



# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

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### Clinical Research Sites with Outstanding Query Resolution!

As we work to prepare the database for the March DSMB meeting, we wanted to recognize the 42 CRSs that had zero outstanding queries in OpenClinica. Each CRS is listed by its CRS ID number.

107, 601, 1001, 1008, 1504, 1505, 2101, 2301, 2401, 2501, 3201, 5401, 5802, 11101, 11301, 11302, 12101, 12201, 30022, 30313, 30329, 31441, 31473, 31730, 31784, 31786, 31787, 31802, 31834, 31856, 31860, 31867, 31881, 31882, 31910, 31915, 31917, 31918, 31924, 31932, 31963, 31971.

From the entire REPRIEVE team, thank you for your efforts to promptly resolve queries. We encourage all sites to regularly check for queries in OpenClinica. If you have any questions about resolving a query, do not hesitate to reach out to the REPRIEVE data managers at [REPRIEVE.dmc@fstf.org](mailto:REPRIEVE.dmc@fstf.org).

*Thank you again for your attention to this critical aspect of the trial.*



## 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).

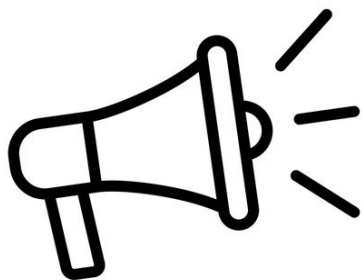
To ensure that the DSMB has the critical information it needs for this meeting, the database must be as complete and accurate as possible. Please continue to focus on timely data entry and be sure your site is up to date with this!

The formal timeline for the March 2023 DSMB is below and was distributed via email previously. Note that **Friday, February 24th** is the **deadline for resolution of follow-up and last-minute critical queries**. To ensure that the DSMB is reviewing complete and accurate data, ***make sure that all follow-up and last-minute queries have been resolved by this date.***

**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.



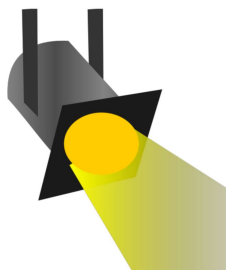
## Important Announcement: PREPARE Substudy (A5361s) Closure to Follow-Up

If your site is participating in the PREPARE Substudy (A5361s), please note that the study is closing to follow-up because all participants have reached the expected follow-up duration.

**For A5361s, please conduct the last study visits by February 24, 2023 and enter all data by March 10, 2023.**

Refer to the closure to follow-up memo distributed on January 6, 2023 or on the A5361s PSWP for details and the full timeline.

Thank you!  
The PREPARE Substudy Team



## Site Spotlight: Chiang Mai University HIV Treatment CRS (31784)



The **Chiang Mai University HIV Treatment CRS**, located in Chiang Mai, Thailand, has been a tremendous contributor to REPRIEVE! This month, the team has shared some of its best practices for participant retention:

1. Maintain a welcoming and comfortable setting through kind and welcoming site staff.
2. Offer participants a snack and water when and if possible.
3. Make phone calls to participants one week before a study visit and two months after their latest study visit to remind them of their upcoming visits; this is a good way to learn about any recent changes in their health.
4. Consider the little things, such as sharing a Thank You or Birthday card.
5. Recognize and commend participants for their excellent study adherence and participation. Remind them that they are helping to increase our knowledge about HIV and heart disease.

**Thank you,** Chiang Mai University HIV Treatment CRS team, for all your efforts, your retention tips, and for sharing your team photo with us!



## Vital Status and Endpoint Assessment CRF (VSW0025)

For participants who are off-study, the Vital Status and Endpoint Assessment CRF (VSW0025) should be completed annually beginning one year after the Date of Off-Study

Keying of the form is based on the attempt of contacting a participant who is off study in an effort to obtain vital status or endpoint information. Even if contact is not obtained, the attempt and date of attempt should be recorded in Section A of the log.

Do not enter on-study data (i.e. contacts, attempts at contact or events) from PRIOR to off study date on the VSW0025 CRF.

Should contact be made, additional information about the participant's vital status should be recorded in Section A of the log.



The Coenrollment Guidelines (dated 06Feb2023) are updated and now posted on the [REPRIEVE \(A5332\) Protocol Specific Webpage](#) in the Coenrollment Guidelines folder.



## 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 CRFs:

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.



 **REPRIEVE**  
INVESTIGATOR'S MEETING @ CROI 2023

**REPRIEVE**  
**Activities**  
**During CROI**  
**2023!**

- Tuesday, February 21st, 12:00 - 1:30 PM PST: REPRIEVE Investigator's Meeting
  - We look forward to seeing some of you in person!
  - There is also a virtual option at <https://partners.zoom.us/j/5185657640>
- Wednesday, February 22nd, 4:00 - 5:30 PM PST, 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
- There are nine poster presentations of REPRIEVE data during CROI!
  - [Click here](#) for the schedule.



## 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.



## Site Appreciation Video from DAIDS

# DIVISION OF AIDS

Success over COVID-19



National Institute of  
Allergy and  
Infectious Diseases

In case you missed it, last month the National Institute of Allergy and Infectious Diseases and Division of AIDS shared a thank you to clinical research sites to recognize their outstanding efforts during the COVID-19 pandemic. We are so appreciative of your dedication, commitment, and persistence which has sustained our research despite unprecedented challenges. Click [here](#) to read the memo issued alongside the site appreciation video.

**View the Site Appreciation Video Here!**



**Join Us for the Next Team/Site  
Call  
April 18th**

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.

## **REPRIEVE (A5332): Are You Up to Date?**

**For A5332 please use:**

*Protocol Version 6.0 dated 05/16/2022*

*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*

**Updated! Coenrollment Guidelines dated 02/06/2023**

*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](mailto:reprieve.news@fstrf.org).*



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### **REPRIEVE Trial Clinical Coordinating Center**

Massachusetts General Hospital  
55 Fruit Street, 5LON 207  
Boston, MA USA 02114

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