Clinical Trial Operational Analytics (CTOA) 24.2
Sheet Descriptions Table

There are 19 standard public sheets in this version

.Sheet	Information included
Home Page	This is the landing page for CTOA, which displays key summary information and metrics across all studies, or the selected study(s). Please see CTOA 24.2 Home Page Description document for more information.
Enrollment Summary	Use this sheet to view enrollment metrics and information by Study, Country, Site, Status, and Group Assignment. • Filters: Study, Country, Site, Status, and Group Assignment (includes Screen Failure selection) • KPIs - Sites: Total number of sites and countries participating in the study(s) selected. The number of sites is displayed in large blue font and the number of countries is displayed in small gray font. - Total Planned Enrollment: Total number of planned subjects. Select a single Study (or Country or Cohort, depending on where the planned enrollment is stored), and the number will automatically populate in large blue font. - Subjects Screened: Total number of subjects screened, and total number enrolled. The number of subjects is displayed in large blue font, and enrolled subjects is displayed in small gray font. - Screen Failure Rate: Number of subjects who were screen fails divided by the number of subjects screened. This value is displayed as a percentage in large blue font. - Days Since Last Patient Screened: Number of days since the last patient was screened, displayed in large blue font. • Enrollment Summary by Site Number, Country, or Study (use the drop-down on the X-axis to change the view). Combo chart displaying 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: A stacked bar chart that displays enrollment details for the number of subjects by Site Number, Country, or Study (use the drop-down arrow on the Y-axis). Features status comparisons with segment labels on each status. Footer indicates that Subjects may appear in more than 1 category. - Legend is located on the right indicating the number of subjects that were Consented, Screened, Screen Failures, Eligible, Enrolled, or Treated by color. • Listing Table

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Recruitment and Retention	Use this sheet to monitor the subject recruitment and retention metrics for sites 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, Under Target, or Action Required. Planned 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 • Gauge Charts - Planned vs Actual Enrollment by Country or Cohort - Screen Failed vs Screened subjects (updates according to the filters applied) - Consented vs Actual Enrolled (updates according to the filters applied) - Discontinued (for any reason) vs Actual Enrolled (updates according to the filters applied) • Listing Table

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Enrollment Trend	Use this sheet to view actual, planned, 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, Country, Site, Group Assignment (includes Screen Failure selection), Year-Month, and Planned Enrollment Type • KPIs - Number of Planned Enrollment, Number of Actual Enrollment, and Enrollment Rate. All values are displayed in large blue font. Enrollment Rate is the actual number of subjects enrolled divided by the number of subjects screened, displayed as a percentage. - Min Site Enrollment: Lowest number of subjects enrolled in a single site (updates according to the filters applied). This value is displayed in large blue font. - Median Site Enrollment: Median enrollment count out of all sites, displayed in large blue font. - Max Site Enrollment: Highest number of subjects enrolled in a single site of all sites (updates according to the filters applied), displayed in large blue font. - Inactive Sites: Number of inactive sites, displayed in large blue font. • Cumulative Actual Enrollment, Cumulative Enrollment, or Cumulative Screen Failure: Select a tab to view Cumulative Actual Enrollment, Cumulative Enrollment, or Cumulative Screen Failure. Based on your selection, the graph will update accordingly. If Cumulative Actual Enrollment is selected, a line graph displays a line for the actual cumulative enrollment for all sites; and a line showing the actual enrollment for all sites, per month, indicated by color; and a reference line showing the Planned Enrollment for the cohort, country, and or site. If Cumulative Enrollment is selected, the cumulative number of enrolled subjects by year-month displays for each site. If Cumulative Screen Failure is selected, the cumulative number of screen failures by year-month displays for each site. • Planned vs Actual Totals by Study/Site/Country: A combo chart of the actual enrollment (blue bars) vs the planned enrollment (red diamonds), broken out by study/site/country. Select Study, Site, or Country from the X-axis. • Actual Study Enrollment vs Actual Site Enrollment: User must select one site to compare that site to the entire study. The study enrollment is depicted by a blue bar (using the primary/left y-axis), the site enrollment is depicted by a green bar (using the primary/left y-axis), the study screen failure is depicted by a yellow line (using the secondary/right y-axis), and the site screen failure is depicted by a red line (using the secondary/right y-axis).

