



Randomized Trial to Prevent Vascular Events in HIV

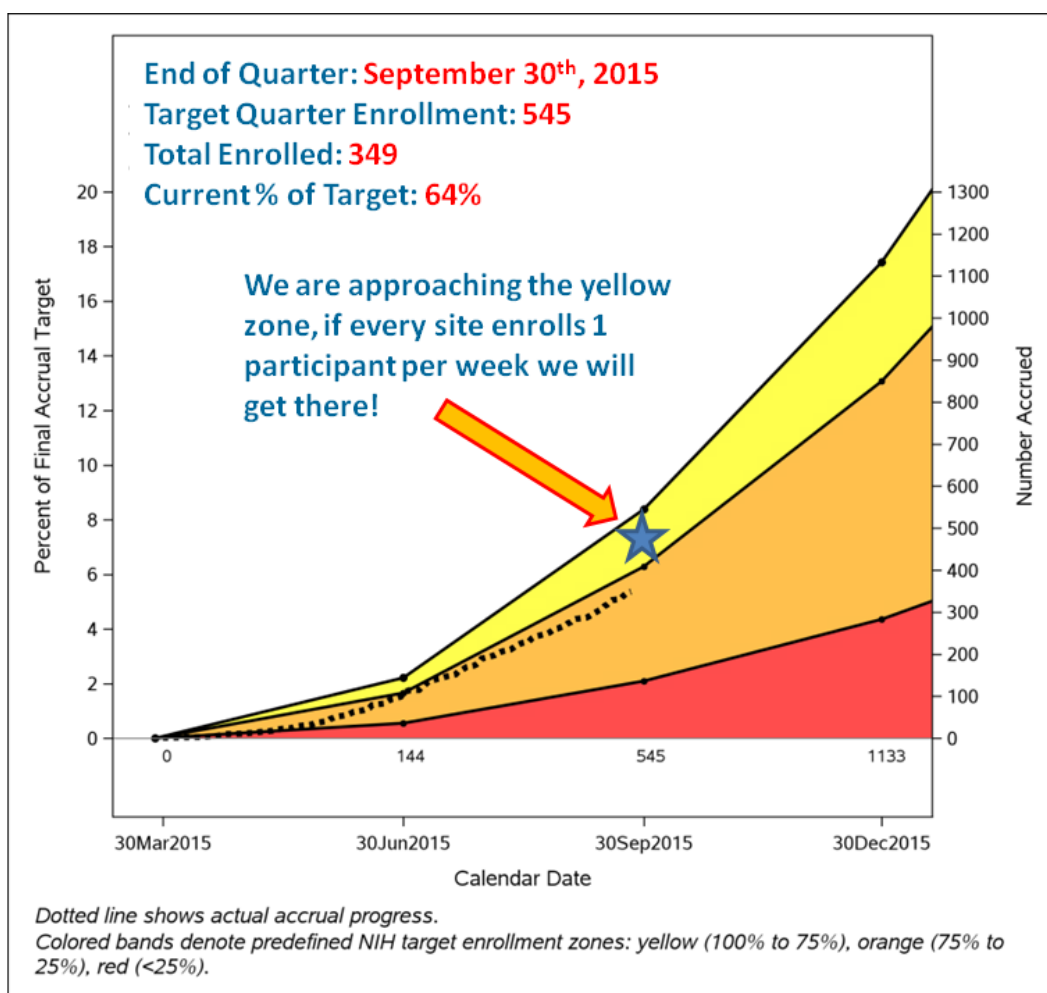
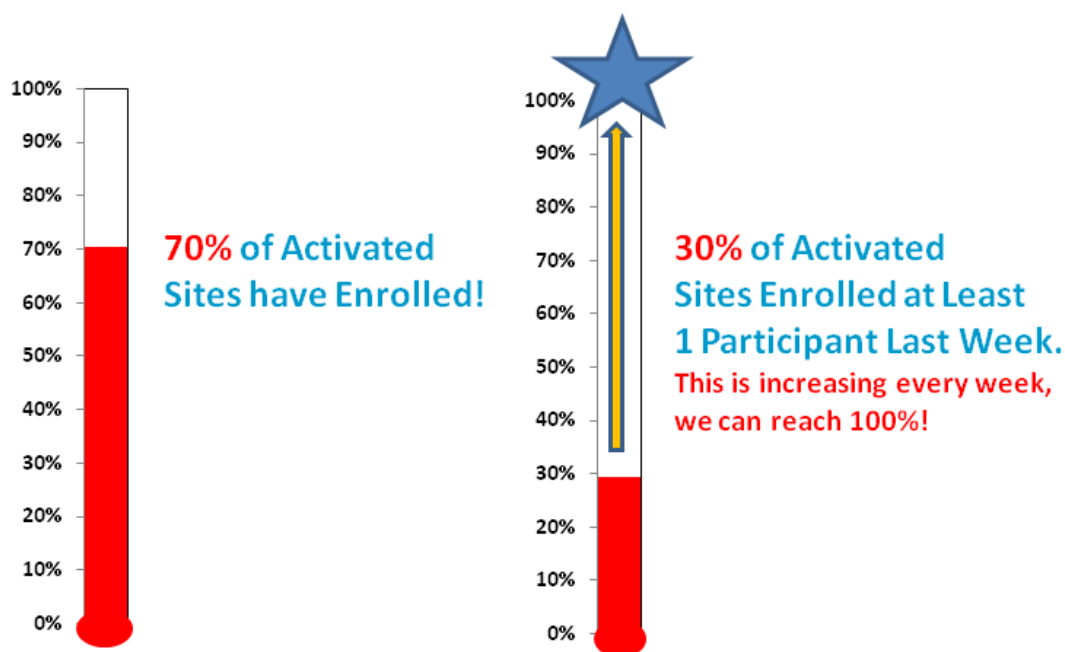
Site Newsletter 9/28/2015

