

## MTN-026 Data Communiqué #2 - April 13, 2018

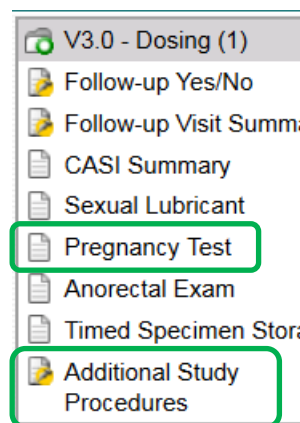
This is official study documentation for MTN- 026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-026 SSP Manual.

### UPDATES

#### 1. CRF Completion for Pregnancy Testing under Letter of Amendment #01, dated 22 March 2018

Under Letter of Amendment (LoA) #01, dated 22 March 2018, pregnancy testing is now required for female participants at Visit 3 and Visit 13 and no longer required at Visit 14. Please complete the following steps to align with the change in pregnancy testing under LoA #01:

- Because pregnancy testing is no longer required at Visit 14, please leave the Pregnancy Test CRF blank within the Visit 14 folder. SCHARP will manually inactivate the Pregnancy Test CRF.
- As pregnancy testing is still required at Visit 7, the Pregnancy Test CRF will continue to dynamically add as part of the required CRFs within this visit folder once the Follow-up Yes/No CRF is completed within the Visit 7 folder.
- The Pregnancy Test CRF is not automatically added to the participant's visit folder at Visit 3 and Visit 13. In order to add this form to the applicable visit folder, please complete the following steps for Visits 3 and 13:
  - 1) On the Follow-up Visit Summary CRF, select 'Yes' for item "*Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?*". This will dynamically add the Additional Study Procedures CRF to the participant's visit folder.
  - 2) On the Additional Study Procedures CRF, check the box for 'Pregnancy Test'. This will dynamically add the Pregnancy Test CRF to the participant's visit folder.
  - 3) Complete the Pregnancy Test CRF as applicable.



The change in pregnancy testing should be implemented once your site has received approval of LoA #01. For example, if a participant has completed Visit 10 but has not yet completed Visit 11 when LoA #01 is approved, then pregnancy testing should be completed at Visit 13 only.

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## 2. CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to v1.2 (dated 13 April 2018) and are posted on the MTN-026 Atlas webpage (<https://atlas.scharp.org/cpas/project/MTN/026/begin.view?>) for download.

### CLARIFICATIONS

If a system query triggers in error, note within the query response that the data is correct and SCHARP will close out these erroneous system queries.

Did the participant complete study product use through Visit 13 (Last Study Product Administration Visit)?

? "Did the participant complete study product use through Visit 13?" is "Yes", but it is indicated study product was permanently discontinued prior to Visit 13. Please review and update as appropriate.  
Opened To Site from System (23 Mar 2018)

Yes  No

### REMINDERS

No updates