



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 10/24/2016

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REPRIEVE Announcements!



The week of October 17th was a strong enrollment week for REPRIEVE; 46 participants were enrolled from 27 sites! There are now 2138 participants total enrolled and 95 sites are activated.

REPRIEVE's weekly accrual goal for this fall is to enroll at least 50 participants per week. We have gotten really close recently and are confident this goal can be met.

Welcome to our newest sites in South Africa, Site 11101 University of the Witwatersrand Helen Joseph CRS and Site 8950 Family Clinical Research Unit CRS. Also, welcome to our newest domestic sites, Site 31908 Albany Medical College CRS and Site 31964, Center of Translational AIDS Research at Temple

University. We look forward to working with you on REPRIEVE.

REPRIEVE's Fall 50 Updates

Reminder! Between October 1st and December 30th, all sites enrolling an average of 3 participants per month will receive a \$50 gift card and all sites enrolling an average of 4 or more participants per month will receive a \$100 gift card.

Several sites are on track for meeting the milestone after the first month of the Fall 50 competition! Another 13 sites are very close!

Check out the standings below

#	Site Name	Participants Enrolled This Month
12101	Instituto de Pesquisa Clinica Evandro Chagas CRS	20
31802	Thai Red Cross AIDS Research Center	11
30347	University of Illinois at Chicago	5
31784	Chiang Mai University HIV Treatment CRS	5
31788	Alabama CRS	4
31930	Tufts Medical Center CRS	3
2702	Rush University CRS	3
3201	Chapel Hill CRS	3
3203	Greensboro CRS	3
31470	Denver Public Health	3
31673	Orlando Immunology Center CRS	3
31871	University of Kentucky	3
2701	Northwestern University CRS	3

These sites are close to having 3 participants enrolled in October!

#	Site Name	Participants Enrolled This Month
201	Johns Hopkins University CRS	2
1601	Duke University Medical Center	2
6101	University of Colorado Hospital CRS	2
31791	Whitman-Walker Health CRS	2
31881	Mt Sinai St Lukes Morningside Clinic	2
31921	Abbott Northwestern Hospital CRS	2
603	Harbor UCLA CRS	2
701	UCSD Antiviral Research Center CRS	2
6201	Penn Therapeutics CRS	2
31834	AIDS Research Treatment Center of the Treasure Coast	2
31845	Wake Forest University	2
31882	Mt Sinai St Lukes Samuels Clinic	2
31883	Mount Sinai Clinical and Translational Research	2

Site 31843, Medical College of Wisconsin at the Wisconsin AIDS Walk!

Sonija Parker, Site Coordinator at the Medical College of Wisconsin, helped to get the word out about REPRIEVE at the Wisconsin AIDS Walk on October 1.

Despite the rainy weather, spirits were high at the event, where more than 1,000 walkers, runners, community supporters, and volunteers came together.

If your site is interested in receiving promotional materials for REPRIEVE for a similar event, email Laura Sanchez (lsanchez12@partners.org) with details.

Attached is a [list](#) of AIDS Walks/Runs in your local area!



Thank You to All Sites Enrolling Participants Week of 10/17/2016!

- Thai Red Cross AIDS Research Center
- Chiang Mai University HIV Treatment CRS
- UCSD Antiviral Research Center CRS
- Alabama CRS
- Chapel Hill CRS
- Case CRS
- University of Colorado Hospital CRS
- Northwestern University CRS
- Harbor UCLA CRS
- UCLA CARE Center CRS
- Instituto de Pesquisa Clinica Evandro Chagas CRS
- Trinity Health and Wellness Center
- Brigham and Women's Hospital Therapeutics CRS
- Rush University CRS
- University of the Witwatersrand Helen Joseph CRS
- University of Illinois at Chicago
- Florida Department of Health
- Denver Public Health
- University of Kentucky
- Wake Forest University
- Mount Sinai Clinical and Translational Research Center
- Mt Sinai St Lukes Samuels Clinic
- Medical College of Wisconsin
- Mt Sinai St Lukes Morningside Clinic
- Mt Sinai Comprehensive Health Program
- Abbott Northwestern Hospital CRS
- Tufts Medical Center CRS



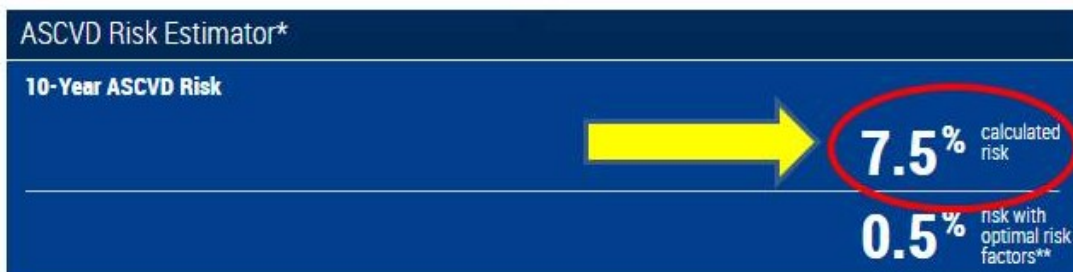
FAQ

Q. After calculating a potential participant's 10-year ASCVD risk estimate, I noticed there are 2 results:

- **calculated risk %**
- **risk % with optimal risk factors**

Which result do I use for eligibility?

A. When assessing eligibility, the calculated 10-year ASCVD risk % is to be used, *not* the risk % with optimal factors.



Q. The Targeted Medical History CRF (HXW0202), which is done at screening, asks for an estimate of exposure to TDF (tenofovir disoproxil fumarate) in Question 10. Should I include exposure to TAF (tenofovir alafenamide) in that estimate?

