



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 05/23/2016

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Updates: REPRIEVE's March Madness Competition!!!

Week 7 of the March Madness Competition is now complete, there are 6 more weeks to go and the competition is really heating up!

UT Southwestern CRS is still holding strong in the number 1 spot - this team has enrolled 14 participants since April 1st!!! We also have a new site in the bracket since our last newsletter. **Chapel Hill CRS** is now part of our Fantastic Five, and **Florida Department of Health CRS** has moved up to join the Thrilling Three.

Below is the newest bracket with site enrollment numbers since April 1st, 2016 when the competition began.

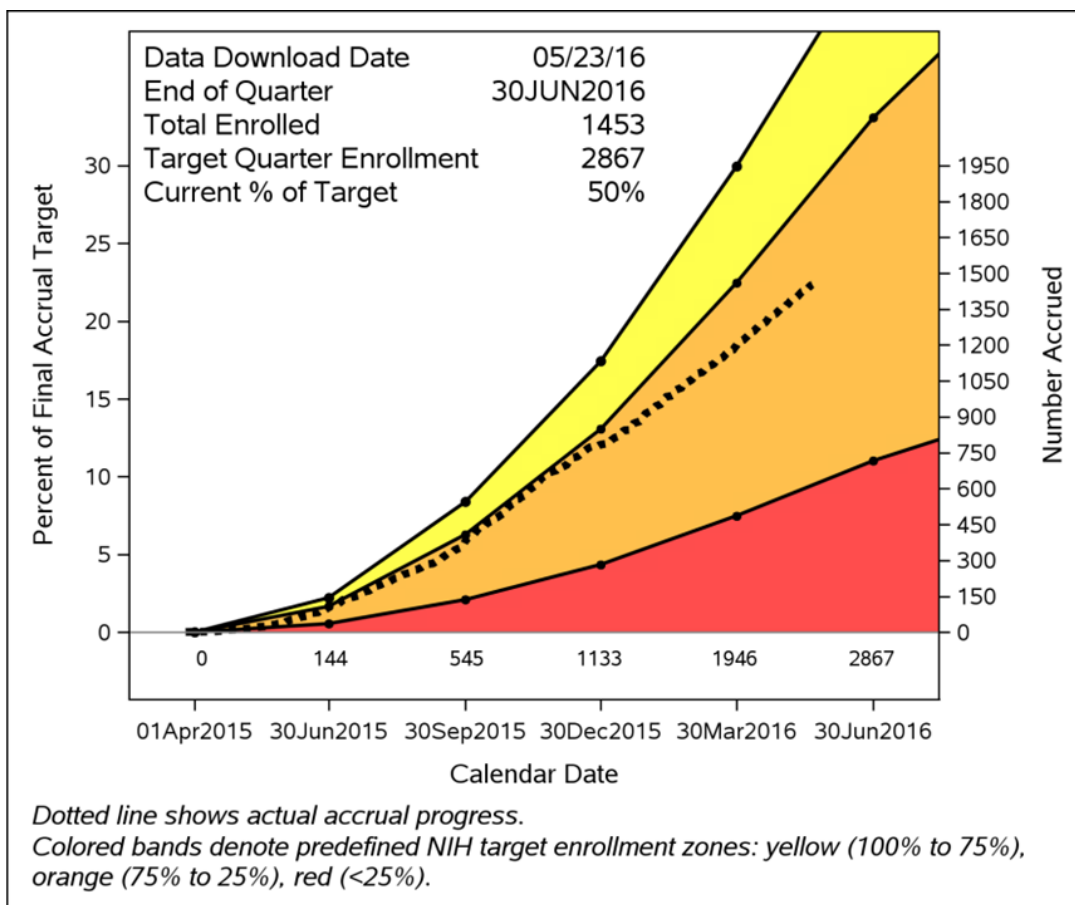


March Madness: REPRIEVE Style!

Fantastic Five Enrolled 7-8 Participants	Thrilling Three Enrolled 9 Participants	Week 7 Champion Enrolled 14
<ol style="list-style-type: none"> Chiang Mai University HIV Treatment CRS UCSD Antiviral Research Center CRS Case CRS Wake Forest University Chapel Hill CRS 	<ol style="list-style-type: none"> Thai Red Cross AIDS Research 550 Clinic at U Louisville Florida Department of Health 	<ol style="list-style-type: none"> UT Southwestern

Our June 30th target enrollment is quickly approaching and current enrollment is at 50% of our goal. There are 6 weeks left in this enrollment period, and we can approach our goal if every activated site enrolls at least 1 participant per week.





Reminder Regarding the Data Entry Deadline for the DSMB Meeting!

In preparation for the DSMB meeting on Friday, June 24th, please note that all queries must be resolved by Friday, June 3rd.

