REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 7/13/2015
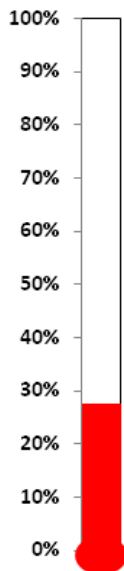
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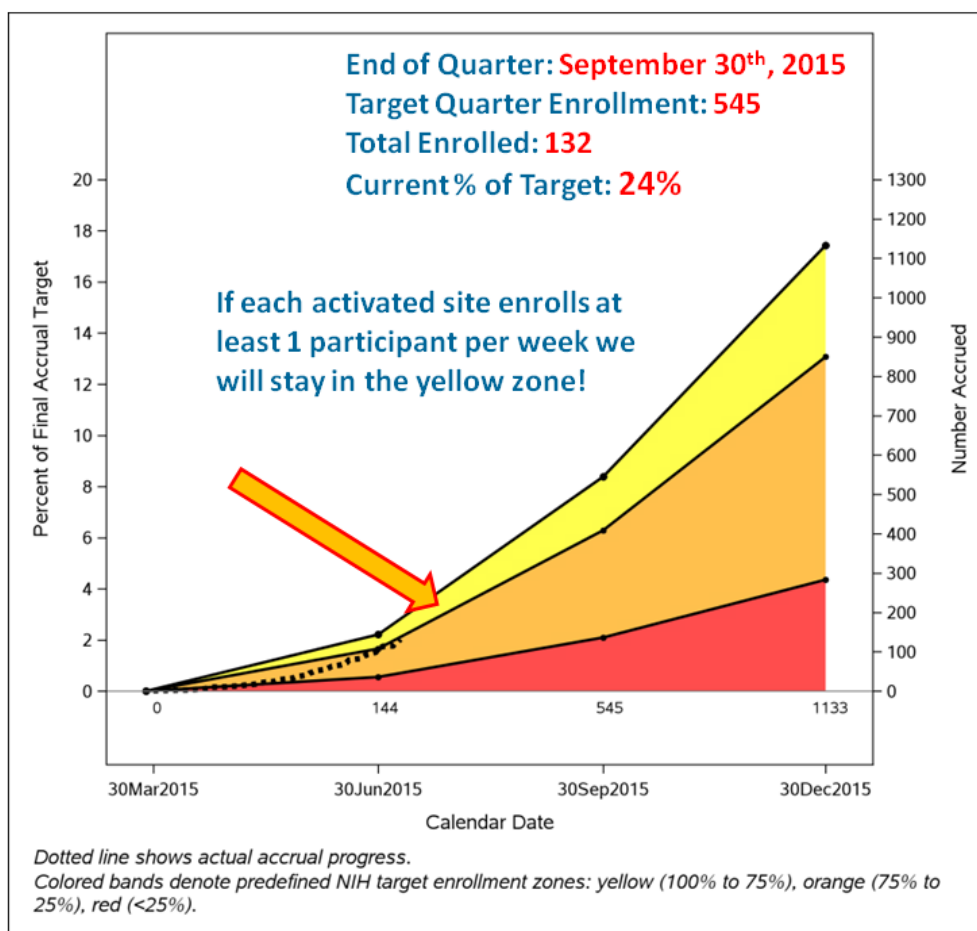- What's New on the A5332 PSWP?
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Trial Status Week of 7/6/2015
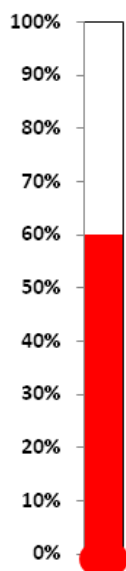
60% of Activated Sites are Enrolling!

28% of Activated Sites Enrolled at Least 1 Participant Last Week!

End of Quarter: September 30th, 2015
Target Quarter Enrollment: 545
Total Enrolled: 132
Current % of Target: 24%

If each activated site enrolls at least 1 participant per week we will stay in the yellow zone!

Percent of Final Accrual Target

Number Accrued

Calendar Date

Dotted line shows actual accrual progress.
Colored bands denote predefined NIH target enrollment zones: yellow (100% to 75%), orange (75% to 25%), red (<25%).

Congratulations to Sites That Enrolled Participants Week of 7/6/15

UCLA CARE Center CRS

Chapel Hill CRS

Houston AIDS Research Team CRS

University of Colorado Hospital CRS

Cincinnati CRS

University of Washington AIDS CRS

Harbor UCLA CRS

Vanderbilt Therapeutics (VT) CRS

The Miriam Hospital (TMH) CRS

Help Make REPRIEVE a Success:

Enroll at Least 1 Participant per Week!

