

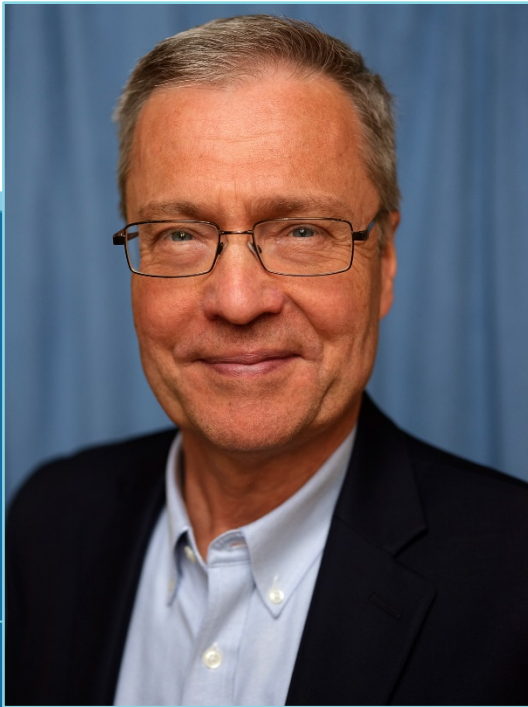
Vaccines and Related Biological Products Advisory Committee Meeting

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BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine – Request for Emergency Use Authorization in Individuals 5 to <12 Years of Age

Vaccines and Related Biological Products
Advisory Committee

October 26, 2021



William C. Gruber, MD, FAAP, FIDSA, FPIDS

Senior Vice President
Vaccine Clinical Research
and Development
Pfizer Inc

Presentation Agenda

1 Introduction

2 Unmet Medical Need

3 Clinical Data

- Phase 2/3 Immunogenicity and Safety
- Efficacy Analysis

4 Benefit Risk

Pfizer/BNT Seeking Emergency Use Authorization of 10ug Dose of BNT162 in Children 5 to <12 Years of Age

10ug dose level was selected as optimal to elicit robust immune responses with an acceptable safety profile

Proposed Indication and Schedule

Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 5 to <12 years of age

Administered intramuscularly as a primary series of 2 doses (0.2 mL each), 3 weeks apart

BNT162b2 – Meets EUA Guidance for 5 to <12 Years of Age

Clear and Compelling Data



Meets all safety data expectations for follow up durations and subject number

Meets Immunobridging criteria comparing 5 to <12 yo to 16 to 25 yo subjects

90.7% efficacy was observed

Plans for active safety follow up under EUA

Vaccine's benefits outweigh its risks

Unmet Medical Need in Children 5 to <12 Years of Age

Based on CDC data, among children 5 to <12 years, the cumulative burden of COVID-19 to date is:

- **1.8M cases¹**
- **8622 hospitalizations²**
- **143 deaths¹**

- **COVID-19 causes additional long-term sequelae in children**
 - >5200 cases of multisystem inflammatory syndrome in children (MIS-C), 50% in 5–13 year-olds³
 - 67% of children experience symptoms ≥60 days after COVID-19 diagnosis⁴
- **Severe outcomes are unpredictable and can occur in healthy children, prompting need for broad age-based vaccination**
 - 1 in 3 hospitalizations occur among children without comorbidities⁵
 - MIS-C can affect healthy children⁶
- **Vaccinating children has other societal benefits**
 - Children likely play role in transmission⁷; vaccinating children can help reach herd immunity
 - Vaccination will help ensure in-person learning critical for childhood development, by limiting community spread and school outbreaks⁸

1. Cases and deaths through October 14, 2021. CDC COVID Data Tracker. Demographic Trends of COVID-19 cases and deaths in the US reported to CDC. Available from: <https://covid.cdc.gov/covid-data-tracker/#demographics>. Accessed 14 October 2021 ;
2. Hospitalizations through September 18, 2021. CDC COVID Data Tracker. COVID-NET Laboratory-confirmed COVID-19 hospitalizations. Available from: <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network>. Accessed 07 October 2021
3. Centers for Disease Control and Prevention. COVID Data Tracker: Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States 2021 [updated August 27, 2021]. Available from: <https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance>. Accessed 07 October 2021
4. Buonsenso D, Munblit D, De Rose C, Sinatti D, Ricchiuto A, Carfi A, et al. Preliminary evidence on long COVID in children. *Acta Paediatr*. 2021;110(7):2208-11.
5. Preston LE, Chevinsky JR, Kompanyets L, et al. Characteristics and Disease Severity of US Children and Adolescents Diagnosed With COVID-19. *JAMA Netw Open*. Apr 1 2021;4(4):e215298. doi:10.1001/jamanetworkopen.2021.5298
6. Feldstein LR, Rose EB, Horwitz SM, et al. Multisystem Inflammatory Syndrome in U.S. Children and Adolescents. *N Engl J Med*. Jul 23 2020;383(4):334-346. doi:10.1056/NEJMoa2021680
7. Leidman E, Duca LM, Omura JD, Proia K, Stephens JW, Sauber-Schatz EK. COVID-19 Trends Among Persons Aged 0-24 Years - United States, March 1-December 12, 2020. *MMWR Morb Mortal Wkly Rep*. 2021;70(3):88-94.
8. Centers for Disease Control and Prevention. Science Brief: Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs – Updated 2021; updated July 9, 2021. Available from: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html. Accessed 07 October 2021.

Clinical Data

Pfizer-BioNTech Pediatric COVID-19 Vaccine BNT162b2: Study Overview: 5 to <12 Years

Phase 1

48
PARTICIPANTS

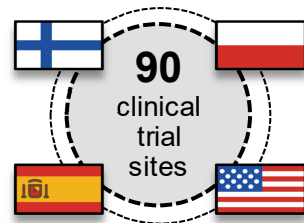


Identification of
preferred dose
level(s)

10 µg

Phase 2/3

2:1
randomization



~1500   BNT162b2

750   placebo

~Additional 1500 BNT162b2 and 750 placebo recipients
most with ≥2 weeks post dose 2 safety data

