MTN-036 Behavioral Assessments

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Overview

- Behavioral protocol objectives and endpoints
- Computer-assisted self-interview (CASI) assessments
- In-depth interview (IDIs)
- Ring Adherence CRF
The big picture - objectives

- **Secondary Objectives**
  - **Adherence**
    - To evaluate participant adherence to the three DPV VRs when used for 13 weeks
  - **Acceptability**
    - To compare overall acceptability of the two extended duration DPV VRs (100 mg and 200 mg) to the current 25 mg DPV VR

- **Exploratory Objectives**
  - **Acceptability**
    - To evaluate components of acceptability of ring use for the three DPV VRs
The big picture - endpoints

- **Secondary Endpoints**
  - **Adherence**
    - Frequency of study VR removal/expulsions (voluntary and involuntary) and duration without VR in vagina (by self-report)
    - VR use initiation and persistence (whether the VR is in place when participants come to the clinic for their study visits)
  - **Acceptability**
    - Degree to which study participants liked or disliked using the three DPV VRs (by self-report)

- **Exploratory Endpoints**
  - **Acceptability**
    - Self-reported attitudes about VR attributes, including dosing regimen, and willingness to use the VR in the future
    - Interest/preference in a single vs. dual-purpose indication
    - Proportion of participants who find the study VRs to be at least as acceptable as other HIV prevention methods
CASI questionnaires
CASI assessments

Baseline (enrollment)
Visit 8
Day 28
Visit 9
Day 56
Visit 10
Day 91
PUEV/early termination
Domains

- Demographic
- Drug/alcohol use
- Vaginal practices
- Sexual history
- Recent sexual behavior
- Condom and other HIV prevention method use
- Adherence
- Acceptability
- Preference
Acceptability details

- Acceptability questions include:
  - Rating scale of 1-10 (dislike very much – like very much)
  - Whether the ring was felt during sex by woman and her partner and if so, whether this was bothersome
  - Vaginal changes experienced and whether these were bothersome
  - Worries about the ring such as being dirty/unhygienic or causing infection/infertility/other health problems
  - Experiences with the ring during menses
  - Perceived comfort of the ring
  - Likelihood of future use of an active product

- Will examine changes over time
Preference details

- Preference questions include:
  - Preference for 1 month vs 3 month ring
  - Preference for event-driven dosing (with sex) vs a continually worn ring
  - Preference for dual purpose (combined HIV and pregnancy prevention) ring
  - Preference for ring vs condom vs oral PrEP

- Assessed at the end of the study
Adherence details

- Adherence questions include:
  - How often was the ring in the vagina during sex
  - Removals
  - Expulsions
  - Partial expulsions
  - Self-reported adherence (“how good of a job did you do?”)

- Note reasons for removals/expulsions are collected on adherence CRF
## CASI assessment time points

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<th>Domain</th>
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<th>Day 28</th>
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In-depth Interviews (IDIs)

- Goal: to assess acceptability and use experiences in greater depth using a semi-structured interview guide
- Interviews will be recorded, transcribed, and analyzed for themes
- Topics:
  - Challenges of use
  - Effect of ring use on sex
  - Perceived benefits and barriers to ring use
  - Perceived method preferences for HIV prevention and multipurpose prevention technologies
IDI selection and randomization

- Subset of 24 randomly selected participants across both sites
- Only include women who have had penile-vaginal sex in past year
- Will oversample in SF to account for higher likelihood of lesbian participants
IDI implementation

- Interviewer will be based in SF and will conduct IDIs over video (webcam)
- Site staff will email interviewer to notify her of scheduled interviews in advance
  - Confirmed IDIs will be entered on a Google calendar
- Responses will be audio recorded but not video recorded
CRFs – Adherence and Insertion/Removal

- Two CRFs with behavioral components
  - Ring Adherence CRF
    - Reasons for removal/expulsion
  - Insertion and Removal CRF
    - After inserting the ring, how easy or difficult was it to insert
    - Reasons for difficulty
    - Did the participant require help inserting
    - Was the ring correctly inserted by the participant
Questions?

Note additional, in-depth behavioral assessment training sessions will be scheduled with both sites to:

- Walk through CASI (tablet computer) system (prior to activation)
- Conduct practice video IDI (prior to IDIs)