REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 10/26/2015

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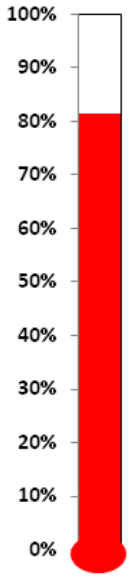
Trial Status: 10/19/2015-10/26/2015

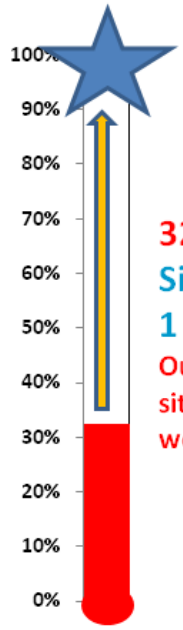
Enroll at least 1 participant per week to hit our December 30th enrollment target!

There are 487 participants enrolled in REPRIEVE. Our target enrollment for December 30th is 1133 participants, therefore if every activated site enrolls at least 1 participant per week we will hit this target. To hit this target we need to enroll 64 participants per week. With 65 sites now activated, this is possible!



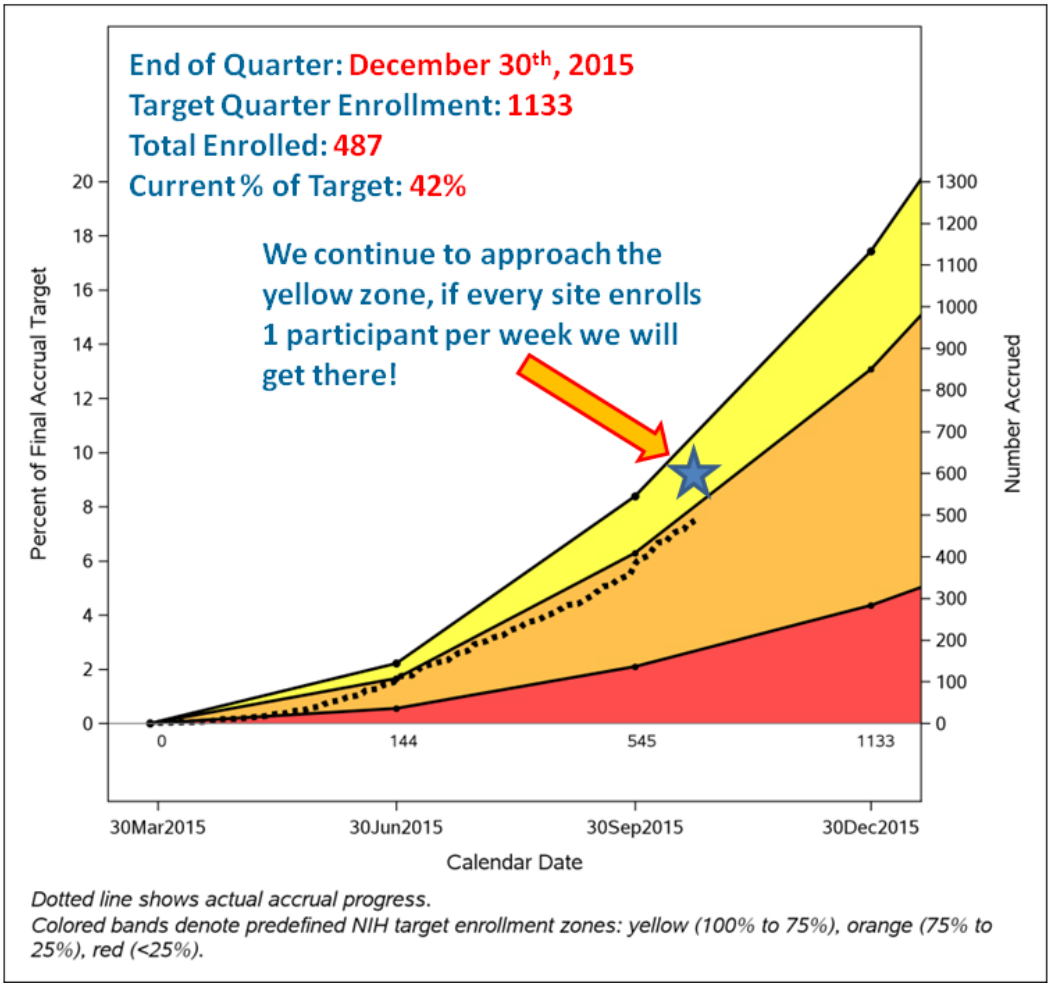
82% of Activated Sites have Enrolled!

