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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

August 13th, 2018

6912 participants are enrolled
22 participants enrolled in the past week
125 participants are in screening
117 sites are open for enrollment
15 sites enrolled at least 1 participant in the past week
24 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!

Harbor UCLA CRS
Duke University Medical Center
Cincinnati CRS
The Miriam Hosp (TMH) CRS
University of Colorado Hospital CRS
Chennai Antiviral Research and Treatment (CART) CRS
Gaborone CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
Chiang Mai University HIV Treatment CRS
Drexel University
U of Miami Infectious Disease Research Unit Jackson Memorial Hosp
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation

Important Reminder About the Heart-related Health Questionnaire

In order to prompt an accurate recall of any potential adjudicated event experienced by participants, please give **all participants** the brief **Heart-related Health Questionnaire (HRHQ)** at **each visit.** The questionnaire asks yes/no questions about potential adjudicated events that may have occurred, as well as about tests and procedures since the last study visit. Upon completion, review the responses with the participant and use the information to complete the Adjudicated Events Tracking CRF (TRK0150)

If a participant answers **'yes'** to one of the **HRHQ** questions, but **a yes answer was not indicated on the Adjudicated Events Tracking CRF**, please provide a note of justification in your source documents as **monitors will be checking for this!**

The HRHQ can be found on the REPRIEVE (A5332) PSWP in the Protocol Specific Support Documents folder.

Q: I have a question regarding how to key two hypertensive events that occurred for one of our REPRIEVE participants.

We entered both events as "hypertension" on the AE Log (ADE0001). One of the events is a grade 3 event for an ER visit for exacerbation of ongoing hypertension. The second hypertension entry on the AE Log refers to an actual diagnosis of chronic hypertension, occurring after randomization which is grade 2 and is actively ongoing.

Did we record these events correctly on the AE Log and are there other CRFs where hypertension should be entered?

We recommend the following:
The grade 3 event should be captured on the AE log but we recommend that you capture it as “elevated blood pressure” rather than using the diagnosis of hypertension.

The diagnosis of hypertension which occurred after randomization is a diagnosis of interest that is being captured, read section 6.3.2 of the REPRIEVE (A5332) protocol and section 4.2 of the REPRIEVE (A5332) MOPS for more details.

The diagnosis of hypertension should be recorded on the AE Log and also on the Non-Adjudicated Events Tracking CRF (TRK0152), by answering "yes" to the question, "Has the subject been diagnosed with incident hypertension since the last evaluation or at this evaluation?" for the visit the diagnosis of hypertension was captured.

If the participant initiated antihypertensive medications for hypertension, these should be added to the Medications Log with start dates because we are interested in capturing this class of medication.

Site Spotlight: GHESKIO IMIS (31730) & GHESKIO INLR (30022)

GHESKIO Institue of Infectious Diseases and Reproductive Health (GHESKIO – IMIS) CRS

Location: Port-au-Prince, Haiti
Activated for: 33 weeks
Participants Recruited: 38
Retention: 100%

Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS

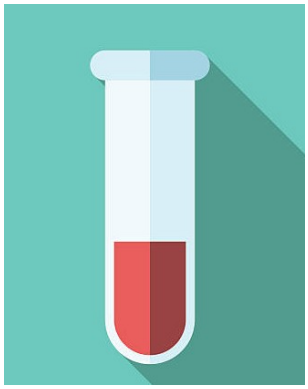
Location: Port-au-Prince, Haiti
Activated for: 33 weeks
Participants Recruited: 66
Retention: 100%

When asked, "What helps your site successfully recruit participants for REPRIEVE?" the recruitment teams shared that they have implemented the following strategies at their sites:

- Training to HIV-care providers about REPRIEVE eligibility criteria
- Use of informational materials, such as flyers
- Provision of participant education about cardiovascular disease and its risk factors to potential participants
- Well-trained staff to welcome the potential participants

The site teams provide frequent patient education about cardiovascular disease and its risk factors to potential participants while they wait for their clinic visits.

"Participants are always excited to receive information about prevention and management of cardiovascular disease!"



Blood Collection Reminder!

Blood collection is *extremely* important in REPRIEVE (A5332) *and* the Mechanistic Substudy (A5333s). Please make every effort to collect blood as per section 6.0 Schedule of Evaluations in the protocol and ALWAYS refer to the Lab Processing Chart for detailed instructions about collection, processing, storing and shipping.

It is important to note that for REPRIEVE (A5332) there are 2 different LPCs dependent on site designation, ACTG vs. non-network (or non-ACTG).

Please make sure you are using the LPC for your site designation as there are slight differences in the collection schedule depending on site designation. For example, ACTG sites collect fasting serum and plasma for stored biomarkers at Mo. 24 and non-network (or non-ACTG) sites do not.

If you have any questions about this please email the REPRIEVE Lab Committee at reprieve.labcom@fstrf.org.

A Note About Shipment Evaluation Procedures

Establishing standards for the shipment of specimens from each site participating in REPRIEVE to the Repository (BRI) strengthens the ability of the Repository to guarantee the integrity of stored specimens and eventually for protocol testing. This system which has been put in place to actively evaluate and monitor every shipment to the Repository has been shown to improve overall site performance.
Click here to review the Shipment Evaluation Procedure SOP which goes over how shipments are scored and evaluated. The SOP also includes a sample evaluation form, problem shipment reference sheet and, a problem shipment scoring table.

Helpful LDMS Tips

1. If the primary tube is not full
Change the primary tube condition code from SAT (satisfactory) to SHV (short volume), add a brief

description of the reason in the comment section of the primary tube (i.e. vein collapsed, difficult draw, etc...), sign, and date.

2. If the desired number of aliquots could not be obtained

Change the missing aliquot condition code from SAT to SNC (sample not collected), QNS (quantity not sufficient), or ANP (aliquot not prepared), add a brief explanation in the aliquot comment section, sign, and date.

Labels will not be generated for aliquots marked as SNC and QNS, and those aliquots will not go into inventory.

Save the Date!

Tuesday, August 21st 2018
1:00 - 2:00 PM ET

For the next monthly site call!

Watch for the email announcement with more details about the call.

Dial-in so you don't miss an exciting announcement from REPRIEVE Leadership!

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

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