MTN-003D Stage 2 PK Discussion

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Purpose of PK Discussion

- To present former VOICE participants with their individual PK results
  - Will be simplified to one of three patterns: high/ inconsistent/ low
- To elicit more honest and informative data regarding
  - Product use experiences: trajectories and challenges ~~actual adherence~~
  - Trial-related reasons for non-disclosure of low adherence by self-report

Available PK Data is a Prerequisite to Stage 2 participation

- **Inclusion Criteria**:
  - Able and willing to perform the study procedures
  - Able and willing to provide informed consent in one of the MTN-003D study languages
  - Participated in VOICE and received at least three consecutive months of study product at any time during VOICE trial participation
  - Stage 2 participants must have PK data available *[**NOTE:** Women from Stage 1 who have PK data available will be considered eligible for Stage 2.]*

Prior to Enrollment of Participants

- Review data collection tools and ensure 003D staff is aware of which category of participant they will be interviewing (i.e. overall PK classification and corresponding visual tool, study product assignment, and HIV status).

8 Recruitment Lists

1G:	1T:	2G:	2T:
• Gel participants • HIV-negative • Low drug detection	• Tablet participants • HIV-negative • Low drug detection	• Gel participants • HIV-negative • High drug detection	• Tablet participants • HIV-negative • High drug detection
3G:	**3T:**	**4G:**	**4T:**
• Gel participants • HIV-positive • Low drug detection	• Tablet participants • HIV-positive • Low drug detection	• Gel participants • HIV-positive • High drug detection	• Tablet participants • HIV-positive • High drug detection

Recruitment Lists

VOICE PTID	Study Arm (Gel/ Tablet)	Drug Detection Level (A-E) or %	VOICE SEV Date (if complete)	Did participant give PTC? (If no, do not contact)	Participant enrolled in MTN-003D (Y/N)	Staff Initials

Timing of PK Discussion

- IDI participants:
  - Informed consent
  - DEM
  - Interview starts (begin recording)
  - PK Discussion (Section A – B of Discussion Guide)
  - Record response on PSF
- FGD participants:
  - Individual session before FGD – same day or previous day*
    - IC
    - DEM
    - PK Discussion (A-B of guide). No recording.
    - PSF

*preferable to do same day

Approach to the Discussion

- Neutral – no judgment
- Straightforward and clear – no ambivalence about the accuracy of the results
- Use tool to help explain results:
  - Overall rough estimate of adherence level (tea pot)
  - Approximate pattern of drug detection (tea cups)

High adherence/ High-level drug detection

A

B

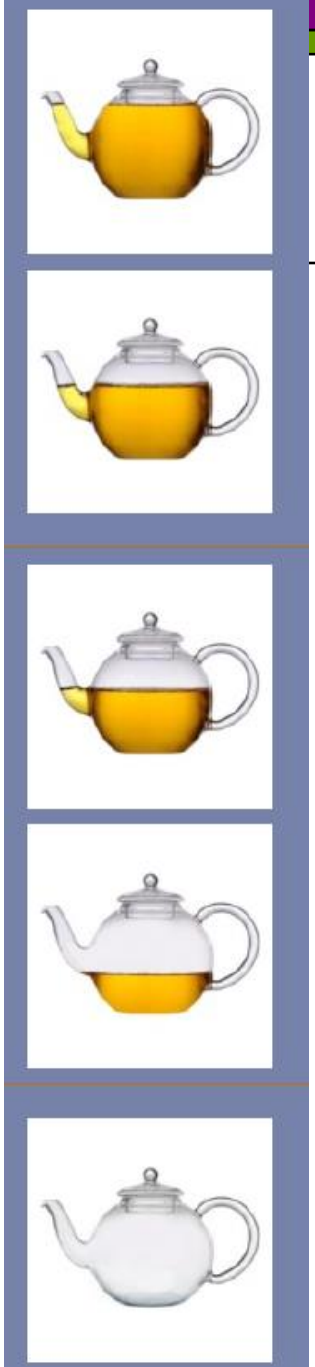
Inconsistent adherence/ Occasional drug detection

C

D

Non adherence/ No drug detection

E



Tea Pots

- Average overall adherence level for that participant (%)

$$\frac{\text{Number of specimens with detectable drug}}{\text{Number of specimens taken}}$$

- Range: 0% (No drug) – 100% (drug every time)

Tea Cups

- Detectable drug in a specimen = full cup
- Undetectable drug in a specimen = empty cup

- NOTE: This tool is an average representation with 6 cups in each row, participants may have had more or fewer blood tests

Stage 2 Participants

- Most will either be A/B (High drug detection, 75% - 100% of samples) or E (No drug detected in any sample)
  - "A" means: drug was detected in blood every time a specimen was tested.
    - Does not mean: drug taken daily
  - "B" means: drug was detected in blood >=75% of samples, but <100% of samples
  - "E" means: drug never detected in specimens taken
    - Does not mean: drug never taken (more on this coming)
- C/D will be recruited only if needed

“Detectable” is a key word!

- “Detectable” emphasizes OUR (the researchers’) ability to measure the drug
  - Does not put “blame” on participant, e.g. “you didn’t do this…”, rather “there was no evidence of this in your specimen…”
- BUT blood plasma test is a very objective measure of the presence of drug
  - HOWEVER there are limitations…

Drug Detection with Plasma Testing:

- Tablets:
  - Detectable for a range of ~7 days
  - No drug detected = no dosing in past week
  - Drug detected = AT LEAST one dose in past week
- Gel:
  - Detectable for a range of ~ 3 days
  - No drug detected = no dosing in past 3 days
  - Drug detected = AT LEAST one dose in past 3 days

Process for Delivering Results

1. Explain the tool
2. Show which row (A-E) corresponds to their PK results
3. Guide:

The results of your blood tests showed that you had drug in your system [<u>none of the time/ only some of the time/ most or all of the times</u>]…. we'd like your help to understand these results.

- What do these results mean to you?

Record Reaction on PSF

- Collecting information on participant's reaction and comprehension of PK results is AS important as getting her acknowledgement that she wasn't using the product consistently and discussing why

8	What is the participant's drug detection level classification *(mark one)*?	_1 Low drug _2 Inconsistent drug _3 High drug	
9	Record your assessment of the participant's physical/emotional reaction upon hearing her PK results. *(Select all that apply)*	_1 Anger _1 Fear _1 Sadness _1 Disbelief _____	_1 Distress/ Unhappiness _1 Happiness _1 Surprise _1 Other, specify:

Write as much detail as possible!

Comments:

Debriefing Report

- Item 2:
  - How did the participant respond to the PK results discussion? *(Record which visual representation was used to describe results to the participant, if any, as well as details about the participant's emotional/physical reaction that expand upon their reaction recorded on the PSF)*

Thank you

Questions and Discussion