



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 04/25/2016

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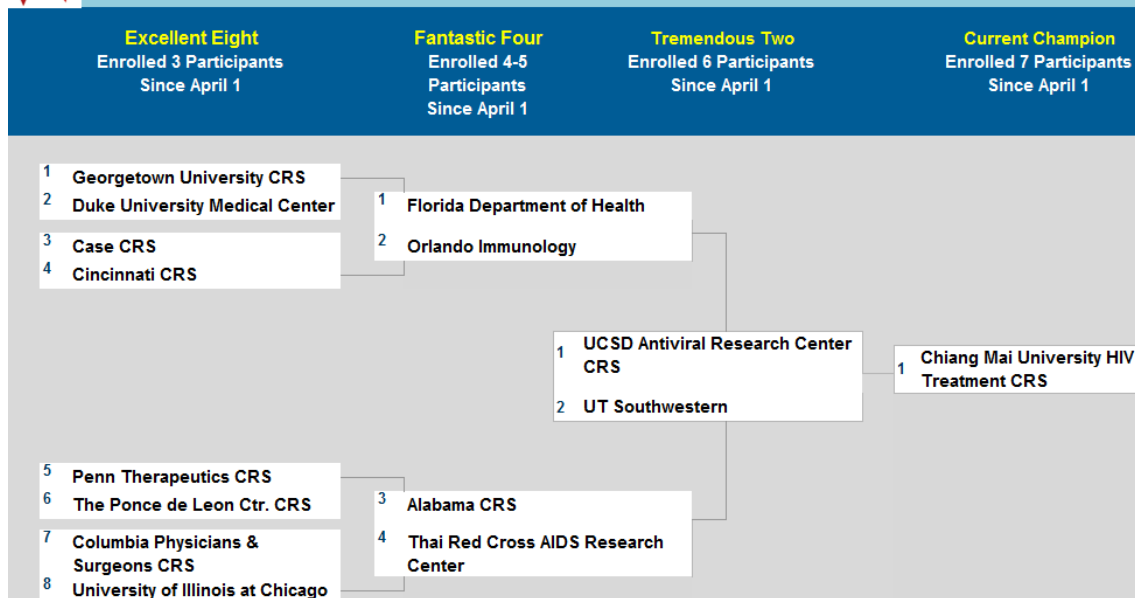
Updates: REPRIEVE's March Madness Competition!!!

As the weather gets warmer outside the REPRIEVE March Madness competition is beginning to heat up. There are now 4 distinct brackets with 15 sites in the running and there is definitely room for more sites in the competition!

Check out the current standings below!



