



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

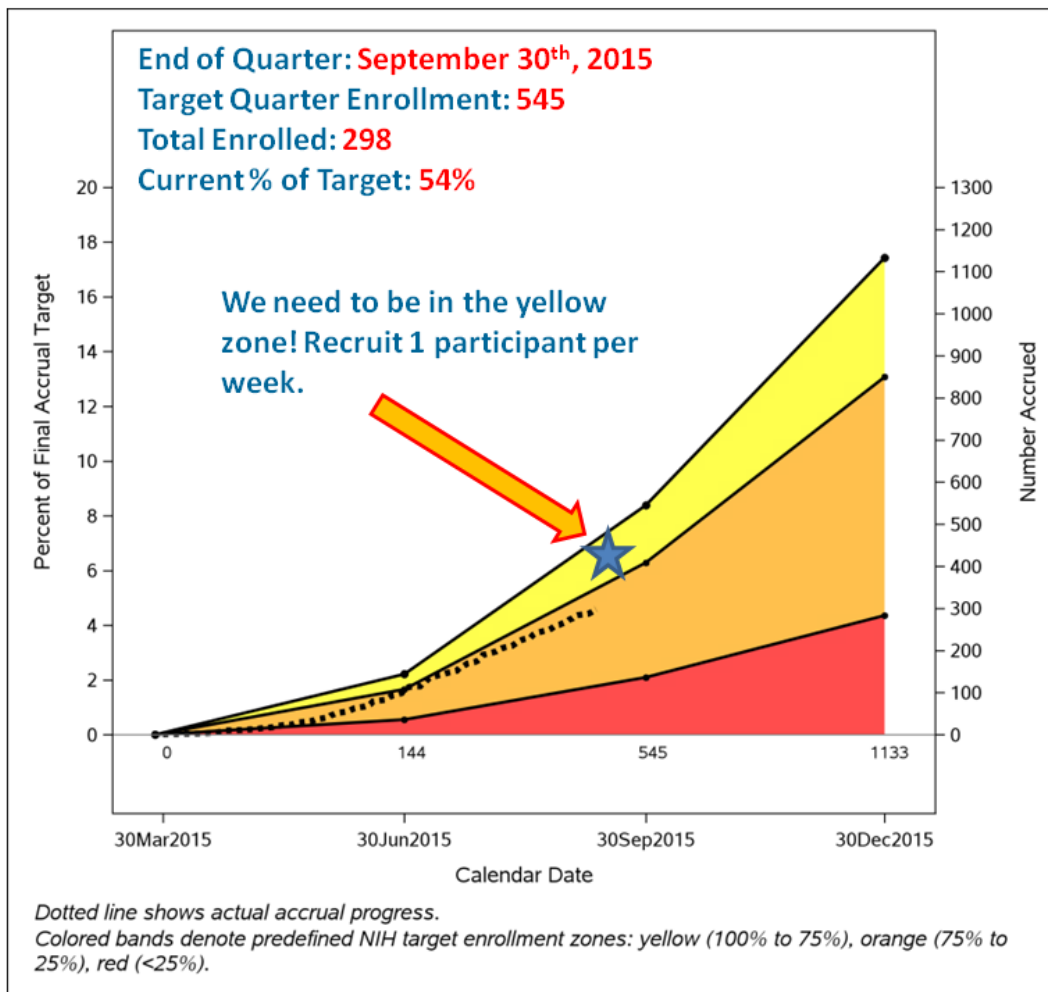
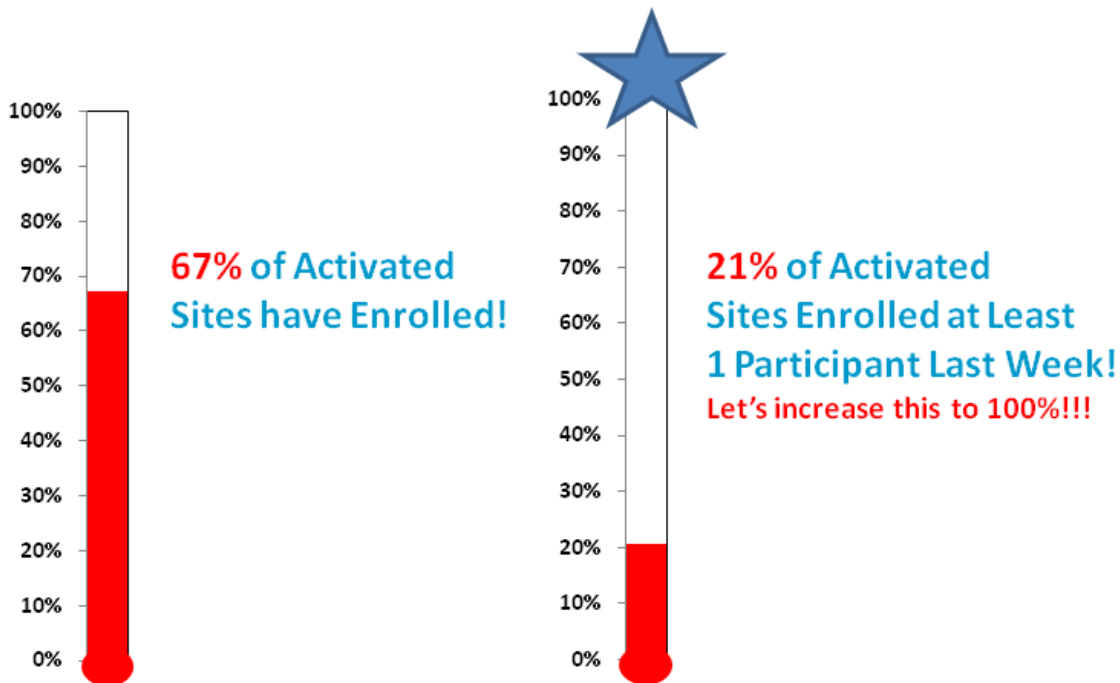
Site Newsletter 9/14/2015

