



Randomized Trial to Prevent Vascular Events in HIV

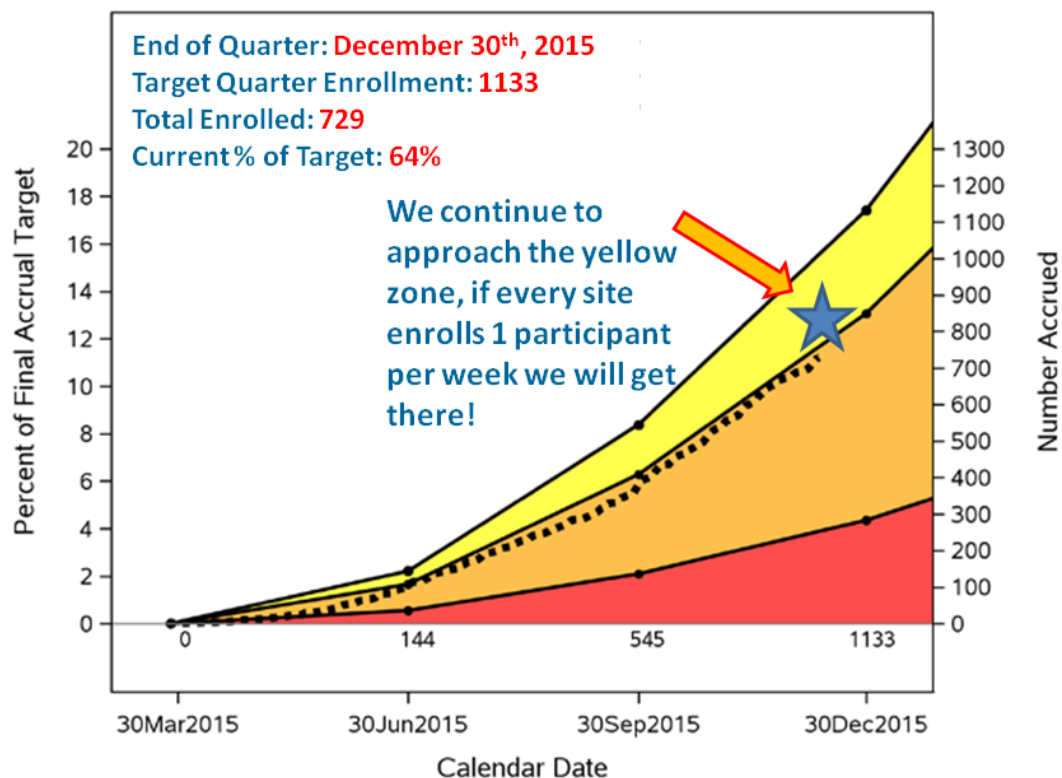
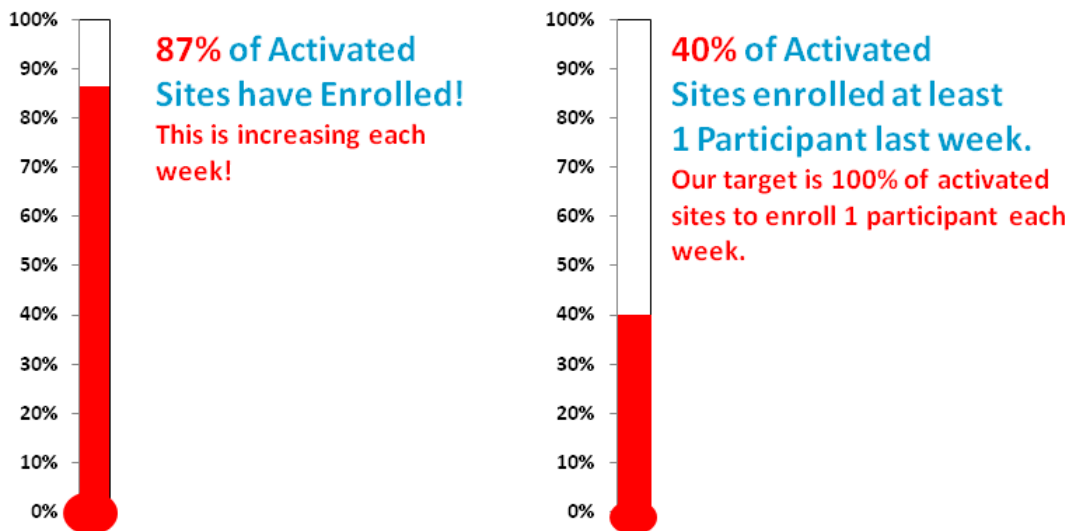
Site Newsletter 12/14/2015

