

[View as Webpage](#)

Sentinel

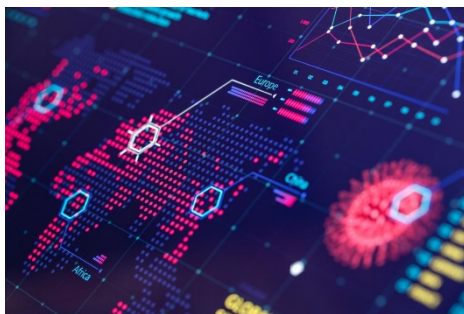
Sentinel Newsletter

Second Quarter 2021

In This Issue

- Spotlight on COVID-19
- Sentinel Project Highlights
- Sentinel Website Redesign
- The Sentinel Innovation and Methods Seminar Series
- New Analytic Packages, Methods, Data and Tools
- Recent Publications and Presentations

Spotlight on COVID-19



In concert with the worldwide, intensive response to the COVID-19 pandemic, FDA has enhanced the Sentinel System to better capture information about the [natural history of the COVID-19 disease](#). To achieve this end, Sentinel has worked with national health care claims and integrated delivery system partners across the United States to improve available COVID-19 related laboratory data, and to provide the “freshest” available data through routine updates to the Sentinel Distributed Database. A recent article: “[A COVID-19-ready public health surveillance system: The Food and Drug Administration’s Sentinel System](#),” by Noelle Cocoros, et

al., describes Sentinel’s multi-pronged COVID-19 response, which includes incorporation of new data sources, creation of a rapidly refreshed database, development of protocols studying the natural history of the disease, and more.

To enhance laboratory data, [additional COVID-19 tests were added to the Sentinel Common Data Model \(SCDM\) laboratory results table](#). The Sentinel Operations Center has monitored COVID-19 laboratory test usage and provided subsequent guidance to all Sentinel Data Partners to ensure laboratory test data are thoroughly and accurately populated in the routine database updates.

Data is being updated much more rapidly to address changing COVID-19 data needs. Typically, Sentinel Data Partners update their databases at least annually. To respond to the urgent needs of the pandemic, the Sentinel System’s [Rapid COVID-19](#) database was created to integrate the most recent diagnostic COVID-19 testing data with the most current population-based claims and electronic health record data. This database is now currently updated as often as every four weeks.

These enhancements to the Sentinel System were rapidly implemented in the latter half of 2020. Sentinel will continue to add enhancements to the Sentinel System to address dynamic data needs in 2021 in response to COVID-19.

Sentinel Highlights COVID-19 Studies on Pregnancy and Coagulopathy

As part of the efforts to expand capabilities and address FDA's emerging needs during the COVID-19 pandemic, new protocols were developed and implemented in Sentinel.

COVID-19 in Pregnancy

This study is implementing two aims from the European Medicines Agency's CONSIGN (COVID-19 infection and medicines in pregnancy) protocol study, with goals to: identify cohorts of pregnant patients diagnosed with and without COVID-19 and nonpregnant patients with COVID-19 in the Sentinel System; compare medications used for treatment of COVID-19 and other medical conditions; and describe severity and clinical outcomes of COVID-19 within Sentinel. The study protocol is available on the [Sentinel website](#). Analyses of these cohorts address key knowledge gaps to improve the understanding of the treatment and severity of COVID-19 in pregnant patients.

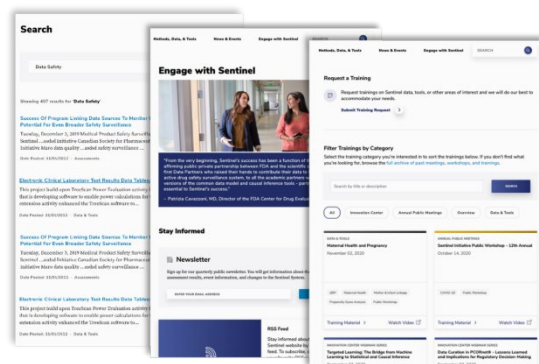
Assessment of the Natural History of Coagulopathy in COVID-19

This project describes the natural history of coagulopathy among COVID-19 patients. A study is being implemented to assess the risks of arterial and venous thrombotic events among COVID-19 patients. This project utilizes the Rapid COVID-19 Sentinel Distributed Database resource, which incorporates both health care claims and electronic health record data. The project is a partnership between the Sentinel Operations Center, FDA and leading infectious disease and hematology specialists from the University of Pennsylvania Perelman School of Medicine. The workgroup is actively engaging with the FDA Reagan Udall Foundation Evidence Accelerator Parallel Analysis Workgroup.

Sentinel Website Redesign

On May 13th, the Sentinel System deployed major new features to the public website to better serve the Sentinel community. This deployment marked the culmination of the end-to-end redesign of the Sentinel website to improve the usability and findability of information. The latest update includes the following new features:

- [Integrated Google Search Engine](#): Google's search engine is now directly integrated into the website interface—allowing users to complete site-specific searches powered by Google's algorithm to improve the relevancy of results for the site's global search.
- [Sentinel Training Center](#): An easy to navigate, aggregate location for quick access to the video recordings and materials of key Sentinel trainings and workshops.
- [Engage with Sentinel](#): A dedicated space to explain and encourage different opportunities to stay informed, get involved and engage with the Sentinel Initiative.
- [Drug Assessments](#): Information on drug assessments conducted in ARIA and other Sentinel data resources can now be accessed from a new table that consolidates, when available, analytic code,



results, communications and regulatory outcomes for all queries that are associated with the same underlying safety question.

