



<u>Treatment and Care Received by</u>
<u>Children Hospitalized with COVID-</u>
<u>19:</u>

Learn How Large Networks Care for and Treat Children With COVID-19



Evaluation of Existing
Approaches to EHR-based
Signal Detection:

Explore Methods for EHRbased Signal Detection



VIDEO: The Strengths
and Limits of EHR
and Claims-based
Data:

Check out Sentinel Initiative's Latest Video



# Treatment and Care Received by Children Hospitalized with COVID-19 in a Large Hospital Network:

Sentinel investigators used inpatient electronic health record (EHR) data from HCA Healthcare to conduct a retrospective descriptive study among children <18 years of age hospitalized with COVID-19 or multi-system

inflammatory syndrome in children (MIS-C) from February 20, 2020, to September 30, 2021. Investigators examined patient demographics on admission, high-risk conditions, inpatient treatments, and complications. Read the full article, published in the Public Library of Science (PLOS) A Peer Reviewed, Open Access Journal, on July 11,

2023, to learn about the important treatment trends reported by Sentinel investigators, which may improve the understanding of real-world treatment patterns in this population: <a href="https://doi.org/10.2016/j.com/news/">here >></a>

# **Evaluation of Existing Approaches to EHR-based Signal Detection:**

This project conducts a scoping review that evaluates available methods for adverse event signal identification using EHR data, identifies the gaps in current knowledge, and guides future projects aimed at empirical evaluations to identify and test the most promising approaches for EHR-based signal identification. Ultimately, the project aims to inform the Sentinel Innovation Center's (IC) roadmap for the integration and development of methods of signal identification from EHR data with IC activities. Learn more about the results of this evaluation: 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 (NLP), machine learning, and techniques to advance causal inference improving Sentinel's capabilities.

**2023 Sentinel Public Webinars** 



# Optimizing the Use of Post Approval Pregnancy Safety Studies Workshop

On September 18, 2023, Duke-Margolis Center for Health Policy, under a cooperative agreement with the U.S. FDA, convened a two-day hybrid Public Workshop to discuss designs of post approval pregnancy safety studies for drug and biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

### **Learn more >>**



# Scalable Incident Detection via Natural Language Processing and Probabilistic Language Models

On September 20, 2023, Dr. Colin G. Walsh presented on a scalable approach to identifying clinical events at the health system scale using natural language processing (NLP) and probabilistic language models. Methods were discussed and demonstrated in two challenging and clinically important use-cases: suicide prevention and sleep-related behaviors. This approach has implications for postmarket safety surveillance, clinical prevention, population health, and more.

### Learn more >>

# Leveraging Missing Data and Measurement Error Approaches in Propensity Score-Based Analyses of Real-World Data Webinar

On August 21, 2023, Epidemiologist, Dr. Rebecca Hubbard presented an evaluation of measurement error and missing data approaches. Motivated by a real-world study of the comparative effectiveness of treatments for advanced urothelial cancer, Dr. Hubbard concluded with reflections on how to embrace modern advances in data

# Multi-wave Validation Sampling to Improve Estimates Derived from Electronic Health Record Data

On July 11, 2023, Dr. Bryan E. Shepherd described his experience performing a multi-wave validation study to target informative records for validation and then combined the validated data (~1000 records) with error prone EHR data (~10,000 records) to estimate the association between maternal weight change during

sources and methodology while preserving time-tested principles that support research rigor and reproducibility.

Learn more >>

pregnancy and the risk of her child developing obesity.

Learn more >>

### **2023 Sentinel Events**



# 15th Annual Sentinel Initiative Public Workshop

This workshop allowed attendees to hear about Sentinel Initiative's recent achievements and developments to date. This event was virtual and in-person at the National Press Club, Washington, D.C. The keynote speaker for this event was Dr. Janet Woodcock, FDA's Principal Deputy Commissioner.

#### **Learn more >>**

### **2023 American Medical Informatics Association Symposium**



### **Annual AMIA Symposium**

Joshua Smith from Vanderbilt University Medical Center (VUMC) presented at the AMIA 2023 Annual Symposium in New Orleans, LA, on 11/13/2023. The title of the podium presentation was "Drug Safety Surveillance with EHR Data – A Promise Not Yet Fulfilled." The presentation described work from the Innovation Center Detection Analytics (DA1) project "Evaluation of existing approaches to EHR-based Signal Detection." The project consisted primarily of a literature review of research using routinely collected EHR data for adverse event signal identification.

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 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 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 v. 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.



For more meetings, workshops, trainings, and events, click here!

**CBOC AND IC 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 watch the video.



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

Select an option below.

Spotlight: Treatment and Care Received by Children Hospitalized with COVID-19

Highlight: Existing Approaches to EHR-based Signal Identification

**Engage with Sentinel Training Section** 

New Analytic Packages, Methods, Data, and Tools Project

**Recent Reports, Publications, and Presentations** 

## New Analytic Packages, Methods, Data, and Tools Projects

Characterization of COVID-19 Genomic Data in Sentinel Distributed Database

Effectiveness of Fixed Triple Combination Inhaled Corticosteroid (ICS), Long-Acting Beta-Agonist (LABA), and Long-Acting Muscarinic Antagonist (LAMA) Products vs. Multiple Inhaler ICS, LABA, LAMA Therapy in Patients With COPD

#### Learn more >>

Data Expansion Implementation: Linking the National Death Index (NDI) to the

Sentinel Distributed Database (SDD)

**Learn more >>** 

### Learn more >>

**Subset Calibration Methods** 

**Learn more >>** 



For new analytic packages, methods, data, and tools projects, click here!

### **Recent Documents, Presentations, and Publications**

Risk of Admission to Hospital with Arterial or Venous Thromboembolism Among Patients Diagnosed in the Ambulatory Setting with COVID-19 Compared with Influenza: Retrospective Cohort Study

**Learn more >>** 

Preliminary Analysis of Drug Utilization Data to Inform the Development of the Pregnancy Safety Study Framework

**Learn more >>** 

Using Real-World Data to Evaluate Comparative Effectiveness Cohorts of Azithromycin Relative to Roflumilast in Individuals with Uncontrolled Chronic Obstructive Pulmonary Disease

Learn more >>

Percutaneous Transluminal Septal Myocardial Ablation and Common Procedural Complications Before and After the Approval of Ablysinol

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Want more recent documents, presentations, and publications? Click here!