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Subject Early Discontinuation	Use this sheet to get detailed information for subjects who withdrew, dropped out, or discontinued from the study (or studies) for various reasons. • Filters: Study, Country, Site, Group Assignment, Sex, Reason, and Subject • KPIs - Enrolled | Discontinued: Displays the number of enrolled subjects and the number of discontinued subjects. - Discontinued Rate: Displays the percentage of enrolled subjects who discontinued from the study in large blue font. - Discontinued Male | Female: Displays the number of male subjects who discontinued and the number of female subjects who discontinued in large blue font. - Disc. Avg Age Male | Female: Displays the average age of discontinued males and the average age of discontinued females in large blue font. • Discontinued Rate by Study/Country/Site: A bar chart displaying the discontinued rate (Y-axis) in percentages by study (default), site, or country (X-axis). The red line identifies the study average discontinued rate. • # of Discontinued By Site (default) / # of Discontinued By Reason: Stacked bar chart with two tabs to view the number of discontinued subjects by site, or reason. – Y-axis: # of Discontinued Subjects, % of Discontinued of Enrolled – Reference Line: Red line identifying the study average of discontinued subjects; however, this line does not appear when '% of Discontinued of Enrolled' is selected as the Y-axis parameter. – X-axis: Site or discontinued reason (depending on which tab is selected). – Legend to the right of the chart indicates the discontinued reason or site numbers by color (depending on which tab is selected). • # of Discontinued Reasons: A treemap displaying the number of subjects for each discontinuation reason, indicated by color. – The size of the box is proportionate to the count. • Listing Table

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Query Metrics	Use this sheet to find information regarding query metrics. Use the filters to customize your results. • Filters: Study, Country, Site, Query Type, and Query Status • KPIs - Enrolled Subjects | Total Queries: Displays the number of enrolled subjects and the total number of queries in large blue font. - Current Open Queries: Displays the total number of currently opened queries in large blue font. - Current Answered Queries: Displays the total number of answered queries in large blue font. - Current Closed Queries: Displays the total number of closed queries in large blue font. - Current Cancelled Queries: Displays the total number of cancelled queries in large blue font. • Queries vs Subjects / Current Query Statuses / # of Queries by Sender-Recipient/Query Status: Combo charts with 3 tabs: • Queries vs Subjects: A combo chart displaying the number of open, answered, closed, cancelled, or total queries and number of screened subjects by study, site, or country. - X-axis: Site, Country, or Study - Y-axis (left): Open Queries, Answered Queries, Closed Queries, Cancelled Queries, Total Queries - Y-axis (right): # of Screened Subjects (indicated by red diamonds), Open Queries, Answered Queries, Closed Queries Cancelled Queries, Total Queries • Current Query Statuses: A stacked bar chart displaying the number of queries or number of Queries Per Subject by site, study, or country, broken out by the query's status, country, or study. - X-axis: Site, Country, or Study AND Query Status, Country, or Study - Y-axis: # of Queries, # of Queries Per Subject - Legend to the right of the chart indicates Opened, Closed, Cancelled, and Answered queries by color. • # of Queries by Sender-Recipient/Query Status: A stacked bar chart displaying the number of queries or number of queries per subject by sender-recipient or query status, and site or query status. The red line identifies the Study Average number of queries. - X-axis: Sender-Recipient or Query Status AND Site or Query Status - Y-axis: # of Queries, # of Queries Per Subject - Legend to the right of the chart indicates Site number or Status (depending on the x-axis selection) by color. • Enter Open Query Threshold %: Enter a value into the field to view the corresponding data highlighted within the listing. Values exceeding the defined threshold are highlighted in yellow. • Listing Table

