Pfizer-BioNTech
Pre-licensure Data for 5-11 years of age

January 19, 2022

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

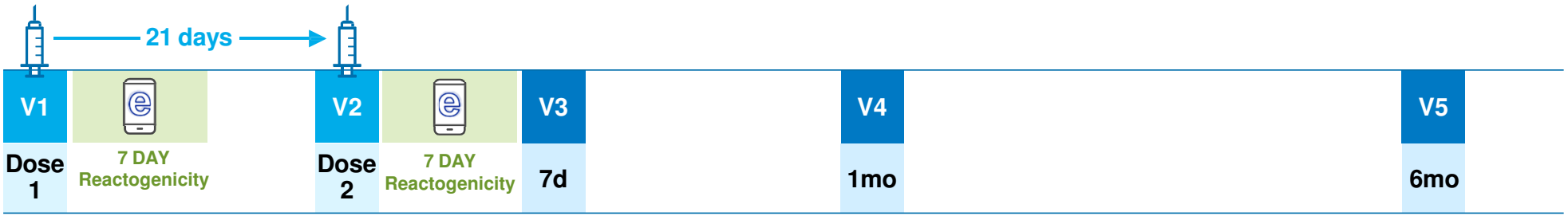
Non-inferior immune responses have been established to infer vaccine efficacy

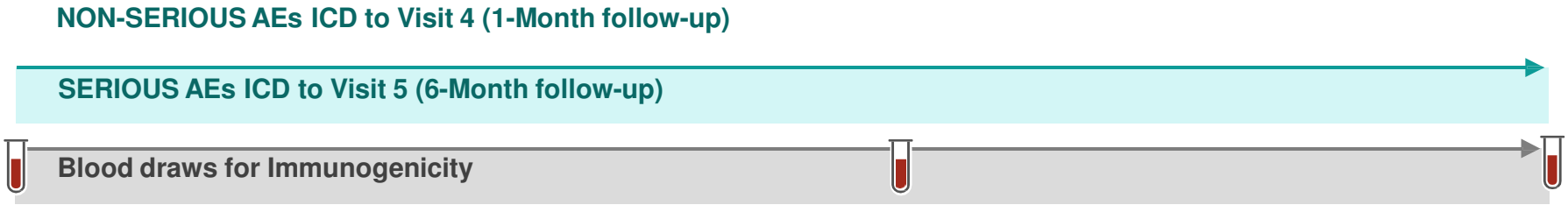
Children 5 to <12 years of age	Compared to	16–25-year-olds from the pivotal Phase 3 study

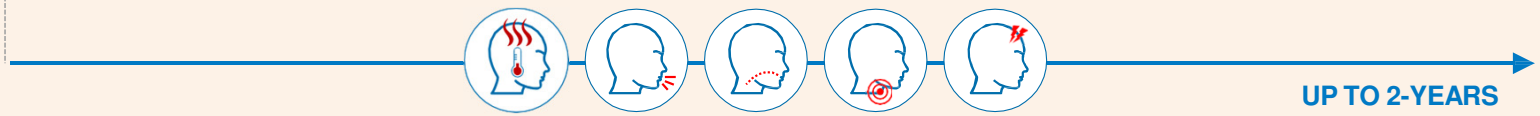
Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

Slides presented to ACIP by Pfizer on November 2, 2021

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)

Slides presented to ACIP by Pfizer on November 2, 2021

Demographics for 5 to <12 Year Olds

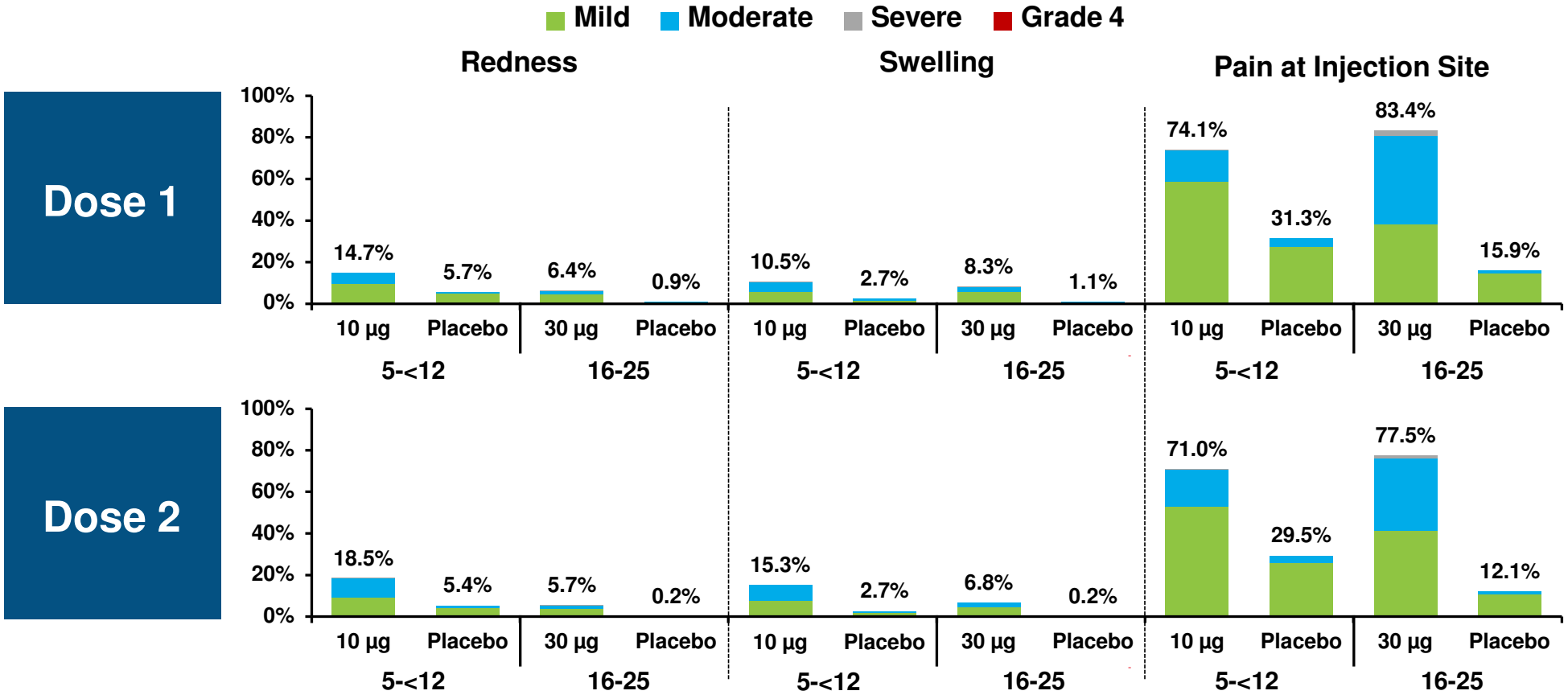
Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

		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.

