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Version	Effective Date	Summary of Changes
4.0	06-March-2026	Removed all references to the 360 Enrollment Tracking Dashboard.
3.0	22 October 2025	Updated section 3 <i>Accessing Rave Reports</i> , section 9 <i>Report Help</i> , section 12 <i>360 Enrollment Tracking Dashboard</i> , and section 13 <i>360 Query Management Dashboard</i> to reflect the updated Medidata user interface. Updated DMACC to DMASC throughout the document. Minor editorial updates were made throughout the document for clarity.
2.0	26 March 2025	Updated section 3 <i>Accessing Rave Reports</i> and section 10 <i>eLearning</i> to reflect the updated Medidata user interface. Minor editorial updates were made throughout the document for clarity.
1.0	02 February 2023	Converted to USRMAN03, formerly REFGD010. Updated all sections.

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1. INTRODUCTION AND PURPOSE

This document provides an overview of Medidata Rave (Rave) reports that CP-CTNet Lead Academic Organization (LAO) and Affiliated Organization (AO) staff may find useful for quality assurance and internal performance review. The initial sections detail functions that are common to many reports in Rave. Each report overview includes a description, instructions for general use, and examples of how the report can be used to support CP-CTNet clinical trials.

2. DEFINITIONS

Term	Definition
AO	Affiliated Organization
AQuIP	Accrual Quality Improvement Program
CRF	Case Report Form
.csv	Comma-Separated Values File
DM	Data Manager
DMASC	Data Management, Auditing, and Statistical Center
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
Environment	An area in a Rave study that enables study administrators to fine-tune a study before moving it to production. Each environment in a study has its own unique dataset and inventory control, as well as users and sites. Most site users work exclusively in the production study environment to enter and manage study data. Some studies and sites use non-production testing and training environments to train site users in Rave.
PROD	Production
Query	Individual questions, generally written to request clarification of discrepancies in study data. These questions must be addressed within a project-specific timeline (e.g., 14 days).
SAS	Statistical Analysis System: a statistical software suite developed by SAS Institute for data management, advanced analytics, multivariate analysis, business intelligence, criminal investigation, and predictive analytics.
Sticky Note	A reminder and a means of communication with another user. It is used in the same way a sticky note or a Post-it® would be used on a paper-based study. The user can acknowledge that they viewed and understand the reminder in Rave, but sticky notes are not held to the strict response times enforced for queries.
.txt	Text File

3. ACCESSING RAVE REPORTS

1. Reports are located in the *Reporter* module of Rave. To access the *Reporter* module, the user:
 - 1.1. Logs into Medidata and selects **CP-CTNET** from the *Study groups* dropdown at the top of the Medidata homepage.



Figure 1: Study groups dropdown at the top of the Medidata homepage.

- 1.2. Selects **Rave EDC** under the CP-CTNET container.



Figure 2: Rave EDC under the CP-CTNET container.

- 1.3. Selects the appropriate role from the *Role Selection* dropdown and clicks the **Continue** button.



Figure 3: Role Selection dropdown.

Note: If only one role is assigned, this dropdown is not displayed. Proceed to step 1.4.

- 1.4. Selects **Reporter** from the *Installed Modules* list in the sidebar on the left.

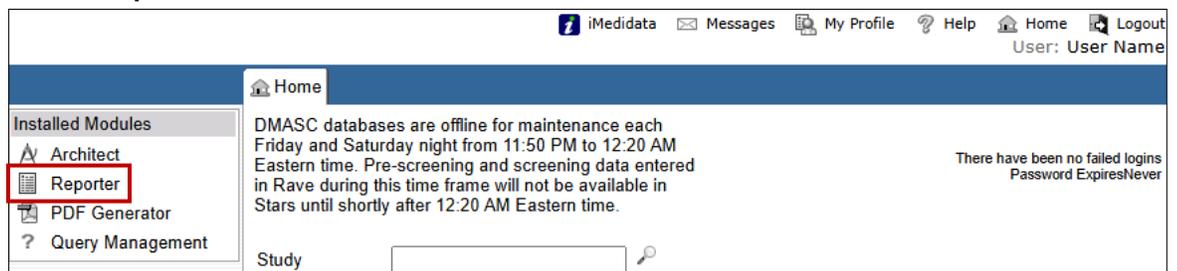


Figure 4: Installed Modules list.

Rave reports are available for selection in the *My Reports* list. The reports that are available vary depending on the user's permissions and whether the user has created any customized reports.

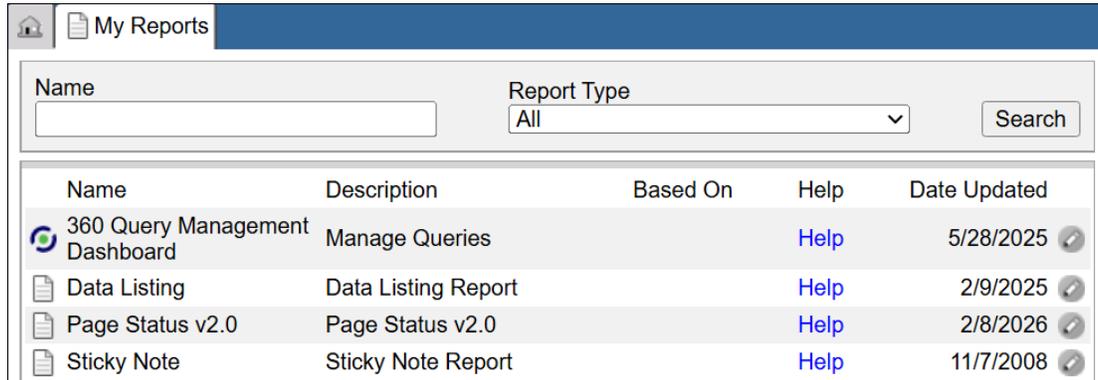


Figure 5: My Reports list.

4. SETTING PARAMETERS

All Rave reports include *Report Parameters* that users can set to customize the report output. The parameters that are included vary based on the report. Bolded parameters must be set before saving or submitting the report. To set criteria for a parameter, the user clicks the **arrow icon** to the right of that parameter (e.g., *Sites*).

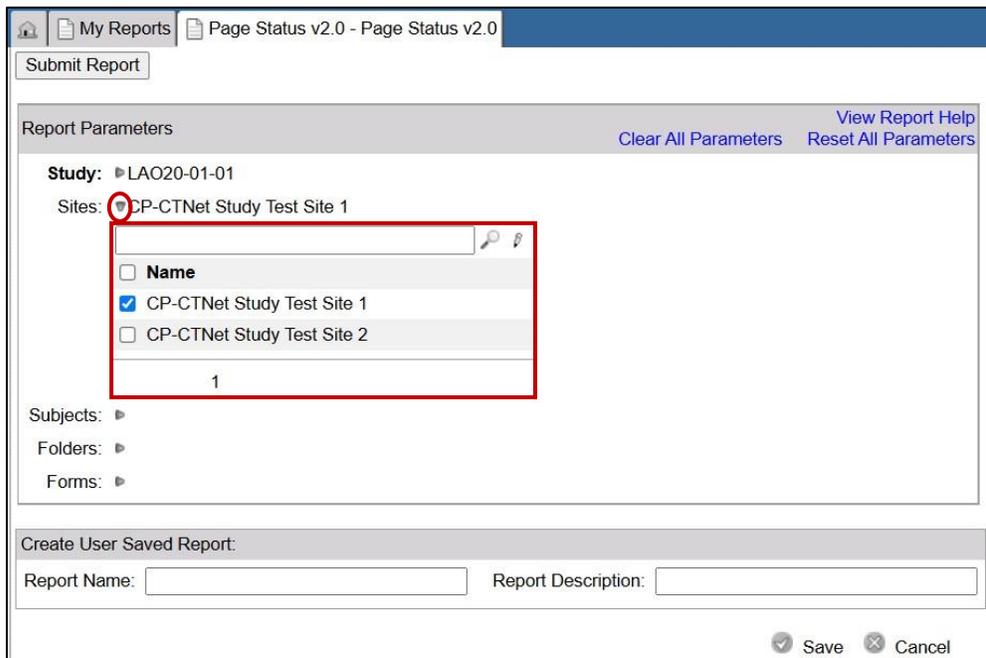


Figure 6: Report parameters interface.

