



Sentinel Newsletter

Second Quarter 2022

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



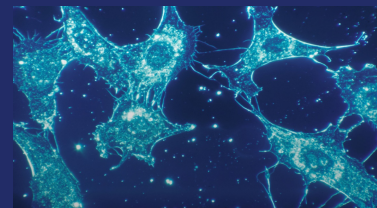
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Sentinel Deploys New Featured Pages on Trending Topics in Public Health

Sentinel Creates New Data Visualization Dashboard Called Sentinel Views

Sentinel Views (Views) is a new web-based data visualization platform, designed to increase access to study results from the Sentinel System. Since Views was released to the public in April 2022, it has been integrated into the existing Sentinel querying and reporting infrastructure and supports analyses from Sentinel's Routine Querying Tool's Propensity Score (PS) Analysis and Covariate Stratification modules. Views works with the full suite of PS options, including matching, stratification, stratum weighting, inverse probability of treatment weighting (IPTW), and high-dimensional propensity score (HDPS). It can visualize both descriptive and inferential results and will serve as a supplemental resource for eligible queries.

Eligible queries and approved dashboards will be made available to the public within Views. Users will be able to download data, customize graphs, and have the capability to download images of configured Results Table dashboards.

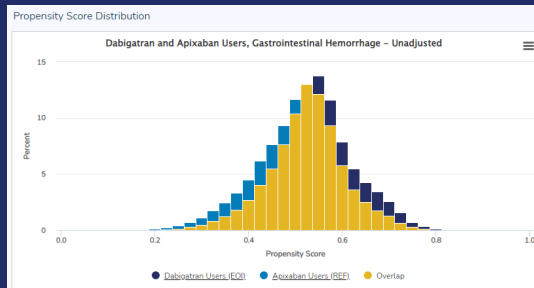
Advanced Research Highlighted at the 2022 Innovation Day & 13th Sentinel Public Training

On April 28 & 29, 2022, Sentinel held its [Innovation Day](#) and 13th Annual Public [Training](#).

The Innovation Day focused on the vision, progress, and challenges with leveraging electronic health record (EHR) data to support FDA's assessments of regulated medical products. Dr. Sebastian Schneeweiss described four overarching Innovation Center (IC) initiatives: 1) Data Infrastructure; 2) Feature Engineering; 3) Causal Inference; and 4) Detection Analytics. He described a focus on scalable data processing and analytic methods using structured, semi-structured, and unstructured EHR data to expand FDA's data analytic reach and compliment Sentinel's current infrastructure. Dr. Robert Ball, Deputy Director of the FDA CDER Office of Surveillance and Epidemiology, placed the IC work in the context of Sentinel's [Five-Year Strategy](#).

Afterward, additional presenters focused on specific areas of active methodological work including the challenges and opportunities in integrating electronic health record-based data

In April 2022, the first query to have a [Modular Program report](#) with associated Views content went live on the Sentinel Website. [Click here to view the Sentinel Views visualization platform.](#) More queries will become accessible within Views in the coming months. The implementation of Views progresses Sentinel's vision of serving as a national resource for medical product safety surveillance and real-world evidence generation.



Pictured above is a Sentinel Views data visualization

Sentinel Views dashboard displaying analysis groups for various exposures of interest.

Exposure Group	Exposure ID	Reference Group	Number of Events in Exposure	Number of Events in Reference	Relative Risk (95% CI)	Adjusted Relative Risk (95% CI)	Number of Events in Exposure	Number of Events in Reference	Relative Risk (95% CI)	Adjusted Relative Risk (95% CI)
Exposure Group 1	Exposure ID 1	Reference Group 1	100	100	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	100	100	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 2	Exposure ID 2	Reference Group 2	150	150	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	150	150	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 3	Exposure ID 3	Reference Group 3	200	200	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	200	200	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 4	Exposure ID 4	Reference Group 4	250	250	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	250	250	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 5	Exposure ID 5	Reference Group 5	300	300	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	300	300	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 6	Exposure ID 6	Reference Group 6	350	350	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	350	350	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 7	Exposure ID 7	Reference Group 7	400	400	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	400	400	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 8	Exposure ID 8	Reference Group 8	450	450	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	450	450	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 9	Exposure ID 9	Reference Group 9	500	500	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	500	500	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)
Exposure Group 10	Exposure ID 10	Reference Group 10	550	550	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)	550	550	1.00 (0.80, 1.25)	1.00 (0.80, 1.25)

