REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 04/13/2015

REPRIEVE has been quite active in the last few weeks! Since the last newsletter we have almost 3 times as many sites protocol registered and 5 times as many sites activated, more importantly the first participant was randomized on March 26th and 8 participants are in screening.

We would like to thank staff at all the clinical sites participating in REPRIEVE, we know that sites are at different stages in the process of activating to enroll and we greatly appreciate all your hard work to launch REPRIEVE.

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?

The A5332 non-ACTG Lab Processing Chart (LPC) has new details regarding shipping

The A5332 non-ACTG LPC has been revised to include instructions for the shipment of specimens and a notification that the site specific shipping schedule will be posted on the PSWP in the next few weeks. An announcement will be included in a future newsletter when the schedule is posted.

The A5332 Protocol Specific Web Page (PSWP) has many helpful documents

We have recently posted a list of **FAQs** on the PSWP, this list will be updated frequently during the course of the trial. The PSWP now has **Spanish translations** of questionnaires, the participant summary

and the participant hand out. Also, in case you didn't know the PSWP also has **sample phone screen sheets**, **recruitment flyers**, and a **sample participant visit schedule**. Please use your IRB's guidance for submission and approval of the participant materials.

webLDMS training will be starting soon

If your site does not already have windows LDMS, FSTRF will be contacting your site regarding webLDMS training. Training announcements will only be sent and forwarded to those sites that have submitted an LDMS registration form and have an LDMS lab ID assigned.

Do you need to complete the Human Subject (HSP)/Good Clinical Practice (GCP) training through CITI and your institution is not listed?

There are two options to access the HSP/GCP training through CITI if your institution is not listed:

Option A:

Establish User Account and Password in DAIDS LMS in order to access CITI HSP/GCP training

Option B:

Log into the CITI website and follow steps 2-8

1. Log into the CITI website (www.citiprogram.org).
2. Choose 'Click here to affiliate with another institution.'
3. Enter 'Division of AIDS (DAIDS).'
4. Click 'Next.'
5. Complete all required fields; note users may select 'Other' for the 'Which course do you plan to take?' question.
6. Click 'Next.'
7. Answer questions 1, 5, and 6 on the next page.
8. Click 'Submit.'

Once the process has been finalized, DAIDS courses will be listed with the two pertinent trainings (GCP and HSP)

We would like to introduce...

As REPRIEVE Project Specialists at the ACTG Network Coordinating Center (NCC), Barbara Bastow and Laura Moran coordinate protocol implementation and act as liaisons to the ACTG. They collaborate with the protocol team to develop training materials, draft protocol documents, and correspond with site staff. Barbara and Laura maintain the protocol-specific web pages (PSWPs) for the main REPRIEVE study and the Mechanistic Substudy. If site staff have any questions about implementing the protocol at the site level or ACTG processes, please contact Barbara at bbastow@s-3.com or Laura at lmoran@s-3.com.

Which members of the site staff should receive A5332 email announcements, and how can these site staff members be added to the protocol e-mail group?

All relevant study staff should receive A5332 email announcements. Examples of relevant study staff are: Principal Investigator, Clinical Research Site Leader, Investigator of Record, Clinical Research Site Coordinator, study/protocol coordinators, pharmacist, data manager, and laboratory staff. Sites should email actg.support@fstrf.org to request that relevant study staff at the site be added to the actg.prota5332@fstrf.org e-mail group so that important study information will be relayed to them. Indeed, the 'A5332 prot logon' is the primary means of communication between the team and site staff. A site may place as many staff on the protocol e-mail group as are considered necessary.

If the REPRIEVE informed consent form requires change to meet local IRB requirements, does the revised informed consent form need to be reviewed prior to IRB submission?

The draft informed consent form is not formally reviewed **prior** to submission to your local IRB. The DAIDS Regulatory Support Center will review all relevant materials once they have been approved by your local IRB.

