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

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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 cases[1]**
- **8622 hospitalizations[2]**
- **143 deaths[1]**

- **COVID-19 causes additional long-term sequelae in children**
  - >5200 cases of multisystem inflammatory syndrome in children (MIS-C), 50% in 5−13 year-olds[3]
  - 67% of children experience symptoms ≥60 days after COVID-19 diagnosis[4]
- **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 comorbidities[5]
  - MIS-C can affect healthy children[6]
- **Vaccinating children has other societal benefits**
  - Children likely play role in transmission[7]; vaccinating children can help reach herd immunity
  - Vaccination will help ensure in-person learning critical for childhood development, by limiting community spread and school outbreaks[8]

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, Kompaniyets 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

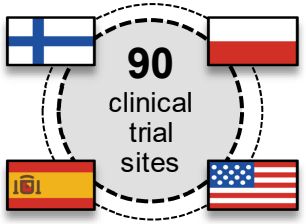
5 to <12 yrs

Identification of preferred dose level(s)

10 µg		

Phase 2/3

2:1 randomization



- ~1500 BNT162b2
- 750 placebo

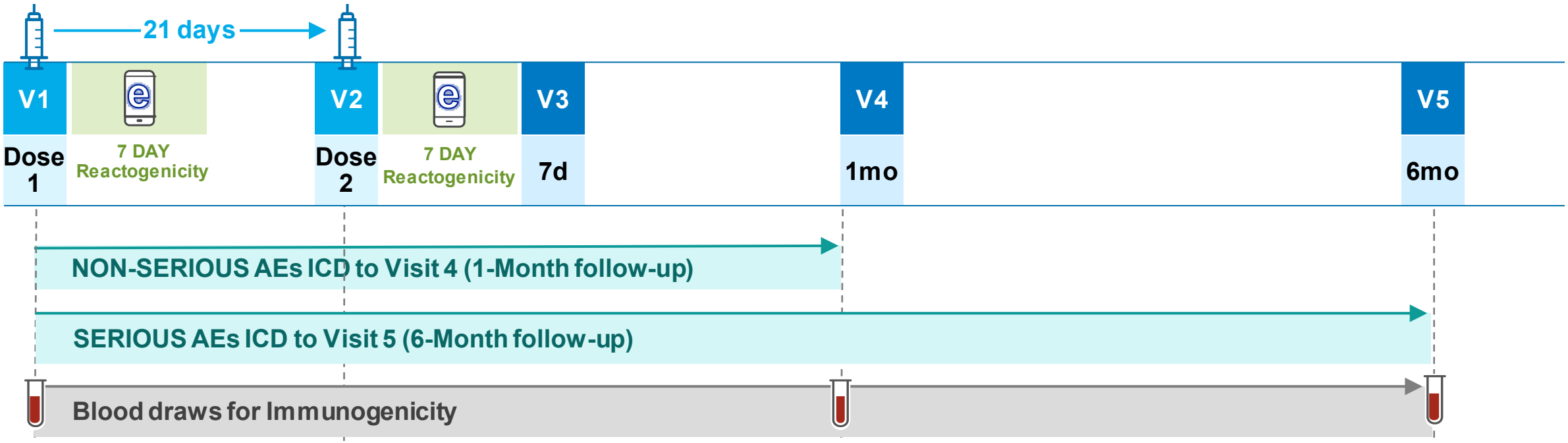
~Additional 1500 BNT162b2 and 750 placebo recipients most with ≥2 weeks post dose 2 safety data

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

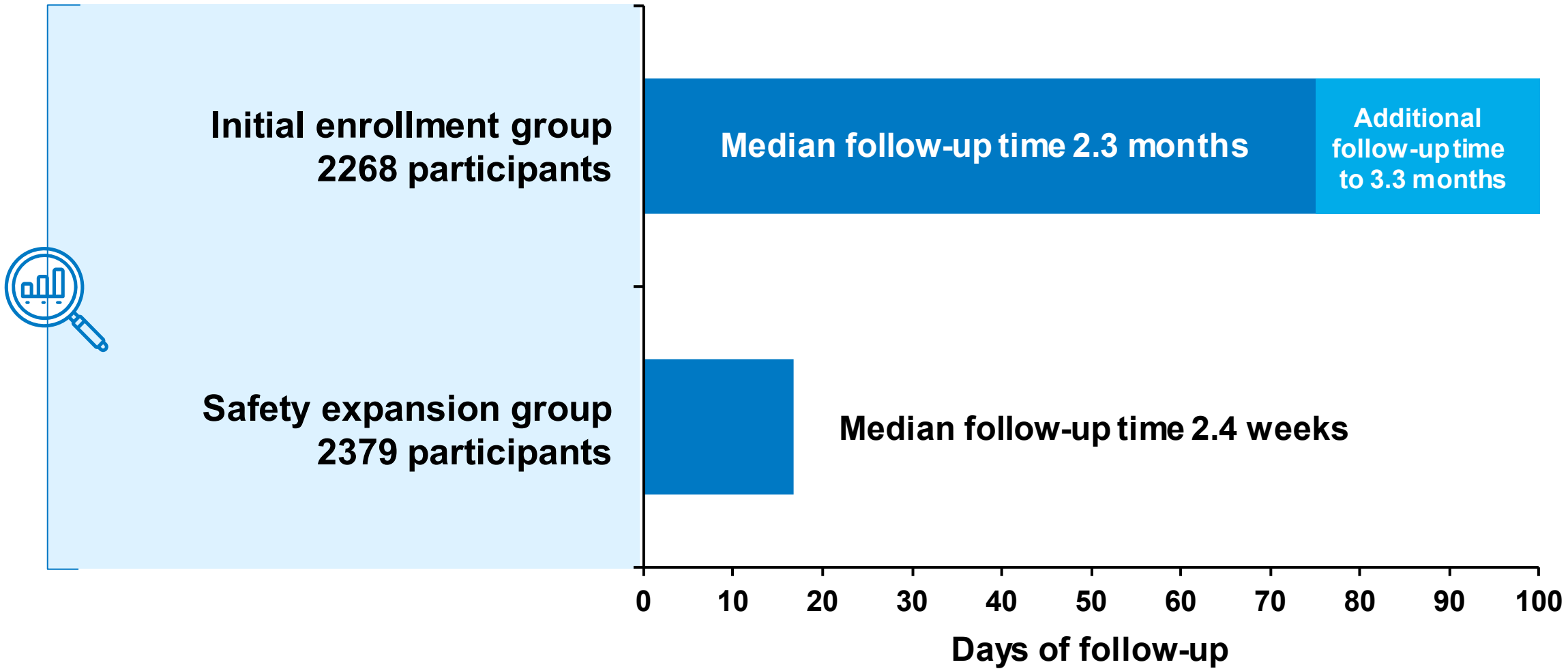
Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

