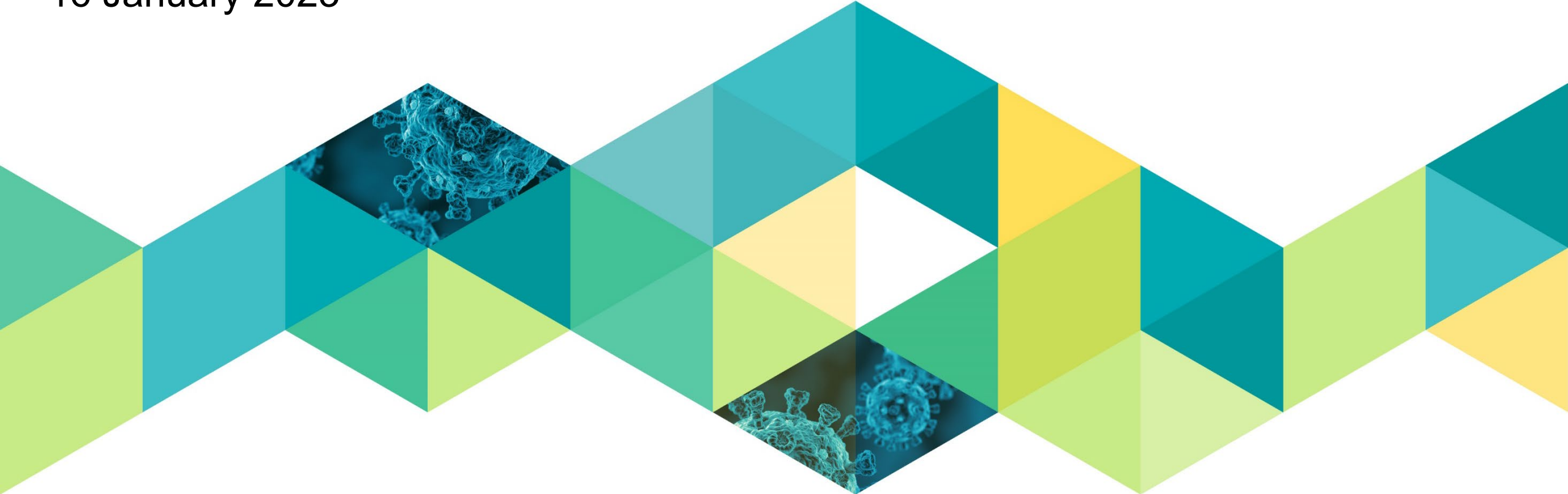


COVID-19 Vaccine BNT162b2 Myocarditis

16 January 2023



Important Disclaimer:

*The information in these slides and discussed during the presentation constitutes **proprietary information** of BioNTech and Pfizer and should not be copied or distributed by any third party without BioNTech and Pfizer's explicit approval.*

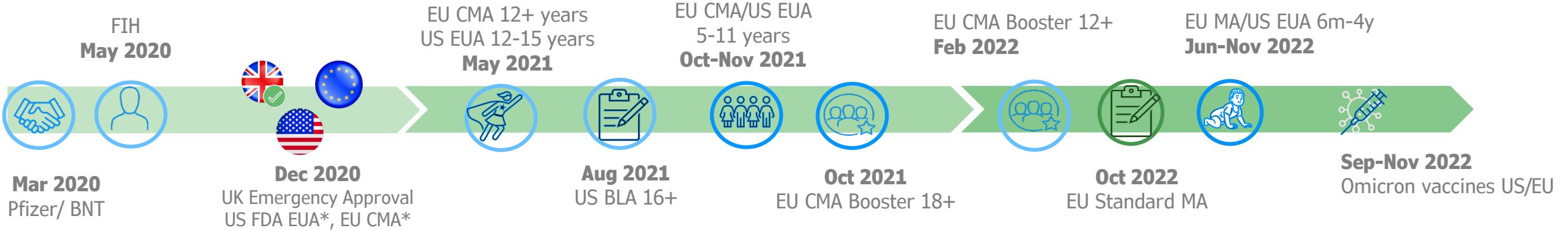
*In addition, the information contained in this document, including scientific approaches, assumptions regarding potential safety and efficacy, clinical trial and manufacturing plans and timing estimates, **are subject to change** based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks.*

There may be country specific regulations and considerations in your market.



