VOLUME 28, ISSUE 2 DECEMBER 2017

DATA MANAGEMENT CENTER NEWSLINE

ICH Seriousness Questions for IMPAACT Studies

For many ongoing IMPAACT protocols, seriousness assessments are now required to be reported on the case report forms (CRFs) for each diagnosis, sign/symptom, and laboratory event. Source documentation for each event, regardless of severity grade, must include the site investigator's seriousness assessment. This assessment must be recorded on the study CRFs per protocol reporting requirements for each grade and event. This change comes in response to a European Medicines Agency (EMA) finding as part of a recent site inspection.

Studies affected by this change include 2001, 2002, 2013, 2018, P1026S, P1090, P1093, P1097, P1101, P1106, P1108, P1110, P1112, and P1115. Due to the number of studies impacted by this update, implementation of CRF updates will be staggered by study and will take several months to complete for all studies.

To collect these data for the study database, the CRFs for diagnoses, signs and symptoms, chemistry, and hematology forms for the studies referenced above will be updated to capture whether or not each event reported on these forms meets the International Conference on Harmonization (ICH) definition of a Serious Adverse Event. For these studies, collection of the investigator's seriousness assessment for each event will only be done prospectively; sites should not go back to previously reported data to make or record this assessment. This CRF update will not affect data collection in any other fields that are currently on the forms.

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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, at wojcik@fstrf.org.

frontier science foundation

ICH Seriousness Questions for IMPAACT

As the CRFs for each study are updated, notification of the update and how to implement it will be sent to each study team and participating sites.

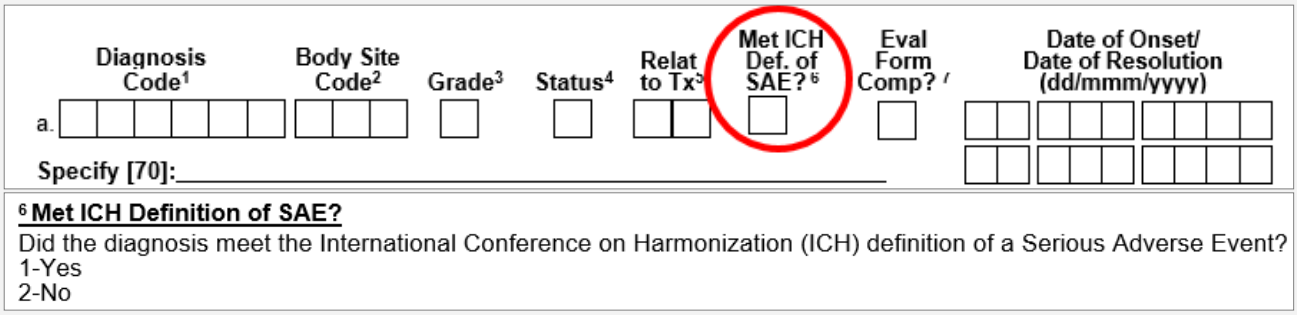
As before, events that meet the study's reporting criteria for the completion of the event evaluation form, must still be reported on the event evaluation form.

While study CRFs are being updated, continue to use the "form view" in eData's Online Correct. Do not use the "table view" in eData's Online Correct for the diagnoses, signs and symptoms, chemistry, or hematology CRFs, or you will not be able to change back to the "form view." If you use the "table view," you may also find the seriousness assessment field may be visible before the study-specific memo is issued indicating that this field is now required for the study.

If you do switch to "table view" by mistake, you may still make any needed changes to the CRFs in Online Correct. However, the site investigator's seriousness assessment for each event should not be entered on the CRF until the update memo is received for the specific study.

The definitions of (and distinctions between) assessment of the seriousness and severity of AEs are detailed in the DAIDS Manual for Expedited Reporting of Adverse Events.

If you have any questions, please contact the protocol data manager for your study.



Electronic Signatures in Rave

As of October 1, 2017, the DMC has implemented investigator electronic signatures on eCRFs in *Rave* for all ACTG and IMPAACT studies. As a result, staff at your sites who are assigned the **Clinical Research Coordinator - IVRS** role in *Rave* will see a different icon when an item (such as a visit, eCRF, or data field) is successfully completed for these studies.

