MTN-025 Data Communiqué #12 – July 5, 2018

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

Medidata Database Updates

The MTN-025 clinical database was updated on 05 July 2018. The main purpose of updating the clinical database was to update edit check programming, including system queries and form dynamics.

System Queries

Some of the updated system queries will trigger retrospectively on forms that were submitted within Medidata for completed visits. Please note that specific items were previously hidden after the form was saved based upon form skip instructions. As part of this recent database update, these fields will no longer be hidden and a system query may trigger if data is discrepant with what is expected. If data was originally entered when it is not required, the data should be removed and the form re-saved. Conversely, if data was not entered when it was expected, then the item should be completed as applicable. However, if this data cannot be obtained (e.g., the form was participant administered), then please include this specific information in the query response field in response to the system query and SCHARP will resolve the query. Please refer to the Clarifications section below for specific forms that have been updated.

Visit Schedule and Visit Folders for HOPE Late Enrollees

Participants who enrolled in HOPE between 16 September 2017 and 25 May 2018 have a shortened follow-up period. As such, some participants who enrolled later into HOPE will not have certain visits in their visit schedule, due to the shortened follow-up period. The visit windows are narrower for specific visits and adjusted accordingly, depending on when the participant enrolled into the study. As a reminder, the modified Visit Calendar Tool specific to that participant's date of enrollment should be used to calculate the participant's visit windows.

For participants who enrolled after 15 September 2017, SCHARP has manually added the V8 – PUEV (Month 12) visit folder to the participant casebooks within Medidata Rave. As a reminder, the V9 – Study Exit/Termination folder will automatically populate after the Follow-up Visit Summary has been completed and submitted within Medidata Rave. Any visit folders that are not relevant to the participant's visit schedule and populate within the participant's casebook will also be inactivated by SCHARP. Please note, however, that visit window edit checks will remain in place based on the full visit schedule. If a system query triggers stating that the entered visit date is before the visit window has opened, please provide a response within the query response box noting that the participant is on a shortened visit schedule, and SCHARP will close out these queries.

The Product Use End Visit (PUEV) and Study Exit Visit (SEV) will still be labelled V8 - Month 12 and V9 - Study Exit/Termination within Medidata, and the visit numbers will remain 8.00 and 9.00, respectively. Interim visits will follow the same visit structure and will be labeled according to where they fall within the participant's visit schedule. **Please note that although the visit folder for V8 is labeled Month 12 within Medidata, this visit folder will always refer to the participant's PUEV.**

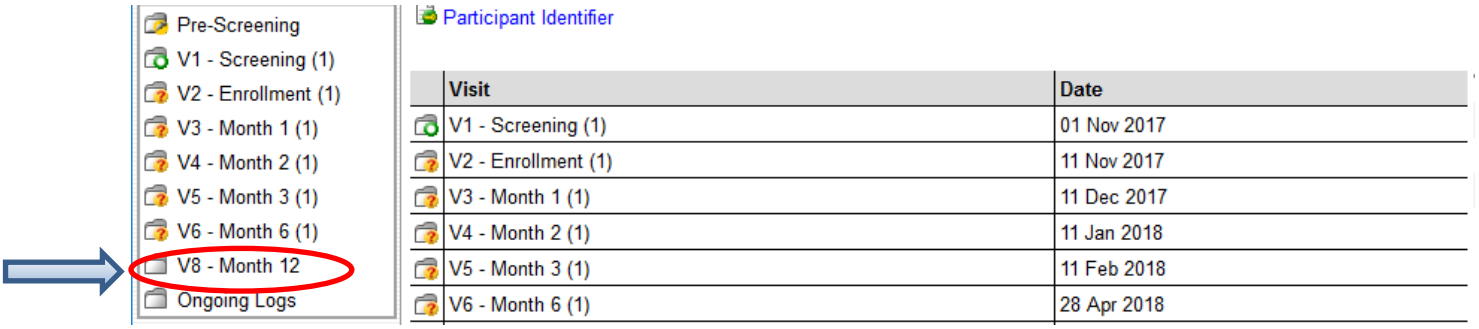
The table below represents the adjusted visit schedules, depending on when the participant enrolled into HOPE. Depending on when the participant enrolled into HOPE, not all of the visits may be required and visible within the participant's casebook.

	Up until 15 Sep	16 Sep – 13 Oct	14 Oct – 10 Nov	11 Nov – 8 Dec	9 Dec – 5 Jan	6 Jan – 2 Feb	3 Feb – 2 Mar	3 Mar – 30 Mar	31 Mar – 27 Apr	28 Apr – 25 May
V1 - Screening	X	X	X	X	X	X	X	X	X	X
V2 - Enrollment	X	X	X	X	X	X	X	X	X	X
V3 - Month 1	X	X	X	X	X	X	X	X	X	X
V4 - Month 2	X	X	X	X	X	X	X	X	X	X
V5 - Month 3	X	X	X	X	X	X	X	X	X	
V6 - Month 6	X	X	X	X	X	X				
V7 - Month 9	X	X	X							
V8 – PUEV (Month 12)*	X	X (Month 11)	X (Month 10)	X (Month 9)	X (Month 8)	X (Month 7)	X (Month 6)	X (Month 5)	X (Month 4)	X (Month 3)
V9 – Study Exit/Termination	X	X	X	X	X	X	X	X	X	X

*A participant's PUEV has been adjusted so that this occurs no later than 30 August 2018 and is targeted to occur earlier than Month 12 for participants who enrolled after 15 September 2017.