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



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



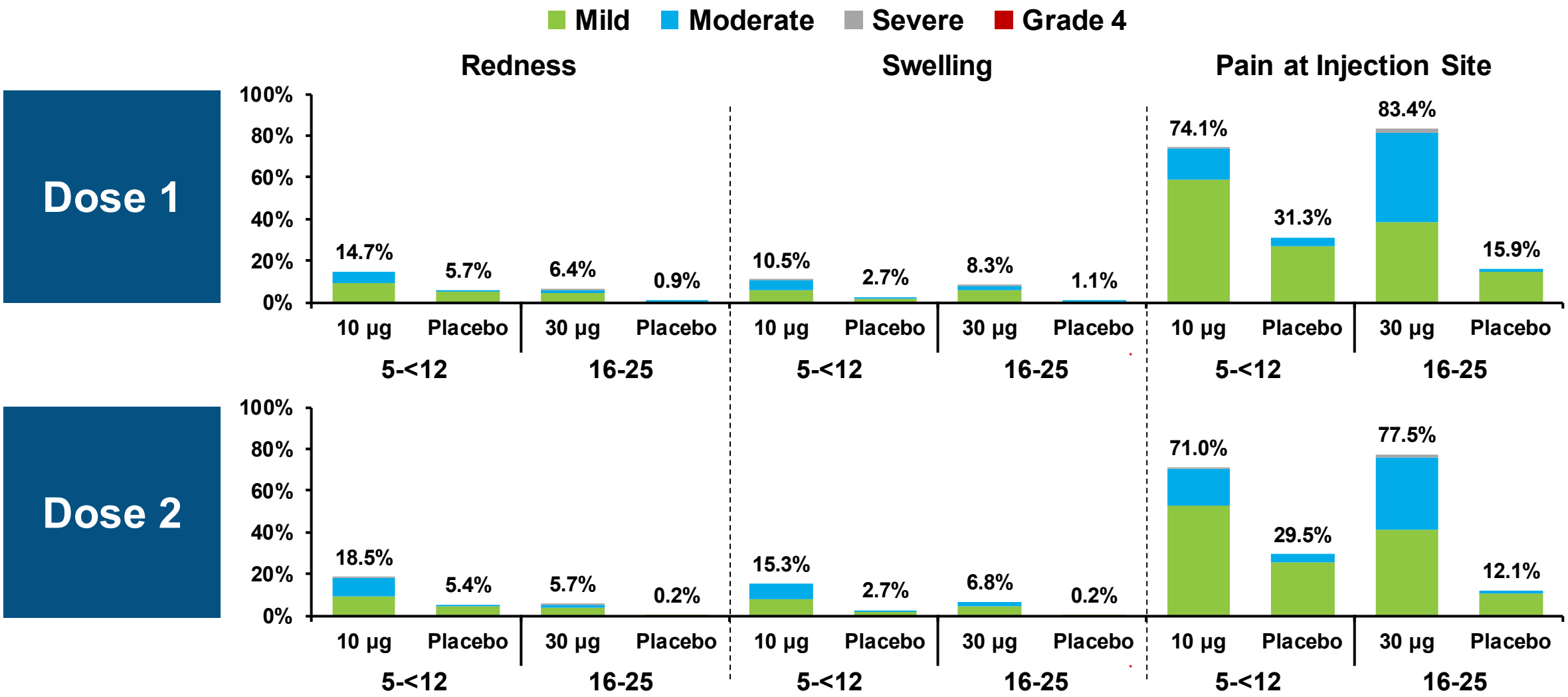
Demographics for 5 to <12 Year Olds

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)

