I-VAC Pediatric Learning Collaborative for COVID-19 Vaccination

Please use your first name and health center name when you join the session

Use the **“chat”** feature to let us know if you have a question

Please remember to **mute your microphone** unless speaking

If you can’t connect audio via computer or lose computer audio at anytime, you can call in to session at **(669) 900-6833, Meeting ID 958-5486-4417##**

I-VAC ILLINOIS VACCINATES AGAINST COVID-19

THE UNIVERSITY OF CHICAGO Department of Pediatrics Established 1930

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Disclosures

- No one in a position to control the education content of the activity has any relevant financial disclosures with ineligible companies to disclose.
- What gets said here today may change based on new data and recommendations
  - Knowledge is shared more rapidly through ECHO

Agenda

- Pfizer vaccine for kids under 6 months - <5 years old
- Moderna vaccine for 6 months – 17 years
- Cases
- Q & A

The Case for Vaccination of 6 M – 5Y

- Severe COVID-19 occurs in children <5 years of age
  - As of May 2022, 45,000 hospitalizations (24% require ICU) and 475 deaths
  - Roughly 50% of these hospitalizations were likely due to Omicron
  - Burden comparable to influenza –for which children are routinely immunized
- Severe COVID-19 outcomes are unpredictable and can occur in healthy children
  - 64% of hospitalizations in children <5 years occur in those without comorbidities
- COVID-19 can cause additional long-term sequelae in children
  - 3–6% of children report continued symptoms for >12 weeks
- Pandemic adversely impacts developmental and psychosocial well-being

Gruber W. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Demographics of Most Recent Vaccine Studies are Not Ideal If Looking for Data for People of Color

- For both Pfizer and Moderna, the number of Black and to lesser extent Hispanic participants is small in these studies
- Black
  - Pfizer 2y-<5y: 94
  - Pfizer 6m-<2y: 42
  - Moderna 12y-17y: 75
  - Moderna 6y-11y: 300
  - Moderna 2y-5y: 152
  - Moderna 6m-23m: 53
- Hispanic
  - Pfizer 2y-<5y: 264
  - Pfizer 6m-<2y: 161
  - Moderna 12y-17y: 273
  - Moderna 6y-11y: 571
  - Moderna 2y-5y: 424
  - Moderna 6m-23m: 229
- White
  - Pfizer 2y- <5y: 1469
  - Pfizer 6m-<2y: 922
  - Moderna 12y-17y: 2088
  - Moderna 6y-11y: 1955
  - Moderna 2y-5y: 2304
  - Moderna 6m-23m: 1391

FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Pfizer for 6m to <5 Years

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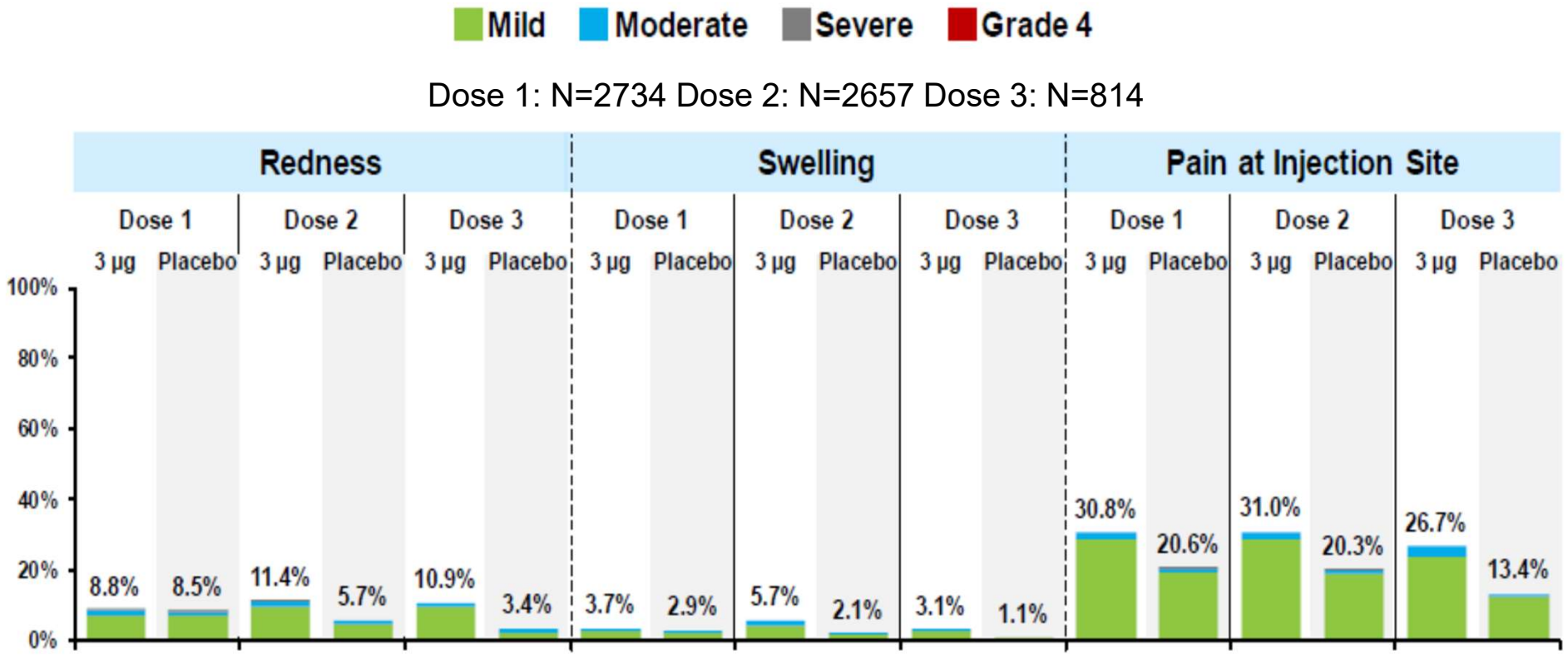
Pfizer Dosing Age 6 Months to <5 Years

3 microgram dosing

Gruber W. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Pfizer Local Reactions: Age 2 Years to <5 Years



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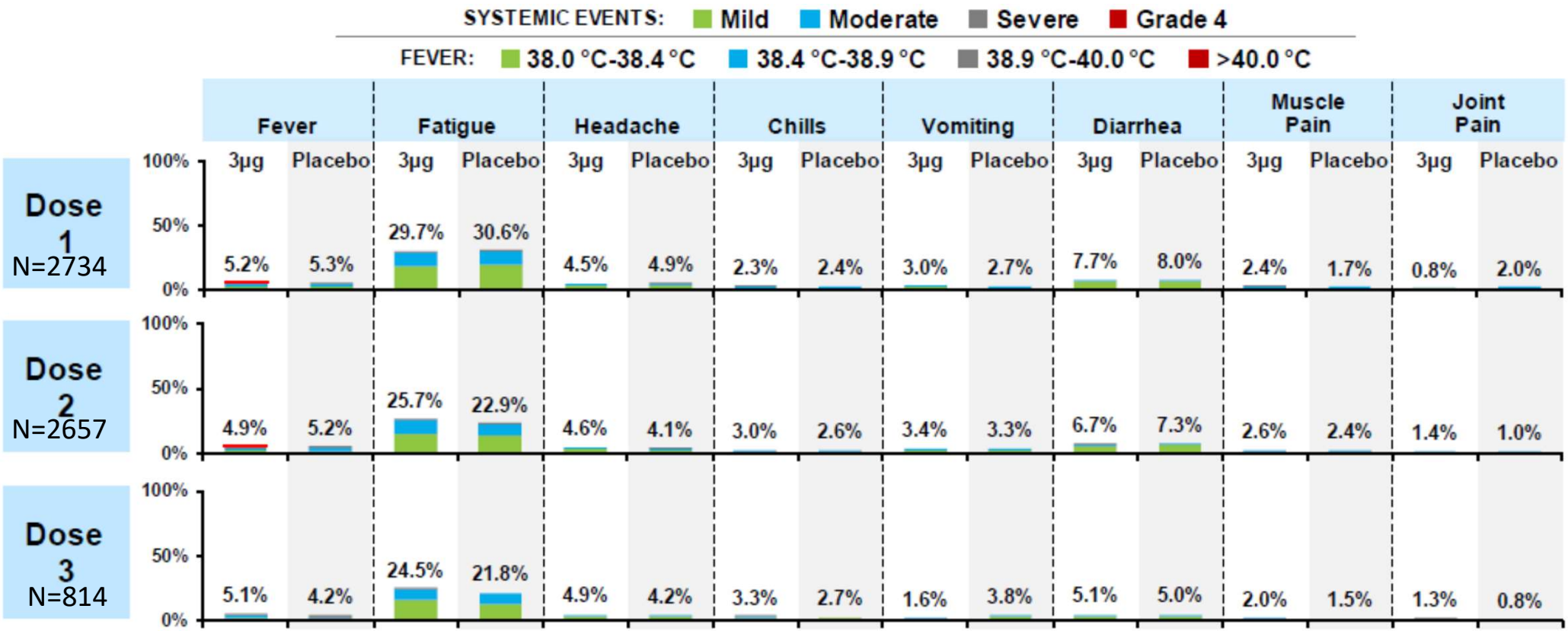
Pfizer Systemic Reactions: Age 2 Years to <5 Years



