REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 04/11/2016

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REPRIEVE ended the March 30th quarter with strong enrollment numbers. Although we did not reach above 75% of our target enrollment, we came quite close at 64% of the target. As you know, our targets continue to be steep, and we want to take a moment to thank all of our REPRIEVE sites for continuing their hard work to screen, enroll, and follow participants in REPRIEVE.

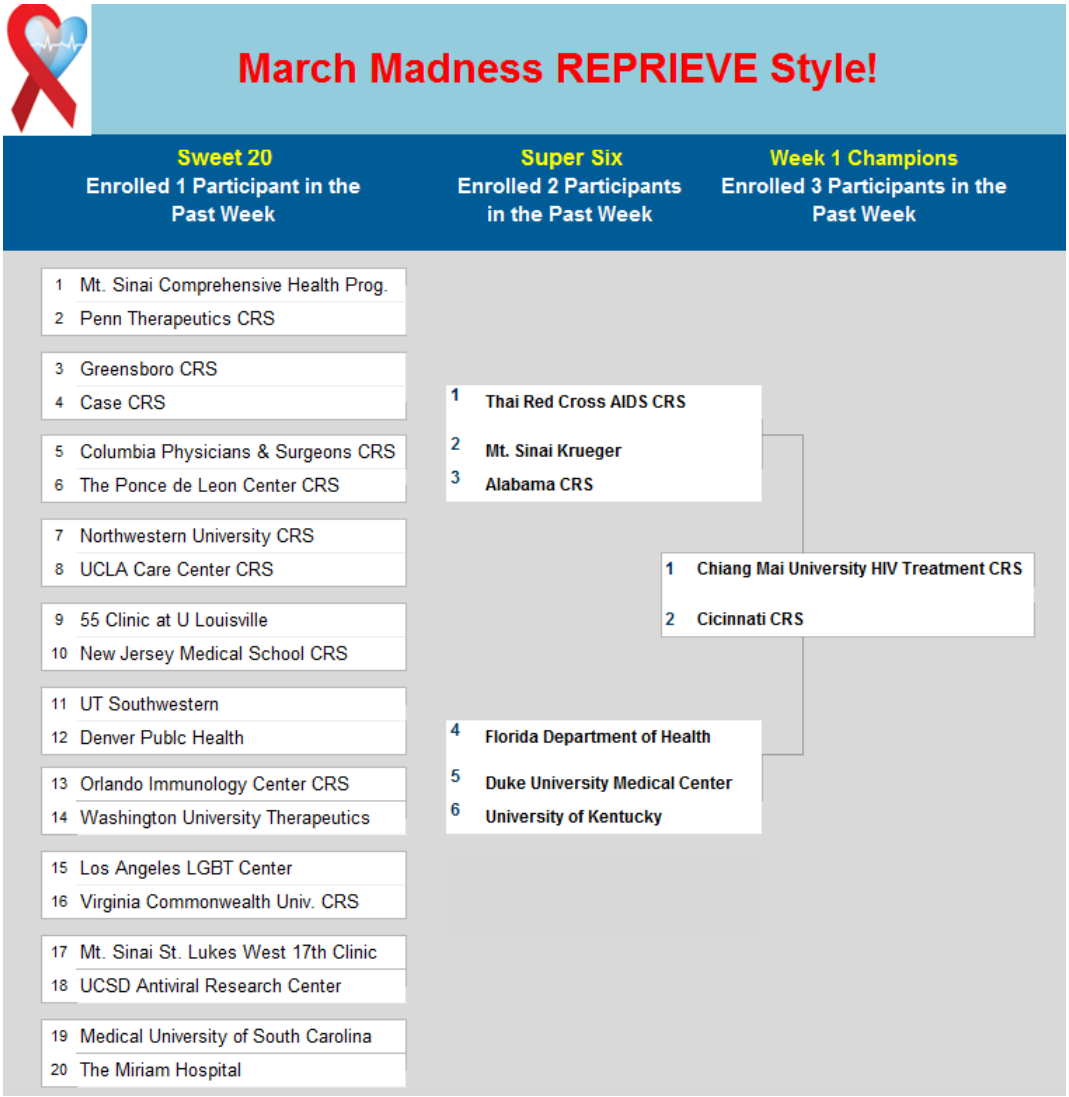
It is also an important time to recognize that **the first participant in REPRIEVE was enrolled approximately 1 year ago** at the University of Alabama site! Since this day, almost 85 sites have open for enrollment with **1823 total screenings** and **1253 participants enrolled**. In honor of this important milestone we are

