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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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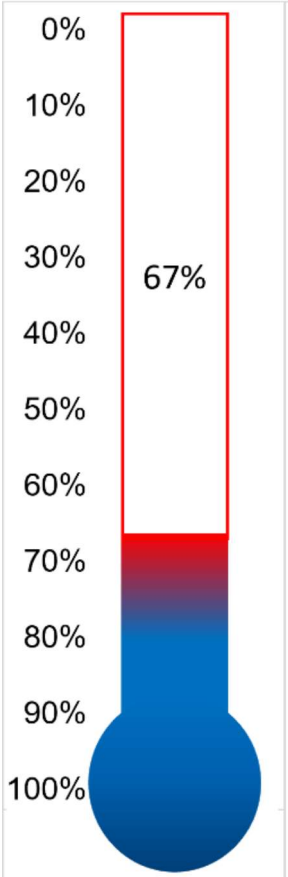
Trial Status

Last week was a great week with 396* 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
4178 participants*
(67%)

On-Study
2055 participants
(33%)

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 visits may have already taken place, but because of the 3-week data entry timeline RP0001 may still be pending completion.

Frontier Science programming and OpenClinica support are actively working to resolve a database issue that is resulting in recently entered data and data changes in OpenClinica not appearing in the study monitoring report. There may be some discrepancies between what your site has entered in OpenClinica and what is shown in the report; we apologize for any confusion this may cause.

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 (4178) and percent (67%) 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!

Sites are doing an incredible job working toward completion of study termination visits. Below we have highlighted a few that have already met important milestones.

Sites that have completed all termination visits AND have complete data entered!

Augusta University
University of Iowa
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Medical University of South Carolina
UNIVERSITE LAVAL
Petersen HIV Clinic, University of Arizona

Sites that have surpassed 75% of participants taken off-study!

Augusta University
Centro de Referencia e Treinamento
Chiang Mai University HIV Treatment CRS
Chronic Viral Illness Service of McGill University
Dallas VA Medical Center
Gaborone CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
Hospital Federal dos Servidores do Estado
Houston AIDS Research Team CRS
Instituto de Infectologia Emilio Ribas CRS
Medical Universitry of South Carolina
Mount Sinai Clinical and Translational Research Center CRS
Mount Sinai Downtown CRS
Mt Sinai West CRS
Ohio State University CRS
Orlando Immunology Center CRS
Petersen HIV Clinic, U of Arizona
San Miguel CRS
Thai Red Cross AIDS Research Center
UCSD Antiviral Research Center CRS
University of Iowa
Virginia Commonwealth Univ. Medical Ctr. CRS
Abbott Northwestern Hospital
Alabama CRS
Chapel Hill CRS
Cincinnati CRS
Georgetown University CRS
Hamilton Health Sciences
Institute de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Les Centres GHESKIO Clinical Research Site CRS
Louisiana Community AIDS Research Program
Puerto Rico AIDS Clinical Trials Unit CRS
School of Medicine, Federal University of Minas Gerais CRS
Soweto CRS
Université Laval
University of Cape Town Lung Institute CRS
University of Mississippi
University of Rochester Adult HIV Therapeutic Network CRS
University of Southern California CRS
Washington University Therapeutics CRS

Please be sure to **complete the Specimen Tracking Form in a timely manner and ensure the collection time entered on the Specimen Tracking CRF and in LDMS are identical**. This is important for monitoring the specimen collection status of the trial as well as to prevent lab data queries. If your site does receive a query, please respond in a timely fashion.

A note about Lab queries
A lab query is a tracked inquiry sent to your laboratory from Frontier Science. Queries resolve data discrepancies between LDMS and other sources (such as CRFs).

Please respond to Lab queries as soon as you receive them, this will ensure we meet the study closure deadlines. Click here to download tips about Lab queries.

Do you have a lab question? We will be having our next site call on July 18th. Please email any questions in advance of this call to the lab team (reprieve.labcom@fstrf.org).

Data Management Reminders and Tips

Data timeliness is critical during the study closure period. Entering data immediately after the study termination visit is preferred and ensure your site enters

data no later than 3 weeks from the 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 Final Medication Status (RP0003) CRFs completed is 95%, we would love to see this reach 100% before the deadline for Study Termination visits on July 31!

The 'Treatment end date' for pitavastatin on the Medications Log (TXW0295) Section B MUST match Question 5 'Date of last known dose of study medication' in the Final Study Medication Status (RP0003) form.

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: How should sites manage open EAEs in DAERS?

A: EAEs are to be collected, reported, and followed until a protocol reaches the status "Closed to Follow-up". Since REPRIEVE (A5332) has not reached this status, sites may still reply to and close open EAEs in DAERS. It is the RSC Safety Office's standard process to follow-up with sites and close queries in the system in a timely manner and they will continue to do so for A5332. As per the DAIDS EAE Manual, all EAEs need to be followed to resolution. If the status of the EAE is unresolved at the time of participant's completion of the study, the site can state that in NCRMS DAERS and select the appropriate status code "Unknown- Study Participation Completed".

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.

Last month, REPRIEVE team members gave a plenary presentation at the annual ACTG Network Meeting as well as presentations at two business sessions! Thank you to all who were able to attend the REPRIEVE events in person or remotely!

A few photos from the plenary session are below!

Are you attending IAS 2023?

We are pleased to share that on Monday, July 24th between 2:45 - 3:45 PM (Brisbane, Australia), ***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 July 18th

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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