

Operational Oversight Application 24.1 Sheet Descriptions Table

There are 14 standard public sheets in this version.

Sheet	Information included
Home Page	<p>This is the landing page for Operational Oversight, which displays high-level summary metrics from operational data repository tables.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Key Performance Indicators (KPIs): Enrollment Rate, Screen Failure Rate, Subjects Enrolled, and Activated Sites • Bar Chart: Count of Studies by Phase
Studies by Life Cycle	<p>Use this sheet to see the overall count of studies in each status as well as 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.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, Site, and Study Status • The top listing is broken out by Study Status. Click on each tab to see the studies pertaining to each status. • Key Performance Indicators (KPIs): Planning, Active Pre-Enrollment, Active Enrollment, and Completed • Listing Table: Protocol Status Info
Study Overview	<p>Use this sheet to view the high-level status and metrics for ODR studies for reporting and presentation purposes. For some charts, only one protocol can be displayed at once.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Graphs (use the scroll bar to see all charts) <ul style="list-style-type: none"> - Site Status - Site Subject Status - Patient Enrollment Data: Use the x-axis drop-down to view by Enrolled or Screened - Site Milestone Progress • Cross Tabulations <ul style="list-style-type: none"> - Major Milestones - Subject and Site Metrics - Site Milestones Progress

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Enrollment Summary	<p>Use this sheet to view enrollment metrics by Protocol Id, Country, and Site.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Key Performance Indicators (KPIs): Sites, Total Planned Enrollment (select one protocol), Subjects Screened, Screen Failure Rate, and Days Since Last Patient Screened • Bar Charts: Enrollment Summary and Enrollment Details • Listing Table
Enrollment Trend	<p>Use this sheet to view planned / actual enrollment and cumulative enrollment trends by site and country.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Key Performance Indicators (KPIs): # Planned Enrollment # Actual Enrollment Enrollment Rate (select one protocol), Min Site Enrollment, Median Site Enrollment, and Max Site Enrollment • Bar Charts: Planned vs Actual Enrollment by Site and Planned vs Actual Enrollment by Country
Protocol Deviations	<p>Use this sheet to view high-level data relevant to subjects who had protocol deviations.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, Site, and Severity • Display Threshold: Enter the threshold (Sites with Rate $\geq n$) • PD Rate • Bar Graphs <ul style="list-style-type: none"> - Protocol Deviations by Site - Category and Protocol Deviations by Site: use the y-axis drop-downs to view by Protocol Deviation or Site, and Site or Category • Line Graph: Protocol Deviations Over Time: use the y-axis drop-down to view by # of PDs or PD Rate; use the x-axis drop-down to view by Date Began or Date Recorded • Listing Table: Protocol Deviations Data

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Recruitment and Retention	<p>Use this sheet to monitor enrollment metrics based on thresholds the user 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 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.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Gauge Charts: Country Count Planned vs Actual, Site Count Planned vs Actual, Enrollment Planned vs Actual, Screen Failed vs Screened, and Discontinued vs Enrolled • Enter target thresholds to highlight problem areas with recruitment: Planned Enrollment Target % (\geq) and Action Required Threshold % (\leq) • Enter target thresholds to highlight problem areas with retention: Discontinued on Target % (\leq) and Action Required Threshold % (\geq) • Listing Table
Site Monitoring	<p>Use this sheet to highlight site-related metrics to support site monitoring activities.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Cross Tabulation: Site Milestone (select one protocol) • Listing Tables: Investigator Performance and Sites Utilization • Sites Utilization Map
KPI Summary	<p>Use this sheet to review the actuals vs. targets for the following Study Performance Indicators. Select one protocol.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Key Performance Indicators (KPIs): First Site Active / Planned and Protocol Deviations • Bullet Charts: Investigator Sites, Active Sites, Non-Performing Sites, Screened Count, Screen Failures, Failure Rate, Enrolled Count, Enrollment Rate, Completed Count, and Discontinued Count • Listing Table: Protocol Info
Study Progression Metrics	<p>Use this sheet to view key summary information and metrics across ODR studies. You can filter the data by Protocol Id, Country, and Site.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Bar Graphs: Subject Status and Site Initiation Status • Gauge Charts: Screening Progress, Enrollment Progress, and Completion Progress • Key Performance Indicators (KPIs): Screen Failure Rate, Enrollment Rate, Discontinued Rate, Total Screened Subjects, AE / SAE Rate, and PD Rate / Major/Minor PD Rate

Sheet	Information included
Study Milestone Calendar	<p>Use this sheet to view Protocol related Milestones in calendar form.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Protocol Milestones Calendar (select one protocol) • Listing Table: Protocol Milestones
Site Milestone Calendar	<p>Use this sheet to display all site related milestones along with the planned and critical date of each milestone.</p> <ul style="list-style-type: none"> • Filters: Repository, Inv. Product, Clinical Development Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Site Milestones Calendar (select one protocol) • Listing Table: Site Milestones
Clinical Development Plan	<p>Use this sheet to monitor Clinical Development Plan milestone progress across multiple criteria.</p> <ul style="list-style-type: none"> • Filters: Repository, Milestone, Inv. Product, Clinical Dev Plan, Therapeutic Area, Indication, Program, Protocol ID, Country, and Site • Cross Tabulation: Clinical Development Plan Milestones
Application Information	<p>This sheet displays the following sections:</p> <ul style="list-style-type: none"> • Application Name • What's New • Glossary • Data Refresh Details • Sheet Info • Link to SDTM Standards • Support Contact Information • Last Reload Details • Version Details