



# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

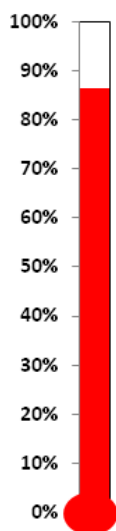
### Site Newsletter 11/23/2015

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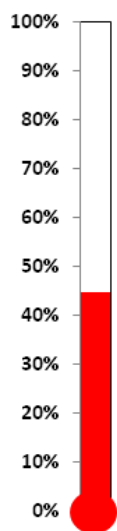
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### Trial Status: 11/16/2015-11/23/2015

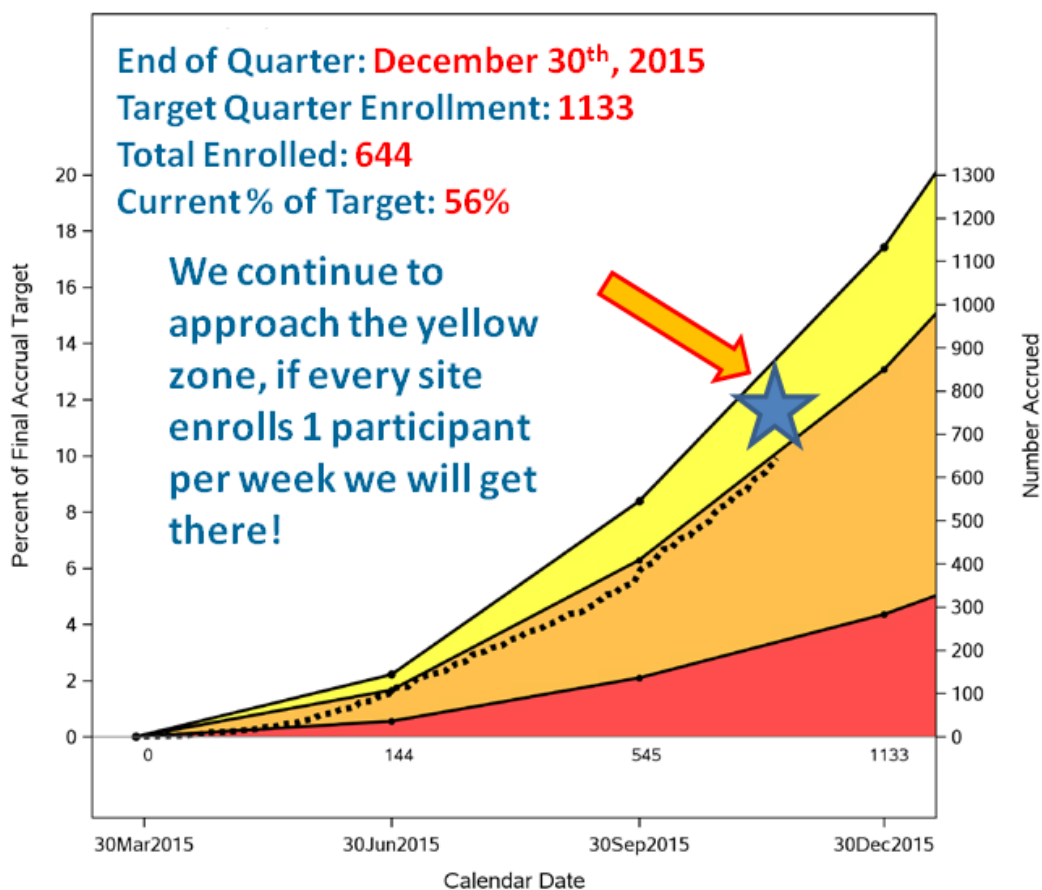
Thank you for all your hard work to enroll participants in REPRIEVE! We enrolled 43 participants last week, therefore achieving our first enrollment milestone and our 2nd best enrollment week so far!!! Please read the thank you note below from the REPRIEVE NIH Team.



**87% of Activated Sites have Enrolled!**  
 This is increasing each week!



**45% 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%).*

## Thank You from the NHLBI-NIAID REPRIEVE Team!

NHLBI and NIAID want to congratulate you on enrolling **644 patients in 7.5 months** and achieving the first enrollment milestone for REPRIEVE!!!

