



CTSU BREAKOUT SESSION

Alliance Meeting
Spring 2017
Kathi Celii

Agenda

- Serious Adverse Event Integration
- Data Quality Portal
- Central Monitoring



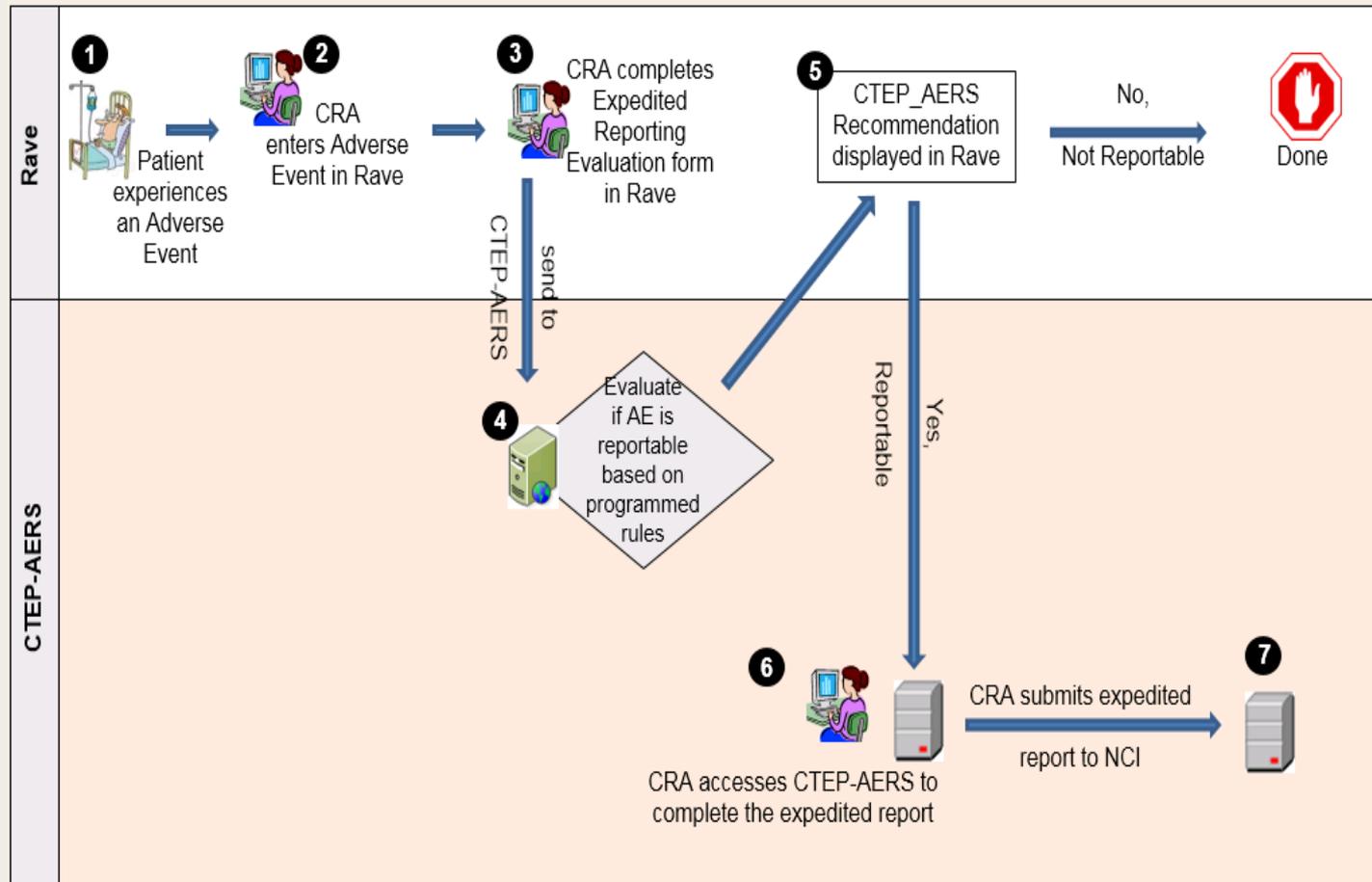


SERIOUS ADVERSE EVENT (SAE) INTEGRATION

SAE Integration

- The Serious Adverse Event (SAE) integration links the system for reporting *routine* Adverse Events (AEs) with the system for the *expedited reporting* of SAEs.
 - Rave is the Clinical Data Management System used for reporting routine AEs
 - Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) is the system used for the *expedited reporting* of SAEs.
- The integration between the two systems allows for a single sign-on approach to reporting and managing SAEs, and reduces the double data entry that results from two separate systems.
- All routine AEs entered in Rave will be evaluated for possible expedited reporting, and if an expedited report is recommended, the system can launch CTEP-AERS directly from Rave in order to complete the report.