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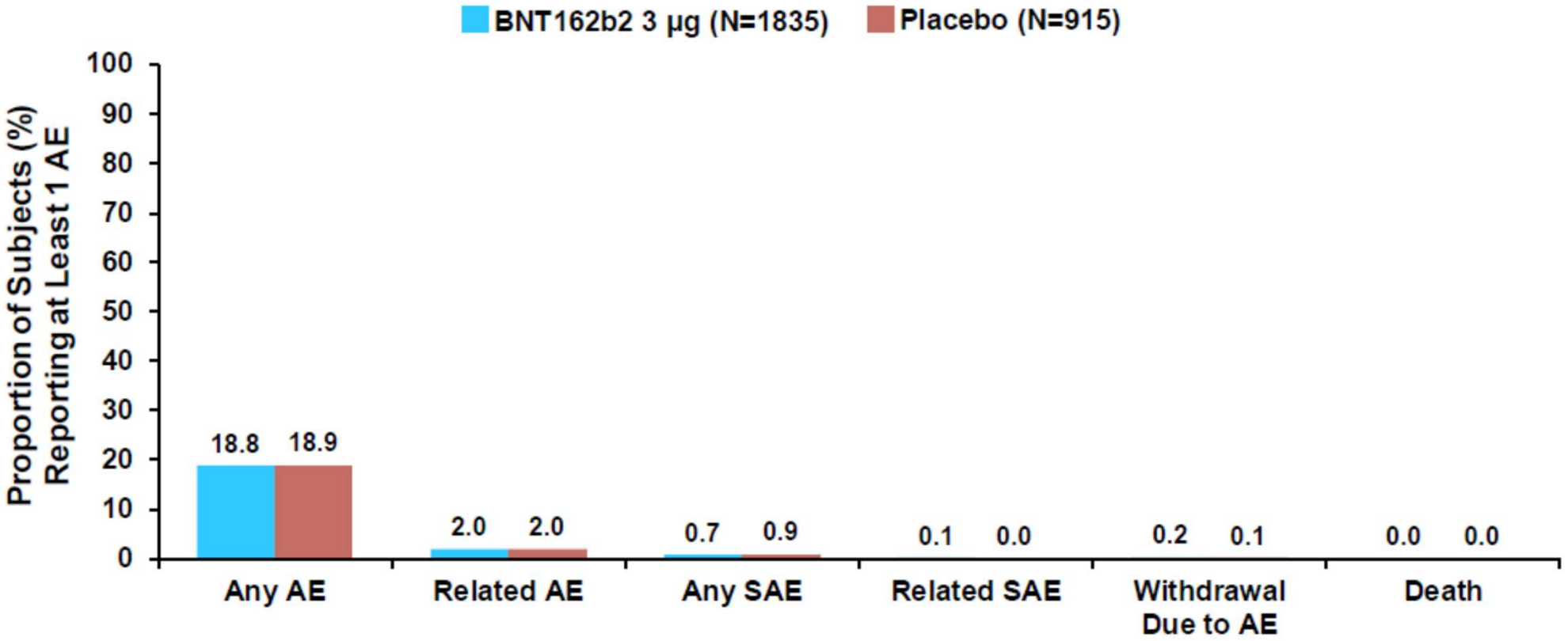
Pfizer Adverse Events: Age 2 Years to <5 Years



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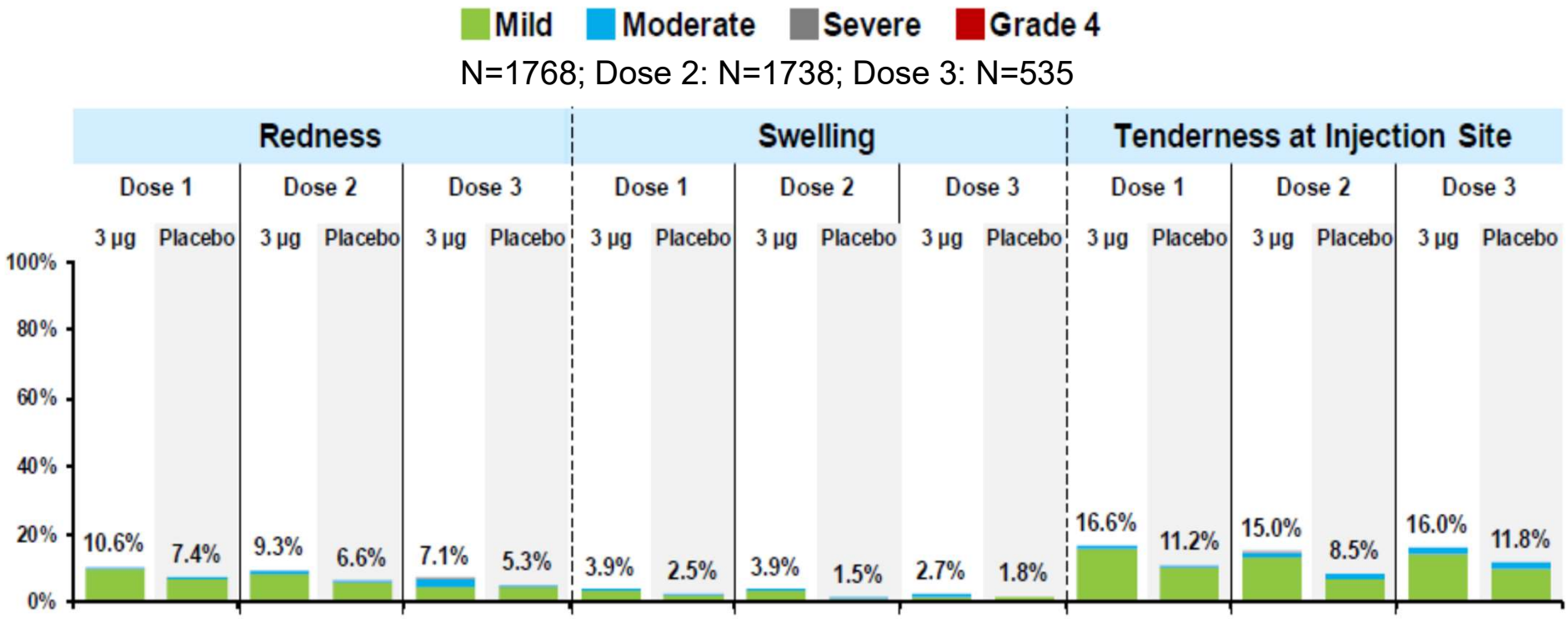
Pfizer Local Reactions: Age 6 M to <2 Years



