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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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!**

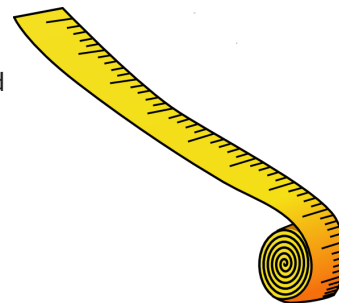
Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment (CART) CRS	158
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	114
31441	Byramjee Jeejeebhoy Government Medical College (BJMC) CRS	113
31946	Tropical Medicine Foundation	74
11301	Barranco CRS	64
31802	Thai Red Cross AIDS Research Center	48
30022	Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS	46
31954	Centro de Referencia e Treinamento	46
31924	Instituto de Infectologia Emilio Ribas CRS	43
12701	Gaborone CRS	42
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	32
11302	San Miguel CRS	28
31927	HGNI HIV Family Care Clinic HHFCC	25
31864	UT Southwestern	20
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	19
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	19
31925	Hospital Escola Sao Francisco de Assis	18
31915	School of Medicine, Federal University of Minas Gerais CRS	17
31879	Mount Sinai Downtown CRS	16
31784	Chiang Mai University HIV Treatment CRS	14
31980	Palmetto Health Clinical Trial Department	13
6101	University of Colorado Hospital CRS	12
12301	SOWETO	11
6201	Penn Therapeutics CRS	9
31788	Alabama CRS	9
2501	Case CRS	9

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!



www.reprievetrial.org
1-877-29-HEART

Participant Newsletter
Vol. 3 | 2018

A Note from REPRIEVE Leadership: Partners in REPRIEVE

We want to thank you once again for joining the REPRIEVE Trial! We have been so impressed with the dedication and commitment of REPRIEVE participants who clearly believe that getting answers about heart disease and HIV is well worth the effort. In order to reach our enrollment target, our dedicated staff at the Clinical Coordinating Center at Massachusetts General Hospital in Boston, MA, USA and at each of the 120 clinical sites worldwide (REPRIEVE will be working very hard to get the word out about REPRIEVE in your community. Please continue to do all you can to let anyone you think might be interested in REPRIEVE know about the study. We welcome and appreciate your help in spreading the word about REPRIEVE!

Of course, staying active in REPRIEVE is an important ongoing in the first place. Each of you is making such an important contribution to this study. The information you are providing may be valuable to your health as well as the health of so many other people living with HIV. By studying all the participants who join and remain in the trial, investigators will be able to make accurate conclusions not only about heart health but also about non-specific differences in heart disease in HIV and the effects of preserved kidney health and muscle function. These conclusions may provide important information for people living with HIV including future generations. We value every participant in REPRIEVE and we hope you will continue your participation with us for the entire length of the study.

Thank you again for your dedication to this important effort!

David Geisler, MD
Massachusetts General Hospital
Clinical Investigator
REPRIEVE Trial

Parvati Douglas, MD
Celia Ornelas
Co Principal Investigator
REPRIEVE Trial

Follow the latest on REPRIEVE

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www.twitter.com/reprievetrial

Meet Other REPRIEVE Participants

REPRIEVE participants are highly motivated individuals seeking the future of heart disease prevention in HIV. Read about our participants' experiences in the trial.

"REPRIEVE participation is important, not only to me but to other participants, because it helps me advance to discover new ways to improve our life quality." - Agnaldo da Silva Santos, MCHB HIV Family Care Clinic, Rio de Janeiro, Brazil

"Before joining this study, I only focused on my HIV infection. Since joining this study, I am now concerned about my overall health. Being in this study, I am receiving health information through the REPRIEVE website and newsletter. It has given me more opportunities to access health information." - Participant at Thai Red Cross, Bangkok, Thailand

"This is a very interesting study and I think the study will be helpful in providing care to patients and other related people in the future. If the result of the study is good, it can be used to prevent other patients from cardiovascular disease. After joining the study, I got results about disease and being monitored for cardiovascular disease during the study which had never been tested on us until about the disease at all. The doctor we worked with during the disease and prevented the disease prevention is better than treatment." - Participant at CMU HIV Treatment, Chiang Mai, Thailand

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.

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

*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=gf9vOnj3WMO>

OpenClinica Enterprise Edition A5332 REPRIEVE : holquin (Data Manager) en | Log Out

Change Study/Site

Home | Subject Matrix | **Notes & Discrepancies** | Study Audit Log | Tasks | Report Issue | Support | Study Subject ID | Go

Alerts & Messages

Instructions

The table lists discrepancy notes that have been created for a given study/site and by default displays the **oldest items first**. Sort or filter using the column headers. To view or update the note, please select the "View" or "View within record" action icons.

Other Info

Notes and Discrepancies

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	1	0	0	0	1
Updated	0	0	0	0	0
Resolution Proposed	0	0	0	0	0
Closed	0	0	0	0	0
Not Applicable	0	0	0	0	0
Total	1	0	0	0	1



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](#)

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](#)

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](#)

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

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Our mailing address is:
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