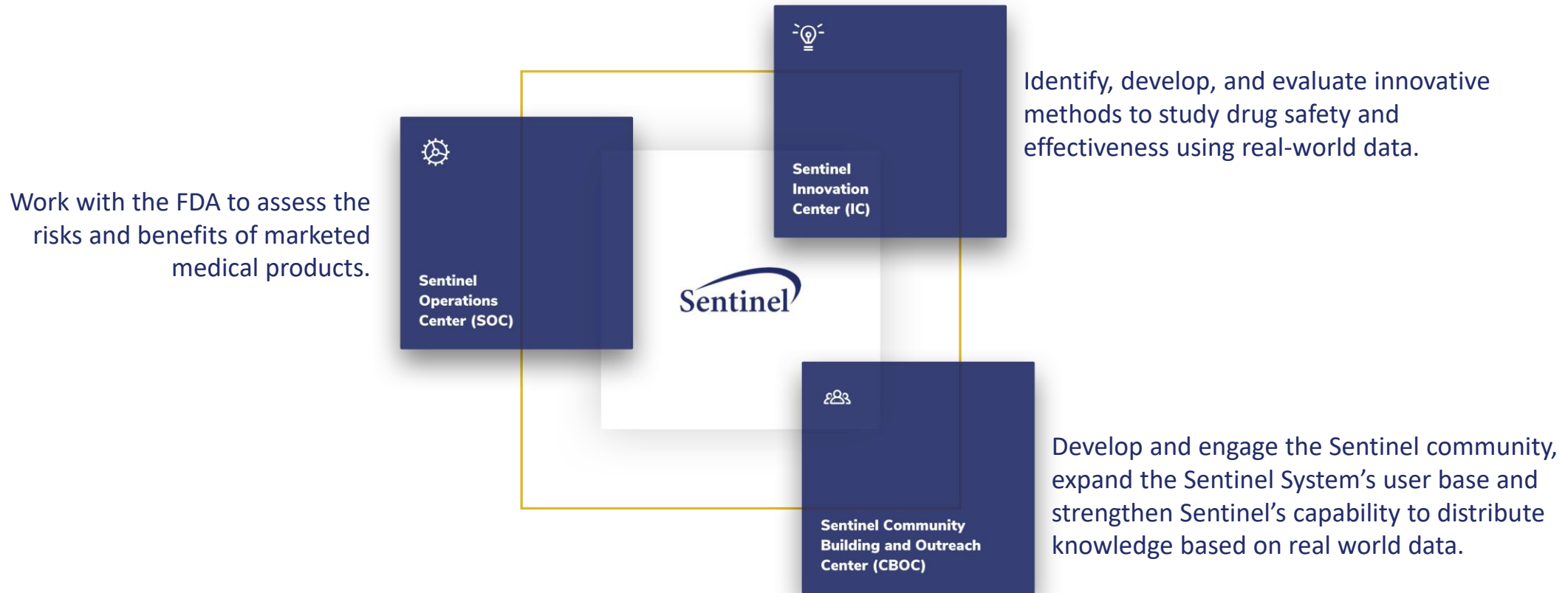




An Overview of the Sentinel Website for Health Advocates

Sentinel Community Building and Outreach Center (CBOC)

Welcome and Introductions






Agenda and Learning Objectives

The purpose of this webinar is for the Sentinel Community Building and Outreach Center (CBOC) to guide Health Advocates on how to navigate the Sentinel website to find information and resources relating to studies on the use of medical products and their impact conducted in Sentinel.

Agenda

Welcome and Introductions	12:00 – 12:05 PM
Agenda and Learning Objectives	12:05 – 12:10 PM
What is the Sentinel System?	12:10 – 12:25 PM
How is health data protected?	12:25 – 12:35 PM
How can I use the Sentinel website as a Health Advocate?	12:35 - 12:45 PM
Conclusion and Q&A	12:45 – 1:00 PM

Objectives

-  Learn about the Sentinel System and its key components
-  Learn how Sentinel uses health data while protecting privacy
-  Learn how to use the Sentinel website as a Health Advocate

How can Sentinel benefit Health Advocates?

Sentinel is a national resource that generates evidence that can inform a range stakeholders, including Health Advocates.

What is a Health Advocate?

CBOC defines Health Advocates as those who are concerned with advocacy for patients, and who seek health care information to better understand, educate, and empower individuals to make well-informed health care decisions.

Why focus on Health Advocates?

