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Randomized Trial to Prevent Vascular Events in HIV February 2022 Table of Contents

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HAPPY HEART MONTH FROM THE REPRIEVE TEAM



Happy Heart Month from the REPRIEVE Team!

To recognize heart health during February, take a moment to reach out to your REPRIEVE participants, check in and remind them of the importance of REPRIEVE to confront the emerging challenge of HIV-related heart disease. Ultimately, helping people with HIV to live in good health even longer. Their continued dedication to the trial is vital to its success!

[Click here](#), to access some great Heart Health Month resources!

Join us during CROI 2022!



When: February 15th at 3:30PM EST (2:30PM CST, 1:30PM MST, 12:30PM PST)

Where: [Click here](#) to join the virtual meeting! Registration is not necessary.

This virtual meeting will take place during CROI 2022 and ALL are welcome to attend.



We are so excited to announce that **Pradeep Natarajan, MD, MMSc, PI** of the REPRIEVE genetics grant, will be presenting data on the genetic basis of inflammation and cardiovascular disease, including key preliminary data on clonal hematopoiesis (CHIP) and CVD among PWH. In addition to his work on the the REPRIEVE genetics grant, Dr. Natarajan is a preventive cardiologist, cardiovascular geneticist, and physician-scientist. He is the Director of Preventive Cardiology at Massachusetts General Hospital. [Click here](#) to read more about Dr. Natarajan.

In addition to the keynote speech by Dr. Natarajan we will be providing important REPRIEVE updates during the meeting. **Join us!!!**

Additionally, REPRIEVE team members will be presenting baseline data at CROI , covering topics from COVID-19 to physical function. [Be sure to visit our website for detailed information.](#)



Tips from the Data Management Team

Tip 1: How to access all data queries in OpenClinica assigned to your site

OpenClinica allows only one person per site, per query to be notified/assigned. Typically, the person who last did data entry on the queried form is the one alerted/assigned to the newest query on that form, but this can vary.

Also, staff members frequently change, so queries may be assigned to a staff member who is no longer at the site and may not have addressed it before their departure. These queries can languish unresolved unless current staff members address them.

How can these queries be addressed? Go to OpenClinica to 'Notes and Discrepancies' and look for **all queries** at your site, not just the ones assigned to you.

To look for all queries at your site select 'New' from the

'Resolution Status' drop-down in Notes and Discrepancies and let the system return the listing of New queries at your site.

Reach out to the REPRIEVE Data Managers via email reprieve.dmc@fstrf.org with any questions.

Tip 2: Ensure the collection time entered on the Specimen Tracking CRF and in LDMS are identical

Our lab data managers have noticed there are discrepancies in collection times keyed on the Specimen Tracking CRF (SPW00492) and in LDMS. This may be because there is a lag between the visit and when the CRF is keyed. The downstream implications of this are that site staff are required to resolve the discrepancies in coordination with the lab staff in the FSTRF query system and that samples cannot be selected for assay testing in a timely manner.

Please only key tubes collected on the SPW00492 as instructed by the Lab Processing Chart (LPC). For example, urine samples for pregnancy testing are to be recorded on the Pregnancy Test CRF (LBW0138) CRF, not on the SPW00492.

[Click here](#) to download slides about resolving Lab Queries.

Reach out to the REPRIEVE Lab Committee via email reprieve.labcom@fstrf.org with any questions.



FAQ About 2nd COVID Diagnosis!

Q: Our site recently had a participant test positive for COVID a 2nd time. We already completed the COVID Symptom Duration (SSW0090) CRF for the participant's 1st COVID diagnosis, but we are unsure of how to document the 2nd diagnosis since all questions on the SSW0090 ask about symptoms since the 1st confirmed diagnosis of COVID. Please advise.

A: The SSW0090 in the Logs visit of OpenClinica corresponds to long COVID symptoms that are associated with the participant's **1st confirmed COVID infection only**; please do not add any new symptoms that developed or worsened after the participant was infected with COVID a 2nd time. If a given symptom that developed or worsened after the 1st infection did not resolve by the time the participant received a 2nd positive COVID result or confirmed clinical diagnosis, simply update the corresponding duration rating for that symptom in relation to when it developed or worsened after the 1st COVID infection.

There is currently no way to enter another SSW0090 form in the Logs visit of OpenClinica for a 2nd COVID infection, but the team is adjusting to the current situation related to Omicron and is in the process of adding a new Supplemental COVID Symptom Duration form for long COVID symptoms related to any subsequent COVID infection(s) after the 1st COVID infection.

Until this new form becomes available, please hold onto the long COVID data related to the participant's 2nd COVID infection. You will be able to enter them on the new Supplemental form just as soon as it becomes available, likely within the next month or so - full instructions will also be on the way at that same time.



Don't Forget! Next REPRIEVE DSMB

Meeting: March 25, 2022

See below for key dates!

Responsibility	Task	Due Date* (2022)	Weeks to DSMB
Sites	All queries resolved	Feb 18 (Fri)	5
	<i>President's Day holiday (observed in the US)</i>	<i>Feb 21 (Mon)</i>	
Sites/TIMI	Resolution of last-minute critical queries	Feb 25 (Fri)	4
	DSMB MEETING	Mar 25 (Fri)	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 next **Data and Safety Monitoring Board** meeting will take place on Friday, March 25th, 2022. The timeline above outlines important tasks and deadlines. Please mark these important dates in your calendar and note that **February 18th is the date on which all queries should be resolved.**

The final data download will take place on Monday, February 28th. To ensure that the DSMB is reviewing complete data, *please make sure that all data related to potential adjudicated events and COVID-19 diagnoses have been entered in the study electronic data capture (OpenClinica) and that packets for potential adjudicated events with workup complete have been submitted for adjudication.*



Next Team/Site Call!

April 19th

1:00 PM US (EDT)
 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 04/20/2021 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 09/13/2021
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@fstrf.org.



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