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Queries Duration	Use this sheet to view the duration of queries in the opened status, the average number of days it took for the opened queries to be answered, and the average number of days it took for the answered queries to be closed, along with other relevant metrics. • Filters: Study, Country, Site, Query Type, and Sender-Recipient • Average Days Outstanding: Enter an acceptable number of average days outstanding in the threshold field to focus the data on the sites with average days outstanding greater than or equal to the number entered. • KPIs - Avg Days Outstanding: Displays the average number of days current queries are in Open status in large blue font. - Avg Days Open to Answered: Displays the average number of days from when a query was opened to when it was answered in large blue font. - Avg Days Answered to Closed: Displays the average number of days from when a query was answered to when it was closed in large blue font. - Avg Days Open to Closed: Displays the average number of days from when a query was opened to when it was closed in large blue font. • Outstanding (Currently Opened Queries): A combo chart displaying the number or percentage of queries, including the average number of days outstanding and number of subjects, by site. - X-axis: Site - Y-axis: # of Queries or % of Queries (indicated by blue bars) - Legend to the right of the chart indicates blue bars as # of Queries, the yellow line as Avg Days Outstanding, and the red line as # of Subjects. • Open to Answered: A scatter plot displaying the average number of days for a query to go from Open to Answered (or the percent of queries) by the number of queries (or the percent of queries), broken out by site. - X-axis: Avg Days Open to Answered or % of Queries - Y-axis: # of Queries or % of Queries - Legend to the right of the chart indicates Site number by color. • Answered to Closed: A scatter plot displaying the average number of days for a query to go from Answered to Closed (or the percent of queries) by the number of queries (or the percent of queries), broken out by site. - X-axis: Avg Days Answered to Closed or % of Queries - Y-axis: # of Queries or % of Queries - Legend to the right of the chart indicates Site number by color. • Open to Closed: A scatter plot displaying the average number of days for a query to go from Open to Closed (or the percent of queries) by the number of queries (or the percent of queries), broken out by site. - X-axis: Avg Days Open to Closed or % of Queries - Y-axis: # of Queries or % of Queries - Legend to the right of the chart indicates Site number by color.

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Query Details	Use this sheet for detailed information on all queries by site, folder, form, or data field in the form of bar charts and a listing table. • Filters: Study, Country, Site, Subject, Query Type, Query Status, Query Sender, Query Recipient, and Sender-Recipient • Queries by Sender / Site / Recipient: A stacked bar chart displaying the number of queries by Site or Query Recipient AND Query Sender or Query Recipient. Use the drop-down arrows on the Y-axis to adjust the view. - X-axis: # of Queries - Y-axis: Site or Query Recipient AND Query Sender or Query Recipient - Legend to the right of the chart indicates Query Sender by color. • Queries by Sender-Recipient and Site, Folder, Form, or Data Field: A stacked bar chart displaying the number of queries by Sender-Recipient and Folder, Form, Data Field, or Site. Use the variable buttons above the chart to toggle between these options and 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 only. - X-axis: # of Queries - Y-axis: Site, Folder, Form, or Data Field AND Sender-Recipient - Legend to the right of the chart indicates Sender-Recipient by color. • 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. In addition, see Query Details by Site and Subject in the form of pivot tables. • Filters: Study, Site, Subject, Folder, and Sender-Recipient • Cumulative Queries per Subject by Date and Site: A line chart of the cumulative number of Queries per Subject broken out by date (Year to Month to Week to Day) and site. Click on a year to view the query details for that year by month, click on a month to get down to the weeks, and click on a week to get down to the days. - X-axis: Queries by Open Date (Year to Month to Week to Day) and Site - Y-axis: Cumulative # of Queries - Legend to the right of the chart indicates Site number by color. • Cumulative Queries per Subject by Date and User/Sender-Recipient: A line chart of the cumulative number of Queries per Subject broken out by date (Year to Month to Week to Day) and user/sender-recipient. Click on a year to view the query details for that year by month, click on a month to get down to the weeks, and click on a week to get down to the days. - X-axis: Queries by Open Date (Year to Month to Week to Day) or Sender-Recipient AND User or Sender-Recipient - Y-axis: Cumulative # of Queries - Legend to the right of the chart indicates User identification by color. • Query Details: A pivot table of the sites drilled down to users displayed by the number of queries per subject for each sender-recipient and query status. • Queries by Subject: A pivot table of subjects, displayed by the number of queries per subject for each sender-recipient and query status.

