Data Management Center
NEWSLINE

Sending Laboratory Data as External Data Transfers

Laboratories often need to send data sets to the DMC outside of CRFs or LDMS. These data sets are considered External Data Transfers, and need to be sent in a controlled and secure way in order to be compliant with Good Clinical Data Management Practices.

Step 1: Work with your Laboratory Data Manager to define the format and frequency

The Laboratory Data Manager (LDM) will need to know what your data look like. If you have a LIMS system or instrument software that can generate an electronic file output, it is helpful to send an example of that file to your LDM. The LDM may suggest an Excel file template that you can use to report your data. Please also provide a Data Dictionary or any other information along with your file to assist the LDM with understanding the data.

Step 2: Sign a Data Transfer Agreement (DTA)

The LDM will send you a draft of the Data Transfer Agreement, which includes the details on the format of the data you are planning to submit, the frequency you plan to submit it, and information about who is responsible for submitting this data at your lab. Please review this document prior to signing in order to be sure that you agree to the plan outlined in the document for submitting the data and that the format defined in the document matches what you are planning to send. Both a Supervisor or designee, as well as the Data Submitter, will need to sign off on the document.

After signing the DTA, it is very important that your dataset follows the format outlined in the DTA and columns are not added, removed, or rearranged without first consulting with the LDM and signing a new DTA. Each time a data format is changed, the DMC will need to take additional steps to revalidate it, which can delay analyses. *(continued on page 4)*

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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Invisible Fields in Rave & Queries

Any time Site from System queries are not answered in Rave and the response to a leading question is changed, the queries based on the original response will become invisible. These queries are not considered outstanding and do not appear on the site data management reports. However, these **errors will reappear with the original query date** if the field is changed back to the original response and related queries **will then impact** the site data management reports.

If you change a leading question and see past queries reappear, contact the protocol data manager providing the visit, form, and PID information. The queries will be reviewed and removed from the site data management report, if appropriate.

Subject: **IFDEMO**
Page: **EVW10030: ACTG A5360 Model for End-Stage Liver Disease Score - Step 1, Week 0, Entry (1)**

INSTRUCTIONS:
Complete the LBW10028: Chemistry/Hematology Test Results Log prior to completing this form.

Was a model for end-stage liver disease (MELD) calculation performed at this visit?   ● Yes ○ No

Total Bilirubin

Sodium

INR

Serum Creatinine

> Invisible fields, until form is saved

Subject: **IFDEMO**
Page: **EVW10030: ACTG A5360 Model for End-Stage Liver Disease Score - Step 1, Week 0, Entry (1)**

INSTRUCTIONS:
Complete the LBW10028: Chemistry/Hematology Test Results Log prior to completing this form.

Was a model for end-stage liver disease (MELD) calculation performed at this visit?   Yes

Assessment Date:
? Data is required. Please complete.
Opened To Site from System (05 Jun 2019)
Forward
☐ Cancel

Data Entry Error ▾ [   ] ... ▾ [   ]

Total Bilirubin

Result available?
? It is indicated that a model for end-stage liver disease (MELD) calculation was performed at this visit, however 'Result available' for Total Bilirubin has been answered as 'No'. Please reconcile.
Opened To Site from System (05 Jun 2019)
Forward
☐ Cancel

Data Entry Error ▾
○ Yes ● No

> Queries generate when form is not completed as expected

Subject: **IFDEMO**
Page: **EVW10030: ACTG A5360 Model for End-Stage Liver Disease Score - Step 1, Week 0, Entry (1)**

INSTRUCTIONS:
Complete the LBW10028: Chemistry/Hematology Test Results Log prior to completing this form.

Was a model for end-stage liver disease (MELD) calculation performed at this visit?   No

Total Bilirubin

Sodium

INR

Serum Creatinine

> When leading question is changed, queries become invisible

Log eCRFs: Print Matrix PDFs vs Rave

When reviewing log eCRFs in particular, it's important to note a few key differences:

- **Orientation:** Print Matrix PDFs are printed in portrait orientation. In Rave, log forms are typically keyed in landscape orientation with clear indication that log lines can be added.

- **Header text:** Question text on log fields may differ slightly between the Print Matrix and Rave. Log forms in Rave typically have abbreviated header text in an effort to condense the screen and reduce the need for scrolling.

- **Fields visible on print and invisible in Rave:** Using edit checks, fields can be made visible based on the response to previous questions. In the print matrix, most fields and drop down lists will be visible. In Rave, some fields and dictionary options won't be visible until answering the associated question and clicking Save.

- **Help text:** Help text is not visible in the Print Matrix. It can be viewed in Rave by clicking the question mark icon.

- **Dynamic search lists:** The contents of drop down lists can be set dynamically based on the answer to a previous question. Dynamic search list contents are not visible on the print matrix—they will become visible once the associated field is answered.

Print Matrix PDF version:

LGW10006: Informed Consent Status Log

INSTRUCTIONS: Maintain a separate log line for each consent that is provided. Specimen consent for non-protocol defined testing should be reported on the TRK10000: Specimen Consent for Non-Protocol Defined Testing form and not on this form.

For Protocol A0000: Optional Consents are captured on the [LGW00000: Optional Consent Status Log] and not on this form.

Indicate the type of consent:	Protocol version ◯
	Pregnancy ◯
	Other consent ◯

If Other consent, specify [70]: _____

If Protocol version, select version:	[Version 1.0] ◯
	[Version 2.0] ◯
	[Version 3.0, LoA #1] ◯

| Description: | [Cohort 1] ◯ |
| | [Cohort 2] ◯ |

Initial consent for this (cohort/group/step/etc.)?　　☐

Date of consent: _____

Medidata Rave version:

Dates are reported in the format dd/MMM/yyyy with a three-letter abbreviation for the month. For example, 15/JAN/2015. A complete date is required for the date of consent.

