# Clinical Data Analytics (CDA) 24.2

## Sheet Descriptions Table

There are 53 standard public sheets in this version (including Oncology sheets).

| Sheet | Information included |
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| Home Page | This is the landing page for CDA, which displays high-level summary information across all studies, or the selected study(s). Please see the CDA 24.2 Home Page Description document for more information. |
| Demographics | Use this sheet to view counts and percentages for all subjects.<br>• Filters: Study, Country, Site, Group Assignment, and Subject<br>• Current Subject Population Table: Columns are Subject Status and # of Subjects. Totals are displayed in the top row. The following rows are In Screening, Screen Failed, Eligible, Consented, Randomized, Enrolled, On Treatment, Discontinued Treatment, Completed Treatment, Discontinued Study, Completed Study, and Death. Select a status(es) and the other visualizations update accordingly.<br>• Subject Counts Charts<br>- By Group Assignment, Sex, Race, Ethnicity, or Age Range<br>- By Site or Country<br>- By Sex, Cohort, Country, Site, Race, or Ethnicity<br>• Listing Table |
| Adverse Event Summary | Use this sheet to identify Adverse Events 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Treatment Emergent, and Special Interest AE<br>• View by Buttons: Subject Counts or Event Counts<br>• Variable Buttons: System Organ Class, High Level Group Term, High Level Term, Preferred Term, or Reported Term<br>• Variable Buttons: Toxicity or Severity*, Highest Toxicity or Severity*, Seriousness, Action Taken, Outcome, Causality, AE Duration, Group Assignment<br>* 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.<br>• Treemap Chart: AE Subject Counts or Event Counts by System Organ Class, High Level Group Term, High Level Term, Preferred Term, or Reported Term<br>- The size of the box is proportional to the count.<br>• Stacked Bar Chart: AE Subject Counts or Event Counts by System Organ Class, High Level Group Term, High Level Term, Preferred Term, or Reported Term and Toxicity*, Highest Toxicity*, Seriousness, Action Taken, Outcome, Causality, AE Duration, or Group Assignment<br>• Distribution Plot: AE Subject % by System Organ Class, High Level Group Term, High Level Term, Preferred Term, or Reported Term. Shows the percentage of enrolled subjects with AEs reported.<br>• Listing Table |

| Sheet | Information included |
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| 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), and Subject, available for each chart<br>• View by buttons: Subject % by Subcategory or Unique Subjects %<br>• Variable Buttons: System Organ Class, Preferred Term, Reported Term<br>• Variable Buttons: Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, Group Assignment, Trt Emergent<br>* 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.<br>• Stacked Bar Charts: default set to % of Subjects with Events by System Organ Class and Toxicity/Severity for Group 1. The chart changes when you make different variable selections, and the corresponding title changes as well.<br>• Listing Table |
| Adverse Events Cross Tabulation | Use this sheet to examine Adverse Events for all subjects by System Organ Class, High-Level Group Term, High-Level Term, Preferred Term, or Reported Term.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject Status, Subject, Treatment Emergent, Special Interest AE, and AE Study Day<br>• Variable Buttons: Study, Country, Site, Group Assignment<br>• Variable Buttons: Toxicity/Severity*, Highest Toxicity/Severity*, Seriousness, Action Taken, Outcome, Causality, AE Duration<br>* 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.<br>• % Threshold: Enter the value to highlight in yellow where the highest and lowest values in a row differ by at least the entered value percentage.<br>• 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.<br>• Cross Tabulation Listing Table: Click the + to expand and view the selected variable.<br>• Use the Adverse Event Summary button to navigate to that sheet. |

