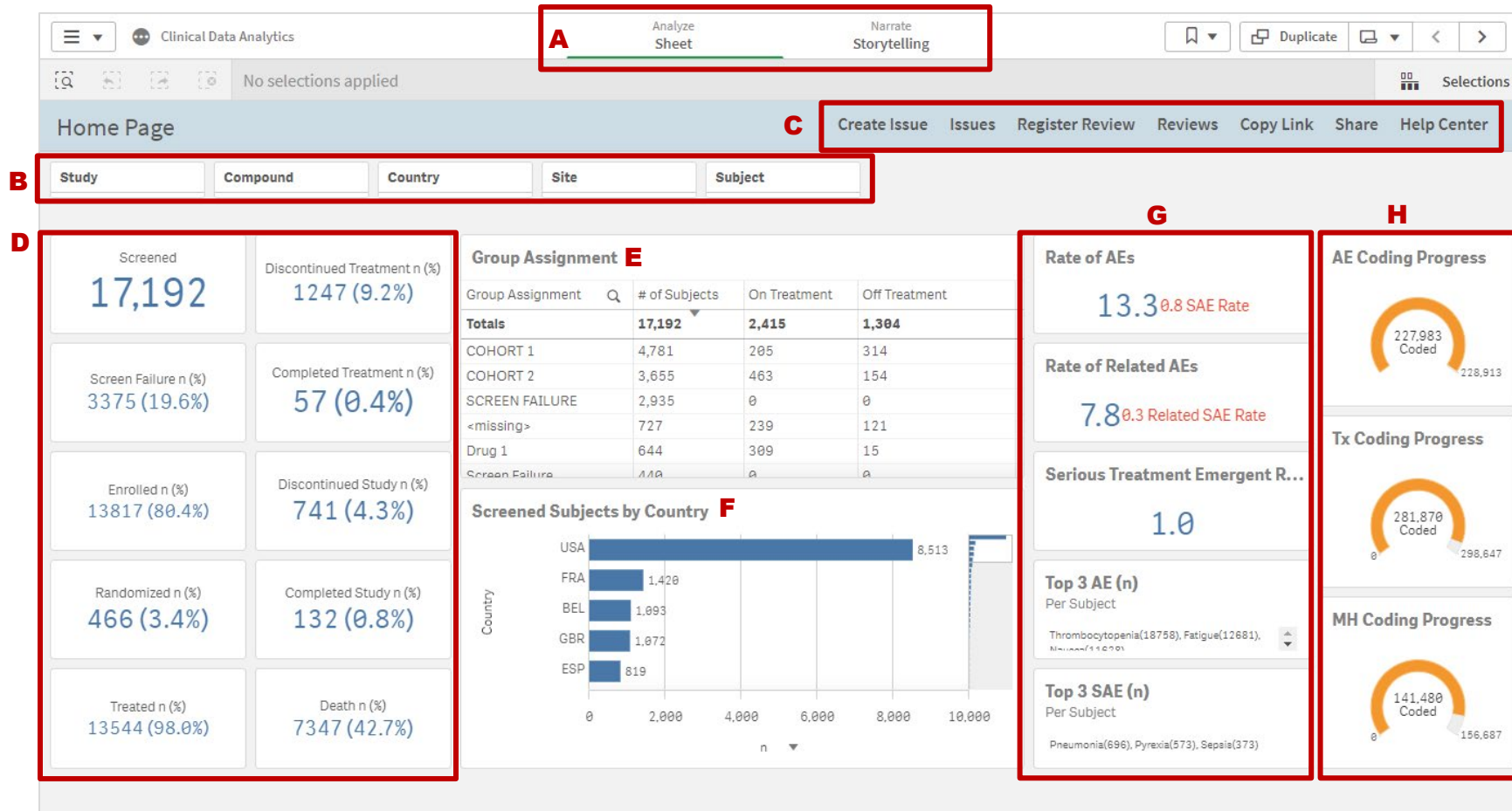



Clinical Data Analytics 22.3

Home Page Description Table



Note: Hover over any section of the Home Page to display icons such as the , or Show details, to see how the number was calculated, Take snapshot, Full screen, and Exploration menu.

	Items on Page	Description
A	Analyze Sheet / Narrate Storytelling	Analyze Sheet is selected as the default, indicated by the orange underline. Visualization sheets are available from Analyze Sheet. Click on Narrate Storytelling to create a story, or to access any published stories.
B	Available Filters	Filters display across the top of the page to limit the results on the Home Page. Any filters applied from the Home Page still apply when you move to another sheet. Click in a filter field to display all available items and then make your selection. Click the green checkmark to confirm the selection. Data updates immediately. Filters available from the Home Page include: Study, Compound, Country, Site and Subject.
C	Action Buttons	<ul style="list-style-type: none"> • 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 where your review of the sheet can be logged, 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 an email with a link to the sheet in view, preserving applied filters. Appropriate privileges are required to open and view the sheet. • Help Center: Click to access the Help Center.
D	Subject Study Status	<p>This section provides key performance indicators (KPIs) on the status of the subjects in the study(ies).</p> <ul style="list-style-type: none"> • Screened: The count of screened subjects. • Screen Failure n (%): The count / percent of subjects who did not meet study requirements, based on Disposition, End of Study page, or Inclusion / Exclusion criteria out of all subjects screened. • Enrolled n (%): The count / percent of screened subjects who were not screen failures. • Randomized n (%): The count / percent of enrolled subjects who were assigned a treatment group. • Treated n (%): The count / percent of enrolled or randomized subjects who have a study drug start date. • Discontinued Treatment n (%): The count / percent of treated subjects who are off treatment for reasons other than completion. • Completed Treatment n (%): The count / percent of treated subjects who completed treatment. • Discontinued Study n (%): The count of screened subjects who are no longer on study and did not complete. • Completed Study n (%): The count of screened subjects who are no longer on study and did complete the study. • Death n (%): The number of subjects for whom death was reported.

	Items on Page	Description
E	Group Assignment	<p>This table displays the number of enrolled subjects in each group assignment:</p> <p># of Subjects: The total number of enrolled subjects in a group</p> <p>On Treatment: The total number in that group who are on treatment</p> <p>Off Treatment: The total number in that group who are off treatment</p> <p>Note that number of subjects on treatment and off treatment may not add up to the total number in the group, as not all subjects may have started treatment.</p>
F	Screened Subjects by Country	<p>This bar chart displays the number of screened subjects by the countries participating in the study.</p>
G	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 percent of AEs that were reported per screened subject as the large blue font, and the percent of SAEs that were reported per screened subject as the small red font. • Rate of Related AEs: Rate of Related AEs displays the percent of AEs that were reported per screened subject as the large blue font, and the percent of Related SAEs that were reported per screened subject as the small red font. • Serious Treatment Emergent Rate: Rate of SAEs for treated subjects that were Treatment Emergent displays as the large blue font. • Top 3 AE (n): Top 3 AE displays the top three Adverse Events that were reported per screened subject. The number of times the AE was reported displays in the parentheses. • Top 3 SAE (n): Top 3 SAE displays the top three Serious Adverse Events that were reported per screened subject. The number of times the SAE was reported displays in the parentheses.
H	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.