MTN-017 Site Training Guide

Behavioral Assessments at Follow-up

Overview

- Web-based Computer Assisted Self-Interview (CASI)
 - Follow-up Behavioral Questionnaires (FUP)
- SMS Diary Follow-up
- In-depth Phone Interview
- Data Convergence Interview
- PK Data Interview

Study Timeline

Study Visit	Behavioral Measures and Activities	
Visit 1, Screening	(Conduct SMS Readiness Assessment)	
Visit 2, Enrollment, Initiate Period 1	Baseline Behavioral Questionnaire (CASI)	
Visit 2 , Enrollment, Initiate Period 1	Initiate SMS Diary	
Visit 5 , Initiate Period 2	(Conduct SMS Participant Training &	
Visit 8, Initiate Period 3	Provide SMS Instruction Postcard)	
Visit 3, Mid Period 1	Data Convergence Interview/PK Data Interview (when data available)	
Visit 4, End Period 1		
Visit 6, Mid Period 2		
Visit 7, End Period 2		
Visit 9, Mid Period 3		
Visit 10, End Period 3		
Visit 4, End Period 1	In-depth Phone Interview (subset)	
Visit 4, End Period 1		
Visit 7, End Period 2	Follow-up Behavioral Questionnaire (CASI)	
Visit 10, End Period 3		

Acceptability Measures

Participant self-report of ease of use, liking the product, and likelihood of product use if shown to be effective

- Follow-up Behavioral Questionnaire
- In-depth Phone Interview

Adherence Measures

Percentage of prescribed doses taken orally or administered rectally in an 8-week period

- Follow-up Behavioral Questionnaire:
- Short Message Service (SMS) Diary
- Applicator and Pill Counts
- PK Test Results
- Data Convergence Interview/PK Data Interviews
- In-depth Phone Interview

CASI Assessments

Follow-up Behavioral Questionnaire:

- Administered at all End Period Visits, or upon study termination. Tailored to each study regimen.
- Acceptability of study product:
 - liking the product,
 - ease of use,
 - likelihood to use,
 - experiences using the study product,
 - sexual behavior,
 - adherence,
 - use of rectal products,
 - recommendations, feedback on the SMS system.

Administering CASI Assessments

These assessments are web-based.
Participants' responses are recorded as they fill in the questionnaires and stored on a server at SCHARP.

Access

- www.scharp.org/MTN017/followuptablet_thai
- www.scharp.org/MTN017/followupdailygel_thai
- www.scharp.org/MTN017/followupRAlgel_thai

Troubleshooting

- Check power cord/mouse/Internet
- Email: mtn017webtrouble@mtnstopshiv.org

SMS at Follow-up

Mid-period Visits

 Provide compensation, remind to continue reporting

End-period Visits

 Provide compensation, reminders will discontinue until next Initiate Period Visit, when they will join the system again

SMS Follow-up with Participants

Non-compliant Participants

- When participants do not send a message to the system within 48 hours after the prior reminder, a staff member at BRWG will alert the study staff at the site.
- Study staff should contact participants to make sure they did not lose their phone or have any trouble with the system.

In-depth Phone Interviews (IDPI)

- Purpose: To explore factors across cultures that may facilitate or hinder adherence to product use and trial procedures and to explore product acceptability.
- 40 participants, 10 per country (5 at Bangkok site), participants with high adherence and poor adherence
- End of Period 1 Visit (Visit 4) via telephone, audio-recorded and transcribed
- Participants must opt-in during Informed
 Consent

IDPI: Preparation

Equipment:

 Landline telephone in a private, noise-free room

Pre-IDPI Communication:

- Two weeks before Visit 4, BRWG will alert staff via email if participant is selected for IDPI (based on adherence rates per SMS)
- Inform participants of selection and to allot about 30 mins extra for Visit 4
- Email Rebecca and Titcha appointment time, expected time of interview

Data Convergence Interview

- Adherence data collected via:
 - Product return counts
 - SMS reporting
 - PK test results
- Discrepancies between measures may occur
- Data Convergence and PK Data Interviews allow for clarification of discrepancies and confirmation of correct number of doses taken