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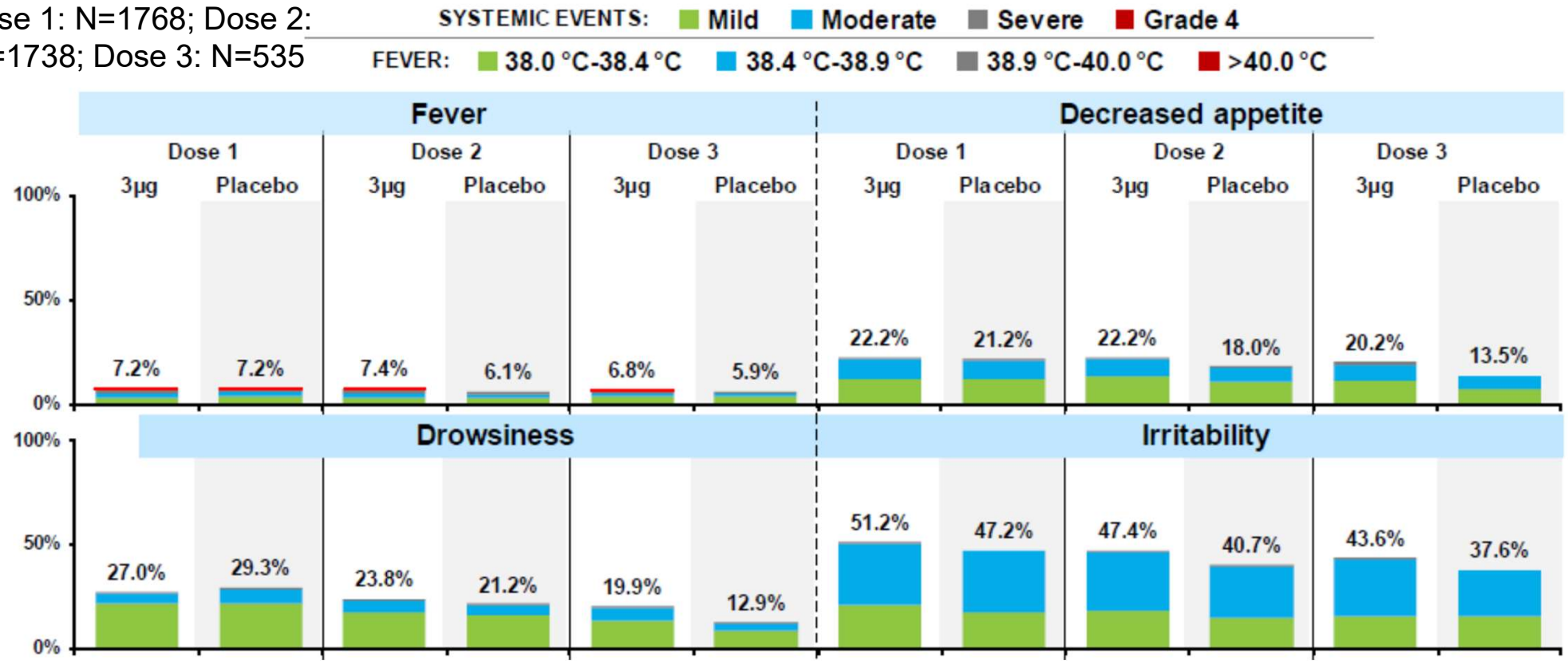
Pfizer Systemic Reactions: Age 6 M to <2 Years

Dose 1: N=1768; Dose 2: N=1738; Dose 3: N=535



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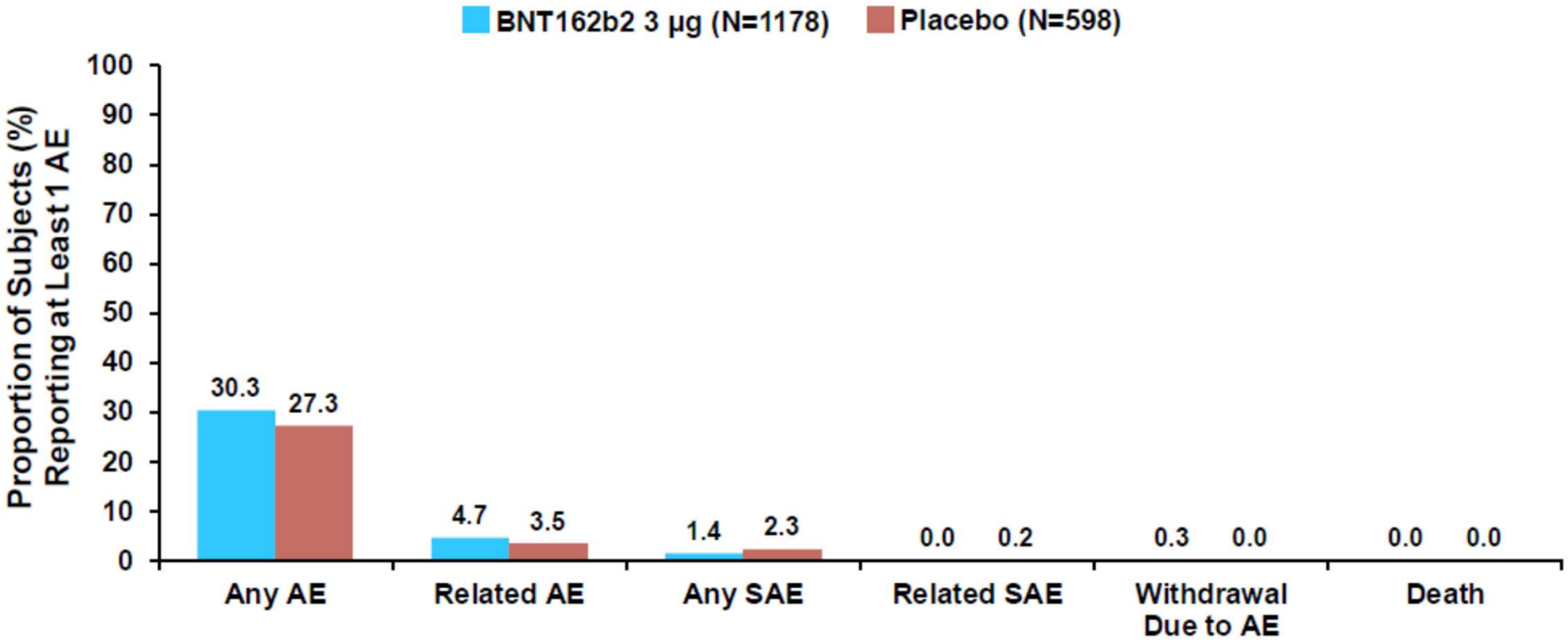
Pfizer Adverse Events: Age 6 M to <2 Years



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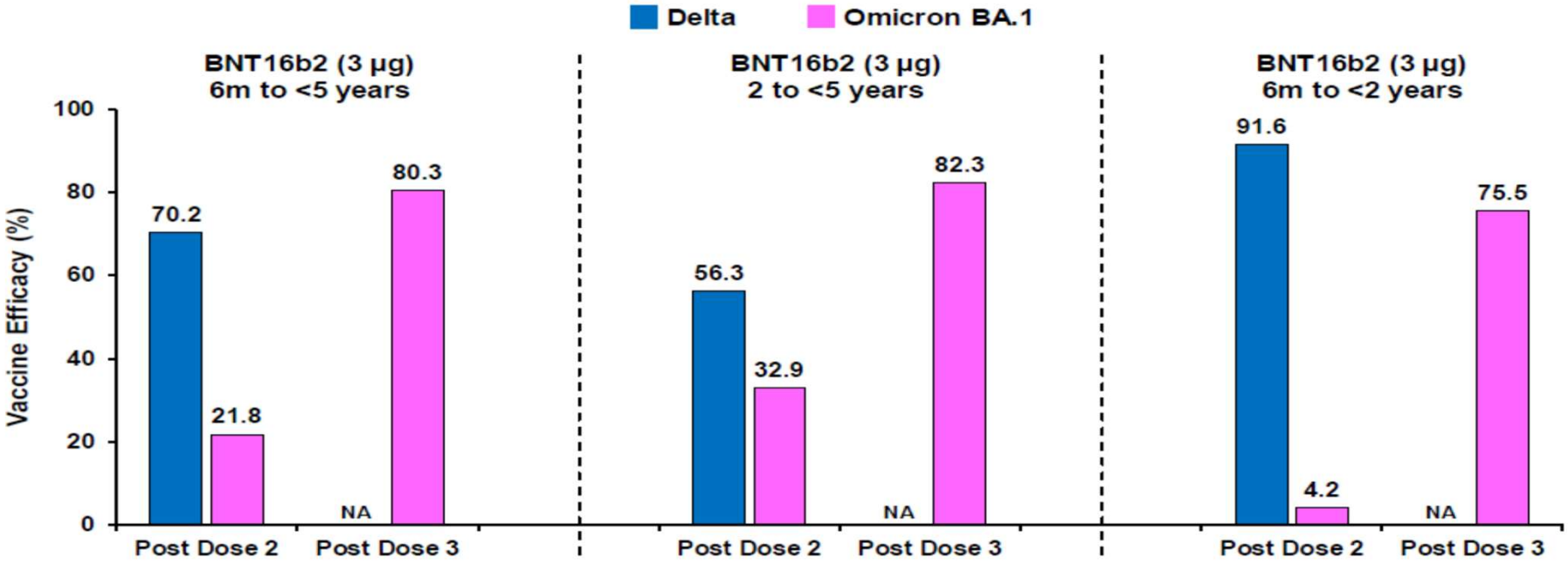
AGE
6 mo. to <5

Few Adverse Events of Special Interest (AESIs) Were Reported

- **FDA AESIs (both age groups):**
  - Predominant categories were potential angioedema and hypersensitivity comprising mainly urticarias and rashes
  - Similar incidence between BNT162b2 and placebo for these categories
- **CDC Defined AESIs:**
  - No vaccine related anaphylaxis
  - No myocarditis/pericarditis
  - No Bell's palsy (or facial paralysis/paresis)
  - No MIS-C

Gruber W. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Neutralizing AB Response Post 2nd and 3rd Dose by Variant



The confidence intervals are very wide (2-sided 95% CI: 13.9%, 96.7%) because based on a very low number of cases (3 cases in the vaccine group and 7 cases in the placebo group)

Gruber W. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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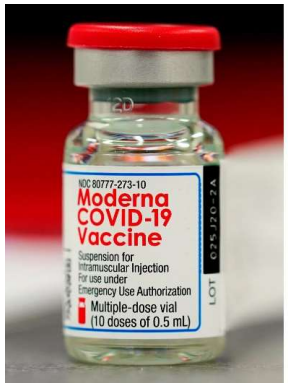
Storage & Handling Pfizer

Age Indications	5 through 11 years	12 years and older	6 months through 4 years
Formulation	Primary Series and Booster Dose	Primary Series and Booster Dose	Primary Series
Vial Cap Color/Label with Color Border	ORANGE	GRAY	MAROON
Preparation	Dilute Before Use	**Do Not Dilute**	Dilute Before Use
Amount of Diluent Needed per Vial[a]	1.3 mL		2.2 mL
Dose Volume/Dose	0.2 mL/10 mcg	0.3 mL/30 mcg	0.2 mL/3 mcg
Doses per Vial	10 (after dilution)	6	10 (after dilution)
ULT Freezer (-90°C to -60°C)[b]	12 months	12 months	12 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C) *including any thaw time*	12 hours prior to first puncture	12 hours prior to first puncture	12 hours prior to first puncture
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

[a] Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
[b] Regardless of storage condition, vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.

