U.S. FOOD & DRUG ADMINISTRATION

Pediatric Advisory Committee Meeting

November 13, 2025

10:00 a.m. – 4:00 p.m. EST

Meeting notice and materials are available on the PAC website

2025 Meeting Materials, Pediatric Advisory Committee | FDA

Please direct all technical inquiries to the email listed below

Virtual-WOCC-Support@fda.hhs.gov

Information for Media/Press and Public

- For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202-690-6343 to document your attendance, ask questions, or make interview requests for any FDA speakers

- For Open Public Hearing speakers, industry and the press, please sign in by sending an email to PAC@fda.hhs.gov

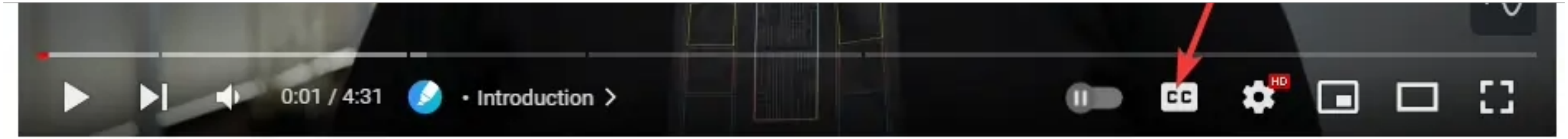
- Please direct all technical inquiries to the email listed below
  - Virtual-WOCC-Support@fda.hhs.gov

Closed Captioning

- Closed captioning can be accessed by clicking on the icon pictured here within YouTube

<u>How to enable closed captions on YouTube:</u>

- On the video player: Click the "CC" (Closed Captioning) icon at the bottom right of the video player.
- If you are signed into your YouTube account, you may access closed captioning through default settings: Navigate to your YouTube account settings, navigate to "Playback and performance," and select "Always show captions"



Pediatric Advisory Committee Meeting

November 13, 2025

Call to Order

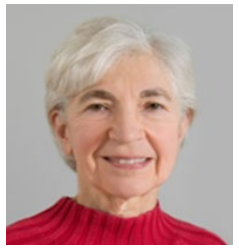
Gwenyth Fischer, MD

Chairperson, PAC

Pediatric Advisory Committee Meeting Roster

Gwenyth Fischer, MD
PAC Chairperson

Premchand Anne, MD, MBA, MPH



Susan Baker, MD, PhD

David Callahan, MD

Douglas Diekema, MD, MPH

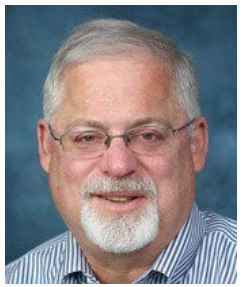
Randall Flick, MD, MPH

Charleta Guillory, MD, MPH

Sarah Hoehn, MD, MBe

Liza-Marie Johnson, MD, MPH, MSB

Sandra Juul, MD, PhD



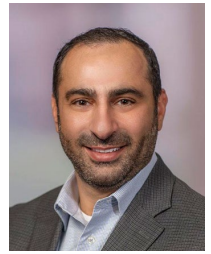
Steven Krug, MD

Jennifer Lee-Summers, MD

Gianna McMillan, D. Be
Patient/Family Representative

Robert Nelson, MD, PhD
Industry Representative

Roberto Ortiz-Aguayo, MD



Wael Sayej, MD

Introduction of FDA Representatives

Shivana Srivastava, RN, MS, DCPM, PMP
Designated Federal Officer, PAC

Conflict of Interest Statement

Shivana Srivastava, RN, MS, DCPM, PMP
Designated Federal Officer, PAC

FDA Opening Remarks

Prabha Viswanathan, MD, FAAP
Deputy Director, Office of Pediatric Therapeutics
Office of the Chief Medical Officer
Office of the Commissioner, FDA

Opening Remarks

- Personnel updates
- Upcoming pediatric workshops
- Non-compliance letters
- Purpose of the meeting
- Summary of prior meeting discussion
- Agenda

Personnel Updates

- Pediatric Advisory Committee Membership
  - No changes since the meeting held on July 9, 2025

- Office of Pediatric Therapeutics
  - Dr. Dionna Green

Upcoming Pediatric Workshops

Pediatric Developmental Safety: New Approach Methods Workshop

- Friday, December 5, 2025
- 8:00 am - 4:00 pm
- Register here

Triangle CERSI

Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development – Leveraging Rare Disease Frameworks

- Dates and times: TBA
- Register here

CERSI University of Maryland

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (CBER, n=7)
  - https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/prea-non-compliance-letters
- Center for Drug Evaluation and Research (CDER, n=187)
  - https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act
- Websites list the sponsor, product, a copy of the non-compliance letter, the sponsor's response (if available), and the status of the PREA requirement (e.g., released, replaced, fulfilled)

PREA Non-Compliance Letters

- CBER: No new letters since the last PAC meeting
- CDER: 7 new letters since the last PAC meeting*