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Trial Status: 9/21/2015-9/28/2015

73 participants were screened last week and 20 participants were enrolled. There are 61 sites activated. If all activated sites enroll 1 participant this week we have the potential to enroll 61 participants!





If you are going to ID Week, stop by the **REPRIEVE booth (#540)**. Members of the team will be there October 8-10 from 10:00 AM to 2:00 PM. We will have some cool giveaways and would love to meet you!

Congratulations to Sites Enrolling Participants Week of 9/21/15

Houston AIDS Research Team CRS
Alabama CRS
UCSD Antiviral Research Center CRS
University of Colorado Hospital CRS
Cincinnati CRS
Puerto Rico AIDS Clinical Trials Unit CRS
Case CRS
Vanderbilt Therapeutics CRS
The Miriam Hospital CRS
Cornell Chelsea CRS
University of Pittsburgh CRS
New Jersey Medical School Clinical Research Center CRS
Trinity Health and Wellness Center
Georgetown University CRS
UT Southwestern
AIDS Research Treatment Center of the Treasure Coast
Mt. Sinai Comprehensive Health Program
University of Nebraska Medical Center

FAQ



If a potential participant is taking a medication classified as an anti-

hypertensive med, but he/she is prescribed the medication for another indication (for example, urinary retention or anxiety), what do we enter in "treatment for hypertension" in the ASCVD risk estimator?

If the participant is using medication for NON-BLOOD PRESSURE control reasons, in the "treatment for hypertension" question you would enter 'No' in the ASCVD risk estimator.

Also, please note that if a participant is using an anti-hypertensive medication for an indication other than hypertension, this medication should NOT be recorded on the Medications log. **We ask only for anti-hypertensive medications that are taken for the treatment of hypertension**, not for other reasons such as anxiety or urinary retention.

The schedule of events indicates that CD4+/CD8+ obtained from clinical care should be recorded at study entry and annually thereafter. What if, for a particular participant, CD4+ count is available from clinical care, but not CD8+ count?

If the CD8+ cell count is not available from clinical care, it is acceptable to report only the CD4+ count. Moreover, it is preferable to report only the CD4+ count if the CD4+ value is closer to the visit date than is a concomitant CD4+/CD8+ assessment. To illustrate an example, upon review of the participant's medical record, a CD4+ (without CD8+) was measured 15 days ago while a CD4+/CD8+ was measured 30 days ago. The CD4+ (without the CD8+) from 15 days ago should be entered. (See Section 4.2 of the REPRIEVE MOPS for details).



**Click on these video messages about REPRIEVE
from Dr. Grinspoon and Dr. Fichtenbaum!**



SAVE THE DATE!

Tuesday, October 20th 1:00 PM EDT

We are asking all Site PIs to join the Monthly Site Call on **Tuesday, October 20th at 1:00 PM EDT**. An email announcement regarding this call will be sent closer to the date so please stay tuned.

Data Management Center Updates

There have been updates to some REPRIEVE (A5332) CRFs, please read below for the changes. The new versions of these CRFs are posted in OpenClinica and to the Forms Management Utility.

