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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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Update From the 15th REPRIEVE DSMB Meeting

On March 25th, we held our 15th Data and Safety Monitoring Board (DSMB) meeting! We are so pleased to share that the DSMB noted no safety concerns and unanimously approved the continuation of REPRIEVE. We look forward to sharing updates from the meeting, the formal memo will be available shortly.

THANK YOU to all site staff for your data entry efforts in preparing for this important meeting.

The 16th meeting is anticipated to take place September 2022

Hot of the Press
REPRIEVE Participant Newsletter!!!


APRIL 2022

REPRIEVE

PARTICIPANT NEWSLETTER

A message from Dr. Steve Grinspoon and Dr. Pam Douglas, REPRIEVE Co-Principal Investigators

Greetings to you! We hope this newsletter finds you in good health. We recognize it has been a challenging year given the global COVID-19 pandemic, and we are so appreciative of your ongoing participation in REPRIEVE. As contributors to a trial of over 7,000 people living with HIV across 5 continents, we achieved many milestones together this past year. With your help, we have generated key results to improve cardiovascular and overall health among people with HIV. We have come to understand how heart disease risk relates to optimal lifestyle habits and showed factors relating to decreased physical function among our participants. Importantly, we continue to move steadily toward our goal of trial completion, without any major problems or safety issues.

In the upcoming months, you will be asked to sign a revised consent form that extends the trial follow-up, further ensuring that we achieve our goals. Your maximum anticipated length of follow-up will be between 6-10 years, depending on when you enrolled in REPRIEVE. It is important to know that we are not sure if this length of follow up will be needed. We are setting a maximum length to ensure the necessary trial infrastructure over time, but it is likely the follow-up period will be shorter.

As you may know, the Data and Safety Monitoring Board (DSMB) that oversees REPRIEVE decides when the trial is completed, and their decision is based on the number of heart disease events (things like heart attacks and strokes) that are reported. For this reason, it is important that you report any potential heart events to your study team. Even if you are not sure if you've had a heart event or if you have vague symptoms, please alert your study team as soon as possible so that we can capture every single possible heart event. By answering this study's primary research question, we hope to be able to develop heart disease prevention and treatment guidelines tailored specifically for people living with HIV.

REPRIEVE Facts

Thank you for your continued participation!

- We're celebrating the completion of an additional year of follow up since the enrollment of the first participants were enrolled in REPRIEVE, with an average participation of about 4 years.
- REPRIEVE has published almost 20 manuscripts … with more on the way!
- Findings from REPRIEVE have been presented over 10 times at conferences including the Conference on Retroviruses and Opportunistic Infections, AIDS, Association of Nurses in AIDS Care and the International Association of Clinical Research Nurse conference.

Heart Health Tip!

Mental health and heart health go hand in hand

Mental health is part of overall health. We can't be healthy if we neglect our bodies, and we can't be well if we neglect our mental health. Here are some tips that may positively impact your mental health AND heart health!!!

1. Be active
2. Eat healthy foods
3. Be mindful
4. Avoid smoking and substance abuse

The annual REPRIEVE Participant Newsletter* is now available, click here! Translated versions will be available shortly!

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.

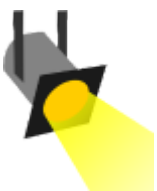
**The newsletter has been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.*

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.



Site Spotlight: Thai Red Cross AIDS Research Center CRS 31802

The Thai Red Cross CRS, located in Bangkok, Thailand has been a tremendous contributor to REPRIEVE!

This team prioritizes its retention efforts in many ways, below are a few tips they shared with us.

1. We work to develop a strong relationship between the study clinician(s), the study team, and all participants.
2. We use the best practices to take care of and handle participants in all situations.
3. We collect up-to-date current contact information (i.e telephone, email address, mail address, emergency contact info, etc.) for participants at every study visit.
4. We conduct remote visits and ship study drug when participants cannot come to the site for the in-person visit.

***Thank you*, Thai Red Cross team, for all your efforts and for sharing your retention tips!**

Tips From the Data Management Team

Post-entry CD4+/CD8+/HIV Viral Load evaluations are specified in Protocol Section 6.3.6

Please ensure that your site is entering in OpenClinica CD4+/CD8+*/HIV viral load results obtained from clinical care since the last annual study visit.

The most recent values obtained since the last annual visit will be used.

If there is no new value available since the last annual visit, re-enter the value entered at the last annual visit along with the date on which the value was obtained.

Example: a participant is coming in for their month 48 visit, their CD4+ at month 36 was 800 cells/mm3, and there is no new value since the month 36 visit, therefore enter this same value of 800 cells/mm3 at the month 48 visit along with the date it was obtained.

