



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 08/08/2016

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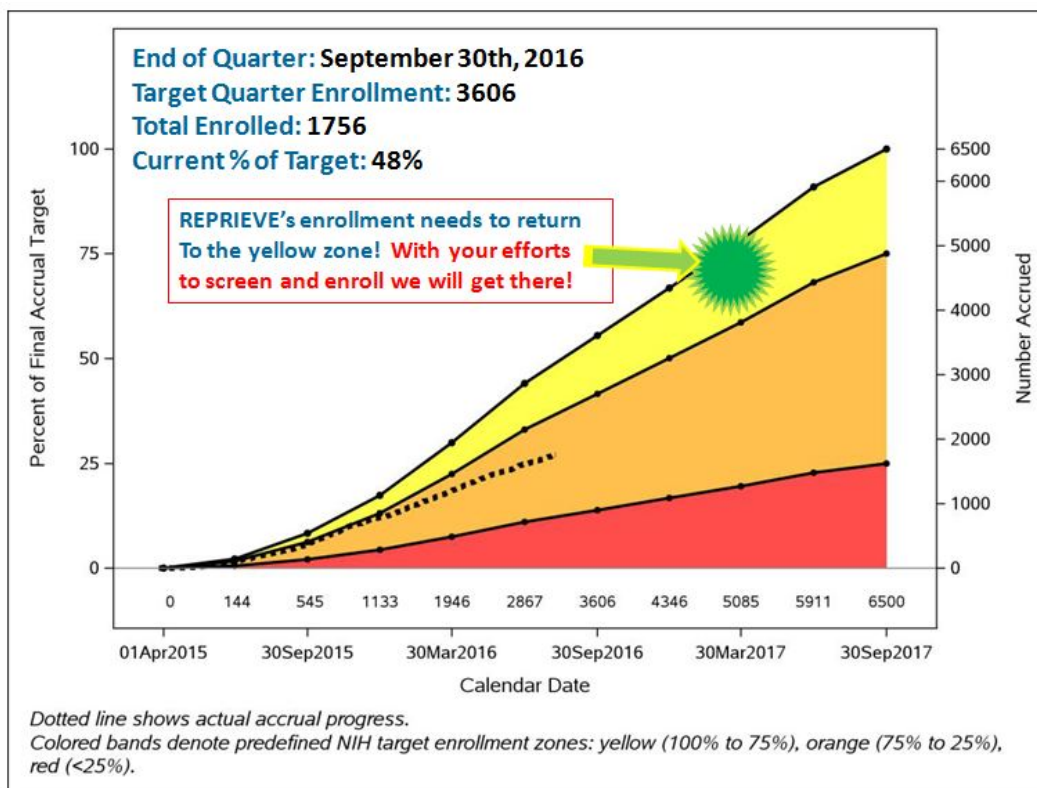
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### Enrollment Updates

Thank you to every site enrolling participants in REPRIEVE. With your help, **we have enrolled 1756 participants, and 32 participants were enrolled last week! 164 participants are in screening and 90 sites are open for enrollment.**

**To bring us closer to our target enrollment, at least 50 participants need to be enrolled each week. With 90 sites activated, this is possible! If 50 participants are enrolled each week, our enrollment will be over 2,000 very soon!**



## Thank you to all sites enrolling participants week of 08/01/2016

- Thai Red Cross AIDS Research Center
- UCSD Antiviral Research Center CRS
- Chiang Mai University HIV Treatment CRS
- Penn Therapeutics CRS
- Alabama CRS
- Greensboro CRS
- Case CRS
- University of Colorado Hospital CRS
- Northwestern University CRS
- UCLA CARE Center CRS
- Ohio State University CRS
- University of Rochester Adult HIV Therapeutic Network CRS
- University of Pittsburgh CRS
- University of Southern California CRS
- Brigham and Women's Hospital Therapeutics CRS
- Washington University Therapeutics (WT) CRS
- University of Illinois at Chicago
- Florida Department of Health
- Orlando Immunology Center CRS
- 550 Clinic at U Louisville
- Mt Sinai St Lukes West 17th Clinic
- Mt Sinai Kreuger Clinic
- Mt Sinai St Lukes Morningside Clinic
- Mt Sinai Comprehensive Health Program

- Massachusetts General Hospital (MGH) CRS
- Abbott Northwestern Hospital CRS



#### Frequently Asked Questions

### How do I get access to the ACTG Member website?

- Go to <https://actgnetwork.org> and click on Member, then download the Directory Update form located on the login screen. The direct link is <https://www.actgnetwork.org/sites/default/files/files/DirectoryUpdateForm-PublicWebsite-102513.docx>
- Email completed form to [dirchanges@s-3.com](mailto:dirchanges@s-3.com)
- Completed forms will be verified before processing.
- User will be emailed account set up confirmation.
- Please allow up to 5-7 business days for processing.

### I forgot my user name / password for the ACTG Member website. How do I proceed?

To assist you in retrieving your user name and password, please note the following:

1. Your username is: firstname.lastname
2. To retrieve your password:
  - Go to <https://actgnetwork.org>
  - Click on Member.
  - Click on "Help! I don't remember my password"
  - On the following page, to the right of User Account, click on "request new password"
  - Enter your email address and submit.

