

Clinical Data Analytics 23.1

Sheet Descriptions Table

There are 54 standard public sheets in this version (including Oncology sheets).

Sheet	Information included
Home Page	This is the landing page for CDA, which displays high-level summary information across all studies, or the selected study(ies). Please see the CDA 23.1 Home Page Description document for more information.
Demographics	Use this sheet to view counts and percentages for screened subjects. - Filters: Study, Country, Site, and Subject - Subject Population Table: Screened, Enrolled, Treated, Death. Select a status(es) and the other visualizations update accordingly. - Subject Counts Charts: - By Group Assignment, Sex, Race, Ethnicity, or Age Range - By Site or Country - By Age and Sex or Cohort, Country, Site, Race or Ethnicity - Listing Table
Adverse Event Summary	Use this sheet to identify AEs that are prevalent in the subject population and 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, or evaluate all reported events for potential safety signals and trends. - Filters: Study, Site, Subject, Country, Group Assignment, Special Interest AE, and Treatment Emergent - View by Buttons: Subject Counts or Event Counts - Variable Buttons: System Organ Class, Preferred Term, Reported Term, Toxicity or Severity*, Highest Toxicity or Severity*, Seriousness, Action Taken, Outcome, Causality, AE Duration, 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. - TreeView Chart: AE Subject or Event Counts by System Organ Class, Preferred Term or Reported Term - Size of the box is proportional to the count - Stacked Bar Chart: AE Subject or Event Counts by System Organ Class, Preferred Term, or Reported Term and Toxicity*, Highest Toxicity*, Seriousness, Action Taken, Outcome, Causality, AE Duration, or Group Assignment - Dot Plot: Adverse event Dot Plot shows the percentage of AEs reported by Preferred Term, High Level Term, High Level Group Term, System Organ Class, or Reported Term - Listing Table

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 variable buttons. 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, available for each chart - View by buttons: Subject % or % Total Subj - Variable Buttons: System Organ Class, Preferred Term, Reported Term, Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, Group Assignment, 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 Charts: % of Subjects by or % of Subjects in defined by the selected variable buttons - Listing Table
Adverse Events Cross Tabulation	Use this sheet to examine AEs for all subjects by System Organ Class, High-Level Group Term, High-Level Term, Preferred Term, or Reported Term. - Filters: Study, Site, Subject, Country, Group Assignment, Treatment Emergent, Special Interest AE, AE Study Day, and Subject Status - Variable Buttons: Study, Site, Group Assignment, Country, Severity/Toxicity*, Highest Severity/Highest Toxicity*, Seriousness, Action Taken, Outcome, Causality, AE Duration * 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. % Threshold: Enter the value to highlight in yellow the lowest and highest difference in a row by the entered percentage. - Drop-down menu: Select from System Organ Class, High-Level Group Term, High-Level Term, Preferred Term, or Reported Term to adjust the AEs that display down the left column. - Cross Tabulation: Click the + to expand and view the selected variable. - Use the Adverse Event Summary button to access that sheet.
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 – type ‘alanine’ in the Event filter search box and see all related AEs and LBs). The Subject filter then only shows available subjects. 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 Day and AE End Day. - Upper and lower limits are displayed 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

Sheet	Information included
Adverse Events Bubble	Use this sheet to check the number of AEs along with the time to onset by System Organ Class or Preferred Term. Obtain an idea of when the AEs started during the course of a clinical trial. - Filters: Study, Site, Subject, Country, Group Assignment, Treatment Emergent, Special Interest AE, System Organ Class, and Preferred Term - Variable Buttons: System Organ Class or Preferred Term - SAE: Click to limit results to just SAEs - Drop-down menu: Define the x-axis by Study Day, Study Week, or Study Month
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 or Organ Class, High-Level Group Term, High-Level Term, and Preferred Term - Variable Buttons: System Organ Class, High-Level Group Term, High-Level Term, 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. - Bar Chart: AE Duration Distribution by PTs - Listing Table: Adverse Events Listing
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. - Filters: Study, Program, Site, Subject, Country, Group Assignment, Special Interest AE, and Treatment Emergent - Table: MedDRA Comparison Analysis 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.

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, Special Interest AE, and AE Start Date • Variable Buttons: Broad SMQ, Narrow SMQ • Table: Standardized MedDRA Queries - 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.
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, TEAE, Ethnicity, Race, Sex, and Age Group Boundaries • 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. • Table: Demographic Output shows 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.

