Trial Status

April 23rd, 2018

6436 participants are enrolled
56 participants enrolled last week
349 participants are in screening!
118 sites are open for enrollment
31 sites enrolled at least 1 participant in the past week
32 sites screened at least 1 participant in the past week

Since the last newsletter, 120 participants have been enrolled. Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.

Thank You to All Sites Enrolling Participants
Week of April 16th, 2018!

Brigham and Women's Hospital Therapeutics CRS
UCSD Antiviral Research Center CRS
Cincinnati CRS
Case CRS
The Miriam Hosp (TMH) CRS
Chapel Hill CRS
Vanderbilt Therapeutics (VT) CRS
The Ponce de Leon Ctr. CRS
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Barranco CRS
San Miguel CRS
Chennai Antiviral Research and Treatment (CART) CRS
Joint Clinical Research Centre (JCRC)/Kampala CRS
Gaborone CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Parirenyatwa CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
University of Rochester Adult HIV Therapeutic Network CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
Medical College of Wisconsin
VA West Los Angeles Medical Center
UT Southwestern
Hamilton Health Sciences
Mt Sinai West CRS
Centro de Pesquisas Clinicas ICHCFMUSP CRS
Instituto de Infectologia Emilio Ribas CRS
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Centro de Referencia e Treinamento
Palmetto Health Clinical Trial Department
FINAL PUSH! Full Speed to 1500 Challenge

Since the Full Speed to 1500 Challenge began on December 4th, 2017 almost 1500 participants have been enrolled, only 64 participants are needed to reach the target! We may reach the target next week!!

Winners of the challenge will be announced in the newsletter, week of May 14th!

Don’t forget prizes include:

- $500 gift card for 1st place
- $250 gift card for 2nd place
- All other sites that enroll 15 participants by May 1st will win a $100 gift card

So many sites have already won prizes and so many are very close. Check out the standings below!
Waist Circumference Reminder

**Waist circumference is to be measured at screening** and end of study visits and entered onto the Detailed Vital Signs CRF (VSW0013).

Waist circumference measurement is explained in section 3.1 of the REPRIEVE (A5332) MOPS.

Please obtain this data as it is required for the study.

*Clarification, in the previous newsletter we indicated that waist circumference was to be measured at entry, this is not correct, waist circumference should be measured at screening.*
Retention is Key

- Retention is incredibly important for the success of REPRIEVE and the substudies.
- Please remember to utilize the retention strategies below:
  - Telephone or text contacts between visits to engage participants*
  - Directing participants to REPRIEVE-specific Twitter and Facebook*
  - Ensure participants have a positive experience during every study visit
  - Ask about feelings and attitudes re study participation and try to address any concerns
- We are here to help!
  - Retention Champions will be contacted in the next few weeks

Blood Collection Reminder

Blood collection is important in REPRIEVE (A5332) and the Mechanistic Substudy (A5332) and you may have noticed, the blood collection schedule is very straightforward! Please make every effort to collect blood as per section 6.0, Schedule of Evaluations and always refer to the Lab Processing Chart for the detailed instructions about processing, storing and shipping.

Important Reminders About Shipping

- All sites/laboratories must fax or e-mail the Shipping Notice for Ambient, Refrigerated, and Frozen Shipment form to the Repository (BRI) prior to shipping. Click here to download.
All non-US sites/laboratories need to complete and fax or e-mail an “ACTG International Shipping Checklist” to BRI prior to shipping specimens. This document can be found on the ACTG website.

Include the LDMS-generated Shipping Manifest and LDMS-generated Shipping Container Report (box map) in every shipment to BRI.

All documents above must be emailed to BRI the day of the shipment. Email to: brirepository@afbr-bri.com

Before you ship, do a 100% QA/QC of your storage box prior to shipping!
  - Check the Global Specimen ID on your vials (the global ID is specific to each aliquot and ends with -001, -002, etc...).
  - Each vial location in the physical box should perfectly match your Shipping Manifest and Shipping Container Report (box map)

For sites using FedEx to ship to BRI, ship PRIORITY OVERNIGHT this will assure that your shipments arrive on time and during BRI’s business hours.

