



The Sentinel Userbase

Sentinel Community Building and Outreach Center

The Sentinel System can benefit a variety of stakeholders

Sentinel was established to meet FDA regulatory needs, with the Agency as the system's primary user; yet Sentinel's infrastructure and outputs can serve stakeholders from various organizations and backgrounds.

Stakeholders may leverage Sentinel in multiple ways:



FDA regulators generate evidence on medical product safety by submitting queries to Sentinel.

*The U.S. Food and Drug Administration (FDA) created the Sentinel Initiative to meet a mandate by Congress in the FDA Amendments Act of 2007 (FDAAA) to create an **active safety surveillance system**.*



Industry, academics, and others may submit queries through the Reagan-Udall Foundation.

*The Innovation in Medical Evidence Development and Surveillance (IMEDS) program at the Reagan-Udall Foundation enables organizations outside of FDA access to Sentinel, **expanding usability for industry and others**.*



All stakeholders can access Sentinel's tools, methods and study results through the Sentinel website.

*Sentinel's analytic tools, methods, and results reports are publicly available, **enhancing accessibility to all stakeholders** such as health advocates, academia, other health agencies, and industry.*



FDA Regulators

Sentinel was created to support postmarket risk identification and analysis functions that were mandated by FDAAA in 2007 and has expanded its data, informatics, and methods capabilities over time to support these activities.



The Sentinel System was created to answer the FDA's questions related to medical product safety.

- The Sentinel System is comprised of a distributed network of Data Partners that format their electronic healthcare data in a common data model and apply routine analytic tools to address regulatory questions.
- Sentinel was established to supplement existing FDA monitoring systems and expand capacity for evaluating a variety of safety issues.

How FDA uses Sentinel:

- FDA regulators use Sentinel for multiple purposes including describing medical product utilization, describing occurrence of health outcomes in a population, and understanding relationships between exposures to medical products and health outcomes.
- FDA regulators design and submit queries to Sentinel by working with the Sentinel Operations Center (SOC).

<https://www.sentinelinitiative.org/about/how-sentinel-gets-its-data>

<https://www.sentinelinitiative.org/methods-data-tools/sentinel-common-data-model/sentinel-common-data-model>

<https://www.sentinelinitiative.org/about>



Industry Organizations

In 2013, the Reagan-Udall Foundation for the FDA created an opportunity for private sector entities, including industry, academia and others to access Sentinel infrastructure through the Innovation in Medical Evidence Development and Surveillance (IMEDS) Network.

IMEDS serves as a mechanism for entities outside of the FDA to access a system based on Sentinel.



- The IMEDS Network is comprised of a subset of Sentinel Data Partners that format their data in the Sentinel Common Data Model and use Sentinel's routine analytic tools.
- IMEDS enables direct experience with FDA postmarket assessment safety methods and tools.

How industry organizations outside of FDA can use Sentinel:

- Regulated industry, academics, and others in the private sector can design and execute queries in order to gain insights on medical product safety and related health outcomes.
- IMEDS allows private organizations to use Sentinel's infrastructure in many of the same ways as FDA.



All Stakeholders

All stakeholders, regardless of background and organizational affiliation, can leverage existing Sentinel resources and outputs to support their work and research.



The Sentinel website provides the public with access to Sentinel's tools, methods, and study results.

- As part of Sentinel's commitment to transparency, the tools and methods used to produce analyses are publicly accessible at <https://www.sentinelinitiative.org/methods-data-tools>.
- Sentinel's study reports, presentations, and publications produced from studies conducted by the FDA are available on the website.

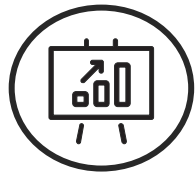
How all stakeholders can use Sentinel:

- Sentinel's study reports, presentations, and publications can be valuable to stakeholders with interests in understanding findings of FDA's medical product studies.
- For technical stakeholders, supporting documentation is published on the Sentinel website on how to convert their own data to the Sentinel Common Data Model and conduct medical product safety analyses using Sentinel analytic tools and methods.

Expanding Awareness & use of Sentinel to support public health

As part of the strategic aims outlined in the *Sentinel System: Five-Year Strategy 2019-2023*, FDA is committed to expanding awareness and enabling broader utilization of Sentinel System tools, methods and data infrastructure.

Expanding the use of Sentinel's tools and methods is valuable for several reasons:



Expanding the breadth and volume of questions asked of Sentinel accelerates its growth and expands its potential scope.



Increasing the number of stakeholder interactions with Sentinel helps establish it as a robust and transparent-resource to support public health.



Involving the public allows a variety of stakeholders to translate public health insights into actions that benefit patients.

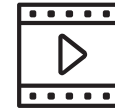
Stay Engaged with Sentinel

<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.