| Sheet | Information included |
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| Adverse Events Overlay Labs | Use this sheet to review Adverse Events against the relevant lab test(s) per subject. 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.<br>• Filters: Study, County, Site, Subject, Event, Standard Toxicity Grade, Severity, and Event Date<br>• Overlay Graph: Displays the lab values for the selected test(s) by Collection Day and Adverse Event (AE) Start Day and Adverse Event (AE) End Day<br>- Upper and lower limits are displayed for each lab test with horizontal lines at the associated value, if available.<br>- 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.<br>• Listing Tables: AE Listing and Lab Listing |
| Adverse Events Bubble | Use this sheet to track the number of Adverse Events along with the time to onset by System Organ Class or Preferred Term. Using this sheet, users can obtain an understanding of when the AEs started during the course of a clinical trial.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Treatment Emergent, Special Interest AE, System Organ Class, and Preferred Term<br>• Variable Buttons: System Organ Class or Preferred Term<br>• SAE: Click to limit results to just SAEs<br>• Drop-down menu: Define the x-axis by Study Day, Study Week, or Study Month<br>• Grid chart: Count of AEs by Time to Onset and System Organ Class or Preferred Term. Results and graph title change depending on which variable button is selected. |
| Adverse Events Duration | Use this sheet to identify the abnormal durations with respect to Adverse Events.<br>• Filters: Study, Country, Site, Subject, Sex, Race, Ethnicity, Severity/Toxicity, Seriousness, System Organ Class, High-Level Group Term, High-Level Term, and Preferred Term<br>• Variable Buttons: System Organ Class, High-Level Group Term, High-Level Term, Preferred Term<br>• AE Duration Chart: A box-and-whisker chart showing the range and distribution of AE duration (in days) with the ability to toggle between coding hierarchy levels of System Organ Class, High-Level Group Term, High-Level Term, or Preferred Term<br>• Bar Chart: AE Duration Distribution by PTs (by the selected Preferred Term)<br>• Listing Table: Adverse Events Listing |

| Sheet | Information included |
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| MedDRA Comparison Analysis | Use this sheet to review Adverse Event information by the levels of MedDRA classification. Review can be for a study, group of studies, or across a program. Tabulations are presented by group assignment.<br>• Filters: Study, Program, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Treatment Emergent, and Special Interest AE<br>• 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)<br>- Values in red text identify the highest proportion in each row, and values in green text identify the lowest proportion in each row.<br>- 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.<br>- Highlight Proportions: This field allows the user to select the value to determine where the highest and lowest values in a row differ by at least the percentage you enter, across all Group Assignments. |
| SMQ Comparison Analysis | Use this sheet to review Adverse Event information by Standard MedDRA Queries (SMQ). Review can be for a study, group of studies, or across a program. Tabulations are presented by group assignment. Right clicking on the table and toggling the Expand / Collapse button allows the user to expand the table to see the full cross tabulation, and to collapse it when done. An uncategorized bucket has been included. When expanded, it will list all AEs that do not fit into any of the Broad or Narrow SMQ terms.<br>• Filters: Study, Program, Group Assignment (includes Screen Failure selection), Subject, Special Interest AE, and AE Start Date<br>• Variable Buttons: Broad SMQ, Narrow SMQ<br>• MedDRA button: Displays the version of MedDRA being used in the sheet and links to a list of MedDRA versions.<br>• Table: Standardized MedDRA Queries<br>- Values in red text identify the highest proportion in each row, and values in green text identify the lowest proportion in each row.<br>- 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.<br>- Highlight proportions: This field allows the user to select the value to determine where the highest and lowest values in a row differ by at least the percentage you enter, across all Group Assignments. |