The REPRIEVE informed consent form template recommends a pattern of reimbursement for participants. Can this pattern of reimbursement be modified?

Yes, the pattern of reimbursement delineated in the REPRIEVE informed consent form template can be modified at the discretion of the site PI pending approval of changes by the DAIDS Regulatory Support Center. The total reimbursement may stay the same as originally allocated but may be subdivided in a pattern other than the pattern suggested. Alternately, the total reimbursement may be augmented at the discretion of the site PI (e.g. if the site PI draws from site start-up funds to supplement participant remuneration).

Helpful Hints from the Data Management Center

Here at the DMC we are working on making easy to follow guides for correct data entry of Adverse Events.

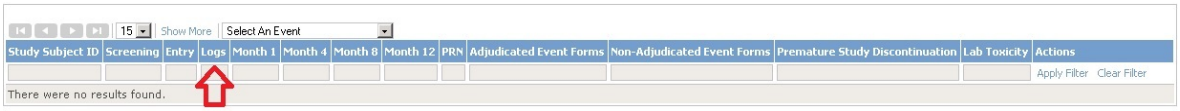
Below are examples displaying the difference between a standard adverse event and an adverse event that is also a clinical event.

Information and instructions on Adverse Event reporting—including Expedited Adverse Events—can be found in the A5332 MOPS.

Any event that is NOT an Adjudicated Event would follow this route:

Scenario 1: Subject is hospitalized for **Influenza at Month 10**

- You would only complete a log line entry in **ADE0001- Adverse Events Log** in the **Logs** event.
- You would not enter any data in the Month 12 visit until the visit for Month 12 occurred.



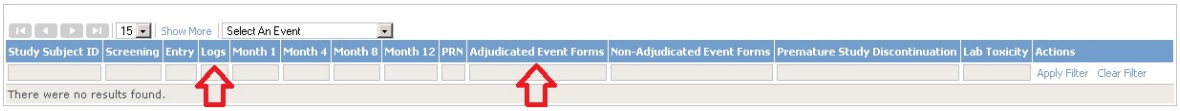
(Click to enlarge in a new window)

The Adjudicated Events would follow these routes:

Scenario 2: Subject is hospitalized for a **Stroke at Month 10** and you find out at **Month 10**

- You would complete a log line entry in **ADE0001- Adverse Events Log** in the **Logs** event
- You would complete **TRK0150 - Adjudicated Events Tracking** in the **Adjudicated Events Forms** event.
- You would complete **EVW0338 – Cerebrovascular Event (Stroke or TIA)** in the **Adjudicate Event Forms** event.

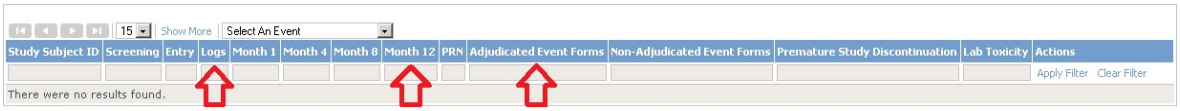
This scenario has the caveat that at the Month 12 visit you would enter the TRK0150 – Adjudicated Events Tracking form again but not re-report this info.



(Click to enlarge in a new window)

Scenario 3: Subject is hospitalized for a **Stroke at Month 10** and you find out at **Month 12**

- You would complete a log line entry in **ADE0001- Adverse Events Log** in the **Logs** event
- You would complete **Month 12** event forms (most importantly TRK0150- Adjudicated Events Tracking)
- You would complete **EVW0338 – Cerebrovascular Event (Stroke or TIA)** in the **Adjudicate Event Forms** event.



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Site Updates

Number of Participants in Screening:

- 8

Number of Participants Randomized:

- 1

Number of Sites Open to Enrollment:

- 10 sites

Number of Sites Protocol Registered:

- 7 in progress
- 27 registered

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

Number of CT Activated Sites:

- 10 sites

Number of Sites Protocol Registered:

- 14 registered

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

All documents are found on the 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.