Sentinel Views User Guide

Sentinel Operations Center

Version 1.0

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The Sentinel System is sponsored by the U.S. Food and Drug Administration (FDA) to proactively monitor the safety of FDA-regulated medical products and complements other existing FDA safety surveillance capabilities. The Sentinel System is one piece of FDA's Sentinel Initiative, a long-term, multi-faceted effort to develop a national electronic system. Sentinel Collaborators include Data and Academic Partners that provide access to healthcare data and ongoing scientific, technical, methodological, and organizational expertise. The Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number 75F40119D10037.

Sentinel Views User Guide

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1 Key Sentinel Views Terminology

Sentinel Views User Guide – A resource for basic instruction on how to access and use the Sentinel Views application

Sentinel Views – A web-based data visualization application designed to increase access to drug analysis results prepared by the Sentinel Operation Center. Views enables users to gain added insight into Sentinel results using interactive visuals and on-screen components.

Views dashboards – Located on the Sentinel Views website and enable users to see and interact with Sentinel drug analysis results. Views dashboards are organized according to the categories defined below.

Propensity Score Analysis (PSA) modules – A Sentinel tool that performs propensity score adjusted inferential analyses. Within the PSA module, propensity scores can be used for matching, stratification, or weighting.

Covariate Stratification (CS) modules – A Sentinel tool that performs covariate stratified inferential analyses. The covariates available for stratification within the CS module are age group, sex, and calendar year.

Single Analysis – Provides links to Views dashboards corresponding to each unique combination of exposure, reference, outcome, patient population, and methodological parameters.

Multiple Analysis – Provides Views dashboards that facilitate comparisons across multiple user-selected Single Analyses.

Patient Attrition – A dashboard displaying the number of patients or episodes included and excluded at each step of the cohort generation process.

Covariate Balance – A dashboard displaying plots of standardized and absolute differences for each covariate before and after confounding adjustment.

Propensity Score Distribution – A dashboard displaying histograms of the propensity score distribution in each exposure group before and after confounding adjustment.

Results Table – A dashboard displaying exposure group sizes, time at risk, outcome counts, incidence rates, incidence proportions, and effect estimates (e.g., hazard ratios) before and after confounding adjustment.

Incidence Rate – A dashboard displaying a bar chart of the incidence rate in each exposure group before and after confounding adjustment.

Forest Plot – A dashboard displaying a forest plot of user-selected effect estimates (e.g., hazard ratios).

K-M Curve – A dashboard displaying Kaplan-Meier (K-M) curves before and after confounding adjustment.

Analysis Type – Specifies which data to display within a dashboard based on the desired amount of covariate adjustment. Options are Unadjusted, Adjusted, and Trimmed Unweighted (relevant to weighted PS analyses only).

Monitoring Period – Specifies the calendar start and end dates for the analysis.

Design Diagram – A visual representation of the temporal relationships between analysis parameters such as the enrollment requirement, inclusion/exclusion assessment period, follow-up strategy, and covariate assessment period.

Design Parameters – Specifies the length of the enrollment requirement prior to cohort entry along with the length of the maximum allowable enrollment gap.

Adjustment Method – Specifies the technique used for confounding adjustment. Options include propensity score matching, propensity score stratification, inverse probability of treatment weighting, propensity score stratum weighting (fine stratification), and covariate stratification.

Weighting Method – Specifies the type of weight and target population when a weighted adjustment method is used. Options include Average Treatment Effect (ATE), Average Treatment Effect, Stabilized (ATES), and Average Treatment Effect in the Treated (ATT).

Study ID – Unique study identifier.

Exposure of Interest – The exposure group of primary scientific interest.

Reference Group – The exposure group to which the Exposure of Interest group is compared.

Health Outcome of Interest – The event of scientific interest on which the Exposure of Interest and Reference Group are compared.

2 Accessing Sentinel Views

Sentinel Views is a web-based data visualization application designed to increase access to drug analysis results prepared by the Sentinel Operations Center. It enables users to gain added insight into Sentinel results using interactive visuals and on-screen components.

Sentinel Views is available to the public to view results from queries approved by the FDA. **Public users do not require a user account**. Sentinel Views can be accessed directly by navigating to views.sentinelsystem.org.

