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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

July 9th, 2018

- 6805 participants are enrolled
- 41 participants enrolled in the past two weeks
- 254 participants are in screening
- 117 sites are open for enrollment
- 20 sites enrolled at least 1 participant in the past two weeks
- 30 sites screened at least 1 participant in the past two weeks

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 Two Weeks!

- University of Washington AIDS CRS
- Duke University Medical Center
- Weill Cornell Uptown CRS
- Wits Helen Joseph Hospital CRS (Wits HJH CRS)
- Barranco CRS
- San Miguel CRS
- Chennai Antiviral Research and Treatment (CART) CRS
- Gaborone CRS
- Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
- Columbia Physicians and Surgeons CRS
- Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
- Henry Ford Hospital
- Houston AIDS Research Team CRS
- Chiang Mai University HIV Treatment CRS
- Whitman-Walker Health CRS
- Los Angeles LGBT Center
- Hospital Escola Sao Francisco de Assis
- HGNI HIV Family Care Clinic HHFCC
- Maple Leaf Research
- Tropical Medicine Foundation

Reminder: Push to the Finish Line!



If you were unable to join the Monthly Site Call on June 19th the new target enrollment timeline was discussed. The new date to reach target accrual is April 2019.

- While REPRIEVE continues to move forward at a steady pace, we need YOUR help getting to the finish line!
- We are less than 1000 participants away from the trial's accrual target.
- How can we reach target accrual?
 - **Site Goal:** We ask that sites continue to actively recruit participants and attempt to maintain an accrual rate of at least 2 participants/month.
 - **Trial Goal:** Overall trial weekly accrual goal is 20 participants/week.



Report Potential Adjudicated Events

One essential task we remind sites of periodically is to **identify and report potential adjudicated events.**

What triggers or adjudicated events are we looking for?

Cardiovascular endpoints (REPRIEVE MACE)

Atherosclerotic or other CVD death

Nonfatal myocardial infarction

Unstable angina hospitalization

Coronary or peripheral arterial revascularization

Peripheral arterial ischemia

Cerebrovascular events (REPRIEVE MACE)

Nonfatal stroke or transient ischemic attack (TIA)

Death from any cause

Additional adjudicated cardiac event not part of the primary endpoint

Heart failure

- Sites must report all potential adjudicated (endpoint) events using all established procedures.
- All endpoint events must be adjudicated centrally and independently.
- Refer to the A5332 MOPS for instructions on reporting potential adjudicated events.

[Click here](#) to for an informative slide set on identifying, recording, and reporting potential adjudicated events.

REPRIEVE Session at 2018 ACTG Annual Network Meeting



The REPRIEVE Leadership Team recently presented REPRIEVE updates at the 2018 Annual ACTG Network Meeting. Approximately 300 joined this informative session which included a presentation by Dr. Gail Pearson from NHLBI as well as our Team Cardiologist, Dr. Pam Douglas. [Click here](#) to view the slides.



Q: 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.

Further, MOPS section 7.0 specifies that all SAEs are reported to DAIDS as EAE *except* the following: Any REPRIEVE MACE, Cerebrovascular Event, Heart Failure Event, or AIDS-Defining Event (see section 11.4.2 of the REPRIEVE protocol).

NOTE: If a REPRIEVE MACE, Cerebrovascular Event, Heart Failure Event, or AIDS-defining Event is felt to be related to pitavastatin or placebo for pitavastatin, it is to be reported to DAIDS as an EAE.

Thus, unless your site PI feels this event was related to pitavastatin or placebo, this event does not need to be reported to DAIDS as an EAE because it was a suspected REPRIEVE MACE event.

Ultimately, if the event is rejected by the adjudication committee, your team will be notified and you will at that time be expected to report the event to DAIDS as an EAE if the event meets the threshold for reporting. Therefore, update the AE Log and report to DAIDS as an EAE in DAERS.

If, on the other hand, the event is indeed deemed by the adjudication committee to be a cerebrovascular event, you will not be notified and you will not need to change/update your reporting procedures related to this event.



Biannual Performance Evaluations

The SSPC will be sending site-specific biannual evaluation letters this month. If your site has not received one already, you can expect it within the next two weeks. These letters are meant to ensure that each site is conducting the trial efficiently while producing high quality results. Please review the evaluations with your team to discuss progress at your site and areas which might need improvement.

Save the Date!



Tuesday, July 17th 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 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 03/22/2018

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



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