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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

February 26th, 2018

5954 participants are enrolled

59 participants enrolled last week!

324 participants are in screening

119 sites are open for enrollment

37 sites enrolled at least 1 participant in the past week

34 sites screened at least 1 participant in the past week

Since the last newsletter, 118 participants have been enrolled. Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.

Welcome!

We would like to extend a warm welcome to the newest site to open for enrollment in REPRIEVE! **Site 30313 Parirenyatwa, located in Harare, Zimbabwe.**

**Thank You to All Sites Enrolling Participants
Week of February 19th, 2018!**

Duke University Medical Center
Case CRS

Northwestern University CRS

The Ponce de Leon Ctr. CRS

University of Colorado Hospital CRS

Penn Therapeutics CRS

Weill Cornell Uptown CRS
Family Clinical Research Unit
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Barranco CRS
San Miguel CRS
Chennai Antiviral Research and Treatment (CART) CRS
Hospital Nossa Senhora da Conceicao CRS
SOWETO
Joint Clinical Research Centre (JCRC)/Kampala CRS
Gaborone CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Columbia Physicians and Surgeons CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Denver Public Health
GHESKIO Institute of Infectious Diseases and Reproductive Health
Chiang Mai University HIV Treatment CRS
Thai Red Cross AIDS Research Center
Los Angeles LGBT Center
Drexel University
Florida Department of Health Hillsborough County
UT Southwestern
James J Peters VA Medical Center
Mount Sinai Downtown CRS
Toronto General Hospital
Centro de Pesquisas Clinicas ICHCFMUSP CRS
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Universtiy of Toledo Medical Center
Centro de Referencia e Treinamento
Inova Heart and Vascular Institute
Palmetto Health Clinical Trial Department



Full Speed to 1500



Full Speed to 1500 Challenge Updates!

Since the Full Speed to 1500 Challenge began on December 4th, 2017, [831 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!

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment (CART) CRS	128
31441	Byramjee Jeejeebhoy Government Medical College	105
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	50
31946	Tropical Medicine Foundation	44
11301	Barranco CRS	40
31802	Thai Red Cross AIDS Research Center	37
31924	Instituto de Infectologia Emilio Ribas CRS	35
31954	Centro de Referencia e Treinamento	28
30022	Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS	27
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	18
31879	Mount Sinai Downtown CRS	14
31927	HGNI HIV Family Care Clinic HHFCC	14
12701	Gaborone CRS	14
31915	School of Medicine, Federal University of Minas Gerais	13
31864	UT Southwestern	13
31784	Chiang Mai University HIV Treatment CRS	13
31925	Hospital Escola Sao Francisco de Assis	12
6101	University of Colorado Hospital CRS	8
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	8
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	8
2501	Case CRS	7
30329	Columbia Physicians and Surgeons CRS	7
6201	Penn Therapeutics CRS	7
31980	Palmetto Health Clinical Trial Department	7

Entering Medications on the Medications Log (TXW0295)



Q. How should medications be recorded on the Medications Log?

A. Refer to the REPRIEVE (A5332) MOPS, section 5.0 for instructions about the time frames for all medication/treatment categories we wish to have entered. Medications need to be recorded as they are taken per pill. Do not record the full medication history for the participant on the Medications Log.

Q. What is considered the medication Start Date?

A. Provided the participant has been continuously taking the medication/treatment in the current formulation, the Start Date would be the date of the first dose. Likewise, the End Date should be the date of the last dose.

Q. In the case of a drug being taken initially in a combination, then later and currently

individually, what should be considered the Start Date of the drug?

A. If the drug is currently taken individually as a single pill, enter the Start Date when the first dose of the drug was initiated as a single pill and continue until the present (assuming there has been no extended interruption in use).

Example Record 1:

Participant reports ARV history below:

Estavudine, Lamivudine and Indinavir **5/15/1996 – 1/14/1998**

Biovir, Indinavir **1/15/1998 – 1/20/2000**

Lamivudine , Tenofovir Dexoproxil Fumarate, Efavirenz – **1/21/2000-7/14/2017**

Lamivudine, Tenofovir Dexoproxil Fumarate, Darunavir/r, Etravirine, Dolutegravir – **7/15/2017 – present**

The following would be entered on the Medications Log:

Category	Term	Prior?	Start Date:	End Date:	On going?
ARV	Lamivudine	Y	21-Jan-00		Y
ARV	Tenofovir Dexoproxil Fumarate	Y	21-Jan-00		Y
ARV	Etravirine	Y	15-Jul-17		Y
ARV	Dolutegravir	Y	15-Jul-17		Y
ARV	Darunavir/r	Y	15-Jul-17		Y

Example Record 2:

If the participant had held all ARVs for an extended period prior to the most recent regimen:

Lamivudine, Tenofovir Dexoproxil Fumarate, Efavirenz **1/21/2000-5/10/2014**

Lamivudine, Tenofovir Dexoproxil Fumarate, Darunavir/r, Etravirine, Dolutegravir – **7/15/2014 – present**

In this case, all drugs in the current regimen would have a start date of **7/15/2014**

The following would be entered on the Medications Log:

Category	Term	Prior?	Start Date:	End Date:	Ongoing?
ARV	Lamivudine	Y	15-Jul-14		Y
ARV	Tenofovir Dexoproxil Fumarate	Y	15-Jul-14		Y
ARV	Etravirine	Y	15-Jul-14		Y
ARV	Dolutegravir	Y	15-Jul-14		Y
ARV	Darunavir/r	Y	15-Jul-14		Y

If you have questions about this email the REPRIEVE Data Managers

at reprieve.dmc@fstrf.org

Report Potential Adjudicated Events

One essential role we want to remind sites of periodically is to identify and report potential adjudicated events!

