

Sentinel System Overview

D. Tyler Coyle, MD, MS

Center for Drug Evaluation and Research

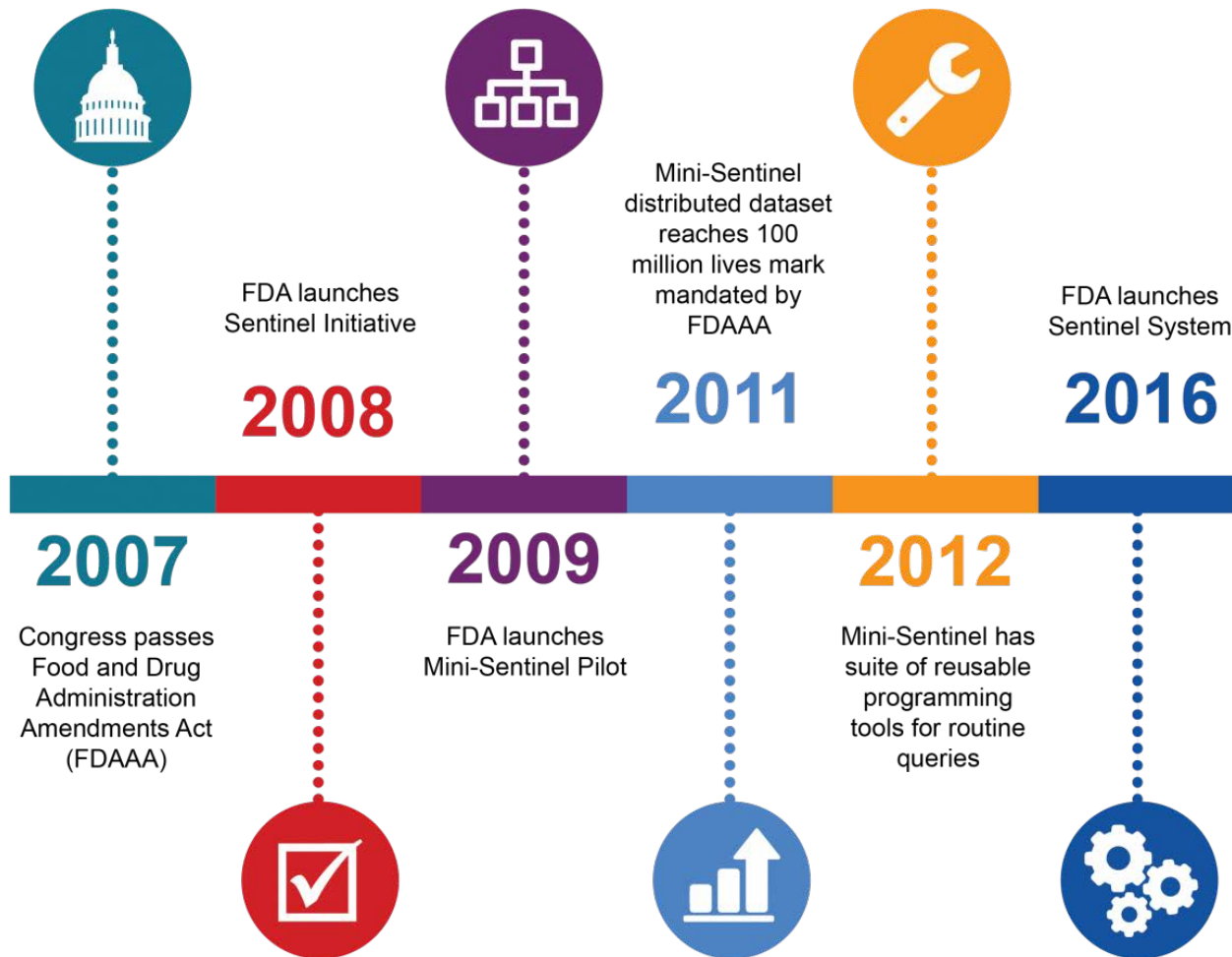
United States Food and Drug Administration



Sentinel is:

- FDA's medical product safety surveillance system created in response to a Congressional mandate
- Primarily electronic healthcare and administrative claims data
- Based on a distributed data network and a common data model

History of the Sentinel Initiative



Sentinel Uses Secondary Data

- Patient interaction with the U.S. healthcare system generates data
- Why is data collected?
 - Payment/billing
 - Document clinical care
 - Physician decision support
 - Recordkeeping
 - Registries
- Data provide rich source of information for patient safety evaluations

