

# DATA MANAGEMENT CENTER NEWSLINE

## Web LDMS 10.0 Coming Soon

Frontier Science plans to release Version 10.0 of Web LDMS this summer. This release includes support for pharmacology tests that will allow Frontier Science to receive PK results through LDMS. Plans to migrate pharmacology labs onto the Web version of LDMS will occur later in the year.



Other new key features include:

- Overall bug fixes, performance improvement, and optimization
- A new Administration setting requires users to enter a comment for all specimen record changes
- A new feature allows users to add samples for multiple participant IDs in Quick Add simultaneously. The user will be able to define a list of participant IDs and then define a sample collection kit to be applied to all participants at once.
- Support for the Abbott COVID SARS-2 assay
- Added ability to QA/QC shipments by scanning non-LDMS generated barcodes. The value in the scanned barcode must match to the value set in Other Specimen ID or PID for QA to pass.
- ID3 (SID) field is now optional for the ACTG/IMPAACT project and when data are entered, no validation checks will be run.



## INSIDE THIS ISSUE

Web LDMS 10.0 Coming Soon	1
Helpful Tips for Rave Reports	2-4
Daily QA for Rave	5-6
Protocol Deviation Reporting System (PDRS)	7
Recorded Data Management Training	7
Employee Spotlight: Felicia Lenzo, LDMS Lead Trainer	7
DMC Training Schedule	8

## SUBMIT AN ARTICLE TO THE DMC NEWSLINE

The DMC Newsline encourages readers to submit articles, news releases, and event listings. Materials submitted are subject to editorial review. Please email information in Microsoft® Office Word format to the Editor, Mary Wojcik-Cross (wojcik@frontierscience.org).

# Helpful Tips for Rave Reports

In *Rave*, the *Reporter* module provides several reports that site staff can use for quality assurance and internal performance review. This article offers a brief overview of how to use *Reporter* reports and a few reports that will be useful for quality assurance. You can find more information in the *Rave Reports* reference guide, which is available on the DMC Portal on the Medidata Rave Resources link.

Several eLearning courses are also available through *iMedidata*: “Foundations of JReview,” “Medidata Rave 360 Reports,” and “Rave Reporter.” To access these eLearning courses, log into *iMedidata* and select the *eLearning* link in the sidebar to the right.

To access the *Reporter* module, log into *iMedidata* and select *ACTG-IMPACT* under *Rave Modules*. On your dashboard, select *Reporter* under *Installed Modules* in the sidebar on the left. A list of reports to which you have access appears. These reports may vary depending on your role at your site.

## Setting Parameters

All Rave reports include Report Parameters that users can set in order to customize the report output. At minimum, these include Study and Sites.

Click the arrow to expand the selected parameter. You must set criteria for parameters in order from top to bottom; for example, you cannot select Forms without first selecting Study, Site, Subject, and Folder.

Report Parameters View Report Help  
Clear All Parameters Reset All Parameters

Study:  A9999 | PROD

Name	Environment
<input checked="" type="checkbox"/> A9999	PROD
1	

Sites: ▾  
Subjects: ▾  
Folders: ▾  
Forms: ▾

## Save versus Submit

For most *Rave* reports, the interface allows users to *Save* and to *Submit Report*.

My Reports | Page Status v2.0 - Page Status v2.0

**Submit Report**

Report Parameters View Report Help  
Clear All Parameters Reset All Parameters

Study: ▾ A9999 | PROD

Name	Environment
<input checked="" type="checkbox"/> A9999	PROD
1	

Sites: ▾  
Subjects: ▾  
Folders: ▾  
Forms: ▾

Create User Saved Report:

Report Name:  Report Description:

Save  Cancel

Saving and submitting reports are two separate functions. Saving a report does not automatically submit it, or vice versa.

## Helpful Tips for Rave Reports, cont'd

### Save

Select *Save* to store the report parameters you have selected. You may then generate the report again later with the same parameters. The report appears in your list of available reports under the report name you have entered.