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Trial Status: 12/7/2015-12/14/2015

REPRIEVE has over 700 participants enrolled!!! As of Friday, December 11th, 1117 participants had screened and 729 were enrolled, this means **39 participants were enrolled last week!** Last week was a strong week for REPRIEVE despite the holiday season that is upon us. Thank you for continuing to push enrollment right now, we greatly appreciate it.



Dotted line shows actual accrual progress.
Colored bands denote predefined NIH target enrollment zones: yellow (100% to 75%), orange (75% to 25%), red (<25%).

Congratulations to Sites Enrolling Participants Week of 12/7/15

- UCSD Antiviral Research Center CRS
- Chapel Hill CRS
- Weill Cornell Uptown CRS
- Northwestern University CRS

UCLA CARE Center CRS
 University of Washington AIDS CRS
 Ohio State University CRS
 Vanderbilt Therapeutics CRS
 Cornell Chelsea CRS
 The Miriam Hospital CRS
 University of Rochester Adult HIV Therapeutics Network CRS
 Washington University Therapeutics
 University of Miami AIDS Clinical Research Unit CRS
 University of Southern California CRS
 Georgetown University cRS
 UT Southwestern
 University of Illinois at Chicago
 Denver Public Health
 Mount Sinai Clinical and Translational Research Center
 Stanford CRS
 St. John Newland Medical Associates
 Florida Department of Health
 Baystate Infectious Diseases Clinical Research
 Drexel University
 Louisiana Community AIDS Research Program
 Wake Forest University
 Mt. Sinai St. Lukes Morningside Clinic
 Bluegrass Care Clinic



2013 Prevention Guidelines Tools

CV RISK CALCULATOR

Notes About the 10-Year ASCVD Calculator

A Note About Calculating ASCVD Risk Score for a Potential Participant >59 Years

When calculating the [10-Year ASCVD Risk Score](#) at screen for a participant >59 years of age, once you enter age in the calculator, a

message will appear regarding the calculator's inability to calculate the Lifetime Risk Score.

Please disregard this message and continue to enter the required values in order to calculate the 10-Year ASCVD Risk Score.

A Note About Calculating ASCVD Risk Score for a Potential Participant <59 Years

For a participant <59 years of age, upon calculating the [10-Year ASCVD Risk Score](#), please

make sure you use the 10-Year ASCVD Risk Score rather than the Lifetime Risk Score as both these scores appear next to each other on the screen.

FAQ



I am confused by the urine collection at entry for REPRIEVE (A5332). Is there a urine specimen that goes to our local lab and one that goes to the central lab*?

Depending on the gender of the participant, there are up to 2 tests done on the urine specimen collected at entry:

- Urine pregnancy test (as per the A5332 Protocol) is sent to the local lab for testing.
- Albumin/creatinine, urine for this test is processed, frozen and shipped to BRI as per your site's shipping schedule (please refer to your designated [A5332 Lab Processing Chart](#) for more instructions).

*This will be clarified in the Full Protocol Amendment that is forthcoming.

**For Sites Not Yet Activated to Enroll:
What is DAIDS Protocol Registration and When Should I Complete This Task?**

DAIDS Protocol Registration is a requirement for Protocol Activation and is included on the Site Protocol Activation checklist. DAIDS Protocol Registration verifies that sites have received the necessary approvals (i.e. IRB) and have provided to DAIDS all documentation related to investigator qualifications and responsibilities. Protocol registration verifies that site-specific informed consent forms contain the necessary information to comply with U.S. federal regulations.

