Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 5/11/2015

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Trial Updates

Since the last newsletter, we have met the milestone of 15 sites activated by June 30\textsuperscript{th}. The number of screens has doubled and so has the number of sites actively recruiting. We know that many sites are still very actively moving through all the steps for Activation, thank you for all your hard work, we know these sites will be ready to recruit very soon! \textbf{For sites that are activated, enrolling at least 3 participants per month will get us to our goal of 144 participants enrolled by June 30\textsuperscript{th}.}
15 Participants Have Enrolled

Goal = 144 participants by June 30th

21 Sites are Now Activated

Goal = 85 sites by September 30th

Featured Site!

The 1917 Clinic at UAB is our top enrolling site. Thank you to this team for all their hard work. They have enrolled 11 participants!!!

The research nurses have shared some of their tips for successful recruiting:

1. Contact folks who have participated in other studies. Our CRS has several interested folks who have been in other studies.
2. We also plan to do a weekly data search of patients scheduled to come to our clinic and approach them during clinic about the study.
3. Post a recruitment flyer in the clinic for the clinic providers and talk with them about the study.

We came up with a strategy where by our 4 nurses each identify 3 patients per month to screen. It takes very little time (especially following tip #1 above) and the REPRIEVE visits have proven to be extremely easy compared to many other trials. The electronic data entry system is also very simple to use and does not require very specialized training.

**Background about the 1917 Clinic at UAB?**

Our clinical trials unit is located in the 1917 HIV Clinic in Birmingham, Alabama. The clinic follows 3,100 people living with HIV and others with Hepatitis C mono-infection. The clinic was founded in 1988 by Dr. Michael Saag and research has been one of the clinic’s major missions since its inception. The ACTG research team currently consists of the CRS Coordinator, 3 study nurses, 3 data managers, a regulatory manager and QC specialist. Our site also cross covers among our 3 networks (HVTN, MTN and ACTG) which has proven to be really useful and successful, including with the REPRIEVE study.

Periodically, the newsletter will feature the Clinical Research Site with the most participants randomized in 1 month. Can your team bump the 1917 Clinic at UAB from this spot????

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**RECRUITMENT**

**Recruitment Tips**

REPRIEVE presents a unique opportunity to answer an important question for patient-care regarding HIV and cardiovascular disease (CVD), the results of this study will help us in developing guidelines for the prevention of CVD in HIV. Therefore, REPRIEVE holds tremendous promise and we need your help to be successful. We want to enlist your support to make this trial successful and provide some ideas that may be useful to achieve our goals.

We know that your site works hard and has been very successful in prior studies. Here’s the challenge we face in REPRIEVE- we need to accrue 6500 participants in 2.5 years- so every site needs to enroll 3 participants per month right out of the gate. We think we can do this but we need your help! We need screening and accrual to begin within 1-2 weeks of site activation, and we need this to continue throughout the study. NHLBI, our funder, has strict guidelines on accrual in order to continue to provide funding, another strong incentive for us to stay on target.

The 1917 Clinic at UAB has offered some excellent ideas for recruitment, here are some additional ideas that might be helpful.

The goals of REPRIEVE will be best achieved through active recruitment of study participants.
Examples of active recruitment include:

- Utilize databases from previous studies that identify eligible participants who may be interested in REPRIEVE.
- IRB approved review of medical records to identify eligible participants.
- IRB approved use of searchable electronic medical record in your clinic/hospital to filter out potential participants based on inclusion/exclusion criteria.
- Collaborate with local providers to refer pre-qualified participants.
- Offer community presentations to providers and people living with HIV.

In addition, we’d like to make you aware of study related materials for advertisement that we have created for sites. You can:

- Post flyers in local community health centers and/or hospitals and AIDS service organizations (sample flyers located on the PSWP: [https://member.actgnetwork.org/study/53278#profile=4](https://member.actgnetwork.org/study/53278#profile=4)).
- Email provider and/or participant summaries to clinicians, social workers, case managers, and dieticians who provide care to potential participants (sample summaries located on the PSWP: [https://member.actgnetwork.org/study/53278#profile=4](https://member.actgnetwork.org/study/53278#profile=4)).

As we embark on this important trial we want you to know that we are collaborators in this effort. We need to hear from you about what is and what isn’t working with regards to recruitment and conduct of the trial. There are many ways in which you can communicate your thoughts will us. We hold monthly site calls on the 3rd Tuesday of each month at 1 PM Eastern Time (please email actg.user.support@fstrf.org if you do not receive announcements about these calls) or you can email the team at actg.corea5332@fstrf.org with your questions.

Please consult your local IRB regarding prior approval of any recruitment methods and/or materials.

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Lab Tips

Revised Lab Processing Charts (LPCs) for A5332 (ACTG and non-network LPCs) and A5333s will be posted on the PSWP this week, please watch for an email announcement regarding this.

