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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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The REPRIEVE Leadership Team would like to wish you all a healthy and safe holiday season!

As 2022 comes to a close, we would like to thank the community of clinical research teams and study participants who have remained dedicated to REPRIEVE.

During this past year, we recognized that continuing to work in the midst of a global pandemic was a common challenge, and we are incredibly appreciative of your continued efforts to ensure participant safety and the integrity of REPRIEVE. While 2022 continued to bring us new challenges, we achieved and maintained many accomplishments together, including:

- Reaching 7 years of follow-up from the first participant enrollment in March 2015!*
- Close to 90% of participants continue to be engaged in REPRIEVE.
- Publication of 9 additional manuscripts, with over 10 new manuscripts in development.
- Two successful DSMB meetings, after which the REPRIEVE team was commended on the trial's excellent data collection and safety profile.

These accomplishments would not have been possible without your hard work and our shared mission to better understand how to maintain health, especially heart health, as people with HIV age.

We look forward to continuing our work together in 2023! Thank you, and we wish you all well over the holiday season.

**Average duration of participant follow-up in REPRIEVE is about 5 years*

Holiday Closures

The BRI Repository will be **closed on Friday – 24 December 2022 and Friday – 31 December 2022** in observance of the holiday season. Domestic labs should only ship on Monday or Tuesday during these weeks, or wait and ship after the holidays. International labs should check with the courier so that shipments are not expected to arrive on December 24 or 31.

Frontier Science user support will be unavailable on Saturday, December 25th. User support can otherwise be reached by email at user.support@fstrf.org.



Data Timeliness is Critical in Preparation for the March 30th 2023 DSMB Meeting

The next DSMB review will include a prespecified interim analysis at 75% of the data (see Table 6.3.2 in the A5332 protocol).

To ensure that the DSMB has the critical information it needs for this meeting, the database must be as complete and accurate as possible. Please continue to focus on timely data entry and be sure your site is up to date with this!

The formal timeline for the March 2023 DSMB is below and was distributed via email earlier last month. Please mark these important dates in your calendar and note that **Friday, January 13th** is the data entry deadline. To ensure that the DSMB is reviewing complete data, ***please make sure that all data related to potential adjudicated events have been entered in the study electronic data capture (OpenClinica) and that packets for potential adjudicated events with workup complete have been submitted for adjudication by Friday, January 13th.***

REPRIEVE DSMB Timeline (for the DSMB meeting scheduled for Thursday, March 30, 2023)

Responsibility	Task	Due date*	Weeks to DSMB
Sites	Last date for evaluation for which complete data will be included	Dec 30 (Fri)	12.9
	<i>New Year's day (observed)</i>	<i>Jan 2 (Mon)</i>	
Sites	All data for visits through Dec 30 entered into OpenClinica	Jan 13 (Fri)	10.9
Sites	All adjudication packets for potential MACE endpoints by Dec 30 with work-up complete submitted to MGH DCC**	Jan 13 (Fri)	10.9
	<i>MLK holiday (observed in the US)</i>	<i>Jan 16 (Mon)</i>	
Sites	All queries resolved	Feb 10 (Fri)	6.9
	<i>Presidents' Day holiday (observed in the US)</i>	<i>Feb 20 (Tue)</i>	
Sites	Resolution of follow-up and last-minute critical queries	Feb 24 (Fri)	4.9
All	DSMB Meeting	Mar 30 (Thu)	0.0

*Deadlines are close-of-business on the given date.
**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.



Thank REPRIEVE participants for their continued participation this holiday season!

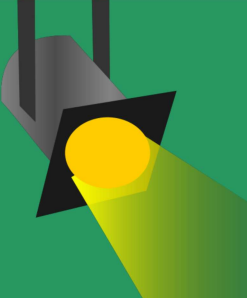
Small tokens of appreciation or acts of kindness can go a long way, especially during the holidays.

Take a moment to use the REPRIEVE thank you cards to write a note to your participants, or simply give them a quick call to wish them a safe and happy holiday season and thank them for all

they have done for REPRIEVE this year!

To request REPRIEVE thank you cards or other tokens of appreciation, please complete the form [here](#) or email Marissa Diggs at mdiggs@mgh.harvard.edu.

Click Here to request REPRIEVE tokens of appreciation!



Site Spotlight: Cincinnati CRS (2401)



The **Cincinnati CRS**, located in Cincinnati, Ohio, USA has been a tremendous contributor to REPRIEVE! See below for a summary of their site's outstanding performance:

Participants Enrolled: **112**
Participants in Follow-Up: **100**
Off-Treatment Rate: **0.8 / 100PY**
Off-Study Rate: **1.0 / 100PY**
% Expected Data Submitted: **100%**
% Expected Specimens Shipped: **100%**

Thank you, Cincinnati CRS team, for all your efforts and for sharing your team photo with us!



