

DATA MANAGEMENT CENTER NEWSLINE

Introduction to Medidata Rave Imaging

Per the FDA's guidance on the conduct of clinical trials during the COVID-19 Public Health Emergency and to expand the scope of remote source monitoring to include remote Source Document Verification (rSDV) by clinical site monitors, DAIDS has implemented Medidata Rave Imaging Solutions on select ACTG and IMPAACT clinical trials. This electronic platform is accessed through your existing iMedidata account and is hosted by the DMC. Access for clinical site monitors and all permissions are assigned by Frontier Science.

Redacted and unredacted source documents can be uploaded to Medidata Rave Imaging Solutions. Uploaded documents must retain all original attributes in order to be considered a certified copy. All redacted documents should clearly note that they are certified copies of the original that have been redacted for PII/PHI.

If your site is participating in one of the selected studies, you will be invited as Rave Imaging is configured. After accepting the invitation, sites will be initially blocked from Rave EDC until a brief eLearning for Medidata Imaging is completed. All studies are expected to be activated in Rave Imaging by November 1st, 2020. IRB approval is required for the rSDV option selected by your site. Institutional policies may require additional approvals and signed agreements.

Selected studies include A5359, A5300B, P1093, IMPAACT 2010, IMPAACT 2014, and IMPAACT 2017.



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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 (wojcik@frontierscience.org).





Medidata Rave Imaging FAQ

How can I find study visits that align with Rave EDC?

Visits 		
Visit Name	Complete	Img Reqs
Week 0, Screening	✓	1
Week 0, Entry	✓	1
Antepartum Week 4	✓	2
Antepartum Week 8	✓	2
Antepartum Week 12	✓	2
Antepartum Week 16	✗	1
Antepartum Week 20	✗	0
Antepartum Week 24	✗	0

When you initially access an individual participant's page, the participant-level view displays by default. The participant-level view contains the following sections: Participant Details, View, Actions, and Visits. Visit names have been preloaded to align with the study visit folders within *Medidata Rave*.

Clicking a visit name displays the visit-level view, where you can view details about the visit, complete visit requirements, and submit visits for review.

Antepartum Week 16 Visit Details 			
Visit Name	Antepartum Week 16	Visit Date	18-Sep-2020 
Status	Active 		
Antepartum Week 16 Visit Requirements 			
Type	Info	Requirement	Commands
Exam	Source Documents	1 Exam	Upload Exams Comment
Exam	Laboratory Reports	1 Exam	Upload Exams Comment
Exam	Clinic Notes	1 Exam	Upload Exams Comment
Exam	Other/Miscellaneous	1 Exam	Upload Exams Comment
E-Form	Document Submission Confirmation	1 E-Form	E-Form

The status of the visit is "Locked" and I need to upload additional documents. How should I proceed?

If the visit is locked and you have additional documents to upload for review, please contact usersprt@fstf.org to have the visit reset.

Medidata Rave Imaging FAQ (cont'd)

If I do not see the study visit, can I add an additional visit folder in Rave Imaging?

In the event that a participant experiences an unexpected visit where information is collected and that documentation is relevant to the study, you can add unscheduled visits. Unscheduled visits only apply to the participant for whom the visit is created.

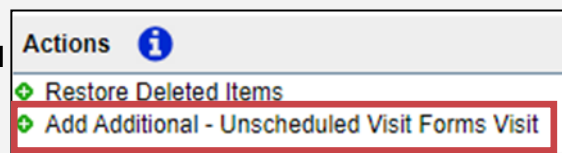
Steps:

Access the appropriate study.

On the Home page > Subjects list, find and access the participant for whom you want to add an unscheduled visit.

On the participant's page > Actions section, click **Add Unscheduled Visit**.

In the **Add Visit** dialog, click **Ok**.



The unscheduled visit displays as “Unscheduled 1” at the bottom of the Visits section. If there are already unscheduled visit folders as part of the standard set of folders for the study, the number will be appended to the last unscheduled visit. You can click the visit name in the calendar to access that visit. You cannot rename unscheduled visits.

How do I upload a document? When uploading a document, should I upload a DICOM or non-DICOM image?

You can upload documents or non- DICOM files that are required for your visit.

1. Access the appropriate study
2. Select the appropriate participant visit.
3. In the **Visit Requirements** section, click **Upload Files** for the associated requirement you want to fulfill.

Incomplete requirements that are essential to the visit are highlighted in red; optional requirements are not highlighted. Completed requirements—whether required or optional—are highlighted in green.


Antepartum Week 16 Visit Requirements i		
Type	Info	Requirement
Exam	Source Documents	1 Exam
Exam	Laboratory Reports	1 Exam
Exam	Clinic Notes	1 Exam
Exam	Other/Miscellaneous	1 Exam
E-Form	Document Submission Confirmation	1 E-Form

4. Click **Choose File** and select the file you want to upload. Repeat for each file you need to upload.
5. Click **Save Uploads**. The completed requirement now displays in green in the Visit Requirements section.

Medidata Rave Imaging FAQ (cont'd)

My document contains PHI. How do I redact a document in Rave Imaging?

After uploading your non-DICOM image, it will appear in the **Exam** grid of the participant visit:

Exam ⓘ					
Preview	Requirement	Modality	Study Date	Images / Series	Upload Date
	Source Documents	SC	18-Sep-2020 1:49 PM	3 / 1	18-Sep-2020 1:49 PM

Click on the uploaded document to Preview. On the left side of the screen, click the small box to redact text on the uploaded document.

