Site Newsletter 09/25/2017

Table of Contents

- REPRIEVE Trial Status
- 1by1by1 Enrollment Challenge Standings
- Don't Forget: Complete Medications Log (TXW0295)
- Please Use ASCVD Risk Calculator Spreadsheet
- REPRIEVE (A5332) MOPS Updates
- DAIDS RSC Website Updates
- Reminder for Mechanistic Substudy (A5333s) Sites
- Timeline for REPRIEVE DSMB Meeting
- Lab Tips
- Meet the New REPRIEVE Team Members!
- Miss the Last Monthly Site Call?
- Next WebLDMS Training for Non-ACTG Sites
- Training Opportunities
- REPRIEVE (A5332): Are you up to date?
- REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

REPRIEVE Trial Status: September 25th

4494 participants are enrolled
285 participants are in screening
116 sites are open for enrollment
29 sites enrolled at least 1 participant in the past week
36 sites screened at least 1 participant in the past week

Thank You to All Sites Enrolling Participants Week of 09/18/2017!
Brigham and Women's Hospital Therapeutics CRS
Johns Hopkins University CRS
UCLA CARE Center CRS
Harbor UCLA CRS
Univ. of Miami AIDS Clinical Research Unit (ACRU) CRS
Washington University Therapeutics (WT) CRS
Case CRS
The Miriam Hosp (TMH) CRS
Greensboro CRS
Weill Cornell Chelsea CRS
Family Clinical Research Unit
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Durban International CRS
Chennai Antiviral Research and Treatment (CART) CRS
Gaborone CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Cooper University Hospital
Chiang Mai University HIV Treatment CRS
University of Rochester Adult HIV Therapeutic Network CRS
Thai Red Cross AIDS Research Center
Indiana University School of Medicine
Vancouver ID Research and Care Centre Society
OSU Health Science Center
Centro de Pesquisas Clinicas ICHCFMUSP CRS
Hospital Federal dos Servidores do Estado
Hospital Escola Sao Francisco de Assis
HGNI HIV Family Care Clinic HHFCC
Maple Leaf Research
Tropical Medicine Foundation

1by1by1 Enrollment Challenge
Standings
It's THE FINAL COUNTDOWN, approximately 6 weeks remain in the 1by1by1 Enrollment Challenge!

If 64 participants are enrolled each week between now and October 31st, we will achieve 75% of the 6,500 target enrollment. Only 381 participants are needed to reach this goal, with 116 activated sites this is possible!

Remember, many sites will win!

- The site that enrolls the MOST participants during this challenge will be #1 of the 1by1by1 competition and win a $200 gift card!
- Each site that enrolls 11 participants or more between July 1-October 31, 2017 will receive a $100 gift card.
- Each site that enrolls 8-10 participants between July 1-October 31, 2017 will receive a $50 gift card.

The clock started ticking on July 1st and will stop October 31st. 11 sites have already won prizes and several more sites are very close!
Please make sure to **complete the Medications Log (TXW0295)** at entry and **update at every visit post entry** with all current antiretroviral (ART) medications and other concomitant medications that are required to be reported per protocol.
At entry, only record ART medications that the participant is currently taking; do not record prior regimens. (An estimate of prior ART duration is reported on the HXW0202--Targeted Medical History eCRF).

When entering names of medications please be specific:
Write out names of antiretrovirals or use the trade name: "Tenofovir Disoproxil Fumarate" or Tenofovir Alafenamide Fumarate”.

- If only "Tenofovir" is entered we cannot tell which medication a participant is on.
- If the abbreviation ATV is entered this is coded as atorvastatin, therefore please write out atazanavir or Reyataz.

For each visit, remember to update the date of review on the first eCRF page of the Medications Log to document that the log has been reviewed, even if there are no updates or changes to be made. (Please do the same on the AE Log!)

To check if you have any outstanding medication data or queries please email the REPRIEVE Data Management Team at reprieve.dmc@fstrf.org

Thank you for your careful attention to this matter, complete data entry is of utmost importance to the trial.