Workflow of Integration



Rave to CTEP-AERS Data Flow (I)

- Sites enter AE data in Rave and submit to CTEP-AERS rules engine for expedited reporting evaluation.
- All AE data in Rave that is required for expedited reporting will be pushed to CTEP-AERS.
- A direct link will be used to automatically log into CTEP-AERS.

Rave to CTEP-AERS Data Flow (2)

- In CTEP-AERS, the AE data that is pushed from Rave will be viewable but not modifiable.
 - Modifications to AE data will be made in Rave since it is the data source.
 - Any data modified in Rave will require the rules evaluation to be run again.
 - This will cause the updated data to be pushed into CTEP-AERS.
 - Verbatim Term and AE Start Date fields can be set as optional in Rave.
 - These values may be entered in CTEP-AERS even if they are not present in RAVE.
 - If entered in Rave, they cannot be updated in CTEP-AERS.

Rave Reminders

For studies using the SAE Integration:

- AE data should be entered in Rave and sent for rules evaluation at the time the AE is experienced.
- AE data should not be entered in CTEP-AERS before entering it in Rave.
 - A warning will appear if a report is initiated in CTEP-AERS rather than from following the direct link in Rave.
- AE data should be updated in Rave, not in CTEP-AERS
 - If the verbatim term is entered in Rave, this value will be passed to CTEP-AERS and will only be editable in Rave.
 - If the verbatim term is first entered in CTEP-AERS and then later entered in Rave, this could result in reconciliation issues as the value in CTEP-AERS will not synchronize with the Rave verbatim term once the expedited report has been submitted to NCI.

Expedited Reporting Recommendations

For studies using the SAE Integration:

- Reporting recommendations are determined based on rules set up in CTEP-AERS using protocol requirements.
 - Exceptions are programmed into the rules (for CTEP-IND studies).
- Reporting recommendations may be overridden.
 - Example (*CREATE* → *NONE*): Laboratory abnormality is recommended as an SAE but is not considered clinically significant by the Investigator.
 - Example (*NONE* → *CREATE*): AE is not related to study treatment, but results in hospitalization.

AE Entry in Rave

Verbatim term		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Solicited (<i>derived</i>)		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
* Adverse event term (CTCAE v4.0)	Vomiting	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MedDRA adverse event code (CTCAE v4.0) (<i>derived</i>)	10047700: Gastrointestinal disorders	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
* Adverse event evaluated this cycle?	Yes [▲]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adverse event (<i>grade</i>) grade description (<i>first 120 characters</i>)	(5) Death [▲]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adverse event (<i>grade</i>) grade description (<i>full description</i>)	(5) Death [▲]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AE start date		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
End date		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AE ongoing		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Attribution to study intervention	Unrelated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- AE is entered in Rave at the time it is experienced.

AE Evaluation

Send all AEs for evaluation

? Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this check box and save the form to determine if expedited reporting is recommended.

Opened To Site from System (28 Apr 2017)

Value changed.

Per Query   

- Query “*Send all AEs for evaluation*” appears on the Expedited Reporting Evaluation form when:
 - An AE is added to the AE form
 - OR
 - An existing AE is modified.

SAE Report Recommendation “CREATE”

Recommended action for report *(derived)*

An expedited report is RECOMMENDED. If the Investigator believes an expedited report is not warranted, (e.g., per protocol, commercial agent/arm, medical judgement, etc.), edit the 'Recommended action for report' field to indicate 'NONE'.
Opened To Site from System (13 Mar 2017)

CREATE   

Click this link to complete the safety report

Report ID *(derived)* REP0592367   

Recommended report type *(derived)* CTEP 24 Hour SAE Notification   

Report due by *(derived)* Monday, March 13, 2017 8:00:00 PM (Eastern Standard Time)   

- A recommended action = “CREATE” indicates that an expedited report is expected based on the programmed rules setup in CTEP-AERS for the study.
- If the Investigator chooses not to report, the recommended action should be edited to “NONE”.
 - Note: editing the recommendation on the Expedited Reporting Evaluation /Late AE reporting form will not affect the value of the field “SAE report recommended (derived)” on the AE / Late AE form.