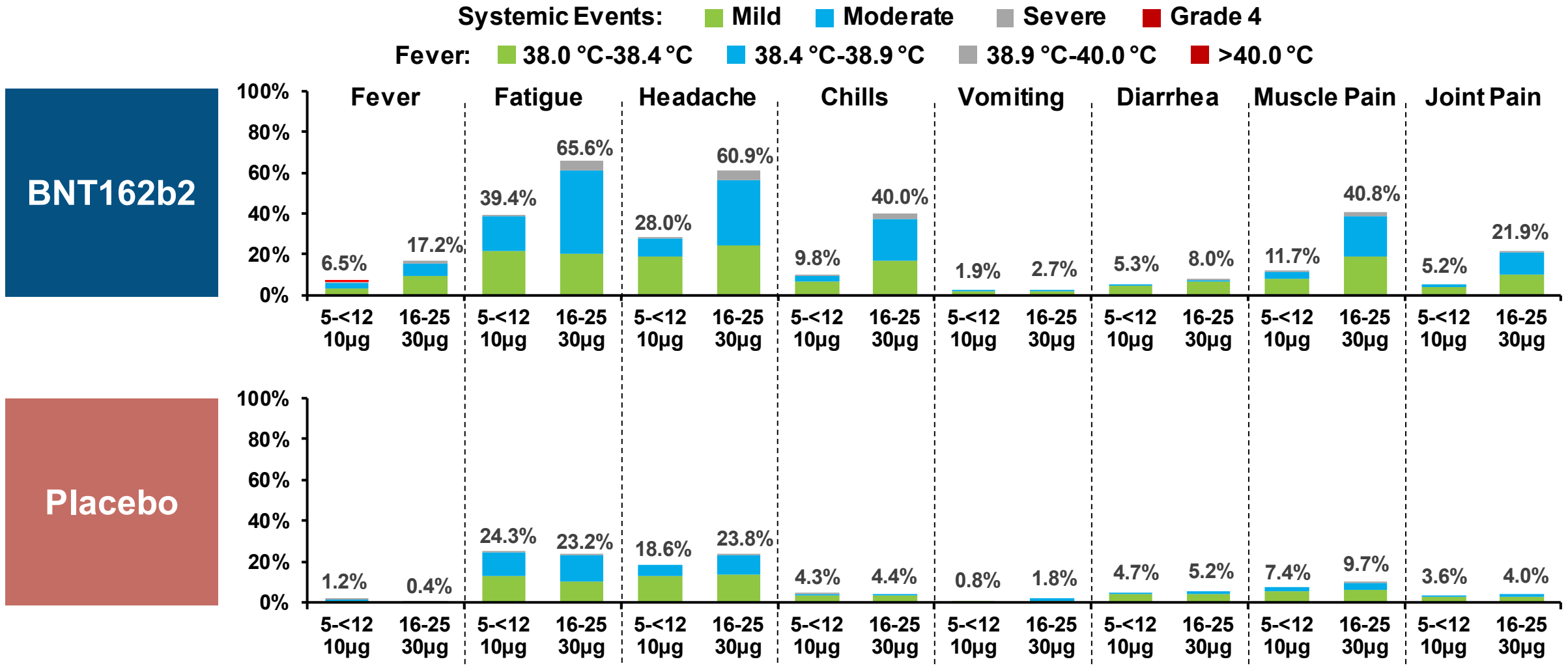
a. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
b. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 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



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
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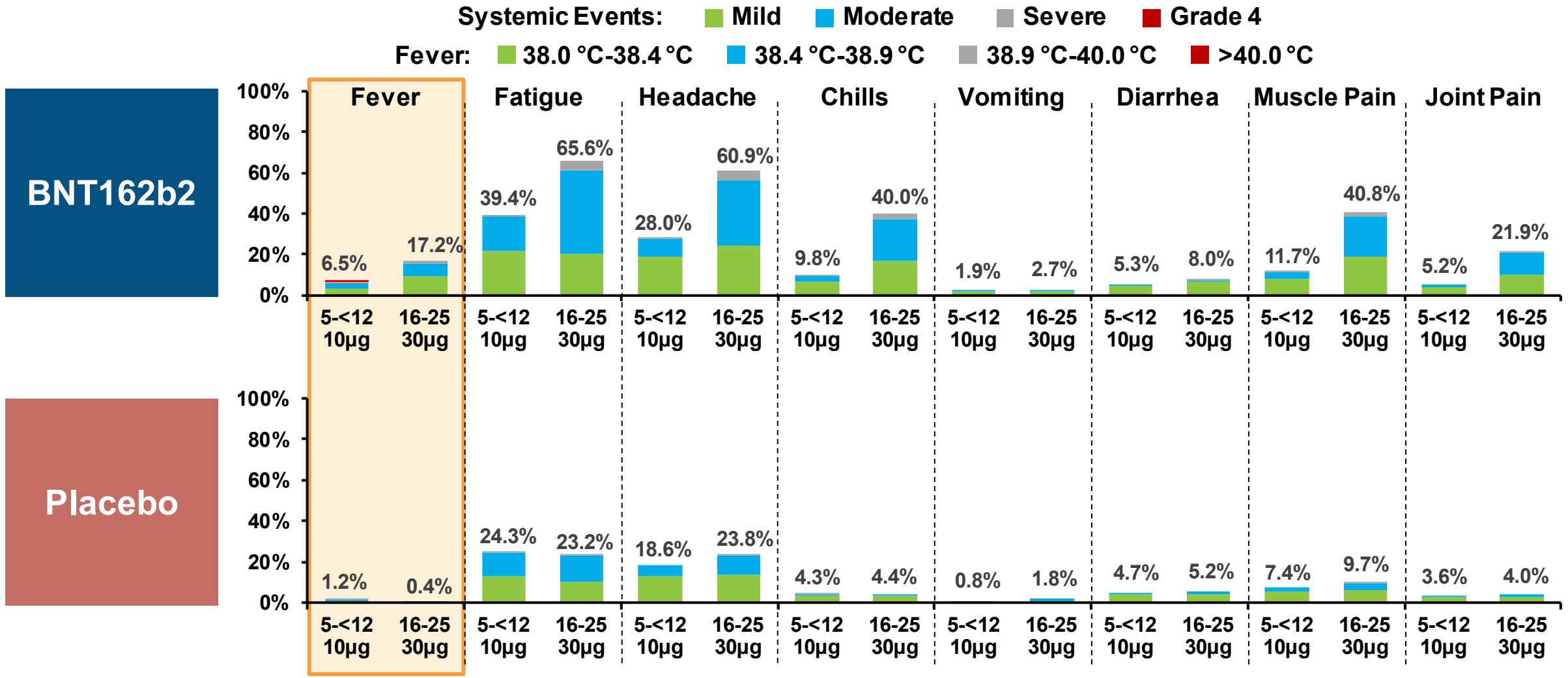

