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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

October 22nd, 2018

7144 participants are enrolled

18 participants enrolled in the past week

185 participants are in screening

116 sites are open for enrollment

14 sites enrolled at least 1 participant in the past week

26 sites screened at least 1 participant in the past week

Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.

**Thank You to All Sites That Enrolled At
Least 1 Participant in the Past Week!**

UCSF HIV/AIDS CRS
 Washington University Therapeutics (WT) CRS
 Durban International CRS
 Chennai Antiviral Research and Treatment (CART) CRS
 Parirenyatwa CRS
 Columbia Physicians and Surgeons CRS
 Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
 Whitman-Walker Health CRS
 Thai Red Cross AIDS Research Center
 Positive Health Clinic
 U of Miami Infectious Disease Research Unit Jackson Memorial Hosp
 School of Medicine, Federal University of Minas Gerais CRS
 Centro de Pesquisas Clinicas ICHCFMUSP CRS
 HGNI HIV Family Care Clinic HHFCC



Don't forget, we are in our final push to the finish line! The REPRIEVE Leadership Team wants to recognize the *extra* effort and cost of recruiting these final participants.

We are keeping track of enrollment from September 10th until the enrollment of the 7500th participant!

The top 3 enrolling sites over the course of the challenge, will receive \$1000 USD, \$750 USD, or \$500 USD respectively for the extra effort to enroll.

Any site that enrolls more than 5 participants during the course of the campaign will receive 100 USD.

Check out the current standings below!

Standing	Site Name and Number	Participants Enrolled Since 9/10/18
1 st Place	Parirenyatwa CRS 30313	21
2 nd Place	Thai Red Cross AIDS Research Center Site 31802	9
3 rd Place	HGNI HIV Family Care Clinic Site 31927	7
4 th Place (<i>Tied</i>)	Durban International CRS 11201	6
4 th Place (<i>Tied</i>)	Gaborone CRS 12701	6
5 th Place	GHEKIO-INLR CRS 30022	5

December 3rd, 2018: Next DSMB Meeting

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 important dates in your calendar and note that **Friday, November 9th**, is the next important deadline to resolve any outstanding queries.

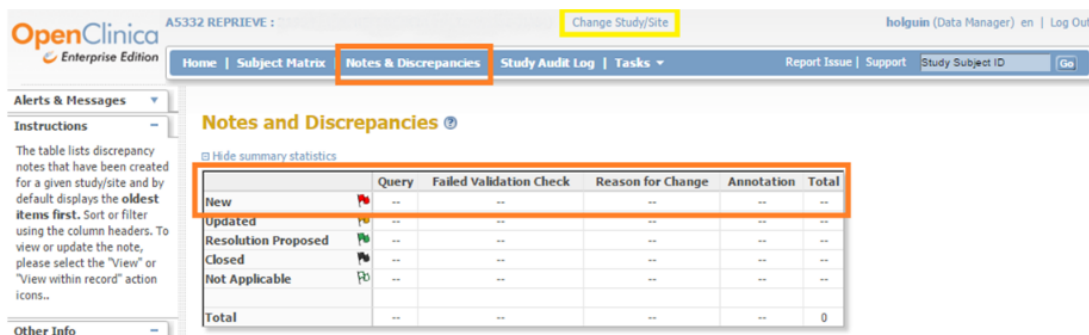
Task		Deadline* (2018)
Sites	Latest date for the occurrence of an evaluation for which complete data is expected for inclusion in this DSMB review	Sep 30 (Sun)
Sites	All data for visit through Sep 30 entered into <u>OpenClinica</u>	Oct 8 (Mon)
Sites	All adjudication packets for potential MACE events with a work-up complete by Mar 31 submitted to DCC (MGH)**	Oct 12 (Fri)
Sites	All outstanding queries resolved	Oct 22 (Mon)
Sites	Respond to last minute outstanding queries	Nov 9 (Fri)
All	DSMB Meeting	Dec 3 (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.

Instructions to See Outstanding Queries in OpenClinica

- 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/queries: <https://www.youtube.com/watch?v=gf9v0nj3WMO>



REPRIEVE (A5332) Coenrollment Guidelines are Updated!