If your site has not been entering CD4+/CD8+/HIV VL in this manner, it should be done as of this notification going forward. Sites do not need to go back and enter missing CD4+/CD8+/HIV viral load data.

***If CD8+ cell count is not available, CD4+ cell count alone is acceptable.**

Ensure that ALL CRFs related to a visit are marked complete in OpenClinica within 3 weeks of the visit!

Please ensure that you adhere to the 3 week timeline to mark complete in OpenClinica ALL CRFs related to a visit. Adhering to this timeline helps to ensure that preparation for future DSMB meetings goes smoothly and that the data is as complete as possible prior to the next review.

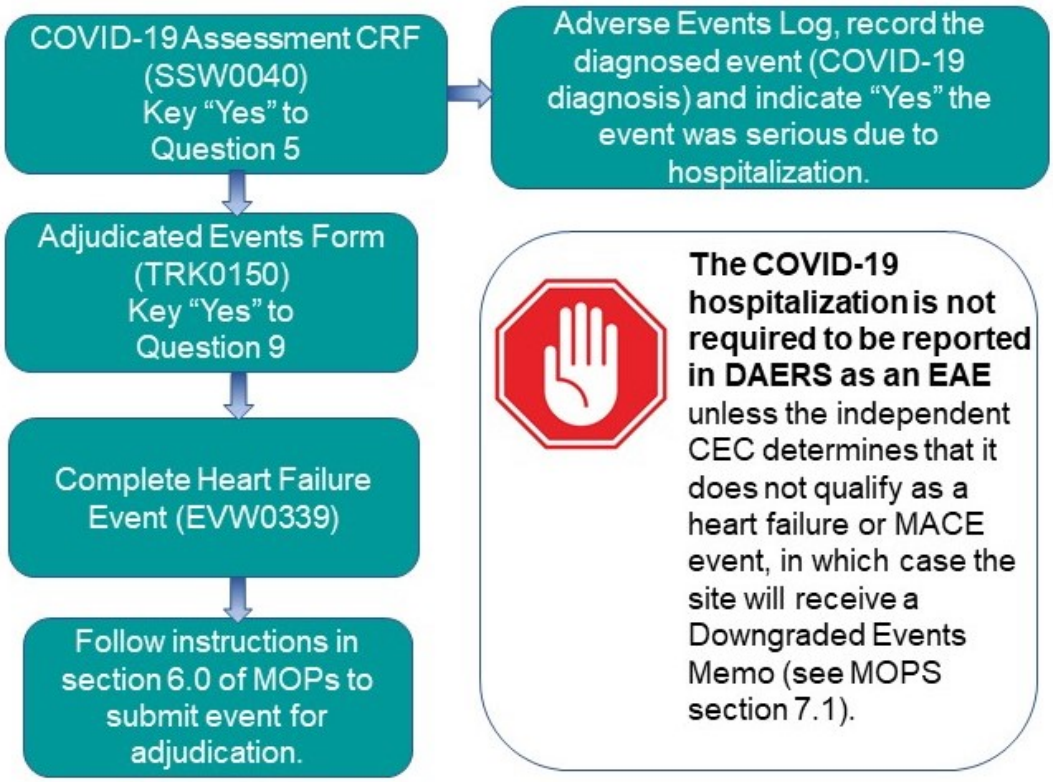
This timeline is important for ALL CRFs related to a visit, ***even the Specimen Tracking CRF (SPW00492).***

FAQs

Q: One of our participants was hospitalized due to COVID-19; we have two questions about reporting this event:
1. On the AE Log, do we indicate that this a serious adverse event (SAE) because of the hospitalization?
2. Should this hospitalization be reported as an expedited adverse event (EAE) in DAERS?

A: Regarding data entry on the AE Log and reporting pertaining to the COVID-related

hospitalization:
1. The hospitalization would be reported as an SAE on the AE Log.
2. The hospitalization may need to be reported as an EAE in DAERS, depending on the adjudication result.
See below for instructions on reporting COVID-19 hospitalizations. These instructions are in the A5332 MOPS section 4.2.



The rationale for submitting COVID hospitalizations for adjudication is because severe COVID is often associated with subclinical cardiac injury and we are investigating as such-even in the absence of an overt, clinically recognized MACE or heart failure event.

Q: One of our participants was hospitalized with a leg fracture and was found to test positive for COVID during the hospitalization. Should this hospitalization be reported as a COVID hospitalization?

A: If a participant was hospitalized and COVID was an incidental finding, not the primary admission diagnosis, this hospitalization is required to be reported in DAERS as an EAE, see A5332 MOPS section 7.0. Do also enter the "COVID-19 diagnosis" on the AE Log. In the event the hospital course was complicated or prolonged by COVID (i.e. participant was placed on a ventilator due to deteriorating COVID) COVID diagnosis should be marked as hospitalized and submitted for adjudication as instructed above. Otherwise, the COVID diagnosis should not be reported as hospitalization.

