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<tbody>
<tr>
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<td>MAY 15</td>
<td>jmb 19may15</td>
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<td>Participant has symptoms of burning with urination, treated presumptively with bactrim.</td>
<td>Ongoing at Enrolment? yes no not gradable</td>
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</tbody>
</table>
Participant ID

Safety Laboratory Results

2. SERUM CHEMISTRIES
   2a. AST (SGOT)  
       Not reported  
       Go to item 3.  
       Not done/Not collected  
       alternate collection date: 0021 UL
   2b. ALT (SSPT)  
       Not reported  
       alternate collection date: 0048 UL
   2c. Creatinine  
       Not reported  
       alternate collection date: 00.8 mg/dL

   2d. Creatinine clearance: 111 ml/min

3. DIPSTICK URINALYSIS TESTS
   3a. Leukocyte esterase (LE)  
       Not done: negative  
       alternate collection date: End of form.
   3b. Nitrates  
       Not done: negative  
       alternate collection date: End of form.

Comments: ________________________________

______________________________

______________________________
<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Staff Initials/Log Entry Date</th>
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</thead>
<tbody>
<tr>
<td><strong>Bactrim</strong></td>
<td><strong>JMB 19/5/15</strong></td>
</tr>
</tbody>
</table>

**Indication**

urinary tract infection

**Date Started**

19 MAY 15

**Dose/Units**

1 tablet daily

**Route Mark only one**

- [ ] PO
- [X] IM
- [ ] IV
- [ ] TOP
- [ ] JHL
- [ ] VAG
- [ ] REC
- [ ] SC
- [ ] other, specify

**AE Log page(s)**

- [ ] taken for a reported AE?
  - [ ] yes
  - [X] no

**Date Stopped**

- [ ] continuing at end of study

**Version 1.0. 01 APR 15**

**JMB 19 MAY 15**
<table>
<thead>
<tr>
<th>Condition</th>
<th>Onset Date</th>
<th>Staff Initials/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dysuria</strong> Urinary Tract Infection</td>
<td><strong>May 15</strong></td>
<td>jmb-17may15</td>
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<td><strong>Proteinuria</strong></td>
<td><strong>May 15</strong></td>
<td>jmb-20may15</td>
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<thead>
<tr>
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<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Severity Grade</td>
<td>2</td>
<td>or</td>
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<tbody>
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<tr>
<td>Bactrim</td>
<td>JMB 19/5/15</td>
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**Indication**

urinary tract infection

<table>
<thead>
<tr>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Continuing at end of study</th>
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<tbody>
<tr>
<td>19 MAY 15</td>
<td>29 MAY 15</td>
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**Dose/Units**

1 tablet daily

**Frequency**

Mark only one.

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<th>qd</th>
<th>td</th>
<th>qhs</th>
<th>once</th>
<th>bd</th>
<th>qd</th>
<th>other, specify</th>
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<td>![X]</td>
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**Route**

Mark only one.

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<th>PO</th>
<th>IM</th>
<th>IV</th>
<th>TOP</th>
<th>JHL</th>
<th>VAG</th>
<th>REC</th>
<th>SC</th>
<th>other, specify</th>
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<td>MAY 15</td>
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<td>Comments: Participant has symptoms of burning with urination, treated presumptively with bacterium. Urine culture and microscopy results positive for urinary tract infection. Resolved.</td>
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Eligibility Criteria

1. Does this participant meet all eligibility criteria? **Yes**  

   1a. Obtain signature  
   Signature of Principal Investigator (or designee)  
   Date: 02JUN15

   1b. Obtain signature  
   Signature of second staff member verifying eligibility  
   Date: 02JUN15

2. Was the participant enrolled? **No**  

   If yes, go to item 2

3. Why was the participant not enrolled?  
   - participant did not complete all screening procedures  
   - eligible but declined enrollment  
   - not eligible

   If yes, end of form.

4. Reason(s) for ineligibility Mark all that apply:
   - participant < 18 or > 45 years old  
   - plans for relocation/travel  
   - participant is pregnant or planning to become pregnant within the next 3 months  
   - participant is breastfeeding  
   - participant unwilling to refrain from receptive sexual activity  
   - participant has enrolled in another research study in the last 6 months  
   - participant is HIV-positive  
   - participant declines effective method of contraception  
   - participant has a grade 1 or higher pelvic exam finding  
   - participant does not meet laboratory eligibility criteria. Specifying or providing test results:
     positive for chlamydia infection
Follow-up Visit Summary

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? □ yes □ no
   If yes, record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.

2. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV? □ yes □ no
   If no, go to item 3.
   2a. Was oral or topical PrEP used? □ oral □ topical □ both
   Record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.

3. hCG for pregnancy □ not done/Not collected □ go to item 4.
   □ negative □ positive
   If positive, complete the Pregnancy Report and History. Complete Clinical Product Hold/Discontinuation Log, if applicable.

4. Were any new Adverse Experience Logs completed for this visit? □ yes □ no

5. Were any new Clinical Product Hold/Discontinuation Logs completed for this visit? □ yes □ no

6. Is this an interim visit? □ yes □ no
   If no, go to statement above item 7.
   6a. Reason for interim visit
   Mark all that apply.
   □ AE report or follow-up
   □ return of product or need new product
   □ other, specify: __________________________

   6b. Which forms, besides this form and the log forms, were newly completed for this interim visit? Mark “None” or all that apply.
   □ None
   □ Pelvic Exam
   □ Ring Collection and Insertion
   □ STI Test Results
   □ Pharmacokinetics
   □ HIV Results
   □ Specimen Storage
   □ Physical Exam
   □ Safety Laboratory Results
   □ other, specify: __________________________

Item 7 for Day 35/Final Clinic Visit or early termination visit. For all other visits, end of form.

7. Was an in-depth interview completed? □ yes □ no

Comments: __________________________________________

Version 1.0, 01-APR-15

Staff Initials/Date
Pharmacokinetics Specimens—Days 1, 2, 3, 7, 14, 21, 29, 30, 31, 35 (PKD)

### Specimen Collection Date

**Participant ID**

Site Number | Participant Number |_chk
--- | --- | ---

**Specimen Collection Date**

**dd MMM yy**

13 JUL 15

### Pharmacokinetics Specimens—Days 1, 2, 3, 7, 14, 21, 29, 30, 31, 35

1. **Last menstrual period:**
   - None

   **Start Date**
   - **dd MMM yy**
   - 08 JUL 15

   **Stop Date**
   - **dd MMM yy**
   - 12 JUL 15

   **Not done/Not collected**

   **Specimen**
   - Single time-point blood draw

   **Stored**
   - X

   **Not Stored**
   - 

   **If not stored, specify:**
   - 

   **Was blood visible on swab?**
   - Yes

   **No**

2. **Single time-point vaginal fluid for PK**

   **Stored**
   - X

   **Not Stored**
   - 

   **If not stored, specify:**
   - 

   **Was blood visible on swab?**
   - Yes

3a. **Number of vaginal swabs collected:**

   **2**

### Comments:

Version 1.0, 01-APR-15
Follow-up Visit Summary

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?  
   - yes  
   - no  
   - If yes, record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.

2. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?  
   - yes  
   - no  
   - If no, go to item 3.

2a. Was oral or topical PrEP used?  
   - oral  
   - topical  
   - both  
   - Record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.

3. hCG for pregnancy  
   - Not done/Not collected  
   - Go to item 4.  
   - negative  
   - positive  
   - If positive, complete the Pregnancy Report and History. Complete Clinical Product Hold/Discontinuation Log, if applicable.

4. Were any new Adverse Experience Logs completed for this visit?  
   - yes  
   - no

5. Were any new Clinical Product Hold/Discontinuation Logs completed for this visit?  
   - yes  
   - no

6. Is this an interim visit?  
   - yes  
   - no  
   - If no, go to statement above item 7.

6a. Reason for interim visit  
   - AE report or follow-up  
   - return of product or need new product  
   - other, specify: ________________

6b. Which forms, besides this form and the log forms, were newly completed for this interim visit?  
   - None  
   - Pelvic Exam  
   - Ring Collection and Insertion  
   - STI Test Results  
   - Pharmacokinetics  
   - HIV Results  
   - Specimen Storage  
   - Physical Exam  
   - Safety Laboratory Results  
   - other, specify: ________________

Item 7 for Day 35/Final Clinic Visit or early termination visit. For all other visits, end of form.

7. Was an in-depth interview completed?  
   - yes  
   - no
### Ring Collection and Insertion

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</table>

**Visit Date:** 23 MAY 15

#### 1. Did the participant have a ring in place at the start of the visit?

- **Yes** [X]
- **No**

If yes, go to item 2.

#### 2. When was the ring last in place?

- **22 MAY 15**
- **Not applicable**

(ring not in place since last visit)

#### 2a. If none, specify reason:

- None

#### 2. Number of used rings collected:

- None [X] 1

If "1," go to item 3.

