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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

May 2022 Table of Contents

Don't Forget to Order Copies of the REPRIEVE Participant Newsletter!!!

The annual REPRIEVE Participant Newsletter* and translations in 9 languages are now available, click here!

The newsletter is a great way to keep participants updated about and engaged in REPRIEVE. This year's newsletter includes a message from REPRIEVE leadership, REPRIEVE facts, heart health tips, a message from the Community Advisory Board, a few words from a REPRIEVE participant, and other exciting updates!

If your site has not already requested hard copies please click here to let us know how many copies you would like and in which languages.

**The newsletter has been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.*

Site Spotlight: Centro de Referencia e Treinamento DST/AIDS CRS 31954

The Casa da Pesquisa site, located in São Paulo, Brazil has been a tremendous contributor to REPRIEVE!

Casa da Pesquisa is the Clinical Trials Unit of the Centro de Referência e Treinamento - DST/AIDS. They have been conducting clinical trials for over 25 years and are an exemplary site for clinical trials in HIV/STI treatment, prevention, and vaccines.

Their site has been participating in REPRIEVE since 2016. A key driver for the team is providing the best care possible to study participants. Enrolled participants receive their clinical care from the study team, which allows for scheduling study visits and clinic visits in tandem.

The team has shared some of their retention tips:

1. Keep in touch with participants - for example, by sending birthday cards and messages.
2. Send reminder messages prior to each scheduled visit, for example, send a reminder visit the day before the scheduled visit.

3. Contact any participants who have not been seen recently through various channels, for example, telephone, text or social media depending on your local IRB/EC approvals.
4. Tailor care during the COVID-19 pandemic to be more flexible, for example, conduct study visits over the phone.

This CRS has very high retention rates (100% of 100 participants are still in follow up) showing that their retention strategies are key for this long-term study.

***Thank you*, Casa da Pesquisa team, for all your efforts and for sharing your retention tips!**

Important Reminders From the Data Management Team

- Remember to **review the AE Log and Medications Log at every visit and update the "Review Date"**, regardless of whether there were updates to make or the data were current.
- The Vital Status and Endpoint Assessment CRF (VSW0025) should be completed for participants who are off-study for reasons other than withdrawal of consent or death.
  - Completion of the form should be yearly, beginning one year from the Off-Study date for the participant based on the RP0001 Off-Study CRF.
  - Section 12.6 of the A5332 MOPS has additional details about Vital Status and Endpoint Assessment
  - If you would like a list of PIDs for whom this CRF may be overdue for completion, contact Evelynne at efulda@mgh.harvard.edu.

FAQs

Q: A participant took a COVID home antigen test in preparation for attending an event, *the test came back positive but he noted no symptoms (asymptomatic).* This

episode has not been recorded in the participant's medical chart as he made no mention of it to his provider at their last encounter. How do I report this in Openclinica?

A: The team has decided that *participant report* of a positive COVID test (antigen or PCR) is acceptable. When completing the COVID-19 Symptom Assessment CRF (SSW0040), please answer "yes" to Questions 4 and 4a and record the event (asymptomatic COVID-19) on the AE Log. Record the start date as date of test; record end date as 10 days after start date. Do not enter grade on the AE Log, OpenClinica will prompt a grade to be recorded, in place of grade enter message that COVID-19 was asymptomatic. Additional instructions are in section 4.2 of the A5332 MOPS.

Q: A participant took a COVID home antigen test after waking up with a runny nose and slight fever, the test came back positive, the participant did not seek medical attention because the symptoms continued to be mild and resolved after a few days. This episode has not been recorded in the participant's medical chart as she made no mention of it to her provider at their last encounter. How do I report this in Openclinica?

