Clinical Data Analytics 22.3

Sheet Descriptions Table

There are 58 standard public sheets in this version (including Oncology sheets).

Sheet	Information included
Home Page	Summary information across all studies, or the selected study(ies). Please see CDA 22.3 Home Page Description document for more information.
Demographics	Use this sheet to view counts and rates for screened subjects by group assignment, demographic information, site, and country. • Filters: Study, Country, Site, and Subject • Subject Population Table: Screened, Enrolled, Treated, Death. Select status(es) and the other visualizations update accordingly. • Bar Chart: Subject counts and percentages summarized by Group Assignment, Sex, Race, Ethnicity, or Age Range • Bar Chart: Subject counts and percentages summarized by Site or Country • Line Chart: Subject counts by age and Sex, Cohort, Country, Site, Race, or Ethnicity • Listing Table
Adverse Event Summary	Use this sheet to identify AEs that are prevalent in the subject population so as to respond to trends in a timely manner. The user can identify event prevalence that is not in alignment with the safety profile of a drug, examine all AEs that led to treatment discontinuation, and evaluate all reported events for potential safety signals and trends. • Filters: Study, Site, Subject, Country, Group Assignment, Special Interest AE, and Treatment Emergent • TreeView Chart: Tiles represent each System Organ Class or Preferred Term; the size of the box is proportional to the number of Adverse Event Subject or Event counts in that category. • Stacked Bar Chart: AE Subject or Event Counts by System Organ Class or Preferred Term. Sections of the bar can be colored by Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, AE Duration, or Group Assignment. * Depending on the variable(s) used, Severity and Highest Severity or Toxicity and Highest Toxicity display. If multiple variables are used Toxicity/Severity and Highest Toxicity/Severity display. • Adverse event Dot Plot: Provides the frequency (percentage) of AEs that are being experienced. Use the toggles to view by Preferred Term, High Level Term, High Level Group Term, or System Organ Class. • Listing Table: Study start day and stop day of Adverse Events are provided, along with date and time of last study treatment to give context to Adverse Events relative to treatment.

Sheet	Information included
Adverse Event Comparison	Use this sheet to do a side-by-side graphical comparison of Adverse Event data using the filters and toggles. By doing a side-by-side comparison of AEs the user can evaluate differences in response to a therapy. • Filters: Study, Site, Subject, Country, and Group Assignment • Toggles: Subject %, %Total Subj • Toggles: System Organ Class, Preferred Term • Toggles: Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, Group Assignment, or Trt Emergent * Depending on the variable(s) used, Severity and Highest Severity or Toxicity and Highest Toxicity display. If multiple variables are used Toxicity/Severity and Highest Toxicity/Severity display. • Stacked Bar Chart: Subject %, or % Total Subj defined by any of the toggles • Listing Table
Adverse Events Cross Tabulation	Use this sheet to examine AEs for all subjects by System Organ Class and the Preferred Terms. • Filters: Study, Site, Subject, Country, Group Assignment, Treatment Emergent, Special Interest AE, AE Study Day, and Subject Status • Enter the % of Subjects Threshold. Subjects above the defined threshold highlight in yellow. • Cross Tabulation: Use the column toggle filters in the center to view Subject or Event counts by selecting Study, Site, Group Assignment, or Country from the top row, and Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, or AE Duration from the bottom row, by System Organ Class (click the + to expand row/column subcategories) in rows. * Depending on the variable(s) used, Severity and Highest Severity or Toxicity and Highest Toxicity display. If multiple variables are used Toxicity/Severity and Highest Toxicity/Severity display. • Use the Adverse Event Summary button to access that sheet.

Sheet	Information included
Adverse Events Overlay Labs	Use this sheet to review lab-related AEs against the relevant lab test(s). From the Event filter, select both the AE and LB events desired. For example, select AE: Alanine aminotransferase increased and then select LB: Alanine Aminotransferase (hint – to find LB:Alanine Aminotransferase type LB in the Event filter search box). The Subject filter then only shows those who have the selected AE based on the Preferred Term. Select a single subject to see the data graphically. • Filters: Study, Site, Subject, Country, Event, Standard Toxicity Grade, Severity, and Event Date • Overlay Graph: Displays the lab values for the selected test(s) by collection day and Adverse Event start and end day. - Upper and lower limits are shown for each lab test with horizontal lines at the associated value, if available. - The start day and the end day of the Adverse Event are presented with right and left arrows connected by a line if the end day is specified and are color coded by the AE Toxicity Grade/Severity. • Listing Tables: AE Listing and Lab Listing
AE Incidence Table	Use this sheet to examine the incidence of Adverse Events by group assignment. Review can be for a study or group of studies, or across a program. Tabulations can be performed by any of the MedDRA classifications as selected. • Filters: Study, Program, Site, Subject, Country, Group Assignment (includes Screen Failure selection), Special Interest AE, and Treatment Emergent • Adverse Events Incidence Table: Displayed by System Organ Class, High-Level Group Term, High-level Term, Preferred Term, or Reported Term. - Values in red text identify the highest value and values in green text identify the lowest value in a row. - The Proportion (%) column is calculated by the number of subjects who reported an AE in that Group Assignment, divided by the total number of subjects in that Group Assignment. • Highlight proportions where the highest and lowest value in row differ by at least (n%): This field allows the user to select the value for the proportional differences they want highlighted between the highest and lowest values across Study Group Assignments. Enter a number into this field and then press Enter to apply the value.
Adverse Events Bubble	Use this sheet to check the duration of AEs along with the time of onset at a preferred term and SOC level. Obtain an idea of how the AEs start during the course of a clinical trial. • Filters: Study, Site, Subject Country, Group Assignment, Treatment Emergent, Special Interest AE, System Organ Class, Preferred Term, and SAE • Count of AEs by Time to Onset and System Organ Class or Preferred Term - View by Study Day, Study Week, or Study Month