Data is Collected for Several Purposes



Administrative Data

- Collected for transactional recordkeeping, reimbursement

Clinical Data

- Collected to document elements of clinical care and support physician decision-making



Registries

- Collected to provide information on a specific population of interest

Sentinel Captures Billions of Encounters with the Healthcare System

- Populations with well-defined person-time for which most medically-attended events are known
- 223 million members*, 2000-2016
 - 178 million members* with medical and pharmacy benefits
- 43 million people currently accruing new data
- 425 million person-years of observation time

*Counts distinct "PatID" values in the database, 2000-2016

Common Data Model

- A common data “language” across different health system data sources that allows for aggregation of large amounts of data
- Patient data stay secure because the source information stays at the health care system in the Sentinel Distributed Database

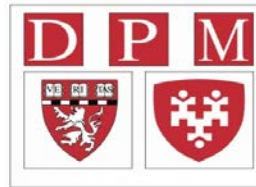
Sentinel Distributed Database Ensures Data Security



 Data transferred securely

Scientific Partners Bring Expertise

Lead – HPHC Institute



Data and scientific partners



Scientific partners



Data Partners Respond to Queries





Why Is Sentinel Important?

- Sentinel generates real-world evidence to support regulatory actions aimed at protecting the public's health
- This evidence helps inform healthcare provider decision-making for patients

What kinds of questions can Sentinel answer?

- Number of tablets of X dispensed to outpatients in 2015?
- Fraction of patients who filled a prescription for X who also filled a prescription for Y?
- Risk of a problem among patients dispensed both drug X and drug Y compared to patients dispensed drug X and drug Z?

Sentinel Webpage:

www.sentinelinitiative.org

FDA



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Sentinel

Drugs

Vaccines, Blood & Biologics

Communications

FDA-Catalyst

Report Finder

Sentinel is a National Medical Product Monitoring System

LEARN MORE



ABOUT

- Background
- Coordinating Center
- Privacy and Security
- The Sentinel System Story
- Reagan-Udall Foundation and IMEDS



MEDICAL PRODUCT ASSESSMENTS

- Active Risk Identification and Analysis System
- Ongoing ARIA Assessments
- Assessments of Drugs
- Assessments of Vaccines, Blood, & Biologics
- FDA-Catalyst

Latest Postings

SPOTLIGHT

- Registration is Open for the Sentinel Initiative Public Workshop and Training - February 7-8, 2018
Mon, 12/04/2017
- CDER Conversation: The FDA's Sentinel Initiative
Mon, 11/27/2017

PUBLICATIONS AND PRESENTATIONS



How is FDA Using Sentinel?



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Communications

FDA-Catalyst

Report Finder

Home >> Drugs >> How ARIA Analyses Have Been Used By FDA

DRUGS

- About CDER
- Assessments
- Ongoing ARIA Assessments
- [How ARIA Analyses Have Been Used by FDA](#)

How ARIA Analyses Have Been Used by FDA

This page summarizes how select analyses conducted in Sentinel's [Active Risk Identification and Analysis \(ARIA\)](#) system have been used by FDA. ARIA can contribute to FDA's regulatory process in a variety of ways, such as contributing evidence to support a label change, respond to a Citizens Petition, or become part of an Advisory Committee deliberation. Information from ARIA can also provide evidence that alleviates concerns about a particular safety issue and might lead FDA to determine that no regulatory action is necessary based on the available information.

Each ARIA analysis listed below contributed in some material way to inform an important regulatory discussion or action. FDA makes decisions about drug safety issues based upon the totality of evidence. The listing of an ARIA analysis in the table means that Sentinel's ARIA system was one important source of evidence considered.

Drug Name	Outcome Assessed	ARIA Analysis	Regulatory Determination / Use	Date Posted
Keppra (levetiracetam)	Anaphylaxis and angioedema	Level 1	Drug Safety Label Change, Warnings and Precautions <ul style="list-style-type: none"> • Results • FDA Drug Safety Labeling Changes Page 	11/30/2017



What Can Patients Do?

- Patients can engage with FDA's Sentinel System by:
 - Talking with their healthcare providers and insurance plans about the Sentinel System to build awareness
 - Visiting our website for news and updates
 - Attending Sentinel's public workshops and meetings

10th Annual Public Workshop



Duke

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Home > Events > 2018 Sentinel Initiative Annual Public Workshop

2018 Sentinel Initiative Annual Public Workshop

February 7, 2018 - 9:00 am

[Register now](#)

[Hyatt Regency Bethesda](#)
1 Bethesda Metro Center
Bethesda, MD 20814

Description

This annual workshop serves as a forum to bring together leading experts and interested stakeholders to discuss the ongoing development of the Sentinel Initiative. The Food and Drug Administration (FDA) is pleased to host the 10th Sentinel Initiative Annual Public Workshop on February 7, 2018.

