



Atrium Health
Levine Children's

COVID 19 Update

UGGGHHHHH!

World

- 248.2 million cases
- 5.02 million deaths

United States

- 46.1 million cases
- 747,033 deaths

North Carolina

- 1.49 million cases
- 18,191 deaths
- 1194 currently hospitalized

South Carolina

- 721,558 cases
- 11,927 deaths
- 533 currently hospitalized

- **Cystic Fibrosis**

- **Cases:** 2,087

- **Adult:** 1406

- **Pediatric:** 681

- **Hospitalizations:** 301

- **Adult:** 243

- **Pediatric:** 58

- **Deaths:** 16

- **Vaccinations:** 10,456

- **Pediatric (12-16):** 903

COVID 19 Vaccination

- Overview of Vaccination Development:
 - **Phase I Trial:** designed to test vaccine safety, dose ranges may also be included (immunogenicity may also be measured)
 - **Phase II Trial:** expand safety profile and include immune response assessment performed in larger population
 - **Phase III Trial:** determine efficacy in preventing a predefined endpoint (randomized placebo control)

COVID 19 Vaccination

- Why so fast?!?
- Learning from SARS-CoV-1 and MERS-CoV
 - Preclinical studies performed
 - Large surface spike protein identified as a target
- Phase I and II & Phase II and III combined to seamlessly transition from one to the next

COVID 19 Vaccination

- Where are we today:
- BNT162b2 (Pfizer-BioNTech COVID-19 vaccine) is indicated for individuals aged 5 years or older.
 - Approved by FDA
- mRNA-1273 (Moderna COVID-19 vaccine) is indicated for individuals aged 18 years or older.
 - Granted EUA
- Ad26.COV2.S (Janssen COVID-19 vaccine) is indicated for individuals aged 18 years or older.
 - Granted EUA

History of COVID infection:

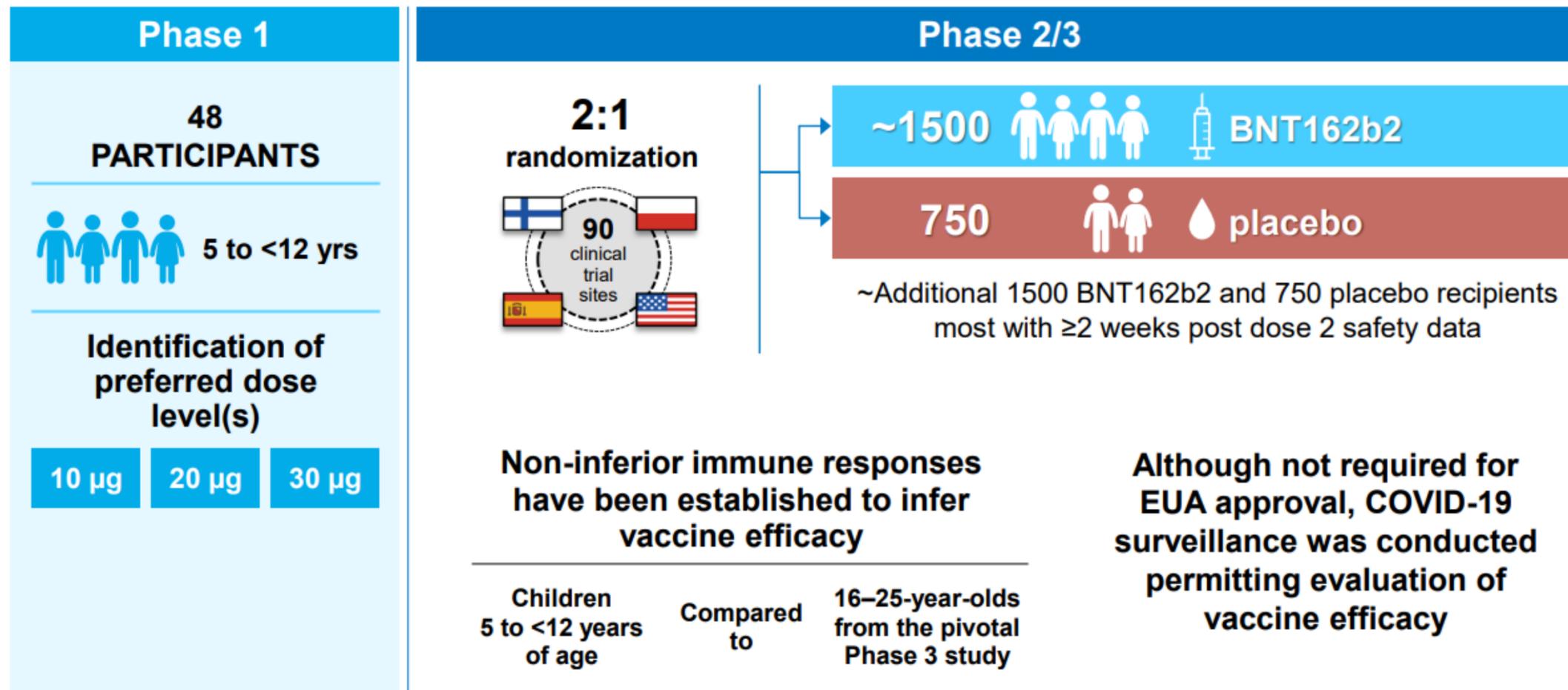
- Recommended to still receive COVID-19 vaccination
- If infection between doses
 - Recover from acute infection and met criteria for discontinuation of isolation before second dose
- If treated with monoclonal abs or convalescent plasma
 - Delay vaccination for 90 days