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: Cause of Death - Line Chart: Number of Deaths (Deaths Per Month/Week/Day, Cumulative Deaths) - 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 respect to study protocol Inclusion / Exclusion criteria. - Filters: Study, Site, Subject, Country, and Group Assignment (includes Screen Failure selection) - View By Buttons: Subject Counts or Event Counts - TreeView Chart: MH Subject or Event Counts by System Organ Class - Size of the box is proportional to the count - Stacked Bar Chart: MH Subject or Event Counts by System Organ Class or Preferred Term and 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. - Filters: Study, Site, Subject, Country, and Group Assignment (includes Screen Failure selection) - Variable Buttons: Subject Counts, Event Counts - Variable Buttons: Category, MH Duration, Race, Sex, Ethnicity, SubCategory, Occurrence, Completion Status - Bar Chart: Top 10 System Organ Class/Preferred Terms by Subject or Event Counts - Table: Subject or Event Counts by System Organ Class and (click the + to expand the rows) Preferred Term, by selected Variable Button (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 Meds • Variable Buttons: Subject Counts, Medication Counts • Variable Buttons: Standardized Medication, ATC 2 Text, Occurrence, Route CM Duration, Race, Sex, Ethnicity • TreeView Chart: CM Subject or Medication Counts by Medication Class - Size of the box is proportional to the amount • Stacked Bar Chart: CM Subject or Medication Counts by Standardized Medication or ATC 2 Text and selected Variable Button (Occurrence, Route, CM Duration, Race, Sex, or Ethnicity), and sorted in the order of magnitude from highest to lowest. • Listing Table
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. 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) • Variable Buttons: Subject Counts, Medication Counts • Variable Buttons: Occurrence, Route, CM Duration, Race, Sex, Ethnicity • Bar Chart: Top 10 Medication Class/Standardized Medication by # of Subjects or Medications and % of Subjects or Medications • Table: Cross Tabulation of Subject or Medication Counts by Medication Class and (click the + to expand the rows) Standardized Medication Names, by selected Variable Button (Occurrence, Route, CM Duration, Race, Sex, or Ethnicity)
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 <i>AND</i> statement rather than an <i>OR</i> statement. - The filtered list only shows subjects who took all the medications selected. <u>Note:</u> 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 <i>OR</i> statement.

Sheet	Information included
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 the test results. The user can also select to view the minimum, maximum, and median values. • Filters: Study, Subject, Category for Lab Test, Test, Study Period, nxULN Range, and Group Assignment • Drop-down menu: Average, Minimum, Maximum, Median • Variable Buttons: Visit Name, Vendor Name, Group Assignment, Site, Sex, Toxicity • Table: Cross Tabulation: Lab Numerical Results by Visit Name, Vendor Name, Group Assignment, Site, Sex, or Toxicity (click the + to see individual Subjects) in rows and the selected Variable Button 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.
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. • Filters: Study, Subject, Category for Lab Test, Test, nxULN Range, Vendor Name, Study Period, and Group Assignment (includes Screen Failure selection) • Bar Chart: Lab Results Count, and Lab Results Distribution • Scatter Plot: Lab Results • Listing Table
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. • Filters: Study, Site, Subject, Country, Lab Category, Test, nxULN, Vendor Name, Study Period, and Toxicity • Drop-down menu: Visit Name, Visit Number, Study Day, Study Week, Study Month, Date of Collection, Visit & Timepoint • Line Charts (4): Lab Results Over Time. Choose up to 4 Lab Tests to view associated - X-axis are viewable by Visit Name, Visit Number, Study Day, Study Week, Study Month, Date of Collection, or Visit & Timepoint (selection from the drop-down menu), and Subject. - Y-axis are viewable by Results (default), Change from Baseline, % Change from Previous Visit, % Change from Baseline, or Change from Previous Visit. • Listing Table

Sheet	Information included
Lab - Descriptive Stats	Use this sheet to view the distribution of lab test 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. - Filters: Study, Site, Subject, Country, Category for Lab Test, Test, Group Assignment, and Study Period - Variable Buttons: Visit Name, Vendor Name, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, Group Assignment - Cross Tabulation: Descriptive Stats – Lab Results by selected Variable Button - Columns include # Results, Mean, Standard Deviation, Coefficient of Variation, Min, Q1, Median, Q3, Max for Lab Results by Test (click the + to see all Subjects) in rows. - Box and Whisker Chart: Lab Results by selected Variable Button - X-axis: Variable Button - Y-axis: Lab Results. - This only displays when only 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. - Filters: Study, Site, Subject, Country, nxULN, Vendor Name, and Study Period - Variable Buttons: Study Week, Study Day, ALT, AST - Drop-down menu: All ALP Results, ALP <2xULN, ALP >2x=ULN - Drop-down menu: No Window, Window 30 Days or Less, Window Same Day - Scatter Plot: Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH). 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 - 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. <u>Note:</u> Counts are cumulative, so numbers included in 10x ULN are also included in 5x ULN.
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) - Drop-down menu: Average, Maximum, Minimum, and Median - Scatter Plot: Select two Lab Tests to view Lab Results against one another. Select Vendor to display reference lines. - Listing Table