Important Information about CROI 2023

Save the Date: Tuesday ~~January~~ February 21st!

- Join us for the REPRIEVE Investigator's Meeting on **Tuesday, February 21st at 12:00 PM PT** at the **Grand Hyatt**, adjacent to the **Washington State Convention Center!**
- We are pleased to share that REPRIEVE has so far had seven abstracts selected for a poster presentation at CROI and we are planning to share some of these findings during the meeting.
- Invites to the meeting will be sent to all REPRIEVE Site PIs in January 2023 and we also hope to be able to have this as a hybrid meeting.

We hope you can join us!



Important Goal: Submit All Potential Adjudicated Events

The goal of REPRIEVE is to determine whether pitavastatin vs. placebo reduces the risk of Major Adverse Cardiovascular Events (MACE) among People with HIV at low-to-moderate traditional cardiovascular disease risk...

In order to properly answer this clinically-relevant question, we need to make sure we don't miss even a single potential adjudicated event! In preparation for the next DSMB review it is essential to report every single possible trigger between now and the end of 2022.

What potential events are we looking for?

- Atherosclerotic or other CVD death
- Nonfatal myocardial infarction
- Unstable angina hospitalization
- Coronary or peripheral arterial revascularization
- Peripheral arterial ischemia
- Nonfatal stroke or transient ischemic attack (TIA)
- Death from any cause
- Heart failure, including all COVID-19-related events resulting in hospitalization



Section 6.0 of the A5332 MOPS has additional details and reporting workflows. Contact the Core Team at actg.corea5332@fstf.org if you have any questions about reporting one of these events.



The Clinical Coordinating Center Needs Your Help!

The REPRIEVE CCC would love to include a few words from a participant at your site about what their participation in REPRIEVE means for them and their health*! Please reach out to kfitch@mgm.harvard.edu if your site has participants who would be interested in this opportunity.

**It is not required that the participant share their name or picture in order to be featured.*

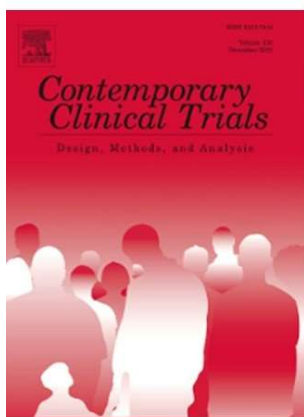
Recognizing an Important Publication Milestone!

With the publication of "The importance of methods for site performance evaluation in REPRIEVE, a longitudinal, global, multicenter trial" **25 manuscripts have been published!**



We could not have achieved this milestone without the dedication of our REPRIEVE site teams and participants! Your contributions are helping us find an effective preventative treatment strategy for HIV-specific heart-related disease and to improve the care of people with HIV worldwide.

[Click here](#) to read this most recent publication.





The importance of methods for site performance evaluation in REPRIEVE, a longitudinal, global, multicenter trial

Evelynne S. Fulda^a, Carl J. Fichtenbaum^b, Emma M. Kileel^a, Markella V. Zanni^a, Judith A. Aberg^c, Carlos Malvestutto^d, Sandra Wagner Cardoso^e, Baiba Berzins^f, Rita Lira^g, Regina Harden^h, Gregory Robbinsⁱ, Maria Martinez^j, Sylvia Davila Nieves^k, Sara McCallum^a, Jorge Leon Cruz^l, Triin Umbleja^l, Heather Sprenger^m, Francoise Giguelⁿ, Frederic Bone^m, Ken Wood^m, Mark Byroads^m, Kayla Paradis^o, Michael T. Lu^o, Pamela S. Douglas^p, Heather J. Ribaud^l, Steven K. Grinspoon^a, Kathleen V. Fitch^a  , on behalf of REPRIEVE Investigators

Key findings from this paper:

1. The performance of clinical research sites (CRSs) in REPRIEVE has been consistent over time and in line with prespecified trial performance goals.
2. REPRIEVE's methods for evaluating trial performance have allowed for real-time feedback and support and, when needed, site-specific assistance. This was particularly helpful amidst the ongoing COVID-19 pandemic and allowed for a change in certain study procedures.

All REPRIEVE publications can be found on our website [here](#).



Join Us for the Next Team/Site Call January 17th

If you have any questions in advance of the site call we'd love to hear from you!
Please email them to [Katie Fitch](#) at the REPRIEVE CCC.

1:00 PM US (EST)
1:00 PM HAITI (EST)
1:00 PM PERU (PET)
2:00 PM PUERTO RICO (AST)
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 01/18/2023 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 6.0 dated 05/16/2022

Revised! MOPS Version 6.0 dated 10/27/2022

LPC for ACTG Sites Version 6.0 dated 06/03/2022

LPC for Non-ACTG Sites Version 6.0 dated 09/08/2022

FAQs dated 09/02/2022

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@fstfrf.org.



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