

[Subscribe](#)[Share ▲](#)[Past Issues](#)[Translate](#)

Facebook

0

Twitter

0

Google +1

Short URL

<http://eepurl.com/>

REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 02/22/2016

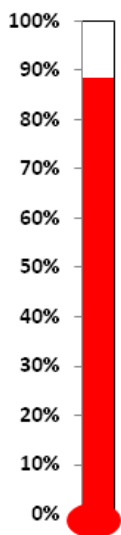
Table of Contents

- [Trial Status](#)
- [Congratulations to Sites Enrolling Participants Week of 02/15/2016](#)
- [What's new on the REPRIEVE \(A5332\) PSWP?](#)
- [Version 3.0 of the MOPS has a new section \(Section 5.6\) to provide additional guidance on Exclusion Criterion 4.2.9](#)
- [FAQ](#)
- [Training Opportunities](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)

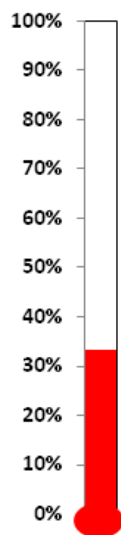
Trial Status: 02/15/2016-02/22/2016

REPRIEVE has officially enrolled over 1,000 participants! We want to thank all of our sites who have helped REPRIEVE get this far!

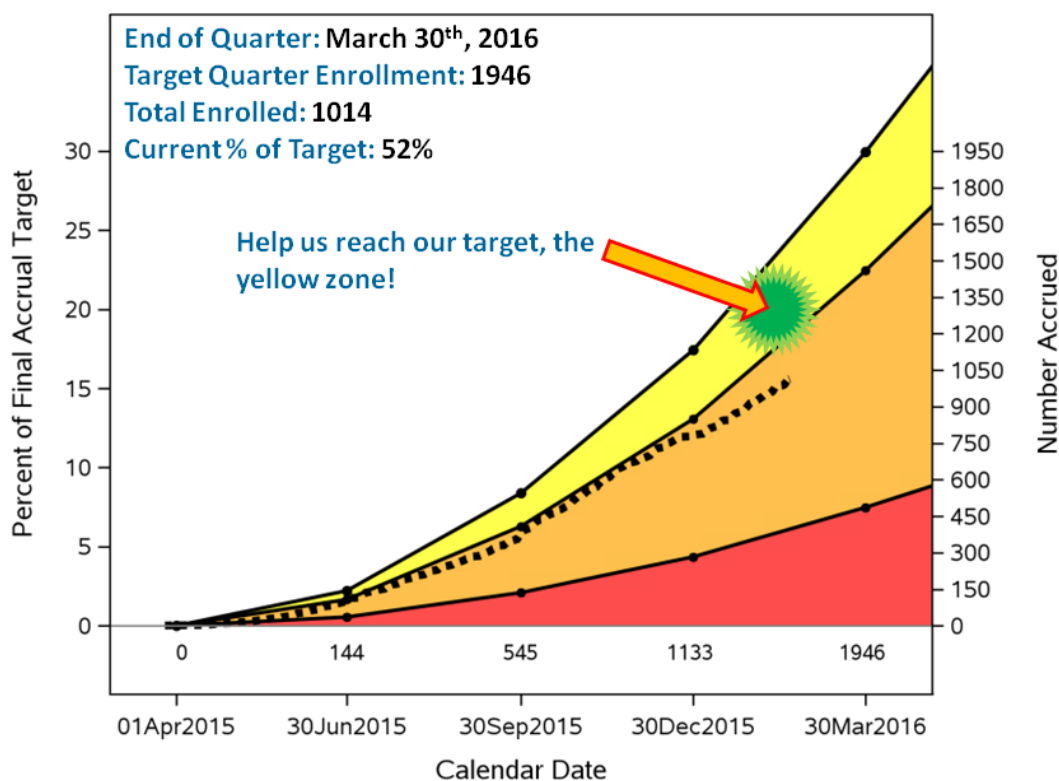
Currently, there are 1512 screenings complete, 1014 participants enrolled and 170 participants in screening. With 78 sites now activated to enroll, can 78 participants be enrolled this week?



88% of Activated Sites are Enrolling!



33% of Activated Sites Enrolled at Least 1 Participant Last Week!