This is increasing each week!



32% of Activated Sites enrolled at least 1 Participant last week.

Our target is 100% of activated sites to enroll 1 participant each week.



Dotted line shows actual accrual progress.
Colored bands denote predefined NIH target enrollment zones: yellow (100% to 75%), orange (75% to 25%), red (<25%).

With the holidays approaching please schedule pending screening and entry visits as soon as possible to avoid the holiday rush!

Congratulations to Sites Enrolling Participants

Week of 10/19/15

Chapel Hill CRS

Puerto Rico AIDS Clinical Trials Unit CRS

The Ponce de Leon Center CRS

Case CRS

Northwestern University CRS

Weill Cornell Uptown CRS

Harbor UCLA CRS

Cornell Chelsea CRS

The Miriam Hospital CRS

Chiang Mai University HIV Treatment CRS

Brigham and Women's Hospital Therapeutics CRS

New Jersey Medical School Clinical Research Center CRS

Whitman-Walker Health CRS

Georgetown University CRS

Cooper University Hospital

UT Southwestern

University of Illinois at Chicago

Mount Sinai Clinical and Translational Research Center

Mt Sinai Kreuger Clinic

Medical College of Wisconsin

Orlando Immunology Center CRS

If you are going to the Association of Nurses in AIDS Care annual conference October 28th-31st, stop by the REPRIEVE booth (#136). Members of the team will be there, we will have some cool giveaways and would love to meet you!

FAQ

We recently screened a participant who qualified with an ASCVD risk score between 7.5% and 10% and an LDL <160 mg/dL. Since our IRB has not approved the Letter of Amendment to modify the ASCVD risk score, how should we proceed?

We recommend that your site submit the Letter of Amendment and corresponding Informed Consent changes to your IRB as soon as possible so that you can take advantage of the 90 day window between screen and entry. If approval does not occur in this time period you will need to screen fail and rescreen the participant. Sites are encouraged to try and enroll all such patients, taking advantage of the new, more expanded enrollment criteria.

Also, please note that participants with an ASCVD risk score >10% who also have an LDL cholesterol of < 70 mg/dL are permitted to enroll.

Growth factors are listed among the medications that are exclusionary for REPRIEVE (A5332) in Exclusion Criteria 4.2.9. However, is growth hormone or growth hormone releasing hormone considered a growth factor?

Growth hormone or growth hormone releasing hormone are not considered exclusionary growth factors for the purposes of REPRIEVE and therefore not exclusionary to participation in REPRIEVE.

Is there a waiting period before screening for patients that have had flu or pneumonia vaccines?

The REPRIEVE Manual of Procedures (A5332) Section 13.0 gives some guidance on this question. This section indicates that sites should attempt to separate routine vaccinations by 7 days for visits for which blood will be stored. Alternatively, sites may administer vaccinations on same day as the study visit but after all blood to be banked has been drawn.

Regulatory Update: How are Changes Made to the Protocol?

There are three methods for clarifying or making changes to a DAIDS sponsored protocol document:

Clarification Memo (CM):

- Written by the protocol team after a full version of a protocol (eg, Version 1.0, 2.0, etc.) has been distributed to sites.
- Provides further explanation or details related to information that is already present in the protocol.
- *Unless the CM specifies otherwise*, DAIDS does not require a CM to be submitted to a site's IRB/EC and other regulatory entities. However, sites must follow local IRB/EC review requirements for CMs prior to implementation.

Letter of Amendment (LOA):

- Makes a limited number of modifications to the protocol as an alternative to a full version protocol amendment.
- Protocol version stays the same – the LOA changes are considered part of the previously approved protocol version (eg, REPRIEVE (A5332) Version 1.0, LOA #1, LOA #2 etc.).
- LOAs must be submitted to the site's IRB/EC and other regulatory entities as required for review and approval prior to its implementation.

Full Version Protocol Amendment:

- Used when required changes to a protocol are substantive in number and/or nature.
- Results in a change in protocol version number.
- Changes made in all CMs and LOAs that have been approved since the finalization of the previous protocol version are incorporated into a full version amendment.