Non-inferior immune responses
have been established to infer
vaccine efficacy

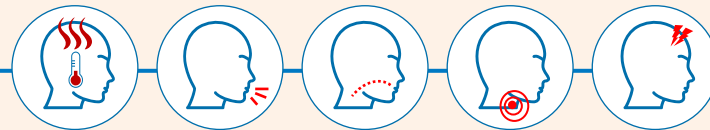
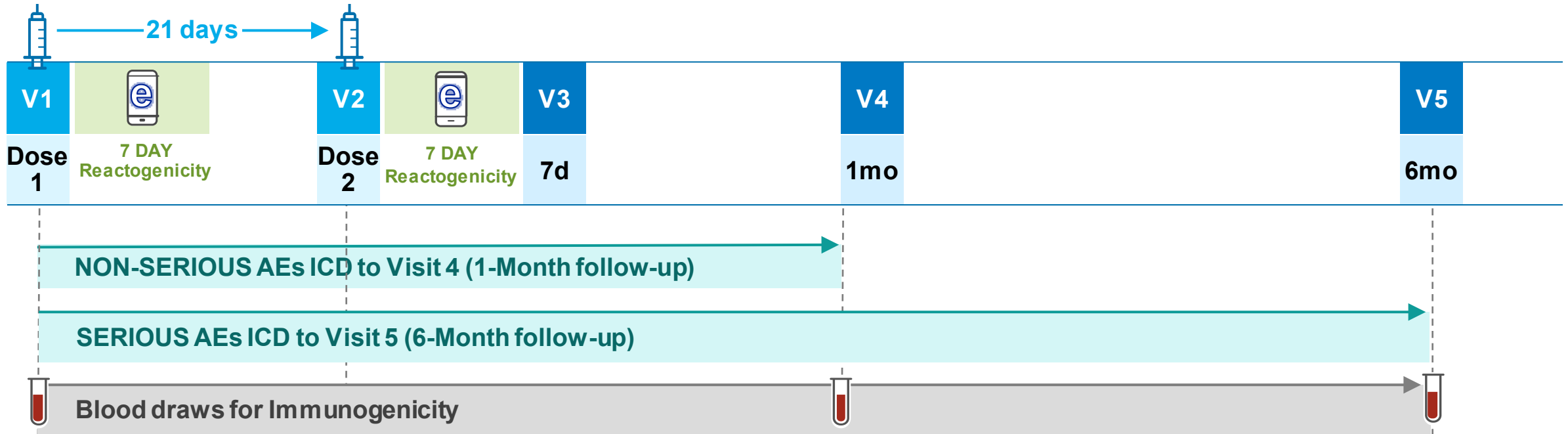
Children
5 to <12 years
of age

Compared
to

16–25-year-olds
from the pivotal
Phase 3 study

Although not required for
EUA approval, COVID-19
surveillance was conducted
permitting evaluation of
vaccine efficacy

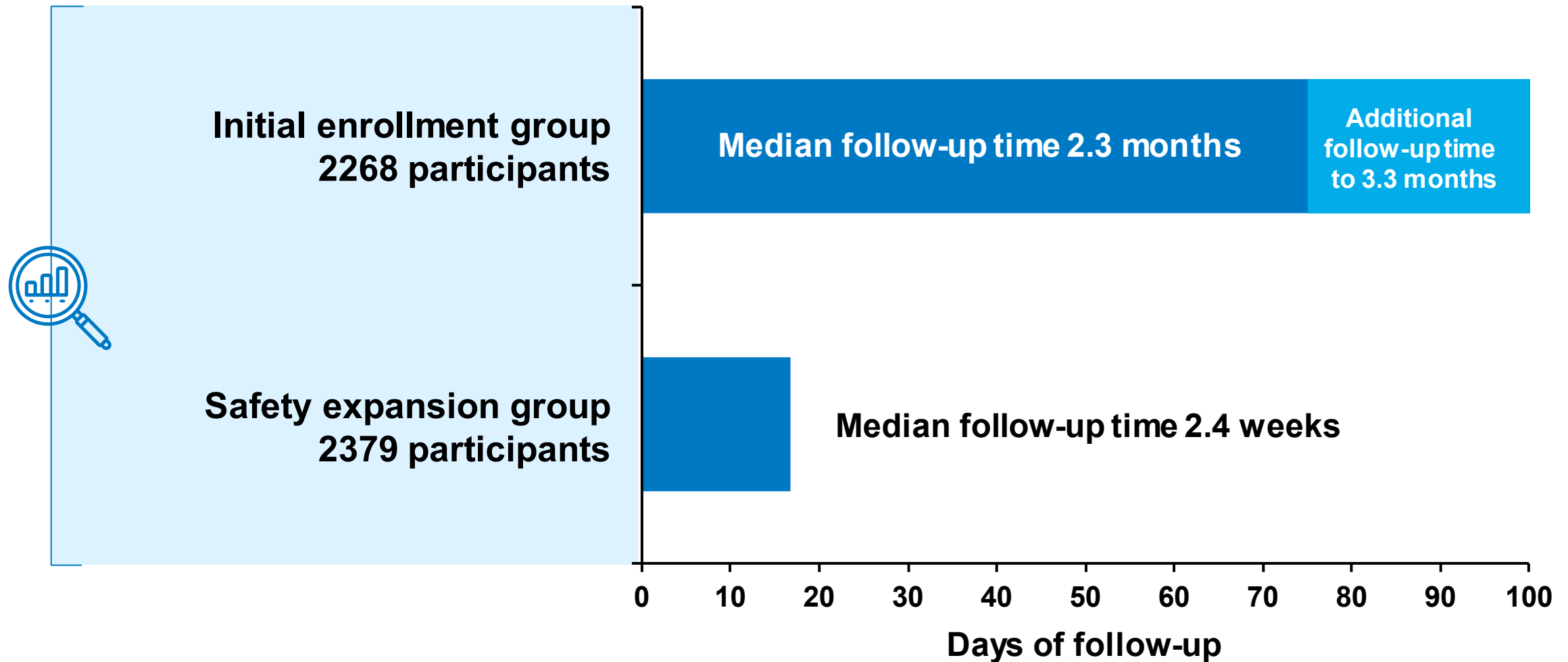
Phase 2/3 Timelines of Participants 5 to <12 Years of Age Through 6 Months Post-dose 2



UP TO 2-YEARS

COVID-19/MIS-C Visit: triggered if a participant reports experiencing a COVID-19/MIS-C Symptom reported on the Illness diary or reported directly by the participants → potential COVID-19 Illness visit (telehealth/in-person visit + nasal swab) must be scheduled (optimally within 3 Days after illness onset)