distributing a press release which has been posted on the web and will be distributed to HIV advocacy groups. **Thank you again for all your efforts to reach this point, and we look forward to your continued collaboration!**

Updates: REPRIEVE's March Madness Competition!!!

In the last newsletter we announced that March Madness has been extended for REPRIEVE! **We are keeping track of each site's enrollment between April 1st and June 30th, sites will be awarded prizes depending on their final standing.** Right now there are 3 brackets: Sweet 20, Super Six and Week 1 Champions.

Check out the results from last week!!!

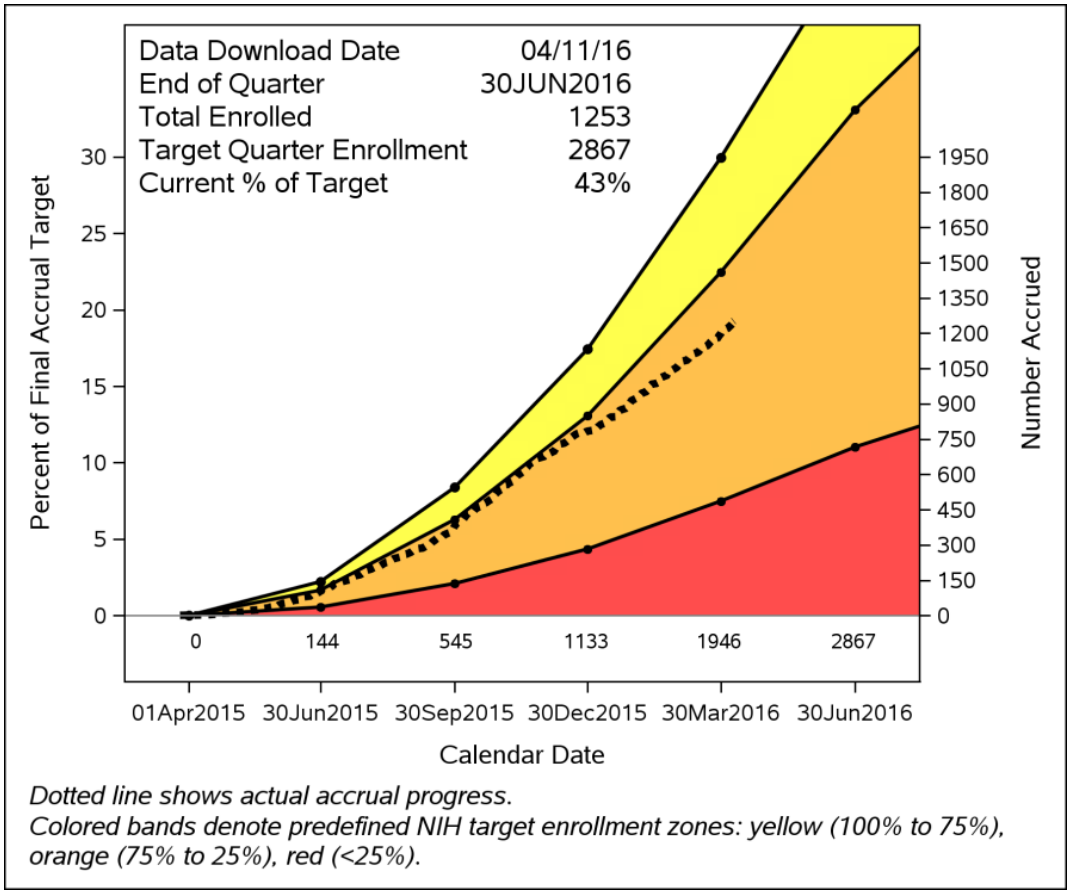


39 Participants Were Enrolled Last Week!

Thank you to all sites enrolling participants week of 04/04/2016

Thai Red Cross AIDS Research Center
UCSD Antiviral Research Center CRS
Chiang Mai University HIV Treatment CRS
Alabama CRS
Penn Therapeutics CRS
Greensboro CRS
Cincinnati CRS
Case CRS
Columbia Physicians and Surgeons CRS
The Ponce de Leon Ctr. CRS
Northwestern University CRS
UCLA CARE Center CRS
New Jersey Medical School Clinical Research Ctr. CRS
The Miriam Hospital CRS
Washington University Therapeutics CRS
UT Southwestern
Denver Public Health
Florida Department of Health
University of Kentucky
Orlando Immunology center CRS
Duke University Medical Center
Los Angeles LGBT Center
Mt Sinai Kreuger Clinic
Virginia Commonwealth University Medical Ctr. CRS
Mt Sinai St Lukes West 17th Clinic
Mt Sinai Comprehensive Health Program
550 Clinic at University of Louisville
Medical University of South Carolina


June 30th Target =
2867 Participants
2867 Target Enrollment
1253 Current Enrollment



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

Study Medication Tips

Requesting Study Medication

If your site is about to be activated or has just become activated for REPRIEVE (A5332), your site pharmacist can request study drug using the *Study Product Request Form* located in the Pharmacy Guidelines manual.

Don't Forget to Periodically Review Section 11.0 of the REPRIEVE (A5332) MOPS: Study Medication Specific Instructions .

Below is some guidance taken from Section 11.0 of the A5332 MOPS to be reviewed with participants at every visit post-screen.

Section 11.2 Study Medication Adherence

