REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 4/27/2015

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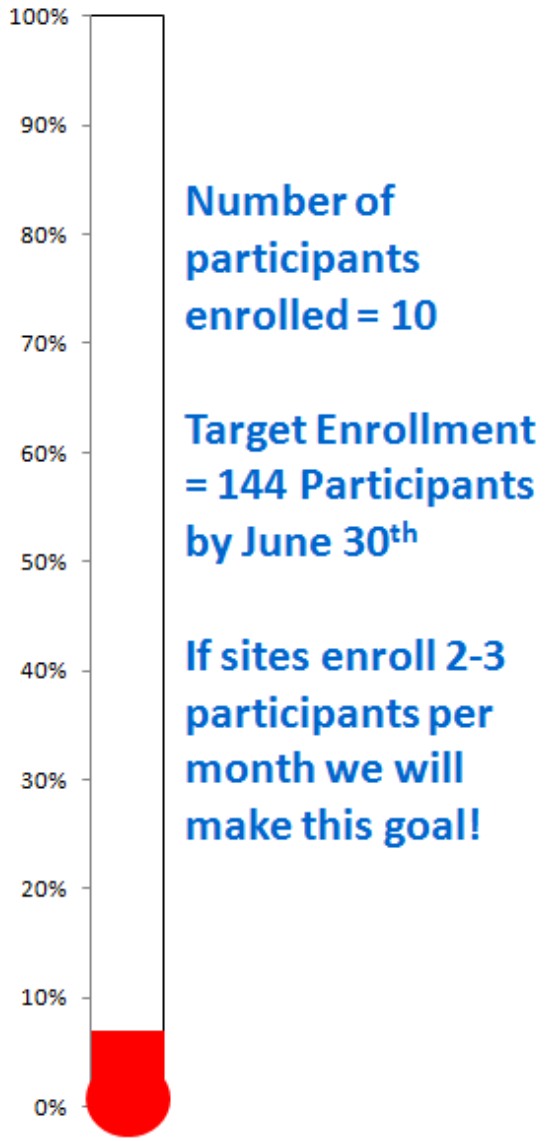
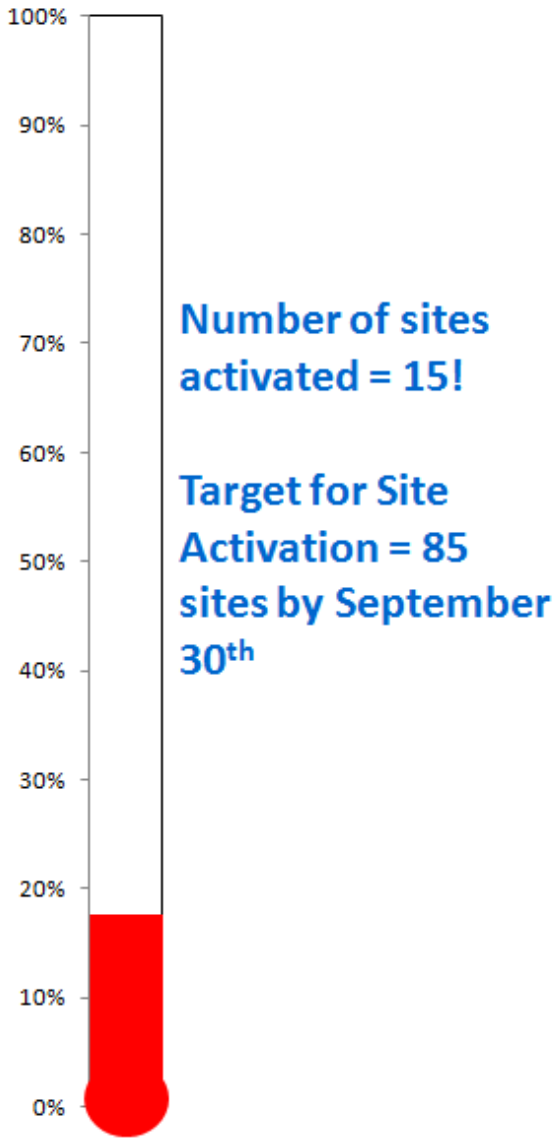
Trial Updates

In the last few weeks more sites continue to activate, participants are enrolling, and the Mechanistic Substudy (A5333s) has opened for enrollment! Below is a picture of our important milestones, if sites continue to work efficiently toward activation and actively recruit participants we will reach these milestones.





