BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine –in Individuals 5 to <12 Years of Age

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Presentation Agenda

Introduction

Clinical Data

- Phase 2/3 Immunogenicity and Safety
- Efficacy Analysis

Pfizer/BNT Received 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

Clinical Data

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

Phase 1

48 PARTICIPANTS

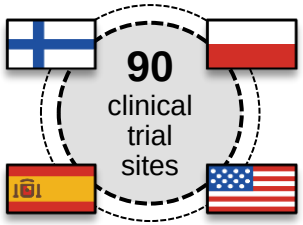
5 to <12 yrs

Identification of preferred dose level(s)

10 µg	20 µg	30 µg

Phase 2/3

2:1 randomization



- **~1500** BNT162b2
- **750** placebo

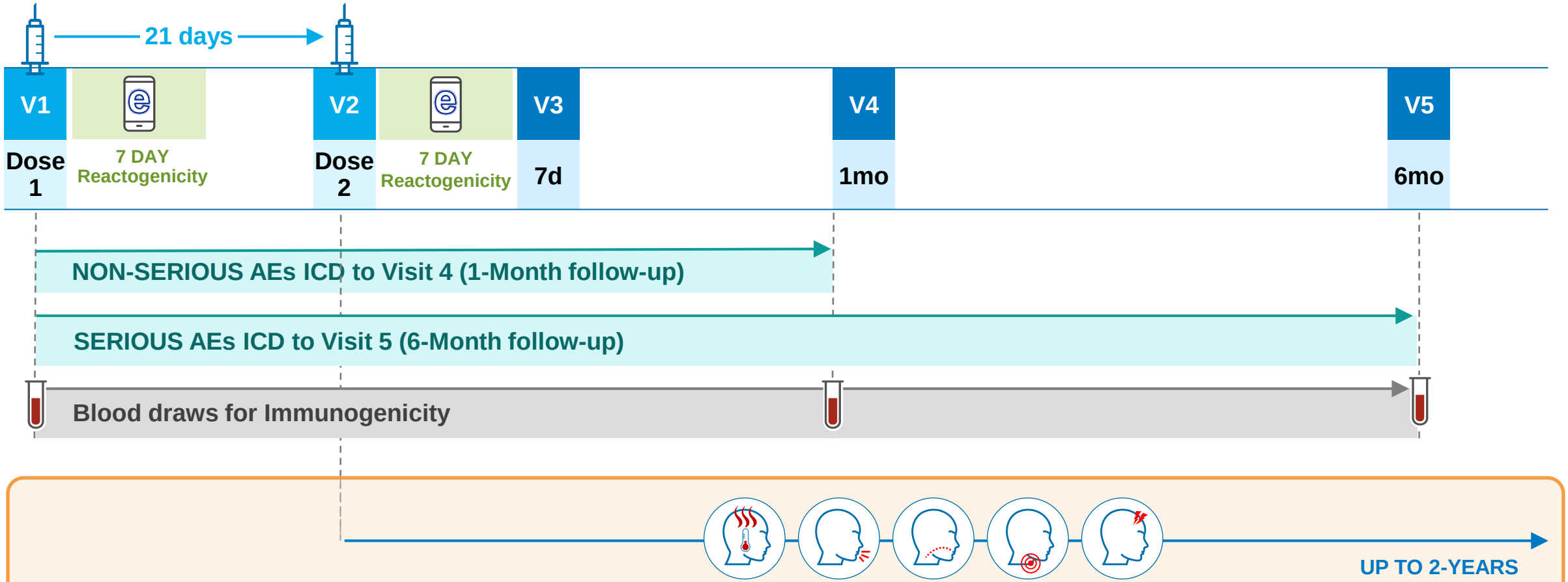
~Additional 1500 BNT162b2 and 750 placebo recipients most with ≥2 weeks post dose 2 safety data

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

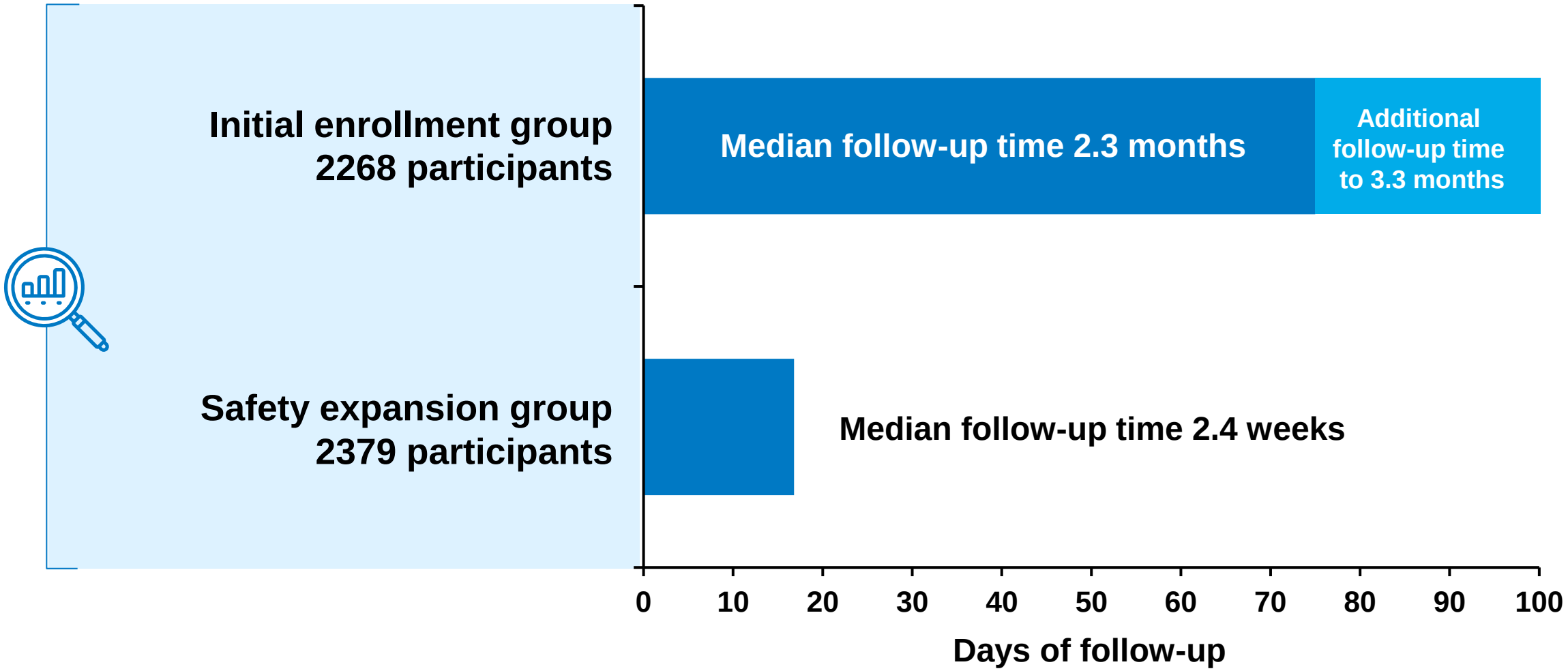
Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

