Trial Status
March 12th, 2018

6087 participants are enrolled
59 participants enrolled last week!
390 participants are in screening
119 sites are open for enrollment
24 sites enrolled at least 1 participant in the past week
31 sites screened at least 1 participant in the past week

Since the last newsletter, 133 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 March 5th, 2018!

University of Pittsburgh CRS
Duke University Medical Center
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
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
VA West Los Angeles Medical Center
Los Angeles LGBT Center
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
Mt Sinai West CRS
Toronto General Hospital
Positive Health Clinic
Centro de Pesquisas Clinicas ICHCFMUSP CRS
Hospital Federal dos Servidores do Estado
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Palmetto Health Clinical Trial Department

Full Speed to 1500 Challenge Updates!
Since the Full Speed to 1500 Challenge began on December 4th, 2017, 
964 participants have been enrolled, we are over halfway to the goal of 1500 participants!
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

Check out the standings below!

<table>
<thead>
<tr>
<th>Site #</th>
<th>Site name</th>
<th># Enrolled</th>
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<tbody>
<tr>
<td>11701</td>
<td>Chennai Antiviral Research and Treatment CRS</td>
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<tr>
<td>31441</td>
<td>Byramjee Jeejeebhoy Government Medical College (BJMC) CRS</td>
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<tr>
<td>12401</td>
<td>Joint Clinical Research Centre /Kampala CRS</td>
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<td>31946</td>
<td>Tropical Medicine Foundation</td>
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<td>Barranco CRS</td>
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<td>31802</td>
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<td>31924</td>
<td>Instituto de Infectologia Emilio Ribas CRS</td>
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<td>30022</td>
<td>Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS</td>
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<td>Centro de Referencia e Treinamento</td>
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<td>Hospital Escola Sao Francisco de Assis</td>
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<td>Federal University of Minas Gerais CRS</td>
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<td>Chiang Mai University HIV Treatment CRS</td>
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<td>Centro de Pesquisas Clinicas ICHCFMUSP CRS</td>
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<td>31918</td>
<td>Hospital Federal dos Servidores do Estado</td>
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</table>
Reminder About Making Changes in the LDMS

- Be sure to document any changes made in the LDMS with a comment explaining the change. The comment should include the date of the change, the initials of the person making the change and enough detail for another individual to understand.
- For example "Corrected collection time in the LDMS from 9:42 to 8:42 per clinic request. 01Mar2018jd"

The Non-ACTG Site Shipping Schedule to BRI is Updated!

Please note that no changes have been made for sites on the previous shipping schedule, only new sites have been added or inactive sites deleted.

- Please see the updated non-ACTG site shipping schedule here
- The schedule is also located in the Lab Resources Folder on the A5332 PSWP, click here.

Important Reminder: Specimen Shipping

Results from REPRIEVE rely on the timely shipment of specimens to BRI. Unlike many studies, testing on stored specimens is done at regular intervals during the trial and not only after the study ends.

Please note:
- ACTG sites please ship as per your usual schedule.
- Non-ACTG sites please ship to the repository as per your assigned schedule which is located on the PSWP, in the Lab Resources folder.
- Notify the REPRIEVE Lab Committee reprieve.labcom@fstrf.org and BRI brirepository@afbr-bri.com if your site cannot ship as scheduled.
Q. Are people with diabetes eligible to participate in REPRIEVE?

A. People with diabetes (defined below) with an LDL < 70 mg/dL and who are otherwise eligible may be eligible for REPRIEVE. There is no HbA1c cutoff. Diabetics with an LDL ≥ 70 mg/dl are not allowed because guidelines recommend that they be on a statin.

Current diabetes is defined by patient report of physician diagnosis. Candidates with a history of diabetes that has resolved and who no longer require therapy are not considered to have current diabetes, eg, history of gestational diabetes, steroid-induced or medication-induced diabetes.

Candidates who have diet-controlled diabetes and otherwise qualify for REPRIEVE may be eligible. Also, people on oral medications for diabetes but with some lifestyle modification to improve blood glucose may be able to come off these medications and may then be eligible to participate in REPRIEVE. This is an excellent opportunity to encourage lifestyle modification to improve blood glucose!

**Entering Antiretroviral Medications on TXW0295-- Medications Log 1.02**

- At entry, only record antiretroviral medications that the participant is currently taking; **do not record prior regimens**.
- When entering names 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 they are on.
- If ATV is entered, this is coded as atorvastatin, therefore please write out atazanavir or Reyataz.

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**Next Monthly Site Call**

Please join us for the next Monthly Site call on Tuesday, March 20th at 1:00 PM ET.

**Topics will include:**

- Enrollment challenge update
- Full protocol version amendment update (purpose, timeline etc.)
- Important reminders from DAIDS OCSO

If you have suggestions for a monthly site call in the future we would love to hear from you, please email Katie Fitch at kfitch@partners.org.

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**American Heart Month**

We are excited to feature another team who promoted heart health awareness and the REPRIEVE trial this month, Site 1601 at Duke University Medical Center. Emily Hecker, RN, MSN of the Duke team said, "It was a great success – there was a lot of patient interest, which is always a challenge for us, as we are not a dedicated HIV clinic, but an Infectious Disease clinic."

Thank you to the Duke REPRIEVE Team for promoting heart health awareness & the REPRIEVE Trial in February!
Emily Hecker, RN, MSN, and Dr. Lance Okeke at the REPRIEVE heart health awareness table at Site 1601, Duke University Medical Center

**REPRIEVE in CROI News!**

REPRIEVE is featured in one of HIV.gov’s CROI summaries, which recaps day two of CROI!

- Check out the first video on this webpage, where Dr. Carl Dieffenbach, Director of NIH’s DAIDS, discussed interim results on a study of a vaginal ring for HIV Prevention & studies
about heart disease among PLWH, where REPRIEVE is mentioned

- Discussion about HIV and CVD by Dr. Dieffenbach and Anne Rancourt begins at 13:33 and discussion of REPRIEVE begins at 15:00

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**CROI Investigator's Meeting Summary**

Thank you to everyone who joined us for the REPRIEVE Investigator's Meeting at CROI on March 6 in Boston, MA USA.

It was a great turnout with some helpful updates

For those who could not attend, here’s a summary of the meeting:

- "Arterial Inflammation in HIV: Detection and Therapy" by guest speaker Ahmed Tawakol, MD
- REPRIEVE accomplishments in 2017
- What to Focus on in 2018: Retention and Adjudicated Events
- Ancillary Study Updates

Please see the attached slides from the meeting for more details.

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**REPRIEVE (A5332): Are you up to date?**

For A5332 please use

- **Current Protocol Documents:**
  - 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

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https://mailchi.mp/9e84cf717088/c46vbcmmx9-1343917
Mechanistic Substudy of REPRIEVE (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

These documents are on the A5333s 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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