REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 5/25/2015

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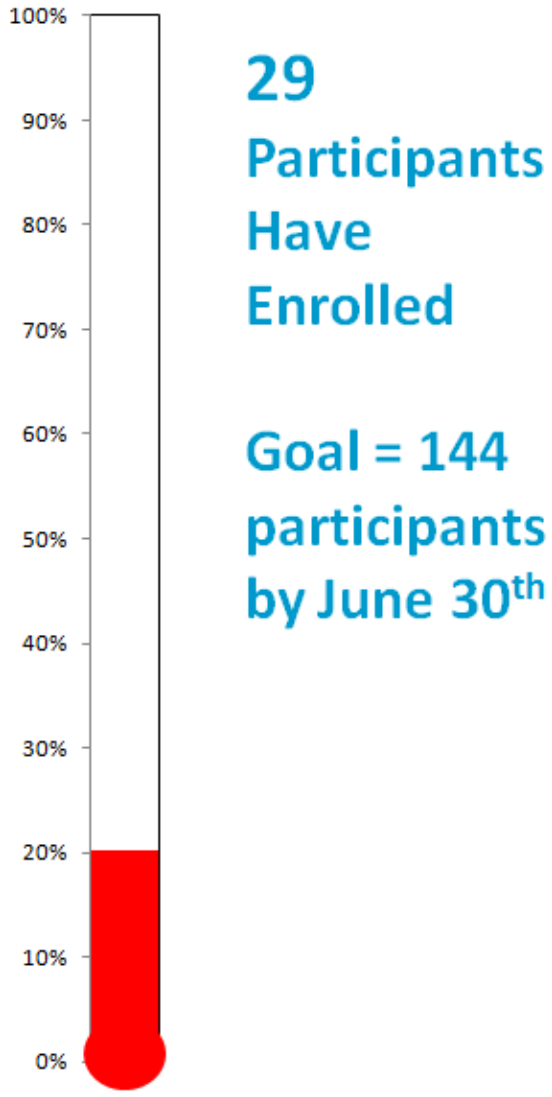
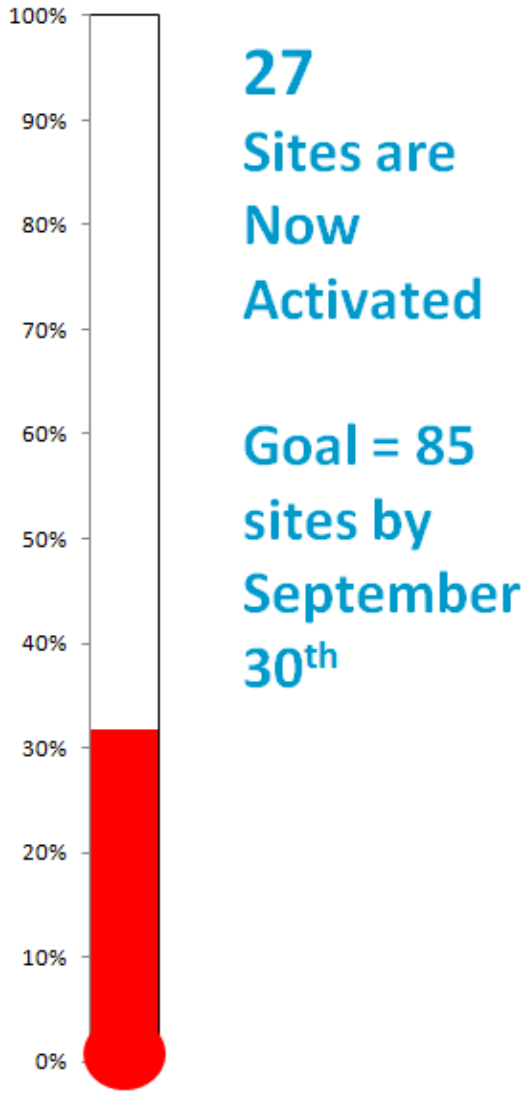
Trial Updates

We are 20% of the way to our June 30th goal of 144 participants enrolled, 89 participants have screened and 39 are pending enrollment. The 1917 Clinic at UAB is still the top enrolling clinical research site, but the Greensboro CRS is quickly catching up. While 27 sites are activated, 8 sites are actively enrolling, let's see if all activated sites can be enrolling at the time of the next REPRIEVE Newsletter!





