

Clinical Data Analytics (CDA) 25.1 Home Page Description Table

A Analytics app Sheet Burnino Clinical Data Analytics ...

B Assets Sheets Bookmarks Insight Advisor No selections applied **C**

D Home Page Create Issue Issues Register Review Reviews Copy Link Share Help Center

E Study Therapeutic Area Program Compound Country Site Subject

F

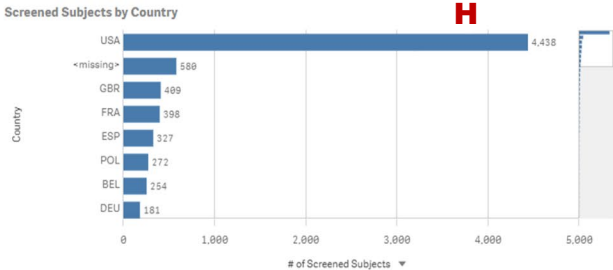
Screened In Screening 8435 44	Discontinued Treatment n (%)... 3622 (58.0%)
Screen Failure n (%) <input type="checkbox"/> 1669 (19.8%)	Completed Treatment n (%) <input type="checkbox"/> 478 (7.6%)
Enrolled n (%) <input type="checkbox"/> 6769 (80.2%)	Discontinued Study n (%) <input type="checkbox"/> 1821 (26.9%)
Randomized n (%) <input type="checkbox"/> 2561 (37.8%)	Completed Study n (%) <input type="checkbox"/> 452 (6.7%)
Treated n (%) <input type="checkbox"/> 6250 (92.3%)	Death n (%) <input type="checkbox"/> 2261 (33.4%)

G

Group Assignment	# of Subjects	On Treatment	Off Treatment	Untreated
Totals	8,479	1,373	4,877	2,229
Screen Failure	1,069	0	0	1,069
COHORT 2	1,044	36	1,008	0
COHORT 1	828	21	797	10
Drug 1	812	396	387	29
SCREEN FAILURE	626	0	0	626
Cohort8:Drug H	390	0	375	15

H

Screened Subjects by Country



I

Rate of AEs
14.3 0.8 SAE Rate

Rate of Related AEs
7.2 0.3 Related SAE Rate

Serious Treatment Emergent Rate
0.7

Top 3 AE (n) Per Subject
Thrombocytopenia(5252), Nausea(4347), Diarrhoea(4228)

Top 3 SAE (n) Per Subject
Pneumonia(233), Pyrexia(201), Disease progression(197)

J

AE Coding Progress
95,289 Coded

Tx Coding Progress
147,381 Coded

MH Coding Progress
60,891 Coded

Includes all MH categories.

Note: Hover over any section of the Home Page to display three action icons: View Details, Full Screen, and More. Clicking 'More' expands the menu to include Full Screen, Show Details, View Data, Share, Storytelling Snapshots, and Download as.

	Items on Page	Description
A	Analytics App Drop-down Selector / More	<ul style="list-style-type: none"> • Analytics App Drop-down Selector: <ul style="list-style-type: none"> - Home - Overview: Provides a consolidated view of all the Sheets, Bookmarks, and Stories within the app for quick access and overview. - Analyze - Sheet: Selected as the default, indicated by the green underline. This view allows users to explore and interact with the sheets, one at a time, in the app. - Narrate - Storytelling: Click on Narrate Storytelling to create a story, or to access any published stories. • More (beside App Name): <ul style="list-style-type: none"> - Show Details: Expands a panel displaying app details such as date data last loaded, published timestamp, published to environment, and the app description. - Download Sheet as PDF: Allows users to download the sheet as a PDF. - Duplicate Sheet: Duplicates the sheet currently open, - Touch Screen Mode: Turns on touch screen mode (great if using a tablet or touch screen computer). - Help: Link to Qlik Help Documentation.
B	Assets / Sheets / Bookmarks / Insight Advisor / Smart Search / Selections Bar	<ul style="list-style-type: none"> • Assets: Opens a panel for browsing Sheets and Bookmarks, with grid or list views, and a built-in search bar. <ul style="list-style-type: none"> - Sheets: Click the Sheets icon to see all available sheets. - Bookmarks: Allows users to save selections for easy access to the data they want to view. Click the icon to access existing bookmarks and to create new bookmarks. • Insight Advisor: Click to open / close the Insight Advisor window. • Smart Search: A global search tool enabling users to search the entire data set in the app. Click the search icon to open or close Smart Search. • Selections Bar: Smart Search, Step back, Step forward, Clear all selections, and see any applied selections (filters).
C	Selections Tool / Duplicate	<ul style="list-style-type: none"> • Selections Tool: Provides an overview of every dimension and field in the app, allowing users to make selections from this view as well. It also provides a more detailed view of selected data, allowing users to explore associations in dimensions that have not been used. • Duplicate: Click to duplicate a sheet, then modify as needed (users must have the Analytics Edit privilege).
D	Menu Toolbar with Action Buttons	<ul style="list-style-type: none"> • Navigate sheets: Click the side arrows to navigate to the previous or next sheet. • Create Issue: Click to create an issue on the sheet in view, preserving applied filters. • Issues: Click to open the Global Issues listing. The listing has pre-programmed filters to show open issues assigned to the logged in user. • Register Review: Click to open a dialog window to log your review of the sheet, and to schedule the next review. • Reviews: Click to access the Analytic Sheet Review Log Report. • Copy Link: Click to copy the link to the sheet in view, preserving applied filters. Paste in an email, chat, or document. Appropriate privileges are required to open the link and view the sheet. • Share: Click to open a new email message with a link to the sheet in view, preserving applied filters. A pop-up window will appear confirming you want to redirect to your Mail platform. Appropriate privileges are required to open the link and view the sheet. • Help Center: Click to access the elluminate Help Center.

