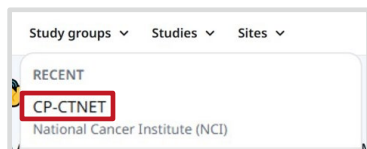


Accessing Reports via the Reporter Module in Medidata Rave

Medidata Rave (Rave) reports and dashboards are available to Cancer Prevention Clinical Trials Network (CP-CTNet) members via the *Reporter* module in Rave (see [QKREFGD13 Accessing Medidata Rave](#) for more information about accessing Rave). This section highlights the steps that users follow to access Rave reports.

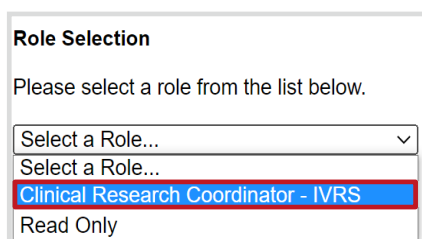
1. Select **CP-CTNET** from the *Study groups* dropdown at the top of the Medidata homepage.



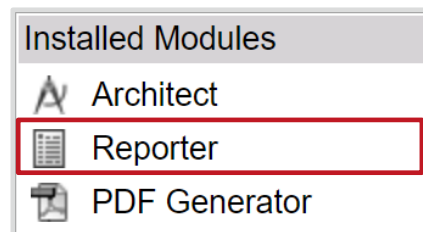
2. Select **Rave EDC** under the CP-CTNET container.



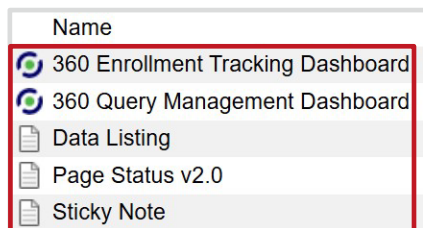
3. Select the appropriate role from the *Role Selection* dropdown and click the **Continue** button. If only one role is assigned, this dropdown is not displayed. Proceed to step 4.



4. Select **Reporter** from the *Installed Modules* list.



5. Rave reports and dashboards are available for selection in the *My Reports* list.



Setting and Saving Rave Report Parameters

All Rave reports include parameters that users can set to customize the report output. Once a user sets all applicable parameters, they can either submit the report or save the selected parameters for later use. If saved, a custom report appears in the user's *My Reports* list in the *Reporter* module. This section highlights the key Rave interface components that are relevant to setting report parameters, saving report parameters, and submitting reports.

Submit Report

- Click the **Submit Report** button to run the report.

Report Parameters

Study: LAO20-01-01 | DEV

Name	Environment
☒ LAO20-01-01	DEV
☐ Recruitment	DEV

1

Sites ▶
Subjects ▶
Folders ▶
Forms ▶

Create User Saved Report:

Report Name: Report Description:

Save Cancel

Parameter Options

- Click the arrow next to each parameter to display a list of options that can be selected to refine the report output.

Report Parameters

- Different parameters are included for each standard report and are listed from broadest to narrowest. **Note:** Bolded parameters are required.

Save Report

- To save any selected report parameters as a custom report, add a report name and description and click the **Save** button.

360 Enrollment Tracking Dashboard Overview

The *360 Enrollment Tracking Dashboard* tracks the overall status of participant pre-screening, screening, and enrollment for a selected study and enables the user to assess various aspects of study and site enrollment performance. The dashboard offers visualization tools to aid in the understanding and sharing of study enrollment data. This section highlights key components of the *360 Enrollment Tracking Dashboard* interface and common uses for CP-CTNet. **Note:** The *Enrollment (standard) Status, Rates, and Reference Status Mapping* dashboard sections are not set up for CP-CTNet.

Dashboard Section Tabs

- Click each tab to navigate between dashboard sections.

Undo, Redo, and Reset

- Click the undo or arrow buttons to display a list of undo, redo, and reset options.

Explore

- Click the Explore button to display a new window with additional filter, sort, and data compare options for the visualization.

360 Enrollment Tracking Dashboard

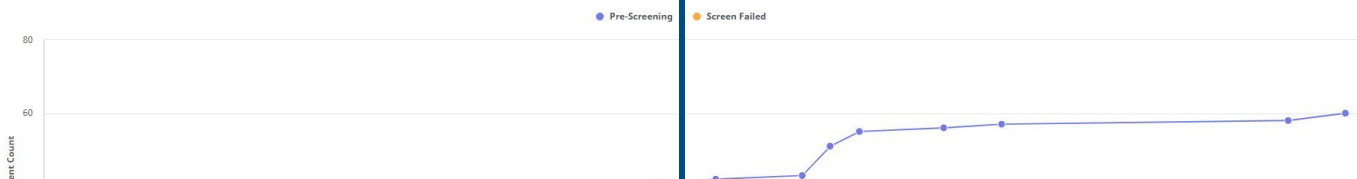
Patient (custom) Status Enrollment (standard) Sta... Rates Reference Status Mapping

Site Group (Select) Country (Select) Site (Select) Patient Status (Select) Patient Status Date (Select) Enrollment Status (Select) Enrollment Status Date (Select)

Current Patient Status Progression



Cumulative Patient Status Progression



Filter Categories

- Select one or more filter categories to refine the data displayed on the dashboard.