Did you know?

Sites are reimbursed on a per-participant-enrolled basis and the site will be paid the amount indicated in the REPRIEVE payment schedule. If the participant has successfully completed the protocol visit and all case report forms have been submitted and accepted, the site will received the full amount; the full amount is paid even if there are labs collected from standard of care. For participants who enroll in REPRIEVE but do not complete any required follow-up, the site will be paid only for completed milestones.

DAIDS Regulatory Support Center website http://rcc.tech-res.com/default.aspx **has several resources including:**

- 1572 form

- Pitavastatin package insert
- DAIDS Adverse Event Grading Table
- Information about Expedited adverse event(EAE) reporting and the DAIDS Adverse Event Reporting System (DAERS)

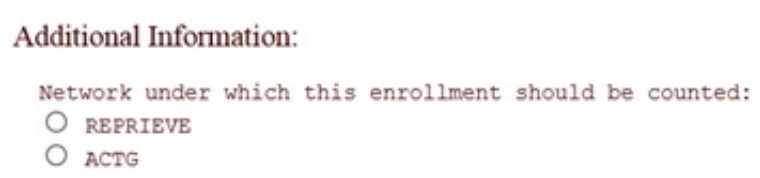
Helpful Hints from the Data Management Center

Selecting Network in the Subject Enrollment System

One of the questions in the Additional Information section of the A5332 and RS1001 Screening enrollment checklists asks what network the enrollment should be attributed to.

For ACTG sites, ACTG should be selected. This will ensure that your REPRIEVE enrollment counts towards your site ACTG accrual targets. If you select REPRIEVE and need to have this changed please email the study data manager at dmc.reprieve@fstrf.org.

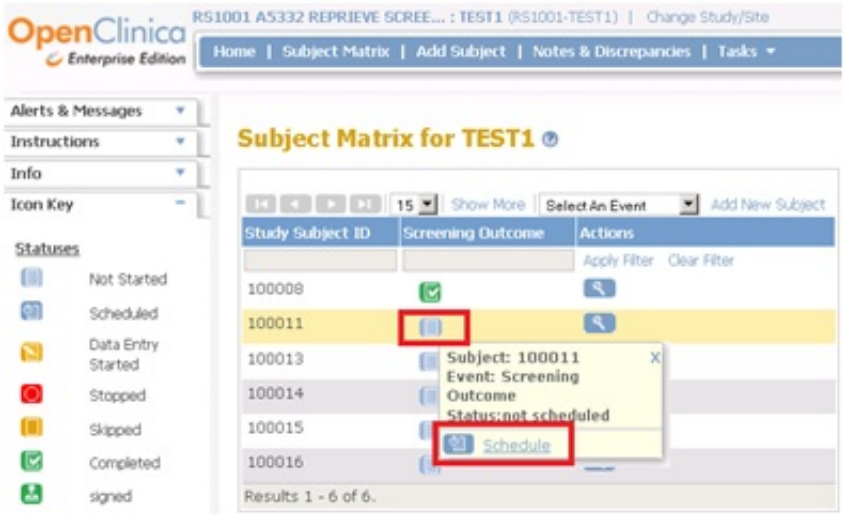
For REPRIEVE Only, the REPRIEVE network should be selected.



