEM DISORDERS	360 (2.8)	(2.5, 3.1)	187 (1.4)	(1.2, 1.7)
Headache	314 (2.4)	(2.2, 2.7)	150 (1.2)	(1.0, 1.3)
Dizziness	12 (0.1)	(0.0, 0.2)	19 (0.1)	(0.1, 0.2)
Migraine	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Paraesthesia	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population				
System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	19 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Insomnia	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	35 (0.3)	(0.2, 0.4)	36 (0.3)	(0.2, 0.4)
Oropharyngeal pain	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Nasal congestion	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Cough	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)

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	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Rhinitis allergic	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Throat irritation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sneezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	35 (0.3)	(0.2, 0.4)	35 (0.3)	(0.2, 0.4)
Rash	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pruritus	1 (0.0)	(0.0, 0.0)	10 (0.1)	(0.0, 0.1)

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	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Urticaria	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Night sweats	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pruritic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Hot flush	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12995)		Placebo (N ^a =13026)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Hypertension	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Any event	2810 (22.1)	(21.4, 22.8)	561 (4.4)	(4.0, 4.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	54 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Lymphadenopathy	50 (0.4)	(0.3, 0.5)	1 (0.0)	(0.0, 0.0)
Lymph node pain	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	12 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Tachycardia	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	12 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)
Vertigo	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ear pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Eye irritation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	228 (1.8)	(1.6, 2.0)	86 (0.7)	(0.5, 0.8)
Nausea	138 (1.1)	(0.9, 1.3)	21 (0.2)	(0.1, 0.3)
Diarrhoea	64 (0.5)	(0.4, 0.6)	43 (0.3)	(0.2, 0.5)
Vomiting	36 (0.3)	(0.2, 0.4)	3 (0.0)	(0.0, 0.1)
Abdominal pain	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyspepsia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Toothache	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flatulence	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Odynophagia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental caries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2390 (18.8)	(18.1, 19.5)	294 (2.3)	(2.1, 2.6)
Injection site pain	1107 (8.7)	(8.2, 9.2)	127 (1.0)	(0.8, 1.2)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Pyrexia	977 (7.7)	(7.2, 8.2)	23 (0.2)	(0.1, 0.3)
Fatigue	765 (6.0)	(5.6, 6.4)	121 (0.9)	(0.8, 1.1)
Chills	827 (6.5)	(6.1, 6.9)	32 (0.3)	(0.2, 0.4)
Pain	356 (2.8)	(2.5, 3.1)	23 (0.2)	(0.1, 0.3)
Injection site erythema	64 (0.5)	(0.4, 0.6)	8 (0.1)	(0.0, 0.1)
Malaise	52 (0.4)	(0.3, 0.5)	5 (0.0)	(0.0, 0.1)
Injection site swelling	45 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Asthenia	32 (0.3)	(0.2, 0.4)	6 (0.0)	(0.0, 0.1)
Injection site pruritus	15 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Influenza like illness	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Axillary pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	26 (0.2)	(0.1, 0.3)	27 (0.2)	(0.1, 0.3)
Urinary tract infection	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ear infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	17 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Procedural pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	70 (0.6)	(0.4, 0.7)	8 (0.1)	(0.0, 0.1)
Body temperature increased	59 (0.5)	(0.4, 0.6)	6 (0.0)	(0.0, 0.1)
Blood pressure increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Heart rate increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	23 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.1)
Decreased appetite	17 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	852 (6.7)	(6.3, 7.1)	78 (0.6)	(0.5, 0.8)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Myalgia	707 (5.6)	(5.2, 6.0)	42 (0.3)	(0.2, 0.4)
Arthralgia	109 (0.9)	(0.7, 1.0)	15 (0.1)	(0.1, 0.2)
Pain in extremity	44 (0.3)	(0.3, 0.5)	7 (0.1)	(0.0, 0.1)
Back pain	16 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Neck pain	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	755 (5.9)	(5.5, 6.4)	134 (1.1)	(0.9, 1.2)
Headache	693 (5.4)	(5.1, 5.9)	105 (0.8)	(0.7, 1.0)
Dizziness	26 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Paraesthesia	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Migraine	11 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Somnolence	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Lethargy	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Tension headache	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	12 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Anxiety	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Insomnia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Irritability	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematuria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	32 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.2)
Oropharyngeal pain	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nasal congestion	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Rhinorrhoea	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reflux laryngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	49 (0.4)	(0.3, 0.5)	19 (0.1)	(0.1, 0.2)
Rash	12 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	BNT162b2 (30 µg) (N ^a =12727)		Placebo (N ^a =12757)	
	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Alopecia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Hypertension	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hot flush	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	n ^b (%)	(95% CI) ^c	n ^b (%)	(95% CI) ^c
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Subjects who did not receive Dose 2 or who received a different vaccine at Dose 1 and Dose 2 were excluded from this table.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.

b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (11:52)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001 EUA 1655/adae s130 d27d 1655 saf