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Query Response	Use this sheet to view the details on query response time. • Filters: Study, Country, Site, and Subject • KPI - Avg Days Open to Answered: Displays the average number of days from when a query was opened to when it was answered in large blue font. - Avg Days Answered to Closed: Displays the average number of days from when a query was answered to when it was closed in large blue font. • Query Open to Answered: A bar chart displaying the average number of days a query went from Open to Answered by site. The red line identifies the average for the study(s) and adjusts based on your selected filter. - X-axis: Site - Y-axis: Avg Days Open to Answered • Average Response in Days by Site Over Time: A line chart displaying the average response in days by site. Enter the number of months into the Enter graph timeframe textbox to see relevant data based on the value entered. - X-axis: Months - Y-axis: Average Response in Days - Legend to the right indicates site number by color. • Queries by Open to Answered Duration: A stacked bar chart displaying the number of queries and the length of time for those queries to go from Open to Answered. Use the dropdowns on the Y-axis to adjust your view. - X-axis: # of Queries - Y-axis: Site, Country, or Study AND Open to Answered Duration, Country, or Study - Legend to the right of the chart indicates Open to Answered Duration by color.

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Protocol Deviations – Overview	Use this sheet to find details related to subjects who had protocol deviations. • Filters: Study, Country, Site of Deviation, Group Assignment, Severity, Class, and Subject • PD Severity Variable Buttons: Major or Minor – Switch between the Major and Minor variable buttons to customize your view. • Enter a value into the # of Major PDs/Subject (>=) threshold field to filter by threshold value and quickly identify outliers. • KPIs - # of PDs/Subject: Displays the number of protocol deviations per enrolled subject in large blue font. - # of Major PDs/Subject: Displays the number of major protocol deviations per enrolled subject in large blue font. - # of Minor PDs/Subject: Displays the number of minor protocol deviations per enrolled subject in large blue font. • Protocol Deviations by Site: A combo chart displaying the # of PDs (indicated by red diamonds) and # of PDs/Subject (number of PDs divided by the number of enrolled subjects; indicated by blue bars) by Site of Deviation or Current Site. - X-axis: Site of Deviation, Current Site - Y-axis: # of PDs/Subject (indicated by blue bars) and # of PDs (indicated by red diamonds) • Protocol Deviations Over Time: A line graph displaying the # of PDs or # of PDs/Subject by Date or Visit (including a 'missing' category for protocol deviations not attached to a visit). - X-axis: Date or Visit - Y-axis: # of PDs or # of PDs/Subject • Class, Form, Field, and Protocol Deviations by Site: A stacked bar chart displaying the number of protocol deviations by Site of Deviation, Current Site, Form, Field, or Protocol Deviation AND Class, Current Site, Form, Field, or Protocol Deviation. - X-axis: # of PDs - Y-axis: Site of Deviation, Current Site, Form, Field, or Protocol Deviation AND Class, Current Site, Form, Field, or Protocol Deviation - Legend to the right of the table indicates Site of Deviation by color. • Listing Table: Protocol Deviations