#### 3. Number of new rings dispensed to participant:

- None [X] 1

If "1," go to item 4.

#### 3a. Reason ring not dispensed:

- Participant on clinical hold
- Participant has been permanently discontinued from product
- Participant declined study ring, specify: ____________________________
- Early termination
- Day 28 ring removal visit
- Other, specify: ____________________________

#### 4. Was a new ring inserted at this visit?

- Yes [X]
- No

If no, go to item 5.

#### 4a. Time new ring was inserted:

- 13:20 (24-hour clock)

#### 4b. Who inserted the new ring?

- Participant
- Study staff

#### 5. Was a ring in place at the end of the visit?

- Yes [X]
- No

If yes, end of form.

#### 5a. Reason ring not in place at end of visit:

- Participant declined to have ring inserted
- Participant had to leave before ring could be inserted
- Other, specify: ____________________________
**Specimen Storage**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Initial Specimen Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Number</td>
<td>2MAY15</td>
</tr>
<tr>
<td>Participant Number</td>
<td></td>
</tr>
<tr>
<td>Chk</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Alternate Collection Date</th>
<th>Reason not stored</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Vaginal smear for gram stain</td>
<td></td>
<td>Stored/Not stored</td>
</tr>
<tr>
<td>2. Quantitative vaginal culture</td>
<td></td>
<td>Stored/Not stored</td>
</tr>
<tr>
<td>3. Vaginal swab for biomarkers:</td>
<td></td>
<td>Stored/Not stored</td>
</tr>
<tr>
<td>3a. Was blood visible on the swab?</td>
<td>Yes/No</td>
<td>Stored/Not stored</td>
</tr>
<tr>
<td>4. Cervical cytobrush</td>
<td></td>
<td>Stored/Not stored</td>
</tr>
<tr>
<td>5. Used vaginal ring</td>
<td></td>
<td>Stored/Not stored</td>
</tr>
</tbody>
</table>

**Collection Time (24-hour clock):**

<table>
<thead>
<tr>
<th>hour</th>
<th>minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>30</td>
</tr>
</tbody>
</table>

**Comments:**

______________________________

______________________________

______________________________

______________________________

**Version 1.0 01-APR-15**

**JMB 28-APR-15**
<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Date AE Reported to Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Number</td>
<td>22 May 15</td>
</tr>
<tr>
<td>Participant Number</td>
<td></td>
</tr>
<tr>
<td>Ck</td>
<td></td>
</tr>
</tbody>
</table>

### Adverse Experience Log

**1. Adverse Experience (AE)** Record diagnosis (in English) if available. Include anatomical location, if applicable.

**Pelvic Discomfort**

<table>
<thead>
<tr>
<th>2. Onset date</th>
<th>22 May 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>dd MMMM yy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. At which visit was this AE first reported?</th>
<th>06.1 visit code</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4. Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1—mild</td>
</tr>
<tr>
<td>Grade 2—moderate</td>
</tr>
<tr>
<td>Grade 3—severe</td>
</tr>
<tr>
<td>Grade 4—potentially life-threatening</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Relationship to study product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related</td>
</tr>
<tr>
<td>Not related</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Study product administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
</tr>
<tr>
<td>Held</td>
</tr>
<tr>
<td>Permanently discontinued</td>
</tr>
<tr>
<td>M/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Status or Outcome of AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing</td>
</tr>
<tr>
<td>Resolved</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Severity/frequency increased</td>
</tr>
<tr>
<td>Report as new AE</td>
</tr>
<tr>
<td>Continuing at end of study participation</td>
</tr>
</tbody>
</table>

**7a. Status/Outcome Date** (Leave blank if item 7 is “continuing” or “continuing at end of study participation.”)

<table>
<thead>
<tr>
<th>dd MMMM yy</th>
<th>23 May 15</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>8. Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark “none” or all that apply</td>
</tr>
</tbody>
</table>

- None | ☑ |
- Procedure/surgery | Comment below |
- Other, specify | Comment below |

<table>
<thead>
<tr>
<th>9. Is this an SAE according to ICH guidelines?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Has or will this AE be reported as an EAE?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. Was this AE a worsening of a pre-existing condition?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

**Comments:**

Temporal relationship - discomfort abated once removed.
### Ring Adherence

**1.** Date and visit code this form was last completed for this participant?  
   - **Visit Code:** 06.0
   - **Visit Date:** 22 May 15

**2.** Since this form was last completed, has the ring been out at any time?  
   - **Yes**  
   - **No**  
   - If no, end of form.