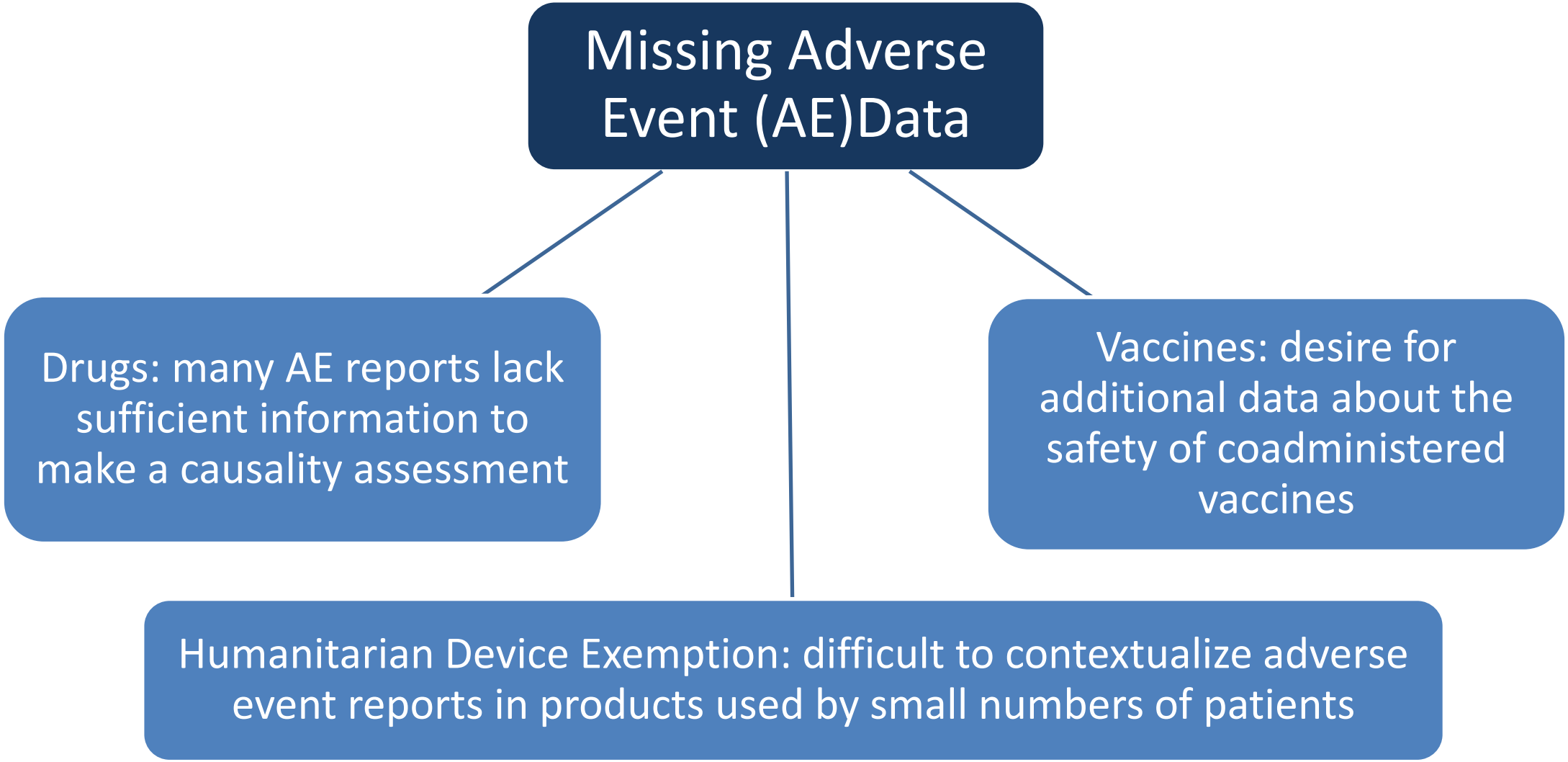
Sponsor	Product	Date of Letter
Genus Lifesciences Inc.	Oxycodone Hydrochloride capsules and oral solution	6/25/2024
Acer Therapeutics Inc.	Olpruva (sodium phenylbutyrate) powder	11/14/2024
Athena Bioscience, LLC	QDOLO (tramadol hydrochloride) oral solution	4/24/2025
Paratek Pharmaceuticals, Inc.	Nuzyra (omadacycline) tablets and Nuzyra (omadacycline) injection	5/6/2025
Carmel Biosciences, Inc.	Prexxartan (valsartan) oral solution	8/26/2025
60 Degrees Pharmaceuticals, Inc	Arakoda (tafenoquine) tablet	9/8/2025

*Table includes letters not previously displayed at PAC meetings and excludes letters yet to publish on the FDA website

Purpose of the Meeting

- The Pediatric Advisory Committee (PAC) is meeting to discuss pediatric-focused postmarket safety reviews as mandated by statute:
  - Best Pharmaceuticals for Children Act (Pub. L. 107-109)
  - Pediatric Research Equity Act of 2003 (Pub. L. 108-155)
  - Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110-85, title III)

July PAC Meeting Recap



FDA Response to July Meeting

- FDA acknowledges the recommendation from several committee members to have a dedicated discussion on ways to improve data capture and quality, for example:
  - Expand knowledge about how to report adverse events to FDA
  - Improve the completeness of adverse event reports to facilitate FDA's analysis (e.g., age of patient, key clinical variables, product identifiers)
  - Capture adverse event reports from other fora (e.g., social media)

Meeting Agenda

- 10:20 a.m. FDA Presentation
  - FDA's Pediatric Safety and Monitoring Framework
  - Q&A
- 11:00 a.m. PAC Committee Discussion on Non-Voting Question
- 12:15 p.m. Lunch
- 1:15 p.m. Open Public Hearing
- 2:15 p.m.* Products evaluated in the pediatric-focused postmarket safety reviews
  - Center for Devices and Radiological Health (CDRH)
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
- 4:00 p.m.* Closing Remarks and Adjournment

*Times subject to change based on number of speakers

Discussion and Voting Procedures

- One non-voting discussion question in the morning
- Three separate voting sessions (one each for CDRH, CBER, and CDER) following the PAC's discussion
  - Voting will occur via the Zoom platform
  - A separate ballot will be launched for each Center's vote
  - The voting question and answer choices will be the same for all Centers and all products
  - Each ballot will contain a series of voting questions – one for each of the products listed on the ballot
    - *Note*: Some CDER products were grouped into the same pediatric-focused postmarket safety review, and these products will be grouped for voting purposes as well

Non-Voting Discussion Question

FDA encourages the public to submit adverse event reports when safety concerns arise. However, there are many factors that may impact reporting.

What steps can patients/consumers, providers, and healthcare systems take to optimize reporting of pediatric adverse events?

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the <CDRH/CBER/CDER> products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Voting Procedures

- Meeting participants trying to join the meeting during voting or vote tabulation will be placed in a waiting room until the meeting resumes, which may be ten minutes or more
- The PAC will have a short break while FDA staff tabulate the votes
- Once the meeting resumes, the vote results will be displayed and read into the record
- PAC members will be called upon to read out their individual vote for the record and provide commentary, if desired

Ensuring Safe and Effective Therapies for Children: FDA's Pediatric Safety Monitoring Framework

Mohamed Mohamoud PharmD, MPH
Senior Clinical Analyst, Office of Pediatric Therapeutics
Office of the Chief Medical Officer
Office of the Commissioner, FDA

Objectives

- Review key legislation and regulatory processes shaping pediatric product development
- Highlight the Pediatric Advisory Committee's role in ensuring the safety and effectiveness of medical products used in children
- Explain the FDA's approach to postmarket pediatric safety monitoring and signal detection
- Discuss FDA initiatives to enhance pediatric safety monitoring and reporting of adverse events

Pediatric Product Development Laws

Best Pharmaceuticals for Children Act (BPCA) of 2002

115 STAT. 1408 PUBLIC LAW 107–109—JAN. 4, 2002

Public Law 107–109
107th Congress

An Act

Jan. 4, 2002
[S. 1789]

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

Best Pharmaceuticals for Children Act.
21 USC 301 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Best Pharmaceuticals for Children Act".

Pediatric Research Equity Act (PREA) of 2003

117 STAT. 1936 PUBLIC LAW 108–155—DEC. 3, 2003

Public Law 108–155
108th Congress

An Act

Dec. 3, 2003
[S. 650]

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

Pediatric Research Equity Act of 2003.
21 USC 301 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Equity Act of 2003".

Pediatric Medical Device Safety and Improvement Act (PMDSIA) of 2007

PUBLIC LAW 110–85—SEPT. 27, 2007 121 STAT. 859

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

Pediatric Medical Device Safety and Improvement Act of 2007.

