MTN-017 Data Communiqué #6 - August 7, 2014

This is official study documentation for MTN-017. Please circulate it among relevant staff for their review, print it, and place it in your MTN-017 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-017 SSP manual and is posted on the MTN web site at http://www.mtnstopshiv.org/node/4643.

UPDATES

1. MTN-017 Data Collection & Management Training Slides Available On-line

   The MTN-017 data collection and management slides presented during study-specific training are now posted on the MTN web site and are available for download: http://www.mtnstopshiv.org/node/5845. The slides include audio narration, which can be heard via the slideshow feature in Microsoft PowerPoint.

CLARIFICATIONS

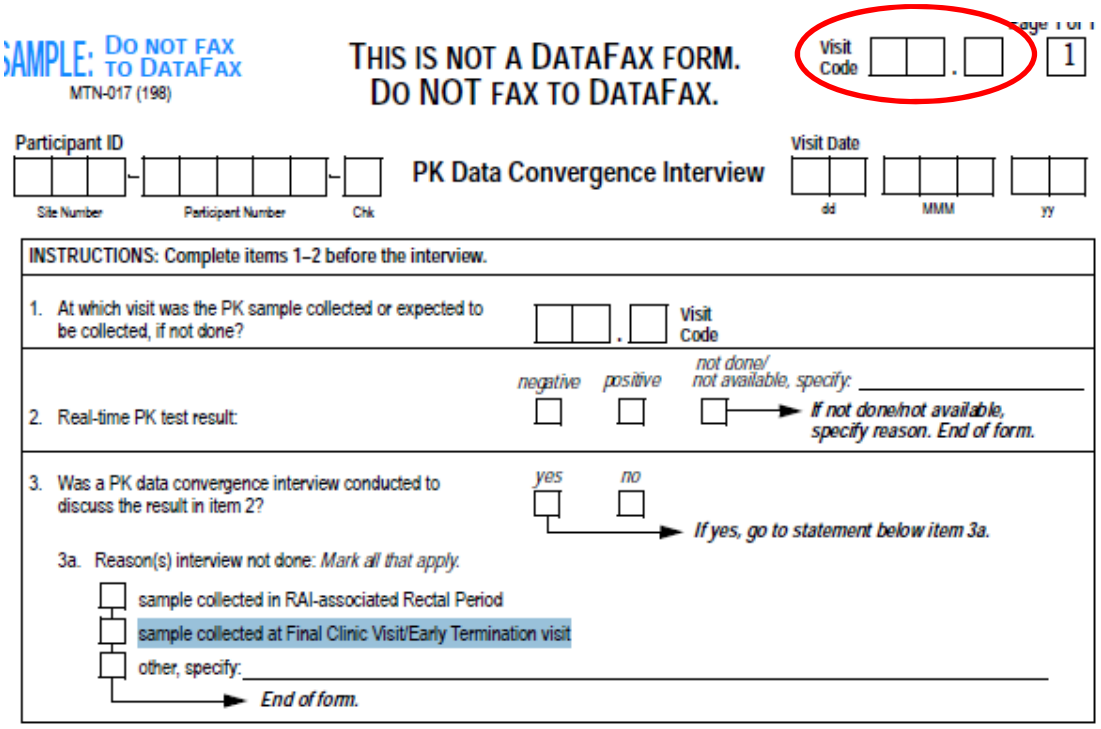
1. Required Completion of the Data Convergence Interview (DCI) and PK Data Convergence Interview (PK DCI) CRFs

   Per Table 11.3 of the SSP, completion of the DCI form is required at all Mid-period and End-period visits, regardless of whether or not the data convergence interview was actually done. If a Mid-period or End-period visit is conducted but the interview is not done for whatever reason, complete items 1-5, mark item 6 “no, specify” and document the reason the interview was not done on the adjacent line. If a Mid-period or End-period visit is missed in its entirety, a DCI form is not required. Rather, only a Missed Visit CRF needs to be completed to document the missed visit.

   Per Table 11.3 of the SSP, completion of the PK DCI form is required at all End Period Visits (visit codes 4.0, 7.0, and 10.0) and the second and third Mid-period visits (visit codes 6.0 and 9.0), regardless of whether or not the PK interview was actually done. If one of these visits is conducted but the interview is not done for whatever reason, indicate the reason in item 2 or 3 as appropriate. If one of these visits is missed in its entirety, a PK DCI form is not required. Rather, only a Missed Visit CRF needs to be completed to document the missed visit.

2. Documenting the Final Blood PK Result

PK interviews are not conducted to discuss participants' final blood PK result, since the blood is drawn at the participant's final clinic visit (visit code 10.0 or early termination). However, SCHARP still requires completion of the PK DCI form to document the result. Record in the Visit Code field (circled in red below) the visit code of the final clinic visit. This will be the same visit code that is recorded for item 1. Complete items 1-3, and mark item 3a "sample collected at Final Clinic Visit/Early Termination visit".



SAMPLE: DO NOT FAX TO DATAFAX
MTN-017 (198)

THIS IS NOT A DATAFAX FORM.
DO NOT FAX TO DATAFAX.

Visit Code ☐☐.☐ Page 1 of 1

Participant ID ☐☐☐-☐☐☐☐-☐ (Site Number / Participant Number / Chk)

PK Data Convergence Interview

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

INSTRUCTIONS: Complete items 1–2 before the interview.

1. At which visit was the PK sample collected or expected to be collected, if not done? ☐☐.☐ Visit Code

2. Real-time PK test result: ☐ negative ☐ positive ☐ not done/not available, specify: _____ → If not done/not available, specify reason. End of form.