Sheet	Information included
Adverse Events Duration	Use this sheet to identify the abnormal durations with respect to adverse events. • Filters: Study, Site, Subject Country, Sex, Race, Ethnicity, Severity/Toxicity, Seriousness, System Organ Class, High Level Group Term, High Level Term, and Preferred Term • AE Duration Chart: A box and whisker chart plotted on the AE durations with ability to toggle between coding hierarchy levels of System Organ Class, High-Level Group Term, High-Level Term, or Preferred Term. • AE Duration Distribution Chart: A histogram plotted on the AE durations at a specific PT level wherein a user selects a specific PT from the filter and the corresponding data displays in the chart. • Adverse Events Listing: A listing with all the adverse events listed along with the coding terms. This provides insights on the start and end of adverse events along with the duration of adverse events.
MedDRA Comparison Analysis	Use this sheet to review Adverse Event information by the levels of MedDRA classification. Review can be for a study or group of studies or across a program. Tabulations are presented by group assignment. Right clicking on the table and following the Expand / Collapse option allows the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Program, Site, Subject, Country, Group Assignment (includes Screen Failure selection)), Special Interest AE, and AE Treatment Emergent • MedDRA Comparison Analysis Table: Displays the AEs by the MedDRA terms (System Organ Class, High Level Group Term, High Level Term, Preferred Term or Reported Term). - Values in red text identify the highest value and values in green text identify the lowest value in a row. - The Proportion (%) column is calculated by the number of subjects who reported an AE in that Group Assignment divided by the total number of subjects in that Group Assignment. • Highlight Proportions: This field allows the user to select the value for the proportional differences they want highlighted between the highest and lowest values across Group Assignments. Enter a number into this field and then press Enter to apply the value.

Sheet	Information included
SMQ Comparison Analysis	Use this sheet to review Adverse Event information by Standard MedDRA Queries (SMQ). Review can be for a study or group of studies or across a program. Tabulations are presented by group assignment. Right clicking on the table and following the Expand / Collapse option allows the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Program, Group Assignment (includes Screen Failure selection), Special Interest AE, and AE Start Date • Standardized MedDRA Queries Table: Displays AEs by SMQ Term, Preferred Term, Broad SMQ, or Narrow SMQ - Values in red text identify the highest value and values in green text identify the lowest value in a row. - The Proportion (%) column is calculated by the number of subjects who reported an AE in that Group Assignment divided by the total number of subjects in that Group Assignment. • Highlight proportions where the highest and lowest values in row differ by at least (n%): This field allows the user to select the value for the proportional differences they want highlighted between the highest and lowest values across Group Assignments. Enter a number into this field and then press Enter to apply the value.
Treatment Emergent AE Analysis	Use this sheet to review the incidence of Adverse Events that started on or after the first dose of study medication. Tabulations present the numbers of events and subjects by various demographic parameters. • Filters: Study, Country, Site, AE Start Date, Program, Group Assignment (includes Screen Failure selection), TEAE, Ethnicity, Race, Sex, and Age Group Boundaries • Demographic Output Table: Treatment Emergent AE counts and percentages. - Values in red text identify the highest value and values in green text identify the lowest value in a row. - The Proportion (%) column is calculated by the number of subjects who reported an AE in that Group Assignment divided by the total number of subjects in that Treatment Group. • Highlight proportions where the highest and lowest values in row differ by at least (n%): This field allows the user to select the value for the proportional differences they want highlighted between the highest and lowest values across Study Group Assignments. Enter a number into this field and then press Enter to apply the value. • Age Group Boundaries: Allows the user to select up to two ages to define a specific age or age range. - When the user selects one age, two groups display: totals for anything less than that age and totals for anything greater than or equal to that age display. - When the user selects two ages, three groups display: totals for anything less than that age, totals for anything greater than or equal to that age and less than the second age selected, and anything greater than or equal to the second age.

Sheet	Information included
Death Summary	Use this sheet to view the primary cause of death and the relationship of death to Adverse Events for the identification of potential safety signals. • Filters: Study, Site, Subject, Country, Date of Death, and Group Assignment (includes Screen Failure selection) • Bar Chart: Number of subjects for each Cause of Death • Line Chart: Number of Deaths per Month/Week/Day and Cumulative Number of Deaths over time • Listing Tables: Death and Adverse Events
Medical History Summary	Use this sheet to review Medical History for all subjects and to examine Medical History events in light of study protocol Inclusion / Exclusion criteria. • Filters: Study, Site, Subject, Country, and Group Assignment (includes Screen Failure selection) • TreeView Chart: Tiles represent each System Organ Class; the size of the box is proportional to the number of Medical History Subject or Event counts in that category. • Stacked Bar Chart: MH Subject or Event Counts by System Organ Class or Preferred Term y. Sections of the bar are colored by Category. • Listing Table
Medical History Cross Tabulation	Use this sheet to examine Medical History for all subjects by System Organ Class and the Preferred Terms. Users can also use this sheet to review either subject counts or event counts. Select a single bar for a System Organ Class in the chart and the chart changes to display Preferred Terms within the selected System Organ Class. The table on the right provides a cross tabulation of events. If a system organ class is selected from the bar chart, the table automatically updates. Right clicking on the table and following the Expand / Collapse option allows the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Site, Subject, Country, and Group Assignment (includes Screen Failure selection) • Bar Chart: Top 10 System Organ Class / Preferred Terms by Subject or Event counts and percentage • Cross Tabulation: Subject or Event counts by System Organ Class (+ for Preferred Terms) in rows, and choice of Category, MH Duration, Race, Sex, Ethnicity, SubCategory, Occurrence, or Completion Status in columns