Using simple, everyday language, please briefly review the following with study participants at every visit post screen.

- Name of study medication.

- Indication for pitavastatin and why it is being studied in REPRIEVE (use language from Consent Form).
- Dose, route, and frequency of study medication administration. Remind participants that the study medication should be taken at the same time each day, with or without food.
- In order for the study medication to work effectively, it must be taken every day.
- Instruct participants to take ONE tablet per day and to complete one bottle before starting another.
- All study medication will be supplied by the study.
- Review potential side effects related to study medication.
- If a dose of study medication is missed and this is noted within 12 hours of the scheduled dose, the participant should take the missed dose, if the missed dose is noted to have been missed >12 hours after the scheduled dose the participant should wait until the next scheduled dose.

Important Reminder Regarding Possible MACE Events

There are certain events participants may report such as syncopal episodes, seizures, dizziness or hospitalizations for unspecified reasons. Please remember that these events may possibly constitute a Major Adverse Cardiovascular Event (MACE).

It is important to remember to review Section 6.0, Endpoint Assessment and Adjudication of the REPRIEVE (A5332) MOPS. If after review of this section, you feel it is possible that an event could potentially be a MACE event, please report as indicated in Section 6.0 of the REPRIEVE (A5332) MOPS. Your determination need only be that this *could potentially* be a MACE event. Reported events in this regard will undergo a formal adjudication by an independent committee for a final determination.

Visit Forecaster Tool is Available in OpenClinica!

Our data management team has provided some helpful tips on the Visit Forecaster Tool in OpenClinica.

In OpenClinica, once a site enters data for a visit, the ideal visit date is automatically set for the next visit and the status of the visit is set to "scheduled".

For example, once data entry for Month 1 is initiated, Month 4 is scheduled with a date of the randomization date +120 days, once data entry for Month 4 is initiated, the Month 8 is scheduled with a date of randomization date +240 days.

