REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 6/22/2015

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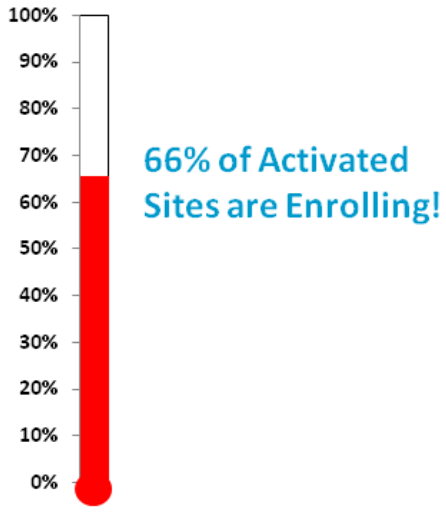
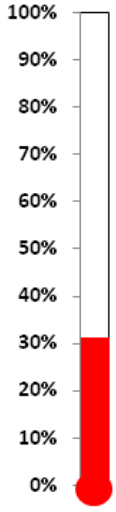
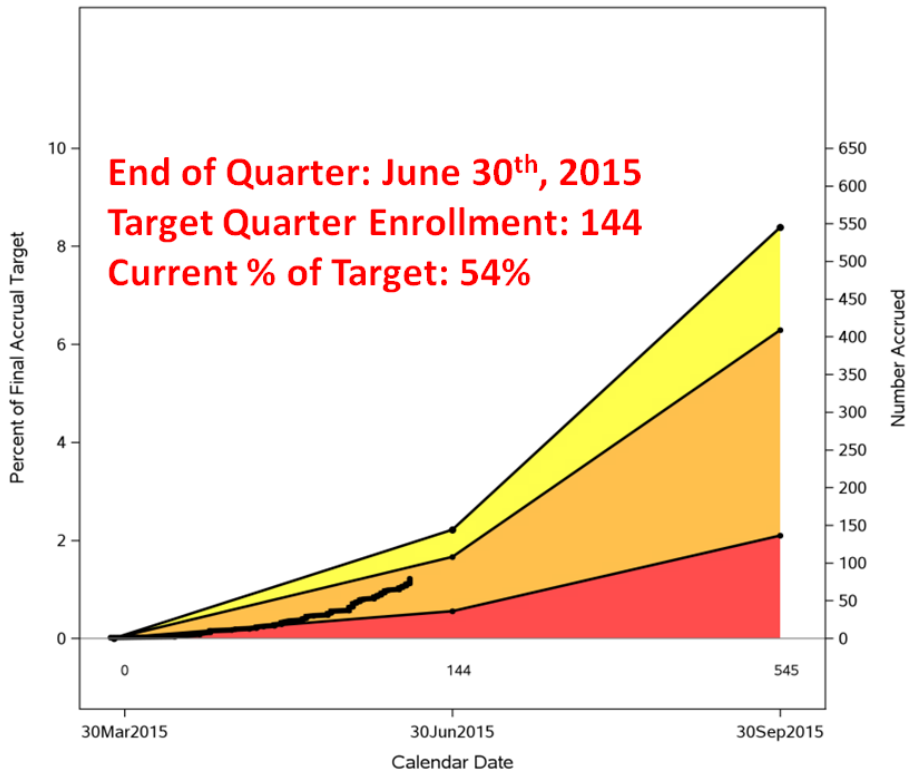
Trial Updates Week of 6/15/2015



66% of Activated Sites are Enrolling!



31% of Activated Sites Enrolled at Least 1 Participant Last Week!



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

Cincinnati

Chapel Hill

Massachusetts General Hospital

UCSD Antiviral Research Center

Puerto Rico AIDS CTU

Northwestern University

Houston AIDS Research Team

University of Colorado

Cooper University

Miriam Hospital

Weill Cornell Uptown

Help us to Make REPRIEVE a Success:

Enroll at Least 1 Participant per Week!