A: The team has decided that *participant report* of a positive COVID test (antigen or PCR) is acceptable. When completing the COVID-19 Symptom Assessment CRF (SSW0040), please answer "yes" to Questions 4 and 4a on the SSW0040 (see snip below) and record the event (COVID-19 diagnosis) on the AE Log. Do not record the related symptoms on the AE log, COVID symptoms are recorded on the SSW0040. Close the COVID-19 diagnosis upon symptom resolution in case the participant develops another episode. Additional instructions are in section 4.2 of the A5332 MOPS.

FAQs in case of collection tube supply shortages!

As you may be aware, the COVID pandemic continues to disrupt supply chains and many labs are experiencing shortages of specimen collection tubes. Therefore, we developed an FAQs document to guide you in case you experience collection tube supply shortages, click here to download! Please review the FAQs and let the team (actg.corea5332@fstrf.org) know if you have any questions.

Reporting Potential Adjudicated Events: A Brief Review

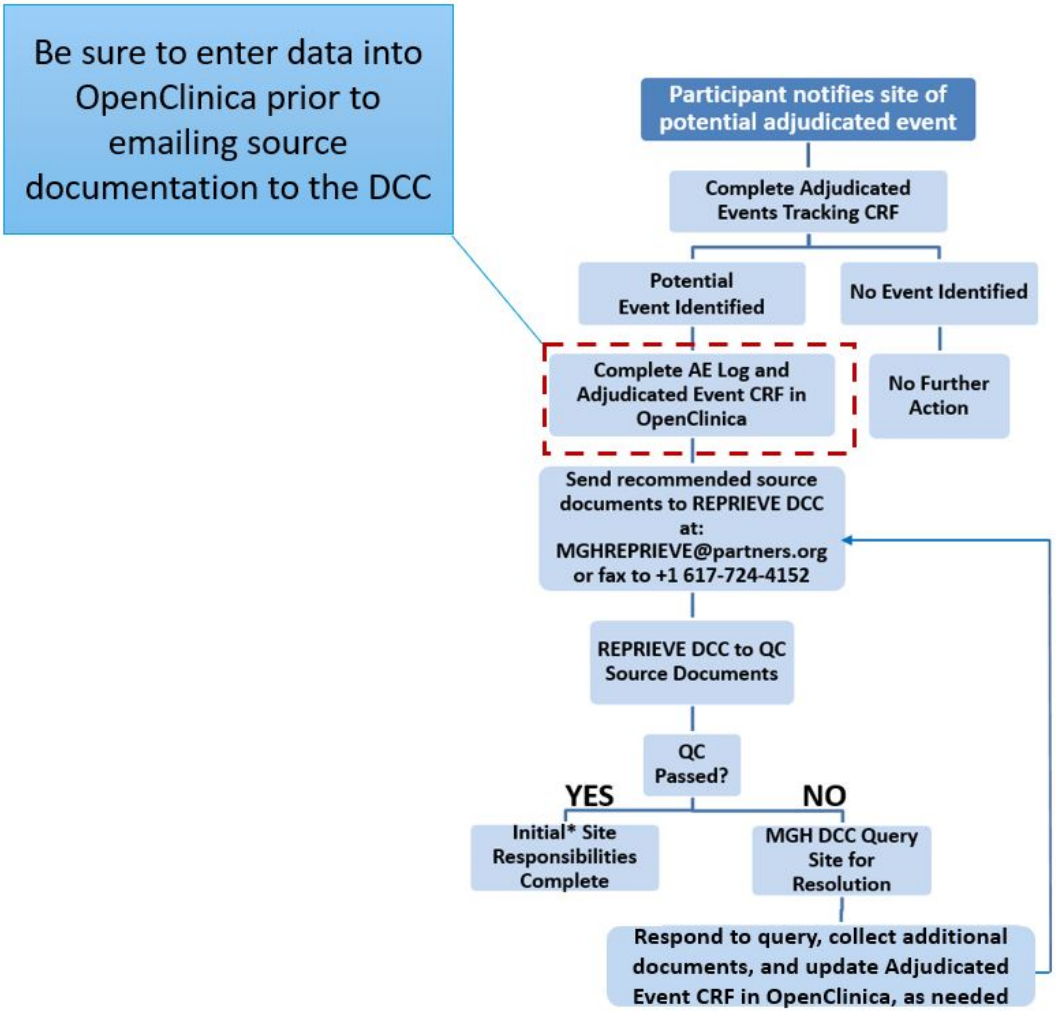
What potential events are we looking for?

