Arkansas Immunization Coalition

VACCINE SAFETY 2025:

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DISCLOSURES

- I have no financial disclosures or conflicts
- I have many biases, most relevant here:

  FOR Science

  FOR Patients

  AGAINST Mis- and disinformation

  AGAINST Spreading Mis- and disinformation
- My slides contain far too much text/information, lets have a conversation and use slides for reference

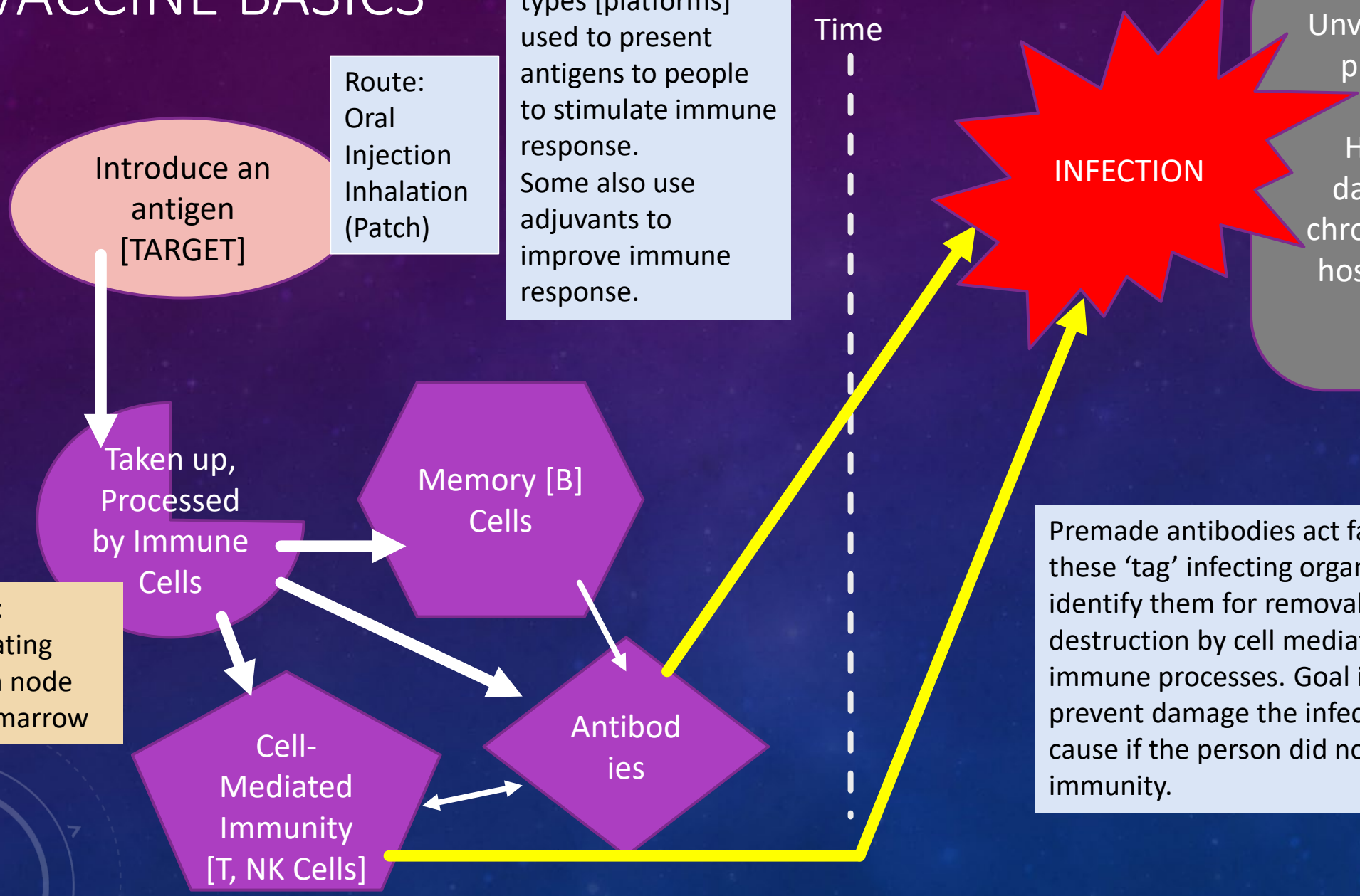
OUTLINE

- Vaccines, Vaccine development
- Vaccine Safety Process/Systems
- Vaccine Concerns and Evaluations

VACCINE BASICS

There are many different vaccine types [platforms] used to present antigens to people to stimulate immune response.
Some also use adjuvants to improve immune response.

Route:
Oral
Injection
Inhalation
(Patch)



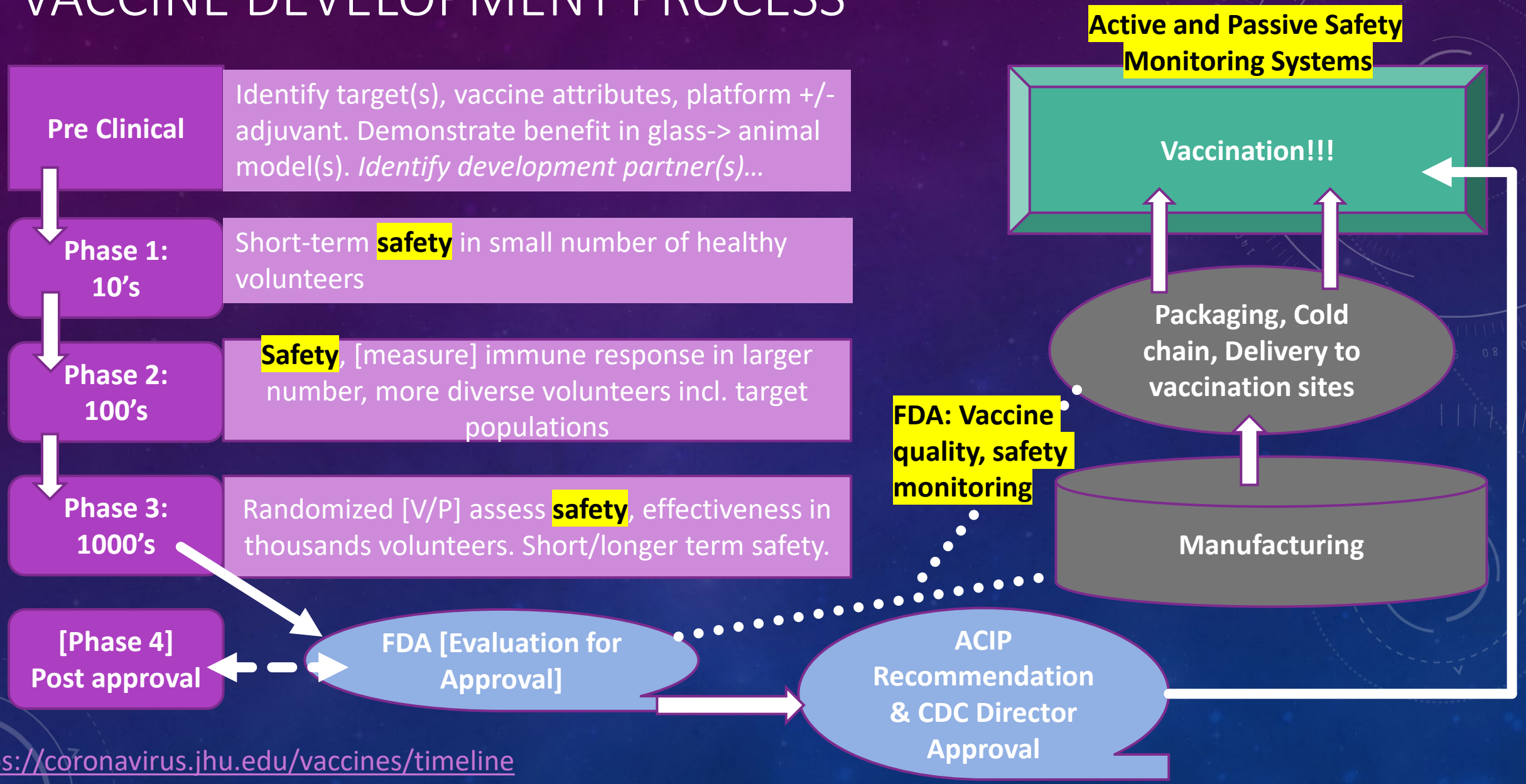
Where:
-Circulating
-Lymph node
-Bone marrow