Interactive Data Visualizations

- Hover over a data point to display data details or click the arrow next to the axis labels to filter and sort the displayed data.

More Options

- Click the ellipsis (...) buttons to download, present, or show the underlying data for the dashboard or visualization.

Common Uses for CP-CTNet:

Lead Academic Organization (LAO) Administrative Teams can use this dashboard to review the current and cumulative participant enrollment status and progression at a specific accruing LAO or Affiliated Organization (AO) or across the entire study. Accruing LAOs and AOs can use this dashboard to review the current and cumulative participant enrollment status and progression at their own accruing LAO or AO. See [USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project](#) for more information.



360 Query Management Dashboard Overview

The *360 Query Management Dashboard* provides an up-to-date, detailed summary of a study's open, answered, and closed queries over time. The dashboard offers visualization tools and data listings to aid in the understanding and sharing of study query data. This section highlights key components of the *360 Query Management Dashboard* interface and common uses for CP-CTNet.

Dashboard Section Tabs

- Click each tab to navigate between dashboard sections.

Explore

- Click the Explore button to display a new window with additional filter, sort, and data compare options for the visualization.

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)

Total Queries

136

Open Queries

90

Closed Queries

39

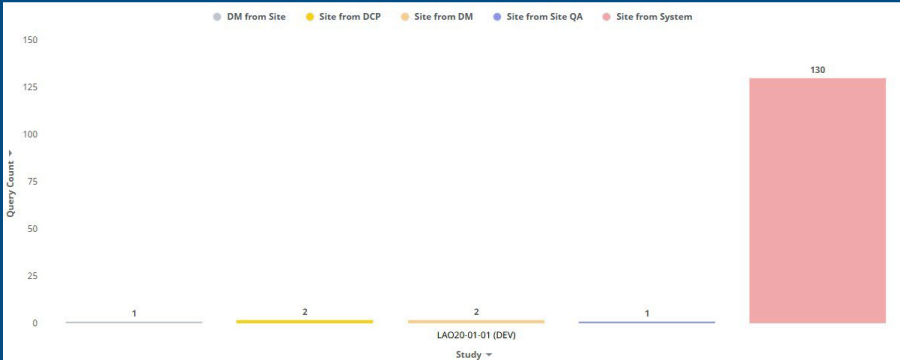
Cancelled Queries

5

Answered Queries

2

Query Type Distribution



Query Aging Range Distribution



Median Cycle Times

Entry to Close Entry to Open Open to Close Open to Answer Answer to Close

Filter Categories

- Select one or more filter categories to refine the data displayed on the dashboard.

Interactive Data Visualizations

- Hover over a bar to display data details or click the arrow next to the axis labels to filter and sort the displayed data.

More Options

- Click the ellipsis (...) buttons to download, present, or show the underlying data for the dashboard or visualization.

Common Uses for CP-CTNet:



LAO Administrative Teams can use this dashboard to review the progress that their accruing LAOs and AOs are making toward resolving queries and retrieve details about each query. Accruing LAOs and AOs can use this dashboard to assess their own progress at resolving queries and view query details. This dashboard allows users to identify trends, review outstanding queries, and guide corrective action plan development (as needed) to increase query responsiveness. See [USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project](#) for more information.

Data Listing Report Overview

The *Data Listing* report provides users with a method to browse up-to-date participant data entered into a specific electronic Case Report Form (eCRF) in a simple, tabular format. This report generates four types of views, but *Production Clinical Views Raw* is the recommended view because it displays data entered on eCRFs in the Rave production environment for the selected study. The tabular database views of the clinical study data can be extracted and analyzed by third-party software (e.g., SAS). This section highlights key components of the *Data Listing* report interface and common uses for CP-CTNet.

Data Source

Form

Run

➤ Select *Production Clinical Views Raw* as the data source.

➤ Select the desired eCRF to include in the report output.

➤ Click the *Run* button to retrieve data based on the selected data source (view) and eCRF.