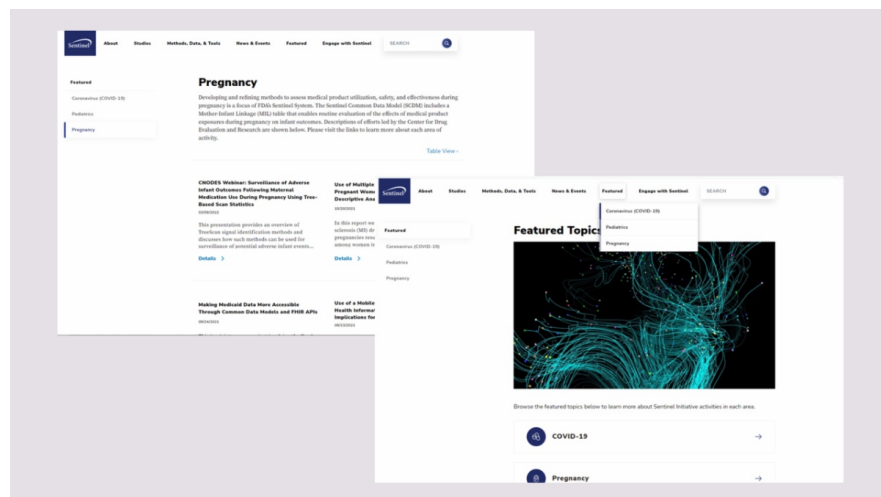
Pictured above is the Sentinel Views dashboard displaying analysis groups for various exposures of interest

in common data models (Dr. Keith Marsolo), computable phenotyping to aid medical product safety investigations (Drs. David Carrell, Joshua Smith and Cosmin Bejan), advanced analytic approaches to improve confounding adjustment in Sentinel investigations (Dr. Richard Wyss), and a causal inference framework for Sentinel (Dr. Rishi Desai). Through these initiatives, the IC is making strides in helping to achieve the FDA's vision of a Medical Data Enterprise with a query-ready system containing >10 million EHR lives.

Dr. Jennifer Lyons from the Sentinel Operations Center (SOC) moderated Sentinel's 13th Annual Public Training on April 29th. After a welcome from the Director of the Office of Surveillance and Epidemiology, Dr. Gerald Dal Pan, Dr. Lyons provided an overview of the Sentinel System and its analytic capabilities. Later presenters introduced Inverse Probability Weighting (Dr. Xiaojuan Li) and applied Inverse Probability of Treatment Weighting (IPTW) to work being done with Sentinel data (Dr. John Connolly). IPTW is a recently added analytic method for Sentinel Analyses that can be used to address covariate imbalance between exposed and unexposed groups, reducing confounding bias in observational studies of medical treatments. Importantly, IPTW does not produce the sample size loss that can occur with 1:1 matching methods of confounding control. Those interested in using the IPTW tool on data that is formatted in the Sentinel Common Data Model can [find more information here](#).

Sentinel Deploys New Featured Pages on Trending Topics in Public Health

Check out the new 'Featured' tab released on the Sentinel website, where users can find information dedicated to Sentinel activities in trending topics such as [COVID-19](#), [Pregnancy](#), and [Pediatrics](#)—look out for new topics in the coming future!



Engage with the Sentinel Community

[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 Innovation Center (IC) and the Sentinel Operations Center (SOC). 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:

- [Can We Train Machine Learning Methods to Outperform the High-Dimensional Propensity Score Algorithm?](#)
- [Data Leakage Due to Care Provided Outside of the Study Electronic Health Record System: Potential Biases and Solutions](#)
- [Do All Roads Lead to FHIR? Imagining FHIR as a Meta-Common Data Model for Research](#)
- [An Introduction to Negative Control and Proximal Causal Learning](#)

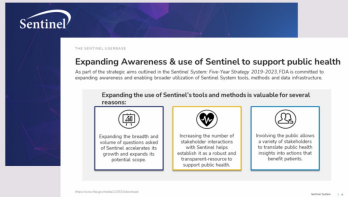
Visit the [Sentinel Meetings, Workshops, & Trainings page](#) to view past seminars, webinars, and workshops and to register for upcoming events in 2022.