SEC. 301. SHORT TITLE.

21 USC 301 note.

This title may be cited as the "Pediatric Medical Device Safety and Improvement Act of 2007".

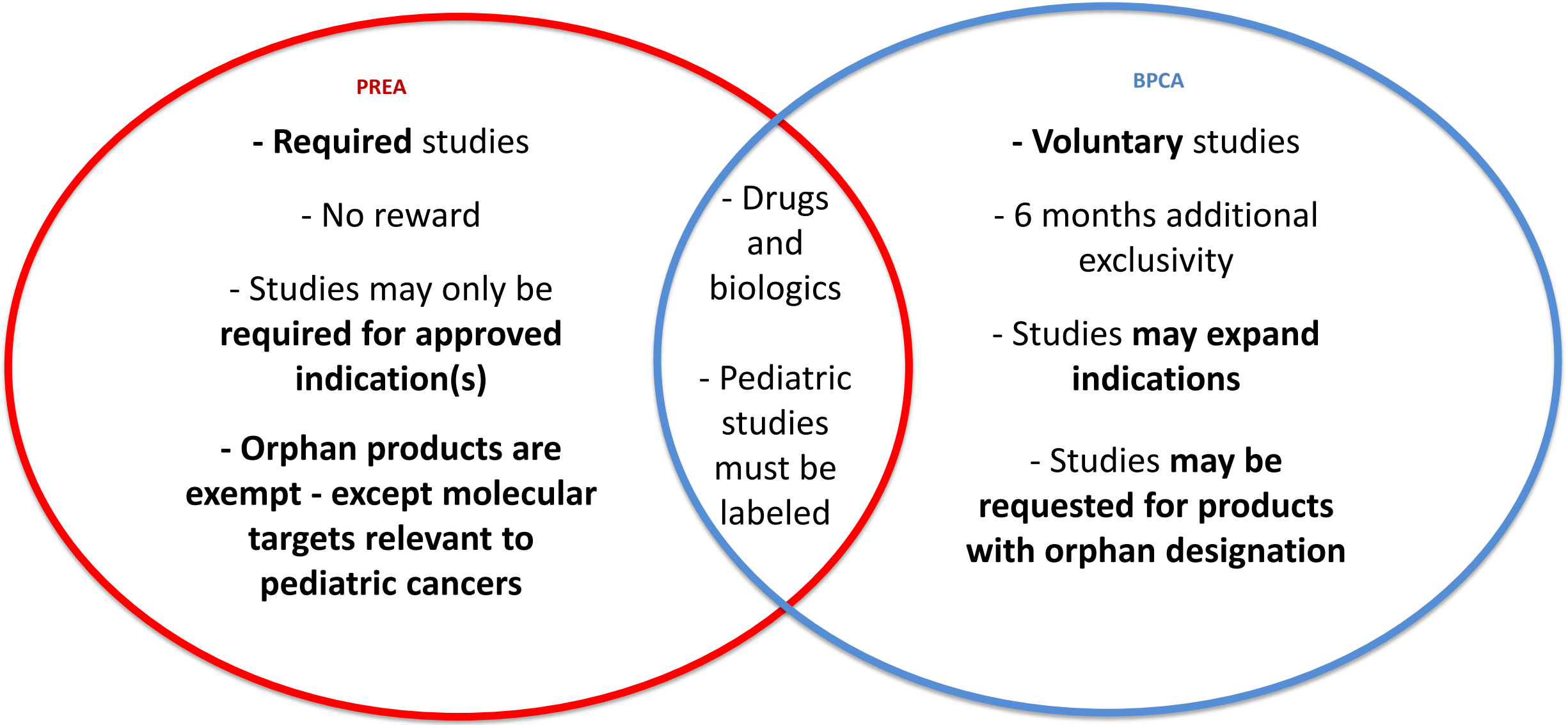
Best Pharmaceuticals for Children Act (BPCA) 2002

- Followed Food and Drug Administration Modernization Act (FDAMA) of 1997
- Established voluntary incentive program for completion of pediatric studies of drugs and biologics
- FDA Office of Pediatric Therapeutics (OPT)
- Program for the studies for off-patent products through the National Institute Child Health and Human Development (NICHD)
- Requirement for pediatric-focused postmarket safety reviews
  - During the **one-year** following the date on which a pediatric drug receives market exclusivity, any report of an adverse event must be reviewed by the FDA Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee
  - First safety presentation on June 12, 2003

Pediatric Research Equity Act (PREA) 2003

- Followed the 1998 Pediatric Rule
- Requirement for drugs and biologics to include an assessment of safety and effectiveness for the indication claimed in all relevant pediatric subpopulations
  - Support dosing and administration in pediatrics
- Established the Pediatric Advisory Committee (PAC)

PREA vs. BPCA

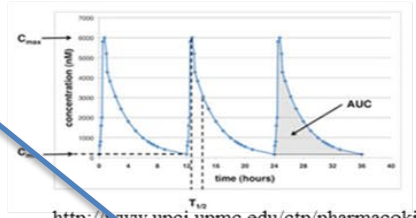

PREA
- Required studies
- No reward
- Studies may only be required for approved indication(s)
- Orphan products are exempt - except molecular targets relevant to pediatric cancers
- Drugs and biologics
- Pediatric studies must be labeled
BPCA
- Voluntary studies
- 6 months additional exclusivity
- Studies may expand indications
- Studies may be requested for products with orphan designation

Product Development Paradigm

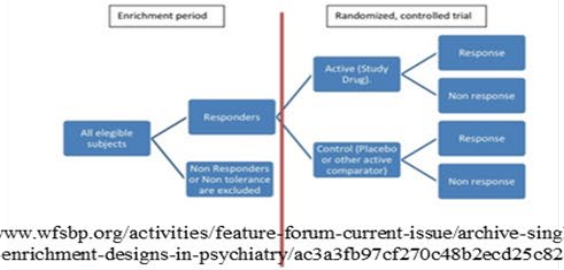
Right Drug

Right Population

Right Dose

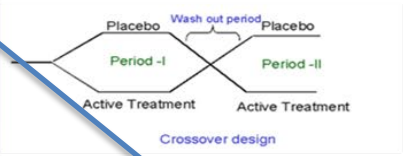


http://www.upci.upmc.edu/ctp/pharmacokinetics.cfm

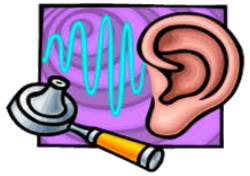


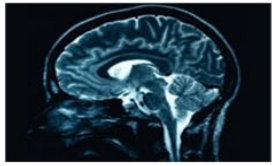
http://www.wfsbp.org/activities/feature-forum-current-issue/archive-single/should-we-accept-enrichment-designs-in-psychiatry/ac3a3fb97cf270c48b2ecd25c825ee9b.html