A. No, the Targeted Medical History CRF (HXW0202) is specifically collecting information about TDF, not TAF. Please estimate TDF exposure only on this CRF.

The Medications Log (TXW0295), which is completed at entry and updated at every visit, collects specific antiretroviral agents that a participant is currently taking, therefore please document current usage of any TAF or TDF according to the instructions in Section C of the Medications Log.

What to do Regarding Potential Open Label Statin Use

Remind your participants to notify you if another clinician is considering statin use for them.

If your participant notifies you of potential open-label statin use, please:

- Follow up with prescribing clinician

- What precipitated consideration of open-label statins?
- Could there have been a potential MACE, like angina?
- Notify the core team if open-label statin use is under consideration at actg.corea5332@fstrf.org



Not Able to Join the Monthly Site Call on Tuesday, October 18th?

Reminder About Potential MACE

The focus of the Monthly Site Call this past week was the importance of reporting all potential Major Cardiovascular Events (MACE) in REPRIEVE.

As a reminder, the goal of REPRIEVE is to determine whether pitavastatin vs. placebo reduces the risk of MACE among HIV-infected individuals with low-to-moderate traditional CVD risk.

In order to properly answer this clinically-relevant question, we need your help in ensuring we don't miss even a single potential MACE!

Please take a moment to review the [slides](#) that were presented. For future reference, these slides and slides from all other Monthly Site Calls are also posted on the REPRIEVE (A5332) PSWP, in the Protocol Training folder.

The next Monthly Site Call will be Tuesday, November 15th at 1:00PM ET. Watch for the email announcement closer to the date.

Timeline for the Next REPRIEVE DSMB Meeting

The next REPRIEVE DSMB meeting will take place on Friday, December 16th.

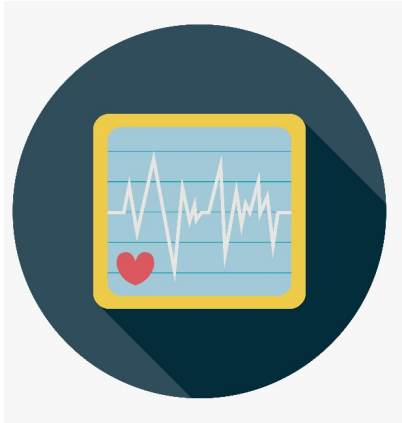
The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial. This timeline will be posted under the Study Monitoring tab on the REPRIEVE (A5332) PSWP for future reference.

Task		Deadline (2016)	Weeks to DSMB
Sites	Latest date for the occurrence of a clinic visit for which complete data must be included in this DSMB review	Oct 28 (Fri)	7
Sites	All data for visits through October 30 entered [note: expedited - within 2 weeks of visit]	Nov 11 (Fri)	5
Sites	All queries resolved by this date	Nov 23 (Wed)	3
All	DSMB Meeting	Dec 16 (Fri)	0

A Reminder About ECGs!

Please make sure you are entering participant demographic information when you perform an ECG. The required information to be entered is outlined in the ECG Training Slides and in the image below. **For example, when prompted to enter the Screening #, please ALWAYS enter the Patient ID (PID).**

Training slides are [attached here](#) and located in the Protocol Training folder on the REPRIEVE PSWP.



Screen Prompt	Data Entry Instructions for Site Staff
REPRIEVE-A5332 <i>*Note: this will be hard-coded into the ECG unit</i>	Skip this field. Press ENTER or F2.
Subject Initials	Subject initials are <u>not</u> being collected, skip this field. Press ENTER or F2.
Subject Gender	Type Female or Male . Press ENTER or F2.
Age	Skip this field. Press ENTER or F2
Screening #	Type in the Patient ID . Press ENTER or F2. <i>(*Note: the PID should not BEGIN with any alpha values. Do not enter the Screening number of the Subject)</i>
Visit Code**	Enter the appropriate visit identifier from the visit schedule (D0 or U). Press ENTER or F2
Study site ID	Type your Site ID Press ENTER or F2



Did You Know the DAIDS Regulatory Support Center Has a New Website?

The url is the same rcc.tech-res.com but if you were linking directly to any file on the old website you will have to update your links.

The new website has some very useful FAQs such as:

If there is information that affects subject participation as a result of protocol amendment /LoA, should the participants re-consented?

Re-consenting participants as a result of an amendment and/or LoA (change or new information that may affect subject participation) is the decision of the CRS's IRB/EC. CRSs should follow their IRB/EC/RE/Approving Entity instructions for re- consenting participants as a result of the amendment and/or LoA.

Where should completed Financial Disclosure (FD) forms/statements be filed?

All original, completed and signed FD forms/statements must be filed and retained in a CRS's regulatory binder along with the original and/or updated, signed Form FDA 1572 for that study. These forms should not be submitted to DAIDS or the Network Operations Center unless requested.

Beginning First Quarter 2015, monitors will verify during a review of a site's regulatory binder that every investigator listed on all Form FDA 1572s has accurately completed and signed the required FD disclosure form/statement. In the event FD forms/statements are collected, sites will be required to provide the original signed documents and to keep a copy of all forms/statements in the regulatory binders at the site.

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)

Letter of Amendment, Version 3.0 #1 dated 08/17/16

MOPS:

Version 3.0, revision 1, dated 09/09/16

A5332 LPC for ACTG Sites:

Version 3.0 dated 09/28/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 09/27/2016

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 09/29/2016*

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@fstrf.org.



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