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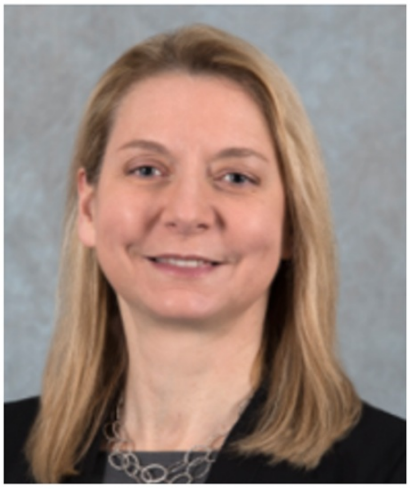
Spotlight on 13th Annual Sentinel Initiative Public Workshop

On November 8th and 9th, the Duke-Margolis Center for Health Policy hosted the Thirteenth Annual Sentinel Initiative Public Workshop. The keynote of the conference was delivered by the Director of the FDA Center for Drug Evaluation Research (CDER), Dr. Patrizia Cavazzoni. She highlighted the key messages from the Sentinel System Five-Year Strategic Plan, the development of Master Plans to achieve the Strategic Plan goals, and described Sentinel projects initiated based on the Master Plans. Dr. Cavazzoni also emphasized how Sentinel's infrastructure was leveraged during the COVID-19 pandemic in areas that included monitoring critical drugs among hospital settings and describing the course of illness among COVID-19 patients.


Dr. Patrizia Cavazzoni

The Workshop also featured a fireside chat with FDA Sentinel Initiative leadership, Dr. Gerald Dal Pan, Dr. Steven Anderson, and Dr. Daniel Caños. Dr. Dal Pan described a proof-of-concept project evaluating concordance between claims-based capture of pediatric hypertension and vital-sign capture of pediatric hypertension populated by Data Partners with Integrated Delivery Systems. Dr. Dal Pan also discussed Sentinel's new analytic capabilities, abilities to conduct analyses in new electronic health record-based (EHR-based) systems, increasing stakeholder contribution to the Sentinel community, and international collaborations (which were highlighted further in subsequent presentations).

During the Workshop, the leadership of the Sentinel Coordinating Centers provided their perspectives on recent accomplishments and looked ahead to planned activities. Dr. Richard Platt, lead of the Sentinel Operations Center (SOC), highlighted Sentinel's contributions as an evolving national resource, including recent expansions of data and analytic infrastructure, activities to support the FDA's COVID-19 response, and expanding study collaborations, including those with other federal partners and international health agencies. Dr. Sebastian Schneeweiss, lead of the Innovation Center (IC), presented initiatives to improve FDA's capabilities for the Active Risk Identification and Analysis (ARIA) system. He highlighted ongoing and upcoming projects in the IC Master plan in the areas of data infrastructure, feature engineering,

causal inference, and detection analytics. Dr. Asif Dhar, lead of the Community Building and Outreach Center (CBOC), spoke to the CBOC Master Plan goals and projects, designed to increase engagement and collaboration among the Sentinel community and broaden the Sentinel userbase. Additional sessions included panelists and speakers from the Sentinel Initiative, other government agencies, and private organizations.

Sentinel Highlights: Public Workshop

Improving Causal Inference for Real-World Evidence (RWE) Generation

On Day 1 of the Public Workshop, speakers discussed activities within the Sentinel System, FDA Catalyst, and the Center Biologics Evaluation and Research (CBER) Biologics Effectiveness and Safety (BEST) System to support the FDA's RWE framework, particularly in relation to advancing causal inference methods. Dr. Robert Ball, from the FDA Sentinel Leadership, provided an overview of FDA's RWE program and highlighted existing activities under the Sentinel System to enhance FDA's understanding of RWE. Given the important role of causal study design and analysis for generating robust evidence on the safety and effectiveness of medical products, the IC Master Plan incorporates a series of projects to enhance causal inference methods in observational data. The IC is currently working on two causal inference projects and has more under development:

1. Enhancing Causal Inference in the Sentinel System: An Evaluation of Targeted Learning and Propensity Scores for Confounding Control in Drug Safety
2. Development and Illustration of a Framework for Conducting Non-Randomized Studies of Medication Safety and Effectiveness Using Healthcare Databases

Sentinel International Collaboration

On Day 2 of the Public Workshop, presenters described work by Sentinel and its external partners in response to the COVID-19 pandemic. The Sentinel Initiative has a strong relationship with international partners enabling important collaborations across the globe. Sentinel recently executed a query as part of a multi-aim study to examine changes in angiotensin receptor blocker (ARB) utilization following an international recall of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) contaminated ARBs in July 2018. Sentinel's analytic tool was run on databases formatted in the Sentinel Common Data Model in the United States, Canada, the United Kingdom, and Denmark and results were aggregated across sites. This aggregation strengthens studies across the various countries, allowing investigators to look at diverse data around a given topic.

