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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

May 7, 2018

6552 participants are enrolled

41 participants enrolled last week

324 participants are in screening!

118 sites are open for enrollment

22 sites enrolled at least 1 participant in the past week

29 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 Enrolling Participants Week of April 30th, 2018!

Cincinnati CRS

The Miriam Hosp (TMH) CRS

Family Clinical Research Unit

Wits Helen Joseph Hospital CRS (Wits HJH CRS)

Barranco CRS

San Miguel CRS

Chennai Antiviral Research and Treatment (CART) CRS

SOWETO

Joint Clinical Research Centre (JCRC)/Kampala CRS

Gaborone CRS

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

Parirenyatwa CRS

Byramjee Jeejeebhoy Government Medical College (BJMC) CRS

Houston AIDS Research Team CRS

Chiang Mai University HIV Treatment CRS

New Jersey Medical School-Clinical Research Ctr. CRS

Los Angeles LGBT Center

HGNI HIV Family Care Clinic HHFCC

Tropical Medicine Foundation

Inova Heart and Vascular Institute

Center of Translational AIDS Research, Temple University

Palmetto Health Clinical Trial Department

The Final Results Are In!

Thank you to each and every site for helping REPRIEVE to reach this important goal, approximately 1500 participants were enrolled in 5 short months- this is an **amazing effort** and REPRIEVE Leadership is so appreciative of every team working together.

Below is a list of sites who won prizes, staff from the REPRIEVE CCC will be reaching out to you shortly to make arrangements to get your prize to your team.

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment CRS	159
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	140
31441	Byramjee Jeejeebhoy Medical College (BJMC) CRS	119
31946	Tropical Medicine Foundation	76
11301	Barranco CRS	67
30022	Les Centres GHESKIO Clinical Research Site CRS	51
31954	Centro de Referencia e Treinamento	49
31802	Thai Red Cross AIDS Research Center	48
12701	Gaborone CRS	45
31924	Instituto de Infectologia Emilio Ribas CRS	43
31730	GHESKIO Institute of Infectious Diseases & Reproductive Health	34
11302	San Miguel CRS	34
31927	HGNI HIV Family Care Clinic HHFCC	27
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	24
31864	UT Southwestern	21
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	19
31925	Hospital Escola Sao Francisco de Assis	19
31915	School of Medicine, Federal University of Minas Gerais CRS	19
31879	Mount Sinai Downtown CRS	16
12301	SOWETO	16
31784	Chiang Mai University HIV Treatment CRS	15

Retention Tool: Participant Newsletter

The 3rd annual participant newsletter is now available!


REPRIEVE
www.reprievetrial.org
1-877-29-HEART
Participant Newsletter
A Note from REPRIEVE Leadership: Partners in REPRIEVE
Meet Other REPRIEVE Participants

- Participant newsletters are an excellent retention tool.
- The English version can be found online here
  - Non-English versions are in the process of being IRB approved and will be available soon.
- We can also provide **hard copies**!
  - In English, Spanish, Canadian French, Brazilian Portuguese, and Haitian Creole
- Want to receive hard copies for participants? Please email Laura Sanchez at lsanchez12@partners.org by **Friday, May 11th**
- Sharing the newsletter with participants is a great way to keep participants engaged in REPRIEVE!

*The participant newsletter has been approved by the IRB for the REPRIEVE CCC, however, please submit to your local IRB/EC as per your local requirements.

Forthcoming Changes to Enrollment: 10-year ASCVD Risk Score

Following the email sent on Monday, April 30th about the forthcoming Version 4.0, LOA #1, the team has received a few questions regarding when to stop enrollment of participants with a 10-year ASCVD risk score <5.0%

The team would like to clarify that if you have already screened participants with a 10-year ASCVD risk score <5.0%, you may enroll those participants until the LOA is approved. However, we ask that you immediately stop screening additional participants with a risk score <5.0%.

If you have any questions about this please email the team at actg.corea5332@fstrf.org.

Thank you for your attention to this matter and thank you for all your hard work to continue to enroll participants in REPRIEVE.

http://www.reprievetrial.org/outreach-toolkit/

Utilize the REPRIEVE Outreach Toolkit!