Immunocompromised individuals: (NOT CF)

- Certain populations may require third dose as part of initial series
- Limited role for post vaccination serology

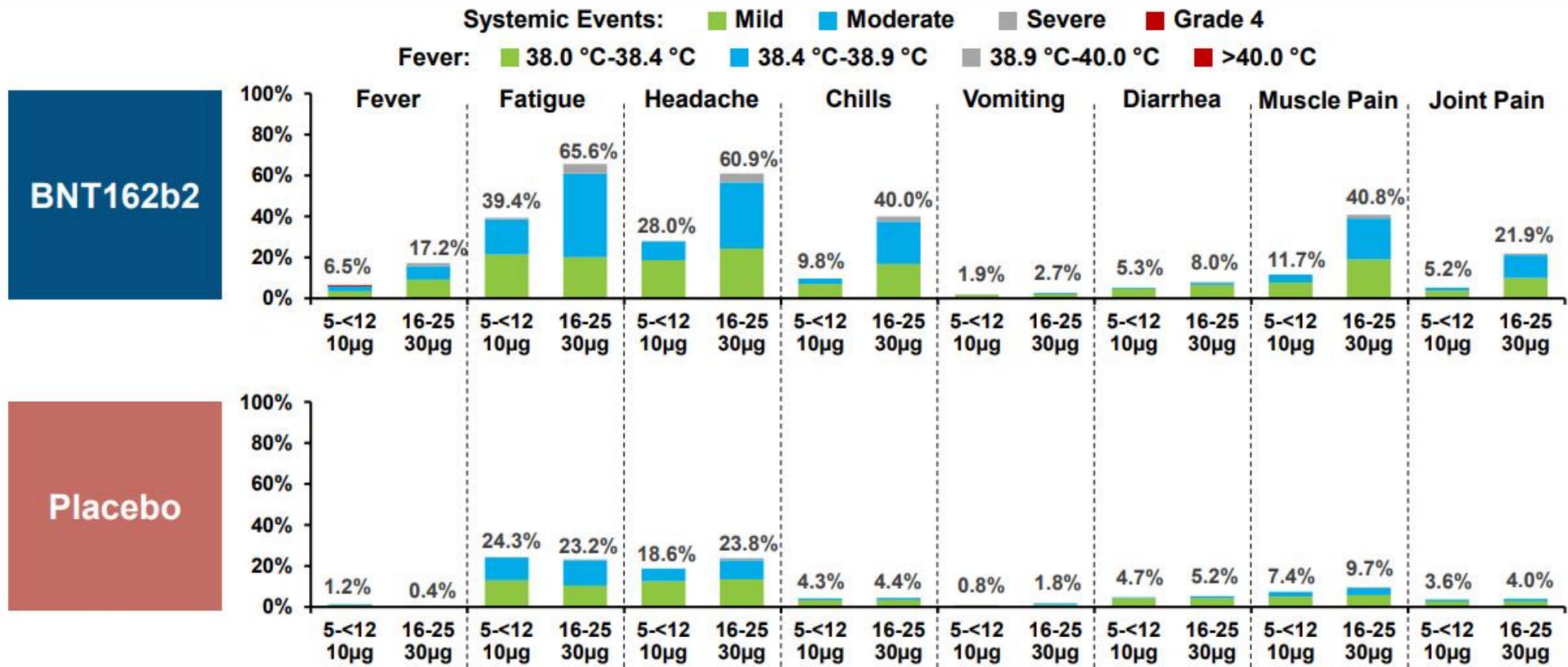
COVID 19 Vaccination - Kids

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



COVID 19 Vaccination - Safety

