REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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The REPRIEVE team is pleased to announce the availability of a one-time supplemental payment! This COVID-related supplement is in addition to the next annual retention supplement which will be distributed early. Both of these supplements will be paid out before the end of 2022.

The one-time supplement, based on the number of participants retained, is to recognize the incredible effort that every site team contributed during the COVID pandemic. The REPRIEVE Leadership Team is so appreciative of the numerous challenges everyone has worked incredibly hard to overcome over the past few years.

The supplement is not restricted to specific budgetary items and is designed for flexible use by sites to promote retention, for example, to provide for increased infrastructure or participant remuneration, based on individual site needs and policies.

The supplement will be available to all participating sites, both ACTG and non-ACTG. Site teams will be made aware of the timing of payment via email. If you have any questions

about this please email the REPRIEVE Finance Team reprieve.finance@mgh.harvard.edu

Data Timeliness is Critical in Preparation for the March 2023 DSMB Meeting

The next DSMB review will include a prespecified interim analysis for efficacy/futility at 75% of the data (see Table 6.3.2 in the A5332 protocol).

To ensure that the DSMB has the critical information it needs for this meeting, the database must be as complete and accurate as possible. Please continue to focus on timely data entry and be sure your site is up to date with this!

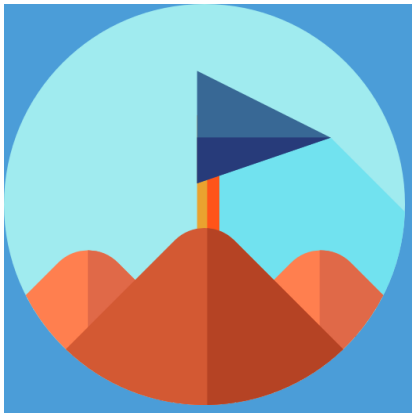
The formal timeline for the March 2023 DSMB is below and was distributed via email earlier today. Aim to have all data entered within the 3-week timeline and resolve queries as soon as you receive them. If you plan to take time off at the end of the year, please make sure you've completed all data entry and resolved all queries before you leave for your time off.

If your site has experienced recent staff changes, please ensure that new personnel have access to OpenClinica and have reviewed the OpenClinica training videos on the FSTRF REPRIEVE portal.

REPRIEVE DSMB Timeline (for the DSMB meeting scheduled for Thursday, March 30, 2023)

Responsibility	Task	Due date*	Weeks to DSMB
Sites	**Last date for evaluation for which complete data will be included**	**Dec 30 (Fri)**	**12.9**
	New Year's day (observed)	*Jan 2 (Mon)*	
Sites	**All data for visits through Dec 30 entered into OpenClinica**	**Jan 13 (Fri)**	**10.9**
Sites	**All adjudication packets for potential MACE endpoints by Dec 30 with work-up complete submitted to MGH DCC****	**Jan 13 (Fri)**	**10.9**
	MLK holiday (observed in the US)	*Jan 16 (Mon)*	
Sites	**All queries resolved**	**Feb 10 (Fri)**	**6.9**
	Presidents' Day holiday (observed in the US)	*Feb 20 (Tue)*	
Sites	**Resolution of follow-up and last-minute critical queries**	**Feb 24 (Fri)**	**4.9**
All	**DSMB Meeting**	**Mar 30 (Thu)**	**0.0**

*Deadlines are close-of-business on the given date.
**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.



Important Goal: Submit All Potential Adjudicated Events

The goal of REPRIEVE is to determine whether pitavastatin vs. placebo reduces the risk of Major Adverse Cardiovascular Events (MACE) among People with HIV at low-to-intermediate traditional CVD risk…

In order to properly answer this clinically-relevant question, **we need to make sure we don't miss even a single potential adjudicated event! In preparation for the next DSMB review it is essential to report every single possible trigger between now and the end of 2022.**

What potential events are we looking for?

Atherosclerotic or other CVD death
Nonfatal myocardial infarction
Unstable angina hospitalization
Coronary or peripheral arterial revascularization
Peripheral arterial ischemia
Nonfatal stroke or transient ischemic attack (TIA)
Death from any cause

Additional adjudicated cardiac events not part of the primary endpoint:
Heart failure, including all COVID-19-related events resulting in hospitalization

Section 6.0 of the A5332 MOPS has additional details and reporting workflows.

