

Pfizer-BioNTech COVID-19 Vaccine

EUA 27034

**Response to CBER Information Request Received on
31 March 2021 Regarding 508-Compliant Clinical Data Presentations in the
Emergency Use Authorization Request for Individuals 12-15 Years of Age**

April 2021

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1. INTRODUCTION

Reference is made to the Emergency Use Authorization (EUA 27034) for Pfizer-BioNTech COVID-19 Vaccine (BNT162/PF-07302048) issued on 11 December 2020. The authorized indication is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. Further reference is made to BB-IND 19736 and CBER's 31 March 2021 Information Request received via email from Ramachandra S. Naik, PhD (CBER) to Neda Aghajani Memar (Pfizer Inc.). Dr. Naik provided CBER's recommended shell tables in Microsoft Word (508-compliant) to present clinical safety and efficacy data in the Amendment to EUA 27034 to extend the emergency use authorization for Pfizer-BioNTech COVID-19 Vaccine to individuals 12-15 years of age. The purpose of this Response is to provide the completed 508-compliant clinical data tables requested 31 March 2021.

CBER requests are presented in ***bold italics*** and Pfizer/BioNTech responses follow in plain text.

2. CBER REQUEST (31 MARCH 2021)

Attached please find the recommended shell tables to present clinical safety and efficacy data to include in your EUA submission to extend indication to adolescents 12 through 15 years of age. Please fill in the safety and efficacy data in the respective tables in Microsoft Word (508-compliant) and include them with the EUA submission. You may have other tables and listings and those tables can also be included in EUA submission.

Pfizer/BioNTech Response

Safety and efficacy data have been populated into the respective shell tables in the Agency-provided template. These tables are provided in both [Microsoft Word](#) (508-compliant) and [PDF](#) formats in Module 5.3.5.1. Pfizer/BioNTech have also presented several data tables, in addition to those requested, to provide more comprehensive information regarding the program results and to facilitate review.

Please see [Appendix 1](#) for additional information and clarifications to explain certain necessary adjustments to the shell templates provided by CBER.

Appendix 1. Additions and Clarifications to the Requested Tables

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
I. SUMMARY OF CLINICAL DATA		
CLINICAL OVERVIEW		
A. All Clinical Trials, Participants 12 to 15 Years and 16 to 25 Years	A. All Clinical Trials, Participants 12 to 15 and 16 to 25 Years of Age – <u>Randomized Subjects</u>	“Randomized Subjects” was added to the P-B table title for completeness/ clarity, as underlined in the left column.
SUBJECT DISPOSITION		
B. Disposition of Immunogenicity Populations, Participants 12 to 25 Years, Treatment Groups as Randomized	B. Disposition of Immunogenicity Populations, Participants 12 to 15 <u>and 16 through 25 Years of Age (Immunogenicity Subset)</u> , Treatment Groups as Randomized	<p>“...and 16 through 25 Years of Age (Immunogenicity Subset)” was added to the title for completeness/clarity, as underlined in the left column.</p> <p>The following data rows were deleted because the data rows added to the P-B table (described directly below) provided this information with similar or more detail.</p> <ul style="list-style-type: none"> - Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1) - Had other important protocol deviations on or prior to 7 days after Dose 2 <p>The following data rows were added to the P-B table (based on the EUA table) for completeness/clarity:</p> <ul style="list-style-type: none"> - Did not have at least 1 valid and determinate immunogenicity result after Dose 2 - <u>Dose 2</u> Evaluable immunogenicity population [“Dose 2” added] - Did not receive 2 doses of the vaccine to which they were randomly assigned - Did not receive Dose 2 within 19-42 days after Dose 1 - Did not have at least 1 valid and determinate immunogenicity result after Dose 2 - Did not have blood collection within 28-42 days after Dose 2 - Had important protocol deviation(s) as determined by the clinician <p>Row deleted from P-B table because of redundancy/not needed:</p> <ul style="list-style-type: none"> - Evaluable immunogenicity population (After “Unblinded prior to 7 days after Dose 2) <p>In addition, the following footnotes were added:</p> <ul style="list-style-type: none"> - NA = Not Applicable - Notes: Dose 1 All-Available Immunogenicity Population is not applicable for 12-15 and 16-25 Years of age subjects in Phase 3 of the study as blood sample was collected only at Dose 1 and 1 Month after Dose 2. - Notes: Immunogenicity subset is based on a random selection of 280 subjects from BNT162b2 and 50 subjects from Placebo for each of the age groups