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



COVID 19 Vaccination - Safety

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

COVID 19 Vaccination - Efficacy

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

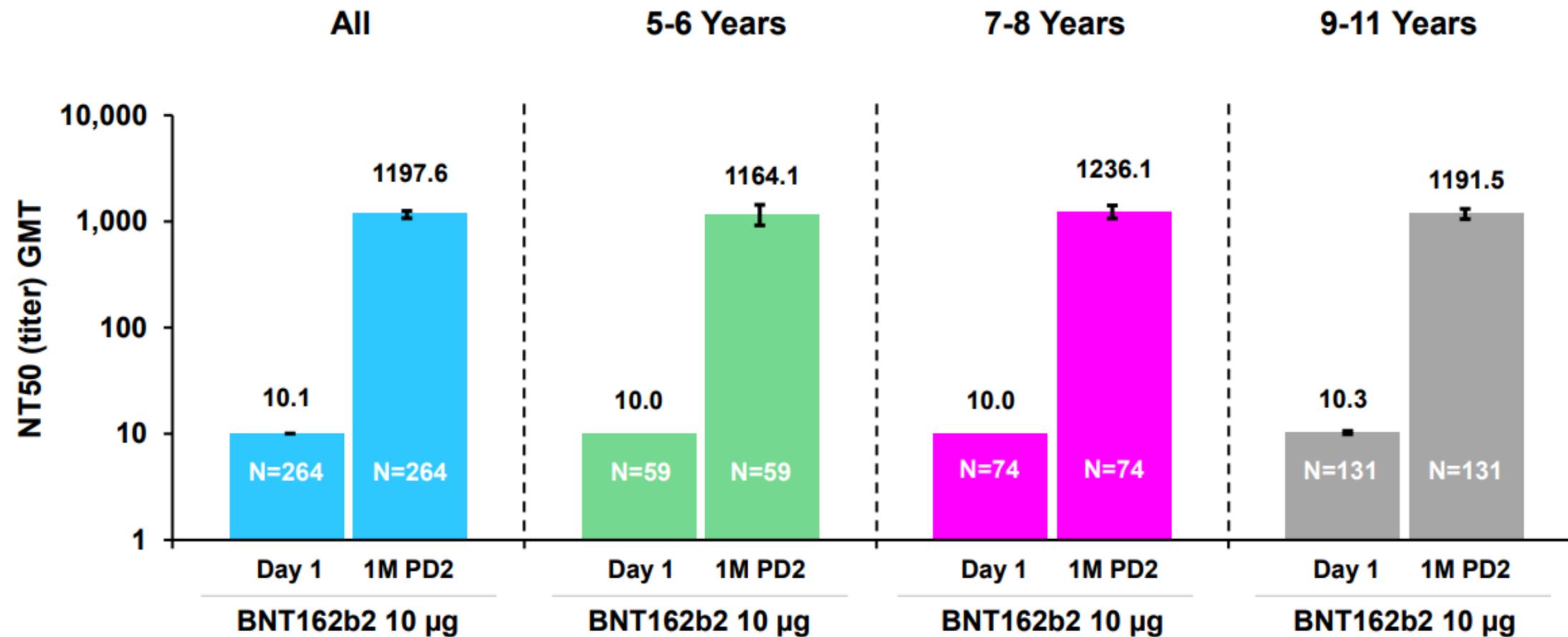
Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