Contact the Core Team at actg.corea5332@fstrf.org if you have any questions about reporting one of these events.

Data Management Tips

The Cardiovascular Risk Assessment (TRK0151) now appears in OpenClinica for all participants at the Premature Study Discontinuation and Premature Study Medication Discontinuation visits. Please know that this CRF only needs to be completed for **participants who discontinue prematurely *under the A5332 Protocol Version 6.0.*** You can disregard the CRF for participants who have not consented for Version 6.0 or who discontinued under an earlier protocol version.

Q. We are seeking clarification on submitting potential adjudicated events in OpenClinica and to the REPRIEVE DCC for adjudication. What is the overall submission timeframe?

A. We request that the AE Log (ADE0001) and Adjudicated Events Tracking CRF (TRK0150) are keyed as soon as possible in OpenClinica after the site is notified of a potential event.

The A5332 MOPS (key sections 6.1.1 and 6.1.2) provides guidance on the timetable for the provision of source documents to the DCC (with timetables relative to the point at which the participant's clinical evaluation for the potential event is considered complete).

Q. How should COVID-19 vaccines be entered in the Medications Log in OpenClinica with the COVID-19 bivalent vaccine now being administered?

A. Fourth doses of the COVID-19 vaccine can continue to be reported as per the medications log: Vaccine manufacturer, "COVID-19 vaccine", dose number. You do not need to indicate that the vaccine is bivalent.

Remind REPRIEVE participants that the results of REPRIEVE will influence the standard of clinical care strategies to prevent heart disease

among people living with HIV worldwide!

People living with HIV have played an essential role in the work to advance the field of HIV care and treatment, and their participation in clinical trials has made an incredible impact and has increased the life expectancy of people with HIV. *Continuing participation until the end of the REPRIEVE trial is essential to helping us find an effective preventative treatment strategy for HIV-specific heart-related disease and helps to ensure that the important scientific questions posed in REPRIEVE are answered properly.* This cements the importance of the investment participants have made in the trial by taking part thus far.

Share REPRIEVE publications with your participants!

REPRIEVE participants are playing an essential role in the work to find an effective preventative treatment strategy for HIV-specific heart-related disease. We encourage you to share with your participants recent publication from REPRIEVE to show them the impact of their contributions to the field of HIV care and treatment.

All REPRIEVE publications can be found on our website here as well as plain language summaries.*

The REPRIEVE Clinical Coordinating Center has developed a number of materials to support your site's retention efforts. Learn more about these resources in the REPRIEVE Retention Toolkit found here.

**Please note that the plain language summaries have been approved by the MGB IRB for the Clinical Coordinating Center. If you plan to distribute these summaries to your participants, please submit these to your IRB/EC as per your local requirements.*

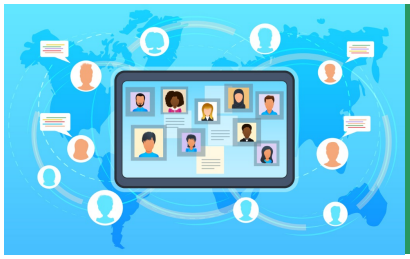
Would You Like to Join the Site Selection and Performance Committee?

The REPRIEVE Site Selection and Performance Committee (SSPC) is seeking additional members!

The SSPC is responsible for Clinical Research Site performance evaluation. Members of the SSPC assist with the review of sites within their team and meet via teleconference twice

annually.

If you are interested in joining the SSPC, please contact Marissa Diggs at mdiggs@mgh.harvard.edu**.**



Join Us for the Next Team/Site Call
January 17th

If you have any questions in advance of the site call we'd love to hear from you! Please email them to Katie Fitch at the REPRIEVE CCC.

1:00 PM US (EST)
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 01/18/2023 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 6.0 *dated 05/16/2022*
Revised! MOPS Version 6.0 *dated 10/27/2022*
LPC for ACTG Sites Version 6.0 *dated 06/03/2022*
LPC for Non-ACTG Sites Version 6.0 *dated 09/08/2022*
Revised! FAQs *dated 09/02/2022*
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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REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02114