Additional training materials and resources can be found on the Help Page for Sentinel Views. This page contains Frequently Asked Questions (FAQ) and Training Video resources.

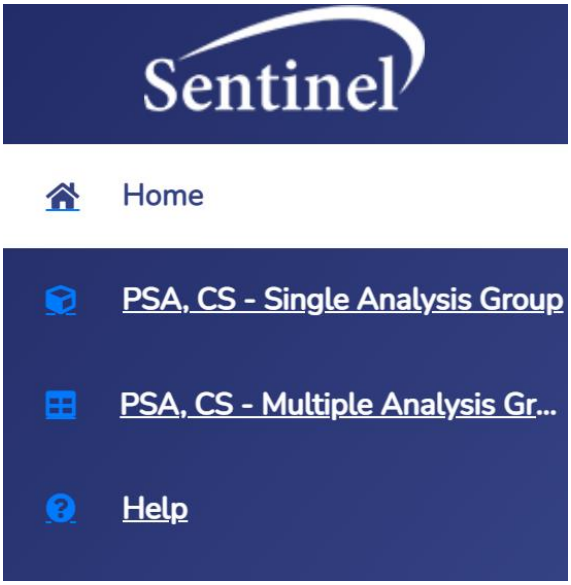
Please reach out to info@sentinelsystem.org with any questions, comments, or should you need any assistance with accessing Sentinel Views.

3 Data Available within Sentinel Views

Sentinel Views currently supports analyses from Sentinel's Routine Querying Tool's Propensity Score Analysis (PSA) modules and Covariate Stratification (CS) modules. Individual drug analyses that employ these modules, with minimum custom coding, will continue to be loaded and made available on Sentinel Views as their results are published on the Sentinel website. All drug analysis results for the data presented are sourced from the Sentinel Distributed Database.

4 Navigating Sentinel Views

Users can navigate Sentinel Views by using the sidebar located on the left-hand portion of the screen. This sidebar will always be available when using the application and can be collapsed or expanded by clicking on the Sentinel logo within it. The sidebar selections take you to the following portions of Sentinel Views:



- **Home Page** – This section contains useful information about Sentinel's Routine Querying Tools as well as an introduction to the Sentinel Views.
- **PSA, CS – Single Analysis Group** – This section allows users to view results for a single comparison of exposure/outcome pairs using a specified method of comparison, termed "analysis group." Users will be taken to a screen to select from available studies and the user will specify the desired Analysis Group.
- **PSA, CS – Multiple Analysis Groups** – This section allows users to select multiple Analysis Groups (i.e. comparison groups) and view results side by side. Users will be taken to a screen to select from available studies and the user will specify the desired Analysis Groups.
- **Help Page** – This section contains a FAQ, training video, and this user guide. Contact information is also contained here.

4.1 Selecting an Analysis Type

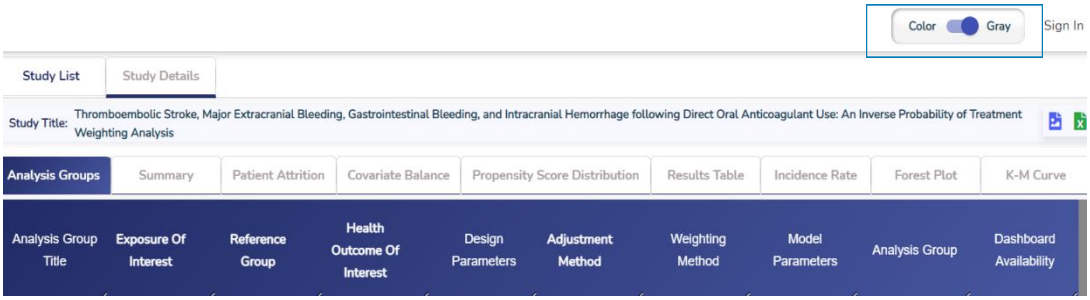
Sentinel Drug Analyses' results are available for review in two formats: **PSA, CS – Single Analysis Group** and **PSA, CS – Multiple Analysis Groups.** To access Views dashboards for the drug analyses' results available within Sentinel Views, select the section of interest from the left-side navigational sidebar.