Speakers

Dr. Gerald Dal Pan, Director of the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research

Summary:

The Sentinel System

- Sentinel is FDA's national medical product monitoring system
- Uses a common data model and a distributed database
- Generates evidence to inform clinical decision-making
- Multiple ways to stay informed and active
 - Sentinel website: <https://www.sentinelinitiative.org/>
 - Annual Public Workshop: <https://www.sentinelinitiative.org/rss/registration-open-sentinel-initiative-public-workshop-and-training-february-7-8-2018>

Thank you!

D. Tyler Coyle

David.Coyle@fda.hhs.gov

301-796-3338

SENTINEL ENGAGEMENT PARTNERS WORKGROUP

Steve Mikita, JD

Lead, Sentinel Engagement Partners Workgroup

Sentinel Planning Board Member

Patient Advocate



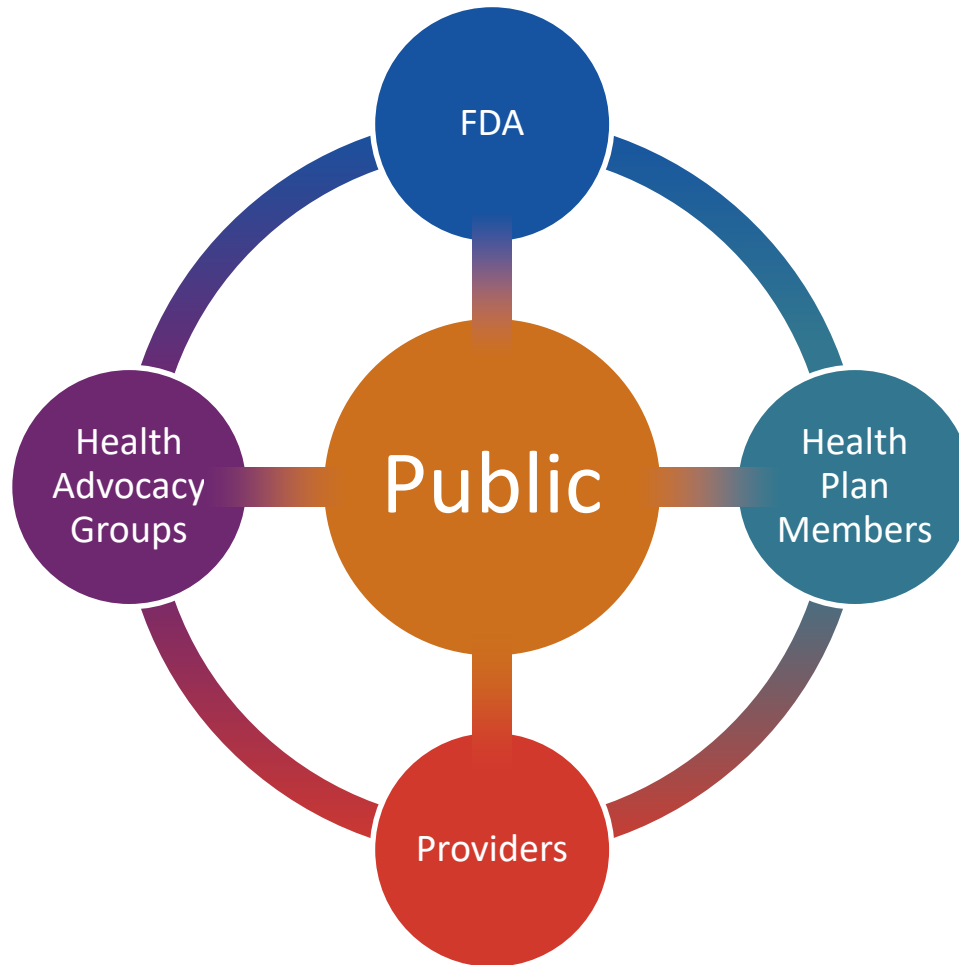
SENTINEL ENGAGEMENT PARTNERS WORKGROUP

- **Issue:** Critical Stakeholders are largely unaware of the Sentinel System, its commitment to health, safety, and protection of patient privacy.
- Public
- Health Advocacy Groups
- Providers
- Health Plan Members

WORKGROUP CHARTER

- **“Create a Plan of Action** to Increase Awareness and Tell the Sentinel System’s Story, Successes, and Value”
- **“Develop Messages and Tools** to Increase Awareness of the Sentinel System’s Public Health Value and Commitment to Privacy”

THE ENGAGEMENT PARTNERS WORKGROUP



WORKGROUP OBJECTIVES

- **Foundational Principles**
 - Transparency
 - Relevance
 - Effective Communication

STRATEGIES FOR ENGAGEMENT

- **Coordinated Communication Strategy**—Key Elements of the Sentinel System.
- **Targeted Messages**—Tailored to Each Engagement Partner's Critical Role.

