

Sentinel Views User Guide

Sentinel Operations Center

Version 1.0

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The Sentinel System is sponsored by the <u>U.S. Food and Drug Administration (FDA)</u> 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 <u>Sentinel Initiative</u>, 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 <u>views.sentinelsystem.org</u>.

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

Please reach out to <u>info@sentinelsystem.org</u> 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. <u>Individual drug</u> <u>analyses</u> 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 <u>Sentinel</u> website. All drug analysis results for the data presented are sourced from the <u>Sentinel Distributed Database</u>.

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.

Study List	Study Details	jor Extracranial Bleedir	ng, Gastrointestinal Blee	ding, and Intra	cranial Hemorrhage follo	owing Direct Oral Ant	ticoagulant Use: An Ir	Color Color	Gray Sign In
Analysis Groups	nting Analysis Summary	Patient Attrition	Covariate Balance	Propensity	/ Score Distribution	Results Table	Incidence Rate	Forest Plot	K-M Curve
Analysis Group Title	Exposure Of Interest	Reference Group	Health Outcome Of Interest	Design Parameters	Adjustment Method	Weighting Method	Model Parameters	Analysis Group	Dashboard Availability

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.

	Sentinel							Color 🔊 Gray	Sign In
	Home	Study List	Study Details						
	PSA, CS - Single Analysis Group						Search Exposure of Interest / Refere	rce Group / Health Outcome of	Interes Q
	PSA. CS - Multiple Analysis Gr	Stu	dy ID	Title	Exposure Of Interest	Reference Group	Health Or	acome of Interest	
•	the	cdermpi2pwp028	_nsdp,v01	Thromboembolic Stroke, Mejor Extracarsia Bleedee, Gastrontestinal, Bleedee, and Interacarsia Henorohoe Stolowing Direct Con Actocomputer Ac Inverse Probability of Theatment Weighting Analysis	R male Dabigatran Users Dabigatran Users Fernala Riverosaban Users Ri artsvaban Users	Female Apixaban Users Female Dabigatran Users Dabigatran Users Apixaban Users	Risk of Stroke or Bleeding		
							10 rows -	. C C 1-1 of 1	2 21



• 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.

Sentinel									Color	💭 Gray Sign In
. Home	Study List	Study Details								
PSA, CS - Single Analy	sis Group Study Title: Thrombo	pembolic Stroke, Maj	or Extracranial Bleeding.	Gastrointestinal Bleedin	g, and Intracranial Hemorrhage	following Direct Oral A	nticoagulant Use: An Inv	erse Probability of Treat	ment Weighting Analysis	8 8
PSA. CS - Muttiple Ana	Analysis Groups	Summary	Patient Attrition	Covariate Balance	Propensity Score Distributio	n Results Table	Incidence Rate	Forest Plat	K-M Carve	
🤗 Hele	Analysis Group Title	Exposure Of Interest	Reference Group	Health Outcom Of Interest	e Design Parameters	Adjustment Method	Weighting Method	Model Parameters	Analysis Group	Dashboard Availability
	Dabigatran.and Aciuaban Users. Gastrointestinal	Dabigatran Users	Apixaban Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	dab_apx_gi_0	00000
	Elivarssaban and Dabigatran Uters. Thromboembolic Stroke	Rivaroxat an User	s Dabigatran Users	Risk of Stroke or Bleeding	Enrollment: 183 days; Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	riv_dab_stroke_0	00000
	Bivaroxaban and Asixaban Usera Thromboembolis Stroke	Rivaroxaban User	s Apixaban Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	riv_apx_stroke_0	00000
	Dabigatran and Asixaban Users. Thromboembolic Stroke	Dabigatran Users	Apixaban Users	Risk of Stroke or Bleeding	Enrollment: 183 days; Enrollment Gap: 45 days	inverse Probability Treatment Weighted	ATES	Trimmed	dab_apx_stroke_0	00000
	Elizarostaban and Dabigatran Usera. Major Extracranial Bleeding	Rivaroxaban User	s Dabigatran Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	riv_dab_meb_0	00000
	Riveroxaban and Apixaban Users.	Rivaroxaban User	s Apixaban Users	Risk of Stroke or	Enrollment: 183 days; Enrollment Gap: 45	Inverse Probability	ATES	Trimmed	riv apx meb 0	

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.

	Sentinel					Col	M D Gray Sign in
	Home	Study List Study Detail	tis				
۰	PSA. CS - Single Analysis Group					Search Exposure of Interest / Reference Group	/ Health Outcome of Interes Q
	PSA, CS - Multiple Analysis Gr	Study ID	Tile	Exposure Of Interest	Reference Group	Health Oulcome o	Interest
•	tide	cder,mpi2p,wp028,nedp,v01	Thrombombolic Strake, Mavier Extractional, Bleeding, Gastrointestinal Bleeding, and httscanal.Hemothape following Direct Carl. Antoneousland Usia An Inverse. Probability of Treatment Weighting Analysis	F male Dabigatran Users Dabigatran Users Fendele Rivaroxaban Users R varoxaban Users	Female Apixaban Users (Female Debigatran Users (Debigatran Users (Apixaban Users	Risk of Stroke or Bleeding	
						10 rows + 10	< 14.011 > >1



• 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.

