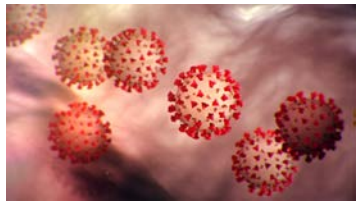
The Safety, Efficacy, and Logistics of COVID-19 Vaccination in Pediatrics



Pablo J. Sánchez, MD

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

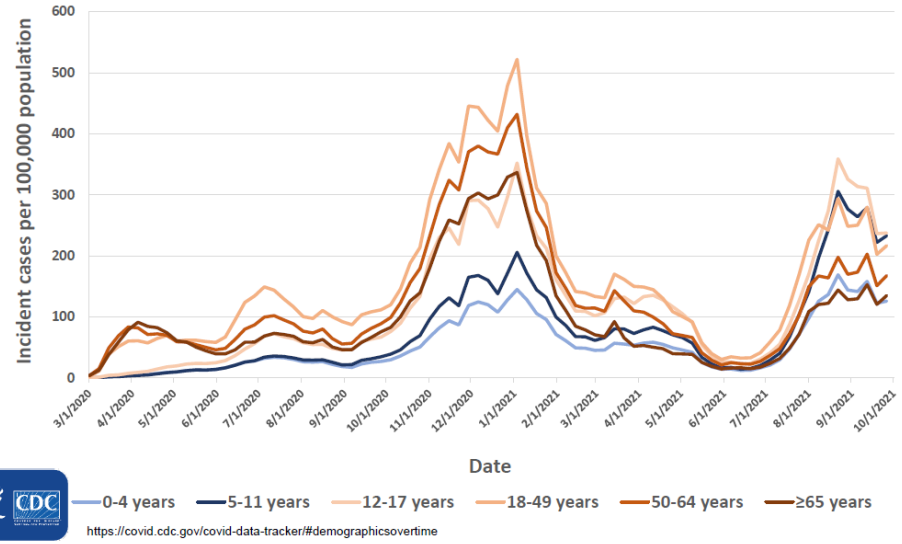
THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

11/12/2021

DISCLOSURE STATEMENT

Dr. Pablo Sánchez has nothing to disclose.

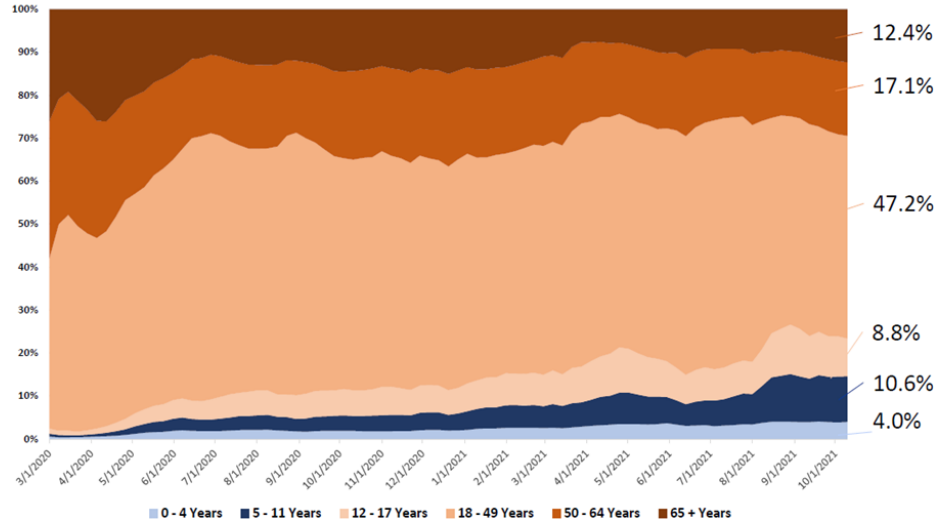
COVID-19 Weekly Cases per 100,000 Population by Age — United States, March 1, 2020–October 10, 2021



https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

>1.9 million cases among children 5-11 years of age

Proportion of Total COVID-19 Cases by Age Group — United States, March 1, 2020–October 10, 2021



https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

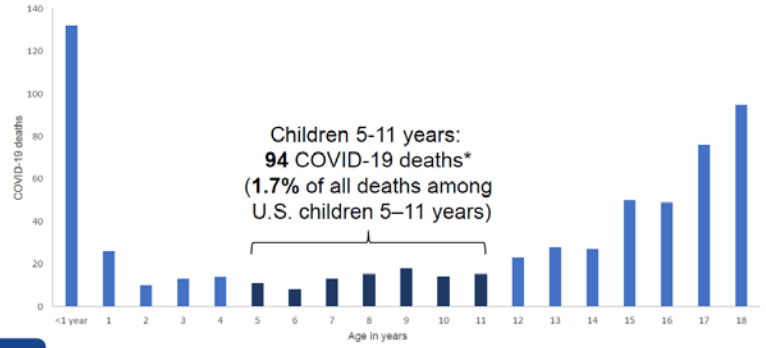
Children 5-11 years are making up a greater proportion of total cases: **10.6%** of cases the week of October 10, 2021

Burden of COVID-19 in children 5-11 years of age

- **1.9 million** cases
- **8,300** hospitalizations
- **2,316** Multisystem Inflammatory Syndrome in Children (MIS-C) cases
- **94** deaths

- Burden extends beyond case counts; school interrupted, lives disrupted

COVID-19 Deaths by Age Group, NCHS — United States. January 1, 2020–October 16, 2021



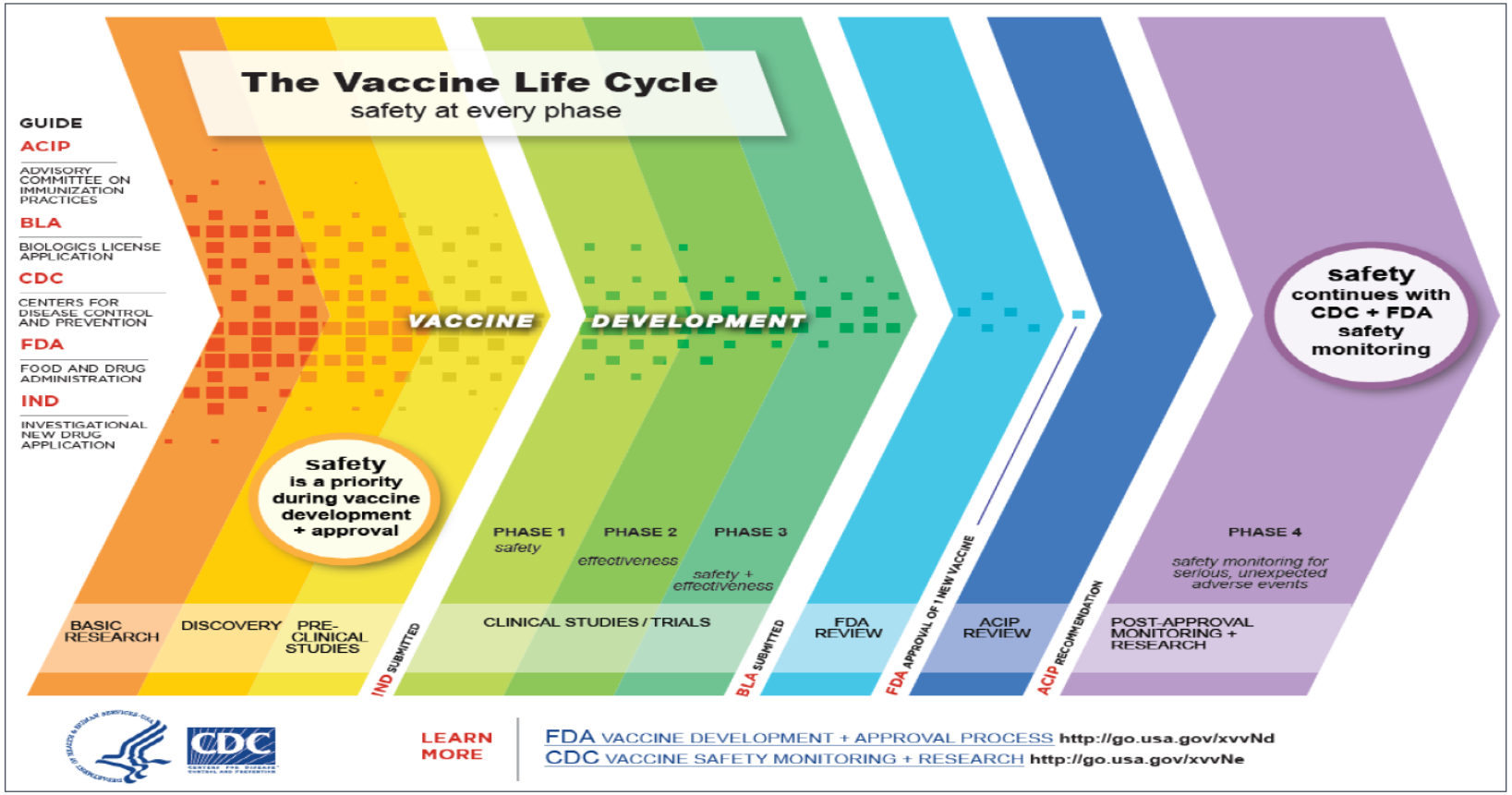
*Lag in reporting of deaths might result in underestimate
https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Summary: COVID-19 Epidemiology in Children Aged 5–11 years

