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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

March 26th, 2018

6210 participants are enrolled

60 participants enrolled last week!

402 participants are in screening

119 sites are open for enrollment

27 sites enrolled at least 1 participant in the past week

38 sites screened at least 1 participant in the past week

Since the last newsletter, **123** 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 19th, 2018!**

University of Pittsburgh CRS

The Miriam Hosp (TMH) CRS

Penn Therapeutics CRS

Weill Cornell Uptown 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
Trinity Health and Wellness Center
Houston AIDS Research Team CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
Alabama CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
Wake Forest University
Mt Sinai West CRS
Chronic Viral Illness Service of McGill University
School of Medicine, Federal University of Minas Gerais CRS
HGNI HIV Family Care Clinic HHFCC
Capital Medical Associates
Tropical Medicine Foundation
Augusta University
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, **1083 participants have been enrolled**, we are getting closer to the goal of enrolling 1500 participants! If 70 participants are enrolled each week between now and the first week of May we will meet the challenge. Stay tuned for updates.

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	144
31441	Byramjee Jeejeebhoy Government Medical College (BJMC) CRS	110
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	88
31946	Tropical Medicine Foundation	60
11301	Barranco CRS	54
31802	Thai Red Cross AIDS Research Center	45
31924	Instituto de Infectologia Emilio Ribas CRS	37
30022	Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS	37
31954	Centro de Referencia e Treinamento	31
12701	Gaborone CRS	30
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	26
11302	San Miguel CRS	21
31927	HGNI HIV Family Care Clinic HHFCC	17
31879	Mount Sinai Downtown CRS	16
31864	UT Southwestern	16
31925	Hospital Escola Sao Francisco de Assis	15
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	15
31915	School of Medicine, Federal University of Minas Gerais CRS	15
31784	Chiang Mai University HIV Treatment CRS	13
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	12
31980	Palmetto Health Clinical Trial Department	11
6101	University of Colorado Hospital CRS	10
6201	Penn Therapeutics CRS	9
2501	Case CRS	8
8950	Family Clinical Research Unit	8
12301	SOWETO	8
31788	Alabama CRS	8
30329	Columbia Physicians and Surgeons CRS	7
1601	Duke University Medical Center	7
31918	Hospital Federal dos Servidores do Estado	7
11201	Durban International CRS	7
1001	University of Pittsburgh CRS	7
31786	New Jersey Medical School-Clinical Research Ctr. CRS	6
31889	Toronto General Hospital	6
31871	Bluegrass Care Clinic/University of Kentucky Research FDN CRS	6

Non-Adjudicated Events

Don't forget that detailed information is being collected on events of interest. These events do not go through a formal adjudication process which is why they are referred to as "Non-Adjudicated Events".

Non-Adjudicated Events include:

Non-cardiovascular Disease Events not Associated with Death

- AIDS-defining events (including AIDS-defining cancers)
- Non-AIDS-defining cancers (except squamous/basal cell of the skin)
- End-stage kidney disease (requiring initiation of dialysis or renal transplantation, see 6.2.4 below)
- End-stage liver disease (cirrhosis or hepatic decompensation requiring hospitalization)
- Incident diabetes mellitus requiring the use of hypoglycemic agents



Other Events Requiring Reporting

- Incident hypertension
- Incident active hepatitis B (HBV) infection
- Incident active hepatitis C (HCV) infection
- Incident venous thromboembolism (VTE)
- Incident pulmonary thromboembolism (PTE)

Identifying these events and reporting them as per section 6.2 of the REPRIEVE (A5332) MOPS is very important!



Q. Is Herpes Simplex virus (HSV) exclusionary per section 4.2.14 of the protocol? What is considered active or resolved HSV?

A. In most situations, HSV infection does not automatically exclude a person from participation, eg, an HSV oral or genital outbreak would not be exclusionary. However, a person with a serious HSV infection (eg, HSV encephalitis or esophagitis requiring IV treatment or hospitalization) would be excluded per 4.2.13 of the protocol.

Q. A potential participant's blood pressure was slightly elevated at screening although previous measurements were always normal. The elevated BP will make the 10-year ASCVD risk score too high for eligibility--what should I do?

A. Blood pressure is somewhat variable and can be intermittently elevated depending on a number of things (caffeine, activity prior to the visit, etc.). It would be appropriate to recheck the blood

pressure. Have participants return, assure they are relaxed, sitting in a quiet area without their legs crossed, and check the blood pressure again. You may use any blood pressure reading within the 90 day window specified in the protocol and you can use the lowest blood pressure obtained when it is rechecked.

Measuring Site Performance

Curious about how your site's performance is measured by the Site Performance and Selection Committee (SSPC)? Read on for details!

- Site performance is evaluated on a continual basis.
 - Important issues brought to the attention of site PI.
- Twice a year (in January and July) the SSPC formally reviews cumulative performance and letters are sent to PIs
- The Site Selection and Performance Committee (SSPC) evaluates each site's:
 - Enrollment
 - Retention / On and Off Treatment Rates
 - Specimen management
 - Data management
 - EAE reporting

Important Targets to be Aware of

- **Enrollment**
 - Target is approximately 2-4 participants enrolled per month per site
- **Retention / Study Treatment**
 - Target is $\leq 5\%$ annual loss to follow up
 - Target is $\leq 5\%$ off study treatment and still on study.
- **Data management**
 - Target is complete data entry within 3 weeks of visit
 - Target is to address data queries within 3 weeks of receipt
- **Laboratory management**
 - Target is to ship 100% of specimens within 90 days of data entry
 - Target is to ship specimens according to the rules in the Lab Processing Chart (on the PSWP)
- **EAE Reporting**
 - Target is 100% of EAEs reported within 3 reporting days of site awareness



For more details, please review the Site Performance Plan (SPP) on the REPRIEVE PSWP



LDMS Training Resources

The Laboratory Data Management System (LDMS) website (<https://www.ldms.org>) offers links to numerous training resources that can help familiarize laboratory staff with the LDMS.

The Training menu includes:

- upcoming workshops and webinars and a link to register for training and,
- more information about the content and format of training events.

The Resources menu includes:

- LDMS user manuals
- general and project-specific documentation
- training materials (workbooks and quizzes)
- LDMS video tutorials such as:
 - Completing PBMC Processing Information
 - Locating Specimens Not Stored,
 - Shipping for REPRIEVE
 - Specimen Management for REPRIEVE
 - Storage Management for REPRIEVE,
 - Specimens Not in Storage Report
 - These tutorials are also on the Frontier Science YouTube channel:
<https://www.youtube.com/user/FSTRFfilms>

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, Apr 9** is the data entry deadline.

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



Did You Miss the Monthly Site Call?

If so, [please find the March call slides attached](#).

Topics discussed:

- Version 4.0 full protocol amendment (status update!)
- Protocol registration and submission requirements; change of key personnel
- Non-adjudicated events
- Measuring Site Performance
- Specimen Shipping
- CROI Meeting Summary

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.

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@fstf.org



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