Sheet	Information included
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 • Variable Buttons: Lab Test or Examination Name, Lab Test or Examination Short Name • Drop-down menu: Average, Minimum, Maximum, and Median • Scatter 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. • Filters: Study, Site, Subject, Country, Category for Lab Test, Vendor Name, and Study Period • Drop-down menu: Visit Name, Visit Number, Study Day, Study Week, and Study Month • Variable Buttons: Lab Test or Examination Name, 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 from the drop-down menu options (Visit Name, Visit Number, Study Day, Study Week, or Study Month) in columns. - The table can be limited to a specific Visit Name or Sample Type.
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 Value thresholds: Enter a number into these fields and then press Enter to apply Reference Lines to the chart. • Line Chart: ECG Results Over Time - X-axis is viewable by Visit Name, Study Week, Study Day, Study Month, Date of Collection, Visit Number, Visit & Timepoint, and Subject - 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."

Sheet	Information included
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. • Filters: Study, Site, Subject, Country, Test, and Date of ECG • Variable Buttons: Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, and Group Assignment • Cross Tabulation: Descriptive Stats (# Results, Mean, SD, Coefficient of Variation, Min, Q1, Median, Q3, Max) for ECG Results by Tests and (click the + expand) Subjects, by selected Variable Button (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: ECG Results by selected Variable Button (Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment)
Vital Signs Result Trends	Use this sheet to review vital signs data by test to identify outliers for potential safety signals. Identify inclusion/exclusion violations based on average, minimum, and maximum baseline values. Review Vital Sign Test Results Distribution by frequency. • Filters: Study, Subject, Test, Date of Measurements, and Group Assignment (includes Screen Failure selection) • Scatter Plot: Vital Signs Results (by selected filter(s)) - X-axis: Baseline (Min Post Baseline, Max Post Baseline) - Y-axis: Average Post Baseline (Max Post Baseline, Min Post Baseline) • Histogram: Vital Signs Results Distribution (by selected filter) - X-axis: Result Value - Y-axis: Frequency • Listing Table
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. • Filters: Study, Site, Subject, Country, Test, Reference Range Indicators, Group Assignment (includes Screen Failure selection), and Date of Measurements • Enter Low Limit Value and High Limit Value thresholds to identify results that fell within the entered range values. • Line Chart: Vital Results Over Time (by selected filter) - X-axis: Visit Name, Study Week, Study Day, Study Month, Date of Measurements, Visit Number, or Visit & Timepoint AND Subject, Study Week, Study Day, Study Month, Date of Measurement, Visit Number, or Visit & Timepoint - Y-axis: Results, % Change from Previous Visit, or % Change from Baseline • Line Chart: Vital Signs Results Over Time (Systolic vs Diastolic) - X-axis: Visit Name, Date of Measurements, Study Month, Study Day, Visit Number, Study Week or Visit & Timepoint • Listing Table

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. • Filters: Study, Site, Subject, Country, Test, and Date of Measurements • Variable Button: Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment • Cross Tabulation: Descriptive Stats – Vital Signs Results by selected Variable Button values - Row Values: Results by Tests and (click the + to expand) Subjects - Column Values: # Results, Mean, Standard Deviation, Coefficient of Variation, Min, Q1, Median, Q3, Max - Choice of Variable Button in columns: Visit Name default selected. • Box and Whisker Chart: Vital Signs Results by selected Variable Button and only one Test selection
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. • Filters: Study, Site, Subject, Country, Date of Finding, and Group Assignment (includes Screen Failure selection) • Stacked Bar Chart: ECOG Performance Score - X-axis: Visit Name, Study Day of Assessment, Score - Y-axis: # of subjects • Line Chart: ECOG Performance Score Over Time - X-axis: Visit Name, Study Day of Assessment, Subject - Y-axis: Score • Listing Table
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: Physical Examinations Performed • Bar Chart: PE System over Visits - X-axis: PE System, Visit Name - Y-axis: Count of PE System Examination • Bar Chart: PE Result Category by Body System - X-axis: Body System, Result Category - Y-axis: Count of Result Category • Listing Table