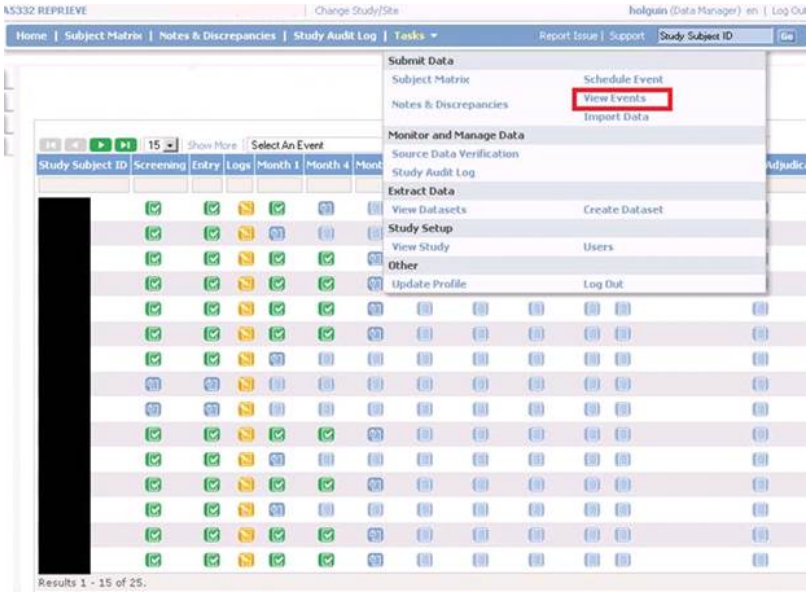
Please note that in this tool you will only be able to see the next forecasted visit date for each participant.

For example, if your site has not entered data for the Entry visit for a participant, you would not see Month 1, or if you have not entered data for Month 1 you would not see Month 4, etc.

Accessing Visits Which Were Forecast for a Given Time Frame

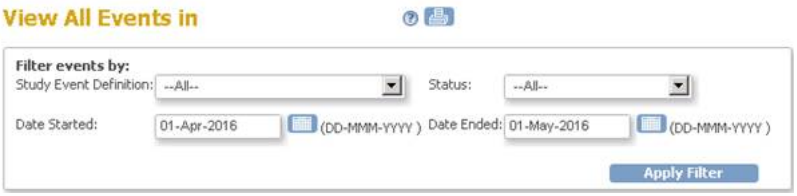
You can access this tool by clicking on **Tasks** on the top navigation bar and within Tasks, click **View Events.** The Visit Forecaster will open once you click **View Events.**

Click on image to enlarge



There is a filter at the top of the screen which can be used to set the date range to forecast.

Click on image to enlarge



Below is an output of a sample site for the visits expected to occur in April.

In the image below, 8 participants sorted by the post-entry visit that is due are displayed.

This image displays Month 1, Month 4, and Month 8.

There are three columns of importance in each table. Subject ID, Event Date Started, and Subject Event Status.

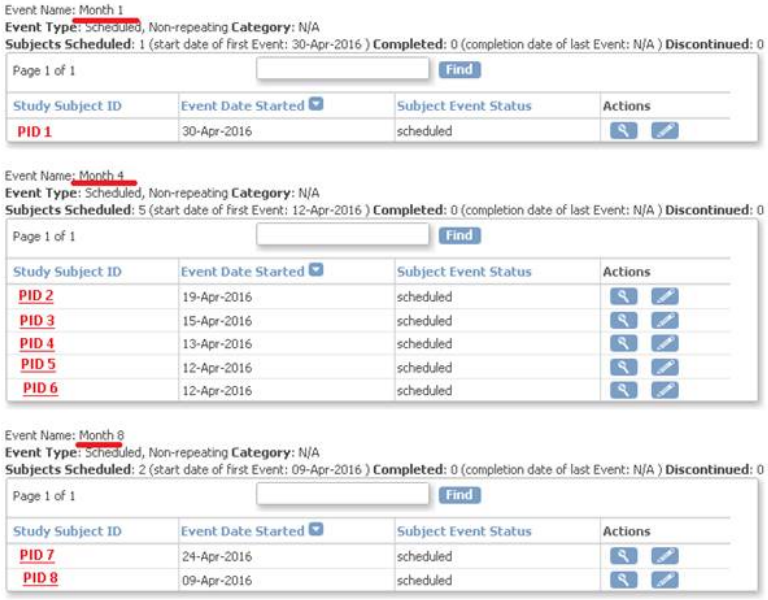
The Subject ID is your subject's PID.

