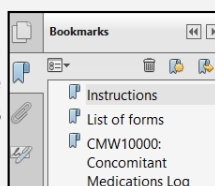# DATA MANAGEMENT CENTER

NEWSLINE

Updated eCRF Completion Guide and Annotated Print Matrix

An updated format of the **eCRF Completion Guide** and an **Annotated Print Matrix** was introduced last month for all future ACTG & IMPAACT studies in Rave. Examples of the updated documentation are included below. These documents are available on the Medidata Rave Resources page of the FSTRF portal, under the study-specific headings.

The new **eCRF Completion Guide** contains **help text**, **footnotes** to expanded help text, and **links** to the applicable data dictionary information located at the end of the document. Use the document bookmarks (to the left of the form) to return to the desired form location from the data dictionary information.

The new **Annotated Print Matrix** provides field reference numbers that link to the field annotation, when clicked. The reference number on the field annotation page can then be clicked to return to the respective form display.

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.

New Rave Metrics

After review and discussion with the ACTG PEC and IMPAACT Rave Data Metrics Working Group, the DMC is currently piloting new metrics for Rave studies. The new metrics are described below and will include data for a rolling three month window. Please note that the ACTG and IMPAACT metrics differ only in the number of days considered in Data Timeliness.

Error Responsiveness – This metric will assess site responsiveness to Site from System queries (errors). These are queries automatically triggered on the eCRF in pink/red, immediately after saving/submitting the record. The expectation is that Site from System queries (errors) will be answered within 3 days, 95% of the time.

$$\frac{Number\ of\ Errors\ Answered\ Within\ 3\ Days}{Total\ Number\ of\ Errors}$$

This metric is calculated by the following equation:

Based on reviewing data over a period of several months, the majority of errors were addressed by site staff within 3 calendar days. A separate error rate will no longer be calculated for Rave data.

Query Responsiveness – This metric will assess site responsiveness to Site from DM and Site from Coder queries. These are queries manually entered by DMC staff after review of the submitted data. The expectation is that Site from DM and Site from Coder queries will be answered within 2 weeks, 90% of the time.

$$\frac{Number\ of\ Queries\ Responded\ to\ Within\ 2\ Weeks}{Total\ Number\ of\ Queries}$$

This metric is calculated by the following equation:

The Query Responsiveness metric is unchanged from the Query Responsiveness metric from the eData Site Data Management report.

Data Completeness – This metric will assess the current form status of Rave eCRFs that are not marked as overdue. The expectation is that the percent of forms entered will be 90% or higher.

$$\frac{Number\ of\ eCRFs\ Entered}{Total\ Number\ of\ eCRFs\ Entered + Overdue}$$

This metric is calculated by the following equation:

Monthly site evaluation report generation dates will be posted on the Frontier Science portal so sites can prepare and key eCRFs accordingly.

ACTG Data Timeliness – This metric will assess the amount of time to key eCRFs based on the participant's visit date. The expectation is that visit tracking and study event tracking eCRFs will be keyed within 21 days, 90% of the time. These forms are designated as key forms since they control how the full set of eCRFs are rolled out dynamically in Rave for a study visit.

$$\frac{Number\ of\ Key\ eCRFs\ Entered\ Within\ 21\ Days}{Total\ Number\ of\ Key\ eCRFs}$$

This metric is calculated by the following equation:

IMPAACT Data Timeliness – This metric will assess the amount of time to key eCRFs based on the participant's visit date. The expectation is that visit tracking and study event tracking eCRFs will be keyed within 14 days, 90% of the time. These forms are designated as key forms since they control how the full set of eCRFs are rolled out dynamically in Rave for a study visit.

$$\frac{Number\ of\ Key\ eCRFs\ Entered\ Within\ 14\ Days}{Total\ Number\ of\ Key\ eCRFs}$$

This metric is calculated by the following equation:

Metric assessments will be assigned for the various categories:

Metric Assessment Ranges	Unsatisfactory	Approaching	Satisfactory	Exceeding
Data Timeliness	<85%	85-89%	90-98%	99-100%
Data Completeness	<90%	90-94%	95-99%	100%
Error Responsiveness	<90%	90-94%	95-98%	99-100%
Query Responsiveness	<85%	85-89%	90-98%	99-100%

Please direct questions regarding the new Rave metrics to the following:
    For ACTG: ACTG.ADLTSITEEVAL@fstrf.org
    For IMPAACT: IMPAACT.SITEDATAMGMTRPT.QUESTIONS@fstrf.org

New ACTG Site Laboratory Metrics

The ACTG Performance and Evaluation Committee (PEC) and DMC are currently piloting three new site laboratory metrics: **PBMC Shipping Compliance**, **Query Responsiveness**, and **LDMS Export Timeliness**. Please see the descriptions below. The new metrics, as well as two existing metrics, **Specimen Handling and Shipping** and **Timely Shipping of Specimens to BRI**, will be sent to site and laboratory staff on a monthly basis.

Specimen Handling and Shipping – This metric, called "Shipping Evaluation Score" on the new laboratory evaluation report, assesses site laboratory compliance with proper handling and safe shipping of specimens to the ACTG specimen repository at the Biomedical Research Institute (BRI). The specimen shipment score is calculated on a rolling 12-month window. The maximum shipment score for each site is determined by multiplying the total number of shipments by a factor of 4. A site's total penalty score is the sum of all penalties reported to the DMC on shipment evaluation forms available on the HANC website: https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx
The site's total penalty score is divided by the maximum shipment score to determine the proportion of shipments with penalties. The Specimen Handling and Shipping metric is not changed from the Site Data Management report.

$$Shipment\ Score = 100 - \left[\ 100\ \left(\frac{Total\ Problem\ Penalty}{4\ (Total\ Number\ of\ Shipments)}\right)\right]$$

Standard: shipment score >=90 points
Troubleshooting tip: review your shipment evaluation reports in real time

Timely Shipping of Specimens to BRI – This metric, called "Percent Shipped" on the new laboratory evaluation report, assesses site laboratory compliance with required shipping of specimens to the ACTG specimen repository at BRI within 6 months of specimen collection, excluding those samples earmarked for protocol testing within 6 months. Eligible aliquots evaluated in this metric include all specimens collected more than 6 months ago and described in the Specimens Approved for Shipment to BRI document on the ACTG Member website. This metric applies to all sites; however, the PEC will consider whether local and national shipping restrictions at non-US sites influence the site's ability to comply with the 6-month period. The Timely Shipping of Specimens to BRI metric is not changed from the Site Data Management report.

$$Percent\ Shipped = \frac{Number\ of\ Aliquots\ Shipped\ to\ BRI}{Total\ Eligible\ Aliquots}\ X\ 100$$

Standard: >=95% specimens shipped to BRI within 6 months
Troubleshooting tip: review your inventory in LDMS regularly and make plans for shipping

NEW: PBMC Shipping Compliance – This metric assesses site laboratory compliance with required shipping of viable cryopreserved PBMCs to the ACTG specimen repository at BRI within 5 weeks of collection. The PBMC Shipping Compliance metric is calculated on a rolling 6-month window. Specimens stored locally in LN2 are also counted as being compliant. The PBMC Shipping Compliance metric is new and was not included on the Site Data Management report.

$$Percent\ PBMCs\ Shipped\ Within\ 5\ Weeks = \frac{Number\ of\ PBMCs\ Shipped\ or\ Stored\ in\ LN2\ Within\ 5\ Weeks}{Total\ Number\ of\ PBMCs\ Collected}\ X\ 100$$

Standard: >=95% PBMCs shipped or stored in LN2 within 5 weeks
Troubleshooting tip: review your inventory in LDMS regularly and make plans for shipping

