



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 09/26/2016

Table of Contents

- [REPRIEVE's FALL 50!](#)
- [First Brazilian Site is Open for Enrollment!](#)
- [Enrollment Updates](#)
- [Don't Forget! Actively Assessing for Adjudicated Events is Essential!](#)
- [FAQ](#)
- [Fall Startup Training Call](#)
- [2016-2017 Flu Season is Approaching](#)
- [Mechanistic Substudy of REPRIEVE \(A5333s\) Updates](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)



REPRIEVE's FALL 50!

We are entering the next quarter of enrollment! **Our goal is** to enroll at least 50 participants per week during the next quarter! **Between October 1st and December 30th all sites enrolling 3 participants per month will receive a \$50 gift card and all sites enrolling 4 or more participants per month will receive a \$100 gift card.** Stay tuned for each newsletter when we will update you on this **FALL**

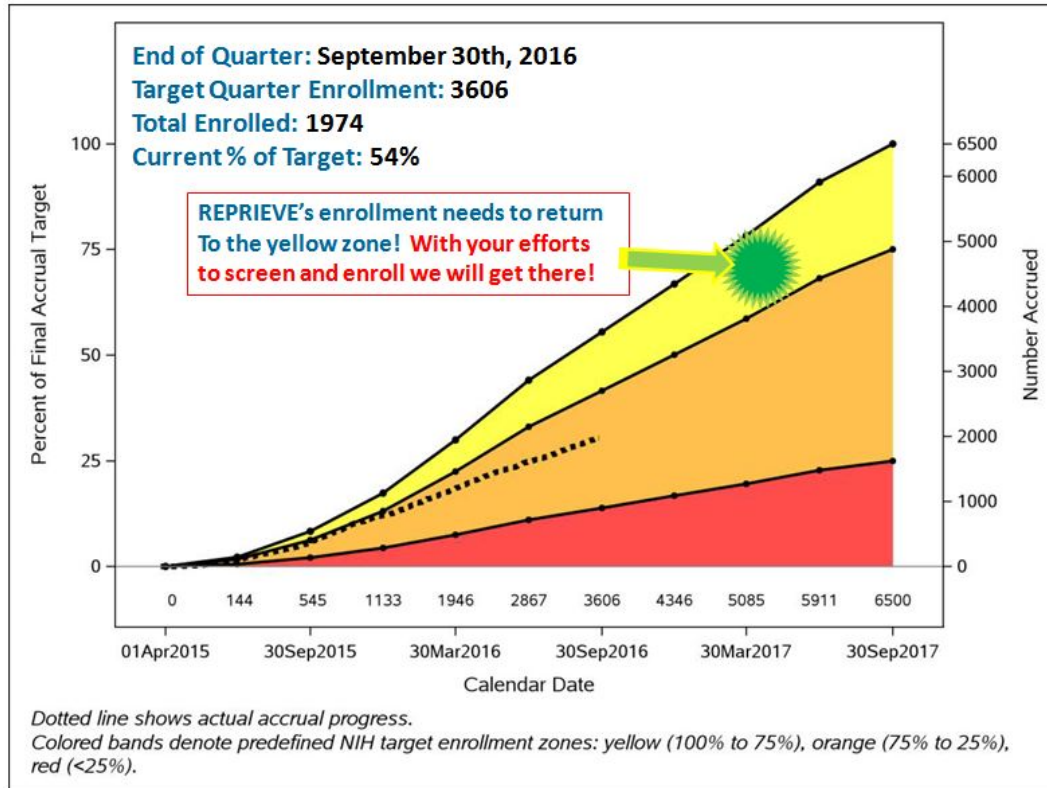
competition.

First Brazilian Site is Open for Enrollment!

We would like to welcome the first Brazilian site to open for enrollment, **site 12101 Instituto de Pesquisa Clinica Evandro Chagas CRS!** Congratulations to this team for their efforts to open for enrollment and congratulations on already enrolling the first participant!

Enrollment Updates

This past week, **33 participants** were enrolled in REPRIEVE, total enrollment is now at **1,974!** We are rapidly approaching the **2,000 participant milestone**. If 50 participants are enrolled this week REPRIEVE's enrollment will tip past 2,000.



Thank You to All Sites Enrolling Participants Week of 09/19/2016!

