REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

July 23rd, 2018

6849 participants are enrolled

16 participants enrolled in the past week

261 participants are in screening

117 sites are open for enrollment

11 sites enrolled 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!

Community AIDS Network/Comprehensive Care Clinic

Federal University of Minas Gerais, School of Medicine CRS

Drexel University CRS

Los Angeles LGBT Center

Barranco CRS

San Miguel CRS

Chennai Antiviral Research and Treatment (CART) CRS

Byramjee Jeejeebhoy Government Medical College (BJMC) CRS

HGNI HIV Family Care Clinic HHFCC

Durban International CRS

University of Pittsburgh CRS

Dr. Judith Aberg is the IDSA 2018 Woman of ID Honoree!

Congratulations to REPRIEVE Co-Investigator, Dr. Judith Aberg, on being honored by the Infectious Diseases Society of America Foundation as a 2018 Woman of ID! Dr. Aberg has dedicated her career to HIV/AIDS research. She has led numerous studies exploring drug interactions, vaccine responses and management of co-morbidities, most notably her work in cardiovascular complications associated with HIV. Click here to read Dr. Aberg's story.

As the Chief of the Division of Infectious Diseases, she has established five clinical research sites throughout the Mount Sinai Health System - and all 5 sites are REPRIEVE sites! We are grateful to have such a brilliant mind on our REPRIEVE team and are happy to see her continued successes!

Q1. A potential participant is prescribed metformin for pre-diabetes, the hemoglobin A1C is 6.4% and LDL is 110mg/dL. Is this potential participant excluded from REPRIEVE due to diabetes and the LDL being >70 mg/dL

A: No, the participant is not excluded from participation based on these criteria. Persons who are on hypoglycemic agents for a reason other than diabetes (metabolic syndrome, hepatic steatosis, pre-diabetes) are allowed if they otherwise meet inclusion criteria.

As per the protocol, current diabetes is defined by a patient report of physician diagnosis of diabetes (not pre-diabetes). Please note that the inclusion criteria allow persons with diabetes to enroll but they must also have an LDL (<70mg/dL) and otherwise qualify.

Q2. We have a participant in follow up who was started on metformin for metabolic syndrome by her PCP prior to her month 12 visit. She does not have a diagnosis of diabetes in her medical record, her hemoglobin A1C is 6.4% . Should we report this as a non-adjudicated event due to diabetes?

A: Once a person is on study, the diagnosis of incident diabetes for REPRIEVE requires 2 factors:

1. diagnosis of diabetes and,
2. initiation of a hypoglycemic

Both of these factors must be met to fulfill the requirement that this be reported as a non-adjudicated event. Since your participant does not have a diagnosis of diabetes this would not be reported as a non-adjudicated event.

Site Spotlight: Barranco CRS (11301) & San Miguel CRS (11302)

"2 sites, 2 hearts beating for REPRIEVE in Lima"

BARRANCO CRS

Location: Lima, Peru

Activated for: 33 weeks

Participants Recruited: 80

Retention: 100%

SAN MIGUEL CRS

Location: Lima, Peru
Activated for: 31 weeks
Participants Recruited: 46
Retention: 100%

When asked, "What helps your site successfully recruit participants for REPRIEVE?" the site teams said the following:

Barranco CRS: Pre-screen visits are key to recruiting participants in REPRIEVE!

The IMPACTA Barranco CRS's main recruitment strategy is to utilize rollover from previous ACTG trial participants and persons living with HIV who take HAART treatment at their clinic. The recruitment team across trials joined efforts to bring the participants to their visits, working together to coordinate transportation, dates, and timing.

San Miguel CRS: Partnership and communications are our best tools for recruiting participants in REPRIEVE!

The IMPACTA San Miguel CRS builds strong relationships with community-based organizations and public health institutions to promote participation in REPRIEVE. San Miguel also prides itself on being attentive with REPRIEVE participants, having flexible visit schedules, and is lucky to be located in a central area of Lima!

Both sites agree that one key to successful recruitment and retention is *leadership involvement!*

The Principal Investigators and Site Leaders from both sites take time to participate in informational meetings at local hospitals to inform potential participants about this landmark study!

Meet Retrox REPRIEVE Hero from Lima, Peru!

Retrox, the REPRIEVE Hero for Barraco CRS and San Miguel CRS, took part in the Gay Pride Parade last month in Lima, promoting awareness and participation in the REPRIEVE Trial!

If your site team is interested

in taking part in an event in your community, contact Emma Kileel at ekileel@mgh.harvard.edu!

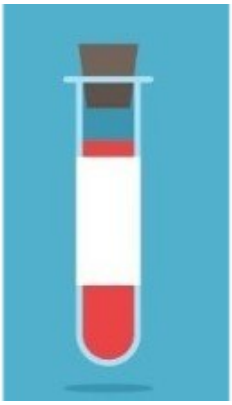
Reminder About Specimen Shipping: Results from REPRIEVE rely on the timely shipment of specimens to BRI. Unlike many studies, testing on stored specimens is done at regular intervals during the trial and not only after the study ends. Remember:

- ACTG sites ship as per your usual schedule
- Non-ACTG site ship as per your assigned schedule which can be found on the PSWP in the Lab Resourced folder.
- Notify the REPRIEVE Lab Committee reprieve.labcom@fstrf.org AND BRI brirepository@afbr-bri.org if your site cannot ship as per your schedule

---

Mechanistic Substudy of REPRIEVE (A5333s) Sites: Are your Paxgene tubes set to expire soon?

Please check your Paxgene tube supply and expiration dates to make sure you have plenty in stock. *Running low?* Email REPRIEVEsupplies@partners.org with the number of tubes requested and an up-to-date mailing address, one of our team members will get them shipped to your site within the week!



Complete the Gender Identity Form for *EVERY* Participant

The DMW0025 – Gender Identity form was made available January 2017.

This form is to be completed at screening for all participants and keyed into OpenClinica after enrollment.

For participants who enrolled *prior* to January 2017 the form is to be completed at their next scheduled visit.

For participants who went off study prior to January 2017, complete the form (with a visit date of the off study date) and for Question 2 complete as "Information Not Collected"

Since this form came out after enrollment began, it was placed in the PRN visit (instead of the Screening visit).
If the data on the form has been collected, but you have not keyed the form for your participants, please key the form as soon as possible.

If the form has not been collected at screening for your participants, it should be collected and keyed at their next visit.

If you have any questions about this form, email the REPRIEVE Data Managers at reprieve.dmc@fstrf.org.

If you missed the Monthly Site Call on Tuesday, July 17th click here to download the slides.

Topics included: adjudicated events, non-adjudicated events, downgraded events, and adverse event reporting.

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

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