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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

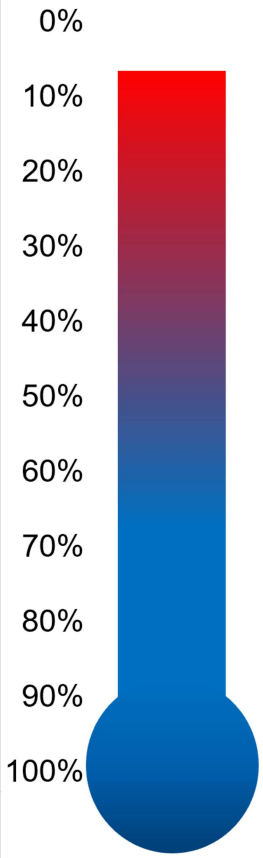
May 2023 Table of Contents

Trial Status

To communicate the status of REPRIEVE closure activities, Weekly Trial Status Updates will be sent during the study closure period.

To ensure that study termination visits are complete by July 31, 2023, all sites should be conducting study termination visits as per A5332 Protocol Version 6.0 at this time.

Thank you to every site team working to complete study termination visits; we are so appreciative of the incredible effort from site teams to meet the July 31 deadline!



Off-Study To-Date
412 participants*
(7%)

On-Study
5864 participants
(93%)

Goal Off-Study
6276
(100%)

~~Week 1 - April 10 - 16~~
~~Week 2 - April 17 - 23~~
~~Week 3 - April 24 - 30~~
~~Week 4 - May 1 - 7~~
Week 5 - May 8 - 14
Week 6 - May 15 - 21
Week 7 - May 22 - 28
Week 8 - May 29 - June 4
Week 9 - June 5 - 11
Week 10 - June 12 - 18
Week 11 - June 19 - 25
Week 12 - June 26 - July 2
Week 13 - July 3 - 9
Week 14 - July 10 -16
Week 15 - July 17 - 23
Week 16 - July 24 - 31

*This number is based on the number of completed RP0001 CRFs in OpenClinica. Additional termination visits may have already taken place, but because of the 3-week data entry timeline the RP0001 may still be pending completion.

In the figure above, the thermometer on the left, illustrates the percent of participants off study to date. In the middle of the figure is the actual number (412) and percent (7%) off study. On the right are the weeks to the deadline to complete study termination visits; each week that has already passed is crossed out.

Study Closure Achievements!

The following sites have achieved double-digit numbers of participants taken off-study!

Cincinnati CRS 2401
UT Southwestern CRS 31864
Washington University Therapeutics CRS 2101
Les Centres GHESKIO (GHESKIO-INLR) CRS 30022
University of Mississippi CRS 31846
University of Southern California CRS 1201
Denver Public Health 31470
Georgetown University CRS 1008
GHESKIO Institute of Infectious Diseases and Reproductive Health 31730
Chiang Mai University HIV Treatment CRS 31784
Alabama CRS 31788

Whitman-Walker Health CRS 31791

There are many ways we are planning to recognize sites in the Weekly Updates during the study closure period. We hope to recognize as many sites as possible for their incredible contributions to REPRIEVE so stay tuned!!!

REPRIEVE Announcements

Site/Team Calls will revert to a monthly schedule during the study closure period. The next call will take place on Tuesday May 16th, see below for more details.

Data timeliness is critical during the study closure period. Please ensure your site follows the 3-week data entry timeline for each study termination visit. This will ensure that the REPRIEVE database is as complete and accurate as possible.

Site performance evaluations will be focused on study termination activities going forward and will be distributed over the next 4-6 weeks. Distribution will be based on your number of participants on study.

REPRIEVE Site PI Sign-Off (TRK0189)

You may have noticed that *eCRF sign-off by site investigators* is an event listed on the Study Closure SOP. This activity is to be *initiated* 11 weeks after the last participant visit at your site and *completed* by November 13, 2023 at all REPRIEVE sites.

Please *do not complete this CRF UNTIL* the following is confirmed for each participant in OpenClinica:

1. *Each required CRF is entered into OpenClinica* at each visit the site performed for each participant, including Supplemental Forms, Adjudicated Event Forms, Non-Adjudicated Event Forms, and PRN visit column CRFs.

2. *There are no outstanding queries for each participant* in OpenClinica or elsewhere.

3. *Each visit conducted for a participant is 'Marked Complete'*, *and each CRF at each visit is also 'Marked Complete'*

More information from the REPRIEVE Data Managers will be reviewed during the May 16th

Site/Team Call. We highly recommend that you wait until after the Site/Team Call on May 16th to initiate this activity.

