

Postmarketing Safety and Pharmacovigilance for Vaccines

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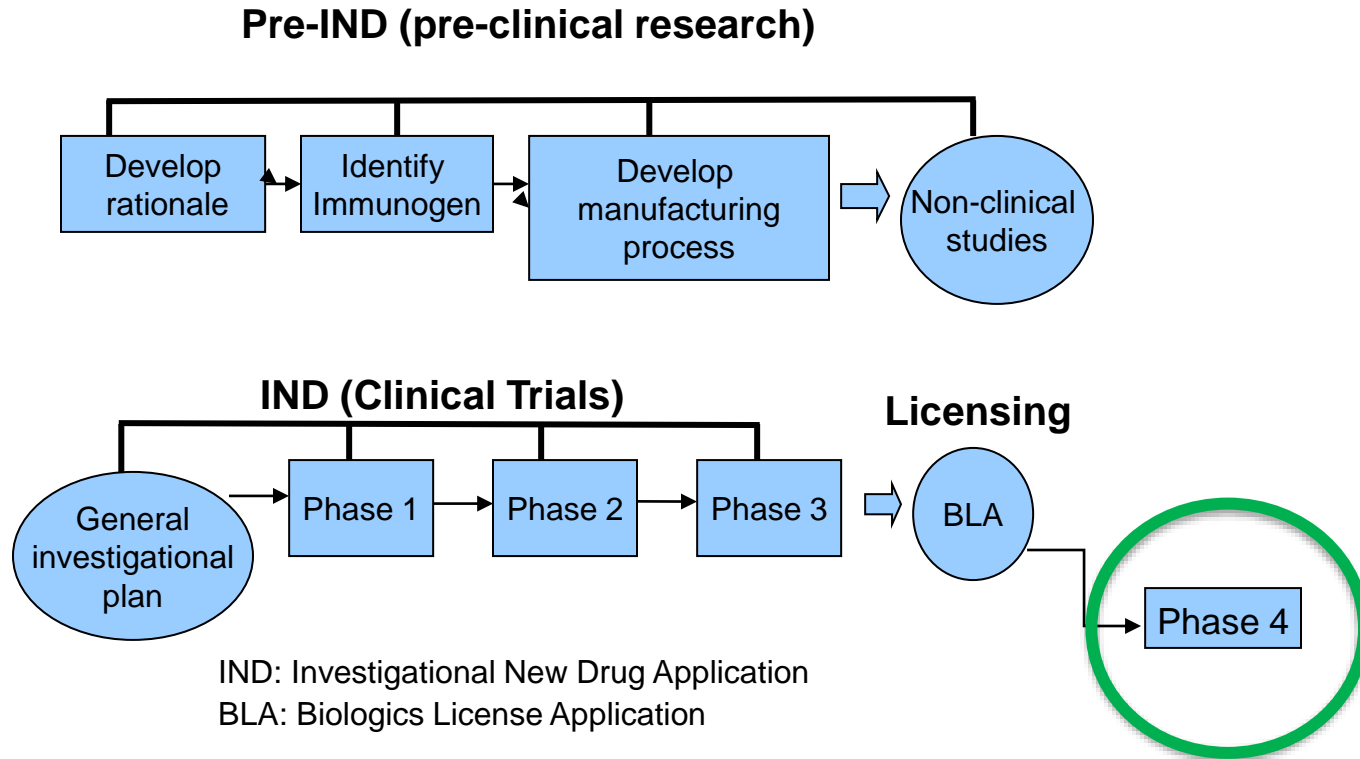
Learning Objectives

- Overview of FDA responsibilities during product lifecycle
- Describe vaccine pharmacovigilance
 - Passive surveillance
 - Active surveillance
- Describe Signal Evaluation and Risk Management
- Examples
- Summary and Conclusions



Overview of FDA responsibilities during product lifecycle

Vaccine Development Life Cycle



FDA Vaccine Safety Throughout the Life Cycle



- FDA ensures that vaccines are safe for their intended use
- Vaccine safety activities occur throughout the life cycle
 - Preclinical research (non-human) testing of candidate vaccines
 - Early phase human studies through large phase III clinical trials
 - Inspection of manufacturing facilities
 - Monitoring of lot release
 - Postmarketing adverse event surveillance
 - Inspection of clinical sites for compliance with Good Clinical Practices
- **Monitoring vaccine safety is equally important during development and during the postmarketing period**

Why does CBER conduct postmarketing vaccine safety surveillance?

