CTMS Insights Application 22.3
Sheet Descriptions Table

There are 30 standard public sheets in this version.

Sheet	Information included
Home Page	Use this sheet to view the overall count of studies in each status plus potential warning messages. Warning messages reflect potential issues within the study data, for example, "The Final Protocol is Behind Schedule by # of days." Studies are categorized into four statuses, Planning, Active Pre-Enrollment, Active Enrollment, and Completed. Use the filters to view more focused data. • Filters: Protocol ID, Protocol Name, Program, Therapeutic Area, Phase, Investigational Product, and Indications. • Listing Table: Protocol Status Info
Study Overview	This sheet displays high-level status and metrics of CTMS studies for reporting and presentation purposes. Only one study at a time can be displayed. You can filter studies by Protocol Id. • Filters: Protocol ID, Protocol Name, Program, Therapeutic Area, Phase, Investigational Product, Indications, Country, and Site • Site Status: Displays a study's Investigator Site Status. • Site Subject Status: A horizontal bar chart displaying the count of subjects by site and site subject status. • Patient Enrollment Data: Number of subjects by Site, or Country (use the drop-down arrow on the Y-axis), with each color showing how many subjects were enrolled or screened (use the drop-down arrow on the X-axis. • Site Milestone Progress: A vertical bar graph where each bar displays as a % of how many sites have met their milestones (meaning the actual date is populated) for each of the following milestones: IRB Submission, IRB Initial Approval, Site Initiation Visit, First Subject In, Last Subject In, Last Subject Out, Data Cleaning Completed, and Closeout Date. • Site Milestone Progress (Table): A table depicting the same data from the Site Milestone Percentage chart but in table form. • Major Milestones: This table displays the following site milestones (baseline, planned, and actual): Final Protocol Date, First Site Activated, First Subject Screened, First Subject In, Last Subject Out, Last Site Closure, Final DBC, Database Lock Date, First Results In, and CSR. • Subject and Site Metrics: This table displays the following subject and site metrics (baseline, planned, and actual): Screened Subjects, Number of Screen Failures, Screening Failure Rate (%), Enrolled Subjects, Number of Subjects Completed, Number of Subjects Discontinued, Investigator Sites, Number of Sites Activated, and Number of Countries.

Sheet	Information included

Enrollment	This sheet is used to view enrollment metrics by Protocol Id, Country, and Site.
	
	• Filters: Protocol ID, Country, and Site
	• 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: Displays the number of subjects enrolled (blue bar) and the percentage of subjects enrolled (red diamond) out of the number screened at that site.
	• Enrollment Details: Number of subjects by Site each color showing how many subjects were screened and enrolled.
	• Listing Table

Enrollment Trend	Use this sheet to view planned / actual enrollment and cumulative enrollment trends by site and country. Data is displayed for one study at a time.
	
	• Filters: Protocol ID, Country, and Site, Country
	• 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
	• Planned vs Actual Totals by Site: A bar chart of the planned vs actual enrollment, broken out by site.
	• Planned vs Actual Enrollment by Country: A bar chart of the planned vs the actual number of enrolled subjects, broken out by country.

Sheet	Information included

Protocol Deviations	Use this sheet to find details related to subjects who had protocol deviations.
	
	• Filters: Protocol ID, Country, Site, Category, 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 (number of PDs divided by the number of screened subjects).
	
	• Protocol Deviations Over Time: A line graph showing the number of PDs or PD rate by date.
	
	• Category and Protocol Deviations by Site: A bar chart showing the number of protocol deviations by Site, Protocol Deviation, and Category.
	
	• Listing Table: Protocol Deviations Data

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.
	