### How do I set up a new FSTRF account (for OpenClinica, Subject Enrollment System, etc.)?

**FSTRF is the Data Management Center for the ACTG. Here are the instructions for registering a new account:**

1. Go to the web registration form: <https://www.fstrf.org/apps/cfm/apps/common/register/index.cfm>
2. On the second screen after you enter your contact information is a project selection drop-down list. The project is REPRIEVE. It is toward the end of the list.
3. For "Position," select the choice that most closely describes yours on REPRIEVE.
4. On the next screen select 'Yes' for "Web/Data access for clinic(s)" and enter your site number.
5. After doing this, a list of check boxes describing various data access and report recipient options becomes available underneath. You may check more than one, it depends on your role at

your site:

- If you are going to be entering eCRF data, check "OpenClinica Data Entry".
- If you are going to be enrolling participants (completing a inclusion-exclusion checklist), also check "Subject Enrollment"
- If you are going to need to access the paper forms and schedules for REPRIEVE, also check "ePortal access only"

6. Select the "Web/Data Access for a Lab(s)" and "General Web/Data Access" selections as "No", click the "Next" button, and on the next screen verify your information and click the "Submit" button.

7. Your registration request will be sent to our user support to create your account. You will receive a message from our user support when your account is ready.

### How do I receive email from the REPRIEVE team about conference calls, revised protocol documents, and other important messages?

Send an email to FSTRF User Support at [user.support@fstrf.org](mailto:user.support@fstrf.org) and request to be put on the A5332 protocol logon. Include your contact information. Contact the same group if/when you want to be removed from this email logon.



## What's New on the REPRIEVE PSWP?

- The official NHLBI DSMB summary from the June 24, 2016 meeting was added to the Study Monitoring folder. Please note that the change in the ASCVD risk score approved by the DSMB cannot be implemented until the team finalizes a Letter of Amendment (LoA) making that change, and the site obtains local IRB/EC approval! Please contact the protocol core team if you have any questions [actg.corea5332@fstrf.org](mailto:actg.corea5332@fstrf.org).
- The [REPRIEVE Site Performance Plan](#) was updated to correct the quarterly accrual period from 4 months to 3 months, and to change the term "site activation" to "protocol activation" in section 6.0. Please see the new version dated July 6, 2016 in the Site Performance folder.
- The Coenrollment Guidelines were revised to allow coenrollment from ACTG 5279, Short Course Treatment of Latent TB, when the participants are in the follow-up phase. The new file is dated July 2, 2016.

- The Quintiles ECG Training Slides dated July 14, 2016 were added to the [Protocol Training](#) » [Quintiles ECG Training](#) folder. These slides include special procedures for sites in Brazil and Botswana to follow.

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## **TRK0150: Adjudicated Events Tracking CRF has been updated!**

As mentioned during the Monthly Site and also in a recent Site Newsletter, we have made some changes to the Adjudicated Events Tracking CRF--TRK0150.

The updated CRF is attached [here](#), you can also download it from the Forms Management Utility in the FSTRF portal.

TRK0150 – Adjudicated Events Tracking v1.01 has been added to OpenClinica.

TRK0150 v1.00 will be available as an option to enter in OpenClinica for the next two weeks. Once the old version (v1.00) is disabled, ONLY the new CRF version (v1.01) will be available for data entry.

If you need the old version available beyond that point please contact the REPRIEVE data managers at [reprieve.dmc@fstrf.org](mailto:reprieve.dmc@fstrf.org).

### **CRF Update:**

#### TRK0150 – Adjudicated Events Tracking v1.01

- New instruction added to Section B
  - Question text modified (for all questions), and notes added (to all questions) for more clarification of the type of events that should be indicated on this form.
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## What's New?

The PowerPoint slides from the Startup Training Calls that are specific to nonACTG sites using webLDMS have been put into their own slide deck for your ease of use. You can find them on the REPRIEVE PSWP, in the » [A5332](#) » [Lab Resources \(Protocol Version 3.0\)](#) folder.

Page 1 of your Lab Processing Chart (LPC) has a useful outline of how the LPC is organized and what is included in each Section, don't forget to review this document periodically!

<b>How the LPC is Organized</b>	
Section 1	Lab components of the protocol Schedule of Events  On LPC page 1, there is a list of suggested supplies that your site needs to purchase in order to process REPRIEVE samples. Their cost is included in the package received for enrolling participants in the study. You must have these onsite in order to be protocol activated.
Section 2	Information for tests that are typically “safety labs” and do not require processing for protocol storage.
Section 3	Instructions for specimen processing for protocol storage.
Section 4	Detailed information for each visit. Includes specimen types & volumes, derivative and aliquoting expectation, LDMS codes.
Section 5	Shipping information.
Section 6	Revision/update history. Note that updated text is bolded throughout the document.

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



## TRAINING OPPORTUNITIES

### ECG Training Dates

Thursday, 11 August, 10:00 AM ET

Thursday, 25 August, 10:00 AM ET

Training Opportunities

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 Barbara Bastow at [bbastow@s-3.com](mailto:bbastow@s-3.com).

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### Data Management Introduction

Thursday, 18 August, 10:00 AM ET

This training is a repeat of the data management training that is given throughout the year, and is geared for sites that have not yet attended a data management training or new staff that will benefit from this training.

This 2-hour training will include information on user accounts, the DMC portal, participant enrollment, case report forms and schedules, and OpenClinica (the electronic data capture system used for REPRIEVE).

**Please note:** At least one person from your site must attend a data management training to meet protocol activation requirements. If someone from your site has already participated in a data management training, your site has met that requirement.

An email was sent to the A5332 protocol logon on Friday, 5 August with conference information, if you did not receive it please email our data management team at [reprieve.dmc@fstf.org](mailto:reprieve.dmc@fstf.org).

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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!**

## 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.



Attached is the July 2016 (summer) edition of the [OCISO/MOB Monitoring Newsletter](#). You may have already read the newsletter but if not we thought you might find several of the articles useful.

This edition features a follow-up article on Informed Consent and an article from the Soweto, South Africa HVTN Clinical Research Site with tips on preparing for a monitoring visit.

## 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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