NEW: Query Responsiveness – This metric will assess site laboratory compliance with the requirement to respond to laboratory queries sent by the DMC through the Query System. Processing laboratories receive email notifications when laboratory queries are sent, and they must log into the DMC Portal and respond to queries using the Query System within two weeks. The Processing Laboratory Query Responsiveness metric is calculated on a rolling 6-month window, and is a new metric that was not previously included on the Site Data Management report.

$$Percent\ Responses\ Received\ within\ 2\ weeks = \frac{Number\ of\ Queries\ Responded\ Within\ 2\ Weeks}{Total\ Number\ of\ Queries\ Sent}\ X\ 100$$

Standard: >=90% queries responded within 2 weeks
Troubleshooting tip: review your new and pending queries regularly; establish communication plans with site staff to help resolve discrepancies

New ACTG Site Laboratory Metrics (cont'd)

NEW: LDMS Export Timeliness – This metric will assess the frequency of LDMS data transfer from site laboratories to the DMC. Laboratories using LDMS for Windows are expected to export their data at least once every week, where weeks examined will start on Sunday and end on Saturday. Exports are expected weekly even when no new data have been entered into LDMS. This requirement does not apply to laboratories using LDMS for the Web. The LDMS Export Timeliness metric is calculated on a rolling 6-month window, and is a new metric that was not previously included on the Site Data Management report.

$$Percent\ LDMS\ Exports\ Occuring\ Weekly = \frac{Number\ of\ Weeks\ Exported}{Total\ Number\ of\ Weeks\ Evaluated} \times 100$$

<u>Standard:</u> >=80% of weeks have at least one LDMS export
<u>Troubleshooting tip:</u> add this task as a recurring appointment to your calendar, review your LDMS Export Log periodically to monitor export frequency

During the pilot phase of this new site laboratory evaluation report, please send your comments, suggestions, or questions to fstrf.labdiv@fstrf.org.

Additional Resources:

Questions about your laboratory's evaluation report should be directed to fstrf.labdiv@fstrf.org.

LDMS User Manual and Reference Guides are available at www.ldms.org.

Questions about LDMS should be directed to ldmshelp@fstrf.org or (716) 834-0900 x7311.

Questions about your queries should be entered into the Query System or directed to your study Laboratory Data Manager.

Questions about your shipment evaluation reports should be directed to brirepository@afbr-bri.org.

October LDMS Introductory Training Workshop

A Windows LDMS Introductory Training Workshop is scheduled to be held at Frontier Science in Amherst, New York on October 22 and 23, 2018. All LDMS users are welcome to attend, subject to space considerations. Please keep in mind that this course is targeted towards new users of the Windows LDMS system. Seating is limited. If you or your staff are interested in attending, registration will start on September 10.

Please register using the following registration link: https://www.ldms.org/training/registration/

Managing the Transition to Full Electronic Data Capture

Authors: Suzen Maonera , Lynda Stranix Chibanda, Barbara Masango & the Seke North Research Team
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Background
Seke North Clinical Research Site (CRS) is a high-volume research clinic with two decades of experience conducting NIH-funded clinical trials within the clinical trials unit (CTU) at the University of Zimbabwe College of Health Sciences. The site has witnessed the successful completion of IMPAACT 1077BF, P1084S, and P1078, as well as trials for other networks. It is currently implementing IMPAACT P1115 and 2010, with 2009 and 2016 pending. A variety of data collection and transmission approaches have been used by the site. This article chronicles the site's recent experience of transitioning from paper to Electronic Data Capture (EDC).

An Opportunity to Change
As the Medidata Rave transition began for IMPAACT studies, the Seke North site did not initially adopt full EDC for a number of reasons. The primary factors were staff uncertainty, lack of supplies, and technical concerns. As continued transcription onto paper CRFs for future entry into the online system by data personnel proved to be cumbersome, highly labor-intensive, prone to error, and produced huge volumes of documents for storage, the problematic hybrid approach prompted the site to make the transition to full EDC. Site staff are now confident in using full EDC and the switch has transformed the site's data management process for the better and have expressed that there is no going back.

