



**Randomized Trial to Prevent Vascular Events in HIV**

## **Site Newsletter 08/22/2016**

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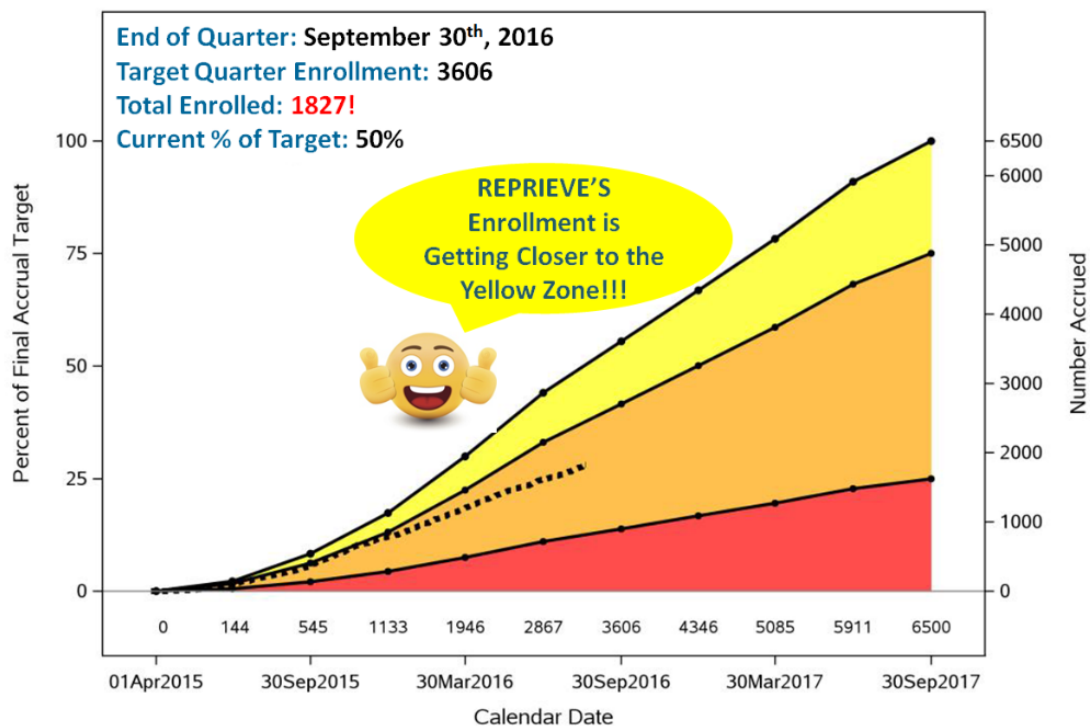
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## **Enrollment Updates**

Thank you to every site enrolling participants in REPRIEVE. With your help, **we have now enrolled 1827 participants, enrollment is quickly approaching 2,000!**

**If 50 participants are enrolled each week REPRIEVE's enrollment will tip to 2,000 in less than 4 weeks! With 90 sites open for enrollment we can do this!**

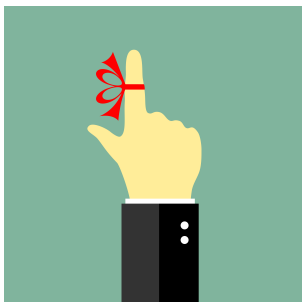


Dotted line shows actual accrual progress.

Colored bands denote predefined NIH target enrollment zones: yellow (100% to 75%), orange (75% to 25%), red (<25%).

## Thank you to all sites enrolling participants week of 08/15/2016

- Thai Red Cross AIDS Research Center
- Penn Therapeutics CRS
- Greensboro CRS
- Columbia Physicians and Surgeons CRS
- UCLA CARE Center CRS
- University of Rochester Adult HIV Therapeutic Network CRS
- New Jersey Medical School-Clinical Research Ctr CRS
- University of Pittsburgh CRS
- The Miriam Hospital CRS
- UT Southwestern CRS
- Orlando Immunology Center CRS
- 550 Clinic at U Louisville
- Vancouver ID Research and Care Centre Society
- Los Angeles LGBT Center
- University of Kentucky
- Cooper University Hospital
- Mt. Sinai Clinical and Transnational Research Center
- University of Nebraska Medical Center
- Mt Sinai St Lukes West 17th Clinic
- Medical College of Wisconsin
- Mt Sinai Kreuger Clinic
- Boston Medical Center
- Mt Sinai Comprehensive Health Program
- Indiana University School of Medicine
- Abbott Northwestern Hospital CRS
- Chronic Viral Illness Service of McGill University



## Don't Forget to Take Advantage of the Full Range of the 10-Year ASCVD Risk Score!

An excellent way to increase screening and enrollment is to take advantage of the full range of the 10-year ASCVD risk score.