Right Trial Design



http://accp1.org/pharmacometrics/theory.htm





Right Endpoints

US Evidentiary Standard: Approval of New Drugs

- Evidence of effectiveness [PHS Act, 505(d)]
  - Evidence consisting of adequate and well-controlled investigations on the basis of which it could fairly and responsibly be concluded that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in the labeling
- **Pediatric product development is held to the same evidentiary standard as adult product development**
- A product approved for children must:
  - Demonstrate substantial evidence of effectiveness/clinical benefit (21 CFR 314.50)
    - The impact of treatment on how a patient feels, functions or survives
    - Improvement or delay in progression of clinically meaningful aspects of the disease
  - Adequate safety information must be included in the application to allow for appropriate risk: benefit analysis [FD&C 505(d)(1)]

Pediatric Medical Device Safety and Improvement Act (PMDSIA) 2007

- PMDSIA 2007 was incorporated into FDAAA 2007
- Humanitarian Use Device (HUD) is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than **8,000 individuals** in the United States per year
  - Requires the PAC to **review** approved products with Humanitarian Use Device designation labeled for pediatric patients that are allowed to make a profit
  - Ensure that the Humanitarian Device Exemption (HDE) remains appropriate for the pediatric population for which it is approved for

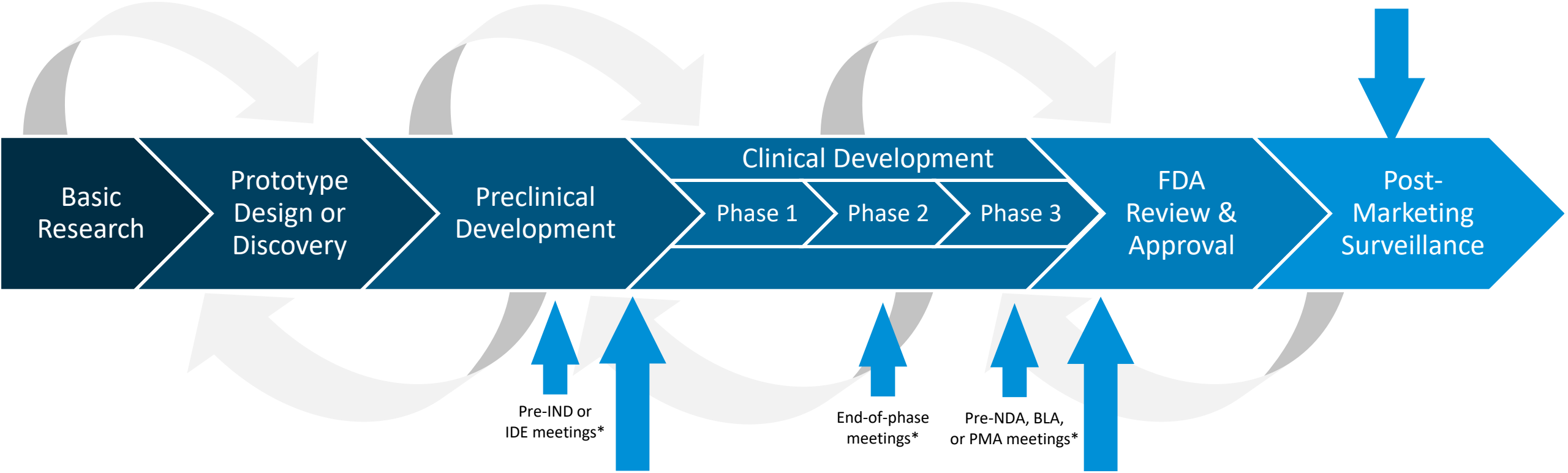
Approval of HDEs

- **Step 1:** Obtain designation of the device as a Humanitarian Use Designation (HUD) from the FDA's Office of Orphan Products Development (OOPD)
- **Step 2**: After HUD designation is granted, submit an HDE application to the Center for Devices and Radiological Health (CDRH) or Center for Biologics Evaluation and Research (CBER)
- **Approval Threshold for HDEs**
  - Reasonable Assurance of Safety

    And
  - Probable Benefit (exempt from requirement to establish reasonable assurance of effectiveness)