WHAT IS SENTINEL SYSTEM'S STORY?

- FDA's Safety Mission/Another Tool
- Critical Components
- Operation
- Sentinel System in Action
- Privacy



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Devices and Radiologic Health

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Mon, 12/04/2017

PUBLICATIONS AND PRESENTATIONS

- Chart Validation of Inpatient ICD-9-CM



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HOW DOES IT WORK?

Health Advocacy Groups

How the Sentinel System Works

The core function of the Sentinel System is to evaluate treatments and outcomes of large groups of patients treated with a particular drug, medical device, or specific vaccine. The main concern of the Sentinel System is evaluating whether patients are having an unexpected adverse event from a medical product.

For example, some of the basic questions are: *How many patients on “Drug A” are having negative side-effects? How many of them are males or females? How many are young, old, pregnant, or taking other medical products? Are the side-effects the result of taking “Drug A” or for another reason?*

Public

How does the Sentinel System work?

The Sentinel System answers questions like these: *How many people are taking the same drug or getting the same vaccine? How many are having bad side-effects? How many are men and women? How many are young, old, pregnant, or take other drugs?*

HOW DOES FDA USE IT?

Health Advocacy Groups

What does the FDA do with all of this information?

The Sentinel System asks questions of many participating organizations, aggregates their responses, and presents the findings to the FDA for its subsequent evaluation and ultimate decision(s) regarding a particular medical product's safety or continued use. The FDA can pursue the following channels after receiving this information:

1. Non-medical product related
2. Labeling
3. Restricted Use
4. Media Alerts/MedWatch
5. Removal of the Drug or Vaccine

Public

What does the FDA do with all of the information?

The FDA gets important answers from the Sentinel System about bad side effects in certain drugs or vaccines. The FDA studies this new information along with other information it gets from doctors and drug companies. The FDA decides the best way to make doctors and patients aware of side effects. The FDA can send out a communication to doctors and patients to warn about potential safety issues.

SENTINEL IN ACTION

Health Advocacy Groups

Examples of the Sentinel System

In 2013, FDA used the Sentinel System to evaluate a vaccine to prevent diarrhea in infants. In response to reports FDA received that some infants experienced side effects from the vaccine, the Sentinel System gathered information from approximately 500,000 infants who had been vaccinated. From the Sentinel System's analysis, FDA concluded that the side effect did occur, but was extremely rare and occurred in less than 2 out of every 100,000 babies. FDA concluded that the benefit of the vaccine outweighed this risk, but the agency alerted clinicians and parents about the possibility of this adverse effect.

Public

Sentinel in Action

In 2013, the FDA used the Sentinel System to look at the safety of a vaccine that was given to about 500,000 babies. The FDA found out that some of the babies who got the vaccine had side effects, but these side effects were very rare. The vaccine caused the side effect in less than 2 out of every 100,000 babies! With this new information, FDA let doctors and parents know that it was better to get the vaccine. But doctors should be aware of this very rare side effect, so that they can treat it, if it happens.

PRIVACY

Health Advocacy Groups

Respecting and Protecting Patient Privacy

The Sentinel System studies summary information from large groups of patients treated with the same drug, medical device, or vaccine, whenever possible. When individual level data are needed, all individual patient identifiers are removed.

Public

Protecting your Privacy

No one at the FDA looks at your personal information. They do not look at your Name, Address, Phone Number, etc. The Sentinel System learns about big groups of patients taking the same medicine or getting the same vaccine.

What is the Sentinel System?

One of the FDA's biggest jobs is to make sure drugs, vaccines, and medical devices are safe. FDA wants to know if patients get bad side effects from these products. To make it faster and easier to learn about problems, FDA created a special program called the Sentinel System.

How the Sentinel System Works



Sentinel System's 3 important parts

- **Information:** The system looks at billing claims and patient records.
- **Expert Team:** Sentinel works with scientists, doctors and computer experts.
- **Computer Programs:** They study large groups of patients who take the same medicine, or use the same device.



Personal privacy

- No one at FDA or the Sentinel Operations Center has access to your name, address, or any other information that identifies you.
- For more information, visit sentinelinitiative.org.