This newsletter will include lab updates periodically, please make sure your site’s lab staff has been added to the “actg.protA5332” email group and, for sites participating in the mechanistic
substudy, to the “actg.prota5333s” substudy email group. Contact actg.user.support@fstrf.org to be added to these email group(s).

For non-ACTG sites only:
On page 1 of the non-network A5332 LPC you will find ordering information for cryovials, freezer boxes, and labels.

The non-ACTG site specific shipping schedule will be posted shortly in the Lab Resources folder on the A5332 PSWP. Please follow this schedule when shipping to the repository, BRI.

Over the course of the trial your processing lab will make about 15 shipments to the repository (BRI). You may be able to use only one or two shippers back and forth, if you protect them by completely covering the outside with clear tape before using them for the first time. One example of a great shipper is the Saf-T-Pak STP320. You will need to include a completed air bill (FedEx number to use is in the non-Network LPC, Section 5) and a sheet of paper with “EMPTY” written on it in your shipment for the return of your shipper. When BRI returns the shipper to you, they will cover all hazard labels with the sheet of paper indicating the box is “EMPTY.”

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**TRAINING OPPORTUNITIES**

Training Opportunities
All training call dates and call details are listed on the public REPRIEVE website calendar: [http://reprievetrial.org/events/](http://reprievetrial.org/events/)

**Start Up Calls**
- Friday, May 15th 2:00 PM EDT: Sites that have not already attended a start up call please join.
- Wednesday, May 20th 8:00 AM ICT—For Thai sites only

**Data Management Training**
- Monday, May 18th at 1:00 PM EDT (REPRIEVE-only sites)

**WebLDMS**
- Webinar for those sites/labs who will be using the web LDMS platform; sites will be contacted by the Data Management Center (DMC).

**ECG Training**
- This training will be completed via a 30 minute webinar, sites have been notified of training dates via email (sent by Barbara Bastow on 5/11/15). Please note that your site does not need to be DAIDS approved or protocol registered, nor do you need to have
your Site Qualification Form (SQF) signed or the 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.

**ACTG Network Meeting (attendance is voluntary), June 22-26, Washington DC**
https://meetings.actgnetwork.org/meeting/2015ACTG

**DMC Demo Room at ACTG Network Meeting**
- Monday, June 22nd
  - 9:00 AM EDT: OpenClinica Overview
  - 3:00 PM EDT: Survival Guide to Reporting Events for REPRIEVE

**Team-Site Meeting: REPRIEVE: A Progress Report**
- Wednesday, June 24th 8:00-9:00 AM EDT

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**Are you up to date?**

**For A5332 please use**
- **Protocol:** Version 2.0 dated 12/19/14
- **MOPS:** dated 04/20/15
- **A5332 LPC for ACTG Sites only:** dated 05/06/2015
- **A5332 LPC for Non-ACTG Sites only:** dated 05/06/2015

*These documents are on the A5332 PSWP*

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**Mechanistic Substudy (A5333s) Updates**

**Number of Sites Activated:**
- 5

**Number of Sites Protocol Registered:**
- 16

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 05/07/2015

*These documents are on the A5333s PSWP*
We would like to introduce... 

The laboratory data managers for REPRIEVE: Brittany White, Heather Sprenger, and Alex Benns. 

Heather, Alex, and Brittany all work at Frontier Science Technology & Research Foundation, Inc. (FSTRF), the Data Management Center for REPRIEVE. 

Heather is the Laboratory Data Division Chief at FSTRF and also the Lab Committee co-chair for REPRIEVE. Heather oversees the laboratory data monitoring duties at FSTRF for REPRIEVE and many other projects. She supervises and directs the work of the laboratory data managers, is responsible for the overall quality of research laboratory data collected at FSTRF, participates in network committees, works with laboratory technicians, scientists, and statisticians on data collection strategies, and coordinates with FSTRF database operations and programming departments to prioritize work and define specifications in support of the laboratory data division.

Alex is the LDMS Project Coordinator at FSTRF and assists in managing the maintenance, ongoing development, and training efforts of the Laboratory Data Management System (LDMS) and other software projects managed within the FSTRF Laboratory Division.

Brittany is a Laboratory Data Manager at FSTRF. Brittany is responsible for the day-to-day laboratory data monitoring duties for the REPRIEVE trial; these duties include specimen inventory monitoring, specimen shipment coordination, and central laboratory assay data monitoring.

Howard Gutzman is the Program Director for the LDMS at FSTRF. He is responsible for efforts regarding the development and maintenance of the LDMS, as well as, overseeing FSTRF’s efforts in providing support and training to LDMS sites and laboratories. Howard interacts with the REPRIEVE sites and laboratories, ensuring LDMS is implemented and training provided prior to site activation.

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.