



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 06/27/2016

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Enrollment Updates

Thank you to every site enrolling participants in REPRIEVE, with your help **we have enrolled almost 1,600 participants! 41 participants were enrolled last week!!! 156 participants are in screening and we now have 89 sites open for enrollment.**

Sites within the **ACTG Network have enrolled over 1,000 participants.** Congratulations to Puerto Rico AIDS CTU for enrolling the 1,000th participant for the ACTG!

The DSMB meeting took place on Friday, June 24th and thanks to your efforts, members of the DSMB were enthusiastic about our progress.

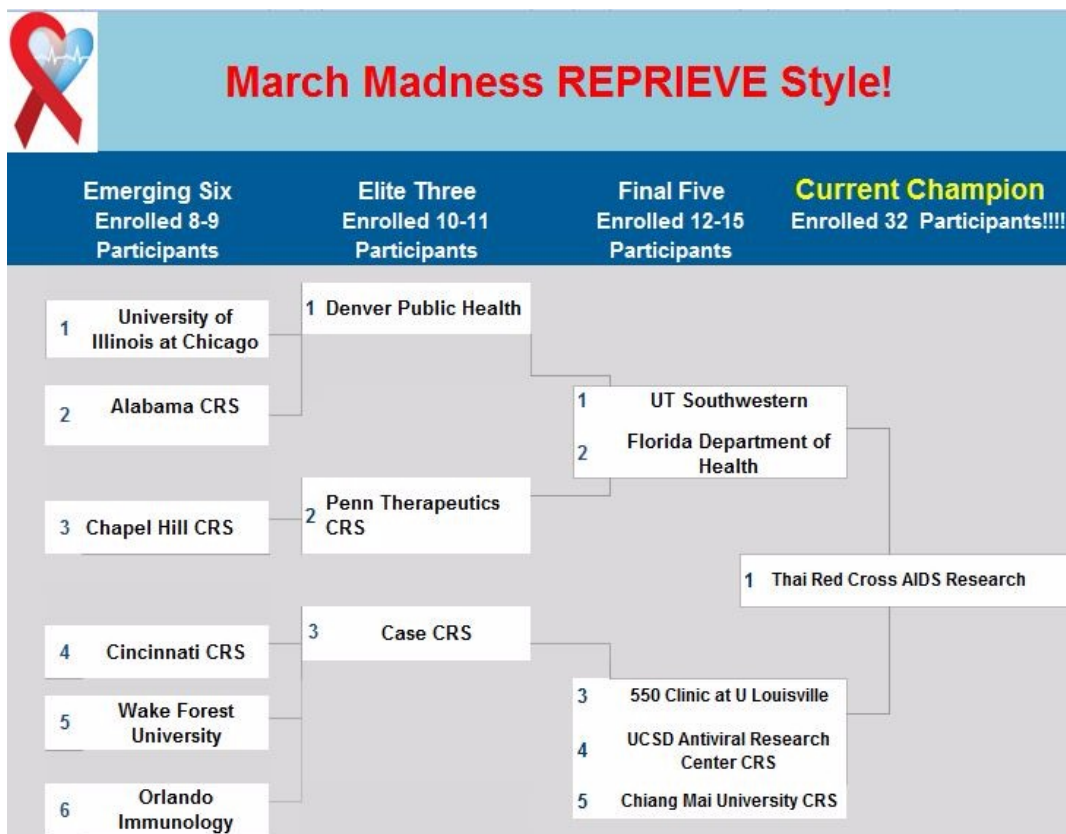
We are nearing the end of 15 months of enrollment and while we may not meet between 75-100% of our enrollment target, we know that with continued efforts from all of our sites, we will meet our target enrollments in the future.

REPRIEVE's March Madness Competition is Coming to an End!!!

Check out the recent action in our REPRIEVE Style March Madness competition! **All enrollment through June 30th is counted and winners will be announced in the July 11th Site Newsletter!**

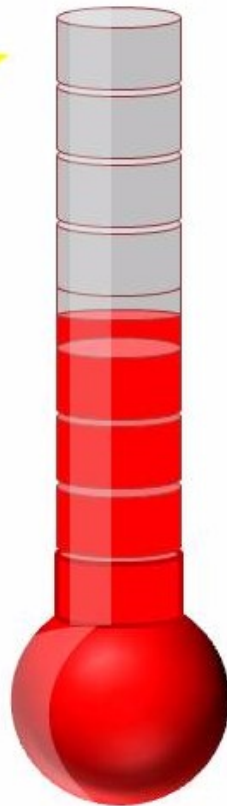
Current Site Standings!!!