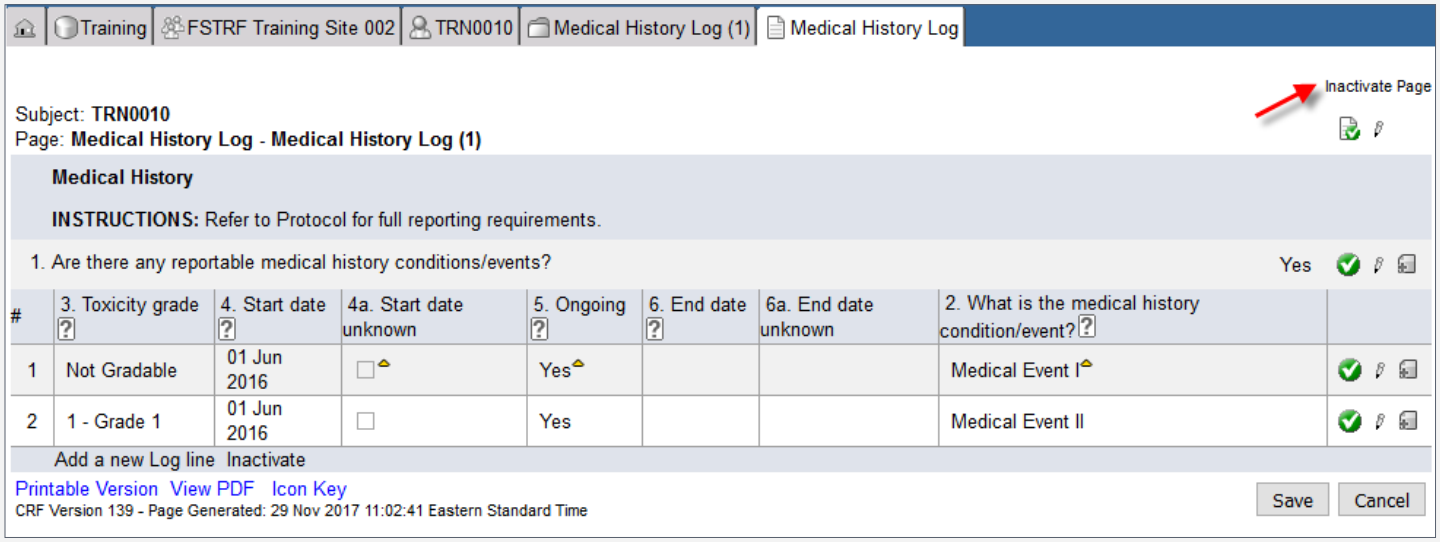
The icon that previously displayed for ACTG and IMPAACT studies on a completed item was the green checkmark (Complete). The icon that now displays on a completed item after implementation of investigator e-signatures is the yellow pen (Requires Signature).

Currently, the Requires Signature icon indicates that the item has been successfully completed. It does not indicate that your site investigator needs to sign the eCRFs at that time. Until further notice, no additional action is required by your site on items displaying the Requires Signature icon for ACTG and IMPAACT studies.

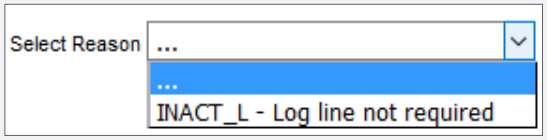
In the near future, we will be updating the system so that completed items display the Complete icon again for users with the CRC - IVRS role. After the update is complete, users with the **Investigator** role will continue to see the Requires Signature icon. They should only sign eCRFs when prompted by the DMC to sign at study milestone events such as data freeze for regulatory submissions and data lock at end of study.

