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In This Issue:

Invitation to the PDUFA VII Workshops and Sentinel Public Training and Innovation Days

PDUFA VII Workshops

Exploring the Utility of Negative Controls for Causal Inference in the Sentinel Initiative

Wednesday, March 8, 2023, 10AM - 3PM ET

As part of the PDUFA VII Commitments, the Duke-Margolis Center for Health Policy, under cooperative agreement with the FDA, will convene a workshop on how negative controls could support new methodological approaches for causal inference in the Sentinel Initiative. Discussion will inform the development of methods demonstration projects aimed at: 1) establishing empirical methods to automate the negative control identification process in Sentinel and integrate it into the Sentinel Initiative tools, 2) developing approaches to use a double-negative control adjustment to reduce unmeasured confounding in studying effectiveness of vaccines and, 3) developing other methods using negative controls.

Register Here

Sentinel Public Training and Innovation Day

The 2023 Sentinel Public Training and Innovation Day will take place over two days in April. The Sentinel Public Training,

Featured Publication: Using the Food and Drug Administration's Sentinel System for Surveillance of TB Infection

This collaboration with the Centers for Disease Control and Prevention (CDC) identified individuals treated for latent TB infection (LTBI) in the Sentinel System, and described key characteristics. The overarching goal of the work is to understand how Sentinel may support CDC's surveillance related to TB and LTBI. As the paper notes, identifying and treating individuals with LTBI is necessary to ultimately eliminate TB in the US. More than 113,000 individuals filled LTBI treatment prescriptions in 2008–2019, with 80% having received isoniazid only, 19% rifampin only, and 2% isoniazid with rifapentine. Despite recommendations since 2000 that support the use of shorter course rifamycin-based regimens (e.g., rifampin and rifapentine), isoniazid alone is the predominant treatment

presented by the Sentinel Operations Center (SOC), will take place on **April 11, 2023**. The Innovation Day event, presented by the Innovation Center (IC), will take place on **April 12, 2023**.

Both events are free and open to the public.

14th Annual Sentinel Public Training
Tuesday, April 11, 2023, 9AM - 1PM ET

The 2023 Sentinel Public Training Day titled "Leveraging the Sentinel System for Signal Identification Among Infants Following Maternal Medication Use During Pregnancy" will feature the following topics:

- Introduction to Sentinel
- Detecting Medication Adverse Effects in Sentinel
- Surveillance of Adverse Outcomes Following Medication Use in Pregnancy
- First Trimester Exposure to Fluoroquinolones: A Case Study in Signal Identification

Presenters: Judith Maro, MS, PhD, Ashley Martinez, PharmD, PhD, and Sruthi Adimadhyam, MS, PhD.

Innovation Day
Wednesday, April 12, 2023, 1PM - 4PM ET

The 2023 Innovation Day will feature the following topics and presenters:

- A general framework for developing computable phenotyping algorithms from electronic health records: by David Carrell, PhD
- Using Unsupervised Learning to Generate Code Mapping Algorithms to Harmonize Data Across Data Systems: by Xu Shi, PhD
- A PRocess guide for INferential studies using secondary data from routine ClinIcal Practice to evaLuate causal Effects of Drugs (PRINCIPLED): by Rishi Desai, MS, PhD
- Approaches to handling partially observed confounder data from electronic health records: by Janick Weberpals RPh, PhD

Register Here

identified. In addition, most individuals do not have evidence of completing the recommended treatment duration, supporting the preferential use of shorter-course regimens. Overall, 80% of the cohort had documentation of a chest radiograph, and 88% overall had at least one element of a TB diagnostic evaluation, before starting treatment.

The study shows that more work is needed to increase the uptake and completion of shorter-course rifamycin-based therapies for LTBI. Importantly, we demonstrated that Sentinel could be used as a complementary source of data for LTBI-related public health surveillance activities. For example, Sentinel could be used to characterize concomitant use of rifamycin-based regimens with other medications that might increase the risk for drug-drug interactions, for surveillance of severe adverse events associated with LTBI therapy, and to monitor trends in treatment regimens over time and by geographic region.

To learn more about this study, click here.

Engage with the Sentinel Community

The 2023 Sentinel Innovation and Methods Seminar Series

The Sentinel Innovation and Methods Seminar Series features presentations by leading experts and innovators on topics related to the work of the Innovation Center and the Sentinel Operations Center. The Seminar Series describes emerging approaches in real world data utilization such as feature extraction, natural language processing, machine learning, and techniques to advance causal inference improving Sentinel's capabilities.

Seminars in 2023:

- January 23, 2023: Identification and Mitigation of Source Mapping Issues in Structured Electronic Health Record Data
- February 28, 2023: Ontology-Driven Weak Supervision for Clinical Entity Classification in Electronic Health Records

Visit the Sentinel Meetings, Workshops, & Trainings page to view past seminars, webinars, and workshops and to register for upcoming events in 2023.