Parameters are listed from broadest to narrowest. When the user selects criteria for a broad parameter (e.g., *Study*), this populates the next parameter in the list with criteria appropriate to all previously set parameters and the user's access permissions. Thus, to narrow down a report's output, the user must set each parameter in order, moving from the topmost level down to the desired level of granularity.

5. TABLE OF PARAMETERS

The following table includes definitions for all parameters listed in this document.

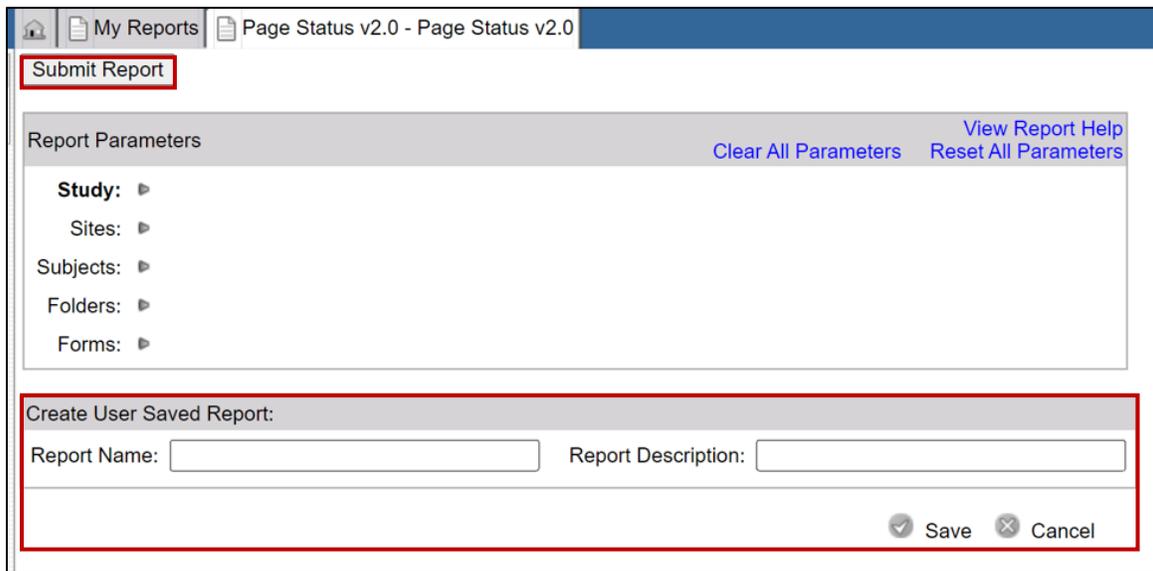
Parameter	Definition
<i>Fields</i>	A data collection field on an eCRF.
<i>Folders</i>	A folder name. This usually corresponds to a study visit.
<i>Forms</i>	An eCRF name.
<i>Marking Groups</i>	The group from whom the query is sent. Includes: <ul style="list-style-type: none"> • <i>Site from DM</i> (a manual query sent by the DM at DMASC) • <i>Site from System</i> (an automatic query sent by the system, usually resulting from an edit check) • <i>Site from Auditor</i> (a manual query sent by the Auditor) • <i>Site from LAO</i> (a manual query sent by the LAO) • <i>Site from DCP</i> (a manual query sent by DCP)
<i>Query Status</i>	The status of the query* (an individual question that requests clarification of discrepancies in study data) being retrieved. Includes: <ul style="list-style-type: none"> • <i>Open</i> (the site has not responded to the query) • <i>Answered</i> (the site has responded to the query) • <i>Closed</i> (the site has responded to the query and the DM has accepted the response and closed the query) • <i>Canceled</i> (the DM has canceled the query before the site responded)
<i>Roles</i>	The role that a user has within the Rave system (e.g., Clinical Research Coordinator - IVRS).
<i>Site Group</i>	An administrative grouping for sites; if the user has access to only one site, this parameter may not display. CP-CTNet only uses the “World” Site Group.
<i>Sites</i>	The name of a site (accruing LAO or AO). Note: LAO Administrative Team staff can see all sites for the study, while accruing LAO/AO staff can only see their own site.
<i>Start/End Date</i>	The beginning and ending of the date range for which data should be retrieved.
<i>Sticky Status</i>	The status of the sticky note* (a reminder and a means of communication with another user in Rave) being retrieved, which includes: <ul style="list-style-type: none"> • <i>Placed</i> (the user or system has placed the sticky note on an eCRF) • <i>Acknowledged</i> (the user has checked the box to acknowledge the sticky note)
<i>Study</i>	A protocol number; this is always paired with an environment* (e.g., production, testing, or training environment).
<i>Subject</i>	A Participant Identification Number.
<i>User</i>	A Rave user. These are always sorted in alphabetical order by first name.

***Note:** See the Definitions Table in Section 2 for more information.

6. SAVE OR SUBMIT REPORTS

For most Rave reports, the interface allows users to save and submit the report.

1. **Save:** Selecting **Save** stores the report parameters that the user selected and allows the user to generate the report again later with the same parameters. To save the report with customized parameters, the user enters a descriptive name in the *Report Name* field, completes the *Report Description* field, and selects **Save** on the bottom right. The report appears in the user's list of available reports under the descriptive name entered by the user.
2. **Submit:** To generate the report with the selected parameters, the user scrolls up and selects the **Submit Report** button on the top left.



The screenshot shows a web application interface. At the top, there is a navigation bar with a home icon, a 'My Reports' tab, and a page title 'Page Status v2.0 - Page Status v2.0'. Below the navigation bar, a 'Submit Report' button is highlighted with a red box. The main content area is titled 'Report Parameters' and contains several dropdown menus: 'Study:', 'Sites:', 'Subjects:', 'Folders:', and 'Forms:'. To the right of these menus are two links: 'Clear All Parameters' and 'View Report Help Reset All Parameters'. Below the 'Report Parameters' section, there is a 'Create User Saved Report:' section, also highlighted with a red box. This section contains two text input fields: 'Report Name:' and 'Report Description:'. At the bottom right of this section are two buttons: 'Save' (with a checkmark icon) and 'Cancel' (with an 'X' icon).

Figure 7: Create User Saved Report interface and Submit Report button.

7. DRILLING DOWN

Several reports include a “drill down” feature, meaning that they allow users to navigate through various levels of detail within the report output. For example, if the user selects the row for their site, new rows appear for each participant at their site for the selected study. The user continues selecting row headers until they reach the desired level. The user may also navigate through these levels using the tabs at the top of the report or the dropdown arrow at the right.

	Total Counts					Queries		Pages Requiring Action								
	Expected Total	Expected To Date	Entered	Over due	Verified	Reviewed	Entry Locked	Open	Answered	Verify	Review	Translate	Coding	Sign	Entry Lock	Lock
Anytown University Hospital CRS - World	1832	1752	1812	96	0	0	0	64	62	0	0	0	0	0	0	0
111111	117	116	116	6	0	0	0	0	0	0	0	0	0	0	0	0
Screening	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Participant Enrollment	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
A9999 - PROD	110008	107473	105917	7806	0	0	0	620	1	0	0	0	0	0	0	0

Figure 8: Drill down feature on the Page Status Report v2.0.