Unvaccinated= little or no protective immunity:

Higher risk for organ damage, worsening of chronic health conditions, hospitalization, death or disability…

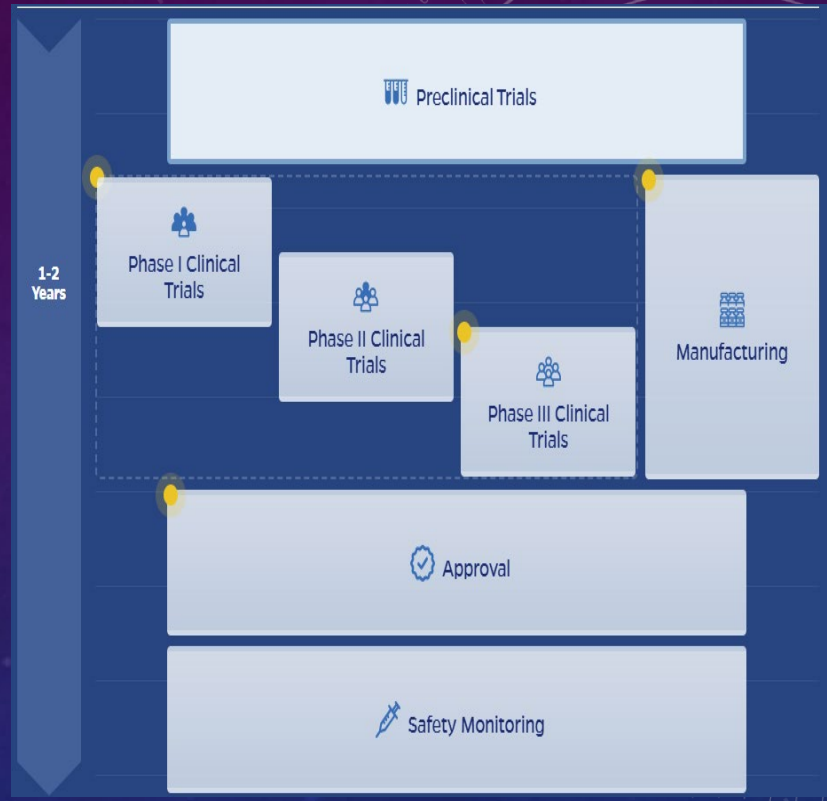
Premade antibodies act fastest- these 'tag' infecting organisms and identify them for removal and destruction by cell mediated immune processes. Goal is to prevent damage the infection could cause if the person did not have immunity.

VACCINE DEVELOPMENT PROCESS



https://coronavirus.jhu.edu/vaccines/timeline
https://www.cdc.gov/vaccines/media/images/2024/08/Vaccine-Safety-Process.png

VACCINE DEVELOPMENT TIMELINE



	Typical	Accelerated
• Preclinical Studies	1-10 years	months
• Phase 1 Studies	6 months	2-3 months
• Phase 2 Studies	2-3 years*	3-4 months
• Phase 3 Studies	2-4 years*	6-9 months (followup for 2+ years)
• Regulatory Approval	12 months+	simultaneous review with trials
• Scale-up, Mfg.	varies	simultaneous with trials [at risk]
• P-L Safety Monitoring	ongoing	ongoing

*Includes search for development partner, commercialization plan

https://coronavirus.jhu.edu/vaccines/timeline

VACCINE TRIALS AND ADVERSE EVENTS

- Trials commonly ask participants about a specific set of adverse events

  [solicited adverse events]
- AND usually include some form of a diary for reporting of any additional signs/symptoms reported at specific time points

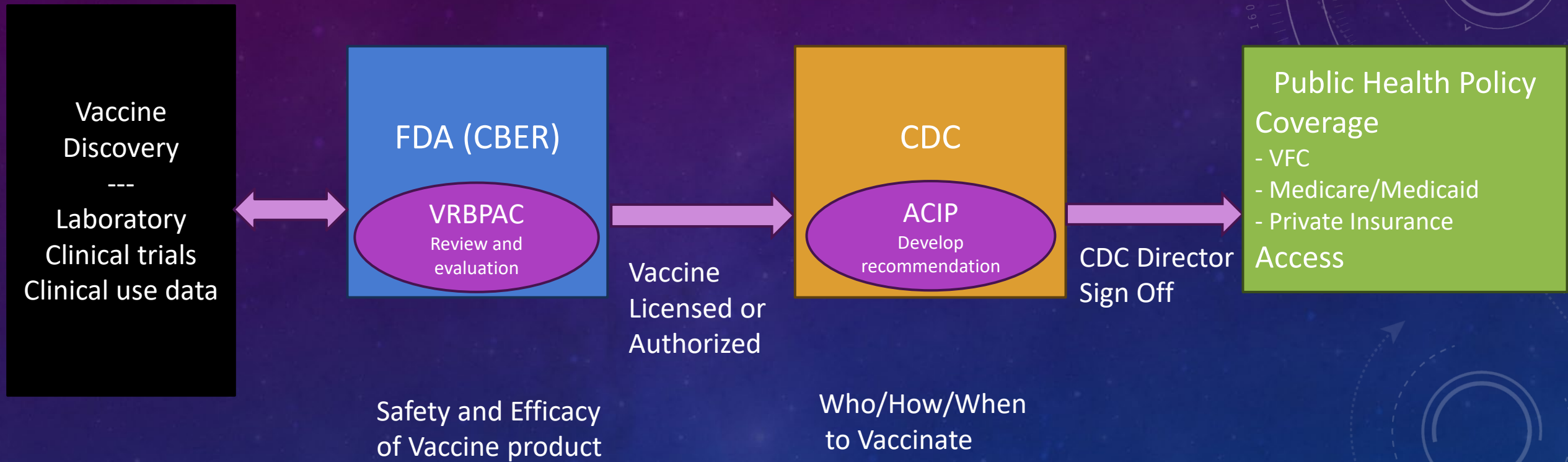
  [spontaneous reports or non-solicited adverse events]
- This is in addition to structured assessments by investigators + lab testing
- Data is reviewed by trial scientists, external data monitoring board, FDA/CBER staff

STANDARD DEFINITIONS [BRIGHTON COLLABORATION]

- Develops **structured case definitions** used in vaccine safety assessment through lifespan of vaccine from early phase trials through implementation/post-licensure evaluation.
  - Includes **specific elements which indicate level of diagnostic certainty** [1-3 levels, 1 =most]
  - Does NOT define severity
  - Does NOT define whether the case is vaccine related
  - **NOT intended to drive clinical care or medical followup**
- Adds diagnostic specificity which allows assessment of vaccine to be comparable by investigators across multiple settings and over time
- Developed for
  - AEFI [Adverse Events Following Immunization] and
  - AESI [Adverse Events of Special Interest]
- https://speacsafety.net/video-what-is-a-brighton-case-definition/ [Video about Brighton Case Definitions]