- Selecting **PSA, CS – Single Analysis Group** enables users to view a single analysis group for a single combination of exposure, outcome, and analysis type.
- Selecting the **PSA, CS – Multiple Analysis Groups** enables users to compare results across analysis groups. For example, when there are multiple analysis groups studying the same outcome but with different exposure comparisons (or, conversely, the same exposure comparison with different analysis groups for several different outcomes).

4.2 Navigating to a Sentinel Views Dashboard

Once the desired format has been selected from the navigational sidebar, the "Study Library" will load and a drug analysis can be selected to review results using the interactive dashboards.

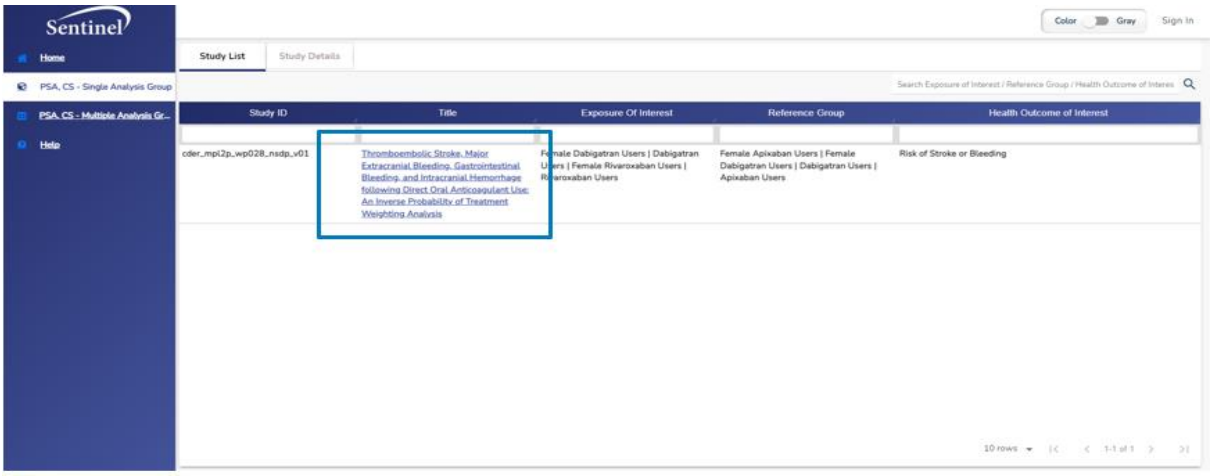
Sentinel Views dashboards each have various interactive elements that can be used to analyze the data in real-time or downloaded to a personal computer device. Sentinel Views also offers color/grayscale viewing which can be accessed by engaging the toggle located near the upper-right corner of any screen.



