

READ THE NEWSLETTER FOR THE NEXT ENROLLMENT CHALLENGE!



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 11/27/2017

Table of Contents

- [REPRIEVE Trial Status](#)
- [We need your ideas for retention!](#)
- [Introducing the New Enrollment Challenge!](#)
- [Study Medication Adherence](#)
- [Enroll Older Participants in REPRIEVE!](#)
- [What's New on the PSWP?](#)
- [Remember to Enroll in the Mechanistic Substudy \(A5333s\)](#)
- [REPRIEVE Key Protocol Deviations](#)
- [Site Spotlight: Hospital Conceição Infectious Diseases Clinic 12201](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)

REPRIEVE Trial Status: November 27th

Over **5000** participants
are now enrolled in
REPRIEVE!!!

Thank you to everyone
for the tremendous
effort to help us reach
another enrollment
milestone!

5056 participants are enrolled
308 participants are in screening

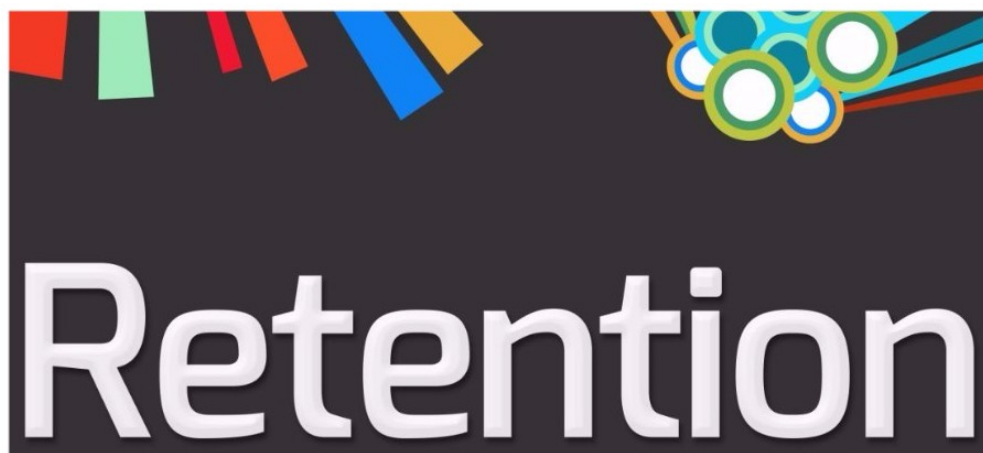
117 sites are open for enrollment

22 sites enrolled at least 1 participant in the past week

21 sites screened at least 1 participant in the past week

Thank You to All Sites Enrolling Participants Week of 11/20/2017!

Brigham and Women's Hospital Therapeutics CRS
Johns Hopkins University CRS
University of Pittsburgh CRS
Ohio State University CRS
Chapel Hill CRS
Family Clinical Research Unit
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Chennai Antiviral Research and Treatment (CART) CRS
Hospital Nossa Senhora da Conceicao CRS
Gaborone CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Chiang Mai University HIV Treatment CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
Mount Sinai Downtown CRS
Positive Health Clinic
Hospital Federal dos Servidores do Estado
Instituto de Infectologia Emilio Ribas CRS
Hospital Escola Sao Francisco de Assis
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Centro de Referencia e Treinamento



As REPRIEVE moves forward, we are thinking of different ways to keep participants engaged.

We need your ideas for retention!

Please take a minute to vote on our retention ideas and suggest your own

HERE: <https://www.surveymonkey.com/r/FFLLDVR>

Introducing the New Enrollment Challenge!



Full Speed to 1500



We need everyone's help to **enroll 1,500 more participants by the end of April 2018!** 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

If your site enrolls 3 participants per month from December through April, your site will win \$100! The clock starts ticking the week of December 4th and ends May 1st.

With every site's help, we can enroll at full speed to meet the 6,500 participant milestone!

Study Medication Adherence

Using simple, everyday language, please briefly review the following with study



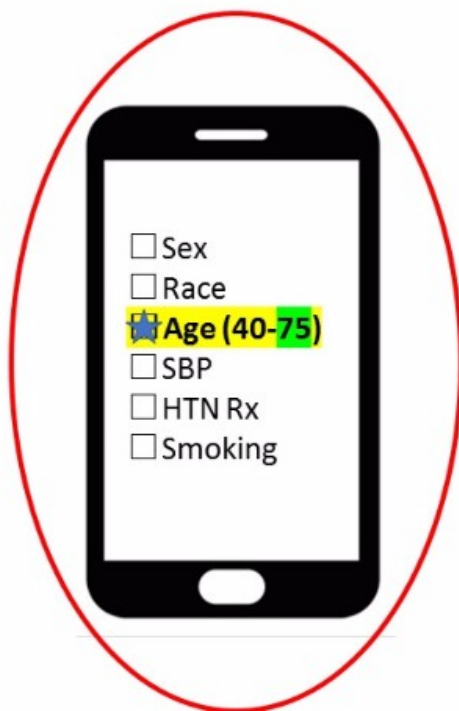
participants at every visit post screen.