Congratulations to Sites Enrolling Participants

Week of 02/15/2016

University of Illinois at Chicago

UT Southwestern

Denver Public Health

Baystate Infectious Diseases Clinical Research

University of Kentucky
Mt Sinai St Lukes Samuels Clinic
Mt Sinai St Lukes Morningside Clinic
Mt Sinai Comprehensive Health Program
Mt Sinai St Lukes West 17th Clinic
Boston Medical Center
Indiana University School of Medicine
UCSD Antiviral Research Center CRS
University of Colorado Hospital CRS
Chapel Hill CRS
Alabama CRS
Penn Therapeutics CRS
The Ponce de Leon Ctr. CRS
Ohio State University CRS
Harbor UCLA CRS
University of Washington AIDS CRS
University of Rochester Adult HIV Therapeutic Network CRS
Cornell Chelsea CRS
University of Pittsburgh CRS
Trinity Health and Wellness Center
Washington University Therapeutics CRS
Brigham and Women's Hospital Therapeutics CRS

**REPRIEVE will be successful if every
activated site enrolls *at least 1* participant per
week!**

What's new on the REPRIEVE (A5332) PSWP?
What's New on the [REPRIEVE \(A5332\) PSWP?](#)

Version 3.0 Spanish ICF » [A5332](#) » [Current Protocol Documents \(Version 3.0\)](#)

Revised recruitment materials » [A5332](#) » [Recruitment Materials](#)

Lab Processing Charts » [A5332](#) » [Lab Resources \(Protocol Version 3.0\)*](#)

Version 3.0 MOPS » [A5332](#) » [Protocol-Specific Support Documents \(Version 3.0\)*](#)

*please use Version 3.0 of the LPC and MOPS when your site has approval to implement Version 3.0 of the protocol.

Version 3.0 of the MOPS has a new section (Section 5.6) to provide additional guidance on Exclusion Criterion 4.2.9

Exclusion Criterion 4.2.9 indicates that the use of specific immunosuppressants or immunomodulatory agents including but not limited to tacrolimus, sirolimus, rapamycin, mycophenolate, cyclosporine, TNF-alpha blockers or antagonists, azathioprine, interferon, growth factors, or intravenous immunoglobulin (IVIG) are not allowed 30 days prior to study entry.

The key point is, if a potential participant is on a medication in one of these classes, the participant can stop the medication and wait 30 days, if agreed upon with the prescribing provider, and then be enrolled into REPRIEVE if s/he otherwise qualifies.

Exclusion Criterion 4.2.9 specifically excludes the following medications:

- Tacrolimus (calcineurin inhibitor) **(please note topical preparations are allowed)**
- Sirolimus (mTOR inhibitor)
- Mycophenolate (antimetabolite)
- Cyclosporine (calcineurin inhibitor)
- TNF-alpha blockers and antagonists
- Azathioprine (antimetabolite)
- Interferons
- Growth factors (not explicitly stated: G-CSF, GM-CSF, Erythropoietin (EPO), Thrombopoietin (TPO) and thrombopoietin mimetics (eltrombopag, romiplostim), Stem cell factor (SCF and Flt 3 ligand (increase stem cell populations))
- IVIG
- >10 mg prednisone per day or the equivalent

Exclusion Criterion 4.2.9 does not specify the following medications, but they should be excluded:

- Methotrexate (reduces IL-6 and IL-1 and IL-8 production; suppresses cell-mediated immunity)

- Cyclophosphamide and chlorambucil (alkylating agents: causes lymphopenia)
- Anakinra (IL-1 receptor antagonist)
- Everolimus (another mTOR inhibitor)
- Various monoclonal Abs (including HIV specific bNmAbs; OKT3, Antithymocyte globulin, rituximab)
- Betalcept (selective T-cell costimulation blocker used in acute organ rejection)
- Cladribine (immunosuppressant for hairy cell leukemia and progressive MS)
- Mitoxantrone (topoisomerase II inhibitor used in acute leukemia, other advanced cancers, and MS)
- Leflunomide (inhibits mitochondrial enzyme decreasing lymphocyte reproduction; RA DMARD)

The following medications are allowable:

- Sulfasalazine (inhibits PMN cell migration)
- Hydroxychloroquine or chloroquine (antimalarial; inhibits Ag presentation; inhibits lysosomal enzymes; previously discussed)
- Dalfampridine (potassium channel blocker used in MS)
- Thalidomide (unclear immunomodulatory agent used for various diseases)
- Glatiramer (Copaxone; 4 AA polymer decoy for myelin; MS agent)
- Tesamorelin for injection (Engrifta) (GHRH analogue)

FAQ



I noticed in Version 3.0 of the Sample Informed Consent that the volume of blood has increased for certain annual visits. We need to explain this to our IRB, can you provide the rationale for the increased blood volume?