Our Approach
Learning from Others
The CRS Coordinator and the Data Manager visited another CRS within the CTU already operating full EDC for another funding network—Seke South CRS—to observe the process involved, the type of data machines required, and the data quality procedures involved. The CRS Data Management SOP was revised accordingly and resources were mobilized for the purchase of laptops with appropriate specifications, increased network capabilities in the clinic, and the enhancement of staff computer literacy skills via in-house training. The transition process involved all data collection personnel, including medical doctors, nurses, and counselors, and required practice, patience, repetition, supervision, ongoing support, training, and the development of an additional standard operating procedure.

Live Demonstration
The Data Manager demonstrated keying an entire visit of eCRF data into Medidata Rave for an active protocol. In turn, each person conducted a visit under supervision of the Data Manager, while encouraged to continue practicing. By the end of the month each team member could perform the task independently, consulting the Data Manager as needed.

Advantages
There are many advantages to using Medidata Rave, such as:
  Electronic capture and transmission of data in real time
  Limiting the collection of unnecessary information
  The one step process eliminates paper source documentation and transcription steps
  Paper source documentation is limited to case narrative of visit summary
  Time-saving
  Data monitoring
  Minimal paper storage per participant

Challenges
One challenge encountered by the site was the need for a stable internet connection.

Recommendations
When presented with the option to transition to direct data entry, sites should welcome the opportunity!

Managing the Transition to Full Electronic Data Capture (cont'd)

Seke North Clinical Research Site Staff

Row 1 (pictured left to right): Teacler Nematadzira (Medical Officer), Suzen Maonera (CRS Coordinator), Betty Jowa (Clinic Manager), Ruvimbo Tapera (Clinic Clerk), Betty Kadzanja (Clinic Assistant), Tendai Goverayi (Research Midwife)
Row 2: *Naume Mazarura (Clinic Assistant), Lucia Mungate (Nurse Counsellor/Outreach Worker), Tracy Manyeruke (Pharmacy Technician), Gift Chareka (Pharmacist), Barbara Masango (Data Manager), Elizabeth Parirenyatwa (Research Midwife)* ***Row 3***: *Eddington Mushonga (Laboratory Scientist)*
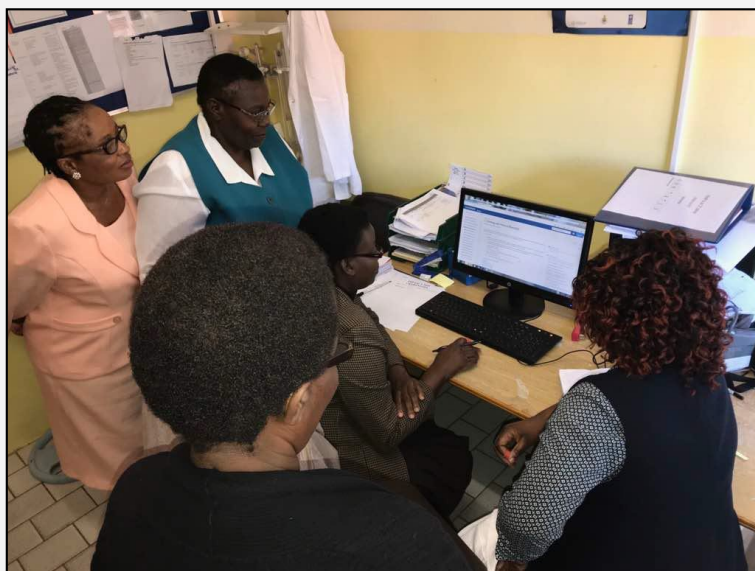
Data officer demonstrates the keying of a complete study visit to site personnel.

By the end of the first month, each clinician was able to key in a visit from start to finish, consulting the data officer as needed.