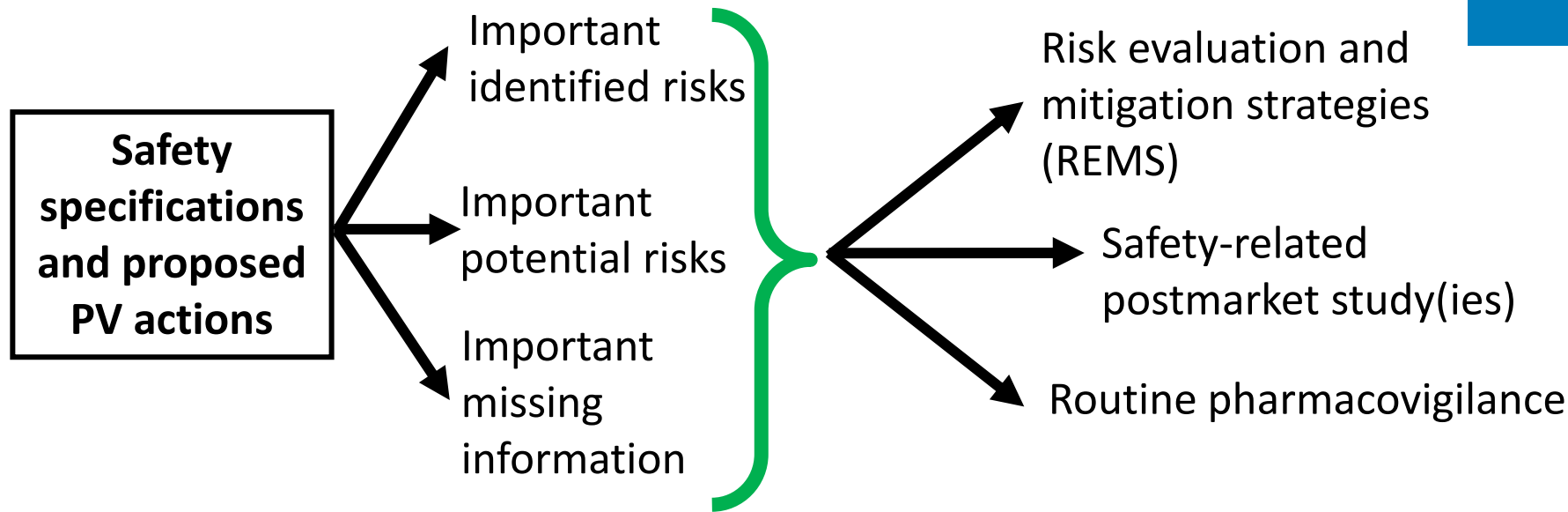


- Limitations of premarket safety database
 - Clinical trials may not detect safety issues that arise when products are marketed to the general population (e.g., postmarketing surveillance may reveal interactions with comorbid conditions)
 - Inclusion criteria may exclude groups within the general population (e.g., pregnant women)
 - Smaller sample sizes and observation periods limit reliable detection to the most common events with shorter latency to onset
 - Unless a trial has a dedicated safety endpoint, inferences about safety are limited by concerns about post hoc analyses with multiple comparisons
- **Postmarketing surveillance further characterizes the safety profile of licensed vaccines**



Pharmacovigilance for Vaccines

Pharmacovigilance Plan (PVP)



FDA Guidance for Industry: E2E Pharmacovigilance Planning (April 2005) available at <https://www.fda.gov/media/71238/download>

FDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (March 2005) available at <https://www.fda.gov/files/drugs/published/Good-Pharmacovigilance-Practices-and-Pharmacoepidemiologic-Assessment-March-2005.pdf>



