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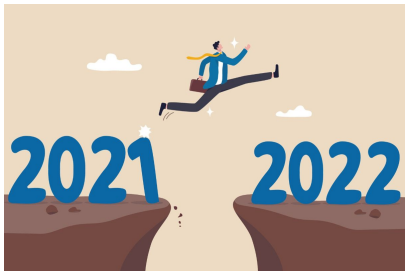
REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

January 2022 Table of Contents



A Few Words from REPRIEVE Leadership

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

Looking ahead we wanted to remind you of a few important activities to be aware of in 2022!

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								
Community Forum						TBD (June/ July)						

Reminders from the Data Management Team!

- If a participant initiates non-study statin, please perform the premature study medication discontinuation visit and ensure that the **Final Study Medication Status (RP0003) CRF has been keyed**. Please also key the RP0003 form for any participants who discontinued study medication but did not start a non-study statin, and even if a premature study medication discontinuation visit was not completed.
    - Non-study statin is prohibited medication and clinical need requires permanent study treatment discontinuation. For additional guidance see A5332 protocol section 8 and the Prohibited Medication List on the PSWP.
- Remember to **update the "Review Date"** on the AE Log and Medications Log every time these logs are reviewed, regardless of whether there were updates to make or the data were current.
- If a participant reports **asymptomatic COVID**, **enter it on the AE Log as "Asymptomatic COVID infection"** and do not complete the "Grade" field. You will get an automatic edit check for leaving the Grade blank, but simply propose resolution to this query to confirm the participant was asymptomatic.

The COVID-19 data collection guidance is being updated in the REPRIEVE (A5332) MOPS and we will discuss this on the January 18th Quarterly Site Call.

FAQs

Q: A study participant passed away recently. Prior to the death, the participant had unstable angina and underwent coronary angioplasty--both of which had been previously reported for adjudication. We had a question about the death, would this death require a separate adjudication packet? Or, should we provide this additional information as a follow-up to the already reported event?

A: Please submit the death event as a separate event for adjudication. You should report the cause of death on the AE Log (if you are unsure you can enter "death of unknown cause" or "sudden death"), complete the Adult Death CRF and the Adjudicated Events Tracking CRF.

Please refer to section 6.0 of the MOPS for additional guidance on reporting requirements.

Q: A participant was hospitalized for cellulitis, during the hospitalization they tested positive for COVID-19, do I report this as a COVID hospitalization as instructed in section 4.3 of the MOPS?

A: No, you would not report this as a COVID hospitalization. If a participant was hospitalized and COVID-19 was an incidental finding or not the primary admission diagnosis, do not report as a COVID hospitalization.

Lab Tips

As we enter a new year the REPRIEVE Lab Committee wants to remind you of a few "to dos" for 2022!

- **Be sure to write down collection time when drawing labs.** The collection time should be entered into LDMS to prevent discrepancies and future data queries. Use the specimen worksheets found on the A5332 PSWP in the Current Laboratory Documents and Memos folder. Using these worksheets will prompt you to collect necessary details at the time of the specimen collection.
- **Utilize resources on the LDMS website!** The website has videos on specimen management, shipping, storage and more. Click here to learn more.
- **Before shipping to BRI, don't forget to do a QA/QC of every single aliquot to ensure that *EVERY* label is clearly printed AND legible!**
    - Illegible labels are one of the most common issues we see on shipment evaluations reported from BRI. Ensuring that all labels are clearly printed BEFORE shipping to BRI will prevent you from having to reprint and resend new labels to BRI.

Don't Forget! Next REPRIEVE DSMB Meeting: March 25, 2022

See below for key dates!

Responsibility	Task	Due Date* (2022)	Weeks to DSMB
Sites	Last date for evaluation for which complete data will be included	Jan 14 (Fri)	10
	Martin Luther King Jr. day (observed in the US)	*Jan 17 (Mon)*	
Sites	**All data for visits through January 14 entered into OpenClinica**	**Jan 28 (Fri)**	**8**
Sites	All adjudication packets for potential MACE by January 14 with work-up complete submitted to MGH DCC**	Jan 28 (Fri)	8
Sites	**All queries resolved**	**Feb 18 (Fri)**	**5**
	President's Day holiday (observed in the US)	*Feb 21 (Mon)*	
Sites/TIMI	Resolution of last-minute critical queries	Feb 25 (Fri)	4
	DSMB MEETING	**Mar 25 (Fri)**	**0**

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

The timeline above lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE Trial.

