REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 06/12/2017

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REPRIEVE Trial Status: June 12th

3632 participants are enrolled

229 participants are in screening

111 sites are open for enrollment

31 sites have enrolled at least 1 participant in the past week

35 sites have screened at least 1 participant in the past week

Thank You to All Sites Enrolling Participants Week of 06/05/2017!

Johns Hopkins University CRS
UCSF HIV/AIDS CRS
Univ. of Miami AIDS Clinical Research Unit(ACRU) CRS
Washington University Therapeutics (WT) CRS

Ohio State University CRS
Cincinnati CRS
Northwestern University CRS
The Ponce de Leon Ctr. CRS
Weill Cornell Chelsea CRS
Family Clinical Research Unit
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Hospital Nossa Senhora da Conceicao CRS
SOWETO
Gaborone CRS
Houston AIDS Research Team CRS
Whitman-Walker Health CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
UT Southwestern
Hamilton Health Sciences
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
James J Peters VA Medical Center
School of Medicine, Federal University of Minas Gerais CRS
Hospital Federal dos Servidores do Estado
Abbott Northwestern Hospital
HGNI HIV Family Care Clinic HHFCC
Capital Medical Associates
Tropical Medicine Foundation
Inova Heart and Vascular Institute
Petersen HIV Clinic, U of Arizona

Enroll Patients in REPRIEVE Over the Entire Range of Permissible ASCVD Risk Thresholds

			Site country					
Characteristic		Total (N=3577)	Botswana (N=55)	Brazil (N=227)	Canada (N=61)	South Africa (N=230)	Thailand (N=383)	USA (N=2621)
ASCVD risk score (%)	Median (Q1-Q3)	3.5 (1.6-6.2)	0.9 (0.4-2.6)	2.5 (1.1-4.2)	5.3 (2.7-7.3)	1.3 (0.6-3.8)	1.4 (0.8-2.9)	4.2 (2.3-6.6)
	10%-90%	0.7-8.3	0.2-5.2	0.6-7.1	1.8-9.9	0.3-5.7	0.5-5.2	1.1-8.8

Overall Trial Median = 3.5%

To ensure that results from REPRIEVE are generalizable to individuals with HIV, **enroll patients over the entire range of permissible ASCVD risk thresholds, up to 15%.**

Revised CRF: EVW0344-- Study Medication Pill Count Adherence (v1.01)

Attached is the new version of the EVW0344 - Study Medication Pill Count and Adherence CRF.

This new version (v1.01) is now on the FSTRF portal in the Forms Management Utility, and is also available to be keyed in OpenClinica. Be sure to switch to v1.01 as soon as you have IRB/EC approval for Protocol Version 3.0 LOA #2, which eliminates collection of pill count data.

v1.00 will remain available for a short time for sites who do not yet have LOA #2 IRB approval.

Below is a brief rundown of changes:

- Changes were made to accommodate the removal of the study medication pill count in Protocol Version 3.0 LOA #2.
- SECTION A, containing questions on Dispensation Date, Pill Amount Dispensed, and Pill Amount Returned, has been removed.
- SECTION B has been expanded, most importantly in reference to the last 7 days of adherence to study medication.

Important to note:

- This CRF has "Pill Count" in the title but pill count data are no longer collected.
- This CRF is NOT a questionnaire and does not need to be maintained with source documents.
- Sites may continue to ask participants to bring ALL study product (opened AND unopened) with them to each study visit so a pill count can be done but this is no longer a protocol requirement and the data will not be recorded on the CRF.

If anyone has any questions, please email holguin@fstrf.org or reprieve.dmc@fstrf.org

Spotlight on The Gaborone Team (Site 12701)

The REPRIEVE Team at Gaborone CRS, located in Gaborone, Botswana, has enrolled 55 participants in just 16 weeks. The team shared their path to successful enrollment below:

"Our **recruitment officers** are stationed in the clinic and are integrated into the clinic system, participating in daily clinic activities such as assisting with clerical work and collection of specimens. This provides knowledge of the clinic processes which allows the recruiters to **incorporate recruitment activities into the daily clinic processes with minimal disruption**. It also facilitates a good working relationship with staff which has resulted in willingness of clinic staff to assist the recruiters with required documentation for the pre-screening process.

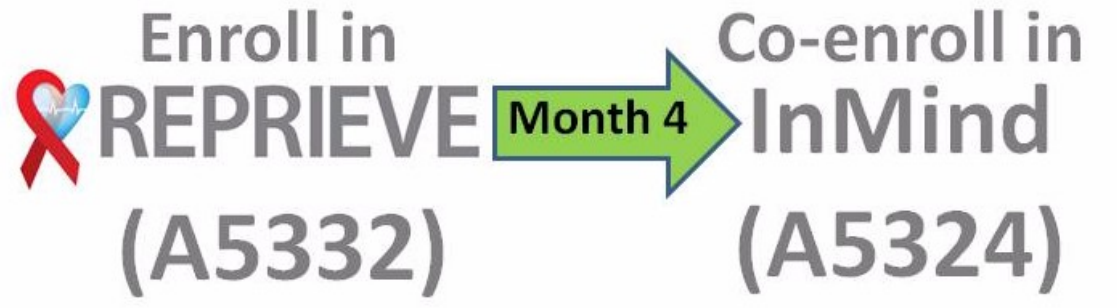
Recruitment officers use a **recruitment script to guide the pre-screening process**. This contains talking points with basic study information to be discussed with the potential participants and basic eligibility criteria. **Real-time feedback from clinicians** to recruitment officers on the outcome of referrals helps to improve the quality of pre-screening and ensure steady flow of participants who are eligible for screening.

