



Sentinel Newsletter

Third Quarter 2021

In This Issue

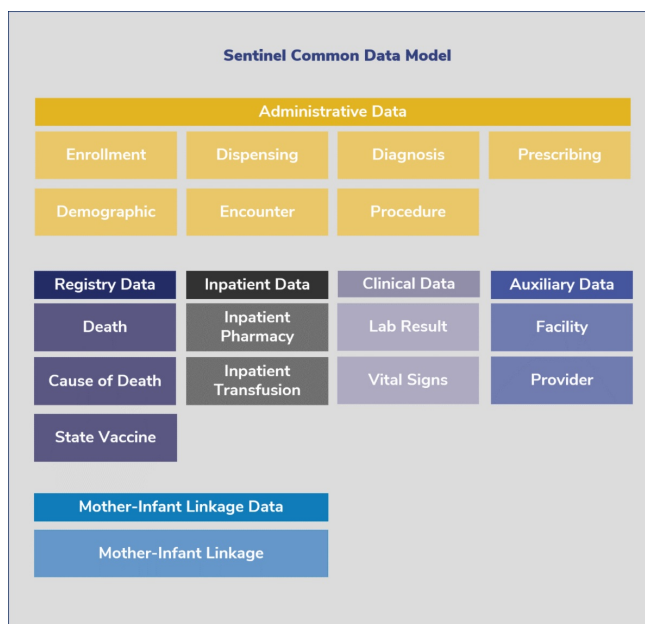
- Spotlight on SCDM 8.0.0
- Register for the 13th Annual Sentinel Initiative Public Workshop
- Sentinel Highlights: Data Infrastructure Projects
- Sentinel at the 37th International Conference on Pharmacoepidemiology and Therapeutic Risk Management
- The Sentinel Innovation and Methods Seminar Series
- New Analytic Packages, Methods, Tools and Reports
- Recent Publications and Presentations

Spotlight on Sentinel Common Data Model 8.0.0

The FDA has enhanced the Sentinel System by releasing the Sentinel Common Data Model (SCDM): v8.0.0. This upgrade represents the culmination of three years of discovery, planning, and development. The improvement expands Sentinel's data capture and precision and allows the addition of international partners. It also introduces efficiencies designed to ensure the Sentinel System will match the growing volume of healthcare data provided by the Centers for Medicaid and Medicare Services, national healthcare claims, and integrated delivery system partners.

Enhancements to the Sentinel System include the addition of a Prescribing Table and a Provider Table. The Prescribing Table allows FDA to better understand prescribing which may affect patterns of medical product safety and use, and the relationship between prescribing and actual dispensing. This table also enables the addition of electronic health record (EHR) prescribing data to the Sentinel model, and along with the addition of international code types, allows international partners to join the Sentinel System. A Provider Table grants the ability to link medical specialty to diagnoses and procedures, as well as dispensing and prescribing, enhancing FDA's ability to understand medical product utilization.

Recognizing that the volume of data in the Sentinel System has grown significantly in recent years, FDA has introduced efficiency improvements to the Sentinel Common Data Model. Underlying technical changes to the data model—including the addition of a facility table to efficiently capture geographic information about medical encounters—reduces its overall storage footprint and the computational resources necessary to query the data.



13th Annual Sentinel Initiative Public Workshop

Register for the 13th Annual Sentinel Initiative Public Workshop

Wednesday November 8, 2021; 10 AM - 2 PM
Thursday November 9, 2021; 10 AM - 2 PM

[Register Here](#)

Sentinel Highlights: Data Infrastructure Projects

EHR Horizon Scan Project

To address the Real-World Evidence (RWE) Data Enterprise mandate, Sentinel is tasked with establishing a query-ready, quality-checked distributed data network containing EHRs for at least 10 million lives with reusable analysis tools. A key first step in establishing such a network is identifying and assessing potential partners that could contribute the necessary data for this system. These potential partners could include existing Data, Expansion, and Innovation Partners, as well as data sources not currently included in Sentinel. The purpose of this project is twofold:

1. Phase 1: Develop and implement a horizon scan and series of interviews to: (1) identify EHR sources and registries; and (2) conduct initial feasibility assessments of potential partners for enhancing the Sentinel System.
2. Phase 2: Conduct empirical queries in three of the most promising EHR databases identified and recommended from Phase 1.

Representation of Unstructured Data Across Common Data Models

A critical step in expanding the Sentinel network is to establish the organizational framework for expanding access to EHR data. The goal of this project is to guide the Sentinel network on how best to incorporate information derived from unstructured data, such as free-text clinical notes from EHR data, into a Common Data Model (CDM) framework. The project will lead to recommendations about how to represent unstructured EHR data in a CDM and which specific data features should be considered.