Daily Quality Assurance in Rave

Beginning of the Day

- In Rave EDC, view **Task Summary** for each study.
- Identify overdue data, nonconformant data, open sticky notes, and outstanding queries.
- In 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	
3333333	
4444444	
6666666	
7777777	
8888888	
▷ 🟨 Sticky Notes	6 ⊡
▷ ⊙ Overdue Data	19 ⊡

Resolving Queries

- In Rave EDC, 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.
- Remember, you may receive additional queries throughout the day.

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
❓ ✎ ▣

Daily Quality Assurance in Rave (cont'd)

Correcting Nonconformant Data

- When data are marked as nonconformant, that means they were entered in a format that the database cannot accept and MUST be corrected. Fields with nonconformant data will be highlighted in red or pink, like fields with queries, but they will have a red, triangular icon with an exclamation point instead of a yellow, circular query icon with a question mark.
- Determine why the data are nonconformant. Common reasons include:
    - Too many characters were entered in a free text field. Check your eCRF Completion Guide to see how many characters may be entered in that field. Trim your response appropriately. Remember: spaces count as characters.
    - The data were entered in the wrong format (such as letters in a field designated for numerical data only). Correct the data. If it is not possible to complete the field accurately without using characters that are considered nonconformant, contact your protocol data manager.
    - The field is a search list, and you typed data in rather than selecting from the list. Select the appropriate response from the drop-down menu.
- Select the reason for change from the drop-down. It is not possible to leave a comment for nonconformant data.
- A single data point may include both nonconformant data and a query; if so, the icon will be the nonconformant data icon. The nonconformance must be addressed before the query.

Addressing Sticky Notes

- In Rave EDC, select the participant ID from the site-level Task Summary under *Sticky Notes*. The Task Summary for the participant then shows the eCRF with the unacknowledged sticky note.
- Verify whether the eCRF indicated in the sticky note has been keyed. If not, key it.
- Acknowledge the sticky note by checking the box.

1. Did the participant start the study/step defined treatment(s) at this visit or since the last visit?
   - ☐ The Study Treatment Log has been added at the participant level. Please report the start of treatment on the Study Treatment Log.
   Opened To Site from System (25 Jul 2016) ☐ Acknowledge

Keying Overdue Data

- In Rave EDC, select the participant ID from the Task Summary under *Overdue Data*. The Task Summary for the participant then shows the eCRFs that need to be keyed.
- Verify that the visit has occurred and that the data are available and ready to be keyed. If so, key the data.
- If the visit was missed, indicate this on the Visit Tracking Form.

Quality Assurance with Portal Programs for eData

Quality assurance is a shared responsibility. Staff at the Data Management Center check to be sure that the data are submitted in a timely, correct, consistent way. Staff at sites and laboratories maintain a clear data submission timeline and check submitted data against source data to ensure that they match and are correct. To help sites understand where they have work to do, the DMC issues the Monthly QA Reports for eData studies.

This quick reference explains resources available to site users to help them meet their data quality assurance goals.

Monthly QA Report

(*Portal > QA Tools > Monthly QA Report*)

▶ Delinquency Report
▶ Missing Screening Failure Report
▶ Unanswered Queries Report
▶ Consecutive Missed Visits Report
▶ Unresolved Error Report

Delinquencies

Basic Information

▶ Delinquency system looks for expected forms not in database; tool for early identification of possible problems
▶ Most forms expected 3 weeks after ideal visit date
▶ Accelerated forms (48- and 72-hour) expected 1 week after ideal date
▶ Expectations do not account for visit weeks

Tips and Tricks

▶ Stick to ideal visit schedule as much as possible
▶ Check form week on form
▶ Check Study Event Tracking form to see if other forms or visits are triggered
▶ Report missed visits on appropriate CRF

Useful Programs

▶ Participant Record History
▶ Participant Calendar Utilities
▶ Visit Forecaster
▶ Delinquency Viewer