Medical Product Development Lifecycle

Mandated pediatric focused safety reviews

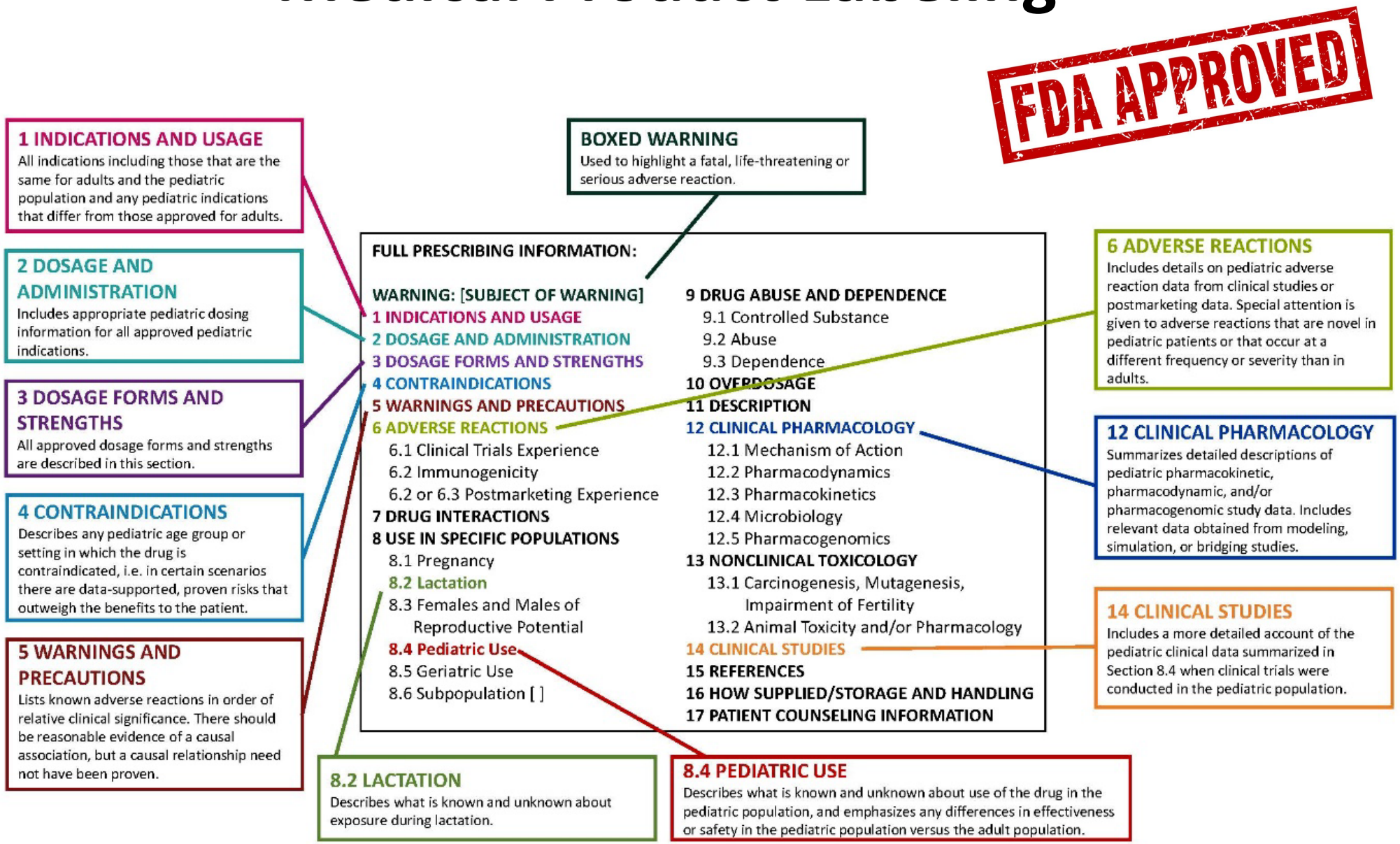


Investigational New Drug (IND)
Investigational Device Exemption (IDE)
Commercial or Research

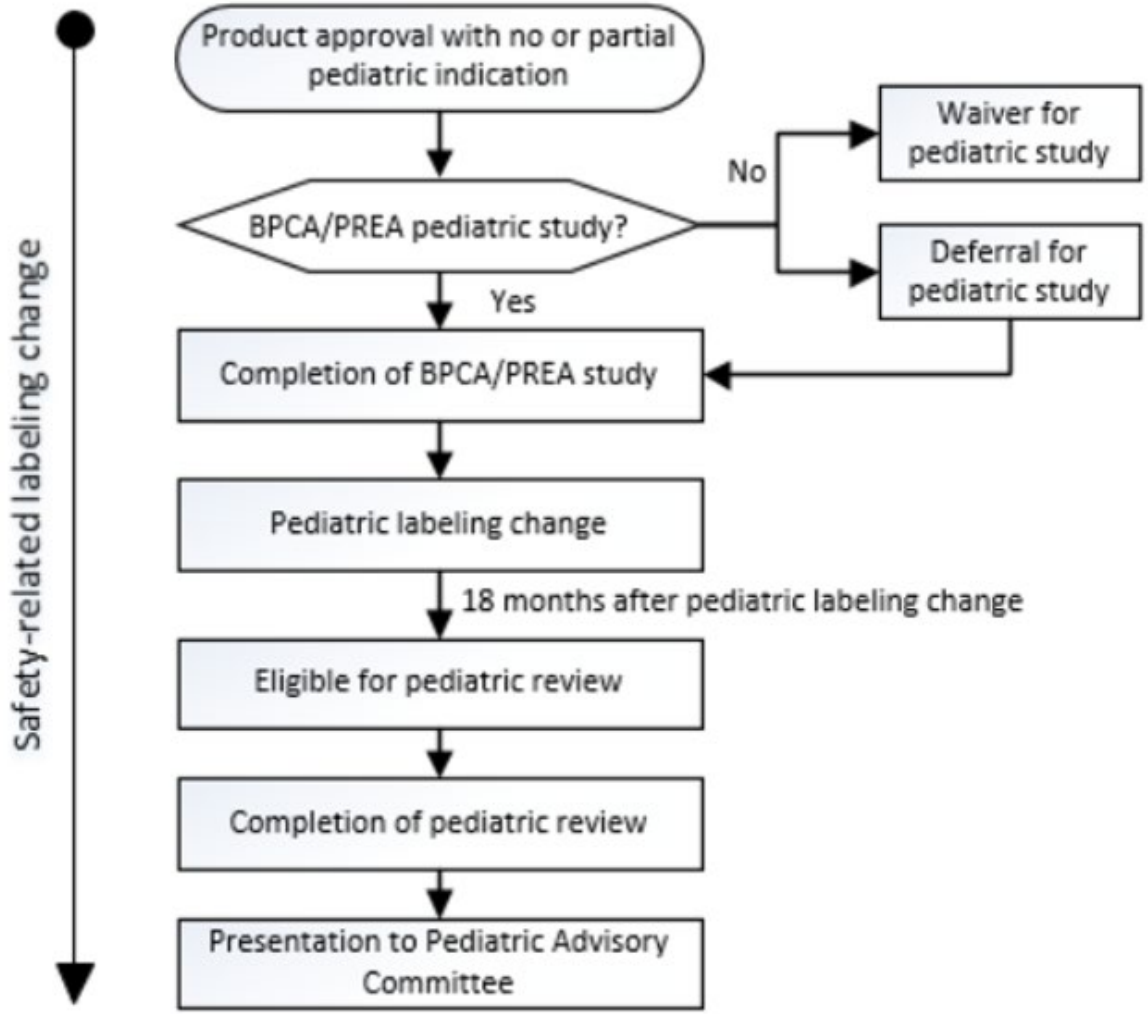
New Drug Application (NDA)
Biologics Licensing Application (BLA)
Pre-Market Application (PMA) [devices]

*There are many meeting types and FDA interaction timepoints that occur as part of the product life cycle; those listed on the slide are select examples.

Medical Product Labeling



Pediatric Labeling Changes for Drugs and Biologics



Mandated Pediatric-Focused Postmarket Safety Reviews

- Legislation mandates for pediatric postmarket safety reviews
  - –Occurs 18 months after pediatric labeling change
- Applies to
  - –Drugs and biologics that have received pediatric exclusivity under BPCA
  - –Conducted required pediatric assessments under PREA
  - –Certain pediatric humanitarian device exemptions (HDEs) under PMDSIA
- Review process
  - –Facilitated by OPT
  - –The goal is to identify potential new and emerging safety signals

Pediatric Advisory Committee (PAC)

- Advises and makes recommendations to the Commissioner of the Food and Drug Administration on pediatric issues under FDA's regulatory authority.
- **The PAC provides input on**
  - –Pediatric research and identification of research priorities.
  - –Ethics, design, and analysis of clinical trials involving children
  - –Adverse event reports for drugs, biologics and certain devices studied in pediatrics
  - –Pediatric safety issues identified post approval
- **The PAC plays a key role in:**
  - –Informing FDA's regulatory decisions
  - –Ensuring pediatric perspectives are integrated into product development, labeling, and postmarket evaluation
  - –Supporting FDA's mission to protect and promote the safety and health of children

