Is your site amongst the Race to 50% winners?

REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 05/08/2017

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REPRIEVE Trial Status: May 8th

3355 participants are enrolled

248 participants are in screening

112 sites are open for enrollment

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

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

REPRIEVE's Race to 50% Winners!

Congratulations to the **35** sites that enrolled ≥ 4 participants between March 6th and April 28th. **72** participants were enrolled the last week of April making it the **best** enrollment week so far. We are so appreciative of the efforts by all sites to help us meet and exceed the 50% target for April.

REPRIEVE

And the winners are....

RACE to 50% Challenge Winners!	
107	Brigham and Women's Hospital Therapeutics CRS
801	UCSF HIV/AIDS CRS
1504	University of Iowa
2101	Washington University Therapeutics (WT) CRS
2301	Ohio State University CRS
2701	Northwestern University CRS
3652	Vanderbilt Therapeutics (VT) CRS
6101	University of Colorado Hospital CRS
7804	Weill Cornell Chelsea CRS
8950	Family Clinical Research Unit
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)
11201	Durban International CRS
12101	Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
12201	Hospital Nossa Senhora da Conceicao CRS
12301	SOWETO
12701	Gaborone CRS
31470	Denver Public Health
31473	Houston AIDS Research Team CRS
31673	Orlando Immunology Center CRS
31784	Chiang Mai University HIV Treatment CRS
31787	University of Rochester Adult HIV Therapeuitc Network CRS
31788	Alabama CRS
31791	Whitman-Walker Health CRS
31792	University of Cape Town Lung Institute
31802	Thai Red Cross AIDS Research Center
31845	Wake Forest University
31846	University of Mississippi
31849	Los Angeles LGBT Center
31864	UT Southwestern
31871	Bluegrass Care Clinic/University of Kentucky Research FDN CRS
31879	Mount Sinai Downtown CRS
31910	Positive Health Clinic
31915	School of Medicine, Federal University of Minas Gerais CRS
31921	Abbott Northwestern Hospital
31927	HGNI HIV Family Care Clinic HHFCC

Laura Sanchez, research coordinator with the REPRIEVE CCC, will be contacting sites shortly to coordinate prizes. Sites can choose one of the following prizes: a gift card, REPRIEVE t-shirts, recruitment materials kit, a bundle of the 2nd Participant Newsletter, or a REPRIEVE banner.

Welcome!

A warm welcome to the newest sites open for enrollment

31962 Malcom Randall VA Medical Center, Gainesville, FL USA
31980 Palmetto Health at the University of South Carolina, Columbia, SC USA
31914 University of Miami ID CRS/Jackson Memorial, Miami, FL USA

Thank You to All Sites Enrolling Participants Week of 05/01/2017!

Massachusetts General Hospital (MGH) CRS
Johns Hopkins University CRS
UCSD Antiviral Research Center CRS
UCSF HIV/AIDS CRS
University of Pittsburgh CRS
Georgetown University CRS (GU CRS)
University of Southern California CRS
Specialty Care Center CRS
Duke University Medical Center
Rush University CRS
Greensboro CRS
The Ponce de Leon Ctr. CRS
Penn Therapeutics CRS
Weill Cornell Uptown CRS
Family Clinical Research Unit
Durban International CRS
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Hospital Nossa Senhora da Conceicao CRS
Gaborone CRS
Columbia Physicians and Surgeons CRS
Denver Public Health
Chiang Mai University HIV Treatment CRS
University of Rochester Adult HIV Therapeutic Network CRS
Alabama CRS
Whitman-Walker Health CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
University of Mississippi
UT Southwestern
Mount Sinai Beth Israel CRS
Toronto General Hospital
School of Medicine, Federal University of Minas Gerais CRS
Hospital Federal dos Servidores do Estado
HGNI HIV Family Care Clinic HHFCC
Tufts Medical Center
Tropical Medicine Foundation
Inova Heart and Vascular Institute

HIGH RETENTION of REPRIEVE Participants is Essential!

Retention Tip #3: Consistent Communication From the Team and Amongst the Team

- Previous retention tips have included creating a welcoming environment and educating participants about their important role in REPRIEVE. Consistent communication amongst the team and from the team to ensure this is carried out is important.
- During team meetings, make sure you communicate as a team to develop consistent messaging about the importance of participating in REPRIEVE.
- For example, as a team decide that, for every participant at every visit, you will remember to remind participants about the importance of REPRIEVE and develop a consistent message.
- - Sample message: People with HIV are at risk of developing heart disease. A strategy is needed to prevent heart disease, REPRIEVE will determine if statins (pitavastatin) are effective to prevent heart disease for people living with HIV. REPRIEVE will be the largest study to date to answer this important question.
- As new staff come on board, please make sure that they are trained to provide the same messaging with the same frequency and that new staff also understand the importance of creating a welcoming environment.
- Share with other team members any unique strategies you have developed that may improve retention.
- REPRIEVE is a team effort!

Does your site have an effective retention strategy?
Please email Katie Fitch, CCC Project Manager, so your strategy can be shared with other sites in future newsletters and/or on site calls.

FAQ

Q: The requirement for the pill count was removed in Version 3.0, LoA #2. Are participants still required to bring in pill bottles at their study visits?

A: Since the requirement to perform the pill count was removed, participants do not need to bring in pill bottles to their study visits.

NOTE: Although the requirement to perform the pill count has been removed, if it is the preference at your site to continue the pill count, please do so. But please note that this is no longer required by the protocol nor is pill count data required to be entered in OpenClinica.

Q: What constitutes a missed visit?

A: A visit is considered missed as long as there has been no contact with the participant between the start of the visit period and the start of the next visit period. If there has been no contact during this window, the visit is considered missed. However, if there are data from the participant, eg, from a phone conversation, the visit is not considered missed because data are available to be entered.