   - **2a.** How many times total has the ring been out?  
     - **01**  
     - If 6 or more, add Comment after completing items 3a-3e.

**3.** For each instance the vaginal ring was out, complete the information below on when the ring was out, how long it was out, and why it was out? Ring removals due to scheduled pelvic exams should not be recorded on this form.

<table>
<thead>
<tr>
<th>Date ring out</th>
<th>Duration ring was out</th>
<th>Removal/Expulsion code</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 May 15</td>
<td>00 23 15</td>
<td>10</td>
</tr>
</tbody>
</table>

**3b.**

**3c.**

**3d.**

**3e.**

**4.** Has the vaginal ring stayed in place for at least the past 8 hours prior to this visit?  
   - **Yes**  
   - **No**  
   - If no, specify details in the Comments section.

**Comments:** participant removed the ring due to pelvic discomfort on 22 May and it was dropped on a dirty floor. The participant brought the ring into the clinic in a bag.
Follow-up Visit Summary

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?  
   - yes  
   - no  
   - If yes, record on Concomitant Medications Log, complete Product Hold/Discontinuation Log.

2. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?  
   - yes  
   - no  
   - If no, go to item 3.

2a. Was oral or topical PrEP used?  
   - oral  
   - topical  
   - both  
   - Record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.

3. hCG for pregnancy  
   - Not done/Not collected  
   - Go to item 4.

3. hCG for pregnancy  
   - negative  
   - positive  
   - If positive, complete the Pregnancy Report and History. Complete Clinical Product Hold/Discontinuation Log, if applicable.

4. Were any new Adverse Experience Logs completed for this visit?  
   - yes  
   - no

5. Were any new Clinical Product Hold/Discontinuation Logs completed for this visit?  
   - yes  
   - no

6. Is this an interim visit?  
   - yes  
   - no  
   - If no, go to statement above item 7.

6a. Reason for interim visit  
   - Mark all that apply:
   - AE report or follow-up  
   - return of product or need new product  
   - other, specify: ________________________________

6b. Which forms, besides this form and the log forms, were newly completed for this interim visit? Mark "None" or all that apply.
   - None
   - Pelvic Exam
   - Ring Collection and Insertion
   - STI Test Results
   - Pharmacokinetics
   - HIV Results
   - Specimen Storage
   - Physical Exam
   - Safety Laboratory Results
   - other, specify: ________________________________
### Pelvic Exam

<table>
<thead>
<tr>
<th></th>
<th>Vaginal pH:</th>
<th></th>
<th>Cervical motion tenderness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>3.7</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Abnormal findings</td>
<td></td>
</tr>
</tbody>
</table>

2a. Abnormal findings. Mark all that apply.

<table>
<thead>
<tr>
<th>Vulvar</th>
<th>Vaginal</th>
<th>Cervical</th>
<th>General/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vulvar edema</td>
<td>Vaginal edema</td>
<td>Cervical edema and/or friability</td>
<td>Odor (vaginal)</td>
</tr>
<tr>
<td>Vulvar erythema</td>
<td>Vaginal erythema</td>
<td>Cervical erythema</td>
<td>Condyloma, specify location:</td>
</tr>
<tr>
<td>Vulvar rash</td>
<td>Vaginal masses (polyps, myomas, possible malignancy)</td>
<td>Cervical masses (polyps, myomas, possible malignancy)</td>
<td>Adnexal masses (based on bimanual exam; not pregnancy or infection-related)</td>
</tr>
<tr>
<td>Vulvar tenderness</td>
<td>Vaginal tenderness</td>
<td>Cervical tenderness</td>
<td>Uterine masses (based on bimanual exam)</td>
</tr>
<tr>
<td>Bartholin's or Skene's gland abnormality</td>
<td>Abnormal vaginal discharge slight moderate pooling</td>
<td>Cervical discharge</td>
<td>Uterine tenderness</td>
</tr>
</tbody>
</table>

#### Vulvar lesions

- Ulcer
- Blister
- Pushula
- Peeling
- Ecchymosis

#### Vaginal lesions

- Ulcer
- Blister
- Pushula
- Peeling
- Ecchymosis

#### Cervical lesions

- Ulcer
- Blister
- Pushula
- Peeling
- Ecchymosis

2b. Other abnormal findings, specify (include anatomical location):

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

3. Are any new pelvic finding AEs reported at this visit? Yes [X] No [ ]

3a. AE Log page (s): Line through any unused boxes.