FAQs in case of collection tube supply shortages!

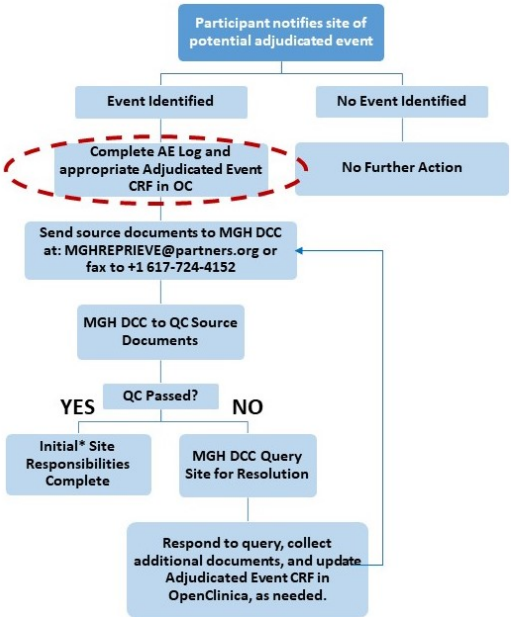
As you may be aware, the COVID pandemic continues to disrupt supply chains and many labs are experiencing shortages of specimen collection tubes. Therefore, we developed an FAQs document to guide you in case you experience collection tube supply shortages, click here to download! Please review the FAQs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

Reminder About Submitting Potential Adjudicated Events

Please be sure to complete the appropriate trigger forms in OpenClinica (OC) *for any* potential adjudicated events prior to sending the documentation to the MGH REPRIEVE mailbox as this can lead to these triggers not being recorded by the electronic data capture (OpenClinica) and falling through the safety net of reconciliation.

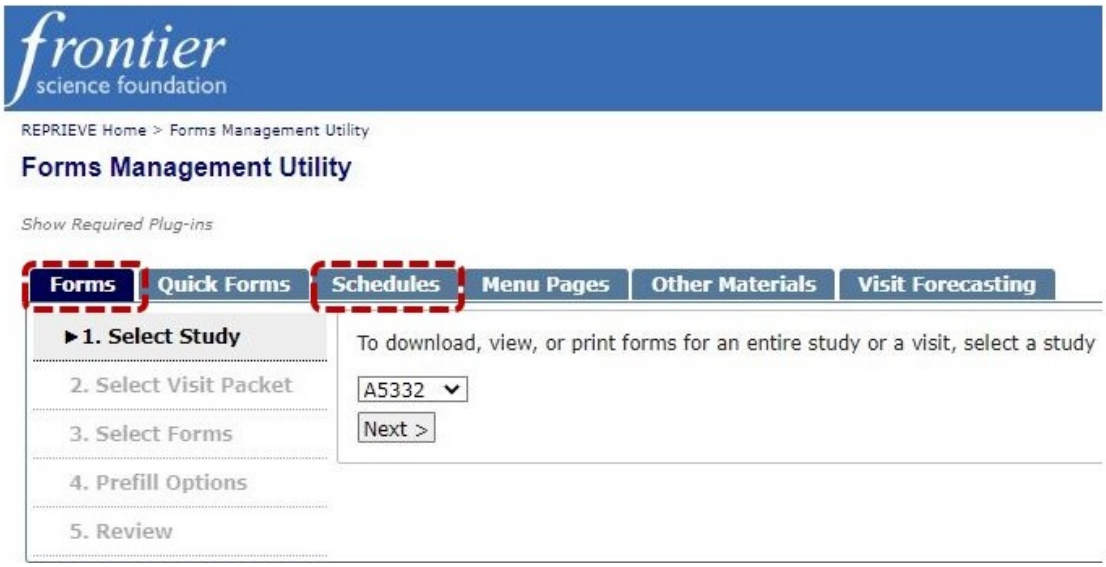
For detailed instructions about submitting potential adjudicated events to the MGH Data Coordinating Center please review section 6.0 of the A5332 MOPS.

*Based on the review by the independent Clinical Events Committee (CEC), additional information may be requested from the site.



Utilize the Forms Management Utility Application on the FSTRF Portal

The Forms Management Utility application can be accessed from the FSTRF Portal Home page, from this application you can download CRFs as well as data collection schedules!



We Want to Hear From You!

To better provide support to sites, we have developed a brief survey. Completion of this survey is completely optional and anonymous; it should take ~1 minute to complete and will help the Clinical Coordinating Center develop resources that are most helpful to sites. Click the link or scan the QR code to complete the survey.

Thank you for taking the time to complete this and thank you to those who have already completed the survey!

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 2/16/2022*
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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