TXW0295 - Medications Log v1.01

[Instructions in SECTION C were modified.](#)

Formerly stated:

- Only record antiretroviral stoppages if the treatment interruption continues for a duration of at least 7 consecutive days
- If an antiretroviral medication/therapy is started again after being stopped for at least 7 days, record it as a new course

Revised version states:

- At entry, only record antiretroviral medications that the participant is currently taking, do not record prior regimens
- Post-entry, only record antiretroviral stoppages if the treatment interruption continues for a duration of at least 7 consecutive days. If an antiretroviral medication is started again after being stopped for at least 7 days, record it as a new course

Participant recall is sufficient to collect this history

SSW0037 – Myalgia Symptom Assessment v1.01

[Instruction in SECTION A was modified.](#)

Formerly stated:

- This questionnaire is intended to be completed as an interview with the subject

Revised version states:

- This questionnaire should be completed by study staff based on an interview with the subject

[Instruction in SECTION B was modified.](#)

Formerly stated:

- Any response of Grades 3 or 4 must also be entered as an Adverse Event on ADE0001 - Adverse Events Log. Also see Protocol section 7.0 for management of myalgias and myopathy

Revised version states::

- AFTER ENTRY any response of Grades 3 or 4 must also be entered as an Adverse Event on ADE0001 - Adverse Events Log. Also see Protocol section 7.0 for management of myalgias and myopathy

SCR0034 – Screening Outcome v1.02**Added 3 additional selections to Question 5.**

- i. Screening period expired
 - j. Subject did not return to clinic
 - k. Screening number inadvertently obtained
- Other, formerly question 5i. is now question 5l.



Lab Tips

Please read regarding shipment evaluation!

The Shipment Evaluation Form is used by BRI to assess your site's shipments. BRI will send your site shipment assessment (Shipment Evaluation Form) for every shipment indicating if the shipment was acceptable or if problems were identified. If problems were found, it is very important that you use the Shipment Evaluation Form to submit a response to them within 1 week. If your shipment had problems identified, please contact the lab committee (reprieve.labcom@fstf.org) right away; the lab committee will assist you with this process.

For more details, information can be found in the following locations:

ACTG/IMPAACT Laboratory Manual:

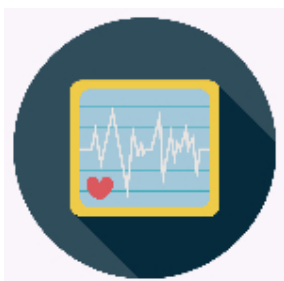
<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>

Shipment Evaluation SOP (and form):

<https://www.hanc.info/labs/labresources/procedures/ACTGIMPAACT%20Lab%20Manual/073-ShipmentEvaluationProcedureSOP-LTC-SOP-073v7-2015-08-31.pdf>

Important ECG Reminder

When entering participant demographics into the ECG machines please enter the **Gender, Participant ID (NOT the Screening ID) and the Site**



ID. The REPRIEVE (A5332) PSWP Training Folder has an ECG Quick Guide that reviews these steps and slides from the Quintiles ECG Training call that reviews these steps.

Training Opportunities



TRAINING OPPORTUNITIES

All training call dates and call details have previously been emailed and are listed on the [REPRIEVE calendar](#).

Save the Date: October 20th, 1:00 PM to 2:00 PM EDT

The next monthly site call will take place on October 20th at 1:00 PM EDT, **we are asking all Site PIs to join this call** as there will be very important updates to discuss regarding REPRIEVE. Barbara Bastow will be sending an email with conference call details closer to the date.

Check out the Web LDMS trainings available on YouTube

LDMS REPRIEVE webinar trainings are now available on FSTRF's YouTube channel. These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories over the past few months. We encourage lab staff to watch these videos as a means of refresher training. Please feel free to share these links with other laboratory staff.

FSTRF YouTube Channel: <https://www.youtube.com/user/FSTRFfilms>

Training videos available:

- LDMS Training: Specimen Management for REPRIEVE
- LDMS Training: Storage for REPRIEVE
- LDMS Training: Shipping for REPRIEVE

ECG Training: Thursday, October 1st, 2:00-2:30 PM EDT

This training will include information on the ECG machine and supplies, performing the ECG, and transmission of data. This training is specific to the REPRIEVE and at least one person from your site must attend one training to meet protocol activation requirements. If you have participated already but would like a refresher, please feel free to attend.

You do not have to have an ECG machine onsite to participate in this training. We encourage you to have all staff that will work with the Quintiles ECG machine to attend the training, e.g., PI, study coordinator, CRA, backup personnel. You may forward this message to others at your site as needed.

JUST POSTED on the A5332 PSWP

ACTG Revised Lab Processing Chart 09/17/2015

Non-ACTG Revised Lab Processing Chart 09/17/15

Please note all revisions are listed in Section 6 of the LPC

These documents are on the [A5332 PSWP](#)

REPRIEVE (A5332): 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 9/17/15

A5332 LPC for Non-ACTG Sites:

dated 9/17/15

These documents are on the [A5332 PSWP](#)

REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?***For A5333s please use***

Protocol: Version 2.0 dated 12/19/14

MOPS: dated 3/16/2015

A5333s LPC : dated 9/17/15

JUST POSTED on the A5333s PSWP

Revised Lab Processing Chart, 09/17/15

Please note all revisions are listed in Section 6 of the LPC

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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