Sentinel Newsletter | 1st Quarter 2024



# Sentinel's SPRING EDITION



Assessing the Risk of Intentional Self-Harm in Montelukast Users:

An Updated Sentinel System Analysis Using ICD-10 Coding



Data-Driven Automated
Classification Algorithms for Acute
Health Conditions:

Applying PheNorm to COVID-19
Disease



A PRocess Guide for INferential Studies Using Healthcare Data:

A New Webinar in the Sentinel Innovation and Methods Seminar Series



Assessing the Risk of
Intentional Self-Harm in
Montelukast Users: An Updated
Sentinel System Analysis Using
ICD-10 Coding:

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes are thought to have better accuracy for capturing suicide intent compared to ICD-9-CM codes. As an update

to a previous study that used ICD-9-CM codes to identify intentional self-harm, Sentinel investigators recently assessed the risk of intentional self-harm events in patients aged 10 and older with asthma following use of either montelukast or inhaled corticosteroids as monotherapy. Intentional self-harm in this study was

defined using ICD-10-CM diagnosis codes, and the analysis used inverse probability of treatment weighting to balance baseline covariates. Investigators performed subgroup analyses by age group, sex, psychiatric history, and whether exposure occurred prior to or after March 2020, when a boxed warning regarding neuropsychiatric adverse events was added to montelukast. Learn about the results of this study in the Journal of Asthma >>

# <u>Data-Driven Automated</u> <u>Classification Algorithms for</u> <u>Acute Health Conditions:</u> <u>Applying PheNorm to COVID-19</u> <u>Disease:</u>

This manuscript, recently published in JAMIA, describes a project led by Joshua Smith, PhD and David Carrell, PhD who co-lead the



Feature Engineering Core within the Innovation Center. The paper focuses on implementing an automated phenotyping approach, PheNorm, to symptomatic COVID-19 disease to evaluate its feasibility for rapid phenotyping of acute health conditions. Further information on this project can be found on the Sentinel Website >>

# **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.

**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

On September 20, 2023, Dr. Colin G. Walsh presented a scalable approach to identifying clinical events at the health system scale using natural language processing (NLP) and probabilistic language models. Dr. Walsh demonstrated methods in these two 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 >>** 

# 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.



<u>THE SENTINEL USERBASE</u> 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

<u>DATA NETWORKS:</u> 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: Assessing the Risk of Intentional Self-Harm in Montelukast
Users

**Highlight: Automated Phenotyping Algorithms** 

**Engage with Sentinel Training Section** 

New Analytic Packages, Methods, Data, and Tools Project

**Recent Reports, Publications, and Presentations** 

### **New Methods, Data, and Tools**

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

Learn more >>

Development and Refinement of a Toolkit for Large Scale Covariate Adjustment in the Electronic Health Record and Claims Data Partner Network

Learn more >>

Monitoring of Safety and Effectiveness of COVID-19 Therapeutics: Aim 1 Protocol Development

**Learn more >>** 

Characterization of COVID-19 Genomic Data in the Sentinel Distributed Database

Learn more >>



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

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

Drug Safety Surveillance with EHR Data: A Promise Not Yet Fulfilled

**Learn more >>** 

Unexpected Issues in Pharmacoepidemiology Studies Applying Natural Language Processing to Clinical Notes

**Learn more >>** 

SMDI: An R Package to Perform Routine Structural Missing Data Investigations in Real-World Data

Learn more >>

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

Learn more >>



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