Select whether the redaction applies to a single image or all images uploaded for the visit.

Click **OK** to **Save**. Once a redaction is applied to a document, it cannot be removed. Confirm that you would like to **Save & Finalize** the Mask.



Recorded Data Management Training Available on the Frontier Science Portal

Site Support

[Computer Account Report](#)
[Computing Manual](#)
[Computing Requirements](#)
[DMC Contacts](#)
[Email Address Book Download](#)
[Email Address Lookup](#)
[Medidata Rave Resources](#)
[Newslines](#)
[Protocol Deviation Reporting System](#)
[Training Pages](#)

Recorded Training is available on the Training Pages of the Frontier Science Portal. This page provides links to individual training sessions recorded during scheduled Data Management Center training events, and currently contains DMC Introductory Workshop sessions and the May 2020 Protocol Deviation Reporting System webinar.

For more information on our training programs and initiatives, or if you have suggestions for new training materials, please contact our Education Director, Mary Wojcik-Cross (wojcik@frontierscience.org or 716-834-0900 ext. 7466).

LDMS Introductory Workshop



As a reminder, the LDMS Training team is hosting our LDMS Introductory trainings virtually on Zoom. All LDMS users are invited to attend, although the material is geared towards new users. Invitations are sent to all registered LDMS (web) users. Please feel free to share the invitation with any new staff members who may not yet have LDMS login credentials. After the webinar, every attendee will receive a certificate of attendance. Only the registered users will receive this document.

The next scheduled LDMS training is November 13th.

The schedule of upcoming trainings is available on the LDMS website: www.ldms.org/training/schedule/

While you are on our website, check out all of the information available under Resources!

Use of Templates in ACTIV-2 (A5401)

We are excited to announce support in the LDMS for the ACTIV-2 (A5401) study. To facilitate data entry into **Quick Add**, the ACTIV-2 study utilizes templates. Templates are predefined specimen entry scenarios for specific study visits that will automatically enter specimens in **Quick Add**. For labs processing ACTIV-2 specimens, and a reminder to ACTG labs in general, templates are accessed by using the **Template** menu in **Quick Add**. All Frontier Science created templates are present in the dropdown. The amount of items in the menu can be limited by setting **Template Filters**.

ID1/PID: 8-digits ID2: ACTIV2 (included in template) ID3: blank

The screenshot displays the 'Quick Add' interface in the LDMS. On the left, the 'Template' dropdown menu is open, showing 'Select a template...'. Below it is a 'Clear Template' button. The 'Template Filters' section includes fields for 'Project' (set to 'ACTIV'), 'Study' (set to 'ACTIV2'), 'Visit', 'Filter by visit value...', 'Visit Unit', and 'Filter by visit unit...'. A 'Clear Filters' button is at the bottom of the filters section. On the right, the 'Participant Information' section shows 'Project' and 'Study' dropdowns, both set to 'ACTIV' and 'ACTIV2' respectively. Below these are 'OPIDs' and 'Add OPID' button. The 'Enrollment Information' section shows 'ID2' dropdown. A red box highlights the 'Quick Add' button in the top right corner. Two callout boxes provide instructions: one says 'After setting the Template Filters, use the Template menu to select the right template for your visit' with arrows pointing to the 'Template' dropdown and the 'Study' field; the other says 'In Quick Add, set the Template Filters' with arrows pointing to the 'Project' and 'Study' dropdowns.

ACTG Coordinating Data Manager: Stephanie Caruso



Stephanie holds a Bachelor of Arts in Mathematics and Economics from SUNY at Buffalo and an MBA in Non-Profit Management from American Public University. She began working at Frontier Science through a summer student work program in 2008 and then moved into a formal position as a Data Manager Assistant for the ACTG and IMPAACT networks. In 2012, Stephanie became a Protocol Data Manager for the ACTG, and began managing multiple long-term trials. She recently accepted the position of ACTG Coordinating Data Manager.

Stephanie is the Data Management Center's representative on the Hepatitis Transformative Science Group and a member of the data management training team. As a new Coordinating Data Manager, Stephanie is excited to continue growing her knowledge of trial development and clinical data management. She is looking forward to developing initiatives that will help PDMs build successful data collection environments and continue to maintain quality data.

Outside of work, Stephanie keeps busy spending time with her husband and three children. She is a youth minister at her church and works with teens on a regular basis. She loves to sing, go bicycling with her family, and spend quality time with her loved ones.

2021

JANUARY

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FEBRUARY

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JUNE

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JULY

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AUGUST

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SEPTEMBER

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OCTOBER

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NOVEMBER

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DECEMBER

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12	13	14	15	16	17	18
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MARK YOUR CALENDARS

Data Management Introductory Workshops

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

Data Management Webinars (2020)

- November 12: Adverse Events Log
- December 10: SES

See *Frontier Science Portal Training Pages* for additional information.

LDMS Introductory Workshops (2020)

- November 13 (virtual)

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ACTG and IMPAACT

Randomization Assistance

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Email: randosupport@fstrf.org

User Support

Phone: +001 716-834-0900 x7302

Email: user.support@fstrf.org

LDMS User Support

Phone: +001 716-834-0900 x7311

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<https://www.ldms.org/contact>