- **Children aged 5–11 years are at least as likely to be infected with SARS-CoV-2 as adults**
  - Over 1.9 million reported cases; seroprevalence estimated to be ~38% in September 2021
  - Seroprevalence data suggests that infections in children less likely to be reported as cases than infections in adults
- **Children aged 5–11 years are at risk of severe illness from COVID-19**
  - >8,300 hospitalizations to date
    - Hospitalization rates are 3x times higher for non-Hispanic Black, non-Hispanic American Indian/Alaska Native, and Hispanic children compared with non-Hispanic White children
    - Hospitalization rates are similar to pre-pandemic influenza-associated hospitalization rates
    - Severity was comparable among children hospitalized with influenza and COVID-19
    - Approximately 1/3 of hospitalized children aged 5–11 years require ICU admission
  - At least 94 COVID-19-associated deaths occurred in children aged 5–11 years
  - MIS-C was most frequent among children aged 5–11 years
  - Post-COVID conditions have been reported in children
  - All might have been more numerous had pandemic mitigation measures not been implemented
- **Secondary transmission from young school-aged children occurs in household and school settings**


COVID-19
VACCINE



- Preclinical studies (animals)
- Clinical studies: Phase 1, 2, 3 (in consultation with FDA)
- Vaccines and Related Biological Products Advisory Committee (VRBPAC) (FDA)
- FDA
- ACIP (CDC): Advisory Committee on Immunization Practices: Implementation
- Published in MMWR
- Phase 4: post-licensure surveillance; safety monitoring

Emergency Use Authorization (EUA)

U.S. FOOD & DRUG ADMINISTRATION

- **Requested by government stakeholder (e.g., CDC, BARDA, DoD) or manufacturer; materials submitted to FDA include, but not limited to:**
  - Specific details of requested product use under EUA: population, dose, regimen
  - Supportive safety, effectiveness, and manufacturing information
  - Fact sheets for patients and healthcare providers
- **Regulations and law allow for more rapid review vs. licensure application**
- **Conditions of authorization:**
  - Monitoring and reporting adverse events required "to the extent practicable"
  - Duration of authorization specified, can be renewed or terminated early
  - Other conditions, as applicable (e.g., distribution, advertising)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age

E.B. Walter, K.R. Talaat, C. Sabharwal, A. Gurtman, S. Lockhart, G.C. Paulsen, E.D. Barnett, F.M. Muñoz, Y. Maldonado, B.A. Pahud, J.B. Domachowske, E.A.F. Simões, U.N. Sarwar, N. Kitchin, L. Cunliffe, P. Rojo, E. Kuchar, M. Rämet, I. Munjal, J.L. Perez, R.W. Frenck, Jr., E. Lagkadinou, K.A. Swanson, H. Ma, X. Xu, K. Koury, S. Mather, T.J. Belanger, D. Cooper, Ö. Türeci, P.R. Dormitzer, U. Şahin, K.U. Jansen, and W.C. Gruber, for the C4591007 Clinical Trial Group*

This article was published on November 9, 2021, at NEJM.org.

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

Phase 1

48 PARTICIPANTS

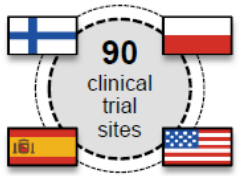
5 to <12 yrs

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

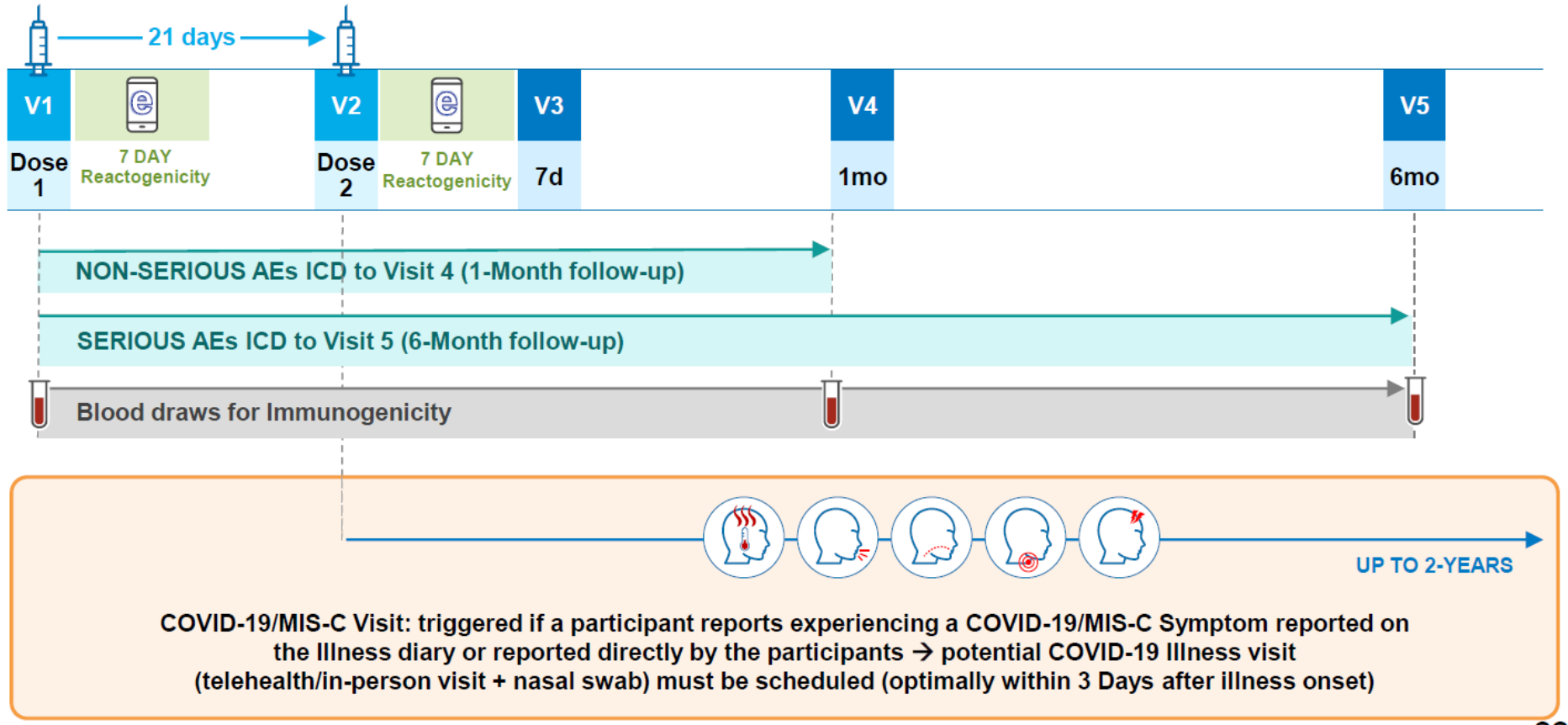
Non-inferior immune responses have been established to infer vaccine efficacy