Safety Data for 5 to <12 Year Olds to Support EUA Application



Demographics for 5 to <12 Year Olds

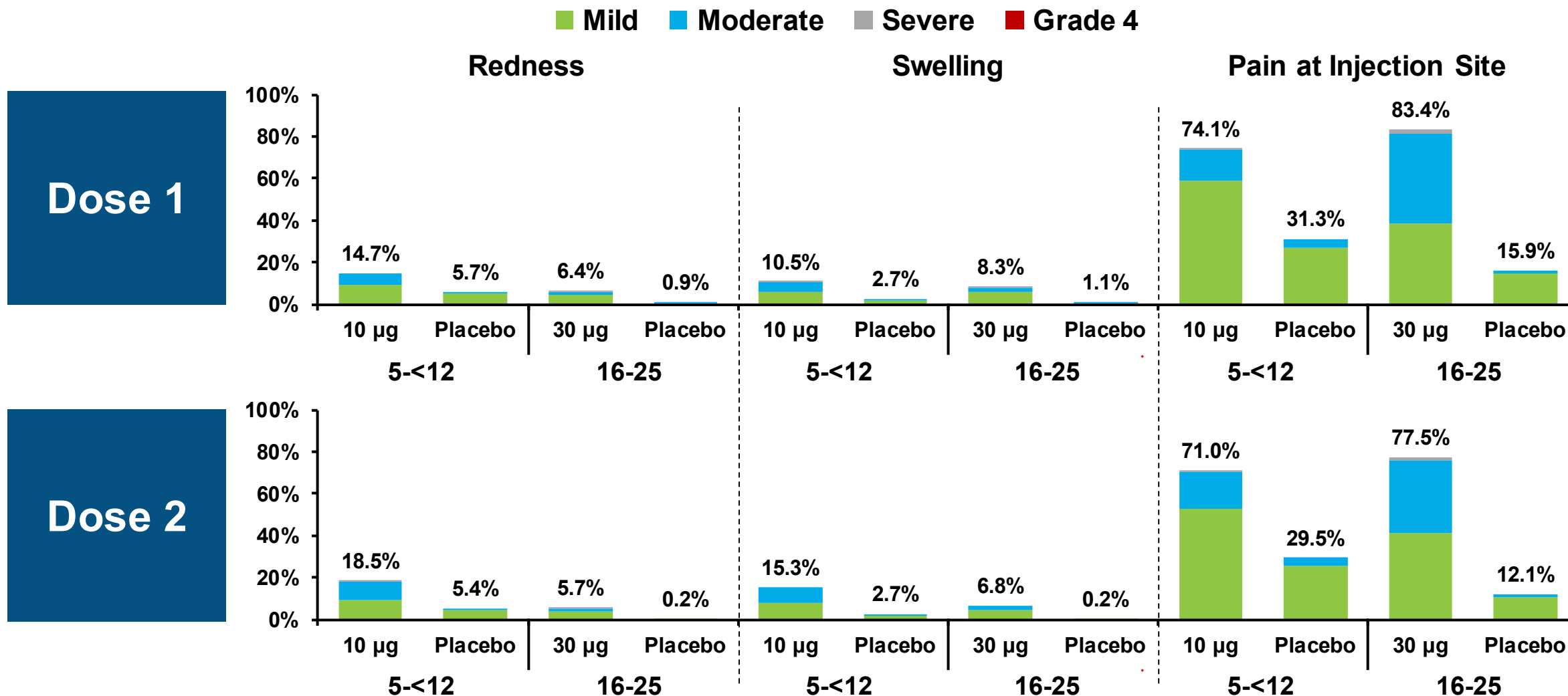
Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

		BNT162b2 (10µg) N=1518	Placebo N=750
Sex, n (%)	Male	799 (52.6)	383 (51.1)
	Female	719 (47.4)	367 (48.9)
Race, n (%)	White	1204 (79.3)	586 (78.1)
	Black or African American	89 (5.9)	58 (7.7)
	American Indian or Alaska native	12 (0.8)	3 (0.4)
	Native Hawaiian or other Pacific Islander	<1%	<1%
	Asian	90 (5.9)	47 (6.3)
	Multiracial	109 (7.2)	49 (6.5)
	Not reported	<1%	<1%
Ethnicity, n (%)	Hispanic/Latino	319 (21.0)	159 (21.2)
	Non-Hispanic/non-Latino	1196 (78.8)	591 (78.8)
	Not reported	<1%	<1%
Age at vaccination	Mean (SD)	8.2 (1.93)	8.1 (1.97)
	Min, Max	(5, 11)	(5, 11)
Obese ^a , n (%)	Yes	174 (11.5)	92 (12.3)
Comorbidities ^b , n (%)	Yes	312 (20.6)	152 (20.3)

a. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

b. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds

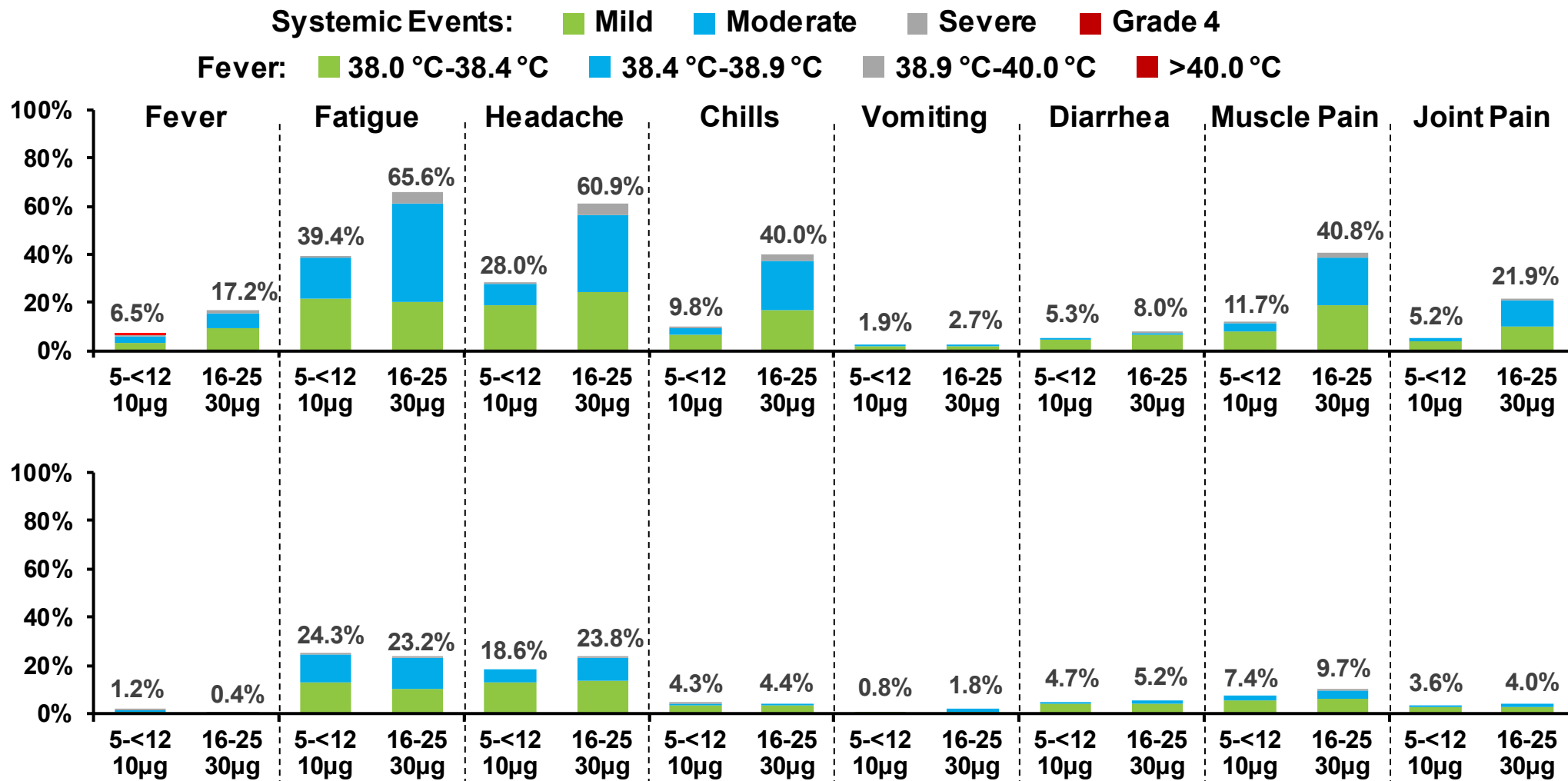


Redness and swelling severity definition: Mild=>2-5cm, Moderate=>5-10 cm; Severe=>10 cm; Grade 4= necrosis
 Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Dose 1: 5-<12yrs N=2260; 16-25 yrs N=1064 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 and 16-25 Year Olds