The Event Date Started is the ideal visit date for the participant.

The Subject Event Status is the status of the visit, this indicates if data entry has been initiated, completed, stopped (missed visits), or if the visit is still set as scheduled.

If this output is run for your site, participants highlighted in yellow may appear. This occurs automatically as an indicator of “overdue" status. It is important to note that the allowable visit window is not accounted for and therefore these visits may not actually be overdue.

Click on image to enlarge



Event Name: Month 1
Event Type: Scheduled, Non-repeating **Category**: N/A
Subjects Scheduled: 1 (start date of first Event: 30-Apr-2016) **Completed**: 0 (completion date of last Event: N/A) **Discontinued**: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
PID 1	30-Apr-2016	scheduled	

Event Name: Month 4
Event Type: Scheduled, Non-repeating **Category**: N/A
Subjects Scheduled: 5 (start date of first Event: 12-Apr-2016) **Completed**: 0 (completion date of last Event: N/A) **Discontinued**: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
PID 2	19-Apr-2016	scheduled	
PID 3	15-Apr-2016	scheduled	
PID 4	13-Apr-2016	scheduled	
PID 5	12-Apr-2016	scheduled	
PID 6	12-Apr-2016	scheduled	

Event Name: Month 8
Event Type: Scheduled, Non-repeating **Category**: N/A
Subjects Scheduled: 2 (start date of first Event: 09-Apr-2016) **Completed**: 0 (completion date of last Event: N/A) **Discontinued**: 0

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Study Subject ID	Event Date Started	Subject Event Status	Actions
PID 7	24-Apr-2016	scheduled	
PID 8	09-Apr-2016	scheduled	

Hot Off the Press!
Two Recent Articles Feature REPRIEVE

Check out the two recent articles about REPRIEVE in the Boston Herald and the Windy City Times.

TRAINING OPPORTUNITIES

Training Opportunities

Helpful Training Resources

Sites New to REPRIEVE: Site Startup Training/Protocol Training

Tuesday, 26 April 2016, 1:00 PM ET

A site startup training call/protocol training for brand new sites (in the US and Canada) and any site that needs a refresher will be held on Tuesday, April 26th. Please note that protocol training is required for site activation. The announcement for this call will be sent shortly.

Web LDMS Training Video

If you are a site using Web LDMS for REPRIEVE, check out the Web LDMS training video available on FSTRF's YouTube Channel.

These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories. We encourage lab staff to watch these videos as a means of refresher training. Please share these links with laboratory staff at your sites if they do not receive the REPRIEVE newsletter.

Data Management Training Video

If you need a data management refresher, you can access the video in the FSTRF portal the video is located under the **Site Support Tab-->REPRIEVE Training Videos**

Protocol Training/ Start-Up Call Slides

Slides used in for protocol training are kept on the A5332 and A5333s protocol-specific websites (PSWPs) on the ACTG web page, in the Protocol Training folder.

Recruitment

Customizable Recruitment Materials are Now Available

Did you know the REPRIEVE Clinical Coordinating Center has developed a portal for each site to login, customize, and order recruitment materials?* The best part about this is you can order a "Sample Kit" of recruitment materials **all paid for by REPRIEVE**! Click here to access the portal, then enter your site ID and the password "reprieve" to login. Attached are instructions that are helpful when ordering.

If you try to login and don't have access, please email Katie Fitch, REPRIEVE CCC Project Manager.

These materials are also available on the REPRIEVE Website, on our new Spread the Word page.

*These materials have been approved by the IRB for the REPRIEVE CCC, however please submit as per your local IRB requirements.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:
Version 3.0 dated 01/28/2016
MOPS:
Version 3.0 dated 02/10/2016
A5332 LPC for ACTG Sites:
Version 3.0 dated 02/23/2016
A5332 LPC for Non-ACTG Sites:
Version 3.0 dated 02/25/2016

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 02/22/2015*

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.