- **Cardiovascular endpoints**
  - Atherosclerotic or other CVD death
  - Nonfatal myocardial infarction
  - Unstable angina hospitalization
  - Coronary or peripheral arterial revascularization
  - Peripheral arterial ischemia
- **Cerebrovascular events**
  - Nonfatal stroke or transient ischemic attack (TIA)
- **Death from any cause (see note below)**
- **Additional adjudicated cardiac events not part of the primary endpoint**
  - Heart failure, including all COVID-19-related events resulting in hospitalization

NOTE: All deaths from any cause (CVD or non-CVD related) must be submitted for adjudication by the external events committee (TIMI) who will determine if the event is

CVD-related. The only time a death should be submitted to DAERS as an EAE without first being adjudicated by the CEC is when the death is felt to be study drug-related.

The workflow below outlines the process for submitting potential events in OpenClinica and to the Data Coordinating Center (DCC). Section 6.0 of the REPRIEVE (A5332) MOPS has additional details.



Please be sure to **complete the Specimen Tracking Form in a timely manner and ensure the collection time entered on the Specimen Tracking CRF and in LDMS are identical**. This is important for monitoring the specimen collection status of the trial as well as to prevent lab data queries.

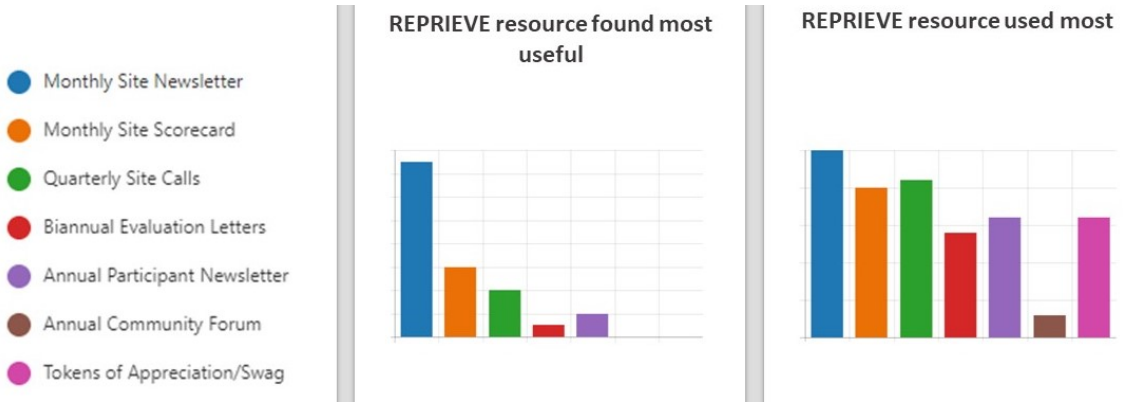
Do you have a lab processing question? We will be having our next site call on July 19th. Please email any questions in advance of this call to the lab team (reprieve.labcom@fstrf.org).

We will also be hosting our annual Shipment/Query refresher call in September 2022! Stay tuned for more details about this call.
Lab Tips

Thank you to everyone who responded to our recent survey about site resources!

Results from the survey showed that site newsletters were identified as the most useful resource, while site newsletters, scorecards, and site calls are utilized most often.

If you have suggestions for additional resources you would like the CCC to develop please don't hesitate to reach out by email!



Next Team/Site Call!
July 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*
Revised Version! MOPS Version 5.0 *dated 04/29/2022*
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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