Data Management Tips: Please Complete the Following at the Study Termination Visit

- All CRFs in the Study Termination visit folder of OpenClinica as well as the following:
  - COVID-19 Assessment (SSW0040) (in the COVID-19 folder)
  - Off Study (RP0001) CRF (in PRN folder)
  - Final Medication Status (RP0003) (if not already completed for participant, in PRN folder)
  - Finalize Adverse Events Log (ADE0001) (located in the Logs folder)
  - Finalize Medication Log (TXW0295) (located in the Logs folder)

DO NOT ENTER CRFs in the Premature Study Discontinuation Visit folder UNLESS the participant discontinued REPRIEVE PRIOR to the notice of study closure.

DO NOT ENTER the VSW0025 Vital Status and Endpoint Follow-up form in the 'Vital Status Follow Up' visit column for PARTICIPANTS WHO WERE STILL ON STUDY at the time of the study closure announcement. Enter the VSW0025 form only for participants who prematurely discontinued (without withdrawing consent) BEFORE the study closure announcement.

Click here for additional guidance to assist you in entering these CRFs.

FAQs on the topics listed below are available on the REPRIEVE website, click here!

1. Study Termination Visits
2. Participants Lost to Follow Up
3. Lab and Clinical Data Collection
4. Vital Status and Endpoint Assessment
5. Study Product

6. Data Management

FAQs are updated frequently to support your efforts to complete study closure activities and ensure that your site meets all REPRIEVE study closure deadlines.

FAQ of the week!

Q: Is the Vital Status and Endpoint Assessment (VSW0025) to be completed for participants at the Study Termination Visit?

A: No, the VSW0025 is NOT to be completed for participants at the study termination visit.

The VSW0025 form should only be completed for participants for whom all of the following are true:

1. Prematurely discontinued REPRIEVE prior to the announcement of study closure and,
2. Have not withdrawn consent and,
3. One year has passed since their date of off-study or last vital status contact attempt.

The REPRIEVE CCC will be reaching out to sites in the next few weeks to notify them of PIDs that are overdue for this assessment.

More details are in the A5332 MOPS, section 12.6 Vital Status and Endpoint Assessment.

If you have a question about study closure that isn't already on the Study FAQ page, please email the Core Team at actg.corea5332@fstrf.org.

Save the Date!
Tuesday June 13th
5:00 - 6:00 PM EDT

We are pleased to share that on Tuesday, June 13th between 5:00 - 6:00 PM EDT we will be sharing Topline Results and Clinical Implications from REPRIEVE during the opening plenary session at the 2023 Annual ACTG Meeting.

This meeting will be a hybrid meeting and is open to all ACTG members and the public. More information can be found by clicking here. Stay tuned for updates from the REPRIEVE CCC.

We hope that everyone is able to join this meeting!

Participant Appreciation Materials

As a small token of our appreciation, the REPRIEVE CCC has developed a packet of participant appreciation materials to thank participants for their contributions to the trial. This packet includes a REPRIEVE Participant Certificate of Appreciation, the 2023 REPRIEVE Participant Newsletter, and a REPRIEVE lapel pin.

If you would like to order any of these items, please do so by

completing the ordering form below. Digital copies of the certificate of appreciation and participant newsletter are also available for download through the ordering form below.

Click Here to Request Participant Appreciation Materials!

An Important Message About Monitoring Visits

PPD is working on completing the monitoring visits for the REPRIEVE. We know that site teams are incredibly busy right now with study termination visits, however we are asking sites to be as cooperative and accommodating as possible during this time so that study termination visits are complete as well as completing monitoring of the study.

For sites that will not be involved in any DAIDS sponsored trials after REPRIEVE, your DAIDS OCSO PO will reach out to touch base about site closure activities.

JAMA Network™

REPRIEVE in Press
Click Here to Read!

Medical News in Brief

ONLINE FIRST FREE

April 26, 2023

Daily Statin Trial for People With HIV Halted Early for Clear Benefit

Emily Harris

Article Information

JAMA. Published online April 26, 2023. doi:10.1001/jama.2023.6619

Join Us for the Next Team/Site Call Tuesday May 16th

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.

Note that REPRIEVE will be holding monthly site calls during study closure to share important updates and answer any questions sites may have.

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 (May 17th 2023) THAILAND (ICT)***
****We do not expect site staff to join these calls during their off-work hours*. Instead, we will post slides from this call on the A5332 PSWP.

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*
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

Like, comment, share, and retweet!

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