SAE Report Recommendation “NONE”

Send all AEs for evaluation 🗑️ ✅ 📄

Recommended action for report (*derived*)

An expedited report is NOT recommended. If the Investigator believes an expedited report IS warranted, use the link below to move to CTEP-AERS to complete the expedited report.
Opened To Site from System (13 Mar 2017) NONE ✅ 📄

Click this link to complete the safety report 

Report ID (*derived*) REP0737392 ✅ 📄

[Printable Version](#) [View PDF](#) [Icon Key](#) Save Cancel

CRF Version 497 - Page Generated: 13 Mar 2017 12:10:49 Central Daylight Time

- A recommended action = “NONE” indicates no expedited report is expected based on the programmed rules setup in CTEP-AERS for the study.
- If the Investigator wishes to report, the hyperlink on the Expedited Reporting Evaluation /Late AE reporting form should be used to launch CTEP-AERS.

?? Questions ??





DATA QUALITY PORTAL (DQP)

DQP Access

The DQP is located on the CTSU website.

- Four “**Rave/DQP**” tab dropdown options. *(Example 1.a)*
- Three DQP subtabs + ‘**Rave Home**’ subtab. *(Example 1.b)*

The screenshot shows the CTSU website interface. At the top left is the CTSU logo and the text "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE". Below this is a navigation bar with tabs: Home, Protocols, Dashboard, Regulatory, OPEN, Rave/DQP, Clinical Data, Education & Resources, Collaboration, RUMS, and Reports. The "Rave/DQP" tab is highlighted with a blue box, and its dropdown menu is open, showing four options: Rave Home, DQP Delinquent Forms, DQP Queries, and DQP Reports. Blue arrows point from each of these four options to the corresponding subtab in the "iMedidata" section below. The "iMedidata" section has subtabs: Rave Home, DQP Delinquent Forms, DQP Queries, and DQP Reports. Below the subtabs is the "iMedidata" logo and the text "Access to iMedidata:". There are two bullet points: "Click this link to access iMedidata directly using Single Sign On (if necessary)" and "If you are unable to access iMedidata using the Single Sign On link above, please try accessing via IIR: https://login.imedidata.com/selectlogin (using your CTEP-T&M credentials)". A box labeled "Example 1.b" is placed over the second bullet point. On the right side of the page, there is a "DQP Aging Report Summary" table with columns "#", "Protocol", and "Status". The table contains three rows of data, with the "Protocol" column containing redacted information.

Example 1.a

Example 1.b

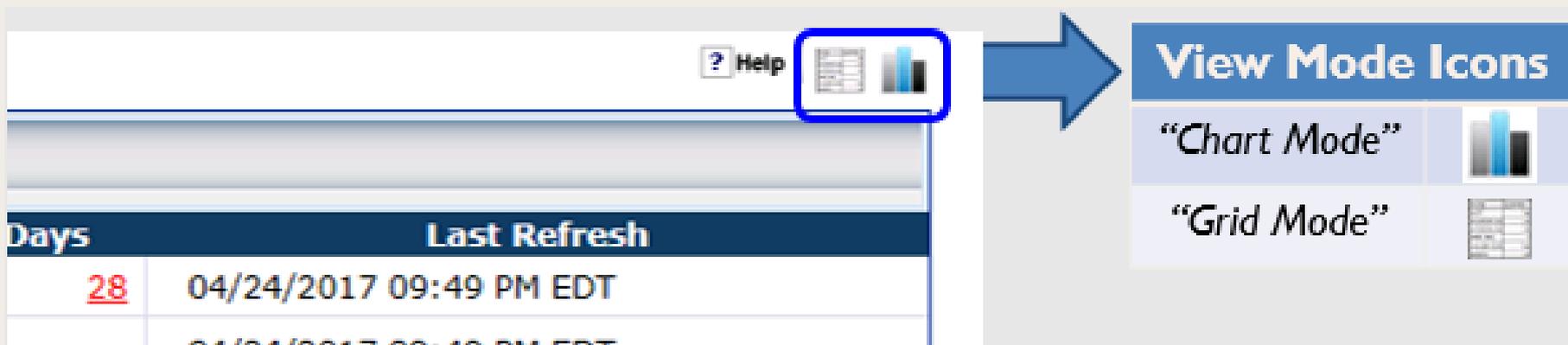
#	Protocol	Status
1	[REDACTED]	
2	[REDACTED]	
3	[REDACTED]	



VIEWING MODE OPTIONS

Grid & Chart Mode (I)

- Query and Delinquent Form details can be viewed in “Grid Mode” or “Chart Mode.”
 - Click on the “Chart Mode” icon to access “Chart Mode.”
 - Click on the “Grid Mode” icon to access “Grid Mode.”