Vaccine pharmacovigilance

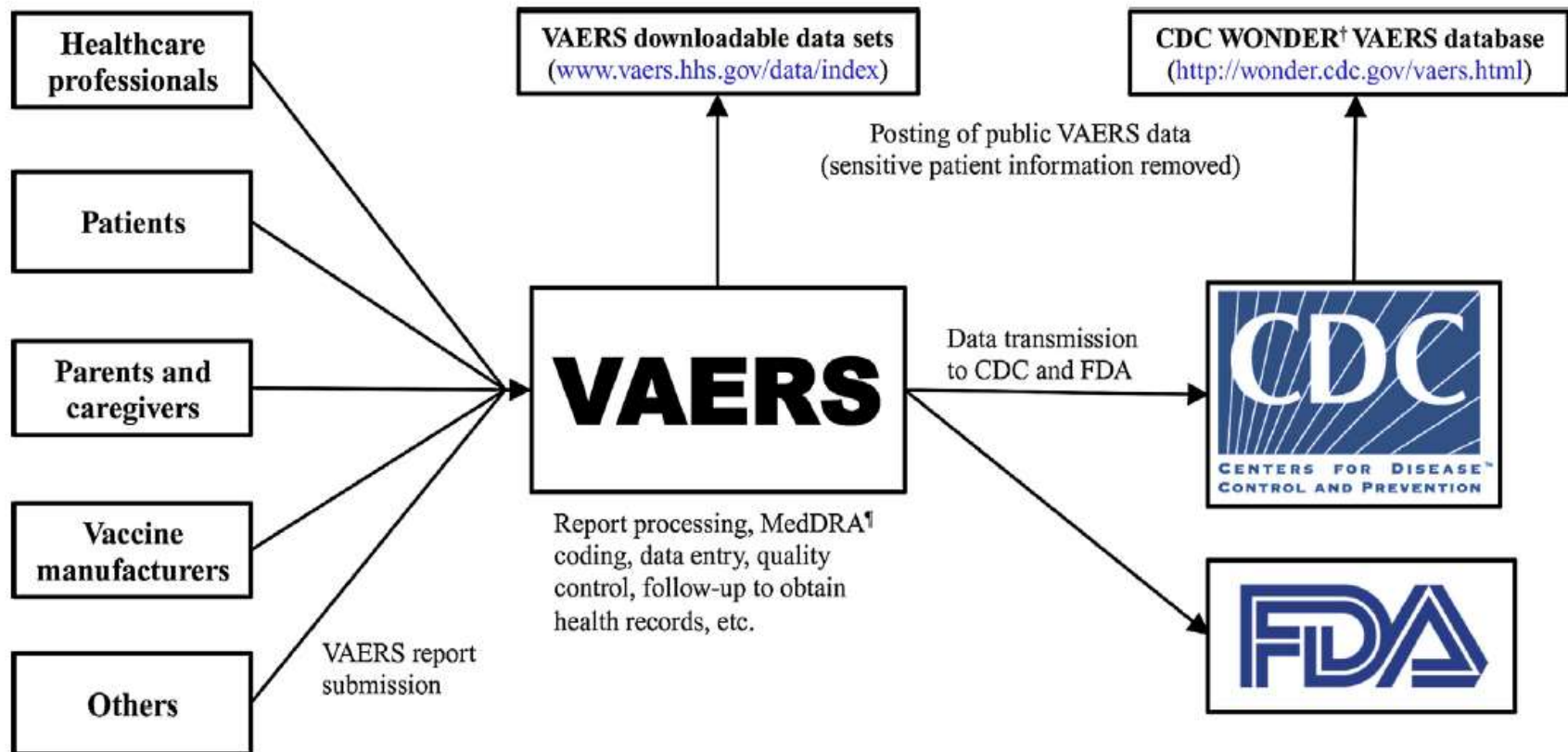
- *Passive surveillance*

Passive Surveillance

- Continuous safety monitoring for licensed prophylactic vaccines
- Spontaneous adverse event (AE) reports
- Reporting regulations:
 - Voluntary AE reporting for healthcare providers and the public
 - Mandatory AE reporting for manufacturers (21 CFR 600.80)
 - Expedited reporting of serious and unlabeled AEs in 15 days

Seriousness: death, hospitalization, life-threatening, disability, congenital anomaly, other medically important event

 - Non-expedited reports
 - Periodic safety reports
- Systems involved
 - Vaccine Adverse Event Reporting System (VAERS)
 - Global pharmacovigilance, WHO Vigibase, public health agencies, other regulators



About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. **New!**

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.



Reporting requirements for healthcare providers administering COVID-19 vaccines



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

Search

CDC WONDER

FAQs

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WONDER Search

About The Vaccine Adverse Event Reporting System (VAERS)

Request Form

Results

Map

Chart

Report

About

[Dataset Documentation](#)

[Other Data Access](#)

[Data Use Restrictions](#)

[How to Use WONDER](#)

Note: Any use of these data implies consent to abide by the terms of the data use restrictions.

CDC Wonder:
Publicly
available
VAERS data

Adverse Event Following Immunization (AEFI)