8. EXPORTING REPORTS

Most reports can be exported to PDF or Excel. Once the user has generated the report using *Submit Report*, the export options appear at the top of the screen. The user selects the desired format (*PDF*, *Excel*, or *Excel - data only*) from the *Export To:* dropdown menu. The *Excel* format option includes formatting designed to mimic the layout of the PDF, including non-data rows and columns as well as bolding, cell shading, and the Medidata logo. The *Excel - data only* format option only contains data. For reports with a drill down feature, the user should determine whether they want to expand all levels. This means that they retrieve data for every available level of granularity. If desired, the user selects **Expand All**. When the user has set all formatting options, they select **Export** and open or save the file in the selected format.

9. REPORT HELP

Most reports have a Help file that can be accessed from the *My Reports* list. To view the Help file, the user selects the **Help** link.

Name	Description	Based On	Help	Date Updated
360 Query Management Dashboard	Manage Queries		Help	5/28/2025
Data Listing	Data Listing Report		Help	2/9/2025
Page Status v2.0	Page Status v2.0		Help	2/8/2026
Sticky Note	Sticky Note Report		Help	11/7/2008

Figure 9: My Reports list with Help links displayed.

The user can also view the Help file after submitting the report by selecting **View Report Help**. This link is on the top right, near the *Export* button.

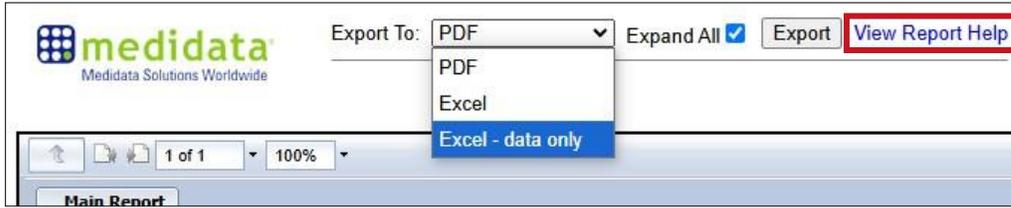


Figure 10: View Report Help link within the Page Status Report v2.0.

10. ELEARNING

Medidata offers a more complete overview of Rave reports in eLearning courses available within Medidata, including *Medidata Rave 360 Reports*, *Rave Advanced Rave EDC for Site Users*, and *Rave Reporter*.

1. To access eLearning courses, the user logs into Medidata, clicks their initials in the top right corner of the Medidata homepage, and selects **My courses** from the user menu.

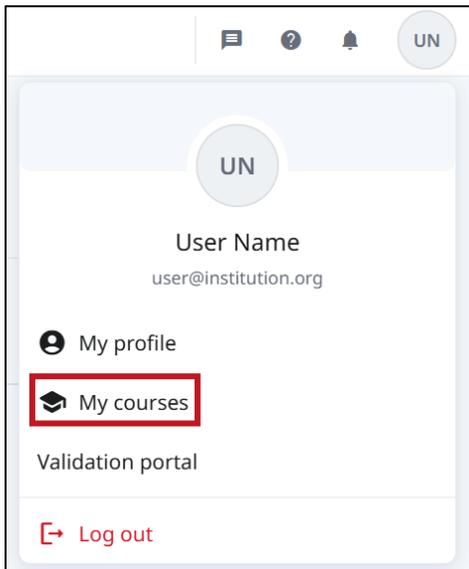


Figure 11: User menu in the top right corner of the Medidata homepage.

2. Next, the user selects the **Start** button, or the **Retake** button for courses that were previously completed, next to the desired course in the *My courses* list.

Each course concludes with a scored review activity. Upon successfully completing the review activity, the user is prompted to log in again to confirm their passing score. The user can access a certificate of completion (PDF) in the *My courses* list. The user may retake an eLearning course as many times as necessary in order to obtain a passing score. Only the final results are retained.

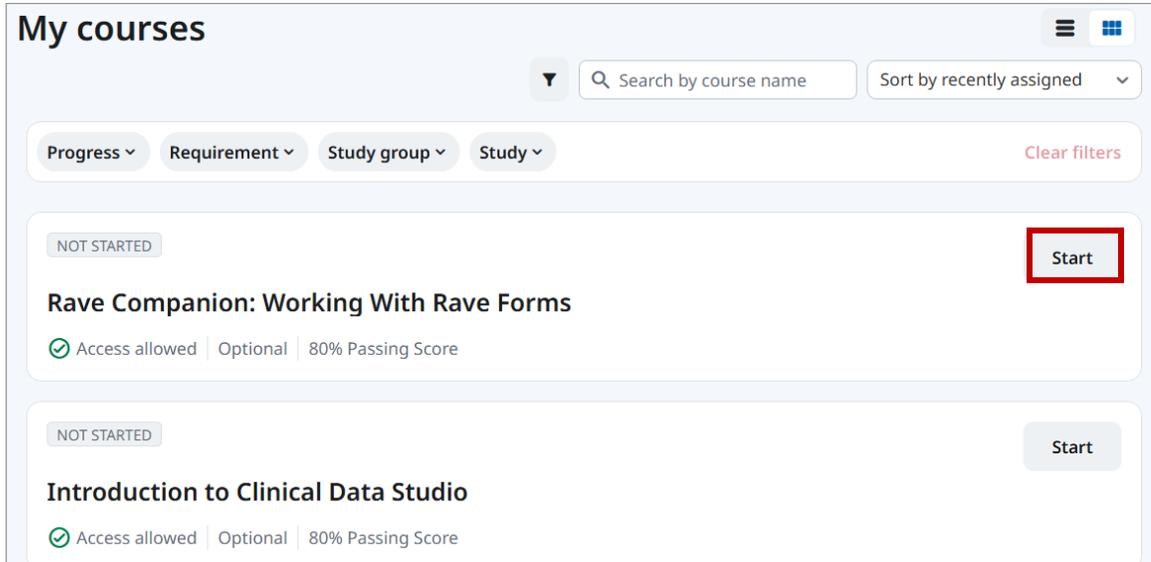


Figure 12: My courses list.

11. REPORT OVERVIEW

This table lists the reports that LAO and AO staff use for quality assurance and performance review. The remaining sections provide brief descriptions, instructions for use, and examples of how each report can be used to support CP-CTNet clinical trials.

Report Name	Purpose
<i>360 Query Management Dashboard</i>	Provides an up-to-date, detailed summary of a study's open, answered, and closed queries over time. The dashboard offers data listings and visualization tools to aid in the understanding and sharing of study query data.
<i>Data Listing</i>	Provides users with a method to browse up-to-date participant data entered into a specific eCRF in a simple, tabular format. This report generates four types of views including: <i>Clinical Views</i> , <i>Clinical Views Raw</i> , <i>Production Clinical Views</i> and <i>Production Clinical Views Raw</i> . These views are detailed in the Data Listing Report section of this guide. The tabular database views of the clinical study data can be extracted and analyzed by third-party software (e.g., SAS).
<i>Page Status v2.0</i>	Indicates how many eCRFs are <i>Expected Total</i> , <i>Expected To Date</i> , <i>Entered</i> , or <i>Overdue</i> ; how many queries are either <i>Open</i> or <i>Answered</i> ; and identifies eCRFs that require action (e.g., to be <i>Reviewed</i> , <i>Locked</i> , etc.). This report includes a drill down feature.
<i>Sticky Note</i>	Retrieves all sticky notes that a site has received, including the full text of the sticky note, date received, status, and the acknowledging user.