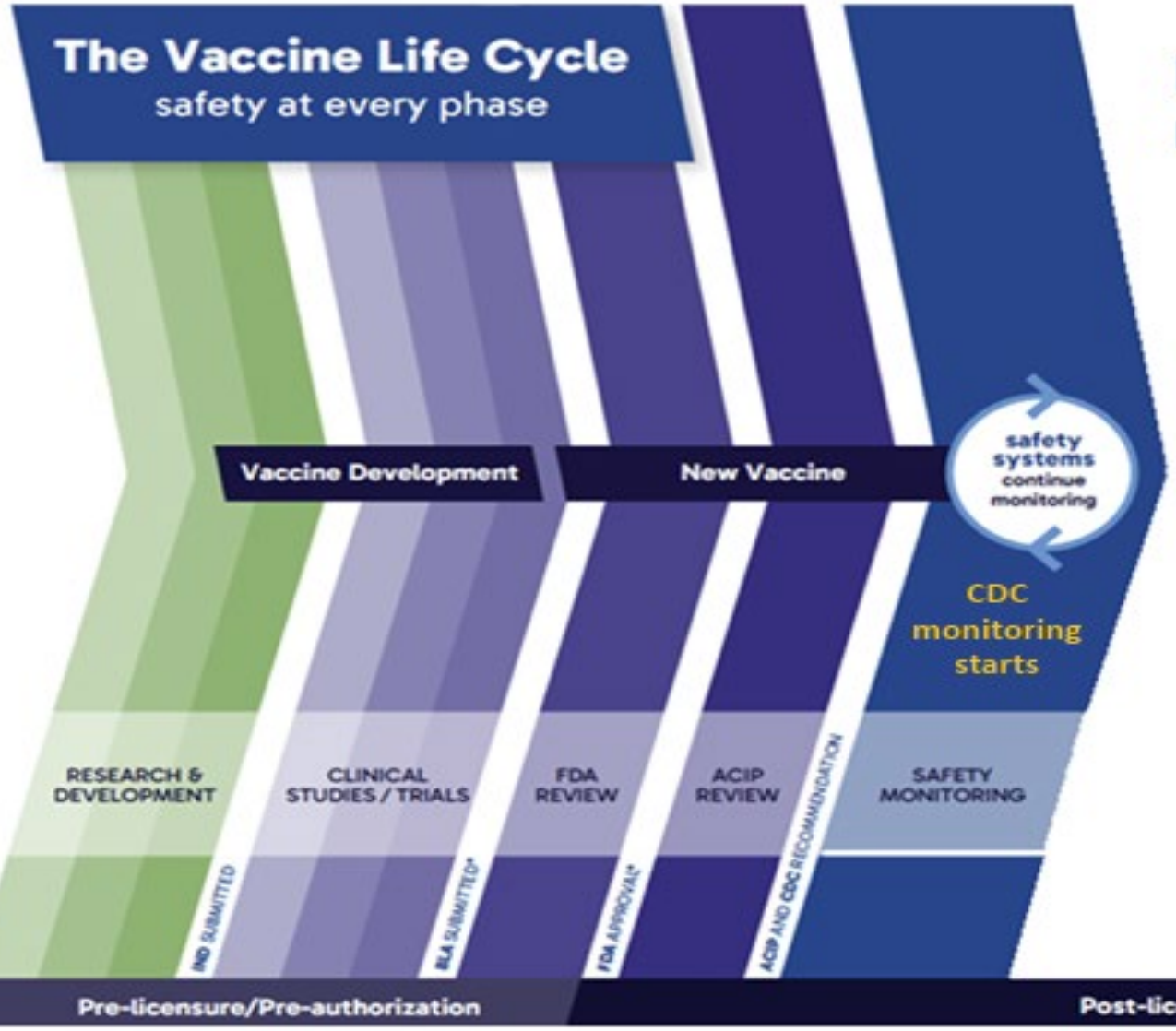
https://brightoncollaboration.org/our-work/

STANDARD VACCINE APPROVAL PROCESS



Modified from figure in https://www.nejm.org/doi/full/10.1056/NEJMsb2509134

VACCINE SAFETY PROCESS/SYSTEMS



Interagency collaboration to monitor post-licensure safety

CDC

FDA

INDIAN HEALTH SERVICE · PHS · 1955 ·

DEPARTMENT OF DEFENSE · UNITED STATES OF AMERICA

DEPARTMENT OF VETERANS AFFAIRS · UNITED STATES OF AMERICA

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

MANUFACTURING AND LOT/DOSE SAFETY

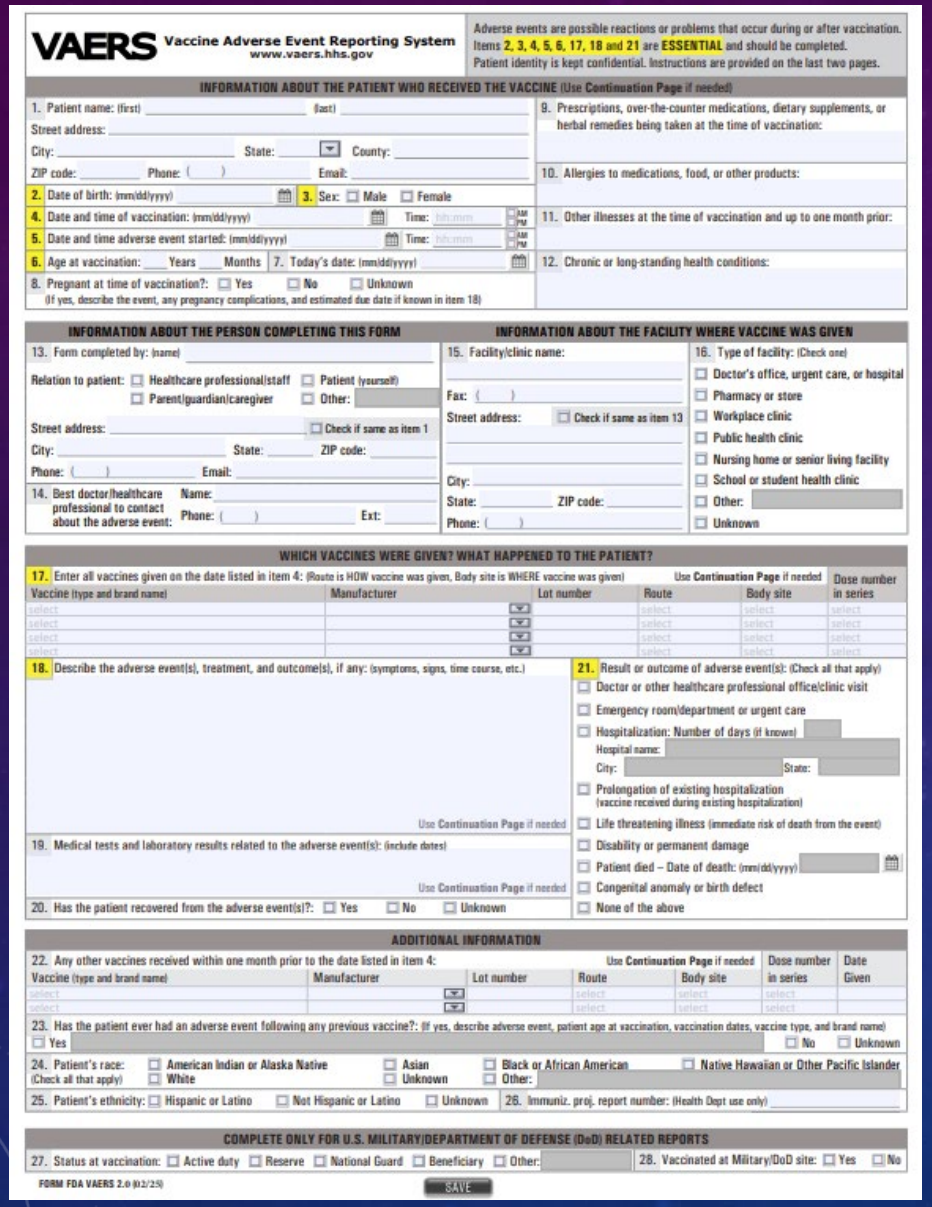
- FDA routinely inspects manufacturing facilities
- To assure safety and quality standards are met
- Manufacturers test every vaccine lot and submit samples to FDA for confirmatory testing to assure purity and potency are maintained
- FDA must approve each vaccine lot before it is released for use

VAERS: SIGNAL IDENTIFICATION

- Established 1990 and Co-Managed by CDC Immunization Safety Office and FDA
- ANYONE can report, structured reporting [next slide]
- PASSIVE reporting system, primary goals:
  - Detect new, unusual or rare adverse events after vaccination
  - Monitor change in rate of known adverse events [increase or decrease]
  - Identify potential patient risk factors for particular adverse events
  - Assess safety of newly licensed vaccines
  - Identify reporting clusters [suspect localized (time or geographic) issue with a lot or batch]
  - May identify ongoing safe-use or administration errors
  - Provides national 'snapshot' from entire US population [response to PH emergency]
- CANNOT determine causality but can assess reporting rates, identify signals or concerns
  - Standardized data reports provide a limited snapshot
  - No control population
  - Some capacity for review, limited by ability to contact event reporters, obtain medical records
  - Has been used as a starting point for followup studies [Myocarditis after C-19V]

https://pmc.ncbi.nlm.nih.gov/articles/PMC4632204/

VAERS REPORTING FORM



VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

1. Patient name: (first) (last)
Street address:
City: State: County:
ZIP code: Phone: ( ) Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: ☐ Male ☐ Female
4. Date and time of vaccination: (mm/dd/yyyy) Time: (hh:mm) AM PM
5. Date and time adverse event started: (mm/dd/yyyy) Time: (hh:mm) AM PM
6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy)
8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
Street address: ☐ Check if same as item 1
City: State: ZIP code:
Phone: ( ) Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name:
Phone: ( ) Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( )
Street address: ☐ Check if same as item 13
City:
State: ZIP code:
Phone: ( )

