



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 12/11/2017

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REPRIEVE Trial Status: December 11th

5199 participants are enrolled

299 participants are in screening

115 sites are open for enrollment

28 sites enrolled at least 1 participant in the past week

35 sites screened at least 1 participant in the past week

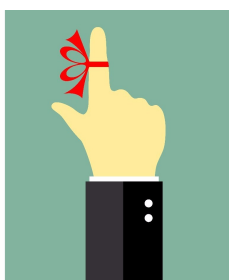
Please note that a newsletter will not go out the week of December 25th.

We wish everyone a happy holiday season!

Thank You to All Sites Enrolling

Participants Week of 12/04/2017!

Massachusetts General Hospital (MGH) CRS
 UCLA CARE Center CRS
 University of Southern California CRS
 Ohio State University CRS
 Dallas VA Medical Center
 The Ponce de Leon Ctr. CRS
 Family Clinical Research Unit
 Chennai Antiviral Research and Treatment (CART) CRS
 Columbia Physicians and Surgeons CRS
 Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
 Orlando Immunology Center CRS
 University of Rochester Adult HIV Therapeutic Network CRS
 Thai Red Cross AIDS Research Center
 University of Mississippi
 UT Southwestern
 James J Peters VA Medical Center
 Mount Sinai Downtown CRS
 Mount Sinai Beth Israel CRS
 Mount Sinai Clinical and Translational Research Center CRS
 Toronto General Hospital
 Centro de Pesquisas Clinicas ICHCFMUSP CRS
 Hospital Federal dos Servidores do Estado
 Instituto de Infectologia Emilio Ribas CRS
 Hospital Escola Sao Francisco de Assis
 HGNI HIV Family Care Clinic HHFCC
 Tropical Medicine Foundation
 Centro de Referencia e Treinamento
 Petersen HIV Clinic, U of Arizona



As REPRIEVE enters its 3rd year of enrollment, we are thinking of different ways to keep participants engaged.

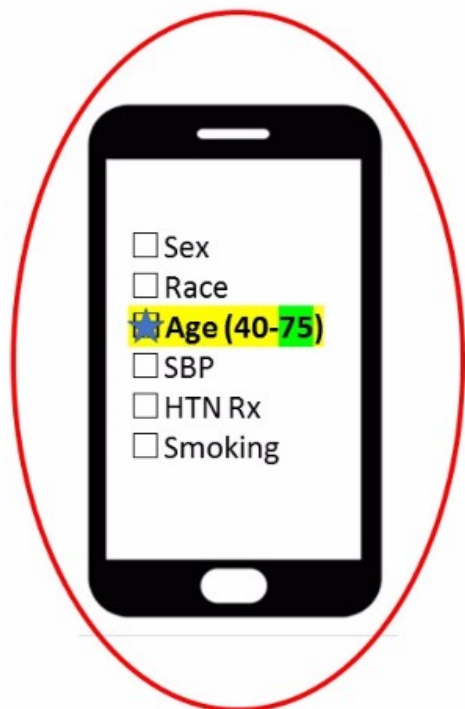
We Need Your Ideas About Retention!

Please remember to take a minute to vote on our retention ideas and suggest your own [HERE](https://www.surveymonkey.com/r/FLLLDVR):

Thank you to everyone who has already completed this survey, more responses would be greatly appreciated!

Enroll Older Participants in

REPRIEVE!



This an excellent way to enroll additional participants in the higher ASCVD risk ranges

The Essential Role Sites Have in REPRIEVE: Report Potential Adjudicated Events

Sites participating in REPRIEVE have so many important roles and we appreciate the hard work by all sites participating in REPRIEVE.

One essential role we do not want sites to overlook is to report potential adjudicated events!



Please remember to:

- Take a thorough history from the participant to identify **any potential adjudicated events**.
- Ensure that the **Heart-related Health Questionnaire** has been completed and is kept with source documents.
- Ensure that **100% of Adjudicated Event Tracking CRFs** have been completed accurately and necessary steps have been taken to submit any potential events for adjudication as per section 6.0 of the MOPS.

If your site does submit a packet for a potential adjudicated event, please make sure that the Site PI or their designee reviews the packet and agrees with the content before it is submitted to the REPRIEVE Data Coordinating Center.



One of our participants was just hospitalized with a stroke, or it may be a TIA, what should I do?

The following steps are recommended in the circumstance of a participant's hospitalization for suspected TIA/stroke:

1. Adhere to the reporting requirements of your local IRB.
2. Report the event on the AE Log, and indicate that it was an SAE.
3. Report the event per MOPS section 6.0 including completion of the Adjudicated Events Tracking CRF and Cerebrovascular Event CRF.

Remember that all SAEs are reported to DAIDS as EAEs *except* the following: Any MACE, Cerebrovascular Event, Heart Failure Event, or AIDS-defining Event (see protocol section 11.4.2 and MOPS section 7.0). However, if your site PI feels that the potential MACE, Cerebrovascular Event, Heart Failure Event, or AIDS-defining Event is related to study treatment, it *does require* reporting to DAIDS as an EAE.

