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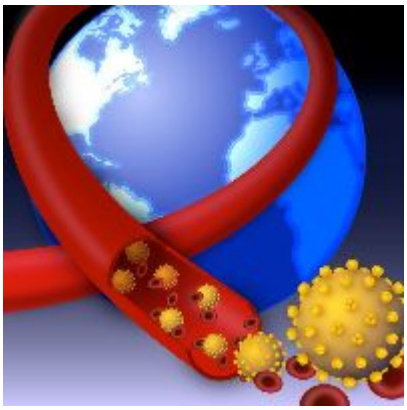
REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV



Hot Off the Press!

We are so excited to share the news that the supplemental issue of the Journal of Infectious Diseases, *Critical Comorbidities in the Modern Antiretroviral Era: Baseline Demographic, Metabolic, and Immune Characteristics of the Global REPRIEVE Trial Population* is now available online! Click here to read each article and share this exciting news with REPRIEVE participants at your site!

Click here to read the press release from the Massachusetts General Hospital and share this with the communications office at your own institution or local media outlets.

The Clinical Coordinating Center is developing participant summaries of each article, we anticipate these will be ready for distribution very soon, so stay tuned...

Important Reminders:

1. Complete the Vital Status and Endpoint Assessment CRF
2. Report Potential Adjudicated Events on the TRK0150
3. Utilize the COVID-19 Tracking Log

Identify and record potential adjudicated events on the Adjudicated Event Tracking CRF (TRK0150) per section 6.0 of the REPRIEVE (A5332) MOPS is essential for the trial.

We do recognize that submission of source documents may present a challenge due to local restrictions in some areas during the pandemic. However, please identify and

report any potential adjudicated events on the TRK0150, collection and submission of source documents can be completed once local restrictions are lifted.

We would like to remind sites to **complete the Vital Status and Endpoint CRF (VSW0025) for participants who are off study but have not withdrawn consent**. The CRF is intended to capture vital status and adjudicated events for participants who discontinued the study prematurely. This CRF is to be completed annually from the Date of Off-Study that is indicated on the Off-Study or at any time the site becomes aware of a potential adjudicated event or death.

See section 12.6 of the REPRIEVE MOPS for more information. If you have questions about this CRF don't hesitate to email the core team at actg.corea5332@fstrf.org.

Update the *A5332 COVID-19 Tracking Log* to document how a participant's participation in REPRIEVE may be altered in relationship to COVID-19.

We will collect this log at the resolution of the current situation. While utilizing this log is not required, it is strongly recommended and site monitors may ask to review the log with you during monitoring visits (either in person or remote).

- This log does not replace or substitute for any existing requirement for data entry.
- The log can be found on the A5332 PSWP in the Current Study-Specific Support Documents folder.

On Friday, July 24th, at 10:30AM ET, ALL REPRIEVE Investigators and site staff are invited to join the REPRIEVE Virtual Meeting!

During this meeting we will share important trial updates, hear a keynote presentation from Dr. Sandra Wagner Cardoso from Brazil, as well as three presentations from REPRIEVE Co-Investigators, Dr. Turner Overton, Dr. Carl Fichtenbaum, and Dr. Kristine Erlandson on key baseline REPRIEVE data being shared widely for the first

time!

You should have received a calendar invite distributed previously, if not email Katie Fitch, kfitch@partners.org, and she can forward the invite to you.

For REPRIEVE Participants!

NEW REPRIEVE Swag Available!

Recognize your participants' ongoing commitment to REPRIEVE with these tokens of appreciation!

In an effort to recognize the dedication of REPRIEVE participants, particularly during these challenging times, the CCC has developed some new swag items! Swag items available include:

- REPRIEVE Hand Sanitizer (pictured above)*
- REPRIEVE cloth face mask
- Birthday and thank you cards
- 2020 calendars

Click here to request REPRIEVE swag for your site!

**Due to the size and weight of hand sanitizer bottles, we will only be shipping a maximum of 20 bottles to sites and we may be limited in our capacity to ship to international sites.*

REPRIEVE

PARTICIPANT NEWSLETTER

Reminder: Order the 2020 Participant Newsletter!

The 5th annual Participant Newsletter is now available for sites to distribute to their participants and is available in over 8 languages! Click here to download the electronic version of the English newsletter. If your site would like to receive hard copies, please click here to let us how many printed copies you would like and in which languages.

If you have already requested participant newsletters, thank you! We will be shipping them to sites in the next few weeks.

**These have been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.*

Introducing Christine Chiou, MD

REPRIEVE's new DAIDS Medical Officer!

Dr. Chiou is the new Medical Officer (MO) for REPRIEVE to replace Dr. Karin Klingman who retired the end of June. Prior to joining DAIDS, Christine served as MO in DMID leading and managing a portfolio of pragmatic clinical trials on antimicrobial resistance. Since joining DAIDS in December 2015, Christine is both a PO and MO managing a grants portfolio consisting of comorbidities and coinfections among people living with HIV, and non-network clinical trials. She also serves as MO for several ACTG clinical trials. Christine is very excited to join the REPRIEVE team!

Christine can be reached at cchiou@niaid.nih.gov or 240-292-4181

Q: Is the Data Management Center's Protocol Deviation Reporting System (PDRS) utilized for REPRIEVE?

A: No, the PDRS is not utilized for REPRIEVE. Instead of the PDRS, REPRIEVE uses the Key Protocol Deviations Tracking Log in OpenClinica to report specific deviations (see REPRIEVE MOPS section 17 for more details). Sites do not need to report deviations in both systems and for REPRIEVE, they need to be reported on the Key Protocol Deviations Log in OpenClinica.

Q: I have questions about completing the COVID-19 Assessment CRF (SSW0040), where can I find more information about completing this CRF?

A: The REPRIEVE MOPS section 4.2 has instructions about completing the COVID-19 Assessment CRF. Also, click here for slides presented during the April 2020 site call on this topic.

REPRIEVE (A5332) contract modifications have been distributed to extend the Period of Performance to April 30th, 2021. Should you have any questions contact the REPRIEVE Finance Team at REPRIEVE.finance@mgh.harvard.edu

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Next Team/Site Call
Tuesday, September 15th, 2020
1:00 - 2:00 PM ET

The Tuesday, July 21st site call has been cancelled due to the REPRIEVE Virtual Meeting on Friday, July 24th at 10:30 AM ET.

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*
New! Version 5.0, Letter of Amendment 1 *dated 06/19/2020*
MOPS Version 5.0 *dated 04/08/2020*
A5332 LPC for ACTG Sites *Version 5.0 dated 05/04/2020*
A5332 LPC for Non-ACTG Sites *Version 5.0 dated 05/04/2020*
These documents are on the A5332 PSWP

Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use

Protocol Version 5.0 *dated 04/01/2019*
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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