16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other:
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use Continuation Page if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use Continuation Page if needed

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply)
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room/department or urgent care
☐ Hospitalization: Number of days (if known)
Hospital name:
City: State:
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died – Date of death: (mm/dd/yyyy)
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
☐ Yes ☐ No ☐ Unknown

24. Patient's race: (Check all that apply) ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other:

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report number: (Health Dept use only)

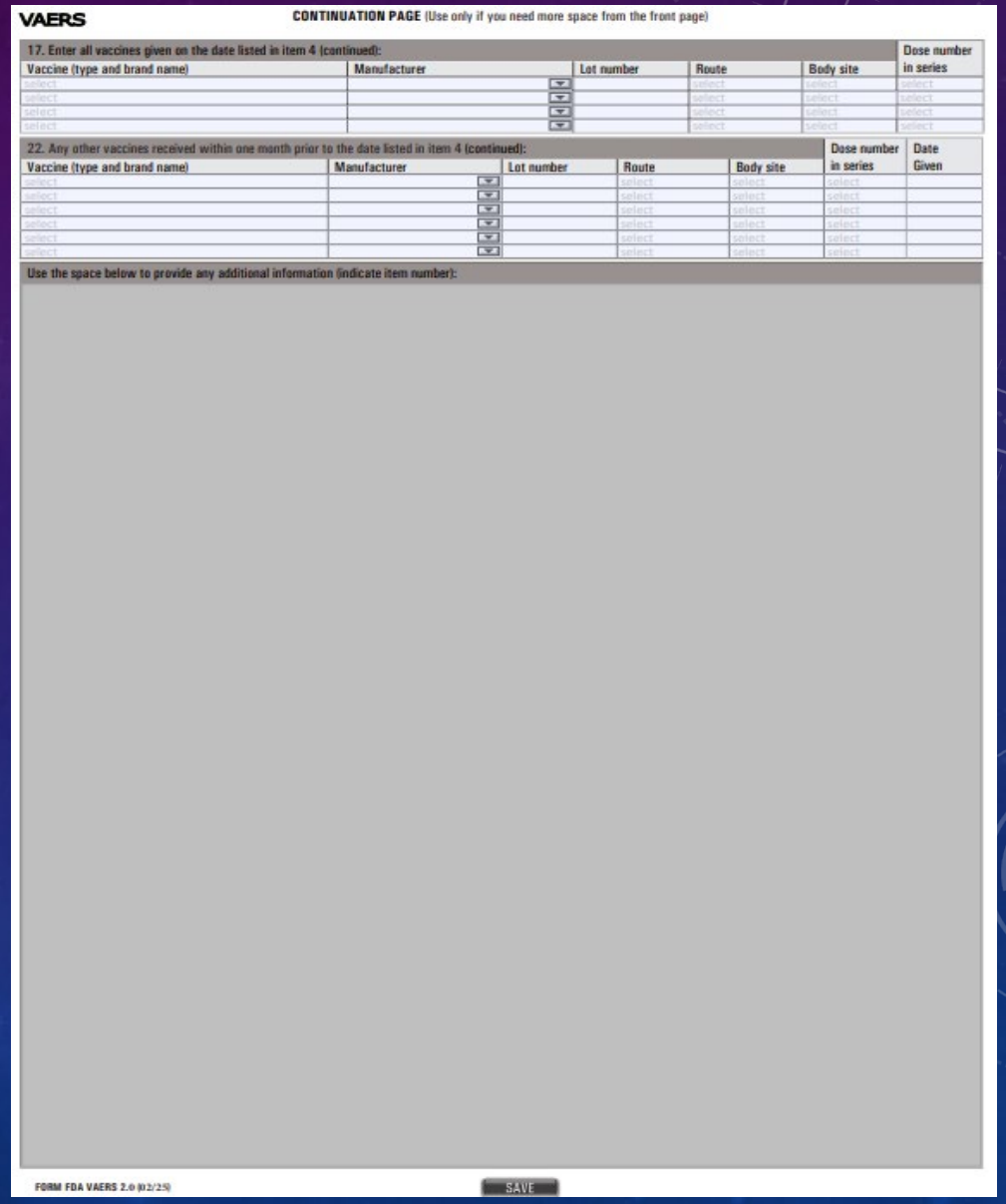
COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other:

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS 2.0 (02/25)

SAVE



VAERS

CONTINUATION PAGE (Use only if you need more space from the front page)

17. Enter all vaccines given on the date listed in item 4 (continued):

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	

Use the space below to provide any additional information (indicate item number):

FORM FDA VAERS 2.0 (02/25)

SAVE

https://vaers.hhs.gov/uploadFile/index.jsp

VAERS DATA

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

VAERS Home

- VAERS Home
- About VAERS
- Report an Adverse Event +
- VAERS Data −
  - VAERS Data Sets
  - Guide to Interpreting Data
- Resources +
- Submit Follow-Up Information
- Frequently Asked Questions
- Contact Us
- Privacy

Home / VAERS Data / VAERS Data Sets / en Español

VAERS Data Sets

NEW! Expanded public access to VAERS data
On May 8, 2025, CDC and FDA expanded public access to VAERS data in the WONDER database (wonder.cdc.gov) and in VAERS downloadable files (vaers.hhs.gov) to provide a more complete picture of all reported adverse events following vaccination received. This enhancement is part of a broader CDC and FDA effort to improve transparency and access to vaccine safety data, while continuing to protect patient privacy.

- Prior to May 8, VAERS public data sets only included the first submitted VAERS report (or primary report) for a patient, vaccine and dose combination.
- VAERS public data sets now include all subsequent reports (or secondary reports) from the same or different reporters, for the same patient, vaccine, and dose combination.
- Based on this enhancement, in the downloadable data file, it will appear that additional reports have been added, but these are actually the subsequent or secondary reports that have previously not been included in the public data sets.
- **It's important to note these new reports are related to already reported events and do not represent additional reports of adverse events.**

VAERS data CSV and compressed (ZIP) files are available for download in the table below. For information about VAERS data, please view the VAERS Data Use Guide [PDF - 310KB], which contains the following information:

- Important information about VAERS from the FDA
- Brief description of VAERS
- Cautions on interpreting VAERS data
- Definitions of terms
- Description of files
- List of commonly used abbreviations

Instructions for Saving Data Sets

1. Click on the file that you want to save.
2. You will be prompted to enter a unique verification code.
3. After successful entry of the code a dialog box will prompt you to open or save the file.
4. To save, click Save As, then specify the location and click Save.
5. Locate the file by navigating to the directory you specified.
6. To un-compress a ZIP file, click on the file and follow the instructions to extract and save the CSV files.
7. Open the CSV files using a spreadsheet application such as Excel or a text editor.

Note for Internet Explorer users: Due to security reasons in your browser's settings you might be prompted to select "show restricted content" in order to view the .csv file as a spreadsheet.

Select the desired time interval to download VAERS data. Each data set is available for download as a compressed (ZIP) file or as individual CSV files. Each compressed file contains the three CSV files listed for a specific data set.

Last updated: July 4, 2025.

