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
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<th>Behavioral Measures and Activities</th>
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<td>(Conduct SMS Readiness Assessment)</td>
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<td><strong>Visit 2, Enrollment, Initiate Period 1</strong></td>
<td><strong>Baseline Behavioral Questionnaire (CASI)</strong></td>
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<td><strong>Visit 2, Enrollment, Initiate Period 1</strong></td>
<td><strong>Initiate SMS Diary</strong></td>
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<td><strong>Visit 5, Initiate Period 2</strong></td>
<td>(Conduct SMS Participant Training &amp; Provide SMS Instruction Postcard)</td>
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<td><strong>Visit 8, Initiate Period 3</strong></td>
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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/followupRAIgel_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

- SMS Reports
- Applicator & Pill Counts
- PK Test Results
- Data Convergence Interview
- PK Data Interview
- Final Converged Rate
## Data Convergence Timeline

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<th>Interviews and CRFs</th>
<th>Interview Discussion Points</th>
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<td>Data Convergence Interview (DCI)</td>
<td>SMS data b/w Visit 2 &amp; 3 Product count, Visit 3</td>
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<tr>
<td>End Period 1, Visit 4</td>
<td>DCI</td>
<td>SMS data b/w Visit 3 &amp; 4 Product count Visit 4</td>
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<td>PK Data Interview</td>
<td>PK result, Visit 3 DCI, Visit 3 &amp; SMS calendar b/w Visit 2 &amp; 3</td>
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<tr>
<td>Mid Period 2, Visit 6</td>
<td>DCI</td>
<td>SMS data b/w Visit 5 &amp; 6 Product count, Visit 6</td>
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<tr>
<td>End Period 2, Visit 7</td>
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<td>SMS data b/w Visit 6 &amp; 7 Product count, Visit 7</td>
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<td>PK Data Interview</td>
<td>PK result, Visit 9 DCI, Visit 9 &amp; SMS calendar b/w Visit 8 &amp; 9</td>
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</table>
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.
Document a summary of the discussion with the participant describing how most likely number of doses taken was determined.

Enter most likely number of doses taken.

If DCI was not conducted, indicate reason.
PK Data Convergence CRF

Enter PK test result

If PK Interview was not conducted, enter reason

Document a summary of the discussion with the participant with comments about any discrepant results
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