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



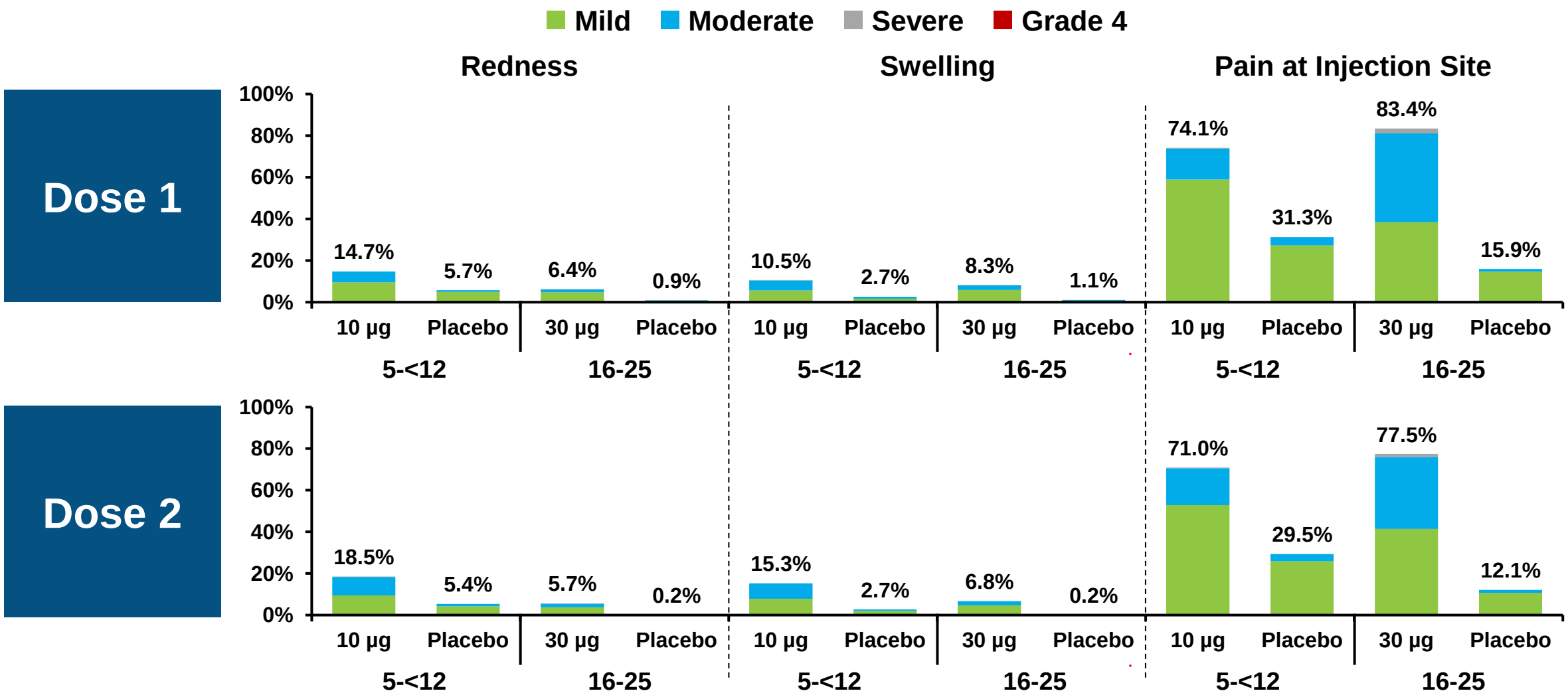
Demographics for 5 to <12 Year Olds

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, n (%)	Yes	174 (11.5)	92 (12.3)
Comorbidities[a], n (%)	Yes	312 (20.6)	152 (20.3)

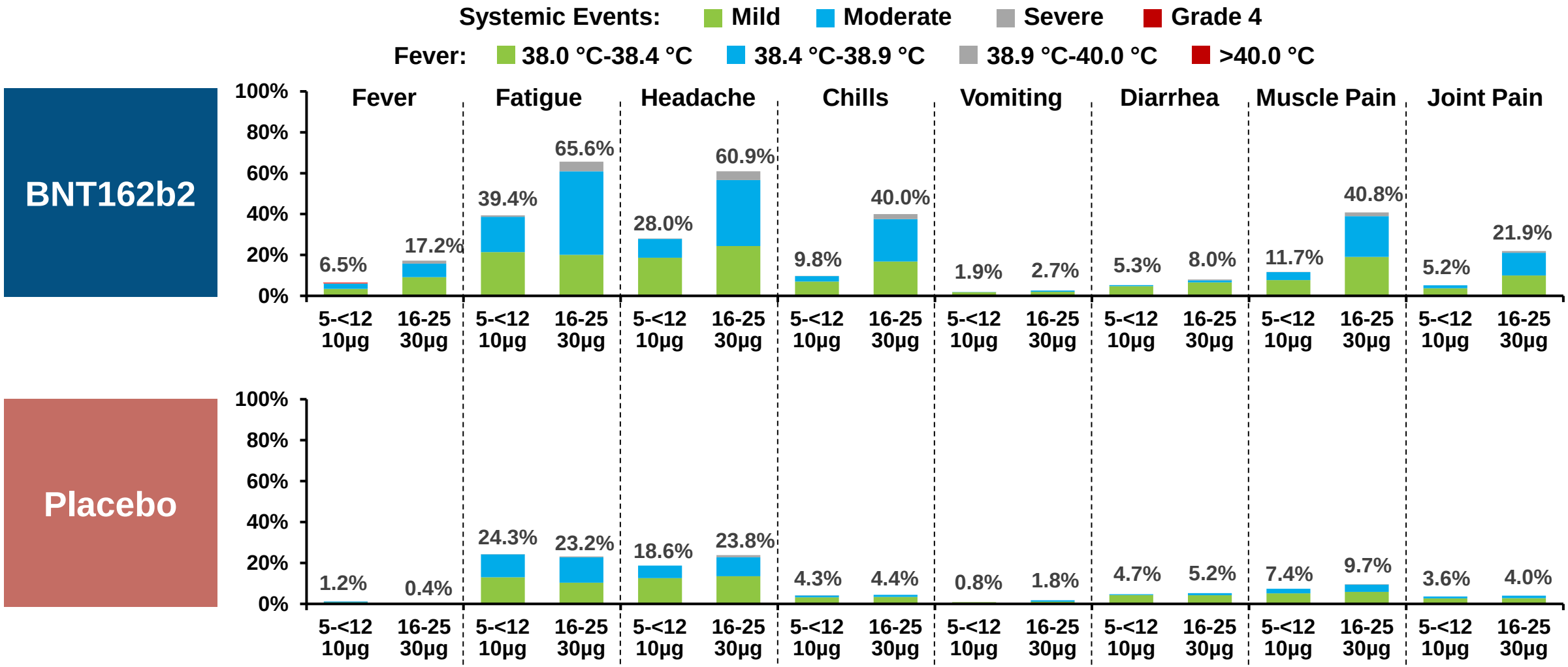
a. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile
b. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

