REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

A Few Words From REPRIEVE Leadership

First and foremost we want to thank you for all your efforts on REPRIEVE this past year, through the most difficult of circumstances related to the COVID-19 pandemic. We appreciate your dedication and professionalism and are pleased to report the study is continues to do well because of your efforts.

We have observed an increase in cardiovascular events reporting during this time. This is important in REPRIEVE not only because major cardiovascular events (MACE) are the primary endpoint of this events driven trial, but also because we are now evaluating COVID-19. Because of this, it is critically important we do not to miss any potential events. Therefore, we ask that you *please make sure that you are completing the Adjudicated Events Tracking CRF (TRK0150) at every visit (remote or in person) and that you are utilizing the Heart Health Status Questionnaire with your participants to elicit any potential events since their last study visit.* We are also asking you to review participants' medical record for any potential events, especially if participants are unable to come to in-person visits. Finally, marking CRFs complete within 3 weeks of the visit is extremely important for data integrity, and site payments are triggered upon completion of a visit.

We also want to point out a memo recently distributed by DAIDS, (click here) As a reminder, COVID-19 vaccinations are to be keyed on the Medications Log in OpenClinica. **REPRIEVE participants are not excluded in any way from receiving the COVID-19 vaccination, and we encourage all participants to be vaccinated, in accordance with public health directives.**) that was recently circulated by DAIDS, in case you have any questions.

Sincerely,
The REPRIEVE Leadership

Q: A REPRIEVE participant has expressed interest in participating in a COVID-19 vaccine trial. Are REPRIEVE participants allowed to co-enroll in COVID-19 vaccine trials?

A: Yes, co-enrollment in such trials is allowed in REPRIEVE. However, please also confirm with the other study team that co-enrollment is allowed.

A few points to be aware of:

- Note the vaccination via the clinical trial on the Medications Log.
- Make sure the vaccine is not administered within 14 days of a blood draw for REPRIEVE.
- Limit blood draws to the volumes allowed by the American Red Cross.

Q: A participant tested positive for SARS-CoV-2 in June, 2020 and tested positive again in November, 2020 prior to a scheduled procedure. Do I record this as 2 separate events on the AE log? If so, are both events ongoing?

A: This should be recorded as a single case of COVID-19 diagnosed in June. The event would not be considered ongoing.

Don't forget to submit the following to your local Institutional Review Board (IRB)/Ethics Committee (EC)!

- ***DSMB Summary Report***

If you missed the email with the DSMB summary, it is available on the REPRIEVE (A5332) protocol specific webpage under Study Monitoring (NHLBI DSMB Reports).

- ***Protocol Version 5.0 Letter of Amendment (LOA) #2***

In addition to submitting the LOA to your local IRB/ECs, please don't forget to register Protocol V5.0 LOA 2.0 with DAIDS PRO within 14 days of IRB/EC approval.

A Reminder About Laboratory Queries

Laboratories may receive queries for a variety of reasons, including: missing assay results, duplicate assay results, date or time discrepancies, visit discrepancies, specimens not shipped, or specimens not logged into LDMS.

Your laboratory's responsibility: If your lab receives a query, it will be sent via email. *Do not respond to the email notification*. This is an indication that you need to log into the DMC Portal under the REPRIEVE project and review the laboratory query in the Query System. Recipients of queries are expected to provide an **adequate response to the query within two weeks.**

Getting Help: If you encounter a problem or need help using Laboratory Query System, contact User Support at ldmshelp@fstrf.org or +1 716 834-0900 x7311.

Click here to download more detailed guidance about Laboratory Queries.

Before shipping to BRI, don't forget to do a QA/QC of every single aliquot to ensure that *EVERY* label is clearly printed AND legible!

Illegible labels is one of the most common issues we see on shipment evaluations reported from BRI. Ensuring that all labels are clearly printed BEFORE shipping to BRI will prevent you from having to reprint and resend new labels to BRI.

Please complete a short survey to tell us about *Remote Source Document Verification* abilities at your site

Onsite monitoring continues to present challenges due to the COVID-19 public health emergency. The FDA is encouraging sponsors to consider optimizing the use of central and remote monitoring programs to maintain oversight of clinical sites. Guidance suggests the sponsor and monitors may consider multiple options to facilitate remote source document verification (rSDV).

To support DAIDS, REPRIEVE's regulatory sponsor in this effort, the REPRIEVE Clinical Coordinating Center is trying to better understand what rSDV systems may already be in place at clinical sites. Therefore, please take a minute to complete this brief survey by clicking here or scanning the QR code!

Thank you in advance for you help with this effort.

Seeking REPRIEVE Community Advisory Board Members!

- The REPRIEVE Clinical Coordinating Center (CCC) is seeking REPRIEVE participants interested in serving on the REPRIEVE Community Advisory Board (CAB).
- The purpose of the CAB is to ensure that community concerns and suggestions are heard and carefully considered.
- The CAB also provides input on the development of participant resources such as the participant newsletter, the website, and many more.
- Meetings take place every 6 months.

Click here to learn more about our current REPRIEVE CAB members and if you might have interested participants, contact Katie Fitch at the REPRIEVE CCC via email kfitch@partners.org.

Who's Who on the REPRIEVE Team? Meet Mark Byroads, *new* REPRIEVE Data Manager

Mark Byroads is replacing Anthony Holguin as the REPRIEVE Data Manager and he will bring an incredible amount of experience with him to this role. Mark has worked as a data manger at Frontier Science, the DMC for REPRIEVE located in Amherst, NY, for at least 17 years. Mark has served as the lead data manager on a variety of projects in many networks, including ACTG-affiliated trials.

As the Lead Data Manager for REPRIEVE, Mark will provide day-to-day clinical data management duties which, this includes building and maintenance of the trial data capture and its forms in OpenClinica along with QA/QC of data entry.

"I'm looking forward to working with all of you while I hit the ground running on REPRIEVE."

One important tip that Mark wanted to share is the importance of data entry and that ALL CRFs related to a visit are expected to be marked complete in OpenClinica within 3 weeks of the visit.

Join the Next Team/Site Site

Call!
January 19th, 2021

1:00 PM HAITI (EST)
1:00 PM PERU (PET)
2:00 PM PUERTO RICO (AST)
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)***

Topics for discussion will include updates from REPRIEVE Leadership! As well as guidance regarding Protocol Version 5.0 LOA #2 and some new CRFs.

If you did not receive the invite with the Zoom link, please email Katie Fitch at kfitch@partners.org

****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*
New! Version 5.0, Letter of Amendment 2 *dated 12/142020*
MOPS Version 5.0 *dated 09/15/2020*
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

Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use

Protocol Version 5.0 *dated 04/01/2019*
MOPS Version 4.0 *dated 04/10/2018*
A5333s LPC Version 4.0 *dated 03/23/2018*
These documents are on the A5333s 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

REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02114

Want to change how you receive these emails?
You can update your preferences or unsubscribe from this list.