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| Treatment Emergent AE Analysis | Use this sheet to review the instances of Adverse Events that started on or after the first dose of study medication. Tabulations present the number of events and subjects by various demographic parameters.<br>• Filters: Study, Program, Country, Site, Subject, Group Assignment (includes Screen Failure selection), TEAE, AE Start Date, Sex, Race, Ethnicity, and Age Group Boundaries<br>• Age Group Boundaries: Allows the user to select up to two ages to define a specific age or age range.<br>- 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.<br>- When the user selects two ages, three groups display: totals for anything less than that lowest age, totals for anything greater than or equal to that age as well as totals less than the highest age selected, and anything greater than or equal to the highest age.<br>• Table: Demographic Output shows Treatment Emergent AE counts and percentages.<br>- Values in red text identify the highest proportion in each row, and values in green text identify the lowest proportion in each row.<br>- The Proportion (%) column is calculated by the number of subjects who reported a TEAE in that Group Assignment divided by the total number of subjects in that Group Assignment.<br>- Highlight proportions: This field allows the user to select the value to determine where the highest and lowest values in a row differ by at least the percentage you enter, across all Group Assignments. |
| Death Summary | Use this sheet to view the primary cause of death and examine the relationship between death and Adverse Events for the identification of potential safety signals.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, and Date of Death<br>• Bar Chart: Cause of Death<br>• Line Chart: Number of Deaths (Deaths Per Month/Week/Day, Cumulative Deaths)<br>• 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), and Subject<br>• View By Buttons: Subject Counts or Event Counts<br>• Treemap Chart: MH Subject or Event Counts by System Organ Class<br>- Size of the box is proportional to the count.<br>• Stacked Bar Chart: MH Subject or Event Counts by System Organ Class or Preferred Term and Category<br>• Listing Table |

| Sheet | Information included |
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| Medical History Cross Tabulation | Use this sheet to examine Medical History for all subjects by System Organ Class and Preferred Terms (make System Organ Class selection to drill down to Preferred Terms). Users can also use this sheet to review either subject counts or event counts.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), and Subject<br>• Variable Buttons: Subject Counts or Event Counts<br>• Variable Buttons: Category, MH Duration, Race, Sex, Ethnicity, SubCategory, Occurrence, Completion Status<br>• Bar Chart: Top 10 System Organ Class/Preferred Terms by selected variable button (Subject or Event Counts), and by # of Subjects (or Events) and % of Subjects (or Events)<br>• 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) |
| 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.<br>• Filters: Study, Country, Site, Subject, CM Start Date, and Prohibited Meds<br>• Variable Buttons: Subject Counts, Medication Counts<br>• Variable Buttons: Standardized Medication, ATC 2 Text<br>• Variable Buttons: Occurrence, Route, CM Duration, Race, Sex, Ethnicity<br>• Treemap Chart: CM Subject or Medication Counts by Medication Class<br>- Size of the box is proportional to the amount.<br>• 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.<br>• 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 toggling the Expand / Collapse button will allow the user to expand the table to see the full cross tabulation, and to collapse it when done.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, and CM Start Date<br>• Variable Buttons: Subject Counts or Medication Counts<br>• Variable Buttons: Occurrence, Route, CM Duration, Race, Sex, Ethnicity<br>• Bar Chart: Top 10 Medication Class/Standardized Medication by # of Subjects or Medications and % of Subjects or Medications<br>• 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) |

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| Con-Med Group | Use this sheet to identify and review subjects who received specific combinations of non-study treatments.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Standardized Medication Name, and CM Start Date<br>• Listing Table: Subjects on Multiple Selected Medications<br>- The Standardized Medication Name filter allows the user to view subjects who took the specified medications.<br>- The filtered list only shows subjects who took all the medications selected.<br>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 a separate feature not integrated with the table. |
| 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 choose to view the minimum, maximum, and median values.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Category for Lab Test, Test, Range Indicator, and nxULN Range<br>• Drop-down menu: Average, Minimum, Maximum, Median<br>• Variable Buttons: Visit Name, Vendor Name, Group Assignment, Site, Sex, Toxicity<br>• Table: Cross Tabulation: Lab Numerical Results by selected Variable Buttons (Visit Name, Vendor Name, Group Assignment, Site, Sex, or Toxicity), (click the + to see individual subjects) in columns. The rows show the test and users can drill down to the subjects to see the individual results.<br>- Average is the default result value. Users may also view by minimum, maximum, or median value.<br>- Colors represent a normalized view; shades of green are within the normal range, shades of red are above the normal range, and shades of blue are below the normal range.<br>- Use the nxULN Range filter to filter the results by a specific range (e.g., 2.51-3.00 times the upper limit of normal). |
| Lab Result Trends | Use this sheet to review lab data by test through various combinations of comparison to identify potential safety signals. Inclusion/Exclusion criteria violations can be identified through this sheet by evaluation of baseline values.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Category for Lab Test, Test, nxULN Range, and Vendor Name<br>• Bar Chart: Lab Result Counts, Lab Results Distribution<br>• Scatter Plot: Lab Results for selected test<br>• Listing Table<br>- If the Result in Standard Units is less than the lower limit, the background color of the cell will be yellow.<br>- If the Result in Standard Units is greater than the upper limit, the background color of the cell will be red. |