BNT162b2

Placebo

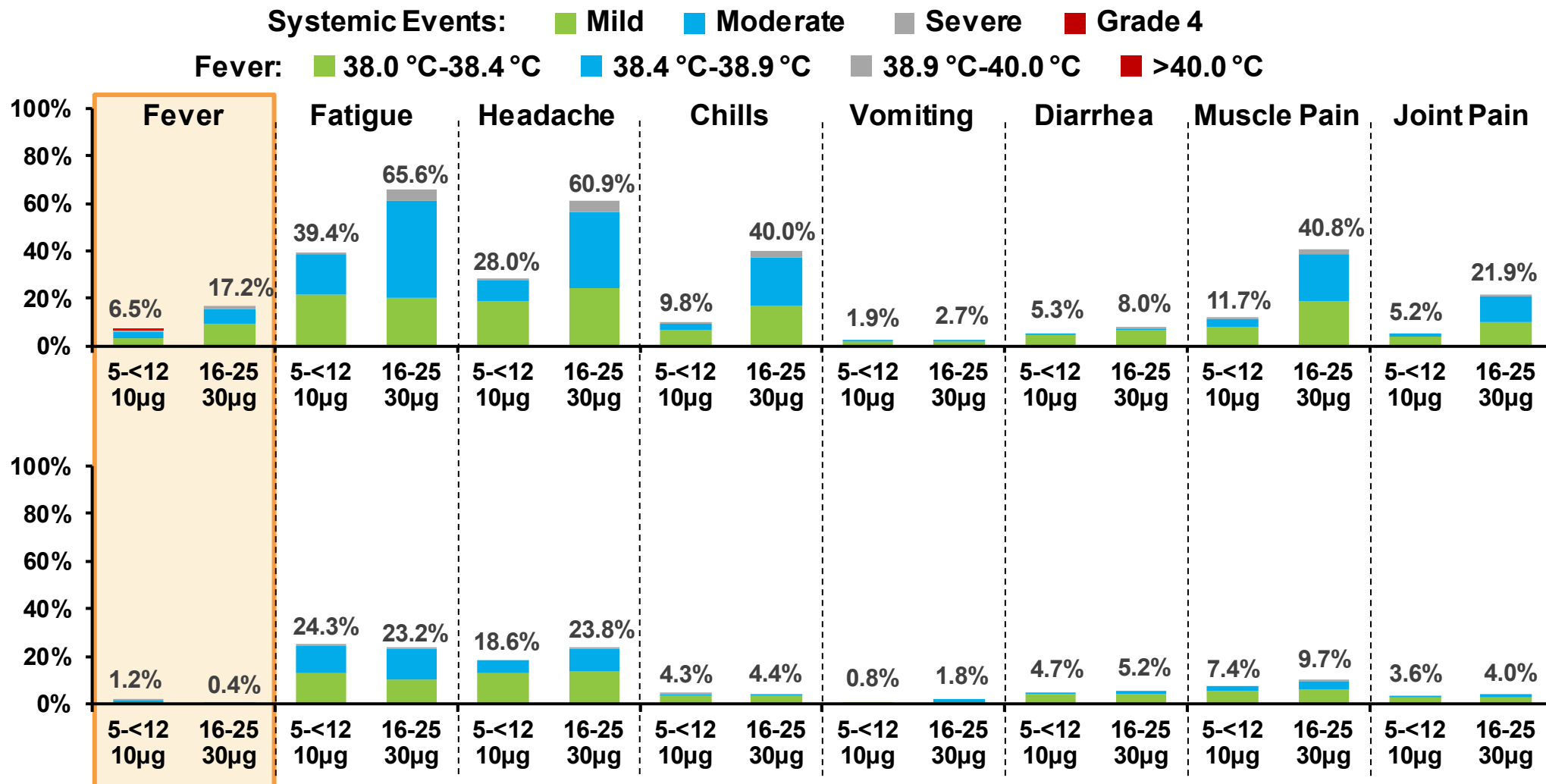


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 and 16-25 Year Olds

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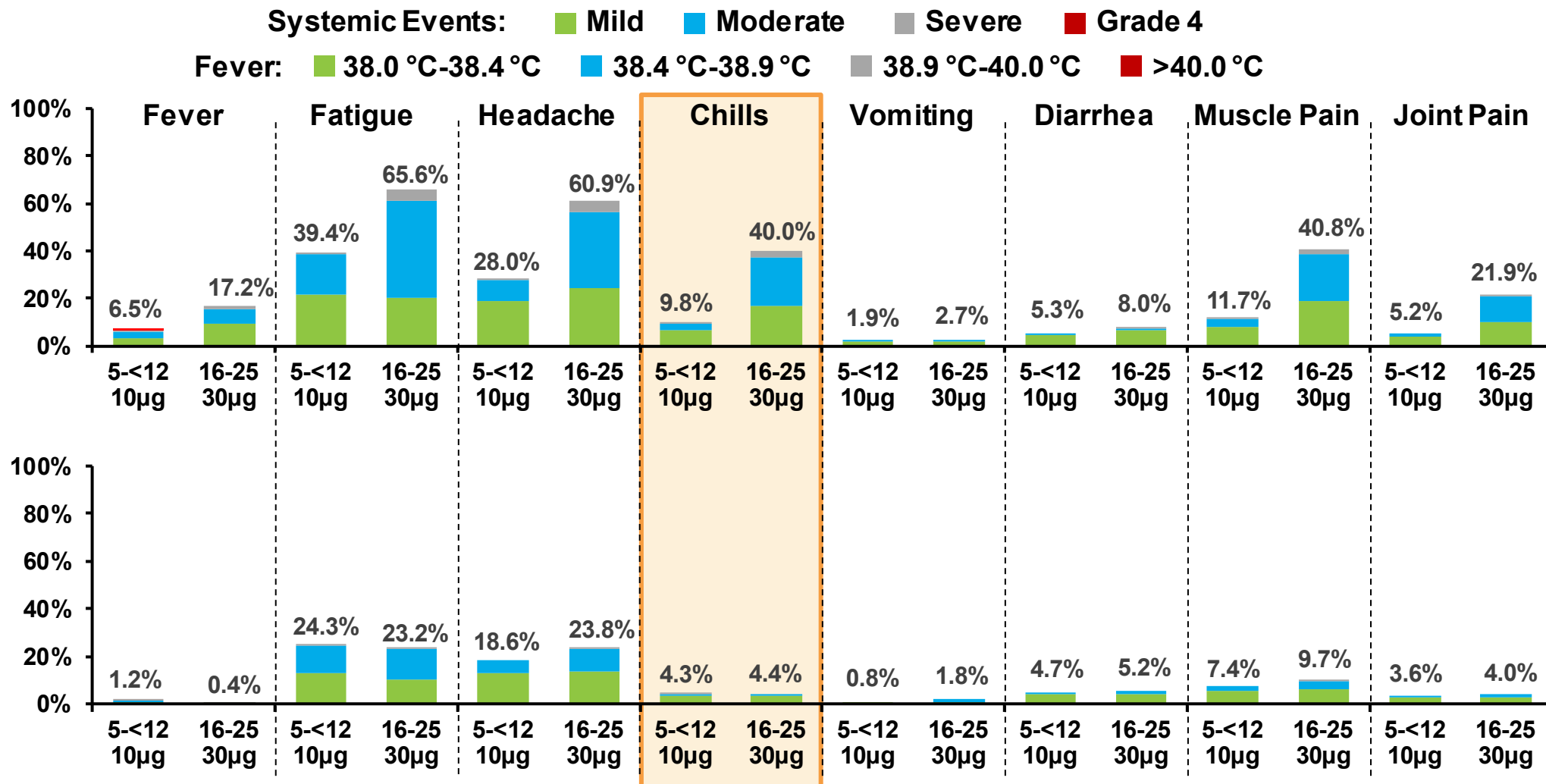


