



# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

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### *Looking Ahead in 2023: A Few Words from REPRIEVE Leadership*

We would like to express our sincere gratitude to every REPRIEVE site team for their incredible efforts to continue to keep REPRIEVE participants engaged and for the continued high-quality data collection. Your efforts have allowed us to share several publications from the baseline data, which we will continue to distribute in various formats to you and the community of people living with HIV. We appreciate your dedication and professionalism, and we are pleased that REPRIEVE continues to do well because of the collective efforts of so many individuals!

Looking ahead, we wanted to remind you of a few important activities to be aware of in 2023!

Activity	Month											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Site Call	X			X			X			X		
Biannual Site Evaluations	Team 1	Team 2		Team 3			Team 1	Team 2		Team 3		
REPRIEVE Meeting during CROI		X										
DSMB Meeting			X									
Participant Newsletter release				X								



## 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 previously. If you haven't done so already, 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, **make sure that all data for visits through December 30th, 2022, and data related to potential adjudicated events are entered** in the 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.

## Data Management Tips: Preventing and Resolving Queries in OpenClinica

The REPRIEVE Data Managers want to ensure you understand common OpenClinica queries, how to



prevent them, and how to resolve them.

[Click here](#) to download a document describing common queries noted on the following:

1. Adverse Event (ADE0001) and Medications (TXW0295) Logs
2. COVID-19 Assessment (SW0040) form
3. Off Study (RP0001) and Final Study (RP0003) Medications Status forms
4. Vital Status and Endpoint Follow-Up (VSW0025) Log

[Click here](#) to download slides on how to resolve queries (also called Notes and Discrepancies) in OpenClinica.

**Please note that to prepare for our DSMB meeting on March 30th, ALL discrepancies MUST be resolved by February 10th.**

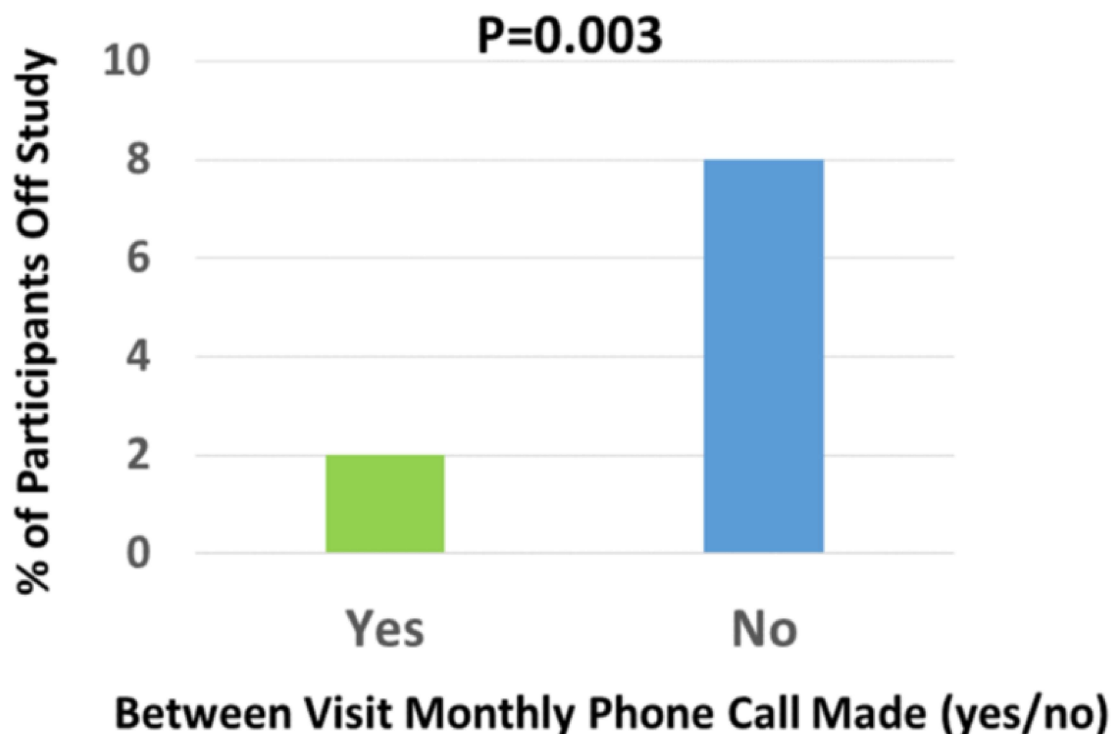
We will review some of these tips on the January 17th Site Call at 1PM ET, please join us!

THANK YOU so much for your attention to this important task!



***Between Visit Check-In Calls Can Help Participants Stay Engaged with REPRIEVE!***

Findings from the **REPRIEVE Retention Champion Initiative** indicate that sites who make regular monthly check-in calls to participants had a significantly lower percentage of participants off-study.



Additional retention tips can be found in the REPRIEVE Retention Toolkit [on our website](#). If your site has retention practices that you would like to share, please reach out to [mdiggs@mgh.harvard.edu](mailto:mdiggs@mgh.harvard.edu).



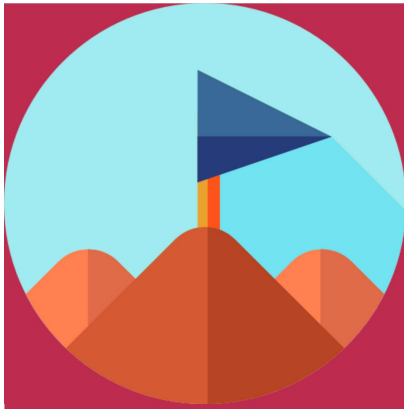
**Important  
Information  
about CROI  
2023**

### **Save the Date: Tuesday, 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 later this month.

***We hope you can join us!***

Please also note that during CROI on Wednesday, February 22nd, 4:00 - 5:30 PM, Pamela Douglas, MD, Co-PI of the REPRIEVE Clinical Coordinating Center, will be a presenter in the CASE-BASED DISCUSSION OF CARDIO-METABOLIC COMPLICATIONS OF HIV AND CONSEQUENCES FOR MANAGEMENT



## 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! It is critical to report every single potential trigger as instructed in Section 6.0 of the A5332 MOPS.

## 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](mailto:actg.corea5332@fstf.org) if you have any questions about reporting one of these events.



## REPRIEVE Publications in 2022

Last month, we shared that REPRIEVE recently published its 25th manuscript since the start of the trial. In 2022, nine new REPRIEVE manuscripts were published and seven abstract were presented at various conferences. If your site requires a list of these publications from 2022 for your continuing review, this is provided below.

[Click Here for List of 2022 Abstracts and Manuscripts](#)





## 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](mailto: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.



## Updated DAIDS Clinical Research Policies

Earlier this month, the Office for Policy in Clinical Research Operations (OPCRO) DAIDS shared that the following policies have been updated:

1. Policy for Study Progress Data and Safety Monitoring Plan, which can be found at: <https://www.niaid.nih.gov/research/daids-clinical-research-event-reporting-safety-monitoring>
2. Storage and Retention of Clinical Research Records Policy, which can be found at: <https://www.niaid.nih.gov/research/daids-clinical-research-protocol-informed-consent>
3. Process for Collection of Financial Disclosure, which can be found at: <https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations>

Please circulate these updated policies as appropriate within your site

## **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 12/14/2022**

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@fstf.org](mailto:reprieve.news@fstf.org).



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