Whenever a clarification memo, letter of amendment, or full protocol amendment is issued, the notice comes by email from the ACTG Network Coordinating Center and provides a description of the document as well as a direct link for download. CMs, LOAs, and full version amendments are posted to the REPRIEVE PSWP here: » A5332 » Current Protocol Documents (Version 2.0).

Summary of Operational Requirements for Protocol Modification

	Clarification Memo	Letter of Amendment	Full Version Protocol Amendment
IRB/EC Approval Required	NO*	YES	YES
Submitted to FDA (IND studies)	NO	YES	YES
Protocol Registration Required	NO	YES	YES
Change in Protocol Version Number	NO	NO	YES

* *Unless otherwise specified in the CM*, DAIDS does not require a CM to be submitted to a site's IRB/EC and other regulatory entities. However, sites must follow local IRB/EC review requirements for CMs prior to implementation.

Recruitment Tips

The University of Cincinnati CRS has shared a really useful recruitment idea!

"We are having students who rotate through help with screening charts. We calculate the ASCVD risk score and send providers this letter. This way we are personalizing screening in the Electronic Medical Record. Also, there are lots of students that want *research experiences*. This is a great way to utilize them. They can put it on their CV. And if you track referrals or starting statins, they can probably do a local poster on a *QI Project*."

Do HIV Advocacy Groups and/or other clinics in your area know about REPRIEVE and that your site is recruiting for REPRIEVE?

If advocacy groups and clinics in your area don't already know about REPRIEVE and that your site is recruiting for REPRIEVE, please connect with these groups and/or clinics and send them recruitment materials or offer to give a presentation about REPRIEVE (examples are on the PSWP). This may be an excellent way to connect with new potential participants and spread the word.

If you have a recruitment tip that has worked well for your site please let us know, we would love to share this in a newsletter, email reprieve.news@fstrf.org.

What is in the *Current Protocol Documents* folder on the REPRIEVE (A5332) PSWP?

In the ***Current Protocol Documents*** folder you will find:

- The current version of the protocol which at this time is version 2.0 dated December 19, 2014
  - The sample informed consent form is in the protocol as an appendix
  - The Mechanistic Substudy of REPRIEVE (A5333s) proocol and sample consent is also located in the REPRIEVE (A5332) protocol as an appendix
- The Spanish translation of the sample informed consent form provided by study sponsor (DAIDS)
- The cover letter distributed with Final Version 2.0 of the protocol.
  - The cover letter includes instructions on joining the site email group, the REPRIEVE websites, The Mechanistic Substudy, and how to send questions to the team.
- Clarification Memos #1, #2, and #3