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



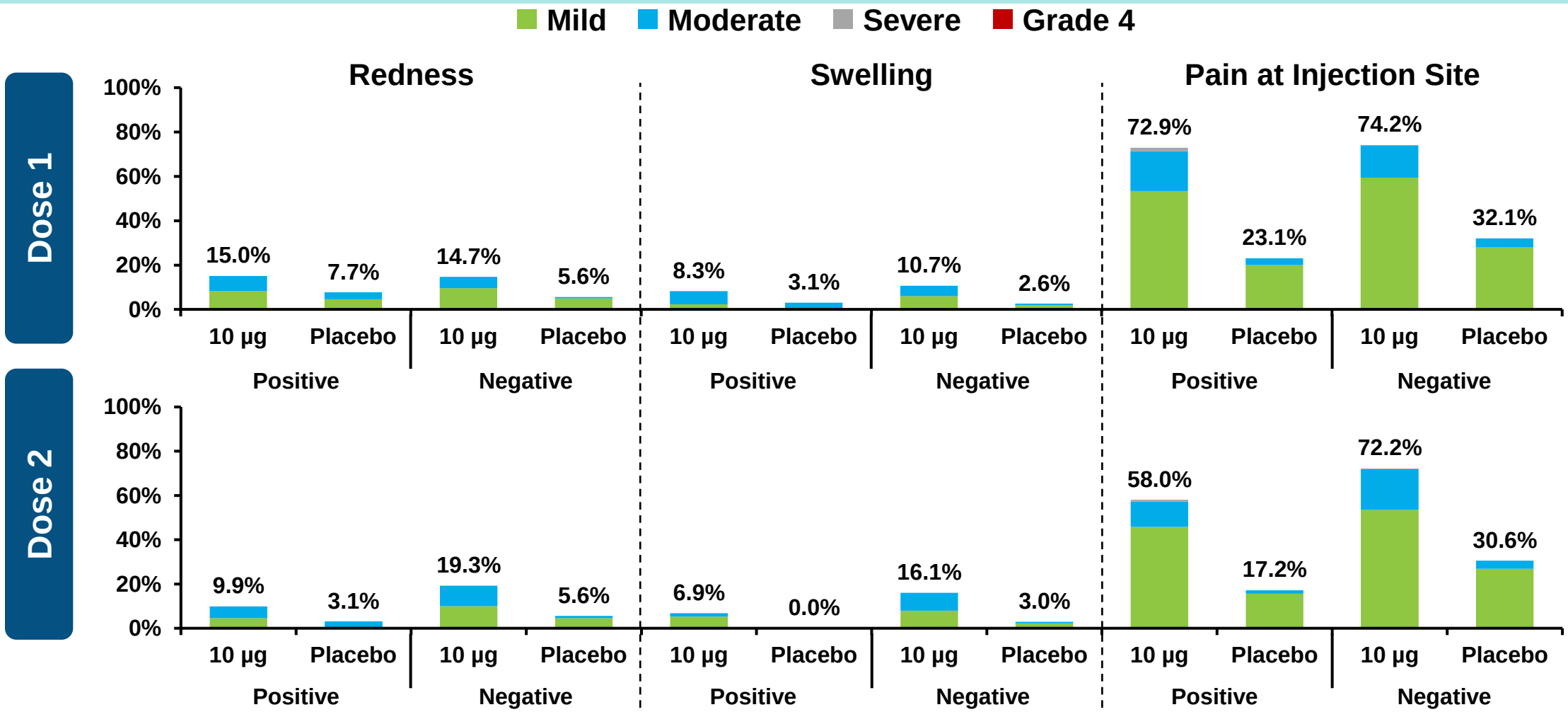
Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Dose 1: 5-<12yrs N=2260; 16-25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

Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status



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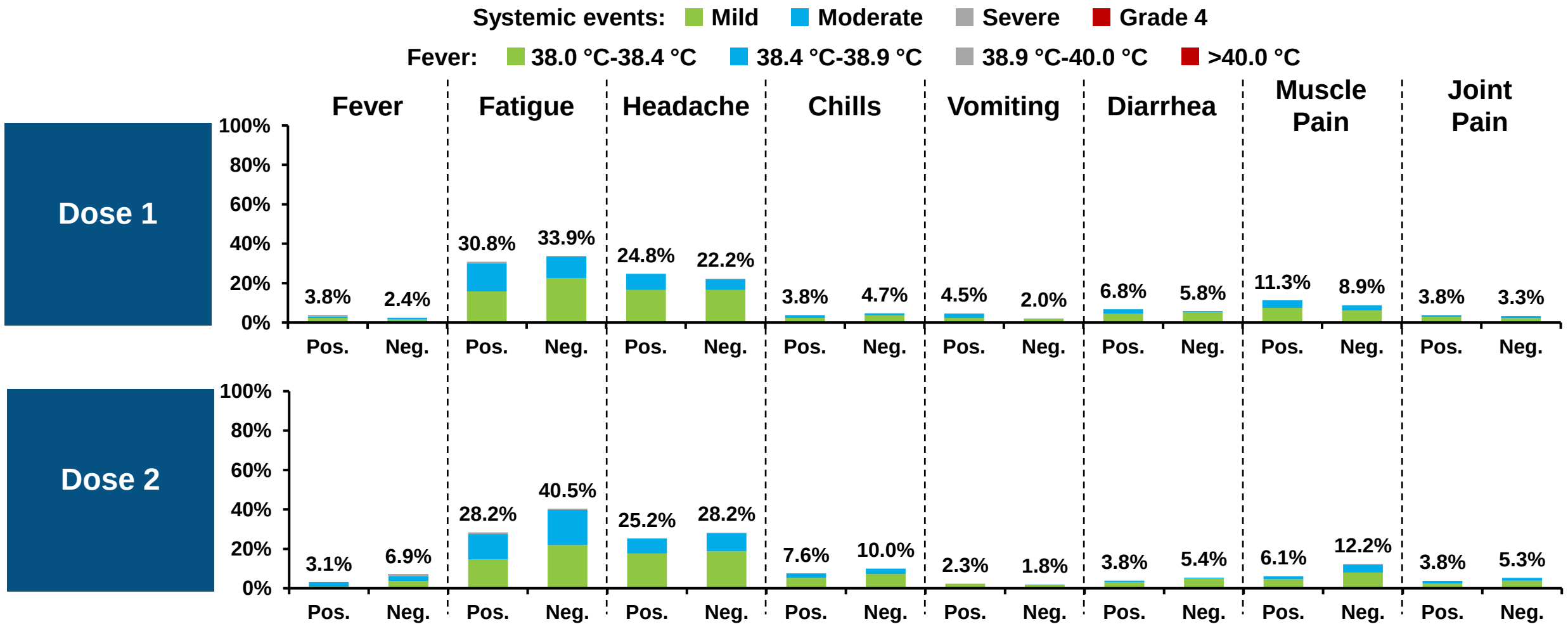
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Dose 1: Positive N=198; Negative N=2062 Dose 2: Positive N=195; Negative N=2047

Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 and Dose 2 in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status



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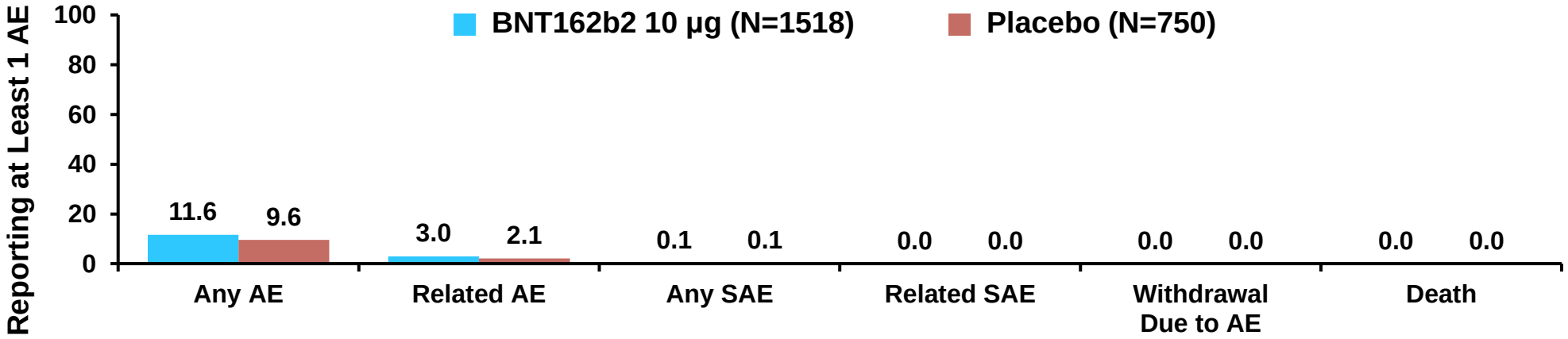
Dose 1 Positive N=198; Negative N=2062 Dose 2: Positive N=195; Negative N=2047