As the COVID-19 pandemic continues, Sentinel is conducting an Assessment of the Natural History of Coagulopathy in COVID-19 to assess arterial and venous thromboembolic events among COVID-19 patients. This study is being replicated by European Medicines Agency (EMA) and Health Canada, with the goal of performing a meta-analysis and developing an associated manuscript.

Sentinel is also conducting a COVID-19 Pregnancy Implementation study, which looks at medication use among pregnant women with COVID-19. The study also investigates disease severity and clinical outcomes for these women compared to non-pregnant women with COVID-19. This study aligns with EMA's COVID -19 Infection and Medicines in Pregnancy – A Multinational Registry Based Study (CONSIGN) project, which will enable FDA and EMA to look at a large body of data as they study COVID-19 in pregnant women.

Engage with the Sentinel Community

Health Advocates Webinar

On January 19, 2022 from 12:00-1:00pm EST, the Sentinel Community Building and Outreach Center will host a webinar on how Health Advocates can use publicly available resources on the Sentinel website. The webinar will instruct viewers on what the Sentinel System is, how the Sentinel System protects health data, and how to navigate the Sentinel website. The webinar will review how to find recent publications, presentations, reports of drug safety assessments, and training and workshop materials. The goal is to enhance Health Advocates' awareness and understanding of Sentinel. Please click the link below to register for the webinar.

Register: An Overview of the Sentinel Website for Health Advocates Webinar

The 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 Operations Center. The Seminar Series utilizes emerging technologies such as feature engineering, natural language processing, advanced analytics, and data interoperability to improve Sentinel's capabilities.

Recent Seminars:

- Synthetic Data to Support Reproducible Clinical Research: Opportunities and Challenges
- Inverse Probability of Exposure and Censoring Weights for Marginal Structural Models

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

Sentinel as a National Resource: NIH Collaboratory Distributed Research Network

The NIH Collaboratory Distributed Research Network (DRN) enables investigators funded by the NIH and other not-for-profit sponsors to collaborate with investigators based in health plans that participate in the FDA's Sentinel System. The DRN is especially useful for supporting multisite research programs. The DRN fully leverages the Sentinel System's data, methods, tools, and querying infrastructure which are developed and supported by the FDA. It can also directly contact providers and health plan members to collect new information or in support of randomized clinical trials.

New Analytic Packages, Methods, Tools and Reports

Methods Projects:

- Identification and Mitigation of Structured Electronic Health Record (EHR) Source Data Mapping Issues
- Making Medicaid Data More Accessible Through Common Data Models and FHIR APIs

Tools:

- Data Quality Review and Characterization Programs v8.1.0
- Sentinel Mother-Infant Linkage Data Quality Review and Characterization Program v3.0.1
- Routine Querying System Documentation (version 11.2.2)
- Sentinel Routine Querying System Reporting Tool v1.2.2

Reports:

- Use of Multiple Sclerosis Drugs Among Pregnant Women with Live-Birth Deliveries: A Descriptive Analysis
- Gimoti (Metoclopramide) & Duration of Use
- Reglan (Metoclopramide) & Duration of Use
- Oral Metoclopramide Use: A Descriptive Analysis
- Brilinta (Ticagrelor) & Concomitant Use with Lipitor (Atorvastatin) or Crestor (Rosuvastatin)

Recent Publications and Presentations

- Self-Controlled Assessment of Thromboembolic Event (TEE) Risk Following Intravenous Immune Globulin (IGIV) in the U.S. (2006–2012)
- Using Inpatient Electronic Medical Records to Study Influenza for Pandemic Preparedness
- Risk of Hospitalized Depression and Intentional Self-harm with Brand and Authorized Generic Sertraline
- Prescription Medication Use and Baseline Health Status of Women with Live Birth Deliveries in a National Data Network
- Monitoring Medication Use During the COVID-19 Pandemic in the Sentinel System: The Case of Anticoagulation for Thrombosis

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