Once your site has received IRB approval, please submit materials for DAIDS Protocol Registration. [Click here](#) for more details and useful tools.

If you have questions about Protocol Activation please email actgsitecoordination@s-3.com.

Important Details Regarding the DAIDS Adverse Experience Reporting System (DAERS)

All clinical research sites (CRSs) must have access to the DAIDS Adverse Experience Reporting System (DAERS) before a study begins to report expedited adverse events (EAEs) to DAIDS. Each CRS must have at least two (2) staff who, among themselves, have a combination of DAERS “reporter” and “submitter” roles. Please refer to the [attached document](#) for further details on DAERS access.

Additionally, the DAERS Reference Guide for Site Reporters and Study Physicians, DAERS Reference Guide for Site Enrollment Users, and DAERS Access User Guide for EAE Reporter and Submitter Rights have been updated and are available on the DAIDS RSC website, Safety and Pharmacovigilance Expedited Reporting via DAERS page located at: <http://rsc.tech-res.com/safetyandpharmacovigilance/expeditedreportingdaers.aspx>

If you have any questions regarding this information, please contact the NIAID CRMS Support team at CRMSSupport@niaid.nih.gov or the DAIDS RSC Safety Office at RSCSafetyOffice@tech-res.com.



TRAINING OPPORTUNITIES

Training Opportunities

Data Management Training will be offered on Wednesday, December 16th at 2:00 PM EDT*

This training is a repeat of the data management training that has been given throughout spring and summer. It is geared for sites that have not yet attended a data management training, or if there are new staff that would benefit from this training. This 2-hour training will include information on user accounts, the DMC portal, subject enrollment, case report forms and schedules, and OpenClinica (the clinical trials data management system used for this trial).

*Please note: **At least one person from your site must attend a data management training to meet protocol activation requirements.** If someone from your site has already attended a data management training, your site has met that requirement.*

*An email from Anthony Holguin was sent on Tuesday, December 8th about this training and included conference call information, if you did not receive this email or if you have any questions regarding this training or other data management issues, please contact REPRIEVE.DMC@fstf.org.