3. Was a PK data convergence interview conducted to discuss the result in item 2? ☐ yes ☐ no → If yes, go to statement below item 3a.

3a. Reason(s) interview not done: *Mark all that apply.*

☐ sample collected in RAI-associated Rectal Period
☐ sample collected at Final Clinic Visit/Early Termination visit
☐ other, specify: _____

→ End of form.

3. Avoiding Duplicate CASI & Web Entry Records

To avoid creating duplicate electronic study records (i.e., CASI surveys, web entries of Data Convergence CRF and PK Data Convergence CRF data) for a given participant visit, please keep in mind the following:

a. Do not begin a CASI survey until the participant/site staff member is in front of the computer and ready to complete the entire survey. This will ensure that the start and end dates for the survey are the same.
b. Do not enter data convergence data (DCI or PK DCI) for the same form over multiple days. Once form data entry begins, do not terminate the session until all of the given form's data is entered and submitted.
c. Review the CASI and data convergence form schedule below (Table 6-3 from the SSP) prior to opening up a new CASI survey or web form for data entry. This will help prevent the creation of incomplete records due to the wrong survey/form being chosen at a given visit.

Table 6-3
Data Convergence Interview Schedule & Components

Study Visits	Required Non-DataFax CRFs	Data Convergence Interview Discussion Points
PERIOD 1		
Week 4: Mid Period 1 Visit 3	Data Convergence Interview	• SMS calendar data between Visit 2/Enrollment and Visit 3 • Product count data at Visit 3
Week 8: End Period 1 Visit 4	Data Convergence Interview	• SMS calendar data between Visit 3 and Visit 4 • Product count data at Visit 4
	PK Data Convergence Interview*	• PK result from blood collected at Visit 3 • SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 3 • SMS calendar data between Visit 2/Enrollment and Visit 3
PERIOD 2		
Week 13: Mid -Period 2 Visit 6	Data Convergence Interview	• SMS calendar data between Visit 5/Initiate Period 2 and Visit 6 • Product count data at Visit 6
	PK Data Convergence Interview*	• PK result from blood collected at Visit 4 • SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 4 • SMS calendar data between Visits 3 and 4
Week 17: End Period 2 Visit 7	Data Convergence Interview	• SMS calendar data between Visit 6 and Visit 7 • Product count data at Visit 7
	PK Data Convergence Interview*	• PK result from blood collected at Visit 6 • SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 6 • SMS calendar data between Visits 5 and 6
PERIOD 3		
Week 22: Mid-period 3 Visit 9	Data Convergence Interview	• SMS calendar data between Visit 8 and Visit 9 • Product count data at Visit 9
	PK Data Convergence Interview*	• PK result from blood collected at Visit 7 • SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 7 • SMS calendar data between Visits 6 and 7
Week 26: End Period 3 Visit 10**	Data Convergence Interview	• SMS calendar data between Visit 9 and Visit 10 • Product count data at Visit 10
	PK Data Convergence Interview*	• PK result from blood collected at Visit 9 • SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 9 • SMS calendar data between Visits 8 and 9

* The PK Data Convergence Interview is conducted only if a PK result is available and only if the visit falls within the daily oral or daily rectal gel regimen periods. If the visit falls within the RAI-associated rectal gel period, the PK Data Convergence Interview CRF is still completed to document the PK result; however, the interview to converge the PK result with the SMS and product count data is omitted. If a PK result is not available at the time of the visit, the PK data convergence interview is omitted; however, the PK Data Convergence Interview CRF is still completed to document that no interview was done.

**At Visit 10, the PK Data Convergence Interview CRF is completed to document a PK result from blood collected at Visit 9, and to document the PK interview itself, if it was conducted. Once the PK result from the blood sample collected at Visit 10 is available, a second (new) PK Data Convergence Interview CRF should be completed to document the Visit 10 sample PK result.

Note: If a participant misses a visit at which a data convergence interview or PK data convergence interview was expected to take place, the missed interview(s) should be made up at the participant's next regularly scheduled visit.

REMINDERS

1. CASI Completion During Product Holds/Discontinuations

   Per protocol section 7.6.2, completion of the Follow-up CASI questionnaire (tablet, daily gel, or RAI gel) is required at the visit in which study product is first held/discontinued, or at the visit in which site staff first learn that the participant has stopped/intends to stop study product use. This may occur at an interim visit, in which case the appropriate interim visit code should be assigned to the questionnaire based on where the participant is in his/her study follow-up period.

   Refer to section 11.6.2 of the SSP for further details on interim visit code assignment.

2. Data Management Quality Goals

   As stated in each site's Data Management SOP, it is expected that sites fax at least 95% of MTN-017 CRFs to SCHARP within 7 days of a completed study visit. Exceptions to these guidelines are allowed for CRFs that record local laboratory results (received after completion of a visit), and Screening Visit CRFs.

   Adverse Experience Log (AE Log) forms documenting an Expedited Adverse Event (EAE) should be faxed to SCHARP within 3 business days.

   The QC rate per 100 records goal is less than 5.

   Please actively review your site's monthly Data Management Quality Report statistics (reports posted on Atlas https://atlas.scharp.org/cpas/project/MTN/017/begin.view?), measure your site's performance against these goals, and implement strategies to meet them (e.g., use of iDataFax). If you have any questions, please do not hesitate to contact the SCHARP Project Manager (karen@scharp.org).