Overview of Enrollment/Initiate Period 1 Visit Procedures
What should occur between the Screening and Enrollment visits?

• Review lab results
  • Chemistries (AST/ALT and Creatinine)
  • CBC with differential and platelets
  • Syphilis RPR
  • HSV 1/2 antibody
  • HBsAg  
    Results will indicate if Hep B Vaccine should be offered at Enrollment
  • HBsAb
  • Hepatitis C antibody
  • Rectal GC/CT
What should occur between the Screening and Enrollment visits?

- Confirm/update Screening column on MTN-017 Eligibility Checklist

<table>
<thead>
<tr>
<th>EXCLUSION CRITERIA</th>
<th>Screening Visit</th>
<th>Enrollment Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
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</table>
| ≥21 Participant-reported symptoms, and/or clinical or laboratory diagnosis of active anorectal or reproductive tract infection requiring treatment per current WHO guidelines or symptomatic urinary tract infection (UTI)  
Source: Baseline Medical History Questions, Pre-existing Conditions CRF, Anorectal Exam CRF, Lab results report |   |   |   |   |   |   |
| 2 History of inflammatory bowel disease  
Source: item 4 in Screening Behavioral Eligibility CRF, Baseline Medical History Questions, Pre-existing Conditions CRF |   |   |   |   |   | not required |
| 3a Positive for hepatitis B surface antigen  
Source: Lab results report |   |   |   |   |   | not required |
| 3b Positive for hepatitis C antibody  
Source: Lab results report |   |   |   |   |   | not required |
| 3c Hemoglobin < 10.0 g/dL  
Source: Lab results report |   |   |   |   |   | not required |
| 3d Platelet count less than 100,000/mm3v  
Source: Lab results report |   |   |   |   |   | not required |
| 3e White blood cell count < 2,000 cells/mm3 or > 15,000 cells/mm3  
Source: Lab results report |   |   |   |   |   | not required |
| 3f Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula  
[(140-Age) * Mass (in kg)] / [72 * Serum creatinine (in mg/dL)]  
Source: Creatinine Clearance calculation worksheet |   |   |   |   |   | not required |
| 3g Serum creatinine > 1.3 x the site laboratory upper limit of normal (ULN)  
Source: Lab results report |   |   |   |   |   | not required |
What administrative procedures should occur before the participant is randomized?

- Confirm participant is within 30-day screening window
- Review/update locator information
- Provide test results from Screening
- Review informed consent and participants’ willingness to continue
What **behavioral** procedures should occur **before** the participant is randomized?

- Enrollment Behavioral Eligibility (non-DataFax) Case Report Form
- Self Administered CASI Baseline Behavioral Questionnaire
What clinical procedures should occur before the participant is randomized?

- Review/update baseline medical/medication history
- Review/update concomitant medications
- Physical exam
- Rectal exam
- Document Pre-existing conditions
- Provide available test results
- Treatment or referral (if indicated)
What **counseling** procedures should occur **before** the participant is randomized?

- HIV pre- & post-test
- HIV/STI risk reduction
- Provision of condoms
What laboratory procedures should occur before the participant is randomized?

- HIV-1 serology
- Plasma archive

**Note:** Sites not conducting HIV rapids via finger stick, can collect plasma archive and HIV samples as part of a single blood draw in order to reduce participant burden.
What other procedure should occur before the participant is randomized?

- Conduct final determination of eligibility status
- Review/complete Enrollment Visit column on Eligibility checklist

<table>
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<tr>
<th>ELIGIBILITY CRITERIA</th>
<th>Screening Visit</th>
<th>Enrollment Visit</th>
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<tbody>
<tr>
<td>Inclusion Criteria</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>1. Male or transgender female $\geq$ age of 18 at Screening</td>
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<tr>
<td>2. Able and willing to provide written informed consent</td>
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<td>3. HIV-1 uninfected</td>
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<td>4. Able and willing to provide adequate locator information</td>
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<tr>
<td>5. Available to return for all study visits and willing to comply with study</td>
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<tr>
<td>participation requirements</td>
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<td>6. In general good health</td>
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<td>7. History of consensual RAI at least once in the past 3 months</td>
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Is study approved lubricant provided at all study visits?

1. No
2. Yes

➢ When is study lubricant required to be provided?
What procedures should occur after the participant is randomized?

• Provide relevant product use instructions and lubricant, if indicated

• Observe participant first dose/simulation of first does
  - Daily tablet - the first dose should be directly observed by study staff.
  - Daily rectal gel - first insertion or simulation of first insertion should be performed in a private space
  - RAI rectal gel - simulation of first insertion should be done in a private space

• Provide protocol adherence counseling
What other **counseling** procedure should occur **after** the participant is randomized?

- Provide participant-centered product adherence counseling

**Note:** Should not be the same staff person who provided product use instruction and protocol adherence counseling
What procedures should occur after the participant is randomized?

• Provide relevant SMS training and SMS diary instructions
• Generate and provide follow-up visit schedule
• Provide reimbursement
• Remind participant of follow-up phone calls:
  • 48-72 hours from date of expected product initiation
  • 2 weeks from date of expected product initiation
Questions?