REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 03/23/2015

On March 17th, 2015 the REPRIEVE Trial officially opened to enrollment!!! Opening the study occurred only 60 working days after sites received the protocol. Thank you all for helping us to reach this goal. We would like to congratulate **Washington University (CRS 2101) and University of Alabama (CRS 31788),** these sites are now open to enrollment! *Many* other sites are also very close to opening as well. We look forward to working with you to reach the next goal which is *enrollment of the first participant.*

Presently, many sites are busy going through the steps of DAIDS site approval, protocol registration and protocol activation. We appreciate your efforts to move the trial forward, please do not hesitate to email the team with any questions you may have at Reprieve.sites@fstrf.org.

Sincerely,
Dr. Steven Grinspoon and Dr. Pamela Douglas, Co-Principal Investigators, REPRIEVE Clinical Coordinating Center
Dr. Udo Hoffmann and Dr. Heather Ribaudo, Co-Principal Investigators, REPRIEVE Data Coordinating Center

Did you know?

There are several websites to assist you with the REPRIEVE Trial

A **Protocol-Specific Web page (PSWP)** has been established for REPRIEVE (A5332)

at https://member.actgnetwork.org/. Please consult the PSWP frequently for protocol information. You will find the protocol, Manual of Procedures, Laboratory Processing Charts, Spanish Sample Informed Consent Form, training materials, communications from the team, and recruitment information posted here.

The **Frontier Science (FSTRF) website** http://www.fstrf.org is the data management center (DMC) portal for the REPRIEVE trial. The portal contains the subject enrollment system, the link to OpenClinica which is the Clinical Trials Data Management System for this trial, information on the Laboratory Data Management System (LDMS), as well as programs to access the case report forms, data collection forms schedules, and various calculators. Please contact User Support at user.support@fstrf.org or (716) 834-0900 x7302 if you need help accessing any of these tools.

The **Laboratory Data Management System (LDMS) website** https://www.fstrf.org/ldms contains information about the LDMS, including access to the LDMS user manual and other user documentation. Sites/labs who are provided access to the web version of LDMS can access the website at https://www.webldms.org. Please contact Howard Gutzman at ldmsinfo@fstrf.org for LDMS implementation questions. LDMS User Support should be contacted for general LDMS questions at ldmshelp@fstrf.org or (716) 834-0900 x7311.

There is also a **public website** at http://reprievetrial.org/ that contains information for collaborating sites and potential participants, a calendar with training dates and dial in information, as well as the latest news about the REPRIEVE Trial. The public website also has login to a secure portal accessible to REPRIEVE team members.

Site Approval and Protocol Activation are both required before enrollment may begin

Site Approval is a process facilitated through your DAIDS OCSO Program Officer and requires completion of various staff trainings and site SOP verifications. This process will ensure that the site's personnel are adequately trained in the electronic systems that will be used to manage the REPRIEVE trial as well as basic Human Subjects Protection (HSP) and Good Clinical Practice (GCP) standards. The approved SOPs, Clinical Quality Management Plan (CQMP) and Pharmacy Establishment Plan (PEP) will serve as resources for staff to ensure that the conduct of REPRIEVE will be to the DAIDS standards to ensure the highest quality data from this trial.

Protocol Activation is a process facilitated through the ACTG and is focused on site-readiness to conduct the specific activities within the REPRIEVE protocol. While there are some Protocol Activation steps that cannot be completed until Site Approval is provided (such as Protocol Registration), sites are encouraged to work on both approval processes concurrently to avoid delays.

Once your site receives approval of DAIDS Protocol Registration, your CRS Leader and Coordinator will receive an email inviting them to review the Protocol Activation Checklist. Instructions for the Protocol Activation checklist are located on the PSWP. *Only after all requirements have been met*, please submit

the completed checklist to proceed with site activation.

Please refer any questions you may have about Protocol Activation to Stephanie Holland or Akbar Shahkolahi at ACTGSiteCoordination@s-3.com

We would like to introduce...

Laura Smith, Education Coordinator.
As the Education Coordinator at Frontier Science, Laura Smith plays a role in training site staff in data management. For the REPRIEVE study, Laura is working with the other Frontier Science data managers to provide training on account set-up, OpenClinica, subject enrollment, case report forms, and events. If site staff have any questions or concerns regarding data management training, please contact Laura at lsmith@fstrf.org or (716) 834-0900 x7351.

Akbar Shahkolahi and Stephanie Holland, Site Support Team.
The Site Support Team at the Network Coordinating Center (NCC) for the ACTG facilitates the process of Protocol Activation. To streamline this process our team works closely with the protocol team, DAIDS, PAB, FSTRF, BWH, Lab group, NHLBI, and REPRIEVE study sites. We are here to guide sites while gaining approvals required for activation of the REPRIEVE trial. We provide training, technical and administrative support to sites for all protocol activation activities. Stephanie Holland and Akbar Shahkolahi can be reached at ACTGSiteCoordination@s-3.com.

How will Appendix 100 be used for REPRIEVE?

Appendix 100, DIAGNOSES APPENDIX CRITERIA FOR CLINICAL AND OTHER EVENTS V1.0, is to be used for REPRIEVE *only* for to the diagnosis criteria for AIDS-defining events. Appendix 100 can be accessed on the PSWP in folder “Current Study-Specific Support Documents”.

What if a participant's PCP wants to prescribe a statin during study participation?

Starting a statin during study participation is prohibited, if this does happen, the participant will discontinue study drug and stay on study/off study drug. However, it is recommended that the Site PI follow up with the prescribing clinician in order to determine equipoise for prescribing the statin. A template for a "participant card" with information about study participation was recently added to the PSWP. If sites choose to use this template, it will need IRB approval. This template has been provided so that participants can alert other clinicians of their participation in REPRIEVE and make them aware that they may already be on statin therapy.

To calculate creatinine clearance, can I use a participant's weight and creatinine obtained on separate days to enter into the calculator?

It is permissible to enter creatinine and weight ascertained on different days but both dates must occur within a 90-day window.

Video recording of the Data Management Start-Up Training is now available

Video recording of the ***Data Management Start-Up Training Webinar for ACTG Sites*** is available on the DMC Portal. It may be found at REPRIEVE Video, or on the DMC Portal on the REPRIEVE tab, under Site Support. Please note, this recording is from the training that took place on 2/11/15. Additional training videos will be posted in the future. You must be a registered DMC Portal user to access the video. If you have any questions on this video, or data management training for REPRIEVE, please contact Laura Smith at lsmith@fstrf.org or (716) 834-0900 x7351.

Site Updates

Number of Sites Open to Enrollment:

- 2 sites

Number of Sites Protocol Registered:

- 4 in progress
- 14 registered

Number of Sites DAIDS Approved:

- 9 sites

Are you up to date? For A5332 Please use

Protocol:
Version 2.0 dated 12/19/2014
MOPS:
dated 03/16/2015
A5332 LPC for ACTG Sites only:
dated 01/23/2015
A5332 LPC for Non-ACTG Sites only:
dated 03/16/2015

All documents are found on the PSWP

Mechanistic Substudy (A5333s) Updates

Are you up to date? For A5333s Please use

Number of CT Activated Sites:

- 10 sites

Number of Sites Protocol Registered:

- 1 in progress
- 7 registered

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

MOPS:

dated 03/16/2015

A5333s LPC:

dated 03/16/2015

All documents are found on the PSWP

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.

To unsubscribe, please email reprieve.news@fstrf.org. Please do not use "unsubscribe" feature below.