



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 11/14/2016

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REPRIEVE Announcements!

100

clinical research sites are open for enrollment!

Thank you to all of our sites that have worked (and are continuing to work) to open for enrollment. This amazing accomplishment,

combined with the efforts of our Site Activation team, is greatly appreciated.

As of November 14th, **2257 participants are enrolled** in REPRIEVE, 252 participants are in screening, 89 sites have enrolled at least 1 participant and 92 sites have screened at least 1 participant.

More exciting news, the Mechanistic Substudy has 402 participants enrolled which is

over 50% of the total enrollment for the Substudy.

Fall is moving on and the holidays are upon us so now is the time to reach the goal of 50 participants enrolled each week. 43 participants were enrolled last week, which is so close to 50. With over 200 participants in screening and 100 sites enrolling participants, we can do this!

Welcome to our newest sites in South Africa, [Site 12301 Soweto CRS](#) and [Site 31792 University of Cape Town Lung Institute \(UCTLI\)](#)! We look forward to working with you on REPRIEVE.

REPRIEVE's Fall 50 Updates

Reminder! Between October 1st and December 30th, all sites enrolling an average of 3 participants per month will receive a \$50 gift card and all sites enrolling an average of 4 or more participants per month will receive a \$100 gift card.

Several sites are on track for meeting the milestone after the first month of the Fall 50 competition! Another 13 sites are very close!

Check out the standings below:

Sites that have met the challenge in October & November!		
#	Site Name	Participants Enrolled Since October
12101	Instituto de Pesquisa Clinica Evandro Chagas CRS	34
31802	Thai Red Cross AIDS Research Center	22
31673	Orlando Immunology Center CRS	9
11101	University of the Witwatersrand Helen Joseph CRS	8
31470	Denver Public Health	7
8950	FAMCRU CRS	7
31871	University of Kentucky	6
31791	Whitman-Walker Health CRS	6
31845	Wake Forest University	6

**These sites are close to meeting the challenge so far.
Keep up the hard work!**

#	Site Name	Participants Enrolled Since October
30347	University of Illinois at Chicago	5
31784	Chiang Mai University HIV Treatment CRS	5
2701	Northwestern University CRS	5
6201	Penn Therapeutics CRS	5
31788	Alabama CRS	4
31930	Tufts Medical Center CRS	4
2702	Rush University CRS	4
3201	Chapel Hill CRS	4
3203	Greensboro CRS	4
1601	Duke University Medical Center	4
6101	University of Colorado Hospital CRS	4
603	Harbor UCLA CRS	4
31834	Center of the Treasure Coast	4
31883	Mount Sinai Clinical and Translational Research	4
2401	Cincinnati CRS	4
31880	Mt Sinai Kreuger Clinic	4
31864	UT Southwestern	4

**Thank You to All Sites Enrolling Participants
Week of 11/07/2016!**

- Brigham and Women's Hospital Therapeutics CRS
- Whitman-Walker Health CRS

- UCSF HIV/AIDS CRS
- Duke University Medical Center
- Cincinnati CRS
- Greensboro CRS
- Vanderbilt Therapeutics (VT) CRS
- University of Colorado Hospital CRS
- Penn Therapeutics CRS
- Family Clinical Research Unit CRS
- University off the Witwatersrand Helen Joseph CRS
- Thai Red Cross AIDS Research Center
- AIDS Research Treatment Center of the Treasure Coast
- Wake Forest University
- University of Kentucky
- Mt Sinai Kreuger Clinic
- Mount Sinai Clinical and Translational Research Center
- Tufts Medical Center CRS
- Instituto de Pesquisa Clinica Evandro Chagas CRS
- Orlando Immunology Center CRS

Help Us Improve the REPRIEVE Site Newsletter!



We want to hear your thoughts about the REPRIEVE Site Newsletter!

Please take a quick, 3 question survey and let us know what you think of the site newsletter. We can only improve it with your feedback.

To complete the survey, [click here](#)

Heart-related Health Questionnaire is on the REPRIEVE (A5332) PSWP

In case you missed the email earlier this week and as discussed on the October Team-Site call, we have developed a new tool to ensure that participants discuss with you all potential cardiovascular events. This tool is posted on the PSWP in the [Protocol-Specific Support Documents folder](#).