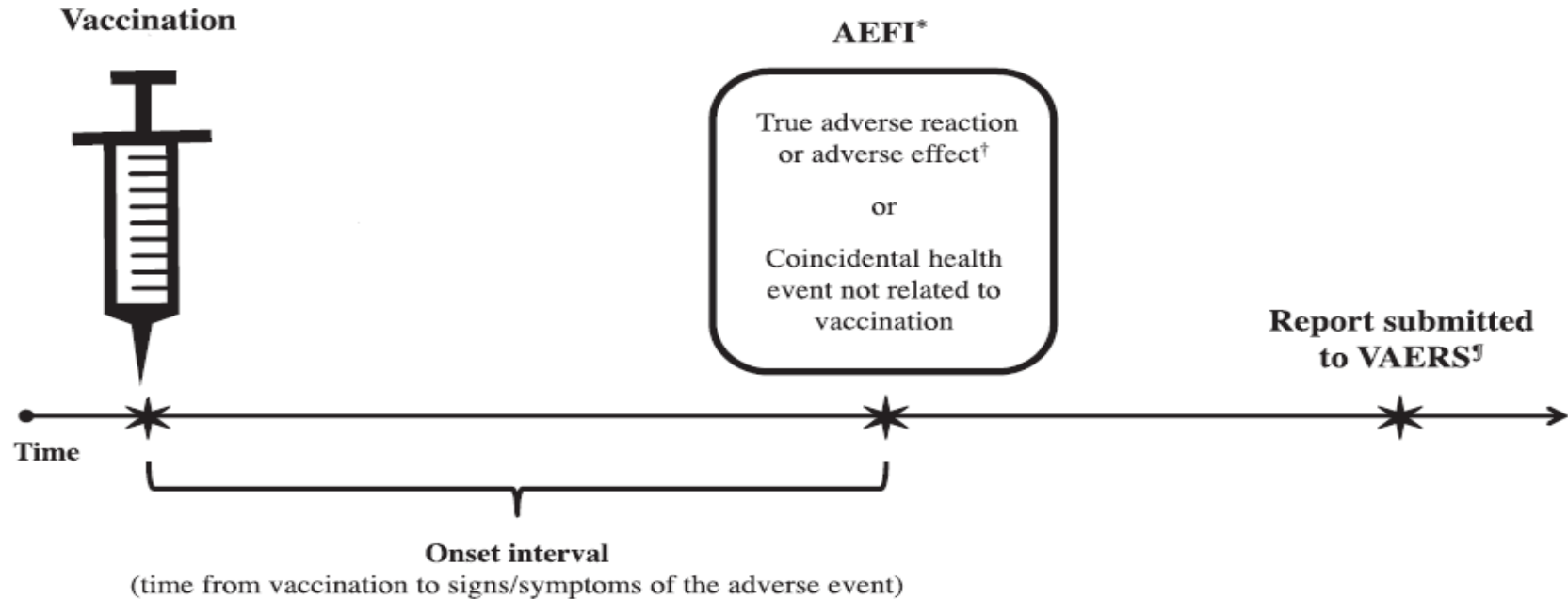


Fig. 1. Adverse event following immunization (AEFI) and the VAERS reporting timeline. *AEFI indicates only that the event happened after vaccination (i.e., a temporal association). [†]"Vaccine adverse reaction" and "vaccination adverse effect" are also AEFIs, but imply that the vaccine caused the event (i.e., a causal association). [‡]There are no deadlines or time limits for the submission of a VAERS report, but reports should be submitted promptly after an adverse event occurs to facilitate surveillance and review. The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an adverse event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).

Vaccine Adverse Event Reporting System

- Nation's early warning system for vaccine safety
- VAERS accepts all reports regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Strengths

- Rapidly detects potential safety problems
- Potential detection of rare AEs
- Open-ended for hypothesis generation
- Geographic diversity
- Capability to monitor product lots

Limitations

- Missing and/or inaccurate data
- Reported diagnoses are not verified
- Under-reporting
- Reporting bias (stimulated reporting)
- Absence of unvaccinated control group
- Inability to assess causation
- Not likely to detect long latency events

Role of Product Utilization Data

- Sponsor distribution data provides context for VAERS reports
 - Accounts for total amount distributed in US
 - Lot-specific
- Interpret with caution
 - Cannot calculate incidence
 - Not all doses distributed were administered
 - Does not include information on age groups (pediatric versus adult)



Challenge Question #1

Routine pharmacovigilance for vaccines includes:

- A. Adverse event reporting in accordance with 21 CFR 600.80
- B. Submission of expedited 15-day reports for serious and unexpected adverse events
- C. Submission of non-expedited reports for serious and expected, and non-serious adverse events
- D. Submission of periodic safety reports at quarterly intervals for 3 years postapproval and at annual intervals thereafter
- E. All of the above

Guidance for Industry

Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2005
Clinical Medical

Vaccine pharmacovigilance

- *Active surveillance*

<https://www.fda.gov/media/71546/download>

Safety-related postmarketing study

A study being conducted specifically to evaluate safety or further investigate a safety issue(s) associated with a product.

NOTE: A study must have a primary safety endpoint to be considered a safety-related study. Examples of safety related studies include pregnancy registries, surveys, and observational epidemiology studies such as studies using healthcare claims and/or Electronic Health Records (EHR) from population based data sources.

Types of post-approval safety studies

- Sponsor studies
 - Postmarketing requirements (PMRs)
 - Postmarketing commitments (PMCs)
 - Voluntary sponsor studies
- Other studies
(examples on next slide)

<https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm>

Vaccine active surveillance

FDA CBER Active Surveillance Program
Biologics Effectiveness and Safety Initiative



www.bestinitiative.org

CMS.gov

Centers for Medicare & Medicaid Services

www.fda.gov

Vaccine Safety Datalink (VSD)

Participating VSD Healthcare Organizations

Sites that do not provide data are denoted with an asterisk().*



Types of sponsor conducted safety postmarketing studies



- **Postmarketing requirement (PMR) study**
 - **Required** under Food and Drug Administration Amendments Act of 2007
 - **Targeted safety study** to assess a specific **serious risk** (see next slide for study purposes under FDAAA)
- **Postmarketing commitment (PMC) study**
 - **“Agreed-upon”** study between FDA and Applicant
 - General safety surveillance; studies for AESIs that do not meet FDAAA criteria
- **Voluntary study**

