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Randomized Trial to Prevent Vascular Events in HIV



The 7000th participant was enrolled on Thursday, September 6th!!!

Congratulations on reaching this incredible milestone and THANK YOU to every REPRIEVE Site Team for the tremendous effort!!!

A special shout out to the Brigham and Women's Hospital Therapeutics

CRS team for enrolling the 7000th participant!

Trial Status

September 10th, 2018
7005 participants are enrolled
22 participants enrolled in the past week
178 participants are in screening
116 sites are open for enrollment
19 sites enrolled at least 1 participant in the past week
20 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!

Brigham and Women's Hospital Therapeutics CRS
Harbor UCLA CRS
Washington University Therapeutics (WT) CRS
University of Colorado Hospital CRS
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Barranco CRS
Chennai Antiviral Research and Treatment (CART) CRS
SOWETO
Joint Clinical Research Centre (JCRC)/Kampala CRS
Gaborone CRS

Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Trinity Health and Wellness Center
Whitman-Walker Health CRS
Thai Red Cross AIDS Research Center
UT Southwestern

U of Miami Infectious Disease Research Unit Jackson Memorial Hosp HGNI HIV Family Care Clinic HHFCC Tropical Medicine Foundation Malcom Randall VA Medical Center

REPRIEVE Leadership is excited to announce the...



With approximately 500 participants to enroll, 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 are keeping track of enrollment from September 10th 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.

Additionally, any site that enrolls more than 5 participants between September 10th and enrollment of the 7500th participant will receive \$100 USD for their efforts to enroll.

Reimbursement payments will be made upon confirmation of enrollment milestones and associated effort.

December 3rd, 2018: Next DSMB Meeting

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial.

Please mark these important dates in your calendar and note that Monday, October 8th is the data entry deadline.

Task		Deadline* (2018)
Sites	Latest date for the occurrence of an evaluation for which complete data is expected for inclusion in this DSMB review	Sep 30 (Sun)
Sites	All data for visit through Sep 30 entered into OpenClinica	Oct 8 (Mon)
Sites	All adjudication packets for potential MACE events with a work-up complete by Sep 30 submitted to DCC (MGH)**	Oct 12 (Fri)
Sites	All outstanding queries resolved	Oct 22 (Mon)
Sites	Respond to last minute outstanding queries	Nov 9 (Fri)
All	DSMB Meeting	Dec 3(Mon)

^{*}Deadlines are Close of Business on the given date unless otherwise noted

^{**} Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for potential adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.



Due to impressive retention efforts thus far in REPRIEVE, we are asking you to identify an individual from your study team to participate in a 15–30 minute phone call to review your site's current retention practices. This individual may be a coordinator, study nurse, research assistant, or person of the like who is familiar with your site's strategies and barriers.

We have had great luck with this strategy thus far and have spoken to more than 50 sites about retention, we hope to share these best practices across all sites.

If you have not already joined in this effort, please have your identified Retention Champion use this link to select their availability, or contact Emma Kileel at ekileel@mgh.harvard.edu to arrange an alternative time.

We truly appreciate each site's contribution to REPRIEVE and we are enthusiastic about completing this landmark trial working in partnership with you.



Reminder About Timing of Vaccinations

With flu season approaching in the Northern Hemisphere, remember that sites may administer vaccinations on the same day as REPRIEVE study visits but please do so after any blood to be banked has been drawn.



Submit Version 4.0, LOA #1 to DAIDS PRO

Time is running out to submit Version 4.0, LOA #1 dated 05/16/2018 to the DAIDS Protocol Registration Office.

You can implement the LoA immediately upon receiving final IRB/EC and any other applicable regulatory entity approval for the LoA (without waiting for successful LoA registration).

Please keep in mind: All sites are required to submit an LoA registration packet to the DAIDS PRO. If you have any questions about registration procedures, contact the DAIDS PRO at protocol@tech-res.com or 1+301-897-1707.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 4.0 dated 03/28/2018

V4 LOA #1 dated 05/16/2018

MOPS Version 4.0 dated 04/10/2018

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 <u>reprieve.news@fstrf.org</u>







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