Checking For Successful ECG Transmission
How to Check the status of an ECG in the Directory on your Quintiles Machine
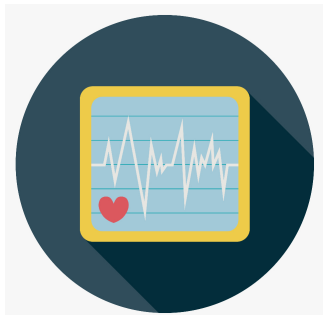
Once the ECG has been transmitted digitally, it will be marked as **PTX** in the machine directory where **P**-stands for Printed, **T**-stands for Transmitted and **X**-stands for marked for deletion. ECGs are only erased from the directory when they are marked for deletion and if the directory becomes full.

To view the machine directory, follow the steps below:

- On the real time ECG view, **Press F1**
- **Press F5** (Directory)
- **Press F5** (More)
- **Press F2** Sort by Subject ID
- Scroll down using function keys F1/ F2 to the check the transmission status of the concerned ECG:
  - If an ECG is transmitted, it will be marked as **PTX** (**P** = printed, **T** = transmitted, **X** = marked for deletion) An ECG is marked for deletion ONLY after it is transmitted
  - If an ECG is not transmitted, it will be marked as **P (without T and X)**. Consequently, please do the **BATCH** transmission. This will transmit all ECGs which have not transmitted until this time.

The standard ECG directory saves up to 125 ECGs depending on the storage space required for

an individual record.

All deleted ECGs marked with "**PTX**" will remain in the directory until it becomes full.

When the directory is full, only those records that have been marked for deletion i.e. records marked with an "**X**" against them will be removed first depending on the size of the record in order to make room for the new ECG.

Note: ECGs transmitted to Quintiles via the QBOX online secured server can be confirmed on the QBOX site.

These instructions are located on the REPRIEVE (A5332) PSWP, in the folder called: Protocol Training.

Did you Know. . .

The link to the updated **ACTG Drug Interactions Database** was recently changed, click here for the new link.

If your site uses EPIC, here is a great tip to help recruit!

The research coordinator can send a message to a provider about REPRIEVE.

- In EPIC, click on *'Message*' in the **'Inbox.'**
- Select the provider in the **'To'** line; in the subject line put **'Your patient is eligible for the REPRIEVE Trial.'**
- Select the correct patient in the patient line by name or MRN, this will populate the field.

When the provider goes to open EPIC, he/she will see the message about REPRIEVE.

If you want to arrange a 'Pop-up' when the provider clicks on the chart, this is possible, but would require programming by your EPIC team.

Alert providers that you are doing this so when they see the message, they'll know it is about a patient they are seeing.

LAB TIPS

Lab Tips

REPRIEVE Web LDMS Laboratories/Sites

If your site will be using Web LDMS, it would be helpful for your lab to begin taking care of the following basic setup in the LDMS, prior to the start of patient enrollment for REPRIEVE:

- Set up your virtual storage configuration.
- Verify that your user accounts are working properly.
    - Do you remember your login credentials?
- Verify your ability to generate labels.
    - Do you have a printer installed?
- Request a "TEST" project setup in your LDMS database

The REPRIEVE (A5332) PSWP will soon have Reference Guides for Web LDMS users. Click on the links below for a quick preview

- Reference Guide for Web LDMS Specimen Management
- Reference Guide for Web LDMS Storage
- Reference Guide for Web LDMS Shipping

If you have any questions concerning your LDMS database or access to it, please do not hesitate to contact our LDMS Support team.

Sites are being contacted by the Data Management Center to participate in training and establish Web LDMS accounts.

LDMS User Support

Email: ldmshelp@fstrf.org

Phone: 716-834-0900 ext. 7311

For Sites doing the Mechanistic Study Study (A5333s), please read regarding the SF-36v2!