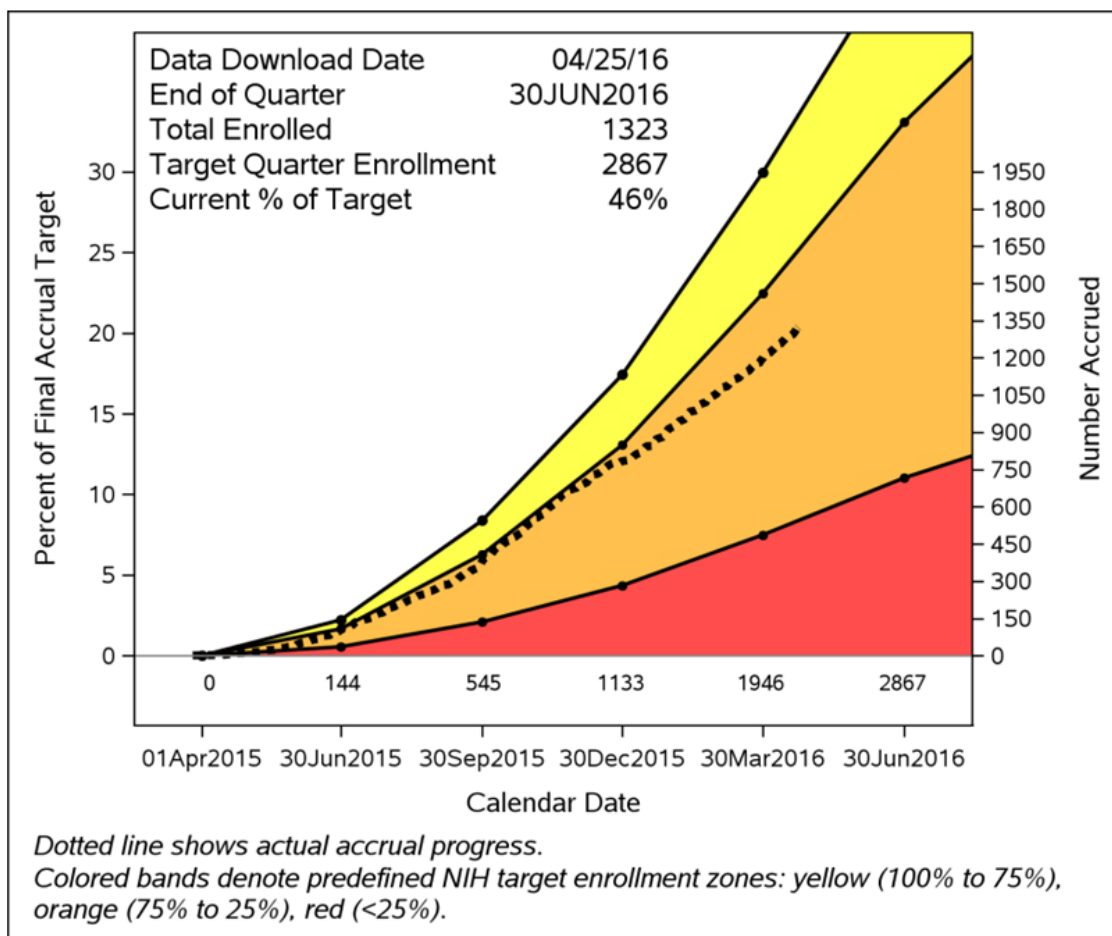
March Madness: REPRIEVE Style!



40 participants were enrolled last week!

The target enrollment for June 30th is 2867, enrollment is approaching 50% of the target.





Featured Sites!

Did you know that there are 2 sites in Thailand participating in REPRIEVE?

The **Chiang Mai University HIV Treatment CRS** and **Thai Red Cross AIDS Treatment CRS** are working very hard to recruit participants for REPRIEVE, both teams have shared some of their unique and successful recruitment strategies.

Meet the Chiang Mai University HIV Treatment CRS Team!

For successful recruitment the CMU Treatment CRS finds the following to be helpful:

Annual Academic Meetings: We organize an annual academic meeting to update clinicians from other area hospitals and health centers about research studies and new findings related to HIV/AIDS.



Provider presentations: Our recruitment team contacts primary HIV providers to request a visit at their facilities to introduce our research in person. The recruitment team will also conduct a survey to assess the number of potential participants from those sites. Study posters and brochures are used as informational materials during these presentations.



Pre-screening: The recruitment team will approach potential participants during their clinic visit and pre-screening activities usually take place the same day as the clinic visit.

Snowball strategy: We encourage study participants and CAB members to introduce REPRIEVE to their friends.

Meet the Thai Red Cross AIDS Treatment CRS Team!



For successful recruitment the Thai Red Cross AIDS Treatment CRS finds the following to be helpful:

- Informational posters posted in clinic
- Provide informational postcards for interested participants to take home
- A dedicated phone number for REPRIEVE
- Staff readily available to answer questions about REPRIEVE



Who Can Answer My Questions?

There are several important resources to help answer questions you may have about various issues such as site start up, co-enrollment, eligibility, exclusionary medications etc.

The REPRIEVE team has developed several resources to help answer your questions!

On the REPRIEVE (A5332) PSWP, you will find [FAQs](#), [Co-enrollment Guidelines](#), MOPS and Lab Processing Charts which include information that may answer your questions.

Also, the REPRIEVE (A5332) Protocol includes a Study Management page with several important email addresses and phone numbers.

For all other questions about REPRIEVE (A5332), please e-mail actg.corea5332@fstrf.org. Emails to this address are received by a group of team members with the expertise to address various clinical and non-clinical issues related to REPRIEVE. To ensure that your email is quickly noticed, *please put REPRIEVE in the subject line and the PID as needed.*

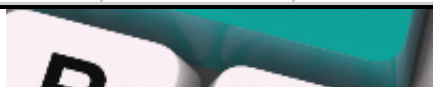
If you have a question specific to the Mechanistic Substudy (A5333s), e-mail actg.corea5333s@fstrf.org.

