DATA MANAGEMENT CENTER
NEWSLINE

Web LDMS Version 10.0 Released

Frontier Science is pleased to announce the release of Web LDMS version 10.0, deployed to all laboratories on March 20th, 2022. As outlined below, this release includes many new features that enhance the user experience and provides additional project support, including an expansion of the Test Results module to now support pharmacokinetics (PK) testing.

Additional information about this version, including detailed release notes and the user manual for version 10.0, can be located on the LDMS website: http://www.ldms.org.

User Experience and Overall Improvement

- Administration setting available to require a comment following specimen record changes. If activated, the user must enter or modify the comment in order to be able to save changes to existing records.

- Unique sounds play for sample passes or fails when scanning in QA/QC.

- Improved loading times for large shipments in the shipping module.

Label and Barcode Generation

- Label options allow labels to have both the standard 2D LDMS barcode, as well as a 1D barcode with embedded Participant ID (PID), to be scanned into other devices (for non-network logged samples).

- 1D and 2D Barcode reports are now accessible from storage, shipping, and test results modules, allowing the user to generate a list of barcodes for all items in a container or on a test run for easy scanning.

INSIDE THIS ISSUE

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).

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Web LDMS Version 10.0 Released (cont'd)

Specimen Logging and Shipping

- Users can now add samples for multiple PIDs in Quick Add simultaneously. The user can define or upload a list of participant IDs and then define a sample collection kit to be applied to all participants at once.

- The Other Specimen ID is now supported for selecting/filtering specimens from an uploaded file.

- Receiving laboratories now have the option to cancel data file imports if an imported shipping file contains a new project that does not exist in their LDMS database.

- QA/QC can be performed on shipments by scanning non-LDMS generated barcodes.

Testing

- LDMS now supports the Abbott COVID SARS-2 assay.

- Expanded capabilities to support PK testing in Web LDMS.

  ◊ Result files include Control Chart Options, creation of QC and Calibrator controls, and upload of result files are supported.

If you have any questions about using LDMS or scheduling a training session, please contact LDMS User Support or the LDMS Training Team. Support is available 24/7.

LDMS User Support Email: ldmshelp@fstrf.org	LDMS Training Team Email: ldms.training@fstrf.org
Phone: +001 (716) 834-0900 ext. 7311 Web: https://www.ldms.org/contact/	

Rave Queries from Medical Coders

Rave queries from Medical Coders ask questions about events to ensure that the event is being captured and coded in the most specific way. When resolving a query in *Rave*, the most important thing to do is to make the change in the data field in question. Next, add a comment indicating the change that was made to this field, as this helps prevent another query from being sent. *See How to Complete Daily QA in Rave on page 3.*

When reporting HIV or COVID-19 (or any other organism), it is important to include information about what the virus is doing in or to the body. Please include this information within the *Specify* description.

For example:

HIV infection (specify if congenital or acquired)	*COVID-19 confirmed infection*
HIV myocarditis	*COVID-19 suspected infection*
HIV neuropathy	*COVID-19 asymptomatic infection*
HIV encephalopathy	*COVID-19 laboratory confirmed infection*
HIV wasting syndrome	*COVID-19 pneumonia*
	COVID-19 respiratory infection

Completing Daily QA in Rave

Beginning of the Day

- In Medidata Rave, view **Task Summary** for each study.
- Identify overdue data, nonconformant data, open sticky notes, and outstanding queries.
- In the Reporter module, view **Query Detail Report** for each study. For the *Query Status* parameter, select "Open."
- Set priorities for entering or correcting data and resolving queries: Which have been outstanding longest? Which are simplest to resolve?

▽ Task Summary: Site	Subjects
▷ 🖊 Requiring Signature	1 ▢
▷ ⚠ NonConformant Data	1 ▢
▽ ❓ Open Queries	7 ▢
1111111	
2222222	
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▷ 🟨 Sticky Notes	6 ▢
▷ 🕗 Overdue Data	19 ▢

Resolving Queries

- In Medidata Rave, select the participant ID from the site-level Task Summary under *Open Queries*. The Task Summary for the participant then shows the eCRF with the outstanding query or queries.
- View the eCRF. Look for questions highlighted in red or pink; these have outstanding queries.
- Evaluate the query and consult your source data.
- For **Site from System** queries:
  - If the data entered in Rave are <u>incorrect</u>, correct the data field in question. Complete the drop-down menu indicating reason for change. DO NOT enter a comment OR a data change in the comment field.
  - If the data entered are <u>correct</u>, complete the comment field explaining why. DO NOT enter data changes here.
- For **Site from DM** queries:
  - If the data entered in Rave are <u>incorrect</u>, correct the data field in question. Complete the drop-down menu indicating reason for change. Enter a comment in the comment field explaining the change. This is important to capture for the Audit Trail. DO NOT enter data changes here.
  - If the data entered are <u>correct</u>, complete the comment field explaining why. DO NOT enter data changes here.

