Clinical Trial Operational Analytics 22.3
Sheet Descriptions Table

There are 19 standard public sheets in this version.

Sheet	Information included
Home Page	Summary information across all studies, or the selected study(ies). Please see CTOA 22.3 Home Page Description document for more information.
Enrollment Summary	Use this sheet to view enrollment metrics and information by Study, Country, Site, and Status. • Filters: Study, Country, Site, and Status • KPIs - Sites: Total number of sites and countries participating in the study(ies) selected - Total Planned Enrollment: Total number of planned subjects - Subjects Screened: Total number of subjects screened, and total number enrolled - Screen Failure Rate: Number of subjects who were screen fails divided by the number of subjects screened - Days Since Last Patient Screened: Number of days since last patient screened • Enrollment Summary by Site, Country, or Study (use the drop-down on the X-axis to change the view): Displays the number of subjects enrolled (blue bar) and the percentage of subjects enrolled (red diamond) out of the number screened at that site (country or study). • Enrollment Details: Number of subjects by Site, Country, or Study (use the drop-down arrow on the Y-axis), with each color showing how many subjects were consented, screened, screen failures, eligible, enrolled, and treated. • Listing Table

Sheet	Information included
Recruitment and Retention	Use this sheet to monitor enrollment metrics based on thresholds you set for key metrics to determine if a site is enrolling at a healthy rate. Based on a threshold the user enters, the report shows values which are on target, off target, or require action. Enrollment target thresholds highlight studies which are under target for enrollment. Screen failure thresholds to highlight sites with a high percentage of screen failure. Consent thresholds to indicate when a site is not 100% consented. Discontinued thresholds indicate if a site has exceeded acceptable numbers and poses a risk to trial data quality. • Filters: Study, Country, and Site • KPIs - Study Planned vs Actual Enrollment by Country or Site - Screen Failed vs Screened subjects per Site, Country, or Study - Consented vs Actual Enrolled per Site, Country, or Study - Discontinued (for any reason) vs Actual Enrolled per Site, Country, or Study • Listing includes Planned Enrollment, Actual Enrollment, Screen Failed Subjects, Consented Subjects, and Discontinued Subjects.

Sheet	Information included
Enrollment Trend	Use this sheet to view enrollment and cumulative enrollment trends in various forms. A user can compare the actual enrollment with the enrollment forecast at a site broken out by year and month. View data for one study at a time. Note that planned enrollment numbers must be provided. • Filters: Study, Site, Country, and Group Assignment • KPIs - Planned Enrollment: Number of Planned Enrollment - Actual Enrollment: Number of Actual Enrollment - Enrollment Rate (% of Planned): The actual number enrolled divided by the number planned. 100% represents that actual enrollment meets the planned enrollment - Min Site Enrollment: Lowest actual enrollment from a single site of all sites - Median Site Enrollment: Median enrollment count of all sites - Max Site Enrollment: Highest actual enrollment count of a single site of all sites - Inactive Sites: Number of initiated but inactive sites • Cumulative Actual Enrollment: A line graph displaying a line for the actual enrollment for all sites, cumulative; and a line showing the actual enrollment for all sites, per month. • Actual Study Enrollment vs Actual Site Enrollment: User must select one site. A line graph displaying a line for the actual enrollment per study, and one line for the actual enrollment per site. • Planned vs Actual Enrollment by Country: A bar chart of the planned vs the actual number of enrolled subjects, broken out by country. • Planned vs Actual Totals by Site: A bar chart of the planned vs actual enrollment, broken out by site. • Scroll down to see Subject Enrollment and Screen Failures Trends: A spaghetti plot that provides insight on site performance. Use the toggles at the top to view the cumulative number of Enrolled Subjects, or Screen Failures.

<table>
<tr><th>Sheet</th><th>Information included</th></tr>
<tr><td>Subject Early Discontinuation</td><td>Use this sheet to get detailed information for subjects who withdrew, dropped out, or discontinued from the study for various reasons.
Filters: Study, Country, Site, Subject, and Sex
KPIs
- Early Termination Rate: Percentage of subjects who terminated early from the study. This does not include subjects who withdrew from the study or were screen fails
- Enrolled | Discontinued: Number of enrolled subjects to number of discontinued subjects
- Withdrawal Rate: Percentage of the subjects who withdrew from the study. This includes subjects whose withdrawal reason is only withdraw
- Discontinued Male | Female: Number of discontinued male subjects to discontinued female subjects
- Disc. Avg Age Male | Female: Average age of discontinued males to discontinued females Early Termination by Site: A bar chart showing the early termination rate, by site. The red line identifies the study average termination rate. Early Termination Subjects by Site or by Reason: A bar chart showing the number of subjects by site and the reason for their early termination; and the number of subjects by reason for their early termination, by site. Hover over a bar section to see the site and exact number of subjects. The red line identifies the average number of subjects, when the user changes the Y axis filter from # of Subjects to % of Subjects, the value of the count changes to a decimal value. The number still represents an average count of subjects. Listing Table</td></tr>
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Sheet	Information included
Query Metrics	Use this sheet to find information regarding query metrics. Use the filters to limit your results. • Filters: Study, Site, Query Status, Query Type, and Country • Enter Open Query Threshold %. Queries that exceed the define threshold highlight yellow. • KPIs - Enrolled Subjects: The number of enrolled subjects - Current Open Queries: The total number of currently opened queries - Current Answered Queries: The total number of answered queries - Current Closed Queries: The total number of closed queries - Current Cancelled Queries: The total number of cancelled queries - Total Queries: The total number of queries • Count of Open Queries by Site/Country/Study: A bar chart showing the number of open queries by study, site, or country. • Count of Current Query Status by Site/Country/Study: A bar chart showing the number of queries by site (or select study or country), broken out by the query's status. • Count of Queries by Sender-Recipient/Query Status: A bar showing the number of queries by sender-recipient, query status, and / or site. Use the drop-down arrows on the X-axis to display in the X-axis. • Listing Table

