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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

February 12th, 2018

5836 participants are enrolled

54 participants enrolled last week!

302 participants are in screening

118 sites are open for enrollment

27 sites enrolled at least 1 participant in the past week

40 sites screened at least 1 participant in the past week

Since the last newsletter, 284 participants have been enrolled. **Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.**

REPRIEVE Substudy Updates

Both the Mechanistic Substudy of REPRIEVE (A5333s) and the PREPARE Substudy (A5361s) have reached their target enrollment!

Thank you to all sites enrolling in these substudies for the amazing effort to complete enrollment.

**Thank You to All Sites Enrolling Participants
Week of February 7th, 2018!**

University of Washington AIDS CRS

Rush University CRS

The Miriam Hosp (TMH) CRS

Vanderbilt Therapeutics (VT) 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
SOWETO
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
Thai Red Cross AIDS Research Center
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
Mount Sinai St. Luke's CRS
Toronto General Hospital
School of Medicine, Federal University of Minas Gerais CRS
Centro de Pesquisas Clinicas ICHCFMUSP CRS
Instituto de Infectologia Emilio Ribas CRS
HGNI HIV Family Care Clinic HHFCC
Maple Leaf Research
Tropical Medicine Foundation
Centro de Referencia e Treinamento
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, [713 participants have been enrolled](#), which is incredible! Less than 1,000 participants are needed to meet this challenge. We'll get there if approximately 65 participants are enrolled each week between now and April 30th, 2018!

Check out the standings below:

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment (CART) CRS	108
31441	Byramjee Jeejeebhoy Government Medical College (BJMC) CRS	91
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	41
31946	Tropical Medicine Foundation	39
31924	Instituto de Infectologia Emilio Ribas CRS	35
11301	Barranco CRS	34
31802	Thai Red Cross AIDS Research Center	32
30022	Les Centres GHESKIO Clinical Research Site CRS	26
31954	Centro de Referencia e Treinamento	25
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	17
31915	School of Medicine, Federal University of Minas Gerais CRS	13
31879	Mount Sinai Downtown CRS	12
31927	HGNI HIV Family Care Clinic HHFCC	12
31925	Hospital Escola Sao Francisco de Assis	12
31864	UT Southwestern	11
12701	Gaborone CRS	11
31784	Chiang Mai University HIV Treatment CRS	11
6101	University of Colorado Hospital CRS	7
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	7
2501	Case CRS	6
30329	Columbia Physicians and Surgeons CRS	6
31788	Alabama CRS	6



Important Reminders

Submit Version 3.0, LOA #3 to DAIDS PRO

Upon receiving IRB/EC and any other applicable regulatory entity approvals for Version 3.0, LOA #3, sites are required to submit an LOA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC).

A copy of the LOA registration notification, along with the LOA itself and any IRB/EC correspondence, should be retained in the site's regulatory files.

Submitting a Packet for Adjudication?

If you are submitting materials to the Data Coordinating Center (DCC) for adjudication, include an up to date AE LOG printed from OpenClinica.

The printed AE Log should include the full participant AE record for the duration of study-follow up. Data entry for the event in question should be complete as known at the time source documents are

sent to the DCC. Please see instructions in section 6.1.3 of the REPRIEVE (A5332) MOPS for more details and instructions to print the AE Log from OpenClinica.

AE Logs with handwritten AEs are not acceptable for formal adjudication. Submitting an up to date, printed AE Log with all adjudication packets will prevent extra work.

Submit your CAP (if needed)

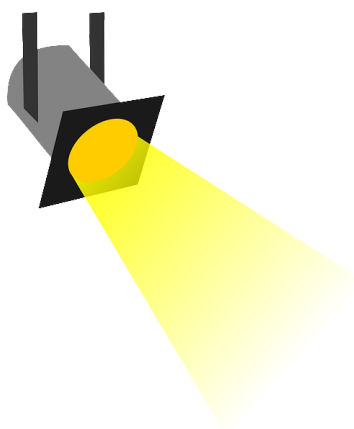
In January, site PIs (of sites activated for more than 25 weeks) received site performance evaluations from the Site Selection and Performance Committee. In those letters, some sites were asked to submit a corrective action plan (CAP) to address any performance deficiencies. **If your site was asked to submit a CAP, please do so as soon as possible.** You can submit your CAP to Laura Sanchez, SSPC Coordinator, at lsanchez12@partners.org.