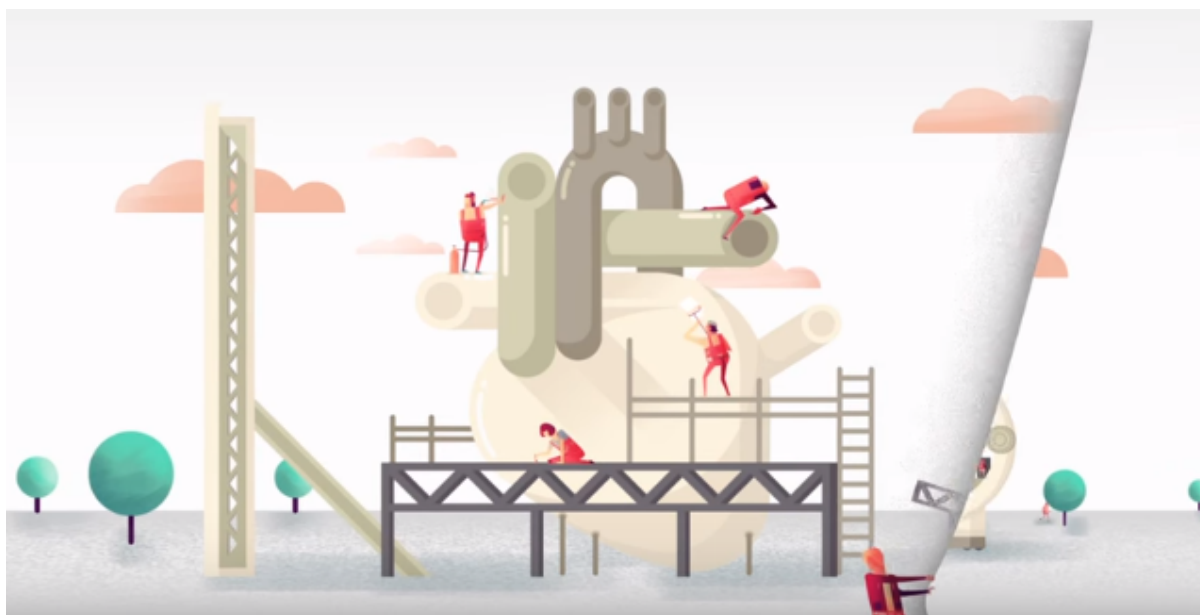
Special Contribution

HIV-Related Cardiovascular Disease, Statins, and the REPRIEVE Trial

Jennifer M. Gilbert, BA; Kathleen V. Fitch, MSN; and Steven K. Grinspoon, MD

Read the Recent REPRIEVE Article

From the REPRIEVE Clinical Coordinating Center! [Click here](#) to read the recent article featuring REPRIEVE in *Topics in Antiviral Medicine*.



Watch the REPRIEVE Video!

You may have seen this announcement last week but just in case, the REPRIEVE video is now live!!! Check it out on [YouTube](#) or the recently updated [REPRIEVE website](#).*

*We received a few comments that the video was a little hard to find on the website, so we have modified the homepage and now hope it is easier to find.

If you would like a digital copy, please email Katie Fitch, Project Manager for the REPRIEVE CCC at kfitch@partners.org.

Also, the video and script have been approved by the IRB for the Clinical Coordinating Center for REPRIEVE (Partners Human Research Committee), however submit to your IRB as per your local guidelines.

JUST POSTED on the A5332 PSWP

- [Spanish Version of the Cardiovascular Risk Assessment questionnaire \(TRK0151\)](#)



This can be found » [A5332](#) » [Protocol-Specific Support Documents \(Version 2.0\)](#) » [Spanish Translations](#)

What's in the Folders on the REPRIEVE (A5332) PSWP?

What's in the "Study Monitoring" folder?

A Data and Safety Monitoring Board (DSMB) was established by the NHLBI to monitor data and oversee patient safety in the REPRIEVE trial. You will find Summary Reports of DSMB meetings in this folder.

Sites are required to forward these reports to their IRBs/ECs and file them in the regulatory files. The monitors will look for documentation of the submission to the IRB during the regulatory file review.

Currently, these memos and reports are in the **Study Monitoring** folder:

- **Summary Report of the June 2015 DSMB Meeting and a memo** from the REPRIEVE team about the findings of that review.
- **Summary Report of the September 2014 DSMB Meeting.** This was the first meeting of the REPRIEVE (A5332) DSMB when the Board reviewed the Study Protocol, Monitoring Plan, Consent Form, and DSMB Charter.

What's in the "Lab Resources" folder?

This folder contains the Lab Processing Charts (LPCs) for the current version of the protocol and other useful resource material related to lab tests and the LDMS. Remember that there are different LPCs for ACTG sites and sites not in the ACTG (non-ACTG sites). Because ACTG sites are collecting additional lab specimens, we felt it would be easier and less confusing to create separate LPCs.

Here is a list of what is currently in the Lab Resources folder:

ACTG Sites:

- **The current LPC** (in Word and in PDF file formats)

Non-ACTG Sites:

- **LPC** (in Word and in PDF file formats)
- **Lab Details from WebLDMS Training**
- **Lab Processing Worksheet**
- **Shipping Schedule** – **very important!** Check your site's schedule of when to ship

- **samples to the specimen repository (BRI).**
- **Specimen Worksheets** - this folder contains worksheets for each visit.
- **Step-by-Step Guide for LDMS Entries using the REPRIEVE Processing Worksheets** – this is a guide that sites can use if their processing lab does NOT have LDMS access.
- **WebLDMS Reference Guides**
 - Shipping
 - Specimen Management
 - Storage
- **FDA 1572 Template**

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 6/15/2015

A5332 LPC for ACTG Sites: dated 9/17/15

A5332 LPC for Non-ACTG Sites: dated 9/17/15

These documents are on the [A5332 PSWP](#)

REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

For A5333s please use

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 3/16/2015

A5333s LPC : dated 9/21/15

These documents are on the [A5333s PSWP](#)

For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at reprieve.news@fstrf.org.

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