(* *Data contains VAERS reports processed as of: 06/27/2025.*)

Year	Zip File	CSV File (VAERS DATA)	CSV File (VAERS Symptoms)	CSV File (VAERS Vaccine)
All Years Data*	543.25 MB			
2025*	4.48 MB	16.85 MB	1.54 MB	1.57 MB
2024	13.65 MB	50.78 MB	5.20 MB	5.13 MB
2023	25.75 MB	102.32 MB	11.39 MB	10.14 MB
2022	64.80 MB	274.73 MB	27.84 MB	21.94 MB
2021	175.80 MB	647.83 MB	81.48 MB	60.03 MB
2020	11.78 MB	43.94 MB	4.82 MB	4.70 MB
2019	12.04 MB	44.84 MB	5.09 MB	4.81 MB
2018	11.16 MB	43.57 MB	5.10 MB	4.93 MB
2017	8.53 MB	33.52 MB	4.12 MB	4.54 MB

https://vaers.hhs.gov/docs/VAERSDataUseGuide_en_March2025.pdf

WHAT DOES VAERS DATA LOOK LIKE? SAMPLE

- Pulled VAERS reports for January to June 2025, filtered to reports from Arkansas
  - 121 reports [some duplicates, some report issues affecting multiple patients]
  - 26 report vaccine mixing, administration, storage and handling errors [+/- harm]
  - 44 report respiratory infections [most COVID followed by RSV, PCV] at various times after vaccination
  - 7 report ‘no adverse event’
  - 21 report local reactions [pain, swelling, rash] after one or more varied vaccines given
  - 16 report systemic symptoms [fever, malaise, weakness, joint pain] after varied vax.
  - 2 report serious adverse events- Bells Palsy, Blood clot with different vaccines…

VSD: ASSESS SIGNALS FOR LINKAGE/CAUSALITY

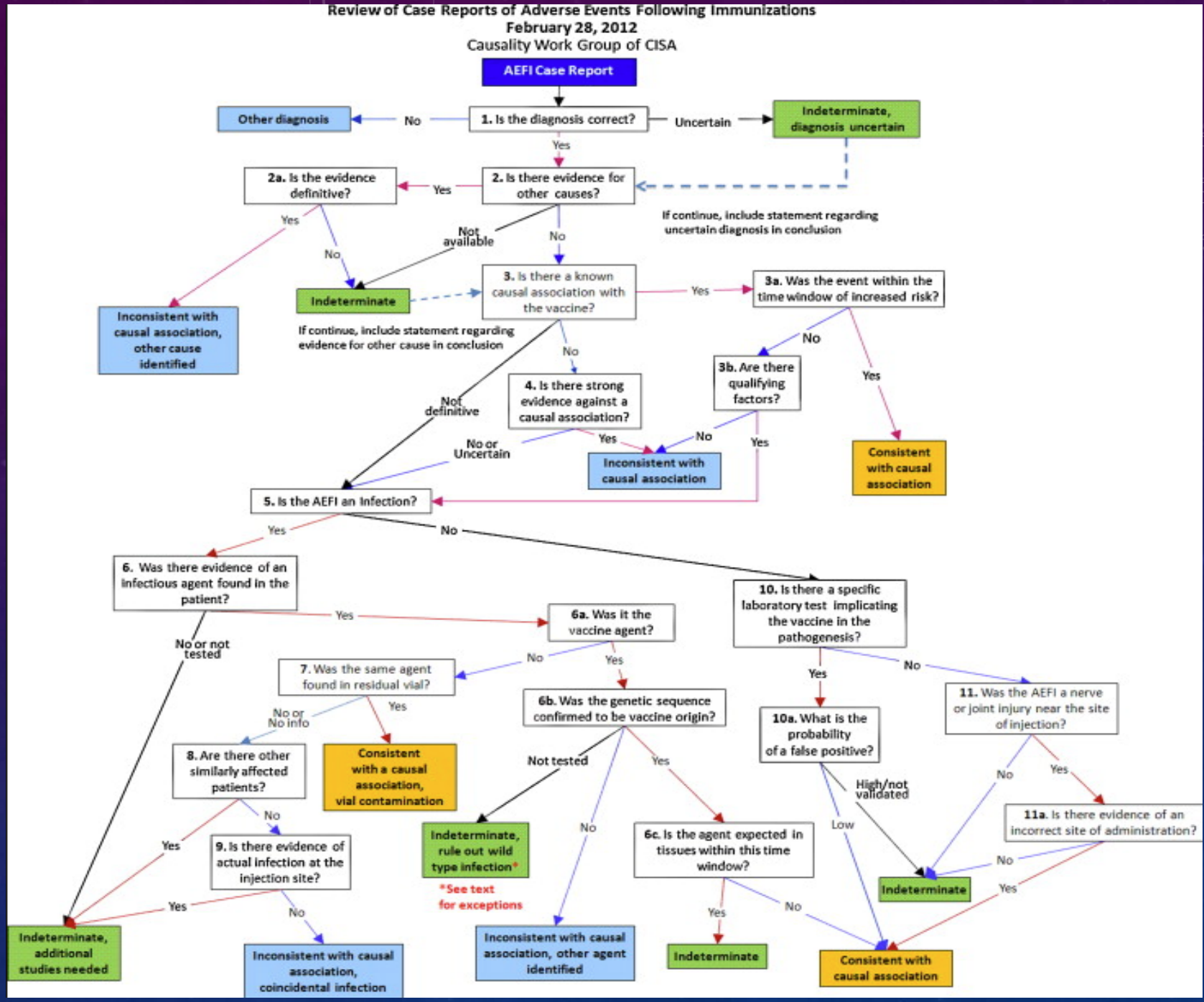
- Collaborative project established 1990
- 13 integrated health systems provide EMR data [>15.5 million individuals]
- Integrated immunization and clinical [EMR] data to allow investigators to assess causality
- Rapidly monitor vaccine safety
  - Conduct studies to detect and assess safety signals [multiple trial designs]
  - Assess pre-specified events and unexpected events
  - Monitor new vaccines after licensed and/or when new recommendations are released
  - Provide timely feedback to ACIP on these studies

https://www.cdc.gov/vaccine-safety-systems/vsd/index.html
https://www.cdc.gov/vaccine-safety/media/pdfs/white-paper-safety-508.pdf
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/64309023/
https://www.sciencedirect.com/science/article/pii/S0264410X2101656X

CISA: CLINICAL IMMUNIZATION SAFETY ASSESSMENT

- Established 2001
- National network of vaccine safety experts
  - From CDC, 8 medical research centers and other partners
  - Consult with US HCP: help answer complex vaccine safety questions about patients
  - Conduct clinical research on vaccine safety
  - Help inform CDC public health guidance on immunization safety

https://www.cdc.gov/vaccine-safety-systems/hcp/cisa/
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/64305088/



https://www.sciencedirect.com/science/article/pii/S0264410X12005130?via%3Dihub#fig0005

V-SAFE ACTIVE MONITORING

- Launched with COVID vaccination campaign, December 2020
  - Voluntary sign up/brief text message based surveys, structured data
  - Following launch: 10.1 M participants> 151 M surveys re: COVID and MPox vaccines
- Greatest strength: active monitor
  - Need to miss work/school and seek healthcare following vaccination
  - Record side effects following vaccination using consumer input of structured data
- Interface to VAERS, Analysts can follow up with individuals to obtain more info
  - Challenging- human resources, time and response rate…
- Expanded beyond COVID to MPox and RSV vaccination
  - Potentially valuable asset as additional new vaccines are launched

https://www.cdc.gov/vaccine-safety-systems/v-safe/index.html
https://pubmed.ncbi.nlm.nih.gov/collections/64312280/?sort=pubdate

FDA CBER: BEST

- BEST: Biologic Effectiveness and Safety System Launch 10/2017
  - Large data sets/analytics/infrastructure for efficient vax/product surveillance
  - Innovative methods to use EMR data for adverse event reporting
- Collaborations between FDA, CMS and payers
  - Mine claims data to assess adverse events following vaccination
- Use the power of large data sets to assess uncommon adverse events

https://bestinitiative.org/
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-biologics-effectiveness-and-safety-best-system
https://bestinitiative.org/best/about/collaborators

OTHER INTERAGENCY COLLABORATIONS:

- VA, IHS, DOD vaccine safety monitoring systems
  - Assess vaccine adverse events in constituencies who receive healthcare in these systems
- VA: assess events in large, mostly older male populations
- IHS: assess for adverse events in Native Americans
- DOD: assess events in a generally young and highly fit population [military members, dependents]

INTERNATIONAL COLLABORATION

- There are a number of additional international vaccine safety systems
- Collaborations between international agencies, CDC and FDA are critical
- [Example] During phases of COVID-19 vaccine use, active collaboration included:
  - Canada
  - Israel
  - EU
  - UK
  - Others

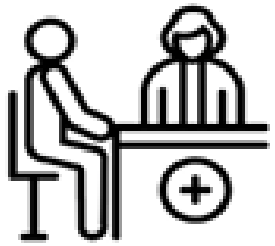
https://pubmed.ncbi.nlm.nih.gov/38341293/