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Please Use ASCVD Risk Calculator Spreadsheet

The online ASCVD Risk Calculator has been modified again by the ACC/AHA. It is now called the Risk Estimator ‘Plus’ and while it provides the same 10-Year ASCVD Risk Score result needed to assess eligibility for the REPRIEVE trial, it calls for the input of additional information that is not collected by the REPRIEVE trial.

For this reason, and to ensure consistency in calculating the 10-Year ASCVD Risk Score for REPRIEVE participants, REPRIEVE will no longer direct sites to use an online calculator. Instead, sites are asked to use the risk calculator spreadsheet that is available on the REPRIEVE PSWP » A5332 » Protocol.
Specific Support Documents (Versions 3.0) » Calculators.

This spreadsheet is titled “ASCVD Risk Calculator for REPRIEVE (A5332)” and was created on 11/13/2008.

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**REPRIEVE (A5332) MOPS Updates**

The REPRIEVE (A5332) MOPS has been revised to include the following:

- Section 2.0: Instructions on the use of the ASCVD risk calculator spreadsheet.
- Section 6.0: New subsection, 6.1.6 Post Submission of Adjudication Packets—clarifies communications after an adjudication packet is submitted.
- Section 7.1: Now has more details about Downgraded Events and the Downgraded Events memo.

The revised version can be found on the REPRIEVE (A5332) PSWP, in the Protocol-Specific Support Documents (Versions 3.0) folder.

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Please email the core protocol team with any questions:

actg.corea5332@fstrf.org.

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**DAIDS RSC Website Updates**

The following content has been updated on the DAIDS RSC Website:

- **Clinical Research Sites – Informed Consent Process Information:**
  - A new webpage has been created to provide requisite information related to the informed consent process. The webpage can be viewed at: [http://rsc.tech-res.com/clinical-research-sites/informed-consent-information](http://rsc.tech-res.com/clinical-research-sites/informed-consent-information)

- **Clinical Research Sites – Delegation Logs:**
  - A new webpage has been created to provide requisite information for study-specific Delegation Logs. The webpage can be viewed at: [http://rsc.tech-res.com/clinical-research-sites/delegation-logs](http://rsc.tech-res.com/clinical-research-sites/delegation-logs)

- **Home Page – News – Latest News:**
  - A Latest News entry has been posted announcing the posting of these two new webpages. This entry can be viewed at: [http://rsc.tech-res.com/news/latest-news](http://rsc.tech-res.com/news/latest-news)

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**Reminder for Mechanistic Substudy (A5333s) Sites**
When sending the CT images to the CT Core lab, please include:
- the Participant ID (PID)
- site number
- date of CT
- whether the CT is an entry or month 24 CT

Please also confirm with your CT colleagues that the radiation dose report is included in the image transfer – this data is important to track the dose and safety of our participants.

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**Timeline for REPRIEVE DSMB Meeting**

**Friday, December 15th, 2017**

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

Please mark these important dates in your calendar and note that **Friday, Oct 13 is the data entry deadline.**

<table>
<thead>
<tr>
<th>Task</th>
<th>Deadline* (2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review</td>
<td>Sep 30 (Sat)</td>
</tr>
</tbody>
</table>
| Sites | All data for visits through Sep 30 entered  
| Sites | All adjudication packets for potential MACE events with a work-up complete by Sep 30 submitted to DCC (MGH) | Oct 13 (Fri) |
| Sites | All outstanding queries resolved | Nov 3 (Fri) |
| Sites | Respond to last minute outstanding queries | Nov 14 (Tue) |
| Sites | US holiday: Thanksgiving | Nov 23-24 |
| All | DSMB Meeting | Dec 15 (Fri) |
It is important to include the correct notifications when shipping specimens to the Repository. Please include the following:

- **All** sites/laboratories must fax or e-mail a notification to the Repository prior to shipping. Use the “Shipping Notice for Ambient, refrigerated, and Frozen shipment” located on the ACTG web site: https://member.actgnetwork.org/cms/folder/7269. Click here to download an example of a completed form.