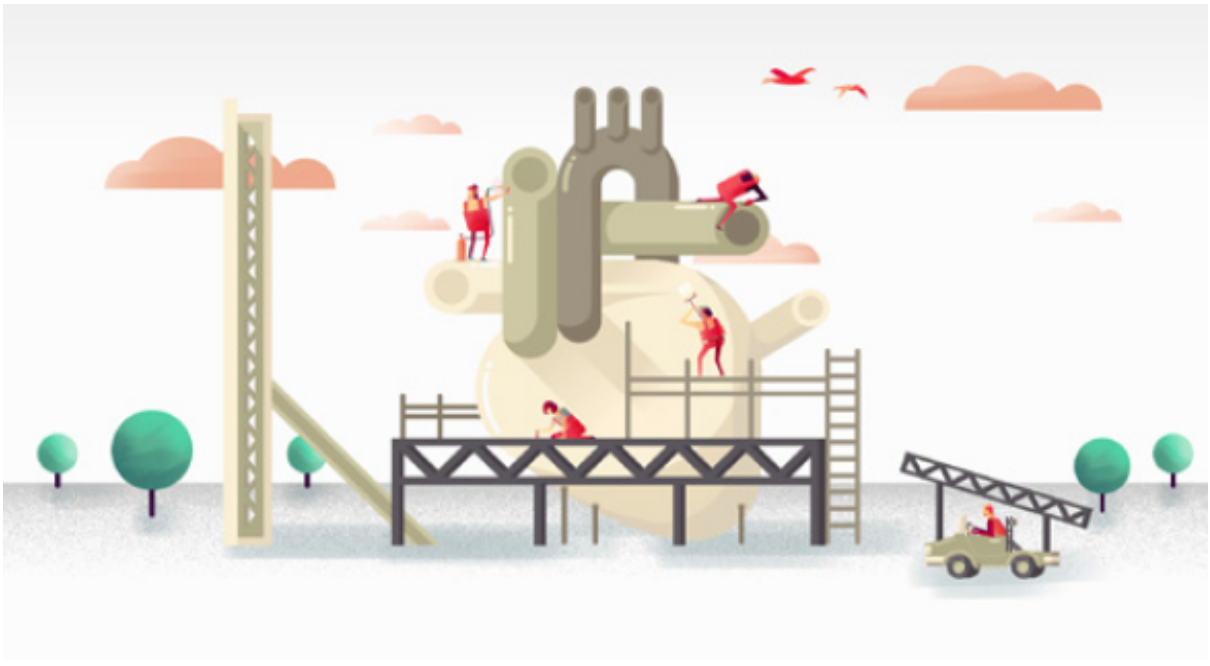
- Letter of Amendment #1

REPRIEVE Staff Changes

Christy Harris, Site Support Team

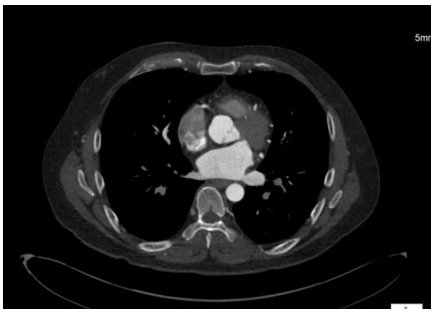
Christy Harris recently joined the REPRIEVE Site Support Team at the Network Coordinating Center, she will be taking over the role of Stephanie Holland. This group works closely with the protocol team, DAIDS, PAB, FSTRF, BWH, Lab group, NHLBI, and REPRIEVE study sites to help streamline the protocol activation process. They provide training, technical and administrative support to sites for all protocol activation activities. Christy Harris and Akbar Shahkolahi can be reached at ACTGSiteCoordination@s-3.com.

Anthony Holguin, one of the REPRIEVE data managers is going to be taking over Laura Smith's role with data management training. This means that in addition to his role to answer questions about case report forms, OpenClinica, eligibility checklists, data collection form schedules, and participant transfers. He will also be training site staff in data management. If you have any questions or concerns regarding data management training, please contact Anthony at holguin@fstrf.org.



REPRIEVE's promotional video is almost complete! We can't wait for the official release, anticipate it will be ready in early November!

REPRIEVE Substudy A5333s
TIPS for Image Transfer



1. Designate one member of your staff to submit images

This team member will get to know the members of the MGH CT Core Lab, become familiar with the transfer system, and learn to avoid the most common image queries. ***HINT: Don't forget the Dose Report!!***

2. Save the sFTP link as a favorite: https://transfer.research.partners.org

Many sites find it helpful to save this as "REPRIEVE Image Transfer" or "REPRIEVE CT" to avoid referring back to the MOP for each transfer.

3. Transfer scans within 2 two days of acquisition

Help the MGH CT Core Lab with their quality review by submitting image data sets within 2 business days of the CCTA exam! The MGH team will assess each CCTA for quality and completeness, if image queries arise, the core lab would like notify the site before images are deleted from the scanner.

4. Submit files as DICOM

Files should be sent as DICOM, if you're unfamiliar with this format look for the file type "DCM"

Technical problems during image transfer? Contact CT Core Lab Lead CRA

Alexander Ivanov
MGHReprieve@partners.org
617-643-5308

JUST POSTED on the A5332 PSWP

Startup Training Slides

Slides used on the A5332 Startup Training Call in October are posted in the ***Protocol Training*** folder.

Letter of Amendment #1 to Protocol Version 2.0

This Letter of Amendment (LOA) revises the eligibility criterion related to the ASCVD risk score and, as required by the DAIDS RSC, includes the recent change in requirements for documenting HIV-1 infection from Clarification Memo #3. Site materials such as the Participant Card, Provider Summary etc. that require revisions due to the LOA will be uploaded shortly.

FAQs

Frequently asked questions and answers are regularly updated and posted to the PSWP in the ***FAQs*** folder. Information added since the last version is highlighted in light grey.

A revised MOPS will be updated shortly, stay tuned...

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 9/21/15*

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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