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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

July 2021 Table of Contents

Next REPRIEVE DSMB Meeting:

September 21, 2021
See below for key dates!

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE Trial.

Mark these important dates in your calendar and note that **Friday, August 6** is the date by which all queries should be resolved.

Please make an effort to reach out to participants who have not been seen in a while, including *other contact* or *chart review*, if 3 consecutive visits have been missed (see Appendix V in the MOPS).

Please also review that vital status and endpoint follow-up of participants who have discontinued study is current (see protocol section 6.3.10).

Task		Deadline* (2021)	Weeks to DSMB
	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	June 25 (Fri)	12.6
	US Independence Day holiday (observed)	Jul 5 (Mon)	
Sites	All data for visits through June 25 entered into OpenClinica	Jul 9 (Fri)	10.6
Sites	All adjudication packets for potential MACE events by June 25 with work-up complete submitted to MGH DCC**	Jul 9 (Fri)	10.6
Sites	All queries resolved	Aug 6 (Fri)	6.6
Sites	Respond to last minute outstanding queries	Aug 13 (Fri)	5.6
	US Labor Day holiday	Sep 6 (Mon)	
	DSMB Meeting	Sep 21 (Tue)	0
*Deadlines are Close of Business on the given date unless otherwise noted			
**Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.			

Important Message About Expired Study Product

Recently, we have seen an increased incidence of participants in possession of or taking expired study product. If a participant inadvertently consumes expired study product, the Pharmacist of Record (PoR) should notify the DAIDS OCSO program officer and all relevant clinic staff of the incident, in a blinded manner. Also, the PoR should submit a PAB Incident Report Form to the PAB protocol pharmacist for REPRIEVE (A5332).

It is imperative that each site PoR manage their study product inventory closely. Products that are expiring between the time of dispensation and the next study visit/dispensation should not be issued to participants. We typically observe site PoRs pulling study products expiring within 6 months of a dispensation, out of active inventory to prevent such occurrences.

In cases where participants are lost to follow-up or miss dispensation visits, the PoR should devise a method of keeping track of the expiration dates of dispensed products and work with the clinic staff to contact these participants to return the expired products before consumption.

If you have any questions about this please email the DAIDS REPRIEVE pharmacy team by emailing pabreprievepep@mail.nih.gov

Thank you for your attention to this very important matter!

Site Spotlight: Site 31871: Bluegrass Care Clinic

Located in Lexington, Kentucky, site 31871 has been a tremendous contributor to REPRIEVE, enrolling a total of 68 participants!

We asked the Bluegrass team to share some retention tips:

Retention is a particular challenge for our site due to the rural nature of our clinic's patient population, with some participants having to travel over 1 hour for a visit. The travel can create economic and livelihood barriers to retention. Our study team utilizes the following strategies to combat barriers to retention:

1. We always strive to **match research follow-up visits with standard-of-care clinic visits**, minimizing the burden of travel and time. This also allows qualifying participants to receive transportation assistance through the clinic's Ryan White grants.
2. When participants are unable to make in person visits, **we offer to conduct the visit remotely by phone rather than rescheduling**. Some of the most common reasons our participants miss or reschedule visits are changes in work schedule or unexpected life events, and we can reduce missed and late visits by conducting the visit remotely.

3. Leveraging our healthcare enterprise's data reporting infrastructure to re-engage difficult to contact participants. **Our team periodically generates future standard-of-care visit reports for study enrollees, allowing study staff to re-engage participants at risk for loss to follow-up when they present for non-research visits.** This has proved particularly helpful for our more rural and disadvantaged participants who may not have reliable phone or internet services.
4. **Developing strong interpersonal relationships with the participants is arguably our most successful – and important – retention practice**. We check in on patients when they present for non-research visits, even if only to say "hey, how's your summer going? How're the kids/grandkids?", we keep the tone of our visits a little more casual, and we take the time to engage with our participants as humans who happen to be in the study.

We are fortunate to be embedded in clinic brimming with kind and empathetic providers, social workers, and clinic staff who work diligently to support and empower their patients. Our colleagues at the Bluegrass Care Clinic laid the foundation for this retention practice by operating a clinic with a culture of compassion, allowing our REPRIEVE study team to simply carry the torch.

Thank you, Bluegrass team, for all your efforts in REPRIEVE!

News from the REPRIEVE Data Coordinating Center (DCC)

Meet Radhika Barve, a new clinical research coordinator at the DCC!

Radhika (Ria) joined the Data Coordinating Center (DCC) in June 2021 as a Clinical Research Coordinator. She is responsible for collecting, completing, and transferring source documentation from clinical research sites to the Clinical Events Committee (TIMI) for adjudication. She also works on adjudication reconciliation between the DCC, FSTRF, and TIMI.

Outside of work, Ria enjoys hiking and skiing in the mountains.

Meet Nagendra Gudipati, a new clinical research coordinator at the DCC!

Nagendra recently joined the adjudication team and is excited to be involved in REPRIEVE. At the DCC, Nagendra is responsible for collecting and transferring completed documents from clinical research sites to the Clinical Events Committee (TIMI).

Outside of work, he takes pleasure in riding his bike and going on hikes in nature.

REPRIEVE Swag is Available!

Provide your participants with a token of appreciation for their participation in REPRIEVE!

We have participant newsletters, thank you cards, and birthday cards available. If you would like to request any of these items, please email Evelynne at efulda@mgh.harvard.edu!

Missed the virtual Community Forum on June 17th?

A recording of the first annual REPRIEVE Community Forum is now available for viewing.

At this virtual event, we heard trial announcements and baseline study findings from Steven Grinspoon, Michael Lu, Katie Fitch, and Emma Kileel. Translations of the Forum transcript will be available shortly and will be posted to the REPRIEVE website.

Visit the Community Forum webpage on the REPRIEVE website for more information

REPRIEVE TRIAL COMMUNITY FORUM

AGENDA

11:00 – 11:05 Welcome
Turner Overton, MD

11:05 – 11:10 REPRIEVE Trial Updates
Steve Grinspoon, MD and Michael Lu, MD, MPH

11:10 – 11:15 Cardiovascular Risk and Health Assessments among PWH Eligible for Primary Prevention: Insights from the REPRIEVE Trial
Steve Grinspoon, MD

11:15 – 11:20 Coronary Artery Disease, Traditional Risk and Inflammation Among PWH in REPRIEVE
Michael Lu, MD, MPH

11:20 – 11:25 Diet Quality by Global Burden of Disease Region in PWH in the REPRIEVE Trial
Katie Fitch, MSN

11:25 – 11:30 Assessment of Obesity and Metabolic Profile by Integrase Inhibitor Use in REPRIEVE
Emma Kileel, MPH

11:30 – 11:50 Question and Answer

Click here to watch the recording!

Hot off the Press! Two new REPRIEVE Publications!

We are thrilled to share that two manuscripts from the REPRIEVE team have recently been published.

- The first, entitled Cardiovascular Risk and Health Among People with HIV Eligible for Primary Prevention: Insights from the REPRIEVE Trial, was published in Clinical Infectious Diseases.
- The second, entitled Assessment of Coronary Artery Disease with Computed Tomography Angiography and Inflammatory and Immune Activation Biomarkers Among Adults with HIV Eligible for Primary Cardiovascular Prevention, was published in JAMA Network Open.

Summaries of these publications to share with your participants will be available in hard copy (pamphlet

style) and online on our website shortly.

We are looking forward to continuing our work together on REPRIEVE and informing the field on HIV, cardiovascular disease, and other comorbidities.

Click here to read a press release from the ACTG!

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

Join us for important REPRIEVE 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

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