- Thai Red Cross AIDS Research Center
- Chiang Mai University HIV Treatment CRS
- Penn Therapeutics CRS
- Cincinnati CRS
- Case CRS
- Northwestern University CRS
- Johns Hopkins University CRS
- Massachusetts General Hospital (MGH) CRS
- Brigham and Women's Hospital Therapeutics CRS
- UT Southwestern
- Orlando Immunology Center CRS
- Los Angeles LGBT Center
- Mt Sinai Kreuger Clinic
- Louisiana Community AIDS Research Program
- Mt Sinai St Lukes Morningside Clinic
- Mt Sinai Comprehensive Health Program
- Michael D. DeBakey VAMC
- University of Toledo Medical Center CRS

- Instituto de Pesquisa Clinica
Evandro Chagas CRS

Don't Forget! Actively Assessing for Adjudicated Events is Essential!



It is important in REPRIEVE that all adjudicated events (AKA REPRIEVE MACE*) are captured. **It is absolutely essential for the REPRIEVE adjudication team to evaluate all possible MACE events to determine if they are actual MACE events. We ask that sites have a LOW THRESHOLD for submitting ANY POSSIBLE MACE event for adjudication.** Don't forget to complete the Adjudicated Events Tracking CRF (TRK0150) at every visit post screen.

The next Monthly Site Call, Tuesday, October 18th at 1:00 PM ET will be focused on REPRIEVE Adjudicated Events/REPRIEVE MACE, please join the call and be ready with any questions you may have.

The team has developed [this tool](#), located in the Protocol Training folder on the REPRIEVE (A5332) PSWP. The tool contains descriptive terms for adjudicated events and may be helpful when completing the Adjudicated Events Tracking CRF. Please review this tool so that you can carefully capture any possible REPRIEVE MACE at every visit post screen.

*MACE= major adverse cardiovascular event



Are all antihypertensive medications recorded in the Electronic Data Capture (EDC)?

No, antihypertensive medications prescribed for off-label uses, e.g., insomnia, are not recorded in the EDC. Also, they are not counted when determining treatment for high blood pressure (yes/no) when calculating the 10-year ASCVD risk score.

I am screening someone who does not smoke cigarettes, but does smoke marijuana. Does this count as smoking when calculating the 10-year ASCVD risk score?

The question about smoking in the ASCVD risk calculator only pertains to cigarettes, not marijuana, e-cigarettes, or cigars. If your participant exclusively smokes only marijuana, e-cigarettes, or cigars, then the answer to the smoking question in the

ASCVD risk calculator is "No".

Why are there 2 different definitions of menopause in the protocol?

One definition is used for safety, i.e., to determine the need for pregnancy testing, and is therefore more strict (the study drug is a US FDA Pregnancy Category X drug). The other definition will be used for analysis, i.e., for characterizing cardiovascular risk factors. The A5332 MOPS, section 4.2, clearly outlines the different definitions.



TRAINING OPPORTUNITIES

Fall Startup Training Call New to REPRIEVE? Need a Refresher? Please Join!

A protocol training conference call has been scheduled on **Tuesday, October 11 at 3 PM ET**.

At least one person from every site must attend a startup training call before the site can begin enrollment. These calls are held quarterly and the agenda is the same. Slides from the most recent training call are available on the protocol-specific website, in the Protocol Training folder.

Everyone is welcome to join this call - the target audience is site PIs, coordinators, backup staff, pharmacists, and lab staff. Your collaborating cardiologist is also welcome.

The final agenda and slide deck will be sent to the protocol logon prior to the call. If you want to check to see if you are on this logon, an email look-up page is available to verify mail addresses and mail group membership. You can find this page at <http://www.fstrf.org/emlookup>. If you need to be added to the protocol logon, [FSTRF User Support](mailto:user.support@fstrf.org) can help: user.support@fstrf.org.

Data Management Training Videos are Now Available!

Check out these excellent training videos just posted on the [FSTRF portal](#). The videos are listed under the Site Support tab.

- Changing Previously Saved Data
- Entering Logs
- Entering Missed Visits
- Answering Notes and Discrepancies
- Entering Out of Window Visit
- Entering Unknown or Missing Values

2016-2017 Flu Season is Approaching!