Errors or Warnings

Basic Information

▶ Automatically generated during eData keying or overnight processing
▶ If data are incorrect, use Online Correct to fix errors
▶ If data are correct, use Resolve to submit proposal
▶ 2 weeks to address errors

Tips and Tricks

▶ Pay attention to errors and warnings generated as you key data in eData
▶ NEVER use both Resolve and Online Correct for the same error
▶ Review emailed Resolve Report to see if Resolve proposal was accepted or rejected

Useful Programs

▶ Unresolved Error List
▶ Warnings

Queries

Basic Information

▶ Written by DMC staff to confirm or clarify data; can include questions from statisticians or study team
▶ Common queries include dates and resolutions, code queries, longitudinal queries
▶ 2 weeks to address queries

Tips and Tricks

▶ Respond to queries promptly
▶ Check previously entered data for inconsistencies over time

Useful Programs

▶ Unanswered Query Report
▶ Diagnoses Report
▶ Medications Report
▶ Signs and Symptoms Report
▶ Participant Data Reports
▶ DataView
▶ TJoin

Employee Spotlight: Kaileigh Johnson

What is your name and job title?

Kaileigh Johnson, ACTG Coordinating Data Manager

Where are you from?

I grew up in a town outside of Binghamton, NY.

What is your education?

I have a B.S. in Biochemistry from Rochester Institute of Technology and a M.S. in Health Care Management from Johns Hopkins University.

How long have your worked at Frontier

Science?

I started at Frontier Science a little over 2 years ago as a Protocol Data Manager.

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

No two days are the same. My day typically starts out responding to emails but can quickly shift to addressing staff questions, training new protocol data managers, or writing SQL statements for data retrievals. There are typically numerous conference calls or meetings throughout the day as well.

What is your favorite part about working at Frontier Science?

Working with amazing, positive people makes the job enjoyable! No matter the department, there are people who are more than happy to answer any questions I may have or help with a project that I am working on.

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

Developing and deploying the new Rave metrics for the Monthly Site Data Management Report over this past year has been my greatest work-related accomplishment. During the process, I was able to work with various departments within Frontier Science and the Network, with whom I previously had little interaction. Though it was a challenging process to replicate and update the previous eData metrics for the new EDC system, it has been very rewarding to pilot these new metrics and receive positive feedback from the network.

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

I am excited to see the outcomes for several trials related to long-acting ARVs, especially in underrepresented populations. With these hopefully positive outcomes, I think there will be a shift from daily oral medications to monthly injectable ARV regimens.

What are your passions/interests outside of the workplace?

My passions outside of work revolve around enjoying nature. I really enjoy being outside and try to spend as much time hiking, kayaking, or backpacking with my English Springer Spaniel, Remi, as I can. Over the past few years I have completed several sections of the Finger Lakes Trail, North Country Trail, Continental Divide Trail, Appalachian Trail, and the Northern Forest Canoe Trail.

What is the best part of your job?

My role allows me to apply my scientific research background in a global clinical setting, while having a positive impact on global public health and contributing to the field of HIV/AIDS research.

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

I worked at a farm and garden store while in high school. I learned everything from the feed requirements for cows and goats, to staving off tomato blight and the temperature at which chicken eggs should be incubated.

2018

January

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

February

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March

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July

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29	30	31				

August

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September

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23	24	25	26	27	28	29
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October

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November

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December

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23	24	25	26	27	28	29
30	31					

Mark Your Calendars

Data Management Introductory Workshops

October 17-19, 2018

January 16 -19, 2019

April 10 -12, 2019

October 23 -25, 2019

Webinar Series

See DMC Portal Training Pages for schedule

Contact

Data Management Center

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ACTG and IMPAACT

Randomization Assistance

Phone: +001 716-834-0900 x7301
Email: rando.support@fstrf.org

User Support

Phone: +001 716-834-0900 x7302
Email: user.support@fstrf.org