| Sheet | Information included |
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| Lab Result Review Over Time | Use this sheet to review up to four lab tests over time at once. Review for potential safety signals, Inclusion/Exclusion violation criteria, 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.<br>• Filters: Study, Country, Site, Subject, Study Period, Category for Lab Test, Test, Toxicity, nxULN, and Vendor Name<br>• Drop-down menu: Visit Name, Visit Number, Study Day, Study Week, Study Month, Date of Collection, Visit & Timepoint<br>• Line Charts (4): Lab Results Over Time. Choose up to 4 Lab Tests to view associated graph data.<br>- X-axis: Viewable by Visit Name, Visit Number, Study Day, Study Week, Study Month, Date of Collection, or Visit & Timepoint (selection from the drop-down menu). The chart itself graphs each subject's results over time.<br>- Y-axis: Viewable by Results (multiple) (default), Change from Baseline, % Change from Previous Visit, % Change from Baseline, or Change from Previous Visit.<br>• Listing Table |
| 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Study Period, Category for Lab Test, and Test<br>• Variable Buttons: Visit Name, Vendor Name, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, Group Assignment (includes Screen Failure selection)<br>• Cross Tabulation: Descriptive Stats – Lab Results by selected Variable Button (Visit Name, Vendor Name, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, Group Assignment).<br>• 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.<br>• Box and Whisker Chart: Lab Results by selected Variable Button (Visit Name, Vendor Name, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, Group Assignment).<br>- X-axis: Variable Button<br>- Y-axis: Lab Results (multiple)<br>- This only displays when only one test is selected. |

| Sheet | Information included |
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| 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.<br>• Filters: Study, Country, Site, Subject, Study Period, nxULN, and Vendor Name<br>• Variable Buttons: Study Week, Study Day<br>• Variable Buttons: ALT, AST<br>• Drop-down menu: All ALP Results, ALP <2xULN, ALP >2x=ULN<br>• Drop-down menu: No Window, Window 30 Days or Less, Window Same Day<br>• Scatter Plot: Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) Plot. Data points represent subjects, and are color-coded by group assignment:<br>- Refine criterion by changing the default All ALP Results to alkaline phosphatase (ALP) < 2xULN, in alignment with the Hy's Law criteria.<br>• Line Charts (4): ALP, BILI, ALT, and AST Over Study Day or Study Week depending on variable button selected.<br>• Listing Table |
| Liver Lab Test Analysis | Use this sheet to support review of liver function test abnormalities and to detect possible Hy's Law subjects.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Category for Lab Test, and Vendor Name<br>• Cross Tabulation: Displays data from the liver-related labs by ULN in a tabular format, broken out by group assignment.<br>Note: 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 by utilizing the scatter plot to compare two tests against each other.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Category for Lab Test, Test, nxULN Range, and Vendor Name<br>• Drop-down menu: Average, Minimum, Maximum, and Median<br>• Scatter Plot: Select two Lab Tests to view Lab Results against one another. Select Vendor Name to display reference lines.<br>• Listing Table |
| Labs Summary – Distribution Plot | Use this sheet to explore differences in test results by group assignment, which may identify safety issues. The distance between the dots indicates the magnitude of differences in the test results between the group assignments based on the selected parameter (average, minimum, maximum, or median).<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Visit Name, Category for Lab Test, Test, Range Indicator, nxULN Range, and Vendor Name<br>• Variable Buttons: Lab Test or Examination Name, Lab Test or Examination Short Name<br>• Drop-down menu: Average, Minimum, Maximum, and Median<br>• Scatter Plot: Lab Numerical Test Results by Group Assignment<br>- Provides the average, minimum, maximum, or median value for the tests by group assignment.<br>- The colors allow users to easily identify results that fell within the normal range, above the normal range, or below the normal range. |