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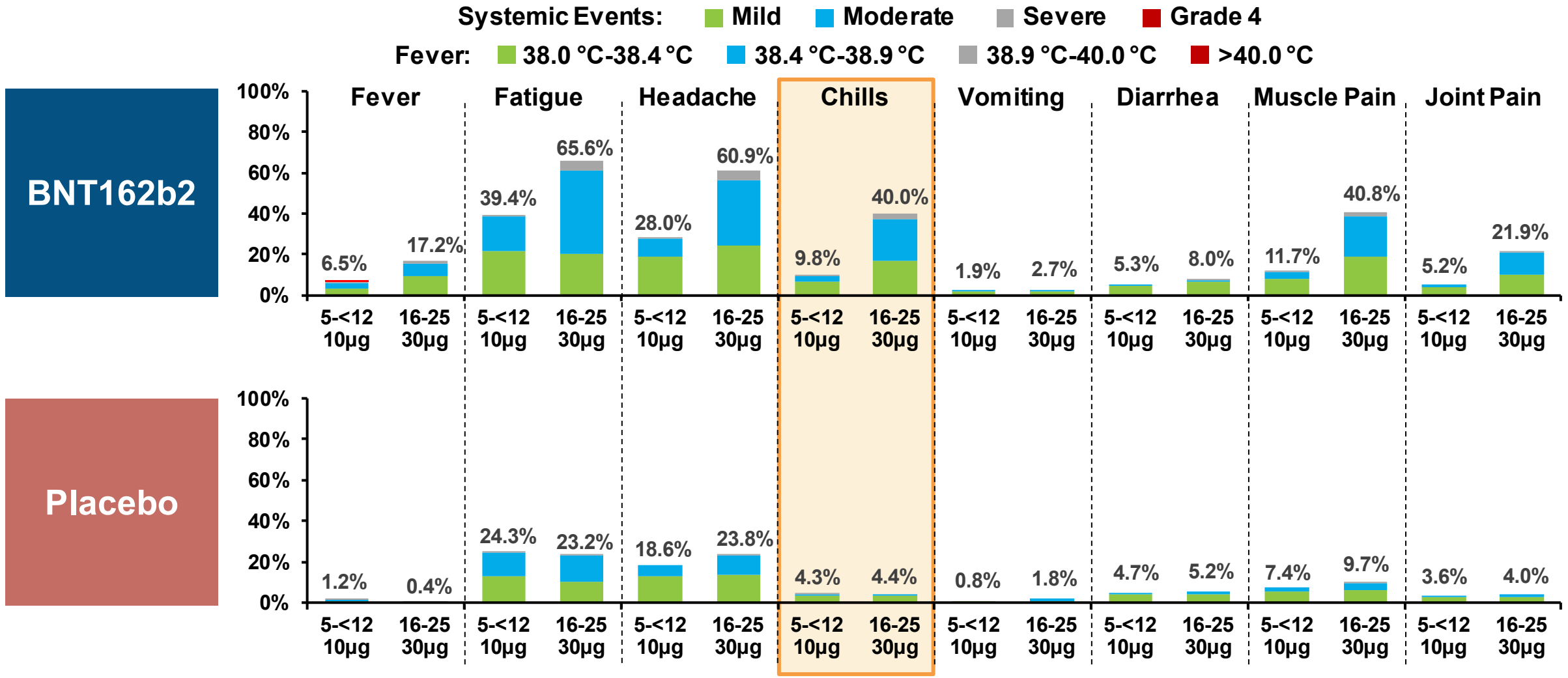

