DATA MANAGEMENT CENTER
NEWSLINE

Protocol Deviation Reporting System Update

The Protocol Deviation Reporting System (PDRS), developed to facilitate the collection of mass protocol deviations for multiple studies or multiple participants on a study, has been updated. The PDRS now allows the reporting of site-level deviations, as well as CAPA information for deviations that were not due to the COVID-19 pandemic.

What does this deviation apply to?
- All participants on study
- Some participants on study
- Site and Study only

Site-level deviations are experienced at the site level, but may directly impact study participants. Individual, participant-level protocol deviations should continue to be reported per Network or study guidelines.

Protocol deviations should be reported by the communicating staff member, which may be the Investigator of Record or other designee. Within the utility, users will be 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.

As a reminder, documentation of any deviations should be entered in participant study charts in real-time, consistent with DAIDS SOPs for source and essential documentation. In addition, please also continue to follow your site's IRB/EC policies and procedures for reporting protocol deviations.

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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).

Character Limits within Fields in Rave

Frontier Science sets character limits for questions where text or numbers are entered. These limits are contained within brackets, such as [70] or [nnnn.nnn] at the end of the question. In some cases, these limits are contained within the help text and can be accessed by clicking a ? button near the question. These limits are the underlined maximum number of characters that can be entered into that field and that can be incorporated into the database. If data exceed the defined maximum number of characters, a non-conformance system query will automatically be triggered, or typing additional characters into the field will be prevented.

Example #1:

[70] - The entered data should contain no more than 70 characters of any type, including letters, numbers, and spaces, as well as punctuation. If more characters are added to this field than allowed, a notification will appear indicating that the limit has been exceeded, as seen on the right.

> actg-impaact.mdsol.com says
>
> You cannot enter more than 70 characters in this field.
>
> OK

Hint: Draft text using Microsoft Word and take advantage of the word count feature before entering and saving the data in Rave.

Example #2:

[nnnn.nnn]- The entered data should be a number, containing no more than 4 numbers before the decimal and no more than 3 numbers after the decimal. The character limit does not mean that the format needs to match exactly; for example, by adding leading or trailing zeros.

Acceptable entries for this example would be:

<div align="center">

10

100.5

1.2

</div>

Unacceptable entries for this example would be:

10005.00 - Too many characters reported before the decimal place. Confirm accuracy of the data, and if the data are deemed correct as entered, note that in the query reply for the PDM to review. Otherwise, make the necessary corrections to ensure that the value falls within the allowable character limit for the field (i.e. [nnnn.nnn]). Correcting the data will automatically close the automated non-conformance System query.

> a. Enter weight in kilograms [nnnn.nnn]:
> ? Data entered is non-conformant. Please correct.
> Opened To Site from System (15 Dec 2020)
> Data Entry Error
> 10005.00   kg

100.0500 - Too many characters reported after the decimal place. Use proper rounding conventions to report the value with a precision of two decimal places to ensure that it falls within the allowable character limit for the field (i.e. [nnnn.nnn]). Correcting the data will automatically close the automated non-conformance System query.

> a. Enter weight in kilograms [nnnn.nnn]:
> ? Data entered is non-conformant. Please correct.
> Opened To Site from System (15 Dec 2020)
> Data Entry Error
> 100.0500   kg

0010.500 – The leading zeros are not required and should be removed. No query will be produced as a result of this entry; however, it is best practice to not include leading zeros. In addition, zeros after the decimal place should only be present if that level of precision is noted within the source documentation.

Signing eCRFs in Rave: Quick Reference

Who Is Authorized to Sign an eCRF?

In order to be authorized to sign eCRFs, investigators must meet three criteria:

- Must be listed on FDA Form 1572 for the site (sections 1 and 8) or DAIDS Investigator of Record agreement.
- Must be a clinician, such as a medical doctor or nurse.*
- Must be able to make a "direct and significant contribution to the data," which means they have direct responsibility for treating or evaluating research participants.

Listed on FDA Form 1572

Is a clinician

Makes "direct and significant contribution to the data"

How Do I Sign an eCRF?

Log into *iMedidata* and select the *Rave* link for the desired study. If you have multiple roles in the system, select the "Investigator—IVRS" role. Access eCRFs requiring signature via the Task Summary. At the study level, select the right-pointing arrow for "Requiring Signature" to show sites with eCRFs to sign. At the site level, clicking this arrow shows subjects; at the subject level, it shows the eCRFs themselves.