CONCERNS AND EVALUATION OF OUTCOMES…

CDC's Comprehensive Approach to Studying COVID-19 Vaccine Safety

Surveillance
Analyze spontaneously reported events

Epidemiologic studies
Assess specific safety questions

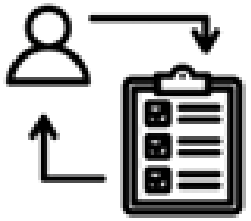


Clinical Research
Safety studies to guide clinical practice

Pregnancy Registry
Longitudinal assessment of maternal and infant outcomes

Rapid cycle analyses
Quickly detect potential concerns for investigation

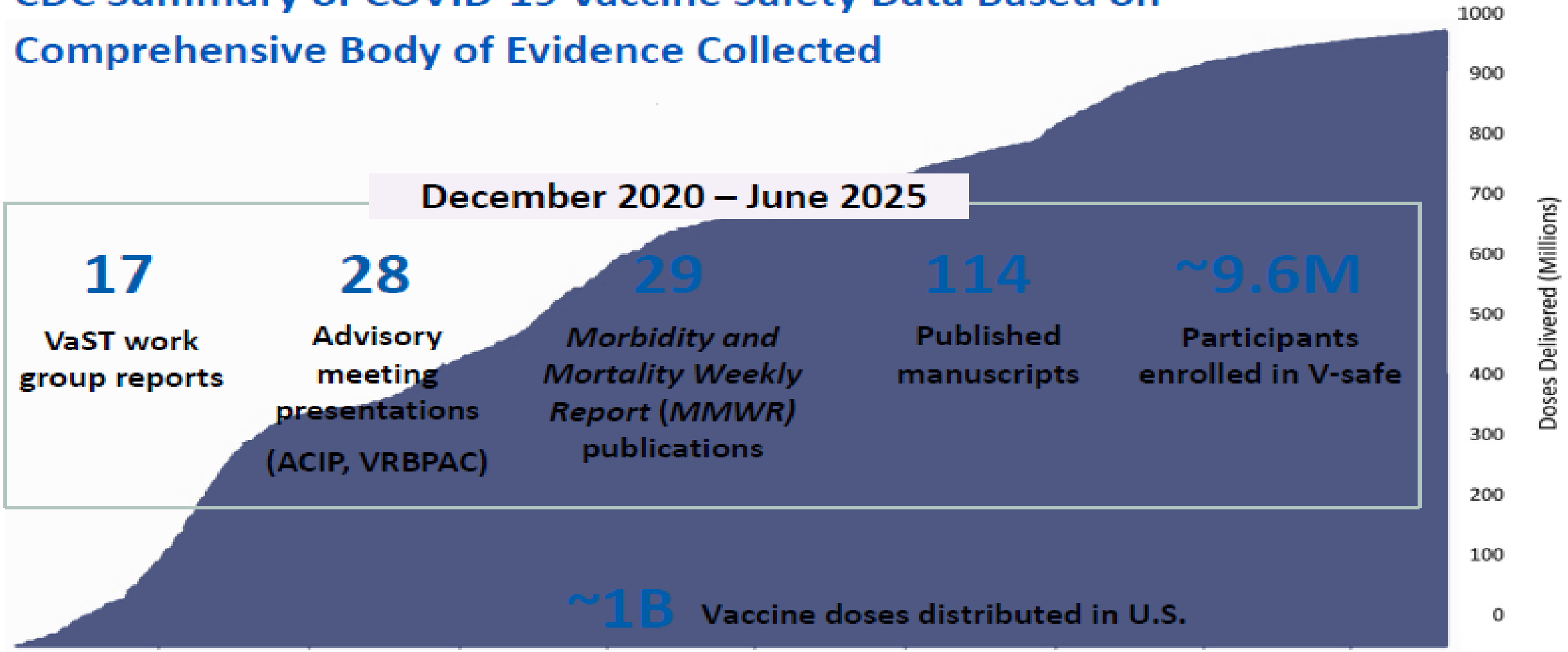
Data mining
Assess >60,000 outcomes for unexpected events



Patient surveys
Assess symptoms and health impacts

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

CDC Summary of COVID-19 Vaccine Safety Data Based on Comprehensive Body of Evidence Collected



ACIP: Advisory Committee on Immunization Practices; VRBPAC: Vaccines and Related Biological Products Advisory Committee; VaST: Vaccine Safety Technical Work Group

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

VACCINE CONCERNS: COVID AND MRNA

- mRNA [Messenger RNA] was discovered in the 1960's
  - Studies on mRNA delivery into cells began in the 1970's
  - 1st FDA approved RNA therapeutic medication [Onpattro] approved in 1998 [siRNA]
  - mRNA COVID vaccines are 1st FDA approved mRNA products [but 1st mRNA vaccines/lipid envelope developed for Ebola]
- How do mRNA vaccines work: https://www.youtube.com/watch?v=w4sUuFBEo2g
- Every active cell in our body makes and uses mRNA to translate coding from DNA into proteins
  - Neither injected mRNA nor the lipid envelope is durable following injection
- Vaccine safety systems have identified uncommon but real risks of these vaccines
  - mRNA vaccines are reactogenic- commonly cause muscle pain, redness, fever and swollen regional lymph nodes
  - Anaphylaxis in ~5 cases/million doses of COVID-19 vaccine [less since initial covid vaccines]

https://publichealth.jhu.edu/2021/the-long-history-of-mrna-vaccines
https://jbiomedsci.biomedcentral.com/articles/10.1186/s12929-023-00977-5
https://www.sciencedirect.com/science/article/pii/S2772829322000959
https://www.bmj.com/content/384/bmj.q488
https://www.cdc.gov/vaccine-safety/vaccines/covid-19.html

CDC Has Evaluated At Least 65 Specific Outcomes to Assess COVID-19 Vaccine Safety Using a Variety of Systems and Epidemiologic Methods

Acute myocardial infarction • ICU admission • Acute disseminated encephalomyelitis • Thrombotic thrombocytopenic Purpura • Encephalopathy • Gestational diabetes • Trigeminal neuralgia and related disorders • Meningitis • Deep vein thrombosis • Anaphylaxis • Thrombocytopenia • Postmenopausal bleeding • Myocarditis • Cataplexy • Myelitis • Chronic inflammatory demyelinating polyneuropathy • Non-COVID mortality • Pulmonary embolism • Stillbirth • Major birth defects • Encephalitis • Local reactions • Vaccine-Associated Enhanced Disease after COVID-19 Vaccines • Hemorrhagic stroke • Administration errors • Acute respiratory distress syndrome • Narcolepsy • Perinatal death • Bell's Palsy • Thrombosis with thrombocytopenia syndrome • Multiple sclerosis • Systemic reactions • Spontaneous abortion • Ataxia • Hospitalization • Acute disseminated encephalomyelitis • Menstrual irregularities • Immune thrombocytopenic purpura • All-cause mortality • Pericarditis • Early childhood infections in infants of vaccinated mothers • Ischemic stroke • Shoulder injuries • Multisystem Inflammatory Syndrome in Children • Multisystem Inflammatory Syndrome in Adults • Tinnitus • Disseminated intravascular coagulation • Acute respiratory distress syndrome • Venous thromboembolism • Arthritis • Seizure • Kawasaki Disease • Arthralgia • Menstrual irregularities • NICU admission • Chronic inflammatory demyelinating polyneuropathy • Small-for-gestational age • Post-COVID conditions • Trigeminal neuralgia and related disorders

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

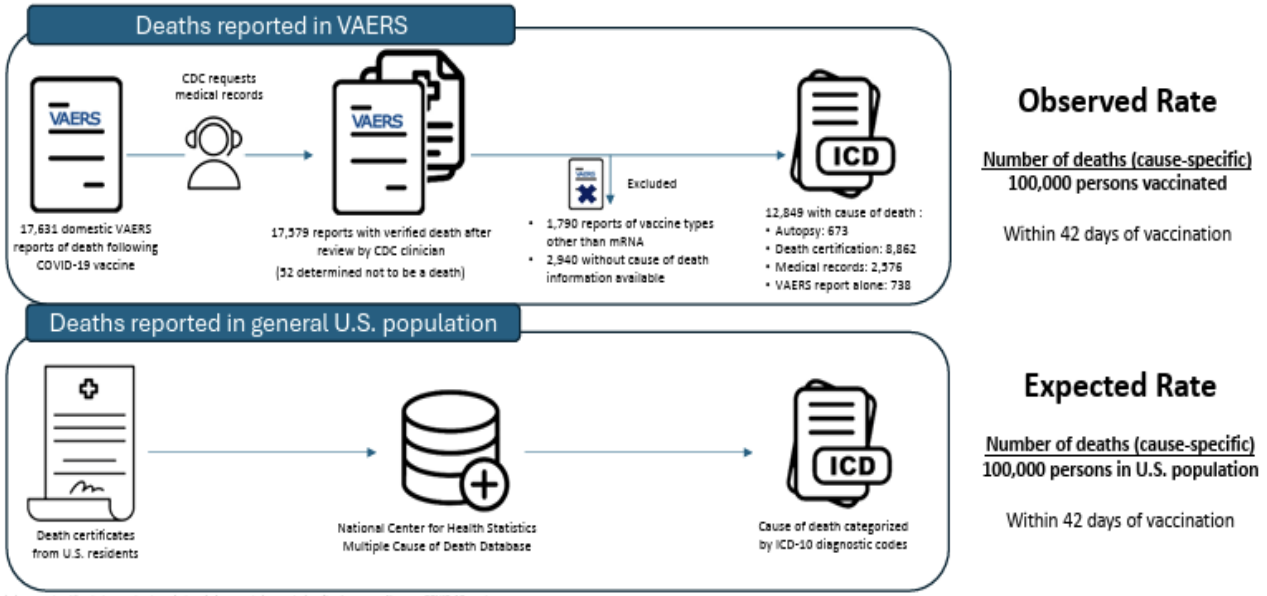
COVID VACCINE [CONTINUED]