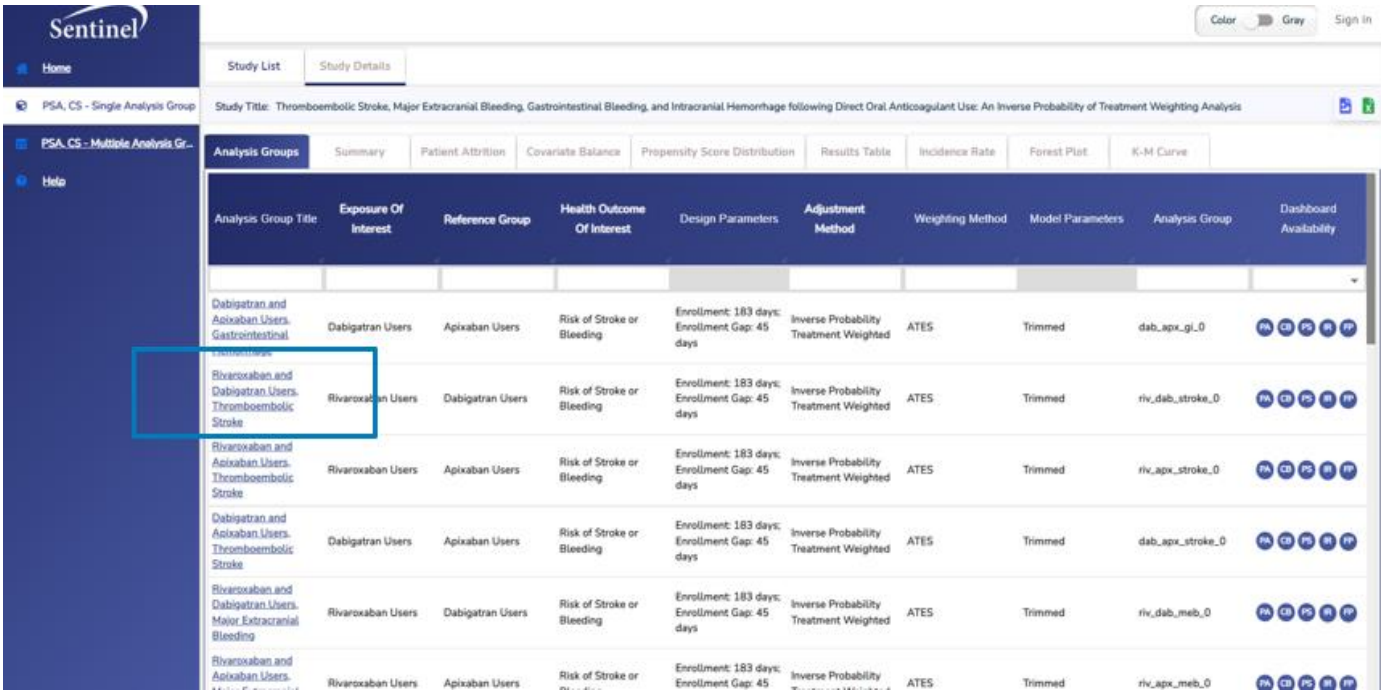
Below are step-by-step instructions on how to access available dashboards in the **PSA, CS – Single Analysis Group** or **PSA, CS – Multiple Analysis Groups** sections of Sentinel Views.

4.2.1 PSA, CS – Single Analysis Group

- Select the drug analysis of interest by clicking on the Title of the analysis under the Title column.

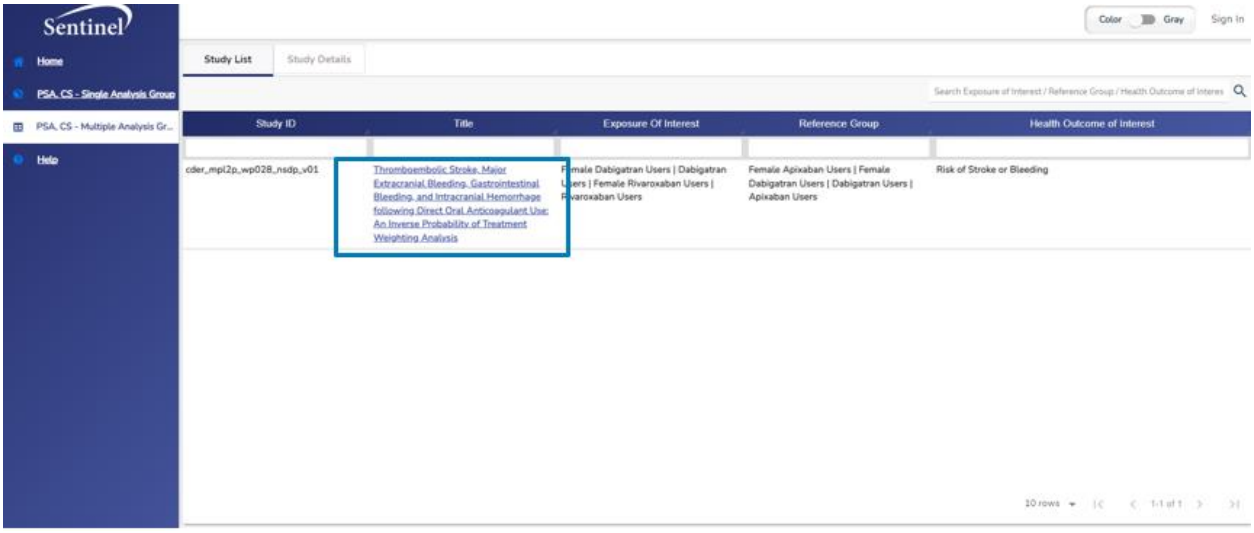


- The next screen will be the library page. This page will show available results within the "Analysis Groups" tab (other tabs will be greyed out) for the drug analysis of interest. From there, select the analysis group of interest under the "Analysis Group Title" column to access the "Summary" dashboard and other related available / interactive dashboards.