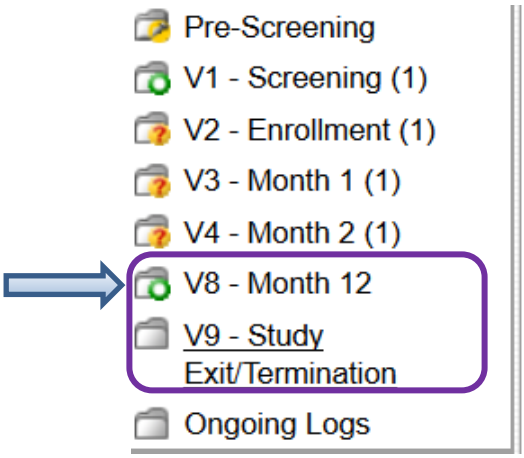
Example 1

A participant enrolled on 11 November 2017. The visit folders V1 – Screening, V2 – Enrollment, V3 – Month 1, V4 – Month 2, V5 – Month 3, and V6 – Month 6 would be present within the participant's casebook. After the Visit 6 window has closed, the next visit would be V8 - PUEV, followed by V9 – Study Exit/Termination. The V8 – Month 12 visit has been manually added to the participant's casebook (see below). Note there is no Visit 7 – Month 9 folder present for this participant as this folder has been inactivated by SCHARP. The V9 – Study Exit/Termination folder will populate after completion of the Follow-up Visit Summary CRF within the V8 – Month 12 folder.



Example 2

A participant enrolled on 15 May 2018. Visit folders would be present from V1 – Screening through V4 – Month 2. After the Visit 4 window has closed, the next visit folder present would be V8 - PUEV, followed by V9 – Study Exit/Termination. The V8 – PUEV (Month 12) folder has been manually added to the participant's casebook (see below) and the V9 – Study Exit/Termination folder will populate after completion of the Follow-up Visit Summary CRF within the V8 – Month 12 folder. Note that there will be no visit folders for V5 – Month 3, V6 – Month 6, V7 – Month 9 associated with this participant.



Participant Identifier

	Visit	Date
	V1 - Screening (1)	28 Apr 2018
	V2 - Enrollment (1)	15 May 2018
	V3 - Month 1 (1)	26 May 2018
	V4 - Month 2 (1)	23 Jun 2018
	V8 - Month 12	07 Aug 2018

Example 3

A participant enrolled on 16 September 2017 will have all visit folders present (V1 – Screening through V9 – Study Exit/Termination). However, the V8 - PUEV visit schedule is adjusted so that the PUEV is targeted to occur around Month 11, rather than Month 12.

CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to v2.1 (dated 5 July 2018) and are posted on the MTN-025 Atlas webpage for download. In addition, a Summary of Changes that highlights the specific updates is now included at the end of the document.

CLARIFICATIONS

1. Behavior Assessment

Items 21 – 26 on the Behavior Assessment should be completed at the Product Use End Visit (PUEV) or Early Termination Visit only, with the exception that Item 26 should be blank if "At any time during the past three months, have you had a primary sex partner" (Item 1) is 'No'. If item 22 is 'not applicable – never used the ring during HOPE', then item 23 (23a, 23b, and 23c) should be skipped. The remaining items 24, 25, and 26, should still be completed as applicable.

2. Study Exit Assessment

If “How many participants do you personally know in the HOPE study” (Item 2) is greater than 0, a numerical value should be completed for each item 2a – 2e. If the participant does not know any women in a given category, ‘0’ should be entered rather than leaving the field blank. In addition, the number of women reported in items 2a – 2e should add up to the number of participants that the participant reported knowing personally in the HOPE study, per item 2.

3. Vaginal Practices

If ‘NA’ is indicated for “In the last 3 months, what have you used to control or manage the menstrual blood or spotting?” (Item 1), then 1a-1g1, including ‘Specify’, should not be completed.

4. Social Influences Assessment

If “How many people in your life did you talk to about the HOPE study besides clinic staff” (Item 1) is 0, then this is the end of the form and the questions for Person 1 – Person 5 should not be completed.

5. Pelvic Exam

If “Pelvic exam assessment” is ‘No abnormal findings’, then there should be at least one or more responses documenting an abnormal finding(s).

If “Pelvic exam assessment” is ‘Not done’, then this is the end of form, and the remaining items should not be completed.

6. Pregnancy Outcome

If “Specify outcome” (Item 4) is anything other than ‘Full-term live birth’, then “Provide a brief narrative of the circumstances” (Item 5) should be completed. Conversely, if “Specify outcome” (item 4) is ‘Full-term live birth’, then “Provide a brief narrative of the circumstances” (Item 5) should not be completed.

7. Seroconverter Laboratory Results

If Absolute CD4+ and CD4% test results are completed, then a T Cell Subsets Collection Date is required.

8. Specimen Storage

If a vaginal swab was not stored or not required, then “Was blood visible on the swab?” (Item 2b) and “Was a used ring in place at the time of swab collection?” (Item 2c) should not be completed.

9. Adverse Experience

The “Onset Date” (Item 2) must be on or prior to the “Date reported to site”.

10. Protocol Deviation Log completion for deviations not associated with a PTID

If a protocol deviation is associated with multiple participants or is a non-PTID specific protocol deviation (e.g. study product exceeds storage temperature while at the pharmacy), a Protocol Deviation Log CRF must be completed for each participant impacted by the deviation

This guidance supersedes the guidance issued in Data Communiqué #11, dated April 12, 2018.

REMINDERS

None