Recording Adverse Events for REPRIEVE (A5332)

Record the following on the REPRIEVE (A5332) AE log at post entry visits:

- Any of the primary and/or secondary endpoints.
- All signs and symptoms that led to a change in treatment (pitavastatin or placebo for pitavastatin) regardless of grade.
- Any adverse event classified as a Serious Adverse Event (SAE)
- Signs and symptoms, including any laboratory values with a severity of Grade 3 or higher.

If signs and symptoms are related to a diagnosed event, please record primary event and do not grade or record related sign and symptoms. If Grade 3 or higher signs and symptoms occur independent of a related diagnosis, they should be recorded.

Example: A participant reports gastroenteritis with nausea, vomiting, and diarrhea. Only the gastroenteritis is required to be recorded.

Example: A participant reports a diffuse macular rash, but no medical diagnosis was made. The rash should be recorded.

IMPORTANT TO NOTE!

Do NOT record the following on the REPRIEVE (A5332) AE log at post entry visits:

- Signs and symptoms, including any laboratory values with a severity of Grade 2 or lower.

Example: A participant reports mild muscle soreness, there is no change in study medication. This should NOT be recorded on the AE log.

Adapted from the REPRIEVE (A5332) MOPS

TIPS from the MGH CT Core Lab

Don't Forget the Paperwork!

1. CCTA CRF

Ask for help from the Imaging Team at your site! Questions # 6 - 16 on the CCTA Case Report Form (CRF) are imaging specific. The CT Technologist or CT MD will be able to assist with this section of the CRF. The REPRIEVE team suggests study coordinators bring a copy of the CCTA CRF to the imaging appointment and request the CT Tech of CT MD complete questions #6 – 16 while the participants undergoes imaging.

REMINDER!

There is a 48 hour rule for completion of the CCTA CRF in OpenClinica.

2. CCTA Performed Data Tracking Sheet

This is a simple tracking form and should be submitted at the time of each scan. This sheet can be found on page 14 of the A5333s MOPs or on the A5333s PSWP.

All about the Image Query

The MGH CT Core Lab is responsible for the collection of all CCTA data for the Mechanistic Substudy (A5333s). For every CCTA submitted the site will receive a Case Acceptance Notification OR a Case Query Notification. Site responsibilities are complete upon receipt of a Case Acceptance Notification! A Case Query indicates that the CCTA does not meet the REPRIEVE CCTA Imaging Protocol (A5333s MOPs Section 2.4.2) and there is more work to be done to achieve case acceptance.

How to Avoid the Case Query Notification

The most common reason for a case query is a missing "Patient Protocol Page." This page contains important radiation dose information and is typically called the Patient Protocol OR Dose Report Page.

Sample: Dose Report/Patient Protocol Page

Ward: RESEARCH
Physician:
Operator:

Total mAs 2530 Total DLP 257 mGycm

	Scan	kV	mAs / ref.	CTDIvol* mGy	DLP mGycm	TI s	cSL mm
Patient Position F-SP							
LAT Topogram	1	100	34 mA	0.08 L	3	3.6	0.6
PA Topogram	2	100	34 mA	0.08 L	3	4.3	0.6
DS_CaScSeq	3D	120	64 / 80	2.45 L	34	0.17	1.2
Last scan no. Contrast	6						
TestBolus	7	100	20	3.03 L	3	0.28	10.0
Last scan no. Contrast	11						
Retro Systo	12D	100	122 / 354	15.15 L	214	0.28	0.6

Medium Type	Iodine Conc. mg/ml	Volume ml	Flow ml/s	CM Ratio
Contrast	0	0	0.0	100%
Saline		0	0.0	

Featured Site! Greensboro CRS

Our research staff has shared some tips for successful recruitment:

#1 Optimizing provider engagement, enthusiasm for REPRIEVE

The site leader and our 4 other Infectious Disease Physicians have been very proactive in recruiting their own patients during regular clinic visits. At the end of a clinic visit, providers will frequently walk a patient from the exam room to the research offices to introduce them to research staff.

#2: Engage CAB members, former and current study participants

Many of the REPRIEVE enrollees are current or previous research study participants, who ardently enjoy participating in research trials. Most know the study staff very well, and are eager to do anything they can to help the cause of research at our site.

#3 Increase awareness in the clinic and in the community

We have placed flyers in the lab, in all exam rooms and all provider work pods to prompt interest in REPRIEVE.