[Postmarketing Studies and Clinical Trials—Implementation of Section 505\(o\)\(3\) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](#)

Postmarketing requirement (PMR) to assess a serious risk

Postmarketing studies and clinical trials may be required for any or all of the following three purposes:¹¹

- To assess a known *serious risk* related to the use of the drug
- To assess *signals of serious risk* related to the use of the drug
- To identify an *unexpected serious risk* when available data indicate the potential for a serious risk

[Postmarketing Studies and Clinical Trials—Implementation of Section 505\(o\)\(3\) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](#)

Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Ayanna Augustus at 301-796-3980 or (CDER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2019
Drug Safety
Revision 1

879224B.docx
10/17/2019

Regulatory considerations for safety PMR



- Postmarketing studies and clinical trials may be **required**:
 - To assess a known serious risk related to the use of the drug
 - To assess signals of serious risk related to the use of the drug
 - To identify an unexpected serious risk when available data indicate the potential for a serious risk
- **Before** a PMR, FDA must find that AE reporting under section 505(k)(1) of the FD&C Act and the active postmarketing risk identification and analysis system as available under section 505(k)(3) of the FD&C Act will not be sufficient to meet above purposes
- Similarly, **before** requiring a PMR clinical *trial*, FDA must find that a PMR study(ies) will not be sufficient to achieve these same purposes.

[Postmarketing Studies and Clinical Trials—Implementation of Section 505\(o\)\(3\) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](https://www.fda.gov/oc/ohrt/implementation-section-505-o-3-federal-food-drug-and-cosmetic-act-guidance-for-industry)

Challenge Question #2

Safety-related postmarket study may include:

- A. A postmarketing requirement study under FDAAA
- B. An agreed-upon postmarketing commitment study
- C. A voluntary sponsor study
- D. An active surveillance study using population-based data sources
- E. All of the above

Challenge Question #3



FDA tracks study milestone dates for the following:

- A. Postmarketing requirement (PMR) studies under Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA)
- B. Postmarketing commitment (PMC) studies under section 506B of the FDCA
- C. Voluntary sponsor studies
- D. A and B



Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff

DRAFT

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For questions regarding this draft document, contact (CDER) Office of Communications, Division of Drug Information, 855-543-3784 or 301-796-3400; or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2019

