REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

# Site Newsletter 01/11/2016

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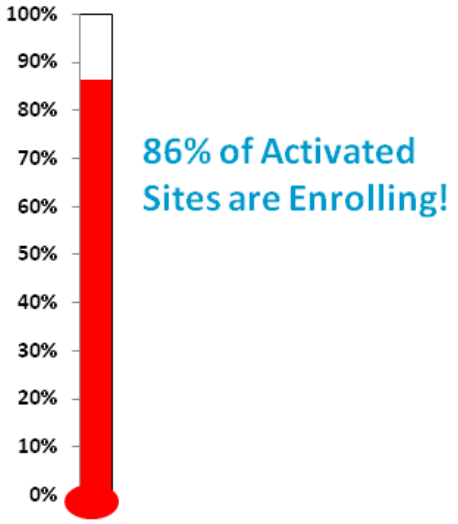
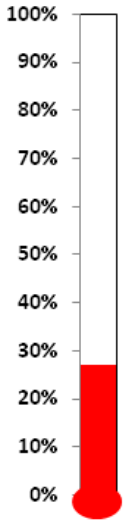
# Trial Status: 01/04/2016-01/11/2016

As of 1/8/16 there are 74 sites activated, 1231 screening visits completed and 813 participants randomized. Last week we screened 35 participants and randomized 29 participants.

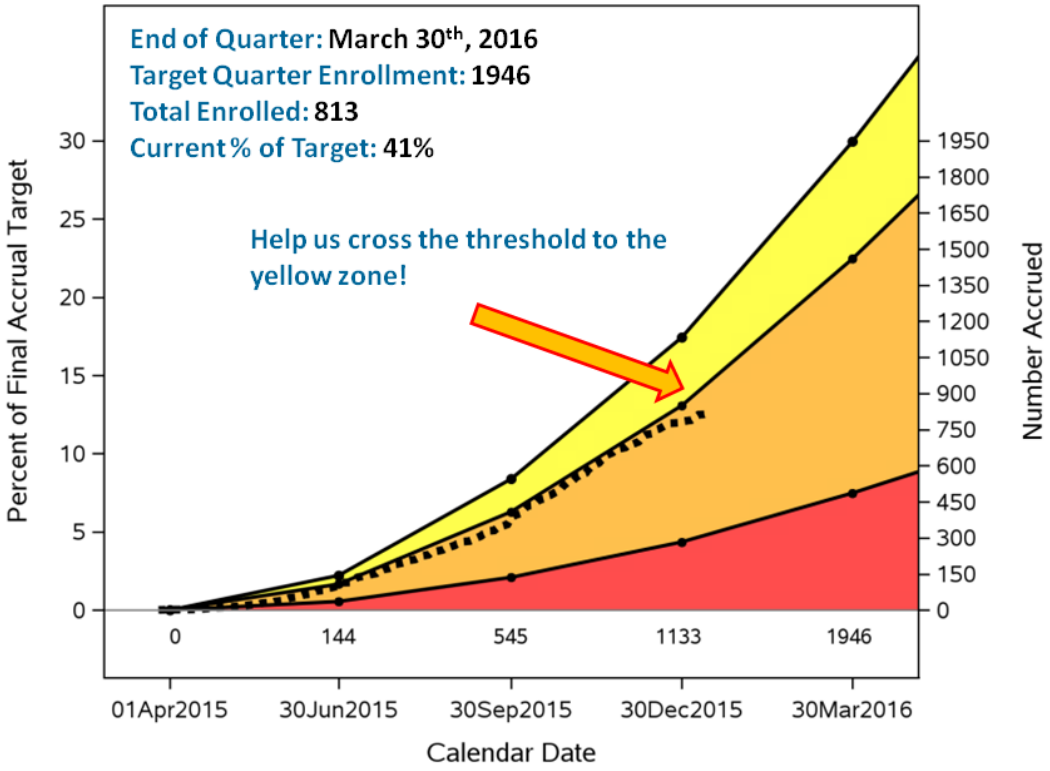
Our target enrollment for March 30th is 1946 participants and we need to enroll at least 75% of 1946 participants to meet the target. If every site open for enrollment randomizes at least 1 participant a week we will make it! Now is the time to increase recruitment and screening efforts in order to increase number of participants randomized.