Moderna Vaccine



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Approvals, Authorizations and Use of Moderna COVID-19 Vaccine for Children and Adolescents 6-17 Years

- Worldwide approvals / authorizations
  - Adolescents 12-17 in 42 countries (100 µg 2-dose primary series)
  - Children 6-11 in 40 countries (50 µg 2-dose primary series)

Adolescents 12-17 Years

>6.4 Million

Fully vaccinated worldwide

Children 6-11 Years

>300,000

Fully vaccinated worldwide

*Estimated data as of April 15, 2022**

*Data based on estimates from Moderna Bi-Monthly Summary Safety Reports

Vinals C. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

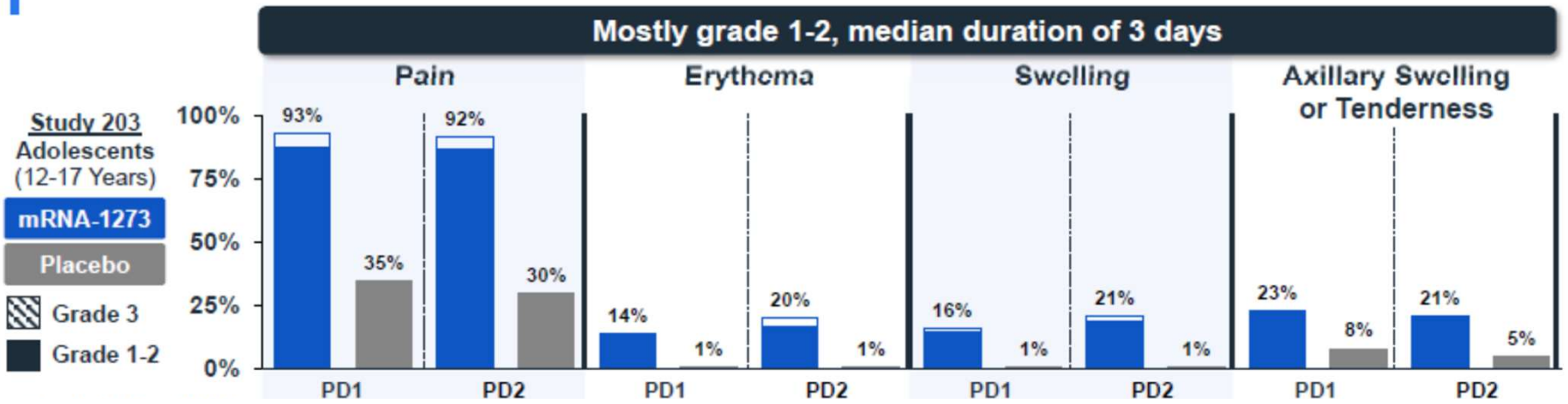
Pediatric Studies

	6-23 months	2-5 years	6-11 years	12-17 years
Dose/regimen:	25 µg Two doses (0, 28 days)	25 µg Two doses (0, 28 days)	50 µg Two doses (0, 28 days)	100 µg Two doses (0, 28 days)
Pediatric Study	P204	P204	P204	P203
mRNA-1273 recipients	1,761	3,031	3,007	2,486
Immunobridging to 18-25-year-old participants in P301 (GMC and seroresponse)	✓	✓	✓	✓
Descriptive efficacy	✓	✓	✓	✓

Wisch R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Solicited Local Adverse Reactions within 7 Days After Dose 1 & 2

Study 203: Adolescents (12-17 Years) vs Study 301: Young Adults (18-25 Years)



Solicited Safety Set: No Grade 4 solicited local adverse reactions were reported

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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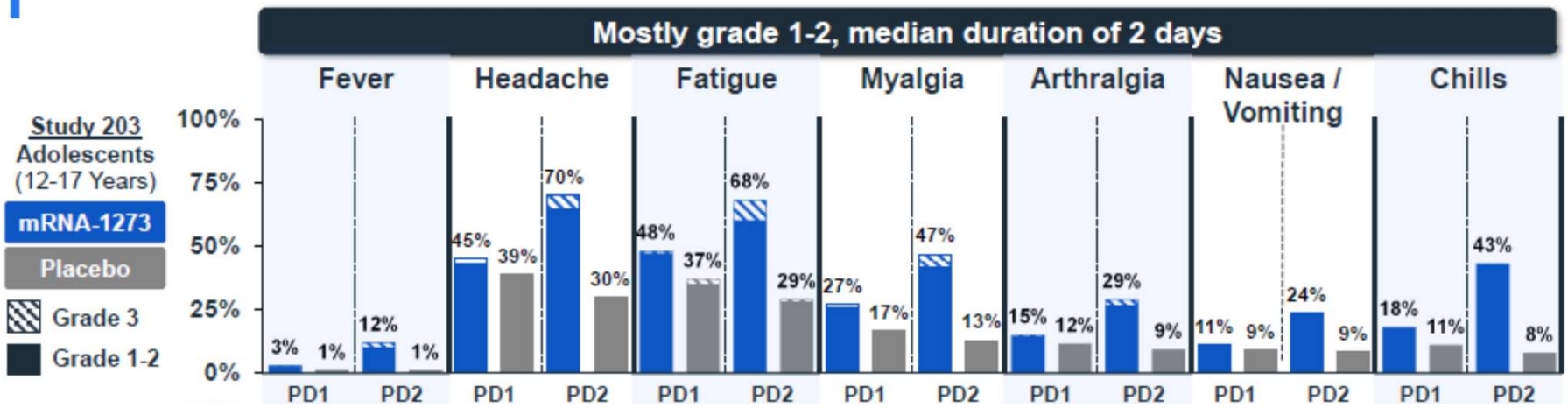
Solicited Systemic Adverse Reactions within 7 Days After Dose 1 & 2

Study 203: Adolescents (12-17 Years) vs Study 301: Young Adults (18-25 Years)



Solicited Safety Set; 4 Grade 4 systemic adverse reactions reported PD2 (fever, headache, and nausea/vomiting in 3 vaccine recipients & fever in 1 placebo recipient)

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Summary of Moderna COVID-19 Vaccine