Please remember to periodically review section 6.0 of the A5332 MOPS for more details about Potential Adjudicated Events.

A participant has agreed to come in next week for their Month 24 visit, this visit will be approximately 20 days out of window. Should we do the visit out of window or miss the visit and have the participant come in for Month 28 and perform the Month 24 labs at that time?

It is preferred that visits occur within the specified windows in the protocol, this allows for a more robust analysis. However, if this is not possible please have the participant come in for the Month 24 visit even though it is out of window. Out of window visits are preferred over missed visits. Please refer to the A5332 MOPS section 4.3, Timing of Data Collection for more details.

Note: There is no late visit form – just respond to the query that the visit was out of window but completed.

There is an instructional video developed by our data managers on how to enter an out of window visit in OpenClinica that can be accessed here: <https://www.youtube.com/watch?v=sDvzzqWwfp8>.

For monitoring purposes, remember to reflect in the source document that a visit was late.



Don't forget! We need everyone's help to **enroll 1,500 more participants by the end of April 2018!** The goal is to enroll at least 15 participants per site through the last week in April. **Many sites will win!**

- 1st place site wins \$500
- 2nd place site wins \$250
- All other sites that enroll 15 participants by May 1st will win \$100

If your site enrolls 3 participants per month from December through April, your site will win \$100! The clock started ticking the week of December 4th and stops May 1st.

With every site's help, we can enroll at full speed to reach 1,500 participants.

Site standings will be announced in the next REPRIEVE Newsletter the week of January 8th.



Using Preloads or Quick Add is Strongly Encouraged!

There are *MANY* Benefits of Using Preloads (LDMS for Windows) or Quick Add (LDMS for the Web)

These tools will:

- Make your data entry faster and more accurate
- Reduce data queries
- Ensure correct specimen codes are used
- Ensure correct aliquot counts are entered
- Ensure all samples are accounted for and can be set to QNS or ANP as needed in cases of collection anomalies

Your lab's responsibility: Preloads and Quick Add are not required, but **they are highly recommended**. Whether a laboratory chooses to use these tools or not, the laboratory is still required to **log all required specimens** for a given visit, and then adjust the volumes and condition codes to reflect what was actually processed and stored.

Note of Caution: Laboratories must follow the schedule and instructions in protocol documentation such as the Laboratory Processing Charts. The Preloads and Quick Add are helpful data entry tools but they are not meant to replace these protocol documents.

Getting Help: Please let us know if you have any questions regarding Preloads or Quick Add or how you can take advantage of them. Email us at ldmshelp@fstrf.org

Training materials can be found at www.ldms.org including quick reference guides, user manuals, training materials, and demonstration videos. As always, our in-house 24/7 User Support group is available to assist, and our training team can provide refresher training as needed.

Please Join the Next Monthly Site Call!

Tuesday, December 19th between 1:00 - 2:00 PM Eastern Time



Don't miss the important REPRIEVE updates, clarifications and Q&A that are shared during these calls!

Watch your inbox for the announcement from Barbara Bastow with dial-in details.



TRAINING OPPORTUNITIES

The LDMS Training Team would like to extend an invitation to all Web LDMS users on the REPRIEVE project to our next webinar. The webinar will cover the processing, storage, and shipment of specimens for the ACTG REPRIEVE study.

As a reminder, videos are available on our website at:

<https://www.ldms.org/resources/videos/> which cover these topics. These videos are hosted on YouTube and can also be viewed through the mobile app.

Topic: WebLDMS for REPRIEVE

Time: Dec 13, 2017 12:00 PM Eastern Time (US and Canada)

If you would like to join the training session but did not receive the email with the webinar information please email ldms_training@fstrf.org to request this information.

Protocol Training

We're holding a REPRIEVE (A5332): Refresher Training Call for Sites on **Thursday**.

December 14 at 12:00 PM Eastern Time.

If you or your site would benefit from a REPRIEVE training refresher, please email Laura Sanchez at lsanchez12@partners.org for details.

**REPRIEVE In the News**

- **"Cardiovascular disease: the next great challenge for HIV care"** in **STAT**: REPRIEVE Co-Principal Investigator, Steve Grinspoon, MD discusses the need for cardiovascular disease care for people living with HIV, despite the immense improvements in HIV treatment since the 1980s.

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)

Clarification Memo #3 dated 12/27/2016

Letter of Amendment, Version 3.0 #1 dated 08/17/16

Letter of Amendment, Version 3.0 #2, dated 04/14/17

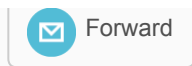
MOPS:**MOPS Version 3.0**, dated 09/20/2017**A5332 LPC for ACTG Sites:**

Version 3.0 dated 09/21/2017

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 09/21/2017

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:** Version 3.0 dated 06/05/2017**A5333s LPC:** Version 3.0, dated 09/21/2017These 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@fstf.org.

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