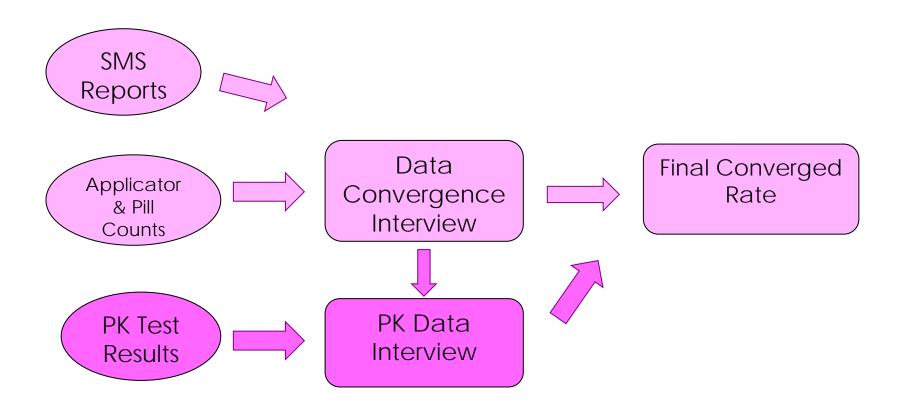
Data Convergence Interview

Final Converged Rate

- BRWG will review each Data
 Convergence Interview and PK Data
 Convergence CRF
- BRWG will confirm most likely rate of adherence to product use and provide Final Converged Rate that will be sent to SCHARP only.

Data Convergence Interview

Method for Converging Adherence Measures



Data Convergence Timeline

Study Visits	Interviews and CRFs	Interview Discussion Points
Mid Period 1, Visit 3	Data Convergence Interview (DCI)	SMS data b/w Visit 2 & 3 Product count, Visit 3
End Period 1, Visit 4	DCI	SMS data b/w Visit 3 & 4 Product count Visit 4
	PK Data Interview	PK result, Visit 3 DCI, Visit 3 & SMS calendar b/w Visit 2 & 3
Mid Period 2, Visit 6	DCI	SMS data b/w Visit 5 & 6 Product count, Visit 6
	PK Data Interview	PK result, Visit 4 DCI, Visit 4 & SMS calendar b/w Visit 3 & 4
End Period 2, Visit 7	DCI	SMS data b/w Visit 6 & 7 Product count, Visit 7
	PK Data Interview	PK result, Visit 6 DCI, Visit 6 & SMS calendar b/w Visit 5 & 6
Mid Period 3, Visit 9	DCI	SMS data b/w Visit 8 & 9 Product count, Visit 9
	PK Data Interview	PK result, Visit 7 DCI, Visit 7 & SMS calendar b/w Visit 6 & 7
End Period 3, Visit 10	DCI	SMS data b/w Visit 9 & 10 Product count, Visit 10
	PK Data Interview	PK result, Visit 9 DCI, Visit 9 & SMS calendar b/w Visit 8 & 9

Data Convergence CRF

SA		THIS IS NOT A DATAFAX FORM. DO NOT FAX DO NOT FAX TO DATAFAX.	Data Convergence Interview (non-DataFax) Page 1 of 2 Visit Code
[articipa Ste Nat	Data Convergence Interview Oix	Visit Date
	INSTRU	ICTIONS: Complete items 1–5 before the introdice.	
	1. D.1		No product given to participent at or since lest completed egularly scheduled list.
	1a.	See form instructions for participants who were given study product at an interim visit. Total number of days since product given to participant: # of days Calculate by subtracting item 1-days from Visit Date.	
	2. Inw	hich period was the last PDR-1 CRF completed? Oral period Daily rectal period	→ Go to item 4.
ŀ		RAI-associated rectal period	Go to item 5.
		AL DEFINIOU Total number of tablets taken based on product return: # of tablets	
١		Transcribe from item 1h on the current visit's PDR-1 CRF. See form instructions for perticipants who were dispensed or returned study product at an in	telm visit
	3b.	Total number of tablets taken based on SMS: # of tablets OB	No SMS data available Go to Item 6
		Iran mile from screedshood provided by the October Research Working Group.	on page 2.
	4. DAI	MECTAL PERIOD	
	42.	Total number of applicators used based on product return:	
		Transcribe from item 1d on the current visit's PDR-1 CRF. See form instructions for participants who were dispensed or returned study product at an in	
	4b.	Total number of applicators used based on SMS: # of applicators	No SMS date evailable Go to item 6 on
		Transcription screenshard accorded by the Robertonal Research Working Group.	page 2.
	5. RA	ASSOCIATED RECTAL PERIOD	
	5a.	Total number of applicators used based on product return: # of applicators	V
		Transcribe from item 1d on the current visit's PDR-1 CRF. See form instructions for participants who were dispensed or returned study product at an in	/
V	5b.	Total number of applicators used based on SMS: # of applicators OB	No SMS data available
Į		Transcribe from spreadsheet provided by the Behavioral Research Working Group.	