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
C. Disposition of Efficacy Populations, Participants 12 to 15 Years, Treatment Groups as Randomized	C. Disposition of Efficacy Populations, Participants 12 to 15 Years of Age, Treatment Groups as Randomized	<p>Rows added to P-B table for completeness/clarity:</p> <p>Under “Reason for exclusion,”</p> <ul style="list-style-type: none"> - Unblinded prior to 7 days after Dose 2 <p>Under “Evaluable efficacy (7 days) population”</p> <ul style="list-style-type: none"> - Subjects without evidence of infection prior to 7 days after Dose 2 <p>Under “Reason for exclusion”</p> <ul style="list-style-type: none"> - Unblinded prior to 7 days after Dose 2 <p>The following footnotes was added to the P-B table for completeness/clarity:</p> <ul style="list-style-type: none"> - Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
D. Disposition of All Randomized Participants 12 to 25 Years, Safety Population	D. Disposition of All Randomized Participants 12 to 15 <u>and 16 Through 25 Years of Age</u> , Safety Population	<p>“and 16 Through 25 years of age” was added to the P-B table title for completeness/clarity as indicated in the column to the left.</p> <p>The following addition, as underlined, was made to the first column heading for completeness/clarity:</p> <ul style="list-style-type: none"> - <u>Treatment Group as Randomized</u> <p>The following additions were made to the data rows for the P-B table for completeness/clarity:</p> <ul style="list-style-type: none"> - Safety Population <ul style="list-style-type: none"> - Reactogenicity subset - HIV-positive - Participants excluded from safety population - Reason for exclusion <ul style="list-style-type: none"> - Did not receive study vaccination - Unreliable data due to lack of PI oversight - Completed 1-month post-Dose 2 visit (vaccination period) - Discontinued from vaccination period but continued in the study up to 1-month post-Dose 2 visit <ul style="list-style-type: none"> - Discontinued after Dose 1 and before Dose 2 - Discontinued after Dose 2 and before 1-month post-Dose 2 visit - Reason for discontinuation from vaccination period <ul style="list-style-type: none"> - No longer meets eligibility criteria - Withdrawal by subject - Pregnancy - Adverse event - Physician decision - Protocol deviation - Lost to follow-up - Other - Withdrawn from study before 1-month post-Dose 2 visit

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
		<ul style="list-style-type: none"> - Withdrawn after Dose 1 and before Dose 2 - Withdrawn after Dose 2 and before 1-month post-Dose 2 visit <p>The following data rows were added under “Reason for Withdrawal”:</p> <ul style="list-style-type: none"> - Protocol deviation - Withdrawal by parent/guardian - Physician decision <p>The following footnotes were added to the P-B table for completeness/clarity:</p> <p>* The numbers in this row are based on subjects who got Dose 2 as administered. Duration of follow-up is based on blinded placebo-controlled follow-up period only.</p> <p>Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.</p>
II. CLINICAL EFFECTIVENESS		
SUBJECT DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS		
E. Demographics and Other Baseline Characteristics, Evaluable Immunogenicity Population Participants 12 to 25 Years	E. Demographics and Other Baseline Characteristics, <u>Dose 2</u> Evaluable Immunogenicity Population Participants 12 to 15 <u>and 16 Through 25 Years of Age</u> (<u>Immunogenicity Subset</u>)	<p>“Dose 2” and “...and 16 through 25 Years of Age (Immunogenicity Subset)” added to P-B table title for completeness/clarity, as underlined in left column.</p> <p>The following data rows were added to the P-B table:</p> <ul style="list-style-type: none"> - Race: Multiracial - Race: Not reported - Ethnicity: Not reported - Baseline Evidence of Prior SARS-CoV-2 Infection: Unknown <p>The following revisions were made to data rows in the P-B table:</p> <ul style="list-style-type: none"> - From: BMI: <30 kg/m² TO Obese: Yes - From: BMI: ≥30 kg/m² TO Obese: No <p>(NOTE: The definition of “obese” for children varies by age and sex (BMI-for-age), and is adjusted per CDC guidelines. [Centers for Disease Control and Prevention, Defining Childhood Obesity, https://www.cdc.gov/obesity/childhood])</p> <p>Text was added to the footnote, as underlined below:</p> <p>¹ Obese is defined as BMI ≥30 kg/m² (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).</p> <p>² Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥30 kg/m² (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).</p>
	E2. Demographics and Other Baseline Characteristics, Evaluable	<p>ADDITIONAL TABLE to present data for participants 12 to 15 years of age, based on FDA Shell Table E.</p> <p>The following data rows were added to the P-B table:</p>