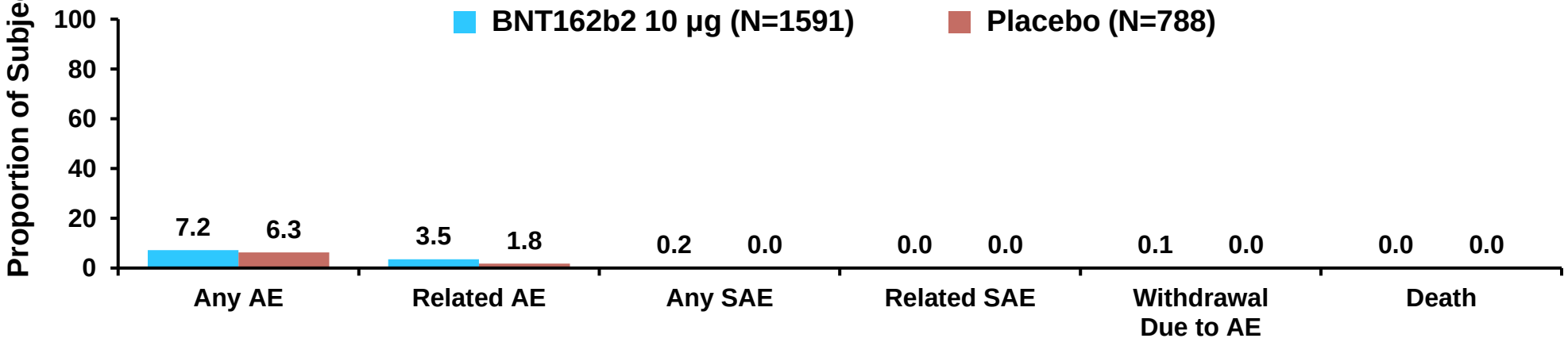
Adverse Events

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

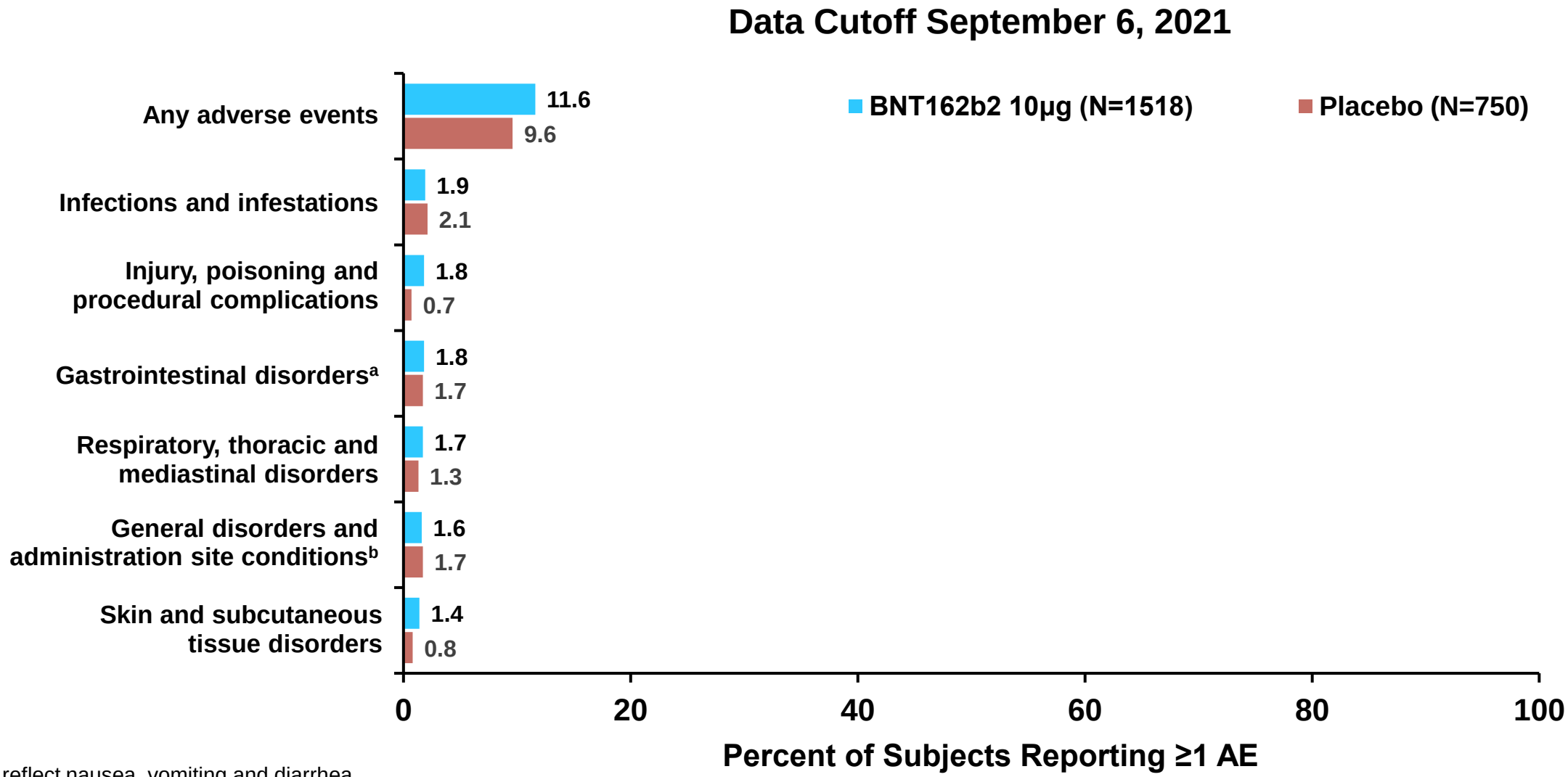
Initial enrollment group:
Median follow-up time 2.3 months
Cutoff date September 6, 2021



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

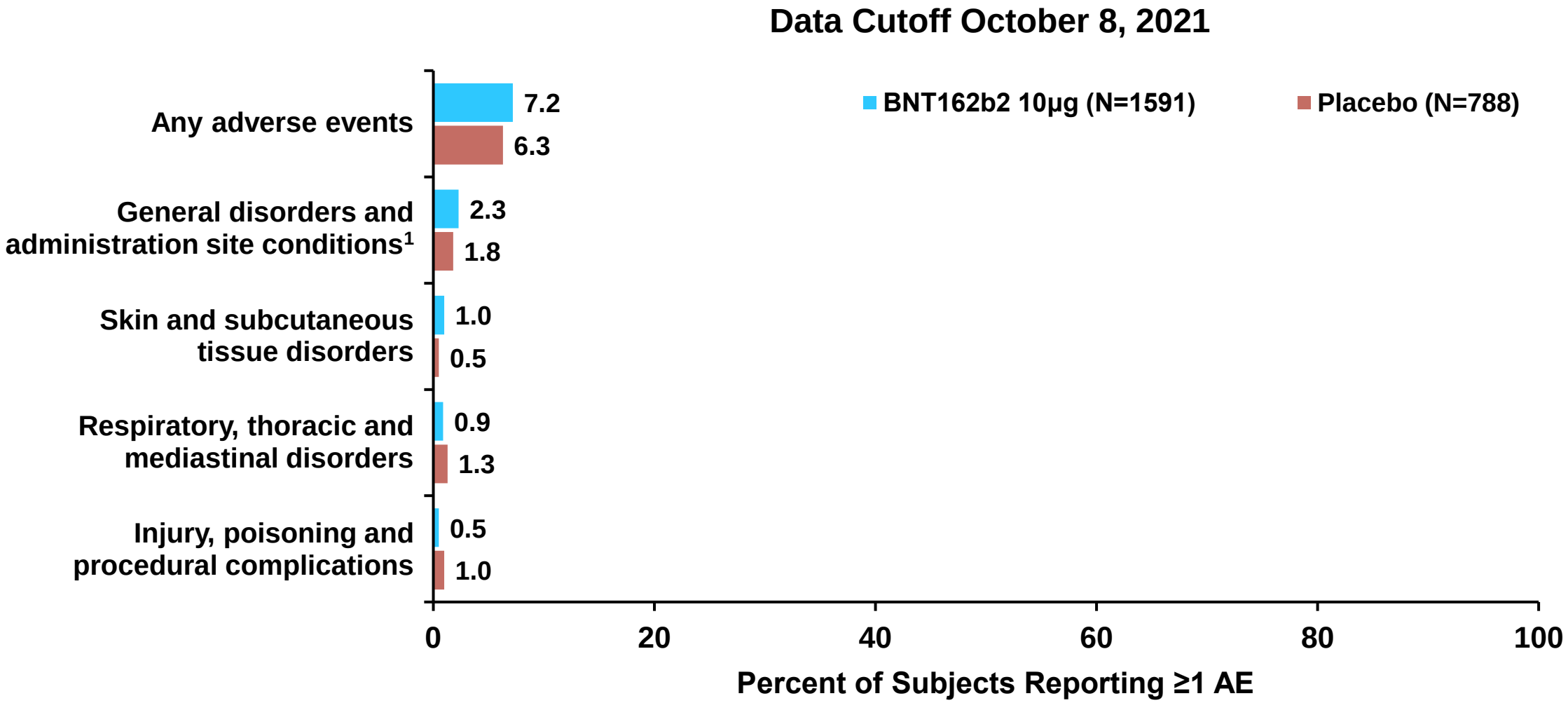


Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)