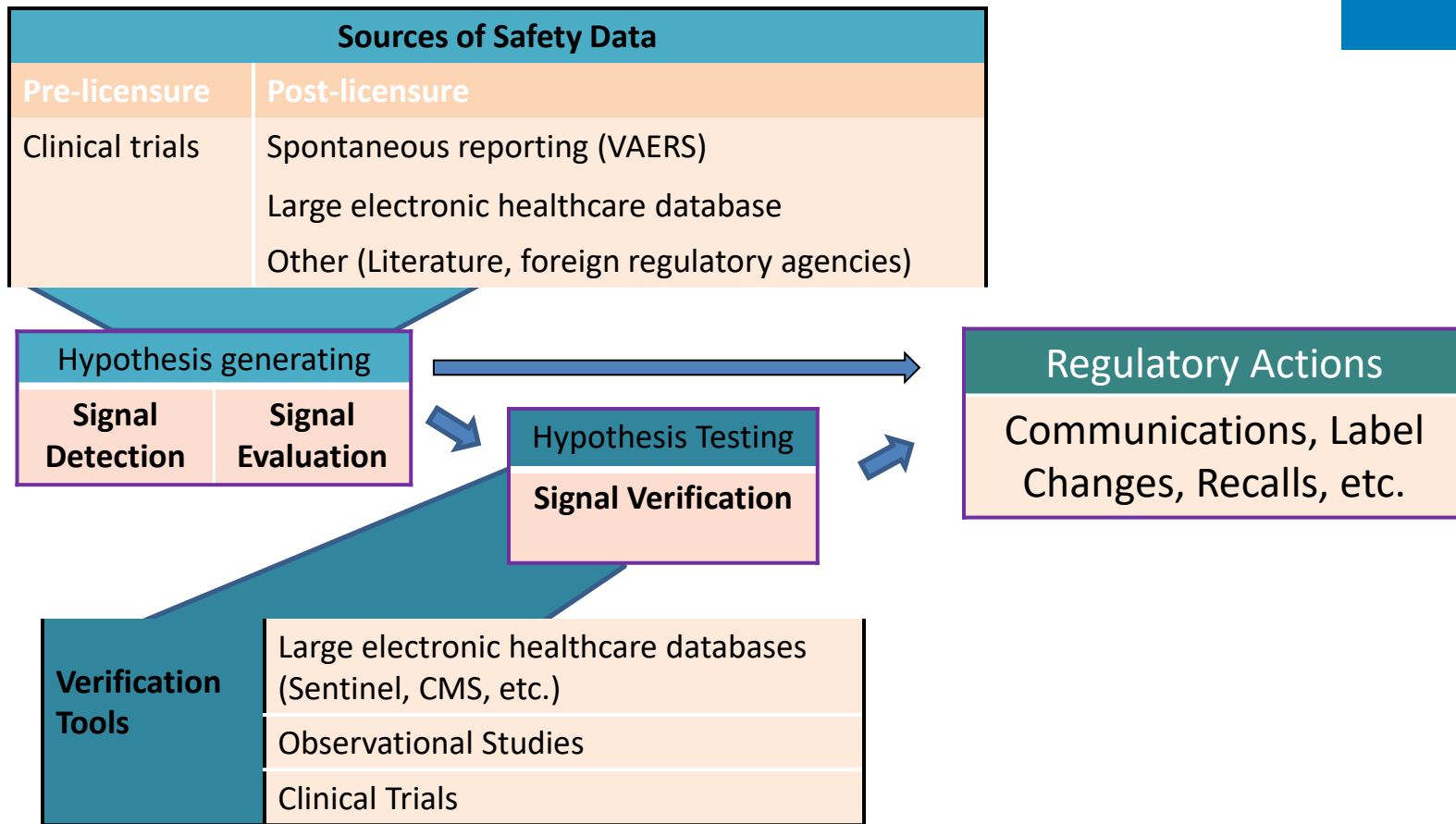
Signal Evaluation and Risk Management

<https://www.fda.gov/media/130216/download>

Signal Evaluation

Postmarketing safety issue is defined broadly as information from one or multiple sources which suggests a new potentially causal association, or a new aspect of a known association...that is judged to be of sufficient likelihood to justify verifactory action.

Signal Detection, Evaluation, and Verification



Analysis of passive surveillance data:

Qualitative Methods



- Sequential review of incoming Individual Case Safety Reports (ICSRs)
 - Look for patterns to detect “signal” of AE
 - Unexpected clinical or demographic clustering
 - Biological plausibility/consistency with known effects
 - Absence of alternative explanations (concomitant medications, underlying conditions)
 - “Positive re-challenge” reports
- Case series

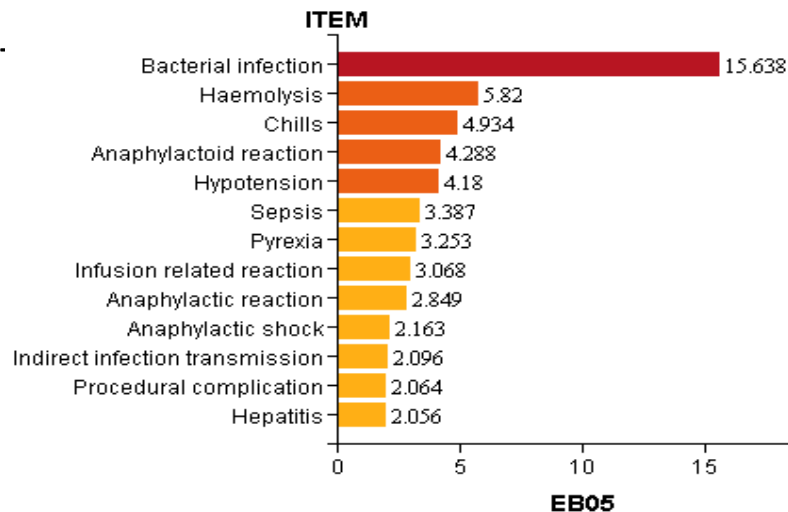
Analysis of passive surveillance data:

Quantitative Methods

- Data Mining: screening for disproportional reporting
- Reporting Rates
 - Number of reports/ time
 - Number of reports/ number of doses distributed
 - Reporting rates vs. background rates

Data Mining

- Assess the proportion of reports with a specific vaccine –AE pair
- An elevated score does not mean there is a causal association between a product and event, although such an association might exist. This graph shows adverse events, reported for a specific product, with high statistical scores, alerting staff that further investigation may be warranted.
- If data mining score is elevated, the vaccine-
 - Unexpected and/or unlabeled?
 - Confounding by indication?
 - Case series analysis
 or epidemiologic study



Risk Management

- Changes to Package Insert (voluntary or required safety labeling change)
- Safety communications
- Inspections
- Product Withdrawal/Recall
- Postmarket requirement/commitment study (PMR/PMC)
- Additional surveillance activities
- Active surveillance study using population-based data sources
- Professional meeting presentation/abstract; peer-reviewed publication



Challenge Question #4

FDA has the authority to require safety-related postmarketing studies or clinical trials, and to require safety labeling changes

True or False.