86% of Activated Sites are Enrolling!




27% of Activated Sites Enrolled at Least 1 Participant Last 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%).*

## Congratulations to Sites Enrolling Participants

## Week of 01/04/16

UCSD Antiviral Research Center CRS
Thai Red Cross AIDS Research Center
Greensboro CRS
University of Colorado Hospital CRS
Penn Therapeutics CRS

Columbia Physicians and Surgeons CRS
University of Washington AIDS CRS
Harbor UCLA CRS
Vanderbilt Therapeutics CRS
University of Rochester Adult HIV Therapeutic Network CRS
UT Southwestern
Denver Public Health
AIDS Research Treatment Center of the Treasure Coast
Florida Department of Health
St. John Newland Medical Associates
Orlando Immunology Center CRS
Mt. Sinai St. Lukes Morningside Clinic
Mt. Sinai Comprehensive Health Program
Bluegrass Care Clinic
Mt. Sinai St. Lukes Samuels Clinic

## ACTG Sites: Don't Forget to Co-enroll in A5128 or A5243

Please don't forget to co-enroll participants in A5128 (US ACTG Sites) or A5243 (International ACTG Sites). Optimal timing for co-enrollment would be at any REPRIEVE visit after entry when blood is drawn (for example the 1 month or 12 month visit).


## Biomedical Research Institute (BRI) is MOVING!!!

****Please alert the relevant laboratory personnel at your site****

Biomedical Research Institute (BRI) is moving the repository to a new location in Rockville. Therefore BRI will be closed between January 18 - January 29. **No shipments should arrive to the current repository location after Jan 15th.** Shipments can begin again the week of Feb 1st and should be sent to the new address listed below.

As of February 1, 2016 the new repository address will be:

**Biomedical Research Institute**
9410 Key West Avenue, First Floor
Rockville, MD 20850*

All contact information, phone numbers, and email addresses will remain the same.

BRI personnel will be at both locations during the transition process to ensure problems don't arise that could compromise clinical trial samples. Sites using LDMS for Windows should perform an LDMS export prior to preparing a shipment for the new repository; this step will allow the DMC to deploy the new repository address to the LDMS shipping module.

If you have any questions or concerns please email John Ward at brirepository@afbr-bri.com or call him at 301-881-7636.

*The LPCs will be revised shortly to include the new shipping address.

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FAQ


### Exclusion Criteria 4.2.9 in the REPRIEVE Protocol (Version 2.0 12/19/2015), indicates that immunomodulatory agents are excluded, does this include topical agents such as imiquimod?

Topical agents such as imiquimod are not exclusionary, only systemic immunomodulatory agents are exclusionary to participation in REPRIEVE.

The REPRIEVE team is in the process of providing more detailed information regarding immunosuppressant and immunomodulatory agents in the MOPS as we have received several questions regarding these agents. The next version of the MOPS will be released toward the end of January/beginning of February, stay tuned...

### I have a new staff member, how do I make sure this person has been added to the appropriate directories, websites etc.?

All site staff who will need access to protocol documents should sign up for access to the ACTG Member website. Anyone at your site who already has access, can electronically submit a directory update form on behalf of all others requesting access by downloading the form on the ACTG website login page and submitting it by email to dirchanges@s-3.com. An email will be generated automatically (after a few days) and sent directly to the new staff member, providing them access to the website.

Anyone who needs access to OpenClinica, the REPRIEVE portal on the Data Management Center website (www.fstrf.org) or the REPRIEVE site email group should contact FSTRF User Support at user.support@fstrf.org. The site email group is a priority because this is how we communicate with sites.