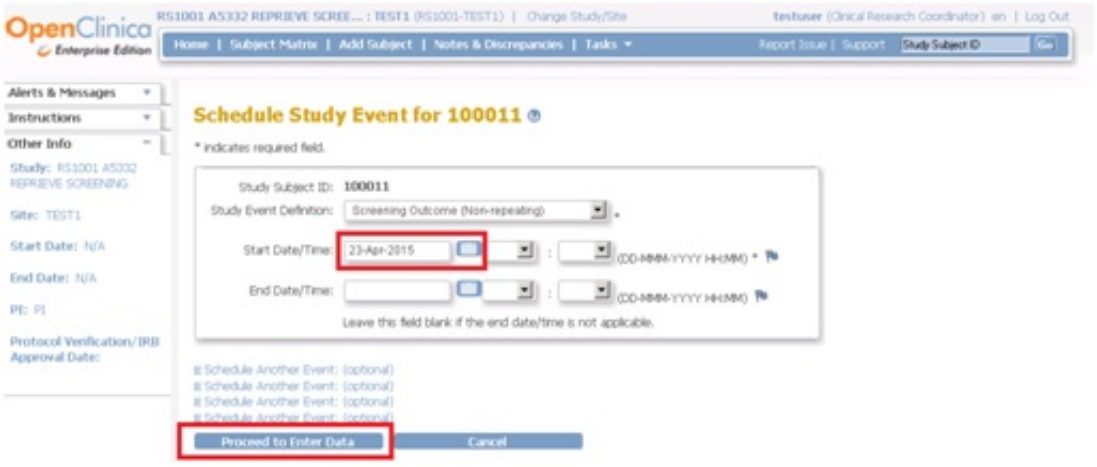
Completing the Screening Outcome Form

All subjects who screen for A5332 are required to have a completed SCR0034 – Screening Outcome form. This form is located in the RS1001 study in OpenClinica, and can be navigated to by clicking on the Change Study/Site link at the top of the page.

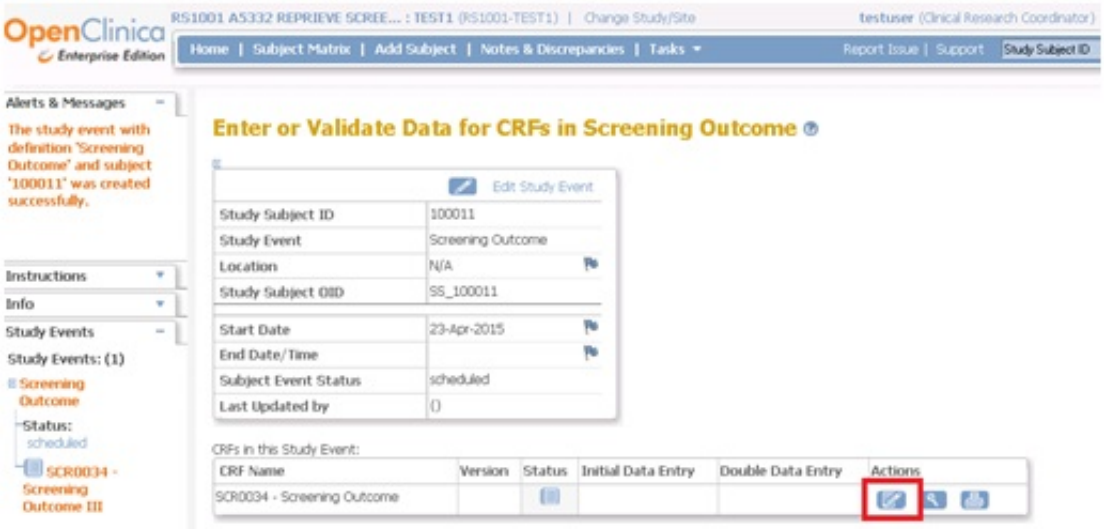
In the subject matrix, click on the Not Started status icon for the subject you wish to complete the form for and click Schedule.