12.360 QUERY MANAGEMENT DASHBOARD

The 360 Query Management Dashboard provides users with an up-to-date, detailed summary of a study's open, answered, and closed queries over time. Users can view and assess total query counts and rates, overdue queries, and query cycle times. The 360 Query Management Dashboard metrics

are viewable at multiple levels of detail (e.g., study, accruing LAO or AO, eCRF, and individual query). Users can use the visualization tools to aid in the understanding and sharing of study query data and view query-level details and export them into Excel for further processing.

1. **Instructions for Use:** The user selects specific parameters to customize the report results. Once all desired parameters are selected and the report is saved (if desired), the user can submit the report and view the results by clicking **Submit Report** at the top of the page.

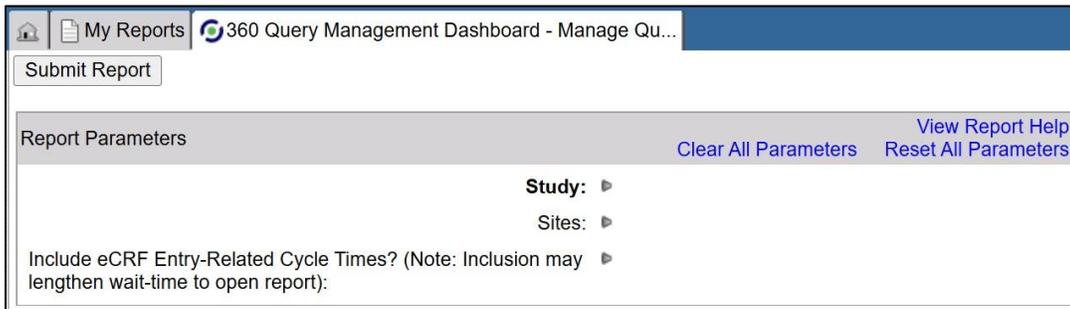


Figure 13: Report parameters for the 360 Query Management Dashboard.

2. **Navigation:** The 360 Query Management Dashboard includes eight sections, each on a separate tab within the report. To navigate between different sections of the report, the user selects the tab corresponding to the desired section. The filters at the top of the page can be clicked to display a popup window that allows the user to refine the data displayed in the dashboard by including or excluding criteria. Available filters include *Site Group*, *Country*, *Site*, *Patient Name*, *Patient Status*, *Instance Name*, *Form*, *Query Status*, *Query Type*, *Query Aging Ranges*, *Days Unresolved*, *Created*, *Resolved*, and *Answered*. Additional filter, sort, and data compare options for the dashboard visualizations are available by clicking the **Explore** button above each visualization. The visualizations are interactive. The user can hover over a data point or bar to display data details or click the arrow next to the axis labels to filter and sort the displayed data. The user can click the **ellipsis (...)** button in the upper right of the dashboard or visualization to download, present, or show the underlying data for the dashboard or visualization.
 - 2.1. **Query Summary:** Provides users with a high-level summary of the eCRF queries at each status in various levels of detail and *Query Type Distribution*, *Query Aging Range Distribution*, and *Median Cycle Times* data visualizations. The *Query Type Distribution* data visualization allows users to view counts of eCRF queries by the marking group that placed them (e.g., *DM from Site*, *Site from DCP*, *Site from DM*, *Site from Site QA*, and *Site from System*). The *Query Aging Range Distribution* data visualization allows users to view counts of unresolved queries by days unresolved (e.g., *0-5 Days*, *11-30 Days*, and *120+ Days*). The *Median Cycle Times* data visualization allows users to view queries based on the time it takes them to change from one status to another (e.g., *Entry to Close*, *Entry to Open*, *Open to Close*, *Open to Answer*, and *Answer to Close*).

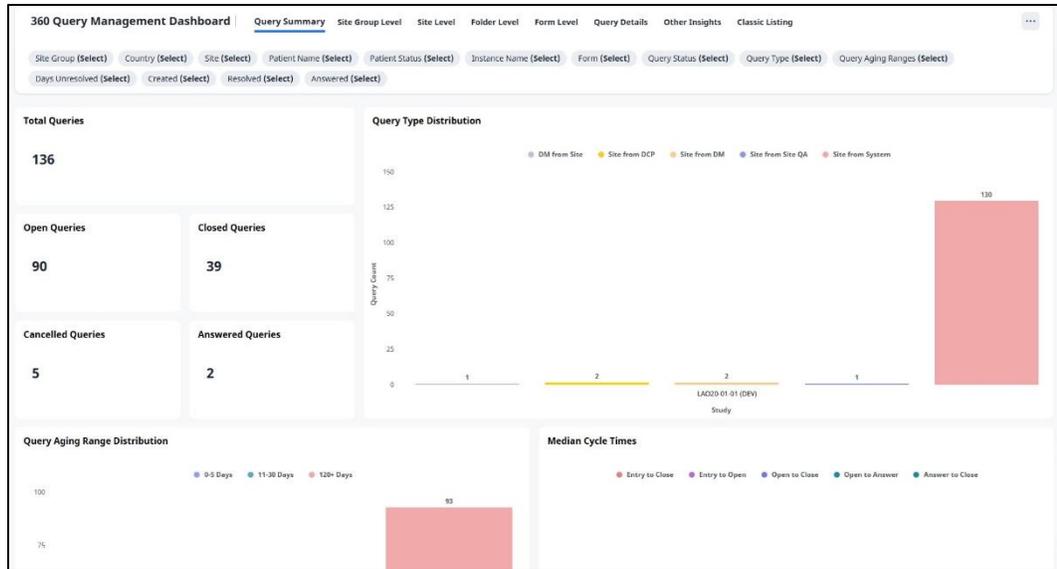


Figure 14: Query Summary tab on the 360 Query Management Dashboard.

- 2.2. **Site Group Level:** Provides users with site group-level *Query Status Distribution*, *Query Type Distribution*, *Median Cycle Times*, and *Query Aging Range Distribution* data visualizations. The *Query Status Distribution* data visualization allows users to view counts of queries by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Type Distribution* data visualization allows users to view counts of queries by the marking group that placed them (e.g., *DM from Site*, *Site from DCP*, *Site from DM*, *Site from Site QA*, and *Site from System*). The *Median Cycle Times* data visualization allows users to view queries based on the time it takes them to change from one status to another (e.g., *Entry to Close*, *Entry to Open*, *Open to Close*, *Open to Answer*, and *Answer to Close*). The *Query Aging Range Distribution* data visualization allows users to view counts of unresolved queries by days unresolved (e.g., *0-5 Days*, *11-30 Days*, and *120+ Days*).

Note: CP-CTNet only uses the “World” site group.

