Major Moments in the Development of Sentinel

Sentinel Community Building and Outreach Center

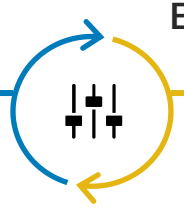
The Origins of the Sentinel Initiative

The U.S. Food and Drug Administration (FDA) established the Sentinel Initiative (Sentinel) to meet a mandate by Congress in the **FDA Amendments Act of 2007 (FDAAA) to create a system to assess the safety of approved drug and biologic products**. Sentinel was developed to address the following provisions from Section 905 of FDAAA.

DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION & ANALYSIS METHODS

FDA in collaboration with public, academic, and private entities shall:

- ✓ Develop methods to obtain access to **disparate electronic healthcare data sources**
- ✓ Develop validated methods for establishment of a postmarket risk identification and analysis system to **link and analyze safety data from multiple sources** with a goal of including at least 100,000,000 patients by July 1, 2012
- ✓ Convene a **committee of experts from the public, academic, and private entities** to provide recommendations on data privacy, security, development of analytic tools and methods for ethical and scientific uses for, and communication of, postmarketing data from the postmarket risk identification and analysis system



ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION & ANALYSIS SYSTEM

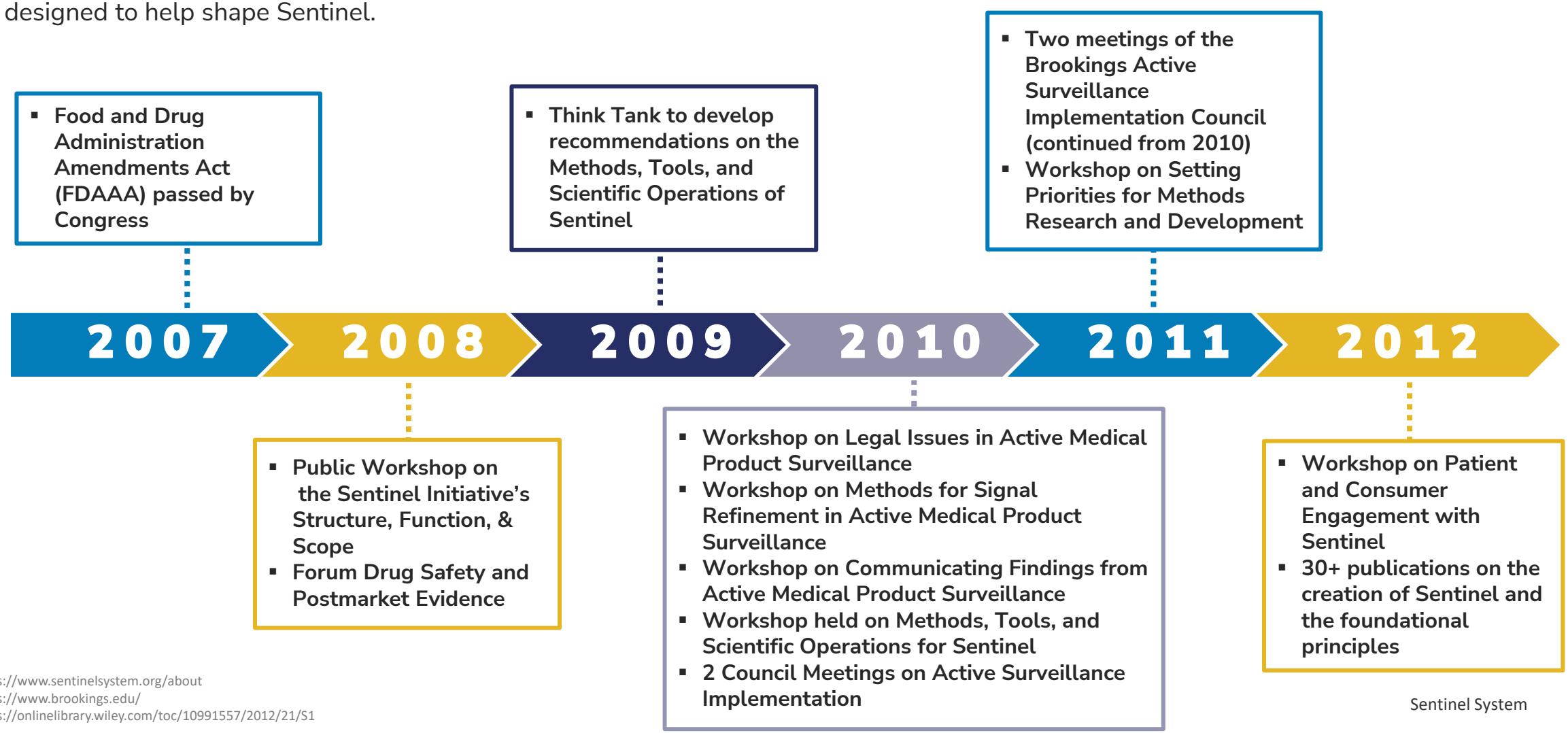
FDA establish and maintain procedures to:

- ✓ Identify risk and analysis based on electronic health data, in **compliance with federal regulations**
- ✓ Provide for active adverse event surveillance by using **federal and private sector** health-related electronic data
- ✓ Identify **adverse event trends** and patterns and **provide regular reports** with respect to data accessed by the system
- ✓ Ensure that data are accessed, analyzed, and reported in a **timely, routine, and systematic manner**

https://www.govinfo.gov/content/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf

Timeline of Major Meetings, 2007-2012

FDAAA presented legal, technical, methodological, and policy considerations for Sentinel's implementation. This led to **a series of meetings with various stakeholders** facilitated by the Brookings Institution, and the **commissioning of several publications** designed to help shape Sentinel.



https://www.sentinelsystem.org/about
https://www.brookings.edu/
https://onlinelibrary.wiley.com/toc/10991557/2012/21/S1

The 5 Major Foundational Principles

The provisions outlined in **FDAAA led to five foundational principles, which informed the development of Sentinel's large, linked database system** to assess and monitor postmarket safety of drug and biologic products. Expert recommendations and insights on each of the principles were obtained through a series of stakeholder engagements.

Engaging the Scientific Community

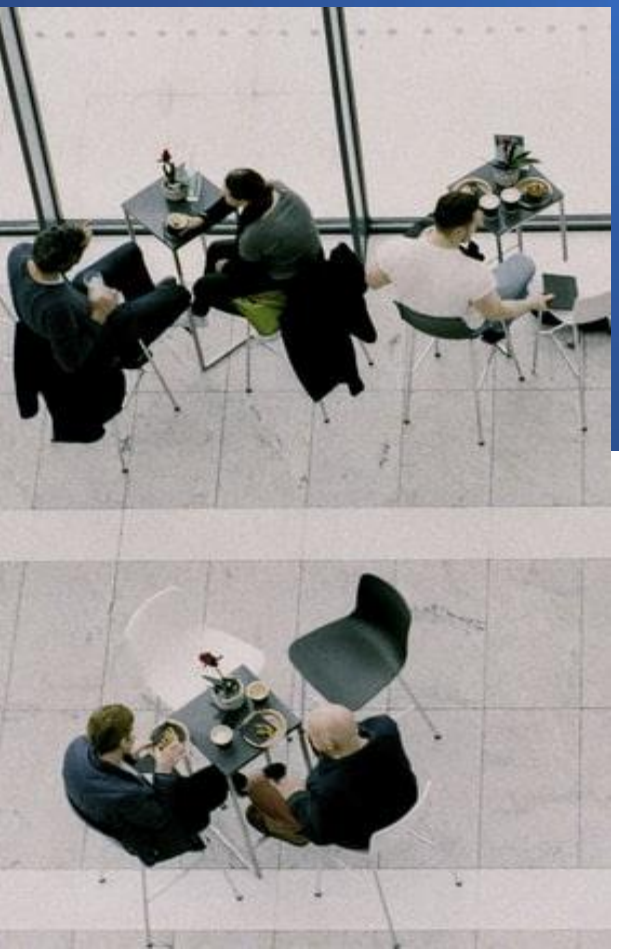
Creating Large Study Cohorts

Ensuring Data Privacy

Communicating Findings Effectively

Fostering Public-Private Collaboration

Engaging the Scientific Community



Learning Objective:

Importance of and approaches to engaging various stakeholders

- FDAAA called for **inclusion of various stakeholder inputs and perspectives** from the scientific community in developing an active, postmarket surveillance system.
- FDA approached engagement through multiple mechanisms:
  - Convened 12+ **workshops/roundtables/forums and commissioned several white papers** from 2008-2012**,** with involvement from **diverse audiences** including academics, industry, consumers, and scientific journalists
  - An **Annual Public Workshop** was established to keep the public informed about Sentinel, and later a Public Training and Innovation Day was added to further engage stakeholders
  - Established collaborative partnerships with external groups to serve as **public convener** to effectively engage with scientific community
- By engaging the scientific community, stakeholders from different backgrounds were able to provide valuable perspectives and inputs that directly **informed the foundations of Sentinel.**

https://www.brookings.edu/events/expert-workshop-patient-and-consumer-engagement-in-fdas-sentinel-initiative/
https://www.brookings.edu/wp-content/uploads/2012/04/Patient-Consumer-Summary.pdf
https://www.sentinelsystem.org/about/engaging-sentinels-stakeholders
https://www.fda.gov/regulatory-information/food-and-drug-administration-amendments-act-fdaaa-2007/fdaaa-implementation-highlights-one-year-after-enactment

Creating Large Study Cohorts

Learning Objective:

Create large cohorts to study rare events in a fragmented healthcare system to quickly assess safety concerns

- In 2009, FDA awarded a contract to the Harvard Pilgrim Health Care Institute to assemble a network, known as **Sentinel Data Partners**, of health insurers and integrated delivery systems that collectively had data on at least 100 million lives.
  - A distributed data network was developed, in which each Data Partner's data are **kept behind their respective firewalls.**
  - Data Partners generate a copy of their data that is then formatted into the **Sentinel Common Data Model (SCDM).**
- Sentinel's tools are a **set of re-usable, executable programs** applied to the SCDM to address FDA's medical product safety questions.
  - Tools can perform **descriptive and adjusted analyses** with control for confounding.
- When FDA plans an analysis in Sentinel, agency scientists work with the Sentinel Operations Center (SOC) to **determine the analytic approach and study specifications**; an associated program is then sent to the Data Partners.
  - Each Data Partner then **returns summary results** to the SOC, which aggregates the findings for FDA.

https://www.sentinelinitiative.org/methods-data-tools/
https://www.brookings.edu/events/forum-on-drug-safety-and-post-market-evidence/
https://www.brookings.edu/events/brookings-active-surveillance-implementation-council-meeting-1/
https://www.brookings.edu/events/expert-workshop-setting-priorities-for-methods-research-and-development-for-active-medical-product-surveillance/

Ensuring Data Privacy

2010

Expert Workshop held on Legal Issues in Active Medical Product Surveillance

2012

Article published on how Mini-Sentinel pilot was conducted in compliance with federal & state laws and attributes of Mini-Sentinel that enhance privacy & public trust

2018

Sentinel designated as public health surveillance under Common Rule.

Learning Objective:

The technical and legal considerations of data privacy and public health surveillance

- With the large amount of data that contribute to Sentinel across multiple Data Partners, **protection of patients' healthcare data** is essential. Sentinel addressed data privacy considerations by:
  - **Adhering to all applicable state and federal laws**, including HIPAA, FISMA, and NIST standards
  - Establishing **secure portals between each Data Partner and the SOC** for communications, data checking, and query submissions to maximize privacy and security
  - Allowing **Data Partners to maintain complete autonomy** over their data contributions for a query
  - Ensuring Data Partners **remove direct patient identifiers** behind their own firewalls prior to sharing information with Sentinel
  - Ensuring data provided by Data Partners are **aggregate,** and adhere to the minimum necessary standard
- Under the Common Rule, Sentinel is designated public health surveillance
  - Therefore, IRB approval is not sought when FDA conducts a new surveillance activity within the Sentinel System