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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, Group Assignment, and Subject • Eligible vs. Ineligible Subjects (%) with PDs: A stacked bar chart displaying the percentages of subjects by site who were eligible or ineligible. - X-axis: % of Subjects - Y-axis: Eligibility or Current Site AND Site of Deviation or Current Site - Legend to the right indicates Eligibility (Yes or No) by color. • PD Subjects: A bar chart displaying the number of subjects by site with a PD. - X-axis: # of Subjects - Y-axis: Subject has PD? or Current Site AND Site of Deviation or Current Site • Listing Table: Protocol Deviations
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, Group Assignment, and Subject • Rate, Sorting, and Reference line by Variable Buttons: AEs or SAEs – Switch between the Major and Minor variable buttons to customize your view. • # of AEs/Subject (>=) threshold entry textbox: Enter a value to quickly identify outliers. • KPIs - # of AEs & SAEs Per Subject: Displays the number of AEs per enrolled subject (in large blue font) and the number of SAEs per enrolled subject (in small red font). - # of AEs & SAEs: Displays the number of reported AEs (in large blue font) and SAEs (in small red font). • # of AEs & SAEs Per Subject: A bar chart displaying the # of AEs/Subject and # of SAEs/Subject reported by site as well as the # of enrolled subjects by site. The red line identifies the median AEs or SAEs per subject across the study(s) and adjusts based on your filters. • Subject, Event, or Unresolved Ratio: A bar chart displaying the number of screened subjects, number of enrolled subjects, number of subjects with AEs (or the number of AEs or the number of unresolved AEs), and the number of subjects with SAEs (or the number of SAEs or the number of unresolved SAEs) by site. Customize your view by switching between the variable buttons: Subject, Event, or Unresolved. - X-axis: Site - Legend to the right indicates # of Screened Subjects, # of Enrolled Subjects, # of AE Subjects (or # of AEs or # of AEs Unresolved), and # of SAE Subjects (or # of SAEs or # of SAEs Unresolved) by color. • Listing Table

.Sheet	Information included
Time to SDV and Details	Use this sheet to view metrics related to Source Data Verification. • Filters: Study, Country, and Site • Enter a threshold for the Average Days to SDV to quickly identify outliers. • KPIs - Avg Days to SDV: Displays the average number of days from initial entry to Source Data Verification in large blue font. - Enrolled Subjects: Displays the count of enrolled subjects in large blue font. • Initial Entry to Verification: A combo chart displaying the number of subjects enrolled and the average number of days between initial entry of the data to SDV by Site. - X-axis: Site - Y-axis: # of Enrolled (indicated by blue bars) and Avg # of Days (indicated by red diamonds) • Listing Table
Timeliness	Use this sheet to view various metrics related to source data. • Filters: Study, Site, Subject, and Audit Action Type • Average Days from Initial Entry to Review: A combo chart displaying 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. Blue bars indicate Enrolled Subjects, red diamonds indicate Review Action. - X-axis: Site, Form, Subject, Folder, Study, or Field - Y-axis: Enrolled Subjects (left) and Review Action (right) • Average Days from Initial Entry to Verification: A combo chart displaying 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. Blue bars indicate Enrolled Subjects, red diamonds indicate Verification Action. - X-axis: Site, Field, Study, Folder, Form, or Subject - Y-axis: Enrolled Subjects (left) and Verification Action (right) • Average Days from Initial Entry to Query Open: A combo chart displaying 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. Blue bars indicate Enrolled Subjects, red diamonds indicate Query Open Action. - X-axis: Site, Study, Field, Subject, Form, or Folder - Y-axis: Enrolled Subjects (left) and Query Open Action (right) • Audits by Audit Date: A line graph displaying 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. - X-axis: Audit Time Stamp (Year) -> Month, Subject, Study, Form, Folder, or Field AND Site, Subject, Study, Form, Folder, or Field - Y-axis: # of Audits - Legend to the right of the table indicates Site number by color.