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Placebo

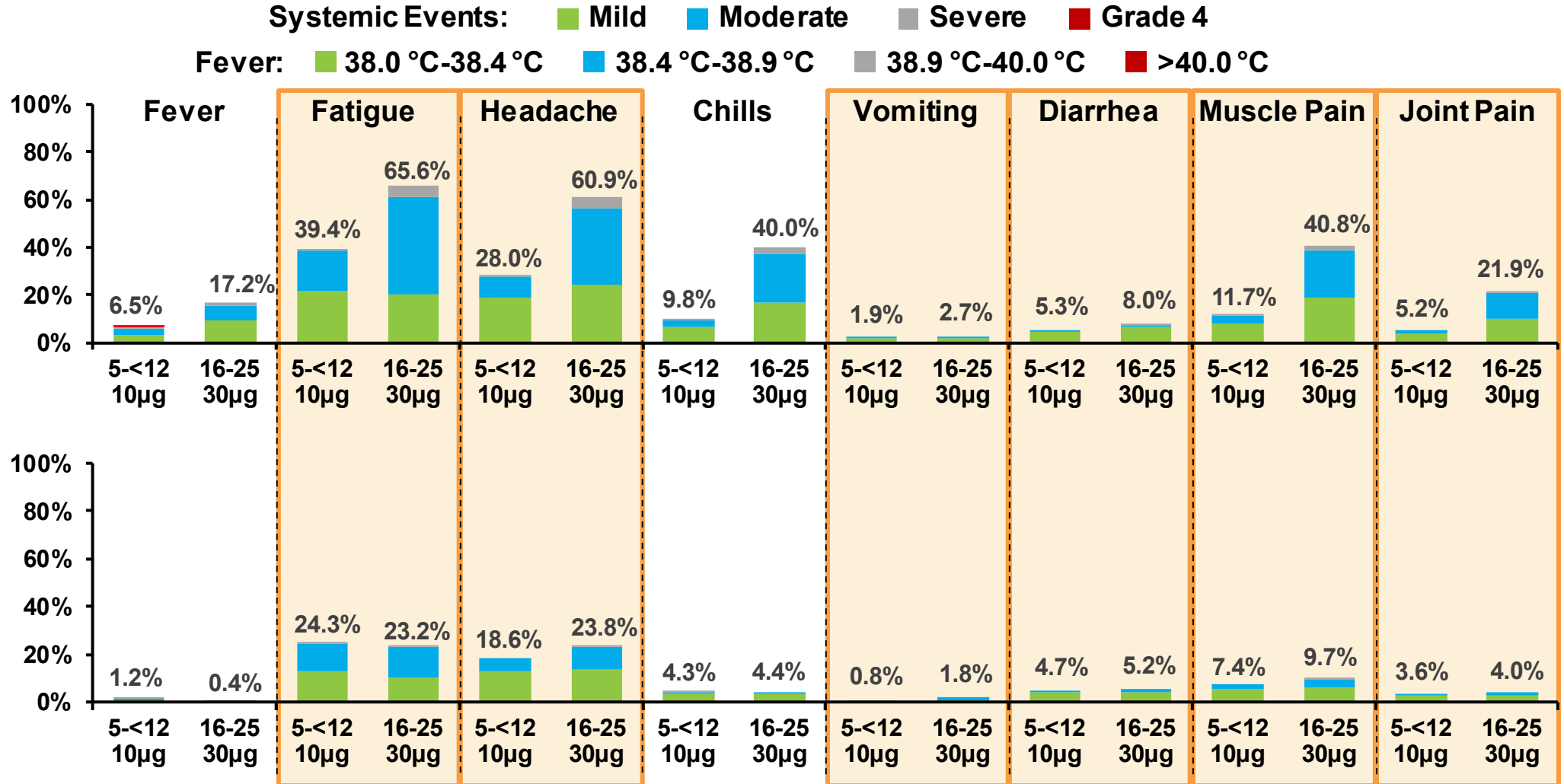


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BNT162b2

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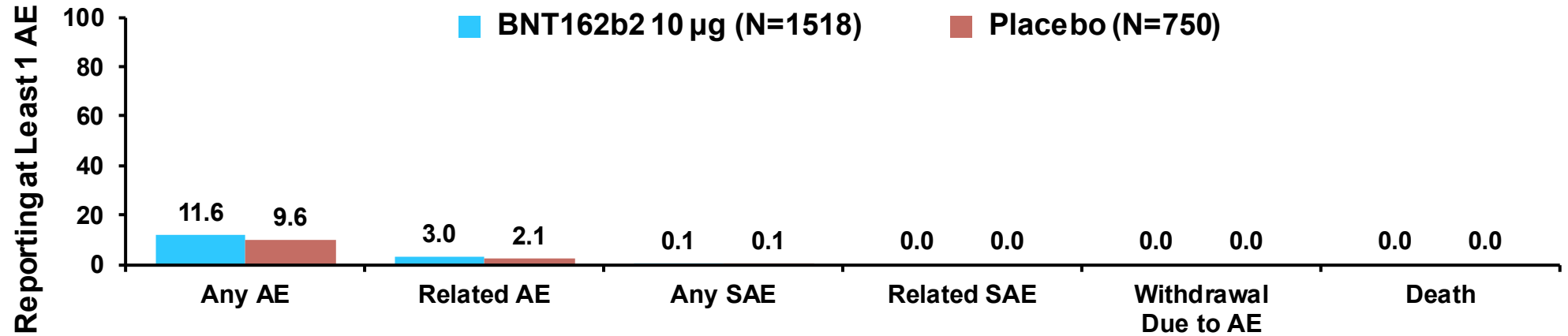