- Name of study medication.
- Indication for pitavastatin and why it is being studied in REPRIEVE
- Dose, route, and frequency of study medication administration. Remind participants that the study medication should be taken at the same time each day, with or without food.
- In order for the study medication to work effectively, it must be taken every day.
- Instruct participants to take ONE tablet per day and to complete one bottle before starting another.
- Review potential side effects

Ensure that participants have study medication after every study visit (i.e If study product is dispensed directly to participants by pharmacy and not sent to the clinic for dispensation, please ensure participants picked it up and are taking as directed.

Enroll Older Participants in REPRIEVE!

This an excellent way to enroll additional participants in the higher ASCVD risk ranges



What's New on the PSWP?

- Coenrollment Guidelines dated 11/17/2017
- FAQs for A5332, dated 11/17/2017
- FAQs for A5333s, dated 11/17/2017

Remember to Enroll in the Mechanistic Substudy (A5333s)!

For participating sites - the Mechanistic Substudy only needs to enroll **64 participants to reach the enrollment target of 800** and we need your help to get there! Please remember to keep asking every participant screening for REPRIEVE (A5332) if they would also like to participate in the Mechanistic Substudy. Enrollment in the Mechanistic Substudy in the past few weeks has been excellent, thank you!

Remember! Enrollment strategies for the substudy include:

- Explain the purpose
- Explain the procedures in simple terms
- Explain the additional compensation
- Show pictures, such as a healthy heart and a heart with blocked arteries, a CT scan machine, etc.

REPRIEVE Key Protocol Deviations are deviations from the protocol that the team is interested in tracking.

REPRIEVE Key Protocol Deviations may differ from what is reported to your IRB and/or DAIDS.

[Click here](#) to view slides that briefly discuss what a **REPRIEVE Key Protocol**



Deviation is as well as how to report these to the REPRIEVE core team.

Site Spotlight: Hospital Conceição Infectious Diseases Clinic 12201



The Hospital Conceição Infectious Diseases team, CRS 12201, located in Porto Alegre, Brazil, has shared their recruitment tips, which you can read below. Thank you to the team at CRS 12201!

Question: What helps your site successfully recruit participants for REPRIEVE?

The Hospital Conceição Infectious Diseases clinic, opened back in 1984, takes care of a large HIV infected population and is a referral center for a large portion of the city of Porto Alegre. The clinic has conducted a large number of different clinical trials and consequently had developed a seasoned multi-professional team.

We see a large number of people living with HIV each month, **more than 1,000 people living with HIV are seen each month**, making it relatively easy to identify potential participants.

Also, **the Community Advisory Board, gives notice of every trial, to stakeholders around the city**, which broadens the catchment area.

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](#)

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

For A5333s please use

Protocol: Version 3.0 dated 01/28/2016

MOPS: Version 3.0 dated 06/05/2017

A5333s LPC: Version 3.0, dated 09/21/2017

These documents are on the [A5333s PSWP](#)

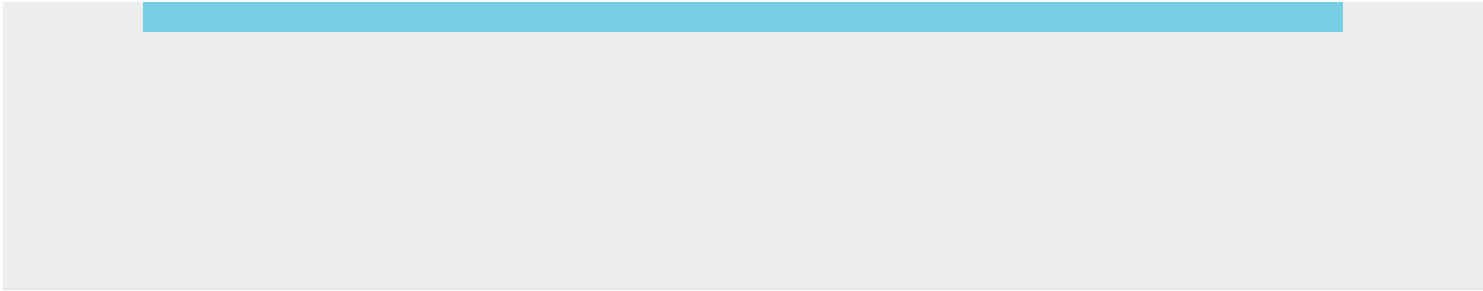


For future reference, all newsletters are available on the [REPRIEVE Website](#)

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

REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, LON 207
Boston, MA 02114

Want to change how you receive these emails?
You can update [your preferences](#) or [unsubscribe from this list](#)



This email was sent to <<Email Address>>
[why did I get this?](#) [unsubscribe from this list](#) [update subscription preferences](#)
Massachusetts General Hospital · 5 Longfellow Place · Boston, MA 02214 · USA

