

MTN-025 Data Communiqué #7 - July 31, 2017

This is official study documentation for MTN- 025. Please circulate it among relevant staff for their review, print it, and place it in your MTN-025 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-025 SSP manual.

UPDATES

1. SCHARP Clinical Data Manager Update

Melissa Peda has assumed responsibility as Lead Clinical Data Manager on MTN-025. Please contact Melissa (mapeda@scharp.org) regarding any questions related to data collection or data management in MTN-025.

2. Query Management Module

The Medidata Rave Query Management module is available for site that that allows one to search, view, and answer queries. A Rave Query Management slide set is available on the MTN-025 ATLAS webpage under the Medidata Rave Materials section (<https://atlas.scharp.org/cpas/project/MTN/025/begin.view?>) that provides additional details about this module and steps that are needed in order to access and use this module within Rave. Site staff who have access to the Query Management module will need to complete the Query Management e-Learning. Please contact the SCHARP Clinical Data Manager with a list of site staff who should be assigned this e-Learning no later than August 11.

CLARIFICATIONS

1. Adding Interim Visit Folders in Error

If an interim visit folder was added in error (i.e. three interim visit folders were accidentally added for one interim visit conducted), leave all items within the extraneous interim visit folder blank on the Date of Visit eCRF and Interim Study Procedures CRF. Please save the Date of Visit eCRF blank. A system query will trigger; please respond to the system query in the query response text field that the interim visit was added in error and re-save the page. This will alert the SCHARP Clinical Data Manager so that the extraneous forms within the interim visit folder can be inactivated as well as any system queries that are triggered can be canceled or resolved.

2. Inactivating Log Lines

If a log line needs to be inactivated, please do not remove the data on the specific log line. Each log line can be inactivated by clicking "Inactivate" at the bottom of the log page and selecting the log line that needs to be inactivated.

However, if a form that is not set up as a log page (i.e. Ring Collection and Insertion, Laboratory Results, etc.) needs to be inactivated for some reason, please remove all of the data from the form and contact the SCHARP Clinical Data Manager so that the form can be inactivated.

REMINDERS

1. Completion of the Pre-Screening Outcome CRF

One Pre-Screening Outcome form should be completed for each former MTN-020/ASPIRE participant. Even if the participant was not eligible to screen and enroll into HOPE per the site-specific Participant Eligibility List, a Pre-Screening Outcome CRF should be completed to document the reason why she was not contacted. Participants who do not screen for HOPE (i.e., participants who do not sign an informed consent) are assigned a Pre-Screening ID and the Pre-Screening Outcome CRF is completed, but their name is NOT entered onto the PTID-Name Linkage Log for HOPE. All Pre-Screening Outcome CRFs should be completed no later than September 15. However, if a participant screens after the formal accrual period for HOPE, the Pre-Screening Outcome CRF should be updated for that participant.

2. ACASI Questionnaire Listing Available on Atlas

A cumulative listing of all ACASI questionnaires that have been uploaded and processed at SCHARP is available on each site-specific ACASI page on the ATLAS webpage (<https://atlas.scharp.org/cpas/project/MTN/025/ACASI/begin.view?>). To view and download this listing, click on your site-specific ACASI page. Under the section “Processed Files to Date”, select the “click here” link to view the PDF that lists in ascending order by PTID the survey name, the date survey completed, and the survey status. Please note that if a file was recently uploaded, it is possible that it will not appear within the listing for a few days until the file is processed at SCHARP.

Processed Files to Date ▾

Please [click here](#) for a cumulative list of all site ACASI files that have been uploaded and processed at SCHARP to date. Please keep in mind that SCHARP requires a few days to process ACASI files. Therefore, if a file was recently uploaded, it is possible that it will not appear in this list for a few days until processing is complete. This list is updated on a nightly basis.

For any ACASI issues, including technical issues related to uploads or backups, please email mtn025acasi@mtncshiv.org.

3. Inactivating Log Lines

If a log line needs to be inactivated, there is no need to remove the data on the specific log line. Each log line can be inactivated by clicking “Inactivate” at the bottom of the log page and selecting the log line that needs to be inactivated.

However, if a form that does not have log lines needs to be inactivated for some reason, please remove all of the data from the form, contact the SCHARP Clinical Data Manager so that the form can be inactivated.

4. Administrative Forms

With the exception of the Additional Study Procedures form, **all** forms in a participant’s casebook are required to be completed, including the Adverse Event Y/N and Concomitant Medications Y/N.

5. Resolving Rave System and Manual Queries

Please remember that when resolving Rave system and manual queries, the data point itself needs to be updated by using the pencil icon to open up the field so that it can be edited. The updated data point should not be inputted in the query response text field; rather, the query response text should be used to document any clarifying information regarding the data point or to request additional guidance from SCHARP on query resolution. In addition, the query response text field is *optional* when responding to **system** queries. The query response text field is *mandatory* when responding to manual queries that are placed by SCHARP or PPD.