A Lightspeed Journey 2020-2022


**More than
3.6B**
doses shipped to
180 countries and
territories to date⁽⁵⁾



 **46,000** participants  **150** sites  **6** countries... in only **4** months. 

FIH (First in Human); CMA (Conditional Marketing Authorization); EUA (Emergency Use Authorization); BLA (Biologics License Application); (5) From December 2020



**Post-Marketing
Safety
Surveillance**



Individual AE assessment

Aggregate safety reports

Signal and benefit risk management

COVID-19 Vaccine BNT162b2 Myocarditis (1)

Interventional clinical trials

In Pfizer-run clinical trials to support licensure, myocarditis and pericarditis were reported infrequently. Due to the cross-over design of clinical trials, the actual incidence of myocarditis cannot be reliably estimated.

The low number of study cases preclude any firm or statistically powered conclusions regarding factors that could have contributed to the event. There are no endomyocardial biopsies from confirmed study cases of myocarditis.

Epidemiology studies

Overall, in aggregate, studies report higher risk after Dose 2 compared to Dose 1, and among younger males compared to older males or females of any age post-vaccination. Reported risk was lower for individuals 5-11 years, higher for 16-19 years, and generally declining thereafter with age.

Reported risk for myocarditis after COVID-19 infections is substantially higher when compared with reported rates for individuals without COVID-19 infection or after vaccination.

COVID-19 Vaccine BNT162b2 Myocarditis (2)

Post-marketing safety data

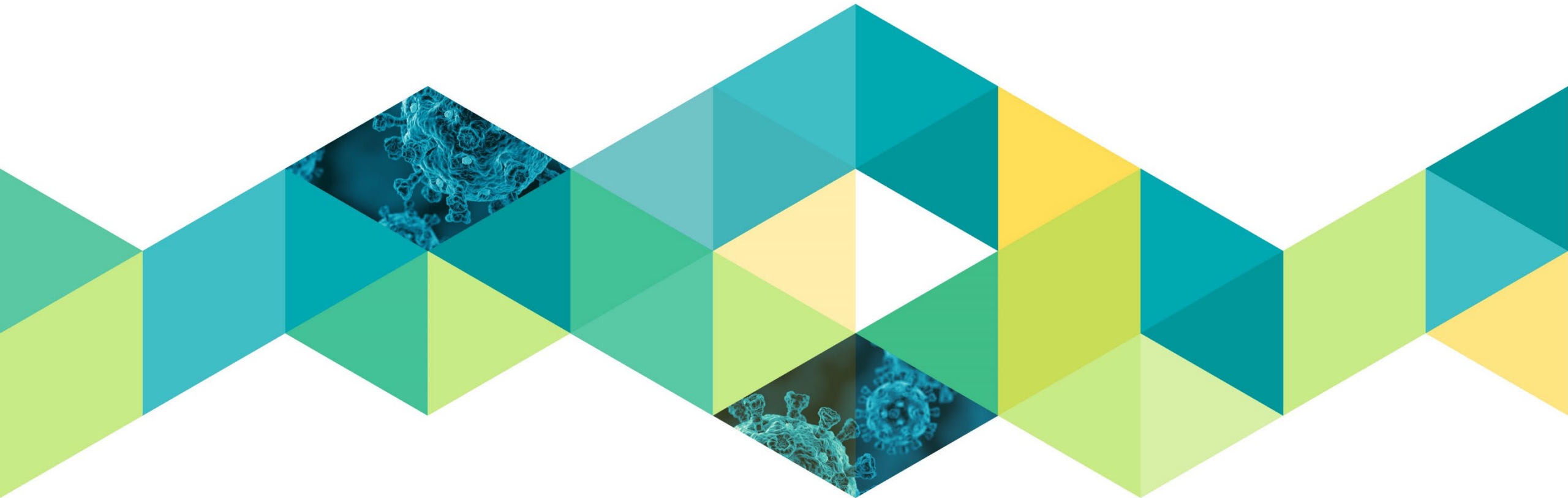
To date, the review of the post-marketing cases of myocarditis found that although the number of cases increased as vaccine exposure increased (ie, the number of vaccinated individuals), the profile of cases remained largely unchanged.

