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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

August 2023 Table of Contents

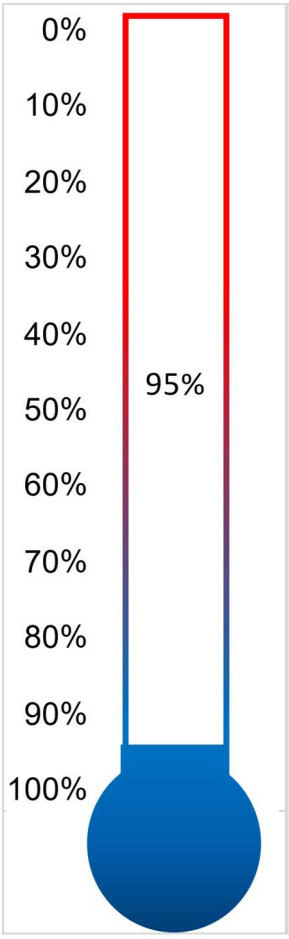
Trial Status

Last week was a great week with 266* new termination visits completed in OpenClinica!

95% of participants are off-study to date. THANK YOU site teams for your incredible efforts, we are so close to 100% off-study!!!

August 21st marks the next important deadline to complete data entry. Sites are to be completing data entry from any study termination visits for which data has not yet been entered, for this reason, the off-study numbers in the closure reports are not yet final and we anticipate we'll reach 100% off study during the data entry period.

We are allowing sites having trouble completing the last few study termination visits, to do any of these remaining visits during the data entry period. This will allow an additional 2 weeks from now to complete study termination visits. However, the data entry deadline will not be moved; therefore, you must complete data entry for each termination visit immediately after the visit so that all data is entered by August 21st.



Off-Study To Date
5822 participants*
(95%)

On-Study
300 participants
(5%)

Goal Off-Study
6122
(100%)

For sites that completed all study termination visits on or after July 31st, clinical data entry must be complete by Monday, August 21st

*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.

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 (5822) and percent (95%) off study.

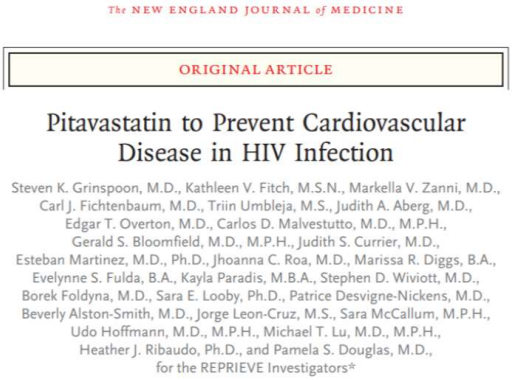
Study Closure Achievements!

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!

Johns Hopkins University CRS (USA)
Stanford CRS (USA)
UCSD Antiviral Research Center CRS (USA)
UCSF HIV/AIDS CRS (USA)
University of Pittsburgh CRS (USA)
University of Southern California CRS (USA)
University of Washington AIDS CRS (USA)

Duke University Medical Center (USA)
Washington University Therapeutics (WT) CRS (USA)
Case CRS (USA)
The Miriam Hosp (TMH) CRS (USA)
Dallas VA Medical Center (USA)
Puerto Rico AIDS Clinical Trials Unit CRS (USA)
The Ponce de Leon Ctr. CRS (USA)
University of Colorado Hospital CRS (USA)
Wits Helen Joseph Hospital CRS (Wits HJH CRS) (South Africa)
Barranco CRS (Peru)
Chennai Antiviral Research and Treatment (CART) CRS (India)
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (Brazil)
SOWETO (South Africa)
Joint Clinical Research Centre (JCRC)/Kampala CRS (Uganda)
Milton Park CRS (Zimbabwe)
UIC Project WISH CRS (USA)
Trinity Health and Wellness Center (USA)
Henry Ford Hospital (USA)
Houston AIDS Research Team CRS (USA)
Virginia Commonwealth Univ. Medical Ctr. CRS (USA)
University of Rochester Adult HIV Therapeutic Network CRS (USA)
University of Cape Town Lung Institute (South Africa)
Baystate Infectious Diseases Clinical Research (USA)
Michael E. DeBakey VAMC (USA)
Medical College of Wisconsin (USA)
Medical Universitry of South Carolina (USA)
Drexel University (USA)
Louisiana Community AIDS Research Program (USA)
Kinder Medical Group (USA)
Hamilton Health Sciences (Canada)
Universite Laval (Canada)
Vancouver ID Research and Care Centre Society (Canada)
James J Peters VA Medical Center (USA)
Mount Sinai St. Luke's CRS (USA)
Mt Sinai West CRS (USA)
Mount Sinai Clinical and Translational Research Center CRS (USA)
Eisenhower Health Center at Rimrock (USA)
School of Medicine, Federal University of Minas Gerais CRS (Brazil)
Centro de Pesquisas Clinicas ICHCFMUSP CRS (Brazil)
Hospital Federal dos Servidores do Estado (Brazil)
Abbott Northwestern Hospital (USA)
Maple Leaf Research (Canada)
Petersen HIV Clinic, U of Arizona (USA)
Augusta University (USA)