Sheet	Information included
Inclusion / Exclusion Criteria Not Met	Use this sheet to review inclusion/exclusion criterion to identify specific inclusion/exclusion criteria that may be preventing enrollment. - Filters: Study, Site, Subject, Country, Date of Collection, and Group Assignment (includes Screen Failure selection) - TreeMap 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 examine adverse events (AEs) that were treated against treatments used for AEs. This may be useful to ensure that treatment correlates clinically with the AE. Users can then verify that the date of treatment initiation agrees with the AE information. - Filters: Study, Site, Subject, Country, Special Interest AE, AE/Treatment, AE Start Date, and CM Start Date - Listing Tables: AE Listing, Prior and Concomitant Treatment
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
Med Hist, AE and Prior and Concom Treatment	Use this sheet to ensure that the Medical History, Prior and Concomitant Treatments, and Adverse Events (AEs) are consistent with logical date relationships. Users can 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. - 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. - When a filter is applied to a field within one listing, the other two listings will automatically be filtered to the relevant subjects.
Disposition Summary	Use this sheet to review disposition/status events for all subjects and the period in which they occurred. Users can examine all events or only the latest. - 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 of Standardized Disposition Term - Cross Tabulation: Disposition Summary - Row: Standardized Disposition Term and (click + to expand) Reported Term for the Disposition Event - Column: Values - Listing Table

Sheet	Information included
Exposure Data	Use this sheet to review Exposure data. Explore the dosing trend over time for each subject along with any dose adjustment reasons. • Filters: Study, Subject, and EX Start Date • Line Chart: Dosing Trend Over Time per Subject - X-axis: Study Day of Start of Treatment, Start Date of Treatment, Name of Treatment - Y-axis: Total Dose • Bubble Chart: Exposure Metrics by Group Assignment - Size of bubble depends on measure (Total Dose) • Bar Chart: Dose Adjustment Reasons by Event Counts - X-axis: # of Events - Y-axis: Reason for Dose Adjustment • Listing Table
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 -X-axis: # Days on Treatment, Name of Treatment -Y-axis: # of Subjects -Legend: Name of Treatment. - The bars and legend are interactive. When 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 amount of time between the earliest start date of dosing and the latest stop date of dosing. The distribution of those calculations is displayed in the chart. • Listing Table
Exposure and Adverse Events	Use this sheet to identify safety signals in Adverse Events (AEs) and dosing data, as well as correlate changes to dosing based on AEs. • Filters: Study, Site, Subject, Country, Name of Treatment, Reason for Dose Adjustment, Preferred Term, Reported Term, Action Taken, System Organ Class, High-Level Group Term, and High-Level Term • Stacked Line Chart: Subject(s) by Preferred Term and Dosing Adjustment. - 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 displayed for insight into correlations. <u>Note:</u> The footer displays 'Number of Subjects (n).' • Listing Tables: Exposure Listing and Adverse Events Listing

Sheet	Information included
Graphical Patient Profile	Use this sheet to review select subject data across time in a graphical form. The chart will allow users to review AEs, 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 • Variable Buttons: Study Day, Study Week, Study Month, Event Date • Visualization: Select one subject from the Subject Filter to view Adverse Events, Concomitant Medications, Exposure, and Laboratory Test Results, by choice of Start Date, End Date, Normal, High/Abnormal, Low, Other, SAE and No Result. - While selection of Adverse Events is by Preferred Term, display on the patient profile is by reported term. • Listing Table
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. • 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 subject's 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 • Variable Buttons: Months, Days • Bar Chart: Subject Duration - X-axis: Treatment Duration, Follow-up Duration, and Overall Duration - Y-axis: Subject Number - Legend color-coded for Treatment Duration, Follow-up Duration, and Overall Duration • Bar Chart: Survival Days by Group Assignment - X-axis: # of subjects - Y-axis: Study Free Survival, Overall Survival, Progression Free Survival, Group Assignment. • Listing Table