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	Immunogenicity Population, Participants 12 to 15 Years of Age	<ul style="list-style-type: none"> - Race: Multiracial - Race: Not reported - Ethnicity: Not reported - Obese: Yes - Obese: No - Baseline Evidence of Prior SARS-CoV-2 Infection: Unknown <p>Text was added to the footnote, as underlined below: ¹ Obese is defined as BMI ≥ 30 kg/m² (≥ 16 Years of age) or BMI ≥ 95th percentile (12-15 Years of age). ² Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥ 30 kg/m² (≥ 16 Years of age) or BMI ≥ 95th percentile (12-15 Years of age).</p>
Immunogenicity Results – Secondary Immunogenicity Endpoints		
F. Geometric Mean SARS-CoV-2 Neutralizing Titers One Month After BNT16b2 Dose 2 in Participants 12 to 25 Years, Evaluable Immunogenicity Population	F. Geometric Mean SARS-CoV-2 Neutralizing Titers (NT50) 1 Month After BNT16b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of Infection up to 1 Month After Dose 2, Dose 2 Evaluable Immunogenicity Population	<p>“(NT50)” and “Dose 2” and “16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of Infection up to 1 Month After Dose 2, ” added to P-B table title for completeness/clarity, as underlined in left column. The following footnotes were added: - * Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67. N: Number of participants with valid and determinate assay results for the specified assay at 1 month after Dose 2.</p>
G. Seroconversion Rates One Month After BNT16b2 Dose 2, Participants 12 to 25 Years, Evaluable Immunogenicity Population	G. Seroconversion Rates - - NT50 -- 1 Month After BNT16b2 Dose 2, Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of	<p>“NT50” and “and 16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of Infection up to 1 Month After Dose 2” and “Dose 2” added to P-B table title for completeness/clarity, as underlined in left column. The following footnotes were added to the P-B table: * Seroconversion is defined as achieving a ≥ 4-fold rise from baseline (before vaccination). N: number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2. n: number of participants with ≥ 4-fold rise from before vaccination to 1 month after Dose 2</p>