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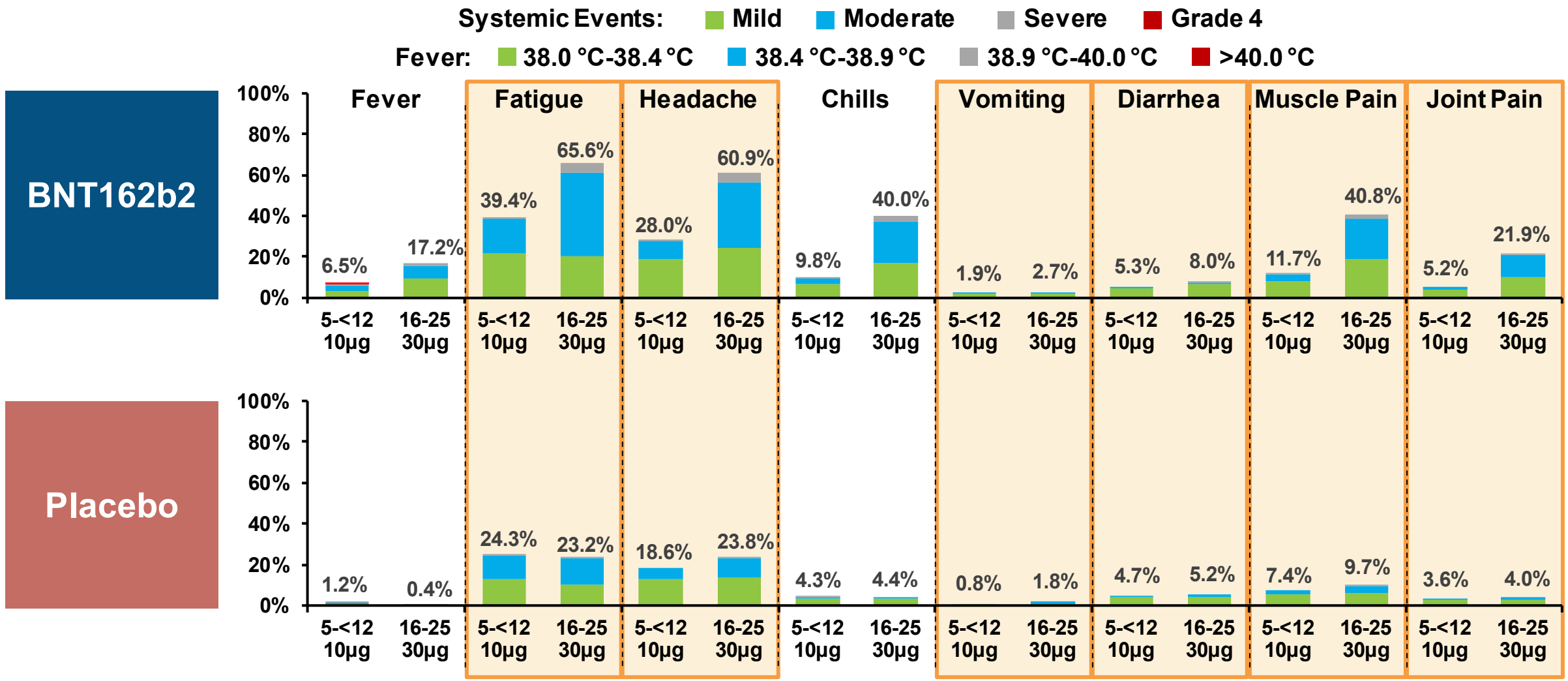

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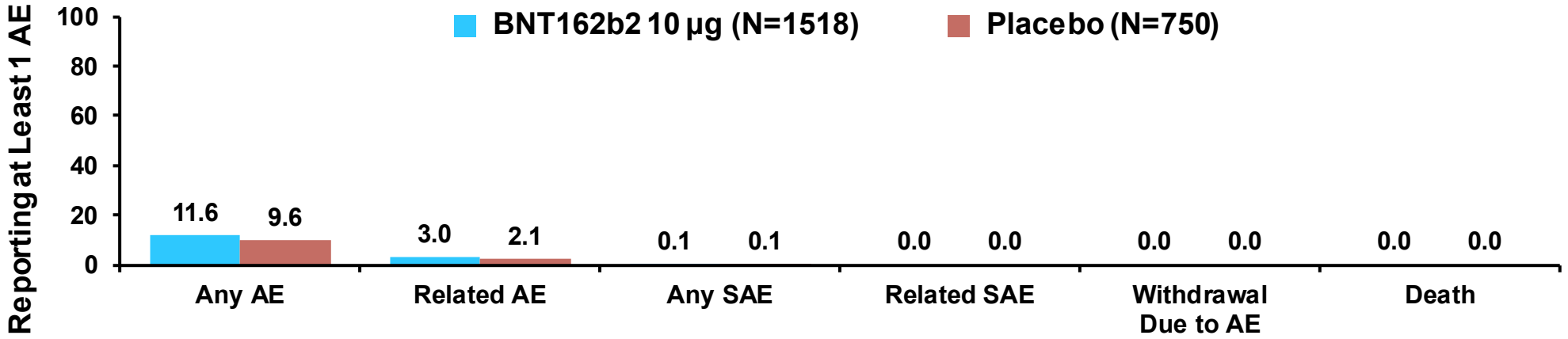
Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