Slides presented to ACIP by Pfizer on November 2, 2021

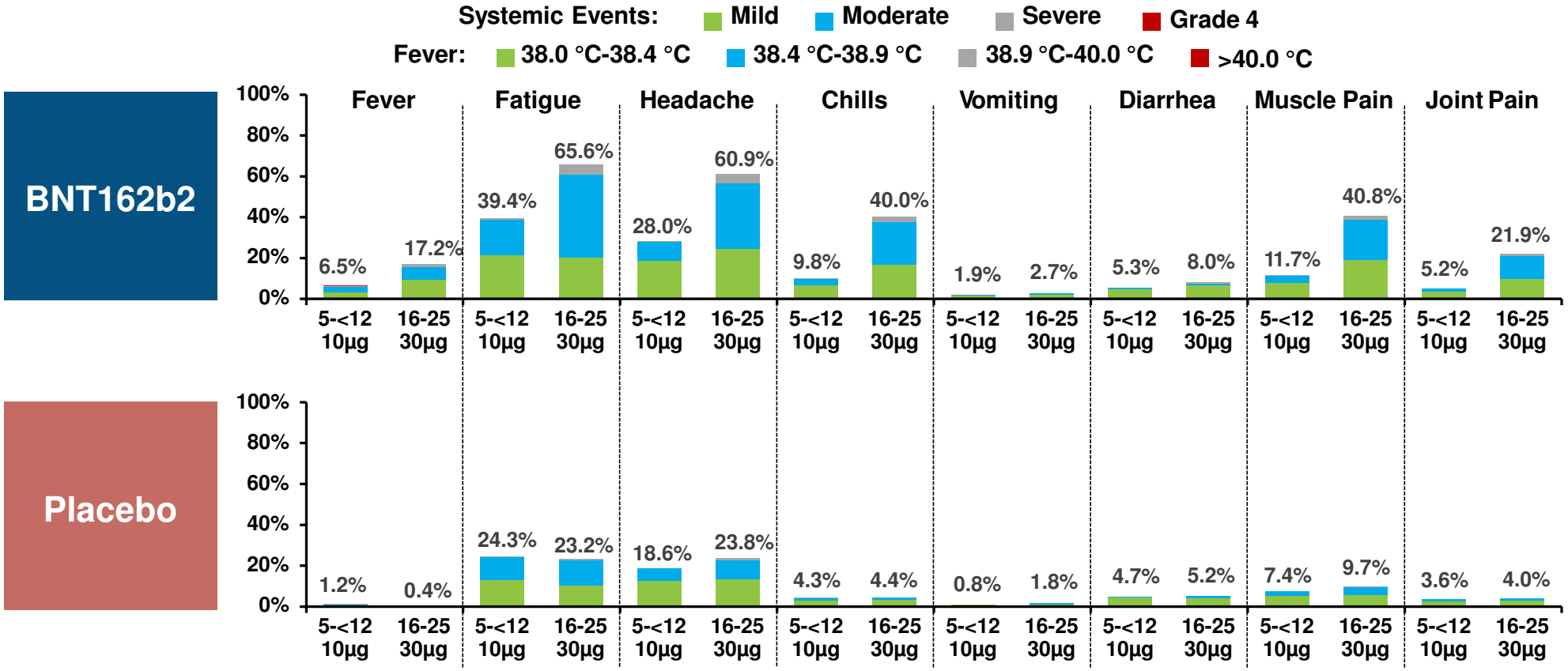
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds



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

Slides presented to ACIP by Pfizer on November 2, 2021

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

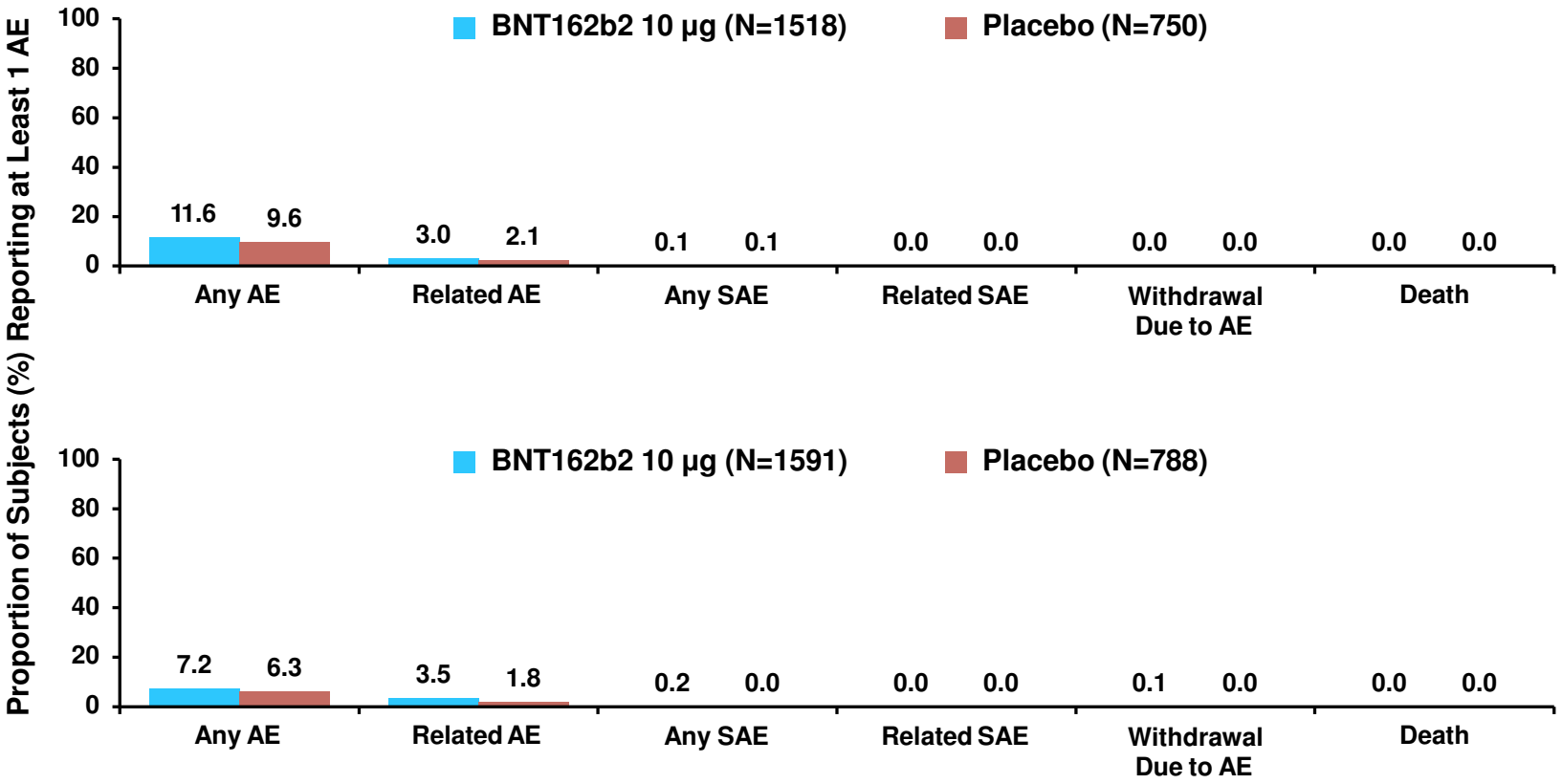


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 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