Sentinel asks questions like:

- How many patients take the same drug?
- How many patients are getting bad side effects (swelling, bleeding, etc.)?
- Are side effects more common after taking one drug than after another drug that treats the same problem?



How does FDA use the information?

- FDA can choose to collect more information.
- FDA can provide updated safety information for patients and providers.
- If you have concerns about your own medical products, please contact your doctor.

FREQUENTLY ASKED QUESTIONS

- **What is the Sentinel System’s Engagement Partners Workgroup?**
- It is a workgroup launched in January 2016 by the FDA to raise awareness about the Sentinel System as a valuable health and safety tool involving the following stakeholders: 1) The Public; 2) Health Plan Members; 3) Health Advocacy Groups; and 4) Providers.
- **What did this Sentinel System Workgroup actually do?**
- The Workgroup developed customized narratives for each stakeholder. Each narrative describes, the “How?”, “What?”, and “Why?” of the Sentinel System. For more information, please refer to “The Sentinel System Story: For Health Advocacy Groups”, or check out this link: www.sentinelinitiative.org.
- **What about Privacy and Confidentiality?**
- Each Sentinel System narrative emphasizes that the Sentinel System studies aggregate data and that all identifiers are removed, such as name, address, telephone number, Social Security Number, etc.
- **What can I do to share this message with our members?**
- You can feature the Sentinel System Story and your critical role in its success, through a variety of media channels to your members.

FREQUENTLY ASKED QUESTIONS

- **What media channels are you referring to?**
- For example, you can describe the Sentinel System in your member newsletter, organization's website, brochures, pamphlets, Facebook, Twitter, etc.

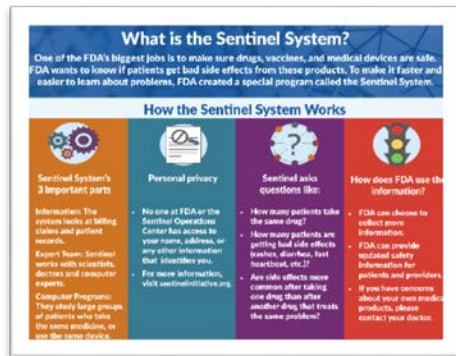
- **Am I required to use all of these channels to tell the Sentinel System story to our members?**
- No. We would encourage you to reach out to as many members as possible, using the most effective media channels in which you typically communicate to your members.

- **Is there a budget for these strategies?**
- Unfortunately, no. We appreciate everything you have done and continue to do to increase the value of this critically important safety tool.

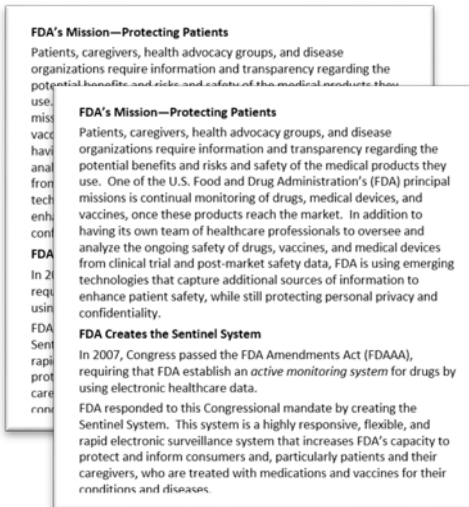
- **Is there someone I can talk to or will give me feedback? Who can I call, if I need assistance?**
- For help, please contact the Stakeholder Engagement Workgroup Lead, Steve Mikita, at smikita@agutah.gov and Susan Forrow, Senior Project Manager, Sentinel Operations Center, susan_forrow@harvardpilgrim.org

TOOLKIT

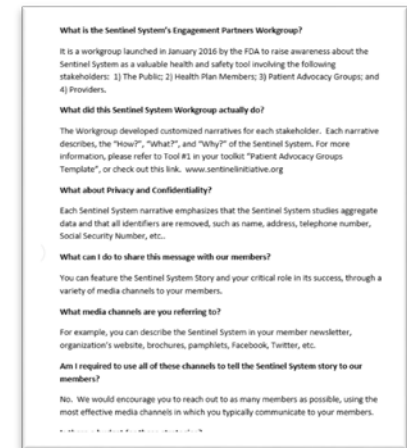
1. The Infographic



2. Copies of the Public Story and Health Advocacy Group Story



3. FAQs for Health Advocacy Groups



THANK YOU!

Special Thanks:

- Susan Forrow, Senior Project Manager
- Katherine Freitas, Research Assistant