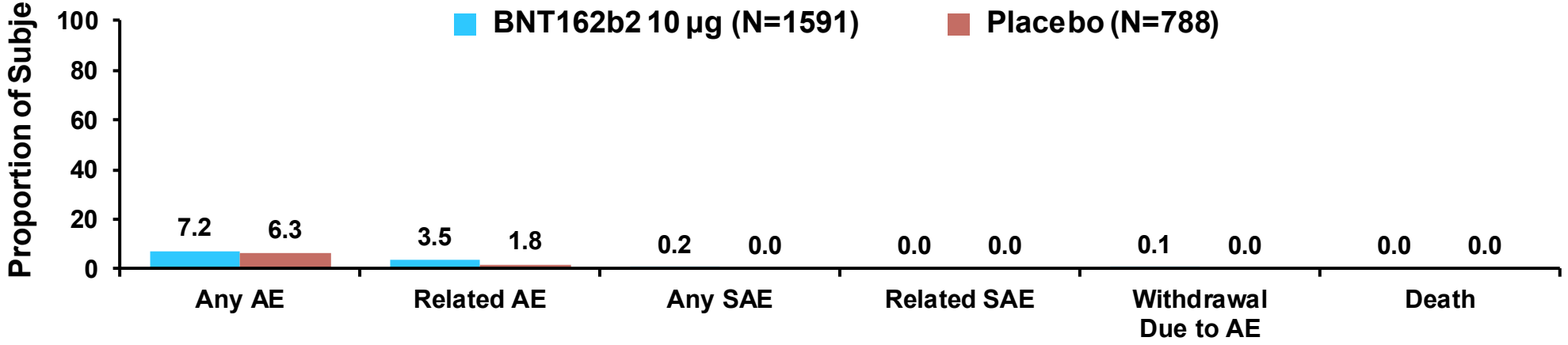
Adverse Events

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

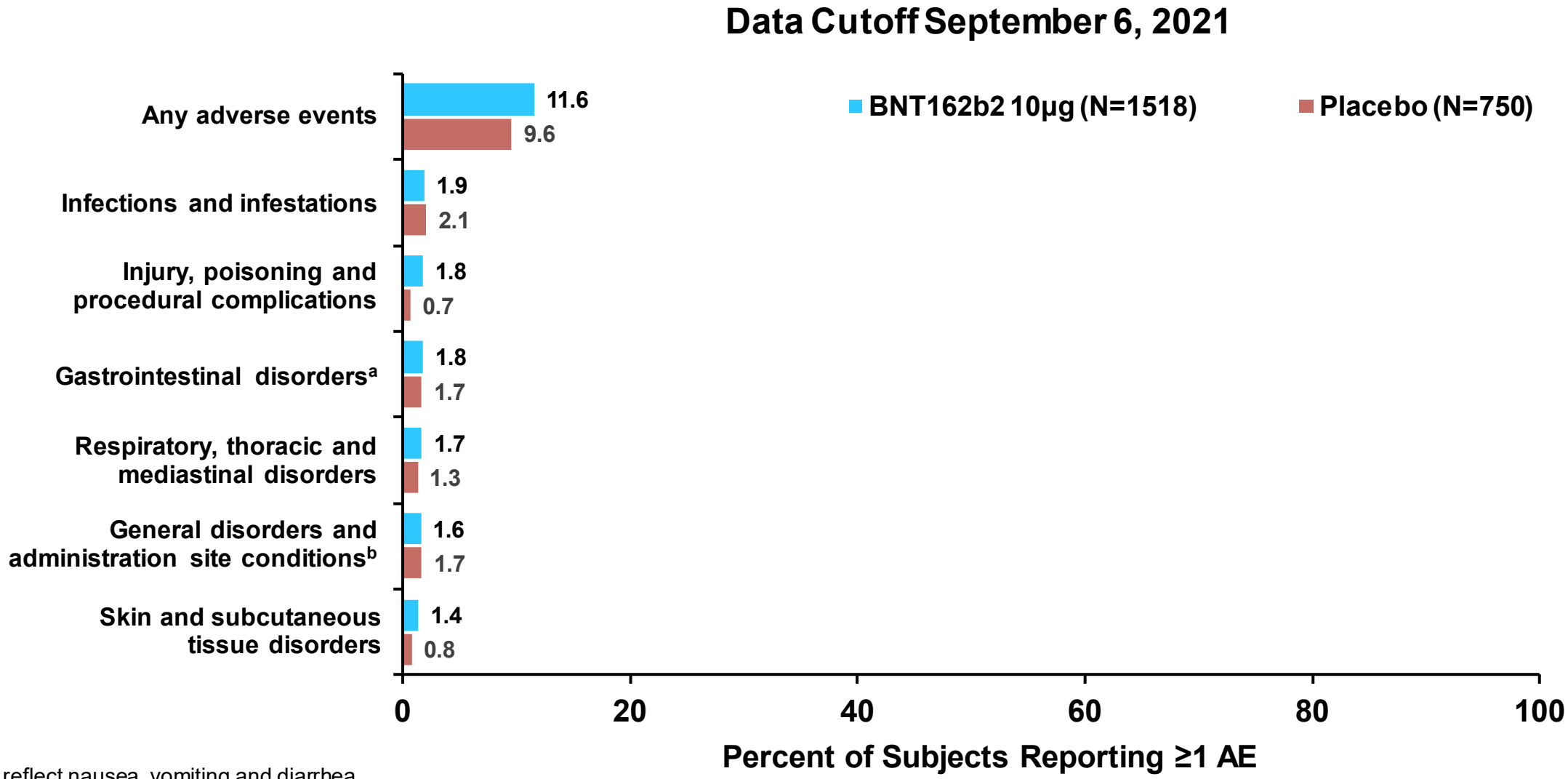
Initial enrollment group:
Median follow-up time 2.3 months
Cutoff date September 6, 2021



