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Update from the 16th REPRIEVE DSMB Meeting!

On September 29th, we held our 16th Data and Safety Monitoring Board (DSMB) meeting! We are so pleased to share that the DSMB noted no safety concerns and unanimously approved the continuation of REPRIEVE. We look forward to sharing updates from the meeting, the formal memo will be available shortly.

THANK YOU to all site staff for your data entry efforts in preparing for this important meeting.

The 17th meeting is anticipated to take place in March 2023.

An Important Reminder about Data Timeliness



Adhering to data management timelines is essential during this phase of REPRIEVE.

- Key data and mark ALL CRFs related to a visit complete in OpenClinica within 3 weeks of the visit.
- Review logs (e.g. Medications log, AE log) and update "Review date" regardless of whether there were updates to make or the data were current.

- Resolve queries as soon as you receive them. [Click here](#) to watch a video about resolving data queries.

Keeping up to date with data entry and query resolution ensures that REPRIEVE data are as complete and accurate as possible for the next DSMB review.

Wait, but you say this every 6 months ...Why is now different?

- The next DSMB review will include an interim efficacy analysis (see Table 6.3.2 in the A5332 protocol for more details)
 - Should the trial be stopped for efficacy, the primary analysis will be based on the study database used for the March 2023 DSMB meeting.
- So we are best prepared, the database for the March 2023 DSMB meeting needs to be complete and accurate to ensure the highest quality for this review.
 - **Get started today**, aim to enter all data for visits within the 3 week timeline and resolve queries as soon as you receive them. If you plan to take time off at the end of this year please make sure you've completed all data entry and resolved all queries.

Thank you for your attention to this important detail!

The formal DSMB timeline for the March meeting will be sent as soon as the meeting is scheduled.



Special Site Recognition!

As you may know, site performance evaluation in REPRIEVE is carried out by grouping sites into 4 teams. The **Site Selection and Performance Committee (SSPC)**, the committee responsible for reviewing performance, just completed the review of sites in Team 3.

There were some Team 3 sites that demonstrated great improvement in their efforts to contact and/or enter data for participants at risk of being lost to follow-up that we wanted to recognize:

GHEKIO Institute of Infectious Diseases and Reproductive Health CRS (31730)
AIDS Research Treatment Center of the Treasure Coast CRS (31834)
Drexel University CRS (31856)

We are grateful for your outstanding work! Thank you for your incredible efforts!

Would You Like to Join the Site Selection and Performance Committee?



The REPRIEVE Site Selection and Performance Committee (SSPC) is seeking additional members!

The SSPC is responsible for Clinical Research Site performance evaluation. Members of the SSPC assist with the review of sites within their team and meet via teleconference twice annually.

If you are interested in joining the SSPC, please contact Marissa Diggs at mdiggs@mgh.harvard.edu.

Don't Forget About the Abundance of Tools Available to Support Your Efforts on REPRIEVE

REPRIEVE materials are found on several different websites/portals. Information about gaining access to these portals is summarized in the "[Accounts for New Site Staff](#)" document.

On the [A5332 Protocol Specific Webpage \(PWSP\)](#), you can find current and previous versions of the protocol, clarification memos, letters of amendment, and current study-specific support documents, like the COVID-19 Medication List and Prohibited and Precautionary Medication List. Also, we have recently updated the Frequently Asked Questions (FAQ) document and the Patient Calendar Template (Version 6.0). If you have not yet downloaded these tools, [click here!](#)

On the [Frontier Science \(FSTRF\) website](#), in the REPRIEVE Portal, you'll find:

- Case Report Forms (CRFs)
- CRF Data Collection Schedules
- Training Videos on topics such as Entering Missed Visits, Answering Queries (also called Notes and Discrepancies), and Entering Out of Window Visits. These videos can also be found [here](#).

On the [LDMS website](#), there is a whole page dedicated to REPRIEVE! This page has several quick reference guides and the link to the *LDMS for REPRIEVE* training video.

Hot Off the Press!

Sex-Differences in Subclinical Atherosclerosis and Systemic Immune Activation/Inflammation among People with HIV in the U.S.