LGW10006: Informed Consent Status Log

INSTRUCTIONS: Maintain a separate log line for each consent tha protocol defined testing should be reported on the TRK10000: Specimen Consent for Non-Protocol Defined Testing form and not on this form.
For Protocol A0000: Optional Consents are captured on the [LGW00000: Optional Consent Status Log] and not on this form.

#	Type of consent [?]	If Other consent, specify [70]	Select version	Description:	Initial consent for this (cohort/group/step/etc.)?	Date of consent [?]
1	... ▼					◯ 🖉 🖫

Add a new Log line Inactivate

Sending Laboratory Data as External Data Transfers, cont'd

(continued from page 1)

Step 3: Register for a DMC Portal Account

Visit www.frontierscience.org/register and enter the required information that Frontier Science needs to create your account. It is also helpful to know for which project and study you plan to initially submit data.

Step 4: Review your data file

Before sending data, it is very important to review your data file to confirm that data entered are correct, including patids, dates, and global specimen IDs. Confirm that your file is in the right format and compliant with the DTA. Unexpected data format changes could result in improper processing of your data. Lastly, verify that the file does not contain any unapproved PII/PHI, such as participant names or initials.

Step 5: Submit your data

Login to the Portal and click on the Data Submission System (DSS) link under the Laboratory Data Programs header. If you have never used this tool before, please refer to the Help file (found by clicking the Help button on the top right of the screen) for step-by-step instructions on how to proceed with uploading your files.
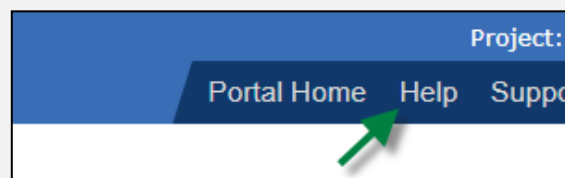
LDMS End-User Validation

As part of the development of the LDMS software, Frontier Science performs validation to ensure the software is functioning as intended. The suite of documents recording this process is maintained by Frontier Science and is available to laboratories when requested. However, the validation process does not end there. It is the responsibility of the lab to perform its own validation to confirm the software functions as intended within the end user's environment.

Frontier Science has created a suite of templates to assist our laboratories with creating and maintaining end-user validation documentation for the LDMS. Developer and end-user documentation packets, as well as a training presentation on this topic, can be requested from the LDMS website:

https://www.ldms.org/resources/validation/

A recent training presentation on this topic is available via the URL provided above, while a recorded webinar can be viewed on the Frontier Science YouTube channel: FSTRFfilms.

LDMS Training

LDMS Introductory Workshops are scheduled to take place at the Frontier Science office in Amherst, New York on the following dates:

- **March 6, 2020**
- **May 29, 2020**
- **August 21, 2020**
- **November 13, 2020**

The one-day training will include a full demonstration of all functions within the web application, with a hands-on component for participants. Ad hoc training requests to fit your laboratory's needs are also welcome. Training requests can be submitted via the LDMS website: **https://www.ldms.org/training/**

Employee Spotlight: Barrett Beck

What is your name and job title?

Barrett Beck, ACTG/IMPAACT Technical Writer/Trainer.

Where are you from?

I've lived all over the United States – Connecticut, New Hampshire, Utah, Nebraska, Ohio, Florida, and now, New York. I don't consider myself as coming from anywhere in particular.

What is your education?

I have two Bachelor of Arts degrees, in English and History of Art, from Ohio State University. I also have a Master of English, specializing in medieval literature, from Florida State University.

How long have your worked at Frontier Science?

I've worked at Frontier Science for roughly a year and a half.

What does a typical day for you at Frontier Science look like?

As a technical writer, organizing and assisting with the timely review of documents is my main responsibility. My job involves a great deal of collaboration with subject matter experts here at Frontier Science, so I'm usually nose deep in email. The training aspect of my job involves giving webinars on such topics as QA in Rave and the DMC Portal, as well as participating in the Introductory Training Workshops at Frontier Science Amherst.

What is your favorite part about working at Frontier Science?

I enjoy being part of a progressive not-for-profit research organization. Every day, I know I'm contributing to a mission to improve people's health and quality of life.

What was your greatest work-related accomplishment of the past year?

I was part of the eTMF Implementation Team that organized the switch from using a Content Management System for Essential Documents to a commercial electronic Trial Master File. I had the opportunity to develop several new documents and trainings for staff.

What changes have you seen over your years of working at Frontier Science?

Frontier Science has grown a great deal since I've arrived, particularly in terms of leadership positions. It's been a pleasure to see so many talented people being granted more opportunities to excel.

How do you think things will change over the next five years in HIV/AIDS clinical trials?

Something that I find very heartening is the increase in studies on individuals with HIV/AIDS who are aging—it's wonderful to see people living longer lives than ever.

What is the best part of your job?

I enjoy working with so many talented and driven people. It's quite inspiring and I feel like I always have to bring my best work to the table.

2020

JANUARY

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NOVEMBER

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DECEMBER

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MARK YOUR CALENDARS

Data Management Introductory Workshops

January 15-16, 2020

April 22-23, 2020

October 21-22, 2020

Webinar Series

See DMC Portal Training Pages for schedule

CONTACT

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ACTG and IMPAACT

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