We worked with our communications colleagues at NIAID to bring sites an online outreach toolkit. This webpage contains guidance and resources to help boost enrollment and retention at your site!

Check it out at:

http://www.reprievetrial.org/outreach-toolkit/

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 **Friday, May 11th,** is the next important date. All outstanding queries are to be resolved at the close of business.

Thank you for your attention to this matter, having complete data for the DSMB review is very important.

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)

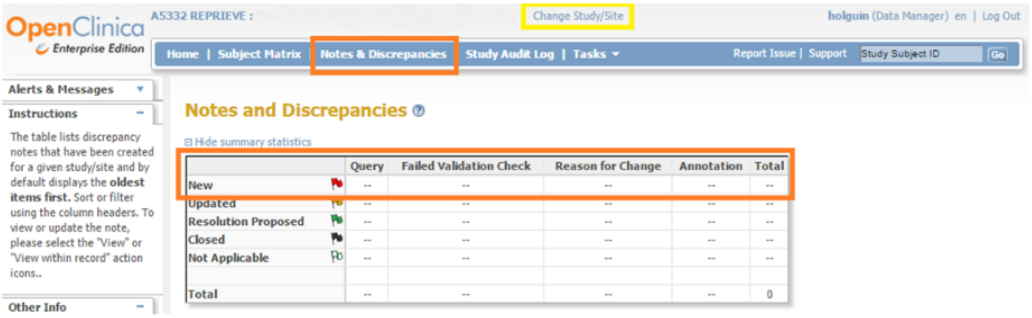
*Deadlines are Close of Business on the given date unless otherwise noted

** 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

Instructions to See Outstanding Queries

- 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: https://www.youtube.com/watch?v=gf9v0nj3WM0



LDMS 101: Condition Codes

The following information is important for LDMS users, please forward to your lab team members if they do not already receive the REPRIEVE Newsletters.

If the Primary tube is underfilled

1. At the Primary tube level, change the LDMS code from SAT (Satisfactory) to SHV (Short Volume).
2. Replace the primary tube volume in the preload with the accurate volume of blood. (You may be asked to confirm that you intend to modify the preload)
3. Do not cascade the code to all aliquots as it may only apply to the Primary.
4. Add a short explanation in the Primary tube comment section. (i.e. difficult stick, vein collapsed, etc...)

If the volume in the aliquot is less than expected

1. At the aliquot level, change the LDMS code from SAT to SHV.
2. Change the aliquot volume to reflect what was banked.
3. Save and reprint the label.
4. Repeat for all concerned aliquots.
5. If desired, add a short explanation in the Aliquot comment section.

If an aliquot was frozen after the specified time allowed

1. At the aliquot level, change the LDMS code from SAT (Satisfactory) to PST (Past Specified Time).
2. Cascade to all concerned aliquots
3. If desired, add a short explanation in the aliquot comment section.

If the aliquot is already frozen: Work fast and in dry ice, remove the incorrect label, and adhere the label with the correct volume. Secure the label with a rubber band if needed.

If the blood arrived after specified time: At the primary tube level, change the LDMS code from SAT (Satisfactory) to PST (Past Specified Time).

Please Join the Next Monthly

Tuesday, May 15th between 1:00 - 2:00 PM ET!

One important topic to be discussed will be the forthcoming Version 4.0 LOA #1 and ideas to maintain enrollment at your site.

Watch for the email from Laura Moran with dial-in details and the agenda.

Check out the Latest NIAID Now Blog!

Why does HIV Pose a Greater Threat to Women's Hearts?

This blog highlights findings from a recent publication in the *Journal of Acquired Immune Deficiency Syndromes* by REPRIEVE team members Markella Zanni, MD and Katie Fitch, MSN, among others, which compares differences between coronary plaque manifestations among women and men living with HIV.

Reference: B Foldyna, *et al.* Sex Differences in Subclinical Coronary Atherosclerotic Plaque Among Individuals with HIV on Antiretroviral Therapy. (link is external) *Journal of Acquired Immune Deficiency Syndromes* DOI: 10.1097/QAI.0000000000001686 (2018).

REPRIEVE (A5332): *Are you up to date?*

For A5332 please use

Current Protocol Documents:

Protocol Version 4.0 dated 03/28/2018

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 03/22/2018

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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