Sentinel Presents Novel Research at ICPE 2022 Conference

The 38th International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) was held in Copenhagen, Denmark on August 24-28, 2022. A variety of Sentinel-related work was featured, including symposia, oral presentations, spotlight posters, and a webinar. These materials can all be found on the Sentinel Website here.

See below for some additional presentation information:

**Symposia**

*Methods and Considerations for Hypothesis-Free Signal Detection Studies Accommodating Various Types of Medications, Populations, and Regions*

- This symposium provided a forum to explore considerations around conducting signal detection studies across different scenarios, and to obtain consensus on how to accommodate various medications, populations, regions, and settings.


Sentinel Innovation Center Uses Machine Learning in Computable Phenotyping Framing Project

The Sentinel Innovation Center (IC) has been working on a computable phenotyping framework project that is set to be completed on September 30, 2022. The project, also known as “Health Outcome of Interest (HOI) 2.0,” uses natural language processing (NLP) and machine learning (ML) to improve computable phenotype algorithms for identifying anaphylaxis and acute pancreatitis. The IC is also using this project to work towards developing a general framework for computable phenotyping in its Sentinel System analyses.

This activity is one of the pilots in a series being launched to support the Food and Drug Administration’s (FDA) use of the
This symposium explored approaches to assess and improve the validity of variable definitions, including those for exposures, outcomes, entry criteria, and confounders.

Data Harmonization, Standardization, and Quality Assessment in Distributed Health Data Networks: Lessons from Around the World

This symposium discussed lessons learned, challenges, and opportunities related to federated health data networks, data standardization, harmonization, curation, and quality assessment for regulatory decision-making.

Oral Presentations

Arterial and Venous Thrombotic Events in Patients with COVID-19 Compared to Influenza

This presentation explored the risk of inpatient arterial and venous thrombotic events in patients with COVID-19 and compared those risks to patients with influenza.

Systemic Corticosteroids for COVID-19 in U.S. Outpatient Settings

This presentation examined new systemic corticosteroid use among non-hospitalized patients with COVID-19 from April 2020 - September 2021 in four large U.S. databases.

Characterizing Medication Use Patterns of Pregnancies with COVID-19 in the Sentinel System

This presentation discussed implementation of the CONSIGN study (COVID-19 in preGNancy). As part of an international collaboration across several countries, the study assessed the prevalence of medication use and characterized severity and clinical outcomes in pregnancies with COVID-19 compared to those without COVID-19 and reproductive aged patients with COVID-19.

Comparative Evaluation of Automated Approaches for Confounder Selection in Ultra High-dimensional Data with Rare Outcomes

This presentation explored the performance of several lasso-based methods for large-scale confounder selection in ultra high-dimensional data with rare outcomes using simulated datasets.

Spotlight Posters

Racial Differences in U.S. COVID-19 Positivity, Hospitalization, and Mortality

This poster examined racial differences in COVID-19 testing, positivity, hospitalization, and mortality during the first year of the pandemic.


This poster described (v)GCV use for the treatment of post-market Active Risk Identification and Analysis (ARIA) system to assess the safety of its regulated medical products. The overall purpose of this pilot series is to develop a framework to leverage ML and NLP techniques in improving HOI identification algorithms that may later be used in the larger Sentinel Distributed Database to assess drug safety questions.

The project has three core aims:

- **Aim 1**: Expand on the Phase 1-2 anaphylaxis analysis plan and conduct additional secondary analyses.
- **Aim 2**: Develop and conduct a more scalable automated NLP feature engineering process (i.e., compare a PheNorm-like automated model to the current model, based on manual feature curation).
- **Aim 3**: Further develop the high-level general framework for HOI 2.0 identification into a more formalized and comprehensive guidance document for Sentinel (i.e., a publishable manuscript).