- **Thai Red Cross AIDS Research Center has taken the lead, enrolling 32 participants since April 1st!**
- **UT Southwestern is very close behind, enrolling 15 participants!**



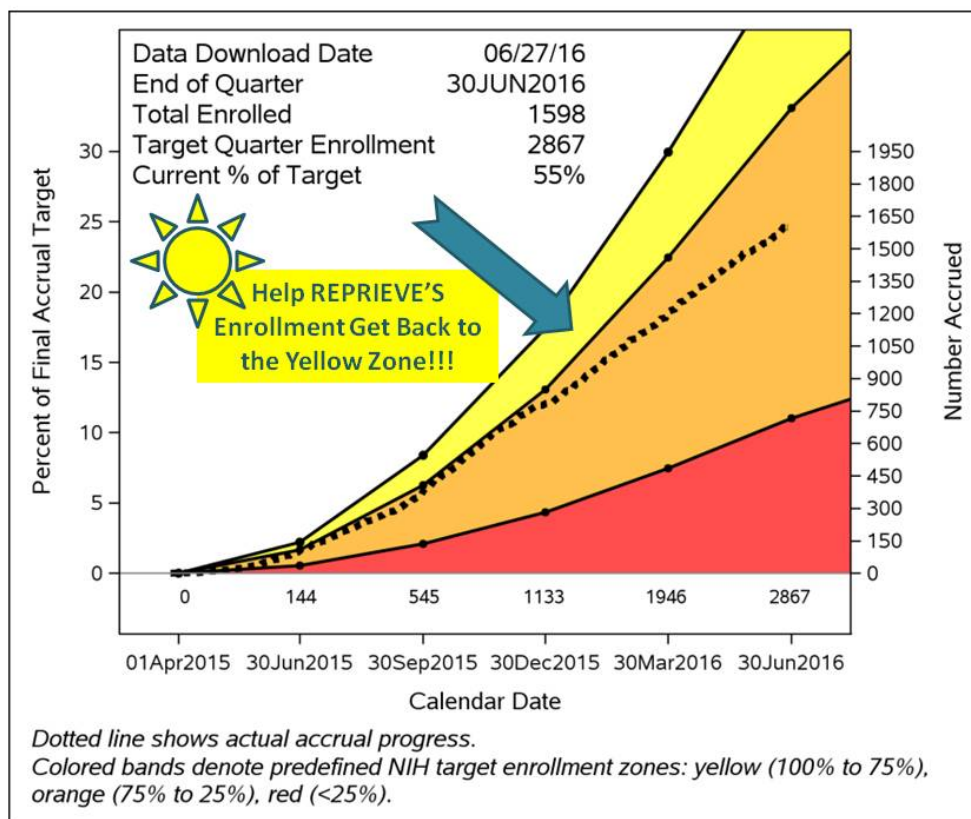


2867 Target Enrollment



1598 Current Enrollment





How do you capture a missed visit?

There is no 'missed visit' form. Data entry depends on the scenario:

- If there was *no contact* at all, change the status of that visit from Started or Completed to Stopped and no data entered.
- If you do have *some but not all* of the information for that visit, complete with the data you do have – this is not considered a missed visit.

The team prefers to have a late visit rather than a missed visit. **There is no late visit form** – just respond to the query that the visit was out of window but completed.

For monitoring purposes, remember to reflect in the source document that a visit was late or missed.

How do I get the lab supplies I need?

The lab processing chart (LPC) for non-ACTG sites has a list of recommended lab supplies on the first page. Sites are responsible for obtaining their own lab supplies (the costs are covered by site startup funds).

We lost the samples drawn at entry for storage. Should we draw them at the month 1 visit? The participant has already started treatment.

Do not collect these baseline samples at month 1 since study treatment has started. If you need help changing completed CRFs or with the LDM, please contact the data managers.

We are coming up on our participant's first year in the study. What should we do if lipids done for standard of care show an upward trend?

The fasting lipid panel that is drawn for the study at month 12 is batched for future testing and the results are not shared with the team or with sites. Any standard of care lipid test results should be managed by the health care provider as would be done usually. Remember too, that there is some variability with lipid panel results.



Social Media Messages for Sites to Use to Promote REPRIEVE!!!

Does your site use Twitter and/or Facebook to get the word out about REPRIEVE and other trials?

If so, our colleagues from the National Institute of Allergy and Infectious Diseases, Office of Communications Government Relations have developed some social media messages for us.

Some messages are targeted for specific days of awareness such as National Black HIV/AIDS Awareness Day, National Women and Girls HIV/AIDS Awareness Day, World AIDS Day etc. [English](#) and [Spanish](#) versions are attached (and [COA](#) for the Spanish Translation). Feel free to use these to promote REPRIEVE in your area.

These messages have been approved by the IRB for the REPRIEVE Clinical Coordinating Center; please submit to your local IRB as per your IRB's policy.



Don't Forget: Periodically Review the REPRIEVE (A5332) MOPS!

The MOPS is an essential tool for the following reasons:

- It was developed to assist sites with operationalizing the REPRIEVE trial.
- It outlines study-specific procedures.
- It ensures accuracy and consistency in study implementation across different study sites and research staff over time.
- It is an important tool for the initial training of study staff and an invaluable reference when staff turnover occurs.