Sheet	Information included
Prior and Concomitant Treatment Summary	Use this sheet to review non-study treatments in relation to Inclusion / Exclusion criteria, use of prohibited medications, and per-protocol use of required non-study treatments. Can also be used to evaluate whether certain medications are recorded on the proper CRF page per instructions based on treatment type, indication for use or date. • Filters: Study, Site, Subject, Country, CM Start Date, and Prohibited Medication • TreeView Chart: Tiles represent each medication class; the size of the box is proportional to the number of subjects or the number of times a medication was taken (Subject Counts vs Medication Counts). • Stacked Bar Chart: Displays non-study treatments colored by Occurrence, Route, CM Duration, Race, Sex, or Ethnicity by Subject Count or Medication Count, and sorted in the order of magnitude from highest to lowest - The user may click on bars/boxes to display a list of the subjects that have received the selected treatments. - The user can switch between the Standardized Medication Name or the ATC 2 text. • Listing Table: Contains calculated fields indicating whether a treatment was given prior to the start of study treatment, during study treatment and / or after study treatment based on the start and stop dates. Filtering with these fields can be helpful to ensure medications on a concomitant treatment page were truly concomitant to study treatment.
Con-Med Cross Tabulation	Use this sheet to examine Prior and Concomitant treatments for all subjects by Medication Class and the Standardized Medication Name. Users can also use this sheet to review either subject counts or medication counts. Select a single bar for a Medication Class in the chart, and the chart will change to display by Standardized Medication name within the selected Class. The table on the right will provide a cross tabulation of medications. If a medication class is selected from the bar chart, the table will automatically update. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Subject, CM Start Date, and Group Assignment (includes Screen Failure selection) • Bar Chart: Top 10 Medication Class / Standardized Medication by Subject or Medication count and percentage • Cross Tabulation: Subject or Medication counts by Medication Class (+ for Standardized Medication Names) in rows, and choice of Occurrence, Route, CM Duration, Race, Sex, or Ethnicity in columns

Sheet	Information included
Con-Med Group	Use this sheet to identify and review subjects who received specific combinations of non-study treatments. • Filters: Study, Subject, Standardized Medication Name, CM Start Date, and Group Assignment (includes Screen Failure selection) • Listing Table: Subjects on Multiple Selected Medications. - The Standardized Medication Name filter allows the user to view subjects who took the specified medications - works as an *AND* statement rather than an *OR* statement. - The filtered list only shows subjects who took all the medications selected. Note: The user must select from the Standardized Medication Name filter or column for this to work. If they select from another column, the results display as an *OR* statement.
Labs Summary	Use this sheet to examine summary lab test results for each Lab Test collected. The default table displays the average test result score across all subjects who had that test. The user can also select to view the minimum, maximum and median values. The cells are color coded based on the upper and lower limits of normal for easy identification of abnormalities requiring further investigation. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Subject, Category for Lab Test, Test, Study Period, nxULN Range, and Group Assignment • Cross Tabulation: Lab Numerical Results by Visit Name (click the + to see individual Subjects) in rows, and choice of Visit Name, Vendor Name, Group Assignment, Site, Sex, or Toxicity in columns. - Average is the default result value, or view by minimum, maximum, or median value. - Colors represent a normalized view; anything in green is within the normal range, shades of red represent above the normal range and shades of blue represent below the normal range. - Use the nxULN Range filter to limit the normalized results.