The screenshot shows a web application interface. On the left, there is a table with two columns: "Days" and "Last Refresh". The "Days" column has a value of "28" in red. The "Last Refresh" column has a value of "04/24/2017 09:49 PM EDT". Above the table, there is a "Help" icon and a "View Mode Icons" button. A blue arrow points from the "View Mode Icons" button to a legend on the right. The legend is titled "View Mode Icons" and contains two entries: "Chart Mode" with a bar chart icon and "Grid Mode" with a grid icon.

Days	Last Refresh
28	04/24/2017 09:49 PM EDT
	04/24/2017 09:49 PM EDT

Help

View Mode Icons

“Chart Mode”

“Grid Mode”

Grid & Chart Mode (2)

- **Grid Mode** is the default view for all screens for the DQP Delinquent Forms and DQP Queries modules.

All Sites [Go]

Delinquency Aging Report Summary

Protocol	Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days	Last Refresh
	28	-	-	-	-	28	04/24/2017 09:49 PM EDT
	4	4	-	-	-	-	04/24/2017 09:49 PM EDT
	12	-	-	1	-	11	04/24/2017 09:49 PM EDT
	23	13	2	8	-	2	04/24/2017 09:49 PM EDT
	4	4	-	-	-	-	04/25/2017 01:33 PM EDT
TOTAL	73	21	2	9	-	41	

Grid & Chart Mode (3)

- **Chart Mode** provides similar information as “Grid Mode” organized in a visual display.
 - Hover cursor over bar graph to view details.
 - Click on bar graph to review details.

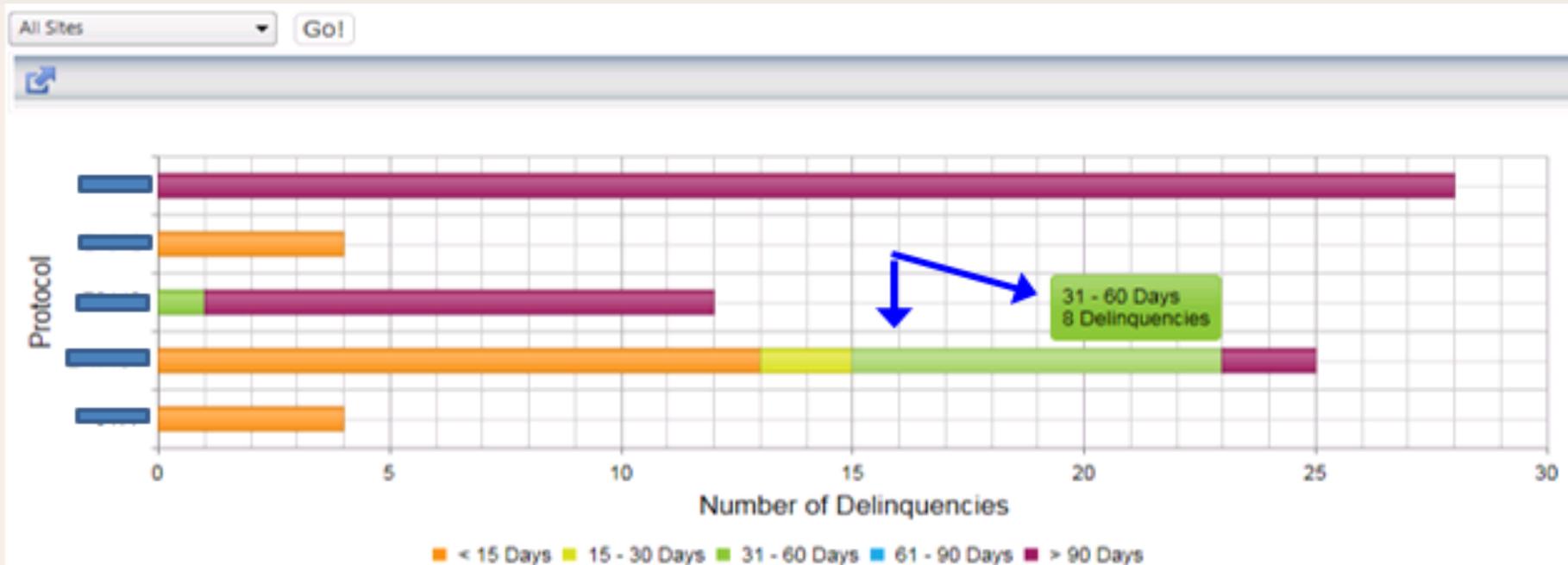


Chart Mode Views

- ‘Rave Delinquencies by Form’
 - Available for both forms and queries.
 - Hover cursor over bar graph to view details.
 - Click on bar graph to review details.