Slides presented to ACIP by Pfizer on November 2, 2021

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

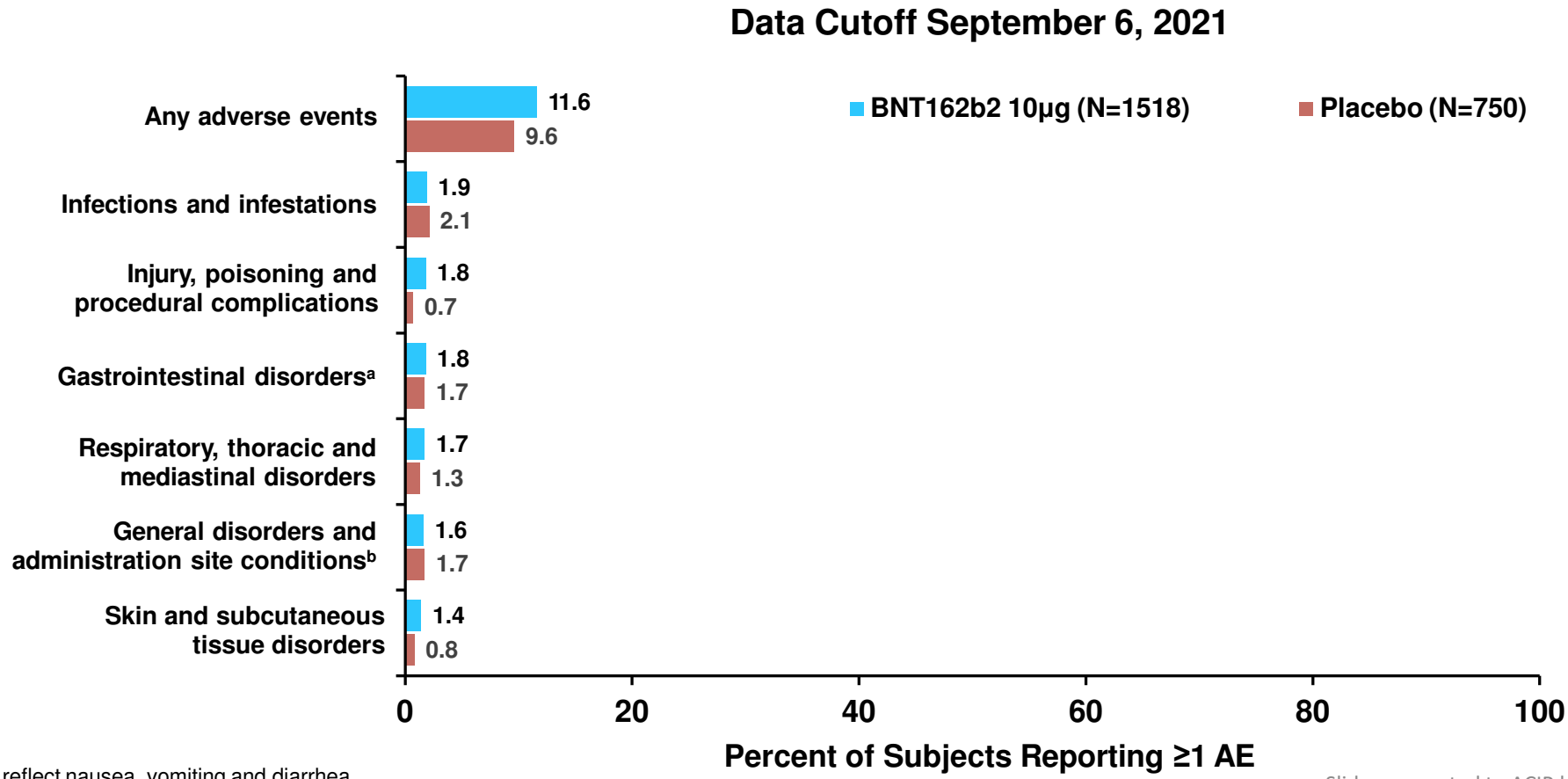


Safety expansion group:
Median follow-up time 2.4 weeks
Cutoff date October 8, 2021

Slides presented to ACIP by Pfizer on November 2, 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

Slides presented to ACIP by Pfizer on November 2, 2021

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

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

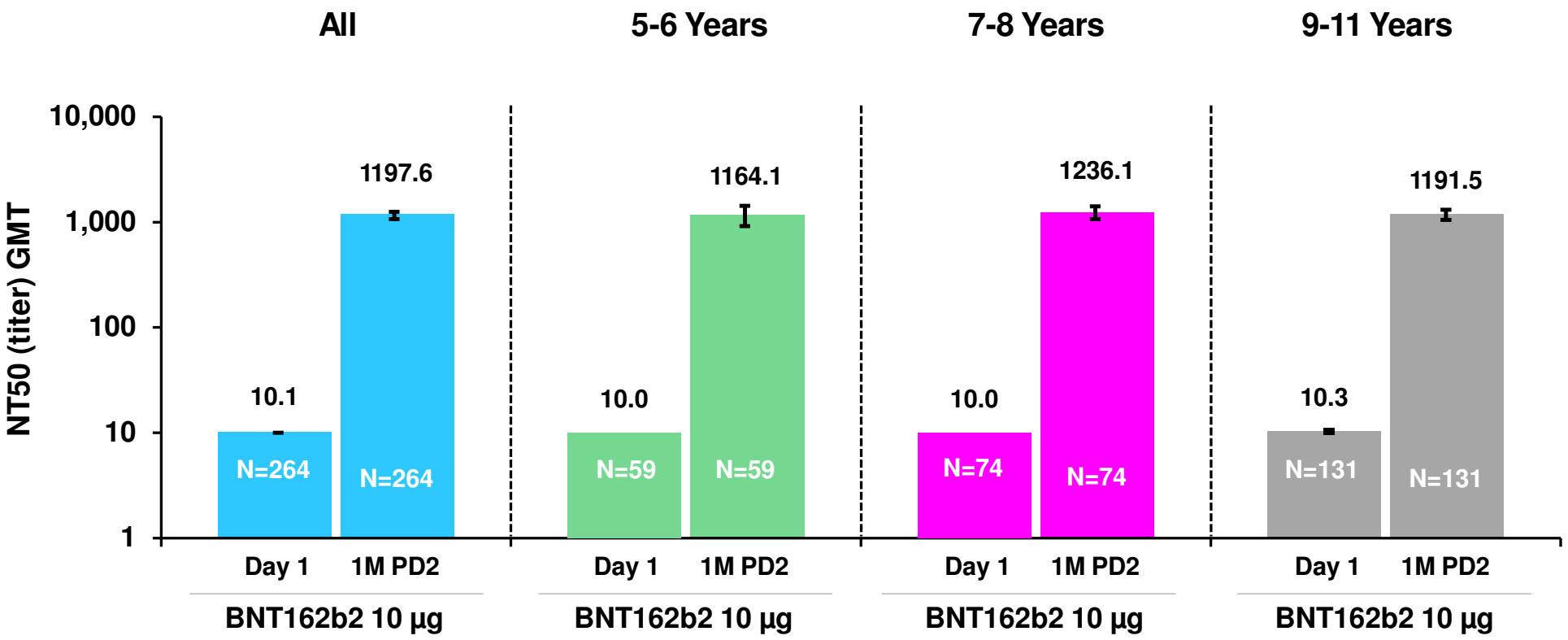
Seroresponse defined as achieving a ≥4 fold rise from baseline (before Dose 1)
Immunobridging is declared if the lower bound of the 95% confidence interval for the percentage difference is greater than -10

Slides presented to ACIP by Pfizer on November 2, 2021

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



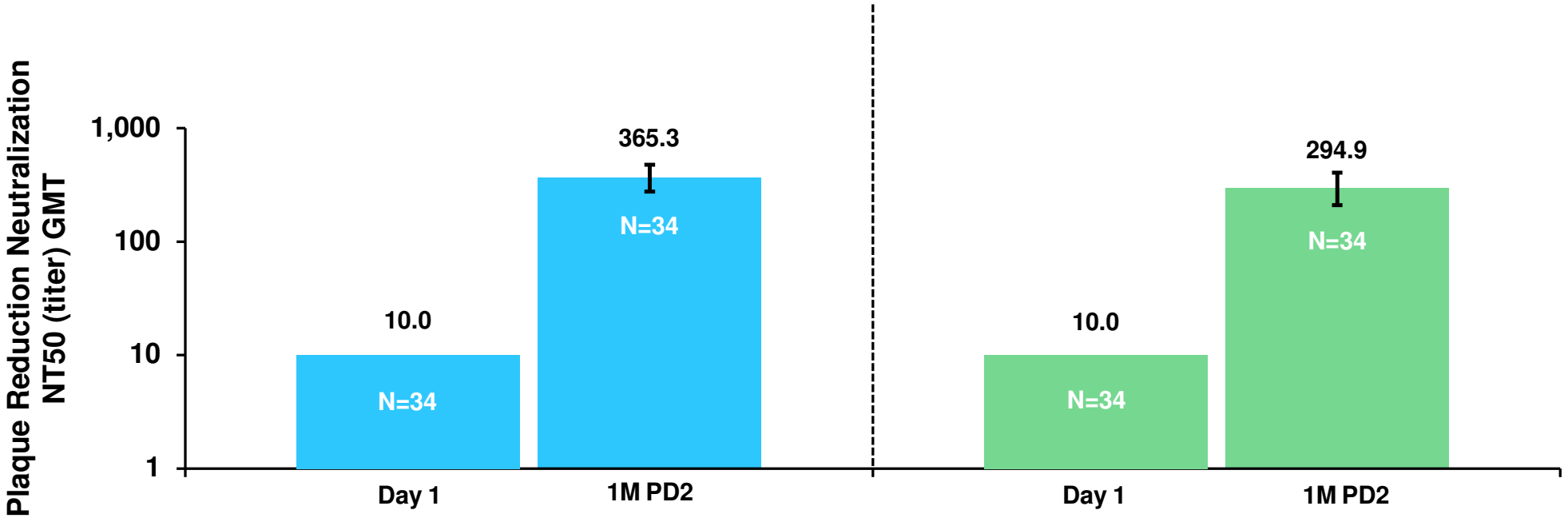
Slides presented to ACIP by Pfizer on November 2, 2021

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)