- Janssen Viral Vector vaccine: April 2021- TTS detected. FDA/CDC Paused use before resuming. 12/2021 ACIP issues preferential recommendation for mRNA. FDA revoked EUA June 2023.
- Novavax: Limited post-authorization safety data [authorized 7/2022, limited uptake]
- mRNA: VSD Rapid Cycle Analyses 2020-2025:
  - 8 statistical signals detected: AMI, TTP, Seizure, Bells Palsy, VTE, Ischemic Stroke, GBS, Myocarditis
  - Further investigation found only increased myocarditis risk in males > females, peak 16-17 years, rare < 12 and ≥50 yr.
    - Very uncommon, 2022-23 vaccine [~27 cases/million doses in Males 12-24]. Most mild, recover completely.
  - No increased risk of 22 other pre-specified outcomes in children in VSD rapid cycle analyses
  - CDC Pregnancy registry and VSD: NO increased risk of maternal, pregnancy or infant outcomes

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

COVID VACCINE: Deaths??

Safety Monitoring of Death Reports Following mRNA* COVID-19 Vaccination in VAERS – December 22, 2020 – January 31, 2023



Observed Rate

Number of deaths (cause-specific)
100,000 persons vaccinated

Within 42 days of vaccination

Expected Rate

Number of deaths (cause-specific)
100,000 persons in U.S. population

Within 42 days of vaccination

* Includes reports with missing vaccine type, but excludes reports known to be after Janssen or Novavax COVID-19 vaccine
Reports to the Vaccine Adverse Event Reporting System (VAERS) reviewed and processed during December 22, 2020 — January 31, 2023; reported date of vaccination during December 22, 2020 — January 31, 2023 or missing
Abara WE, et al. Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring | The Journal of Infectious Diseases; Mahaux O, et al.

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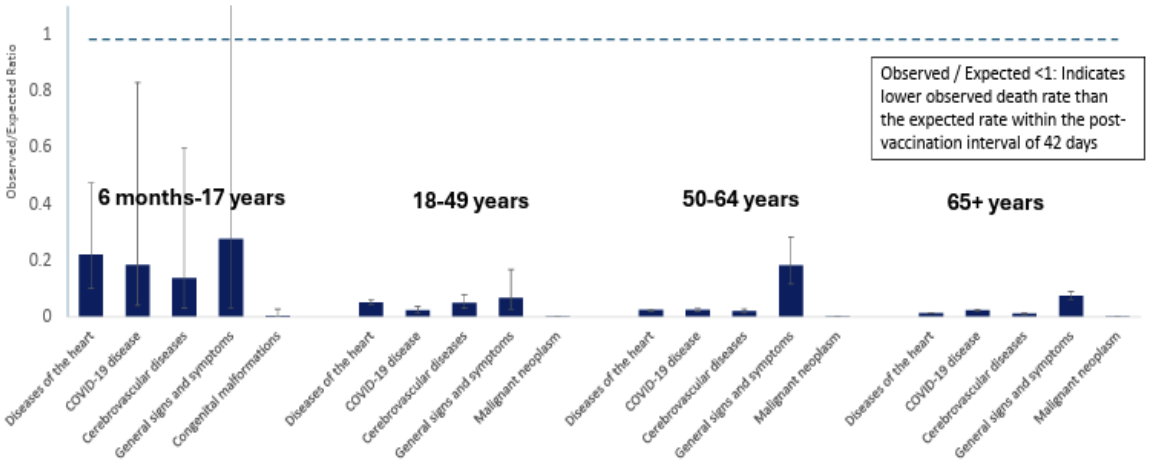
Reporting Rates of Death After mRNA* COVID-19 Vaccination Were Below Background Rates of Death in the General U.S. Population

The most common causes of death reported to VAERS are consistent with the leading causes of death in the U.S. population



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Hoyert DL, Xu J. Deaths: preliminary data for 2011. Natl Vital Stat Rep. 2012; 61:1–51 ; U.S. Centers for Disease Control and Prevention. CDC WONDER. Available at https://wonder.cdc.gov/controller/datarequest/D157 Accessed March 20, 2025
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National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2021. 73:4. Published April 8, 2024. https://www.cdc.gov/nchs/data/nvsr/nvsr73/nvsr73-04.pdf National Center for Health Statistics, National Vital Statistics System. Deaths: Leading Causes of Death for 2020. 72:13. Published December 5, 2023. https://www.cdc.gov/nchs/data/databriefs/db492-tables.pdf#4

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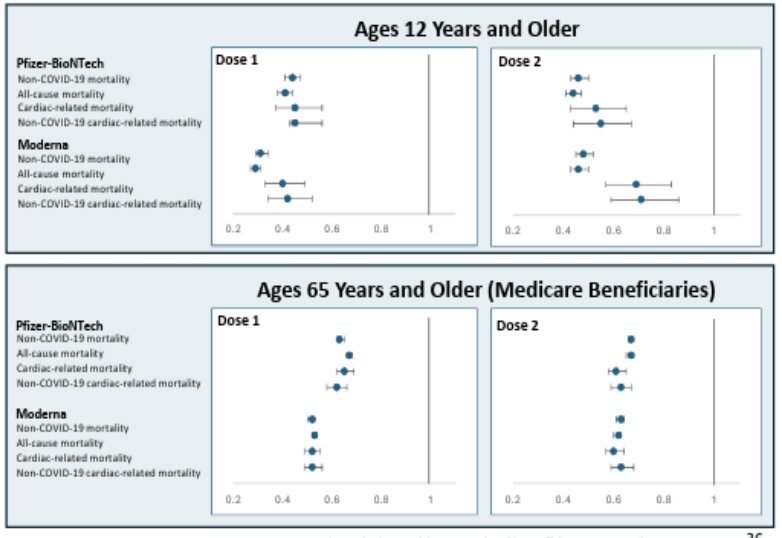
Data From CDC's Vaccine Safety Datalink Shows No Increased Risk of Death Following mRNA COVID-19 Vaccines

- 2 self-controlled case series evaluations
- No increased risk in the 28 days after vaccination of:
  - Non-COVID mortality
  - All-cause mortality
  - Cardiac-related mortality
  - Non-COVID cardiac-related mortality
- Similar findings in VSD cohort study of people ages 12+ years



Mortality risk after COVID-19 vaccination: A self-controlled case series study
https://pubmed.ncbi.nlm.nih.gov/38388239/
A Modified Self-Controlled Case Series on Mortality Risk following Primary Series Doses of COVID-19 Vaccines in U.S. Medicare Beneficiaries Aged 65 Years and Older - Acumen and Vaccine Safety Datalink, unpublished pending review at journal
A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination - PubMed
Data from December 14, 2020 through August 11, 2021

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https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

CDC Summary: Adverse Events Associated with mRNA COVID-19 Vaccines

Occur with any vaccines:

- Local reactions
- Systemic reactions
- Acute allergic reactions (e.g., anaphylaxis)
- Syncope (fainting)
- Shoulder injuries

Occur with COVID-19 vaccines:

- Myocarditis and pericarditis

CDC evaluated at least 65 specific safety outcomes, conducted data mining of >60,000 potential outcomes for unexpected concerns, investigated numerous signals, and conducted many epidemiologic studies