Most often, cases are reported in young males and with the second dose and report a mild and uneventful clinical course with prompt recovery.

Accumulating reports on longer term outcomes (3-6 months) confirm clinical recovery and absence of recurrences/complications.

CCI

MAH Post Authorization Safety Studies and the Evaluation of Myocarditis/Pericarditis and other Cardiovascular Events



MAH Real World Safety Studies are adaptable, comprehensive and scientifically robust to evaluate myocarditis/pericarditis

- Myocarditis/pericarditis has been reported following vaccination with mRNA vaccines, including COMIRNATY.
- In addition to following up on any clinical and spontaneously reported cases of myocarditis/pericarditis, we are conducting several large, retrospective database studies that assess vaccine safety including myocarditis/ pericarditis since EUA in each age group.
- These studies take time to accrue sufficient data to be informative given rarity of event

MAH Real World Safety Studies are adaptable, comprehensive and scientifically robust, and include **primary** and **secondary** data collection studies in the **US** and **Europe** to evaluate myocarditis/pericarditis

HERO-
Together

Harvard
Pilgrim

VAXPATH

DOD
Study

VHA
Study

VAC4EU
Study

PHN
Study

Natural
History
Substudy

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Low Interventional Cohort Study of Myocarditis/ Pericarditis Associated with COMIRNATY in Persons Less than 21 Years of Age

- **Objectives:**
 - To characterize hospital course, long term sequelae, risk factors and quality of life in children and young adults <21 years old who develop post-vaccine myocarditis/pericarditis
 - To compare long-term cardiac outcomes of post-vaccine myocarditis/pericarditis with those of myocarditis/pericarditis associated with Multi-system Inflammatory Syndrome in Children (MIS-C) in children and young adults <21 years old
- **Setting:** NIH-funded Pediatric Heart Network clinical centers in US and Canada
- **Study Design:** Low-interventional cohort study
- **Participants:** All persons < 21 years of age who receive care at one of the centers associated with the Pediatric Heart Network and who meet study inclusion criteria
- **Study Period:** Enrollment for 2 years and follow up for up to 5 years after enrollment



About the Pediatric Heart Network

A consortium of leading hospitals conducts research in children and families living with congenital heart disease, adults living with congenital heart disease, and children affected by acquired heart disease.

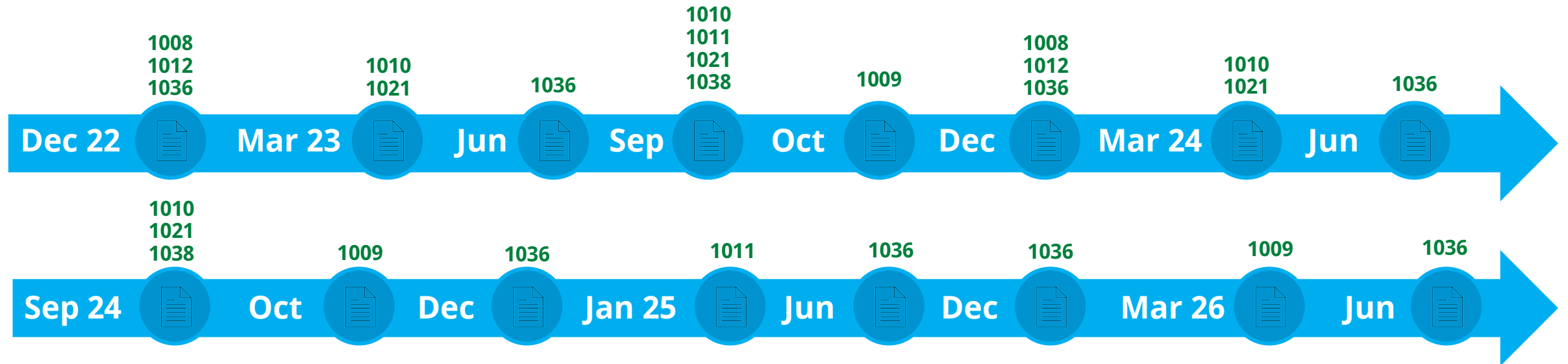
Created and funded since 2001 by the National Heart, Lung and Blood Institute (NHLBI)