Right now you are able to enroll participants with a 10-year ASCVD risk score up to and including 10%, and it is especially important to enroll people with a 10-year ASCVD risk score close to 10% so that the participants enrolled are representative of people living with HIV.

A forthcoming Letter of Amendment (LOA)—see *FAQ section for description of an LOA*—will allow for enrollment up to and including 15% therefore please remember to re-contact any potential participants who may qualify for REPRIEVE using the new 10-year ASCVD entry criteria. You can implement the LOA immediately upon receiving final IRB/EC and any other applicable regulatory entity approvals for this LOA (without waiting for successful LOA registration).

- ASCVD < 7.5 Eligible if LDL < 190 mg/dL
- ASCVD 7.5 -10 Eligible if LDL < 160 mg/dL
- ASCVD >10 - 15 Eligible if LDL < 130 mg/dL\* **NEW**

\*If ASCVD >15%, eligible if LDL < 70 mg/dL



## Important Update Regarding Sending the Shipping File to BRI

Due to security concerns, the LDMS-generated electronic shipping file can no longer be placed on external media (floppy disks, CDs or thumb drives). Therefore, going forward (effective now), please send all batch files as an email attachment to [brirepository@afbr-bri.com](mailto:brirepository@afbr-bri.com) when you send your shipping notification to BRI per [SOP 144 "Shipment of Clinical Specimens to the ACTG Specimen Repository"](#)

Please note that SOP 144 "Shipment of Clinical Specimens to the ACTG Specimen Repository" will reflect this change in October after its scheduled annual review. In the interim, please [file this memo](#) for your records.

Please share this with the appropriate laboratory staff and contact the ACTG Laboratory Science Group [ACTGLaboratoryCoordination@s-3.com](mailto:ACTGLaboratoryCoordination@s-3.com) or BRI [brirepository@afbr-bri.com](mailto:brirepository@afbr-bri.com) if you have any questions.

For any questions regarding lab processing, storage or shipping, email the Laboratory Committee at [Reprive.labcom@fstf.org](mailto:Reprive.labcom@fstf.org). **We are here to help!**



## What is a Letter of Amendment (LOA)?

- An LOA makes a limited number of modifications to the protocol as an alternative to a full version protocol amendment.
- The version number of the protocol does not change.
- You can implement the LOA immediately upon receiving final IRB/EC and any other applicable regulatory entity approvals for this LOA (without waiting for successful LOA registration).
- These instructions are included in the LOA.
- If you have any questions about registering the LOA, please contact the DAIDS Protocol Registration Office via e-mail at [protocol@tech-res.com](mailto:protocol@tech-res.com), or by phone at 301-897-1707.
- Watch for an email from the ACTG Network Coordinating Center which will provide a link to download the LOA.
- The LOA will be posted to the REPRIEVE PSWP in the Current Protocol Documents folder.



## What's New on the REPRIEVE PSWP?

» [A5332](#) » [Coenrollment Guidelines](#) - the guidelines were updated on 8/2/16 to allow coenrollment from ACTG trial 5279, Short Course Treatment of Latent TB, for participants in the follow-up phase of that study.

» [A5332](#) » [Protocol Training](#) » [Site Calls](#) - the slides used on the August 16th monthly team-site call were uploaded. The main topic was a review of upcoming changes to the protocol, MOPS, and Lab Processing Charts based on the Letter of Amendment to Version 3.0, currently in DAIDS regulatory review.



## TRAINING OPPORTUNITIES

## ECG Training Dates

Thursday, 25 August, 10:00 AM ET\*

**\*This is the LAST training scheduled at the present time, if someone from your site has not attended an ECG training please make every effort to attend this training!**

This 30-minute training webinar includes information on the ECG machine and supplies, performing the ECG, and transmission of data to Quintiles. This training is specific to the REPRIEVE trial and at least one person from your site must attend one training to meet protocol activation requirements, although we encourage you to have all staff that will work with the Quintiles ECG machine to attend the training, eg, PI, study coordinator, CRA, backup personnel. If you need a refresher, please join!

Your site does *not* need to be DAIDS site activated or protocol registered, nor do you need to have your Site Qualification Form (SQF) signed or the ECG machine onsite to participate in this training.

If you have not received a calendar invite regarding ECG training and would like to attend please email Katie Fitch at [kfitch@partners.org](mailto:kfitch@partners.org).

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## NEW Data Management Training Videos are Now Available!

Check out these excellent training videos just posted on the [FSTRF portal](#). The videos are listed under the Site Support tab.

- Changing Previously Saved Data
- Entering Logs
- Entering Missed Visits
- Answering Notes and Discrepancies
- Entering Out of Window Visit
- Entering Unknown or Missing Values

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## Protocol Training/ Start-Up Call Slides

Slides used for protocol training are kept in the Protocol Training Folder on the A5332 and A5333s protocol-specific pages (PSWPs). The PSWP is located in the Member portal of the [ACTG website](#).