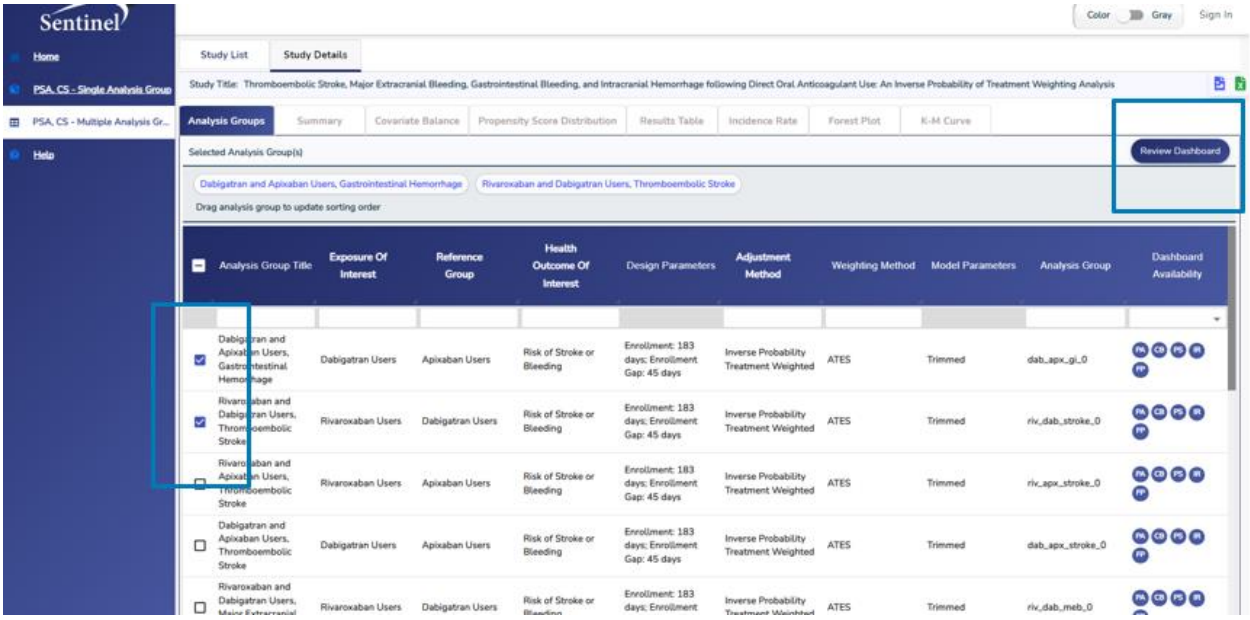


4.2.2 PSA, CS – Multiple Analysis Groups

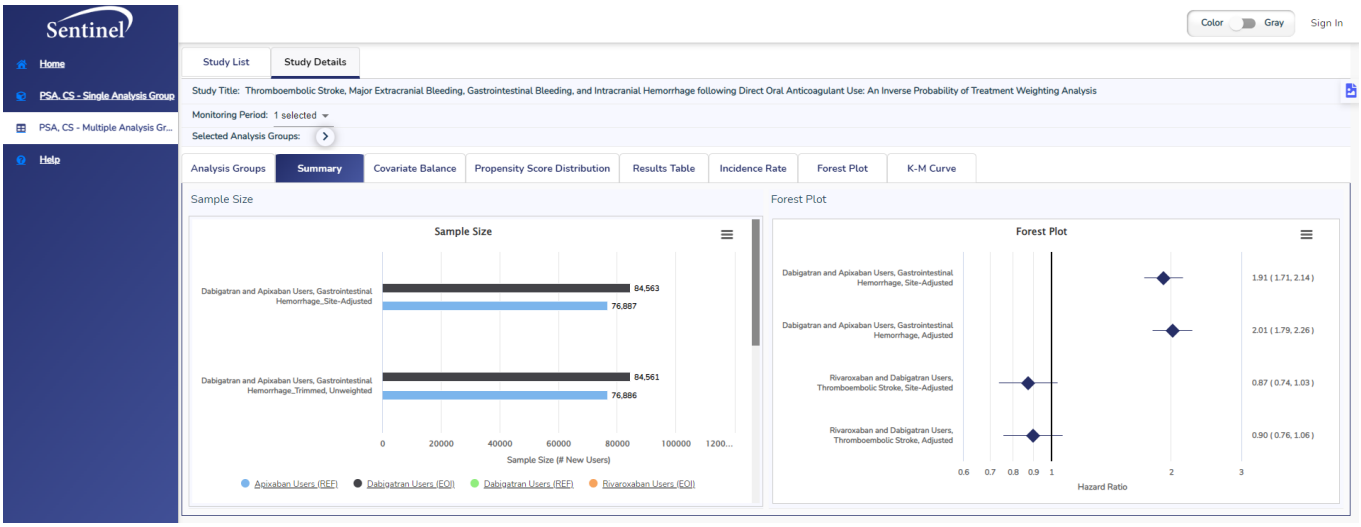
- Select the desired drug analysis by clicking on the Title of the analysis under the Title column.



- The next screen will be the library page. This page will show available results within the "Analysis Groups" tab (other tabs will be greyed out) for the drug analysis of interest. Select one or more analysis group using the checkboxes (left-most