Next steps: MAH Pharmacoepidemiologic Safety Strategy evolves to meet emerging demands

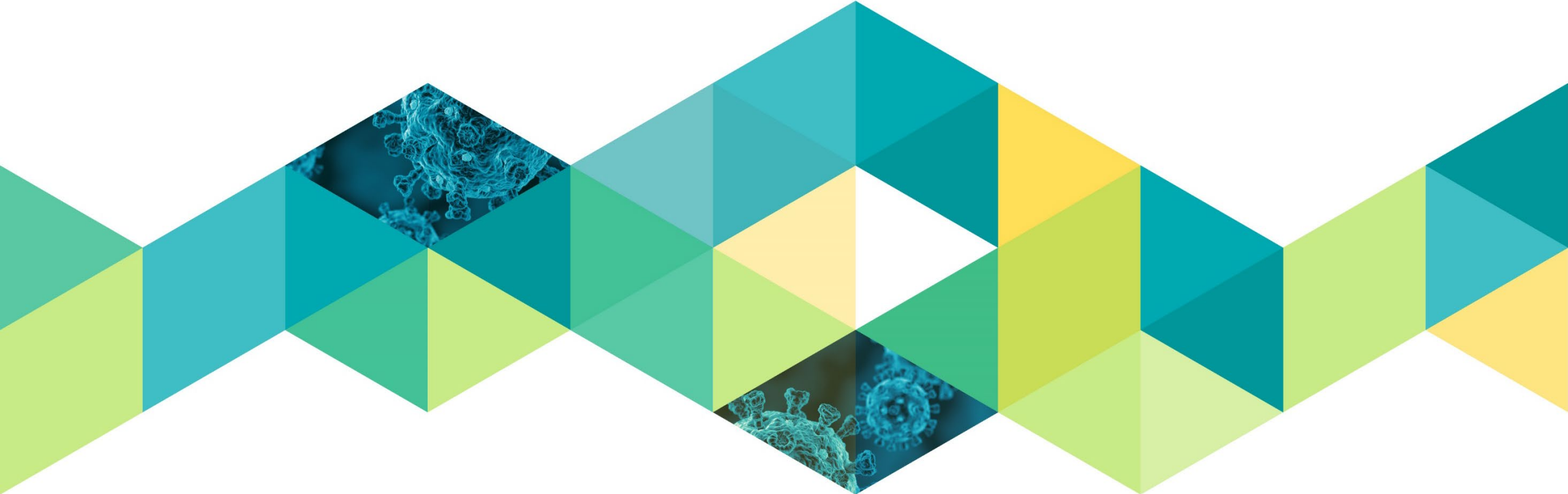
The following activities are already underway to:

- Evaluate the magnitude of risk, risk factors, impact on quality of life and long-term sequelae associated with post-vaccine myocarditis/pericarditis in the real world
- **Results from Post-Authorization Safety Studies (PASS) inform data derived from planned and ongoing clinical trials and other externally conducted epidemiologic studies**
- Existing work becomes the infrastructure for future vaccine safety surveillance needs

Next milestones:



Back up slides



Study ID	Study Population	Study Size	Data Source	Region
C4591008	Health care workers, their families, and their communities	20,000 participants	Primary data collection	US
C4591009	Commercially insured in general population	Vaccinees among >77 million members	Sentinel System	US
C4591010	General population	10,000 participants	Primary data collection	Italy, Spain, Germany
C4591011	Active military and families with EHR	Vaccinees among 10 million members	Department of Defense	US
C4591012	Patients in VA system with EHR	Vaccinees among >18 million members	Veteran's Health Administration	US
C4591021	General population	Vaccinees among 38.9 million members	ACCESS/VAC4EU	Netherlands, Italy, Spain, UK, Norway
C4591036	Persons <21 years with post vaccination myocarditis/pericarditis	300 persons with myocarditis/pericarditis (200 vaccine associated and 100 COVID-19 associated)	Primary data collection within Pediatric Heart Network	US and Canada
C4591038	General population with myocarditis/pericarditis	Vaccinees among 38.9 million members	ACCESS/VAC4EU	Netherlands, Italy, Spain, UK, Norway