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

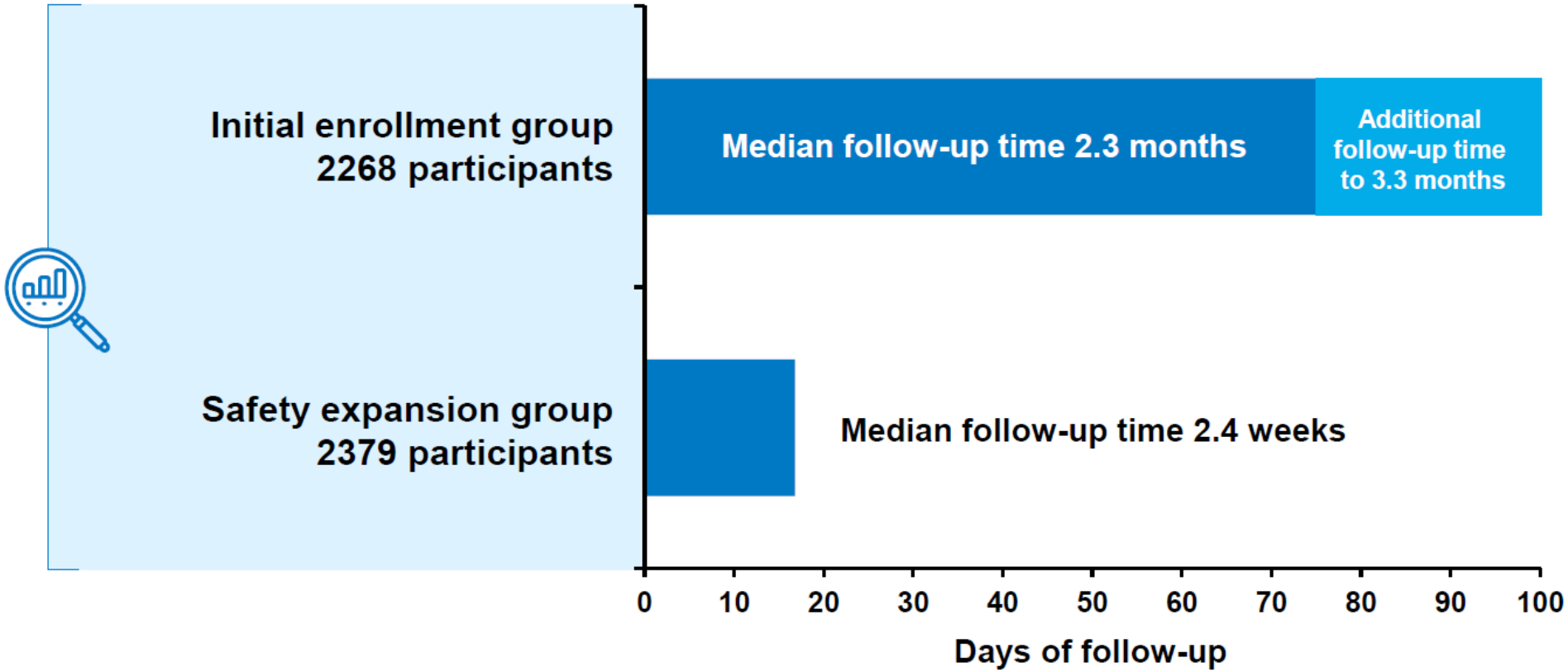
CC-6

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



CC-7

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



Demographics for 5 to <12 Year Olds

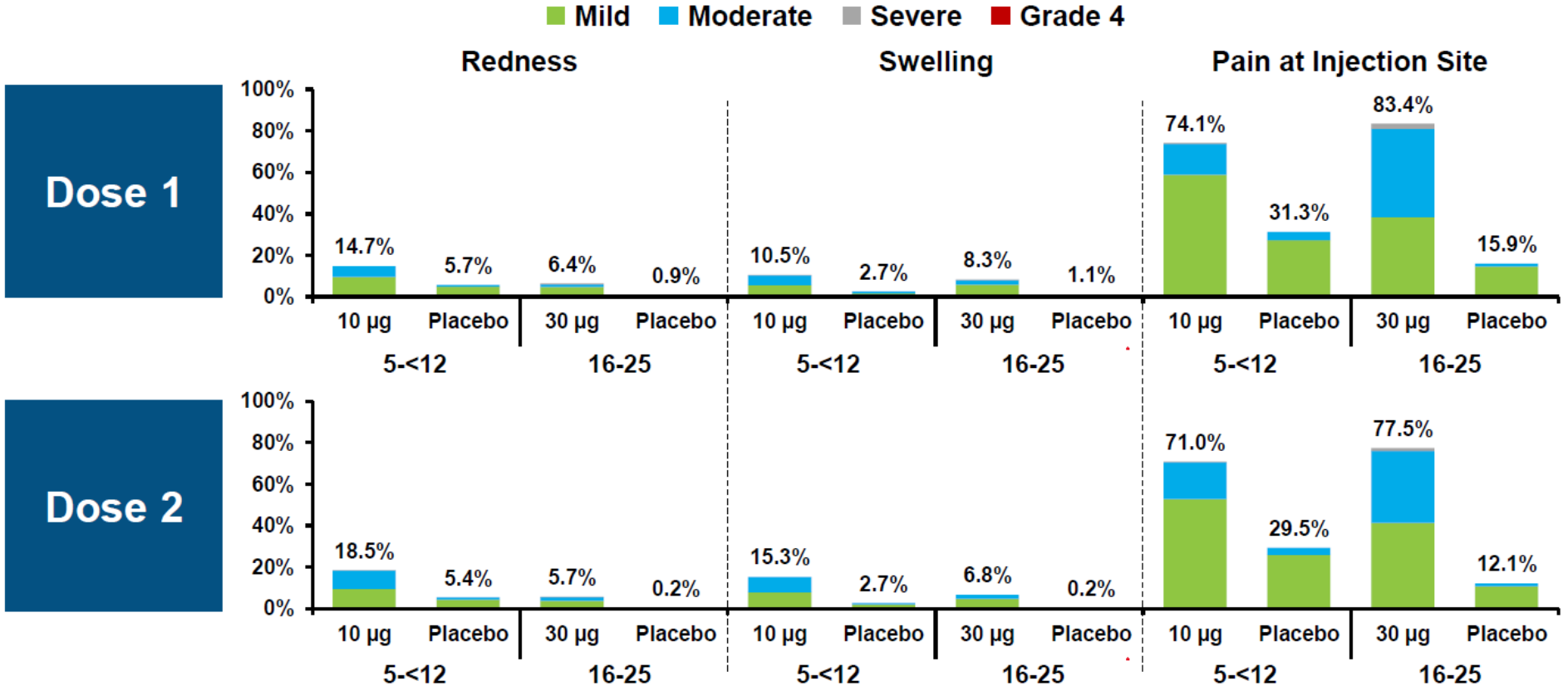
Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

		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.

CC-9

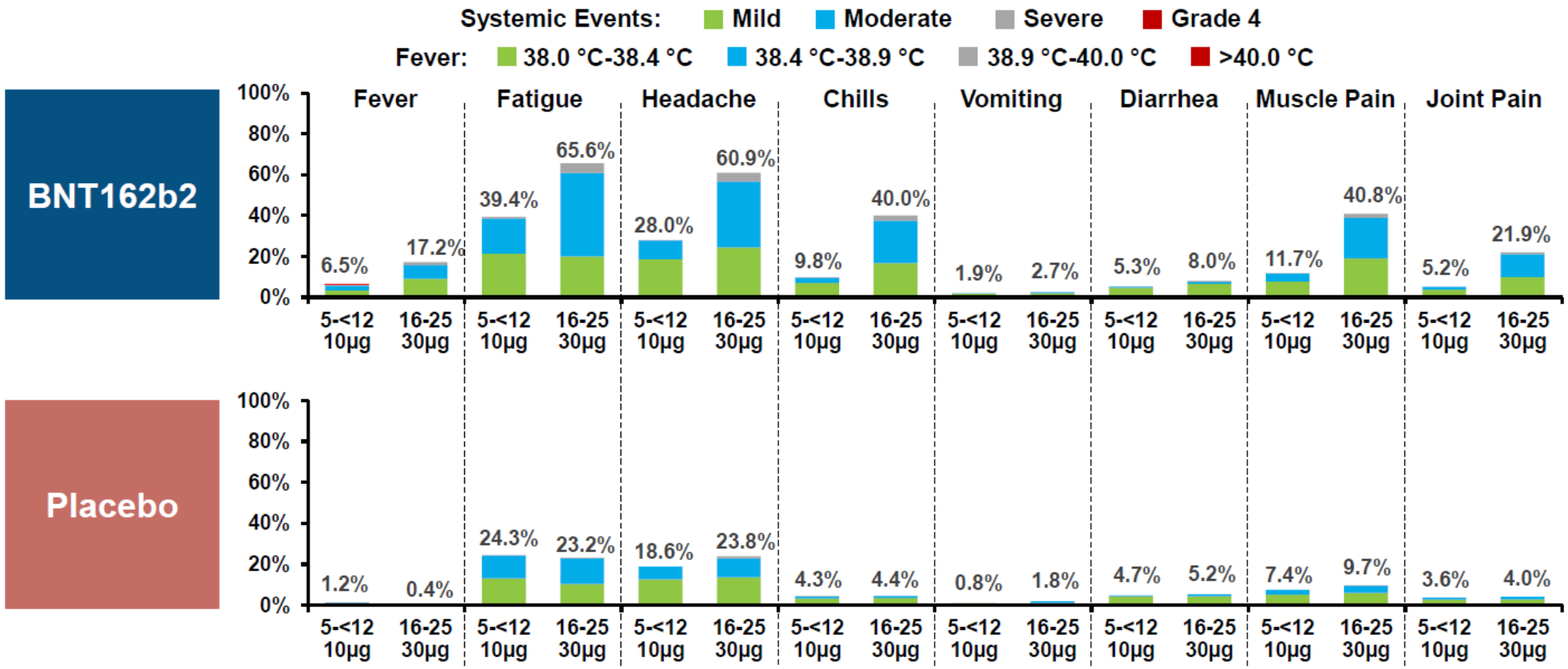
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds



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

CC-10

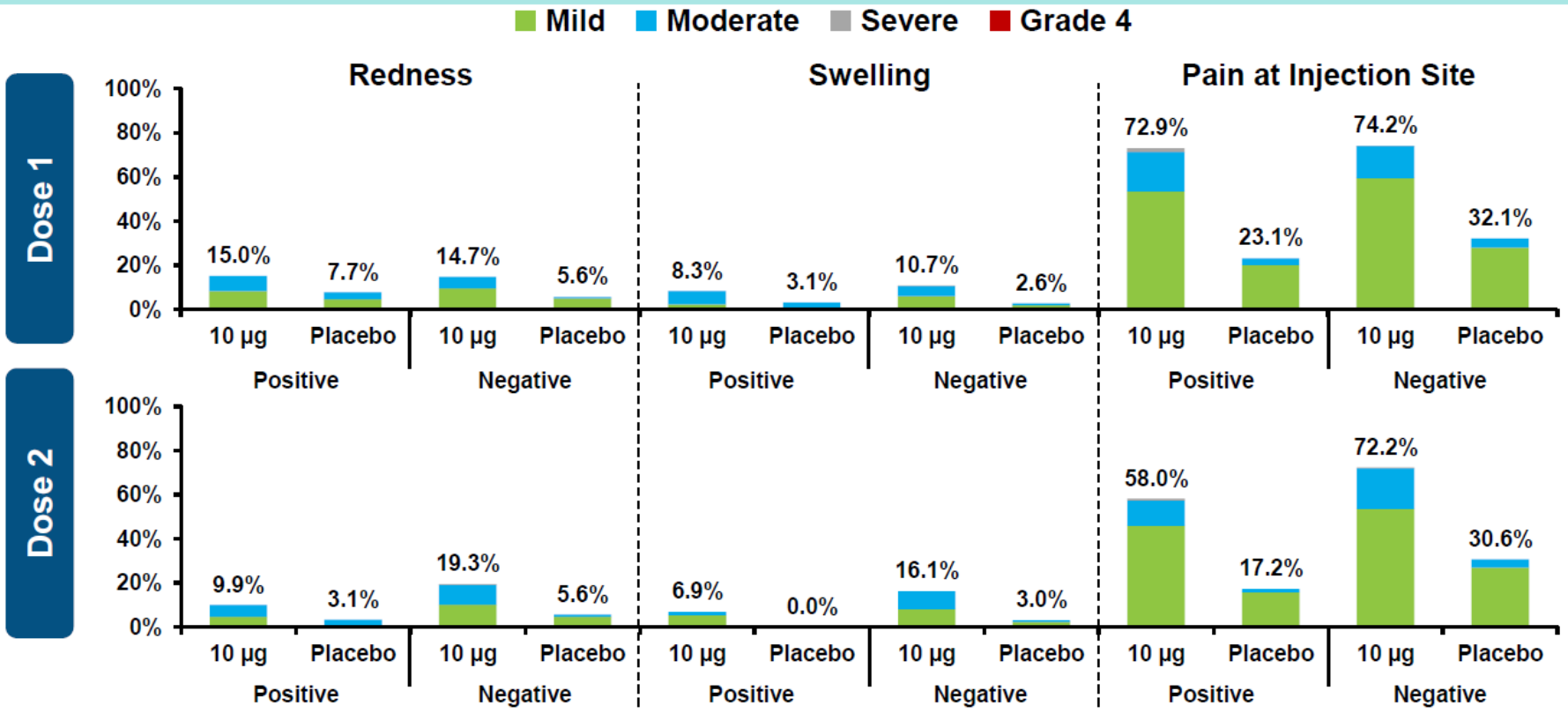
Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 and 16-25 Year Olds



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

CC-11

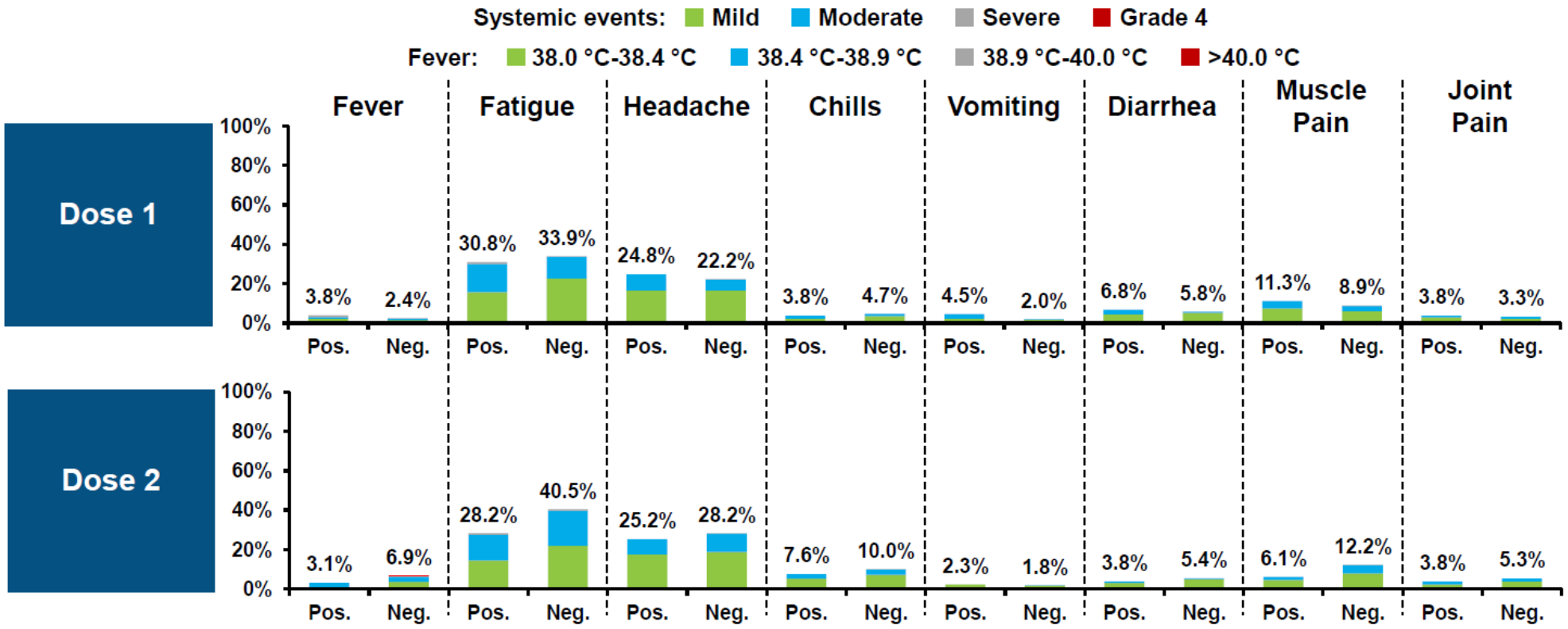
Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status



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

CC-12

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

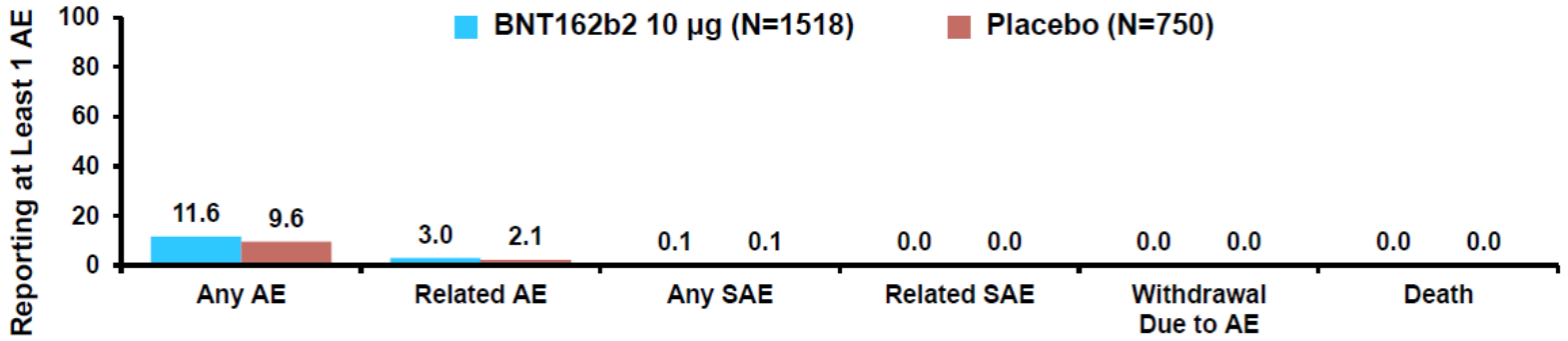


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade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