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

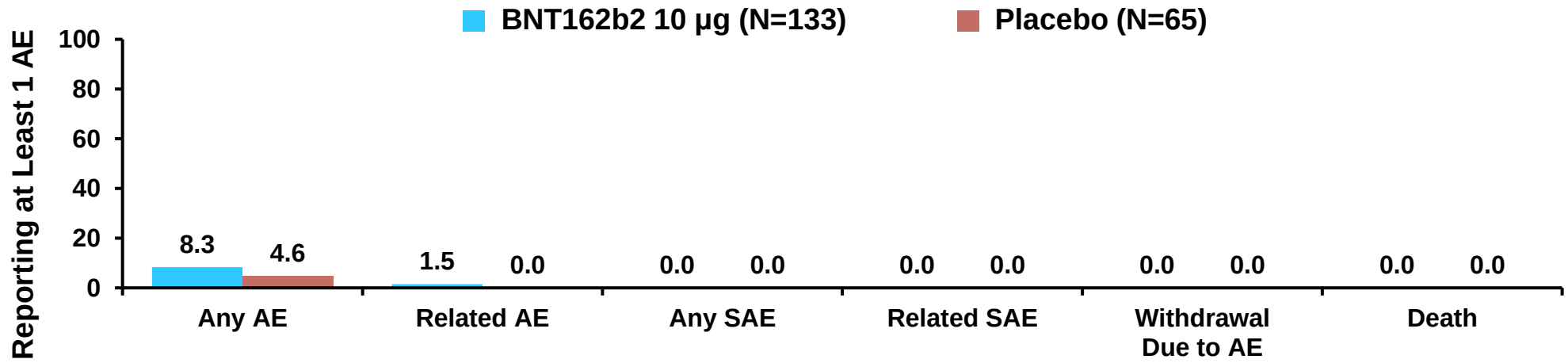
Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Safety Expansion Group (N= 2379)



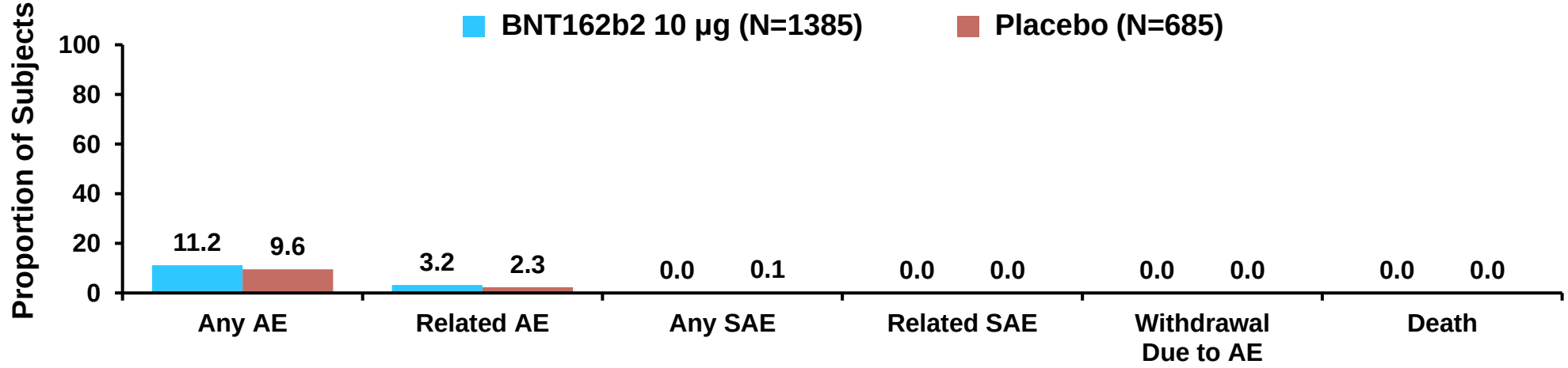
1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue
Lymphadenopathy 0.4% in the BNT162b2 group

Overall Adverse Events from Dose 1 to 1 Month Post Dose 2 in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status

Baseline SARS-CoV-2 Positive



Baseline SARS-CoV-2 Negative



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

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years n	BNT162b2 (10µg) 5 to <12 Years GMT (95% CI)	BNT162b2 (30µg) 16-25 years n	BNT162b2 (30µg) 16-25 years GMT (95% CI)	5 to <12 / 16-25 years GMR (95% CI)	5 to <12 / 16-25 years 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

