



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 05/09/2016

Table of Contents

- [REPRIEVE's March Madness Competition!!!](#)
- [Reminder Regarding the Data Entry Deadline for the DSMB Meeting!](#)
- [Lab Tips](#)
- [What's New on the REPRIEVE PSWP?](#)
- [Don't Forget to Ask Women About Participation in the Mechanistic Substudy \(A5333s\)](#)
- [Read the latest article about REPRIEVE in the AHA news!!!](#)
- [The REPRIEVE Participant Newsletter is Ready for Distribution!](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)

Updates: REPRIEVE's March Madness Competition!!!

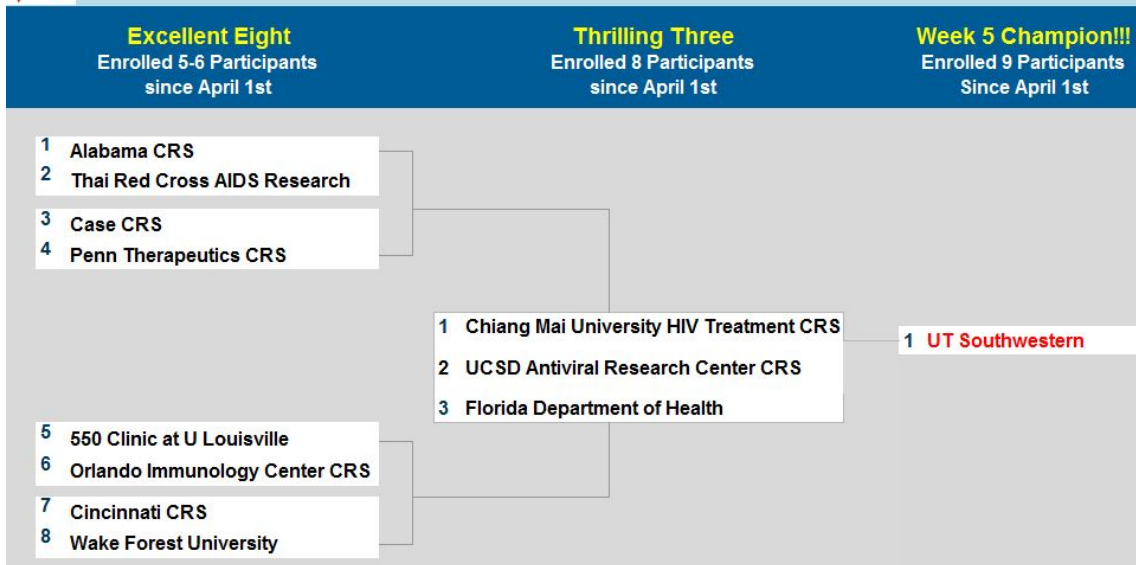
Together, sites have enrolled 1388 participants in REPRIEVE, including 65 participants in the past 2 weeks alone!

As we spring forward into the summer season, we want to remind you of our March-madness style competition for sites that recruit the most participants from **April 1st until June 30th, 2016**. **Aside from considerable bragging rights, the top enrolling sites will be eligible for team prizes including a team lunch, REPRIEVE t-shirts, and swag bags.**

Check out the site standings below. The competition continues to heat up, **with UT Southwestern as the current champion!** There are many sites close behind and many with the potential to get a spot on the bracket, stay tuned...who will be #1 in two weeks from now?

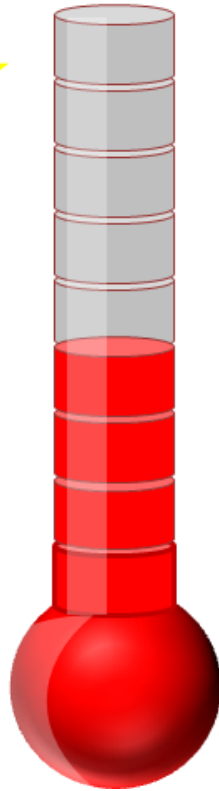


March Madness: REPRIEVE Style!