Sentinel Community Building and Outreach Center (CBOC) Training Series

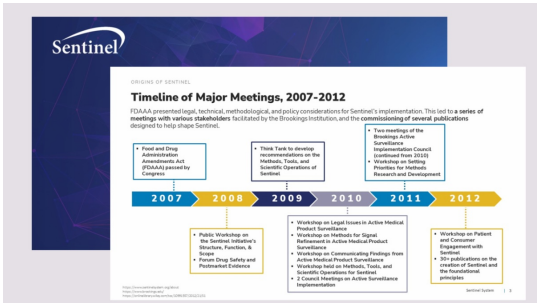
CBOC WEBINAR SERIES

The Community Building and Outreach Center has developed a webinar series to increase stakeholder awareness and engagement with the Sentinel System.

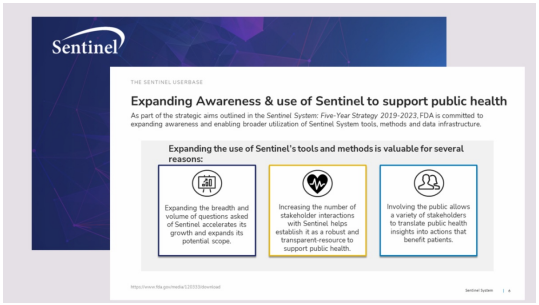
An Overview of Sentinel's Publicly Available Tools: On September 14, 2022, CBOC hosted a webinar to provide an understanding of Sentinel's publicly available analytic tools, the Sentinel Common Data Model, and how to access those resources from the Sentinel website. Click here to view a recording of the recently released webinar.

CBOC INFORMATIONAL VIDEOS

The Community Building and Outreach Center has created informational videos to provide on-demand resources to become more familiar with Sentinel. Click below to learn more about two recently released videos.

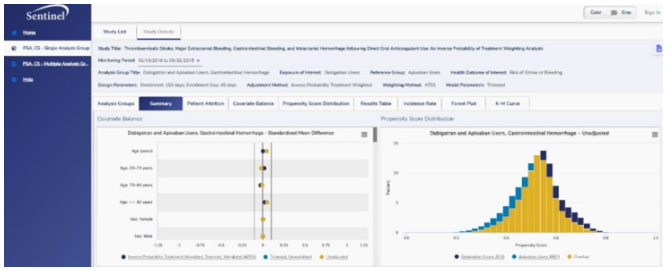


MAJOR MOMENTS details the evolution of Sentinel as a national resource, starting from the Mini-Sentinel pilot in 2009 to Sentinel today. Click here to view the video.



THE SENTINEL USERBASE highlights various groups of stakeholders that can use Sentinel as a resource to inform their work. Click here to view the video.

CBOC VIRTUAL TRAINING SESSIONS



SENTINEL VIEWS is a data visualization application designed to increase comprehension of the Sentinel System study results. It has been integrated into the existing Sentinel querying and reporting infrastructure, to support the work of the Sentinel System. The Sentinel Views web graphics are interactive and help to visualize results. The tool also includes a public facing dashboard accessible to the general public. Click here to view the virtual training.

Sentinel Feedback Poll

What content interests you most in our Sentinel Newsletter?

Select one of the below:

Technical Analytics Projects

Sentinel Publications

Drug Assessments

Meetings, Workshops, and Trainings

Other

New Analytic Packages, Methods, Data, and Tools Projects

- Data Quality Review and Characterization Programs (version 8.6.0) and Mother-Infant Linkage Data Quality Review and Characterization Program (version 3.1.0)
- Heart Failure Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Myocardial Infarction Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Permanent Pacemaker Placement Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
- Permanent Pacemaker Placement Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Septal Myectomy Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
- Septal Myectomy Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Ventricular Arrhythmia Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
- Ventricular Arrhythmia Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Valganciclovir Use in Children with Congenital Cytomegalovirus Infection: Chart Review
- Sentinel Routine Querying System (version 12.0.1)
- Monitoring of Safety and Effectiveness of COVID-19 Therapeutics: Aim 1 Protocol Development
- Inclusion of Semi-Structured and Unstructured Electronic Health Record (EHR) Data in Confounding Adjustment and Outcome Ascertainment

Recent Reports, Publications, and Presentations

- Atrioventricular Block Algorithm Defined in "Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
- Cardiovascular Outcomes Following Percutaneous Transluminal Septal Myocardial Ablation

(PTSMA) Procedures: An Updated Descriptive Analysis

- Comparative Risk of Angioedema with Sacubitril-Valsartan Versus Renin-Angiotensin-Aldosterone Inhibitors
- Olumiant (Baricitinib) & Acute Myocardial Infarction, Deep Vein Thrombosis, Pulmonary Embolism, and Stroke
- Characterization of Patients and Encounters in the TriNetX Live USA Network: A Descriptive Analysis
- Exploring Claims-Based Definitions of, and Characterizing Patients with, Respiratory Failure: A Descriptive Analysis
- Identifying Potential Risk Factors for Respiratory Failure: A Descriptive Analysis
- Provigil (Modafinil) and Nuvigil (Armodafinil) & Congenital Cardiac Malformations

*Explore the **Sentinel YouTube Channel** and **Sentinel Website** for more information.*