We have attached the A5332 MOPS Table of Contents. [Click here](#) to take a look.

The MOPS is located on the A5332 PSWP!

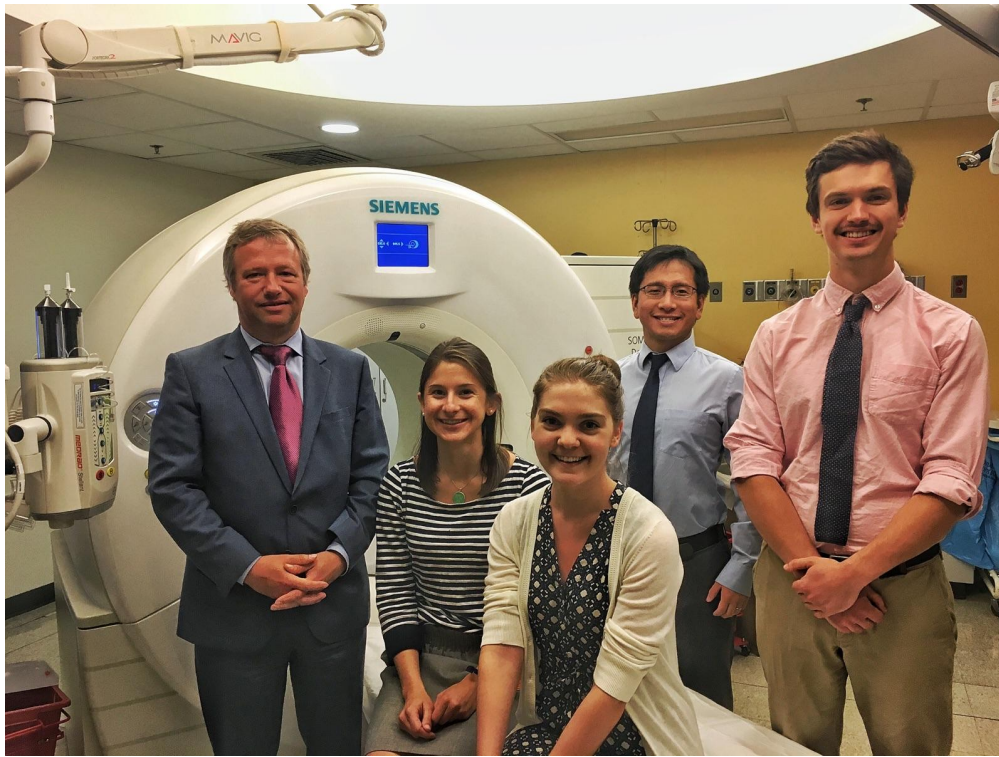
What's New on the REPRIEVE PSWP?

**The REPRIEVE (A5332) recruitment materials have been translated to Spanish!
You can find them on the REPRIEVE (A5332) PSWP.**

To download them, please go to [Recruitment and Participant Materials](#) » [Recruitment Materials in Spanish](#)

These materials will be posted on the REPRIEVE Recruitment Materials web portal shortly for sites to order.

MGH CT Substudy Team



Meet the team! (from left to right)

~ Dr. Udo Hoffmann, Substudy Co-Chair ~ Liz Adami, Project Manager ~ Katie Regan, Research Assistant ~ Dr. Michael Lu, Substudy Co-Chair ~ Alex Ivanov, Research Assistant

Overall, the submission of CCTA data has been of high quality and in compliance with the A5333s MOPs. Thank you to all the substudy sites for their excellent work!

However, there are two areas where there is room for improvement:

1. Timely Submission of Images

Imaging data is not permanently saved on the CT scanner; data is typically deleted after seven days. As a result, it is important to send CT data to the MGH CT Core Lab on the day the CCTA is acquired, or the day after should it not be possible to send on the same day.

The research assistants at the MGH CT Core Lab, Alex and Katie, review all REPRIEVE CCTA's within 24 hours, usually much less! After review at the core lab, a Case Acceptance Notification or Case Query Notification is sent back to the site. This quick turnaround makes it possible to go back to the CT scanner and send additional images or reconstructions if requested in a Case Query Notification. Recently, the full field of view calcium score CT has been a common cause for query....

2. Include the Full Field of View Calcium Score CT

The Full Field of View Calcium Score (FFOV CAC) is part of the noncontrast calcium score CT and is an important part of the REPRIEVE CCTA. Please ensure this reconstruction is performed and images are submitted to the MGH CT Core Lab. This

is not always part of standard clinical imaging practice, so if you often receive a Case Query Notification requesting the FFOV CAC please share this newsletter item with the CT technologists and CT MD at your site!

If you are a study coordinator wondering how to communicate this to your imaging team, let them know the following is requested:

Full Field of View (FFOV) Noncontrast Calcium Score CT including the entire portion of imaged body:

- Slice Thickness = 1.5 - 3.0 mm
- 0% Overlap
- Full FOV

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

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*

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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