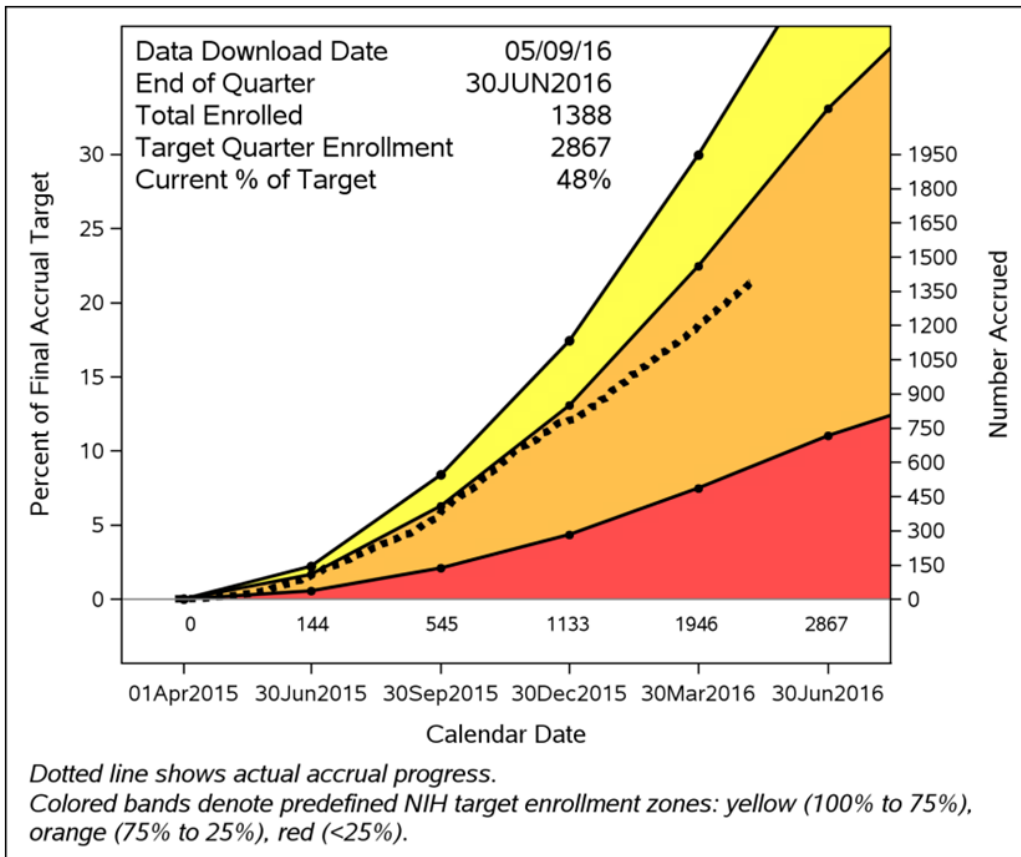




2867 Target Enrollment



1388 Current Enrollment



Reminder Regarding the Data Entry Deadline for the DSMB Meeting!

Please note that **Friday, May 20th** is the data entry deadline for the upcoming DSMB review.

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial. This timeline is posted under the Study Monitoring tab on the REPRIEVE (A5332) PSWP for future reference.

This refers to data for all eCRFs in OpenClinica for visits that have occurred up to and including May 6th.

	Task	Deadline (2016)	Weeks to DSMB
Sites	Latest date for the occurrence of a clinic visit for which complete data must be included in this DSMB review	May 6 (Fri)	7
Sites	All data for visits through May 6 entered [note: expedited - within 2 weeks of visit]	May 20 (Fri)	5
Sites	All queries resolved by this date	Jun 3 (Fri)	3
All	DSMB Meeting	Jun 24 (Fri)	0

Thank you for your attention to this timeline in the weeks ahead. If you have any questions, please email the team at actg.corea5332@fstrf.org.

Lab Tips



SHIPMENTS OF SPECIMENS TO THE BIOREPOSITORY HAVE BEEN EXCELLENT!

Sites are doing an amazing job preparing their shipments to send to our biorepository, BRI. In fact, in the past month BRI received 16 shipments and none of them had issues noted on the shipment reports. Thank you for paying careful attention to your shipments!