REPORTS

DQP Aging Report Summary Table

- Provides a summary of delinquent forms and queries for each Rave protocol a site is participating in.
- Access via “Rave Home” tab.

The screenshot shows the 'DQP Summary Table' interface. On the left, there is a table titled 'Export Options' with two columns: 'CSV' and 'PDF' in the top row, and 'Excel' and 'Print' in the bottom row. A blue arrow points from this table to a dropdown menu that is open, showing options: 'Export PDF', 'Export Excel', 'Export CSV', and 'Print'. A blue circle highlights the 'Export PDF' option. Another blue arrow points from the top of the dropdown menu to the 'DQP Summary Table' header. The main table has columns for 'Total Delinquencies' and 'Total Queries'. The data rows are as follows:

	Total Delinquencies	Total Queries
1	4	1
2	28	4
3	-	2
4	4	7
5	12	11
6	-	1
7	-	-
8	-	-
9	-	-
10	-	-

At the bottom of the interface, it shows 'Page 1 of 2' and 'Last update: 10:08:13 PM UTC'.

DQP Aging Report Summary

- Provides an aging report of delinquent forms or queries for each Rave protocol a site is participating in.
- Access via the “Rave Delinquent Forms” tab or the “DQP Queries” tab.

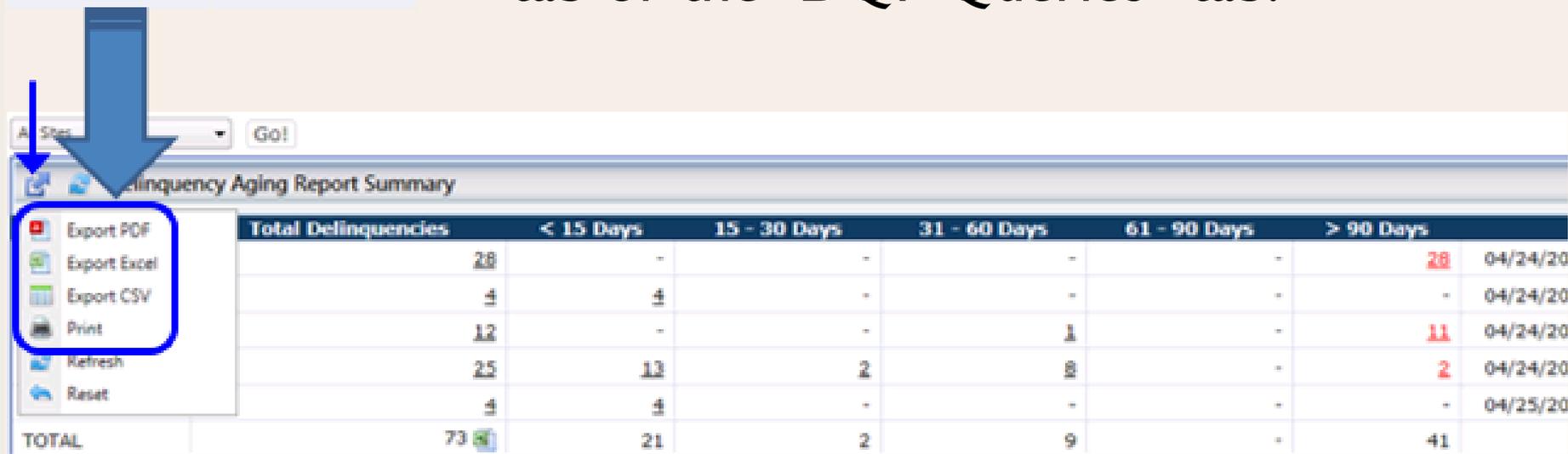
Export Options

CSV

PDF

Excel

Print



Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days	
28	-	-	-	-	28	04/24/20
4	4	-	-	-	-	04/24/20
12	-	-	1	-	11	04/24/20
25	13	2	8	-	2	04/24/20
4	4	-	-	-	-	04/25/20
TOTAL	21	2	9	-	41	

Rave Delinquencies Report (I)

- Provides a complete listing of all delinquent forms or queries for each Rave protocol a site is participating in.
- Access via the “DQP Delinquent Forms” tab or the “DQP Queries” tab.
 - Excel icon on the last row of the report.