column). Once all analysis groups of interest have been selected, click the "Review Dashboard" button.



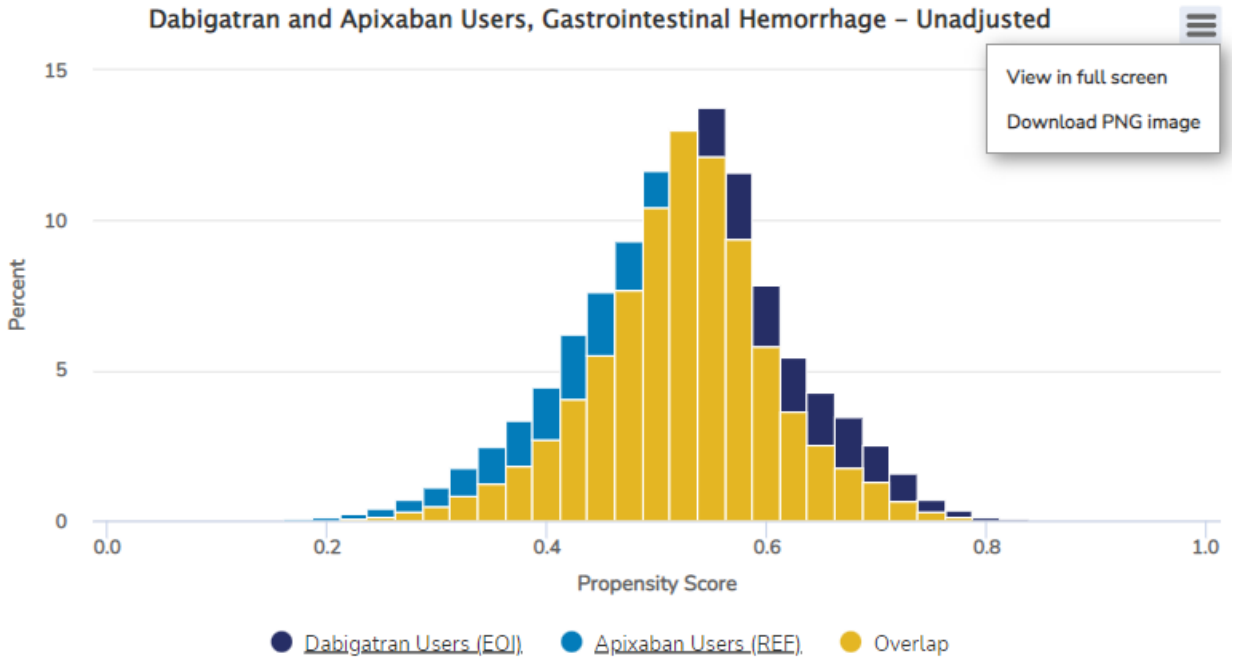
- Clicking the "Review Dashboard" button will lead to the "Summary" dashboard. From here, click on any other tab to review the user-generated dashboard and its visualizations. Each dashboard has a variety of interactive elements including drop-down filters, toggling on/off selected visualization elements, zoom, and grouping capability.