Common Errors to Avoid When Preparing your Shipments

Below are some common issues that we have noted. We wanted to let you know of the issues so you can prevent them at your site.

Shipment Notification Issues

- Using an outdated version of the shipping notification.
 - Please use Version 4 dated April 2015 located on the [ACTG member site](#).
- Shipping notification was incomplete.
 - For example:
 - The total # of vials was missing
 - “REPRIEVE” was not noted in the **Other/ Specify** field
 - The full list of protocols was not included.

Other Issues

- An LDMS shipping file was not sent or was sent in the incorrect format.
- Specimen boxes were not labeled correctly with the lab # and batch #.
- Plastic specimen boxes were used (please use cardboard only).
- The paperwork and file disc were not placed within a protective and waterproof envelope or sealed folder.

Are You a non-ACTG Site and Need Help with the Shipping Module?

For non-ACTG sites needing help with the shipping module in Web LDMS, particularly creating the shipping file, please refer to the **Shipping for REPRIEVE** YouTube video which can be accessed via the link below.

The shipping file is an electronic file that is to be included with all shipments that are sent to BRI.

Instructions for creating the shipping file begin at minute 7:45 of the video.

Similar videos for the other modules of Web LDMS are also available using the same link: <https://www.ldms.org/resources/videos/>

Revised LPCs Have Been Posted on the PSWP

Revised Lab Processing Charts (LPCs) for REPRIEVE (A5332), Non-Network LPC and the Mechanistic Study (A5333s) have been posted.

The modifications are minor and include:

REPRIEVE (A5332) Non-network LPC: A "3" replaced an "x" in Section 1, page 2 to indicate the volume of blood drawn for the CBC at Prem Treatment Disc /Prem. Study Disc.

Mechanistic Substudy (A5333s) LPC: A note was added as a reminder to obtain the CBC with differential required at Entry and Study Termination visits on the same day as the PBMCs are obtained--this enables our lab to analyze the monocyte data.

What's New on the REPRIEVE PSWP?

- The Coenrollment Guidelines were revised: co-enrollment in ACTG 5324 (Integrase and Maraviroc Intensification in Neurocognitive Dysfunction) is acceptable after completion of the REPRIEVE month 4 visit.
- Slides from the most recent ECG training (v6 dated 04/18/16) are in the Protocol Training, Quintiles ECG Training folder.
- Checklists and a screening log for Version 3.0, optional tools shared by REPRIEVE field representatives David Currin and Erin Hoffman at Chapel Hill CRS, are in the Protocol Training, Optional Tools folder.



Don't Forget to Ask Women About Participation in the Mechanistic Substudy (A5333s)!

Enrollment of women is very important in the Mechanistic Substudy! Remember to ask all women screening for REPRIEVE (A5332) if they would also like to participate in the substudy.



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Hot of the Press!

Read the latest article about REPRIEVE in the AHA news!!!

[Researchers evaluating HIV's hidden heart threats](#)



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Participant Newsletter #1 | Spring 2016



The REPRIEVE Participant Newsletter is Ready for Distribution!

[Click here](#) to download the REPRIEVE Participant Newsletter. The newsletter was developed using Microsoft Word and therefore can be modified for distribution to participants at your site.*

The Newsletter is posted on the REPRIEVE (A5332) PSWP and the REPRIEVE trial website: www.reprievetrials.org

Participant newsletters are a wonderful way to update participants about REPRIEVE as well as a great way to help participants stay engaged.

The REPRIEVE Clinical Coordinating Center will develop a participant newsletter annually each spring.

If you have suggestions for future newsletters or have questions about the formatting of the current newsletter please email Laura Sanchez at lsanchez12@partners.org

*The REPRIEVE Participant Newsletter has been approved by the IRB for the REPRIEVE CCC, however please submit to your IRB per your local IRB requirements.

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)

MOPS:

Version 3.0, revision 1, dated 04/15/2016

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/23/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 05/05/2016 (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 05/05/2016 (**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 reprise.news@fstrf.org.



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