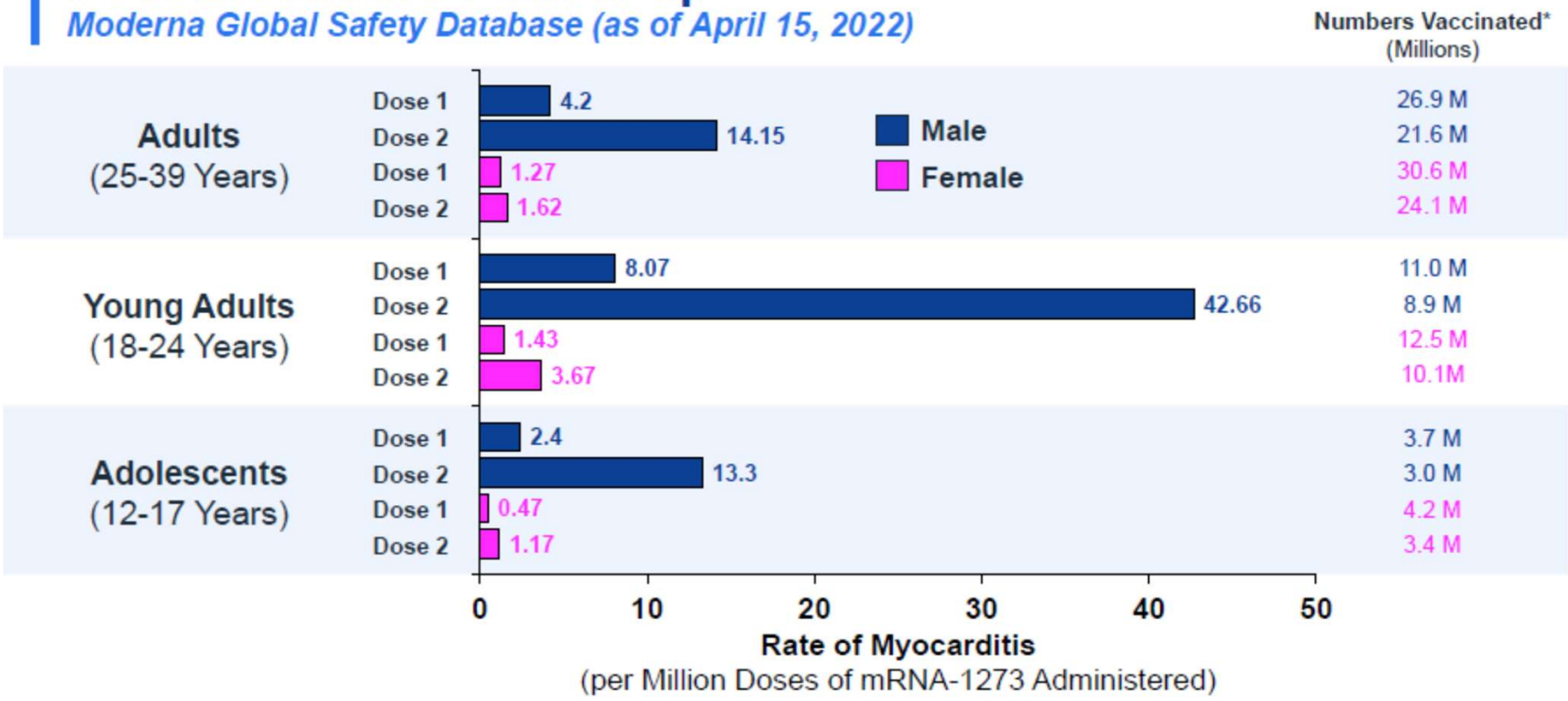
Study 203: Adolescents (12-17 Years)

Safety (Primary Endpoint)	▪ mRNA-1273 was well tolerated ▪ Solicited adverse reactions mostly grade 1-2, median duration of 2-3 days ▪ No SAEs reported within 28 days were considered vaccine-related ▪ No deaths, myocarditis/pericarditis through 11.1 months median follow-up
Immunogenicity (Primary Objective)	▪ Co-primary immunogenicity objectives met for 2-dose primary series ▪ GMTs and seroresponse rates non-inferior to young adults (18-25 years) ▪ GMT Ratio = 1.1; Difference in seroresponse rate 0.2% ▪ Vaccine effectiveness successfully inferred based on immunobridging
Efficacy (Secondary Objective)	▪ 93.3% - 100% vaccine efficacy of mRNA-1273 against COVID-19 infection Efficacy data is pre-Omicron for this study

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Myocarditis Reporting Rates with mRNA-1273 in Post Licensure Follow-up

Moderna Global Safety Database (as of April 15, 2022)



*Numbers vaccinated estimated from April 15, 2022 Moderna Bi-Monthly Summary Safety Reports

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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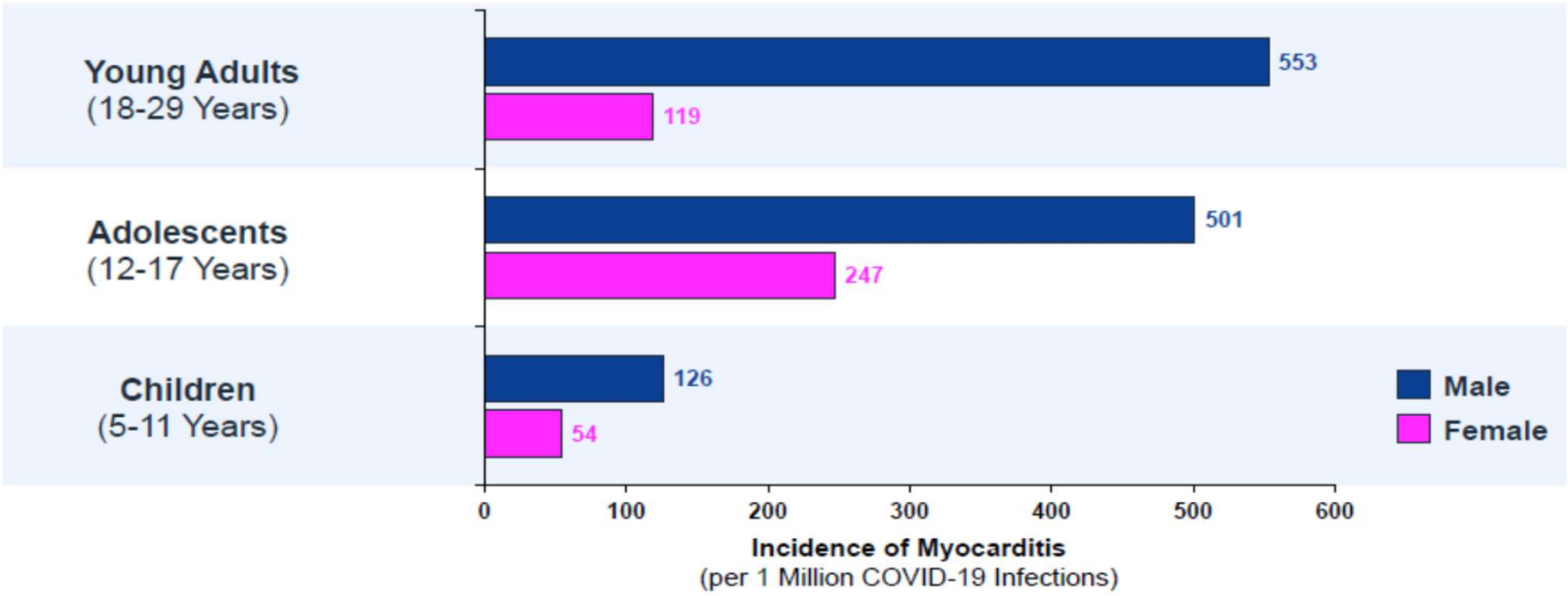
Myocarditis Reporting Rates Associated with SARS-CoV-2 Infections

PCORnet United States, Jan 2021 – Jan 2022

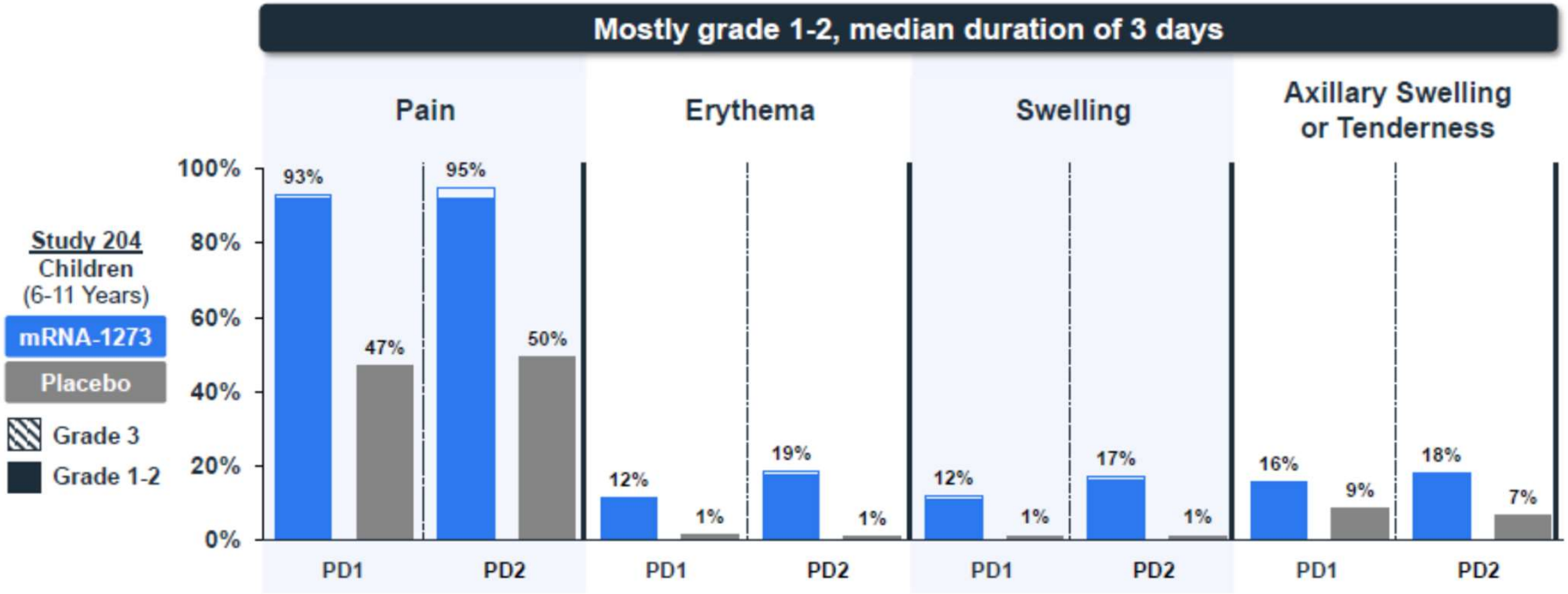


Block, J. P. et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022. Mmwr Morbidity Mortal Wkly Rep 71, (2022).