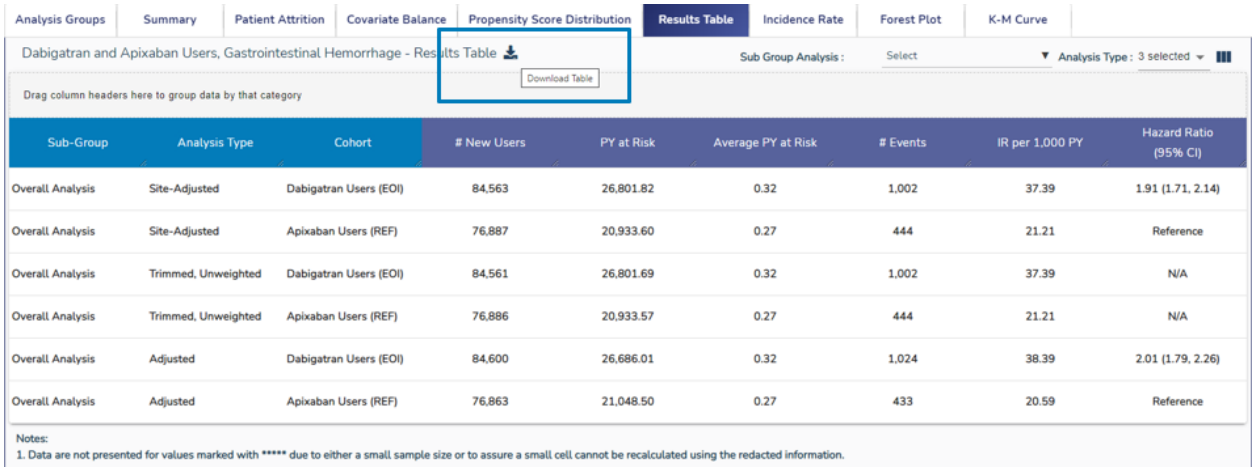
5 Downloading Data 101

Below are quick references on how to access and download data from a Sentinel drug analysis.

The dashboards can be downloaded directly to a PNG image file by using the icon containing three stacked horizontal lines in the top right corner of the visualization.



A Results Table PNG image can be downloaded using the icon containing the down arrow next to the dashboard's title.



Sub-Group	Analysis Type	Cohort	# New Users	PY at Risk	Average PY at Risk	# Events	IR per 1,000 PY	Hazard Ratio (95% CI)
Overall Analysis	Site-Adjusted	Dabigatran Users (EOI)	84,563	26,801.82	0.32	1,002	37.39	1.91 (1.71, 2.14)
Overall Analysis	Site-Adjusted	Apixaban Users (REF)	76,887	20,933.60	0.27	444	21.21	Reference
Overall Analysis	Trimmed, Unweighted	Dabigatran Users (EOI)	84,561	26,801.69	0.32	1,002	37.39	N/A
Overall Analysis	Trimmed, Unweighted	Apixaban Users (REF)	76,886	20,933.57	0.27	444	21.21	N/A
Overall Analysis	Adjusted	Dabigatran Users (EOI)	84,600	26,686.01	0.32	1,024	38.39	2.01 (1.79, 2.26)
Overall Analysis	Adjusted	Apixaban Users (REF)	76,863	21,048.50	0.27	433	20.59	Reference

Notes:
1. Data are not presented for values marked with ***** due to either a small sample size or to assure a small cell cannot be recalculated using the redacted information.

Source data for certain dashboards can be downloaded using the Excel icon located in the upper right corner of your screen. Additionally, if made available within Sentinel Views, a Design Diagram in PDF format can be downloaded which details how the study was configured.