Enter the date it was determined the subject was eligible/ineligible to enroll to A5322 in the Start Date field (Start Time, End Date, and End Time are not required to be entered), and click Proceed to Enter Data.



Click on the Enter Data icon.



Then enter all required data fields within the form, check the Mark CRF Complete box, and

Save.

FAQ

Why are baseline ECGs obtained at entry as part of the REPRIEVE trial and are the results intended to exclude participants from participation in REPRIEVE?

ECGs are obtained for study participants at entry to provide a basis for comparison in the event that a cardiovascular clinical endpoint occurs. A clinical read of the baseline ECG should be performed by approved site staff. Until further notice, the ECG should be kept with source documents until the contract with Quintiles has been executed. Once the contract has been executed ECGs will be transmitted to Quintiles. Site staff will not receive the formal ECG interpretation performed by Quintiles, as this interpretation is not meant to influence further inclusion in/exclusion from the study. Please see A5332 MOPS for more details regarding the ECGs.

Must screening lipid levels for entry into REPRIEVE be tested as part of the study, or can these levels be obtained from standard of care?

The screening lipid panel will need to be drawn and tested locally in order to determine eligibility for REPRIEVE. Lipid values obtained from standard of care are permissible, however the lipid panel must have been drawn fasting as the lipid levels factor so critically into the determination of whether a participant would or would not be recommended to receive statin therapy clinically based on 2013 ACC/AHA guidelines.

Additional FAQs can be found on the A5332 PSWP in the ACTG Member Portal

REPRIEVE in the News!

Read the exciting announcements about REPRIEVE

- "NIH Launches Largest Clinical Trial Focused on HIV-Related Cardiovascular Disease" read the NIH press release about REPRIEVE!
- Read the NIAID blog post about REPRIEVE
- Massachusetts General Hospital also announced the launch of REPRIEVE

- The ACTG mentioned REPRIEVE in their most recent newsletter.

Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14
MOPS: dated 04/20/15 **(revised version!)**
A5332 LPC for ACTG Sites only: dated 01/23/2015
A5332 LPC for Non-ACTG Sites only: dated 03/16/2015

Revised versions of the A5332 ACTG LPC and non-network LPC will be posted soon

These documents are on the A5332 PSWP

Mechanistic Substudy (A5333s) Updates

Number of Sites Activated:

- 3

Number of Sites Protocol Registered:

- 15

Questions on CT Activation? Contact the MGH CT Core Lab MGHReprieve@partners.org

Are you up to date?

For A5333s please use

MOPS: dated 03/16/2015
A5333s LPC: dated 03/16/2015

Revised version of A5333s LPC will be posted soon

These documents are on the A5333s PSWP

We would like to introduce. . .

Project Managers Katie Fitch and Liz Adami

Katie is the Project Manager for the REPRIEVE Clinical Coordinating Center. Katie collaborates with the protocol team to develop protocol documents such as the MOPS, LPCs, CRFs, training slides, and recruitment materials. She monitors site start up

activities and is responsible for developing and maintaining the reprievetrial.org website. Katie collaborates with Liz and Barbara on the site newsletters and she coordinates all interactions with Chesapeake IRB. Katie can be reached at kfitch@partners.org.

Liz is the Project Manager for the REPRIEVE Data Coordinating Center (DCC) and is charged with supporting Drs. Hoffmann and Ribaudo in the collection, transmission, and analysis of all data for REPRIEVE. As a part of the DCC, she is responsible for ensuring that the Clinical Events Committee receives the necessary source documentation to complete their adjudication process. She is also the Project Manager for the Mechanistic Substudy of REPRIEVE and is responsible for substudy documentation, including the MOPS, training slides and CT site certification. Liz can be reached at eadami@partners.org.

Liz and Katie both work at Massachusetts General Hospital in Boston, MA

For future reference, all newsletters will be 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.