Please do not email the Protocol E-mail Group: actg.prota5332@fstrf.org. The protocol logon is the primary vehicle for *the team* to distribute important information about the study *to sites*, therefore this email address includes site staff, pharmacists, laboratory technicians, data entry staff etc.

Did You Know?



If you receive a **Registration with Required Corrections Notification** from DAIDS Protocol Registration, you may proceed with site activation while you are addressing the required corrections. You may submit your site protocol activation checklist online once all of the steps have been successfully completed. (The DAIDS protocol

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FAQ



We have a REPRIEVE participant who would like to co-enroll in ACTG 5324. Is this permissible?

Co-enrollment of REPRIEVE participants into A5324 - Integrase & Maraviroc Intensification in Neurocognitive Dysfunction (InMIND) - is acceptable, as long as the participant has completed the month 12 REPRIEVE visit.

A participant just notified our site that they left their bottle of study medications

on the bus. Can our site dispense replacement study medications to replace those that were lost?

Yes, additional study medication can be ordered and dispensed to the participant. Please also note that the Pharmacist of Record should submit this request in writing to PAB and the CRPMC, detailing why there is a need to reorder study product.

Have you Heard About Follow YOUR Heart?

There is now a [REPRIEVE Video, Song and Campaign](#) called Follow Your Heart!

Strong representation of women living with HIV in clinical research trials is critical to ensure that study findings may be applied to improve clinical care for HIV-infected women.

Dr. Sara Looby and Dr. Markella Zanni of Massachusetts General Hospital have received funding from NIAID to support the evaluation of **sex-specific mechanisms of cardiovascular disease risk and risk reduction in the context of the REPRIEVE trial**. This study is fully integrated into the main REPRIEVE trial, and is not a separate study.



This investigative team has also developed a unique, participant-centered campaign called **“Follow YOUR Heart,”** which is designed to educate HIV-infected women about HIV, heart disease, and the importance of women’s participation in clinical research studies like REPRIEVE.

- The centerpiece of the campaign is the **Follow YOUR Heart Video**. This video features women from the community and healthcare providers.
- **The video can be viewed** at the Follow Your Heart webpage <http://followyourheart.reprievetrial.org/> (accessible from the main reprieve trial website.)
- The webpage also includes the **Follow YOUR Heart song**, REPRIEVE recruitment materials tailored to women living with HIV, educational links for women living with HIV, and a monthly blog.

Check out the Follow YOUR Heart video and webpage, and be sure to share with patients and colleagues! Follow YOUR Heart!

Excellent Resource for Women about Participating in Clinical Trials

The FDA has an **informative webpage with printable resources for women thinking about participating in clinical trials**. The information is available in Spanish too. [Click here](#) for the webpage or [click here](#) to download a printable fact sheet for women interested in participating in clinical trials.



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 will also be posted on the REPRIEVE (A5332) PSWP shortly as well as on the REPRIEVE trial website: www.reprievetrial.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 participant newsletters 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.



TRAINING OPPORTUNITIES

Training Opportunities

Sites New to REPRIEVE: Site Startup Training/Protocol Training

Tuesday, 26 April 2016, 1:00 PM ET

A site startup training call/protocol training for brand new sites (in the US and Canada)

and any site that needs a refresher will be held on Tuesday, April 26th. Please note that protocol training is required for site activation. The announcement for this call was emailed to the protocol logon on April 22nd.

Protocol Training/ Start-Up Call Slides

Need a refresher? Slides used in for protocol training are kept on the A5332 and A5333s protocol-specific websites (PSWPs) on the ACTG web page, in the Protocol Training folder.



Check Out the Latest Article about REPRIEVE

REPRIEVE was recently featured in [HIV Equal Online](#)! The article provides excellent updates about REPRIEVE as well as a nice overview of the recently launched **Follow YOUR Heart Campaign!**

Articles about REPRIEVE are a great way to spread the word about this important trial.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/16

Clarification Memo #2 dated 04/12/16 (corrects an error in CM #1)

MOPS:

Version 3.0, revision 1, dated 04/15/16 (updated version!)

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/23/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 02/25/2016

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: dated 11/10/2015

A5333s LPC : Version 3.0 dated 02/22/2015

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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