FOLLOW-UP VISIT CONSIDERATIONS

MTN-036/ IPM 047 STUDY-SPECIFIC TRAINING
TYPES OF FOLLOW-UP VISITS

Scheduled Visits:

- Must occur on same day:
  - HIV counseling with HIV testing;
  - CASI with Ring Adherence CRFs
  - All PK/DP and DVP specimen collection; and with Ring Adherence CRFs and Ring Insertion and Removal CRF

Interim visits:

- Phone calls and clinic visits that take place between scheduled visits.
- Procedures required will depend on the reason for the visit
  - For administrative reasons,
  - For product-related reasons
  - In response to AEs and/or SAEs.
  - For additional STI counseling and testing in response to STI symptoms.
  - For any needed HIV counseling and testing in response to participant report of symptoms consistent with acute infection or presumed exposure to HIV.
  - For other reasons at participant request
## VISITS 3-7 (DAY 1, 2, 3, 7, AND 14)

<table>
<thead>
<tr>
<th>Administrative</th>
<th>Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral</td>
<td>Ring Adherence CRF</td>
</tr>
</tbody>
</table>
| Counseling     | *[HIV Pre-Post Test and STI Risk Reduction]*  
Contraceptive  
Protocol Adherence |
| Clinical       | Review/update medical/menstrual/meds history  
Assess AEs  
*Targeted Physical Exam*  
Pelvic Exam  
VR placement check  
Evaluate findings; *RX/refer for RTI/UTI/STI* |
| Laboratory     | Blood – DVP levels, *CBC w/ platelets/diff., Syphilis, HIV*  
Pelvic – CVF for DVP levels, *NAAT for Trich and GC/CT, wet mount w/ pH*  
Rectal fluid (Days 3, 7, and 14 only)  
*Urine – Pregnancy/ dipstick/ Culture analysis* |
VISITS 3-7: SPECIMEN COLLECTION FOR DPV LEVELS

Blood

Rectal fluid
• with anoscope

CVF swab
• Prior to speculum placement

speculum insertion & VR placement check

As close time proximity as possible (within 30 minutes)

All specimens collected with VR in place
## VISITS 8 AND 9 (DAY 28 AND 56)

<table>
<thead>
<tr>
<th>Administrative</th>
<th>Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms</th>
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</thead>
<tbody>
<tr>
<td>Behavioral</td>
<td>Ring Adherence CRF Follow-up CASI questionnaire</td>
</tr>
<tr>
<td>Counseling</td>
<td><em>HIV Pre-Post Test and STI Risk Reduction</em> Contraceptive Protocol Adherence</td>
</tr>
</tbody>
</table>
## VISITS 8 AND 9 (DAY 28 AND 56), CON’T

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review/update medical/menstrual/meds history</td>
<td>Blood – DPV levels; <em>HIV-I, AST/ALT, CBC w/ platelets/Diff., Syphilis</em></td>
</tr>
<tr>
<td>Assess AEs</td>
<td>Pelvic – vaginal swabs for microbiota, CVF for DVP levels, Gram stain, cervical biopsies</td>
</tr>
<tr>
<td><em>Targeted Physical Exam</em></td>
<td>(Day 28 only), CVL, <em>NAAT for Trich and GC/CT, wet mount</em></td>
</tr>
<tr>
<td>Pelvic Exam</td>
<td>Rectal fluid (Day 28 only)</td>
</tr>
<tr>
<td>VR placement check</td>
<td>Urine – Pregnancy, <em>dipstick/ Culture analysis</em></td>
</tr>
<tr>
<td>Evaluate findings; <em>RX/refer for RTI/UTI/STI</em></td>
<td></td>
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<tr>
<td>VR re-supply (for ppts with 25mg VR)</td>
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</tbody>
</table>

- DVP: Dilated Vaginal Passage
- CVF: Cervical Fluid
VISITS 8-9: SPECIMEN COLLECTION FOR DPV LEVELS AND VR PROCEDURES

**Blood**

- Rectal fluid (V8 only)
  - With anoscope

**CVF swab**

- Prior to speculum placement

**Vaginal fluid**

- Microbiota
- Gram stain

**Cervical Biopsies (V8 only)**

**CVL**

**VR removal/insertion** (For 25mg ring)

During pelvic exam

As close time proximity as possible (within 30 minutes)

Collect all specimens with the VR worn to the visit in place

Speculum insertion & VR placement check
### VISIT 10/ PUEV (DAY 91)/ EARLY TERMINATION

<table>
<thead>
<tr>
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<th>Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms</th>
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<tr>
<td>Behavioral</td>
<td>Ring Adherence CRF</td>
</tr>
<tr>
<td></td>
<td>Exit CASI questionnaire</td>
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<tr>
<td></td>
<td><em>IDI (if selected/agreed at enrollment)</em></td>
</tr>
<tr>
<td>Counseling</td>
<td>HIV Pre-Post Test and STI Risk Reduction</td>
</tr>
<tr>
<td></td>
<td>Contraceptive Protocol Adherence</td>
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</tbody>
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**Serves as Early Study Termination Visit:** Complete all procedures and Study Discontinuation CRF
### Clinical
- Review(update) medical/menstrual/meds history
- Assess AEs
- Targeted Physical Exam
- Pelvic Exam
- VR placement check
- Evaluate findings; RX/refer for RTI/UTI/STI
- VR removal

### Laboratory
- Blood – DPV levels, HIV-1, AST/ALT, CBC w/ platelets/Diff., Syphilis
- Pelvic – vaginal swab for microbiota, CVF for DVP levels, Gram stain, cervical biopsies, CVL, NAAT for Trich and GC/CT, wet mount
- Rectal fluid
- Urine – Pregnancy, dipstick/ Culture analysis
VISIT 10/PUEV: SPECIMEN COLLECTION FOR DPV LEVELS AND VR PROCEDURES

Pre-VR Removal

- Blood

Rectal fluid
- With anoscope

CVF swab
- Prior to speculum placement

Vaginal fluid
- Microbiota
- Gram stain

Cervical Biopsies

As close time proximity as possible (within 30 minutes)

During pelvic exam

Post-VR Removal

Hour 1
- Blood
- CVF

Hour 2
- Blood
- CVF

Hour 4
- Blood
- CFV
- CVL (w/ Speculum)

*Collect blood and CVF within 30 minutes

Remove VR
## VISIT 11/ FINAL CONTACT (IN-CLINIC)

<table>
<thead>
<tr>
<th>Administrative</th>
<th>Update locator, provide results from last visit, schedule next visit if needed, provide reimbursement, offer condoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral</td>
<td>None</td>
</tr>
<tr>
<td>Counseling</td>
<td><em>HIV Pre-Post Test and STI Risk Reduction</em></td>
</tr>
</tbody>
</table>
| Clinical             | Review/update medical/menstrual/meds history  
Assess AEs  
*Targeted Physical Exam*  
Evaluate findings; RX/refer for RTI/UTI/STI |
| Laboratory           | Blood – DPV levels, *CBC w/ platelets/Diff.*  
Rectal fluid for DPV levels  
Pelvic – CVF for DPV levels, *wet mount*  
Urine – Pregnancy, dipstick/ Culture analysis |

Schedule 24-72 hours after Visit 10/PUEV
QUESTIONS? COMMENTS?