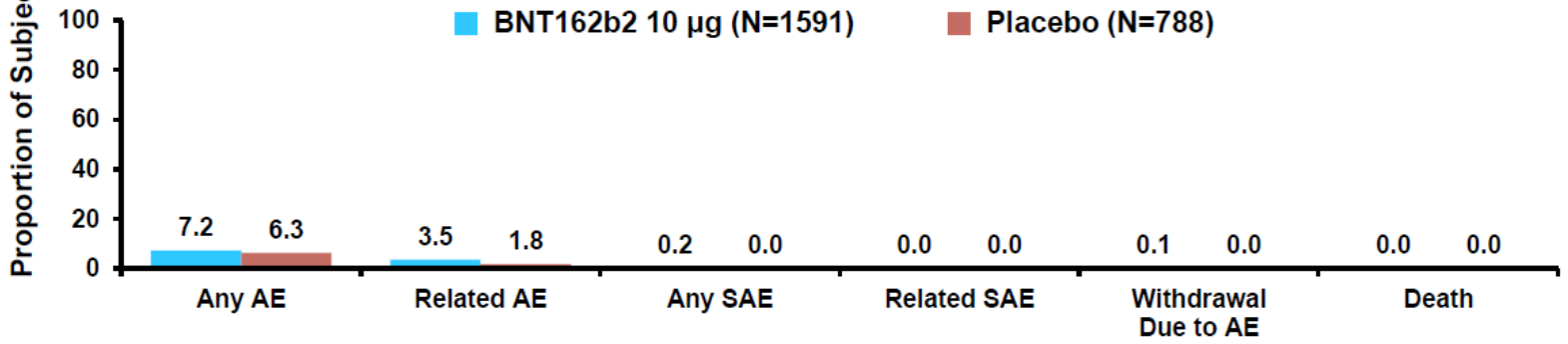
CC-13

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

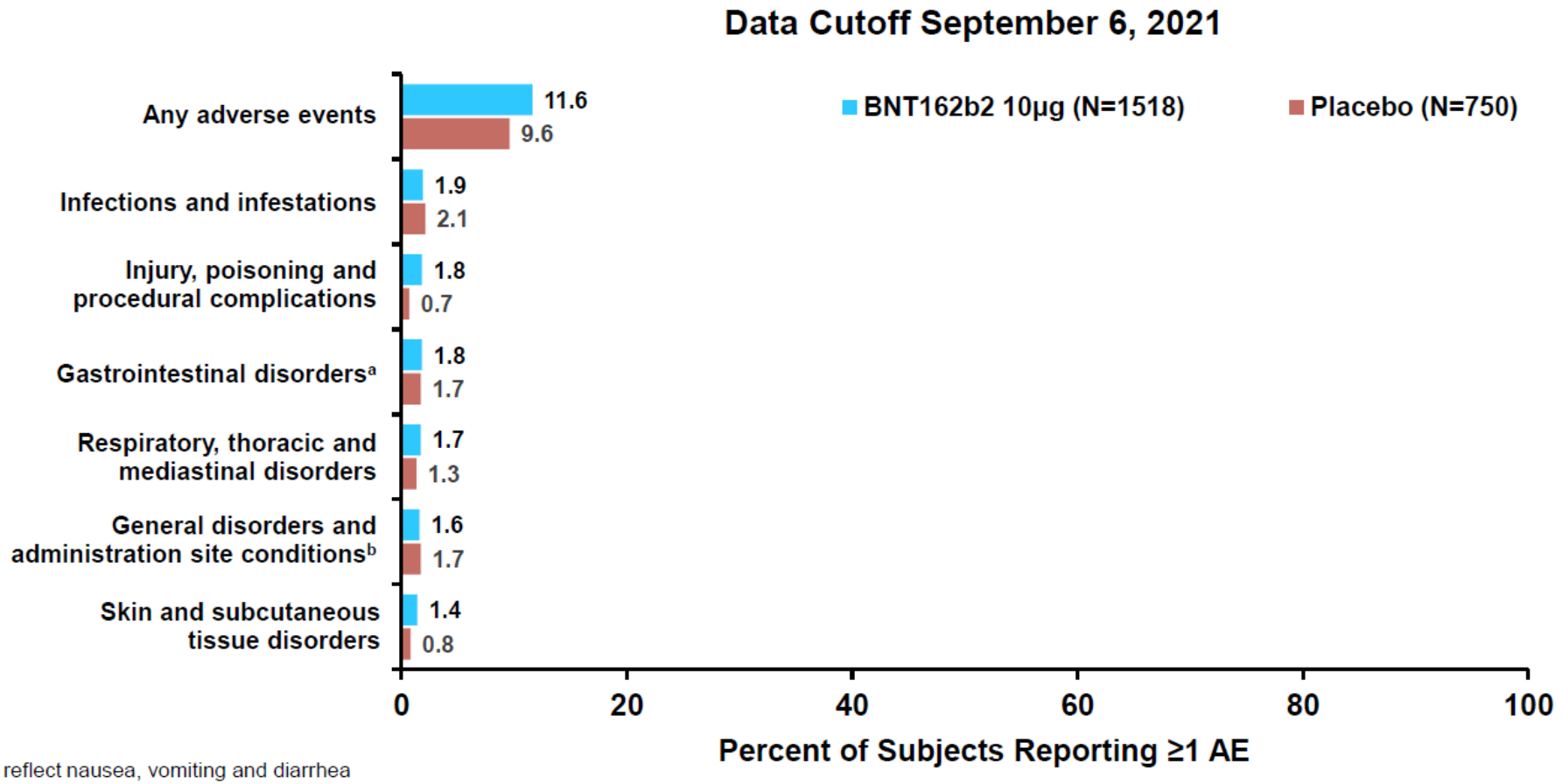


Safety expansion group:
Median follow-up time 2.4 weeks
Cutoff date October 8, 2021



CC-15

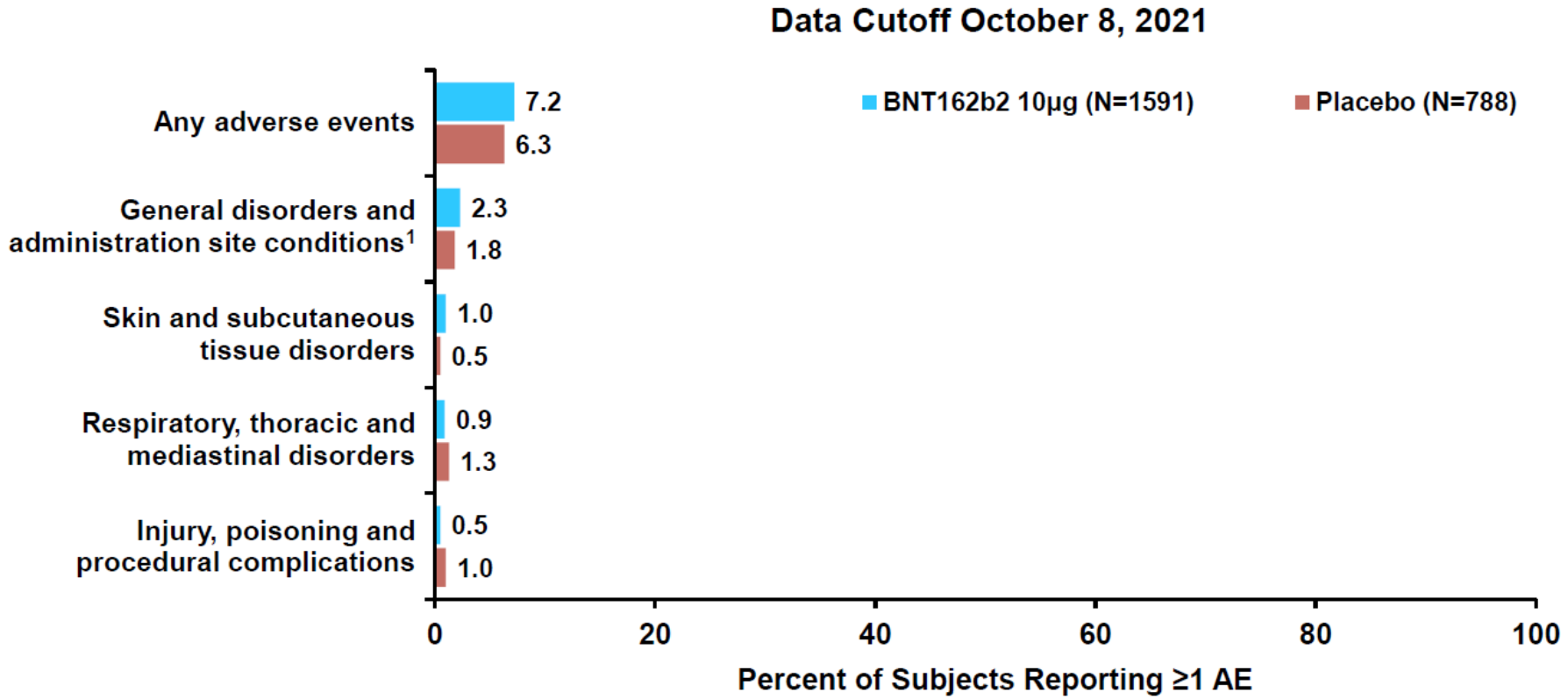
Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)



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

CC-16

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)

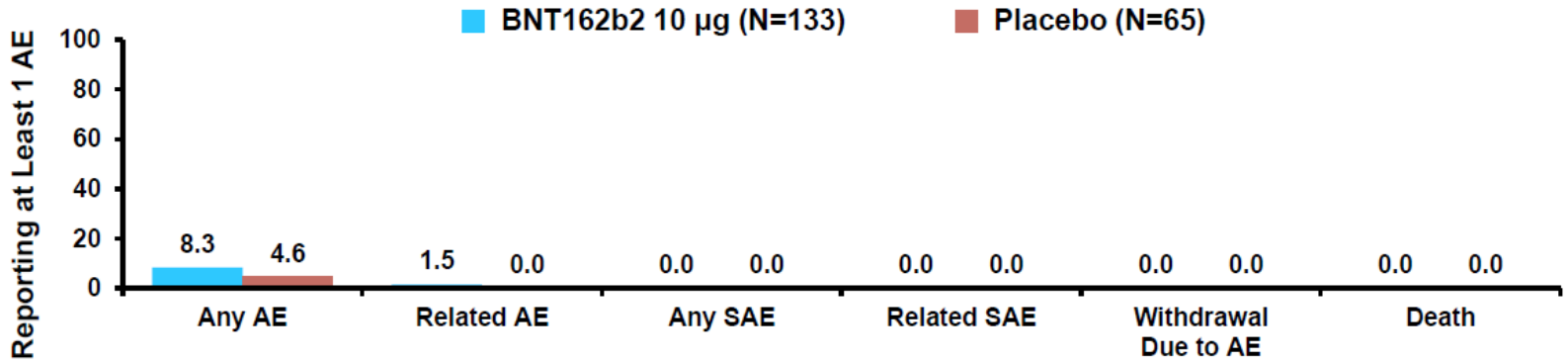


1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue
Lymphadenopathy 0.4% in the BNT162b2 group

