REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

December 10th, 2018

7306 participants are enrolled
25 participants enrolled in the past week
252 participants are in screening
116 sites are open for enrollment
13 sites enrolled at least 1 participant in the past week
23 sites screened at least 1 participant in the past week

Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.

Thank You to All Sites That Enrolled At Least 1 Participant in the Past Week!

Barranco CRS
Chennai Antiviral Research and Treatment (CART) CRS
Gaborone CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Parirenyatwa CRS
University of Cape Town Lung Institute
VA West Los Angeles Medical Center
Drexel University
UT Southwestern
Vancouver ID Research and Care Centre Society
U of Miami Infectious Disease Research Unit Jackson Memorial Hosp
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation

Don't forget, we are in our final push to the finish line! The REPRIEVE Leadership Team wants to recognize the *extra* effort and cost of recruiting these final participants.

We have been keeping track of enrollment since September 10th and will continue until the enrollment of the 7500th participant!

The top 3 enrolling sites over the course of the challenge, will receive $1000 USD, $750 USD, or $500 USD respectively for the extra effort to enroll.

Any site that enrolls more than 5 participants during the course of the campaign will receive 100 USD.

Check out the current standings below!

Standing	Site Name and Number	Participants Enrolled Since 9/10/18
1st Place	Parirenyatwa CRS 30313	45
2nd Place	Durban International CRS 11201	22
3rd Place	HGNI HIV Family Care Clinic Site 31927	17
4th Place	Tropical Medicine Foundation CRS 31946	14
5th Place *(Tied)*	Joint Clinical Research Centre (JCRC)/Kampala CRS 12401	11
5th Place *(Tied)*	Thai Red Cross AIDS Research Center Site 31802	11

Keep up the great work!!

Enrollment is Approaching 7500!

The REPRIEVE Leadership Team has developed a **closure to enrollment plan** so that all sites are aware of current enrollment numbers and the plan to close out enrollment as we approach our target accrual.

How this will work:

- REPRIEVE Leadership will immediately notify all sites when enrollment reaches approximately 7350 participants (anticipated late December/early January); **this will serve as a notice that closure to screening will occur shortly, at approximately 7370-7400.**
- REPRIEVE Leadership will monitor enrollments and screening carefully, communicating frequently with sites, and will make a formal announcement regarding specific timing of screen closures shortly after enrollment of 7350 participants.
- After the closure of screening, **enrollment of participants in screening must be completed within 45 days from the date of the announcement** and not exceed the protocol defined screening period.
- Please be aware, *enrollment cannot exceed 7575 participants*.

Sites will be notified of all the above communications via:
Direct email
Site Newsletter
Monthly Team-Site Call

The REPRIEVE Team would like to wish all of you a very happy holiday season and a prosperous New Year! As we approach the end of 2018, we hope you take time to

reflect on the tremendous work you have accomplished on the REPRIEVE Trial - thank you for your continued efforts on REPRIEVE.

Please be aware, holidays will impact the following:

- There will be **no REPRIEVE Newsletter** until January 14, 2019.
- BRI will be closed over the holidays. ***Please do not ship during the 4th week of December or the 1st week of January.*** If your site is scheduled to ship during this time, please email BRI at brirepository@afbr-bri.com to arrange an alternative shipping time.
- **For sites participating in A5333s**: PaxGene tubes requested between December 21st and January 2nd will be responded to on January 3rd.

Q: Why does the **Myalgia Symptom Assessment CRF** ask participants to grade any *current* muscle pain or weakness that they are experiencing rather than asking them to grade muscle pain or weakness since their last visit?

A: The Myalgia Symptom Assessment questions are intended to identify signs or symptoms of muscle injury, a potential side effect of statin therapy.

The goal is not to quantify all muscle pain or weakness which have occurred since the last visit, but rather, to prompt the participant to inform the clinician if there is an important problem occurring with their muscles in the present.

If a participant has no symptoms *on the day of the visit*, the answers to the myalgia symptom assessment questions should be no.

Communications from the Site Selection and Performance Committee

As we move into the 2019 calendar year and the 4th year of follow-up for REPRIEVE, the Site Selection and Performance Committee (SSPC) is restructuring both the content and the timing of the **Biannual Evaluation Letters.**

What's changing?

- The letters will focus on retention and laboratory/data management, rather than enrollment.
- Sites will be evaluated at different times according to their (random) Team designation. Please click here to find out what Team your site is on and when you will receive biannual evaluation letters from the SSPC.

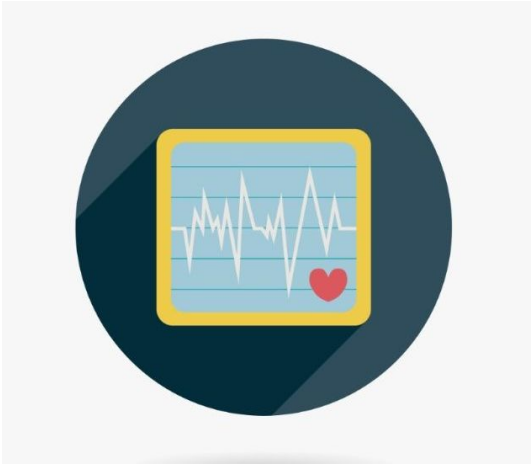
Seeking Additional REPRIEVE Community Advisory Board Members!

As follow-up for REPRIEVE continues it is important that we make sure participants feel involved and that their voices are heard. The purpose of the REPRIEVE Community Advisory Board (CAB), ongoing since 2016, is to ensure that community concerns and suggestions are brought to the attention of trial investigators and carefully considered.

The REPRIEVE Clinical Coordinating Center (CCC) is seeking additional REPRIEVE participants interested in serving on the REPRIEVE CAB.

Members of the REPRIEVE CAB receive important trial updates on a monthly basis via email and meet quarterly via teleconference.

If you have participants who may be interested, please have them contact Emma Kileel at ekileel@partners.org.



A Message About ECG Machines

The REPRIEVE Clinical Coordinating Center (CCC) is beginning to collect ECG machines from sites that are no longer enrolling participants. If you do not anticipate enrolling any additional participants into REPRIEVE please contact Emma Kileel at ekileel@partners.org to initiate the return of your site's ECG machine.

Save the Date!
Tuesday, December 18th 2018
1:00 - 2:00 PM ET

For the next monthly site call!
Watch for the email announcement with more details about the call.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:
Protocol Version 4.0 dated 03/28/2018
V4.0 LOA #1 dated 05/16/2018
MOPS Version 4.0 dated 10/16/18
A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018
A5332 LPC for Non-ACTG Sites Version 4.0 dated 07/23/2018
These documents are on the A5332 PSWP

Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use
Protocol Version 4.0 dated 03/28/2018
MOPS Version 4.0 dated 04/10/2018
A5333s LPC Version 4.0 dated 03/23/2018
These documents are on the A5333s PSWP

For future reference, all newsletters are available on the REPRIEVE Website.

We welcome ideas and suggestions for future newsletters. Please submit any comments or suggestions to the REPRIEVE News team at reprieve.news@fstrf.org

REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02144

Our mailing address is:
reprieve.news@fstrf.org