Sheet	Information included
Queries Duration	Use this sheet to view the duration for queries in the opened status, the average number of days it took for the opened queries to be answered and closed, and the average number of days it took for the answered queries to be closed, along with some useful metrics. • Filters: Study, Site, Country, Sender-Recipient, and Query Type • Enter an acceptable number of average days outstanding in the threshold field to focus on the sites with average days outstanding greater than an acceptable number. • KPIs - Avg Days Outstanding: Average number of days current queries are in Open status - Avg Days Open to Answered: Average number of days from when a query was opened to when it was answered - Avg Days Answered to Closed: Average number of days from when a query was answered to when it was closed - Avg Days Open to Closed: Average number of days from when a query was opened to when it was closed • Outstanding (Currently Opened Queries): A bar chart showing the number or percent of queries including the average number of days outstanding and number of subjects, by site. • Answered to Closed: A scatter plot showing the average number of days for a query to go from Answered to Closed by the number of queries, broken out by site. • Open to Answered: A scatter plot showing the average number of days for a query to go from Open to Answered by the number of queries, broken out by site. • Open to Closed: A scatter plot showing the average number of days for a query to go from Open to Closed by the number of queries, broken out by site.

Sheet	Information included
Query Details	Use this sheet for detailed information of all the queries by query text, folder, form, or field by Site in the form of bar chart and listing. • Filters: Study, Site, Subject, Query Status, Country, Query Type, Sender-Recipient, Query Sender, and Query Recipient • Queries by Sender / Site / Recipient: A bar chart showing the number of queries by Site, Query Sender, or Query Recipient. Use the drop-down arrows on the y-axis to adjust the view. • Queries by Sender-Recipient / Site / Folder / Form / Data Field: A bar chart showing the number of queries by Sender-Recipient, Folder, Form, Data Field, or Site. Use the toggles above the chart to adjust the view. By default, the chart displays all sites, use the drop-down at the top left to view data for the Top 10 sites. • Listing Table
Queries by Open Date	Use this sheet to view the cumulative number of queries opened over time by Site, and User / Sender-Recipient and Query Details in the form of cross-tabulations. • Filters: Study, Site, Subject, Sender-Recipient, and Folder • Cumulative Queries per Subject by Date and Site: A scatter plot of the cumulative number of queries per subject broken out by date and site, displayed by year. Click on a year to then view the query details for that year by month. • Cumulative Queries per Subject by Date and user/Sender-Recipient: A scatter plot of the cumulative number of queries per subject broken out by date and user/sender-recipient. Click on a year to then view the query details for that year by month. • Query Details – Cross Tabulation: A cross tab of the sites or users displayed by the number of selected sender-recipients and status; the default is all sender-recipients and all query statuses. • Queries by Subject – Cross Tabulation: A cross tab of the subjects, displayed by the number of selected send-recipients and status; the default is for all sender-recipients and all query statuses.

Sheet	Information included
Query Response	Use this sheet to see the details on query response time. • Filters: Study, Country, Site, and Subject • KPI - Avg Days Open to Answered: Average number of days from when a query was opened to when it was answered - Avg Days Answered to Closed: Average number of days from when a query was answered to when it was closed • Query Open to Answered: A bar chart showing the average number of days a query went from Open to Answered by site. The red line identifies the average for the study(ies), and adjusts based on your filters. • Average Response in Days by Site Over Time: A line chart showing the average response in days by site. Enter the number of months in the Enter graph timeframe field. • Queries by Open to Answered Duration: A bar chart showing the number of queries and the length of time for those queries to go from Open to Answered. Use the drop-downs on the Y-axis to adjust your view between Site, Study, Country, and Open to Answered duration.

