

# Postmarket Surveillance of Pediatric Cardiovascular Devices: FDA's Perspective

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# Current Landscape: Surveillance

## Passive and Enhanced Reporting Systems

- Medical Device Reporting (passive)
  - Several hundred thousand individual reports/year
  - Dominated by manufacturer reporting
  - ~5% are known pediatric reports (birth to 22 years)
- Medical Product Safety Network (enhanced)
  - Hospital-based national network (N ~ 350)
  - KidNet: pediatric/neonatal intensive care units (N ~ 50)
  - HeartNet: EP labs (N ~ 12)

## Systems Address “Numerator-Driven” Issues

- Out-of-box failures; software glitches; manufacturing defects; packaging error; labeling error; design-induced use error; misconnects/disconnects; poor maintenance?..

# Current Landscape: Mandated Studies

## Postmarket Study Authorities

- Post-approval Studies (PAS)
  - As a condition of approval for class III devices
  - Since 2005, 75% (45/60) of PAS orders involve pediatric patients
  - Amplatzer VSD occluder: 5 year f/u pivotal cohort and new registry (procedural success, complications, shunt status)
- Section 522 Postmarket Studies
  - Typically ordered “for cause”
  - For devices expected to have significant pediatric use (FDAAA)
    - Order as a condition of clearance (class II) or approval (class III)
  - 35 studies underway on 6 devices groups
  - AEDs: experience with OTC usage noted via survey

## Mandated Studies Address “Rate-Driven” Issues

- Procedural success and complications, but small in scope and time limited

# Key Challenges

- Leveraging health-related electronic records
  - Unique device identifiers (UDIs)
- Diverse Registry Landscape
  - FDA efforts
- Active Surveillance Capabilities
  - Sentinel Initiative
- Developing Evidence Synthesis



# UDIs in Health-related Electronic Data

- Efforts continue on the UDI front
  - FDA to issue a draft rule requiring UDIs
  - FDA to establish a UDI database
- Incorporating UDIs is important for many reasons
  - Will improve understanding of the risk/benefit profile
  - May facilitate device tracking and adverse event reporting
- Efforts needed to facilitate incorporation
  - Further engage stakeholders (e.g., insurers, vendors)
  - Explore best practices for incorporating UDIs



# Diverse Registry Landscape

- No comprehensive device registry, but a patchwork of a limited number of registries
- May be used to fulfill requirements of PAS
- Professional society supported – FDA has to pay
- Typically based on procedures, not products (e.g., coronary artery bypass graft)
- Specific device identification as add on
  - exception: academic registries
- Short-term and focused on quality improvement

# FDA Registry Efforts

- Link Registry with Claims Data
  - Using probabilistic methods (TMR, EVH)
  - One-off studies
- Create Compendium of Pediatric Registries
  - Inclusion/exclusion criteria; ~40 identified
  - Type 1 diabetes registry of interest
- Foster Registry Development
  - IMPACT (Improving Pediatric and Adult Congenital Rx)
    - Transcatheter CHD treatments
    - Multi-stakeholder involvement
    - Multi-site testing of short-term data collection instrument



# Active Surveillance: Sentinel Initiative

An effort to develop a national, integrated infrastructure of electronic healthcare data systems for medical product safety surveillance