Inactivating and Reactivating eCRFs in *Rave*

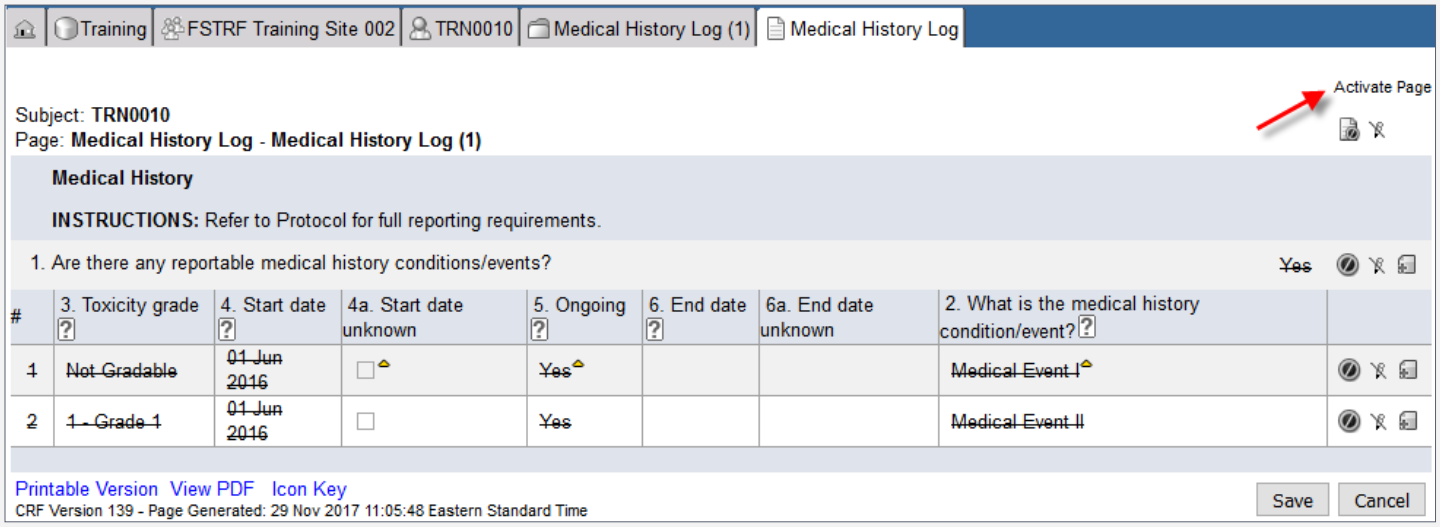
If you determine that you have completed an eCRF in error, you have the option to inactivate the eCRF by clicking on the **Inactivate Page** link in the upper right-hand region of the eCRF page.



When you click this link, you must select a reason for inactivation, then click the **Save** button at the bottom of the page.



Inactive eCRFs can be accessed through the *Rave* EDC system and are identified by the inactive ( ) icon. After you save the eCRF, any previously entered data items are crossed out, and the **Activate Page** link displays in the same location. If you have inactivated the eCRF in error, you can reactivate it by clicking **Activate Page** and providing a reason for activation before saving the form again.



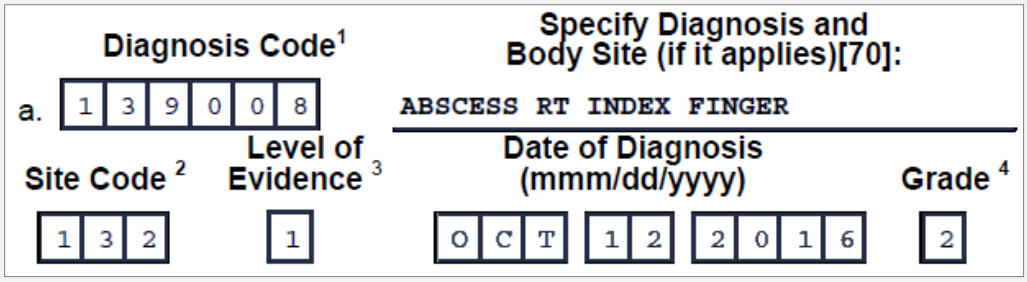
The audit trail is still available for inactive eCRFs and captures both inactivations and activations.

Quash a Query

Body Site

Remember to specify body site for all adverse events for which a body site can be identified, even if the form includes a place for you to enter a coded body site. Medical coders can *only* use what is entered on the Specify line (for *eData*) or Adverse Event term (for *Rave*) to perform MedDRA coding of adverse events; they cannot use data entered in any other field.