Types of Pediatric Focused Safety Reviews

FDA

Center for **D**evices & **R**adiological **H**ealth **(CDRH)**

Humanitarian Device Exemptions

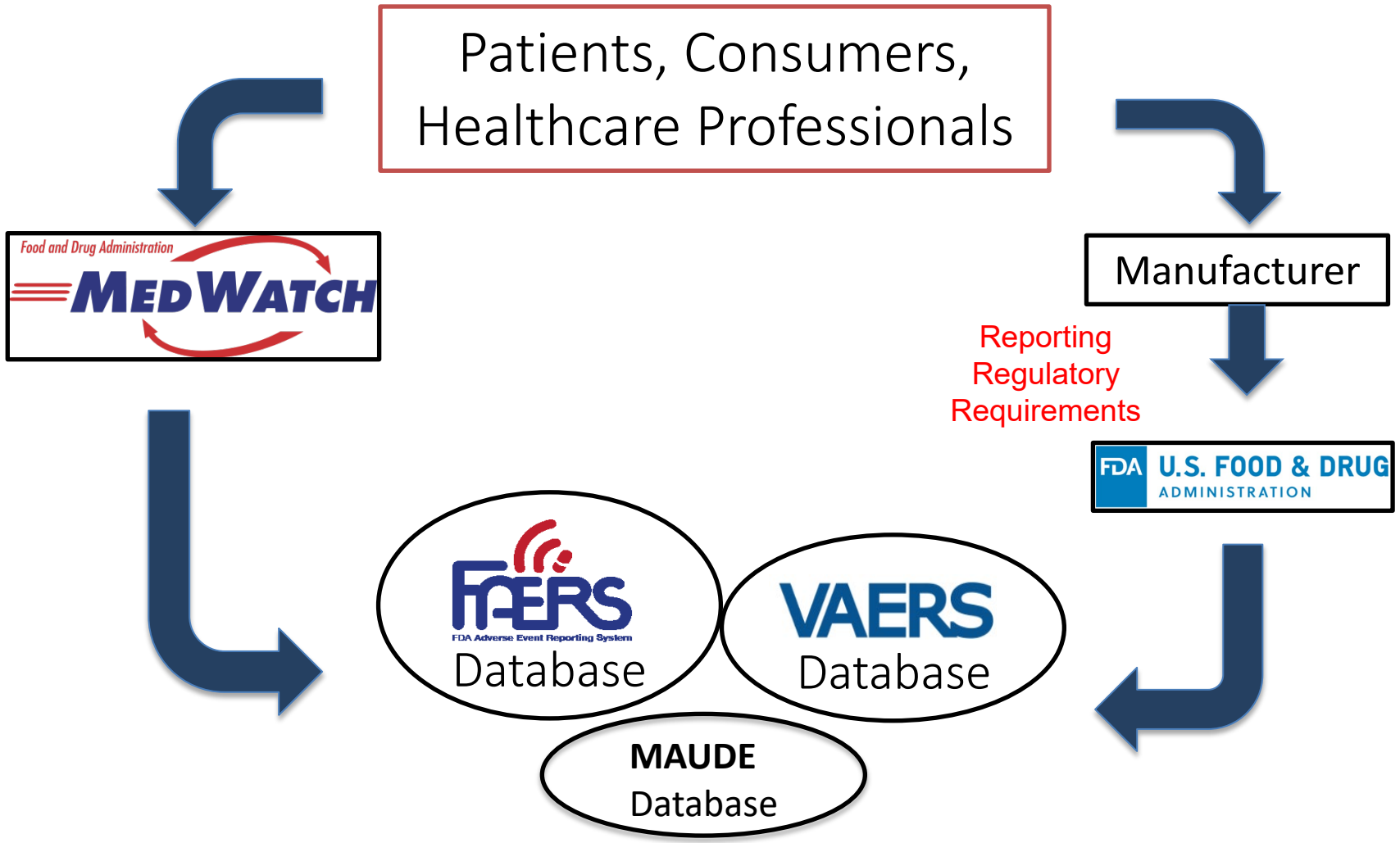
Center for **D**rug **E**valuation & **R**esearch **(CDER)**

Drugs/ Therapeutic Biologics

Center for **B**iologics **E**valuation & **R**esearch **(CBER)**

Vaccines/ Biologics/ Blood derivatives

Postmarketing Adverse Event Reporting for Medical Products



Manufacturer: Postmarket Safety Reporting Requirements

- Postmarket safety reports must be submitted to FDA for the following:
  - **Expedited reports**: Both **serious** and **unexpected** adverse events from all sources (domestic and foreign)
  - **Non-expedited reports**: Domestic spontaneous adverse events that are:
    - Serious and expected
    - Non-serious and unexpected
    - Non-serious and expected
    - Quarterly for the first 3 years then annually

Serious Adverse Event

Results in any of these outcomes:

- Death
- Life-threatening adverse experience
- Inpatient hospitalization – new or prolonged
- Persistent or significant disability or incapacity
- Congenital anomaly/birth defect
- Other serious: based upon appropriate medical judgment, these adverse events may jeopardize the patient and require intervention to prevent a serious outcome

Federal Register - Code of Federal Regulations. ***21 CFR 314.80****(a)*

Passive Surveillance: Strengths and Limitations

Strengths

- Includes all marketed products, uses, and patient populations
- Useful for events
  - With low background rates
  - Occurring shortly after exposure
  - Not seen in clinical trials
- May use to identify
  - Reporting trends
  - Risk factors
  - At risk populations
  - Emerging safety concerns

Limitations

- Dependent on report quality
- Less useful for events:
  - With high background rates
  - Where disease is reflected in the adverse event
  - With long latency
- Not able to calculate incidence rates or compare drugs in the same class
- Reporting biases

What is a Safety Signal?