Sheet	Information included
Lab Result Trends	Use this sheet to review lab data by test through various combinations of comparison to identify potential safety signals. Inclusion / Exclusion violations can be identified through this sheet by evaluation of baseline values. By toggling the X and Y axis options of the scatter plot, the user can review baseline versus maximum post-baseline or minimum post baseline versus maximum post baseline, for example. Outlier points are easily selected for further review. • Filters: Study, Subject, Category for Lab Test, Test, nxULN Range, Vendor Name, Study Period, and Group Assignment (includes Screen Failure selection) • Bar Chart: Lab Result Counts – view count of lab tests by range. • Scatter Plot: Lab Results – view one test at a time. Ability to choose axes to view by Baseline, Average Post Baseline, Min Post Baseline, or Max Post Baseline. • Histogram: Lab Results Distribution – view one test at a time. Displays the distribution of the results, easily identifying trends for selected tests. • Listing Table. Any value in the Results in Standard Units column that falls below the Lower Limit – Std Units displays in yellow and any value that falls above the Upper Limit – Std Units displays in red.
Lab Result Review Over Time	Use this sheet to review up to four lab tests at one time. Review for potential safety signals, Inclusion / Exclusion violations, or situations where study therapy should be modified. The line chart will show one of the selected tests and plot each subject's results over time connected by a line. Lower and upper limits are displayed. By toggling the Y axis of each chart, the user can switch from Results to Change from Baseline or Change from Previous Visit. Use the selection in the upper right-hand corner to change the x axis from visit name to visit number, study week, study day or other visit identifiers. • Filters: Study, Site, Subject, Country, Lab Category, Test, nxULN, Vendor Name, Study Period, and Toxicity • Line Charts (4): Choose up to 4 Lab Tests to view associated Lab Results over time. - X-axes are viewable by Visit Name, Study Week, Study Day, Date of Collection, Study Month, Visit Number, or Subject. - Y-axes are viewable by Results, % Change from Baseline, or % Change from Previous Visit, Change from Baseline, and Change from Previous Visit. • Listing Table: Any value in the Results in Standard Units column that falls below the Lower Limit – Std Units displays in yellow and any value that falls above the Upper Limit – Std Units displays in red. Baseline columns have been added and include Baseline Flag (Y/N), Baseline Result (actual result), Is Post Baseline (Y/null). A flag for Clinically Significant has been added.

Sheet	Information included
Lab - Descriptive Stats	Use this sheet to view the distribution of each lab test result by various parameters. The box and whisker chart beneath the summary tabulations can be used to identify potential trends or outliers in a test requiring further investigation. Drill down in the table for individual subject results beneath each test. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Site, Subject, Country, Category for Lab Test, Test, Group Assignment, and Study Period • Cross Tabulation: Descriptive Stats – Lab Results by Visit Name (# Results, Mean, SD, Coefficient of Variation, Min, Q1, Median, Q3, Max) for Lab Results by Test (click the + to see all Subjects) in rows, and choice of Visit Name, Vendor Name, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment in columns. • Box and Whisker Chart: Displays Lab Results for the selected test summarized by Visit Name on the X-axis and Lab Results on the Y-axis. This only displays when just one test is selected.
eDISH Plot	Use this sheet to identify subjects of interest who show evidence of potential drug induced liver injury based on liver function tests using established criteria such as Hy's Law. The window between the peak AST or ALT and Bilirubin can be widened or narrowed using a filter (No Window, 30 Days or Less, Same Day). Users can quickly see outliers based on limit lines and can hover to view specific subject values. Subjects of interest can also be selected from the main chart, which will then subset the individual lab result charts on the right side of the report. • Filters: Study, Site, Subject, Country, nxULN, Vendor Name, and Study Period • Scatter Plot: Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH). Select to review alanine aminotransferase (ALT) or aspartate aminotransferase (AST) against bilirubin (BILI). Data points represent subjects and are color-coded by group assignment: - Refine criteria by changing the default All Subjects to alkaline phosphatase (ALP) < 2xULN, in alignment with the Hy's Law criteria. • Line Charts (4): ALP, BILI, ALT, and AST over Study Day or Study Week of collection. • Listing Table
Liver Lab Test Analysis	Use this sheet to support review of liver function test abnormalities and in the detection of possible Hy's Law subjects. • Filters: Study, Subject, Category for Lab Test, Group Assignment (includes Screen Failure selection), Vendor Name, and Study Period • Cross Tabulation: Displays data from the liver-related labs in a tabular format, broken out by group assignment. Note: Counts are cumulative, so numbers included in 10x ULN are also included in 5x ULN.

Sheet	Information included
Comparative Lab Results	Use this sheet to investigate the relationship between two lab tests through a scatter plot of one test against the other. • Filters: Study, Subject, Category for Lab Test, Test, nxULN Range, Vendor Name, Study Period, and Group Assignment (includes Screen Failure selection) • Scatter Plot: Select two Lab Tests to view Lab Results against one another. Results can be viewed by selecting Average, Minimum, Maximum, or Median. • Listing Table: Any value in the Results in Standard Units column that falls below the Lower Limit – Std Units displays in yellow and any value that falls above the Upper Limit – Std Units displays in red.
Labs Summary – Distribution Plot	Use this sheet to explore differences in test results by group assignment which could identify a safety issue. The distance between the dots indicates the magnitude of difference in the test results between the group assignments based on the selected parameter (average, minimum, maximum, or median). • Filters: Study, Subject, Category for Lab Test, Test, nxULN Range, Group Assignment (includes Screen Failure selection), Visit Name, Vendor Name, and Study Period • View the full lab test or examination name or the short name by using the toggles: Lab Test or Examination Name or Lab Test or Examination Short Name. • Distribution Plot: Lab Numerical Test Results by Group Assignment – provides the average (minimum, maximum, or median) value for the tests by group assignment. Tooltip information provides group assignment information for that test. The colors provide a normalized view to easily identify results that fell within the normal range, above the normal range, or below the normal range.
Lab Vendor Details	Use this sheet to track lab results by vendor to aid in follow up when there are subjects with missing lab test results. The report displays an accounting of results received for each study visit by sample type. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Site, Subject, Country, Category for Lab Test, Vendor Name, and Study Period • Select whether to display the tabulations by Visit Name, Visit Number, Study Day, Study Week or Study Month. • View the full lab test or examination name or the short name by using the toggles: Lab Test or Examination Name or Lab Test or Examination Short Name. • Cross Tabulation: Lab Vendor Details (# and % of Results) by Lab Test or Examination Name (+ for Subjects) in rows, and choice of Visit Name, Visit Number, Study Day, Study Week, or Study Month in columns. - The table can be limited to a specific Visit Number or Sample Type. - The table can be exported by right clicking and following the appropriate selections to export.

