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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

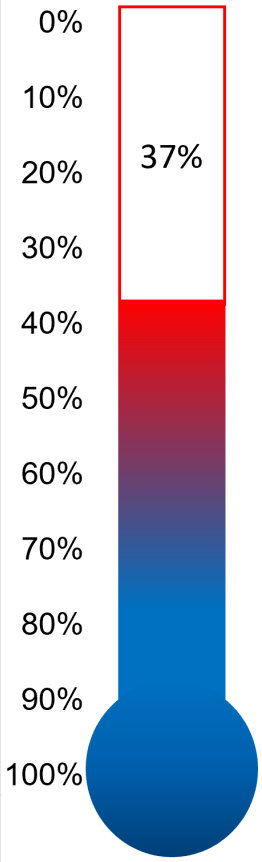
June 2023 Table of Contents

Trial Status

Last week was a great week with 549 new termination visits entered in OpenClinica!

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!

As a reminder, to ensure that study termination visits are complete by July 31, 2023, all sites should be conducting study termination visits at this time.



Off-Study To-Date
2317 participants*
(37%)

On-Study
3916 participants
(63%)

Goal Off-Study
6233
(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 (2317) and percent (37%) 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!

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

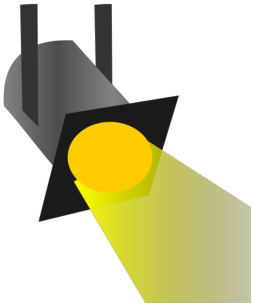
Sites that have surpassed 55% of participants taken off-study!

University of Cape Town Lung Institute CRS
Institute de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Georgetown University CRS
University of Mississippi

Hamilton Health Sciences
University of Southern California CRS
Louisiana Community AIDS Research Program
School of Medicine, Federal University of Minas Gerais CRS
University of Rochester Adult HIV Therapeutic Network CRS
Soweto CRS
Puerto Rico AIDS Clinical Trials Unit CRS
Cincinnati CRS
Vanderbilt Therapeutics CRS
Yale University
Tufts Medical Center
Maple Leaf Research
Washington University Therapeutics CRS
Columbia Physicians and Surgeons CRS
Université Laval
Les Centres GHESKIO Clinical Research Site CRS
Alabama CRS
Abbott Northwestern Hospital
Rush University CRS
UT Southwestern
Chapel Hill CRS

Sites that have the highest number of study termination visits conducted with complete data entered!

Institute de Pesquisa Clinica Evandro Chagas CRS -- 117 visits
Thai Red Cross AIDS Research Center -- 109 visits
Tropical Medicine Foundation -- 101 visits
UT Southwestern -- 90 visits
Chiang Mai University HIV Treatment CRS -- 88 visits
Gaborone CRS -- 85 visits
Cincinnati CRS -- 67 visits
Byramjee Jeejeebhoy Government Medical College CRS -- 67 visits
School of Medicine, Federal University of Minas Gerais -- 64 visits
Soweto CRS -- 58 visits



Site Spotlight: Georgetown University CRS

The **Georgetown University CRS,** located in Washington, D.C., USA, has been a tremendous contributor to REPRIEVE! This month, the team has shared some of its best tips for conducting study termination visits:

Our Lead Study Coordinator here at Georgetown, Jonathan Kumar, is incredibly efficient and was able to confirm termination visits with participants within two weeks of receiving the termination notice. Once Jonathan spoke directly to all of the participants and arranged for them to come in for termination, the Study PI, Dr. Princy Kumar, met with each participant to personally thank them for participating. She also explained the results of the study and notified the appropriate primary care providers. The entire clinical trials team assisted Jonathan with ensuring that all regulatory and trial related matters were taken care of in preparation for study termination.

Study Closure Metrics:

On-Study at Closure to Follow Up (CFU): 21
(%) Off-Study since CFU: 18 (86%)
% RP0003 Complete: 100%

***Thank you*, Georgetown University CRS team, for all your efforts, your study closure tips, and for sharing your team photo with us!**

Reminder about Specimen Collection

It is important for sites to be collecting specimens at the study termination visit. Please be sure to collect labs as per the REPRIEVE lab processing chart found on the PSWP. Thank you for your attention to this matter!

Data Management Reminders and Tips

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.

Remember to complete the RP0003 CRF for every study termination visit. This form is to be completed for all study participants and is located in the PRN folder. The average percent of RP0003 CRFs completed is 96%, and we would love to see this reach 100% before the deadline for Study Termination visits on July 31!

The following CRFs are to be completed in OpenClinica at the Study Termination visit:

- All CRFs in the Study Termination visit folder
- 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: A participant who has not yet completed the study termination visit called and let us know they moved away and cannot return for an in person visit. Shall we complete the study termination visit by phone?

A: To complete the REPRIEVE Study Termination visit, the options are:

- In-person clinic visit
- Phone (remote) Study Termination visit with the participant
- Medical record review if phone contact is not possible
- Combination phone visit and medical record review if both are possible

Mark the Study Termination visit 'Stopped' in OpenClinica if your site *cannot* conduct an in-person visit, phone contact, or medical record review at Study Termination.

However, there are several other CRFs you will need to be sure are updated/completed at Study Termination even if you are marking that visit 'Stopped'. Click here to download detailed instructions.

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.

REPRIEVE @ACTG Annual Network Meeting

Click here for the complete ACTG Network Meeting agenda and for a condensed schedule of REPRIEVE events at ACTG, click here.

If you will be at the meeting in person we would love to see you at the REPRIEVE Team drop-in on Wednesday, June 14th between 12:00 - 2:00 PM in the Senate Room. *Stop by, say hi, and grab a treat!*

REPRIEVE ACTIVITIES @ ACTG 2023

TUES 6/13
5:00-6:00 PM ET
Palladian (West)

REPRIEVE Presentation during Plenary Session I

WED 6/14
12:00-2:00 PM ET
Senate Room

REPRIEVE Drop-In Session for Site Teams (in-person only)

WED 6/14
3:30-4:30 PM ET
Empire (West)

What are We Learning from REPRIEVE about Myocardial Infarction Risks and Mechanisms Specific to Women Living with HIV?
by Dr. Markella Zanni

Women's Health Collaborative Science Group Business Session

WED 6/14
4:30-6:00 PM ET
Ambassador Room

Completing REPRIEVE: Timelines for Study Closure, Publications, and Data Availability
by Dr. Steven Grinspoon

Comorbidities Transformative Science Group Business Session

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!

Are you attending IAS 2023?

We are pleased to share that on Monday, July 24th between 2:45 - 3:45 PM AEST ***The REPRIEVE trial: Developing a cardiovascular disease prevention strategy for people living with HIV*** symposium will take place at the International AIDS Society (IAS) 2023 conference in Brisbane, Australia!

This presentation will surround the results from REPRIEVE and their global implications for people with HIV.

If you are planning to attend the conference, more information can be found by clicking here.

We hope to see some of you there!

Join Us for the Next Team/Site Call Tuesday June 20th

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

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REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital

55 Fruit Street, 5LON 207
Boston, MA USA 02114