Sheet	Information included
Tumor Identification	Use this sheet to examine the prevalence of tumors present among subjects in a study or studies. A tile chart provides the user with a quick summary of the most prevalent and least prevalent location of tumors and types (Target, Non-target, and New). • Filters: Study, Site, Subject, Country, Sex, Date of Tumor Identification, and Group Assignment • Variable Buttons: New Lesion Counts, Subject Counts • TreeMap Chart: Lesion Count for Location by Lesion Type - Size of the box is proportional to the count • Bar Chart: Lesion Count for Location by Lesion Type - X-axis: Lesion Location and Lesion Type - Y-axis: # of Lesions • Bar Chart: New Lesions by Study Days -X-axis: Study Days -Y-axis: Number of New Lesions • Chart: Use the variable buttons to view by New Lesion Counts or Subject Counts by Study Days. • Pie Chart: Tumor Identification Test Type • Listing Table
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. • 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: Visit Name, Subject, Study Day of Tumor Measurement* - Y-axis: Sum of Target Lesions • Line Chart: Change from Baseline – Sum of Lesions (Lines colored by Subject Identifier) - X-axis: Visit Name, Days from Baseline, Subject, Study Day of Tumor Measurement* - Y-axis: Change from Baseline –Sum of Lesions, % Change from Baseline – Sum of Lesions *Note that the Subject drop-down should not be used to adjust the charts. • Listing Table: Tumor Assessments

Sheet	Information included
Tumor Results - RANO	Use this sheet to explore tumor measurement results over time. The sum of the lesions and the change from baseline in the sum of lesions is presented. - Filters: Study, Subject, Group Assignment, and Date of Tumor Measurement - Line Chart: Sum of the Products of Lesion Diameters Over Time(mm) (Lines colored by Subject Identifier) - X-axis: Visit Name, Subject, Study Day of Tumor Measurement* - Y-axis: Sum of the Products of Lesion Diameters - Line Chart: % Change from Baseline – Sum of the Products of Lesion Diameters: (Lines colored by Subject Identifier) - X-axis: Visit Name, Days from Baseline, Subject, Days from Baseline, Study Day of Tumor Measurement* - Y-axis: % Change from Baseline–Sum of the Products of Lesion Diameters, 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 tumor response. A summary of response is provided. 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 - Line Chart: RECIST Response Trend Over Study Day - X-axis: Study Day - Y-axis: Response Assessment - Legend indicating Non-target Response, Target Response, and Overall Response by line color. - Listing Table: All Tumor Responses
Response Duration	Use this sheet to examine the timeline of response relative to participation in the study for each subject. - Filters: Study, Subject, Group Assignment, Response Assessment Name, Category for Response Assessment, and Date of Response Assessment - Swimmer's Plot: - X -axis: Study Month of Response Assessment - Y -axis: Subject - Legend indicating enrollment duration, complete response, partial response, durable responder, response start, response end, continued response.
Swimmer's Plot with Investigator Overall Response	Use this sheet to view subject's overall response over time for each subject in a clinical trial. Subjects can be displayed by group assignment or disease type. - Filters: Study, Country, Site, Subject, Disease Type, Best Overall Response, Most Recent Response, Group Assignment, and Response Type - Variable Buttons: Group Assignment, Disease Type, All, On Treatment, Off Treatment - Swimmer's Plot - X -axis: Treatment Duration in Months - Y -axis: Subject & Group Assignment

Sheet	Information included
Waterfall Plot	Use this sheet to view the best % change in tumor size from baseline by your choice of evaluation criteria. Entering low and high limit values will add indicator lines on the chart. - Filters: Study, Country, Site, Subject, Group, Assignment, Disease Type, and Best Overall Response - Drop-down menu: RECIST, RANOTR, or LUGANO - Entering Low Limit Value and High Limit Value thresholds will add indicator lines on the chart. - Waterfall Plot: Best % Change in Tumor Size from Baseline - X -axis: Subject, Disease Response - Y -axis: Change from Baseline (%)
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. This data is shown based on the selected evaluation criteria similar to the Waterfall Plot sheet. Entering low and high limit values will add indicator lines on the chart. - Filters: Study, Country, Site, Subject, Group Assignment, and Disease Type - Drop-down menu: RECIST, RANTOR, or LUGANO - Variable Buttons: Group Assignment, Disease Type, Best Overall Response, Sex, Race - Entering Low Limit Value and High Limit Value thresholds will add indicator lines on the chart. - Spider Plot: Tumor Measurement % Change from Baseline by Subject and Group Assignment - X-axis: Study Day of Tumor Measurement, Study Month of Tumor Measurement, Study Week of Tumor Measurement, Subject - Y-axis: Change from Baseline (%)
Objective Response Rate	Use this sheet to view the drug efficacy (looking at the objective response rate) over the study duration. - Filters: Study, Country, Site, Sex, Race, Indication, and Age Group - Bar Chart: Objective Response Rate over Time: - X-axis: Amount of Time - Y-axis: Objective Response Rate
Application Information	Use this sheet to view application information. - Name of Application: Clinical Data Analytics - Listings: What's New, Data Last Refresh, Glossary, Special Interest Adverse Events, Prohibited Meds - Link to SDTM Standards - Support Contact Information - Current Version Number and Dates