Example: The participant presented with an abscess on the right index finger (body site code 132). Specify the body site with the diagnosis:



There are also body site terms for conditions that are not necessarily isolated to one site or body system. If an adverse event manifests throughout the body in multiple sites, use terms such as "disseminated," "generalized," or "systemic" to indicate this.

Example: The participant presented with a rash (probably a drug reaction) that covered the arms, legs, chest, and hands. Indicate that the event was disseminated:

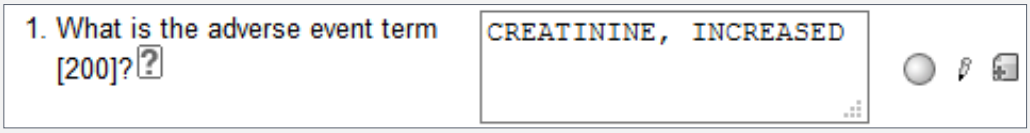
Adverse Event Identifier	SECTION A	1. Adverse Event	2. Severity Grade	3. Start Date (DD MON YYYY)
1000001	SECTION A	Drug Rash, Disseminated	2 - Grade 2	21 Oct 2017

For emotional or psychological diagnoses, such as depression, it is not necessary to specify the body site.

Increased and Decreased Laboratory Value Events

In *Rave*, when you are entering a laboratory value as an event, be sure to indicate whether the value is increased or decreased.

Example: The participant's laboratory results include grade 3 elevated Creatinine. Report the adverse event term on the Adverse Events Log like so:

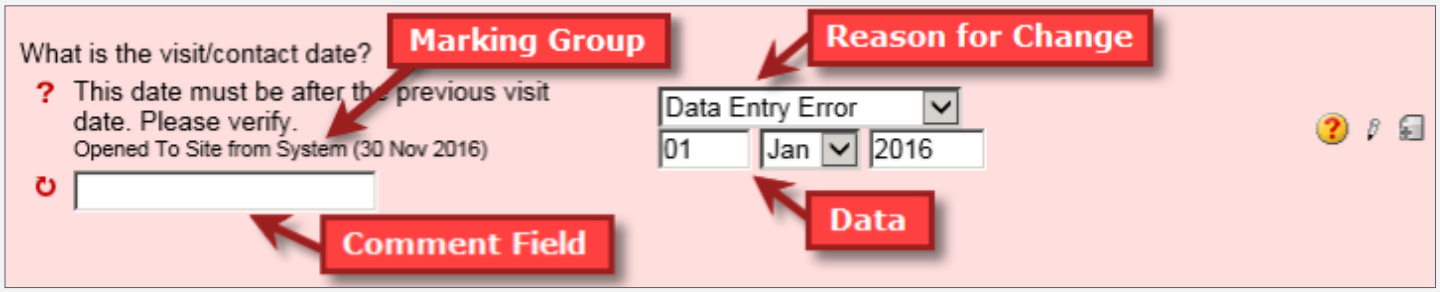


Resolving Queries in *Rave*

The DMC has recently updated its guidance for how site staff should resolve 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 needs 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 ("Site from DM"). These categories of query are called *marking groups.* To decide how to resolve a query, first look at the marking group.



Site from System

For a Site from System query, if the data entered in *Rave* are incorrect, 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 correct, complete the comment field explaining why. DO NOT enter data changes here.

Site from DM and Site from Coder

For a Site from DM or Site from Coder query, if the data entered in *Rave* are incorrect, 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 correct, complete the comment field explaining why. DO NOT enter data changes here.

CONTACT INFORMATION

Contact information for DMC staff for specific protocols can be found on the DMC Portal (https://www.frontierscience.org/) under Site Support > DMC Contacts > ACTG or IMPAACT Data Managers and Laboratory Data Managers by Study.

Employee Spotlight: Carrie Fry

What is your name and job title?

Carrie Fry, CDISC Coordinator

Carrie Fry, CDISC Coordinator.

What is your education?

I hold a B.S. in Biology and A.S. in Veterinary Technology from Medaille College in Buffalo, NY.

How long have your worked at Frontier Science?

As of October 27, I have worked at Frontier Science for 9 years.