	• Filters: Protocol ID, Country, and Site
	
	• KPIs
	  - Study Planned vs Actual Enrollment by Country or Site
	  - Screen Failed vs Screened subjects per Site, Country, or Study
	
	• Listing Table

Site Monitoring	Use this sheet to view a highlight of site related metrics supporting site monitoring activities. You can filter studies by protocol Id, country, and metrics values. • Filters: Protocol ID, Protocol Name, Country, and Site Site performance metrics: • Site Milestone: A grid displaying ERB Submission ERB Initial Approval, Site Initiation Visit, First Subject In, Last Subject In, Last Subject Out, Data Cleaning Completed, Closeout Date (view full screen and scroll to see all columns). • Investigator Performance: A grid displaying Investigator Name, Protocol ID, Site, Experience Rating, Experience Notes, Protocol Deviation, and Notes. Sites Utilization Map: an interactive map presenting a map where each of the sites and countries is identified • Site Utilization: A grid displaying Protocol ID, Site and Utilized Y/N.

Sheet	Information included

CTMS Metrics	This sheet is used to view key summary information and metrics across CTMS studies. You can filter the data by Protocol Id, Country, and Site.
	• Filters: Protocol ID, Country, and Site
	• Subject Status: A bar chart displaying statuses of Screened, Screen Failed, Enrolled, Discontinued, and Completed).
	• Site Initiation Status: A bar chart displaying statuses of Planned, Initiated, Non Performing, and Closed
	• KPIs
	  - Total Screened Subjects
	  - AE Rate
	  - Screening Progress
	  - Screen Failure Rate
	  - PD Rate
	  - Enrollment Progress
	  - Enrollment Rate
	  - Completion Progress
	  - Discontinued Rate

Study Milestone Calendar	This sheet displays all study milestones along with the planned and actual date of each milestone. A protocol must be selected. • Filters: Protocol ID, Protocol Name, Program, Therapeutic Area, Phase, Investigational Product, and Indications • Protocol Milestones Calendar: Select to view Milestone(s) and Month-Year(s). • Listing: Protocol Milestones. A listing of the main data points .
Site Milestones Calendar	This sheet displays all site milestones along with the planned and actual date of each milestone. A protocol must be selected. • Filters: Protocol ID, Protocol Name, Program, Therapeutic Area, Phase, Investigational Product, Indications, Country, and Site • Site Milestones Calendar: Select to view Milestone(s) and Month-Year(s). • Listing: Site Milestones. A listing of the main data points.

Sheet	Information included
KPI Summary	Use this sheet to review the actuals vs. targets for the following Study Performance Indicators. Select one protocol. • Study Related: First Site Active, Protocol Deviations • Site Related: First Active, Investigator, Active Count, Non-Performing • Subject Related: Screened, Screen Failure, Enrollment, Completed, Discontinued • Filters: Protocol ID, Protocol Name, Program, Therapeutic Area, Phase, Investigational Product, Indications, Country, and Site Visualizations within the sheet: • Visual #1: KPI that shows the First Site Active Actual and Planned. A protocol needs to be selected for this KPI to show. • Visual #2: Bar gauge that shows Investigator Sites Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #3: Bar gauge that shows Active Sites Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #4: Bar gauge that shows Non-Performing Sites Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #5: Bar gauge that shows Screened Count Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #6: Bar gauge that shows Screened Failures Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #7: Bar gauge that shows Failure Rate Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #8: KPI that shows the total number of Protocol Deviations. • Visual #9: Bar gauge that shows Enrolled Count Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #10: Bar gauge that shows Enrollment Rate Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #11: Bar gauge that shows Completed Count Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Visual #12: Bar gauge that shows Discontinued Count Planned and Actual count. Actual is represented as the inside bar, planned is represented as a black bar. • Listing Table: Protocol Info

Listing Sheets	Information included
Studies Regulatory Submissions Milestone Sites Clinical Development Plan Comparator Products Study Management Comm Notes Personnel Countries Investigators IRB Preferred Provider Investigational Products Database Cuts Study Site Dev Partner Study Participation Programs	Data displayed in listing sheets reflect data entered or imported into elluminate's CTMS Insights module.
Schedule of Assessment	Use this sheet to review the Timepoints defined for a study and the corresponding events that occur within that timepoint. A protocol must be selected. • Filters: Protocol ID, Protocol Name, SoE Version, SoE Timepoint, SoE • Event, and SoE Value
Application Information	• App Name • Listing of What's New: details of version and features • Glossary table with details of KPI name and description • Support Contact Information • App Version, Deployed date, Published date, and type of last reload