Slides presented to ACIP by Pfizer on November 2, 2021

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)**

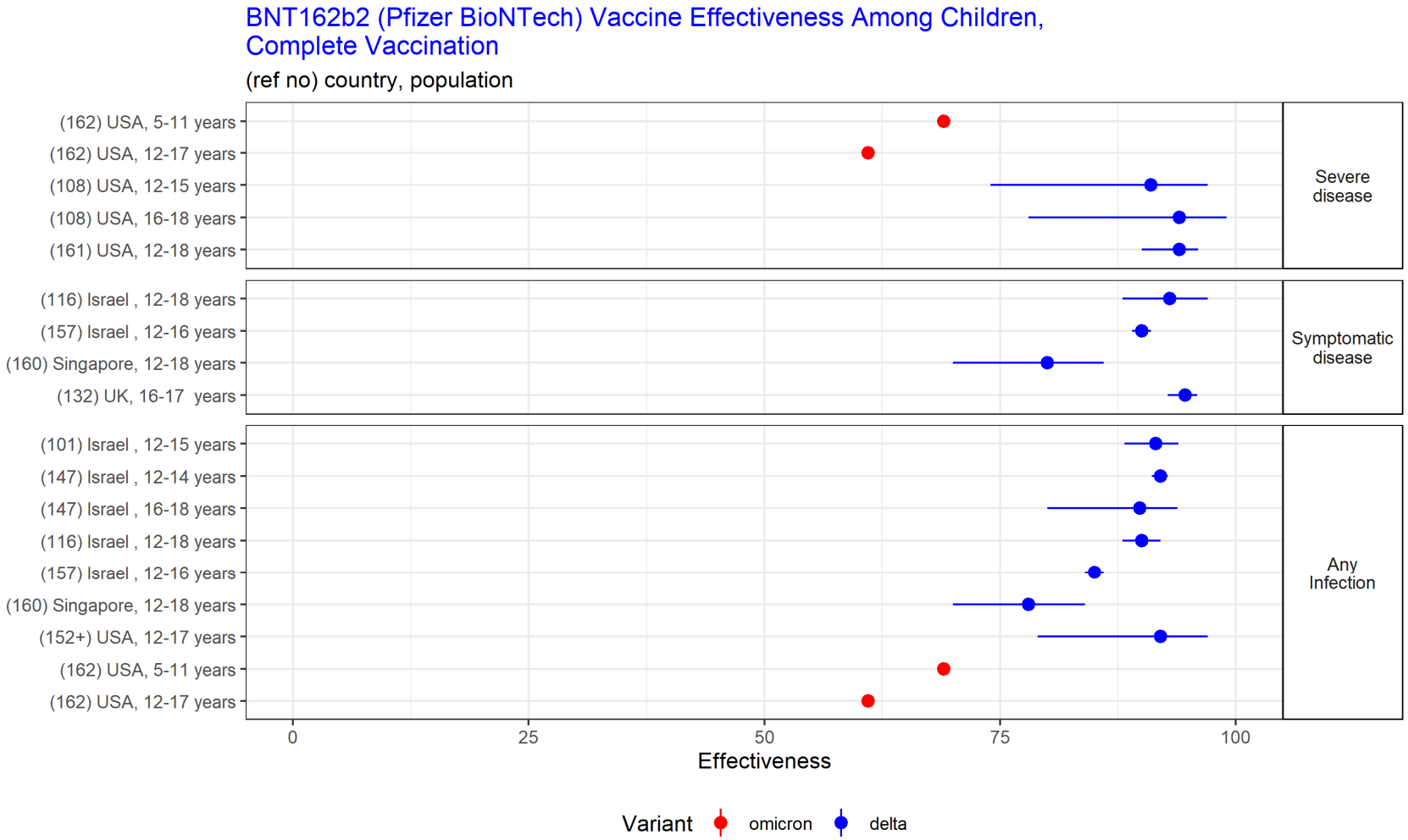
No severe cases of COVID-19 were reported
No cases of MIS-C were reported

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

Pediatric VE Data

Pediatric Studies

- Delta
  - 8 studies in 12-18 year olds
  - 0 <12 year olds
  - Most studies with >90% VE against infection, disease, severe disease
  - Rarely sample size sufficient for evaluating protection against death
  - 2 studies with evidence of waning against infection or disease
- Omicron
  - 1 study with a crude VE in 5-11 and 12-17 year olds <75%



USA: VE against Multisystem inflammatory syndrome (MIS-C)

- TND study among 12-18 year old hospitalized patients at 24 pediatric hospitals in 20 states during July 1–December 9, 2021 (Delta dominant)
- Results
  - 102 MIS-C patients and 181 hospitalized controls (SARS-CoV-2 negative)
  - Median hospital length of stay between vaccinated and unvaccinated same (5 days)
  - VE at ≥28 days post dose 2: 91% (78-97%)
  - 0/38 requiring life support with MIS-C vaccinated

Zambrano, L. D., Newhams, M. M., Olson, S. M., Halasa, N. B., Price, A. M., Boom, J. A., Sahni, L. C., Kamidani, S., Tarquinio, K. M., Maddux, A. B., Heidemann, S. M., Bhumbra, S. S., Bline, K. E., Nofziger, R. A., Hobbs, C. v., Bradford, T. T., Cvijanovich, N. Z., Irby, K., Mack, E. H., … Bowens, C. (2021). Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021. *MMWR. Morbidity and Mortality Weekly Report*, *71*(2). https://doi.org/10.15585/mmwr.mm7102e1

Summary

- Delta
  - VE consistent with findings from RCTs in 12-17 year olds
  - 2 studies with evidence of waning against infection and disease
  - 1 study found 91% VE against MIS-C
  - No VE data in 5-11 year olds (only authorized in 1st country starting November 2)
- Omicron
  - 1 study with lower VE in children during Omicron period, including against hospitalization
    - Unclear if hospitalization because of SARS-CoV-2 or incidental finding given high prevalence of Omicron

Myopericarditis

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

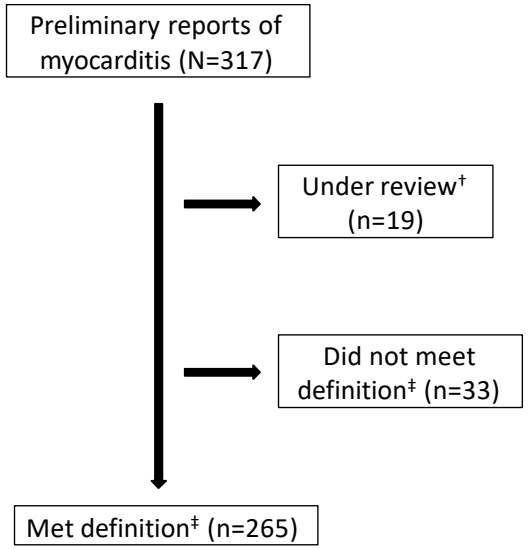
VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

Reports to VAERS of myocarditis after Pfizer-BioNTech COVID-19 vaccination among children and adolescents ages 12–15 years* (as of Dec 19, 2021)

- 265 reports of myocarditis verified to meet case definition
  - Median age: 14 years (IQR: 13–15 years)
  - Median time to onset: 2 days (IQR: 1–3 days)
  - After dose 1 = 41; after dose 2 = 221
  - 238 (90%) males, 27 (10%) females
    - 251 hospitalized patients (241 discharged home)
    - 224 patients with known outcomes
      - 208 (92%) recovered from symptoms at time of report
      - 16 (8%) mostly reported improved, or resolved, symptoms, but ongoing physical restrictions or still under investigation
- Doses administered = 18,707,169§



* Reports of children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021
† Awaiting medical records and/or healthcare provider interview; some still processing
‡ Adjudicated after healthcare provider interview and/or medical record review
§ Doses administered among children and adolescents ages 12–15 years May 12–Dec 16, 2021

Reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech COVID-19 vaccination, 7-day risk interval*

	Males		Females	
Age group	Dose 1	Dose 2	Dose 1	Dose 2
5–11 years	0.0	4.3	Not calculated†	2.0
12–15 years	4.8	45.7	1.0	3.8
16–17 years (included for reference)	6.1	70.2	0.0	7.6

- 37,810,998 total doses 1 and 2 of vaccine administered‡
- Reporting rates exceed background incidence (peach shaded cells) §
  - Males: after dose 1 (ages 12–15 and 16–17 years) and after dose 2 (ages 5–11, 12–15, and 16–17 years)
  - Females: after dose 2 (ages 12–15 and 16–17 years)
  - Reporting rates among males substantially lower among ages 5–11 vs. 12–15 and 16–17 years

* Reports of myocarditis after doses 1 and 2 of Pfizer-BioNTech COVID-19 vaccine during a 7-day risk interval after vaccination (as of Dec 19, 2021); reports verified to meet case definition by healthcare provider interview and/or medical record review.
† Too few reports of females ages 5–11 years to calculate a stable rate.
‡ Children ages 5–11 years vaccinated Nov 3–Dec 19, 2021, children and adolescents ages 12–15 years vaccinated May 12–Dec 19, 2021.
§ An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 1.9 per 1 million person 7-day risk period.