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

As the head of the CDISC Department, a typical day involves a lot of email management and combing through SDTM documentation to assist in the development of eCRFs for individual studies and the Global Library. Depending on the status of my studies, I can also be found attending Study Build meetings, modeling and mapping data, and working with the SDTM Specialist Team to develop Frontier Science standards for data collection and submission.

What is your favorite part about working at Frontier Science?

I am never bored! Each day presents its own challenges, which are never the same from one day to the next. As the science behind the work we do evolves, we have to remain flexible and constantly adapt to new situations. I really enjoy being able to see this process from a bigger picture and contribute to the work we are doing to see our projects succeed.

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

Developing and streamlining a process to see our data standardized through implementation of CDISC foundational standards throughout the entire protocol lifecycle.

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

I think a large amount of our clinical trial work will surround prevention methods as well as treatment refinement to ease the side effects and daily burden on those infected with the disease.

It's the weekend. Where can we find you?

At home making blueberry pancakes and sipping tea, taking care of my small Frys, Ivan, age 3, and Lucy, age 6 months, doing housework and planning for the week ahead. If I had a day to myself, I would probably be getting a pedicure and headed towards the shores of Lake Ontario with a dozen worms and a fishing pole.

One thing that people would be surprised to know about me:

I am a farmer's wife! My husband currently runs his family owned 300-acre farm. We grow corn, soybeans, and hay for a small herd of beef cattle. We have also raised chickens and pigs. I had a 900lb pet pig named Fred, learned to drive with a standard transmission on a tractor, and know more about farming than I ever dreamt I would. I have been late to work more than once because our cows got out and were roaming across town! I am also fascinated by insects and wanted to be an Entomologist growing up. I hope to someday own a greenhouse and use my interest in entomology to cross paths with my husband's agricultural work.

Upcoming DMC Introductory Workshop

A Data Management Introductory Workshop has been scheduled for the ACTG and IMPAACT networks on January 24-26, 2018 at the Data Management Center in Amherst, NY. This is a three-day, interactive workshop for coordinators, data managers, or clinical staff involved with data management.

The workshop will cover the following topics:

- Introduction to Frontier Science
- DMC Portal Website Highlights
- Subject Enrollment System
- General Forms Overview
- Specifying Diagnoses, Signs, and Symptoms
- Rave Overview
- eData
- Quality Assurance Reports
- Rave Reports
- Daily QA in Rave
- ***(New!)*** Hands-On in Rave
- ACTG/IMPAACT Breakout: Event Forms and the AE Log
- Case Report Forms and Grading Laboratory Toxicities
- Database Structure and TJoin
- Expedited Reporting to DAIDS and DAERS Refresher
- LDMS Overview for Clinics
- Getting to Know Clinical User Support

Please note: Additional training for study-specific items can be added and the workshop extended for any participants wanting study-specific assistance. Those requests should be sent to Mary Wojcik-Cross (**wojcik@fstrf.org**) as soon as possible to make arrangements. A link to the full agenda, registration, and local hotel accommodations has been posted on the top center of the Frontier Science Portal website (**www.frontierscience.org**) under the ACTG and IMPAACT project tabs.

2018 Training Webinar Series

The DMC will be hosting a training webinar series on the second Thursday of the month at 9:00 AM, Eastern Time. See the full webinar schedule below:

January 11, 2018	Rave Reports
February 8, 2018	DMC Portal Website Highlights
March 8, 2018	Daily QA in Rave
April 12, 2018	Specifying Diagnoses, Signs, and Symptoms
May 10, 2018	Case Report Forms and Grading Lab Toxicities
August 9, 2018	QA Tips for eData Studies
September 13, 2018	Monthly Reports
October 11, 2018	Daily QA in Rave
November 8, 2018	TJoin
December 13, 2018	Monthly Reports

MARK YOUR CALENDARS FOR 2018

Data Management Introductory Workshops

January 24-26

April 11-13

October 17-19

IMPAACT Network Meeting

June 16-19

ACTG Network Meeting

June 20-24

Webinar Series

2nd Thursday of each month, 9:00 AM Eastern

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Clinical User Support

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Email: user.support@fstrf.org

JANUARY

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