The increase in blood volume allows for the future investigation of thematically-related questions within the REPRIEVE trial. These investigations, approved by the REPRIEVE Leadership Team, include assessments of the effects of statins on kidney function and assessment of sex-specific mechanisms of CVD risk and risk reduction in HIV. These investigations are enfolded into the protocol (Version 3.0) as ancillary objectives of the main study in Appendix IV and V.

Please refer to the LPC (ACTG vs. non-ACTG depending on your site designation) as this document will reflect the blood volume to be drawn for each visit. Version 3.0 Lab Processing Charts which outline the blood volumes reflected in Version 3.0 of the REPRIEVE protocol were recently posted on the

A5332 PSWP.

The following are questions about the pill counts for REPRIEVE (A5332).

What if the participant brings back the bottles but tells me that s/he has x number of tablets at home in their weekly pill dispenser. In such a case, should we still not perform the pill count at all?

Please only include the pills that are brought to the clinic visit as we cannot verify the existence of the other pills. The intent of the question is to capture actual returned amount. You can note in your source documentation that the subject reported having X number of pills at home.

What if the participant reports throwing out empty bottles, how should I proceed?

You can complete the pill count as all pills are present. Please remind the participant to bring in the empty pill bottles the next visit.

When calculating the 10-year ASCVD risk score for trans women (MTF) and trans men (FTM) should we use sex at birth? What if they have been on hormones for a long time, or started hormones before going through puberty?

Sex at birth should be used when calculating the 10-year ASCVD Risk Score, this is based on the inference that the calculator equation was likely developed/validated based on sex at birth.

Please refer to the additional guidance below, located in the REPRIEVE (A5332) Protocol or MOPS regarding the 10-year ASCVD risk score calculation.

- For subjects whose values of HDL cholesterol, total cholesterol, and/or systolic blood pressure fall below or above the acceptable calculator bounds for those parameters, values at the lower or upper bounds, respectively, will be entered.
- Subjects of mixed race will be asked to identify themselves as predominantly African American or predominantly other and the race of predominant identification will be entered; as per calculator guidelines, non-African American race is entered as White or other race.
- **Subjects will be asked to report sex at birth, and this sex will be entered.**
- *Only* subjects currently on 1 or more antihypertensive medication (prescribed for the treatment of high blood pressure) will be counted as undergoing treatment for high blood pressure.
- *Only* subjects who report current active smoking will be counted as smokers.

NOTE: When calculating the ASCVD risk score, the use of e-cigarettes is not considered as current active smoking. Please mark "no" for persons who report only the use of e-cigarettes.

Did you know PDFs of REPRIEVE Site Newsletters are available on the REPRIEVE Website? [Check them out!](#)



TRAINING OPPORTUNITIES

Training Opportunities

Next ECG Training Dates

Wednesday, 24 Mar 2016, 1:00 PM ET

Wednesday, 30 Mar 2016, 1:00 PM ET

ECG training will include information on the ECG machine, supplies, performance, and transmission of data. At least one person from your site must attend one training to meet protocol activation requirements. If you have participated already but would like a refresher, please feel free to attend.

You do not have to have an ECG machine onsite to participate in this training. We encourage you to have all staff that will work with the Quintiles ECG machine attend the training (eg, PI, study coordinator, CRA, backup personnel).

Calendar invites with call details have been sent out. Please email Katie Fitch, kfitch@partners.org, if you did not receive the invites.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

MOPS:

Version 3.0 dated 02/10/2016 (new version!)

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/05/2016 (new version!)

A5332 LPC for Non-ACTG Sites:

Version 3.0 02/05/2016 (new version!)

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

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

For A5333s please use

Protocol: Version 3.0 dated 01/28/2016

MOPS: dated 11/10/2015

A5333s LPC : Version 3.0 dated 02/05/2015 (new version!)

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.