A. TRUE

B. FALSE



Examples

Original Investigation

October 7, 2021

Association of Receipt of the Ad26.COV2.S COVID-19 Vaccine With Presumptive Guillain-Barré Syndrome, February-July 2021

Emily Jane Woo, MD, MPH¹; Adamma Mba-Jonas, MD, MPH¹; Rositsa B. Dimova, PhD¹; et al

» [Author Affiliations](#) | [Article Information](#)

JAMA. 2021;326(16):1606-1613. doi:10.1001/jama.2021.16496

Also presented at Meeting of the Advisory Committee on Immunization Practices (ACIP)
July 22, 2021

From: Association of Receipt of the Ad26.COV2.S COVID-19 Vaccine With Presumptive Guillain-Barré Syndrome, February-July 2021

Table 3. Observed to Expected Analysis of Guillain-Barré Syndrome After the Ad26.COV2.S COVID-19 Vaccine^a

Age groups, y	No. ^b	Vaccine doses administered ^c	Person-years ^c	Background rate per 100 000 person-years	Expected cases	Rate ratio (95% CI)
Onset within 21 days after vaccination						
All (≥18)	105	13 209 858	751 904	2	15.0	6.98 (5.71-8.45)
18-<65	91	11 169 018	635 740	2	12.7	7.16 (5.76-8.78)
18-29	3	2 388 973	135 980	0.88	1.2	2.51 (0.52-7.33)
30-39	10	2 277 609	129 641	1.07	1.4	7.21 (3.46-13.26)
40-49	22	2 345 471	133 504	1.29	1.7	12.77 (8.01-19.34)
50-64	56	4 156 965	236 614	2	4.7	11.83 (8.94-15.37)
≥65	14	2 040 840	116 164	2.4	2.8	5.02 (2.74-8.43)
Onset within 42 days after vaccination						
All (≥18)	123	13 209 858	1 472 162	2	29.4	4.18 (3.47-4.98)
18-<65	105	11 169 018	1 244 722	2	24.9	4.22 (3.45-5.11)
18-29	4	2 388 973	266 237	0.88	2.3	1.70 (0.47-4.37)
30-39	12	2 277 609	253 826	1.07	2.7	4.42 (2.28-7.72)
40-49	25	2 345 471	261 389	1.29	3.4	7.41 (4.80-10.94)
50-64	64	4 156 965	463 270	2	9.3	6.91 (5.32-8.82)
≥65	18	2 040 840	227 440	2.4	5.5	3.30 (1.95-5.21)

^a In this table, the results using the highest published background rates for each age group were used to illustrate the lowest observed to expected ratio, representing the most conservative estimate of the potential association with the vaccine.

^b Reports with missing age, missing onset, or onset after 42 days are not included in these calculations. One report had missing age, sex, and onset information but was still deemed a valid report of Guillain-Barré syndrome.

For 6 people, the onset time was more than 42 days: 62, 70, 75, 85, 89, or 94 days after vaccination.

^c Cumulative Vaccine Administration Data.⁹ Please see the Methods section. Age-specific dose administration data were obtained from the Centers for Disease Control and Prevention and are shown with permission (F. Lee, MPH, statistician, Centers for Disease Control and Prevention, email September 3, 2021).

Updated Janssen COVID-19 Vaccine EUA Fact Sheets



- July 12, 2021: Authorized EUA Fact Sheets were updated to include new information about GBS

EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)

5 WARNINGS AND PRECAUTIONS

Subsection '5.3 Guillain-Barré Syndrome' including the following information was added: Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

Section 6 OVERALL SAFETY SUMMARY and subsection 6.2 Post Authorization Experience were also updated with information about GBS.

EUA Fact Sheet for Recipients and Caregivers

Section on "WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?" was updated to include information under a new subsection entitled "Guillain Barré syndrome"

FDA Safety Communication and Safety Labeling Change

FDA Requires a Warning about Guillain-Barré Syndrome (GBS) be Included in the Prescribing Information for Shingrix



FDA Safety Communication - March 24, 2021

Purpose: To inform the public and healthcare providers that FDA has required and approved safety labeling changes to the Prescribing Information for Shingrix (Zoster Vaccine Recombinant, Adjuvanted) to include a new warning about the risk for Guillain-Barré Syndrome (GBS) following administration of Shingrix. FDA required GlaxoSmithKline (GSK), the manufacturer of Shingrix, to revise the Prescribing Information to include the following language in the Warnings and Precautions section:

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with Shingrix.

FDA evaluated data from a postmarketing observational study that assessed the risk of GBS following vaccination with Shingrix. Based on this evaluation, FDA has determined that the results of this observational study show an association of GBS with Shingrix, but that available evidence is insufficient to establish a causal relationship.