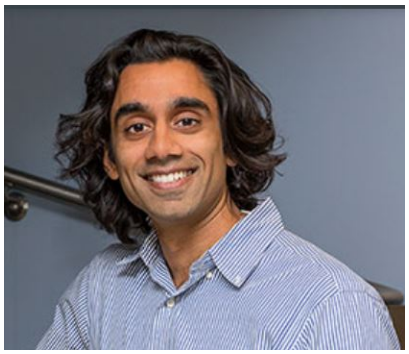
Mark these important dates in your calendar and note that **Friday, January 28th is the data entry deadline.**

To ensure that the DSMB is reviewing complete data, please make sure that all data related to potential adjudicated events and COVID-19 diagnoses have been entered in OpenClinica and that packets for potential adjudicated events with workup complete have been submitted for adjudication by Friday, January 28th. We would appreciate if sites could continue to pay careful attention to this dat collection for an additional month (Monday, February 28th) until the final data download for the meeting. *Thank you for your attention to this important matter!*

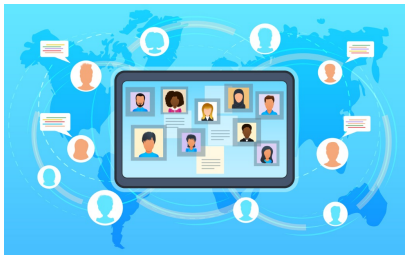
Join us for the REPRIEVE Meeting during CROI 2022!

When: Tuesday, February 15th at 3:30PM EST (2:30PM CST, 1:30PM MST, 12:30PM PST)
Where: Click here to join the virtual meeting! Registration is not necessary.
This virtual meeting will take place during CROI 2022 and ALL are welcome to attend.

We are so excited to announce that **Pradeep Natarajan, MD, MMSc,** PI of the REPRIEVE genetics grant, will be presenting data on the genetic basis of inflammation and cardiovascular disease, including key preliminary data on clonal hematopoiesis (CHIP) and CVD among PWH. In addition to his work on the the REPRIEVE genetics grant, Dr. Natarajan is a preventive cardiologist, cardiovascular geneticist, and physician-scientist. He is the Director of Preventive Cardiology at Massachusetts General Hospital. Click here to read more about Dr. Natarajan.



In addition to the keynote speech by Dr. Natarajan we will be providing important REPRIEVE updates during the meeting.



Next Team/Site Call!

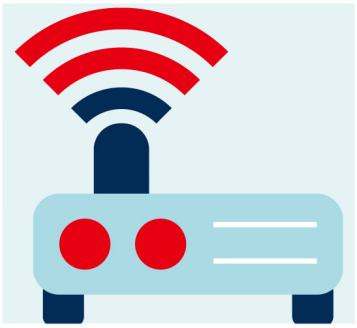
January 18th

During this site call we will focus part of the discussion on COVID-19 and the recent omicron surge. We are working to clarify COVID reporting in the MOPS, please join us if you have suggestions or email the core team suggestions at actg.corea5332@fstrf.org in advance of the meeting.

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 01/20/2021 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 in the News!!!



Volume 8, Issue 12
December 2021

EDITOR'S CHOICE

Assessment of Obesity and Cardiometabolic Status by Integrase Inhibitor Use in REPRIEVE: A Propensity-Weighted Analysis of a Multinational Primary Cardiovascular Prevention Cohort of People With Human Immunodeficiency Virus

Emma M Kileel, Janet Lo, Carlos Malvestutto, Kathleen V Fitch, Markella V Zanni ...

Open Forum Infectious Diseases, Volume 8, Issue 12, December 2021, ofab537, https://doi.org/10.1093/ofid/ofab537

INSTI-based regimens are associated with higher weight but not with increased cardiovascular risk for most INSTI users. Differences in weight are not uniform across PWH, and specific subgroups of INSTI users should be monitored for long-term CVD outcomes.

The REPRIEVE team recently published a report on Integrase Inhibitor Use in REPRIEVE. This publication was selected as an Editor's Choice by the *Open Forum Infectious Diseases* journal.

Don't forget to check our publications page on the REPRIEVE website for links to all publications and plain language summaries to share with participants, click here.

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*
Version 5.0, Letter of Amendment 1 *dated 06/19/2020*
Version 5.0, Letter of Amendment 2 *dated 12/14/2020*
MOPS Version 5.0 *dated 09/13/2021*
LPC for ACTG Sites *Version 5.0 dated 05/04/2020*
LPC for Non-ACTG Sites *Version 5.0 dated 05/04/2020*
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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