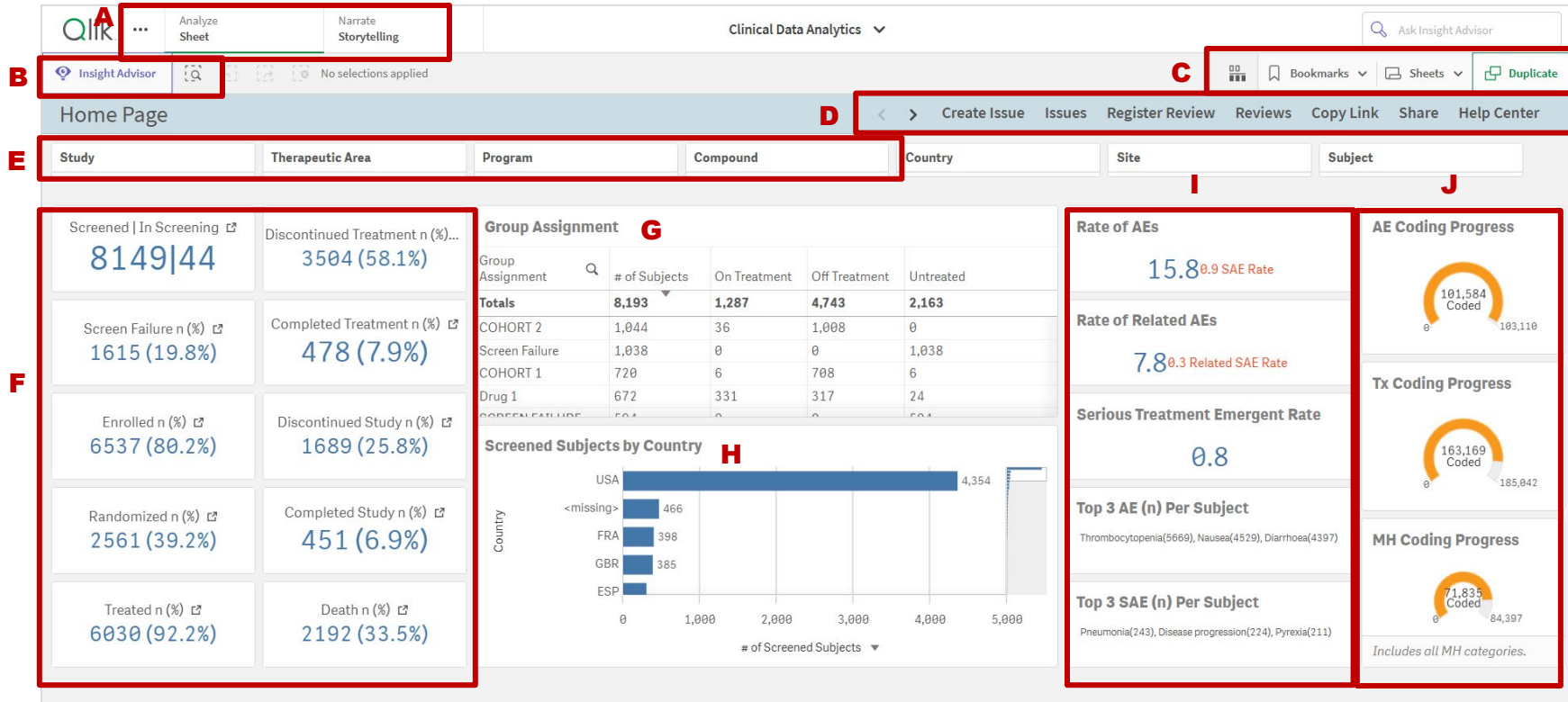


## Clinical Data Analytics (CDA) 24.2 Home Page Description Table



**A** Analyze Sheet, Narrate Storytelling

**B** Insight Advisor, No selections applied

**C** Bookmarks, Sheets, Duplicate

**D** Create Issue, Issues, Register Review, Reviews, Copy Link, Share, Help Center

**E** Study, Therapeutic Area, Program, Compound, Country, Site, Subject

**F** Summary Metrics:

- Screened | In Screening: 8149 | 44
- Discontinued Treatment n (%): 3504 (58.1%)
- Screen Failure n (%): 1615 (19.8%)
- Completed Treatment n (%): 478 (7.9%)
- Enrolled n (%): 6537 (80.2%)
- Discontinued Study n (%): 1689 (25.8%)
- Randomized n (%): 2561 (39.2%)
- Completed Study n (%): 451 (6.9%)
- Treated n (%): 6030 (92.2%)
- Death n (%): 2192 (33.5%)

**G** Group Assignment Table:

Group Assignment	# of Subjects	On Treatment	Off Treatment	Untreated
<b>Totals</b>	<b>8,193</b>	<b>1,287</b>	<b>4,743</b>	<b>2,163</b>
COHORT 2	1,044	36	1,008	0
Screen Failure	1,038	0	0	1,038
COHORT 1	720	6	708	6
Drug 1	672	331	317	24
SCREEN FAILURE	604	0	0	604

**H** Screened Subjects by Country Bar Chart:

Country	# of Screened Subjects
USA	4,354
<missing>	466
FRA	398
GBR	385
ESP	~100

**I** Rate of AEs: 15.8 (0.9 SAE Rate)

**J** AE Coding Progress: 101,584 Coded / 103,110

Rate of Related AEs: 7.8 (0.3 Related SAE Rate)

Serious Treatment Emergent Rate: 0.8

Tx Coding Progress: 163,169 Coded / 185,042

Top 3 AE (n) Per Subject: Thrombocytopenia(5669), Nausea(4529), Diarrhoea(4397)