Sentinel seeks to expand awareness of its capabilities and resources among Health Advocate communities. The Sentinel website is a key means for communicating with the public and enhancing engagement with Sentinel stakeholders.



While the Sentinel System generates information that contributes to FDA's understanding of the use and safety of medical products, information on overall risks and benefits of medical products is provided on the FDA website, www.fda.gov.

What is the Sentinel System?

What is the Sentinel System?

Sentinel is FDA's medical product active safety surveillance system. It can be used to assess the use, safety, and effectiveness of medical products. To support these activities, Sentinel also works to develop new data, infrastructure, and methodologic capabilities.

SENTINEL KEY COMPONENTS

- Distributed data network of Data Partners
- Electronic healthcare information
- Common data model
- Routine querying tools
- Advanced quality assurance processes

WHAT TYPES OF QUESTIONS CAN BE ANSWERED IN SENTINEL?

- Drug utilization patterns
- Switching patterns between multiple drugs
- Adherence to safe use recommendations
- Drug utilization in pregnancy
- Evaluating drug exposure and safety outcomes
- Impact of FDA actions on drug use

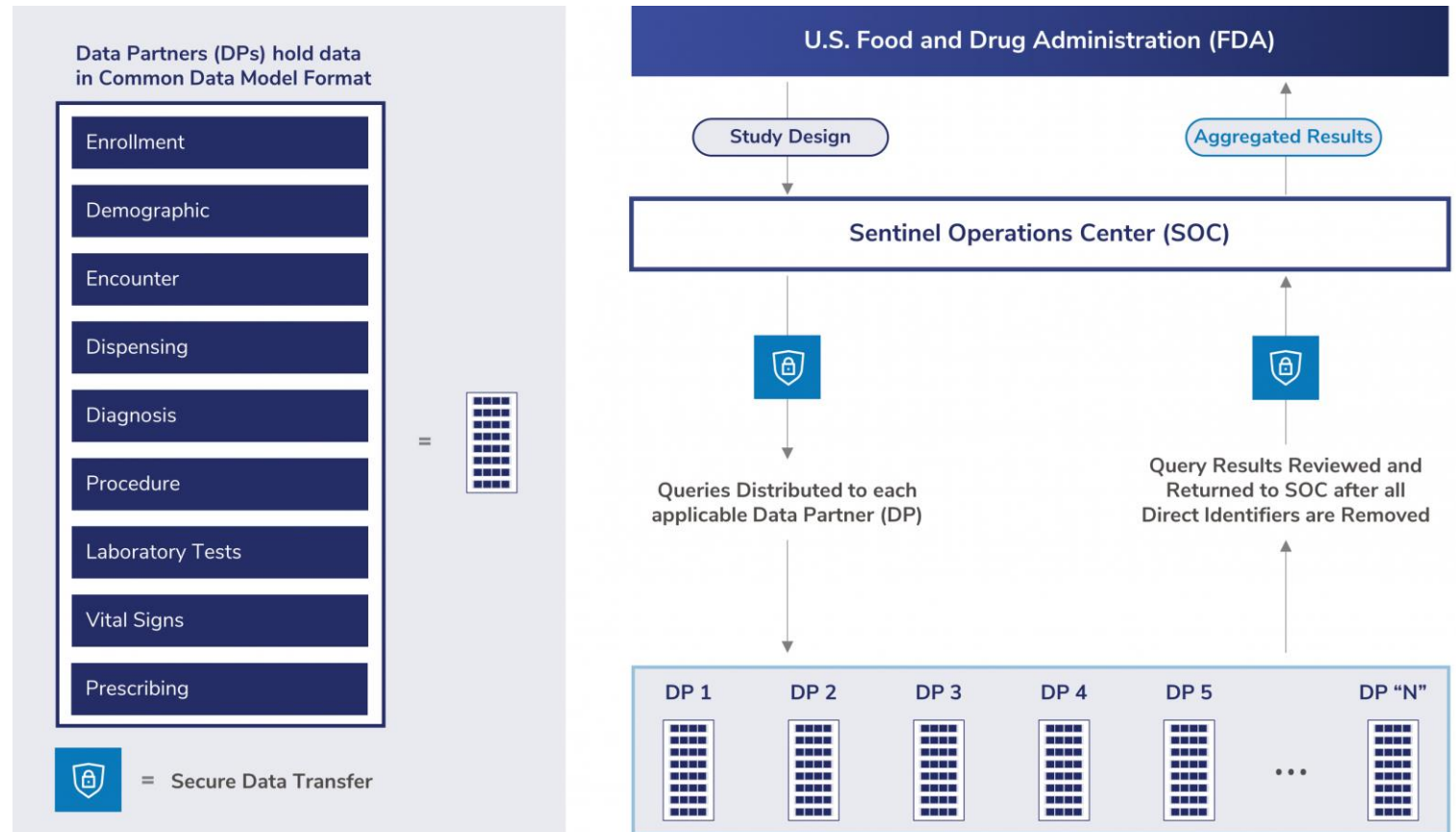
How does Sentinel get its health data?