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Trial Status: 9/7/2015-9/14/2015

The REPRIEVE quarterly report is due to the NIH soon, please make all efforts to enroll all participants pending enrollment in the next 2 weeks and continue to enroll at least 1 participant per week after that time.



Congratulations to Sites Enrolling Participants Week of

9/7/15

Houston AIDS Research Team CRS
University of Colorado Hospital CRS
UCLA Care Center CRS
Massachusetts General Hospital CRS
Penn Therapeutics CRS
University of Washington AIDS CRS
Harbor UCLA CRS
Johns Hopkins University CRS
University of Pittsburgh CRS
UT Southwestern CRS
AIDS Research Treatment Center of the Treasure Coast
Virginia Commonwealth Univ. Medical Center CRS

REPRIEVE Goal: Complete enrollment of 6500 participants within the 2.5 year enrollment period (the end of 2017)!

Why? So that we can follow participants on study long enough to determine if statin therapy reduces atherosclerotic cardiovascular disease events.

How? Every single REPRIEVE site needs to enroll 1 participant per week. Sites may need to screen 2-3 participants per week to enroll at this rate.

**We need your help to achieve this goal!
At the current enrollment rate, enrollment will not be completed until at least 2020**

FAQ



If a participant reports use of E-cigarettes does this count as smoking for the ASCVD risk calculator?

If the participant smokes e-cigarettes exclusively, then the answer for the ASCVD risk score question about smoking is "No". Although the true risk of e-cigarettes may not be zero, it has not

been studied like regular cigarettes and is not included in the established ASCVD risk equation.

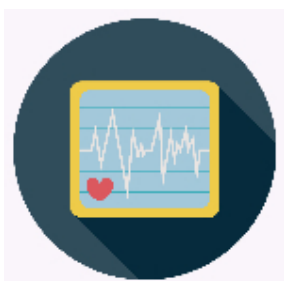
If a participant has HSV, does this disqualify him/her per section 4.2.14? What would be the parameters for considering HSV active or resolved?

In most situations, HSV infection does not automatically exclude a person from participating in the trial. For example, an HSV oral or genital outbreak would not exclude a person from participating in REPRIEVE. However, a person with a serious HSV infection (e.g., HSV encephalitis or esophagitis requiring intravenous treatment or hospitalization) in the 30 days prior to study entry would be excluded per 4.2.13:

- 4.2.13 Serious illness or trauma requiring systemic treatment or hospitalization in the 30 days prior to study entry.

What is a Clarification Memo?

- A clarification memo is a document written by the protocol team, after a full version of a protocol (eg, Version 1.0, 2.0, etc.) has been distributed to sites, that provides further explanation or details to an area of the clinical research that is already present in the protocol.
- A clarification memo does not affect participant safety or the risk assessment of the protocol.
- A clarification memo does not change the Sample Informed Consent (SIC).
- DAIDS does not submit clarification memos to the FDA for IND protocols.
- Each site should file a copy of the clarification memo with the protocol for reference.
- Updates in the clarification memo will be included in the next version of the protocol if it is amended at a future date.
- DAIDS does not require IRB/EC or other regulatory entity approval of clarification memos, and the protocol clarifications contained in a clarification memo should be implemented immediately. **However, each site must follow the requirements of their IRB/EC and other regulatory entities as required prior to implementation at their site.**