Sheet	Information included
ECG Results Over Time	Use this sheet to examine changes in ECG over time to detect proarrhythmic effects. Users can review standard results, change, and percent change from either baseline or the previous visit. Enter low and high limit values for each test to identify subjects of interest. • Filters: Study, Site, Subject, Country, Test, Group Assignment, (includes Screen Failure selection), Date of ECG, and Abnormal Results (Y/N) • Low Limit and High Limit Values: Enter a number into these fields and then press Enter to apply Reference Lines to the chart. • Line Chart: Choose a single Test to review ECG Results Over Time. The X-axis is viewable by Visit Name, Study Week, Study Day, Study Month, Date of Collection, Visit Number, or Subject Identifier, and the Y-axis is viewable by Results, % Change from Previous Visit, Change from Previous Visit, % Change from Baseline, and Change from Baseline. • Listing Table Uses logic to check for a reference range look up table at the study level if available, otherwise, it may be configured to use a URL specific range look up. Uses Excel spreadsheet “Study_RefRange_LKP.xlsx.”
ECG – Descriptive Stats	Use this sheet to view the distribution of ECG results for each test by various parameters. The box and whisker chart beneath the summary tabulations can be used to identify potential trends or outliers in a test requiring further investigation. Drill down in the table for individual subject results beneath each test. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Site, Subject, Country, Test, and Date of ECG • Cross Tabulation: Descriptive Stats (# Results, Mean, SD, Coefficient of Variation, Min, Q1, Median, Q3, Max) for ECG Results by Tests (+ for Subjects) in rows, and choice of Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment in columns. • Box and Whisker Chart: Select one test to view ECG Results over choice of Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Gender, Ethnicity, Race, Site, or Group Assignment.

Sheet	Information included
Vital Signs Result Trends	Use this chart to review Vital Signs data by test through various combinations of comparison to identify outliers for potential safety signals. Identify inclusion/exclusion violations based on average, minimum, and maximum baseline values. By toggling the X and Y axis options of the scatter plot the user can review baseline versus maximum post-baseline or minimum post baseline versus maximum post baseline, for example. Outlier points are easily selected for further review. • Filters: Study, Subject, Test, Date of Measurements, and Group Assignment (includes Screen Failure selection) • Scatter Plot: Select one Test to view Vital Signs Results (Baseline vs Average Post Baseline). Alternate views for the Y- and X-axis include Max Post Baseline and Min Post Baseline. • Histogram: Displays the distribution of the Vital Signs Results, easily identifying trends for the selected tests. • Listing Table Uses logic to check for a reference range look up table at the study level if available, otherwise, it may be configured to use a URL specific range look up. Uses Excel spreadsheet “Study_RefRange_LKP.xlsx.”
Vital Signs Results Over Time	Use this sheet to review Vital Signs results over time. Review for potential safety signals and Inclusion/Exclusion violations as applicable. The line chart will show one of the selected tests and plot each subject’s results over time connected by a line. By toggling the X axis, the user can change the presentation based on various visit identifiers such as from visit name to study day. By toggling the Y axis of each chart, the user can switch from raw results to change from baseline or change from previous visit. • Filters: Study, Site, Subject, Country, Test, Reference Range Indicators, Group Assignment (includes Screen Failure selection),and Date of Measurements • Low and High Limit Value input boxes: Enter low and high limit values. • Line Chart: Select one Test to view Vital Signs Results Over Time. The X-axis is viewable by Visit Name, Study Week, Study Day, Study Month, Date of Measurements, Visit Number, or Subject, and the Y-axis is viewable by Results, % Change from Previous Visit, or % Change from Baseline. • Line Chart: Systolic vs Diastolic Vital Signs Results Over Time provides average results by Visit Name, Date of Measurements, Study Month, Study Day, Visit Number, or Study Week. • Listing Table Uses logic to check for a reference range look up table at the study level if available, otherwise, it may be configured to use a URL specific range look up. Uses Excel spreadsheet “Study_RefRange_LKP.xlsx.”

Sheet	Information included
Vital Signs – Descriptive Stats	Use this sheet to view the distribution of Vital Signs data for each test by various parameters. The box and whisker chart beneath the summary tabulations can be used to identify potential trends or outliers in a test requiring further investigation. Drill down in the table for individual subject results beneath each test. Right clicking on the table and following the Expand / Collapse option will allow the user to expand the table to see the full cross tabulation, and to collapse it again when done. • Filters: Study, Site, Subject, Country, Test, and Date of Measurements • Cross Tabulation: Descriptive Stats (# Results, Mean, SD, Coefficient of Variation, Min, Q1, Median, Q3, Max) for Vital Signs Results by Tests (+ for Subjects) in rows, and choice of Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment in columns. • Box and Whisker Chart: Select one test to view Vital Signs Results over choice of Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment.
ECOG Performance Status	Use this sheet to view data that indicates the ability of subjects to tolerate serious illness, specifically for chemotherapy. The Eastern Cooperative Oncology Group (ECOG) performance assesses how a disease affects the daily living abilities of the subject. It describes the subject's level of functioning in terms of their ability to care for themselves, their daily activity, and their physical ability. Reviewers can track subjects' level of functioning across measured timepoints and can drill down to see how well sites collected the status over time. This report can also be used to examine inclusion criteria related to ECOG performance. • Filters: Study, Site, Subject, Country, Date of Finding, and Group Assignment (includes Screen Failure selection) • Stacked Bar Chart: Number of subjects, by choice of Visit Name, Study Day of Assessment, or ECOG Performance Score in the X axis or colored sections. • Line Chart: ECOG Performance Score Over Time, by choice of Visit Name, Study Day of Assessment, or subject in the X axis or by color. • Listing Table: Includes the date and time of last study drug treatment, the date and time of a study assessment, the visit name and number, a baseline ECOG Performance Score, and the Numeric Score in standard units over time.