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial. This timeline is 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	May 6 (Fri)	7
Sites	All data for visits through May 6 entered [note: expedited - within 2 weeks of visit]	May 20 (Fri)	5
Sites	All queries resolved by this date	Jun 3 (Fri)	3
All	DSMB Meeting	Jun 24 (Fri)	0

Thank you for your attention to this timeline in the weeks ahead. If you have any questions, please email the team at actg.corea5332@fstf.org.

PLEASE NOTE: Frontier Science will be closed on May 30th in observance of the US Memorial Day holiday.

All systems, including the Subject Enrollment System, will be available. No support assistance will be available on Monday, May 30th, but it will be available starting at 12 AM EST on Tuesday, May 31st.

If you have any questions, please contact User Support by email at user.support@fstf.org or by phone at (716) 834-0900 extension 7302.



FAQ

We have a potential participant who would like to screen for REPRIEVE. However, the participant is taking colchicine for gout. Exclusionary Criterion 4.2.10 indicates that current use of colchicine is not allowed. Is there a washout period for this drug so that this person can be considered for enrollment?

We recommend a washout period of 30 days between discontinuation of colchicine and study entry. However, if you believe that the delay could affect the potential participant's willingness to enroll in REPRIEVE, we would accept a minimum of 14 days off colchicine.

Do cigars count as smoking when calculating the ASCVD since they are not cigarettes?

For the purposes of the ASCVD risk score calculation, cigar smoking does not count as smoking. Therefore, if your participants only smoke cigars then the answer to the smoking question in the ASCVD risk estimator is "No".

Exclusion Criterion 4.2.2 excludes participants with current diabetes if LDL \geq 70

mg/dL.

I have a potential participant who has a diagnosis of diabetes mellitus in their chart from 2 years ago. Upon review of this patient's chart, I noticed that they are not prescribed medications for diabetes and their 2 most recent fasting glucose values were <100 mg/dL and HgbA1C was <6.5 %. Can this potential participant enroll in REPRIEVE?

If the fasting glucose and Hemoglobin A1C values that you listed were collected while the patient was not taking any medications for diabetes, then they would be considered to have previous diabetes mellitus (by physician report) that is now resolved. Therefore, exclusion 4.2.2 would not apply to this person as per the note in the protocol:

NOTE: Current diabetes is defined by patient report of physician diagnosis. Subjects with a history of diabetes which has resolved and no longer requires therapy are not considered to have current diabetes, e.g., women with a history of gestational diabetes, steroid-induced or medication-induced.

What's New on the REPRIEVE PSWP?

- A revised **Site Performance Plan, dated 05/11/2016**, has been posted on the PSWP in the Site Performance folder.

Check out these updated **WebLDMS Reference Guides**:

- Shipping
- Specimen Management
- Storage

They are located in the Lab Resources (Version 3.0) folder. on the PSWP

Help Get the Word Out About REPRIEVE!

There are many ways to promote REPRIEVE in the community. Below are some photos that sites have shared with us recently.

Cornell got the word out about REPRIEVE during the recent NY AIDS Walk!



Informational materials about REPRIEVE were recently distributed at a health and wellness fair organized by Healing Our Community Collaborative (HOCC), a support group in the Boston area for women living with or at risk of acquiring HIV.



Do you have a photo to share or a unique way to promote REPRIEVE? If so, we'd love to know, please email Katie Fitch at REPRIEVE's Clinical Coordinating Center,

kfitch@partners.org.



Don't Forget to Ask Women About Participation in the Mechanistic Substudy (A5333s)!

Enrollment of women is very important in the Mechanistic Substudy (A5333s)! Remember to ask all women screening for REPRIEVE (A5332) if they would also like to participate in the substudy.

Training Opportunities



TRAINING OPPORTUNITIES

The annual ACTG Network Meeting is coming up! The meeting will take place at the Omni Shoreham hotel in Washington, DC, between June 26-30th. Go to the [ACTG website](#) for more details.

If you are a non-ACTG site in the DC area please join us for the REPRIEVE sessions (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.

- **REPRIEVE Meeting**
 - Monday, June 27th 9:00-10:00 AM EDT
- **Question and Answer Session with the REPRIEVE Team**
 - Monday, June 27th 10:30-11:30 AM EDT
- **DMC Demo Room at ACTG Network Meeting**
 - Sunday, June 26th
 - 9:00 AM EDT: REPRIEVE DM Training
 - 4:00 PM EDT: Survival Guide to Reporting Events for REPRIEVE
 - Monday, June 27th

- 11:00 AM EDT: REPRIEVE DM Training

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)

MOPS:

Version 3.0, revision 1, dated 04/15/2016

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/23/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 05/05/2016

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: *dated 11/10/2015*

A5333s LPC : *Version 3.0 dated 05/05/2016*

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@fstf.org.



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