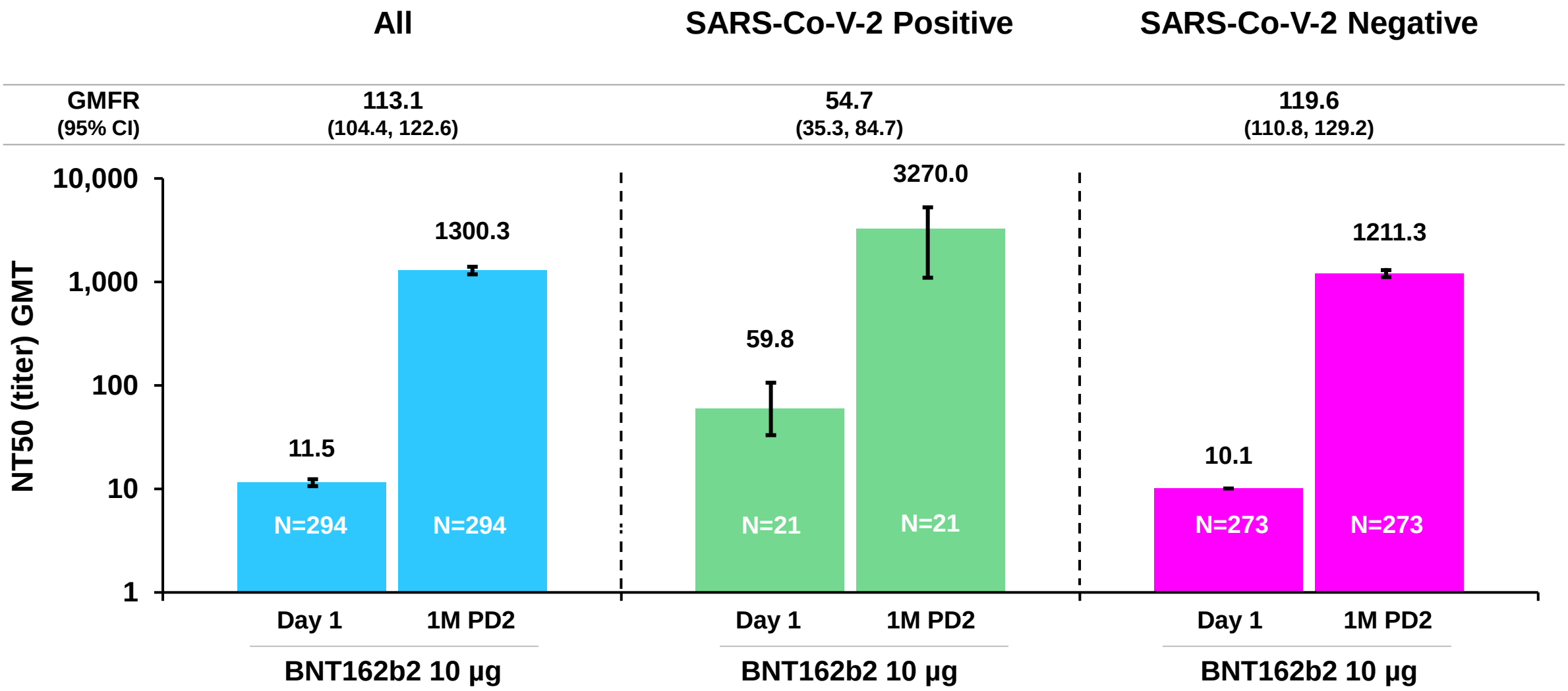
Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8

Assay	Dosing/Sampling Time Point	BNT162b2 (10µg) 5 to <12 Years N	BNT162b2 (10µg) 5 to <12 Years n (%) (95% CI)	BNT162b2 (30µg) 16-25 years N	BNT162b2 (30µg) 16-25 years n (%) (95% CI)	Difference in % 5 to <12 / 16-25 years % (95% CI)	Difference in % 5 to <12 / 16-25 years 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

Geometric Mean Titers (NT50), By Baseline SARS-CoV-2 Status – Subjects 5 to <12 Years – Evaluable Immunogenicity Population

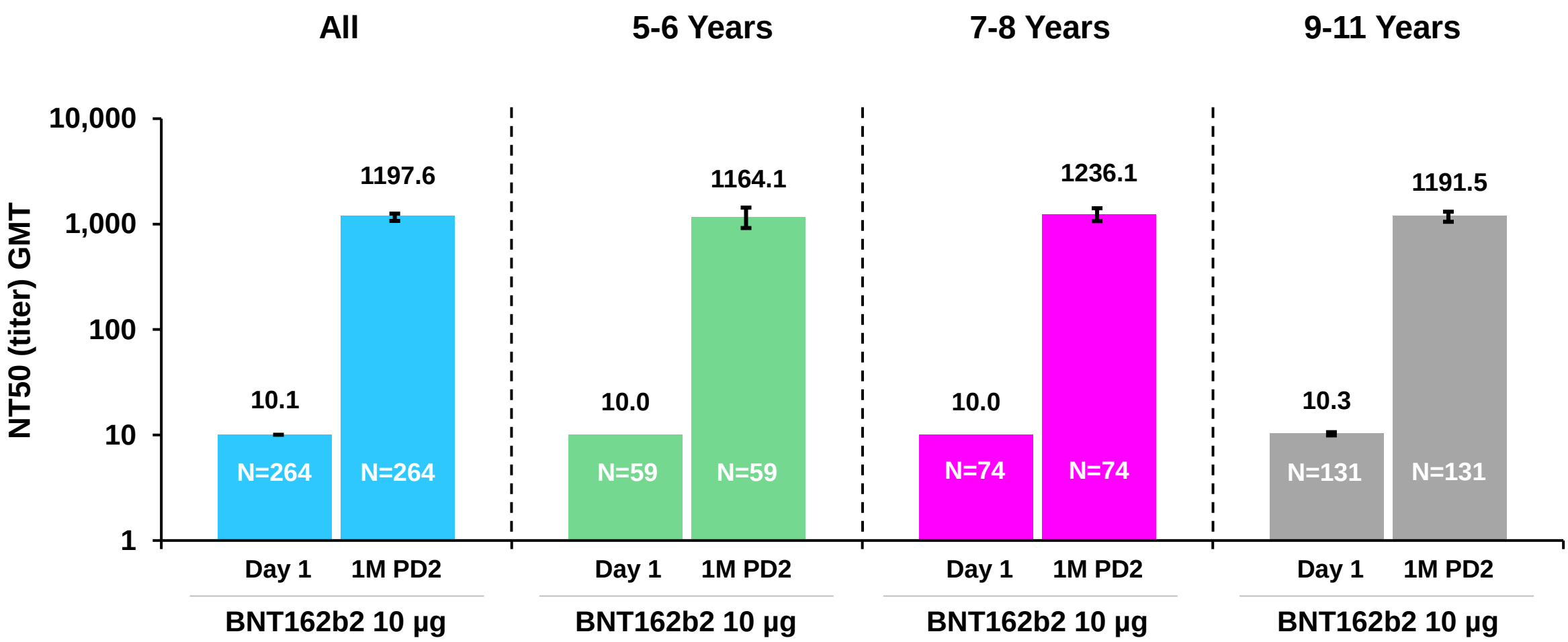
Immunogenicity Subset –



NT50 = 50% neutralizing titers

Geometric Mean Titers (NT50), by Age Subgroup – Subjects 5 to <12 Years – Evaluable Immunogenicity Population

