Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 02/08/2016

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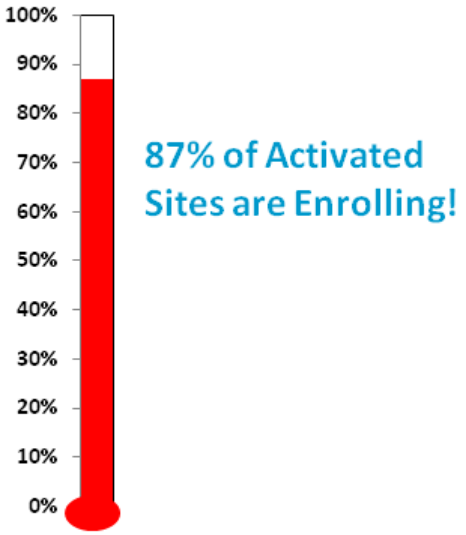
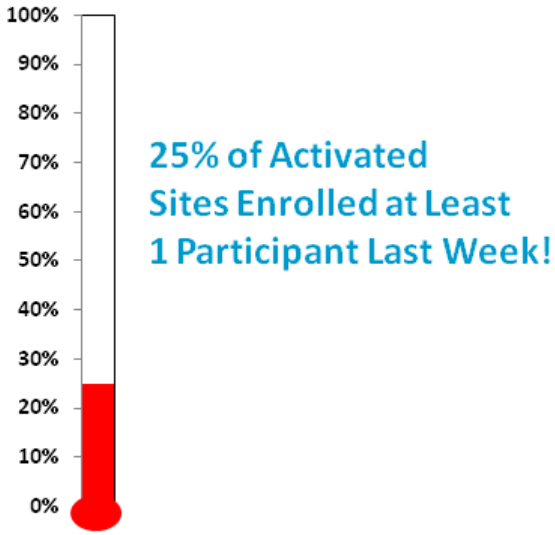
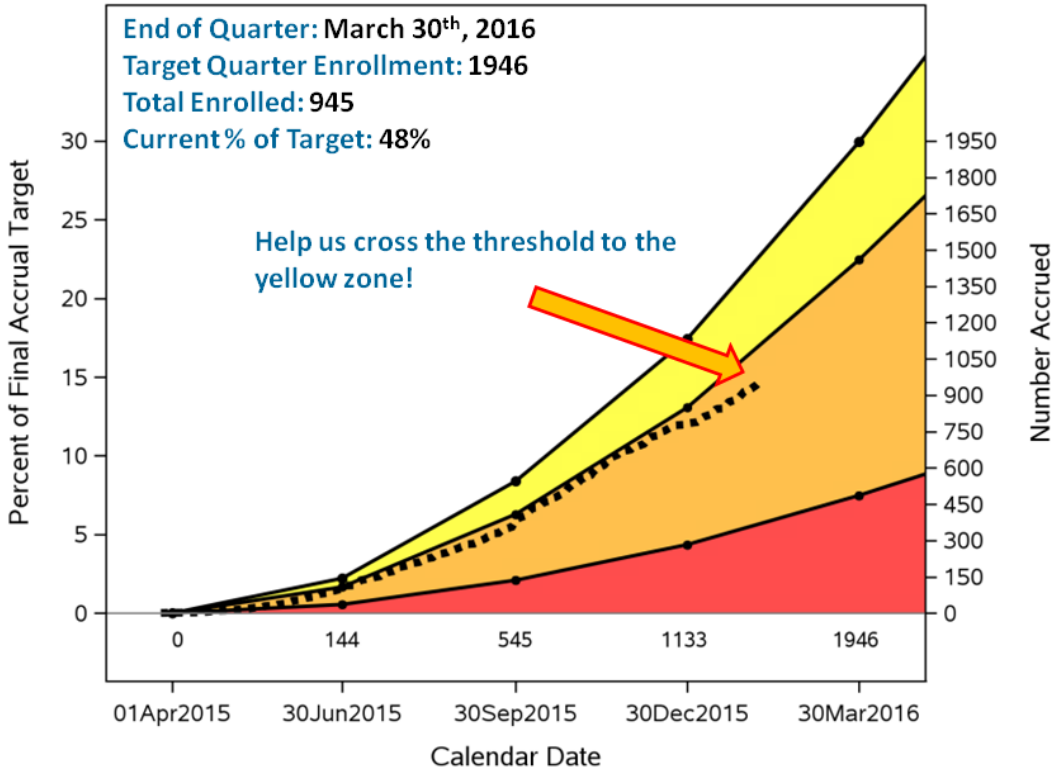
Trial Status: 02/01/2016-02/08/2016

The Race to 1,000 is still on!