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	<u>Infection up to 1 Month After Dose 2, Dose 2</u> Evaluable Immunogenicity Population	
H. Subgroup Analyses of Geometric Mean SARS-CoV-2 Neutralizing Titers One Month After BNT162b2 Dose 2 in Participants 12 to 25 Years, All-available Immunogenicity Population	H. Subgroup Analyses of Geometric Mean SARS-CoV-2 Neutralizing Titers (NT 50) 1 Month After BNT162b2 Dose 2 in Participants 12 to 15 <u>and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2</u> All-available Immunogenicity Population	“(NT50)” and “and 16 Through 25 Years of Age (Immunogenicity Subset)” and “Dose 2” added to P-B table title for completeness/clarity, as underlined in left column. The following data rows were added to the P-B table for completeness/clarity: - Baseline SARS-CoV-2: Unknown - Ethnicity: Not Reported The following addition was made to the footnote of the P-B table for completeness/clarity (as underlined): - ¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥30 kg/m2 [<u>≥16 Years of age</u>] or BMI ≥95th percentile [<u>12-15 Years of age</u>]). The following footnote was added to the P-B table for completeness/clarity: - N = Number of subjects with valid and determinate assay results for the specified assay at 1 month after Dose 2 GMT: geometric mean titer.
	H. Subgroup: Subgroup Analyses of Seroconversion Rates – <u>NT50</u> -- 1 Month After BNT162b2 Dose 2, Participants 12 to 15 <u>and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2</u> All-available Immunogenicity Population	“NT50” and “and 16 Through 25 Years of Age (Immunogenicity Subset),” and “Dose 2” added to P-B table title for completeness/clarity, as underlined in left column. The following data rows were added to the P-B table for completeness/clarity: - Baseline SARS-CoV-2: Unknown - Ethnicity: Not Reported The following addition was made to the P-B table footnote, as underlined: ¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥30 kg/m2 (<u>≥16 Years of age</u>) or BMI ≥95th percentile (<u>12-15 Years of age</u>). The following footnotes were added to the P-B table for completeness/clarity: N = number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2 n = Number of subjects with ≥4-fold rise from before vaccination to 1 month after Dose 2 SCR: Seroconversion Rate
ADDITIONAL ANALYSES CONDUCTED IN THE INDIVIDUAL TRIAL		

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
I. Geometric Mean SARS-CoV-2 Neutralizing Titers One Month After BNT162b2 Dose 2 in Participants 12 to 25 Years, All-available Immunogenicity Population	I. Geometric Mean SARS-CoV-2 Neutralizing Titers (NT50) 1 Month After BNT162b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2 All-available Immunogenicity Population	“(NT50)” and “and 16 Through 25 Years of Age (Immunogenicity Subset)”, and “Dose 2” added to P-B table title, as underlined in left column. The following additions were made to the P-B table footnote, as underlined for completeness/clarity: N: Number of subjects with valid and determinate assay results for the specified assay at 1 month after Dose 2.
J. Seroconversion Rates One Month After BNT162b2 Dose 2 in Participants 12 to 25 Years, All-available Immunogenicity Population	J. Seroconversion Rates – NT50 – 1 Month After BNT162b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), 2, Dose 2 All-available Immunogenicity Population	“NT50” and “and 16 Through 25 Years of Age (Immunogenicity Subset),” and “Dose 2” added to P-B table title for completeness/clarity, as underlined in left column. The following additions were made to the P-B table footnote for completeness/clarity: * Seroconversion is defined as achieving a ≥ 4 -fold rise from baseline (before vaccination). N: number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2. n: number of participants with ≥ 4 -fold rise from before vaccination to 1 month after Dose 2
Efficacy Results		
K. Vaccine Efficacy Analyses, Participants 12 to 15 Years, Evaluable Efficacy Population	K. Vaccine Efficacy Analyses, <u>Without Evidence of Infection Prior to 7 Days After Dose 2</u> , Participants 12 to 15 Years of Age, Evaluable Efficacy Population	“Without Evidence of Infection Prior to 7 Days After Dose 2” added to P-B title, as underlined in column to the left. The following additions were made to the P-B table footnote for completeness/clarity: ^a N = number of participants in the specified group. ^b n1 = Number of participants meeting the endpoint definition. ^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period. ^d n2 = Number of participants at risk for the endpoint. ^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.
	K1. Vaccine Efficacy Analyses, <u>With or Without Evidence of Infection Prior to 7 Days</u>	ADDITIONAL TABLE to present data in participants with or without evidence of infection prior to 7 days after Dose 2, based on FDA Shell Table K. “With or Without Evidence of Infection Prior to 7 days After Dose 2” added to P-B title, as underlined in column to the left.

