View this email in your browser

REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Thank you, Thai Red Cross CRS, for showing your REPRIEVE spirit!!

Q: After a routine colonoscopy a participant informed us that they had one polyp removed/polypectomy. Would this be an adverse event considering it is an abnormal finding?

A: For a routine screening colonoscopy, a polyp would be reported as an AE *only if* the pathology showed that it was malignant. If it was malignant, the event may also need to be reported as a non-adjudicated event for a new cancer diagnosis, see section 6.2 of the REPRIEVE (A5332) MOPS for more details about non-adjudicated events.

Q: One of our participants was hospitalized for an episode of seizure. A diagnosis of TB meningitis was made and the participant started on a rifampicin containing TB regimen. We were alerted to this event during a routine phone call, how should we proceed?

A: This is a new AIDS-defining event, this event *should not be reported* as an EAE in DAERS. Instead, this event requires reporting as a non-adjudicated event. Please follow the instructions in section 6.2 of the MOPS for guidance. The diagram in section 4.4 of the MOPS is a useful summary of the workflow for submission of this non-adjudicated event. Since the participant has been started on a rifampicin containing TB treatment regimen, the study treatment must be held while the participant is taking rifampicin, please enter this on the Medications Log accordingly.

2021 Participant Newsletter Now Available!

Sites may now request hard copies of the 6th Annual Participant Newsletter! The participant newsletter is an excellent way to update your participants about REPRIEVE and keep them engaged in the trial! Click here to request hard copies of the newsletter for your site! Please indicate which language(s) your site would like and the quantity of each. To download the English version, click here.

The newsletter has been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.

Meet Evelynne Fulda, new CRC for the REPRIEVE CCC at MGH!

We are pleased to welcome Evelynne Fulda as the new study coordinator for the REPRIEVE Clinical Coordinating Center (CCC)! Evelynne has worked as a study coordinator at Massachusetts General Hospital (MGH) in Boston, MA USA for the past 2 years and she brings with her a wealth of experience, including working as the coordinator for the REPRIEVE Cardiac MRI study, an ancillary study conducted at a handful of REPRIEVE sites. We are thrilled to be welcoming her aboard REPRIEVE! Evelynne can be reached by email at efulda@mgh.harvard.edu.

Important Reminders from the CCC!

Register Protocol Version 5.0 LoA #2: Please remember to register REPRIEVE (A5332) Protocol Version 5.0, Letter of Amendment (LoA) #2 with DAIDS Protocol Registration. If you need instructions about how to register the LoA, please refer to Section VI, B.2 (page 44) of the Registration Manual (click here to download the DAIDS_prmanual). If you have any questions, contact protocol@tech-res.com.

Complete the Consent/Deconsent CRF: For sites that have protocol registered Protocol Version 5.0, LoA #2, please have your participants complete the ICF addenda for sharing of de-identified

genetic information obtained from a blood sample collected at the entry visit for A5332 (**ACTG sites only**), and at the entry and month 24 visits for A5333s. If you have any questions about this please contact the core team actg.corea5332@fstrf.org.