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

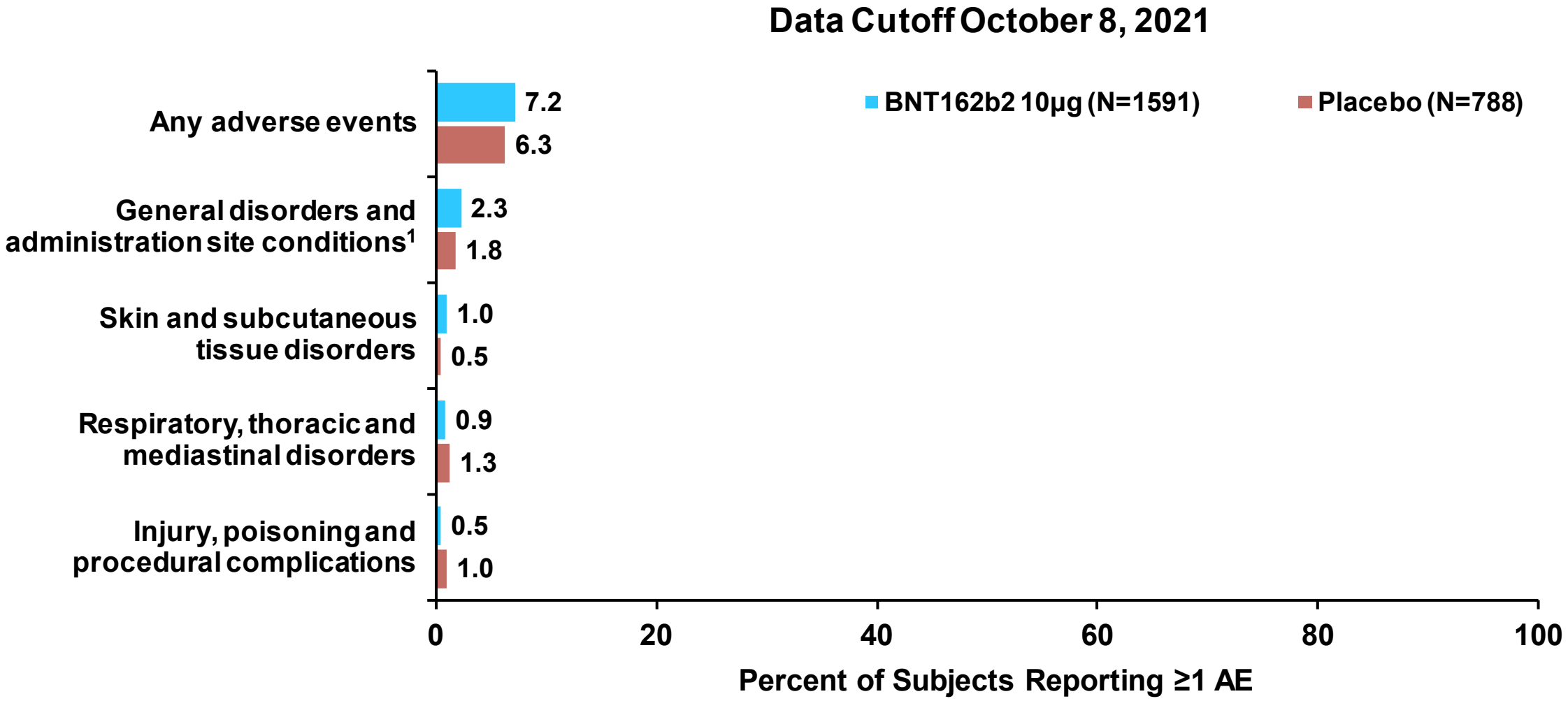


Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)



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



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 ediary 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

		BNT162b2 (10µg) 5 to <12 Years		BNT162b2 (30µg) 16-25 years		5 to <12 / 16-25 years	
Assay	Dosing/Sampling Time Point	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

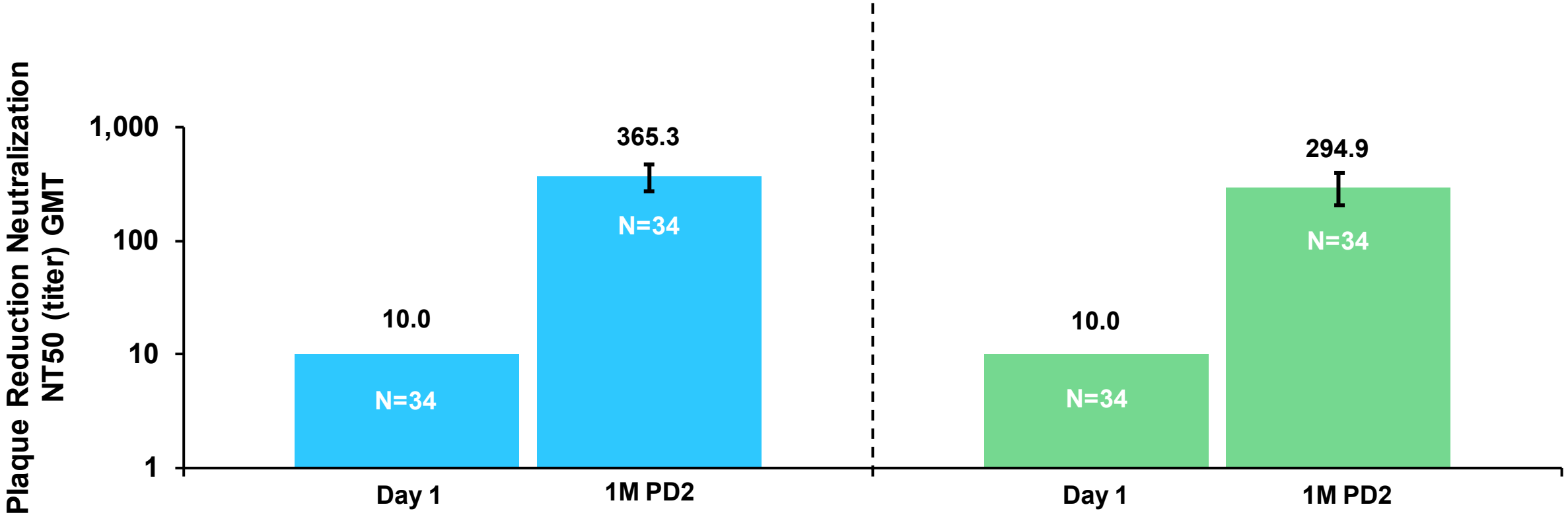
		BNT162b2 (10µg) 5 to <12 Years		BNT162b2 (30µg) 16-25 years		Difference in % 5 to <12 / 16-25 years	
Assay	Dosing/Sampling Time Point	N	n (%) (95% CI)	N	n (%) (95% CI)	% (95% CI)	Met Immuno-bridging (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2 / 1 Month	264	262 (99.2) (97.3, 99.9)	253	251 (99.2)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