### Submit Report

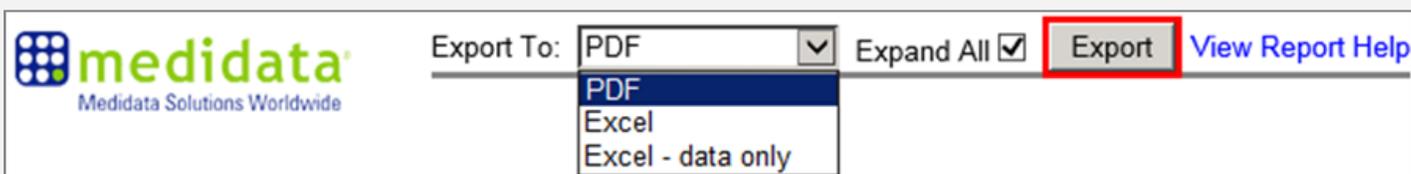
To generate the report with your selected parameters, scroll back up and select the *Submit Report* button.

### 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 you select the row for your site, new rows appear for each participant at your site for the selected study. Continue selecting row headers until you reach your desired level.

### Exporting

Most reports can be exported to PDF or Excel. Once you have generated the report using *Submit Report*, the export options appear at the top of the screen. For reports with a drill down feature, determine whether you want to expand all levels. This means that you will retrieve data for every available level of detail. If so, select *Expand All*. (If you select *Expand All*, the files may take longer to retrieve and may be very large.) When you have set all formatting options, select *Export*. You are then prompted to open or save the file in the selected format.



## Useful Rave Reports

Report Name	Purpose
<b>Page Status Report v 2.0</b>	Indicates how many eCRFs are Expected Total, Expected To Date, Entered, or Overdue, as well as how many queries are either Open or Answered. Includes a drill down feature.
<b>Query Aging Report</b>	Provides an overview of how long it takes for queries (both automatic and manual) to reach a status of “Answered,” “Closed,” or “Cancelled.” Does not use open queries for these calculations. Includes a drill down feature.
<b>Query Details Report</b>	Retrieves all queries that a site has received, including the full text of the query, the query status, the status date, the query response (if any), and the marking group (query sender). Also includes participant identifier, folder, and eCRF.
<b>Query Summary Report</b>	Provides the number of queries with the “Open,” “Answered,” “Closed,” or “Cancelled” statuses that a site has received, as well as the total number. Totals are broken down by marking group (query sender).
<b>Sticky Note Report</b>	Retrieves all sticky notes that a site has received, including the full text of the sticky note, date received, status, and acknowledging user.

# Helpful Tips for Rave Reports, cont'd

## Page Status Report 2.0

### Parameters

Study, Sites, Subjects, Folders, Forms

### Output

The *Page Status Report v 2.0* provides a status summary for eCRFs. This is a drill down report, meaning that you can click the row headers to view status counts down to the eCRF level.

	Total Counts								Queries		Pages Requiring Action						
	Expected Total	Expected To Date	Entered	Over due	Verified	Reviewed	Entry Locked	Locked	Open	Answered	Verify	Review	Translate	Coding	Sign	Entry Lock	Lock
<b>Anytown University Hospital CRS - World</b>	1832	1752	1812	96	0	0	0	0	64	62	0	0	0	0	0	0	0
<b>111111</b>	117	116	116	6	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>A9999, Step 1 (1)</b>	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Screening</b>	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Subject Level</b>	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Week 0 Visit 13 Nov 2015</b>	29	29	29	1	0	0	0	0	0	0	0	0	0	0	0	0	0

In the report output, columns that will be pertinent for site staff include *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), and *Overdue* (number of eCRFs considered overdue) under *Total Counts*. The *Open* and *Answered* col-

## Sticky Note Report

### Parameters

Study, Sites, Start Date, End Date, Sticky Status, User

### Output

The *Sticky Note Report* retrieves all sticky notes that a site has received (similar to the *Query Details Report* for queries).