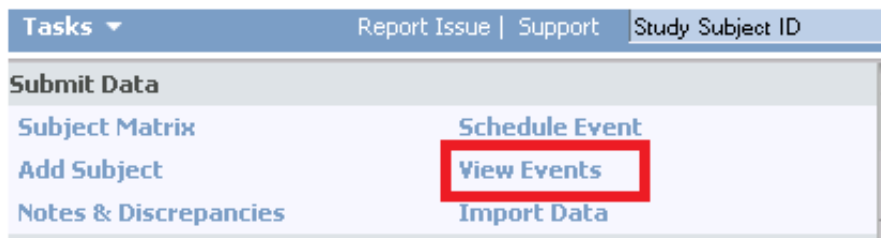
Important ECG Reminder

When entering participant demographics into the ECG machines please enter the **Gender, Participant ID (NOT the Screening ID) and the Site ID**. The REPRIEVE (A5332) PSWP Training Folder has an ECG Quick Guide that reviews these steps and slides from the Quintiles ECG Training call that reviews these steps.

Helpful Tips from our Data Managers: Visit Calendar

We have been asked a few times recently if there is a participant calendar or a scheduler that sites can use to track when a participant's visits have occurred. We are working on a couple of full-feature solutions, but while we do that we do want to make you aware there is a utility within OpenClinica to give you the ideal next scheduled assessment date for your participants.

Once you are logged into OpenClinica, click on Tasks in the toolbar, and click on the View Events link.



Here you have to filter to the dates where the visits could occur. Select a Date Started of your sites approval date, and select a Date Ended of at least 6 months in the future, and click on Apply Filter.

 A screenshot of the 'Filter events by' form. It includes:

- 'Study Event Definition:' dropdown menu set to '--All--'
- 'Status:' dropdown menu set to '--All--'
- 'Date Started:' text input field containing '01-Mar-2015' and a calendar icon, with '(DD-MMM-YYYY)' as a placeholder.
- 'Date Ended:' text input field containing '01-Apr-2016' and a calendar icon, with '(DD-MMM-YYYY)' as a placeholder.
- An 'Apply Filter' button at the bottom right.

You can now see all events that have been scheduled for your participants. Please note that these are the ideal (calculated) dates for participant visits post-entry, and do not represent actual visit dates that may have taken place.

In this example there are three participants. They are sorted into visits, and within those visits you can see the status of the visit.

Participant 1 had an Entry ideal visit date of 01-May-2015, a Month 1 ideal visit date of 31-May-2015, a Month 4 ideal visit date of 29-Aug-2015, and is scheduled to have a Month 8 visit on 27-Dec-2015.

Subject 2 had an Entry ideal visit date of 15-May-2015, a Month 1 ideal visit date of 14-Jun-2015, and is scheduled to have a Month 4 visit on 12-Sep-2015.

Subject 3 had an Entry ideal visit date of 1-Aug-2015, and a Month 1 ideal visit date of 31-Aug-2015. The subject is highlighted yellow, as today's date is after the scheduled date, and the event doesn't have any data entry at the visit yet.

Event Name: Entry

Event Type: Scheduled, Non-repeating Category: N/A

Subjects Scheduled: 0 (start date of first Event: N/A) Completed: 3 (completion date of last Event: N/A) Discontinued: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
Subject 3	01-Aug-2015	completed	
Subject 2	15-May-2015	completed	
Subject 1	01-May-2015	completed	

Event Name: Month 1

Event Type: Scheduled, Non-repeating Category: N/A

Subjects Scheduled: 1 (start date of first Event: 31-Aug-2015) Completed: 1 (completion date of last Event: N/A) Discontinued: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
Subject 3	31-Aug-2015	scheduled	
Subject 2	14-Jul-2015	data entry started	
Subject 1	31-May-2015	completed	

Event Name: Month 4

Event Type: Scheduled, Non-repeating Category: N/A

Subjects Scheduled: 1 (start date of first Event: 12-Sep-2015) Completed: 0 (completion date of last Event: N/A) Discontinued: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
Subject 2	12-Sep-2015	scheduled	
Subject 1	29-Aug-2015	data entry started	

Event Name: Month 8

Event Type: Scheduled, Non-repeating Category: N/A

Subjects Scheduled: 1 (start date of first Event: 27-Dec-2015) Completed: 0 (completion date of last Event: N/A) Discontinued: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
Subject 1	27-Dec-2015	scheduled	



Lab Tips

For Sites New to Web LDMS, set up a "TEST Project" Before Enrolling your First Participant!!!

If you are new to Web LDMS, the REPRIEVE Lab Committee strongly encourages you to do a "TEST project" in your LDMS database. Please send a formal request to our [LDMS Support](#) department (contact information included below). On a per request basis, Frontier Science (FSTRF) will log into your database and set up a TEST project so that staff at your site can practice logging samples into the database without the worries of entering test data under the REPRIEVE project in the database.