Sheet	Information included
Physical Exam Results	Use this sheet to review the results of Physical Exams. Users can identify subjects with abnormal findings for patterns in the subject population. If necessary, the user can compare those findings against Medical History and Adverse Events. • Filters: Study, Subject, Date of Examination, and Group Assignment (includes Screen Failure selection) • Pie Chart: Displays the completion status of completely done, partially done, and completely not done. • Bar Chart: PE System over Visits: Displays the count of PE system examinations by visit name. • Bar Chart: PE Result Category by Body System: Displays the count of result categories by body system. • Listing Table
Inclusion / Exclusion Criteria Not Met	Use this sheet to review inclusion and exclusion criterion to identify specific inclusion or exclusion criteria that may be preventing enrollment. Use to identify a criterion that may be affecting screen failure rates in one study more than others. • Filters: Study, Site, Subject, Country, Date of Collection, and Group Assignment (includes Screen Failure selection) • TreeView Chart: Count of Distinct Subjects by Inclusion or/ Exclusion Criterion Short Name; the size of the box is proportional to the count. • Listing Table
AE / Prior and Concomitant Treatment Association	Use this sheet to compare Adverse Events that were treated against treatments used for Adverse Events. This may be useful to ensure that treatment correlates clinically with the Adverse Event. Users can then verify that the date of treatment initiation agrees with the Adverse Event information. If a study utilizes the concept of an Adverse Event identifier allowing the linkage of Adverse Events treated with the specific treatments, this report can easily show concordant and discordant records through the AE/Treatment filter. For studies that use an adverse identifier to link data from other domains to specific Adverse Events, there may be a need to map the identifier to allow direct comparison. For studies that do not use the concept of an Adverse Event identifier, the user can still identify subjects with treated Adverse Events and the treatments used through filters in both the Adverse Event and Prior and Concomitant Treatment listings. • Filters: Study, Site, Subject, Country, Special Interest AE, AE/Treatment (AE Missing, Treatment Present; AE Present, Treatment Missing; AE Present, Treatment Present), AE Start Date, and CM Start Date • Listing Tables: AE Listing, Prior and Concomitant Treatment Listing with listing counts based on selections.

Sheet	Information included
LB and VS Listings	Use this sheet to review lab data and vital signs together. Use a listing to filter for a particular parameter, and the other listing will filter in the same way. • Filters: Study, Subject, Vendor Name, Study Period, Date of Measurements, and Group Assignment (includes Screen Failure selection) • Listing Tables: Lab Listing, VS Listing with listing counts based on selections, a flag for Clinically Significant has been added. - For VS listing: Uses logic to check for a reference range look up table at the study level if available, otherwise, it may be configured to use a URL specific range look up. Uses Excel spreadsheet "Study_RefRange_LKP.xlsx."
Med Hist, AE and Prior and Concom Treatment	Use this sheet to ensure that the Medical History, Prior and Concomitant Treatments, and Adverse Events are consistent with logical date relationships. Review the indication for a given treatment and verify that it corresponds to data entered on either the Medical History (ongoing) or Adverse Events Listing. Filtering on one listing will filter the others based on subject. It can also be used to review AE and MH together to ensure events are correctly recorded. Users may verify that the treatment start date is on or after the start date of the corresponding Medical History or Adverse Event, and that the duration of dosing is logical for the type of medication / indication. • Filters: Study, Site, Subject, Country, AE Start Date, MH Start Date, CM Start Date, and Group Assignment (includes Screen Failure selection) • Listing Tables: Medical History Listing, Prior and Concomitant Treatment Listing, and Adverse Event Listing. - Once a filter is applied to a field within one listing, the other two listings will be filtered to the relevant subjects.
Disposition Summary	Use this sheet to review Disposition/Status Events and the period in which they occurred for all subjects. Users can examine all or only the latest events. • Filters: Study, Site, Subject, Country, Category for Disposition Event, Show only the latest Subject status, DS Start Date, and Group Assignment (includes Screen Failure selection) • Bar Chart: Subject Counts by Standardized Disposition Term. • Cross Tabulation: Number and % of Subjects for each Standardized Disposition Term (+ for Reported Term for the Disposition Event). • Listing Table
Exposure Data	Use this sheet to review Exposure data. Explore dosing trends over time for each subject along with dose adjustment reasons. • Filters: Study, Subject, and EX Start Date • Line Chart: Select one subject to view Dosing Trend Over Time, viewable by Study Day of Start of Treatment, Start Date of Treatment or Name of Treatment, using the X-axis and colors. • Bubble Chart: Exposure Metrics by Group Assignment, sized by choice of Number of Doses or Total Dose Amount. • Bar Chart: Dose Adjustment Reasons by Event Counts. Number of events by reason for dose adjustment • Listing Table