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
Anytown University Hospital CRS	World	999999	Week 0 Visit 22 Apr 2016	Visit Status Report	CSPECMYN	22 Apr 2016	Site from System	S.User	System	A.Adams	Please complete the newly added ACTG Specimen Consent/Deconsent Tracking for Non-Protocol Defined Testing form.	Acknowledged
Anytown University Hospital CRS	World	999999	Week 0 Visit 22 Apr 2016	Study Treatment Initiation	SDYTRTSTYN	22 Apr 2016	Site from System	S.User	System	A.Adams	The Study Treatment Log has been added at the participant level. Please report the start of treatment on the Study Treatment Log.	Acknowledged
Anytown University Hospital CRS	World	999999	Week 1 Visit 29 Apr 2016	Study Event Tracking	ECYN	29 Apr 2016	Site from System	S.User	System	--	Please update the participant level Study Treatment Log	Placed

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

- **Connect the sticky note to a record:** *Site*, *Site Group*, *Subject*, *Folder*, *Form*, and *Field*
- **Identify the status of the sticky note:** *Sticky Created* (date the sticky note was created) and *Sticky Status*
- **Identify the sender of the sticky note:** *Marking Group*, *Sticky Issued by* (user issuing the sticky note), and *Role Placed by*
- **Record site acknowledgment:** *User Acknowl by* (user acknowledging the sticky note)

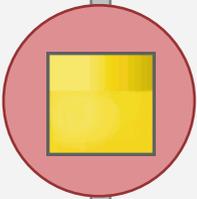


## Daily QA for Rave, cont'd



### Correcting Nonconformant Data

- When data are marked as nonconformant, that means they were entered in a format that the database cannot accept and **MUST** be corrected. Fields with nonconformant data will be highlighted in red or pink, like fields with queries, but they will have a red, triangular icon with an exclamation point instead of a yellow, circular query icon with a question mark.
- Determine why the data are nonconformant. Common reasons include:
  - Too many characters were entered in a free text field. Check your eCRF Completion Guide to see how many characters may be entered in that field. Trim your response appropriately. Remember: spaces count as characters.
  - The data were entered in the wrong format (such as letters in a field designated for numerical data only). Correct the data. If it is not possible to complete the field accurately without using characters that are considered nonconformant, contact your protocol data manager.
  - The field is a search list, and you typed data in rather than selecting from the list. Select the appropriate response from the drop-down menu.
- Select the reason for change from the drop-down. It is not possible to leave a comment for nonconformant data.
- A single data point may include both nonconformant data and a query; if so, the icon will be the nonconformant data icon. The nonconformance must be addressed before the query.



### Addressing Sticky Notes

- In Rave EDC, select the participant ID from the site-level Task Summary under *Sticky Notes*. The Task Summary for the participant then shows the eCRF that has the unacknowledged sticky note.
- Verify whether the eCRF indicated in the sticky note has been keyed. If not, key it.
- Acknowledge the sticky note by checking the box.
- Monitor sticky notes to be informed of event-driven or form requirements, such as adverse events and discontinuation.

1. Did the participant start the study/step defined treatment(s) at this visit or since the last visit?

The Study Treatment Log has been added at the participant level. Please report the start of treatment on the Study Treatment Log.

Opened To Site from System (25 Jul 2016)   
Acknowledge



### Keying Overdue Data

- In Rave EDC, select the participant ID from the Task Summary under *Overdue Data*. The Task Summary for the participant then shows the eCRFs that need to be keyed.
- Verify that the visit has occurred and that the data are available and ready to be keyed. If so, key the data.
- If the visit was missed, indicate this on the Visit Tracking Form.

## Protocol Deviation Reporting System (PDRS)

This utility is intended to supplement existing participant-level Network and study deviation workflows by providing a mechanism for mass deviations. The PDRS can be used to report protocol deviations that apply to multiple studies or multiple participants enrolled on a study. Individual, participant-level protocol deviations should continue to be reported per Network or study guidelines. While the PDRS was introduced in the context of reporting deviations due to the COVID-19 pandemic, this utility can also be used for other reportable deviations impacting large numbers of participants or if the deviation does not involve specific participants.