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Solicited Local Reactions within 7 Days After Dose 1 & 2

Study 204: Children (6-11 Years)



Solicited Safety Set; SARS-CoV2 negative at baseline; No Grade 4 local reactions reported

Creech et al., *NEJM*, 2022

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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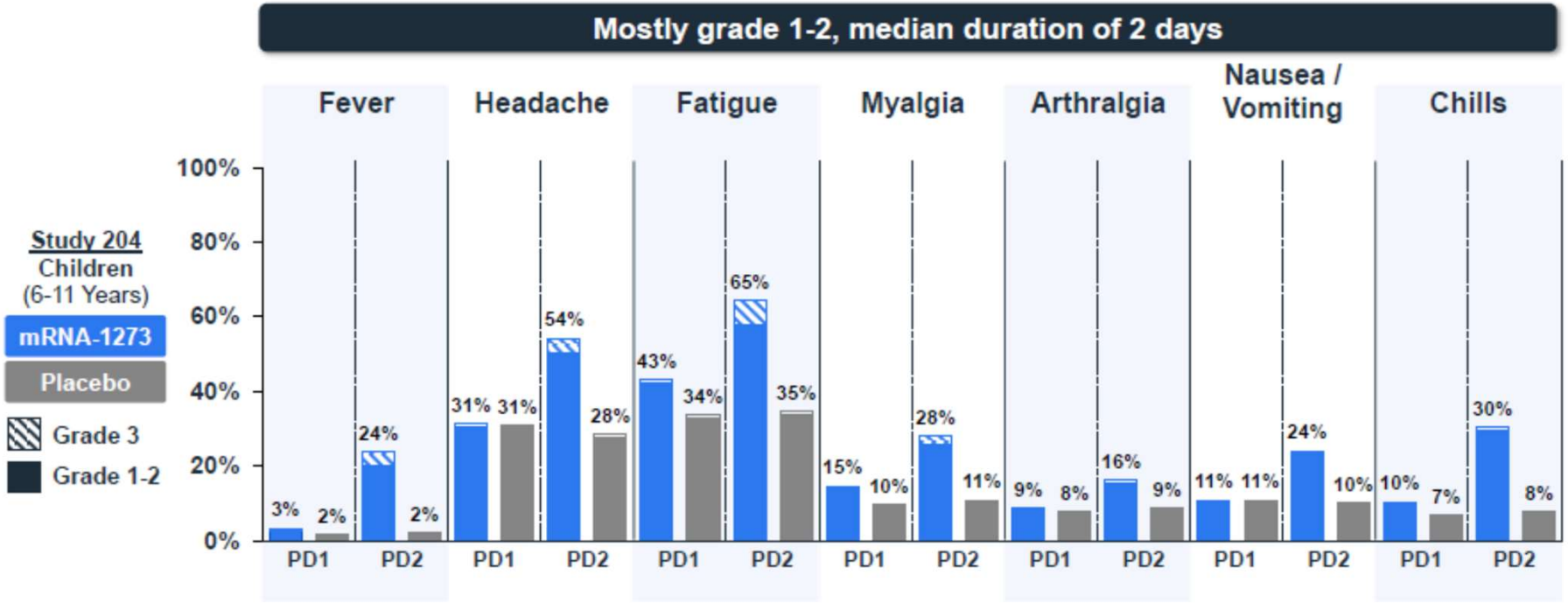
Solicited Systemic Reactions within 7 Days After Dose 1 & 2

Study 204: Children (6-11 Years)



Solicited Safety Set; SARS-CoV2 negative at baseline; No Grade 4 systemic reactions reported

Creech et al., *NEJM*, 2022

Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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Summary of Moderna COVID-19 Vaccine

Study 204: Children (6 - 11 Years)

Safety (Primary Endpoint)	▪ mRNA-1273 was well tolerated ▪ Solicited adverse reactions mostly grade 1-2, median duration of 2-3 days ▪ No related SAEs within 28 days ▪ No deaths, myocarditis/pericarditis through 5.6 months of follow-up
Immunogenicity (Primary Objective)	▪ Co-primary immunogenicity objectives met for 2-dose primary series ▪ GMTs and seroresponse rates non-inferior to young adults (18-25 years) ▪ GMT Ratio = 1.2; Difference in seroresponse rate 0.1% ▪ Vaccine effectiveness successfully inferred based on immunobridging
Efficacy (Secondary Objective)	▪ 88% - 92% vaccine efficacy against COVID-19 infection (mITT1)

Efficacy data is pre-Omicron for this study

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Miller J. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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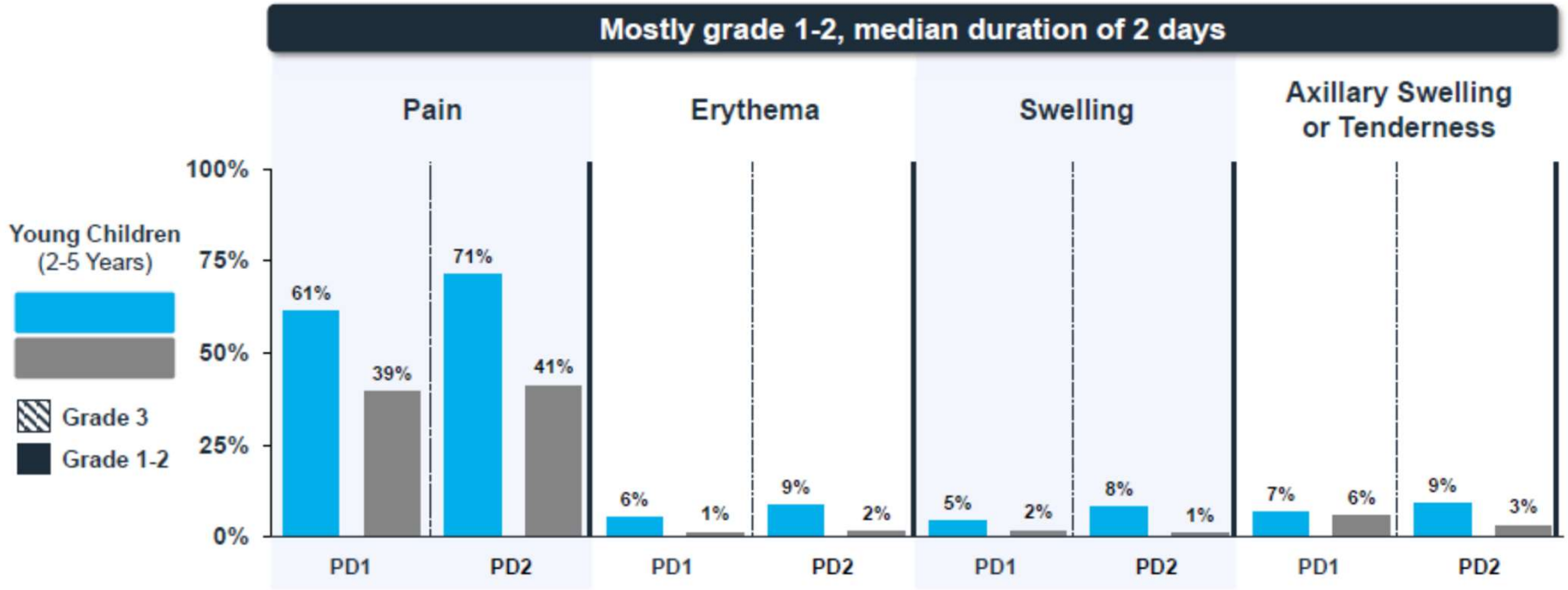
Solicited Local Reactions within 7 Days After Dose 1 & 2

Study 204: Young Children (2-5 Years)



