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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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



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!

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment CRS	138
31441	Byramjee Jeejeebhoy Government Medical College (BJMC) CRS	108
12401	Joint Clinical Research Centre /Kampala CRS	71
31946	Tropical Medicine Foundation	54
11301	Barranco CRS	48
31802	Thai Red Cross AIDS Research Center	41
31924	Instituto de Infectologia Emilio Ribas CRS	37
30022	Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS	34
31954	Centro de Referencia e Treinamento	29
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	20
12701	Gaborone CRS	20
31879	Mount Sinai Downtown CRS	16
31927	HGNI HIV Family Care Clinic HHFCC	15
31864	UT Southwestern	15
31925	Hospital Escola Sao Francisco de Assis	15
31915	Federal University of Minas Gerais CRS	14
31784	Chiang Mai University HIV Treatment CRS	13
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	12
6101	University of Colorado Hospital CRS	10
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	10
11302	San Miguel CRS	10
31980	Palmetto Health Clinical Trial Department	9
2501	Case CRS	8
30329	Columbia Physicians and Surgeons CRS	7
6201	Penn Therapeutics CRS	7
8950	Family Clinical Research Unit	7
1601	Duke University Medical Center	7
12301	SOWETO	7
31788	Alabama CRS	6
31786	New Jersey Medical School-Clinical Research Ctr. CRS	6
31889	Toronto General Hospital	6
31918	Hospital Federal dos Servidores do Estado	6



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 \geq 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.



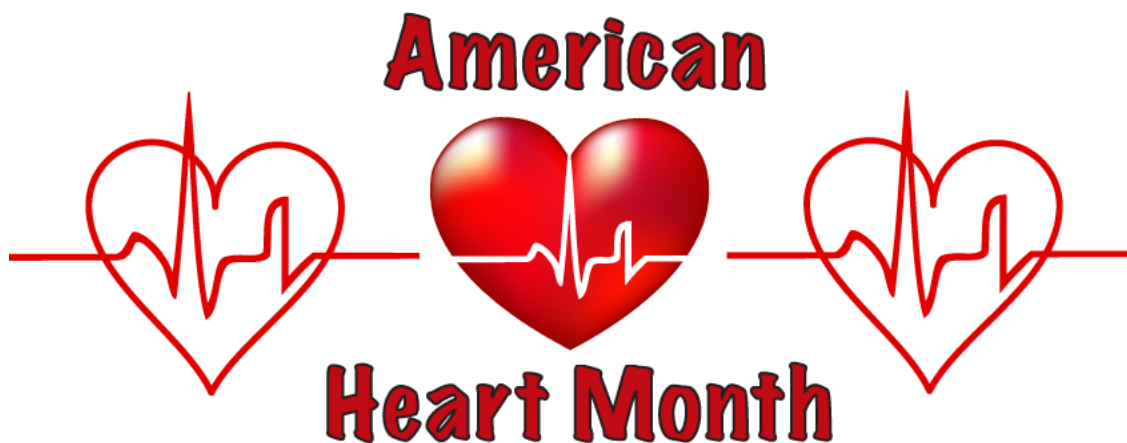
Next Monthly Site Call

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.



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](https://www.hiv.gov/croi) summaries, which recaps day two of CROI!

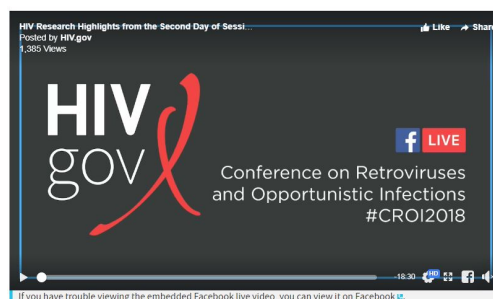
- Check out the **first video** on this webpage, where Dr. Carl Dieffenbach, Director of NIH's DAIDS, discussed interim results on a study of a vaginal ring for HIV Prevention & studies

about heart disease among PLWH, where

REPRIEVE is mentioned

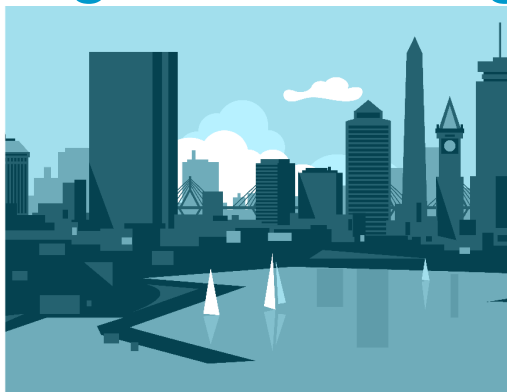
- o Discussion about HIV and CVD by Dr. Dieffenbach and Anne Rancourt begins at 13:33 and discussion of REPRIEVE begins at 15:00

Our coverage from the 2018 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston continued yesterday with three interviews with Federal HIV leaders who shared perspectives about the science coming out of the conference and its implications for HIV prevention, care, and treatment.



NIH's Dr. Carl Dieffenbach Discussed Interim Results on a Study of a Vaginal Ring for HIV Prevention & Studies about Heart Disease among PLWH

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.

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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