The Protocol Deviation Reporting System can be accessed from the Frontier Science DMC Portal under the ACTG and IMPAACT Network tabs. Protocol deviations should be reported by the communicating staff member, which may be the Investigator of Record or other designee. Within the utility, users are provided with a data entry screen to report the site, study, site awareness date, deviation start and end date, the type of deviation, and a summary of the deviation that occurred. The user can also indicate whether the deviation was reported to the local IRB/EC, and if the deviation was a result of the COVID-19 pandemic.

Users click the **Report Deviation** button to initiate a new protocol deviation report.

**Protocol Deviation Reporting System**

The below table displays previously reported deviations. All columns can be sorted in ascending or descending order. Click the **View** button on the right to display full information about a deviation.

Click the **Report Deviation** button to report a deviation.

**This utility should only be used to report deviations that apply to multiple studies or multiple participants enrolled on a study. Individual participant level deviations should continue to be reported per network or study guidelines.**

Report Deviation 

Site	Study	Patid	Site Awareness Date	Start Date	End Date	Report Date	Summary
		All	20-Apr-2020	12-Apr-2020	27-Apr-2020	27-Apr-2020	Does not meet criteria

Scroll to the right to access the "View" button 

## Recorded Data Management Training

### Introductory Workshop Training Sessions

- [Adverse Event Reporting](#)
- [Study Enrollment System](#)
- [Who We Are](#)
- [DMC Portal Website Highlights](#)
- [Medidata Rave Overview](#)
- [TJoin for Rave](#)
- [Rave Forms Overview](#)
- [Specifying Diagnoses, Signs, and Symptoms](#)
- [Rave eCRFs and Grading Laboratory Toxicities](#)
- [Rave Reports](#)
- [Introduction to JReview](#)
- [Rave Metrics](#)

Recorded data management training is available on the Training Pages of the Frontier Science Portal. The Recorded Training tab provides links to videos of individual training sessions provided in recent DMC Introductory Workshops. To learn additional information about the DMC's training programs, please contact our Education Director, Mary Wojcik-Cross, at (wojcik@frontierscience.org or 716-834-0900 ext. 7466).

## Employee Spotlight: Felicia Lenzo, LDMS Lead Trainer



Felicia joined Frontier Science in April 2021, as LDMS Lead Trainer. She holds a Bachelors in Biochemistry, with a minor in Mathematics, from Keuka College, completed her dissertation work at Roswell Park Comprehensive Cancer Center, and holds her Doctorate in Molecular and Cellular Biophysics and Biochemistry from the University at Buffalo. She is a Certified Associate in Project Management (CAPM) through the Project Management Institute.

Felicia fell in love with the city of Buffalo and decided to stay after completing her PhD. She lives downtown with her wife, dog, and two cats. They are patrons of the Buffalo food and art scene, frequently attending shows at Shea's, the Buffalo Philharmonic Orchestra, and Shakespeare in Delaware Park, as well as visiting museums and dining out at the many wonderful restaurants the area has to offer.

# 2021

## JANUARY

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

## MARCH

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

## MAY

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

## JULY

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

## SEPTEMBER

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

## NOVEMBER

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

## FEBRUARY

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

## APRIL

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

## JUNE

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

## AUGUST

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

## OCTOBER

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

## DECEMBER

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

## MARK YOUR CALENDARS

### Data Management Introductory Workshops

- October 26—28, 2021

See *Frontier Science Portal Training Pages* for additional information.

### LDMS Introductory Workshops

- August 13, 2021
- November 05, 2021

## CONTACT

### Data Management Center

Frontier Science Foundation

4033 Maple Road

Amherst, NY 14226, USA

Phone: +001 716-834-0900

Fax: +001 716-834-8432

or +001 716 834 8675



### ACTG and IMPAACT

#### Randomization Assistance

Phone: +001 716-834-0900 x7301

Email: [rando.support@fstrf.org](mailto:rando.support@fstrf.org)

#### User Support

Phone: +001 716-834-0900 x7302

Email: [user.support@fstrf.org](mailto:user.support@fstrf.org)

#### LDMS User Support

Phone: +001 716-834-0900 x7311

Email: [ldmshelp@fstrf.org](mailto:ldmshelp@fstrf.org)

<https://www.ldms.org/contact>