Myocarditis/pericarditis

- Data from Danish population based cohort study*.
- The rate in the youngest age group (12-17 years) was 1.0 (0.2 to 3.0) per 100 000 individuals aged 12-17 years within 28 days of BNT162b2 vaccination.

*Husby A. et al. SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. *BMJ* 2021;375:e068665

EVIDENCE ASSESSMENT

Quality assessment*

Type of bias/ Publication	Walter et al. NEJM. 2021
Randomization	Low
Deviations from intervention	Some concerns
Missing outcome data	Low
Measurement of the outcome	Low
Selection of the reported results	Low
Overall risk of bias	Some concerns

GRADE assessment

PICO question	Statement on quality of evidence	SAGE Working Group Judgement
Efficacy against PCR confirmed COVID-19 (Children 5-11)	High level of confidence	We are confident that 2 doses of BNT162b2 vaccine are efficacious in preventing PCR-confirmed COVID-19 in children (aged 5–11 years) up to approx. 2 months following immunization.
Safety-serious adverse events (Children 5-11)	Low level of confidence	We have low confidence in the quality of evidence that the risk of serious adverse events in children (aged 5–11 years) following 1 or 2 doses of BNT162b2 vaccine is low.

*The risk of bias judgement by domain corresponds to the highest risk of bias among outcomes by domain. The overall risk of bias corresponds to the overall highest risk of bias assessed among outcomes.

- See: www.covid-nma.com/vaccines
- Critical outcomes: Incidence of participants with positive test for SARS-CoV-2 infection by RT-PCR OR Nucleic acid amplification testing (NAAT) or other validated test (symptomatic or asymptomatic), Incidence of symptomatic COVID-19 confirmed with positive test for SARS-CoV-2 infection by RT-PCR OR NAAT, Severe or critical disease defined according to the WHO definition or as reported by trialists, All-cause mortality, Incidence of systemic adverse events (D14), Incidence of any adverse events, Incidence of serious adverse events (SAEs).

Extra slides

USA: Changes in Pediatric Infection and Hospitalization

- Cohort study of NY hospitalizations based on linking administrative databases. Note children 5+ eligible for primary series, 16+ for booster
- Increasing trends in infection rates, with highest 7-day average in 18-64 and 12-17
- Increasing trends in hospitalization rates, highest in 65+
  - BUT most rapid rise in relative hospitalization rates in ≤18 years
  - 55% of hospitalizations in 0-4 (make up 26% of population)
  - ~60% of admissions were indicated with the reason "for COVID-19"; has not changed since the Omicron-associated increase in cases and hospitalization began. Consistent with adult trends, and earlier trends
  - ~50% of children with hospitalization with COVID-19 with comorbidities

Figure 1. Trends in COVID-19 Cases by age, all age groups, January 1, 2021 – December 29, 2021

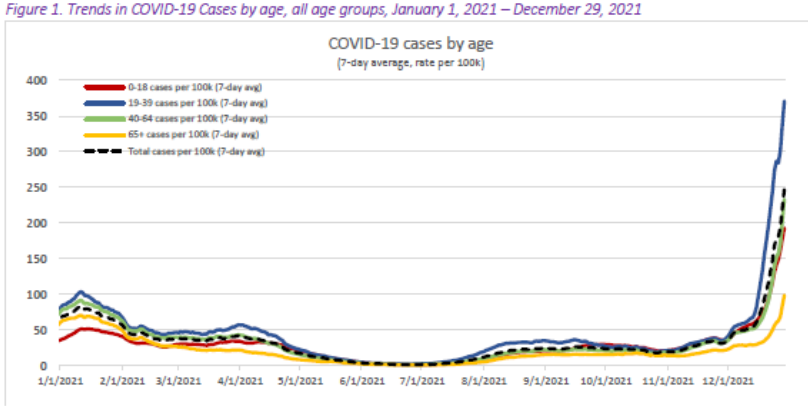


Table 2. COVID-19 new hospital admission rates by age, December 5, 2021 – January 1, 2022

	0-4 years		5-11 years		12-18 years		19-64 years		65+ years	
	Rate	*Change since Dec. 5-11*	*Rate*	*Change since Dec. 5-11*	*Rate*	*Change since Dec. 5-11*	*Rate*	*Change since Dec. 5-11*	*Rate*	*Change since Dec. 5-11*
December 5 - 11	0.44	--	0.18	--	0.13	--	1.87	--	7.62	--
December 12 - 18	0.56	+29%	0.19	+5%	0.34	+153%	2.17	+16%	7.94	+4%
December 19 - 25 (excl. 25th)	1.43	+226%	0.42	+130%	0.60	+353%	2.78	+48%	8.70	+14%
December 26 – January 1	3.91	+791%	0.79	+335%	1.52	+1,047%	6.39	+241%	21.87	+187%

Table 4. Indicated reason for admission, among new admissions with COVID-19, previous 4 reporting weeks

	New York City			Statewide		
Week	*Reason for admission indicated as for COVID-19*	*Admission indicated for other reason, but with positive COVID-19 results*	*Total with COVID-19*	*Reason for admission indicated as for COVID-19*	*Admission indicated for other reason, but with positive COVID-19 results*	*Total with COVID-19*
November 28 – December 4	14	9	23	49	36	85
December 5 - 11	12	10	22	44	26	70
December 12 - 18	26	17	43	58	46	104
December 19 - 25 (excl. 25th)	88	49	137	137	91	228
December 26 – January 1	227	158	385	339	232	571

New York State Department of Health. (n.d.). *Full Report - Pediatric COVID-19 update: January 7, 2022*. Retrieved January 9, 2022, from https://health.ny.gov/press/releases/2022/docs/pediatric_covid-19_hospitalization_report.pdf

USA: Changes in Pediatric Infection and Hospitalization

- Using the screening method, VE against infection for Pfizer in 12-17 year olds has fallen from 87% to 61% and fallen from 95% to 81% against hospitalization
- Their conclusion: pattern of increasing severe disease in the pediatric population
  - May be explained by a combination of lower full vaccination (and booster) coverage, changes in vaccine effectiveness, severity of the Omicron variant, and/or other factors.
- Limitations
  - Not Omicron specific: Delta vs Omicron dominant but not all cases during Dec 20-26 Omicron due to lag between infection and hospitalization. Some portion Delta
  - Unadjusted VE, no CI
  - Unclear if vaccinated is booster dose vs primary series
  - Mixed vaccines

Table 10. COVID-19 Cases among children 5-17 years, by vaccine status

	Distribution of new cases by vaccine status						Rates and vaccine effectiveness			Full-vaccine Coverage
	Vaccinated		Partially-vaccinated		Unvaccinated					
Week	*Cases*	*% of cases*	*Cases*	*% of cases*	*Cases*	*% of cases*	*Vaccinated rate per 100k*	*Unvaccinated rate per 100k*	*VE*	*%*
5 -11 years *										
Dec. 13-19	196	2%	1,275	11%	9,902	87%	38	144	73%	5.4%
Dec. 20-26	777	5%	2,220	13%	14,249	83%	68	216	69%	12.0%
12 – 17 years										
Nov. 29-Dec. 5	947	20%	130	3%	3,727	78%	16	121	87%	60.7%
Dec. 6-12	1,218	23%	139	3%	4,008	74%	21	133	84%	61.1%
Dec. 13-19	4,038	37%	366	3%	6,515	62%	69	221	69%	61.6%
Dec. 20-26	8,321	43%	790	4%	10,326	53%	140	358	61%	62.1%

Source: ECLRS, NYSIIS/CIR

* Full vaccination coverage < 1% in prior weeks

Table 11. New COVID-19 hospital admissions among children 5-17 years, by vaccine status