All ACTG studies listed on the table below have been evaluated for co-enrollment by the REPRIEVE team and the other study team leadership. If a study is listed as allowable for coenrollment, coenrollment has been approved by both teams and sites can proceed with coenrollment as outlined in section 4.5 of the study protocol.

For additional notes on these studies and coenrollment guidelines on 10 additional non-ACTG studies [click here](#).

Co-enrollment status	Inflammation TSG	Hepatitis TSG	Cure TSG	WHISC SC	ARTS TSG	Neuro CSG	TB TSG
Allowed	A5322 A5355*	A5320 A5360 A5379 A5380	A5321 A5345* A5354* A5369* A5370*			A5324* A5341s	
Not Allowed	A5363				A5359 A5378		All current TB studies
Under Consideration	A5383		A5367	A5376	A5357 A5364 A5375 A5377		

A5128/A5243: Host Genetics Study → Please coenroll at any visit when there is a blood draw.

NEW My Heart Matters Blog by Follow YOUR Heart!



REPRIEVE

<http://followyourheart.reprievetrial.org/news/>

Join the Study » Women's Health Info Printable Advertisement Materials **My Heart Matters: Blog**

The REPRIEVE **Follow YOUR Heart Campaign** invites you to read the latest *My Heart Matters Blog*, [A Midlife \[Symptom\] Crisis](#). This blog post, written by Dr. Sara Looby, PhD, ANP-BC, reviews the relationship between menopause symptoms and HIV: *Is HIV affecting menopause symptoms or is menopause affecting HIV symptoms?*



Helpful LDMS Tips

Making changes in LDMS *after* samples have been shipped

Any time you need to make changes to the information entered to LDMS regarding information printed on the label please remember to:

- Enter a comment in LDMS to explain the discrepancy between the printed label and LDMS.
- Notify the recipient lab or repository (BRI) of all the changes you have made.

**Note that you do not need to re-label tubes unless it is a Participant ID correction.*

Frontier Science (FSTRF) is Proud to Announce the Release of LDMS Version 7.1 for the Web!

Below is a summary of key features added to the application with this release. For more information about this version, including detailed release notes and the 7.1 user manual,

go to the [LDMS website](#).

Summary of updates in version 7.1:

- Overall performance improvement and optimization throughout the application
- Ability to scan when moving items/samples in storage
- General bug fixes

*Frontier Science has automatically upgraded all labs' databases
from version 7.0 to version 7.1.*

Important Reminder About IATA/DOT Certification

Anyone shipping specimens must have completed International Air Transport Association (IATA) Dangerous Goods Training, IATA training covers the fundamentals of shipping dangerous goods by air according to the IATA regulations.

Shipping of hazardous materials is regulated by the U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA).

Any person shipping or receiving hazardous materials or dangerous goods must be properly trained on IATA/DOT policies and procedures.

It is important that specimens shipped to BRI are shipped according to IATA regulations in order to assure they arrive safely.

IATA/DOT training is valid for 2 years. Please verify that anyone shipping specimens at your site has certification that is up to date.



Don't Forget About the LDMS Related Resources and Training Materials Available On the [LDMS website](#).

Below are a few highlights of what is available on the website!

- **New & Announcements:**
 - <https://www.ldms.org/news/>
- **Project Specific Documentation:**
 - <https://www.ldms.org/resources/project-documentation/>
- **User Manuals:**
 - <https://www.ldms.org/resources/manuals/>
- **YouTube Training Videos:**
 - <https://www.ldms.org/resources/videos/>

The Final Five Campaign!

REPRIEVE has less than 500 participants to enroll over 100 active sites...

You do the math!

...If each site enrolls *at least* 5 more participants the trial will reach target accrual!!

REPRIEVE Leadership is asking each site to set a goal of enrolling *at least* 5 more participants to bring us across the finish line!



REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 4.0 dated 03/28/2018

V4 LOA #1 dated 05/16/2018

MOPS Version 4.0 dated 10/16/18 (new version!)

A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018

A5332 LPC for Non-ACTG Sites Version 4.0 dated 07/23/2018

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

MOPS Version 4.0 dated 04/10/2018

A5333s LPC Version 4.0 dated 03/23/2018

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@fstfrf.org



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