Select the eCRF from the Task Summary. The eCRF then displays. At the bottom of the screen, select *Sign and Save*.

You will then be asked to enter your username and password to verify that the information you entered on the eCRF is correct.

Task Summary: Study — **Sites**
- ▷ Requiring Signature — 1
- ▷ NonConformant Data — 1

Subject: AG0009
Page: **Visit Tracking - Entry** (1)

Complete and update this form as needed to document the study visit contacts as outlined in the protocol. This includes telephone visit evaluations.

What is the visit/contact date?	01 Jan 2016
What is the visit/contact end date?	01 Jan 2016
Did the visit/contact occur?	Yes

Printable Version   View PDF   Icon Key
CRF Version 324 - Page Generated: 06 Jun 2017 13:09:11 Eastern Daylight Time

Sign and Save   Save   Cancel

When and How Do I Sign a Batch of eCRFs?

Signatures will be requested at specific protocol milestones, generally corresponding to a data lock or freeze. You can apply signatures in a batch for each participant; you cannot apply them on the site level. The DMC will notify sites when a study milestone is met and the investigator is required to sign. However, investigators are encouraged to sign throughout the course of the study as part of their internal QA/QC and data review procedures, keeping in mind that clinical site monitors or the DMC may query data requiring data changes and re-signature at any time while the study is ongoing.

In *Rave*, navigate to the subject level. There, you can sign for all eCRFs collected at one visit, one eCRF collected at multiple visits, or all eCRFs at once.

✉ Messages   📖 My Profile   ❓ Help   🏠 Home   Logout
User: Ana Adams Principal Investigator (Investigator - IVRS)

Grid View

Sign and Save		AG0006	Screening	Entry (1)	Week 1 (1)	Week 2 (1)	Eligibility Checklist (1)	
✓ All								✓ All
Participant Enrollment			✓					Participant Enrollment
Visit Tracking				✓	✓	✓		Visit Tracking
Vital Signs						✓		Vital Signs

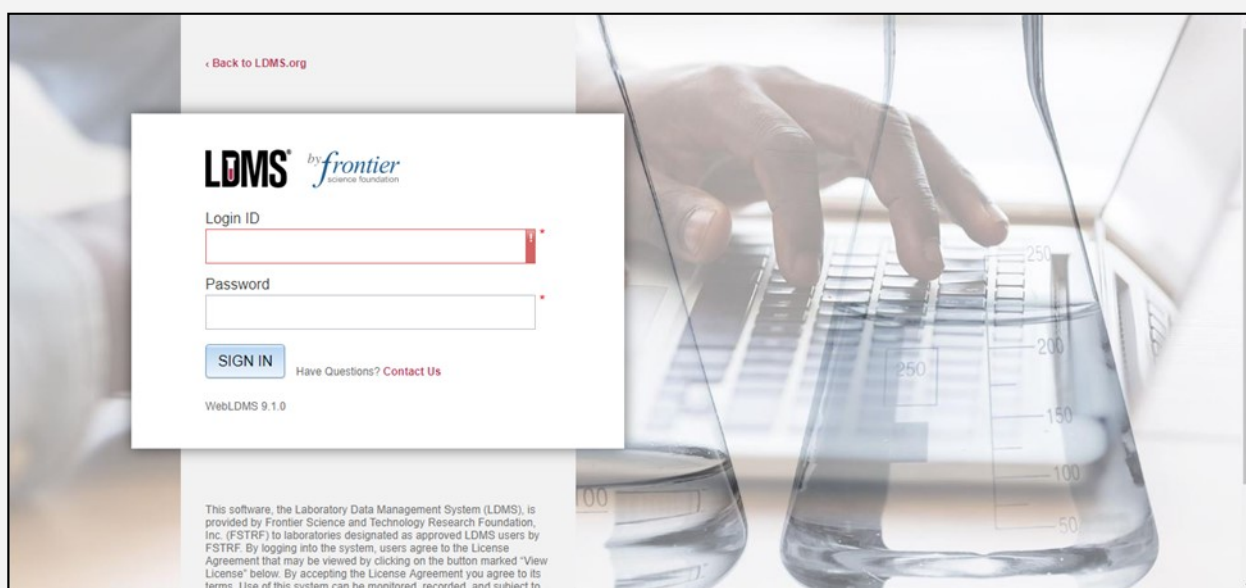In the upper right-hand corner, select the *Grid View* link. In Grid View, you may select a folder (visit) by clicking a column header, select an eCRF by clicking a row header, or select "All." Selected cells will be highlighted. Next, click *Sign and Save* and enter your credentials.