| Sheet | Information included |
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| 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 account of results received for each study visit name by sample type.<br>• Filters: Study, Country, Site, Subject, Study Period, Category for Lab Test, and Vendor Name<br>• Drop-down menu: Visit Name, Visit Number, Study Day, Study Week, and Study Month<br>• Variable Buttons: Lab Test or Examination Name, Lab Test or Examination Short Name<br>• Cross Tabulation: Lab Vendor Details (# of Results and % of Results) by Lab Test or Examination Name (click the + to see individual subjects) in rows, and choice of drop-down menu options (Visit Name, Visit Number, Study Day, Study Week, or Study Month) in columns.<br>- 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 reported 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Test, Date of ECG, and Abnormal Results<br>• Low Limit Value and High Limit Value thresholds: Enter a number into these fields and press Enter to apply Reference Lines to the chart.<br>• Line Chart: ECG Results Over Time by selected Test<br>- X-axis: Visit Name, Study Week, Study Day, Study Month, Date of Collection, Visit Number, or Visit & Timepoint AND Subject, Study Week, Study Day, Study Month, Date of Collection, Visit Number, or Visit & Timepoint<br>- Y-axis: Results, % Change from Previous Visit, Change from Previous Visit, % Change from Baseline, and Change from Baseline<br>• Listing Table: Uses URL-specific Range Look Up or study-specific if it has been configured/imported (Reference Range Look Up table: 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.<br>• Filters: Study, Country, Site, Subject, Test, and Date of ECG<br>• Variable Buttons: Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, and Group Assignment<br>• Cross Tabulation: Descriptive Stats—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)<br>- Columns: # Results, Mean, Standard Deviation, Coefficient of Variation, Min, Q1, Median, Q3, Max<br>- Rows: Test and (click the + to expand) Subjects<br>• 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) |

| Sheet | Information included |
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| Vital Signs Result Trends | Use this sheet to review Vital Signs data by test to identify outliers for potential safety signals. Identify Inclusion/Exclusion criteria violations based on average, minimum, and maximum baseline values. Review Vital Sign Test Results Distribution by frequency.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Test, and Date of Measurements<br>• Lower Limit Value and Upper Limit Value thresholds: Enter a number into these fields and press Enter to apply Reference Lines to the scatter plot.<br>• Scatter Plot: Vital Signs Results (by selected test)<br>- X-axis: Baseline (multiple), Min Post Baseline (multiple), Max Post Baseline (multiple)<br>- Y-axis: Average Post Baseline (multiple), Min Post Baseline (multiple), Max Post Baseline (multiple)<br>• Histogram: Vital Signs Results Distribution (by selected test)<br>- X-axis: Result Value (multiple)<br>- Y-axis: Frequency<br>• 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 criteria violations as applicable. The line chart will show the selected test and plot each subject's results over time connected by a line.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Test, Reference Range Indicators, and Date of Measurements<br>• Low Limit Value and High Limit Value thresholds: Enter a number into these fields and press Enter to apply Reference Lines to the chart.<br>• Line Chart: Vital Results Over Time (by selected test)<br>- 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 Measurements, Visit Number, or Visit & Timepoint<br>- Y-axis: Results (multiple), % Change from Previous Visit, % Change from Baseline<br>• Line Chart: Vital Signs Results Over Time -- Systolic vs Diastolic<br>- X-axis: Visit Name, Date of Measurements, Study Month, Study Day, Visit Number, Study Week or Visit & Timepoint<br>- Y-axis: Numeric Values<br>• Listing Table |