Solicited Safety Set; No Grade 4 events reported

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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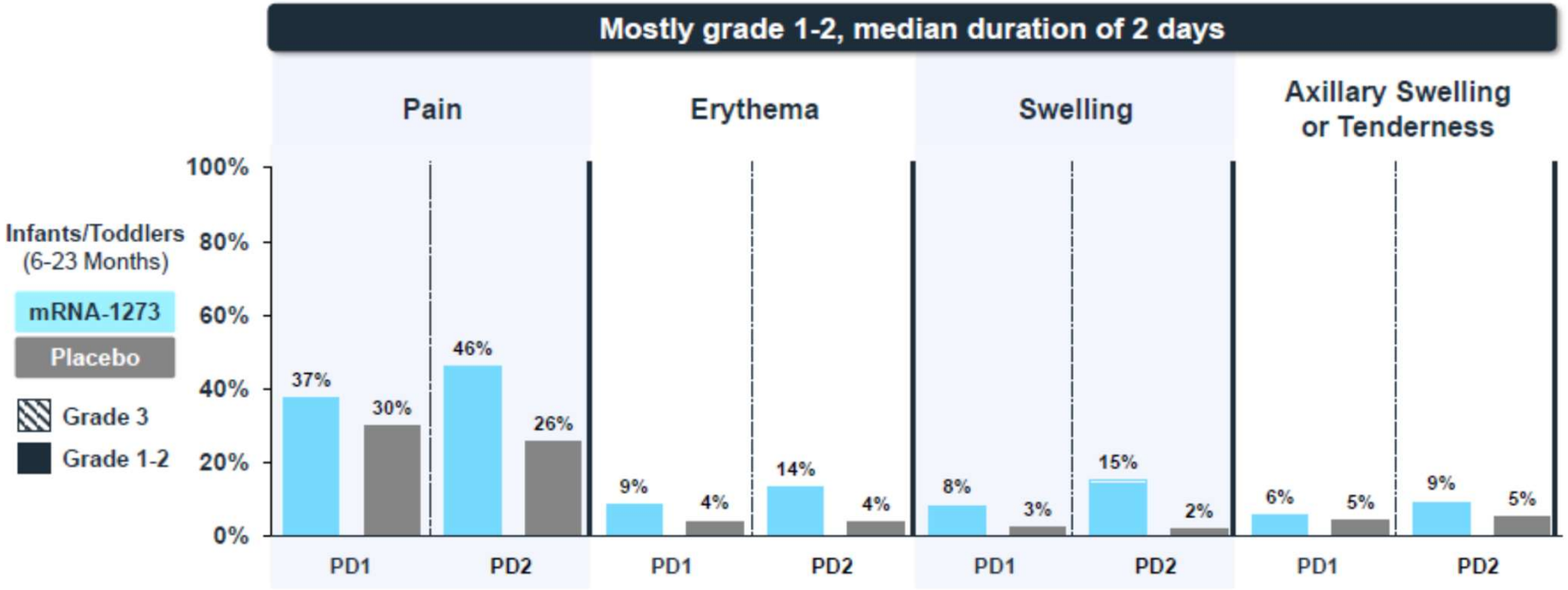
Solicited Local Reactions within 7 Days After Dose 1 & 2

Study 204: Infants & Toddlers (6-23 Months)



Solicited Safety Set; No Grade 4 events reported

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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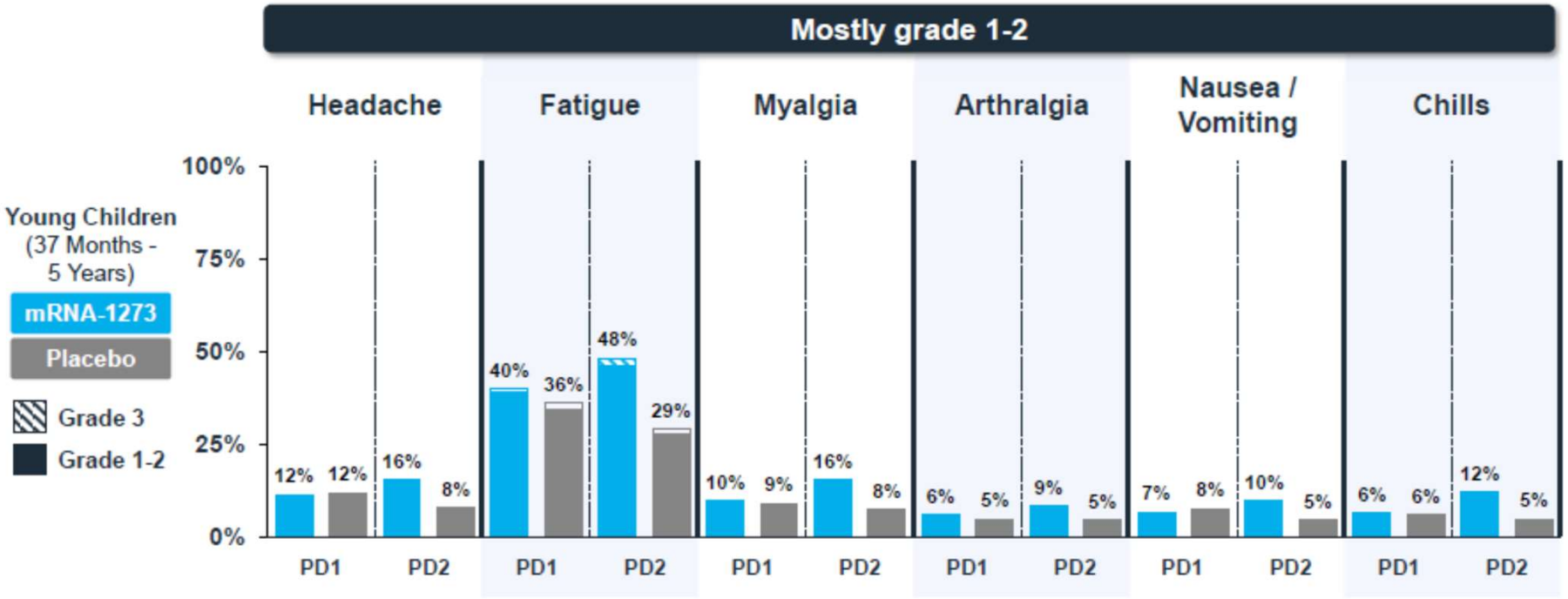
Solicited Systemic Reactions within 7 Days After Dose 1 & 2

Study 204: Young Children (37 Months -5 Years), Pediatric Toxicity Scale



Solicited Safety Set; No Grade 4 events reported except fever (next section)

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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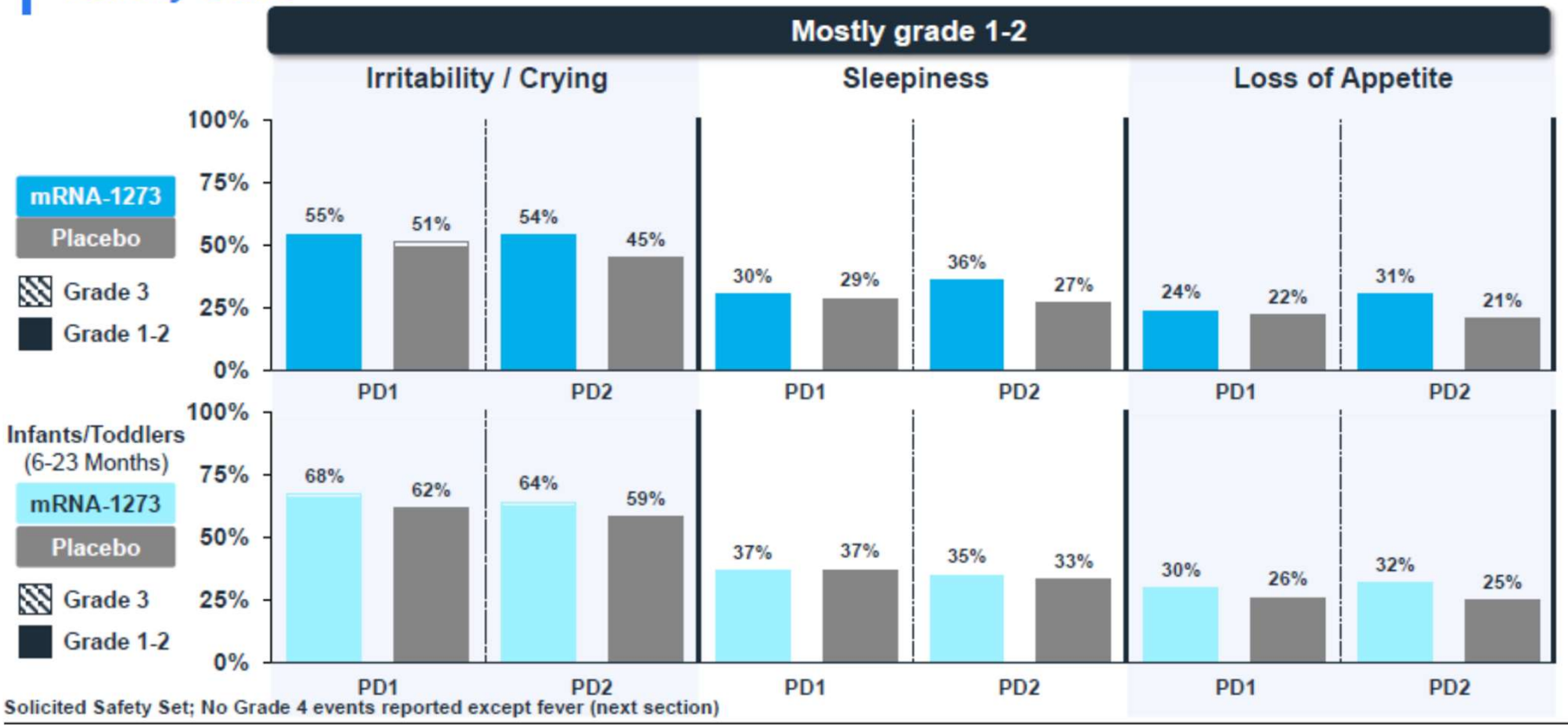
Solicited Systemic Reactions within 7 Days After Dose 1 & 2