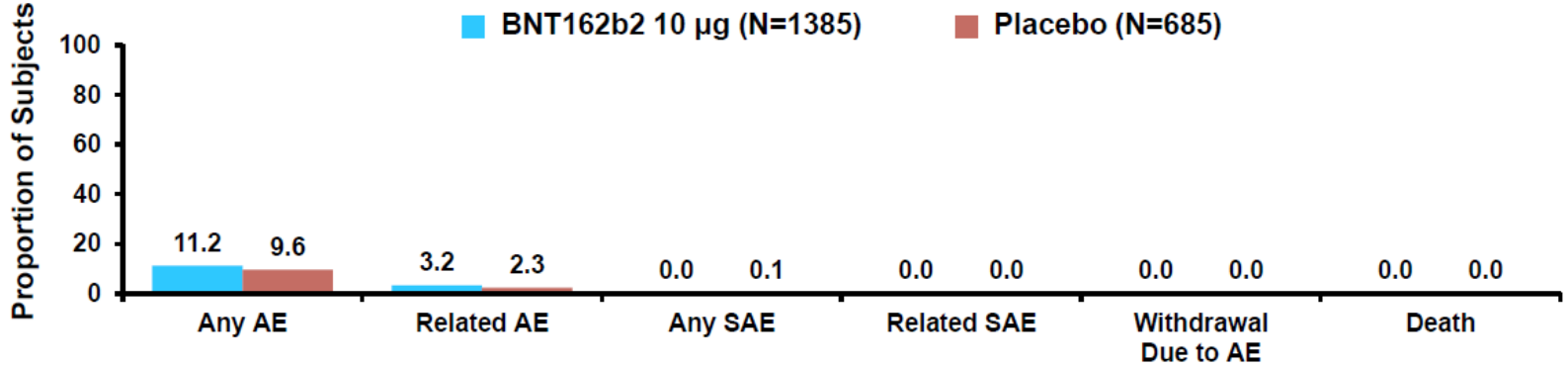
CC-17

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



CC-18

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

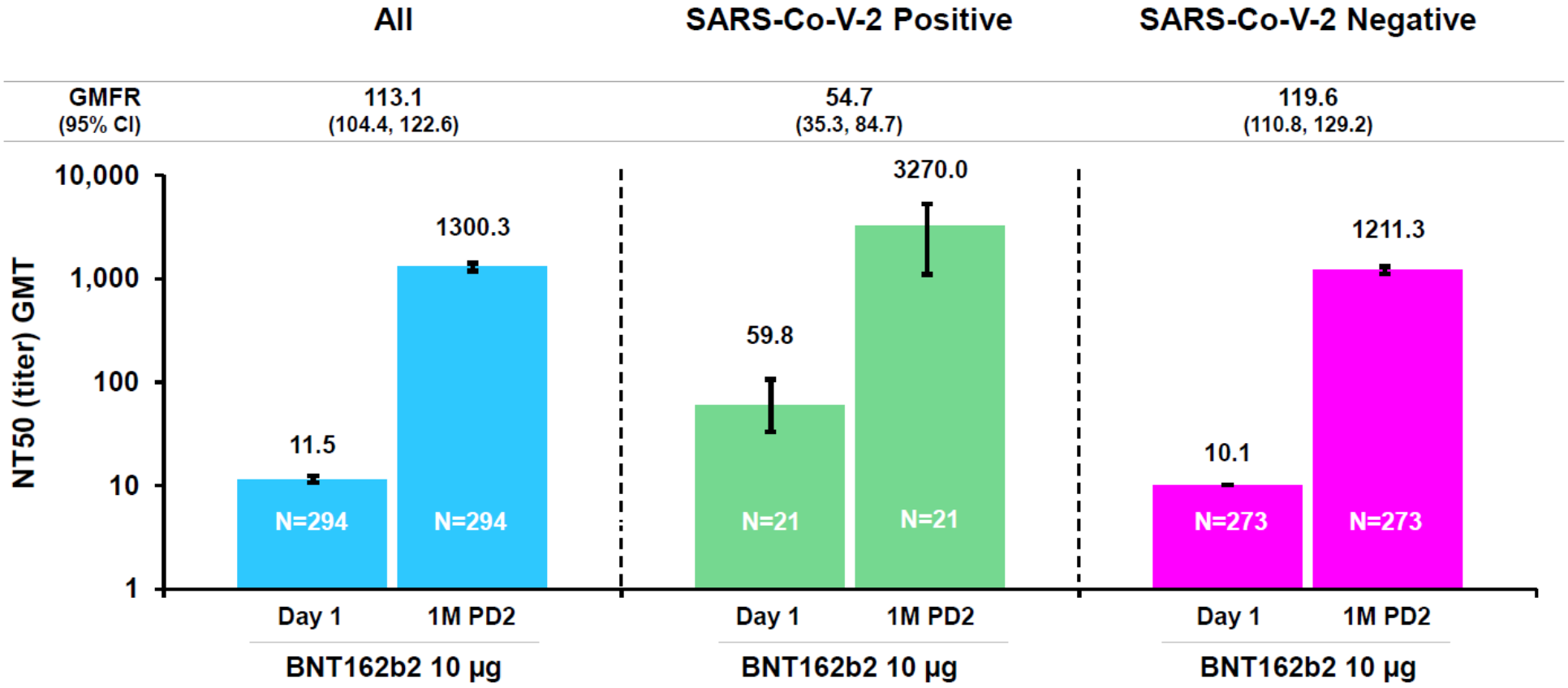
- **FDA AESIs:**
  - No anaphylaxis
  - No myocarditis/pericarditis
  - No Bell's palsy (or facial paralysis/paresis)
  - No appendicitis
- **CDC Defined AESIs:**
  - Potential hypersensitivity (angioedema, and predominantly rash and urticaria)
  - Arthritis (infective)
  - Vasculitis