The SF-36v2 posted to the A5333s PSWP was updated on June 16th, 2015 to match the SF-36v2 in OpenClinica and posted on the FSTRF Portal. If you have participants who filled out the previous version from the A5333s PSWP, there is no need to bring these individuals back to complete the updated version of the SF-36v2. Please make a notation in the source documentation that these study procedures were missed so the monitor can see that you were proactive and recognized and addressed the problem. **More importantly, please utilize the new version on all subsequent participants.**

Featured Site! Cincinnati CRS
TIPS for successful CT Substudy startup:
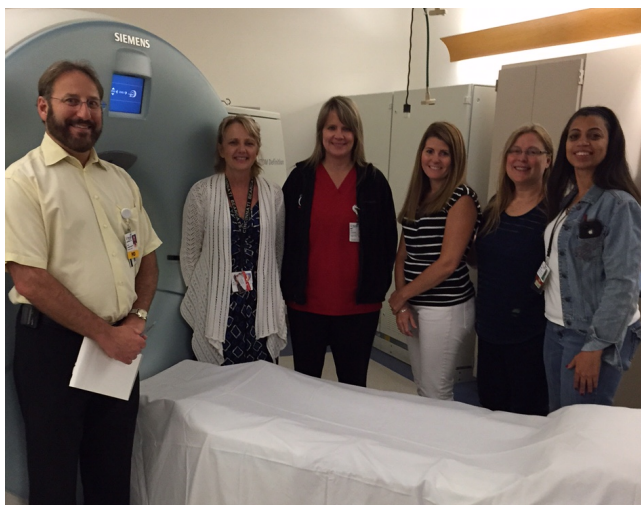
Our team met for a start-up protocol review and discussed ways to recruit participants. We highlighted the benefit of having a CCTA for the patient who will get feedback on their coronary anatomy at the end of the trial. And if anything is seriously wrong, they will know sooner. Patients like the idea of having a test to see what their coronaries look like.

Our study coordinators offer the substudy to every patient as long as they do not have any known contraindication.

We also had a meeting with our CT technologist, Amy Smith, for all the staff to meet her and for her to get to know us. We find that meeting with everyone involved in the study really helps in the long run.

Our PI made initial contacts with our lead cardiologist for the site who is involved in coordinating the CCTAs. Dr. Bob O'Donnell was contacted about the study about 1 year in advance and kept

up to date on progress of the grant. When the study was approved to go forward, Dr. Fichtenbaum met with Dr. O'Donnell to discuss details and plan for the CCTA portion of the substudy. Having a cardiologist affiliated with the CT program is very helpful in sorting through problems. For example, we needed the cardiologist's help to make sure that local reading and local reading charges were not performed on any subjects. And he has taken responsibility for looking at any CTs to ensure there are not critically important issues that require intervention quickly for the patient. Having this connection really helps the study work.

Finally, we have a nice relationship with the CT schedulers as well. This helps us smooth the way to schedule scans. This is what Amy Smith does for the protocol. She ensures that the CT protocol is followed with each study patient by having a detailed protocol to follow and by training a limited number of dedicated research staff in the CT center. The CT technologists complete the questions on the CCTA CRF by talking with the patient before and during the procedure, taking notes during the scan, and evaluating the scan information when completed. All of that information is faxed to our data entry personnel who enter information for the CT portion of the substudy. We did try having the CT technologist enter data from the CRF but the forms can be a challenge to enter data and our site thought it best to have a single person enter all the data including the 48 hour forms. So, our study coordinators ensure that all the data requiring data entry is given to our data entry personnel right after the CT scan is performed.

Every site is different but hopefully some of these ideas might help your site!

Reminder

The **next monthly site call is July, 21st at 1:00 PM EDT** please see the REPRIEVE Calendar for details, an email announcement will be sent shortly. All site staff are welcome to join these calls.

Data Management Training for REPRIEVE! If you have not already attended please attend. **Thursday, July 23rd at 1:00 PM EDT**

See the REPRIEVE Calendar for more details

Please note: At least one person from your site must attend a data management training to meet protocol activation requirements. If someone from your site has already attended a data management training, your site has met that requirement.

REPRIEVE (A5332)   **What's New on the A5332 PSWP?**

Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14
MOPS: dated 6/15/2015
A5332 LPC for ACTG Sites:
dated 05/06/2015
A5332 LPC for Non-ACTG Sites:
dated 5/06/2015

These documents are on the A5332 PSWP

Slide presentations about site monitoring!

Go to the A5332 Site Performance folder, under PPD Mini-Session Slides and look at the following slide presentations to help you with site monitoring.

- Taking the Anxiety out of the Monitoring Visit
- Decoding the Monitoring Codes: A72 versus A17 versus A16
- Top 10 Quality Tips

These documents are on the A5332 PSWP

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

For A5333s please use

MOPS: dated 03/16/2015

A5333s LPC: dated 05/07/2015

Questions on CT Activation?

Contact the MGH CT Core Lab

MGHReprieve@partners.org

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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