Adjudicated Events in REPRIEVE are:

- Atherosclerotic or other CVD death
- Nonfatal myocardial infarction
- Unstable angina hospitalization
- Coronary or peripheral arterial revascularization
- Peripheral arterial ischemia
- Nonfatal stroke or transient ischemic attack (TIA)
- Heart failure
- Death from any cause



Important steps in identifying and reporting adjudicated events include :

- Take a thorough history from the participant and review the medical record to identify **any potential adjudicated events**.
- Ensure that the **Heart-related Health Questionnaire** has been completed and is kept with source documents.
- Ensure that **100% of Adjudicated Event Tracking CRFs** have been completed accurately and necessary steps have been taken to submit any potential events for adjudication as per **section 6.0 of the REPRIEVE (A5332) MOPS**.

If your site does submit a packet for a potential adjudicated event, please make sure that the Site PI or their designee reviews the packet and agrees with the content before it is submitted to the REPRIEVE Data Coordinating Center.

Mechanistic Substudy (A5333s): Critical Need to Complete Month 24 CCTA!

- **Please be aware of upcoming Month 24 CCTAs!**
 - Every participant in A5333s must have their month 24/follow-up coronary CT angiogram (CCTA). If the month 24 CCTA will be out of the window, please email the A5333s team at actg.corea5333s@fstrf.org for guidance on how to proceed.
 - Please contact participants to remind them of their required month 24 CCTA and schedule CCTA appointments as soon as possible.
 - Retention/Scheduling Strategy:

- Schedule a participant's CCTA with concurrent scheduled appointments the participant might have already scheduled. One easy way to accomplish this is by checking participant's EMR (i.e on Epic) for other upcoming appointments.

It is important to obtain the Month 24 follow-up CCTA. We CANNOT assess the primary outcome of A5333s, change in coronary plaque unless the participant has both the entry and month 24 CCTA

Please contact Devvora Olalere (DOLALERE@mgd.harvard.edu) if you have any questions or concerns.



Did You Miss the Monthly Site Call?

In case you missed it, you can review the [monthly site call slides here](#).

Topics covered include:

- Retention
- American Heart Month, with special presentation by the Puerto Rico Site
- LOA Submission/Updated ACTG LPC
- LDMS Preloads and Quick Add
- Medications Log
- Mechanistic Substudy Updates



As Heart Month comes to a close, we would like to share some photos from REPRIEVE teams across the US who promoted heart health awareness and the REPRIEVE trial this month. Sites were overwhelmingly positive about their participation in this effort.

***"The REPRIEVE campaign has given us an extra push to do some outreach we may not have done without the campaign."** - Bob Bucklew, Outreach Coordinator, Site 2501, Case CRS.*



The UT Southwestern REPRIEVE Team in their **Go Red For Women Day** attire for Heart Month



Case CRS's Heart Health Awareness table in the John T. Carey Special Immunology Unit waiting

room at University Hospitals Cleveland Medical Center



The **Puerto Rico AIDS CRS REPRIEVE** Team hosted a Heart Health Awareness event and table at their clinic in San Juan.

Thank you to all sites that hosted Heart Health Awareness tables and events!

New *My Heart Matters Blog* by Follow YOUR Heart



The **Follow YOUR Heart Campaign** invites you to read the newest **My Heart Matters blog post**, [Women Supporting Women in the Community](#). This blog addresses why HIV community organizations are beneficial to women and how women can find HIV community organizations near them. This is helpful for providers and a great resource to share with participants!

The **My Heart Matters blog** is a great resource to help facilitate communication between REPRIEVE investigators and women with HIV who are interested in learning more about heart health, research participation, and the REPRIEVE trial. Please share this [webpage](#) with your participants. The blog is updated every other month.

REPRIEVE In the News

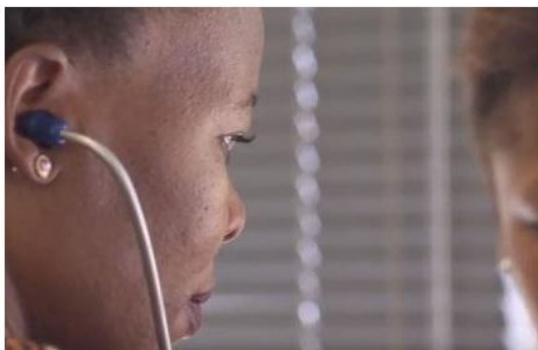
NIAID (National Institute of Allergy & Infectious Disease) featured REPRIEVE on their blog! The post features a summary of REPRIEVE and its importance for those living with HIV, just in time for Heart Health Awareness Month. [Read the article here.](#)

Happy Heart Month: What People Living with HIV Should Know

[NIAID Now](#) | February 14, 2018

Today marks not just a time to exchange valentines and chocolates, but also the midpoint of [American Heart Month](#). Did you know people living with HIV are at an increased risk of experiencing cardiovascular disease? Fortunately, NIH-supported research is getting to the heart of the problem.

Effective anti-HIV medications dramatically reduced the number of AIDS-related deaths in the United States. However, because people with HIV are now able to live longer than before, cardiovascular disease has emerged as a leading cause of death



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

Letter of Amendment, Version 3.0 #2, dated 04/14/17

Letter of Amendment, Version 3.0 #3, dated 01/19/2018

MOPS Version 3.0: dated 09/20/2017

A5332 LPC for ACTG Sites: Version 3.0 dated 02/02/2018

A5332 LPC for Non-ACTG Sites: Version 3.0 dated 09/21/2017

These documents are on the [A5332 PSWP](#)

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

For A5333s please use

Protocol: Version 3.0 dated 01/28/2016

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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