Sentinel also launched a new, [centralized Sentinel Initiative YouTube Channel](#). The channel incorporates major webinars, trainings, and workshops into a single, publicly available repository. The YouTube Channel will provide a video archive of the growing number of webinars and trainings provided by Sentinel and its centers.

[Explore the redesigned Sentinel website](#)

[Explore the Sentinel Initiative YouTube Channel](#)

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 to utilize emerging technologies such as feature engineering, natural language processing, advanced analytics, and data interoperability to improve Sentinel's capabilities.

Upcoming Webinars:

- [Adaptive Validation Designs: Premise and Methods](#): Monday, August 9th, 2021; 12:00 PM - 1:00 PM Eastern Time

Recent Webinars:

- [Electronic Health Records + Natural Language Processing + Machine Learning = Improved Sentinel Outcome Detection Algorithms](#)
- [Introduction to the Signal Detection Analytics Core in the Sentinel Innovation Center](#)
- [The Development and Validation of a Real-World Mortality Variable](#)
- [Advanced Approaches for Evaluating Drug Safety in Pregnancy](#)
- [Introduction to FHIR and Applications for Data Capture and Interoperability in Sentinel](#)
- [Measure What You Treasure: The Challenges and Opportunities of Collecting Real World Endpoints](#)

New Analytic Packages, Methods, Data and Tools

Analytic Packages:

- [Angioedema Following Sacubitril/Valsartan Use in Patients with Heart Failure: A Propensity Score Analysis](#)

Methods Projects:

- [Advancing Scalable Natural Language Processing Approaches for Unstructured Electronic Health Record Data](#): This project uses natural language processing and text mining methods to identify patients with the COVID-19 disease and to extract clinical features from unstructured EHR data. These features will complement structured data already available in the Sentinel Common Data

Model. This project is also developing processes that would allow Sentinel to more rapidly prototype EHR-based information extraction algorithms for new health outcomes of interest in the case of future pandemics and other needs.

- [Extending Machine Learning Methods Development in Sentinel: Follow-up analyses for Anaphylaxis Algorithm and Formalization of a General Phenotyping Framework \(Phase 3\)](#): This project builds on two ongoing activities: Machine Learning Algorithm Development for Anaphylaxis (Phase 1); and Machine Learning Algorithm Development for Acute Pancreatitis - and- Multi-site adaptation for Anaphylaxis Algorithm (Phase 2), with specific aims including:
 - Expanding on Phase 1-2 anaphylaxis analysis plan and conducting additional secondary analyses
 - Developing and conducting a more scalable automated NLP feature engineering process
 - Further developing the high-level general framework for health outcome of interest identification into a more formalized and comprehensive guidance document for Sentinel
- [Improving Probabilistic Phenotyping of Incident Outcomes Through Enhanced Ascertainment with Natural Language Processing](#): Using a representative use case of suicidality (i.e., suicide ideation and suicide attempts), this project advances several themes related to Sentinel's computable phenotyping strategy for EHR data, including focusing on phenotyping methods for identifying incident (versus prevalent) conditions, focusing on a health outcome of interest that relies predominantly on unstructured EHR data and for which a clearly defined reference standard is absent, the need for rapid (near-real-time) NLP, and the evaluation of the generalizability of EHR-based phenotyping to neuropsychiatric events.

Tools:

- [Routine Querying System: Version 10.3.2](#)

Reports:

- [Duration of Follow Up for New Molecular Entities Approved in 2016](#)
- [Duration of Follow Up for New Molecular Entities Approved in 2014 and 2015](#)
- [Patterns in Insulin Product Use and Billing Codes: A Descriptive Analysis](#)
- [Lymphoma Risk following Guselkumab, Risankizumab, or Tildrakizumab Use: A Descriptive Analysis](#)
- [Angioedema following Dipeptidyl Peptidase IV \(DPP IV\) Inhibitors and Angiotensin Converting Enzyme \(ACE\) Inhibitors Use: A Descriptive Analysis](#)
- [Venous and Arterial Thromboembolism among New Users of NuvaRing and Other Combined Hormonal Contraceptives: A Descriptive Analysis](#)
- [Counts of Individuals in the Sentinel Distributed Database](#)

Recent Publications

- [Utilization of Hydroxyprogesterone Caproate among Pregnancies with Live Birth Deliveries in the Sentinel Distributed Database](#)
- [Validation of an Electronic Algorithm for Hodgkin and Non-Hodgkin Lymphoma in ICD-10-CM](#)

- [Validity of ICD-10-CM Diagnoses to Identify Hospitalizations for Serious Infections Among Patients Treated with Biologic Therapies](#)
- [A COVID-19-Ready Public Health Surveillance System: The FDA's Sentinel System](#)
- [Electronic Phenotyping of Health Outcomes of Interest Using a Linked Claims-Electronic Health Record Database: Findings from a Machine Learning Pilot Project](#)