By presenting a Journal Club on HIV and CVD risk, our Site Leader, Dr. Van Dam was able to promote the REPRIEVE trial to the Internal Medicine Faculty and House-staff.

Reach out to local media. While we have not yet landed a TV spot for REPRIEVE, in the past, TV appearances have helped us promote and recruit patients for large trials.

#4 Flexing research staff knowledge of patients

Our research staff, in particular Kim and Elisha Epperson, know our current and former research participants very well. This is invaluable in not just identifying a subject who might look “good on paper”, but in knowing who is going to actually be a fully engaged future research participant.

#5 Query the EMR

We plan on querying our EMR for eligible patients. Our research staff have already been very successful by simply reviewing records of patients with upcoming scheduled clinic visits to identify eligible patients and prompt the attention of the ID provider before a clinic visit takes place.

Background on the Greensboro CRS and the Regional Center for Infectious Diseases:

The Greensboro CRS is co-housed within the Regional Center for Infectious Diseases (RCID), in Greensboro, NC. The RCID cares for over 1400 HIV positive individuals, with African Americans and Hispanics representing 69% and 4% of this population, respectively. The male to female ratio is approximately 3 to 1. At least 152 of our HIV positive patients are also co-infected with Hepatitis C. In addition to being co-housed with the Greensboro CRS, the RCID Clinic shares its roof with several powerful AIDS Service Organizations such as Triad Health Project, Central Carolina Health Network, and Family Health Services of the Piedmont that help to provide case management, “bridge-counseling,” counseling, and substance abuse treatment.

It was in 1990, that the Greensboro CRS enrolled its first patient into an ACTG trial. Working closely with our parent CTU, the University of North Carolina at Chapel Hill, the Greensboro CRS have been a highly efficient, fervent and productive site in the ACTG for more than two decades. Our six member staff is small but cohesive, efficient and experienced. Dr. Cornelius (“Kees”) Van Dam is the Site Leader, Kim Epperson, RN, CCRC, our Site Coordinator, Elisha Epperson, RN and Study Coordinator, along with Marlene Allen who serves as both Data Manager and Regulatory Coordinator, Philip Bozovich our Pharmacist and Charles Hansen provides further administrative leadership.

In addition to participating in the ACTG, we have been one of the top enrolling sites for the Strategic Timing of Anti-Retroviral Treatment (START) Trial from the INSIGHT Network. We have additional interest in HIV Prevention Trials Network Studies, especially given our keen awareness that Greensboro-High Point was recently ranked 20th on the list of major metropolitan areas in numbers of new infections per capita.

REPRIEVE (A5332) Are you up to date?

For A5332 please use

Protocol: Version 2.0 dated 12/19/14

What's New on the A5332 PSWP?

ELI 150C Quick Guide, Version 4 dated 6/11/2015

MOPS: dated 6/15/2015 **(revised version!)**
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

REPRIEVE ECG Waveform shipping instructions (if you have paper ECGs to send to Quintiles, use these instructions posted on the PSWP)

REPRIEVE Site Performance Plan, dated 6/03/15

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

What's New on the A5333s PSWP?

SF-36V2

The SF-36V2 posted to the A5333s PSWP has been updated to match the the SF-36V2 which is on OpenClinica and also that which is posted on the FSTRF Portal (https://www.fstrf.org/portal). If you used the PSWP to obtain the SF-36V2 please download the version no posted on the PSWP.

These documents are on the A5333s PSWP

TRAINING OPPORTUNITIES

Training Opportunities

Need a A5332 or A5333s Site Training Call Refresher?

- Slides from the A5332 training calls are available in the Training Folder of the A5332 PSWP, there is also an audio recording available.
- Slides from the A5333s training calls are available in the Training Folder of the A5333s PSWP.

WebLDMS

- Webinar for those sites/labs who will be using the web LDMS platform; sites will be contacted by the Data Management Center (DMC).
    - July 2nd @ 1pm EST
    - July 16th @ 9am EST
    - July 30th @ 1pm EST

Please see the REPRIEVE Calendar for additional training opportunities

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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.