The team has **weekly recruitment reviews on team email, and fortnightly meetings to address REPRIEVE specific issues** which include recruitment reviews, challenges and strategies for improvement."

Thank you to the Gaborone team for sharing their effective recruitment strategies!

A Note About Co-enrolling in REPRIEVE (A5332) and InMind (A5324)

For ACTG sites only: Are you considering co-enrolling a participant in REPRIEVE (A5332) and Integrase and Maraviroc Intensification in Neurocognitive Dysfunction (InMIND) (A5324)? If so, enroll in REPRIEVE (A5332) first and then co-enroll in InMind (A5324) after the month 4 visit for REPRIEVE.



For comprehensive co-enrollment guidelines (updated 10/28/2016) click here or download them from the Co-enrollment Guidelines folder on the REPRIEVE (A5332) PSWP

REPRIEVE in the News!

Check out the latest article about REPRIEVE in the Baltimore Sun, Study explores way to stave off heart attacks in HIV patients. This article features Jamilla Howard, RN and a REPRIEVE participant from Johns Hopkins (site 201) in Baltimore, MD, USA.

A big thank you to the Johns Hopkins team for helping to make this happen!

2017 ACTG Network Meeting

The annual ACTG Network Meeting is coming up! The meeting will take place at the Omni Shoreham Hotel in Washington, DC between June 25th - June 29th. Go to the ACTG website for more details and click here to download a flyer with REPRIEVE related sessions during the meeting.

The **REPRIEVE Session** will be held on Wednesday, June 28th 12:30 - 1:30 PM. Although registration is not required, we are asking anyone interested in attending to register so we can anticipate how many people will be attending. Please click here to register.

If you are a non-ACTG site in the DC area, please join us at the meeting (note that the hotel block for the meeting is restricted to ACTG sites). For those outside the DC area, we will share the REPRIEVE presentations with you after the meeting, and discuss key topics on the July and August team-site calls.

Is Your Site Participating in PREPARE (A5361s)?

PREPARE currently has over 130 participants enrolled! However, we don't want to miss any potential enrollments! Please remember to make every effort to enroll participants into PREPARE:

- **What are the accrual/enrollment goals?**
  - Ideally, 100% of all new A5333s participants should be co-enrolled into PREPARE at the A5332/A5333s enrollment visit.
    - A5333s is enrolling so quickly...PREPARE needs ALL of these enrollees if possible
    - Please note that these participants should be enrolled at the A5333s visit, prior to starting study drug.
  - 1 participant newly enrolling only into A5332 every other month and enroll 50% of those already enrolled into A5332/A5333S at the site.

Please remember that PREPARE visits do not add a lot of additional time and participation in PREPARE does provide additional remuneration for the participant.

PREPARE Frequently Asked Questions

Q: I have a participant coming in for an A5332/A5333s enrollment visit. I know this visit is going to be really busy, is it ok if I just enroll the participant in 4 months at the follow-up visit?

A: The main priority is to enroll participants in PREPARE at baseline. As enrollment for A5333s nears completion, we are quickly losing our chance to enroll participants PRIOR to starting study drug. We are asking sites to make every effort to enroll these participants at the A5332/A5333s visit. Participants previously enrolled in A5333s (intended to include those enrolled prior to site activation for A5361s) are also welcome up to the month 24 visit.

Q: A participant enrolled in A5332 and A5333s in July 2016, when I called her to remind her of her upcoming A5332/A5333s month 12 visit, she expressed interest in PREPARE...can she enroll in PREPARE at this visit?

A: YES!!! The participant is enrolled in A5332 and A5333s, so they can enroll at ANY A5332 or A5333s visit, up to the month 24 visit.

If your site is planning on participating in PREPARE but is not yet activated, get activated so that your site is eligible for accrual competitions- to be announced soon!

If you have questions about PREPARE, please contact Kristine Erlandson, MD at Kristine.Erlandson@ucdenver.edu

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, revision 3, dated 05/08/2017

A5332 LPC for ACTG Sites:

Version 3.0 dated 05/04/2017

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 05/04/2017

These documents are on the A5332 PSWP

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

For A5333s please use

Protocol: *Version 3.0 dated 01/28/2016*
MOPS: NEW Version 3.0 dated 06/05/2017
A5333s LPC: *Version 3.0 dated 05/04/2017*

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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