Accessing Reports via the Reporter Module in Medidata Rave

Medidata Rave (Rave) reports are available to Cancer Prevention Clinical Trials Network (CP-CTNet) members via the *Reporter* module in Rave (see <u>QKREFGD13</u> *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 <i>Study groups</i>	Study groups 🗸 Studies 🗸 Sites 🗸	4. Select Reporter from the <i>Installed</i>	Installed Modules					
dropdown at the top of the Medidata	CP-CTNET	Modules list.	Architect					
nomepage.	National Cancer Institute (NCI)		Reporter					
 Select Rave EDC under the CP-CTNET container. 	CP-CTNET		PDF Generator					
	Overview Rave Architect Security Rave EDC	5. Rave reports are available for	Name					
3. Select the appropriate role from the <i>Role</i>	Role Selection	selection in the <i>My Reports</i> list.	360 Enrollment Tracking Report					
Selection dropdown	Please select a role from the list below.		🧿 360 Query Management					
button. If only one role	Select a Role		📄 Data Listing					
is assigned, this dropdown is not	Select a Role		Page Status v2.0					
displayed. Proceed to step 4.	Read Only		Sticky Note					

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							-0	Parameter Options
 Click the Submit Report button to run the report. 	🟦 📄 My Submit Re	Reports 📄 Page Status	v2.0 - Page Status v2.0	0		View Report Help ameters Reset All Parameters View Report Help ameters Reset All Parameters Save Report Save Report > To save any selected report parameters as a custom report, add a report name and description and click the Save button.	Click the arrow next to each parameter to display a list of options that	
e reperu	Report Par	rameters			Clear All Parameters	View Report Help Reset All Parameters		can be
	Study:	 ■LAO20-01-01 DEV Name ∠ LAO20-01-01 ⊂ Recruitment 	Environment DEV DEV	D p				selected to refine the report output.
	Π Ι	1						
	Sites	Þ						Save Report
Report Parameters	Subjects	Þ						
T drameters	Folders	Þ					≻	To save any
Different	Forms	۵						selected
parameters are included for each standard report and are listed from broadest to narrowest. Note: Bolded parameters are required.	Create Use Report Na	er Saved Report:		Report Descrip	otion:	Save Save Cancel		report parameters as a custom report, add a report name and description and click the <i>Save</i> button.



360 Enrollment Tracking Report Overview

The 360 Enrollment Tracking report tracks the overall status of participants' pre-screening, screening, and enrollment for a selected study and enables the user to assess various aspects of study and site enrollment performance. The report offers visualization tools to aid in the understanding and sharing of study enrollment data. **Note:** The *Screen Failure Rates* and *Enrollment Performance Summary* report metrics are not set up for CP-CTNet. This section highlights key components of the 360 Enrollment Tracking report interface and common uses for CP-CTNet.



Common Uses for CP-CTNet:

Lead Academic Organization (LAO) Administrative Teams can use this report to identify enrollment trends that occur at a specific accruing LAO or Affiliated Organization (AO) or across the entire study. Accruing LAOs and AOs can use this report to identify the enrollment trends that are occurring at their own accruing LAO or AO. See <u>USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project</u> and the Overview tab within the report for more information.



360 Query Management Report Overview

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

eport Metric About Tabs Click each navigate b metric visu and tables report help	tab to petween julizations and o.					 Action & Export Menu Click the men icon to display a list of undo, redo, and export options
360 QI	uery Management					
Query C	counts by Status Quer	ry Aging Query De	tails Query Cycle Times About This nts By Status	360 Report	12	T E. Filters 5 ∓ X
Site ⑦ Lear	▼ In More	Site CP-CTNet CP-CTNet	Open Answered Clos 70 18 2	ed Cancelled 34 5 4		Type to search filters Query Management Site Group Type to search in list (All) 1 values World
Quert	ry Status Counts			Color by: Query Status Open Answered Closed Cancelled	=	Site Type to search in list (All) 2 values CP-CTNet Study Test Site 1 CP-CTNet Study Test Site 2
Query	60 40 20 0 CP-0	CTNet Study Test Site 1 S	CP-CTNet Study Test Site 2			Subject Type to search in list (All) 17 values 1 100026 100222 100708 11111 KCD123
 View Sel dro dat figu No and bet (tot) 	v Queries By propdown lect from the opdown to change the ta displayed in the ures and tables. te: Dropdown titles d options vary tween report metrics	ne	 Interactive Data Visualizations Select a data bar to highlight the selected data throughout the report. 			Filters Search, select, or de-select filters to refine the data displayed in the report.

Common Uses for CP-CTNet:

LAO Administrative Teams can use this report 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 report to assess their own progress at resolving queries and view query details. This report allows users to identify trends, review outstanding queries, and guide corrective action plan development (as needed) to increase query responsiveness. See <u>USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project</u> and the *About This 360 Report* tab within the report 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.



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 <u>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.</u>



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.



Page Status Report for LAO20-01-01

medidata
Rave [∗]

					Total C	ounts				Querie	S			Pages Re	quiring Act	tion			
	Expect To	ed Ex otal	pected En To Date	tered	Over due	Verified Rev	viewed	Entry Lo Locked	cked	Open Ans	wered	Verify	Review	Translate	Coding	Sign	Entry Lock	Lock	
CP-CTNet Study Test Site 1 - World	j i	404	404	181	62	0	0	0	0	13	0	0	0	0	0	0	0	0	
100059	1 - Ju	17	17	3	4	0	0	0	0	0	0	0	0	0	0	0	0	0	
LAO20-01-01, Step 1 (1)	1 - J	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Pre-Screening	1 - Ju	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Screening (1)	1 - Ju	6	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Subject Level	1 - J	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Visit 1 26 Jun 2023	ul –	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	1 *	584	584	249	62	0	0	0	0	16	1	0	0	0	0	0	0	0	



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 reviewed, verified, 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 <u>USRMAN03 Rave Reports</u> 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.

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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 des the ion, full to status nation fo	ext,					

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 <u>USRMAN03 Rave Reports Resource Guide for the CP-CTNet Project</u> and the *View Report Help* link within the report for more information.