Sentinel?									Color	Gray Sign
tione	Study List Study	Details								
PSA. CS - Single Analysis Group	Study Title: Thromboembol	ic Stroke, Major Extracra	mial Bleeding, Gastroin	testinal Bleeding, and Intra	cranial Hemorrhage fol	lowing Direct Oral Antic	oagulant Use: An Inven	e Probability of Treatme	nt Weighting Analysis	8
PSA, CS - Multiple Analysis Gr	Analysis Groups	mmary Covaria	te Balance Prope	nsity Score Distribution	Results Table	Incidence Rate	Forest Plot	K-M Curve		
Hela	Selected Analysis Group(s)									Review Dashboard
	Dubigatran and Apixaban	Users, Gastrointestinal	Hemorrhage Rivers	waban and Dabigatran Use	rs, Thromboembolic St	roke				
	- Analysis Group Title	Exposure Of Interest	Reference Group	Health Outcome Of Interest	Design Parameters	Adjustment Method	Weighting Method	Model Parameters	Analysis Group	Dashboard Availability
	Dabigs zan and Apixab in Users, Gastro restinal, Hemor hage	Dabigatran Users	Apixaban Users	Risk of Stroke or Blieeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	dab_apx_gi_0	0000
	Rivaro, aban and Dabiga yan Users, Throm-coembolic Stroke	Rivaroxaban Users	Dabigatran Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	riv_dab_stroke_0	0000
	Rivero aban and Apixatian Users, Infomboembolic Stroke	Rivaroxaban Users	Apixaban Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	riv_apx_stroke_0	0000
	Dabigatran and Apixaban Users. Thromboembolic Stroke	Dabigatran Users	Apixaban Users	Risk of Stroke or Bleeding	Enrollment: 183 days: Enrollment Gap: 45 days	Inverse Probability Treatment Weighted	ATES	Trimmed	dab_apx_stroke_0	0000
	Rivaroxaban and Dabigatran Users, Major Extrarranjal	Rivaroxaban Users	Dabigatran Users	Risk of Stroke or	Enrollment: 183 days; Enrollment	Inverse Probability	ATES	Trimmed	riv_dab_meb_0	0000

• 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.

Sentinel	Color Gray	Sign In							
🕋 Home	Study List Study Details								
PSA. CS - Single Analysis Group	Study Title: Thromboembolic Stroke, Major Extracranial Bleeding, Gastrointestinal Bleeding, and Intracranial Hemorrhage following Direct Oral Anticoagulant Use: An Inverse Probability of Treatment Weighting Analysis	Ē							
PSA, CS - Multiple Analysis Gr	Monitoring Period: 1 selected ~								
😧 Help	Analysis Groups Summary Covariate Balance Propensity Score Distribution Results Table Incidence Rate Forest Plot K-M Curve								
	le Size Forest Plot								
	Sample Size 🔳 Forest Plot	=							
	Dabigatran and Apkaban Users, Gastrointestinal Hemorrhing, Site-Adjusted	14)							
	Dabigstran and Apikaban Uters, Gastrointestinul Hemoritage, Adjusted	.6)							
	Dabigatra and Apitaban Users, Castrointestinal Hemotrhage_Trimmed, Unweighted 76,886	.3)							
	0 2000 4000 60000 80000 10000 1200 Riversalan and Dabigatran Users. 0.90 (876.104	/6)							
									



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.

Analysis Groups	Summary Patien	t Attrition Covariate Bala	nce Propensity Scor	e Distribution Rest	Its Table Incidence Rate	Forest Plot	K-M Curve	
Dabigatran and A	pixaban Users, Gastroi	ntestinal Hemorrhage - Re	s ilts Table 🛓		Sub Group Analysis :	Select	Analysis Ty	pe: 3 selected 👻 🎹
Drag column headers	here to group data by that ca	itegory	Downle	oad Table				
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 present	ed for values marked with **	**** due to either a small sample	size or to assure a small (cell cannot be recalculate	d 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.

	Sentinel								Color	Sign In
£	Home	Study List	Study Details							_
R	PSA, CS - Single Analysis Group	Study Title: Throma	oembolic Stroke, Major Ext	racranial Bleeding, Gastrointestinal I	Bleeding, and Intracrania	I Hemorrhage following Dire	ect Oral Anticoagulant Use: An Inv	verse Probability of T	reatment Weighting Analysis	2 8
	PSA. CS - Multiple Analysis Gr	Monitoring Period:	10/19/2010 to 09/30/2015 •	-						
	Help	Analysis Group Title	Dabigatran and Apixaban	Users, Gastrointestinal Hemorrhage	Exposure of Intere	st: Dabigatran Users Re	eference Group: Apixaban Users	Health Outcome	of Interest: Risk of Stroke or I	Bleeding
		Design Parameters:	Enrollment: 183 days; Enro	Riment Gap: 45 days Adjustmer	t Method: Inverse Prob	ability Treatment Weighted	Weighting Method: ATES	Model Parameters	Trimmed	
		Analysis Groups	Summary Pat	ient Attrition Covariate Balar	Propensity Sco	re Distribution Result	ts Table Incidence Rate	Forest Plot	K-M Curve	
		Dabigatran and	Apixaban Users, Gast	rointestinal Hemorrhage - Re	sults Table 🛓		Sub Group Analysis :	Select	Analysis T	ype: 3 selected 👻 🚻
		Drag column heade	rs here to group data by tha	t category						
		Sub-Group	Analysis Type	Cohort	# New Users		Average PY at Risk	# Events		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, Unweighte	d Dabigatran Users (EOI)	84,561	26,801.69	0.32	1.002	37.39	N/A
		Overall Analysis	Trimmed, Unweighte	d 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 prese	nted for values marked wit	h ***** due to either a small sample	size or to assure a small	cell cannot be recalculated	using the redacted information.			