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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

August 27th, 2018

6951 participants are enrolled
21 participants enrolled in the past week
141 participants are in screening
117 sites are open for enrollment
14 sites enrolled at least 1 participant in the past week
26 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!

Massachusetts General Hospital (MGH) CRS
Case CRS
University of Colorado Hospital CRS
Weill Cornell Chelsea CRS
San Miguel CRS
Joint Clinical Research Centre (JCRC)/Kampala CRS
Gaborone CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Whitman-Walker Health CRS
UT Southwestern
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
U of Miami Infectious Disease Research Unit Jackson Memorial Hosp
HGNI HIV Family Care Clinic HHFCC

Get Involved!

LifeWalk

AIDS WALK LOS ANGELES

AIDS RUN & WALK CHICAGO

The REPRIEVE CCC Team would like to encourage REPRIEVE Site Teams to get involved with events happening in your area! By participating in local events in your community, you create awareness of and interest in cardiovascular health, HIV, and the REPRIEVE Trial.

Below are just a few events we know about in the near future, there are many more!

- AIDS Walk Los Angeles 2018: Sunday, October 21
- 2018 Dallas AIDS Walk: Sunday, October 7
- AIDS Run & Walk Chicago: Sunday, October 23rd
- Walk & 5K to End HIV (Organized by REPRIEVE Site Whitman Walker Health): Saturday, October 27

We recognize participating in these events might take some planning, and the REPRIEVE CCC is here to help! We are happy to assist sites with planning for the events and provide resources to make the process easier. Sites can also visit the REPRIEVE Outreach Toolkit from the REPRIEVE Trial website for some Tips & Tricks about participating in community events and some photos/highlights of sites participating in past events.

If you are interested in getting involved, or if an event in your area isn't listed, please contact Emma Kileel at ekileel@mgh.harvard.edu.

Communications From the Site Selection and Performance Committee

Important Metrics to be Aware of!

As we move into the next evaluation period, the SSPC wants to make sure all sites are aware of trial standards and targets to aim for!

Enrollment:

- Target is approximately 2 participants enrolled per month per site

Off-study/Off-study treatment:

- Target is ≤ 5% annual loss to follow-up
- Target is ≤ 5% off study treatment and still on study

Data Management:

- Target is complete data entry within 3 weeks of visit
- Target is to address data queries within 3 weeks of receipt

Laboratory Management:

- Target is to ship 100% of specimens within 90 days of data entry
- Target is to ship specimens according to the rules in the Lab Processing Chart (on the PSWP)

EAE Reporting:

- Target is 100% of EAEs reported within 3 reporting days of site awareness

For more details, please review the Site Performance Plan (SPP) on the REPRIEVE PSWP.

Submit your Corrective Action Plan!

Throughout the month of July and August, site PIs and Coordinators received site performance evaluations from the SSPC. In the evaluations, some sites were asked to submit a corrective action plan (CAP) to address any performance deficiencies. If your site was asked for a CAP and it has not yet been submitted, please do so as soon as possible. You can submit your CAP to Emma Kileel, SSPC Coordinator, at ekileel@mgh.harvard.edu.

As REPRIEVE moves into it's fourth year of participant follow-up, we need all sites to work hard to ensure participant retention, as it is vital to the overall success of the trial.

Click here to read 'Never Say Lost: A Practical Guide for Maintaining Participant Follow-Up in Clinical Trials'.

As a reminder, if your site has yet to identify a **Retention Champion** please do so by reaching out to Emma Kileel at ekileel@mgh.harvard.edu. We are developing a Retention Toolkit with tips and resources to improve and/or maintain strong participant retention in the trial and we need your input!

ATTN: Sites in Hurricane Regions

Please be aware that we are currently in the peak hurricane season (late August - September). If your site is in a region that may be affected by hurricanes, please be cautious when sending specimens to BRI. If you need to send specimens to BRI out of your assigned schedule, make arrangements with the repository manager by emailing: brirepository@afbr-bri.com.

And most importantly... STAY SAFE!

Shipping the First Week of September?

If you use Fed Ex to ship specimens to BRI and are planning on shipping specimens the first week of September, we recommend you postpone the shipment until the second week of September. This is due to the US holiday on Monday, September 3rd.
Please make sure to email our BRI colleagues to notify them of this schedule adjustment by emailing brirepository@afbr-bri.com.

Thank you very much for your attention to this matter!

Submit Version 4.0, LOA #1 to DAIDS PRO

Time is running out to submit Version 4.0, LOA #1 dated 05/15/2018 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.

MOB Report

Office Of Clinical Site Oversight

National Institute of Allergy and Infectious Diseases (NIAID)

Click here to read the August 2018 edition of the OCSO/MOB Monitoring Newsletter; we thought you might find several of the articles useful. This edition features an in-depth analysis of Informed Consent Violations found during PPD monitoring visits, an overview of ICH guidelines for Good Clinical Practice, and more!

A Note About Site Monitoring

During Q3 and Q4 monitors will be performing a focused review of forms related to potential adjudicated events. The review is to ensure:

- The Heart-related Health Questionnaire (HRHQ) was completed and is filed in the participant's chart.
- Physician/nurse probed/questioned the participant further if needed and documented in the chart.
- Adjudicated Events Tracking CRF (TRK0150) was completed.
- Corresponding event forms were completed if necessary.

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 reprieve.news@fstrf.org

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