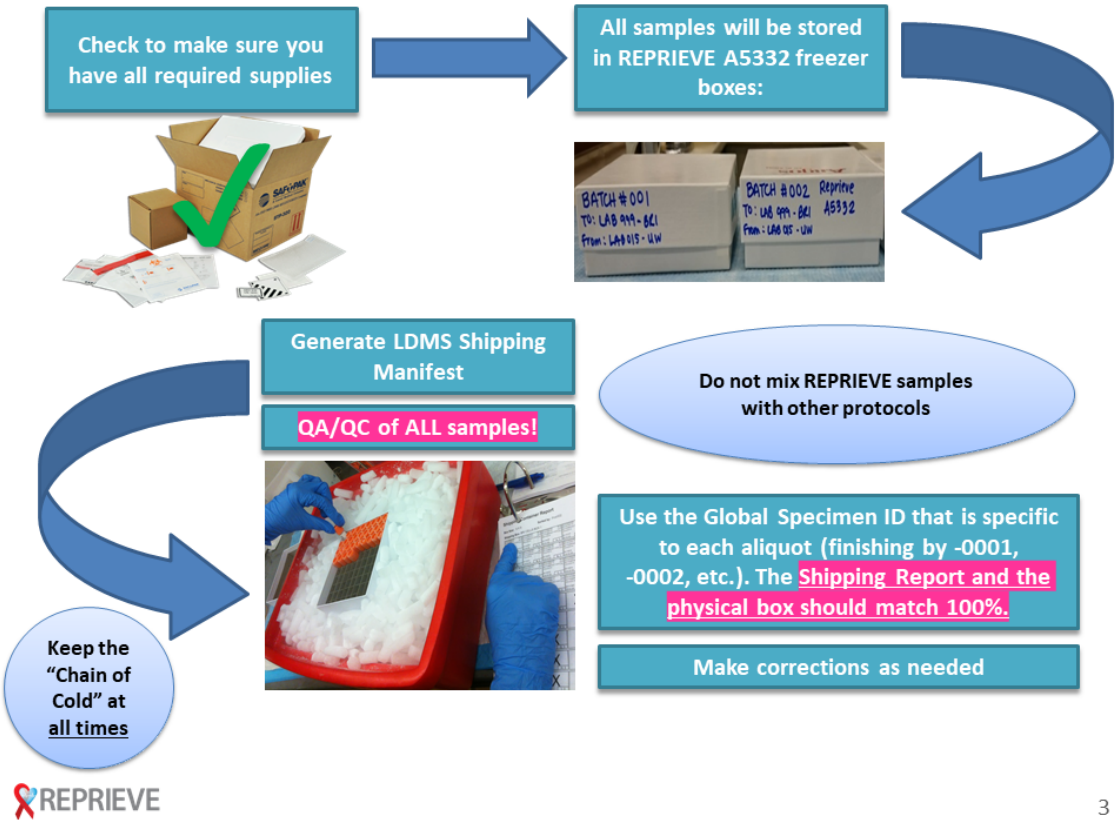
Select a platform to facilitate remote source document verification (rSDV) at your site if you have not done so already and communicate the platform to your DAIDS program officer. If your site has not chosen a platform or plans to use Veeva SiteVault Free, click here to watch a training recently conducted for REPRIEVE sites. Questions? Reach out to Katie Fitch at kfitch@partners.org.

Before you ship, do a 100% QA/QC of your storage box!

When you do a QA/QC, please do the following 3 things for EVERY shipment:

1. **Check the Global Specimen ID.** The global ID is specific to each aliquot and ends with -001, -002, etc..
2. **Check the vial location.** Each vial location in the physical box should PEFECTLY match your Shipping Manifest and Shipping Container Report (box map). Ensure that there are no missing vials or extra vials.
3. **Check that each label is CLEARLY printed and legible.** If a label is not clearly printed or legible please reprint the the label before you ship samples to the repository.

Below is a workflow that will ensure the QA/QC is performed.



FOR ACTG SITES ONLY: ACTG Memo concerning requiring QA/QC performance quality metric

Please make sure that you read the memo (click here) from Dr. Aldrovandi regarding required QA/QC utilizing LDMS barcoding and scanning for all shipments to the ACTG Network Repository and testing laboratories and have forwarded the memo to relevant laboratory personnel at your sites.

Share this exciting event with your REPRIEVE Community!

Ask your participants to ***save the date*** for the first **REPRIEVE Trial Virtual Community Forum on Thursday, June 17th at 11AM EDT**! The forum is intended for REPRIEVE participants and community members but is open to anyone interested in joining. The forum is being held as part of the ACTG Annual Network Meeting but is open to members outside of the ACTG Network. Stay tuned for registration information.

Save the Date Next Team/Site Call!
July 20th 1PM EDT

Join us for important trial updates!

1:00 PM HAITI (EDT)
1:00 PM PERU (PET)
2:00 PM PUERTO RICO (ADT)
3:00 PM BRAZIL (BRT)
8:00 PM BOTSWANA (CAT)***
8:00 PM SOUTH AFRICA (SAST)***
8:00 PM ZIMBABWE (CAT)***
9:00 PM UGANDA (EAT)***
11:30 PM INDIA (IST)***
1:00 AM 01/20/2021 THAILAND (ICT)***

****We do not expect site staff to join these calls during their off-work hours*. Instead we will update you on other scheduled calls, e.g., your calls with the ACTG NCC.

Remember that questions are always welcome at actg.corea5332@fstrf.org and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 *dated 04/01/2019*
Version 5.0, Clarification Memo 1 *dated 04/03/2020*
Version 5.0, Clarification Memo 2 *dated 05/04/2020*
Version 5.0, Letter of Amendment 1 *dated 06/19/2020*
Version 5.0, Letter of Amendment 2 *dated 12/142020*
MOPS Version 5.0 *dated 02/08/2021*
LPC for ACTG Sites *Version 5.0 dated 05/04/2020*
LPC for Non-ACTG Sites *Version 5.0 dated 05/04/2020*
These documents are on the A5332 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 02114