Sheet	Information included
Protocol Deviations – Overview	Use this sheet to find details related to subjects who had protocol deviations. • Filters: Study, Country, Site of Deviation, Subject, Class, and Severity • Enter a value in the Major or Minor threshold field to filter by threshold to quickly identify outliers. • KPIs - PD Rate: The percentage of protocol deviations per subject - Major PD Rate: The percentage of major protocol deviations per subject - Minor PD Rate: The percentage of minor protocol deviations per subject • Protocol Deviations by Site: A bar chart showing the number of PDs and PD rate by Site of Deviation or Current site (number of PDs divided by the number of screened subjects). The diamonds represent the number of PDs and the bars represent the PD Rate. • Protocol Deviations Over Time: A line graph showing the number of PDs or PD rate by date or visit. • Class, Form, Field and Protocol Deviations by Site: A bar chart showing the number of protocol deviations by Site of Deviation, Current Site, Field, Protocol Deviation, Class, or form. • Listing Table: Protocol Deviations
Protocol Deviation Details	Use this sheet to view details regarding subjects with protocol deviations, as well as the number of eligible vs ineligible subjects who had protocol deviations. Easily identify the site of deviation details for subject transfers. • Filters: Study, Country, Site of Deviation, and Subject • Eligible vs. Ineligible Subjects (%) with PDs: A bar chart of the percentage of subjects by site who were eligible or ineligible. • PD Subjects: A bar chart showing the number of subjects by site with a PD and if they were eligible or not. • Listing Table: Protocol Deviations

Sheet	Information included
AE and SAE Rate	Use this sheet to view detailed information and metrics related to adverse events and serious adverse events. • Filters: Study, Country, Site, and Subject • AE or SAE Rate threshold entry box: enter a value to quickly identify outliers. • KPIs - AE and SAE Rate (per Subject): Percentage of AEs/SAEs per subject; SAEs are in red - AE and SAE Counts: Number of reported AEs and SAEs; SAEs are in red • AE and SAE Rate: A bar chart of the rate of AEs or SAEs reported, by site; with the average rate displayed, which adjusts based on your filters. The red line identifies the average across the study(ies), and adjusts based on your filters. • Subject/Event/Unresolved Ratio: A bar chart showing the total number of subjects, events, or unresolved events by site. • Listing Table
Time to SDV and Details	Use this sheet to view metrics related to Source Data Verification. • Filters: Study, Country, and Site • Enter the Average Days to SDV in the threshold field to identify outliers. • KPIs - Avg Days to SDV: The average number of days from entry to first Source Data Verification - Enrolled Subjects • Initial Entry to Verification: A line graph showing the average number of days between initial entry of the data to SDV by site. • Listing Table

Sheet	Information included
Timeliness	Use this sheet to view various metrics related to source data. • Filters: Study, Stie, Subject, and Audit Action Type • Average Days from Initial Entry to Review: A line chart showing the average number of days by Site, Form, Subject, Folder, Study, or Field that it took to go from the initial entry of data to review action. • Average Days from Initial Entry to Query Open: A line graph showing the average number of days by Site, Study, Field, Subject, Form, or Folder that it took to go from the initial entry of data to open a query. • Average Days from Initial Entry to Verification: A line graph showing the average number of days by Site, Field, Study, Folder, Form, or Subject that it took to go from the initial entry of data to the action of Verification. • Audits by Audit Date: A line graph showing the number of audits conducted based on your filter selections. Click on a Year in the X-axis to drill down to months in that year.
Post SDV and Post Query Changes	Use this sheet to view various metrics related to post source data verification and post query changes as mentioned below. • Filters: Study, Site, Subject, and Audit Role • Data Changes After SDV: A bar chart showing the number of data changes made by Site, Form, Subject, Folder, Study, or Field after SDV. Use the drop-down on the Y-axis to switch between these options. • Query Actions After SDV: The number of queries by Site, Form, Study, Field, Subject or Folder that took place after SDV. • Number of Queries Resulting in a Data Change: A bar chart showing the number of queries or number of subjects by Site, Field, Folder, Form, Study or Subject that occurred because of a change in the data. • Number of Data Changes by Role: A bar chart showing the number and percent of data changes by role.

Sheet	Information included
Data Changes	Use this sheet to view information related to folders, forms, fields, and sites with data changes. • Filters: Study, Site, Country, Form, Field, and Subject • KPIs - Enrolled Subjects: Number of subjects enrolled and number of data changes in red - Data Changes per Site: Number of data changes divided by the number of sites - Data Changes / Data Points Entered: Number of data changes divided by the number of data points entered • Studies or Sites with Changes: A bar chart displaying the number of changes after initial entry and number of subjects by study or site. • Forms or Folders with Changes: A bar chart displaying the number of changes after initial entry and the number of subjects by form or folder. • Data Changes Over Time: Enter the number of months in the Enter graph timeframe field. • Fields with Changes: A bar chart with the number of changes made after initial entry by form.
Audit Summary	Use this sheet to view metrics related to data changes by Change Reason and User and Audits by Action Type. • Filters: Study, Site, Subject, and Audit Role • Data Changes by Change Reason: A TreeView chart displaying the reason for the change broken out by the number of reasons by site. • Data Changes and Actions by User: A TreeView chart displaying the number of changes made to the data by a user. • Audits by Action Type: A bar chart showing the number of audits made by the action type, folder, form, field, subject, study, or site. Use the drop-downs on the Y-axis to switch between these types of options.
Application Information	• Application Name • Version Number and Dates • Listing of What's New • Listing of Data Last Refresh • Glossary of items on Home Page • Link to SDTM Standards • Links to Support Contact Information