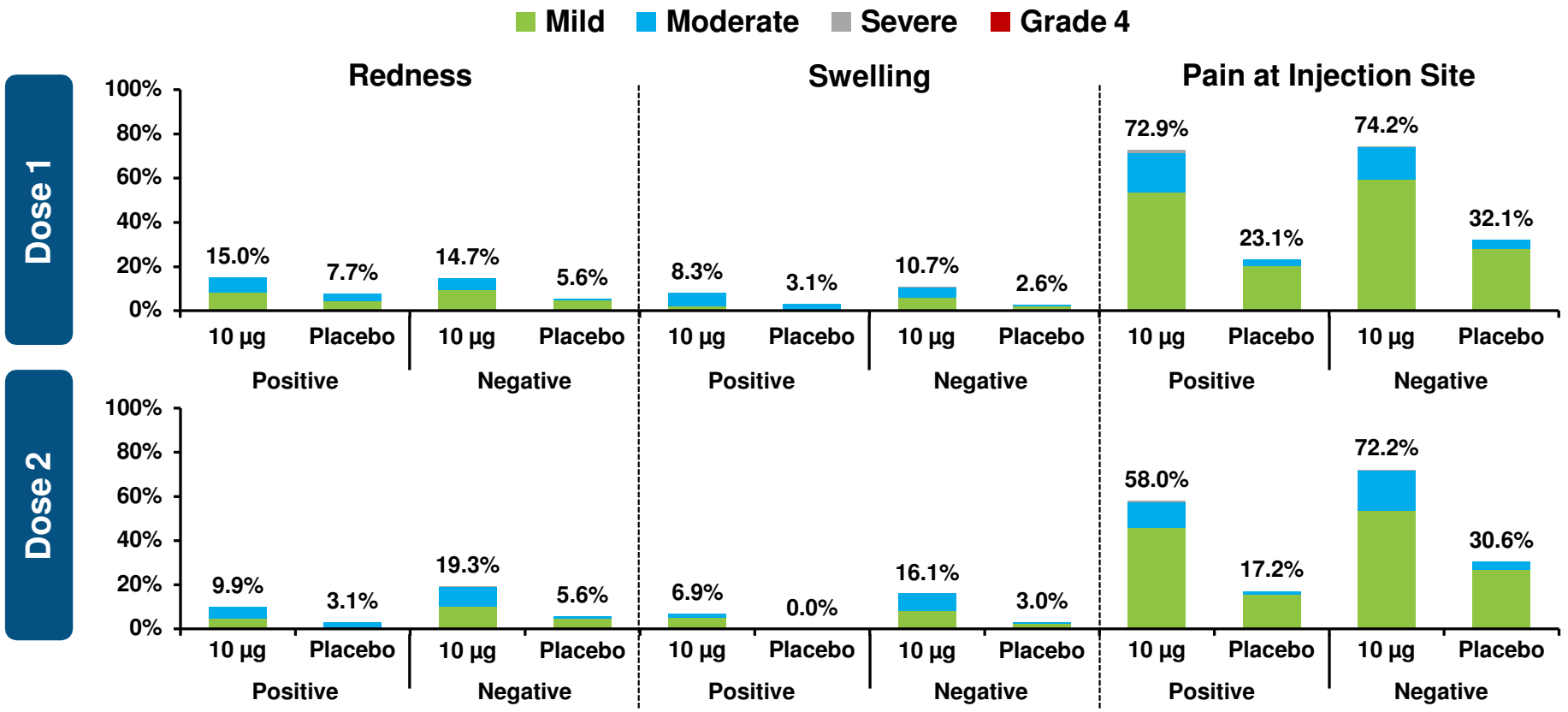
	Distribution of new hospitalizations by vaccine status						Rates and vaccine effectiveness			Full-vaccine Coverage
	Vaccinated		Partially-vaccinated		Unvaccinated					
Week	*Hosp*	*% of hosp*	*Hosp*	*% of hosp*	*Hosp*	*% of hosp*	*Vaccinated rate per 100k*	*Unvaccinated rate per 100k*	*VE*	*%*
5 -11 years *										
Dec. 13-19	0	0%	1	5%	19	95%	0	0.28	100%	5.4%
Dec. 20-26	2	4%	3	6%	49	91%	0.17	0.73	76%	12.0%
12 – 17 years										
Nov. 29-Dec. 5	2	9%	0	0%	20	91%	0.03	0.65	95%	60.7%
Dec. 6-12	1	8%	1	8%	11	74%	0.02	0.36	95%	61.1%
Dec. 13-19	7	23%	1	3%	22	62%	0.12	0.74	84%	61.6%
Dec. 20-26	18	26%	6	9%	45	65%	0.31	1.56	81%	62.1%

Source: HERDS, NYSIIS/CIR

* < 1% of this age group fully-vaccinated in previous weeks

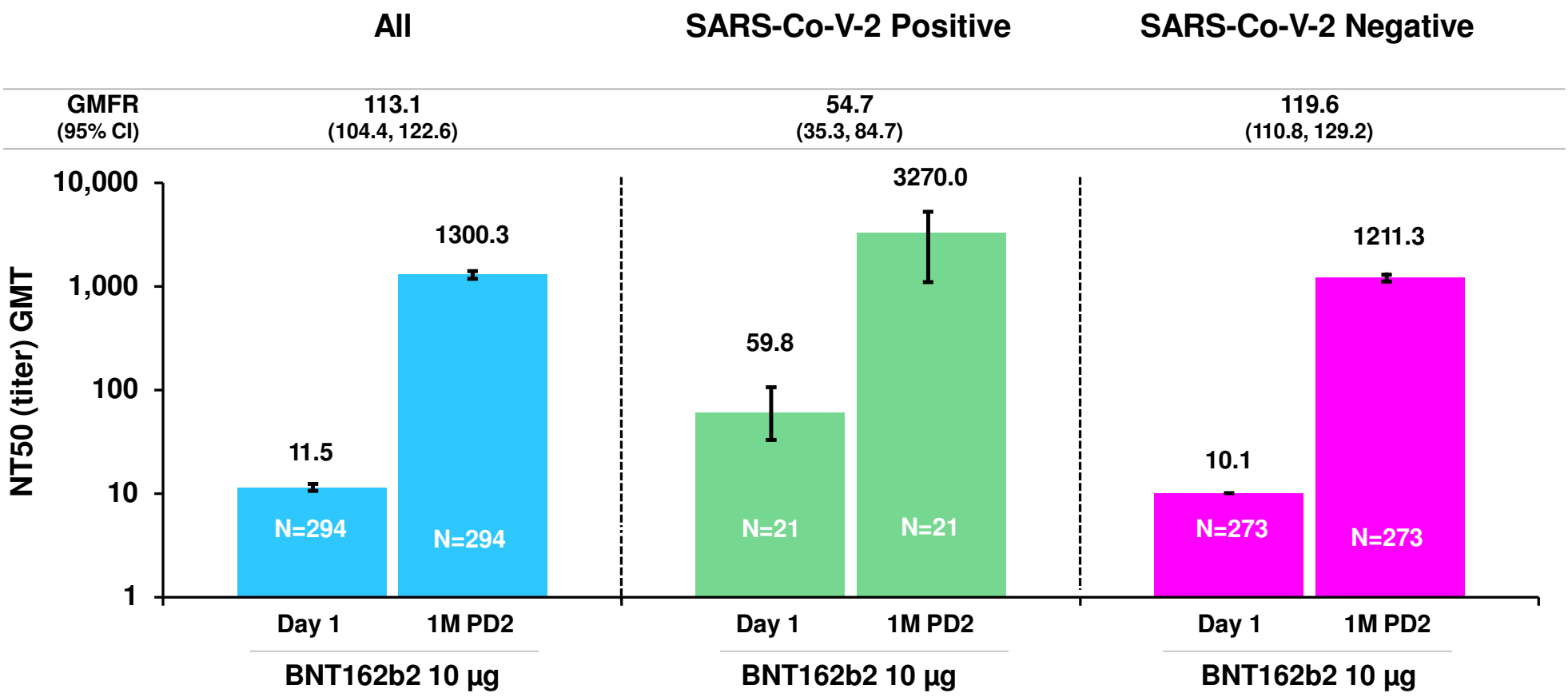
New York State Department of Health. (n.d.). *Full Report - Pediatric COVID-19 update: January 7, 2022*. Retrieved January 9, 2022, from https://health.ny.gov/press/releases/2022/docs/pediatric_covid-19_hospitalization_report.pdf