If you have any questions regarding the above or if you have any questions in general concerning your LDMS database or access to it, please do not hesitate to contact our LDMS Support team.

LDMS User Support
Email: ldmshelp@fstrf.org
Phone: 716-834-0900 ext 7311

Are you a non-ACTG site, wondering about when to ship samples?

The [REPRIEVE \(A5332\) PSWP-->Lab Resources](#) Folder includes the Non-ACTG shipping schedule, this schedule indicates which week and months your site should be shipping to BRI.

Mechanistic SubStudy (A5333s) Sites Please Read Regarding the PaxGene Tubes

If your site is also participating in the Mechanistic Substudy of REPRIEVE (A5333s), please note that 2 PaxGene tubes are used per participant at the entry visit and month 24 visit (total of 4 tubes per participant). If you need additional PaxGene tubes, please email retrievesupplies@partners.org

Congratulations to site AIDS Research Treatment Center of the Treasure Coast, lab 586, the first non-ACTG lab to ship to BRI!!!

If you have a general lab question please email the [REPRIEVE Lab Committee](#), we are here to help!

Training Opportunities



TRAINING OPPORTUNITIES

All training call dates and call details have previously been emailed and are listed on the [REPRIEVE calendar](#).

Monthly Site Call: Tuesday, September 15th 1:00 PM EDT

Please bring questions and REPRIEVE tips to these calls, this is a great opportunity to talk to the team and share what's working well at your site!

This Week's Agenda:

- Study progress
 - Enrollment into main study and substudy
 - Site activation process
- Update on Letter of Amendment (LOA) and Clarification Memos
- Strategies for recruitment success
- Questions

Data Management Training: Wednesday, September 16th, 2:00 PM EDT

This training is a repeat of the data management training that has been given previously. It is geared for sites that have not yet attended a data management training, or if there are new staff that would benefit from this training. This 2-hour training will include information on user accounts, the DMC portal, subject enrollment, case report forms and schedules, and OpenClinica (the clinical trials data management system used for this trial).

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 attended a data management training, your site has met that requirement.

ECG Training: Thursday, October 1st, 2:00-2:30 PM EDT

This training will include information on the ECG machine and supplies, performing the ECG, and transmission of data. This training is specific to the REPRIEVE and 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. You may forward this message to others at your site as needed.



Will you be attending [ID Week 2015](#)? Stop by the REPRIEVE booth (booth 540), we would love to see you there! Some great resources will be available and we will be there to answer any questions you may have.

What is in the Folders on the REPRIEVE (A5332) PSWP?

What is in the "REPRIEVE Presentations" folder?

This folder contains PowerPoint slides from the following presentations given at the ACTG Network Meeting in June 2015:

- [Gender/Sex Issues in CVD Risk and Risk Reduction](#)
- [REPRIEVE - Moving a Landmark Trial](#)
- [REPRIEVE Presentation to CAB](#)
- [Survival Guide for Reporting Events & Tips for Data Collection](#)

Did you know that the PPD (study monitors) Mini-Session Slides from the ACTG Meeting are also on the PSWP?

These slides are available here: [Site Performance](#) » [PPD Mini-Session Slides, ACTG Network Meeting, June 2015:](#)

- [Taking the Anxiety out of the Monitoring Visit](#)
- [Decoding the Monitoring Codes: A72 versus A17 versus A16](#)
- [Top 10 Quality Tips](#)

JUST POSTED on the A5332 PSWP

Clarification Memo #3*. This memo addresses Inclusion criterion 4.1.1 (inclusion regarding HIV-1 documentation)

*This memo was emailed on 9/11/15 from the ACTG Network Coordinating Center, Subject line: A5332: Pitavastatin to Prevent CVD, Version 2.0 Clarification Memo #3, dated 09/10/15

Revised **Prohibited and Precautionary Medication** list, dated 9/2/15. The revised version includes all fibrates as a precautionary medications.

Updated **Coenrollment Guidelines**, dated 9/3/15, to add "Dolutegravir Antiretroviral Strategy to Promote Improvement and Reduce drug Exposure (ASPIRE) Study" to the list of coenrollable studies.

These documents are on the [A5332 PSWP](#)

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 6/15/2015

A5332 LPC for ACTG Sites:

dated 7/30/15

A5332 LPC for Non-ACTG Sites:

dated 7/30/15

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: dated 3/16/2015

A5333s LPC : dated 7/30/15

JUST POSTED on the A5333s PSWP

English, Spanish, and Thai versions of the SF-36v2® Health Survey (Standard) are available on the A5333s PSWP under [Current Study Specific Support Documents](#). This

survey is completed by the participant and the responses are entered into OpenClinica by study staff. Please follow your local IRB/EC procedures with respect to local regulatory review. Please note, questions remain the same, licensing is completed.

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@fstf.org.

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