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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

September 24th, 2018

7064 participants are enrolled

29 participants enrolled in the past week

129 participants are in screening

116 sites are open for enrollment

20 sites enrolled at least 1 participant in the past week

20 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!

Specialty Care Center CRS

Cincinnati CRS

Case CRS

Wits Helen Joseph Hospital CRS (Wits HJH CRS)

Chennai Antiviral Research and Treatment (CART) CRS

SOWETO

Gaborone CRS

Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS

Parirenyatwa CRS

Byramjee Jeejeebhoy Government Medical College (BJMC) CRS

Orlando Immunology Center CRS

Whitman-Walker Health CRS

University of Cape Town Lung Institute

Thai Red Cross AIDS Research Center

VA West Los Angeles Medical Center

Los Angeles LGBT Center

UT Southwestern

Hamilton Health Sciences

School of Medicine, Federal University of Minas Gerais CRS

Centro de Referencia e Treinamento



With approximately 500 participants to enroll, 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 first REPRIEVE 500 standings will be announced in the next newsletter!

Announcing the Final Five Campaign!

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

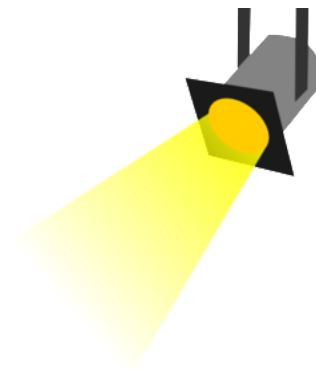
You do the math!

...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!



Site Spotlight: University of Miami Infectious Disease Research Unit at Jackson Memorial Hospital CRS



"The mission of the University of Miami is to work with and support our patient population with disparities and contribute to the community."



Jackson Memorial Hospital REPRIEVE Team (from left to right): Dr. Jose Castro, Sendy Puerto, Annie Salvarrey, Lisa Rohn, Vivian Pastrana, Dr. Dushyantha Jayaweera, Tom Tanner (RN)

REPRIEVE Leadership wants to highlight the **outstanding performance of the team at Jackson Memorial Hospital**. When a neighboring site closed, they truly stepped up to the plate and seamlessly handled the transfer of 26 REPRIEVE participants. Since then, the Jackson Memorial team has continued to perform above and beyond trial standards, setting and meeting ambitious enrollment goals, maintaining perfect retention, and demonstrating exemplary data management and laboratory practices.

When asked, "What makes you excited about REPRIEVE?", the Jackson Memorial Study team said the following:

"We are very excited to participate in the REPRIEVE study as we believe it will be a landmark study in the prevention of cardiovascular disease in people with HIV. We believe we can contribute towards answering very important questions that affect our aging minority population that is infected with HIV. "

The Jackson Memorial REPRIEVE team also wanted to acknowledge their DAIDS OCSO Project Officer, Ms. Blanca Castillo, "who supports and encourages our site".

Thank you, Jackson Memorial team, for your continued efforts on the REPRIEVE Trial!!

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 **Monday, October 8th** is the data entry deadline.

For any potential MACE identified, **ALL work-ups MUST be complete by September 30th and packets submitted to the REPRIEVE DCC by October 12th** (see MOPS section 6.0). If you have any questions email Saeyun Lee at slee158@mgh.harvard.edu

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 OpenClinica	Oct 8 (Mon)
Sites	All adjudication packets for potential MACE events with a work-up complete by Sep 30 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.



Coming Soon: New DAIDS Regulatory Support Center (RSC) Website!

The DAIDS RSC Website is getting a fresh new look and moving to a government-hosted site! The new DAIDS RSC Website will continue to provide current information to facilitate Adverse Event Reporting, Protocol Registration, Protocol Development, and more.

What will be new?

- The URL for the site will change
- The style of the site will match the NIAID website.
- There will be some minor organization updates.
- The process for making website updates will change.

What does this mean for you?

- Any bookmarks for the DAIDS RSC Website will need to be updated.
- Any documents that reference the DAIDS RSC Website and include a link to the site will need to be updated.
- The DAIDS RSC could be contacted as early as possible when developing documents that will be posted to the site.

Stay tuned for more information... or contact the DAIDS RSC Website Support Team at: DAIDSRSCWebsiteSupport@tech-res.com (+1301-897-1783).



ATTN: Changes in GlobalRPh

GlobalRPh has made some changes to their website which has resulted in some changes in their conversion calculator, especially lipids. The [online calculator](#) currently cannot convert from mmol/L to mg/dL.

Please use [this calculator](#) for conversions from Système International units (SI) to conventional units (CU). We will work on updating the A5332 MOPS to reflect this change.

REPRIEVE in the News!
Los Angeles Daily News: "[Clinical](#)



Trial Seeks to Prevent Heart Disease in Those Living with HIV"

An Orange County Register article about Dr. Judith Currier and the REPRIEVE Trial was featured in the Los Angeles Daily News, San Bernardino Sun, and 8 other Southern California News Group newspapers!

"For people who are living with HIV and doing well on medications, this study will give us a good look at some of the challenges they face and the clinical issues or problems people living with HIV have", Dr. Currier says.

Read the full article [here](#).



Dr. Judith Currier, professor of medicine and chief of the Division of Infectious Diseases at UCLA Health.



Reminder About Timing of Vaccinations

With flu season approaching in the Northern Hemisphere, remember that sites may administer vaccinations on the same day as REPRIEVE study visits but please do so after any blood to be banked has been drawn.

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 04/10/2018

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@fstrf.org



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