ASCVD Risk Calculator Tips

Some Helpful Tips Regarding the Atherosclerotic Cardiovascular Disease Risk Assessment Tool

The ACC/AHA 2013 10-year atherosclerotic cardiovascular disease (ASCVD) risk score should be performed as part of screening and will assist in determining eligibility.

The following data obtained as part of screening are required to perform the calculation:

1. **Age**
2. **Race**
3. **Sex at birth**
4. **Total cholesterol**
5. **HDL cholesterol**
6. **Systolic blood pressure**
7. **Treatment for high blood pressure**
8. **Diabetes**

9. **Smoking/tobacco use history**

- **For participants whose values of HDL cholesterol, total cholesterol, and/or systolic blood pressure fall below or above the acceptable calculator bounds for those parameters, values at the lower or upper bounds, respectively, can be entered.**
- **Participants of mixed race are asked to identify themselves as predominantly one race: White, African American or other; this race will be entered.**
- **Participants are asked to report sex at birth and this sex will be entered.**
- **Participants currently on one (1) or more antihypertensive medications for high blood pressure are counted as undergoing treatment for high blood pressure.**
- **Only participants who report current active smoking are counted as smokers.**

Once you have calculated the ASCVD risk score using the web version, please print a copy and maintain with your source documents. Please assure that Participant ID and date are on the print out (handwritten, label etc.).

Every browser is a little different with regards to printing, for Google Chrome and Firefox, right clicking on your mouse and then selecting "print" or ctrl+P works well.

For Internet Explorer, Erin, one of the Field Representatives for REPRIEVE has shared the following:

- **Right click (within the results window), "Select All"**
- **Right clink, "Print Preview"**
- **At the top of the print preview, change "As laid out on screen" to "As selected on screen"**
- **Print**

Once you print, *please make sure all criteria entered into the risk calculator are visible on the print out*.

The calculator to calculate the 10-year ASCVD is located at the following website:

http://my.americanheart.org/professional/StatementsGuidelines/PreventionGuidelines/PreventionGuidelines_UCM_457698_SubHomePage.jsp

FAQ

Can my site enroll participants even if we have not received the ECG machine from Quintiles and have not yet completed the assigned ECG training?

Yes. Presently, the contract with Quintiles is near execution and machines have begun to be shipped to sites. Until your site receives a machine from Quintiles you may use your own ECG machine to perform a 12-lead ECG following procedures outlined in the A5332 Manual of Procedures. There are instructions in the REPRIEVE (A5332) MOPS (Section 3.0, 3.2) about what to do with the paper copy of the ECG. Regarding training – before you use the Quintiles machine, the person performing ECGs at your site must attend training. Please see the "Training Opportunities" section below for ECG training details.

Is any particular ART regimen exclusionary with respect to participation in REPRIEVE?

No. Individuals on any stable ART regimen may be eligible to participate in REPRIEVE.

Can a participant who switches ART regimen during the trial continue to participate and will study drug dose adjustments be necessary?

Participants who switch ART regimens during the trial may continue to participate and no study drug dose adjustments will be necessary. The study drug (pitavastatin) does not interact with antiretrovirals in such a way as to require dose adjustments.

Additional FAQs can be found on the A5332 PSWP in the ACTG Member Portal

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We would like to introduce. . .

David and Erin are the Field Representatives for REPRIEVE.

Their role as FR's is to assist the team in developing and implementing the protocol from a site perspective and ensuring that the study is "doable." Many times the Field Reps are referred to as "Site-ologist"

David is a Registered Nurse and has been with the UNC ACTG for 14 years. He has served in many capacities over the years as a Study Coordinator, Nurse Education Clinician, and now as the Clinical Quality Program Manager in addition to coordinating studies. His passion continues to be following participants in clinic and serving as an advocate for those infected and affected by HIV. David is involved nationally with the ACTG network. He has served as the Clinical Representative to the Data Management Committee, Chair of the Protocol Development and Implementation Subcommittee and Chair of the Outreach, Recruitment, and Retention Subcommittee. He currently is the Chair of the ACTG Site Management and Clinical Care Committee.

Erin is a Research Specialist and joined the UNC ACTG in 2010. She continues to coordinate many of the observational trials at UNC and is now part of the crew implementing REPRIEVE at their site. She is a part of the REPRIEVE team as a junior field rep. working in conjunction with David Currin. Erin most enjoys building relationships with study participants and clinic patients and empowering them to be a part of improving HIV care through participation in research studies as well as helping them understand their health and how to protect it. Outside of work, Erin enjoys being outdoors and working on her small farm which includes gardens, goats, a flock of laying hens and a horse.