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pitavastatin to Prevent Cardiovascular Disease in HIV Infection

Steven K. Grinspoon, M.D., Kathleen V. Fitch, M.S.N., Markella V. Zanni, M.D., Carl J. Fichtenbaum, M.D., Triin Umbleja, M.S., Judith A. Aberg, M.D., Edgar T. Overton, M.D., Carlos D. Malvestutto, M.D., M.P.H., Gerald S. Bloomfield, M.D., M.P.H., Judith S. Currier, M.D., Esteban Martinez, M.D., Ph.D., Jhoanna C. Roa, M.D., Marissa R. Diggs, B.A., Evelynne S. Fulda, B.A., Kayla Paradis, M.B.A., Stephen D. Wiviott, M.D., Borek Foldyna, M.D., Sara E. Looby, Ph.D., Patrice Desvigne-Nickens, M.D., Beverly Alston-Smith, M.D., Jorge Leon-Cruz, M.S., Sara McCallum, M.P.H., Udo Hoffmann, M.D., M.P.H., Michael T. Lu, M.D., M.P.H., Heather J. Ribaudo, Ph.D., and Pamela S. Douglas, M.D., for the REPRIEVE Investigators*

In case you missed the email, the primary results of REPRIEVE were published in the New England Journal of Medicine and are now available online!

Go to the REPRIEVE publications page to access the manuscript and the REPRIEVE Plain Language Summary.

Press releases about the trial results have been issued from The National Institutes of Health, Massachusetts General Hospital, and the AIDS Clinical Trials Group and can be accessed on the REPRIEVE In the News page

Please share this information with your participants and ensure that they are aware of the REPRIEVE results. For more news updates, please refer to the REPRIEVE website: https://www.reprievetrial.org/learnmore/news/.

During September, we will have Community Forums to share the results with participants and anyone interested in learning more. Details about these forums will be shared shortly!

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.

Q: One of our REPRIEVE participants has missed multiple study termination visits and now will not return my phone calls. What should I do in this case regarding data entry in OpenClinica?

A: The REPRIEVE Study Termination visit 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

- ***If your site cannot conduct an in-person visit, phone contact, or medical record review, mark the Study Termination visit 'Stopped' in OpenClinica. Please also complete or update the CRFs as listed below.***
    - SSW0040 Covid-19 Assessment at the Study Termination visit (enter in the Covid-19 column)
    - RP0001 – Off Study CRF (in PRN folder)
    - RP0003 – Final Medication Status (if not already completed for participant, in PRN folder)
    - Finalize ADE0001 – Adverse Events Log.
        - Enter End date for resolved events along with a Resolved status, mark any still-ongoing events 'Still ongoing?/ YES and leave End date blank, mark AE Log 'COMPLETE' in Section C
    - Finalize TXW0295 – Medication Log
        - Enter the Pitavastatin stop date in Section B, ensure it matches the RP0003 form
        - Enter Stop dates for any meds stopped by the Study Termination visit, mark any still-ongoing meds 'Still ongoing?'/YES and leave stop date blank, mark Med Log 'COMPLETE' in Section D

FAQ from a site pharmacist

Q: Our site (located in the U.S.) has conducted its final study termination visit and has returned study product to the NIAID Clinical Research Products Management Center (CRPMC). Are there further steps I need to take at this time?

A: No further action is required. All pharmacy-related duties and processes (such as temperature monitoring) as they relate to REPRIEVE (A5332) can be terminated at this time.

The primary results of REPRIEVE were recently presented in a symposium titled **The REPRIEVE trial: Developing a cardiovascular disease prevention strategy for people living with HIV** at IAS 2023 in Brisbane, Australia!

In case you weren't able to join, Drs. Steve Grinspoon, Gerald Bloomfield, and Markella Zanni who presented during the symposium will join the REPRIEVE Site Call on August 15th to share similar information. For those sites located in time zones which prevent you from joining this call, we will reach out to schedule separate calls with you and your team.

At IAS 2023, Dr. Steve Grinspoon spoke to NAM aidsmap's Roger Pebody about the use of statins in people living with HIV. To watch, click on the preview above!

Join Us for the Next Team/Site Call Tuesday August 15th

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 hold 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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