| Sheet | Information included |
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| 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.<br>• Filters: Study, Country, Site, Subject, Test, and Date of Measurements<br>• Variable Button: Visit Name, Visit Number, Study Day, Study Week, Study Month, Age Range, Sex, Ethnicity, Race, Site, or Group Assignment<br>• Cross Tabulation: Descriptive Stats – Vital Signs Results by selected Variable Button values<br>- Row Values: Results by Tests and (click the + to expand) Subjects<br>- Column Values: # Results, Mean, Standard Deviation, Coefficient of Variation, Min, Q1, Median, Q3, Max<br>- Choice of Variable Button in columns: Visit Name is selected by default<br>• 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(es), specifically for chemotherapy. The Eastern Cooperative Oncology Group (ECOG) performance assesses how a disease affects the daily living abilities of the subject.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, and Date of Finding<br>• Stacked Bar Chart: ECOG Performance Score<br>- X-axis: Visit Name or Study Day of Assessment AND Score or Study Day of Assessment<br>- Y-axis: # of Subjects<br>• Line Chart: ECOG Performance Score Over Time<br>- X-axis: Visit Name or Study Day of Assessment AND Subject or Study Day of Assessment<br>- Y-axis: Score<br>• 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.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, and Date of Examination<br>• Pie Chart: Physical Examinations Performed<br>• Stacked Bar Chart: PE System over Visits<br>- X-axis: PE System, Visit Name<br>- Y-axis: Count of PE System Examination<br>• Stacked Bar Chart: PE Result Category by Body System<br>- X-axis: Body System, Result Category<br>- Y-axis: Count of Result Category<br>• Listing Table |

| Sheet | Information included |
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| Inclusion / Exclusion Criteria Not Met | Use this sheet to review Inclusion/Exclusion criteria to identify specific inclusion/exclusion criteria that may be preventing enrollment.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, and Date of Collection<br>• Treemap Chart: Count of Distinct Subjects by Inclusion or Exclusion Criterion Short Name<br>- The size of the box is proportional to the count.<br>• 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 aligns with the AE information.<br>• Filters: Study, Country, Site, Subject, AE/Treatment, Special Interest AE, AE Start Date, and CM Start Date<br>• Listing Tables: AE Listing, Prior and Concomitant Treatment Listing |
| 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 then filter with the relevant data as well.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Study Period, Date of Measurements, and Vendor Name<br>• Listing Tables: Lab Listing, VS Listing<br>- Lab Listing<br>- If the Result in Standard Units is less than the lower limit, the background color of the cell will be yellow.<br>- If the Result in Standard Units is greater than the upper limit, the background color of the cell will be red. |
| Med Hist, AE and Prior and Concom Treatment | Use this sheet to ensure that the Medical History, Adverse Events (AEs), and Prior and Concomitant Treatments are consistent with logical data relationships. Users can review the information for a given treatment and verify that it corresponds to data entered on either the Medical History Listing (ongoing) or Adverse Events Listing.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, MH Start Date, AE Start Date, and CM Start Date<br>• Listing Tables: Medical History Listing, Prior and Concomitant Treatment Listing, and Adverse Event Listing<br>- When a filter is applied 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Category for Disposition Event, Only Show Latest Subject Disposition, and DS Start Date<br>• Bar Chart: Subject Counts of Standardized Disposition Term<br>• Cross Tabulation: Disposition Summary<br>- Row: Standardized Disposition Term and (click + to expand) Reported Term for the Disposition Event<br>- Column: # of Subjects and % of Subjects<br>• Listing Table |

