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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

August 2022 Table of Contents

Timeline for September 2022 DSMB Review!

Responsibility	Task	Due Date* (2022)	Weeks to DSMB
Sites	All queries resolved	Sep 2 (Fri)	4
	Labor Day Holiday (observed in the US)	*Sep 5 (Mon)*	
Sites/TIMI	Resolution of last-minute critical queries	Sep 9 (Fri)	3
	DSMB MEETING	**Sep 29 (Thu)**	**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.

Please mark these important dates in your calendar and note that **Friday, September 2nd** is the deadline for all queries to be resolved. We would appreciate if sites could continue to pay careful attention to data collection for an additional month until the final data download (Friday, September 9th) for the meeting.

Site Spotlight: UT Southwestern HIV/ID Clinical Trials Unit CRS (31864)

The UT Southwestern CRS, located in Dallas, Texas USA has been a tremendous contributor to REPRIEVE!

This team prioritizes its retention efforts in many ways, below are a few tips they shared with us.

1. **APPRECIATION OF PARTICIPANTS:** We listen, distribute newsletters, mail postcards or birthday cards signed by our research group, and give swag gifts in order to keep channels of communication open. We let each participant know how important, meaningful, and impactful their contribution is to research. We also give them thank you cards with the REPRIEVE link for engagement.
2. **FLEXIBILITY:** Research staff are friendly and ready to accommodate the participant's needs. Our staff will arrange visits based on the participant's preference by either completing their visits by phone or by being flexible with the participant's work schedule and doing the visit early (before work) or late (after work).
3. **COMMUNICATION TOOLS:** We utilize phone calls, text messages, social media, and email to keep participants informed of their appointment dates, protocol procedures, and a clear understanding of what is expected in their research visits.
4. Coordinators not only conduct all the assessments required for their visits, but they also give the participants time to ask questions or talk about other concerns. We take time to listen.
5. **FREE PARKING:** We give participants parking tokens to help with parking costs.

***Thank you*, UT Southwestern team, for all your efforts and for sharing your retention tips!**

Hot Off the Press!

Diet in a global cohort of adults with HIV at Low to Moderate Traditional Cardiovascular Disease Risk

Fitch, Kathleen V.[a]; Mccallum, Sara A.[a]; Erlandson, Kristine M.[b]; Overton, Edgar Turner[c]; Zanni, Markella V.[a]; Fichtenbaum, Carl[d]; Aberg, Judith A.[e]; Fulda, Evelynne S.[a]; Kileel, Emma M.[a]; Moran, Laura E.[f]; Bloomfield, Gerald S.[g,n]; Novak, Richard M.[h]; Pérez-Frontera, Sigrid[i]; Abrams-Downey, Alexandra[e]; Pierone, Gerald Jr.[j]; Kumarasamy, Nagalingeswaran[k]; Ruxrungtham, Kiat[l]; Mngqibisa, Rosie[m]; Douglas, Pamela S.[n]; Ribaudo, Heather J.[o]; Grinspoon, Steven K.[a]

Author Information

AIDS: July 27, 2022 - Volume - Issue - 10.1097/QAD.0000000000003344
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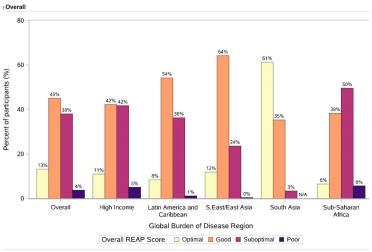


The REPRIEVE team recently published a report on diet in the REPRIEVE cohort. Key findings were:

- Overall diet quality score was optimal in 13% of REPRIEVE participants, but suboptimal in 38% of participants and poor in 4% of participants.
- Participants living in South Asia had the highest overall diet quality score (highest diet quality) and 61% of participants' diet in this region was classified as optimal.

The figure shows diet quality score by Global Burden of Disease in REPRIEVE.

Click here to read the article.

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.

Tips/Reminders from the Data Management Team

Data timeliness is essential, please adhere to the 3-week data entry timeline

Ensure that you adhere to the 3-week timeline by marking complete in OpenClinica ALL CRFs related to a visit.

This helps to ensure that preparation for future DSMB meetings goes smoothly and that the data are as complete as possible prior to the next review.

This timeline is important for ALL CRFs related to a visit, even the Specimen Tracking CRF (SPW00492).

Thank you for your attention to this important detail!

Q. I have a number of REPRIEVE participants interested in receiving the Monkeypox vaccine, is the vaccine permissible in REPRIEVE? Also, do I need to record the vaccine in OpenClinica?

A. Section 13.0, Timing of Routine Vaccinations and Study Visits, of the REPRIEVE (A5332) MOPs (pasted below) provides useful guidance.

- For COVID-19 vaccinations, vaccine doses must not be given within 14 days prior to a scheduled annual blood draw for REPRIEVE.
- ***For all other vaccinations,*** sites should attempt to separate routine vaccinations by 7 days for visits for which blood will be stored. Alternatively, sites may administer vaccinations on same day as the study visit but after all blood to be banked has been drawn.

The Monkeypox vaccine is not required to be recorded on the Medications Log in OpenClinica. Only COVID-19 vaccines are currently required to be recorded on the Medications Log.

