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Randomized Trial to Prevent Vascular Events in HIV

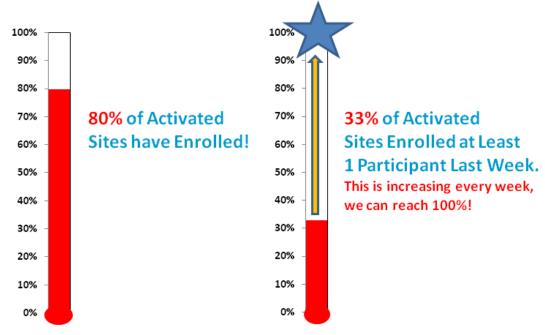
Site Newsletter 10/12/2015

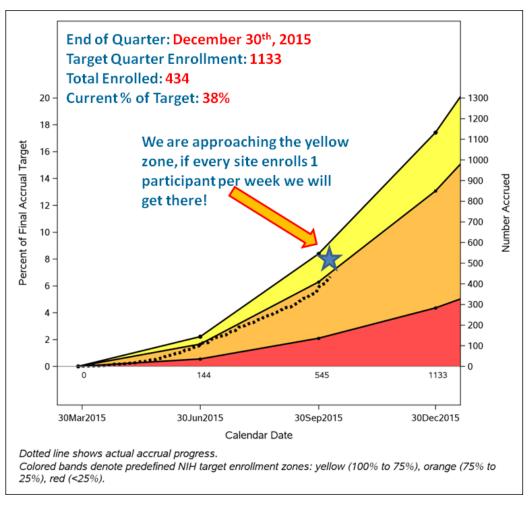
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Trial Status: 10/5/2015-10/12/2015

REPRIEVE had another strong week last week, 61 participants were screened and 40 participants were enrolled. The total enrollment is now 434 participants, we are getting very close to 500 participants enrolled, will we get there this week???





Congratulations to Sites Enrolling Participants Week of 10/5/15

UCSD Antiviral Research Center CRS

Alabama CRS

Greensboro CRS

Chapel Hill CRS

Massachusetts General Hospital CRS

Penn Therapeutics CRS

Columbia Physicians and Surgeons CRS

Weill Cornell Uptown CRS

Ohio State University CRS

The Miriam Hospital CRS

University of Pittsburgh CRS

New Jersey Medical School - Clinical Research Center CRS

Thai Red Cross AIDS Research Center

Georgetown University CRS

Cooper University Hospital

Duke University Medical Center

University of Illinois at Chicago

Denver Public Health

Louisiana Community AIDS Research Program

Medical College of Wisconsin

Florida Department of Health

FAQ



The REPRIEVE informed consent form template recommends a pattern of reimbursement for participants. Can this pattern of reimbursement be modified?

Yes, the pattern of reimbursement delineated in the REPRIEVE informed consent form template can be modified at the discretion of the site PI pending approval of changes by the DAIDS Regulatory Support Center. The total reimbursement may stay the same as originally allocated but may be subdivided in a pattern other than the pattern suggested. Alternately, the total reimbursement may be augmented at the discretion of the site PI (e.g. if the site PI draws from site start-up funds or the most recent supplement announcement in June, 2015 to supplement participant remuneration).

If a potential participant has had a change in the individual medications of their combination antiretroviral regimen recently prior to screen but has been on combination antiretroviral therapy for >6 months continuously, can he/she still be considered for participation?

Yes, individuals may be considered for participation if they have been on continuous antiretroviral therapy for the past 30 days (meaning no breaks) and on combination antiretroviral therapy (ART) for at least 180 days prior to study entry.

Study Product Reminders

- Please remind participants to bring <u>ALL study</u> <u>product (opened AND unopened)</u> with them to each study visit so that the pill count can be completed.
- Please remind participants to <u>finish all tablets from</u> one bottle before they open a new bottle of study product.





SAVE THE DATE! Tuesday, October 20th 1:00 PM EDT

We are asking all Site PIs to join the Monthly Site Call on **Tuesday, October 20th at 1:00 PM EDT.** An email announcement regarding this call will be sent closer to the date so please stay tuned.





Did you know the REPRIEVE Trial is on <u>Twitter</u> and <u>Facebook</u>? Follow us on Twitter @reprievetrial and like us on Facebook!



Lab Tips

If your Site is Using Web LDMS

If your site will be using Web LDMS, we highly recommend that your lab begin taking care of the following basic setup in the LDMS prior to the start of participant enrollment for REPRIEVE.

- Set up your virtual storage configuration.
- Verify that your user accounts are working properly.
 - O Do you remember your login credentials?
- Verify your ability to generate labels.
 - Do you have a printer installed and the correct labels on site (refer to the non-ACTG LPC for label details)?
- Request a "TEST" project setup in your LDMS database. Doing a "TEST" prior to the first
 participant is highly recommended and will help to problem solve prior to the first
 participant visit.

Sites are being contacted by the Data Management Center to participate in Web LDMS training and establish Web LDMS accounts.

Please contact LDMS User Support with any questions and/or to set up a "TEST" project.

Email: ldmshelp@fstrf.org

Phone: 716-834-0900 ext. 7311

Check out the Web LDMS training available on YouTube

Web LDMS REPRIEVE webinar training is now available on FSTRF's YouTube channel. These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories over the past few months. We encourage lab staff to watch these videos as a means of refresher training. Please feel free to share these links with other laboratory staff.

FSTRF YouTube Channel: https://www.youtube.com/user/FSTRFfilms

Training videos available:

- LDMS Training: Specimen Management for REPRIEVE
- LDMS Training: Storage for REPRIEVE
- LDMS Training: Shipping for REPRIEVE

Training Opportunities









TRAINING OPPORTUNITIES

All training call dates and call details have previously been emailed and are listed on the REPRIEVE calendar.

Save the Date: October 20th, 1:00 PM to 2:00 PM EDT

The next monthly site call will take place on October 20th at 1:00 PM EDT, we are asking all Site Pls to join this call as there will be very important updates to discuss regarding REPRIEVE. Barbara Bastow will be sending an email with conference call details closer to the date.



Check out the recent article in POZ Magazine,

<u>Getting to the Heart of the Matter</u>. that references
the importance of the REPRIEVE Trial. This article
might be a helpful resource for potential participants.

JUST POSTED on the A5332 PSWP

Updated ECG Materials from Quintiles

To find these materials on the PSWP, please go to the *Protocol Training folder*. In the subfolder called, *Quintiles ECG Training*, you can download the following revised materials:

Quick Guide (10/1/2015)

Investigator Manual (10/1/2015)

Site Training slides (10/1/2015)

Site Training audio recording (10/1/2015)

These documents are on the A5332 PSWP

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 9/17/15

JUST POSTED on the A5333s PSWP

The SF-36v2 is now available in English, Portuguese, French and Thai

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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