We recognize that this achievement is due to the tremendous collective efforts of **each and every member of the REPRIEVE team** and we want to thank you for your time, efforts, and dedication to this trial!



The next milestone is on June 30, 2016 at which time the target enrollment is 2867 patients. We know it's a steep climb, but based on the team's incredible performance, we are fully confident that this next goal will also be achieved! The REPRIEVE investigators are setting an amazing example of teamwork, creative thinking, and accomplishing goals!

Congratulations again for the terrific work and we are looking forward to continued momentum! Happy Thanksgiving to everyone!

Sincerely,

Monica, Sarah, Patrice, Katharine, Myron, Beverly, Karin, and Trinh (the NHLBI-NIAID REPRIEVE Team)

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### Congratulations to Sites Enrolling Participants Week of 11/23/15

UCSD Antiviral Research Center CRS  
Thai Red Cross AIDS Research Center  
Greensboro CRS  
Chapel Hill CRS  
University of Colorado Hospital CRS  
Cincinnati CRS  
Penn Therapeutics CRS  
Weill Cornell Uptown CRS  
Massachusetts General Hospital CRS  
Chiang Mai University HIV Treatment CRS

**Case CRS****Northwestern University CRS****Harbor UCLA CRS****University of Washington AIDS CRS****Whitman-Walker Health CRS****New Jersey Medical School - Clinical Research Center CRS****Johns Hopkins University CRS****University of Rochester Adult HIV Therapeutic Network CRS****University of Miami AIDS Clinical Research Unit CR****UT Southwestern****University of Illinois at Chicago****Denver Public Health****Mt. Sinai Clinical and Translational Research Center****Orlando Immunology Center CRS****Baystate Infectious Diseases Clinical Research****Medical College of Wisconsin****St. John Newland Medical Associates****Los Angeles LGBT Center****Drexel University****Mt. Sinai St. Lukes Morningside Clinic**

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**FAQ****FAQ****How do I assure that the pill count I am doing is hygienic?**

There are a few different ways to perform a pill count. The most important aspects of the pill count are cleanliness and accuracy. Here are some suggestions from the REPRIEVE team.

**Step 1.** Gather all necessary materials. This could be your pill counter (a chux and a clean/sterile tongue depressor are alternatives to using a pill counter).

**Step 2.** If using a pill counter, use an alcohol pad or gauze and IPA 70 to clean all parts of the tray and spatula and allow to air dry.

**Step 3.** Pour pills onto the try

**Step 4.** Count by fives, place correct amount of pills into dispensing chute of pill counter.

**Step 5.** Close chute and pour pills into bottle and close the pill bottle.



**When should I clean the pill counter tray?**

At the beginning of the day, end of the day, when dirty, after using the tray for drugs known to be common allergens.

If your site does not have a pill counter please contact Katie Fitch, Project Manager at the Clinical Coordinating Center (CCC) at [kfitch@partners.org](mailto:kfitch@partners.org)

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## **Reminder! Data Query Resolution Deadline for This Week!**

Please note that Friday, November 27th is the [data query resolution deadline for the upcoming DSMB review](#).

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial. This timeline will be posted under the Study Monitoring tab on REPRIEVE (A5332) PSWP for future reference.

Task		Deadline	Weeks to DSMB
Sites	Latest date for the occurrence of a clinic visit for which complete data must be included in this DSMB review	Oct 30 (Fri)	6.9
Sites	All data for visits through October 30 entered [note: expedited - within 2 weeks of visit]	Nov 13 (Fri)	5
Sites	All queries resolved by this date	Nov 27 (Fri)	2.9
All	DSMB Meeting	Dec 17 (Thur)	0

Please make a note of this date in your calendar and thank you for your attention to this timeline in the weeks ahead.



## **Sites are Beginning to Share Their Successful Recruitment Tips for REPRIEVE!**

Recruitment Tip

**This week's tip: Send REPRIEVE recruitment materials to nearby**

## clinics (not already recruiting for REPRIEVE)

One site recently shared with us that they have sent flyers and other REPRIEVE recruitment materials to nearby clinics that are not REPRIEVE sites.

The REPRIEVE (A5332) PSWP has some recruitment materials available to use for this purpose and we are working very hard to create new recruitment materials for sites such as postcards, flyers, and brochures, these materials will be able to be customized. Please watch for announcements about these materials soon!