Flu season is almost here and it's time to get your patients immunized. Remember the 7-day rule! Separate routine vaccinations by at least 7 days from study visits at which blood will be stored for future REPRIEVE testing. OR administer the vaccine on the same day as the study visit but after all blood to be banked has been drawn (A5332 MOPS, Section 13.0).



cardiaccare.info



Massgeneral.org/research

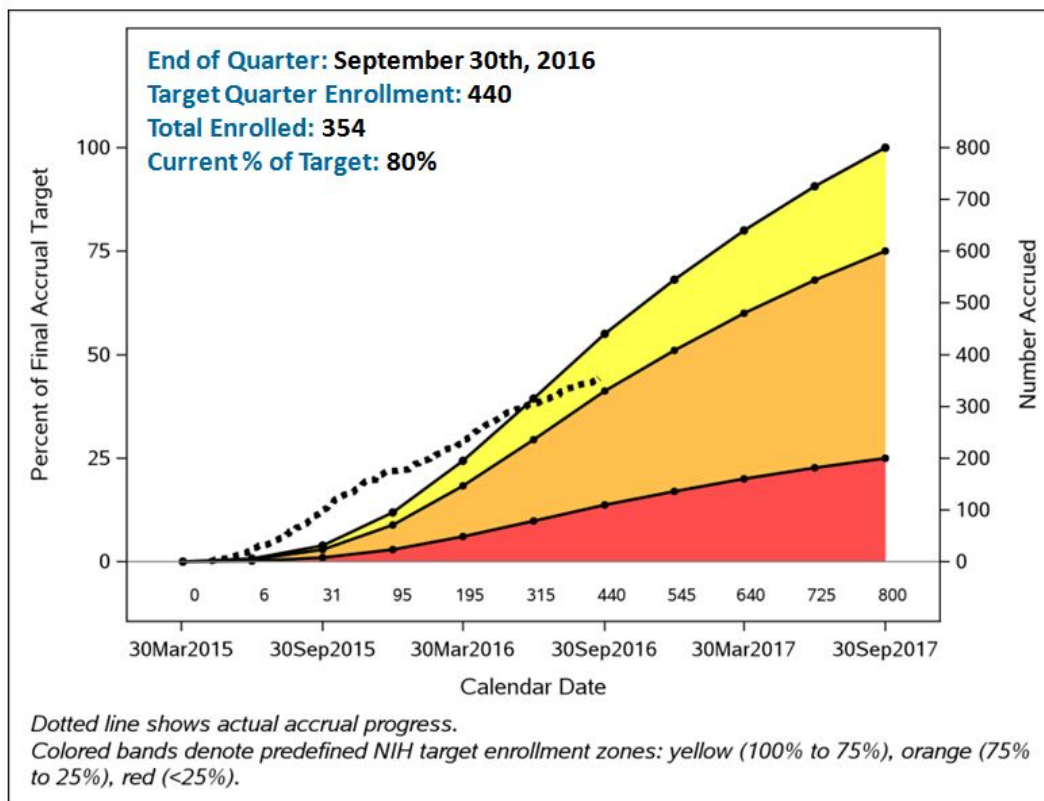
Mechanistic Substudy of REPRIEVE (A5333s) Updates

If you were unable to join the recent Monthly Site call for sites participating in the Mechanistic Substudy of REPRIEVE (A5333s), the slides are available in the Protocol Training folder on the A5333s PSWP and are also attached [here](#).

The slides include some excellent images and ideas developed by the team to help explain the Mechanistic Substudy to potential participants.

The Mechanistic Study has enrolled 354 participants, 5 new participants were enrolled last week!

Please remember to ask every participant screening for REPRIEVE (A5332) if they would also like to participate in the Mechanistic Substudy.



REPRIEVE at the HIV & Aging Conference in Boston, MA!

The REPRIEVE Clinical Coordinating Center team distributed REPRIEVE materials at the recent New England AIDS Education and Training Center's HIV and Aging conference in Boston, MA this past week, and had the opportunity to enjoy an excellent presentation on HIV and Aging by Dr. Paul Sax, site PI from the Brigham and Women's Hospital CRS.



REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/2016

Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)

Letter of Amendment, Version 3.0 #1 dated 08/17/16

MOPS:

Version 3.0, revision 1, dated 09/09/16

A5332 LPC for ACTG Sites:

Version 3.0 dated 08/03/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 08/03/2016

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: Version 3.0 dated 09/02/2016

A5333s LPC : Version 3.0 dated 08/03/2016

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@fstf.org.



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