Data Management Center
NEWSLINE

Preventing Screening and Eligibility Checklists Errors

In recent months, the Data Management Center has seen a substantial increase in data transcription errors on Screening and Eligibility Checklists. In an effort to maintain data integrity, avoid inadvertent enrollments, limit monitoring findings, and reduce the number of corrections to the checklists, the DMC is sharing the following information.

Most Common Checklist Errors:
The types of errors most commonly seen by the Data Management Center are listed below. While minor typographical errors can be corrected fairly easily, other errors are very complex. Errors on these data elements can severely impact stratification and potentially eligibility on a study.

Please pay close attention to the following data elements:
- PID
- Date of birth
- Biological sex at birth
- Date/Time of Informed Consent
- Reproductive potential
- HIV-1 infection status
- Dates lab specimens were obtained
- Lab results
  - ◊ Conversion/Unit
  - ◊ Upper vs. lower limit of normal

When completing the checklists, please do the following:
- Double-check each response before going on to the next question
  - ◊ Compare against source documentation
  - ◊ Are there any typographical errors?
  - ◊ Are lab-related eligibility results keyed/converted to the correct unit?
- Prior to clicking "Enroll," perform a thorough review of the entire checklist

As always, please do not hesitate to contact your protocol data manager if you have any study-specific questions.

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Inside This Issue
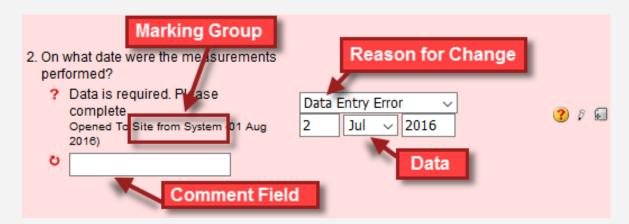
Submit an Article to the DMC Newsline

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).

Resolving Queries in Rave

In *Rave*, queries appear in the Task Summary with a question mark icon and are highlighted on eCRFs in pink or red. A query may indicate an error in the eCRF data that need to be corrected, but in some cases, the queried data are correct.

Queries can include both automated data checks (labeled "Site from System") and questions sent by data managers or coders ("Site from DM" or "Site from Coder"). These categories of query are called *marking groups.* To decide how to resolve a query, first look at the marking group.

When Should I Enter a Comment in Response to a Query in Rave?

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 the 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** and **Site from 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.
- If the data entered are <u>correct</u>, complete the comment field explaining why. DO NOT enter data changes here.

Remember: You may receive multiple queries throughout the day, so keep your eye on the Task Summary! The DMC may also re-query you on the same item.

Chief IMPAACT Data Manager:
Stephanie Popson Neyman

Stephanie Popson Neyman holds a BS in Biology from Syracuse University and a PhD in Molecular Biology and Biochemistry from the University of California, Irvine. Stephanie has been working at the Data Management Center since 2014 and recently accepted the role of Chief IMPAACT Data Manager. In her new role, Stephanie leads the data management components of the project, overseeing the IMPAACT data management staff and coordinating the day-to-day clinical data management operations for the project. She also fulfills the role of Targeted Source Data Verification (TSDV) Coordinator, overseeing and implementing the TSDV configuration for ACTG and IMPAACT studies in Medidata Rave in collaboration with the Monitoring Operations Branch of the Office of Clinical Site Oversight at DAIDS. Her data management expertise lies in Phase I/II drug licensing studies.

When not working, Stephanie enjoys teaching group fitness classes and spending time with her husband, young daughter, and extended family.

The Data Management Center Genetics Team

The Genetics Team at the Data Management Center is available to assist laboratories and clinical sites with performing the following activities:

- **Submitting genetic sequence data through the Biological Sequencing System (BSS).**
  The Genetics team can assist laboratories with questions regarding data issues, which may include formatting issues, sequence alignment issues, and unexpected mutations.

- **Using the BSS Update Retrieval and Query Utility (BURQ).**
  The Genetics Team can assist laboratories with using the BURQ to review and update the status of any sequences that are flagged as 'pending' and require lab review. The BURQ can also be used to search for any and all BSS records that the laboratory has submitted, allowing a laboratory to track their completeness of data submissions. A member of the Genetics Team can also provide a report of this type upon request.

- **Performing specialized QC of genetic sequence data.**
  The Genetics Team assists laboratories by performing specialized QC of their submitted genetic data, including phylogenetic analysis to identify issues such as specimen mix-ups, patid errors, and contamination problems.

- **Completing Drug Resistance and Mutation eCRFs in Rave.**
  Clinical sites may contact the Genetics Team with questions about how to key drug resistance and mutation data onto eCRFs in Rave. If there are any items in a participant's resistant report that are challenging to transcribe into the Rave eCRF, they can help.

For questions or assistance on any of the above items, please contact **genosupport@fstrf.org**

Enhancements to Laboratory Evaluation Reports

The following updates were recently made to the monthly Data Management Center laboratory evaluation reports:

- <u>Queries are now split by site:</u> Many processing laboratories support more than one clinical research site. An update was made so that only queries that apply to a given site will be counted in that site's lab evaluation report in the Query Responsiveness metric.

- <u>Appendix enhancements:</u> A number of appendices were updated to show additional useful information.

A. Query Responsiveness from 30-Jun-2019 to 28-Dec-2019	Target to meet: 90 %	
1. Percentage of queries responded to within 14 days	100.00 %	✔
2. Total number of queries sent	22	

LDMS for the Web 8.1

Frontier Science is pleased to announce that LDMS for the Web version 8.1 was released December 22, 2019. Frontier Science upgraded all labs databases from version 8.0 to version 8.1. A few new features added as part of the update are as follows:

- Overall performance improvement and optimization throughout the application
- Ability to report results for the Roche Taqman Qual Test
- The Tech Initials field now autofills when using the Quick Add Template feature
- General bug fixes

More information about this version, including detailed release notes and the 8.1 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.

<u>User Support Contact Information</u>
E-mail: ldmshelp@fstrf.org
Phone: (716) 834-0900 ext. 7311

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 can be submitted via the LDMS website: **https://www.ldms.org/training/**

2020

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MARK YOUR CALENDARS

Upcoming Data Management Introductory Workshops
- April 22-23
- October 21-22

Upcoming DMC Webinars
- March 12: Rave Reports
- April 9: Subject Enrollment System

See Frontier Science Portal Training Pages for additional information.

CONTACT

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ACTG and IMPAACT

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