Export Options
Excel ONLY

All Sites

Delinquency Aging Report Summary

Protocol	Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days	
		-	-	-	-	28	04/24/20
		4	-	-	-	-	04/24/20
			-	1	-	11	04/24/20
		13	2	8	-	2	04/24/20
		4	-	-	-	-	04/25/20
TOTAL	73	21	2	9	-	41	

Rave Delinquencies Report (2)

Excel Export

Delinquencies_2017425.xls [Read-Only] - Excel

File Home Insert Page Layout Formulas Data Review View Developer Add-ins Bluebeam eDocPrinter Tell me what you want to do...

Clipboard Font Alignment Number Styles Cells Editing

Calibri 11 A A Wrap Text General \$ - % +.00 -.00 Conditional Formatting Table Styles Insert Delete Format AutoSum Fill Clear Sort & Filter

1  Rave Delinquencies | Site: All Sites | Protocol: All Prototols | Form: All User: [redacted]
2 Forms Date: 4/25/2017
3
4
5

#	PROTOCOL	SITE	PATIENT	FOLDER	DATAPAGE ID	FORM DISPLAY NAME	FORM	EXPECTED DATE
7				Step 1 Treatment Cycle (1)	3772586	Disease Follow-Up Status Form	Disease Follow-Up Status Form	4/22/2017
8				Step 1 Treatment Cycle (1)	3797768	Treatment Agent: Pill Drug	Treatment Agent: Pill Drug	4/22/2017
9				Step 1 Baseline (1)	3818227	Baseline Adverse Event Form	Baseline Adverse Event Form	4/22/2017
10				Step 1 Baseline (1)	3818220	Baseline Disease Description	Baseline Disease Description	4/22/2017
11				Step 1 Baseline (1)	3818221	Comorbidity Form	Comorbidity Form	4/22/2017
12				Step 1 Baseline (1)	3818222	Hematology/Chemistry	Hematology/Chemistry	4/22/2017
13				Step 1 Baseline (1)	3818223	Hormone Receptor Status	Hormone Receptor Status	4/22/2017
14				Step 1 Baseline (1)	3818226	Patient Characteristics	Patient Characteristics	4/22/2017
15				Step 1 Baseline (1)	3818224	Prior Therapies - CDUS	Prior Therapies - CDUS	4/22/2017
16				Step 1 Baseline (1)	3818225	Prior Therapies - Primary Cancer	Prior Therapies - Primary Cancer	4/22/2017
17				Follow-Up 4YR	234766	Blood Chemistries	Blood Chemistries	4/14/2017
18				Follow-Up 4YR	234767	Hematology	Hematology	4/14/2017
19				Follow-Up 4YR	234768	Physical Exam	Physical Exam	4/14/2017
20				Follow-Up 4YR	234769	Vitals Follow Up	Vitals Follow Up	4/14/2017
21				Arm A Continuing Treatment Cycles 13 - 15	3556723	Adverse Event Form - Arm A	Adverse Event Form - Arm A	4/14/2017

Form Timeliness Report

- Quarterly report that provides timeliness metrics for forms expected, received on time, received late and not received for each Rave protocol a site is participating in.
- Access via the “DQP Reports” tab.

 Cancer Trials Support Unit <small>A SERVICE OF THE NATIONAL CANCER INSTITUTE</small> <i>Linking practice to progress</i>		Form Metrics for [REDACTED]					
Site	Protocol	Quarter (2017, Q1)				Cumulatively	Form Submission Metric (%) [B] / ([A] + [C])
		Total Number of Expected Forms [A]	Total Number of Forms Received On Time [B]	Total Number of Forms Received Late	Total Number of Forms Not Received	Total Number of Forms Not Received [C]	
[REDACTED]	[REDACTED]	12	12	0	0	0	100%
[REDACTED]	[REDACTED]	474	427	45	2	38	83%
[REDACTED]	[REDACTED]	118	115	3	0	3	95%
[REDACTED]	[REDACTED]	273	252	21	0	0	92%
[REDACTED]	[REDACTED]	148	120	28	0	1	81%
[REDACTED]	[REDACTED]	20	20	0	0	0	100%
[REDACTED]	[REDACTED]	63	28	33	2	2	43%
[REDACTED]	[REDACTED]	There are no Form Metrics to Display					
[REDACTED]	[REDACTED]	There are no Form Metrics to Display					
[REDACTED]	[REDACTED]	22	9	5	8	9	29%
[REDACTED]	Totals	1130	983	135	12	53	83%

Query Timeliness Report

- Quarterly report that provides timeliness metrics for queries issued, answered on time, answered late and not answered for each Rave protocol a site is participating in.
- Access via the “DQP Reports” tab.

