

# Sentinel's FALL ISSUE



**2024 ISPE Conference:**

View Sentinel's Posters and Presentations Shared During This Conference



**2024 Sentinel Webinar Series:**

Learn About Various Topics and Innovative Projects from the Sentinel Program



**16<sup>th</sup> Annual Public Workshop:**

Register for the 16<sup>th</sup> Annual Sentinel Initiative Public Workshop



**2024 International Society for Pharmacoepidemiology (ISPE) Posters and Presentations:**

FDA colleagues including members from the Sentinel Core Team attended the 2024 ISPE Annual Meeting in Berlin, Germany last month. Sentinel work was well represented with 27 posters, presentations, and symposia shared throughout the conference. Topics presented included maternal health, COVID-19, pediatrics, EHR (electronic health records), and drug safety. Review the Sentinel posters

and presentations [here](#).



## **16th Annual Sentinel Initiative**

**Public Workshop:** The 16th Annual Sentinel Initiative Public Workshop is set to occur on November 7, 2024, from 9:00 AM – 4:15 PM ET. This event will be virtual and in-person at the National Press Club, Washington, District of Columbia. This workshop will serve as an opportunity for attendees to hear about recent Sentinel achievements and developments to date. Click [here](#) to register for the event.

---

## **Engage with the Sentinel Community**

### **The 2024 Sentinel Innovation and Methods Seminar Series**

The Innovation and Methods Webinar Series is hosted by the Innovation Center (IC) and serves as a platform to engage with experts and innovators around topics related to the IC strategic priorities. The latest information on upcoming webinars will be made available on the Sentinel Website.

Follow the steps below to access the most recent and upcoming webinars series:

1. Go to the [Sentinel Initiative](#) website homepage.
2. On the homepage, click on the top bar menu option: [News & Events](#).
3. On the [Meetings, Workshops, & Trainings](#), click on the tab located on the left vertical menu bar.
4. The Meeting, Workshops & Trainings page displays details for a variety of events, trainings, and webinars.
5. Access webinars information and materials within the [2024 Sentinel Innovation and Methods Seminar Series](#) page.

---

## **Sentinel Public Webinars**



### **Overview of CDER's Real World Evidence Demonstration Projects**

On August 5, 2024, Dr. Bradley shared an overview of CDER's real-world demonstration projects. Aligned with the U.S. 21st Century Cures Act, FDA established a program to evaluate the potential use of real-world evidence (RWE) in regulatory decision-making. The program is multifaceted and supports activities such as demonstration (research) projects, guidance development, internal Agency processes, external stakeholder engagement, and the Advancing Real-World Evidence initiative. This talk presents an overview of several RWE demonstration projects and describes, for select projects, how learnings directly or indirectly serve to support FDA regulatory decision-making in evaluating the effectiveness and safety of medical products.

**[Learn more >>](#)**



### **Opportunities and Challenges in the Use of Large Language Models for Post-Marketing Surveillance of Medical Products**

On April 22, 2024, Dr. Matheny discussed some of the opportunities and challenges in using large language models (LLMs) in the conduct of post-marketing surveillance of medical products, with a focus on issues relevant to opportunities in the Sentinel Network, such as ARIA insufficiency, detection of exposures, risk factors, and outcomes, and implications for downstream analytic methods.

**[Learn more >>](#)**



### **Data-driven Phenotyping Algorithms for Acute Health Conditions: Applying PheNorm to COVID-19**

On March 25, 2024, Dr. Joshua Smith presented on automated phenotyping algorithms that can reduce development time and operator dependence compared to manually developed algorithms. One such approach, PheNorm, has performed well for identifying chronic health conditions, but its performance for acute conditions is largely unknown. This presentation describes the an evaluation of PheNorm applied to symptomatic COVID-19 disease to investigate its potential feasibility for rapid phenotyping of acute health conditions.