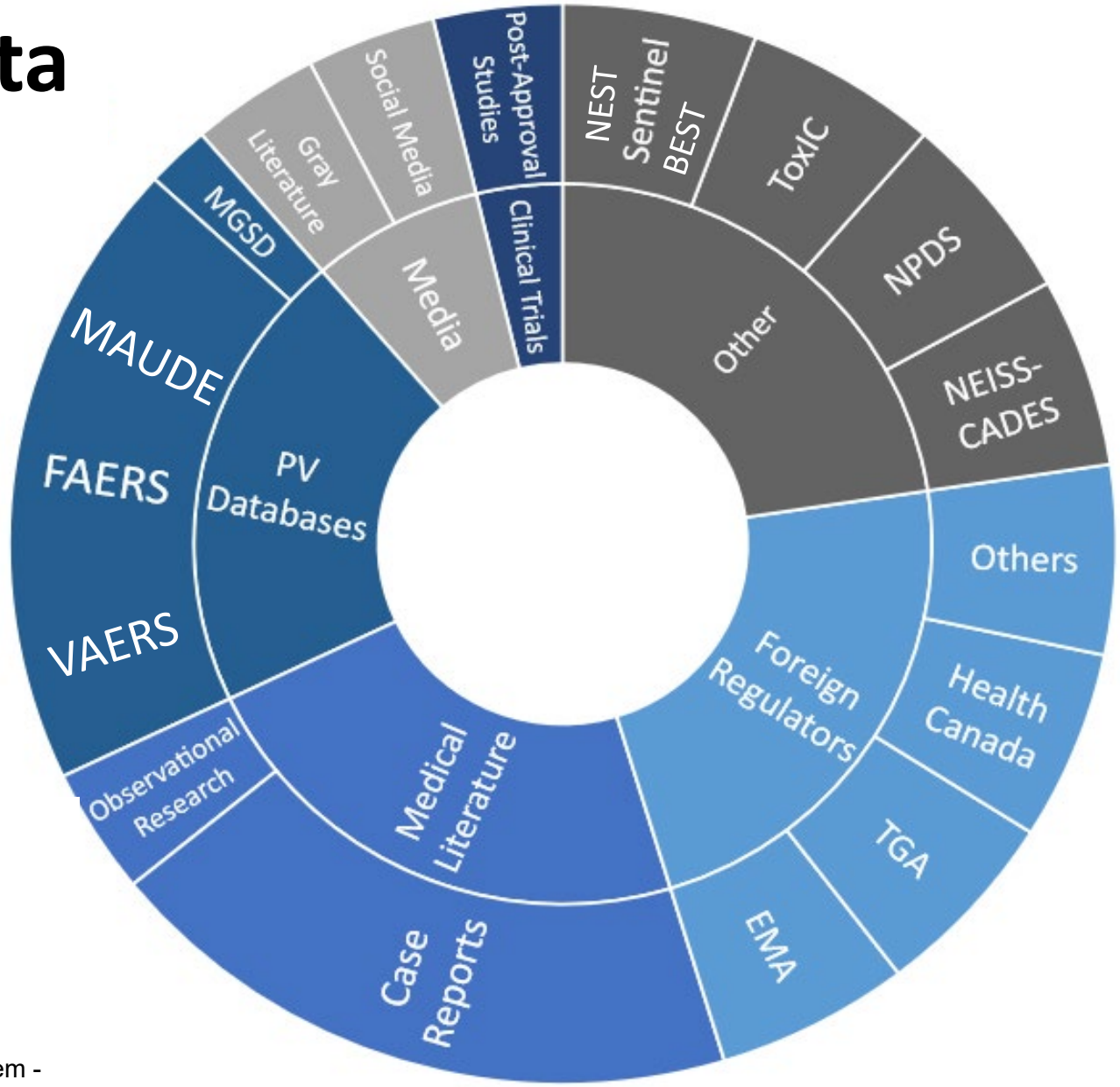
- Information that arises from **one or multiple sources**
- Suggests 1) a **new, potentially-causal** association, or 2) a **new aspect of a known** association
- **Sufficient likelihood** to justify further evaluation

Council for International Organizations of Medical Sciences 2014. Practical approaches to risk minimization for medicinal products: Report of CIOMS Working Group IX.

Analysis of FAERS/VAERS/MAUDE

- Look for patterns to detect "safety signals" of AE's plausibly linked to a product
  - –Temporality
  - –Dose Response
  - –Unexpected clinical or demographic clustering
  - –"Positive re-challenge" reports
  - –New for this product (e.g., not seen in clinical trials, label, literature)
  - –Absence of alternative explanations (concomitant medications, co- or pre-morbid conditions)
  - –Biologic Plausibility
- Case series: What is AE exactly (case definition)?
- Reporting rates: evaluate AEs in context of product use: how do reporting rates compare with background rates?

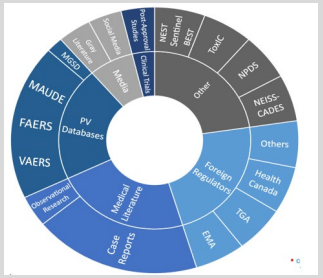
Postmarketing Data Sources



BEST = The Biologics Effectiveness and Safety
FAERS = FDA Adverse Event Reporting System
PV = Pharmacovigilance
MGSD = Manufacturer Global Safety Database
TGA = Therapeutic Goods Administration
EMA = European Medicines Agency
NEST= National Evaluation System for Health Technology
NPDS = National Poison Data System
NEISS-CADES = National Electronic Injury Surveillance System - Cooperative Adverse Drug Event Surveillance Project
ToxIC = Toxicology Investigators Consortium Registry

Signal Detection, Evaluation, and Verification

Sources of Safety Data	
Pre-licensure	**Post-licensure**
Clinical trials	Spontaneous reporting (VAERS, FAERS) Large electronic healthcare database Others (Literature, foreign regulatory agencies)



Hypothesis generating	
Signal Detection	**Signal Evaluation**

Hypothesis Testing
Signal Verification

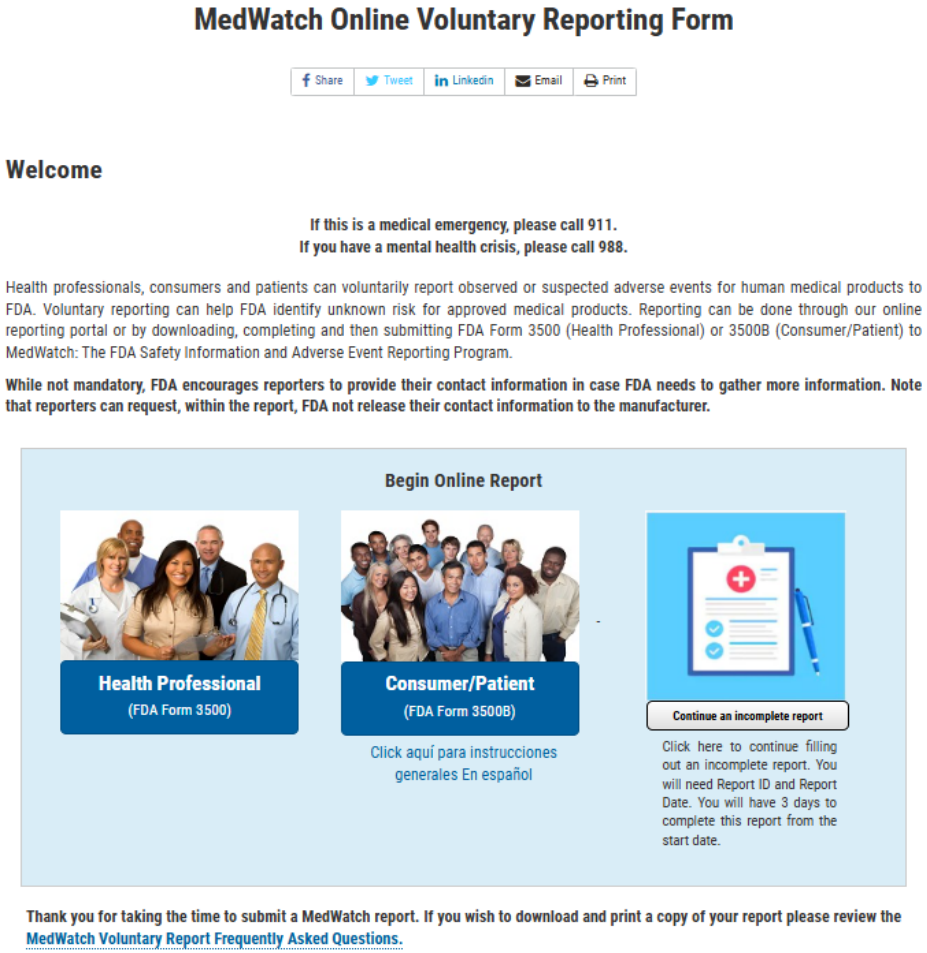
Regulatory Actions
Communications, Label Changes, Recalls, etc.