Markella V Zanni, MD , Borek Foldyna, MD, Sara McCallum, MS, Tricia H Burdo, PhD, Sara E Looby, PhD, Kathleen V Fitch, MSN, Evelynne S Fulda, B.A, Patrick Autissier, PhD, Gerald S Bloomfield, MD, MPH, Carlos D Malvestutto, MD, MPH, Carl J Fichtenbaum, MD, Edgar T Overton, MD, Judith A Aberg, MD, Kristine M Erlandson, MD, Thomas B Campbell, MD, Grant B Ellsworth, MD, Anandi N Sheth, MD, MSc, Babafemi Taiwo, MD, Judith S Currier, MD, Udo Hoffmann, MD, MPH, Michael T Lu, MD, MPH, Pamela S Douglas, MD, Heather J Ribaud, PhD, Steven K Grinspoon, MD 

Author Notes

Clinical Infectious Diseases, ciac767, <https://doi.org/10.1093/cid/ciac767>

Published: 14 September 2022 **Article history** ▼

The REPRIEVE team recently published a report on possible drivers of heart disease risk in the Mechanistic Substudy of REPRIEVE Cohort. Key findings were:

1. Females (compared to males) had a lower prevalence of plaque in the coronary arteries, even after adjusting for heart disease risk factors.
2. Levels of the inflammation markers IL-6, hs-CRP, and D-dimer were higher in females while levels of the inflammation marker Lp-PLA2 were higher in males, even after adjustment for heart disease risk factors.
3. There were no differences by sex in the associations between higher levels of select inflammation markers (MCP-1, LpPLA2, and oxLDL) and higher prevalence of plaque in the coronary arteries.
 - Notably, only among females, higher levels of the inflammatory marker D-dimer were found to relate to a higher prevalence of non-calcified or vulnerable plaque in the coronary arteries.



Change to REPRIEVE FedEx Account

Does your site use the "A5332 non-network Lab Processing Chart" (LPC)?

Is your site located in the US or Canada?

If you answered "yes" to both questions please read the important information below about a change to the REPRIEVE FedEx account.

Due to fraudulent activity on the current **REPRIEVE** FedEx account, we are in the process of altering our shipment processes.

The FedEx account information will be removed from the "A5332 non-network" (NON-ACTG) LPC and a revised version will be distributed shortly.

For all shipments going forward, a PDF of a shipping label will be sent to your site a week prior to your scheduled specimen shipment. Shipments sent with the old REPRIEVE FedEx account number will not be processed.

If you have ANY questions or need to ship outside of the NON-ACTG Shipping Schedule, please email mghreprieveshipping@mgh.harvard.edu

Please note this change does NOT apply to sites using the "A5332 ACTG Only" LPC or non-ACTG sites in Brazil.



Seeking Additional REPRIEVE Community Advisory Board Members!

As follow-up for REPRIEVE continues, **it is important that we ensure participants feel involved and that their voices are heard.** The purpose of the REPRIEVE Community Advisory Board (CAB), ongoing since 2016, is to ensure that community concerns and suggestions are brought to the attention of trial leadership and carefully considered. [Click here](#) to read about the REPRIEVE CAB members!

The REPRIEVE Clinical Coordinating Center (CCC) is **seeking additional REPRIEVE participants interested in serving on the REPRIEVE CAB.**

Members of the REPRIEVE CAB receive important trial updates on a monthly basis via email and meet biannually via teleconference.

If you have participants who may be interested, please have them contact Marissa Diggs at mdiggs@mgh.harvard.edu.

Tokens of Appreciation Are Available

Tote bags



Birthday cards



Thank you cards



Face masks



We have REPRIEVE-branded tote bags, 'Happy Birthday' cards, 'Thank You' cards, and face masks. These tokens are a great way to show appreciation for our dedicated REPRIEVE participants.

[Click Here to Order Swag for Your Site!](#)



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

Agenda items include: Study updates from REPRIEVE leadership, resolving queries, adjudicated event submission tips, discussion of key new publications.

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 (EDT)
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 04/20/2021 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 6.0 dated 05/16/2022

MOPS Version 6.0 dated 06/10/2022

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

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

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@fstrf.org.



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