Sheet	Information included
Exposure Summary	Use this sheet to view dosing profiles and monitor how long subjects are staying on treatment, see if subjects on a combination treatment are dropping one earlier than the other, and understand the impact of dosing on the subject participation in the study. • Filters: Study, Site, Country, Completed Treatment, Name of Treatment, and EX Start Date • Bar Graph: Number of Subjects for each Treatment Name (colors) by the Number of Days on Treatment. - The bars and legend are interactive. When only one treatment is selected, the footer will display the median number of days on treatment followed by the average days on treatment. - Duration of dosing for a treatment is calculated as the latest stop date of dosing minus the earliest start date of dosing for each subject. The distribution of those calculations is what is displayed in the chart. • Listing Table
Exposure and Adverse Events	Use this sheet to identify safety signals and correlated changes to dosing based on adverse events in Adverse Events and dosing data. For studies that use an adverse event identifier (AEID) to link data from other domains to specific Adverse Events, there may be a need to map the identifier to allow direct comparison. The report does not require an AEID to work. • Filters: Study, Site, Subject, Country, Name of Treatment, Reason for Dose Adjustment, Preferred Term, Action Taken, System Organ Class, High-Level Group Term, and High-Level Term • Visualization: Subjects by Preferred Term and Dosing Adjustment. Select a single Subject or Reason for Dose Adjustment. The chart demonstrates the study day start and end of Adverse Events (Preferred Term) relative to the study day start and end of dosing. Ongoing events, dose changes, and dose frequency are also identified for insights into relationships. The footer displays 'Number of Subjects (n).' • Scroll to see AE vs EX Trend Area Chart: Provides insights when the AEs are reported against IP administration dates, and to understand the co-relation of each other. • Listing Tables: Exposure Listing and Adverse Events Listing
Graphical Patient Profile	Use this sheet to review select subject data across time in a graphical form. The chart will allow users to review Adverse Events, Exposure, Laboratory Data, and Concomitant Medications by date with symbols color coded to identify outliers. • Filters: Study, Country, Site, Subject, Event (Preferred Term), Adverse Events, Lab Indicator, and Event Date • Visualization: Select a single subject to view Adverse Events, Concomitant Medications, Exposure, and Laboratory Test Results, by choice of Study Day, Study Week, Study Month, or Event Date. - While selection of Adverse Events is by Preferred Term, display on the patient profile is by reported term. • For an optimal view, limit results to AEs or Labs of interest. • Listing Table

Sheet	Information included
Subject Status	Use this sheet to review a subject's current progress in a study. A link to the graphical patient profile for each subject in Data Central is provided for users with the privilege to access Data Central. • Filters: Study, Country, Site, Subject, Group Assignment (includes Screen Failure selection), and EX Start Date • Listing Table
Survival Summary	Use this sheet to examine the duration of subjects' participation in the treatment and follow-up phases as well as their overall duration in the study. Survival in days is presented in a bar chart with options to view Study Free Survival, Overall Survival or Progression Free Survival. • Filters: Study, Subject, and Date of Collection • Subject Duration by Months or Days (X-axis displays the months or days; Y-axis displays by subject), broken out by Treatment Duration, Follow-up Duration and Overall Duration. • Survival Days by Group Assignment (X-axis displays the number of subjects; Y-axis displays the survival selection by Progression Free Survival, Overall Survival, or Study Free Survival) broken out by Group Assignment. Note that the Group Assignment drop-down on the Y-axis should not be used, as its only purpose is to indicate how the bars are colored. • Listing Table
Tumor Identification	Use this sheet to examine the prevalence of tumors present among subjects in a study or studies. A TreeView chart provides the user with a quick summary of the most prevalent and least prevalent location of tumors and tumor types (Target, Non-target and New). • Filters: Study, Site, Subject, Country, Gender, Date of Tumor Identification, and Group Assignment • TreeView Chart: Lesion Count for Location by Lesion Type. • Bar Chart: Lesion Count for Location by Lesion Type (X-axis displays the lesion location and lesion type; Y-axis displays the number of lesions. • Bar Chart: Provides how new lesions are being observed across the study duration, providing insight into the efficacy of the drug. Use the toggles to view by New Lesion Counts or Subject Counts. • Pie Chart: Tumor Identification Test Type: Provides the proportion of various diagnostic modalities that were used to evaluate tumors in a study that provides insights on the most feasible technique. • Listing Table