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	<u>After Dose 2</u> , Participants 12 to 15 Years of Age, Evaluable Efficacy Population	
L. Subgroup Analyses of Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, Participants 12 to 15 Years, All-available Evaluable Efficacy Population	L. Subgroup Analyses of Vaccine Efficacy, <u>With or Without Evidence of Infection</u> - First COVID-19 Occurrence From 7 Days After Dose 2, Participants 12 to 15 Years of Age, All-available Evaluable Efficacy Population	“With or Without Evidence of Infection” added to P-B title, with other revisions as indicated in column to the left.
	L1. Subgroup Analyses of Vaccine Efficacy, <u>Without Evidence of Infection</u> - First COVID-19 Occurrence From 7 Days After Dose 2, Participants 12 to 15 Years of Age, All-available Evaluable Efficacy Population	ADDITIONAL TABLE to present data in participants without evidence of infection, based on FDA Shell Table L. “Without Evidence of Infection” added to P-B title, with other revisions as indicated in column to the left. Additions made to P-B table footnote, as underlined below: ^f Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity BMI ≥ 30 kg/m ² (<u>≥ 16 Years of age</u>) or BMI ≥ 95 th percentile (12-15 Years of age). ^g Obese is defined as BMI ≥ 30 kg/m ² (<u>≥ 16 Years of age</u>) or BMI ≥ 95 th percentile (12-15 Years of age).
M. Demographic Characteristics, Participants 12 to 15 Years of Age With Protocol Defined COVID-19 (Without Evidence of Infection Prior to 7 Days After Dose 2)	M. Demographic Characteristics, Participants 12 to 15 Years of Age With Protocol Defined COVID-19 (Without Evidence of Infection Prior to 7 Days After Dose 2)	Additions made to the P-B table footnote, as underlined below: ^c Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity BMI ≥ 30 kg/m ² (<u>≥ 16 Years of age</u>) or BMI ≥ 95 th percentile (12-15 Years of age).
	M1. Demographic Characteristics, Participants 12 to 15	ADDITIONAL TABLE to present data for participants with or without evidence of infection prior to 7 days after Dose 2, based on FDA Shell Table M. . Additions made to the P-B table footnote, as underlined below:

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	Years of Age With Protocol Defined COVID-19 (With or Without Evidence of Infection Prior to 7 Days After Dose 2)	^c Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥ 30 kg/m ² (<u>≥ 16 Years of age</u>) or BMI <u>≥ 95th percentile (12-15 Years of age)</u> .
Cumulative Incidence Curve of COVID-19 Cases in Participants 12 to 15 Years of Age, Over Time (Vaccine vs. Placebo)	Cumulative Incidence Curve of COVID-19 Cases in Participants 12 to 15 Years of Age, Over Time (Vaccine vs. Placebo)	No change to title from FDA Shell Table
N. Primary Efficacy Endpoint, Participants 12 to 15 Years, All-Available Efficacy Population	N. Primary Efficacy Endpoint, Participants 12 to 15 Years of Age, <u>Dose 1</u> All-Available Efficacy Population	<p>“Dose 1” added to P-B Title, as indicated by underline in column to the left.</p> <p>The following changes (as stricken and underlined) were made to the P-B footnote:</p> <p>^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint. <u>Dose 1 to the end of the surveillance period</u></p>
III. CLINICAL SAFETY		
1. OVERALL EXPOSURE		
O. Summary of Vaccine Exposure, Participants 12 to 25 Years, Safety Population	O. Summary of Vaccine Exposure, Participants 12 to 25 Years of Age, Safety Population	No differences from the FDA Shell Table.
2. SUBJECT DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS		
P. Demographics and Other Baseline Characteristics, Participants 12 to 25 Years, Safety Population	P. Demographics and Other Baseline Characteristics, Participants 12 to 25 <u>and 16 through 25 Years of Age</u> (Reactogenicity Subset), Safety Population	<p>“and 16 through 25 Years of Age (Reactogenicity Subset)” added to the P-B table title for completeness/clarity.</p> <p>Data rows were added in the P-B table for completeness/clarity, as follows:</p> <ul style="list-style-type: none"> - Race: Multiracial - Race: Not reported - Ethnicity: Not reported <p>Data rows were revised in the P-B table as follows:</p> <p>BMI: < 30 kg/m² <u>Obese: Yes</u></p>