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

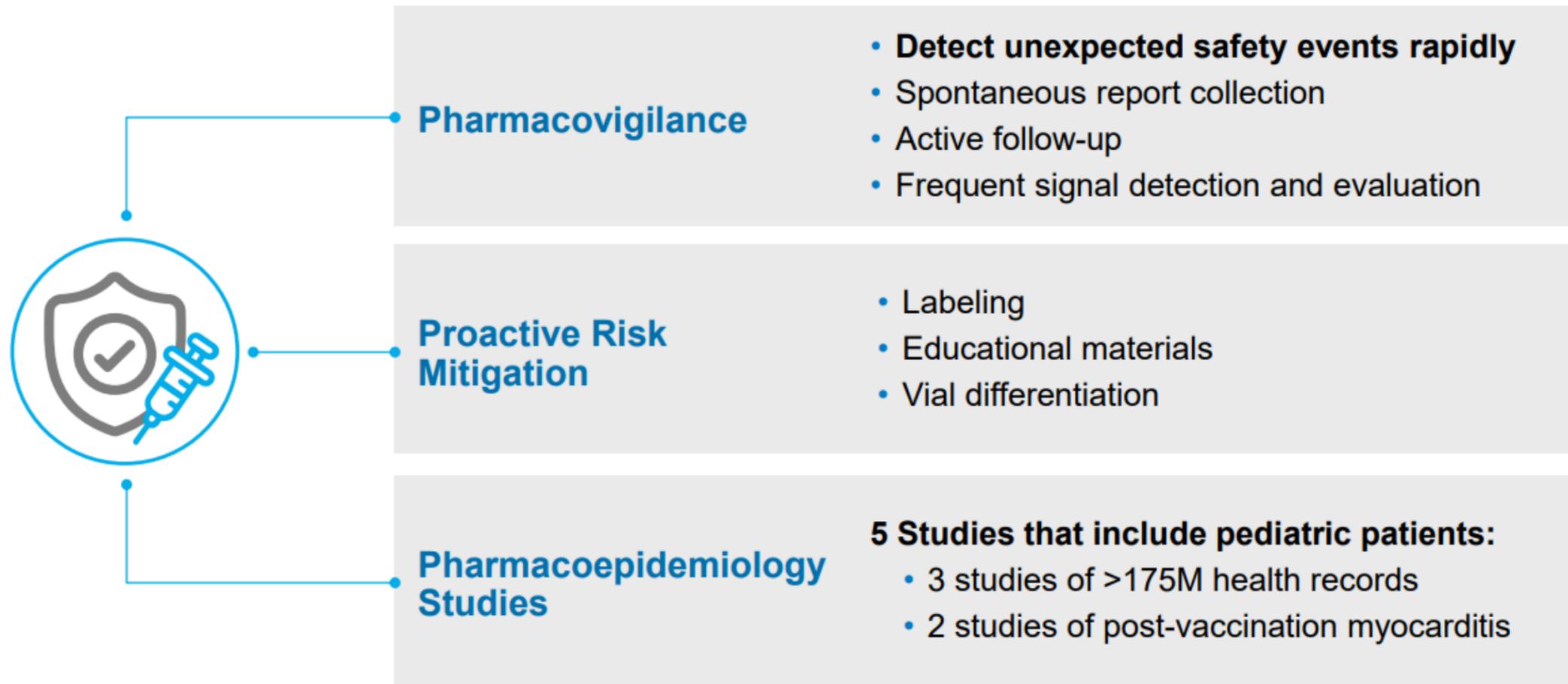
COVID 19 Vaccination - Efficacy

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



Ongoing Monitoring

Ongoing and Active Pharmacovigilance and Pharmacoepidemiology (Pediatric)



A Word About Myocarditis

Vaccine Adverse Event Reporting System (VAERS): Reporting rates (per 1 million doses administered) of myocarditis after mRNA COVID-19 vaccines, 7-day risk period