If the new staff will be using the Lab Data Management System (LDMS), have them contact ldms.training@fstrf.org to set up an account.

## Please Read Regarding Updates to REPRIEVE (A5332) CRFs!

### Revised Version: LBW0140 - Screening Lipid Panel v1.01

On the Screening Lipid Panel CRF, a question was removed and the instructions were modified to clarify that the lipid panel lab values, whether obtained at screening or prior to screening by clinical care, are to be entered onto the form at the screening visit.

Also, this CRF previously had skip logic to prevent sites from entering lab values if the participant had not been fasting. This skip logic was removed. The REPRIEVE team determined even in scenarios where it turned out (after the visit for example), that the participant had not been fasting, or it was unknown if they were fasting, that the values should still be entered in the CRF.

Fasting is still a requirement for the lipid panel per the protocol. However, please see REPRIEVE (A5332) MOPS, *Section 4.2 Protocol Specific Data Collection* for more details regarding the lipid panel.

### New CRF: LGW0139 – Key Protocol Deviations Log v1.00

It was determined that Key Protocol Deviations should be entered into OpenClinica for capture/review. The REPRIEVE (A5332) MOPS, *Section 17 Critical Events and Key Protocol Deviations Reporting,* explains reporting of these types of events. Please read this section in the MOPS as there are additional reporting of these events, including events determined to be Key Protocol Deviations which are now reported in OpenClinica.

If it is determined by the team that another type of deviation should be reported on this form, the Data Management Center will instruct you on how to enter that deviation.

### New CRF: RP0003 - Final Study Medication Status v1.00

The Final Study Medication Status CRF has replaced the RP0002 - Permanent Discontinuation of Study Medication CRF.

The REPRIEVE team decided to replace the Permanent Discontinuation of Study Medication CRF as opposed to updating it. The Final Study Medication Status CRF now captures the scenario where a participant is enrolled, but never starts study medication treatment.

Additionally, for participants that do start study medication treatment, additional information regarding the date the decision was made will be captured on this CRF.

This CRF also holds the condition that if "OTHER" is to be used to please consult the data manager prior to data entry.

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# TRAINING OPPORTUNITIES

Training Opportunities

**We are in the process of scheduling additional ECG Training webinars! These webinars are conducted by Brandi Conrow from Quintiles and last approximately 30 minutes. Email announcements will be sent shortly, so please watch your email.**

This training will include information on the ECG machine, supplies, performing the ECG, and transmission of data. At least one person from your site must attend one training to meet protocol activation requirements. If you have participated already but would like a refresher, please feel free to attend.

You do not have to have an 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, eg, PI, study coordinator, CRA, backup personnel.

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## Check out new press about REPRIEVE in HIV Equal Online

*Call it PrEP to protect against heart disease in HIV*

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# JUST POSTED on the A5332 PSWP

## Participant and Provider Infographics


Infographics for Participants and Providers can be found in the Recruitment Materials Folder on the PSWP.* These are great materials to get the word out about REPRIEVE in your area.

*These materials have been approved by the IRB for the REPRIEVE Clinical Coordinating Center, please submit them to your IRB as per your local requirements.

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## REPRIEVE (A5332): Are you up to date?

### *For A5332 please use*

***Protocol:*** *Version 2.0 dated 12/19/2014*
***Letter of Amendment #1:*** *09/18/2015*
***Clarification Memo #1****: 02/02/2015*
***Clarification Memo #2:*** *08/28/2015*
***Clarification Memo #3****: 09/10/2015*
***MOPS:*** *11/09/15*
***A5332 LPC for ACTG Sites:*** *dated 09/17/2015*
***A5332 LPC for Non-ACTG Sites:****dated 09/17/2015*
***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 11/10/2015*
***A5333s LPC :*** *dated 9/21/15*
***These documents are on the A5333s PSWP***

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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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