 Cancer Trials Support Unit <small>A SERVICE OF THE NATIONAL CANCER INSTITUTE</small> <i>Linking practice to progress</i>		Query Metrics for [Redacted]						
		Quarter (2017, Q1)				Cumulatively	Query Submission Metric (%)	
Site	Protocol	Total Number of Queries Issued [A]	Total Number of Queries Answered On Time [B]	Total Number of Queries Answered Late	Total Number of Queries Not Answered	Total Number of Queries Not Answered [C]	[B] / ([A] + [C])	
[Redacted]	[Redacted]	64	64	0	0	0	100%	
	[Redacted]	75	69	6	0	2	90%	
	[Redacted]	186	169	14	3	3	89%	
	[Redacted]	231	200	26	5	5	85%	
	[Redacted]	73	68	5	0	2	91%	
	[Redacted]	10	6	0	4	4	43%	
	[Redacted]	21	21	0	0	0	100%	
	[Redacted]	<i>There are no Query Metrics to Display</i>						
	[Redacted]	39	39	0	0	0	100%	
	[Redacted]	45	9	35	1	1	20%	
	Totals	744	645	86	13	17	85%	



DEEP LINKING

Deep-Linking Abilities (I)

- ‘*Deep-Linking*’ allows access to Rave for a site, patient, or form directly from the DQP.
 - No separate Rave login is required.
 - Rave study access is required.

A Medidata Rave icon denotes when deep-linking is available:



Deep-Linking Abilities (2)

- Deep-linking is available at the following levels:
 - ‘Site’, ‘Patient’, or ‘Form’.

Rave Delinquencies (Forms) Example 1

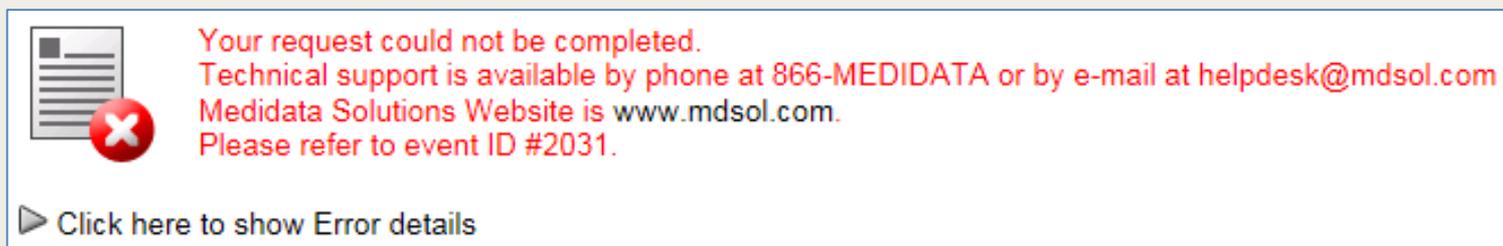
Site	Patient	Folder	Form Display Name	Form
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Rave Queries Example 2

Site	Patient	Folder	Forms Display Name	Form	Log Line	Field	Query
[Redacted]	[Redacted]	[Redacted]	Other Adverse Event Form	[Redacted]	n/A	[Redacted]	[Redacted]

Deep-Linking & Rave Access (I)

- If you **DO NOT** have Rave study access, a Medidata error message will be displayed:

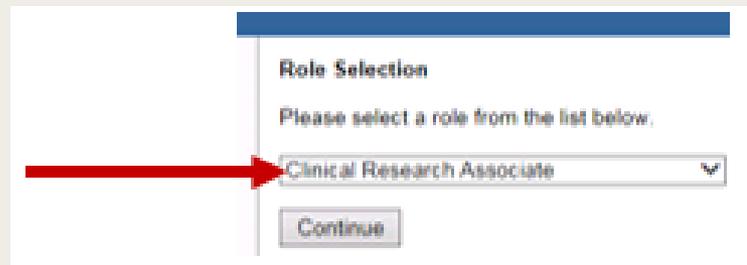


The screenshot shows a red error message box with a document icon and a red 'X' over it. The text inside the box reads: "Your request could not be completed. Technical support is available by phone at 866-MEDIDATA or by e-mail at helpdesk@mdsol.com. Medidata Solutions Website is www.mdsol.com. Please refer to event ID #2031." Below the text is a link that says "Click here to show Error details" with a right-pointing triangle icon.