- **All non-US** sites/laboratories need to complete and fax or e-mail an “ACTG International Shipping Checklist” to the Repository prior to shipping specimens. This document can be found on the ACTG web site: https://member.actgnetwork.org/cms/dl/12686

- All sites must email BRI (brirepository@afbr-bri.com) a copy of the Shipping Manifest and of the Shipping Container Report on the day of the shipment.

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**Meet the New REPRIEVE Team Members!**

**Devvora Olalere**, is the REPRIEVE DCC Project Manager. She manages and oversees trial operations, including site initiation, imaging, and non-imaging data management, QA/QC, clinical trials documentation such as trial operations manuals, EDC systems and reporting, as well as clinical trial regulatory components, including IRB continuing reviews and protocol amendments. Devvora assists in managing all aspects of the REPRIEVE DCC and serves as primary
liaison for the principal investigators, biostatisticians, clinical research sites, and Clinical Events Committee (CEC). She also oversees comprehensive data tracking systems and REDCap database.

Saeyun Lee, BA is a Clinical Research Coordinator for the REPRIEVE DCC. In this role, Saeyun is responsible for the collection, completeness, and transfer of source documentation information between the Clinical Research Site (CRS) and the Clinical Events Committee (CEC). Saeyun also communicates with CRS teams to resolve any outstanding queries received from CEC and produces reports that track number and status of adjudication packets.

Have frequent conversations with your participants about their study participation in REPRIEVE

Remind your participants that they are taking pitavastatin or placebo and that pitavastatin is a statin medication. Advise participants that if another provider (i.e. primary care provider or provider from a hospitalization) wants to start a statin medication, have the provider consult with the study team immediately. This way inadvertent overdoses can be prevented.

- **Best practice:** when you learn of a hospitalization, always review the discharge medications with the participant.
- There is a Participant Card on the REPRIEVE PSWP located in the Protocol Training >Optional Tools folder (or click here) that you can give to your study participants. The card can be used to alert other providers that the individual is participating in the REPRIEVE trail and may be on a blinded statin medication.

Miss the Last Monthly Site Call?

*Topics we discussed were:*

- REPRIEVE team staff changes
- DSMB Meeting
- New DAIDS requirements for informed consent process
- ASCVD Risk Score Instructions
- World AIDS Day and highlighting REPRIEVE in local communities
- Over-reporting potential events for adjudication

Click here to download the slides.

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TRAINING OPPORTUNITIES

Next WebLDMS Training for Non-ACTG Sites
The LDMS Training Team would like to extend an invitation to all Web LDMS users on the REPRIEVE project to their next webinar. The webinar will cover the processing, storage, and shipment of specimens for the ACTG REPRIEVE study. This is a great opportunity to refresh your earlier training - and ask questions!

As a reminder, videos are available on FSTRF's website at: https://www.ldms.org/resources/videos/ which cover these topics. These videos are hosted on YouTube and can also be viewed through the mobile app.

WebLDMS for REPRIEVE
Wednesday, September 27, 2017
12:00 pm | Eastern Daylight Time (New York, GMT-04:00)

If you would like to join the training session but did not receive the email with the webinar information please email ldms_training@fstrf.org to request this information.

Training Opportunities

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REPRIEVE (A5332): Are you up to date?
For A5332 please use

Protocol:
Version 3.0 dated 01/28/2016
Clarification Memo #1 dated 04/04/2016
Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)
Clarification Memo #3 dated 12/27/2016
Letter of Amendment, Version 3.0 #1 dated 08/17/16
Letter of Amendment, Version 3.0 #2, dated 04/14/17

MOPS:
MOPS Version 3.0, dated 09/20/2017--revised version!
A5332 LPC for ACTG Sites:
Version 3.0 dated 09/21/2017--revised version!
A5332 LPC for Non-ACTG Sites:
Version 3.0 dated 09/21/2017--revised version!
These documents are on the A5332 PSWP

REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

For A5333s please use

MOPS: Version 3.0 dated 06/05/2017
A5333s LPC: Version 3.0, dated 09/21/2017--revised version!

These documents are on the A5333s PSWP

For future reference, all newsletters are available on the REPRIEVE Website

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at reprieve.news@fstrf.org.

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