Study 204: Infants/Toddlers (6-23 Months) & Toddlers (24-36 Months), Infant/Toddler Toxicity Scale



Solicited Safety Set; No Grade 4 events reported except fever (next section)

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Time to Onset of Reported Febrile Seizures

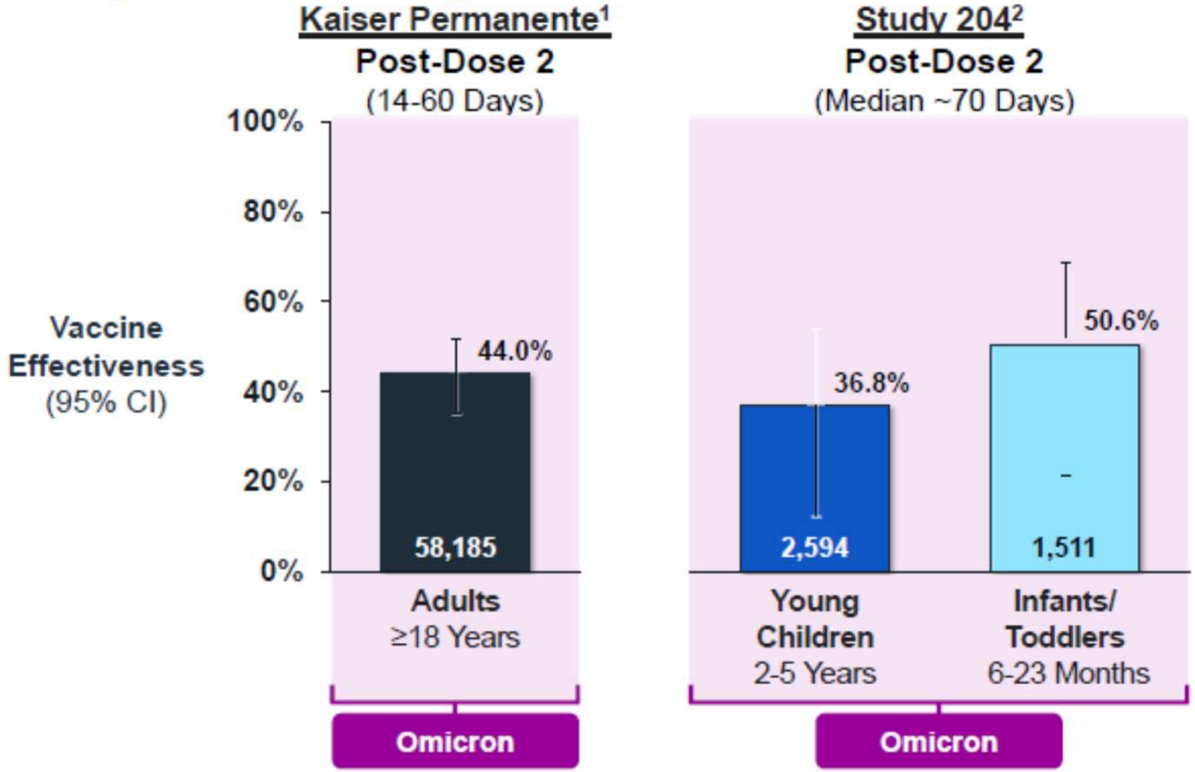
Study 204: Infants/Toddlers (6-23 Months)

Age	Gender	Time to Onset	Related per Investigator	Concurrent AEs
17 months	Female	2 days PD1	Yes	Fever to 103.1°F, maculopapular rash on trunk 2 days post event*
16 months	Male	10 days PD2	No	Fever to 102.2°F; maculopapular rash on trunk, urticaria bilateral cheeks, URI, bilateral otitis media
19 months	Male	21 days PD2	No	Fever to 101°F, diagnosed with Periodic Fever, Aphthous Stomatitis, Pharyngitis, Adenitis Syndrome (PFAPA) after data cut
17 months	Female	66 days PD2	No	Fever to 101.5°F, considered likely viral by ER physician

*Post 21Feb 2022 data cut this child experienced another febrile seizure ~6 weeks later; received Dose 2 with antipyretics – no events reported

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Real-World Effectiveness (Kaiser Permanente) Compared to Study 204 During Omicron Period



1. Tseng HF et al, 2022; Vaccine Effectiveness against infection
2. Study 204 – Vaccine Efficacy based on CDC Definition

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

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Summary of Moderna COVID-19 Vaccine

Study 204: Infants, Toddlers and Young Children (6 Months - 5 Years)

Safety (Primary Objective)	▪ mRNA-1273 was generally well-tolerated in this age group
	  ▪ Local and systemic reactions lower than older children and adults
	  ▪ Fever in ~25% of participants, mostly grade 1-2, short duration
	▪ 1 related SAE of fever/seizure within 28 days

Immunogenicity (Primary Objective)	▪ Pre-specified immunogenicity objectives met
	▪ Vaccine immunogenic, GMCs and seroresponse rates non-inferior to young adults
	  ▪ *Children (2-5 years):* GMC ratio 1.01 & difference in seroresponse rates -0.4
	  ▪ *Infants/Toddlers (6-23 months):* GMC ratio 1.28 & difference in seroresponse rates 0.7
	▪ Vaccine effectiveness successfully inferred based on immunogenicity

Efficacy (Secondary Objective)	▪ Demonstrated efficacy against COVID-19, 14 days after dose 2, during Omicron period
	  ▪ *Children (2-5 years):* 36.8% (CDC definition) & 46.4% (Study 301 definition)
	  ▪ *Infants/Toddlers (6-23 months):* 50.6% (CDC definition) & 31.5% (Study 301 definition)
	▪ Consistent with adult effectiveness against Omicron
	▪ Boosters are under evaluation

Das R. FDA meeting materials. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-14-15-2022-meeting-announcement#event-materials

Storage & Handling Moderna

	Future Moderna Product(s)
Age Indications	6 months through 17 years
Formulation	Primary Series Dose
Vial Cap Color/Label with Color Border	Blue cap, magenta label border
Preparation	Do Not Dilute
Dose Volume/Dose	6 m through 6 y: 0.25 mL/25 mcg 6 to 11 years: 0.50 mL/50 mcg 12 to 17 years 1.0 mL/100 mcg
Doses per Vial	6 months through 6 years: 10 6 to 11 years: 12 to 17 years
ULT Freezer (-90°C to -60°C)	DO NOT STORE
Freezer (-25°C to -15°C) [a]	Until Expiration
Refrigerator (2°C to 8°C)	30 Days
Room Temperature (8°C to 25°C) including any thaw time	24 hours
After First Puncture (2°C to 25°C)	Discard after 12 hours

[a] Regardless of storage condition, vaccines should not be used after the expiration date.

3 Doses is Probably in the Future for All

- Omicron is significantly more transmissible than prior variants
- In adult populations, 2 doses of current mRNA COVID-19 vaccines do not adequately neutralize Omicron
- A 3rd dose increases breadth of coverage and can neutralize Omicron
- Real-world data show that a 3rd dose significantly improves protection against Omicron-related symptomatic disease and severe illness
  - Admittedly we don't know for how long the 3rd dose works to protect against symptoms and severe illness but at least 6 months is likely
- Likely kids will require 3 doses whether Pfizer or eventually Moderna but for now Moderna is 2 doses

Cases


Questions?

Next Session: Tuesday, July 5th

For any questions, email us at
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I-VAC
ILLINOIS VACCINATES AGAINST COVID-19

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