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

VACCINE CONCERNS: MMR, AUTISM

- Autism is a neurodevelopmental disability for which criteria have evolved and screening has increased over the last 30 years
  - Signs and symptoms are often first detected in the second year of life and early diagnosis is important to drive early intervention
  - 'study' by Wakefield published in BMJ in February, 1998 asserted MMR/Autism link

  Retracted by journal as fraudulent and Wakefield was stripped by UK of his medical license.
- There have been **at least** 11 well controlled studies to evaluate for any potential association and NO linkage has been found.

https://www.cdc.gov/vaccine-safety/about/autism.html
https://pubmed.ncbi.nlm.nih.gov/14754936/
https://pubmed.ncbi.nlm.nih.gov/12421889/
https://pubmed.ncbi.nlm.nih.gov/20669467/
https://link.springer.com/article/10.1007/s10803-005-0070-1
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0003140
https://www.cdc.gov/autism/hcp/diagnosis/index.html

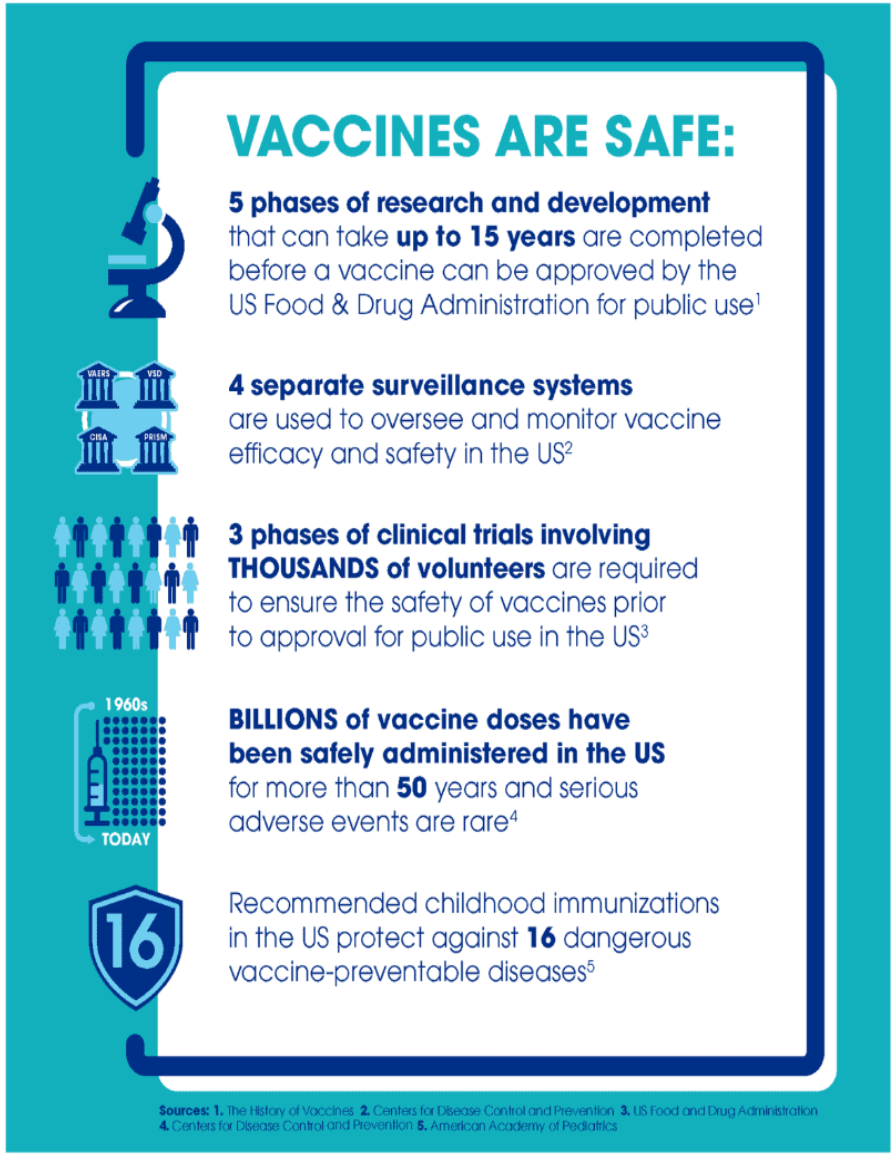
PROCESS WORKS:
RSV VACCINES AND [LOW RISK] GBS

- There were a 2 neurologic events seen in trials of protein subunit RSV vaccines which were FDA approved for use May 2023 [~38K vaccine recipients in trials of 2 vaccines]
  - ACIP recommended use in June 2023
  - ACIP reviewed VAERS data and elevated reporting rate [> expected baseline]
  - ACIP in collaboration with FDA and other partners continued to review post-licensure safety data
- FDA with CMS: observational study, M'Care data of US adults 65+ vaccinated 5/23-7/24

  Preliminary report published on preprint server 1/19/2025
  - >3.2 million vaccine recipients 65+
  - <10 cases GBS/million vaccine recipients
  - FDA required label warning 1/7/2025 noting this small risk

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and
https://www.medrxiv.org/content/10.1101/2024.12.27.24319702v1

THANK YOU FOR YOUR TIME AND PARTICIPATION!



https://www.nfid.org/resource/vaccine-safety-infographic/

CONCLUSIONS

- Vaccines continue to be held to a higher safety standard than other medications/treatments
- Robust safety systems are in place but are under threat with federal cutbacks and leadership changes
    - Systems are only as valuable as the people and expertise dedicated to running them
- Ongoing support of vaccine safety systems will be critical for the health of our society

RESOURCES

https://publichealth.jhu.edu/2025/how-the-us-ensures-vaccine-safety

https://www.vaccinesafety.edu/monitoring-vaccine-safety/

https://vaers.hhs.gov/docs/VAERS_Brochure.pdf

https://www.cdc.gov/vaccinesafety/pdf/vaers_factsheet1.pdf

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

EXTRA SLIDES

VACCINE SAFETY STARTS LONG BEFORE 1ST DOSE IS GIVEN

- Exploration: Multiple steps
  - Research and discovery: may take 10+ years to identify a potential vaccine candidate
  - Proof of Concept [POC] evaluate immune response in small animals. Modify to improve effectiveness…
    If results are promising (enough)-> proceed to human clinical trials
- BEFORE clinical trials start, IND submitted to FDA.
  - Includes data from animal studies, info on technology, manufacturing process and vaccine quality.
- Clinical Trials, 3 phases (generally PC-RCT)
  - Phase 1: assess safety of vaccine in small number [20-100] of healthy people
  - Phase 2: administer to 100-300 people similar to intended vaccine recipients (assess safety and immune response)
  - Phase 3: trial in 1000-10000's to confirm how well vaccine works, assess for side effects and collect other important info re: safe use of vaccine. During phase 3, FDA assesses proposed manufacturing process and inspects manufacturing facility.
- Manufacturer prepares BLA for submission to FDA. BLA includes preclinical and clinical data, details about manufacturing process, info about manufacturing facility, proposed prescribing information.

https://www.hhs.gov/letsgetreal/learn-about-childrens-vaccines/vaccine-safety

VACCINE SAFETY STARTS LONG BEFORE 1ST DOSE IS GIVEN

- FDA VRBPAC [public mtg, FACA committee] review/ make recommendation to FDA.
  FDA review may/may not follow VRBPAC recs- decide on approval [Licensure] or authorization [EUA].
  - FDA may require 'Phase 4' [post licensure] evaluation of the vaccine to provide additional safety/efficacy data
- After FDA approves, manufacturer produces lots of vaccine to distribute. Regular inspections to assure FDA regs are being followed. Routine lot testing for safety, purity and potency to assure product viable and safe.
- CDC ACIP [public mtg, FACA committee] evaluate vaccine after licensure to recommend use, consider:
  - How serious/what is impact of the vaccine-preventable disease
  - Safety/effectiveness in trials and when given to specific age groups
  - Impact on disease if vaccine was not available.
- Once ACIP recommends vaccine, CDC director reviews, makes decision on use approval
  - Once CDC director approves- this is official CDC public health guidance and can be listed on official vaccine schedules.
- After vaccines are licensed + approved by CDC director, monitoring continues… 'Vaccine Safety System'
- This ongoing vaccine safety monitoring jointly done by FDA and CDC [reports through ACIP].

https://www.hhs.gov/letsgetreal/learn-about-childrens-vaccines/vaccine-safety