From February 1st through February 15th, if we reach or exceed 1,000 participants enrolled in REPRIEVE, every site that enrolls at least 2 participants during this time will receive a $75 gift card from the REPRIEVE Coordinating Centers to use for a lunch at your site. We hope to reward as many sites as possible with these team lunches, and are confident that together we can reach 1000 participants!







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 02/01/2016

Thai Red Cross AIDS Research Center

Penn Therapeutics CRS

Chiang Mai University HIV Treatment CRS

UCLA CARE Center CRS

Northwestern University CRS

Massachusetts General Hospital CRS
New Jersey Medical School Clinical Research Ctr. CRS
University of Rochester Adult HIV Therapeutic Network CRS
University of Pittsburgh CRS
Washington University Therapeutics CRS
University of Illinois at Chicago
Georgetown University CRS
UT Southwestern
Denver Public Health
Florida Department of Health
AIDS Research Treatment Center of the Treasure Coast
University of Nebraska Medical Center
Stanford CRS
Indiana University School of Medicine

REPRIEVE (A5332) Protocol Version 3.0 is Now Live!

The amended REPRIEVE protocol (Version 3.0 dated 01/28/16), "Randomized Trial to Prevent Vascular Events in HIV – REPRIEVE (A5332)," is now ready for download on the REPRIEVE PSWP. Please also download the cover letter which has the summary of changes appended to it.

All sites that received protocol registration approval for the previous protocol version (Version 2.0) must submit this protocol amendment to their local institutional review boards or ethics committees (IRBs/ECs) as soon as a possible. Upon receiving final IRB/EC and any other applicable regulatory entity approval(s) for Version 3.0, sites should implement the amendment immediately.

Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual and section 4.3 of the protocol document.

For sites that are DAIDS approved but did not receive protocol registration approval for Version 2.0. please submit Version 3.0 to your IRB/EC before submitting protocol registration materials.

Any sites that have not yet been DAIDS approved, please also submit Version 3.0 to your IRB/EC.

If you have any questions, please contact the DAIDS Protocol Registration Office:
E-Mail: Protocol@tech-res.com

Save the date: REPRIEVE Twitter Chat on HIV and Heart Disease

Did you know February is Heart Month?

To recognize this important month, on **Wednesday, February 17th at 1:00 PM EST**, the REPRIEVE team will host its first ever Twitter chat about HIV and heart disease. NHLBI, NIAID, AIDS Action, The Well Project, and ACTG Network have all signed on, as have several site investigators. Please join us for this informative discussion.

A Twitter chat is where a group of Twitter users meet online to discuss a certain topic, using a designated hashtag (#) for each tweet contributed. A host or moderator poses questions to prompt responses from participants and encourage interaction among the group. If you would like to create a Twitter account so you can participate in the REPRIEVE Twitter chat, click here.

To participate, simply search on twitter for our hashtag, "#HIVheartchat", and put this hashtag at the end of all of your tweets. You can read what others have written and join the conversation by searching this term.

Topics are as follows:

1) Why is #HIV-related #CVD such a big concern? #HIVheartchat

2) What is the science behind #HIV-related #CVD? How does it work and why is it happening? #HIVheartchat

3) What can I do to prevent #HIV-related #CVD? How can I lower my risk? #HIVheartchat

4) How can I help stop #HIV-related #CVD? What can we do as a community? #HIVheartchat

If you are unable to participate in the Twitter chat on February 17th, be sure to visit the REPRIEVE website, Facebook page and Twitterfeed for a complete summary of the event. Please feel free to contact Jenny Gilbert (jgilbert4@partners.org) if you have have any questions.

Reminder!