Data Listings Report - LAO20-01-01

Data Source: Production Clinical Views Raw

Form: CP-CTNet Protocol Deviation Not Rows per page: 1 Run

☐ Show all clinical view columns

project	studyid	Subject	SDVTier	Site	SiteNumber	SiteGroup	InstanceName	InstanceRepeatNumber	FolderName	DataPageName	RecordPosition	SaveTS	StudyEnvSiteNumber	RecordActive
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	6/22/2023 10:39:35 AM		True
LAO20-01-01	7	100027		CP-CTNet Study Test Site 2	ZZ200	World	Protocol Deviation Notification 01 Jan 2022	0	Protocol Deviation Notification	CP-CTNet Protocol Deviation Notification	0	6/22/2023 10:39:35 AM		True
LAO20-01-01	7	100222		CP-CTNet Study Test Site 2	ZZ200	World				CP-CTNet Protocol Deviation Notification	0	6/22/2023 10:39:35 AM		True
LAO20-01-01	7	100690		CP-CTNet Study Test Site 1	ZZ100	World	Protocol Deviation Notification 15 Feb 2021	0	Protocol Deviation Notification	CP-CTNet Protocol Deviation Notification	0	6/22/2023 10:39:35 AM		True

➤ Leave this checkbox unchecked to avoid displaying irrelevant backend fields.

➤ Customize export settings (as needed) before downloading a report output file.

➤ The eCRF location and fields are displayed for each participant with data entered into the selected eCRF.

File type: .csv (text/plain)

Export type: attachment

Separator: ,

Save as Unicode: ☐

Download File

Show All Clinical View Columns

Export Settings

Report Output

Common Uses for CP-CTNet:

LAO Administrative Teams can use this report to browse up-to-date participant data entered into an eCRF across participants in a study. Accruing LAOs and AOs can use this report to view the data entered in a specific eCRF for all participants at an accruing LAO or AO. This report is often used to ensure that similar data are entered consistently across participants, create protocol deviation and adverse event reports, and identify data trends across accruing LAOs and AOs. See [USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project](#) and the *Help* link for the report in the *My Reports* list for more information.



Page Status Report v2.0 Overview

The *Page Status Report v2.0* 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.). A *page* refers to an eCRF in Rave (e.g., the *Pages Requiring Action* section details the number of eCRFs that require an action to be taken in Rave). This report includes a drill down feature, which allows users to view progress at the study, site, participant, folder, and eCRF level. This section highlights key components of the *Page Status Report v2.0* interface and common uses for CP-CTNet.

Navigation & Magnification

- View additional report pages and/or update the zoom settings.

Export Settings

- Customize export settings before downloading a report output file.

Drill Down Tabs

- New tabs are displayed as users drill down into various levels of detail within the report output.

	Total Counts				Queries		Pages Requiring Action											
	Expected Total	Expected to Date	Entered	Overdue	Verified	Reviewed	Entry Locked	Locked	Open	Answered	Verify	Review	Translate	Coding	Sign	Entry Lock	Lock	
CP-CTNet Study Test Site 1 - World	404	404	181	62	0	0	0	0	13	0	0	0	0	0	0	0	0	0
100059	17	17	3	4	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	
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	584	584	249	62	0	0	0	0	16	1	0	0	0	0	0	0	0	

Drill Down Feature

- Select row headers (e.g., site names, participants) to display various levels of detail within the report output (e.g., folders, eCRFs).

Status Columns

- View total counts for expected and completed data entry and management activities, as well as open and answered queries.

Common Uses for CP-CTNet:

LAO Administrative Teams can use this report to determine accruing LAO, AO, and participant progress in relation to eCRF completion windows and overall study timelines. They 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. Accruing LAOs and AOs can use this report to determine the progress of their participants and accruing LAO or AO in relation to eCRF and query completion, and to highlight any eCRFs that require an action to be taken in Rave. Drilling down through the report refines the counts by site, participant, folder, and eCRF. The report can help identify any eCRFs or queries that require attention throughout the study. See [USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project](#) and the *View Report Help* link within the report for more information.



Sticky Note Report Overview

A sticky note is a reminder and a means of communication with another user within Rave. It is used in the same way a sticky note or a Post-it® would be used on a paper-based study. The *Sticky Note* report retrieves all sticky notes that an accruing LAO or AO has received, including the location, full text, and status information for each sticky note placed for a study. This section highlights key components of the *Sticky Note* report interface and common uses for CP-CTNet.

Navigation & Magnification

- View additional report pages and/or update the zoom settings.

Export Settings

- Customize export settings before downloading a report output file.

Site	Site Group	Subject	Folder	Form	Field	Sticky Created	Marking Group	Sticky Issued by	Role Placed by	User Acknowledged 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

Report Output

- Includes the location, full text, and status information for each sticky note placed for a study.

Common Uses for CP-CTNet:



LAO Administrative Teams can use this report to review all the sticky note reminders that have been issued for a study. Accruing LAOs and AOs can use this report to review all the sticky note reminders that have been issued for their accruing LAO or AO. This report helps users identify the sticky notes that have been created, view the location and full text of the sticky notes, verify whether a particular sticky note has been acknowledged, and identify areas to improve workflows (as needed). See [USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project](#) and the *View Report Help* link within the report for more information.