Q: We have a REPRIEVE participant who was recently diagnosed with biopsy-confirmed cirrhosis. This participant had no personal history of liver disease and no history of liver-related symptoms or lab abnormalities other than intermittent mild AST/ALT elevations.

The participant presented with elevated liver stiffness on a FibroScan that they received as part of an observational research study. A biopsy was obtained and showed cirrhosis.

Since known cirrhosis was an exclusion criterion to enter REPRIEVE, does the study team recommend premature discontinuation of study product?

A: Discontinuation of study product is not required if the investigator does not believe that the cirrhosis is related to the study drug.

However, end-stage liver disease (*cirrhosis* or hepatic decompensation requiring hospitalization) is a non-adjudicated event that needs to be reported in OpenClinica. To report the cirrhosis in OpenClinica, complete the following steps:
1. Enter this diagnosis in the AE Log
2. Complete the Non-Adjudicated Events Tracking CRF, and
3. Complete the corresponding Incident Cirrhosis CRF (DXW0044)

Key point: across these CRFs the AE identifier must match, this is how the Data Management Team tracks these events.

See section 6.2.1 and 6.2.5 of the MOPS for detailed guidance on reporting of this event.
FAQs

Join the REPRIEVE Lab Committee's Shipment and LDMS Query Response Refresher Call!

Tuesday, September 13th

See times below

The REPRIEVE Lab Committee is hosting a call to review shipping of specimens and tips on responding to lab queries. Most importantly, Lab Committee members will be available to answer any questions you may have!

Join us on Tuesday, September 13th, at:
1:00 PM EDT
12:00 NOON CDT
11:00 AM MDT
10:00 AM PDT
17:00:00 UTC

12:00 NOON PERU (PET)
1:00 PM HAITI (EDT)
2:00 PM PUERTO RICO (ADT)
2:00 PM BRAZIL (BRT)
7:00 PM BOTSWANA (CAT)***
7:00 PM SOUTH AFRICA (SAST)***
7:00 PM ZIMBABWE (CAT)***
8:00 PM UGANDA (EAT)***
10:30 PM INDIA (IST)***
12:00 AM 7/20/2022 THAILAND (ICT)***
***We do not expect site staff to join these calls during their off-work hours. Instead we will post slides from this call on the PSWP and a link to the recording of this call will be provided at a later date. Remember that questions are always welcome at reprieve.labcom@fstrf.org

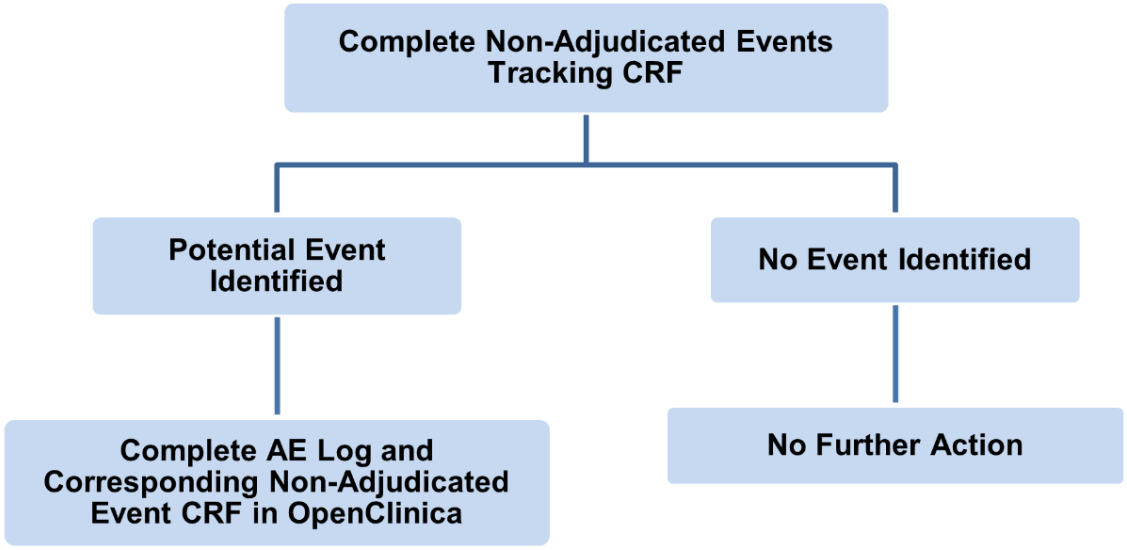
An invite with Zoom link for this meeting has been sent, please reach out to Katie Fitch (kfitch@mgh.harvard.edu) if you did not receive it.

Reporting Non-Adjudicated Events

At each visit post entry, sites must assess for specific non-cardiovascular disease events. These events do not go through an adjudication process. However, they are considered secondary and/or safety events.

A thorough review of non-adjudicated events was recently

presented during the July Site/Teams call, if you were not able to join the call click here to download the slides.



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 1.

There were a few Team 1 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:

Wake Forest Baptist Medical Center CRS (31845)
UCSD Antiviral Research Center CRS (701)
VA West Los Angeles Medical Center CRS (31847)

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

Next Team/Site Call!
October 18th

1:00 PM US (EDT)

1:00 PM HAITÌ (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 06/10/2022*
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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