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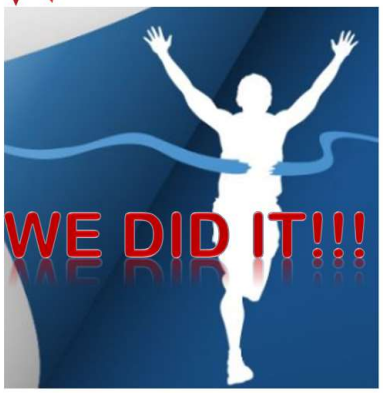
REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

April 2023 Table of Contents

REPRIEVE



THANK YOU!!!
REPRIEVE Site Teams!!!

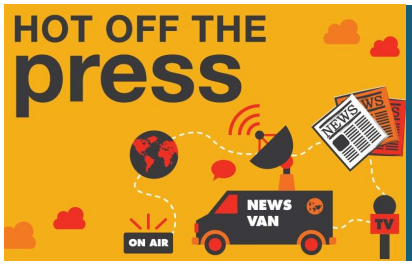
We would like to sincerely thank each site team for their contributions to recruit, enroll and follow participants in REPRIEVE! The dedication that each site team demonstrated during this long study provided the foundation for a well-run trial.

Based on the DSMB's interim review of the data, we have answered key clinical questions about the use of a statin strategy to prevent cardiovascular disease events in people living with HIV between the ages of 40-75.

We will share more information as well as discuss some clinical implications of the findings during the **site call on Tuesday, April 18th**, so please join us! Site call details are further below.

We anticipate our primary findings will be published soon and we will continue to

seek answers to relevant clinical questions from the data that has been collected in REPRIEVE.



Read the NIH Press Release!

Daily statin reduces the risk of cardiovascular disease in people living with HIV, large NIH study finds:

"A National Institutes of Health (NIH) clinical trial was stopped early because a daily statin medication was found to reduce the increased risk of cardiovascular disease among people living with HIV in the first large-scale clinical study to test a primary cardiovascular prevention strategy in this population. A planned interim analysis of data from the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) study found that participants who took pitavastatin calcium, a daily statin, lowered their risk of major adverse cardiovascular events by 35% compared with those receiving a placebo. Adverse drug events observed in the study were like those in the general population taking statin therapy. The interim analysis was sufficiently compelling that the study's independent Data Safety and Monitoring Board (DSMB) recommended it be stopped early given adequate evidence of efficacy. The NIH accepted the DSMB recommendations."

Read the full press release here.

Study Closure FAQs!

Thank you for emailing the Core Team with some excellent questions about study closure. We have created a page of FAQs on the REPRIEVE website that will be updated in (almost) real time, click here! We will also review FAQs on the April 18th Site Call. Below are a few we've received this week.

Q: Should we do the study termination visit at the next scheduled visit? Even if we are waiting for IRB approval of the participant letter?

A: Study termination visits may begin at the discretion of each site immediately. The current version of the protocol includes provisions for final study visits. No additional IRB approval is

required for this to happen. The participant letter should be submitted to your IRB and sites should follow local guidance on informing participants of the content of this letter.

Q: Where can I find the study termination visit in OpenClinica?

A: There is a new visit in OpenClinica called study termination that should be used to enter the information collected at the final study visit. This visit is the last visit to the right in the subject matrix screen.

Q: If a participant comes in for their study termination visit and is non-fasting, should we draw the storage samples at that visit anyway if they are not able to return? (I am concerned that some people just won't come back for their fasting blood draw).

A: It is preferable that participants are fasting for the final blood collection, however, if they are not fasting and you suspect that they would not return for a fasting blood draw, please proceed with the blood collection.

Q: Should participants stay on study drug until their study termination visit?

A: Yes, participants should continue the study drug until their study termination visit.

Q: In the LDMS preload we are supposed to enter month on study. Do we calculate the total number of months the participant has been on study using 30 days = 1 month? We have a study termination visit and the participant is slightly out of window for month 76 (he would be month 77). So we would put 77 EOS into the LDMS preload?

A: According to the LPC, the study termination visit should be the actual study month # with EOS for the visit unit, so you are correct in suggesting to enter 77 EOS in the LDMS preload.

Q. The Schedule of Evaluations in the A5332 protocol indicates that at discontinuation visits, CD4+/CD8+, HIV-1 RNA, CBC, and creatinine from clinical care within 180 days of the visit will be used. If a participant does not have a result available within 180 days what do I do?

A: If results are unavailable from clinical care within 180 days, note on the CRF that they were unavailable within 180 days of the visit.

Study Closure Date Calculator!

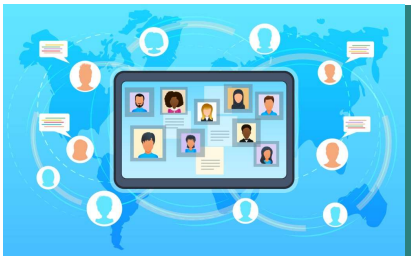
We know that many activities on the Study Closure SOP are based on the *last study termination visit at each individual site*. To help you determine the dates based on the last study termination visit at your site, we developed a Study Closure Date Calculator! Click here to download.

New Site Contracts

As you know, we received an extension grant from the NIH that will begin May 1, 2023 and take us through the end of the trial. Given the new extension grant/source of funds, we are required to execute new site contracts. The new contracts have been distributed. Please know that the financial terms of the new contracts are similar to the original and align with A5332 Protocol Version 6.0.

In order to ensure a seamless continuation of REPRIEVE and reimbursement to sites for study termination visits, **we ask that you return a signed contract by April 15, 2023**, to the REPRIEVE finance team (REPRIEVE.finance@mgh.harvard.edu). We will then return to you a fully executed document by **May 1, 2023**.

The closure of REPRIEVE does not change the requirement to sign and return the new contract, please do so as soon as possible.



Join Us for the Next Team/Site Call
April 18th

During the site call we will hear from REPRIEVE Leadership a brief summary of REPRIEVE findings and their clinical implications and we will provide training on the Study Closure SOP as well as Study Termination visit. Please make every effort to join this call or listing to the recording that will be posted on the A5332 PSWP.

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.

12:00 PM PERU (PET)
1:00 PM US (EDT)
1:00 PM HAITI (EDT)
1:00 PM PUERTO RICO (AST)
2:00 PM BRAZIL (BRT)
7:00 PM BOTSWANA (CAT)***
7:00 PM SOUTH AFRICA (SAST)***
7:00 PM ZIMBABWE (CAT)***
8:00 PM UGANDA (EAT)***
10:30 PM INDIA (IST)***
12:00 AM (April 19th 2023) THAILAND (ICT)***
****We do not expect site staff to join these calls during their off-work hours.* Instead we will post a recording of this call on the A5332 PSWP and the REPRIEVE CCC will arrange for separate calls to ensure you understand the REPRIEVE Study Closure instructions.

Remember that questions are always welcome at actg.corea5332@fstrf.org

REPRIEVE (A5332): Are You Up to Date?
For A5332 please use:
Protocol Version 6.0 *dated 05/16/2022*
MOPS Version 6.0 *dated 12/14/2022*
LPC for ACTG Sites Version 6.0 *dated 06/03/2022*
LPC for Non-ACTG Sites Version 6.0 *dated 09/08/2022*

***FAQs** dated 09/02/2022*
***Updated! Coenrollment Guidelines** dated 02/06/2023*
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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