Putting observational data to use for **active, “real time” surveillance**

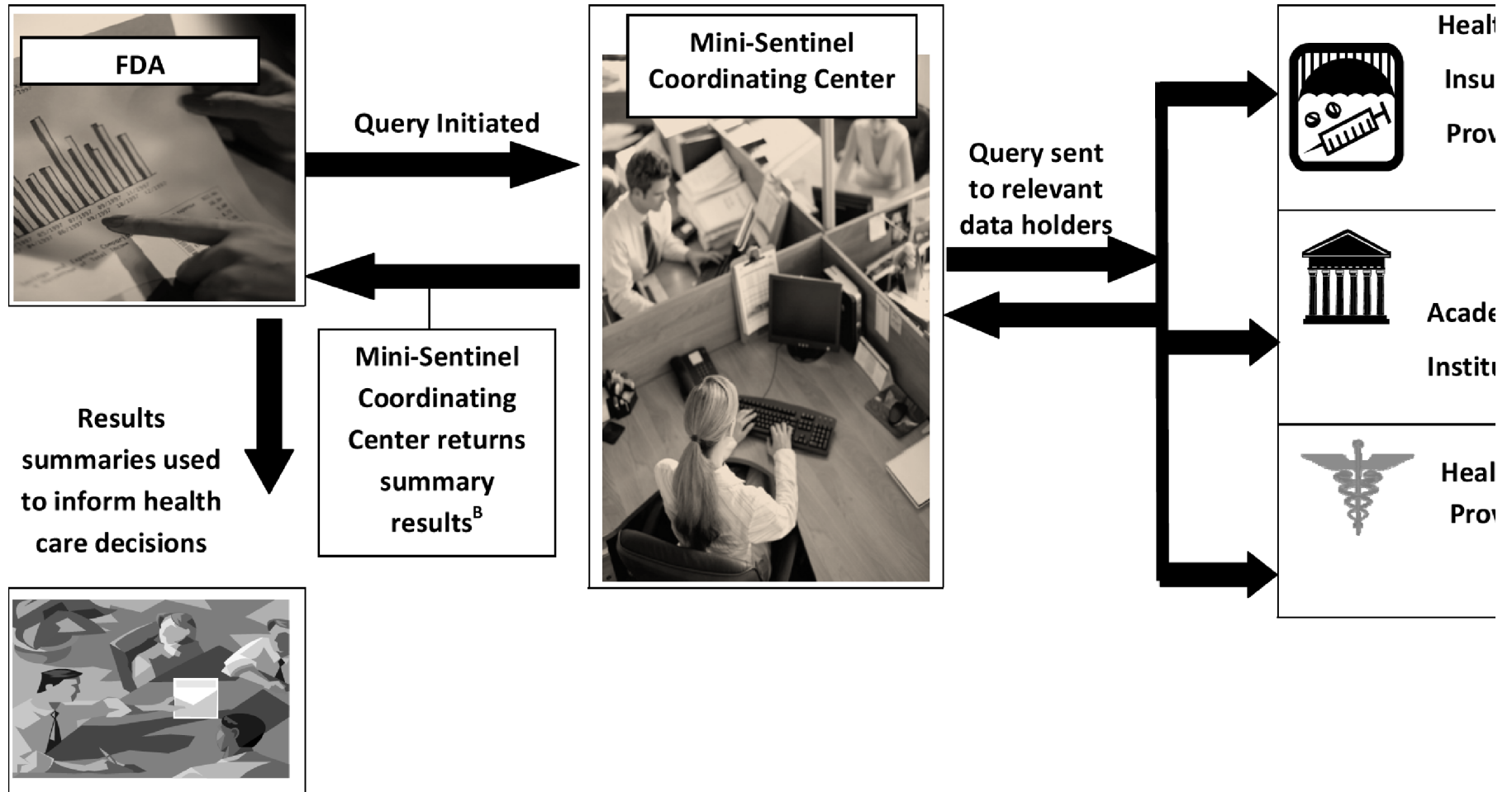
- Complement existing safety monitoring systems
- Provide access to information on sub-groups, special populations, and longer-term outcomes

[www.fda.gov/Safety/FDAsSentinelInitiative/default.htm](http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm)





## Overview of the Mini-Sentinel Query Process

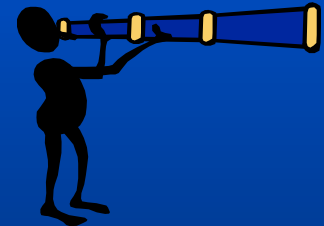


A. Only those academic institutions with automated data will be recipients of queries.

B. No entities will have access to protected health information that they do not already hold. Instead, those whose queries are accepted to the **Mini-Sentinel Coordinating Center** for processing will receive results summaries from analyses conducted by each data holder that do not contain protected health information. Results summaries will not include protected health information.

# Registry-based Active Surveillance

- Exploring use of mandated clinical outcomes registry (NCDR cathPCI) in Massachusetts
  - Common data model and “defined” outcomes
  - Retrospective study with entire state’s data (2003-2007)
    - Short-term follow-up (up to 30 days post-procedure)
    - Stents, hemostasis devices, embolic protection devices
  - Recent publication of early efforts:  
*JAMA* 2010;304(18):2019-2027
- Further considerations
  - Design and analysis methods (e.g., device-specific propensity scores models, testing statistical methods)
  - Alternative/complementary data sources (e.g., exploring registry linkage)



# Evidence Synthesis

What? Combine information from diverse data sources and data types

- Clinical trials, observational studies, claims data, registries

Why? Increasing availability of information, increasing heterogeneity of treatment populations, and *analytic advances*

- Simultaneous analysis of multiple outcomes when measured on different scales
- Accommodation for heterogeneity across studies and data sources
- Combination of information across studies with multiple and different treatment arms
- Combination of different types of studies

# Evidence Synthesis

How? Synthesis of evidence using various data integration methods (e.g., meta-analysis, network meta-analysis, cross-design synthesis)

Central question? Can diverse data sources be combined to build reliable and accurate prognostic models of device performance?

Applications? initial focus on total hip arthroplasty (CV devices next)

# Thanks for Your Attention!



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