**The most recent A5332 training slides "Summer 2016" have been posted on the PSWP!**

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## Web LDMS Training Videos

If your site uses Web LDMS for REPRIEVE, check out the Web LDMS training videos available on [FSTRF's YouTube Channel](#).

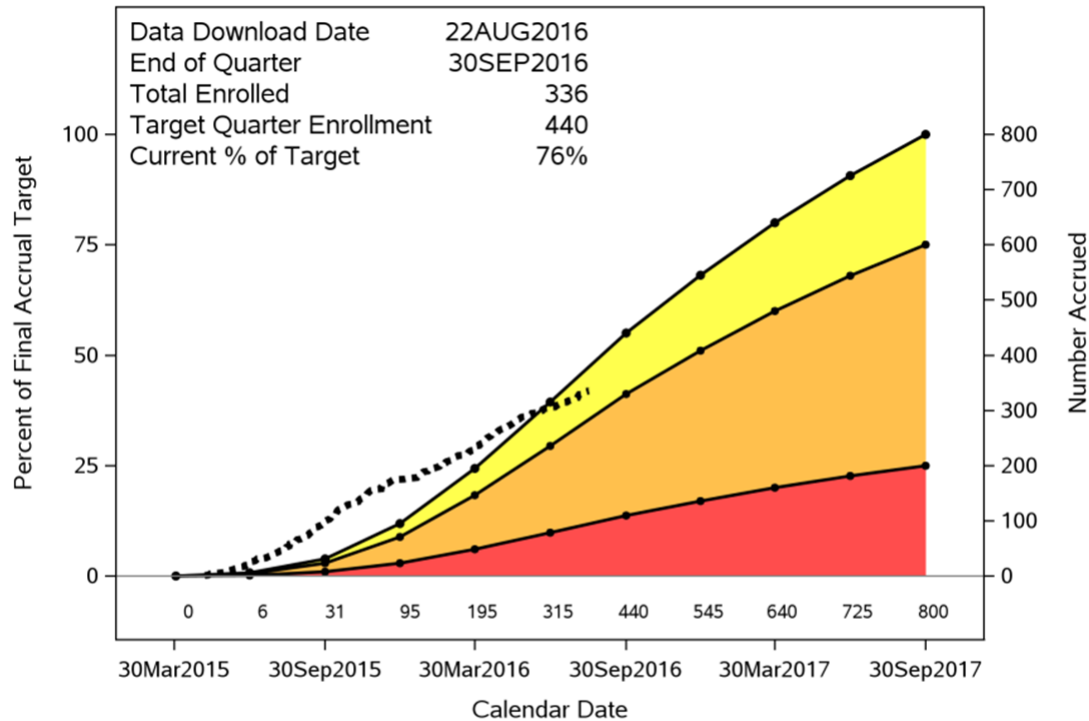
These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories. We encourage lab staff to watch these videos as a means of refresher training. Please share these links with laboratory staff at your sites if they do not receive the REPRIEVE newsletter.

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# Important Message About the Mechanistic Substudy of REPRIEVE (A5333s)

## Is Your Site Enrolling Participants in the Mechanistic Substudy?

If so please remember to ask all participants screening for REPRIEVE (A5332) if they would also like to screen for the Mechanistic Substudy. Enrollment has been strong and it is important to keep it strong!



Dotted line shows actual accrual progress.

Colored bands denote predefined NIH target enrollment zones: yellow (100% to 75%), orange (75% to 25%), red (<25%).

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## Proyecto ACTU holds a REPRIEVE Press Conference & Open House!

The REPRIEVE site in Puerto Rico, Proyecto ACTU, held an open house to promote the trial on August 16, with a press conference the week before to spread the word. The press release generated buzz in the local media, with 5 articles published about the clinic and REPRIEVE! For the open house, the team sported REPRIEVE t-shirts and shared REPRIEVE brochures, flyers, and other swag with visitors.





We are proud of Proyecto ACTU and grateful for their hard work!! If your site would like to put on a similar event to promote the trial and need REPRIEVE materials, email Laura Sanchez ([lsanchez12@partners.org](mailto:lsanchez12@partners.org)) at the REPRIEVE Clinical Coordinating Center.





# Are you going to the Ryan White Conference?

August 23-26, 2016, Washington, D.C., The Marriott Marquis

If you are attending the conference, stop by the REPRIEVE Booth in the exhibit area! Barbara Bastow, REPRIEVE Project Specialist and her team will be at the REPRIEVE booth, they will have REPRIEVE promotional materials and other swag.

For more details about the conference, go to <http://ryanwhite2016.org/>

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## REPRIEVE's Social Media

Have a social media presence and want to stay in touch with REPRIEVE? We are on Twitter and Facebook and regularly share study milestones, related news and articles, and connect with the community. Show your support by following us!



Facebook



Twitter



Website

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## 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](mailto:reprieve.news@fstrf.org).



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