Pediatric Advisory Committee

Verification Tools	Large electronic healthcare databases (Sentinel, CMS, etc.)
	Observational Studies
	Clinical Trials

FDA Educational Efforts to Promote Reporting of Adverse Events For Medical Products

- **Strengthening Reporting Pathways**
  - Efforts to simplify reporting for caregivers and families through MedWatch Online and mobile-friendly tools.
  - Unified Reporting Forms: FDA Forms 3500 (voluntary) / 3500A (mandatory) capture consistent data across product types.
- **Enhancing Awareness and Participation:**
  - Webinars, safety communications, case studies and outreach to professional societies to encourage reporting of adverse events
- **Transparency**
  - FAERS Public Dashboard and MAUDE provide open access to data, enabling review of adverse event data



Pediatric-Focused Safety Monitoring

Assessed the impact of CDER pediatric-focused safety reviews

ARTICLE

Assessment of the Impact of Mandated Postmarketing Pediatric-Focused Safety Reviews on Safety-Related Regulatory Actions 2013–2019

Mohamed Mohamoud[1]*, Carmen Cheng[1], Debra Ryan[1], Ivone Kim[1], Eileen Wu[1], Monica Muñoz[1], Cindy Kortepeter[1], Ellen Pinnow[1] and Gerald Dal Pan[1]

Pediatric Medical Product Safety | FDA

Summary

- BPCA, PREA, and PMDSIA collectively ensure pediatric studies, labeling, and postmarket safety oversight
- Pediatric safety framework is an integrated approach spanning product development, regulatory review, and continuous postmarket monitoring
- The PAC is central to reviewing safety data, identifying emerging risks, and guiding pediatric regulatory decisions
- FDA promotes transparency, education, and reporting to strengthen pediatric safety and protect children's health

Thank You

Questions

Discussion on Non-Voting Question

Committee Discussion on Non-Voting Question

FDA encourages the public to submit adverse event reports when safety concerns arise. However, there are many factors that may impact reporting.

What steps can patients/consumers, providers, and healthcare systems take to optimize reporting of pediatric adverse events?

Lunch

Meeting will resume at 1:15 ET

Pediatric Advisory Committee Meeting

November 13, 2025

Open Public Hearing

All OPH Speakers, please sign in by sending an email to
PAC@fda.hhs.gov

Pediatric Advisory Committee Meeting

November 13, 2025

Open Public Hearing
Speaker #1

Pediatric Advisory Committee Meeting

November 13, 2025

Center for Devices and Radiological Health

George Van Hare, MD

Center for Devices and Radiological Health

1. ENTERRA THERAPY SYSTEM *
2. CONTEGRA PULMONARY VALVED CONDUIT *
3. PLEXIMMUNE *
4. SONALLEVE MR-HIFU *

*Humanitarian Device Exemption

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting
in Progress

Pediatric Advisory Committee Meeting

November 13, 2025

Center for Biologics Evaluation and Research

Craig Zinderman, MD, MPH

Center for Biologics Evaluation and Research

1. QUELIMMUNE *
2. SEVENFACT (coagulation factor VIIa (recombinant)-jncw)
3. VAXCHORA (Cholera Vaccine, Live, Oral)

*Humanitarian Device Exemption

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting
in Progress

Pediatric Advisory Committee Meeting

November 13, 2025

Center for Drug Evaluation and Research (CDER)

Ivone Kim, MD

Center for Drug Evaluation and Research

1. ABRAXANE

(paclitaxel)

2. ARMONAIR RESPICLICK, ARMONAIR DIGIHALER, AIRDUO RESPICLICK, AIRDUO DIGIHALER

(fluticasone propionate/fluticasone propionate and salmeterol xinafoate)

3. AUBAGIO

(teriflunomide)

4. AUSTEDO

(deutetrabenazine)

5. BREXAFEMME

(ibrexafungerp)

6. BYDUREON, BYDUREON BCISE, BYETTA

(exenatide)

7. CIBINQO

(abrocitinib)

8. COSENTYX

(secukinumab)

9. DESCOVY

(emtricitabine and tenofovir alafenamide)

Center for Drug Evaluation and Research

10. DUPIXENT
(dupilumab)

11. EDURANT, EDURANT PED
(rilpivirine)

12. ENBREL
(etanercept)

13. EVOTAZ
(atazanavir and cobicistat)

14. LIALDA
(mesalamine)

15. LINZESS
(linaclotide)

16. LITFULO
(ritlecitinib)

17. MYRBETRIQ EXTENDED-RELEASE TABLETS, MYRBETRIQ GRANULES
(mirabegron)

18. NUCYNTA, NUCYNTA ER
(tapentadol)

19. OPANA
(oxymorphone hydrochloride)

Center for Drug Evaluation and Research

20. PIFELTRO, DELSTRIGO

(doravirine/doravirine, lamivudine, and tenofovir disoproxil fumarate)

21. RAPIVAB

(peramivir)

22. REXULTI

(brexpiprazole)

23. RYALTRIS

(olopatadine hydrochloride and mometasone furoate)

24. SELZENTRY

(maraviroc)

25. SIMPONI ARIA

(golimumab)

26. SMOFLIPID

(lipid injectable emulsion)

27. SOLOSEC

(secnidazole)

28. TAYTULLA

(norethindrone acetate/ethinyl estradiol capsules and ferrous fumarate capsules)

29. TEZSPIRE

(tezepelumab-ekko)

Center for Drug Evaluation and Research

30. TRINTELLIX
(vortioxetine)

31. VIIBRYD
(vilazodone hydrochloride)

32. XOFLUZA
(baloxavir marboxil)

33. YCANTH
(cantharidin)

34. ZEGALOGUE
(dasiglucagon)

35. ZEPATIER
(elbasvir and grazoprevir)

36. ZERBAXA
(ceftolozane and tazobactam)

37. ZOSYN
(piperacillin and tazobactam)

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDER products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting in Progress

Wrap-Up

Adjournment