Immunogenicity Subset – Without Evidence of Prior Infection up to 1 Month Post Dose 2

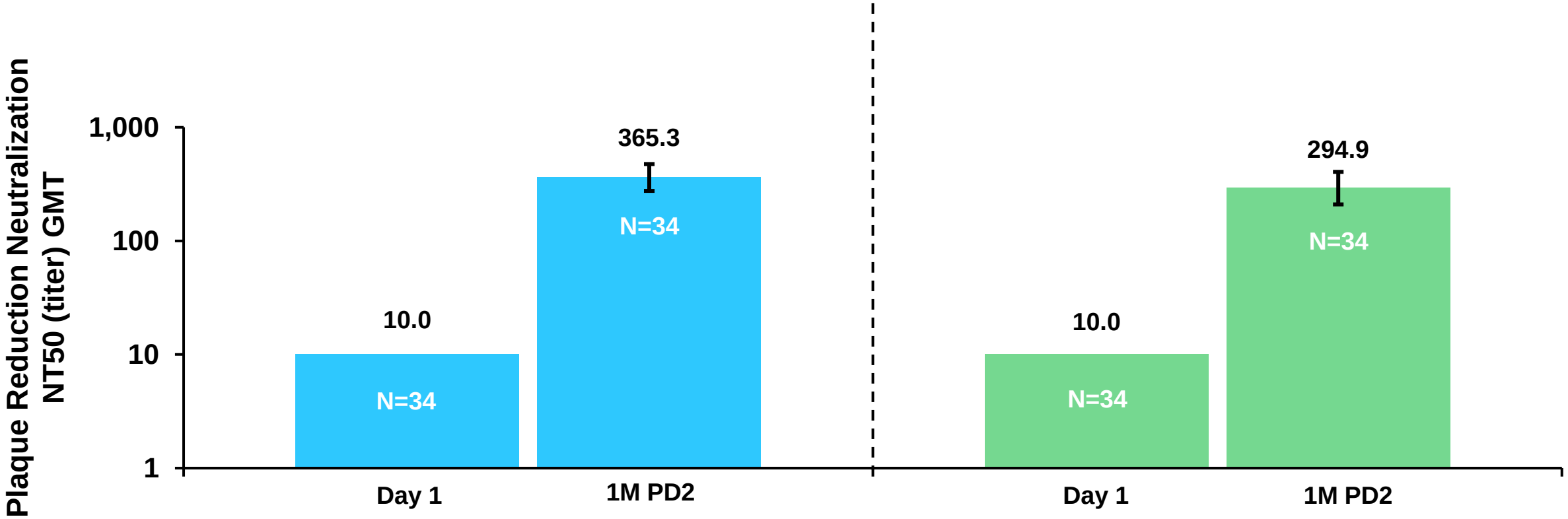


NT50 = 50% neutralizing titers

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

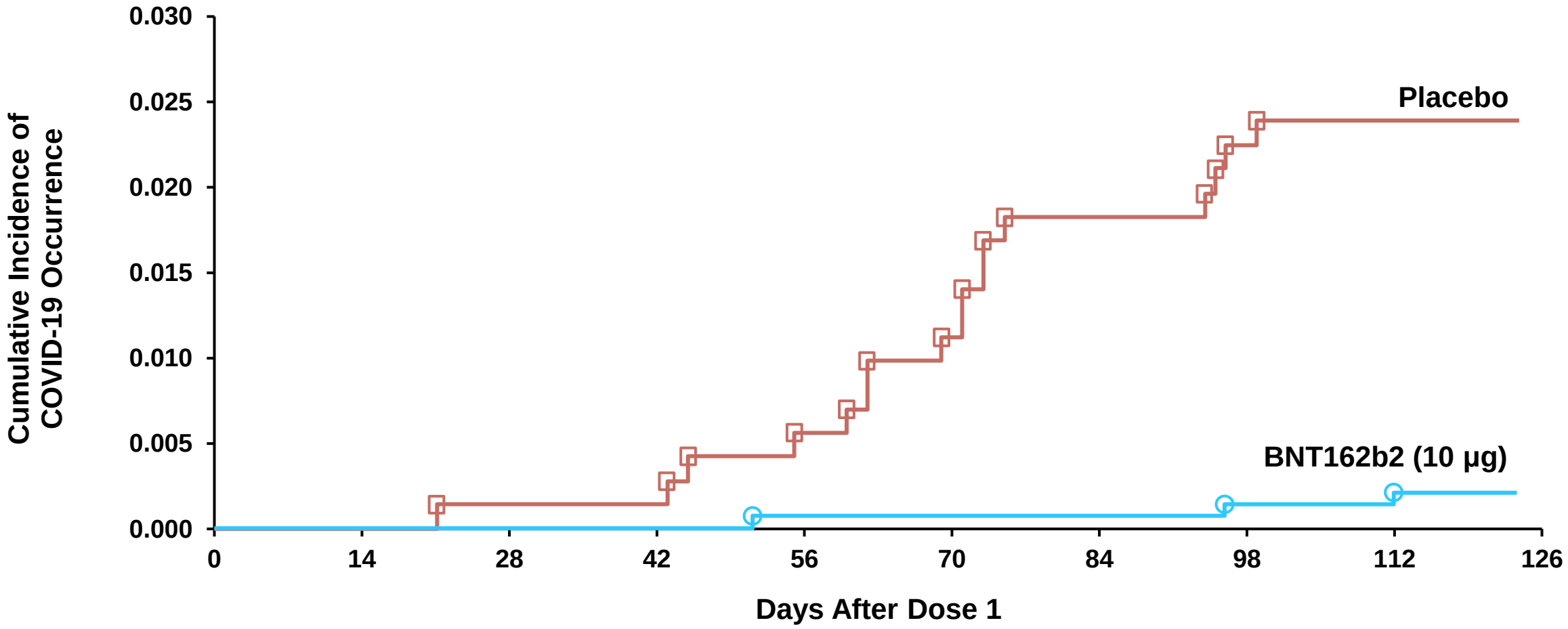
Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

	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

Acknowledgments

Pfizer and BioNTech wish to thank:

- **The clinical trial participants and their families**
- **Sites, Investigators, CRO, our partners and their staff**
- **FDA guidance to assess this urgent medical need**