https://www.sentinelinitiative.org/about/principles-policies
https://www.sentinelsystem.org/about/how-sentinel-protects-privacy-security
https://www.brookings.edu/events/legal-issues-in-active-medical-product-surveillance/
https://www.sentinelinitiative.org/news-events/publications-presentations/policy-framework-public-health-uses-electronic-health-data
Federal Policy for the Protection of Human Subjects, 82 FR 7149, 7172, 7175-76 (Jan. 19, 2017)
2018 Requirements (2018 Common Rule) 45 CFR 46.102(1)(2)
https://www.sentinelinitiative.org/sites/default/files/communications/publications-presentations/HIPAA-Common-Rule-Compliance-in-Sentinel-Initiative.pdf

Communicating Findings Effectively

Learning Objective:

Effectively communicate about early findings with the potential for the science to change

- **Transparency is fundamental to the operations** of the Sentinel System, with knowledge acquired from Sentinel activities placed in the public domain.
- Mechanisms were developed **for timely communication to external stakeholders** (including sponsors, patients, consumers, health care providers, data partners, scientists, and media) on the findings from Sentinel analyses through the Sentinel website, professional meetings, and the scientific literature.
- Considerations were given on how to **communicate and release findings early while taking caution on releasing journal publications in the face of uncertainty** of Sentinel analyses and their implications.
- The **Sentinel website** (sentinelinitiative.org) evolved as a key communications platform regarding information about **ongoing and completed safety analyses,** keeping the scientific community and public informed about latest Sentinel findings and updates.
- It is important to note that Sentinel's findings provide one among many sources of information that FDA evaluates the risks and benefits of a medical product. **Consideration of the entire body of evidence** informs regulatory decision-making.

https://www.brookings.edu/events/forum-on-drug-safety-and-post-market-evidence/
https://www.brookings.edu/events/communicating-findings-from-active-medical-product-surveillance/
https://www.brookings.edu/wp-content/uploads/2012/04/BASIC-3-Summary20111017FINAL.pdf

Fostering Public-Private Collaboration

Learning Objective:

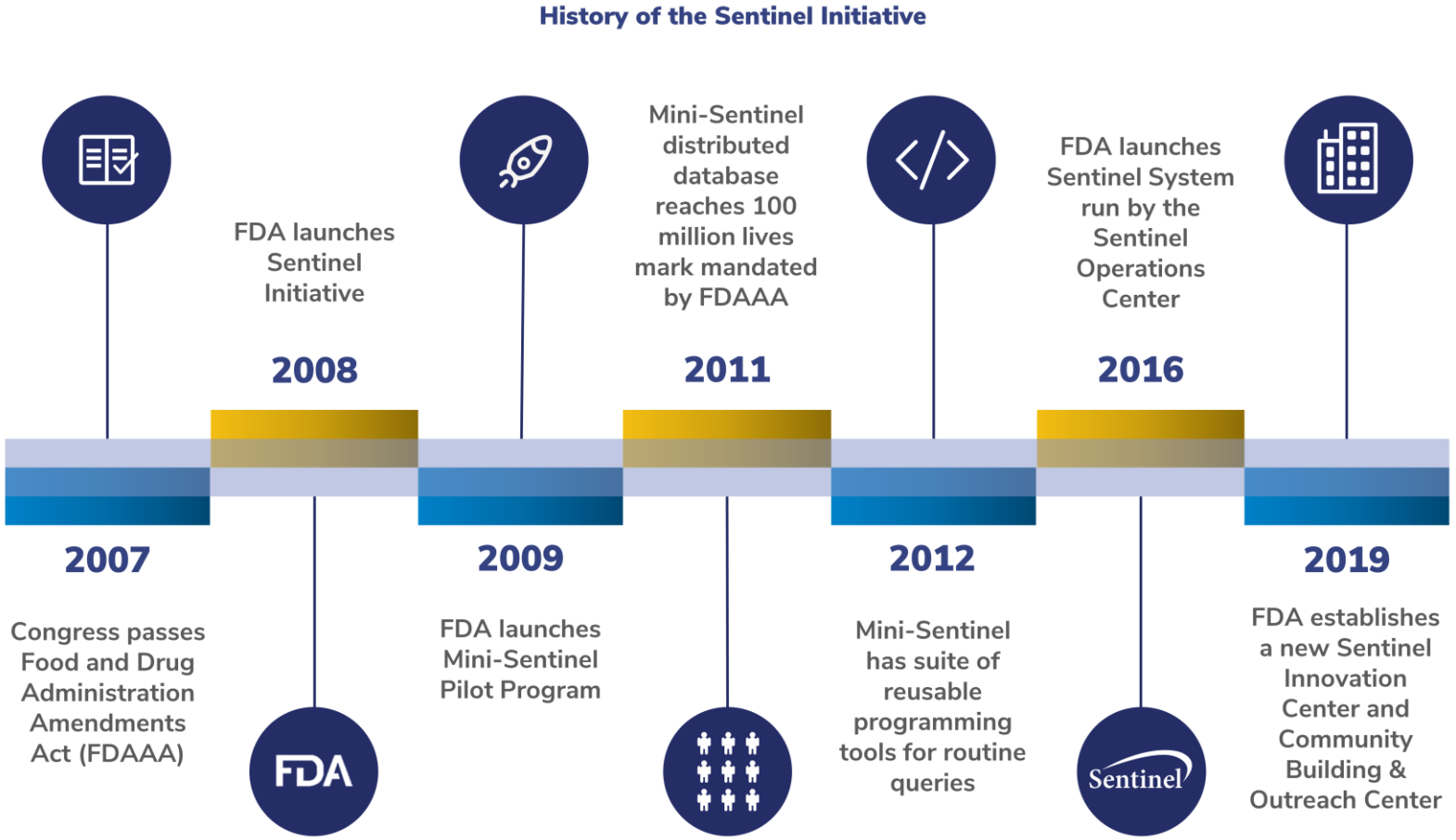
The importance of and approaches to developing collaboration between public and private institutions

- FDAAA mandated that FDA establish an active postmarket risk identification and analysis system in **collaboration with public, academic, and private entities** including but not limited to, national insurers, healthcare systems, and integrated delivery systems.
- As one single source of data would not be sufficient to address questions posed to Sentinel, the system was built upon **access to diverse health care data**.
- The Sentinel Operations Center, or the SOC, serves as the operations coordinator and has individual contracts with **public and private data source partners**, who retain control of their own data.
- In addition, scientific collaborations with both public and private entities increased the **breadth of scientific, technical, and organizational expertise**, creating a network of experts that Sentinel can continuously leverage to advance public health surveillance.

https://www.brookings.edu/events/forum-on-drug-safety-and-post-market-evidence/
https://www.brookings.edu/events/brookings-active-surveillance-implementation-council-meeting-1/
https://www.brookings.edu/events/brookings-active-surveillance-implementation-council-meeting-2/
https://www.brookings.edu/wp-content/uploads/2012/04/BASIC-4-Summary.pdf

Evolution of the Sentinel Initiative

Sentinel's operations today are **rooted in the foundational principles** set forth in early years of the system. After the launch of the Sentinel System in 2016, Sentinel expanded in 2019 to include three distinct Centers to fulfill strategic objectives. This structure continues to reflect the core principles – **engagement, communication, data quality, and data privacy** – that Sentinel was founded upon.



https://www.sentinelinitiative.org/about#history-of-the-sentinel-initiative

Stay Engaged with Sentinel

https://www.sentinelinitiative.org/engage-sentinel

Newsletter

Receive information about the latest Sentinel updates, assessment results, event information, and changes to the Sentinel System.

Public Training

View trainings on Sentinel data, tools, or other areas of interest.

RSS Feed

Stay informed about the latest updates to the Sentinel website by subscribing to our RSS feed.