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Randomized Trial to Prevent Vascular Events in HIV

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Don't Forget! Next
REPRIEVE DSMB Meeting:

September 21, 2021
See below for key dates!

	Task	Deadline* (2021)	Weeks to DSMB
	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	June 25 (Fri)	12.6
	US Independence Day holiday (observed)	Jul 5 (Mon)	
Sites	All data for visits through June 25 entered into OpenClinica	Jul 9 (Fri)	10.6
Sites	All adjudication packets for potential MACE events by June 25 with work-up complete submitted to MGH DCC**	Jul 9 (Fri)	10.6
Sites	All queries resolved	Aug 6 (Fri)	6.6
Sites	Respond to last minute outstanding queries	Aug 13 (Fri)	5.6
	US Labor Day holiday	Sep 6 (Mon)	
	DSMB Meeting	Sep 21 (Tue)	0
*Deadlines are Close of Business on the given date unless otherwise noted			
**Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.			

The timeline above lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE Trial.

Mark these important dates in your calendar and note that **Friday, August 13th** is the date by which all last minute queries should be resolved.

Please make an effort to reach out to participants who have not been seen in a while, including *other contact* or *chart review*, if 3 consecutive visits have been missed (see Appendix V in the MOPS).

Please also review that vital status and endpoint follow-up of participants who have discontinued study is current (see protocol section 6.3.10).

Need Help Responding to Queries in OpenClinica?

The Data Management Center (DMC) at FSTRF has tools to help you!

The REPRIEVE Data Managers have made some useful videos accessible on the FSTRF portal (see image below for location). Check out the video entitled Answering Notes and Discrepancies to help you with responding to queries.

If you still have questions after watching this video don't hesitate to reach out to the REPRIEVE Data Managers at reprise.dmc@fstrf.org

REPRIEVE Data Management Training Videos

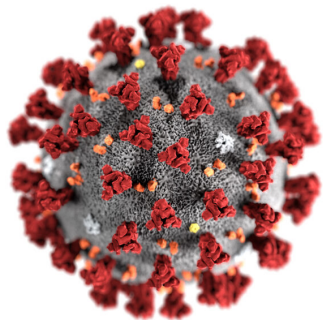
OpenClinica Training Videos

Frontier Science OpenClinica Video Topics (FSTRFfilms YouTube Channel)

- [Changing Previously Saved Data](#)
- [Entering Logs](#)
- [Entering Missed Visit](#)
- [Answering Notes and Discrepancies](#)
- [Entering Out of Window Visit](#)
- [Entering Unknown or Missing Values](#)

Important Message About New COVID CRF

A new form has been added to OpenClinica, the COVID-19 Symptom Duration CRF (SSW0090). This form captures potential long-COVID symptoms, their durations, and activity status in REPRIEVE participants who have either tested positive for COVID-19 (including SARS CoV2 PCR, Rapid Antigen



tests and also antibody tests) OR received a *confirmed* clinical diagnosis of COVID-19 (i.e., COVID diagnosis listed on a discharge summary or in the medical record). This form was discussed on the last site call; slides from this call can be found on the PSWP or [click here](#). Please review the slides and email the core team (actg.corea5332@fstfrf.org) with any questions.

[Click here](#) for detailed instructions about the CRF if you missed the email about this.



FAQ

Q: One of our participants has been hospitalized due to COVID. Is this an SAE and should this be reported as an EAE in DAERS or are COVID hospitalizations not necessary to report as EAEs?

A: Regarding data entry and reporting pertaining to COVID-related hospitalizations, the hospitalization would be reported as an SAE on the AE Log but not as an EAE in DAERS (unless downgraded by the adjudication team). The rationale to report a COVID hospitalization as an SAE (but not as an EAE) is provided in Protocol Version 5.0, LoA#2 – bullet 1. Specifically, COVID hospitalizations are often associated with subclinical cardiac injury, so we are investigating as such - even in the absence of an overt, clinically recognized MACE or heart failure event. Please refer to the A5332 MOPS for details about reporting COVID.

Q: I have a participant who never had a positive COVID test result or symptoms after an exposure to COVID. He did subsequently have a positive antibody test result. Do I need to complete the new COVID Symptom Duration (SSW0090) CRF with the participant?

A: Yes, for a positive antibody test, even in the absence of a positive COVID test and/or symptoms, please complete the SSW0090 CRF with the participant.

New REPRIEVE Team Members at Your Site?

Below are a few helpful tips to ensure the new team member has access to REPRIEVE related portals and



useful training:

1. If the new staff member is going to be a CRS Leader, CRS Coordinator, IoR, or REPRIEVE Pharmacist, approval by DAIDS OCSO is needed *before* these new staff begin their role on REPRIEVE. You must contact your DAIDS OCSO Program Officer or email OCSOREPRIEVETeam@mail.nih.gov before making any such change.

2. [Click here](#) to view a complete list of accounts needed for new staff.

3. For help with signing up for the FSTRF portal and OpenClinica accounts, click on [these instructions](#) for an easy sign-up process.

Most importantly, welcome to the team!



Lab Tips

September 9th, 11AM EDT, the REPRIEVE Lab Committee is hosting a **call to review shipping of specimens and tips on responding to lab queries**. Most importantly, Lab Committee members will be available to answer any questions you may have!

- An invite with Zoom link for this meeting has been sent, please reach out to Evelynne (efulda@mgh.harvard.edu) if you did not receive it.

August 13th, 5PM EDT, join the LDMS Webinar!

- [Click here to register](#). Be sure to register by Thursday, August 12th. These trainings are also available on-demand [here](#).

Ensure that your site is using the most up to date Lab Processing Chart!

- **LPC for ACTG Sites:** Version 5.0 dated 05/04/2020
- **LPC for Non-ACTG Sites:** Version 5.0 dated 05/04/2020
- LPCs are available on the REPRIEVE (A5332) PSWP in the Current Laboratory Documents and Memos folder.



Save the Date Next Team/Site Call! October 19th 1PM EDT

Join us for important REPRIEVE updates!

1:00 PM HAITI (EDT)
 1:00 PM PERU (PET)
 2:00 PM PUERTO RICO (ADT)
 3:00 PM BRAZIL (BRT)
 8:00 PM BOTSWANA (CAT)***
 8:00 PM SOUTH AFRICA (SAST)***
 8:00 PM ZIMBABWE (CAT)***
 9:00 PM UGANDA (EAT)***
 11:30 PM INDIA (IST)***
 1:00 AM 01/20/2021 THAILAND (ICT)***

***We do not expect site staff to join these calls during their off-work hours. Instead we will update you on other scheduled calls, e.g., your calls with the ACTG NCC.

Remember that questions are always welcome at actg.corea5332@fstrf.org and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 dated 04/01/2019
Version 5.0, Clarification Memo 1 dated 04/03/2020
Version 5.0, Clarification Memo 2 dated 05/04/2020
Version 5.0, Letter of Amendment 1 dated 06/19/2020
Version 5.0, Letter of Amendment 2 dated 12/14/2020

MOPS Version 5.0 dated 02/08/2021

LPC for ACTG Sites Version 5.0 dated 05/04/2020

LPC for Non-ACTG Sites Version 5.0 dated 05/04/2020

These documents are on the [A5332 PSWP](#)

For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome ideas and suggestions for future newsletters. Please submit any comments or suggestions to the REPRIEVE News team at reprieve.news@fstf.org



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