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!* 

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**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."

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

<table>
<thead>
<tr>
<th>Task</th>
<th>Deadline* (2018)</th>
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<tbody>
<tr>
<td>Sites</td>
<td>Latest date for the occurrence of an evaluation for which complete data is expected for inclusion in this DSMB review</td>
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<tr>
<td>Sites</td>
<td>All data for visit through Sep 30 entered into OpenClinica</td>
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<tr>
<td>Sites</td>
<td>All adjudication packets for potential MACE events with a work-up complete by Sep 30 submitted to DCC (MGH)**</td>
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<tr>
<td>Sites</td>
<td>All outstanding queries resolved</td>
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<tr>
<td>Sites</td>
<td>Respond to last minute outstanding queries</td>
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<tr>
<td>All</td>
<td>DSMB Meeting</td>
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*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 should be contacted as early as possible when developing documents that will be posted to the site.

Stay tuned for more information... or contact the RAIDS 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.

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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