Sentinel gets its data through the Sentinel Distributed Database, which is the collection of harmonized datasets from many different Data Partners. These datasets are all in the Sentinel Common Data Model format. The figure below illustrates Sentinel's distributed data approach.

The Sentinel System is comprised of **health care organizations, known as Data Partners**, that have medical billing information and electronic healthcare information.

The data are analyzed through **Sentinel's routine querying tools**, which are standardized programs that allow users to:

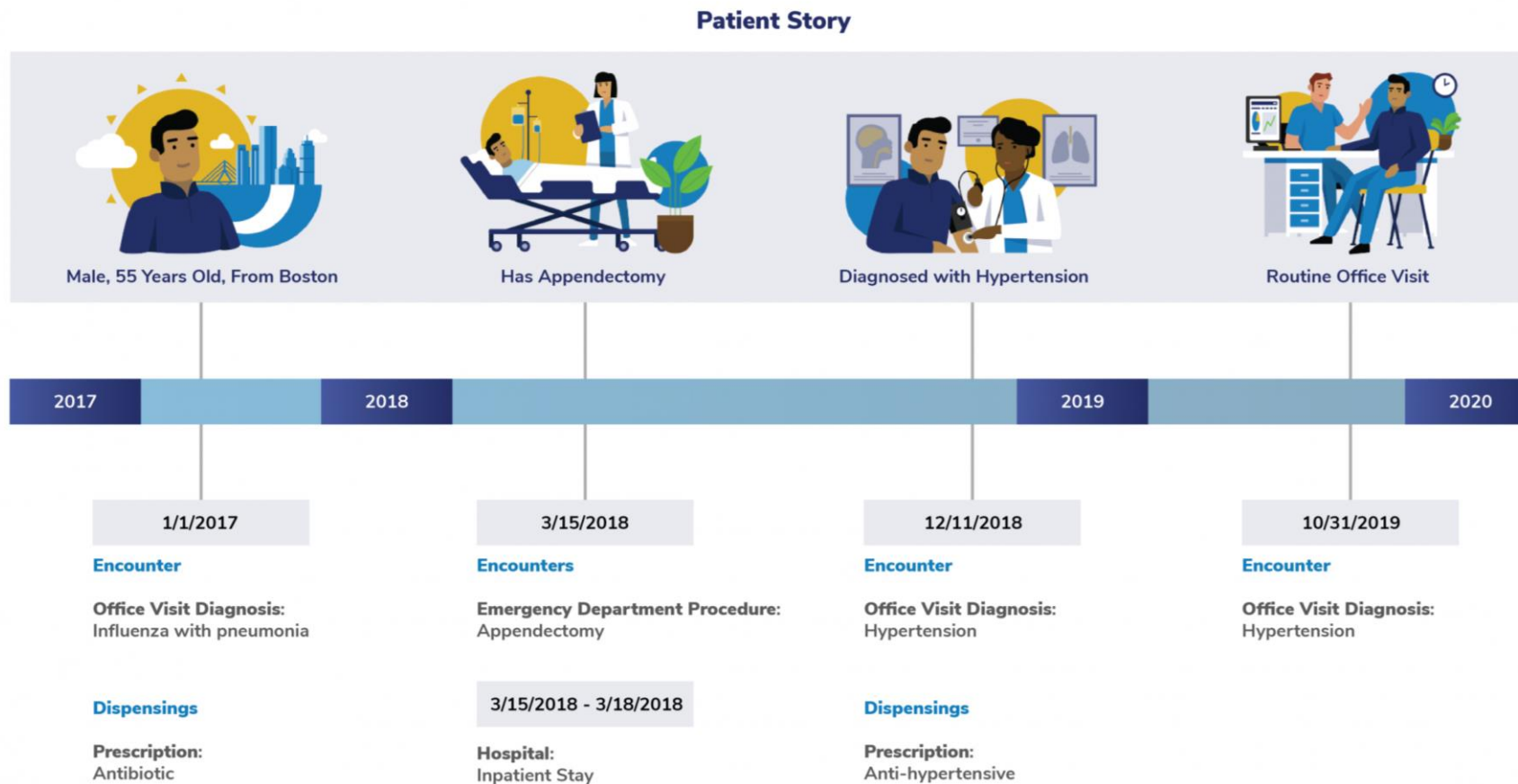
- Identify potential medical product safety concerns
- Characterize populations of interest
- Characterize the use of medical products
- Perform epidemiologic analyses to assess the impact of medical products on health outcomes



