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Randomized Trial to Prevent Vascular Events in HIV

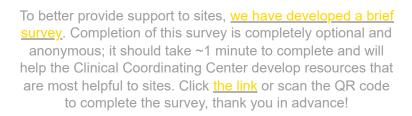
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THANK YOU to all REPRIEVE site teams for the incredible effort to meet the data entry deadlines in preparation for the DSMB meeting on Friday, March 25th. We will provide you with updates from the meeting as soon as we are able to.

We Want to Hear from You!







Tips from the Data Management Team

REPRIEVE Newsletter 03/14/2022



Post-entry CD4+/CD8+ evaluations are specified in Protocol Section 6.3.6

Please ensure that your site is entering in OpenClinica CD4+/CD8+ results obtained from clinical care since the last annual study visit.

• If CD8+ cell count is not available, CD4+ cell count alone is acceptable.

The most recent values obtained since the last annual visit will be used

If there is no new value available since the last annual visit, re-enter the value entered at the last annual visit along with the date on which the value was obtained.

Example: a participant is coming in for their month 48 visit, their CD4+ at month 36 was 800 cells/mm3, and there is no new value since the month 38 visit, therefore enter this same value of 800 cells/mm3 at the month 48 visit along with the date it was obtained.

Non-Adjudicated Event CRFs Require the Signature of the Local PI

For all non-adjudicated events, the event-specific CRFs require the signature of the local PI or designee confirming that she or he has reviewed the documentation and agrees with the diagnosis and the level of evidence.

The signature may be electronic or on the paper CRF. If the signature is on the paper CRF, this CRF should be maintained with source documents.

It is recommended that sites are consistent with the manner in which the PI or designee signs these CRFs.



For Sites Participating in the Mechanistic Substudy of REPRIEVE (A5333s)

In case you missed the email...

As you may recall, the last participant in A5333s received their baseline coronary CTA on

February 1st, 2018, and 688 participants successfully concluded their participation. The substudy is an essential part of REPRIEVE and has been a great success because of your strong efforts to collect data which in turn has facilitated a number of publications from baseline data collected in the substudy. Indeed a number of baseline analyses are ongoing from the substudy with additional longitudinal analyses to follow in the future.

We have received email communications that sites are being asked to de-register the protocol with DAIDS, however REPRIEVE leadership does not plan to close the substudy at this time, we are hoping to obtain additional funding to complete an identical visit to the month 24 visit at the completion of REPRIEVE (A5332). Therefore, we ask that you do not de-register the substudy and that you do not close the study protocol with your local IRB/EC until further notice of plans for this visit.

Thank you, A5333s Team



We are Happy to Share Additional Publications from Baseline Data Collected by You!

ACCEPTED MANUSCRIPT

Geographical Differences in the Self-Reported Functional Impairment of People with HIV and Associations with Cardiometabolic Risk Getacces >

Kristine M Erlandson, MD ☎, Kathleen V Fitch, MSN, Sara A McCallum, MPH, Heather J Ribaudo, PhD, Edgar T Overton, MD, Markella V Zanni, MD, Gerald S Bloomfield, MD, Todd T Brown, MD, PhD, Carl J Fichtenbaum, MD, Sara Bares, MD ... Show more

Clinical Infectious Diseases, ciac098, https://doi.org/10.1093/cid/ciac098

Published: 15 February 2022 Article history ▼

ACCEPTED MANUSCRIPT

Factors Associated with Systemic Immune
Activation Indices in a Global Primary
Cardiovascular Disease Prevention Cohort of Peopl
with HIV on Antiretroviral Therapy

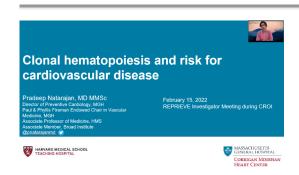
[Getacces >]

Sara E Looby, PhD 🕿, Amy Kantor, MS, Tricia H Burdo, PhD, Judith S Currier, MD, Carl J Fichtenbaum, MD, Edgar T Overton, MD, Judith A Aberg, MD, Carlos D Malvestutto, MD, MPH, Gerald S Bloomfield, MD, MPH, Kristine M Erlandson, M... Show more

Clinical Infectious Diseases, ciac166, https://doi.org/10.1093/cid/ciac166

Published: 02 March 2022 Article history v

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, <u>click here</u>.



Recording from the REPRIEVE Meeting During CROI is Available!

On Tuesday, February 15th, we held our annual REPRIEVE Meeting during CROI. We discussed important trial updates and were fortunate to have Dr. Pradeep Natarajan, PI of the REPRIEVE Genetics Grant as our keynote speaker. If you were unable to make this meeting, you can find a recording hee/ec/he

REPRIEVE (A5332) **contract modifications** are forthcoming to extend the Period of Performance to April 30th, 2023.

Should you have any questions please contact REPRIEVE.finance@mgh.harvard.edu.



Next Team/Site Call! April 19th

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 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
Updated version! MOPS Version 5.0 dated 2/16/2022
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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REPRIEVE Trial Clinical Coordinating Center

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