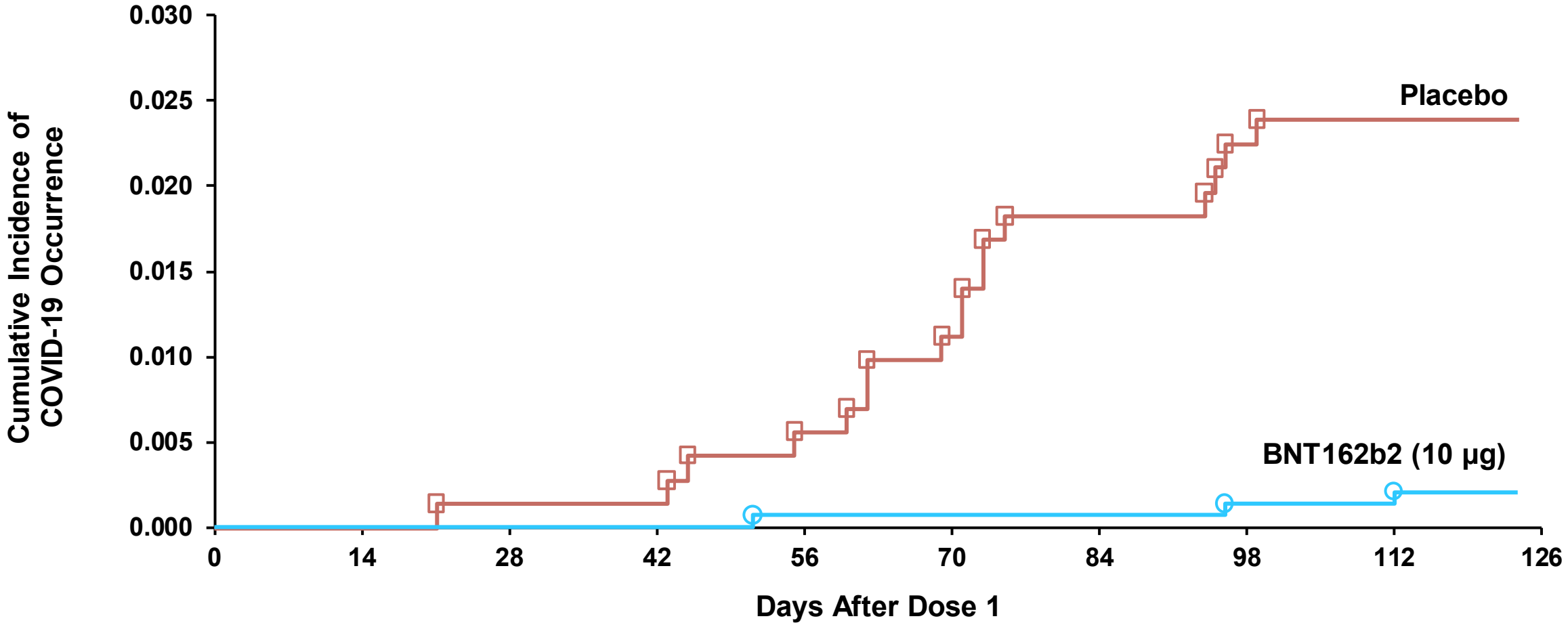
Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

	BNT162b2 (10 µg) N=1305		Placebo N=663			
Efficacy Endpoint	n	Surveillance Time (n)	n	Surveillance Time (n)	VE (%)	(95% CI)
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

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint

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-19[1]
- **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]

1. Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232.
2. Lee GM et al. 30 AUG 2021 Advisory Committee on Immunization Practices Presentation, Slide 21. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/05-COVID-Lee-508.pdf . Accessed 18 October 2021
3. Israel Ministry of Health, Epidemiology Division: COVID-19 Vaccine Safety Update, 25-SEP-2021. Available at: https://www.gov.il/BlobFolder/reports/seav-25092021/he/files_publications_corona_side-effects-after-vaccination-25092021.pdf

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)

	Benefits COVID-19 Outcomes Prevented				Risks Excess Myocarditis Cases		
Model Scenario*	**Cases[1]**	**Hosp.[1]**	**ICU[1]**	**Deaths[1]**	**VAERS[2]**	**VSD[3]**	**Optum[1]**
Males and Females – FDA Scenario 4 *VE=90% against cases VE=100% against hosp.*	**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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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

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)

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

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

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

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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

Pfizer/BNT requests EUA of BNT162b2 for active immunization of individuals 5 to <12 years of age, administered intramuscularly as a series of two 10µg 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

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