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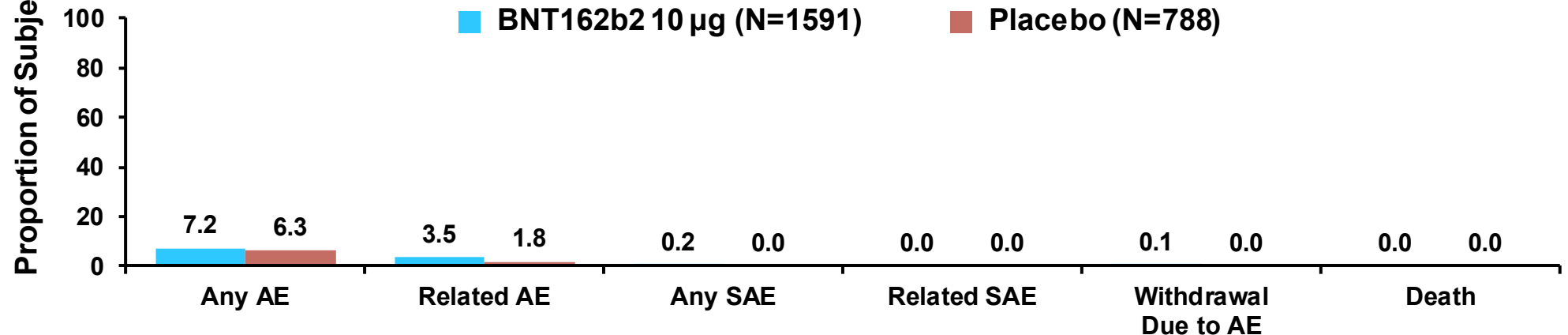
Adverse Events

Overall Adverse Events from Dose 1 to Data Cutoff Date: 5 to <12 Year Olds

Initial enrollment group:
Median follow-up time 2.3 months
Cutoff date September 6, 2021

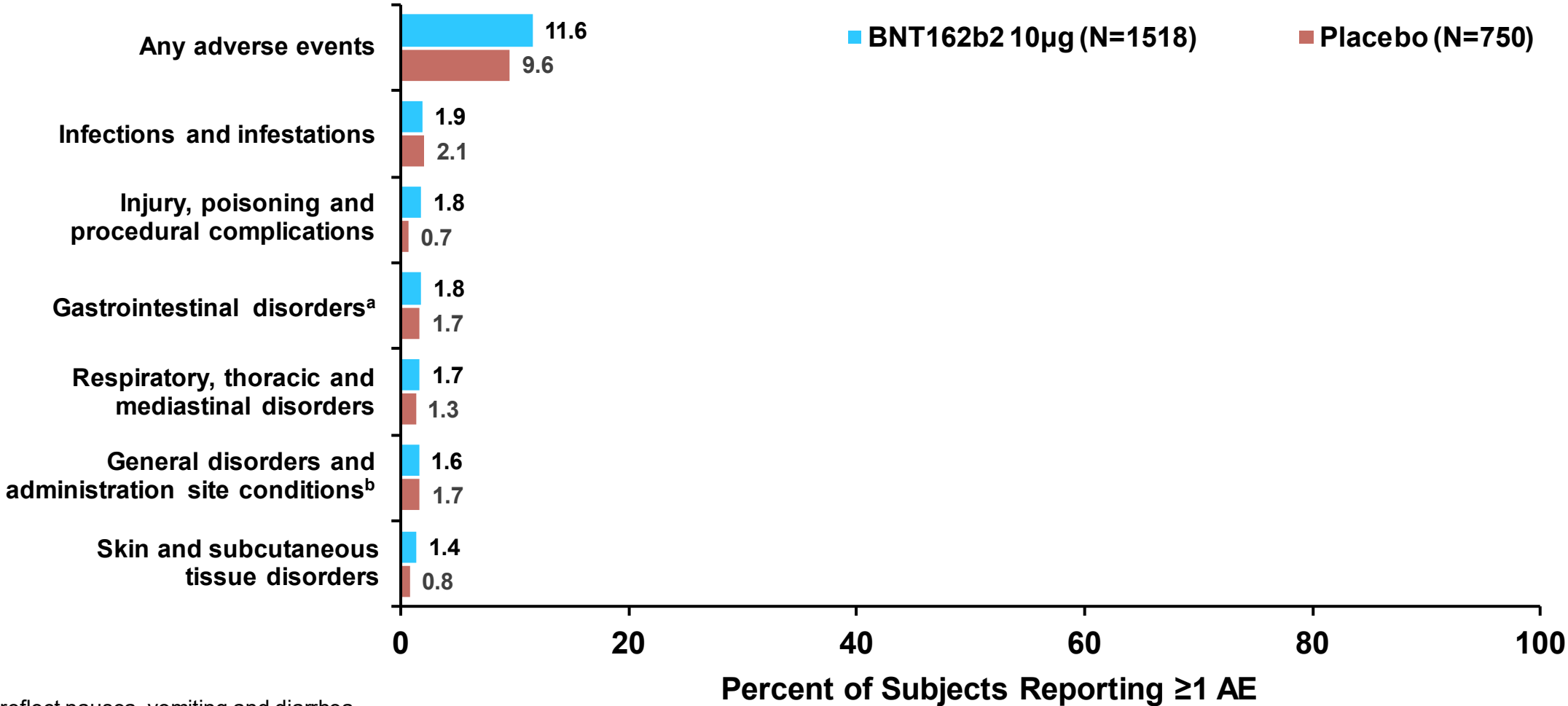


Safety expansion group:
Median follow-up time 2.4 weeks
Cutoff date October 8, 2021



Adverse Events $\geq 1.0\%$ by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)

Data Cutoff September 6, 2021



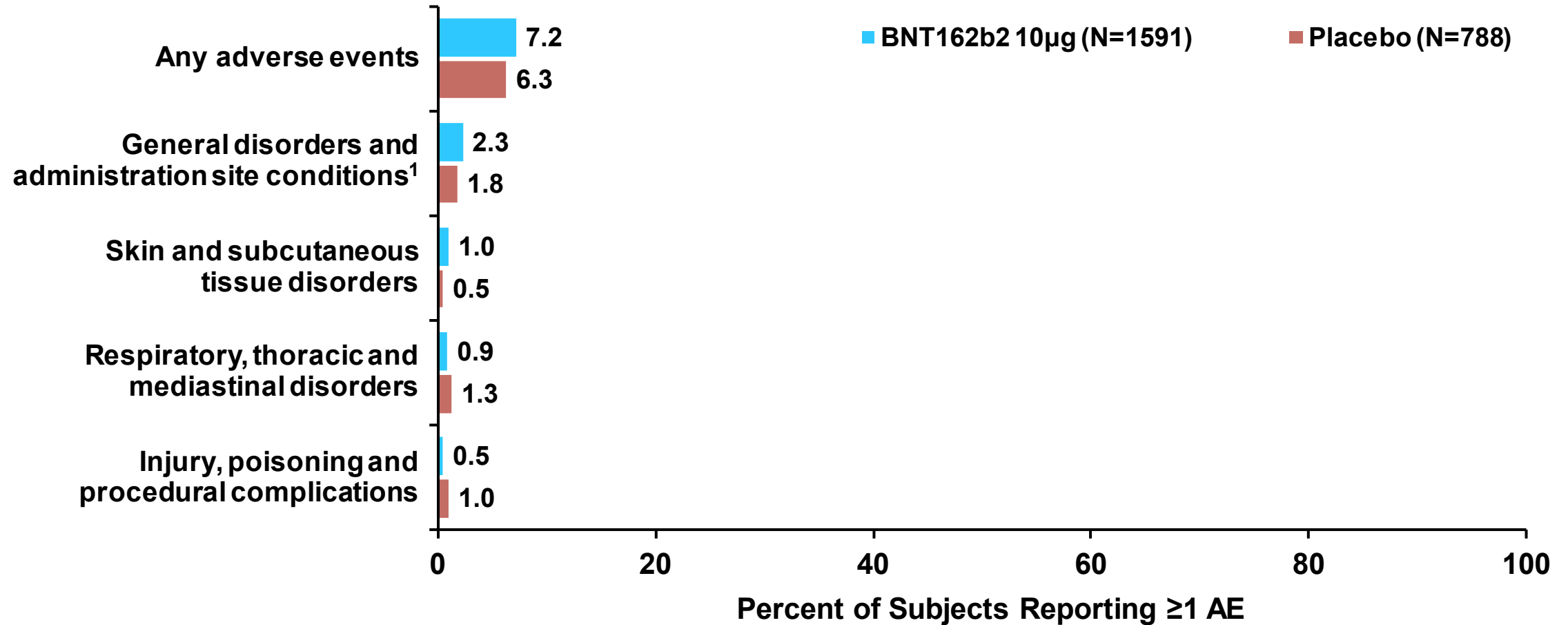
a. Predominantly reflect nausea, vomiting and diarrhea

b. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue

Lymphadenopathy 0.9% in BNT162b2 group

Adverse Events $\geq 1.0\%$ by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Safety Expansion Group (N= 2379)

Data Cutoff October 8, 2021



1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue Lymphadenopathy 0.4% in the BNT162b2 group

Serious Adverse Events from Dose 1 to Cutoff Date in 5 to <12 Year Olds

- **Initial enrollment group (all unrelated):**
 - One participant in the BNT162b2 group reported a SAE of an upper limb fracture
 - One participant in the Placebo group reported a SAE of abdominal pain and a SAE of pancreatitis related to trauma
- **Expansion Safety group (all unrelated; all in the BNT162b2 group)**
 - One participant reported a SAE of infective arthritis
 - One participant reported a SAE of epiphyseal fracture
 - One participant reported a SAE of ingestion of a foreign body

Adverse Events of Special Interest

Initial Enrollment Group and Safety Expanded Group

- **FDA AESIs:**
 - No anaphylaxis
 - No myocarditis/pericarditis
 - No Bell's palsy (or facial paralysis/paresis)
 - No appendicitis
- **CDC Defined AESIs:**
 - Potential hypersensitivity (angioedema, and predominantly rash and urticaria)
 - Arthritis (infective)
 - Vasculitis

Safety Conclusions for 5 to <12 Year Olds

- **Reactogenicity was mostly mild to moderate, and short lived**
- **Observed mild to moderate local reactions (redness, swelling) captured by diary were more common and systemic reactions (including fever) less common than those in 16-25 year-olds**
- **The observed AE profile in this study did not suggest any safety concerns for BNT162b2 vaccination in children 5 to <12 years of age**

Immunogenicity and Efficacy

Immunobridging Criteria Between 5 to <12 and 16-25 Years of Age Were Met Both for GMR and for Seroresponse

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years		BNT162b2 (30µg) 16-25 years		5 to <12 / 16-25 years	
		n	GMT (95% CI)	n	GMT (95% CI)	GMR (95% CI)	Met Immuno-bridging (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2 / 1 Month	264	1197.6 (1106.1, 1296.6)	253	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Y

Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years		BNT162b2 (30µg) 16-25 years		Difference in % 5 to <12 / 16-25 years	
		N	n (%) (95% CI)	N	n (%) (95% CI)	% (95% CI)	Met Immuno-bridging (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2 / 1 Month	264	262 (99.2) (97.3, 99.9)	253	251 (99.2) (97.2, 99.9)	0.0 (-2.0, 2.2)	Y

Seroresponse defined as achieving a ≥4 fold rise from baseline (before Dose 1)

Immunobridging is declared if the lower bound of the 95% confidence interval for the percentage difference is greater than -10

Neutralization of Both Reference Strain and Delta Variant of Concern are Comparable – Randomly Selected Subset

Phase 2/3 - Subjects 5 to <12 Years of Age

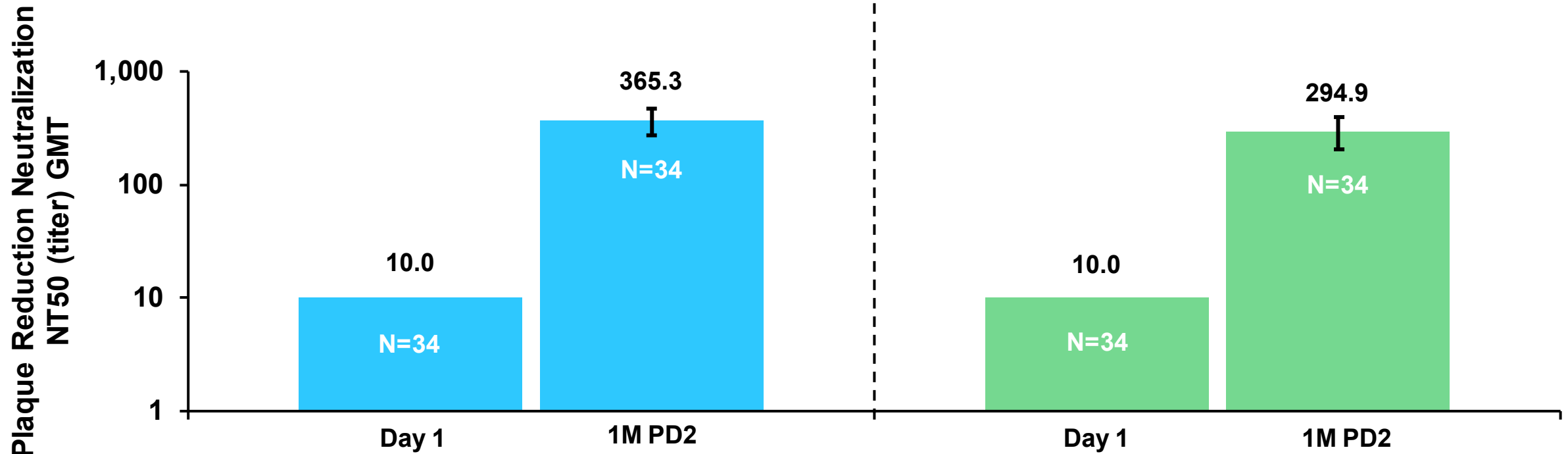
Reference Strain (USA-WA1/2020)
BNT162b2 (10 µg)

Delta Strain (B.1.617.2)
BNT162b2 (10 µg)

GMFR
(95% CI)

36.5
(27.9, 47.8)

29.5
(21.5, 40.5)