- Contact your site administrator regarding questions about Rave study access or invitations.

Deep-Linking & Rave Access (2)

- If you **DO** have Rave study access, a new browser tab will open with a Rave session.
- Select the “Clinical Research Associate” EDC Role if prompted:



- If you *deep-link* at the “Site” level, Subjects and Task Summary details will be visible:

Subject	Task Summary: Site	Subjects
 	  NonConformant Data	0 
 	  Open Queries	5 
 	  Overdue Data	8 

Deep-Linking & Overdue Data

- **“Patient” level** If you *deep-link* at the “Patient” level, the patient will open in Rave, the Task Summary will be displayed and the overdue data will be specified:

Visit	Date	Task Summary: Subject	Pages
Enrollment Forms	14 Aug 2015	▶ ⚠ NonConformant Data	0 📄
Screening	14 Aug 2015	▼ ⚠ Open Queries Course 3 -Serology Course	1 📄
Extent Of Disease	14 Aug 2015	▼ ⚠ Overdue Data Screening-PET	17 📄
Extent Of Disease (2)			
Extent Of Disease (3)			
Extent Of Disease (4)			

- **“Form” level** If you *deep-link* at the “Form” level, the form will open in Rave for data entry to be completed:

The screenshot shows a web-based data entry form for 'Blood Chemistries' under the 'Follow-Up 24MO' visit. The form includes fields for 'Patient Initials (LPM)', 'Subject', and 'Page: Blood Chemistries - Follow-Up 24MO'. A 'Date of Collection' field is present with a dropdown arrow. Below this is a note: 'Enter Sample Collection Date only if different than Date of Collection entered above.' The main data table has columns for '#', 'Lab Test', 'Not Done', 'Sample Collection Date', 'Lab Value', 'UOM', 'LLN (Lower Limit of Normal)', and 'ULN (Upper Limit of Normal)'. The first row shows 'Sodium, Serum' with a 'Not Done' radio button and empty input fields for the other columns.

Deep-Linking & Open Queries

- **“Patient” level** If you *deep-link* at the “Patient” level, the patient will open in Rave, the Task Summary will be displayed and the open queries will be specified:

Visit	Date	Task Summary: Subject	Pages
Enrollment Forms	14 Aug 2015	NonConformant Data	0
Screening	14 Aug 2015	Open Queries	1
Extent Of Disease	14 Aug 2015	Course 3 -Serology Course	
Extent Of Disease (2)		Overdue Data	17
Extent Of Disease (3)		Screening-PET	
Extent Of Disease (4)			

- **“Form” level** If you *deep-link* at the “Form” level, the form will open in Rave for the query to be answered:

Off Study Summary

Patient Initials (LFM):

Subject: Off Study Summary - Off Study

Date Off Study?

? Please complete the Off Treatment Summary form in the Post Treatment folder. This should be completed any time study drug was administered. The folder will populate when the Course Assessment is completed with a NO entered for the last question re: continuing therapy. Email data management to request that the remaining forms in the Post Treatment folder be inactivated.
Opened To Site from DM (24 Aug 2015)

Per Query 5 Sep 2012

?? Questions ??





CENTRAL MONITORING

Central Monitoring vs. On-Site Auditing

Central Monitoring	On-Site Auditing
Patients will be monitored for critical data points based on specifics of the monitoring plan for the protocol.	Minimally 10% of patients selected for audit are reviewed.
Central Monitoring augments other reviews (such as site auditing and on-site monitoring).	On-Site Auditing will continue as per the current process.
Central Monitoring is near real time data review.	On-site auditing is performed every 18 months - 3 years.
Central Monitoring is performed to address safety concerns immediately.	On-site audit is performed to verify data.
Applicable to registration trials in Rave.	Applicable to all trials in Rave.

Central Monitoring Goals

- Streamlined process for performing data monitoring remotely.
 - Data review to be recorded in Rave.
 - Source documents will be uploaded in a central location accessible to monitors to review against the data in Rave.
- Provide an efficient way for sites to track document submission for Central Monitoring.

Central Monitoring Screen

- Ability to redact Personal Identifiable Information electronically while uploading source documents.
- Reminders and Alerts for missing documents.
- Direct links to the source document.
- One place to keep tabs on all the central monitoring activities for all protocols even when led by different Lead Protocol Organizations.

Central Monitoring Screen Demonstration

- Show from different perspectives
 - Site
 - LPO Triage
 - LPO Monitor

?? Questions ??