Original Investigation

November 1, 2021

ONLINE FIRST

Risk of Guillain-Barré Syndrome Following Recombinant Zoster Vaccine in Medicare Beneficiaries

Ravi Goud, MD, MPH¹; Bradley Luffin, MPA, MSES²; Jonathan Duffy, MD, MPH¹; et al

► Author Affiliations

JAMA Intern Med. Published online November 1, 2021. doi:10.1001/jamainternmed.2021.6227

Key Points

Question Is there an increased risk of developing Guillain-Barré Syndrome (GBS) following vaccination with the recombinant zoster vaccine (RZV)?

Findings In an observational study of Medicare beneficiaries, a medical record-based, self-controlled analysis of GBS cases after RZV vaccination identified a rate ratio of 2.84 between the risk and control windows, resulting in an attributable risk of 3 cases per million RZV (Shingrix) doses.

Meaning These findings suggest that there is an increased risk of developing GBS following vaccination with RZV.

Example of a Protocol-Based Assessment in Sentinel, Leading to FDA Safety Communication and Label Change

FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

FDA Safety Communication — June 13, 2013

FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

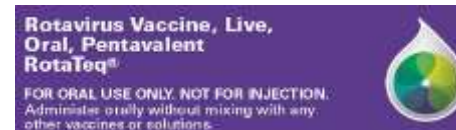
FDA Approves Required Revised Labeling for RotaTeq Based on the Study Results



Intussusception Risk after Rotavirus Vaccination in U.S. Infants

W. Katherine Yih, Ph.D., M.P.H., Tracy A. Lieu, M.D., M.P.H., Martin Kulldorff, Ph.D., David Martin, M.D., M.P.H.,

“The risks of intussusception must be considered in light of the demonstrated benefits of rotavirus vaccination.”



RotaTeq label change:

“Cases of intussusception were observed in temporal association within 21 days following the first dose of RotaTeq, with a clustering of cases in the first 7 days.

...Approximately 1 to 1.5 excess cases of intussusception occur per 100,000 vaccinated US infants within 21 days following the first dose of RotaTeq. In the first year of life, the background rate of intussusception hospitalizations in the US has been estimated to be approximately 34 per 100,000 infants.”

Influenza (Flu)

Seasonal Flu > Prevent Flu > Flu Vaccine Safety

🏠 Seasonal Flu

About Flu +

Who is at Higher Risk of
Flu Complications +

Flu Vaccine Safety Information

Questions & Answers

[Español](#) | [Print](#)

[Flu Vaccine Safety Information | CDC](#)



COVID-19



Your Health

Vaccines

Cases & Data

Specific Settings

Healthcare Workers

Health Depts

Science

More

🏠 Vaccines

Stay Up to Date with
Vaccines +

Your Vaccination +

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Mar. 7, 2023

[Español](#)

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Pediatric Advisory Committee (PAC) meetings

Charter of the Pediatric Advisory Committee to the Food and Drug Administration

Objectives and Scope of Activities

The Pediatric Advisory Committee advises and makes recommendations to the Commissioner or designee in discharging responsibilities as they relate to matters in pediatric therapeutics (including drugs and biological products) and medical devices, pediatric research, pediatric ethical issues and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary pursuant to 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

- [Advisory Committee Vacancies, Qualifications, and Experience](#)
- [Advisory Committee Calendar](#)

[Vaccines and Related Biological Products Advisory Committee | FDA](#)

Examples of Postmarketing Studies



Arexvy (Approval letter, May 3, 2023) available at <https://www.fda.gov/media/167806/download>

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

EPI-RSV-041 VS US DB (220149), a postmarketing active surveillance study, to evaluate atrial fibrillation in adults 60 years and older vaccinated with AREXVY in the United States. Using a self-controlled risk interval (SCRI) design, the study will be conducted in the Sentinel System.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess signals of serious risks of GBS and ADEM.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following study:

3. EPI-RSV-041 VS US DB (220149), a postmarketing active surveillance study, to evaluate Guillain-Barré syndrome (GBS) and acute disseminated encephalomyelitis (ADEM) in adults 60 years and older vaccinated with AREXVY in the United States. Using a self-controlled risk interval (SCRI) design, the study will be conducted in the Sentinel System, and evaluate 1.9 million individuals vaccinated with AREXVY.



Summary and Conclusions

Pharmacovigilance Review

- Signal detection in pre-licensure data
 - Clinical safety database
 - Sponsor's PVP as part of review of Biologics License Applications (BLA)
- Signal detection in postmarketing data

Informs plans for postmarketing studies and/or additional surveillance activities

Summary and Conclusions



- Despite rigorous safety evaluation during premarket phases of clinical development, postmarketing safety monitoring is necessary due to limitations of clinical trials
- FDA conducts ***continuous*** safety monitoring of all licensed vaccines
- Postmarketing surveillance includes many approaches including passive and active surveillance
- FDA may require postmarketing studies by manufacturers
- FDA may require safety labeling changes
- New databases have expanded population-based surveillance capabilities
- FDA and CDC share many vaccine surveillance activities
- **Our goal is to ensure safe and effective vaccines**

Thank you!