Site Newsletter 01/22/2018

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REPRIEVE Trial Status: January 22nd

5552 participants are enrolled
70 participants enrolled last week!
383 participants are in screening
118 sites are open for enrollment
29 sites enrolled at least 1 participant in the past week
36 sites screened at least 1 participant in the past week

During the week of January 8th, 90 participants were enrolled! This is an incredible accomplishment. Thank you for your excellent work!

Substudy Updates

Mechanistic Substudy of REPRIEVE (A5333s)
776 participants are enrolled (only 24 participants left to enroll!)
PREPARE Substudy (A5361s)

571 participants are enrolled (only 29 participants left to enroll!)

Thank You to All Sites Enrolling Participants Week of 01/15/2018!

Johns Hopkins University CRS
University of Washington AIDS CRS
Washington University Therapeutics (WT) CRS
Puerto Rico AIDS Clinical Trials Unit CRS
Weill Cornell Uptown CRS
Family Clinical Research Unit
Barranco CRS
Chennai Antiviral Research and Treatment (CART) CRS
Joint Clinical Research Centre (JCRC)/Kampala CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Denver Public Health
Houston AIDS Research Team CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
Chiang Mai University HIV Treatment CRS
New Jersey Medical School-Clinical Research Ctr. CRS
Whitman-Walker Health CRS
Thai Red Cross AIDS Research Center
UT Southwestern
Mount Sinai Downtown CRS
Mount Sinai Beth Israel CRS
Chronic Viral Illness Service of McGill University
Toronto General Hospital
School of Medicine, Federal University of Minas Gerais CRS
Instituto de Infectologia Emílio Ribas CRS
Hospital Escola Sao Francisco de Assis
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Centro de Referencia e Treinamento
Full Speed to 1500 Challenge Standings!

We know you haven’t forgotten that we need every site’s help to enroll 1500 participants between December 4th, 2017 and April 30th, 2018. 429 participants have already been enrolled.

The goal is to enroll at least 15 participants per site through the last week in April.

Many sites will win!

- 1st place site wins $500
- 2nd place site wins $250
- All other sites that enroll 15 participants by May 1st will win $100

Some sites have already met the challenge, while others are on track, is your site listed below????
Did you Miss the Last Monthly Site Call?

If so, please take a moment to read the call summary and you can review the slides here.

Topics covered include:

- **Important:** The DSMB Recommendations to cease enrollment of people with a risk score less than 2.5% were discussed. A Letter of Amendment (LOA) is being issued as quickly as possible to formalize this change. Sites are asked to limit screening of this population to the extent possible until the LOA is distributed. The slides from the Monthly Site Call have more details and FAQs about this recommendation.
- Transmitting ECGs
- Retention
- New content on the DAIDS RSC website
- Important lab tips
- Mechanistic substudy updates

*Save the date: the next team site call is February 20*
Don't Forget to Transmit ECGs!*  
There are some very important steps about ECGs we want to remind you of:

Remember to transmit ECGs to IQVIA (formerly Quintiles). For detailed transmission instructions see the Investigator's Manual, section 4.2 that was included with your ECG machine. The manual is also located on the A5332 PSWP, Training Folder.

- Document on the CRF (DGW0105) that the ECG recording has been performed.
- Keep the ECG printout with the PI or PI designees signature with the source document.

Section 3.2 of the REPRIEVE MOPS has additional details about the ECG performed at entry.

*For the majority of sites in Brazil, please follow the instructions in the REPRIEVE MOPS, APPENDIX IV

Transmit ECGs after the ECG is performed by either:

1. Batch Transmission
2. Individual ECG Transmission

It is recommended to do a Batch Transmission as this saves time and ensures that all ECGs are transmitted.

For batch transmissions, please determine a regular schedule to transmit ECGs to IQVIA so that ALL ECGs are received in a timely fashion.

We have been reaching out to sites that have entered that an ECG was performed on the DGW0105 CRF in OpenClinica but for which an ECG has not been transmitted. Thank you to sites who have responded to these emails, if you have received an email about missing ECGs and have not yet responded please do so!

If you have an ECG related question please do not hesitate to email: qecg.helpdesk@quintiles.com, if your email make sure to include your site ID and PI.
Create a REPRIEVE Heart Health Awareness Table at Your Site

February 2018 is American Heart Month!

To help improve consumer education about HIV-associated heart disease and the REPRIEVE trial, we invite you to create a "REPRIEVE Heart Health Awareness" table at your clinic or research site during the month of February!

Steps to Creating a Heart Health Awareness Table

1. Designate a space for a table in your waiting room or clinical research site.
   - Can be self-service or staffed with a team member.