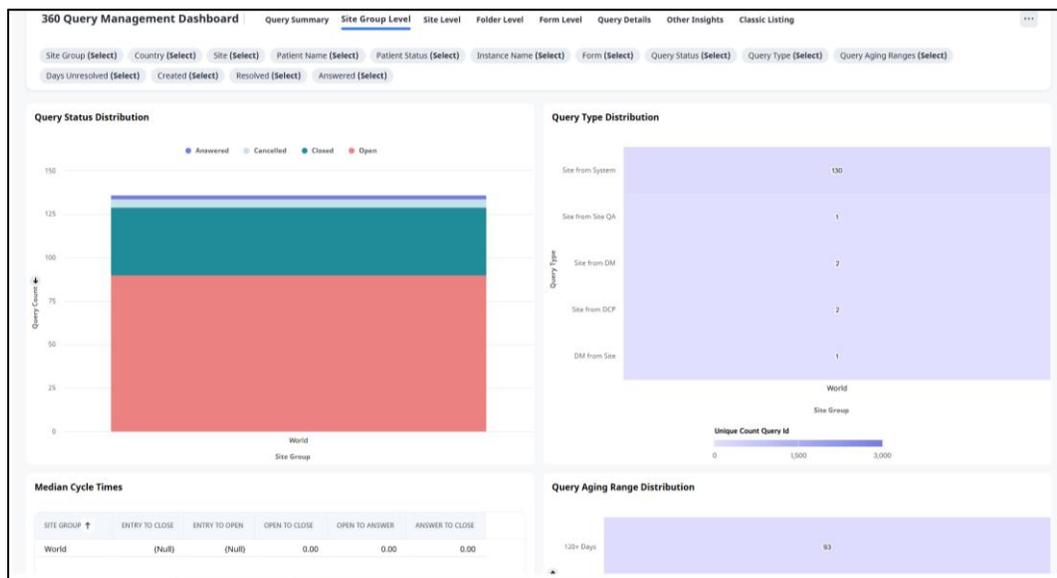


Figure 15: Site Group Level tab on the 360 Query Management Dashboard.

- 2.3. **Site Level:** Provides users with a site-level *Query Status Counts* table and *Query Status Distribution*, *Query Type Distribution*, *Query Aging Range Distribution*, and *Median Cycle Times* data visualizations. The *Query Status Counts* table allows users to view counts of queries at each site by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Status Distribution* data visualization allows users to view counts of queries at each site by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Type Distribution* data visualization allows users to view counts of queries by the marking group that placed them (e.g., *DM from Site*, *Site from DCP*, *Site from DM*, *Site from Site QA*, and *Site from System*). The *Query Aging Range Distribution* data visualization allows users to view counts of unresolved queries at each site by days unresolved (e.g., *0-5 Days*, *11-30 Days*, and *120+ Days*). The *Median Cycle Times* data visualization allows users to view queries at each site based on the time it takes them to change from one status to another (e.g., *Entry to Close*, *Entry to Open*, *Open to Close*, *Open to Answer*, and *Answer to Close*).

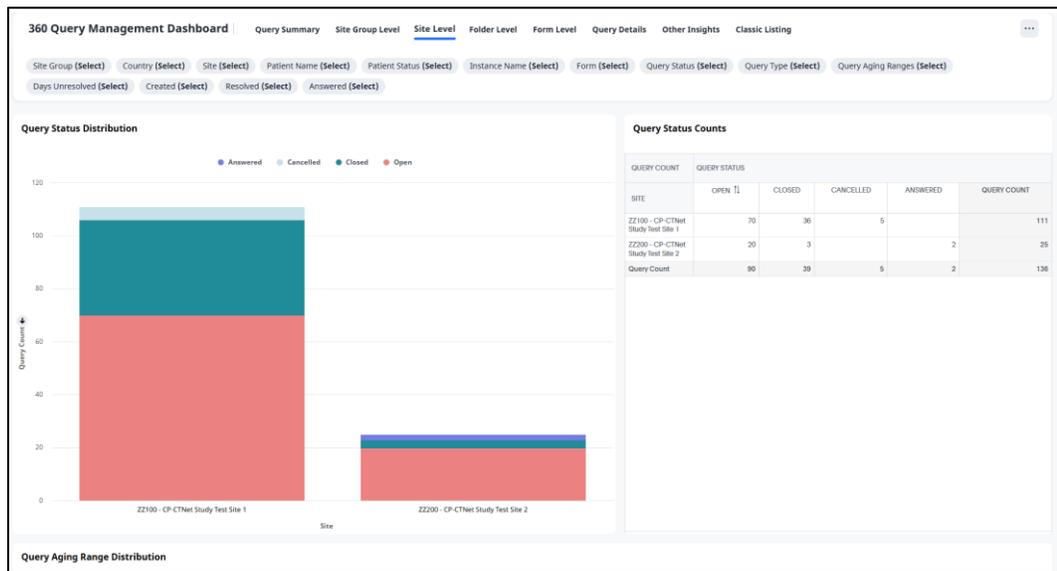


Figure 16: Site Level tab on the 360 Query Management Dashboard.

- 2.4. **Folder Level:** Provides users with folder (visit)-level *Query Status Distribution* and *Query Aging Range Distribution* data visualizations. The *Query Status Distribution* data visualization allows users to view counts of queries at the folder level by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Aging Range Distribution* data visualization allows users to view counts of unresolved queries at the folder level by days unresolved (e.g., *0-5 Days*, *11-30 Days*, and *120+ Days*).

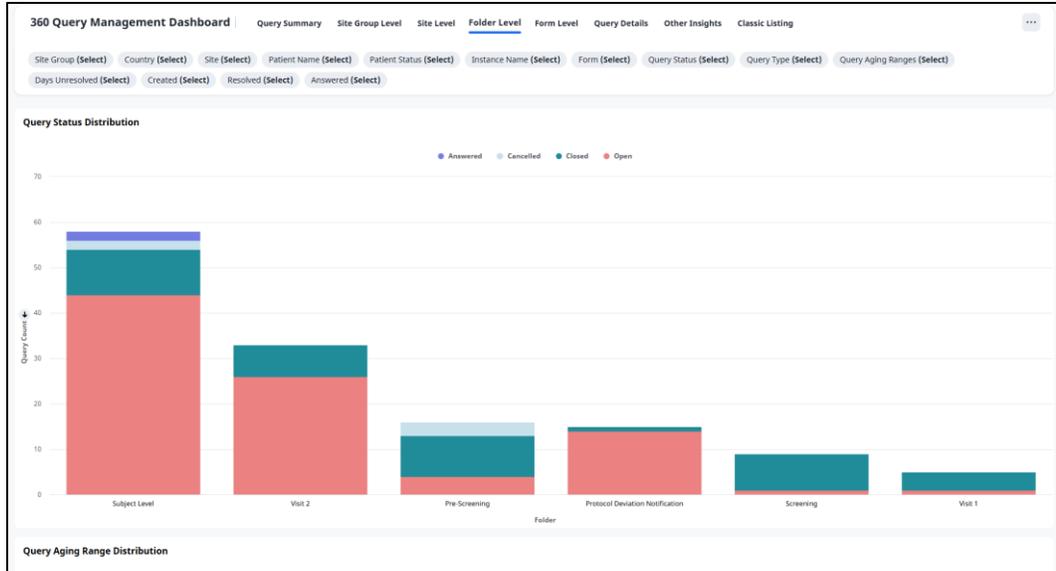


Figure 17: Folder Level tab on the 360 Query Management Dashboard.

- 2.5. **Form Level:** Provides users with form (eCRF)-level *Query Status Distribution* and *Query Aging Range Distribution* data visualizations. The *Query Status Distribution* data visualization allows users to view counts of queries at the form level by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Aging Range Distribution* data visualization allows users to view counts of unresolved queries at the form level by days unresolved (e.g., *0-5 Days*, *11-30 Days*, and *120+ Days*).