Using Unsupervised Learning to Harmonize Data Across Data Systems

With increasingly diverse Sentinel Data Partners and EHR coding systems, there is more potential variation in the way clinical concepts can be coded. Variability in coding habits can affect phenotyping model accuracy and causal inference model performance when models are applied at a new Data Partner. The goal of the project is to assess the potential of data-driven statistical methods for describing and reducing coding differences between healthcare systems in the Sentinel Distributed Database (SDD). Findings of this project will inform development and deployment of statistical methods and computational tools for transferring knowledge learned from one Data Partner to another and pave the way towards automated curation and harmonization of EHR data in the SDD more broadly.

Sentinel at the 37th International Conference on Pharmacoepidemiology and Therapeutic Risk Management

At the 37th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Aug 23-25, 2021, Sentinel conducted two symposia and fourteen oral presentations and posters. The symposia topics are summarized below and a complete list of all presentations and posters can be found on the [Sentinel Website](#).

Strategies for the Use of Real-World Data to Conduct COVID-19-Related Pharmacoepidemiology

The use of real-world data (RWD) to study COVID-19 poses unique challenges given the evolving nature of the pandemic, desire for near real-time data, and need to capture data elements not routinely examined within pharmacoepidemiologic studies. It is therefore critical that the field shares strategies to maximize use of RWD to yield valid and clinically significant evidence on COVID-19. The symposium shares the experiences of the Sentinel System during the development and implementation of its COVID-19-related studies.

New Frontiers in Computable Phenotyping for Medical Product Safety Evaluation

Routinely collected healthcare data, including insurance claims and EHRs, are critical to study the safety of medical products. A key challenge with use of these data sources is the lack of valid and robust computable phenotypes for many medical conditions. This symposium will describe emerging methods to increase efficiency in identification and validation of incident health outcomes of interest based on EHR data, and thus enable identification of appropriate study populations.

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 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.

Upcoming Seminars:

- **Inverse Probability of Exposure and Censoring Weights for Marginal Structural Models:** Thursday, September 30th, 2021; 12:00 PM - 1:00 PM Eastern Time

Recent Seminars:

- [Measure What You Treasure: The Challenges and Opportunities of Collecting Real World Endpoints](#)
- [Natural Language Processing for EHR-based Pharmacovigilance: Current Progress and Future Directions](#)
- [Adaptive Validation Designs: Premise and Methods](#)

Visit the [Sentinel Innovation and Methods Seminar Series webpage](#) to view past seminars.

New Analytic Packages, Methods, Tools and Reports

Analytic Packages:

- [Longitudinal Trends in Incident and Prevalent use of Long-Acting Beta-2 Agonists: An Interrupted Time Series Analysis](#)

Methods Projects:

- [Demographic Characteristics and Length of Enrollment of the Individuals Enrolled over Time in the Sentinel Distributed Database](#)
- [TreeScan in Pregnancy: Use of the Tree-Based Scan Statistic for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use \(Aim 2\)](#)

Tools:

- [Routine Querying System](#)
- [Sentinel Data Visualization Project](#)
- [Routine Querying System: Inpatient Encounter Querying Tool](#)
- [Data Quality Review and Characterization Programs](#)

Reports:

- [Duration of Follow Up for New Molecular Entities Approved in 2017](#)
- [Fungal Keratitis of following Keratoplasty Procedures: A Descriptive Analysis](#)
- [Brand and Generic Tacrolimus Use following Kidney, Heart, and Liver Transplants: A Descriptive Analysis](#)

Recent Publications and Presentations

- [Incidence of Severe Uterine Bleeding Outcomes among Oral Anticoagulant Users and Nonusers](#)
- [Who Gets Treated for Influenza: A Surveillance Study from the US Food and Drug Administration's Sentinel System](#)
- [Use of a Mobile App to Capture Supplemental Health Information During Pregnancy: Implications for Clinical Research](#)
- [Using Prenatal Tests to Estimate Pregnancy Start in Health Insurance Claims Data](#)
- [Validation of an ICD-10-based Algorithm to Identify Stillbirth in the Sentinel System](#)
- [Risk of Severe Abnormal Uterine Bleeding Associated with Rivaroxaban Compared with Apixaban, Dabigatran and Warfarin](#)

Explore the [**Sentinel YouTube Channel**](#) and [**Sentinel Website**](#) for more information.