In order to prompt an accurate recall of possible MACE/adjudicated events by the participant, please give all participants this brief questionnaire at each visit. It should take only a couple of minutes for the participant to answer yes/no questions about potential cardiac events that may have occurred, and tests and procedures that were done, since the last study visit. You will then review the responses with the participant and use that information to assess for cardiovascular endpoints (REPRIEVE MACE) and heart failure events.

The questionnaire is not a data collection tool per se; none of the data on the form is entered in the electronic data capture (EDC) system/OpenClinica. Instead, you will use the information to elicit information about possible events. In addition:

- The Adjudicated Events Tracking CRF (TRK0150) will prompt completion of this questionnaire.
- The completed questionnaire should be retained as a source document.
- Information about the questionnaire will be added to the next version of the REPRIEVE (A5332) Manual of Procedures.

Please download and begin using the questionnaire as soon as you receive approval from your IRB/EC.



Is there a washout period after participants quit smoking and before calculating their risk score?

During screening, my candidate said he quit smoking that day. Do I have to wait any length of time before I calculate his 10-year ASCVD score?

The REPRIEVE trial is an excellent time to discuss the health benefits of smoking cessation! There is no requirement to wait x number of days between quitting and calculating the 10-year ASCVD risk score. If a potential participant says they quit, take them at their word.

Please note, participants are not discontinued from study or study treatment if they begin smoking again.

My participant was diagnosed with diabetes and started on a statin since his last visit. Can he stay in the trial?

In this scenario, the participant may continue on study but off study treatment. After completing the Premature Treatment Discontinuation evaluations per protocol sections 6.1 and 6.2.4, the participant may continue to complete study visits as outlined in the protocol. It is very important to collect any potential MACE or other events from participants who discontinue study treatment.

Regarding the diabetes, please follow the instructions in the A5332 MOPS, section 6.2 to report the diabetes, if it meets the definition provided.



Only ship to BRI on Monday, Tuesday or Wednesday!

As a reminder, shipments must be sent to BRI only on Mondays, Tuesdays or Wednesdays. BRI is closed during the weekend and they do not want to take a chance with delayed shipments arriving after Friday.

Are you Unable to Ship During your Assigned Time?

If you anticipate that your site will be unable to ship during the assigned schedule (non-ACTG sites please see paragraph below for schedule), you must notify the repository (BRI) at brirepository@afbr-bri.com so that they are aware of the delay. Prior to shipping, confirm with BRI that the week you are planning to ship will work with their schedule. After this, your site should resume its assigned schedule.

If you are a non-ACTG site please use the [attached](#) non-ACTG site shipping schedule to determine when your site should ship to the repository. This schedule is also on the REPRIEVE (A5332) PSWP in the Lab Resources folder.

Important Note about Labeling Specimens for a Premature Treatment Discontinuation Evaluation or Premature Study Discontinuation Evaluation in LDMS

If you are entering specimens for a premature termination visit in LDMS, the visit number should be manually entered to reflect your participant's month in REPRIEVE, and EXT should be selected as the unit for the visit. **Example: 14/EXT.**

The Next REPRIEVE DSMB Meeting is Approaching!

The next REPRIEVE DSMB meeting will take place on Friday, December 16th.

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

Task		Deadline (2016)	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 28 (Fri)	7
Sites	All data for visits through October 30 entered [note: expedited - within 2 weeks of visit]	Nov 11 (Fri)	5
Sites	All queries resolved by this date	Nov 23 (Wed)	3
All	DSMB Meeting	Dec 16 (Fri)	0



TRAINING OPPORTUNITIES

ECG Training Dates

Tuesday, 29 November 2016, 8:30 AM ET

Thursday, 1 December 2016, 9:00 AM ET

Tuesday, 10 January 2017, 9:30 AM ET

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.

Since most sites have completed this requirement these are likely to be our last ECG Training calls, if you need a refresher, please join!

Sites still needing to complete this requirement have been contacted already, however, if you did not receive an email or if you would like to attend, please email Katie Fitch at kfitch@partners.org

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)

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

MOPS:

Version 3.0, revision 1, dated 09/09/16

A5332 LPC for ACTG Sites:

Version 3.0 dated 09/28/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 09/27/2016

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

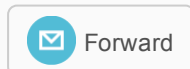
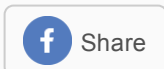
MOPS: Version 3.0 dated 09/02/2016

A5333s LPC : Version 3.0 dated 09/29/2016

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.



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