Remember Retention!

Sites shared some excellent retention ideas in the Retention Survey that were featured in the last newsletter and during the Monthly Site Call. [Click here](#) to read more. **Participant engagement in REPRIEVE will help to ensure retention and ultimately the overall success of the trial.**

Save the Date

The **next monthly site call will be Tuesday, February 20th 1:00 PM ET.** Watch for the email announcement from Barbara Bastow that will include the agenda and conference line detail. We hope you can join!



Site Spotlight: CRS 31441 Byramjee Jeejeebhoy Government

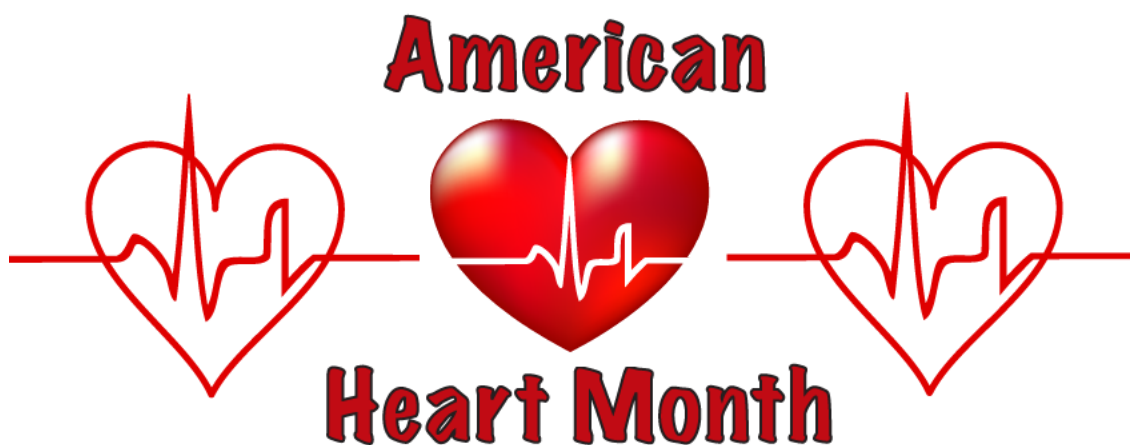
Medical College (BJMC)



Located in [Pune, Maharashtra, India](#), the BJMC site has only been activated in REPRIEVE for 26 weeks and the team there has already enrolled 172 participants! The team credits the following strategies for their successful recruitment:

- **Proper training of site staff** to identify eligible participants from a large number of patients registered at site's ART center.
- Connecting to participants- **"people do not care how much you know until they know how much you care"**.
- Explaining research questions to participants in **simple language helps to minimize screening failure** rate.
- Shortening the turnaround time for screening and eligibility by **effective clinic and laboratory coordination**.
- Last but not least, **a great, dedicated team matters**.

Thank you to the REPRIEVE Team at BJMC for their hard work and great contributions to the trial!



Heart Month @ Puerto Rico AIDS CRS

Despite the recent devastating effects of Hurricane Maria in Puerto Rico, the REPRIEVE Team in San Juan, PR worked together to host an incredibly fun and successful **Heart Month** event!





Thank you to this incredible team for putting on this great event and for sharing your pictures with us.

Heart Month takes place during the **ENTIRE** month of February, there is still time to organize a Heart Health table at your site, it is a wonderful way to promote HIV and heart health and promote REPRIEVE!

[Click here](#) to see how you can do this at your site.

REPRIEVE Investigator's Meeting at CROI 2018

Tuesday, March 6th between 12:15-1:45 PM ET at the Boston Marriott Copley Place



Agenda

Keynote presentation by [Ahmed Tawakol, MD](#), Co-Director of Cardiac MR PET CT at MGH

Important REPRIEVE updates

Q&A

You **MUST RSVP** for this event, if you did not receive an invite and are planning to attend, please email **Laura Sanchez** at lsanchez12@partners.org.

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 (new!)

MOPS Version 3.0: dated 09/20/2017
A5332 LPC for ACTG Sites: **Version 3.0 dated 02/02/2018 (new!)**
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@fstfr.org



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