*Limited exceptions for certain studies (i.e., behavioral studies) where there may not be a medical doctor on site.

LDMS News: LDMS Web Version 9.1

Frontier Science is pleased to announce that LDMS for the Web Version 9.1 was released December 13, 2020. Frontier Science upgraded all labs' databases from Version 9.0 to Version 9.1. With this release and upgrade, the user login page has been redesigned with a more modern look and feel. A few other new features added as part of the update are as follows:

- Overall performance improvement and optimization throughout the application
- General bug fixes
- Users can define storage containers with more than 26 rows
- Added ability to **sort how labels are generated** (e.g., sort by ID1, global ID, etc.)
- Shipping comments and shipping disclaimer added as selectable options in the custom report module
- Easier to **select current date** via the calendar menu option
- Added new **Frontier Science Online Resources** menu option that allows direct access to Frontier Science websites (Portal, validation resources, etc.)
- Added new **2D** and **1D** barcode options when designing custom label formats in the labels module
- Added new **1D Barcode and 2D standard reports** available in the reports module under the **Barcode Reports** category
- Added additional **validation checks** when logging records under the **ACTIV project** (PID validation, study validation, others specimen ID check)

The redesigned Web LDMS login page

More information about this version, including detailed release notes and the 9.1 user manual, is available on the LDMS website (www.ldms.org).

If you have any questions about LDMS, please contact LDMS User Support. Support is available 24/7/360.

User Support Contact Information

E-mail:	ldmshelp@fstrf.org
Phone:	(716) 834-0900 ext. 7311
Web:	https://www.ldms.org/contact/

Regulatory Submissions and Other Protocol Analysis Milestones

Regulatory submission and protocol analysis milestones datasets are inherently important as they drive treatment decisions and possible future directions within research agendas. Protocol teams, in conjunction with monitors, statisticians, and protocol and laboratory data managers, ramp up review prior to a data freeze to provide the best possible data to inform these research decisions.

Individual sites play a major role with preparation for these milestones, ranging from scheduling participant appointments to include the important and much awaited final visit to keying data and shipping specimens. While all sites are expected to perform quality assurance/quality control (QA/QC) activities over the entire course of a study, the DMC would like to remind sites of the importance of performing a more intensive internal QA/QC review ahead of major protocol milestones, particularly regulatory submissions.

The majority of data unfreeze requests that the DMC receives from sites are the result of findings identified during the site's own internal QA/QC after the data freeze date. The result is potentially incorrect data being included in analysis milestone datasets and submission packages. Sites play a key role in ensuring data accuracy and integrity. Internal reviews are one step to help in minimizing the data changes.

As always, the iconic *GOOD DATA IN… GOOD RESEARCH OUT* holds true.

Employee Spotlight: Michele Daneau-Phillips

Michele started as a medical coder at Frontier Science in July of 2007, and was recently promoted to the position of Medical Coding Supervisor. She graduated from SUNY Polytechnic Institute earlier this year with a Bachelor's degree in Health Information Management. Michele will be returning to SUNY Polytechnic Institute in February to begin her MBA in Health Informatics. Certified as a professional coder (CPC-A) through the AAPC since 2007, Michele has also been certified as a Registered Health Information Administrator (RHIA) since September 2020 through the American Health Information Management Association.

A country girl through and through, Michele is a 25 year Girl Scout. Between work and school, Michele does not have a lot of spare time but when time permits, she likes to fish on Lake Ontario during the summer and traveling to Florida to visit her father-in-law. Michele has been living in her newly-built home for just over a year and is looking forward to the spring. She plans to finish the landscaping, plant flowerbeds, and get started growing vegetables. Michele also loves playing volleyball and spending time with her family.

Responding to Queries

When responding to queries, please state in the response what change was made to the data. One change could potentially trigger other issues. If the change is specified, it makes it much easier to ensure that nothing new is triggered.

2021

JANUARY

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MARK YOUR CALENDARS

Data Management Introductory Workshops

- January 27—29, 2021
- April 27—29, 2021
- October 26—28, 2021

See Frontier Science Portal Training Pages for additional information.

LDMS Introductory Workshops

- February 19, 2021
- May 14, 2021
- August 13, 2021
- November 05, 2021

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ACTG and IMPAACT

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