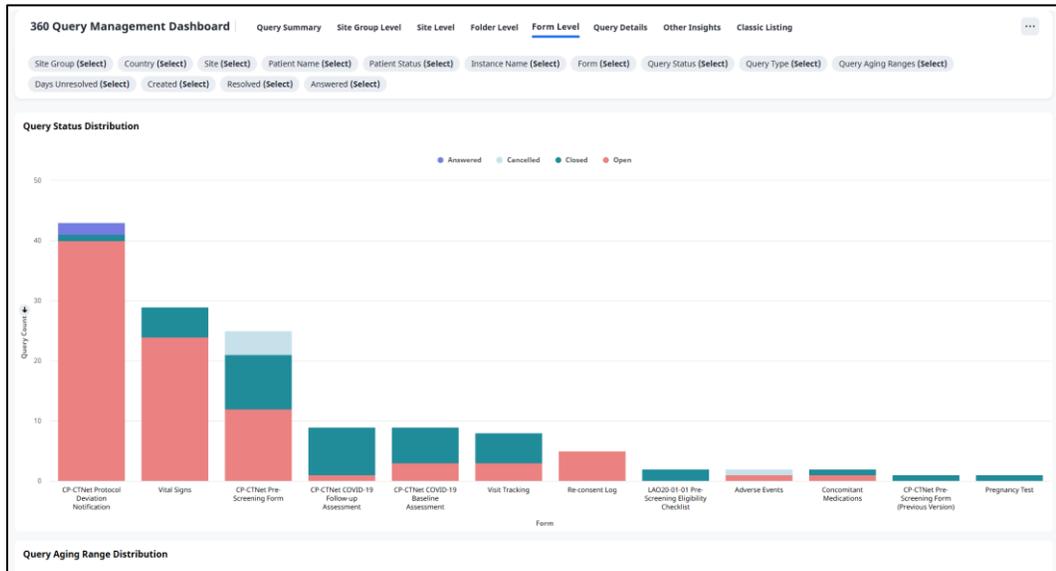


Figure 18: Form Level tab on the 360 Query Management Dashboard.

- 2.6. **Query Details:** Provides users with a detailed data listing of eCRF queries across the selected study.

360 Query Management Dashboard | Query Summary | Site Group Level | Site Level | Folder Level | Form Level | **Query Details** | Other Insights | Classic Listing

Site Group (Select) | Country (Select) | Site (Select) | Patient Name (Select) | Patient Status (Select) | Instance Name (Select) | Form (Select) | Query Status (Select) | Query Type (Select) | Query Aging Ranges (Select)

Days Unresolved (Select) | Created (Select) | Resolved (Select) | Answered (Select)

Query Details

STUDY ↑	SITE GRO UP ↑	COUN TRY ↑	SITE ↑	SITE NUMBER	PATIE NT NAME ↑	PATIENT STATUS	FOLD ER CRED NIAL	INSTANCE NAME ↑	FORM OID	PAGE	RECORD SEQUENCE	FIELD	QUERY ID	QUERY TYPE	QUERY STATUS	QUERY
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	PROT_DEV_NOTI F_DT	6503	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	PROT_DEVIAT_5 UB_CAT	6507	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	AGT_NAME	6505	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	REL_PROT_SEC_NUM	6509	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	LOC_PROT_NUM	6504	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	PROT_DEVIAT_P RVT_TXT	6512	Site from System	Open	Data requi... (req: comp)
LAO20-01-01 (DEV)	World	(Null)	ZZ100 - CP-CTNet Study Test Site 1	ZZ100	1	Pre-Screening	(Null)	Subject Level	DEVIATION	CP-CTNet Protocol Deviation Notification	0	PROT_DEV_ACTI OR_TXT	6511	Site from System	Open	Data requi... (req: comp)

Showing 136 of 136 rows

Figure 19: Query Details tab on the 360 Query Management Dashboard.

2.7. **Other Insights:** Provides users with *Query Status Distribution By Field* and *Query Counts by Query Text* data visualizations. The *Query Status Distribution By Field* data visualization allows users to view counts of queries at the field level by their status (e.g., *Answered*, *Cancelled*, *Closed*, and *Open*). The *Query Counts by Query Text* data visualization allows users to view counts of unresolved queries by matching query text, which is primarily relevant for pre-configured edit checks that display as Site from System queries.

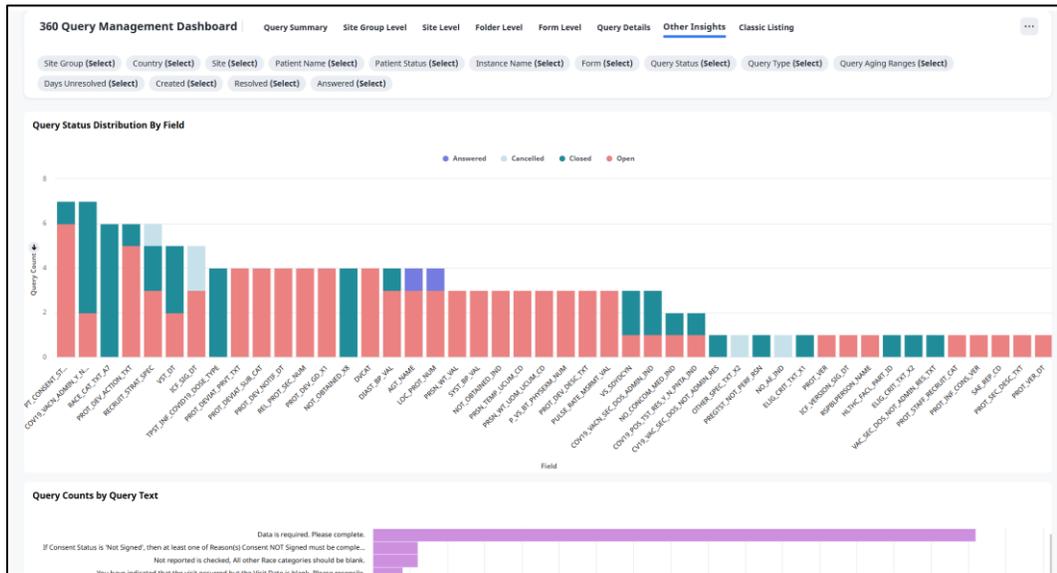


Figure 20: Other Insights tab on the 360 Query Management Dashboard.

2.8. **Classic Listing:** Provides users with a detailed data listing of eCRF queries for the selected study in the legacy Query Management – 360 format.

STUDY	SITE GROUP	SITE	SUBJECT NAME	FOLDER ORDINAL	FOLDER NAME	PAGE	RECORD SEQUENCE	FIELD	QUERY TYPE	DAYS UNRESOLVED	CREATED	CREATED BY	QUERY TEXT	ANSWERED	ANSWERED BY
LA020-01-01 (DEV)	World	ZZ200 - CP-CTNet Study Test Site 2	100222	(Null)	Subject Level	CP-CTNet Protocol Deviation Notification	0	PROT_DEVVAT_S UB_CAT	Site from System	1,370	10/13/2021 10:04:01 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ200 - CP-CTNet Study Test Site 2	100222	(Null)	Subject Level	CP-CTNet Protocol Deviation Notification	0	PROT_DEVVNOTI F_DT	Site from System	1,370	10/13/2021 10:04:01 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ200 - CP-CTNet Study Test Site 2	100222	(Null)	Subject Level	CP-CTNet Protocol Deviation Notification	0	PROT_DEVVGD_X 1	Site from System	1,370	10/13/2021 6:07:11 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ200 - CP-CTNet Study Test Site 2	100222	(Null)	Subject Level	CP-CTNet Protocol Deviation Notification	0	DVCAT	Site from System	1,370	10/13/2021 10:04:01 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ100 - CP-CTNet Study Test Site 1	New Subject	(Null)	Subject Level	CP-CTNet COVID-19 Baseline Assessment	0	COVID19_SACL_SE C_DOS_ADMIN_I ND	Site from System	1,544	4/22/2021 4:30:11 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ100 - CP-CTNet Study Test Site 1	1	(Null)	Subject Level	CP-CTNet Protocol Deviation Notification	0	DVCAT	Site from System	1,370	10/13/2021 9:17:12 PM	System User	Data is required. Please complete.	(Null)	(Null)
LA020-01-01 (DEV)	World	ZZ100 - CP-CTNet Study Test Site 1	Report4	2	Screening (1)	CP-CTNet COVID-19 Follow-up Assessment	0	TPST_INF_COVID 19_DOSE_TYPE	Site from System	0	5/20/2021 4:54:32 PM	System User	Data is required. Please complete.	5/20/2021 4:54:37 PM	(Null)

Figure 21: Classic Listing tab on the 360 Query Management Dashboard.

