



# **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	<b>Baseline Behavioral Questionnaire (CASI)</b>
Visit 2, Enrollment, Initiate Period 1 Visit 5, Initiate Period 2 Visit 8, Initiate Period 3	<b>Initiate SMS Diary</b> (Conduct SMS Participant Training & Provide SMS Instruction Postcard)
Visit 3, Mid Period 1 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	<b>Data Convergence Interview/PK Data Interview (when data available)</b>
Visit 4, End Period 1	<b>In-depth Phone Interview (subset)</b>
Visit 4, End Period 1 Visit 7, End Period 2 Visit 10, End Period 3	<b>Follow-up Behavioral Questionnaire (CASI)</b>



# 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](http://www.scharp.org/MTN017/followuptablet_thai)
- [www.scharp.org/MTN017/followupdailygel\\_thai](http://www.scharp.org/MTN017/followupdailygel_thai)
- [www.scharp.org/MTN017/followupRAIgel\\_thai](http://www.scharp.org/MTN017/followupRAIgel_thai)

## □ Troubleshooting

- Check power cord/mouse/Internet
- Email: [mtn017webtrouble@mtnstopshiv.org](mailto: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



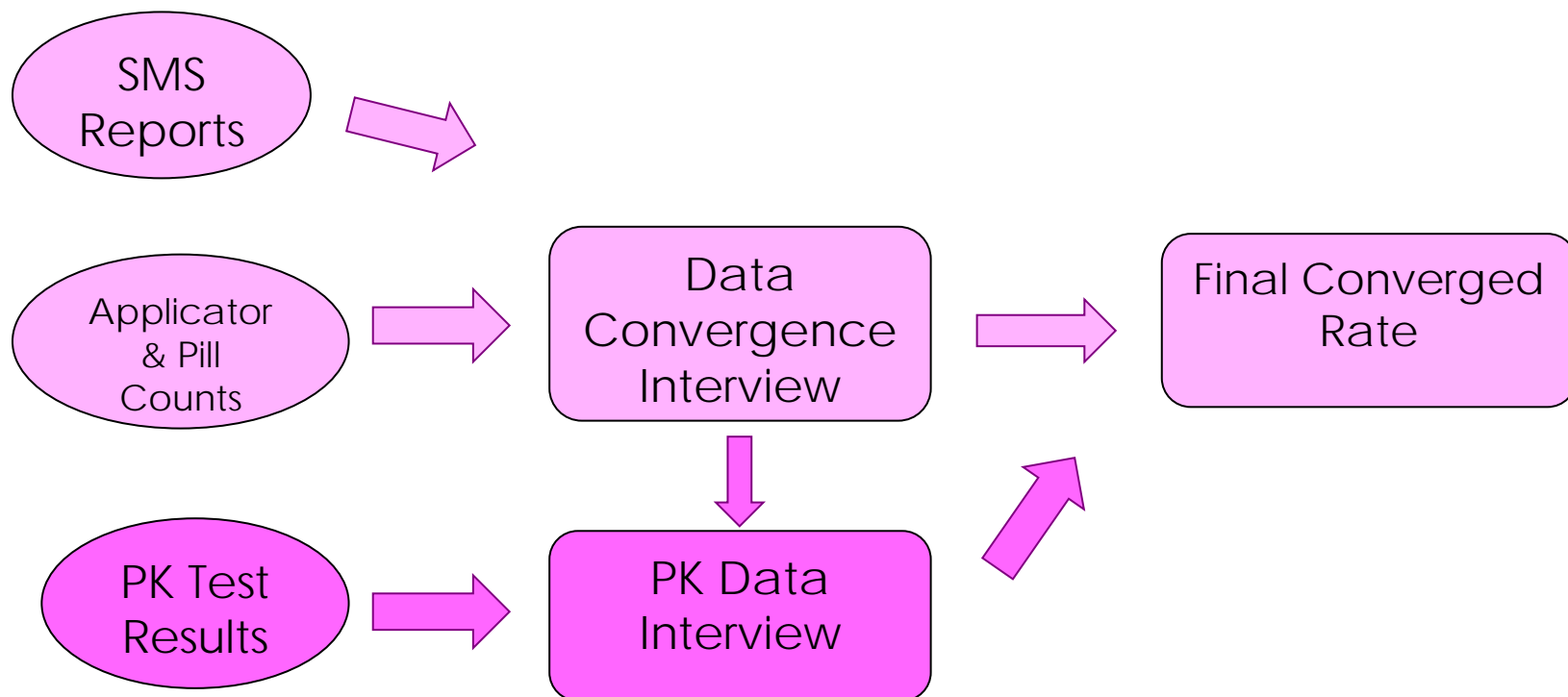
# Data Convergence Interview

## □ 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 Entry Procedures

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

- DCI: [www.scharp.org/MTN017/dc](http://www.scharp.org/MTN017/dc)
- PK: [www.scharp.org/MTN017/pk](http://www.scharp.org/MTN017/pk)



# Questions?

---

Thank you! ขอบคุณค่ะ