The next **Monthly Site Call will take place on Tuesday, February 16th at 1:00 PM EST,** call details will be emailed shortly.

This call will begin with general updates, reminders, and information about a few forms that have been updated.

The main focus of this call is to outline the changes between Version 2.0 and Version 3.0 and the intended audience are sites that are familiar with and currently enrolling under Version 2.0.

New sites that will only enroll under Version 3.0 are welcome to stay for this portion of the call but are free to drop off at this point, because we are planning a more detailed startup training call for these sites at a later date.

FAQ

A participant in REPRIEVE has reported that they lost their study medication, what do I do?

If a participant reports that s/he has lost their study medication and you are wondering how to proceed, please do the following:
1. Document the details of the incident in the participant's source documents.
2. Have the Pharmacist of Record submit a detailed report regarding the incident and what corrective actions took place to PABREPRIEVEPEP@mail.nih.gov, as described in the DAIDS pharmacy guidelines.
3. Have the Pharmacist of Record place a supplemental order with the CRPMC to re-supply the participant.
3. Notify your local IRB as per your local IRB policy.

Please counsel participants during each study visit to report lost medications immediately to avoid extended lapses in therapy.

When is the optimal time to document an adverse event on the Adverse Event Log that is discovered between visits?

Some sites enter data immediately on the Adverse Event Log but others wait until the next scheduled visit. It is recommended to document as soon as possible to

avoid errors and omissions, but there is no requirement to do so. When sites learn of an adverse event between visits, they should enter those data upon site notification of an event or at the next visit, depending on the workflow at the site.

Study Medication and Pill Count Adherence CRF

We have recently received some questions requesting guidance on how to fill out the Study Medication and Pill Count Adherence CRF.

Our Data Managers have shared an example of how this CRF should be filled out.

Month 1

Date pills were last dispensed: Entry visit date

Number of pills dispensed: 180

Number of pills returned at this visit: 150

Month 4

Date pills were last dispensed: Entry visit date

Number of pills dispensed: 180

Number of pills returned at this visit: 60

Month 8

Date pills were last dispensed: Month 4 visit date

Number of pills dispensed: 90

Number of pills returned at this visit: 30

Month 12

Date pills were last dispensed: Month 8 visit date

Number of pills dispensed: 180

Number of pills returned at this visit: 90

Section 9.5 of the current A5332 MOPS has additional guidance on filling out this CRF.

The REPRIEVE Team will be holding "Office Hours" at CROI!

Members of the REPRIEVE Team will be available to answer questions during **REPRIEVE Office Hours on Tuesday, February 23rd between 6:00 PM - 7:00 PM EST** at the Connexion Lounge, Level 2 Boston Marriott Copley Place.

If you are able to stop by for this informal gathering, we would love to meet you.

Updated ECG Materials are on the PSWP!

Go to » A5332 » Protocol Training » Quintiles ECG Training on the REPRIEVE (A5332) PSWP to find the updated:

- *Site ECG Training V5 dated 01/29/16*
- *Investigator Manual V5 dated 01/29/16*

Training Opportunities

Still Need to Participate in a Site Start Up Training Call?

We will be scheduling a detailed protocol training call for new sites and new staff which will focus on current protocol Version 3.0. Watch for the call invitation which will be sent by email! We will also include this information in future newsletters!

Next ECG Training Dates

24 Feb 2016, 1:00 PM EST
30 Mar 2016, 1:00 PM EST

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.

Data Management Introduction Training

Data Management Introduction for REPRIEVE-Only Sites (A5332) training is planned via webinar at the following dates/times:

18 Feb 2016, 10:00 AM EST
18 Feb 2016, 2:00 PM EST

Webinar information will be circulated closer to the date of training. It is only necessary to join one of the webinars, as the information repeats.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol: ***Version 3.0 dated 01/28/2016 (new version!)***
MOPS: *11/09/15*
*(*watch for email about revised MOPS and LPCs)*
A5332 LPC for ACTG Sites: *dated 09/17/2015*
A5332 LPC for Non-ACTG Sites:*dated 09/17/2015*
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 (new version!)***
MOPS: *dated 11/10/2015*
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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