| Sheet | Information included |
|---|---|
| Exposure Data | Use this sheet to review Exposure data. Explore the dosing trend(s) over time for each subject, along with any dose adjustment reasons.<br>• Filters: Study, Subject, and EX Start Date<br>• Line Chart: Dosing Trend Over Time per Subject<br>- X-axis: Study Day of Start of Treatment or Start Date of Treatment AND Name of Treatment or Start Date of Treatment<br>- Y-axis: Total Dose<br>• Bubble Chart: Exposure Metrics by Group Assignment<br>- X-axis: Days Since First Dose<br>- Y-axis: # of Doses<br>- Size of bubble depends on measure (Total Dose)<br>• Bar Chart: Dose Adjustment Reasons by Event Counts<br>- X-axis: # of Events<br>- Y-axis: Reason for Dose Adjustment<br>• 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 stopping one earlier than the other, and understand the impact of dosing on the subject participation in the study.<br>• Filters: Study, Country, Site, Subject, Completed Treatment, Name of Treatment, and EX Start Date<br>• Bar Graph<br>- X-axis: # Days on Treatment, Name of Treatment<br>- Y-axis: # of Subjects<br>- Legend: Name of Treatment<br>- When one treatment is selected, the footer will display the median number of days on treatment followed by the average number of days on treatment.<br>- 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.<br>• 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.<br>• Filters: Study, Country, Site, Subject, Name of Treatment, Reason for Dose Adjustment, Action Taken, System Organ Class, High-Level Group Term, High-Level Term, Preferred Term, and Reported Term<br>• Stacked Line Chart: Subjects by Preferred Term and Dosing Adjustment.<br>- 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.<br>Note: The footer displays 'Number of Subjects (n).'<br>• 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.<br>• Filters: Study, Country, Site, Subject, Adverse Events, Event (Preferred Term), Lab Indicator, and Event Date<br>• Variable Buttons: Study Day, Study Week, Study Month, Event Date<br>• Visualization: Select one subject from the Subject Filter to view Adverse Events, Concomitant Medications, Duration, and Laboratory Test Results. The chart shows the associated Start Day/Week/Month, End Day/Week/Month, Normal, High/Abnormal, Low, Other, SAE and No Result.<br>- While selection of Adverse Events is by Preferred Term, display on the patient profile is by Reported Term.<br>• 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.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, and EX Start Date<br>• Listing Table |
| Survival Summary<br>*Oncology Sheet* | 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.<br>• Filters: Study, Subject, and Date of Collection<br>• Stacked Bar Chart: Subject Duration by Months or Days (depending on tab selection)<br>- X-axis: Treatment Duration and Follow-up Duration with the sum of the two giving you the Overall Duration (shown by the total label) in months or days<br>- Y-axis: Subject Identifier<br>- Legend color-coded for Treatment Duration and Follow-up Duration<br>• Stacked Bar Chart: Survival Days by Group Assignment<br>- X-axis: # of Subjects<br>- Y-axis: Study Free Survival, Overall Survival, or Progression Free Survival AND Group Assignment, Overall Survival, or Progression Free Survival<br>• Listing Table |

| Sheet | Information included |
|---|---|
| Tumor Identification<br>*Oncology Sheet* | 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 tumor locations and types (Target, Non-Target, and New).<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Sex, and Date of Tumor Identification<br>• Stacked Bar Chart: Lesion Count for Location by Lesion Type<br>- X-axis: Lesion Location<br>- Y-axis: # of Lesions<br>- Legend color-coded by Lesion Type<br>• Pie Chart: Tumor Identification Test Type<br>- Shows the method of identification used in identifying the tumor.<br>• Bar Chart: New Lesions by Study Days or Subject Counts by Study Days (depending on tab selection)<br>- X-axis: Study Days<br>- Y-axis: Number of New Lesions or Number of Subjects<br>• Listing Table |
| Tumor Results<br>*Oncology Sheet* | 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.<br>• Filters: Study, Subject, Category for Response Assessment, Tumor Assessment Short Name, and Date of Tumor Measurement<br>• Line Chart: Sum of Lesions Over Time (mm)<br>(Lines colored by Subject)<br>- X-axis: Visit Name or Study Day of Tumor Measurement AND Subject or Study Day of Tumor Measurement<br>- Y-axis: Sum of Target Lesions<br>• Line Chart: Change from Baseline – Sum of Lesions<br>(Lines colored by Subject)<br>- X-axis: Visit Name, Days from Baseline, or Study Day of Tumor Measurement AND Subject, Days from Baseline, or Study Day of Tumor Measurement<br>- Y-axis: Change from Baseline–Sum of Lesions, % Change from Baseline–Sum of Lesions<br>• Listing Table: Tumor Assessments |
| Tumor Response<br>*Oncology Sheet* | Use this sheet to review tumor response. A summary of the response is provided. Drill down to view individual subject response over time for subjects of interest.<br>• Filters: Study, Subject, Visit Name, Category for Response Assessment, Response Assessment Name, and Date of Response Assessment<br>• Donut Chart: Best Overall Response Counts<br>• Line Chart: RECIST Response Trend Over Study Day<br>- X-axis: Study Day<br>- Y-axis: Response Assessment<br>- Legend indicating Non-target Response, Target Response, and Overall Response by line color.<br>• Listing Table: All Tumor Responses |