Click here for the link to an instructional video on “Entering a Missed Visit”

NOTE: If a participant misses a visit when stored specimens are to be collected, eg, the month 12 visit, but returns for the next visit, obtain specimens as per the Lab Processing Chart (LPC) for the month 12 visit, and enter labs in the month 12 folder. See the Lab Tips section below for additional instruction on how to enter these specimens in LDMS.

Announcement: New DAIDS Requirement Protocol Signature Page

As you may know, the Division of AIDS (DAIDS) is implementing a new regulatory requirement, a Protocol Signature Page (PSP).

The PSP will document the commitment of the Investigator of Record (IOR) to conduct the trial in compliance with the protocol as agreed to by the sponsor and in compliance with in-country, state, and local laws and regulations, and other applicable requirements and institutional policies.

REQUIRED ACTION

Have the site IOR sign and date the PSP in Attachment 1. This PSP is affiliated with REPRIEVE (A5332), Version 3.0, Letter of Amendment 2 dated April 14, 2017.

Upload the completed PSP to the DAIDS Protocol Registration System (DPRS) by August 1, 2017.

Send any questions to protocol@tech-res.com.

Signature Authority

The PSP is protocol-specific, and must be signed by the IOR at each participating site. This responsibility cannot be delegated.

Upload to the DPRS

DAIDS requires the PSP to be uploaded to the DPRS, as is done with other regulatory documents.The Regulatory Support Center (RSC) will be tracking the PSP submissions and will contact sites that have not uploaded this PSP by August 1, 2017.

Maintenance of the PSP

Maintain the original PSP in the site's regulatory binder. DAIDS does not require submission of the PSP to an IRB/IEC or regulatory authority, unless required by the regulatory authority.

Monitoring

PPD will start monitoring for the presence of this form during the late third quarter of 2017.

Click here to download the PSP and instructions to upload to DPRS.

- **Did you know?** One of the most frequently reported side effects and reasons for stopping statin therapy is the potential effect of statins on muscle function and quality? PREPARE is investigating this!
- **What is PREPARE?** Pitavastatin to REduce Physical Function Impairment and FRailty in HIV (A5361s) is a REPRIEVE Substudy.
- **Is my site eligible?** Only ACTG sites participating in the Mechanistic Substudy of REPRIEVE (A5333s) may enroll participants to PREPARE.
- **Which participants may enroll?** Ambulatory participants coenrolled in REPRIEVE and A5333s, and ambulatory participants that are newly enrolling to REPRIEVE at A5333s ACTG sites are eligible.
- **How does PREPARE work?**
  - Visits are conducted at the same time as REPRIEVE visits.
  - Take about 15 additional minutes.
  - Require no additional blood draws.
- **What are the benefits?**
  - Additional participant remuneration
  - Additional site funding
  - Site credit
- **What are the accrual goals?**
  - Accrue at least 1 participant newly enrolling into A5332/A5333s a month (ideally ALL participants will enroll into both),
  - 1 participant newly enrolling only into A5332 every other month and,
  - Enroll 50% of those already enrolled into A5332/A5333S at the site.

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

Lab Tips

Below are some important lab announcements. Please forward to your laboratory personnel if they do not already receive the REPRIEVE Newsletter.

Missed Visits and Stored Specimens

If a participant misses a visit when stored specimens are to be collected, eg, the month 12 visit, but returns for the next visit, obtain specimens as per the LPC for the month 12 visit, use LDMS or webLDMS Preloads (depending on your site) for month 12 and add a comment at the Primary tube level to document the missed visit.

Important Reminder for Sites Using FedEx to Ship to BRI

Please make sure to indicate that the samples are shipped **PRIORITY OVERNIGHT** to BRI to assure that samples arrive on time and during BRI's business hours.

Please Use Externally Threaded Cryovials for Stored Specimens

For Stored Specimens Use Externally Threaded Cryovials ONLY and fill only with the volume indicated (i.e. 1.8 mL)—do not overfill.

The cryovials recommended for REPRIEVE are the following:
Sarstedt 72.694.005 or equivalent, 2mL screw cap Micro tube, sterile, externally threaded. Please double check that your laboratory is using these cryovials or an equivalent cryovial.

Check Out the Participant Newsletter!!!

The 2nd Annual Participant Newsletter is available on the REPRIEVE (A5332) PSWP in the Recruitment and Participant Materials folder.

This year's newsletter includes a note from REPRIEVE leadership, study updates, tips for a healthy heart, FAQs for participants, and thoughts from REPRIEVE participants about why they joined REPRIEVE.

Remember: participant newsletters can be an excellent retention and engagement tool, so please distribute the newsletter to your participants. You can print these at your clinic and share them with participants during their next visit, place a pile in the waiting room for others to read, and even post the PDFs on social media or your website.*

Click below for a version in:

English
Spanish
Portuguese
French

*Please note that this newsletter has been approved by the IRB/EC for REPRIEVE's Clinical Coordinating Center, however, please submit to your local IRB/EC as per your local IRB/EC's requirements. If you need a Certificate of Authenticity for the translation, please contact Laura Sanchez, lsanchez12@mgh.harvard.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
New: Letter of Amendment, Version 3.0 #2, dated 04/14/17
MOPS:
New: MOPS Version 3.0, revision 3, dated 05/08/2017
A5332 LPC for ACTG Sites:
Version 3.0 dated 01/04/2017
A5332 LPC for Non-ACTG Sites:
Version 3.0 dated 01/04/2017

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: *Version 3.0 dated 09/02/2016*
A5333s LPC : *Version 3.0 dated 01/04/2017*

These documents are on the A5333s PSWP

Share Tweet Forward

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.

REPRIEVE Trial Clinical Coordinating Center

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