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



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

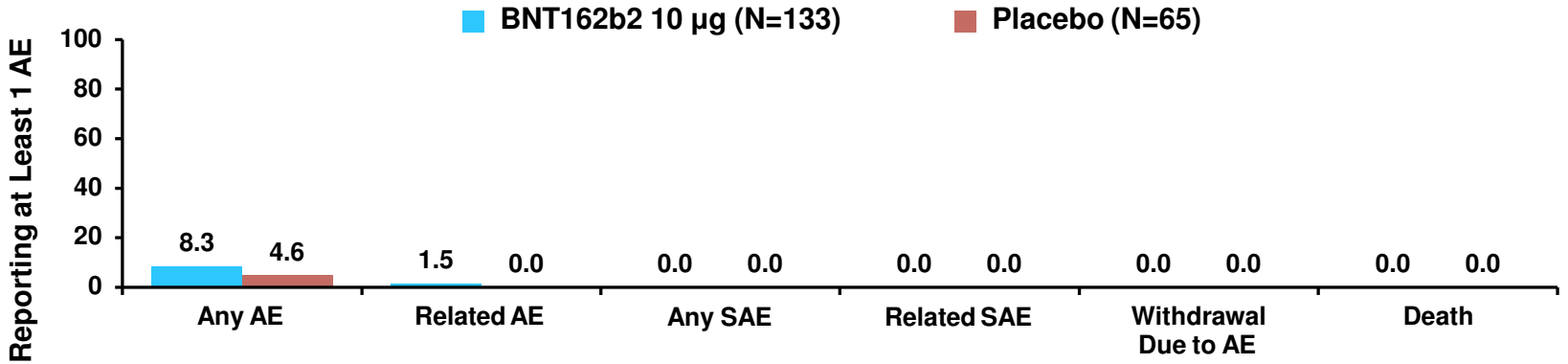
Geometric Mean Titers (NT50), By Baseline SARS-CoV-2 Status – Subjects 5 to <12 Years – Evaluable Immunogenicity Population Immunogenicity Subset –