| Sheet | Information included |
|---|---|
| Response Duration<br>*Oncology Sheet* | Use this sheet to examine the timeline of response relative to participation in the study for each subject.<br>• Filters: Study, Group Assignment (includes Screen Failure selection), Subject, Category for Response Assessment, Response Assessment Name, and Date of Response Assessment<br>• Swimmer's Plot<br>- X-axis: Study Month of Response Assessment<br>- Y-axis: Subject<br>- Legend indicating Response Duration, Complete Response, Partial Response, Durable Responder, Response Start, Response End, Continued Response |
| Swimmer's Plot with Subjects' Overall Response<br>*Oncology Sheet* | Use this sheet to view subjects' overall response over time for each subject in a clinical trial. Subjects can be displayed by group assignment or disease type.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Disease Type, Response Type, Best Overall Response, and Most Recent Response<br>• Variable Buttons: Group Assignment, Disease Type<br>• Variable Buttons: All, On Treatment, Off Treatment<br>• Swimmer's Plot<br>- X-axis: Treatment Duration in Months<br>- Y-axis: Subject & Group Assignment (or Disease Type) |
| Waterfall Plot<br>*Oncology Sheet* | Use this sheet to view the best percentage change in tumor size from baseline by your choice of evaluation criterion.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, Disease Type, and Best Overall Response<br>• Drop-down menu: RECIST, RANO, or LUGANO<br>• Entering Low Limit Value and High Limit Value thresholds will add indicator lines on the chart.<br>• Waterfall Plot: Best % Change in Tumor Size from Baseline<br>- X-axis: Subject, Disease Response<br>- Y-axis: Change from Baseline (%)<br>• Listing Table<br>- Change From Baseline: Best % Change in Tumor Size from Baseline bar chart.<br>- Null Change From Baseline: All records that have a null change from baseline value. |

| Sheet | Information included |
|---|---|
| Tumor Measurement Spider Plot<br>*Oncology Sheet* | Use this sheet to view tumor measurement percentage change from baseline by Subject and Group Assignment, Disease Type, Best Overall Response, Sex, or Race. This data is shown based on the selected evaluation criterion similar to the Waterfall Plot sheet.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Subject, and Disease Type<br>• Drop-down menu: RECIST, RANOTR, or LUGANO<br>• Variable Buttons: Group Assignment, Disease Type, Best Overall Response, Sex, Race<br>• Variable Buttons: All Study Days (default), Study Days >=0<br>• Entering Low Limit Value and High Limit Value thresholds will add indicator lines on the chart.<br>• Spider Plot: Tumor Measurement % Change from Baseline by Subject and selected Variable Button (Group Assignment, Disease Type, Best Overall Response, Sex, or Race)<br>- X-axis: Study Day of Tumor Measurement, Study Month of Tumor Measurement, or Study Week of Tumor Measurement AND Subject, Study Month of Tumor Measurement, or Study Week of Tumor Measurement<br>- Y-axis: Change from Baseline (%) |
| Objective Response Rate<br>*Oncology Sheet* | Use this sheet to view the drug efficacy (reviewing the objective response rate) over the study duration.<br>• Filters: Study, Country, Site, Group Assignment (includes Screen Failure selection), Sex, Age Group, Race, and Indication<br>• Bar Chart: Objective Response Rate Over Time<br>- X-axis: Study Months and Years<br>- Y-axis: Objective Response Rate |
| Application Information | Use this sheet to view application information.<br>• Application: Clinical Data Analytics<br>• Listing Table: What's New, Data Last Refresh, Glossary, Special Interest Adverse Events, Prohibited Meds<br>• Link to SDTM Standards<br>• Link to a list of MedDRA versions and indicates the version used<br>• Support Contact Information<br>• Current Version Number and Dates |