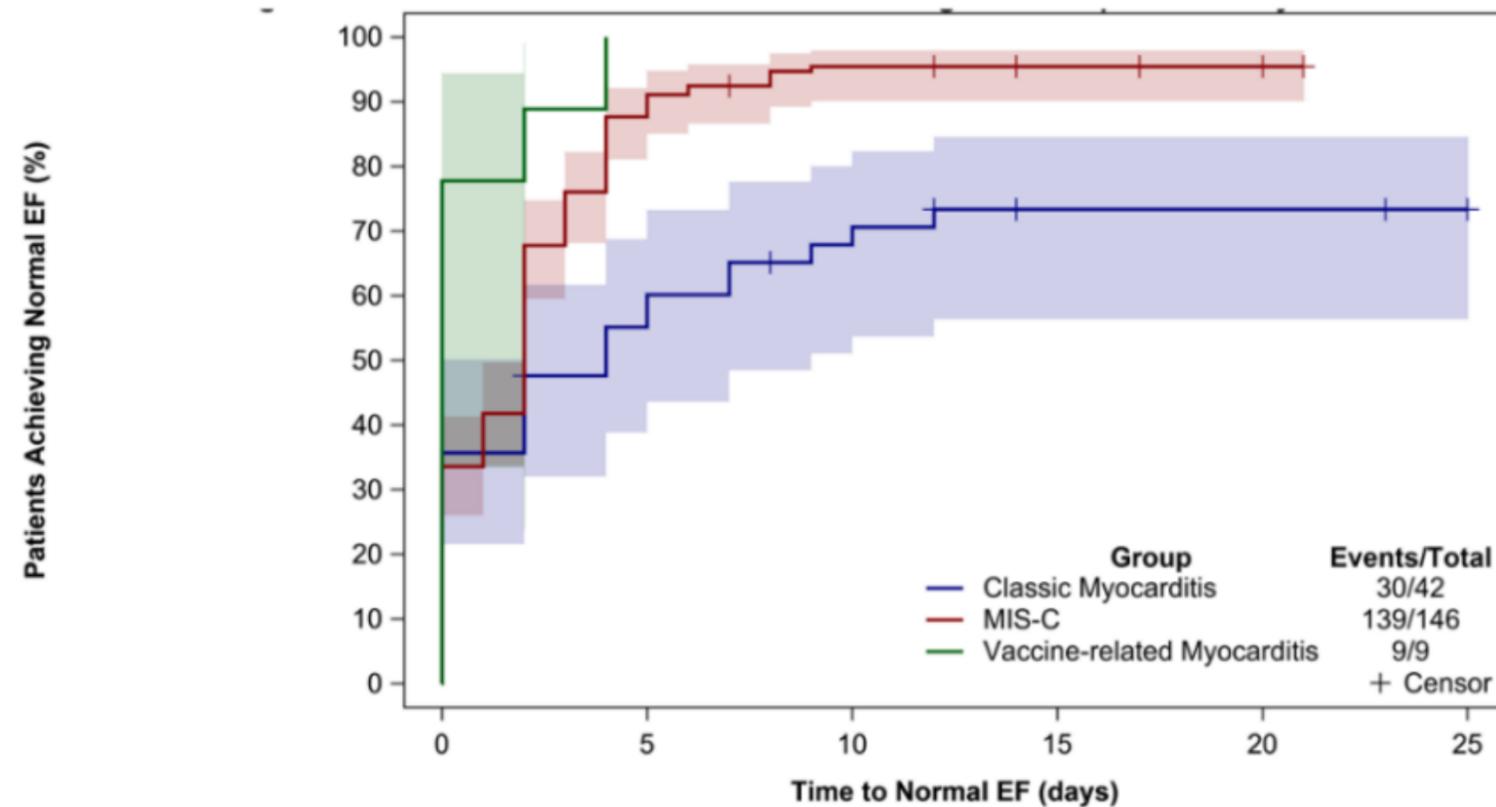
Reporting rates exceed
background incidence*

	Pfizer		Pfizer	
	(Males)		(Females)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9	0.4	3.9
16-17	5.7	69.1	0.0	7.9
18-24	2.3	36.8	0.2	2.5
25-29	1.3	10.8	0.2	1.2
30-39	0.5	5.2	0.6	0.7
40-49	0.3	2.0	0.1	1.1
50-64	0.2	0.3	0.3	0.5
65+	0.2	0.1	0.1	0.3

* 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**

A Word About Myocarditis

Comparing Types of Myocarditis: Time to Normal Ejection Fraction (EF) by Echocardiogram



	N at Risk					
	0	5	10	15	20	25
Classic Myocarditis-	42	16	10	6	6	5
MIS-C-	146	18	6	4	3	0
Vaccine-related Myocarditis-	9	0				



Patel et al. 2021

How do you get the vaccine?

- Patients 12yrs and older
 - Just about anywhere
- Patients 5-11 yrs old
 - Mecklenburg County Public Health
 - www.mecknc.gov/healthdepartment/clinicservices/pages/immunizations.aspx
 - 980-314-9400
 - Atrium Health
 - Primary Care Offices
 - Dosing now with scheduled appts.
 - Starting next week will be live for vaccine appt scheduling
 - Mass Events:
 - Concord – Piedmont Peds
 - Ballentyne – Providence Peds
 - 11/13/21 – 12/04/21
 - Mt Island – Mt Island Peds
 - Matthews – Charlotte Peds
 - 11/20/21 – 12/11/21

QUESTIONS?



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