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

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

Immunogenicity Subset –

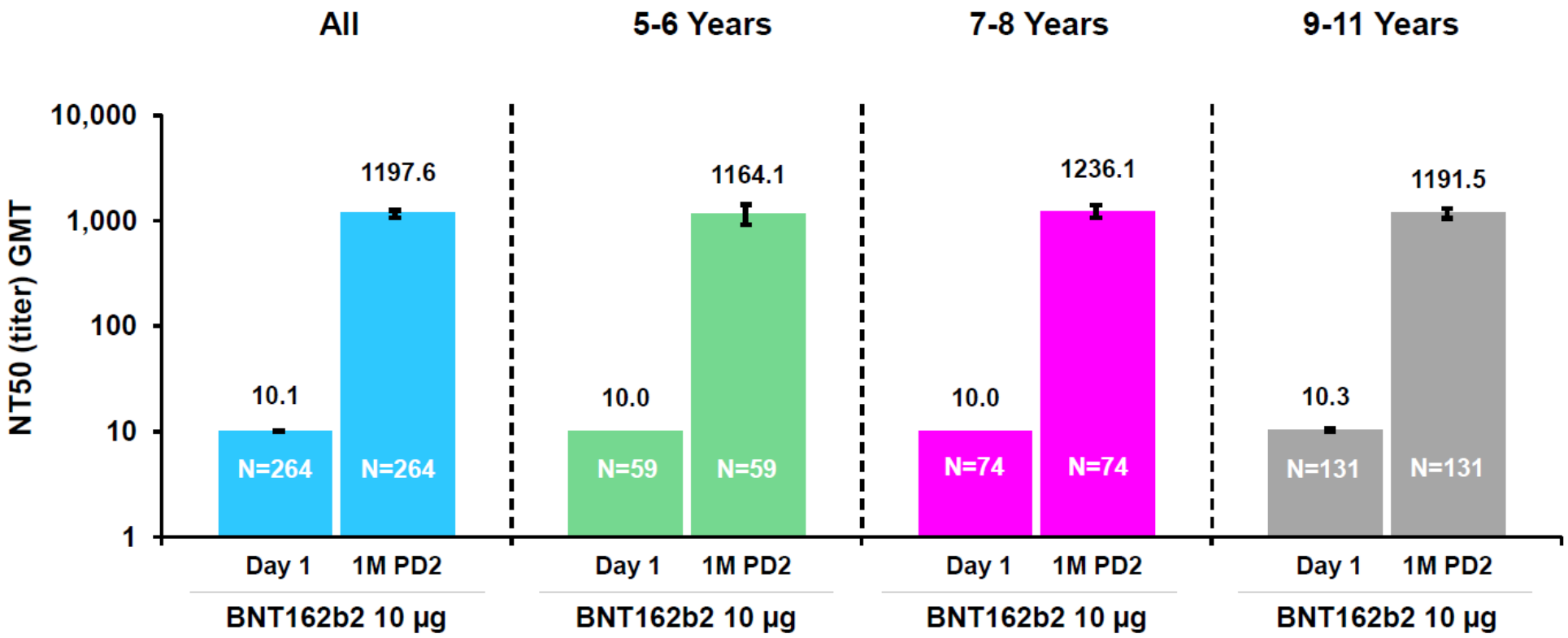


NT50 = 50% neutralizing titers

CC-24

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

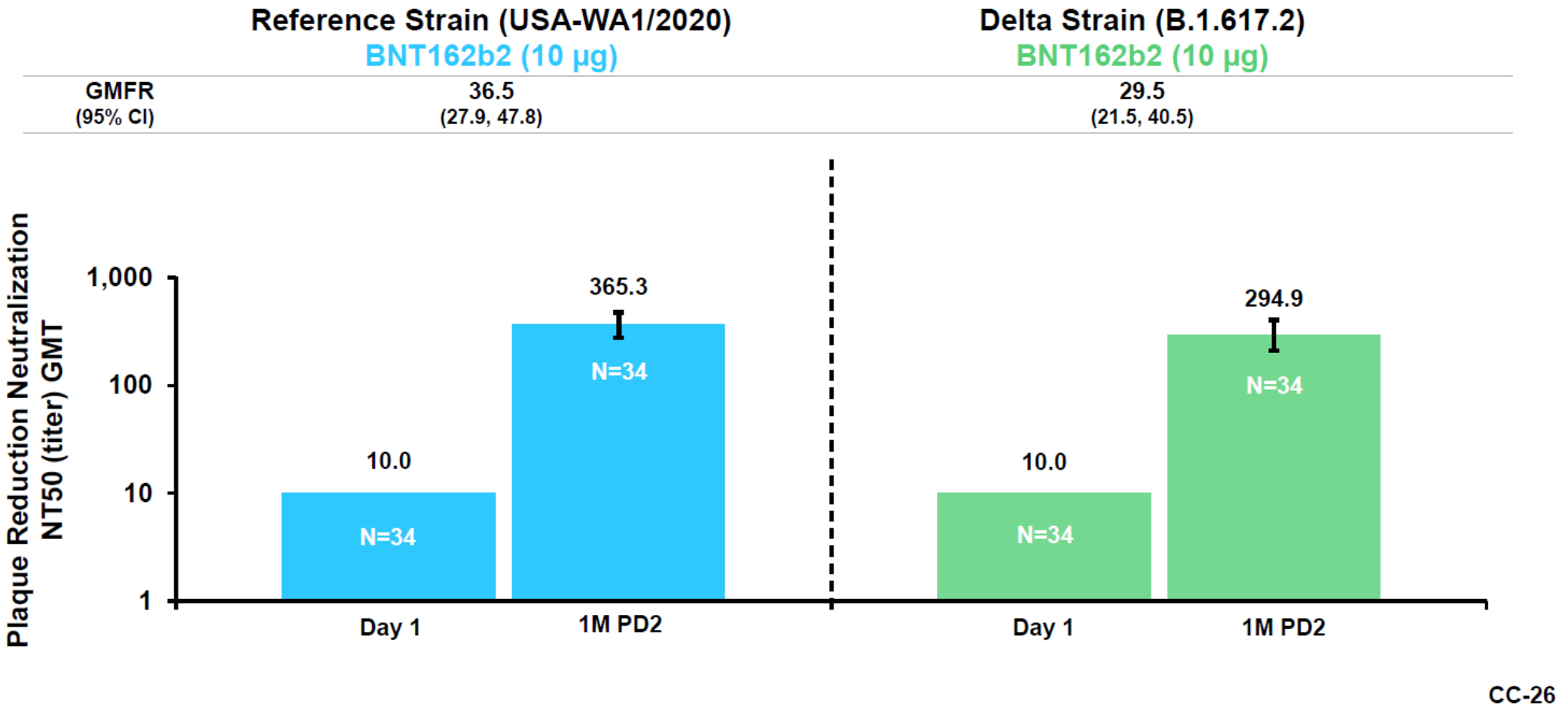


NT50 = 50% neutralizing titers

CC-25

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



CC-26

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

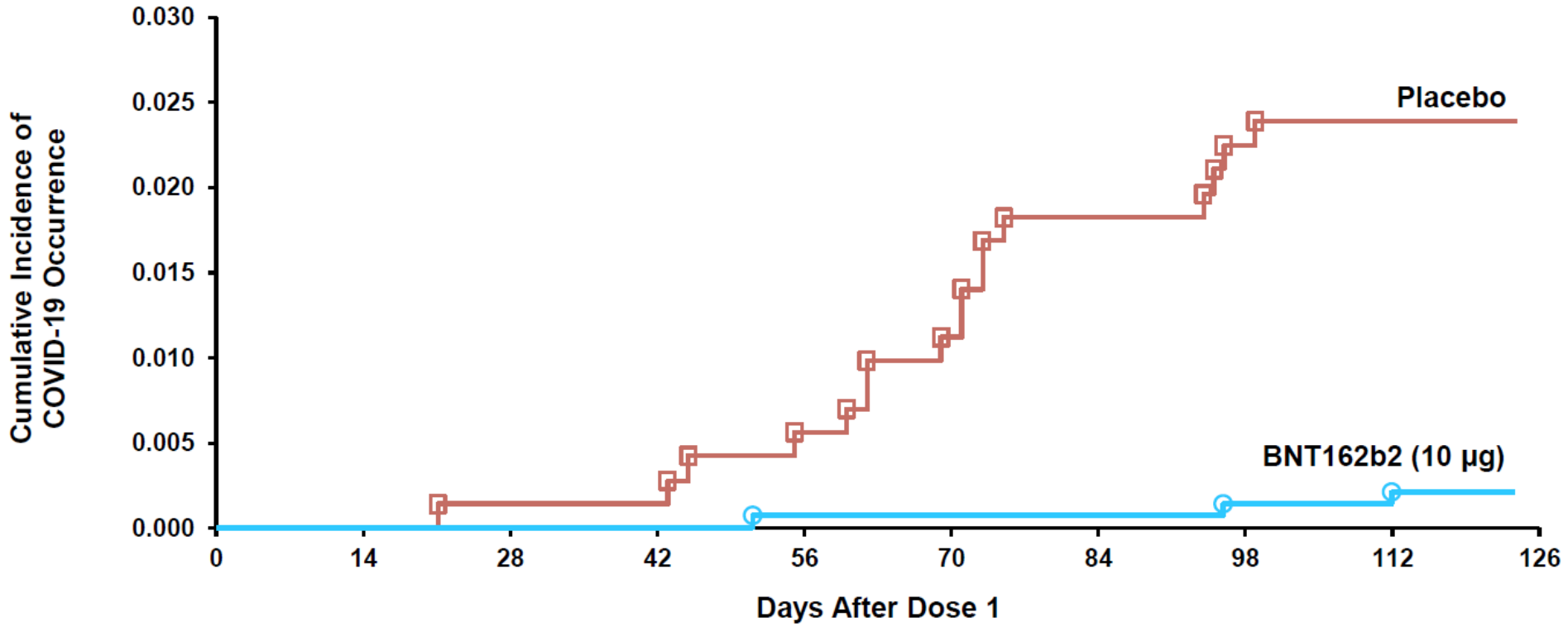
Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

	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



CC-28

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

Underlying Medical Conditions

- Children with underlying medical conditions may be at increased risk for severe illness from COVID-19[1], however, severe COVID-19 can occur in children with and without underlying medical conditions.

- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, **regardless of underlying medical conditions**.

[1]https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#ChildrenAndTeens
[2]https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Current or Prior SARS-CoV-2 Infection

- People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) AND they have met criteria to discontinue isolation[1].
  - Isolation and precautions can typically be discontinued 10 days after positive test if asymptomatic or 10 days after symptom onset and after resolution of fever for at least 24 hours)

- Serologic testing to assess for prior infection is **not** recommended for the purpose of vaccine decision-making[2].

[1] https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html
[2] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Limitations of Antibody Testing

- Antibody tests cannot determine when a person was infected.
- Antibody tests greatly vary in their sensitivity, particularly >3 months after infection.
- People can test positive on commercial antibody tests even after other markers of immunological response, such as neutralizing antibodies, have waned.
- At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.

Prior SARS-CoV-2 Infection

- Data from clinical trials in children ages 5–11 years indicate that the Pfizer-BioNTech COVID-19 Vaccine **can be given safely** to those with evidence of a prior SARS-CoV-2 infection.
- Current evidence suggests that protection from reinfection is high after initial infection but decreases with time due to **waning immunity**.
- Substantial **heterogeneity** exists in individual immune response to infection, and in adults, asymptomatic infection leads to **lower antibody levels**.
- Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection **increases protection** from subsequent infection, including in the setting of more infectious variants.

Dan 2021, Science: https://doi.org/10.1126/science.abf4063; Cavanaugh 2021, MMWR; 70(32):1081-3. Lumley 2021; Clin Infect Dis; doi: 10.1093/cid/ciab608. Gazit 2021, medRxiv; https://doi.org/10.1101/2021.08.24.21262415. Shenai 2021, medRxiv; https://doi.org/10.1101/2021.09.12.21263461.

Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- The benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C are likely to outweigh a theoretical risk of an MIS-like illness or the known risks of COVID-19 vaccination for people who meet all of the following criteria:

  1) Clinical recovery has been achieved, including return to normal cardiac function;

  2) It has been ≥90 days since their diagnosis of MIS-C;

  3) They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission;

  4) Onset of MIS-C occurred before any COVID-19 vaccination.

Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- COVID-19 vaccination may also be considered for children with a history of MIS-C who do not meet all the prior criteria.
- Experts view clinical recovery, including return to normal cardiac function, an important factor when considering COVID-19 vaccination.
- Additional factors when considering individual benefits and risks may include:

    1) An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)

    2) Timing of immunomodulatory therapies

Children Diagnosed with MIS-C after COVID-19 Vaccination

- In the rare instance a person develops MIS-C or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist should be considered.
- Because MIS-C is a condition known to occur with SARS-CoV-2 infection, these individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection.

Any cases should be reported to Vaccine Adverse Event Reporting System (VAERS)

https://vaers.hhs.gov/reportevent.html

Consultation from Clinical Immunization Safety Assessment Project is available

http://www.cdc.gov/vaccinesafety/Activities/CISA.html

Counseling: Possible Risk of Myocarditis

- Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose.
- The observed risk is highest in males 12–29 years of age[1].
- The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is **lower** than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults[2].

[1]Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep 2021;70:977–982. DOI: http://dx.doi.org/10.15585/mmwr.mm7027e2
[2]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. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e5

Vaccine-associated myocarditis

- Identified rates of myocarditis are based on data from adolescents and adults receiving 30ug dose of Pfizer-BioNTech COVID-19 vaccine
  - Dose in pediatric (5–11-year-old) age group: 10ug dose
- Rare event, but most common in males 12–29 years of age
- No cases of myocarditis occurred during the clinical trials with 5–11-year-olds
  - N=3,082 with at least 7 days of follow up reported

Counseling: Possible Risk of Myocarditis

- FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine in children ages 5–11 years based on the determination that **the benefits of COVID-19 vaccination outweigh risks in this population**.
- People receiving mRNA COVID-19 vaccines, especially males ages <30 years, should be made aware of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines.
  - Seek care for symptoms of
    - Chest pain
    - Shortness of breath
    - Feelings of having a fast-beating, fluttering, or pounding heart

Any cases should be reported to VAERS
https://vaers.hhs.gov/reportevent.html

Counseling: Expected Side Effects from Pfizer-BioNTech COVID-19 Vaccine

- Children may experience **fewer side effects** than adolescents or young adults[1].
- Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection[1].
- Expected side effects include
  - Local: pain, swelling, erythema at the injection site
  - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy
- Routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
  - In general, Aspirin is **not** recommended for use in children and adolescents ≤18 years due to risk of Reye's syndrome.

[1]https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Vaccine Dosage

- **Children should receive the age-appropriate vaccine formulation regardless of their size or weight.**
  - As opposed to many medications, vaccine dosages are based on age and not size or weight.

- The dosage should be based on the child's age on the day of vaccination.
  - If a child turns from 11 to 12 years of age in between their first and second dose and receives 5–11 years 10 µg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error per the EUA.

Administration Errors

- Formulations of the Pfizer-BioNTech COVID-19 Vaccines are **NOT** interchangeable.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their first dose, they should receive a single age-appropriate 10 µg dose for their second dose 21 days later and should be considered as having a completed primary series.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their second dose, they should be considered has having a completed primary series.

Administration Errors

- If an individual aged ≥12 years inadvertently receives a 10 µg dose, the dose should be repeated with the age appropriate 30 µg dose immediately.
  - Exception for children who turned from 11 to 12 years in between their first and second dose and receive a second 10 µg dose to complete their series.

- Due to the rare risk of myocarditis, males aged <30 years may consider waiting 21 days (the recommended interval) after the erroneous dose to repeat the dose.

CDC vaccine safety monitoring

- COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe	VAERS	VSD	CISA Project

Full list of U.S. COVID-19 vaccine safety monitoring systems

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

What can you do for vaccine safety?

- Report adverse events following vaccination to VAERS even if you aren't sure if the vaccination caused the adverse event

CDC + FDA

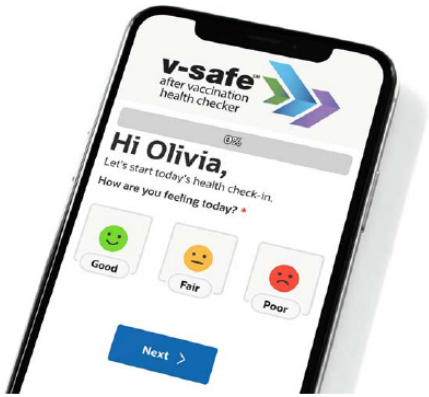
VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

- Enroll yourself in v-safe
- Healthcare providers, encourage your patients to enroll in v-safe
- Parents and guardians, you can enroll your children in v-safe

v-safe℠ after vaccination health checker



vsafe.cdc.gov/en/

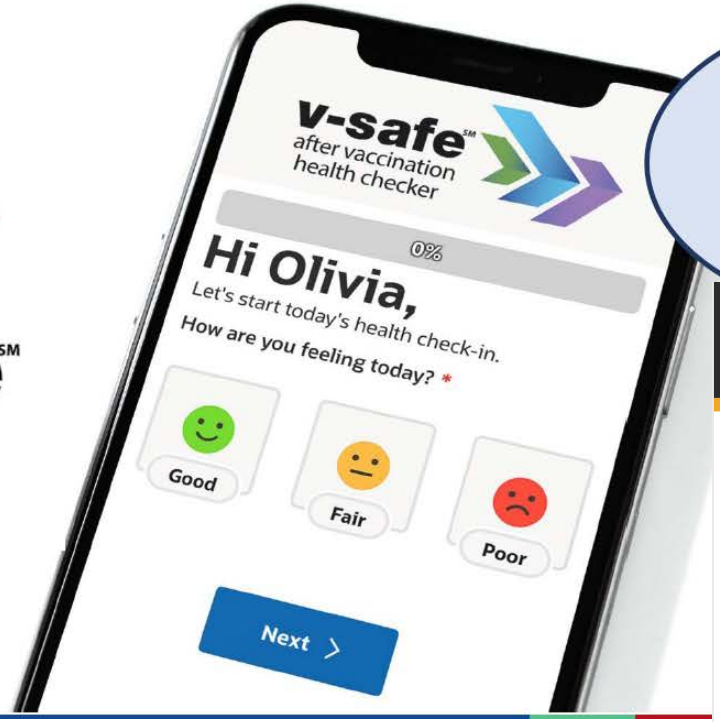
Please get involved, your participation matters

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Smartphone-based active safety monitoring

v-safe℠
after vaccination health checker

http://cdc.gov/vsafe

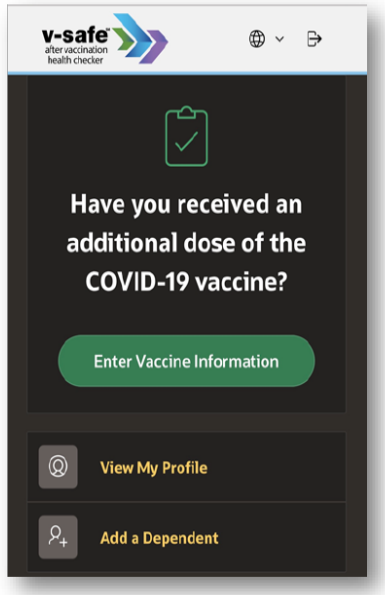


Now available!

- Enrolling **children**
- 3rd **dose** reporting

Adding a dependent in v-safe

- Participants can register themselves or dependents after dose 1, 2, or 3
- Dependents can be added, even if the primary smartphone account is not a **v-safe** participant
  - Parent/guardian must create a profile then add dependent
  - Text messaging directed to parent/guardian
- **V-safe** check in schedule:
  - Once a day (days 0–7)
  - Once a week (weeks 2–6)
  - Once a month (months 3, 6, and 12)
  - Schedule restarts after each dose received



Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥18 years*	

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underying medical conditions, or who work or live in high-risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021

Coadministration

- COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age[1].
  - Separate injection sites by 1 inch or more.
  - For older children (≥11 years), the deltoid muscle can be used.
  - For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

[1]https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Vaccinate with **Confidence**

CDC's strategic framework for strengthening vaccine confidence and preventing outbreaks of vaccine preventable diseases.

Protect communities

Strategy: Protect communities at risk from under-vaccination

- ✓ Leverage immunization data to find and respond to communities at risk
- ✓ Work with trusted local partners to reach at-risk communities before outbreaks
- ✓ Ensure vaccines are available, affordable, and easy-to-get in every community

Empower families

Strategy: Get providers and parents effective information resources

- ✓ Expand resources for health care professionals to help them have effective vaccine conversations with parents
- ✓ Work with partners to start conversations before the first vaccine appointment
- ✓ Help providers foster a culture of immunization in their practices

Stop myths

Strategy: Stop misinformation from eroding public trust in vaccines

- ✓ Work with local partners and trusted messengers to improve confidence in vaccines among key, at-risk groups
- ✓ Establish partnerships to contain the spread of misinformation
- ✓ Educate key new stakeholders (e.g., state policy makers) about vaccines

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Pablo J. Sánchez, MD
Center for Perinatal Research
NEO-ID Clinic (614.722.4452)

700 Children's Drive | Columbus, Ohio | 43205
P 614.355.6638 | F 614.355.5899 | C 214.621.1068
Pablo.Sanchez@NationwideChildrens.org

COVID-19 VACCINES

our children - our future