

# Privacy and Security in Mini-Sentinel: Ensuring Public Trust through Respectful Use of Health Information

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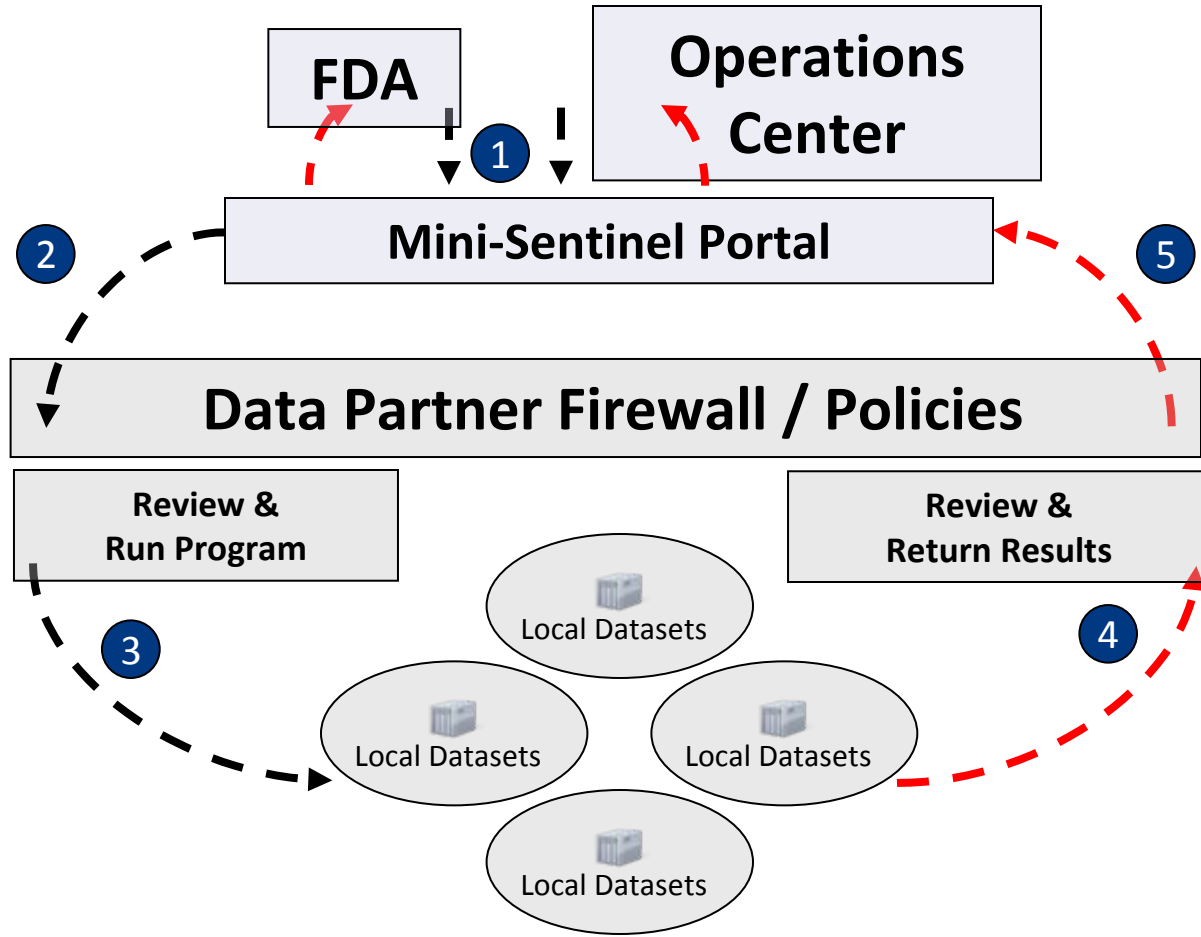
# Agenda

- Data flow in the Mini-Sentinel pilot
- Legal compliance
- Policies that reflect fair information practices

## **The Mini-Sentinel Privacy Panel:**

- Deven McGraw, Director, Health Privacy Project, Center for Democracy & Technology
- Barbara Evans, Associate Professor, Co-director, Health Law & Policy Institute, Director, Center on Biotechnology & Law, University of Houston Law Center
- Kristen Rosati, Partner, Coppersmith Schermer & Brockelman PLC

# Mini-Sentinel Distributed Analysis



# Data Flow in Mini-Sentinel

- Distributed Data Model: Data Partners maintain physical and operational control over the original source data and data is transformed into the Mini-Sentinel Common Data Model (MSCDM) format
  - Operations Center sends standardized queries to Data Partners
  - Data Partners execute queries against data in the MSCDM format and share summary results with Operations Center
  - Data Partners may be asked to provide non-summary, patient-level information as follow-up, but will strip out direct patient identifiers before disclosure to Operations Center

# Data Flow in Mini-Sentinel

- If Data Partners do not maintain original source data, they may ask data source for medical records to further analyze drug safety signal; Data Partners will ensure that direct patient identifiers are redacted before sending to Operations Center

# Health Insurance Portability and Accountability Act (HIPAA)

- HIPAA permits disclosure of protected health information (PHI) to a “public health authority” for public health surveillance (which includes the safety of FDA-approved products)
  - FDA is a public health authority
  - Public health authority also includes a “person or entity acting under a grant of authority from or contract with such public agency” – Mini-Sentinel Operations Center and its subcontractors are acting under a grant of authority from the FDA
- Release of PHI (if any) to the Data Partners, the Operations Center and the FDA is not for “research” that requires approval by an Institutional Review Board

# Federal Substance Abuse Treatment Regulations (the “Part 2 Regulations”)

- Part 2 regulations protect information generated by a federally-assisted alcohol or drug abuse treatment program, if the information identifies a patient as an alcohol or drug abuser or someone who has applied for or received that type of treatment
- Part 2 regulations are unlikely to affect Sentinel, but covered data sources will need to evaluate release of original source data to Data Partners for analysis

# State Confidentiality Laws

- State health information confidentiality laws often provide more protection for “special” health information, such as:
  - Genetic testing
  - Mental health information
  - HIV/communicable diseases
- Most state laws regulate external disclosure, but not internal use of health information
- Many state laws permit release for public health activities
- No state laws (to my knowledge) regulate the release of aggregated, non-identifiable information
- Each data source will need to confirm compliance with its own state laws



# Fair Information Practices

- Data Integrity and Quality
- Collection and Use Limitations
- Purpose Specification and Minimization
- Openness and Transparency
- Individual Participation
- Security Safeguards and Controls
- Accountability and Oversight

# Policies Comply with Fair Information Practices

- Distributed data model: drug safety questions are brought to the data
- All direct identifiers are removed from information provided to the Operations Center or the FDA
- Any identifiable information received by Data Partners to confirm drug safety signals is used only for Mini-Sentinel purposes
- Operations Center may use information it receives only for Mini-Sentinel purposes
- Operations Center manages security in accordance with the HIPAA Security Rule and the Federal Information Security Management Act

# Thank you!

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