	Items on Page	Description
E	Available Filters	<p>Filters display across the top of the page to customize your view of the Home Page. If you navigate to another sheet, the filters will remain until you remove them. Click on a filter to display all available items and then make your selection. Click the checkmark to confirm the selection. The data updates immediately.</p> <p>Filters available from the Home Page include Study, Therapeutic Area, Program, Compound, Country, Site, and Subject.</p>
F	Subject Study Status	<p>This section provides key performance indicators (KPIs) on the status of the subjects in the study(s). Click on a KPI once to see the name of the linked sheet and click again to navigate to it.</p> <ul style="list-style-type: none"> • Screened In Screening: The count of screened subjects and the count of subjects In Screening. A subject In Screening indicates they are still being evaluated and have neither enrolled nor screen failed. This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Screen Failure n (%): The count / percent of subjects who did not meet study requirements, based on Disposition, End of Study page, or Inclusion / Exclusion criterion out of all subjects screened. This KPI is clickable and will navigate users to the Inclusion/Exclusion Criteria Not Met sheet to allow them to explore further. • Enrolled n (%): The count / percent of screened subjects who were not screen failures, and if study is randomized then subjects must also be randomized. This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Randomized n (%): The count / percent of enrolled subjects who were randomly assigned a treatment group. <ul style="list-style-type: none"> – Subject has a (DS.)Protocol Milestone of "Random" This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Treated n (%): The count / percent of enrolled or randomized subjects who have a study drug start date. <ul style="list-style-type: none"> – Subject has a (DM.)Subject Reference Start Date This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Discontinued Treatment n (%): The count / percent of treated subjects who are off treatment for reasons other than completion. Excludes screen failures. <ul style="list-style-type: none"> – Subject is Treated and has a (DS.)Disposition Event of "**Treatment**" or "**Study**" that is not "Complete" or "Screen*Fail" This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Completed Treatment n (%): The count / percent of treated subjects who completed treatment. <ul style="list-style-type: none"> – Subject has a (DS.)Disposition Event of "**Treatment**" that's "Complete" This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Discontinued Study n (%): The count of enrolled subjects who are no longer on study and did not complete. Excludes screen failures. <ul style="list-style-type: none"> – Subject has a (DS.)Disposition Event of "**Study**" that is not "Complete" or "Screen*Fail" This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Completed Study n (%): The count of enrolled subjects who are no longer on study and did complete the study. <ul style="list-style-type: none"> – Subject has a (DS.)Disposition Event of "**Study**" that's "Complete" This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further. • Death n (%): The number of enrolled subjects for whom death was reported. <ul style="list-style-type: none"> – Subject has a (DM.)Subject Death Flag This KPI is clickable and will navigate users to the Death Summary sheet to allow them to explore further.

	Items on Page	Description
G	Group Assignment	<p>This table displays the number of subjects in each group:</p> <ul style="list-style-type: none"> • # of Subjects: The total number of subjects in a group. • On Treatment: The total number in a group who are on treatment. • Off Treatment: The total number in a group who are off treatment (Completed or Discontinued). • Untreated: The total number in a group who have not been treated (have not started study treatment).
H	Screened Subjects by Country	<p>This bar chart displays the number of screened subjects (or user can switch the x-axis to show the percentage of screened subjects) by country.</p>
I	Adverse Events Metrics	<p>This section provides metrics on Adverse Event (AE) reporting, including Serious Adverse Events (SAEs).</p> <ul style="list-style-type: none"> • Rate of AEs: Rate of AEs displays the percentage of AEs that were reported per enrolled subject in large blue font. The percentage of SAEs that were reported per enrolled subject is in small red font. This KPI is clickable and will navigate users to the Adverse Event Summary sheet to allow them to explore further. • Rate of Related AEs: Rate of Related AEs displays the percentage of Related AEs that were reported per enrolled subject in large blue font. The percentage of Related SAEs that were reported per enrolled subject is in small red font. This KPI is clickable and will navigate users to the Adverse Event Summary sheet to allow them to explore further. • Serious Treatment Emergent Rate: Rate of SAEs for treated subjects that were Treatment Emergent displays in large blue font. This KPI is clickable and will navigate users to the Treatment Emergent AE Analysis sheet to allow them to explore further. • Top 3 AE (n) Per Subject: Top 3 AE displays the top three Adverse Events that were reported per enrolled subject. The number of times the AE(s) were reported displays in the parentheses. • Top 3 SAE (n) Per Subject: Top 3 SAE displays the top three Serious Adverse Events that were reported per enrolled subject. The number of times the SAE(s) were reported displays in the parentheses.
J	Coding Metrics	<p>This section provides metrics on the progress of coding on AEs, ConMeds, and Medical History.</p> <ul style="list-style-type: none"> • AE Coding Progress: The total number of AEs reported displays at the right side of the arc with the center number displaying the total number coded. The filled arc provides a visual representation of the status of the coding against all reported AE Terms. • Tx Coding Progress: The total number of non-study drugs reported displays at the right side of the arc with the center number displaying the total number coded. The filled arc provides a visual representation of the status of the coding against all reported ConMed terms. These numbers include treatments taken before and during the study. • MH Coding Progress: The total number of Medical History events reported displays at the right side of the arc with the center number displaying the total number coded. The filled arc provides a visual representation of the coding against all reported MH terms.