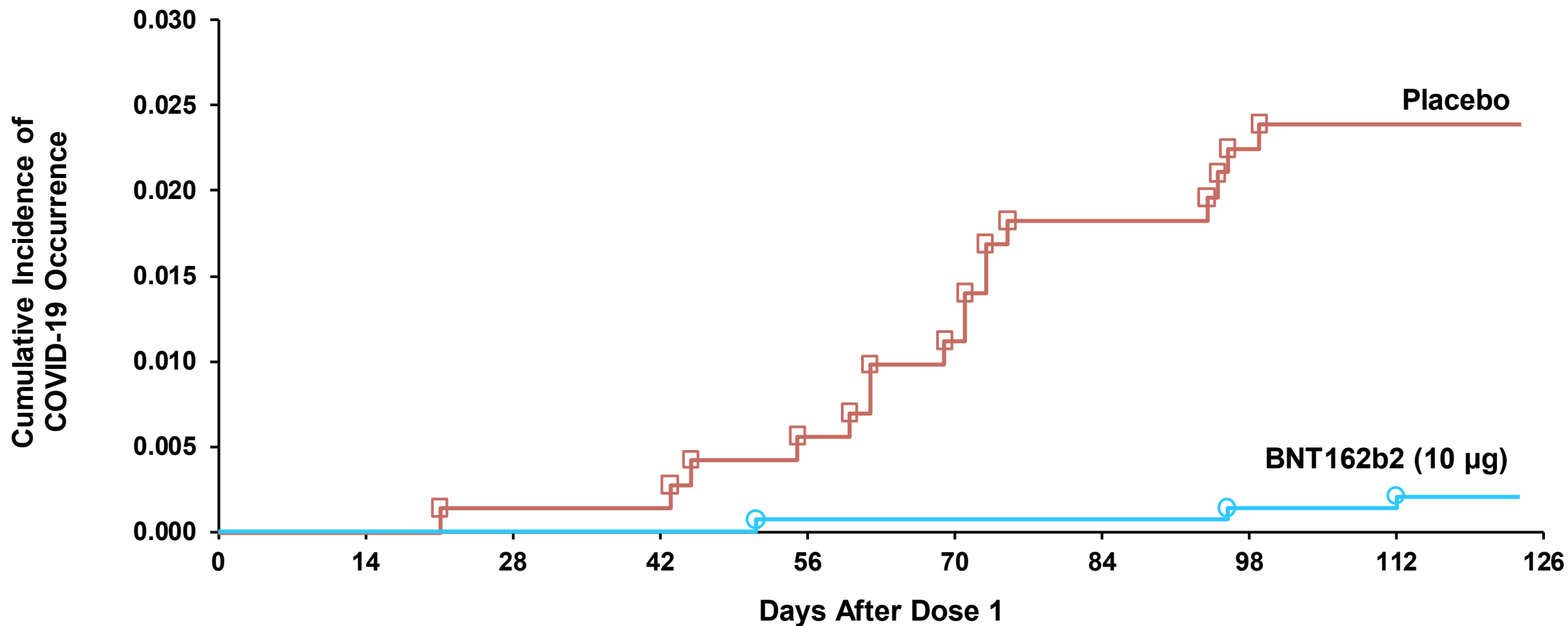
High Efficacy was Observed in 5 to <12 Year Olds Descriptive Analysis of First COVID-19 Occurrence From 7 Days After Dose 2

Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

Efficacy Endpoint	BNT162b2 (10 µg) N=1305		Placebo N=663		VE (%)	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
First COVID-19 occurrence ≥7 days after Dose 2	3	0.322 (1273)	16	0.159 (637)	90.7	(67.7, 98.3)

No severe cases of COVID-19 were reported
No cases of MIS-C were reported

Cumulative Incidence of COVID-19 After Dose 1: 5 to <12 Years of Age



Immunogenicity and Efficacy Conclusions

- **Immunobridging success criteria were met for 5 to <12 year-olds at 10 µg dose level**
- **BNT162b2-immune sera effectively neutralized both USA-WA1/2020 (reference strain) and the highly transmissible B.1.617.2 (Delta) variant of concern**
- **BNT162b2 as a two-dose series is highly protective against COVID-19 in 5 to <12 year-olds when Delta variant was prominent**

Ongoing and Active Pharmacovigilance and Pharmacoepidemiology (Pediatric)



Pharmacovigilance

- **Detect unexpected safety events rapidly**
- Spontaneous report collection
- Active follow-up
- Frequent signal detection and evaluation

Proactive Risk Mitigation

- Labeling
- Educational materials
- Vial differentiation

Pharmacoepidemiology Studies

- 5 Studies that include pediatric patients:**
- 3 studies of >175M health records
 - 2 studies of post-vaccination myocarditis

Background on Myocarditis Risk

- **Typically caused by viral infections**
 - CDC publication based on hospital records recently showed that COVID-19 patients had nearly 16 times the rate of myocarditis compared patients without COVID-19¹
- **In rare cases, myocarditis observed after COVID vaccination in children and adolescents – more frequently after the second dose and in males**
 - Acute clinical course is generally mild with majority experiencing resolution of symptoms with conservative treatment
 - Rates of post-vaccination myocarditis in 12-15 year-olds appear lower relative to older adolescents in both the United States and Israel^{2,3}

Benefit-Risk Supports a Revision to the EUA for BNT162b2 to Include 5 to <12 Years of Age

Model-Predicted Benefit-Risk Outcomes Based on FDA Scenario 4 and CDC Risk Scenarios per One Million Fully Vaccinated Children Ages 5 to <12 Years Over 6 Months

(Assumes a rate of myocarditis in 5 to <12 year-olds equal to that of 12-15 yo which may be an overestimate)

Model Scenario*	Benefits COVID-19 Outcomes Prevented				Risks Excess Myocarditis Cases		
	Cases ¹	Hosp. ¹	ICU ¹	Deaths ¹	VAERS ²	VSD ³	Optum ¹
Males and Females – FDA Scenario 4 <i>VE=90% against cases</i> <i>VE=100% against hosp.</i>	58,851	241	77	1	22	57	106

*FDA scenario assumes the COVID-19 incidence as of September 11, 2021.

1. FDA Briefing Document. EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. VRBPAC October 26, 2021.
2. Su JR. Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse Event Reporting System (VAERS); Slide 7 (7-day risk period post Dose 2). ACIP Meeting October 21, 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf>
3. Klein N. Myocarditis Analyses in the Vaccine Safety Datalink: Rapid Cycle Analyses and “Head-to-Head” Product Comparisons; Slide 18 (12-17 year olds; 21-day risk period post Dose 2). ACIP Meeting October 21, 2021 Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf>

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- **Vaccination likely to confer additional benefits:**
 - **Reduced transmission, improved herd immunity, increased in-person learning supporting child development**

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1. FDA Briefing Document. EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. VRBPAC October 26, 2021.
2. Su JR. Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse Event Reporting System (VAERS); Slide 7 (7-day risk period post Dose 2). ACIP Meeting October 21, 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf>
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Pfizer/BNT requests

EUA of BNT162b2

for active immunization of
individuals 5 to <12 years of age,
administered intramuscularly
as a series of two 10 μ g doses,
3 weeks apart

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BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine – Request for Emergency Use Authorization in Individuals 5 to < 12 Years of Age

Vaccines and Related Biological Products
Advisory Committee

October 26, 2021