Specifically, the IC created gold standard data for model training and evaluation. They utilized NLP and ML to improve models for identifying anaphylaxis and acute pancreatitis, among other phenotypes. Note that the NLP- and ML-enhanced models were proven to be transportable to an external study site, where the models perform well. The IC is currently exploring automated approaches to feature engineering that may improve the scalability of the algorithm development.

This project will ultimately improve the accuracy with which the IC identifies HOIs in Sentinel using electronic data. Note that the current activity is a continuation of Phase 1 and 2 activities involving the anaphylaxis example dataset.

For additional information about this project, please visit this page on the Sentinel Website.
The 2022 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 IC and the Sentinel Operations Center (SOC). The Seminar Series describes the use of emerging technologies such as feature engineering, natural language processing, advanced analytics, and data interoperability to improve Sentinel’s capabilities.

Visit the Sentinel Meetings, Workshops, & Trainings page to view past seminars, webinars, and workshops and to register for upcoming events in 2022.

Recent Seminars:
- Representing and Utilizing Clinical Textual Data for Real World Studies: An OHDSI Approach
- Deep Learning on Electronic Health Records for Research in Pharmacoepidemiology: Examples From the Field of Oncology
- Addressing Missing Data in Comparative Effectiveness Research Using EHR Data

2022 Sentinel Community Building and Outreach Center (CBOC) Informational Videos

The Community Building and Outreach Center has created informational videos to provide on-demand resources for individuals to become more familiar with Sentinel. Click on the image below to be directed to the Sentinel Views Virtual Training video located on the Sentinel YouTube Channel.

Sentinel Views is a data visualization application designed to increase access to Sentinel System study results. It has been integrated into the existing Sentinel querying and reporting infrastructure to support the Sentinel System’s vision of serving as a national resource for medical product safety surveillance and real-world evidence generation.

Community Building and Outreach Center Webinar Series

The Community Building and Outreach Center has developed a webinar series to increase stakeholder awareness and engagement with the Sentinel System. Click on the image below to view a recording of the recently released webinar titled "An Overview of Sentinel's Publicly Available Analytics Tools."

The Webinar provides an understanding of Sentinel’s publicly available analytics tools, the Sentinel Common Data Model, and how to access those resources from the Sentinel website.

Featured Sentinel Publication
A study conducted within Sentinel examined the risk of arterial and venous thrombotic events in patients hospitalized with COVID-19 before and during COVID-19 vaccine availability compared to patients hospitalized with seasonal influenza. The study found that hospitalization with COVID-19 was associated with a higher risk of venous thromboembolism within 90 days, but there was no significant difference in the risk of arterial thromboembolism within 90 days. The risk of death within 30 days of either event type was higher for patients with COVID-19 compared to influenza. This study was published in the Journal of the American Medical Association on August 16, 2022.

The US Food and Drug Administration Sentinel System: A National Resource for a Learning Health System

An article highlighting the Sentinel System as a national resource was published on September 12, 2022 in the Journal of the American Medical Informatics Association. The Sentinel System has completed hundreds of analyses, including many that have directly informed regulatory decisions. The Sentinel System also was designed to support a national infrastructure for a learning health system. The Sentinel System infrastructure now supports multiple non-FDA projects for stakeholders ranging from regulated industry to other federal agencies, international regulators, and academics.

New Analytic Packages, Methods, Tools and Reports

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Reports:

- Comparative Effectiveness of Azithromycin Relative to Roflumilast in Individuals With Uncontrolled Chronic Obstructive Pulmonary Disease Despite Triple Inhaled Therapy
- Use of Monoclonal Antibodies (mAbs) Under an Emergency Use Authorization (EUA) in Patients with COVID-19 Diagnosis: An Updated Descriptive Analysis
- Differences in COVID-19 Testing, Positivity, Hospitalization, and Mortality by Race and Ethnicity in the Sentinel Distributed Database: A Descriptive Analysis
- Women With Heart Failure & Pregnancy
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- Hospitalization and Anaphylaxis Following Monoclonal Antibodies (mAb) Use in Patients with COVID-19: A Descriptive Analysis | Sentinel Initiative |