Calculate number of days since product given to participant using Product Count Tool

Select
Oral,
Daily Rectal,
or RAI Associated Rectal Period
and enter number of tablets or
applicators used based on
product count from PDR-1 CRF
and SMS responses

Data Convergence CRF p.2

CHARP SAMPLE: DO NOT FAX MIN-017 (198) THIS IS NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX. DO NOT FAX TO DATAFAX. DO NOT FAX TO DATAFAX.	
Participant ID Data Convergence Interview Sile Number Puricipant Number Chit	
6. Was a data convergence interview conducted to discuss the data on page 1 of this form? Instructions for the Interviewer: Read accounts statuted declarate the processing of the Interviewer: Read accounts statuted declarate the processing of the Interviewer: Read accounts statuted declarate the processing of the Interviewer: Read accounts statuted declarate the processing of the Interviewer: Read accounts statuted declarate the processing of the Interviewer: Read accounts statuted declarate the Interviewer: Read accounts statuted declar	If DCI was not conducted, indicate reason
We have asked you to bring in your unused study product today, and you have also been responding to text messages about your product use. There are different ways of seeing how people use the product. We do not always expect this information to match up perfectly; it rarely does. People may have trouble remembering to use the product every day or every time they have sex; people may have problems that keep them from responding to text messages, etc. So, we would like your help to understand, as accurately as possible, how many times you used the study product. We will read to you the information we have and we would highly appreciate your help to determine correctly the number of times you used the study product over the last four weeks (that is, since your last regularly scheduled visit). Remember that for us, it is as important to know what happens when people use the product all of the time as it is to understand when they use it only sometimes or not at all.	
Instructions for the Interviewer: Read aloud to the participant, as recorded on this form, the estimated number of doses used based on the available SMS data, if any. Attempt to determine the most accurate estimate of doses used. Document a summary of this conversation in item 7 below. 7. Convergence Comments:	Document a summary of the discussion with the participant describing how most likely number of doses taken was determined
8. Most likely number of doses taken: # of doses # of doses Unside 2, 15-FEB-13	Enter most likely number of doses taken

N:Srive attorns iMTN_0176 orms/m017_nonDF_DCL fro

PK Data Convergence Interview Page 1 of 1 THIS IS NOT A DATAFAX FORM. Wisit 1 1

SAMPLE: DO NOT FAX TO DATAFAX FORM. Visit Code DO NOT FAX TO DATAFAX.	
Participant ID PK Data Convergence Interview Visit Date Visit Date Visit Date Visit Date Oit MMM yy	
INSTRUCTIONS: Complete items 1–2 before the interview.	
At which visit was the PK sample collected or expected to be collected, if not done? Visit Code	
negative positive not available, specify Real-time PK test result: □ □ □ ★ It not done not available, specify reason. End of form.	Enter PK test result
3. Was a PK deliconvergence interview conducted to discuss the result in item 2? If yes, go 80 statement below item 3a.	If PK Interview was not
3a. Reason(s) interview not done: Mark all that apply:	II PK Interview was not
sample collected in RAI-associated Rectal Period sample collected at Final Clinic Visit/Early Termination visit	conducted, enter reason
other, specify:	•
End of form.	
Instructions for the Interviewer: Read aloud the statement below to the participant.	
At your last visit, we compared the number of doses you took based on your phone text messages, and the number of doses you took based on the amount of unused product you had left. We also collected a blood sample to see if we could detect the presence of study product. We now have the result of that blood test. Let's review this information together to better understand it.	
We will start by reviewing the week before the blood sample was taken, which you probably remember best, and then review the prior weeks. To help with remembering, we have a calendar of the phone texts you sent during that period.	
Instructions for the Interviewer: Refer to the Data Convergence Interview CRF (non-DataFax) from the visit in which the PK sample was collected, and read aloud the most likely number of doses taken (item 8). Read aloud the result from the real-time PK test, as recorded in item 2 on this form. Using the SMS calendar as a reference, attempt to determine an explanation for any discrepancies. Document a summary of this conversation in item 4 below.	Document a summary of the
Comments on Real-time PK Discussion:	discussion with the participant
	with comments about any
	
	discrepant results
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SCHARP

Data Entry Procedures

Within 7 working days of completing the interview, access the online CRF Data Entry available at:

- DCI: www.scharp.org/MTN017/dc
- □ PK: www.scharp.org/MTN017/pk

Questions?

Thank you! ขอบคุณค่ะ