[Learn more >>](#)



### **A PProcess Guide for INferential Studies Using Healthcare Data to EvaLuate Causal Effects of Drugs (PRINCIPLED)**

On February 29, 2024, Dr. Rishi Desai delivered a presentation on inferential studies using healthcare data to evaluate causal effect. The presentation introduced a stepwise process covering the range of considerations, including 1) Formulating a causal question, 2) Describing the emulation of each component of the protocol, 3) Assessing expected precision and diagnostic evaluations, 4) Planning the assessment, and 5) Completing Inferential analyses, to foster a generation of reliable and reproducible evidence.

[Learn more >>](#)

---

## **Sentinel Community Building and Outreach Center (CBOC) Training Series**

### **CBOC INFORMATIONAL VIDEOS**

The Sentinel Community Building and Outreach Center has created informational videos to provide on-demand resources to become more familiar with Sentinel. Click below to watch the videos.



**MAJOR MOMENTS** details the evolution of Sentinel as a national resource, starting from the Mini-Sentinel pilot in 2009 to Sentinel today.

[Click here to watch the video.](#)



**THE SENTINEL USERBASE** highlights various groups of stakeholders that can use Sentinel as a resource to inform their work.

[Click here to watch the video.](#)



**EHR vs. CLAIMS:** CBOC explores how claims and EHR data may be used to address different dimensions of a scientific question or problem. This video details the limits and strengths of each identified resource and how they both affect the outcomes of scientific studies.

[Click here to watch the video.](#)



**MACHINE LEARNING IN DISTRIBUTED DATA NETWORKS:** This video discusses how access to larger amounts and more complex types of electronic health data in distributed data networks like the FDA Sentinel System has created a growing interest in the use of data-adaptive machine learning techniques.

[Click here to watch the video.](#)



Tell us what you want to see more of. **Select an option below!**

Select an option below.

[\*\*Spotlight: 2024 ISPE Posters and Presentations\*\*](#)

[\*\*Highlight: Sentinel Webinars\*\*](#)

[Engage with Sentinel Training Section](#)

[New Analytic Packages, Methods, Data, and Tools Project](#)

[Recent Reports, Publications, and Presentations](#)

### [New Methods, Data, and Tools](#)

Maintaining and Expanding the Reach of the Sentinel EHR and Claims Network (DI8)

[Learn more >>](#)

Empirical Application of the Sentinel EHR and Claims Data Partner Network to Enhance ARIA Sufficient Inferential Requests and Atypical Descriptive Requests (Use Case Package 2)

[Learn more >>](#)

Incorporate a Range of Frequently Used Engineering Features from EHRs into the Sentinel Common Data Model in the Sentinel EHR and Claims Linked Data Partner Network

[Learn more >>](#)

COVID-19 Pandemic-Related Changes in Healthcare Utilization Among Insured Persons in the US and its Impact on Pharmacoepidemiologic Research

[Learn more >>](#)



For new analytic packages, methods, data, and tools projects, [\*\*click here!\*\*](#)

[Documents, Presentations, and Publications](#)

Identifying Pediatric Hypertension in Observational Data: Comparing Clinical and Claims Cohorts in Real World Data

[Learn more >>](#)

Research in Action Podcast: Transforming Public Health with Unstructured Data and NLP in FDA's Sentinel Initiative

[Learn more >>](#)

A Distributed Regression Analysis Application Package Using SAS

[Learn more >>](#)

A Simple Cox Approach to Estimating Risk Ratios Without Sharing Individual-Level Data in Multi-Site Studies

[Learn more >>](#)



Want more recent documents, presentations, and publications? [Click here!](#)

## Farewell For Now

*As a valued member of our FDA-Sentinel newsletter community, we want to inform you that after this 2024 Fall issue, our Quarterly Newsletter will be taking a pause. We are using this time to evaluate our communications strategy moving forward. Thank you for your understanding and continued support, we look forward to sharing more information soon!*



 **U.S. FOOD & DRUG**  
ADMINISTRATION

 Sentinel