How is health data protected?

How is patient data generated?

The Sentinel Distributed Database has quality-checked data from a variety of sources. Here is an example of a patient’s interactions in the healthcare system. Records of those interactions are held by the patient’s insurers and providers. A key feature of the Sentinel System is that it can capture each healthcare encounter, diagnosis, and prescription for patients—no matter where they get their healthcare.



How is health data protected?

Protecting health data is foundational to the Sentinel System. Health data is collected routinely with every healthcare encounter by Data Partners and is used to answer FDA's medical product safety questions.

Sentinel protects health data by:

- **Sending data requests through a secure network portal**
 - FDA data requests are sent to Data Partners via a ***FISMA-compliant** secure network portal.
- **Retaining access to their own data**
 - Each Data Partner **keeps their own data and controls who can access it**
- **Using de-identified data**
 - Data Partners run analyses through a data program and routine querying tools and send **de-identified results** to the Sentinel Operations Center (SOC).
 - This approach allows Sentinel to maintain **privacy** and **data security**.
- **Receiving aggregated results**
 - The SOC sends FDA reports that contain **aggregated results**, combined from multiple Data Partners

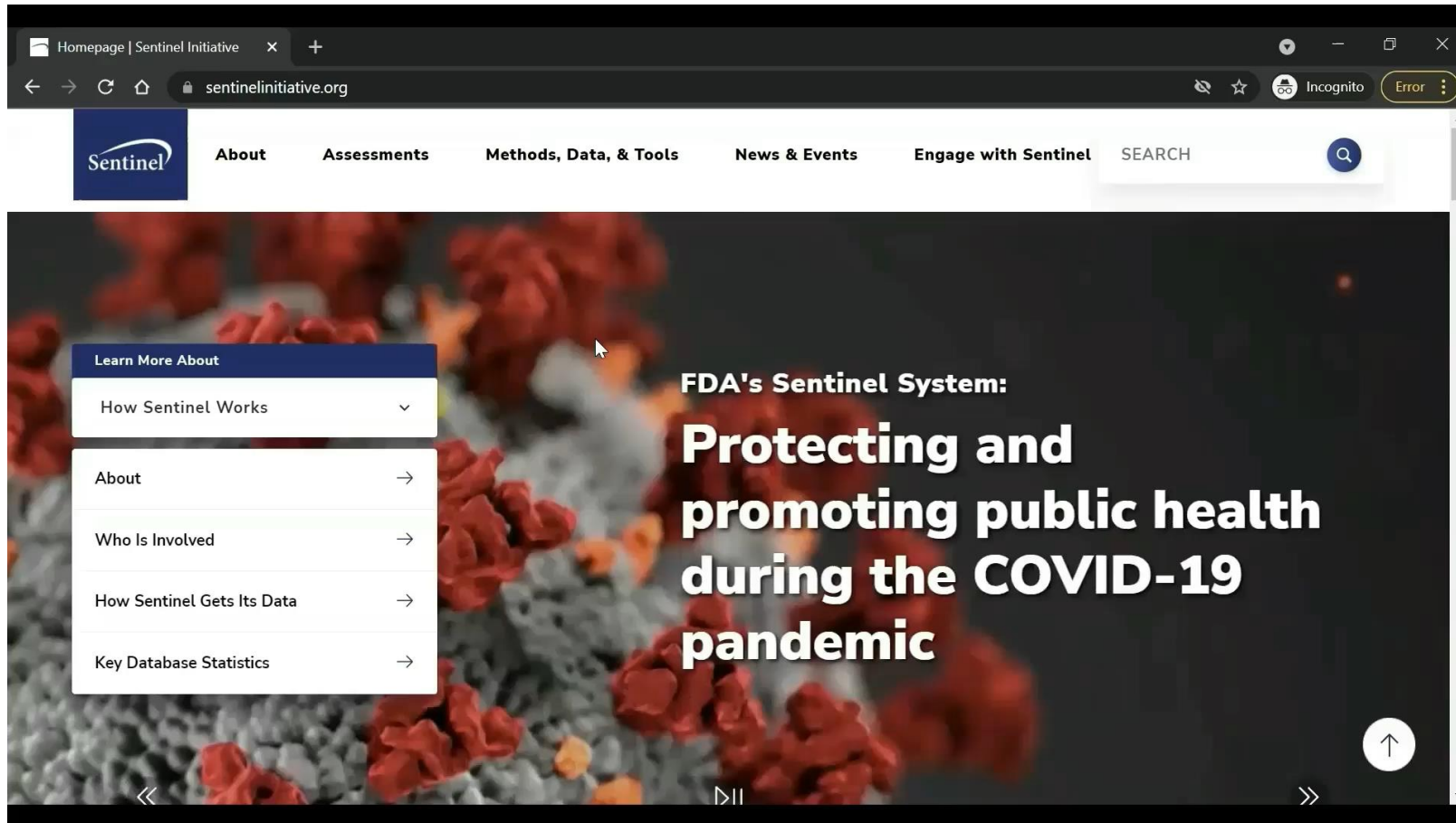


*FISMA: Federal Information Security Management Act

How can I use the Sentinel website as a Health Advocate?

How can I use the Sentinel website as a Health Advocate?

Health Advocates can use the Sentinel website to search for publications, presentations, drug assessments and related FDA regulatory actions or discussions.



Lessons Learned Today

WHAT IS THE SENTINEL SYSTEM



The Sentinel System is FDA's medical product active safety surveillance system. Sentinel's key components include Data Partners, routine querying tools, common data model and advanced quality assurance processes.

HOW SENTINEL PROTECTS HEALTH DATA



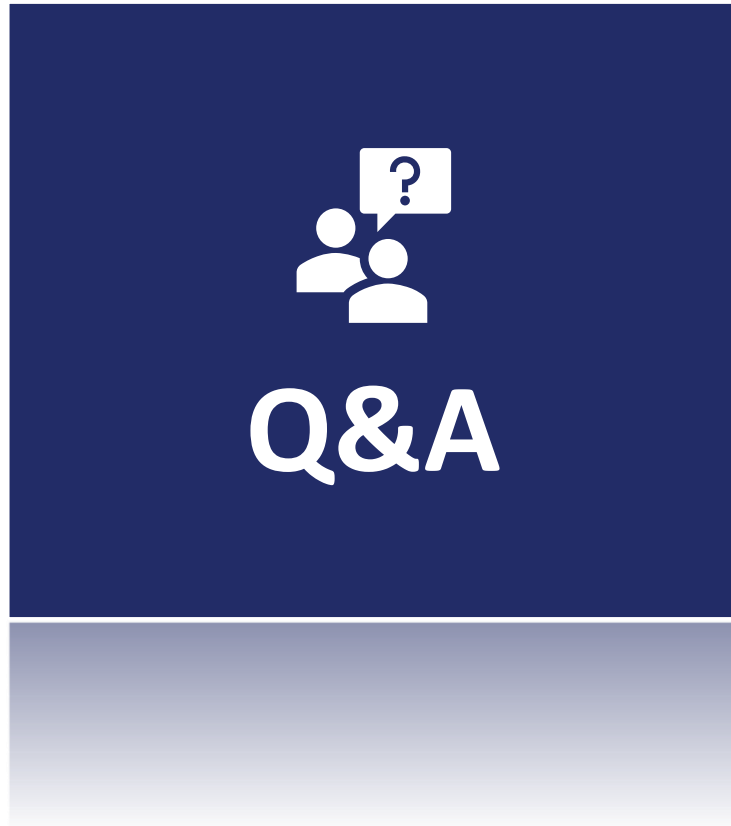
The Sentinel System's distributed approach maintains patient's privacy and data security. Data Partners run data programs at their site and the deidentified results are sent to the Sentinel Operations Center who then aggregate results and send to FDA.

HOW TO USE THE SENTINEL WEBSITE AS A HEALTH ADVOCATE



Health Advocates can leverage resources on the Sentinel website to find the latest drug assessments and associated publications and presentations, along with contributions of Sentinel analyses to FDA regulatory actions.

Questions?



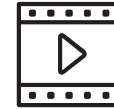
Get Engaged with Sentinel

<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.