- Suggested Uses for CP-CTNet:** For studies in the CP-CTNet Program, the 360 Query Management Dashboard can be used to review the progress that sites are making toward resolving queries. This dashboard allows the user to identify trends, review outstanding queries, and guide corrective action plan development (as needed) to increase site responsiveness to queries.

13. DATA LISTING REPORT

The Data Listing Report provides users with a method to browse up-to-date participant data entered into a specific eCRF in a simple, tabular format. The tabular database views of the clinical study data can be extracted and analyzed by third-party software (e.g., SAS).

- Instructions for Use:** The user selects the study and environment (e.g., Prod = Production) and any site(s) (if desired) that they would like to run the Data Listing Report for. Once the parameters are selected and the report is saved (if desired), the user can submit the report and view the results by clicking **Submit Report** at the top of the page.

Figure 22: Report parameters for the Data Listing Report.

- 1.1. The user selects the type of view to display using the *Data Source* dropdown. This report generates four types of views:
 - Clinical Views
 - Clinical Views Raw
 - Production Clinical Views
 - Production Clinical Views Raw

For CP-CTNet studies, Production Clinical Views Raw is the recommended view because it displays data entered on eCRFs in the Rave production environment for the selected study.

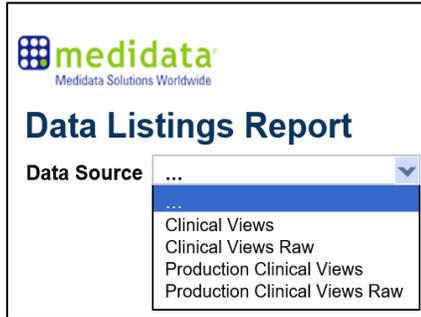


Figure 23: Data Source dropdown in the Data Listing Report.

- 1.2. The user then selects the desired form from the *Form* dropdown. They can enter the number of rows to display in the *Rows per page* field (if desired). When all selections have been made, the user clicks **Run** to generate the report and display all data based on their selections. The *Show All Clinical View Columns* checkbox should be left unchecked, as checking this checkbox will display additional backend fields that are not relevant for LAOs and AOs.

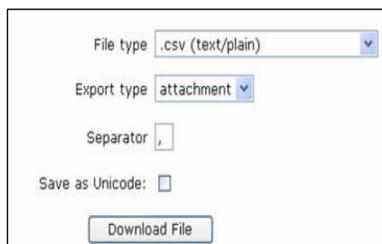
Data Listings Report - LAO20-01-01													
Data Source: Production Clinical Views Raw													
Form: CP-CTNet Protocol Deviation Not													
Rows per page: <input type="text"/> Run													
<input type="checkbox"/> Show all clinical view columns													
project	studyid	Subject	SDVTier	Site	SiteNumber	SiteGroup	InstanceName	InstanceRepeatNumber	FolderName	DataPageName	RecordPosition	SaveTS	StudyEnvSiteNumber
LAO20-01-01	7	100020		CP-CTNet Study Test Site 1	ZZ100	World				CP-CTNet Protocol Deviation Notification	0	7/3/2024 5:39:34 PM	ZZ100
LAO20-01-01	7	100023		CP-CTNet Study Test Site 2	ZZ200	World	Protocol Deviation Notification 15 Apr 2022	0	Protocol Deviation Notification	CP-CTNet Protocol Deviation Notification	0	1/31/2025 5:32:54 PM	ZZ200
LAO20-01-01	7	100026		CP-CTNet Study Test Site 2	ZZ200	World	Protocol Deviation Notification 15 Apr 2022	0	Protocol Deviation Notification	CP-CTNet Protocol Deviation Notification	0	7/3/2024 5:39:34 PM	ZZ200

Figure 24: Data Listing Report.

The report includes columns that detail information about the project (*Study ID*, *Subject*, *Site*), eCRF location (*Folder*), and selected eCRF (specific fields in the eCRF).

2. **Exporting the Results:** To export the results, the user scrolls to the bottom of the report and selects the file type, export type, separator, and if the file should be saved as Unicode. The user clicks **Download File** to save or view the report in the desired format.
 - 2.1. **File type:** The results can be exported as a .csv (application/vnd.ms-excel), .csv (text/plain), or .txt (text/plain). The .csv file types export the results of the report using .csv and can be opened using spreadsheet applications such as Excel. The .txt file type exports the results of the report in a comma-delimited text file and can be opened using applications such as WordPad or Notepad.
 - 2.2. **Export type:** The results can be exported as an attachment or inline. The report displays in a separate window if the *Export type* is set to *attachment*. The report displays in the same window if the *Export type* is set to *inline*.

- 2.3. **Separator:** This is the delimiter for the export output. Comma “,” is the default, but the export function can support other delimiters.
- 2.4. **Save as Unicode:** The user can check the box to save as Unicode.



The screenshot shows a dialog box for exporting a report. It contains the following elements: a 'File type' dropdown menu set to '.csv (text/plain)', an 'Export type' dropdown menu set to 'attachment', a 'Separator' text input field containing a comma, a 'Save as Unicode' checkbox which is currently unchecked, and a 'Download File' button at the bottom.

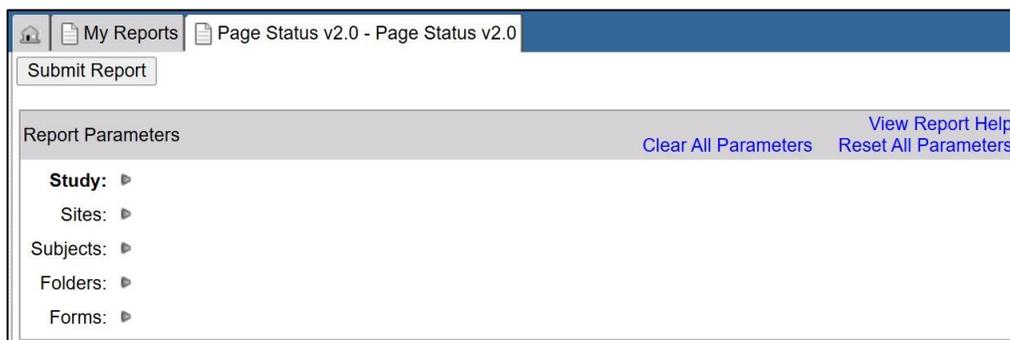
Figure 25: Export options in the Data Listing Report.

3. **Suggested Uses for CP-CTNet:** For studies in the CP-CTNet Program, the Data Listing Report can be used to browse up-to-date participant data entered into an eCRF. Users can view the data entered in a specific form for all participants at a site. The data listing can be reviewed in a table in Rave, or it can be exported into a spreadsheet.