If you have recruitment tips you would like to share in future newsletters, please email Katie Fitch, Project Manager, at the REPRIEVE CCC at [kfitch@partners.org](mailto:kfitch@partners.org)elrk

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## Need to Email a Question to the Protocol Team?



If you are sending a question to the protocol team (for example, questions about eligibility), it is really helpful if you include “REPRIEVE” in the subject line of the email, and if the issue is about a participant, include the patient identification number. This will help the message *pop* in our inboxes and make it easier to search and follow up.

We welcome your questions at any time. The correct email address for sending questions to the protocol team is [actq.corea5332@fstrf.org](mailto:actq.corea5332@fstrf.org), and for substudy questions, [actq.corea5333s@fstrf.org](mailto:actq.corea5333s@fstrf.org).

### **Please do not send email to the protocol site email logon**

- [actq.prota5332@fstrf.org](mailto:actq.prota5332@fstrf.org) – because it includes *all* site staff at *all* REPRIEVE sites. You’ll be inundated with out of office messages!!!

Thank you!

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## REPRIEVE in the News

REPRIEVE continues to get some really good press. Check out the latest in [LGBT Weekly](#) and 2 more detailed articles are in the recent issue of [Healio Infectious Disease News](#)--Carlos Malvestutto, MD, MPH and Steve Grinspoon, MD are featured in these articles!

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## Save the Date!

For **all new** sites working toward enrolling for REPRIEVE, there will be a **REPRIEVE Site Initiation Call** on **Tuesday, December 8th from 9:00-10:00AM EDT.**

This call will provide a brief overview of REPRIEVE, review the DAIDS Site Approval process, Protocol Activation, and contracting. We will also provide a brief orientation to the ACTG website and the OpenClinica electronic data capture system used for REPRIEVE.

Call details will be emailed shortly, watch for the email from Laura Moran!

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## Lab Tips

### Please Notify BRI Before you Ship Using the Most Up to Date Shipping Notification Form!

**US sites/laboratories** must fax or e-mail a notification to the Repository prior to shipping. Use the "Shipping Notice for Ambient, Refrigerated, and Frozen Shipment" form (current

version is Version 4.0, April 8, 2015) located on the [ACTG web site](#).

**Non-US sites/laboratories** need to complete and fax or e-mail an “ACTG International Shipping Checklist” (current version is Version 3.0, September 1, 2015) to the Repository prior to shipping specimens. This document can be found on the [ACTG web site](#).

### **For non-ACTG Sites Only, Important Note about Lab Supplies**

On page 1 of the non-network A5332 Lab Processing Chart (LPC) located on the REPRIEVE PSWP, you will find ordering information for cryovials, freezer boxes, and labels.

Also, Section 5: Helpful Links, Shipping Addresses, and Shipping Instructions, includes detailed information about shipping schedule, shipping containers storage box requirements, and a lot more useful information, please read this section of the non-ACTG LPC!

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## **JUST POSTED on the A5332 PSWP**

**A5332 Manual of Procedures, dated 11/09/15**  
**Revisions are listed in Appendix IV, Section D!**

*The MOPS is on the [A5332 PSWP](#)*



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## **What's in the Folders on the REPRIEVE (A5332) PSWP?**

### **What's in the Site Performance folder?**

PPD Mini-Session Slides, ACTG Network meeting, June 2015

REPRIEVE Site Performance Plan *Dated: 08/06/2015*

### **What's in the Coenrollment Guidelines folder?**

Coenrollment Guidelines *Dated: 10/09/2015*

Coenrollment in ACTG 5128, observational studies, or studies that do not involve a random treatment assignment does not require permission from the REPRIEVE (A5332) protocol team. For specific questions and approval for coenrollment in other studies (including HCV or HIV treatment trials and adjunctive treatment trials), sites should first check the PSWP Coenrollment

Guidelines or contact the protocol core team at [actg.corea5332@fstrf.org](mailto:actg.corea5332@fstrf.org).

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

### **For A5332 please use**

**Protocol:** Version 2.0 dated 12/19/14

**MOPS: Revised Version 2.0 11/09/2015**

**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: Version 2.0 dated 11/10/15**

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

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