2. Download Educational Materials about HIV and Heart Health
   - **FREE** materials from the REPRIEVE website [here](#).
   - **FREE** materials from the Follow YOUR Heart website [here](#).
   - **FREE** materials from the FDA Office of Women's Health website [here](#).
   - **FREE** general heart health educational materials from the [NHLBI](#).
   - **FREE** heart-healthy recipes [here](#).

3. Find additional ideas and materials from the REPRIEVE Outreach Toolkit [here](#).
Check Out the Retention Survey Results!

Thank you to everyone who completed the survey about retention! We have compiled the results below.

The Clinical Coordinating Center is working on some of the ideas you shared so stay tuned...

And don't forget, the annual Participant Newsletter will be out in April! Sites have shared that this is an excellent retention tool. Click here for previous newsletters.

If you have ideas for the newsletter or know of a REPRIEVE participant who might want to be interviewed for the next newsletter, please email Katie Fitch, CCC Project Manager at kfitch@partners.org

<table>
<thead>
<tr>
<th>Rank Participant Retention Ideas</th>
<th>Unique Strategies Shared by Sites</th>
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</thead>
<tbody>
<tr>
<td>Birthday cards</td>
<td>• Make the experience for participants as smooth and enjoyable as possible</td>
</tr>
<tr>
<td>Thank you cards</td>
<td>— Assure that staff are welcoming and respectful</td>
</tr>
<tr>
<td>Printed participant newsletter</td>
<td>— Make sure that participants are comfortable, something a simple as offering water during a visit or a small snack or coffee (after a fasting visit) can go a long way</td>
</tr>
<tr>
<td>Certificate of appreciation</td>
<td>— Time study visits with clinic visits when possible</td>
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<tr>
<td>Pen or similar token of appreciation</td>
<td>• At every study visit remind participants of the goals of REPRIEVE</td>
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<tr>
<td>Gift card for site to host event</td>
<td>• Remind participants why their participation in REPRIEVE is important on a personal level as well as for the HIV community</td>
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<tr>
<td></td>
<td>• Highlight the importance of follow-up visits and review with each participant their visit schedule</td>
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<td></td>
<td>• Provide monthly check in calls if possible and offer visit reminder calls</td>
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</tbody>
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Retention-related FAQ:

Q: A participant told us a while ago that they no longer wanted to be on study medication, so we completed the Premature Treatment Discontinuation Visit and
have been following the participant on-study/off-study treatment per protocol. Now the participant wants to re-initiate study medication. How do we proceed?

The specific criteria for premature and permanent termination of study treatment are listed in the protocol section 8.1. If the participant expresses a desire to stop study medication permanently for other reasons, please discuss their concerns and the importance of staying on study medication.

Every effort should be made to keep participants on the study medication if it is determined safe to do so. If the treatment discontinuation is going to be permanent, complete a Premature Treatment Discontinuation Visit. (Temporary stops only require an update of the study medication stop date on the TXW0295 Medication Log.)

Even after the participant stops study treatment permanently, the team is happy to have participants re-initiate study medication unless it is otherwise prohibited (such as during and after a pregnancy).

When the participant re-initiates study medication:

- Contact the data management team at reprieve.dmc@fstrf.org and request that the RP0003 Final Study Medication Status CRF be removed.
- Create a new entry on the TXW0295 Medication Log. Because the study medication discontinuation date is already in the TXW0295 Medication Log, and you will be entering the study medication re-initiation date, the team will be able to determine the total duration of study medication discontinuation.
Did you know that the Data Management Center/FSTRF now lists WebLDMS training for REPRIEVE on their website?

Click here for a list of future training dates and to register!

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Save the Date!

REPRIEVE Investigators' Meeting at CROI 2018

Tuesday, March 6th between 12:15-1:45pm
Boston Marriott Copley Place

An invite via email will go out to Site PIs toward the end of this month. Please RSVP as space is limited.

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REPRIEVE (A5332): Are you up to date?

For A5332 please use

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

MOPS:
MOPS Version 3.0, dated 09/20/2017
A5332 LPC for ACTG Sites:
Version 3.0 dated 09/21/2017
A5332 LPC for Non-ACTG Sites:
Version 3.0 dated 09/21/2017

These documents are on the A5332 PSWP

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REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

For A5333s please use
MOPS: Version 3.0 dated 06/05/2017
A5333s LPC: Version 3.0, dated 09/21/2017

These documents are on the A5333s PSWP

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For future reference, all newsletters are available on the REPRIEVE Website

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at reprieve.news@fstrf.org.

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