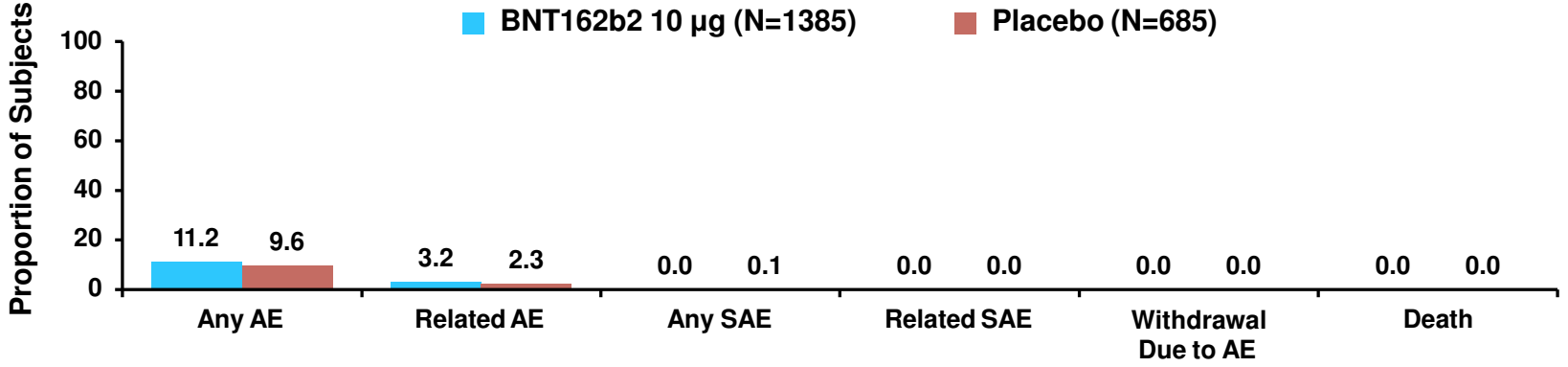
NT50 = 50% neutralizing titers

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

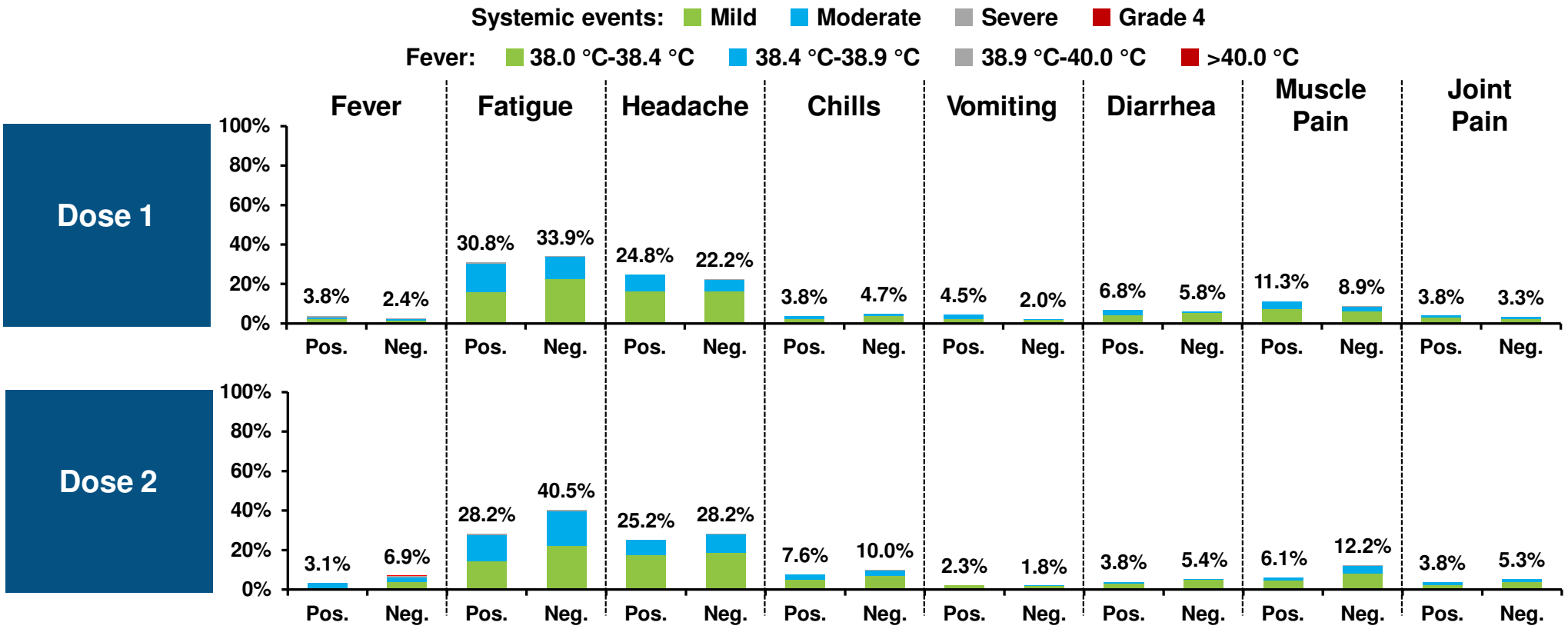
Baseline SARS-CoV-2 Positive



Baseline SARS-CoV-2 Negative



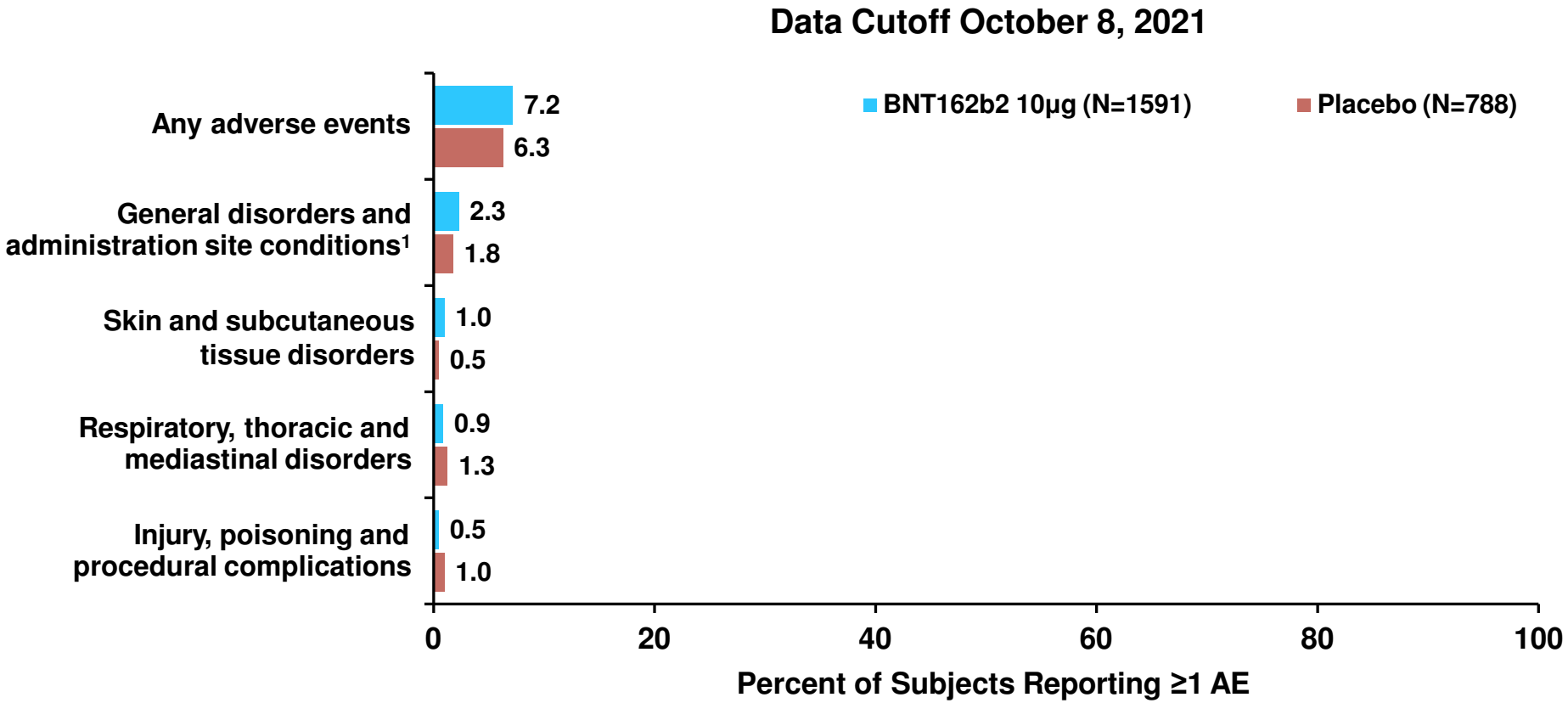
Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 and Dose 2 in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status



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

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)



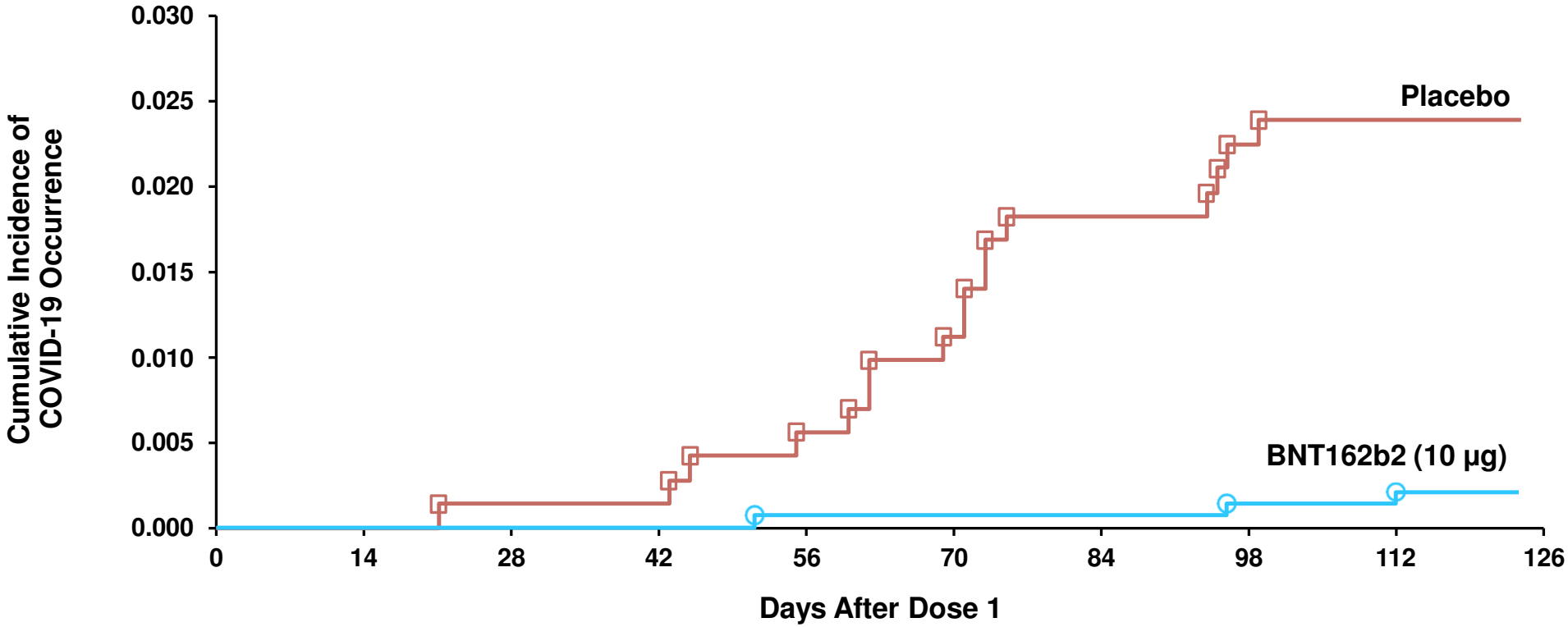
1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue
Lymphadenopathy 0.4% in the BNT162b2 group

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

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

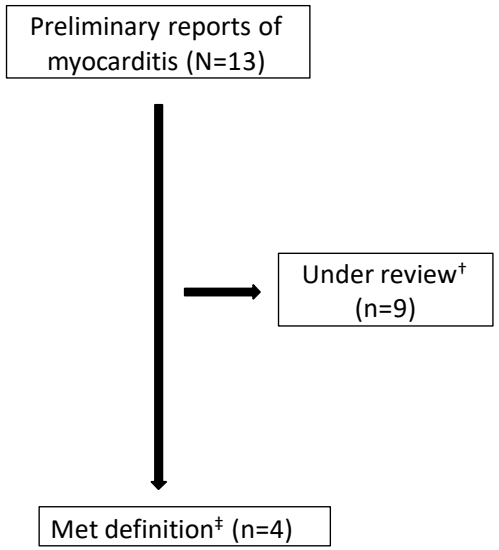


Immunogenicity and Efficacy Conclusions

- **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**

Reports of myocarditis to VAERS after Pfizer-BioNTech COVID-19 booster vaccination among persons ages 16–24 years

- 13 preliminary reports of myocarditis
  - Median age: 21 years (IQR: 20–22 years)
  - Median time to onset: 1 day (IQR: day of vaccination–1 day)
  - 9 (69%) males, 4 (31%) females
  - 4 reports met case definition
    - 2 reports among ages 16–17 years[§]
    - 2 reports among ages 18–24 years
    - All reported patients recovered at time of report
- Doses administered = 976,882[¶]



* Among adolescents ages 16–17 years receiving dose 3 of Pfizer-BioNTech vaccine Dec 9–Dec 19, 2021, and persons ages 18–24 years receiving dose 3 of Pfizer-BioNTech vaccine Sep 22–Dec 19, 2021; reports processed and received as of Dec 19, 2021.

† Awaiting medical records and/or healthcare provider interview; some still processing.

‡ Adjudicated after healthcare provider interview and/or medical record review.

§ One report identified after Dec 19 but vaccinated during Sep 22–Dec 19, 2021.

¶ Doses administered as of Dec 16, 2021.