If a site/laboratory is unable to ship during its designated week, it must make arrangements to ship on another date by emailing the Repository Manager at brirepository@afbr-bri.com.

BRI receives many shipments each day, following the reminders above makes their job much easier, ensures the samples move from the shipping container to freezers with ease and helps to prevent issues you will need to respond to in your Shipment Evaluation.

---

Participant Newsletter

The 3rd annual participant newsletter is now available!

- The English version can be found online here
  - Non-English versions are in the process of being IRB approved and will be available soon.
- We can also provide hard copies!
  - In English, Spanish, Canadian French, Brazilian Portuguese, and Haitian Creole?
- Want to receive hard copies for participants?
  Please email Laura Sanchez at lsanchez12@partners.org by Friday, April 27th
- Sharing it with participants is a great way to keep them engaged in the trial!

https://mailchi.mp/fc004996c055/c46vbcmmx9-1343941
Next REPRIEVE DSMB Meeting is June 4th, 2018

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 dates on your calendar and note that Monday, April 23rd is the next important date. All outstanding queries are to be resolved at close of business.

Thank you for your attention to this matter, having complete data for the DSMB review is very important.

<table>
<thead>
<tr>
<th>Task</th>
<th>Deadline* (2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sites Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review</td>
<td>Mar 31 (Sat)</td>
</tr>
<tr>
<td>Sites All data for visit through Mar 31 entered</td>
<td>Apr 9 (Mon)</td>
</tr>
<tr>
<td>Sites All adjudication packets for potential MACE events with a work-up complete by Mar 31 submitted to DCC (MGH)**</td>
<td>Apr 13 (Fri)</td>
</tr>
<tr>
<td>Sites All outstanding queries resolved</td>
<td>Apr 23 (Mon)</td>
</tr>
<tr>
<td>Sites Respond to last minute outstanding queries</td>
<td>May 11 (Fri)***</td>
</tr>
<tr>
<td>All DSMB Meeting</td>
<td>June 4 (Mon)</td>
</tr>
</tbody>
</table>

*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 potential adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.

***Please note this date has been updated from the email that was distributed

Instructions to See Outstanding Queries

- To see outstanding queries for your site, click on the Notes and Discrepancies tab in OpenClinica. If you see any notes listed as New, then you have an outstanding issue that needs to be responded to.
- Depending on which study your site is participating in you will need to navigate between A5332, RS1001, A5333s and A5361s to see the queries for each study respectively.
- Please refer to the following video for more instructions on resolving outstanding notes: [https://www.youtube.com/watch?v=gf9v0nj3WM0](https://www.youtube.com/watch?v=gf9v0nj3WM0)
April Monthly Site Call

During this month's site call, we discussed:

- A5332 Protocol Version 4.0 and MOPS Version 4.0 Updates
- Lab Processing Chart Updates
- Participant Newsletter

In case you missed it, the slides for this call can be found on the PSWP and [here](https://mailchi.mp/fc004996c055/c46vbcmmx9-1343941).

Save the date! The next monthly site call will be on Tuesday, May 15th at 1:00PM ET.

---

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Current Protocol Documents:
- Protocol Version 4.0 dated 03/28/2018 (new version!)
- MOPS Version 4.0: dated 04/10/2018 (new version!)
- A5332 LPC for ACTG Sites: Version 4.0 dated 03/22/2018 (new version!)
- A5332 LPC for Non-ACTG Sites: Version 4.0 dated 03/22/2018 (new version!)

These documents are on the [A5332 PSWP](https://mailchi.mp/fc004996c055/c46vbcmmx9-1343941).

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

For A5333s please use

Protocol: Version 4.0 dated 03/28/2018 (new version!)
- MOPS: Version 4.0 dated 04/10/2018 (new version!)
- A5333s LPC: Version 4.0, dated 03/23/2018 (new version!)

These documents are on the [A5333s PSWP](https://mailchi.mp/fc004996c055/c46vbcmmx9-1343941).
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

REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02144

Our mailing address is:
reprieve.news@fstrf.org

Want to change how you receive these emails?
You can update your preferences or unsubscribe from this list.