14. PAGE STATUS REPORT V2.0

The Page Status Report v2.0 is a study data monitoring report that provides a summary of the current statuses (overall) of the eCRFs within a specified study, site group, site, subject, folder, and/or eCRF. The report indicates how many eCRFs are *Expected Total*, *Expected To Date*, *Entered*, or *Overdue*; how many queries are either *Open* or *Answered*; and identifies eCRFs that require action (e.g., to be *Reviewed*, *Locked*, etc.). The report shows the relevant eCRF statistics in a tabular format and includes a drill down feature that allows the user to click the row headers to view status counts down to the eCRF level. The report helps in determining which sites or participants have the greatest number of pages in need of signature, entry lock, etc. A page in the context of this report (or any standard report) corresponds to an eCRF in Rave, whether that eCRF contains standard fields, log fields, or both. Standard eCRFs contain standard or typical fields that correspond to one record or entry (e.g., the date entered on a visit tracking form). Log eCRFs are used when multiple instances of the same eCRF are needed (e.g., medical history log eCRFs). A single log eCRF includes multiple records or entries, with each row representing one entry. The fields in that row correspond to that entry.

1. **Instructions for Use:** The user selects specific parameters to customize the report results. Once all desired parameters are selected and the report is saved (if desired), the user submits the report and views the results by clicking **Submit Report** at the top of the page.



The screenshot shows the 'Page Status v2.0 - Page Status v2.0' report parameters interface. At the top, there is a 'Submit Report' button. Below it, the 'Report Parameters' section is displayed, which includes a list of expandable categories: 'Study', 'Sites', 'Subjects', 'Folders', and 'Forms'. To the right of the 'Report Parameters' section, there are three links: 'View Report Help', 'Clear All Parameters', and 'Reset All Parameters'.

Figure 26: Report parameters for the Page Status Report v2.0.

The report includes columns that detail:

- 1.1. **Total Counts:** These columns track *Expected Total* (number of eCRFs available for keying), *Expected To Date* (number of eCRFs that should have been keyed by today's date), *Entered* (number of eCRFs already keyed), *Overdue* (number of eCRFs considered overdue), *Verified* (number of eCRFs that have been verified by DMASC), *Reviewed* (number of eCRFs that have been reviewed by DMASC), *Entry Locked* (number of eCRFs that have at least one field that is locked by DMASC and data cannot be entered), and *Locked* (number of eCRFs that have at least one field that is locked by DMASC and cannot be checked for queries).
- 1.2. **Queries:** These columns track the number of eCRFs that have queries with a status of *Open* (number of eCRFs where at least one field has an open query which has not been answered) or *Answered* (number of eCRFs where at least one field has an open query which has been answered, but has not been closed).
- 1.3. **Pages Requiring Action:** These columns track the number of eCRFs that require action. The actions include: *Verify*, *Review*, *Translate*, *Coding*, *Sign*, *Entry Lock*, and *Lock*.

	Expected Total	Expected To Date	Entered	Total Counts				Queries		Pages Requiring Action							
				Over due	Verified	Reviewed	Entry Locked	Open	Answered	Verify	Review	Translate	Coding	Sign	Entry Lock	Lock	
CP-CTNet Study Test Site 1 - World	469	469	197	62	0	0	0	0	13	0	0	0	0	0	0	0	0
100059	19	19	3	4	0	0	0	0	0	0	0	0	0	0	0	0	0
DMC Use Only (1)	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LAO20-01-01, Step 1 (1)	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LAO20-01-01, Step 1 (DMC Use Only) (1)	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pre-Screening	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Screening (1)	6	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Subject Level	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Visit 1 26 Jun 2023	4	4	1	3	0	0	0	0	0	0	0	0	0	0	0	0	0
Visit 2 (1)	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
LAO20-01-01 - DEV	469	469	197	62	0	0	0	0	13	0	0	0	0	0	0	0	0

Figure 27: Page Status Report v2.0.

2. **Suggested Uses for CP-CTNet:** For studies in the CP-CTNet Program, the Page Status Report v2.0 can be used to determine site and participant progress in relation to eCRF completion windows and overall study timelines. Users can also view the number of queries that are open and answered as well as any eCRFs that need to be verified, reviewed, signed, entry locked, or locked by DMASC. Clicking through the report allows the user to view the counts by site, participant, or eCRF. The report can help identify which sites are in most need of support and if there are any eCRFs or queries that require attention throughout the study.

15. STICKY NOTE REPORT

The Sticky Note Report is a study data monitoring report that provides a detailed listing of sticky notes that have been placed for the selected study, site group, site, folder, and/or eCRF. This report retrieves all sticky notes that a site has received, including the full text of the sticky note, date received, status, and acknowledging user.

1. **Instructions for Use:** The user selects specific parameters to customize the report results. Once all desired parameters are selected and the report is saved (if desired), the user can submit the report and view the results by clicking **Submit Report** at the top of the page.

Figure 28: Report parameters for the Sticky Note Report.

Note: Both the *Start Date* and *End Date* parameters refer to the date the sticky note was created. Applying *Start Date* and *End Date* parameters capture sticky notes that were created between the two specified dates.

Site	Site Group	Subject	Folder	Form	Field	Sticky Created	Marking Group	Sticky Issued by	Role Placed by	User Acknowl by	Sticky Note Text	Sticky Status
CP-CTNet Study Test Site 1	World	Report1	Subject Level	Participant Contact	CONCOM_MED_REP_IND	20 May 2021	Site from System	S.User	System	---	Please navigate to the Participant Logs folder and update the Concomitant Medications form as needed.	Placed
CP-CTNet Study Test Site 1	World	Report1	Subject Level	Participant Contact	SM_OR_AE_OC_UR_IND	20 May 2021	Site from System	S.User	System	---	Please navigate to the Participant Logs folder and update the Adverse Events form as needed.	Placed
CP-CTNet Study Test Site 1	World	Report3	Subject Level	Participant Contact	CONCOM_MED_REP_IND	20 May 2021	Site from System	S.User	System	K.Denson	Please navigate to the Participant Logs folder and update the Concomitant Medications form as needed.	Acknowledged
CP-CTNet Study Test Site 1	World	Report3	Subject Level	Participant Contact	SM_OR_AE_OC_UR_IND	20 May 2021	Site from System	S.User	System	K.Denson	Please navigate to the Participant Logs folder and update the Adverse Events form as needed.	Acknowledged

Figure 29: Sticky Note Report.

In addition to the full text of the sticky note, the report includes columns that:

- 1.1. **Connect the sticky note to a record:** Site, Site Group, Subject, Folder, Form, and Field
- 1.2. **Identify the status of the sticky note:** Sticky Created (date the sticky note was created) and Sticky Status (whether the note has been placed or acknowledged)
- 1.3. **Identify the sender of the sticky note:** Marking Group, Sticky Issued by (user issuing the sticky note), and Role Placed by (e.g., system)
- 1.4. **Record site acknowledgment:** User Acknowl by (user acknowledging the sticky note)

2. **Suggested Uses for CP-CTNet:** For studies in the CP-CTNet Program, the Sticky Note Report can be used to review all of the sticky note reminders that have been issued for a study. Sticky notes are often pre-programmed on an eCRF based on how a site answers a particular question. They usually direct the site to report additional information on another eCRF. Once the action in the sticky note is taken, the site acknowledges the note in Rave. This report can help users identify the sticky notes that have been created and acknowledged for the study or site, verify whether a particular sticky note was acknowledged, and identify areas to improve workflow if necessary.

Send questions and comments to DMASC at DataManagement_CP-CTNet@frontierscience.org

16. RESOURCES

Rave has eLearning courses that provide comprehensive demonstrations of many of the reports discussed in this guide.

CP-CTNet_USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project_v4_0

Final Audit Report

2026-02-25

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By:	Leslie Mundy (mundy@frontierscience.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAppAKh3wnsAHLbBNyTu6bzz8VXgfVQKz

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-  Document created by Leslie Mundy (mundy@frontierscience.org)
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