TRAINING OPPORTUNITIES

Training Opportunities

All training call dates and call details are listed on the public REPRIEVE website calendar.

85 sites have participated in a site start up call, 79 have participated in data management training!

WebLDMS

- Webinar for those sites/labs who will be using the web LDMS platform; sites will be contacted by the Data Management Center (DMC).

ECG Training

- ECG training is conducted via a 30 minute webinar
- Please note that your site does not need to be DAIDS approved 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. We encourage you to have all staff that will work with the Quintiles ECG machine to attend the training, e.g., PI, study coordinator, CRA.
- ECG training call dates for the next 2 weeks are:
  - Tuesday, May 26th 1:00 PM EST
  - Friday, May 29th 4:00 PM EST
  - Tuesday, June 2nd 1:00 PM EST
  - Wednesday, June 3rd 3:00 PM EST
- See the REPRIEVE calendar for more dates and details to join each call if you have not already received invites from Barbara Bastow for these calls.

Data Management Refresher

- REPRIEVE training videos from the Data Management training sessions are located in the

Frontier Science portal

ACTG Network Meeting (attendance is voluntary), June 22-26, Washington DC

https://meetings.actgnetwork.org/meeting/2015ACTG

If you are at a non-ACTG site and in the DC area please join us!

- **DMC Demo Room at ACTG Network Meeting**
  - Monday, June 22nd
    - 9:00 AM EDT: OpenClinica Overview
    - 3:00 PM EDT: Survival Guide to Reporting Events for REPRIEVE
- **LDMS demo room will be open from 9:00 AM – 5:00 PM**
  - Tuesday, 6/23 – Thursday, 6/25
  - LDMS trainers available to answer questions regarding the LDMS. I encourage anyone who has questions about LDMS and/or how to use it for REPRIEVE to stop by.
- **Team-Site Meeting: REPRIEVE: A Progress Report**
  - Wednesday, June 24th 8:00-9:00 AM EDT

REPRIEVE (A5332) Updates

Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14
MOPS: dated 04/20/15
A5332 LPC for ACTG Sites only: dated 05/06/2015
A5332 LPC for Non-ACTG Sites only: dated 05/06/2015

These documents are on the A5332 PSWP

What's New on the PSWP?

In the A5332 Protocol Training folder, you will find these helpful tools:

- **PowerPoint slides** used in past Site Initiation Calls and **Startup Training Calls**.
- **Subfolder "Optional Tools"** with **screening sheets, checklists, and flow sheets** (as a reminder, these forms are not sanctioned by the REPRIEVE team – they are shared by participating sites and may be used and edited as needed).
- **Subfolder "Quintiles ECG Training"** with the training slideset, investigator

manual, and quick guide.

These documents are on the A5332 PSWP

Mechanistic Substudy (A5333s) Updates

Number of Participants Enrolled:

- 4

Number of Sites Activated:

- 7

Number of Sites Protocol Registered:

- 17

Questions on CT Activation? Contact the MGH CT Core Lab MGHReprieve@partners.org

Are you up to date?

For A5333s please use
MOPS: dated 03/16/2015
A5333s LPC: dated 05/07/2015

These documents are on the A5333s PSWP

IRBshare

IRB Share

Streamlined IRB Approval is Available for REPRIEVE (A5332)

IRB approval of the "**Randomized Trial to Prevent Vascular Events in HIV-REPRIEVE**" study (**A5332**) has been uploaded to IRBshare by Vanderbilt (IRBshare.org). IRBshare is a collaborative IRB review model for multisite studies that provides a mechanism to streamline IRB submission and the IRB review of multisite studies. IRBshare has **over 50 participating institutions** across the US and is now available for use with **any multisite study** (federal or industry) and **all phases of review** (initial review, continuing review, and review of amendments).

If your institution is in IRBshare (view sites and IRB contacts here) **AND** you have not submitted the study for IRB review, contact the IRBshare Liaison listed and ask if you can submit an shorted application for approval of this study given that the full application is in IRBshare for your IRB to review (sample abbreviated application).

Not on the IRBshare site list? Contact your IRB Director and ask if your institution can join. Institutions sign a one-time master agreement to join (here).

Of note, Vanderbilt received an R01 from NHLBI in September 2014 to expand IRBshare to include multiple reliance models (shared and central IRB) in hopes of providing more flexibility and exploring the rationale for selecting a reliance model for a given study. For more information, contact Emily Sheffer, IRBshare Project Manager, at 615-343-2384 or emily.sheffer@IRBshare.org.

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.