What is the visit/contact date?
? This date must be after the previous visit date. Please verify.
Opened To Site from System (30 Nov 2016)

Reason for Change
Data Entry Error
01 Jan 2016
Data
Comment Field

- For **Site from Medical Coder** queries:
  - If the data entered in Rave are <u>incorrect</u>, correct the data field in question. Complete the drop-down menu indicating reason for change. Enter a comment in the comment field explaining the change. This is important to capture for the Audit Trail. DO NOT enter data changes here.
- Remember, you may receive additional queries throughout the day.

Clinical Data Management eLearning Update

An *Ongoing Data Review* eLearning has been added to the Training Pages of the Frontier Science Portal (Site Support > Training Pages > eLearning Courses).

The New Investigator Topics section of the eLearning Courses tab currently features modules focused on the following content:

- *Data Freeze and Data Lock*
- *The Study Build Process*

The General Clinical Data Management section features modules geared toward clinical site staff, with the following topics currently available:

- *Electronic Data Capture: Study Start-up and Planning Activities*
- *Data Standards Implementation*
- *Targeted Source Data Verification*
- ***Ongoing Data Review***

eLearning development at the Data Management Center is ongoing.

Site Support
Computer Account Report
Computing Manual
Computing Requirements
DMC Contacts
Email Address Book Download
Email Address Lookup
Medidata Rave Resources
Newslines
Protocol Deviation Reporting System
Training Pages ←

Employee Spotlight: Laura Hovind, Lead Laboratory Data Manager

Laura Hovind has been working at Frontier Science since 2010, and has been a Lead Laboratory Data Manager since 2016. She holds a BS in Biology from Canisius College, an MS in Ecology, Evolution and Behavior from the University at Buffalo, and an MS in Bioinformatics from Johns Hopkins University.

Laura works on laboratory data management for numerous ACTG and IMPAACT protocols, currently including A5300B (PHOENIx), A5321, A5357, and A5381 (The Hakim Study). She is the lead of the Genetics Team, which manages the Biological Sequencing System and all associated sequence data programs and assists with genetic and genomic data that have been submitted to the Data Management Center, in addition to supervising a team of Laboratory Data Manager Assistants. Laura also participates in a number of working groups and committees, including the SDMC Lab Data Committee, DMC Generics, and the CDISC Biospecimens Subteam.

Outside of work, Laura enjoys hiking, birding, photography, crafting, and spending time with her husband, two toddlers, and their pets.

DMC Introductory Training Recordings

On-demand data management training is available on the Training Pages of the Frontier Science Portal. The Recorded Training tab provides links to video recordings of the individual training sessions provided in recent DMC Introductory Workshops. To learn additional information about the DMC's training programs, please contact Mary Wojcik-Cross (wojcik@frontierscience.org).

2022

JANUARY

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MARK YOUR CALENDARS

Data Management Introductory Workshops

- October 19—20, 2022

Web LDMS Introductory Trainings

- First Friday of Each Month

See https://www.ldms.org/training/schedule/ for more information

CONTACT

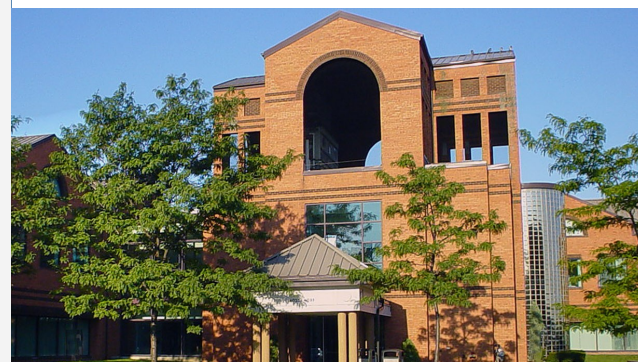**Data Management Center**

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ACTG and IMPAACT

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Email: **user.support@fstrf.org**

LDMS User Support

Phone: +001 716-834-0900 x7311
Email: **ldmshelp@fstrf.org**
https://www.ldms.org/contact