Sheet	Information included
Tumor Results	Use this sheet to explore tumor measurement results over time. The Sum of Lesions and the Change from Baseline in the Sum of Lesions is presented. The user can also select to review the % Change from Baseline by toggling the Y-axis on the right-side plot. Use the plot to drill down into the data for subjects of interest. • Filters: Study, Subject, Tumor Assessment Short Name, and Date of Tumor Measurement • Line Chart: Sum of Lesions Over Time (mm); Lines colored by Subject Identifier (X-axis displays by Visit Name or Study Day of Tumor Measurements*; Y-axis displays the Sum of Target Lesions) • Line Chart: Change from Baseline – Sum of Lesions; Lines are colored by Subject Identifier (X-axis displays by Visit Name, Days from Baseline or Study Day of Tumor Measurement*; Y-axis displays Change from Baseline – Sum of Lesions or % Change from Baseline – Sum of Lesions) * Note that the Subject drop-down should not be used to adjust the charts. • Listing Table: Tumor Assessments
Tumor Results - RANO	Use this sheet to explore tumor measurement results over time. The sum of the products of lesion diameters and the change from baseline in the sum of the products of lesion diameters is presented. • Filters: Study, Subject, Group Assignment, and Date of Tumor Measurement • Line Chart: Sum of the Products of Lesion Diameters Over Time; Lines colored by Subject Identifier (X-axis displays by Visit Name or Study Day of Tumor Measurements*; Y-axis displays the Sum of the Products of Lesion Diameters) • Line Chart: % Change from Baseline – Sum of the Products of Lesion Diameters; Lines are colored by Subject Identifier (X-axis displays by Visit Name, Days from Baseline or Study Day of Tumor Measurement*; Y-axis displays Change from Baseline – Sum of the Products of Lesion Diameters or Change from Baseline – Sum of the Products of Lesion Diameters) * Note that the Subject drop-down should not be used to adjust the charts. • Listing Table: Tumor Assessments
Tumor Response	Use this sheet to review counts of Best Overall Responses across the duration of study to provide better insights on the responses. Drill down to view individual subject response over time for subjects of interest. • Filters: Study, Subject, Visit Name, Response Assessment Name, Category for Response Assessment, and Date of Response Assessment • Donut Chart: Best Overall Response Counts by Response Type • RECIST Response Trend Over Study Day: Select one subject (X-axis displays the Study Day; Y-axis displays the response assessment for Non-target Response, Overall Response and Target Response as applicable) • Listing Table: All Tumor Responses

Sheet	Information included
Response Duration	Use this sheet to examine the timeline of response relative to participation in the study for each subject through Swimmer's Plots. • Filters: Study, Subject, Group Assignment, Response Assessment Name, Category for Response Assessment, and Date of Response Assessment • Swimmer's Plot: A graphical display of a patient's response over the duration of treatment for each patient. A line connecting a triangle or circle for a patient identifies that the visits were consecutive.
OMR-Overall Metabolic Response	Use this sheet to review by subject and visit the overall metabolic response that compares eCRF recorded responses with derived or calculated responses. • Filters: Study, Subject, Outlier, Visit Date • Visualization: Recorded Overall Response vs Calculated Overall Response • Listing Table
TRR-Target Radiological	Use this sheet to review by subject and visit the targeted radiological response that compares eCRF recorded responses with derived or calculated responses. • Filters: Study, Subject, Outlier, Visit Date • Visualization: Recorded Target Response vs Calculated Target Response • Listing Table
ORR-Overall Radiological	Use this sheet to review by subject and visit the overall radiological response that compares eCRF recorded responses with derived or calculated responses. • Filters: Study, Subject, Outlier, and Visit Date • Visualization: Recorded Overall Response vs Calculated Overall Response • Listing Table
Swimmer's Plot with Investigator Overall Response	Use this sheet to view investigator overall response over time for each subject in a trial. Subjects can be displayed with disease type or group assignment details. Filters allow for selection of specific disease types, best overall response, or group assignment. Selection of one study and one response type is required. • Filters: Study, Country, Site, Subject, Disease Type, Best Overall Response, Most Recent Response, Group Assignment, and Response Type • Visualization: Swimmer's Plot: Toggle to view by Subject & Group Assignment, or Disease Type. View by All, On Treatment, or Off Treatment
Waterfall Plot	Use this sheet to view the best % change in tumor size from baseline. Entering low and high limit values will add indicator lines on the chart. Filters allow for selection of specific disease types, best overall response, or group assignment. • Filters: Study, Country, Site, Subject, Group Assignment, Disease Type, and Best Overall Response • Visualization: Waterfall Plot: Use the drop-down to view by type of response, RECIST, RANOTR, or LUGANO.

Sheet	Information included
Tumor Measurement Spider Plot	Use this sheet to view tumor measurement % change from baseline by subject and group assignment, disease type, best overall response, gender, or race. Entering low and high limit values will add indicator lines on the chart. Filters allow for selection of specific disease types or group assignment. Selection of one study and one response type is required. • Filters: Study, Country, Site, Subject, Group Assignment, and Disease Type • Visualization: Spider Plot: Use the drop-down to view by type of response, RECIST, RANOTR, or LUGANO. Toggle to view by Group Assignment, Disease Type, Best Overall Response, Gender, or Race.
Objective Response Rate	Use this sheet to view the drug efficacy in clinical trial set up. This chart provides insights into the ORR of a study over the study duration. • Filters: Study, Country, Site, Sex, Race, Indication, and Age Group • Bar Chart: Objective Response Rate over Time: View the ORR at intervals of 3 months, 6 months, 1 year, 2 years, 3 years, and 5 years.
Application Information	• Listing of What's New • Data Last Refresh: A listing of studies and domain names and the date that each domain was last refreshed • Glossary of items included on the Home Page • List of Special Interest Adverse Events: These display if the client has provided them. • List of Prohibited Meds: These display if the client has provided them. • Link to SDTM Standards • Support Contact Information • Current Version Number and Dates