MH Coding Progress: 71,835 Coded / 84,397

Top 3 SAE (n) Per Subject: Pneumonia(243), Disease progression(224), Pyrexia(211)

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	Navigation Menu / Analyze Sheet / Narrate Storytelling	<ul style="list-style-type: none"> <li>• <b>Navigation Menu:</b> Click the 3-dot ellipsis to open the Navigation menu.</li> <li>• <b>Analyze Sheet:</b> Selected as the default, indicated by the green underline. This view allows you to explore and interact with the sheets in the app.</li> <li>• <b>Narrate Storytelling:</b> Click on Narrate Storytelling to create a story, or to access any published stories.</li> </ul>
B	Insight Advisor / Selections Bar / Smart Search	<ul style="list-style-type: none"> <li>• <b>Insight Advisor:</b> Click to open / close the Insight Advisor window.</li> <li>• <b>Selections Bar:</b> Smart Search, Step back, Step forward, Clear all selections, and any applied selections (filters).</li> <li>• <b>Smart Search:</b> A global search tool enabling you to search the entire data set in the app. Click the search icon to open / close smart search.</li> </ul>
C	Selections Tool / Bookmarks / Sheets / Duplicate	<ul style="list-style-type: none"> <li>• <b>Selections Tool:</b> Provides an overview of every dimension and field in the app and allows you to make selections from this view as well. It also gives a more detailed view of selected data, so that you can explore associations in dimensions that have not been used.</li> <li>• <b>Bookmarks:</b> Allows you to save selections for easy access to the data you want to view. Click to access existing bookmarks, and to create a new bookmark.</li> <li>• <b>Sheets:</b> Click the Sheets drop-down to see all available sheets.</li> <li>• <b>Duplicate:</b> Click to duplicate a sheet, then modify to as needed (users must have the Analytics Edit privilege).</li> </ul>
D	Action Buttons	<ul style="list-style-type: none"> <li>• <b>Navigate sheets:</b> Click the side arrows to navigate to the previous or next sheet.</li> <li>• <b>Create Issue:</b> Click to create an issue on the sheet in view, preserving applied filters.</li> <li>• <b>Issues:</b> Click to open the Global Issues listing. The listing has pre-programmed filters to show open issues assigned to the logged in user.</li> <li>• <b>Register Review:</b> Click to open a dialog window to log your review of the sheet, and to schedule the next review.</li> <li>• <b>Reviews:</b> Click to access the Analytic Sheet Review Log Report.</li> <li>• <b>Copy Link:</b> 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.</li> <li>• <b>Share:</b> 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.</li> <li>• <b>Help Center:</b> Click to access the Help Center.</li> </ul>
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>

	Items on Page	Description
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"> <li>• <b>Screened   In Screening:</b> 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.</li> <li>• <b>Screen Failure n (%):</b> 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.</li> <li>• <b>Enrolled n (%):</b> 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.</li> <li>• <b>Randomized n (%):</b> The count / percent of enrolled subjects who were randomly assigned a treatment group. <ul style="list-style-type: none"> <li>– Subject has a (DS.)Protocol Milestone of "Random*" <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Treated n (%):</b> The count / percent of enrolled or randomized subjects who have a study drug start date. <ul style="list-style-type: none"> <li>– Subject has a (DM.)Subject Reference Start Date <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Discontinued Treatment n (%):</b> The count / percent of treated subjects who are off treatment for reasons other than completion. Excludes screen failures. <ul style="list-style-type: none"> <li>– Subject is Treated and has a (DS.)Disposition Event of "**Treatment*" or "**Study*" that is not "Complete*" or "Screen*Fail*" <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Completed Treatment n (%):</b> The count / percent of treated subjects who completed treatment. <ul style="list-style-type: none"> <li>– Subject has a (DS.)Disposition Event of "**Treatment*" that's "Complete*" <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Discontinued Study n (%):</b> The count of enrolled subjects who are no longer on study and did not complete. Excludes screen failures. <ul style="list-style-type: none"> <li>– Subject has a (DS.)Disposition Event of "**Study*" that is not "Complete*" or "Screen*Fail*" <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Completed Study n (%):</b> The count of enrolled subjects who are no longer on study and did complete the study. <ul style="list-style-type: none"> <li>– Subject has a (DS.)Disposition Event of "**Study*" that's "Complete*" <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Demographics sheet to allow them to explore further.</li> </ul> </li> </ul> </li> <li>• <b>Death n (%):</b> The number of enrolled subjects for whom death was reported. <ul style="list-style-type: none"> <li>– Subject has a (DM.)Subject Death Flag <ul style="list-style-type: none"> <li>This KPI is clickable and will navigate users to the Death Summary sheet to allow them to explore further.</li> </ul> </li> </ul> </li> </ul>

	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"> <li>• <b># of Subjects:</b> The total number of subjects in a group.</li> <li>• <b>On Treatment:</b> The total number in a group who are on treatment.</li> <li>• <b>Off Treatment:</b> The total number in a group who are off treatment (Completed or Discontinued).</li> <li>• <b>Untreated:</b> The total number in a group who have not been treated (have not started study treatment).</li> </ul>
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"> <li>• <b>Rate of AEs:</b> 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.</li> <li>• <b>Rate of Related AEs:</b> 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.</li> <li>• <b>Serious Treatment Emergent Rate:</b> 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.</li> <li>• <b>Top 3 AE (n) Per Subject:</b> 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.</li> <li>• <b>Top 3 SAE (n) Per Subject:</b> 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.</li> </ul>
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"> <li>• <b>AE Coding Progress:</b> 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.</li> <li>• <b>Tx Coding Progress:</b> 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.</li> <li>• <b>MH Coding Progress:</b> 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.</li> </ul>