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
		<p>BMI: ≥ 30 kg/m² <u>Obese: No</u></p> <p>Rows were added to the P-B table for completeness/clarity, as follows:</p> <ul style="list-style-type: none"> - Baseline evidence of Prior SARS-CoV-2 Infection: Missing Country: Argentina Country: Brazil Country: Germany Country: South Africa Country: Turkey <p>The following substitution was made from the 1) FDA Shell Table to 2) the P-B table footnote for clarity:</p> <ol style="list-style-type: none"> 1) *All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician 2) *All randomized participants who receive at least 1 dose of the study intervention <p>Addition was made to the footnote in the P-B table, as indicated by underline:</p> <p>¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥ 30 kg/m² (<u>>16 Years of age</u>) or BMI ≥ 95th percentile (<u>12-15 Years of age</u>).</p>
3. SAFETY RESULTS		
Q. Safety Overview, Participants 12 to 15 Years	Q. Safety Overview, Participants 12 to 15 Years of Age	“From Dose 1 through cutoff date (all enrolled)” row was deleted because P-B did not collect these data.
	Q1. Safety Overview, Participants 16 to 25 Years (<u>Reactogenicity Subset</u>)	<p>ADDITIONAL TABLE to present data for participants 16 to 25 years of age, based on FDA Shell Table Q.</p> <p>“(Reactogenicity Subset)” added to the P-B table title for clarity.</p> <p>“From Dose 1 through cutoff date (all enrolled)” row was deleted because P-B did not collect these data.</p>
SOLICITED ADVERSE EVENTS		
R. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity,	R. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity, Participants 12 to 15	“(Reactogenicity Subset)” added to the P-B table title for clarity.

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
Participants 12 to 15 Years	Years (<u>Reactogenicity Subset</u>)	
	R1. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity, Participants 16 to 25 Years of Age (<u>Reactogenicity Subset</u>)	ADDITIONAL TABLE to present data for participants 16 to 25 years of age, based on FDA Shell Table R. “(Reactogenicity Subset)” added to the P-B table title for clarity.
S. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity, Participants 12 to 15 Years	S. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity, Participants 12 to 15 Years of Age	No differences from FDA Shell Table.
	S1. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity, Participants 16 to 25 Years of Age (<u>Reactogenicity Subset</u>)	ADDITIONAL TABLE to present data for participants 16 to 25 years of age, based on FDA Shell Table S. “(Reactogenicity Subset)” added to the P-B table title for completeness/clarity, as underlined in left column.
T. Characteristics of Solicited Local and Systemic Adverse Reactions, Participants 12 to 15 Years, Safety Population	T. Characteristics of Solicited Local and Systemic Adverse Reactions, Participants 12 to 15 Years of Age, Safety Population	“n” is included in each row of the P-B table, rather than in the column header. The following Local Reaction events were added for completeness/clarity: Redness, Swelling, Pain at the injection site The following Solicited System Reaction events were added for completeness/clarity: Fever, Fatigue, Headache, Chills, Vomiting, Diarrhea, New or worsened muscle pain, New or worsened joint pain, Use of antipyretic or pain medication
	T1. Characteristics of Solicited Local and Systemic Adverse Reactions, Participants 16 to 25 Years, Safety	ADDITIONAL TABLE to present data for participants 16-25 years of age, based on FDA Shell Table T. “n” is included in each row of the P-B table, rather than in the column header. “(Reactogenicity Subset)” added to P-B table title for clarity. The following Local Reaction events were added for completeness/clarity:

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	Population (<u>Reactogenicity Subset</u>)	Redness, Swelling, Pain at the injection site The following Solicited System Reaction events were added for completeness/clarity: Fever, Fatigue, Headache, Chills, Vomiting, Diarrhea, New or worsened muscle pain, New or worsened joint pain, Use of antipyretic or pain medication
U. Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in Any Treatment Group From Dose 1 to One Month After Dose 2, Participants 12 to 15 Years, Safety Population	U. Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in Any Treatment Group From Dose 1 to One Month After Dose 2, Participants 12 to 15 Years of Age, Safety Population	No difference from FDA Shell Table
	U1. Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in Any Treatment Group From Dose 1 to One Month After Dose 2, Participants 16 to 25 Years of Age (<u>Reactogenicity Subset</u>), Safety Population	ADDITIONAL TABLE to present data for participants 16-25 years of age, based on FDA Shell Table U. “(Reactogenicity Subset)” added to P-B table title for clarity.
V. Percentage of Subjects Reporting SAEs, by MedDRA Primary System Organ Class and Preferred Terms, Participants 12 to 15 Years, Safety Population	V. Percentage of Subjects Reporting SAEs <u>From Dose 1 Through Cutoff Date (13MAR2021)</u> , by MedDRA Primary System Organ Class and Preferred Term, Participants 12 to 15 Years of Age, Safety Population	“...From Dose 1 Through Cutoff Date (13MAR2021)” added to P-B table title for clarity. Specific SOC and PTs added for completeness/clarity.
	V1. Percentage of Subjects reporting SAEs <u>From Dose 1 Through</u>	ADDITIONAL TABLE to present data for participants 16-25 years of age, based on FDA Shell Table V.

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	<u>Cutoff Date (13MAR2021)</u> , by MedDRA Primary System Organ Class and Preferred Term, Participants 16 to 25 Years of Age (<u>Reactogenicity Subset</u>), Safety Population	“...From Dose 1 Through Cutoff Date (13MAR2021) and “(Reactogenicity Subset)” added to P-B table title for clarity. Specific SOC and PTs added for completeness/clarity.
W. Name of Standard MedDRA Query, Participants 12 to 15 Years, Safety Population	W. Name of Standard MedDRA Query <u>From Dose 1 to 1 Month After Dose 2</u> , Participants 12 to 15 Years of Age, Safety Population	“From Dose 1 to 1 Month After Dose 2” added to P-B table title for completeness/ clarity. Specific SMQ terms (SOCs and PTs) added for completeness/clarity. The following footnotes were added to the P-B table for completeness/clarity: 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 category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
	W1. Name of Standard MedDRA Query <u>From Dose 1 to 1 Month After Dose 2</u> , Participants 16 to 25 Years of Age, (<u>Reactogenicity Subset</u>), Safety Population	ADDITIONAL TABLE to present data for participants 16-25 years of age, based on FDA Shell Table W. “From Dose 1 to 1 Month After Dose 2” and “(Reactogenicity Subset)” added to P-B table title for clarity. Specific SMQ terms (SOCs and PTs) added for completeness/clarity. The following footnotes were added to the P-B table for completeness/clarity: 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 category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
X. SAEs considered related by Investigator – Participants 12 to 15 Years, Safety Population	X. SAEs Considered Related by Investigator <u>From Dose 1 Through Cutoff Date</u> – Participants 12 to 15 Years of Age, Safety Population	“From Dose 1 Through Cutoff Date” was added to P-B table title for completeness/clarity.

FDA Shell Table	Pfizer-BioNTech (P-B) Table	Comment/Clarification
	X1. SAEs considered related by Investigator – <u>From Dose 1 Through Cutoff Date</u> Participants 16 to 25 Years of Age, Safety Population	ADDITIONAL TABLE to present data for participants 16-25 years of age, based on FDA Shell Table X. “From Dose 1 Through Cutoff Date” was added to P-B table title for completeness/clarity.
Y. Deaths, Participants 12 to 15 Years, Safety Population	Y. Deaths, Participants <u>12 through 25 Years of Age</u> , Safety Population	“12 to 15 Years” revised to “ 12 Through 25 Years of Age” in the P-B table title, as underlined in the left column, for accuracy.

Document Approval Record

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