2022 Sentinel Community Building and Outreach Center 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 below to learn more about two recently released videos.



MAJOR MOMENTS details the key milestones in the evolution of Sentinel as a national resource, starting from the Mini-Sentinel pilot in 2009 to how Sentinel stands today.



THE SENTINEL USERBASE highlights the various groups of stakeholders that can use Sentinel to inform their work.

New Analytic Packages, Methods, Tools and Reports

Methods Projects:

- [Improving Capture of Race and Ethnicity Data in Sentinel](#)
- [Augmenting Date of Death & Cause of Death Ascertainment in Sentinel](#)

Tools:

- [Sentinel Routine Querying System Reporting Tool](#)
- [Sentinel Routine Querying System](#)

Reports:

- [Aldactone \(spironolactone\) & Indications for Use](#)
- [Makena \(Hydroxyprogesterone Caproate Injection\) and Its Generics & Use in Pregnancy](#)
- [Serious Infection Following Ustekinumab Use in Patients with Crohn's Disease or Ulcerative Colitis: A Descriptive Analysis](#)
- [Characterization of Pediatric Demographics and Enrollment in the Sentinel Distributed Database: A Descriptive Analysis](#)
- [Death Data Exploration: A Descriptive Analysis](#)
- [Incidence and Prevalence of Confounding Variables Over Time in the Sentinel Distributed Database \(SDD\): A Descriptive Analysis](#)
- [Duration of Follow Up for New Molecular](#)
- [Utilization of Brodalumab: A Descriptive Analysis](#)
- [Hydroxyurea Use Among Patients with Sickle Cell Disease \(SCD\): A Descriptive Analysis](#)
- [Estimated Prevalence of Glomerular Diseases: An Updated Descriptive Analysis](#)
- [Epidiolex \(prescription cannabidiol\) Utilization Patterns: A Query Builder Analysis](#)
- [Valganciclovir Use in Children with Congenital Cytomegalovirus Disease \(cCMV\) or Cytomegalovirus \(CMV\) Infection: A Descriptive Analysis](#)
- [Incident and Prevalent Use of Loop Diuretics: A Descriptive Analysis](#)

[Entities Approved in 2018: A Descriptive Analysis](#)

- [Counts and Characteristics of Individuals With Drug-Device Combination Use: A Descriptive Analysis](#)
- [Thromboembolic Stroke, Major Extracranial Bleeding, Gastrointestinal Bleeding, and Intracranial Hemorrhage following Direct Oral Anticoagulant Use: An Inverse Probability of Treatment Weighting Analysis](#)
- [Human Epidermal Growth Factor Receptor 2 \(HER2\) Antagonist Use in Patients with Live Birth Deliveries: A Descriptive Analysis](#)
- [Mometasone Furoate \(MF\) Sinus Implant Use in Patients with Nasal Polyps: A Descriptive Analysis](#)
- [Incidence and Prevalence of N-Nitrosodimethylamine \(NDMA\) and N-Nitrosodiethylamine \(NDEA\) Contaminated Valsartan Use: A Descriptive Analysis](#)

Recent Publications and Presentations

- [Scalable Algorithm Development: An Alternative to Algorithm Reuse?](#)
- [Use of Real-World Data for Surveillance of Medications in Pregnancy](#)
- [Systemic Corticosteroid Use for COVID-19 in US Outpatient Settings From April 2020 to August 2021](#)
- [A Landscape Analysis of Valganciclovir Treatment for Congenital Cytomegalovirus Infection in the United States \(US\), 2008-2021](#)
- [CNODES Webinar: Surveillance of Adverse Infant Outcomes Following Maternal Medication Use During Pregnancy Using Tree-Based Scan Statistics](#)

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

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