.Sheet	Information included
Post SDV and Post Query Changes	Use this sheet to view various metrics related to post source data verification and post query changes as detailed below. • Filters: Study, Site, Subject, and Audit Role • Data Changes After SDV: A bar chart displaying the number of data changes made after SDV by Site, Form, Subject, Folder, Study, or Field. Use the drop-down on the Y-axis to switch between these options. - X-axis: # of Changes After Verification - Y-axis: Site, Form, Subject, Folder, Study, or Field • Query Actions After SDV: A bar chart displaying the number of queries that occurred after SDV by Site, Form, Study, Field, Subject, or Folder. - X-axis: # of Queries After Verification - Y-axis: Site, Form, Study, Field, Subject, or Folder • Number of Queries Resulting in a Data Change: A bar chart displaying the number of queries resulting in a data change (or number of subjects) by Site, Field, Study, Subject, Form, or Folder. - X-axis: # of Queries Resulting in a Data Change or # of Subjects - Y-axis: Site, Field, Study, Subject, Form, or Folder • Number of Queries Resulting in a Data Change by Role: A combo chart displaying the number and percentage of data changes by role. Blue bars indicate # of Data Changes, red diamonds indicate % of Data Changes. - X-axis: Role - Primary Y-axis: # of Queries Resulting in a Data Change - Secondary Y-axis: % of Queries Resulting in a Data Change

.Sheet	Information included
Data Changes	Use this sheet to view information related to folders, forms, fields, and sites with data changes. • Filters: Study, Country, Site, Form, Field, and Subject • KPIs - Enrolled Subjects: Displays the number of subjects enrolled (in large blue font) and the number of data changes (in small red font). - Data Changes per Site: Displays the number of data changes divided by the total number of sites (in large blue font) and the total number of sites (in small red font). - Data Changes / Data Points Entered: Displays the number of data changes after initial entry divided by the number of data points entered (in large blue font) and displays the total number of data points entered (in small red font). • Studies or Sites with Changes: A combo chart displaying the number of changes after initial entry (indicated by blue bars) and the number of subjects (indicated by red diamonds) by study or site. - X-axis: Study or Site - Y-axis: # of Changes After Initial Entry (left) and # of Subjects (right) • Forms or Folders with Changes: A combo chart displaying the number of changes after initial entry (indicated by blue bars) and the number of subjects (indicated by red diamonds) by form or folder. - X-axis: Form or Folder - Y-axis: # of Changes After Initial Entry (left) and # of Subjects (right) • Data Changes Over Time: A line chart displaying the data changes over time by Month-Year, Study, Country, Folder, or Form AND Site Number, Study, Country, Folder, or Form. Enter the number of months in the Enter graph timeframe textbox to view relevant data to the entered value. - X-axis: Month-Year, Study, Country, Folder, or Form AND Site Number, Study, Country, Folder, or Form - Y-axis: Data Changes Legend to the right of the chart indicates Site Number by color. • Fields with Changes: A bar chart displaying the number of changes made after initial entry by form. - X-axis: # of Changes After Initial Entry - Y-axis: Form and Field - Legend to the right of the chart indicates Form by color.

.Sheet	Information included
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 treemap chart displaying the reason for the change broken out by site and the number of data changes (per site). - The size of the box is proportional to the count. Legend to the right of the chart indicates Site number by color. • Audits by User: A treemap chart displaying the number of audits by a user. - The size of the box is proportional to the count. • Audits by Action Type: A stacked bar chart displaying the number of audits by the Action Type, Folder, Form, Field, Subject, or Study AND Site, Folder, Form, Field, Subject, or Study. Use the dropdowns on the Y-axis to switch between these options. - X-axis: # of Audits - Y-axis: Site, Folder, Form, Field, Subject, or Study AND Action Type, Folder, Form, Field, Subject, Study - Legend to the right of the chart indicates site number by color.
Application Information	Use this sheet to view application information for Clinical Trial Operational Analytics. • Application Name • What's New Listing: Version Number and Features • Data Last Refresh Listing: Study, Schema Name, Domain Name, and Data Last Refresh • Glossary Table: KPI and Description • Link to SDTM Standards • Links to Support Contact and Version Information