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 0 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Version 1.0 01.APR.15
### Pelvic Exam Ring Assessment

1. **Was the vaginal ring present in the vagina at the start of the exam?**
   - **Yes** [X] No → If no, go to item 3.

2. **Was the vaginal ring removed during the exam?**
   - **Yes** [x] No → If no, end of form.
   - **If yes,** how long was the vaginal ring removed from the vagina?
     - **00** Hours **10** Minutes

3. **Was the vaginal ring rinsed prior to reinsertion?**
   - **Yes** [X] No [ ] **Not reinserted**
     - If yes or no, end of form.
   - **Specify reason ring not reinserted:**

---

**Scenario 4a**

**Site Number** | **Participant Number** | **Chk** | **Exam Date**
--- | --- | --- | ---
0 | 0 | 0 | 0 1 JUN 15

---

**Version 1.0, 01 APR 15**
## Ring Adherence

### Scenario 4a

<table>
<thead>
<tr>
<th></th>
<th>Date and visit code this form was last completed for this participant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23 MAY 15</td>
</tr>
</tbody>
</table>

2. Since this form was last completed, has the ring been out at any time? Yes [X] No
   - If no, end of form.

2a. How many times total has the ring been out?
   - If 6 or more, add Comment after completing items 3a-3e.

3. For each instance the vaginal ring was out, complete the information below on when the ring was out, how long it was out, and why it was out? Ring removals due to scheduled pelvic exams should not be recorded on this form:

<table>
<thead>
<tr>
<th>Date ring out (dd-MMW-yy)</th>
<th>Duration ring was out (days, hours, minutes)</th>
<th>Removal/Expulsion code</th>
<th>If other, specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3d.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3e.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Has the vaginal ring stayed in place for at least the past 8 hours prior to this visit?
   - Yes [X] No
   - If no, specify details in the Comments section.

**Comments:**

---

Version 1.0. 01 APR 15
**Adverse Experience Log**

1. Adverse Experience (AE) Record diagnosis (in English) if available. Include anatomical location, if applicable.

   **Vaginal erythema**

2. Onset date: **01 Jun 15**

3. At which visit was this AE first reported? **08.0** visit code

4. Severity:
   - [ ] Grade 1—mild
   - [ ] Grade 2—moderate
   - [ ] Grade 3—severe
   - [ ] Grade 4—potentially life-threatening
   - [ ] Grade 5—death

5. Relationship to study product:
   - [x] related
   - [ ] not related
   Record rationale or alternative etiology in Comments.

6. Study product administration:
   - [x] no change
   - [ ] held
   - [ ] permanently discontinued
   - [ ] N/A

7. Status or Outcome of AE:
   - [x] continuing
   - [ ] resolved
   - [ ] death
   - [ ] severity/frequency increased (report as new AE)
   - [ ] continuing at end of study participation

7a. Status/Outcome Date (Leave blank if item 7 is "continuing" or "continuing at end of study participation")

   - dd
   - MMM
   - yy

   If severity/frequency increased, record the new AE page #

8. Treatment:
   Mark "none" or all that apply.
   - [x] none
   - [ ] new/prolonged hospitalization
   - [ ] medication(s)
   - [ ] procedure/surgery
   - [ ] other, specify

9. Is this an SAE according to ICH guidelines?
   - [ ] yes
   - [x] no

10. Has or will this AE be reported as an EAE?
    - [ ] yes
    - [x] no

11. Was this AE a worsening of a pre-existing condition?
    - [ ] yes
    - [x] no

Comments:

*Temporal relationship and biologically plausible*
Follow-up Visit Summary

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? [ ] yes [ ] no
   - If yes, record on Concomitant Medications Log; complete Product Hold/Discontinuation Log.
   - If no, go to item 2.

2. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?
   - [ ] yes [ ] no
   - If no, go to item 3.
   - Was oral or topical PrEP used?
     - [ ] oral
     - [ ] topical
     - [ ] both

3. hCG for pregnancy
   - [ ] Not done/Not collected
   - [ ] negative
   - [ ] positive
   - Go to item 4.
   - Alternate Collection Date [ ] [ ] [ ]

4. Were any new Adverse Experience Logs completed for this visit? [ ] yes [ ] no

5. Were any new Clinical Product Hold/Discontinuation Logs completed for this visit? [ ] yes [ ] no

6. Is this an interim visit? [ ] yes [ ] no
   - If no, go to statement above item 7.
   - Reason for interim visit
     - AE report or follow-up
     - return of product or need new product
     - other, specify:

6b. Which forms, besides this form and the log forms, were newly completed for this interim visit? Mark "None" or all that apply.
   - [ ] None
   - [ ] Pelvic Exam
   - [ ] Ring Collection and Insertion
   - [ ] STI Test Results
   - [ ] Pharmacokinetics
   - [ ] HIV Results
   - [ ] Specimen Storage
   - [ ] Physical Exam
   - [ ] other, specify:

   [ ] Safety Laboratory Results
### Pelvic Exam

1. **Vaginal pH:**
   - [ ] Not done
   - [ ] If > 4.5, mark Positive
   - [ ] Positive

2. **Pelvic exam assessment:**
   - [ ] Not done
   - [ ] Abnormal findings
   - [ ] No abnormal findings
   - [ ] End of form

2a. Abnormal findings. Mark all that apply.

**Vulvar**
- [ ] Vulvar edema
- [ ] Vulvar erythema
- [ ] Vulvar rash
- [ ] Vulvar tenderness
- [ ] Bartholin's or Skene's gland abnormality

**Vaginal**
- [ ] Vaginal edema
- [ ] Vaginal erythema
- [ ] Vaginal masses (polyps, myomas, possible malignancy)
- [ ] Vaginal abrasions or lacerations
- [ ] Vaginal tenderness
- [ ] Abnormal vaginal discharge slight moderate pooling

**Cervical**
- [ ] Cervical edema and/or friability
- [ ] Cervical erythema
- [ ] Cervical masses (polyps, myomas, possible malignancy)
- [ ] Cervical motion tenderness
- [ ] Cervical discharge

**General/Other**
- [ ] Odor (vagina)
- [ ] Condyloma, specify location:
- [ ] Adnexal masses (based on bimanual exam, not pregnancy or infection-related)
- [ ] Uterine masses (based on bimanual exam)
- [ ] Uterine tenderness
- [ ] Adnexal tenderness
- [ ] Observed blood or bleeding, describe:

2b. Other abnormal findings, specify (include anatomical location):

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

3. **Are any new pelvic finding AEs reported at this visit?**
   - [ ] Yes
   - [ ] No
   - [ ] End of form

3a. AE Log page # (s): Line through any unused boxes.

002
Ring Collection and Insertion

1. Did the participant have a ring in place at the start of the visit?  
   - Yes [X]  
   - No [ ]  
   - If yes, go to item 2.

   1a. When was the ring last in place?  
       - [ ] dd  
       - [ ] MMM  
       - [ ] yy  
       OR [ ] Not applicable (ring not in place since last visit)

2. Number of used rings collected:  
   - None [ ]  
   - 1 [X]  
   - If "1," go to item 3.

   2a. If none, specify reason: ______________________________________

3. Number of new rings dispensed to participant:  
   - None [ ]  
   - 1 [X]  
   - If "1," go to item 4.

   3a. Reason ring not dispensed:  
       - Participant on clinical hold [X]  
       - Participant has been permanently discontinued from product  
       - Participant declined study ring, specify: __________________________  
       - Early termination  
       - Day 28 ring removal visit  
       - Other, specify: ____________________________________________  
       - End of form.

4. Was a new ring inserted at this visit?  
   - Yes [ ]  
   - No [X]  
   - If no, go to item 5.

   4a. Time new ring was inserted:  
       - hh [ ]  
       - mm [ ] (24-hour clock)

   4b. Who inserted the new ring?  
       - Participant [ ]  
       - Study staff [ ]

5. Was a ring in place at the end of the visit?  
   - Yes [ ]  
   - No [X]  
   - If yes, end of form.

   5a. Reason ring not in place at end of visit:  
       - Participant declined to have ring inserted  
       - Participant had to leave before ring could be inserted  
       - Other, specify: ____________________________________________
### Specimen Storage

<table>
<thead>
<tr>
<th>Not done/Not collected</th>
<th>Alternate Collection Date</th>
<th>Collection Time (24-hour clock)</th>
<th>Reason not stored</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X</strong> 1. Vaginal smear for gram stain</td>
<td>dd MMM yy stored not stored</td>
<td>04 Jun 15</td>
<td></td>
</tr>
<tr>
<td><strong>X</strong> 2. Quantitative vaginal culture</td>
<td>dd MMM yy stored not stored</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>X</strong> 3. Vaginal swab for biomarkers:</td>
<td>dd MMM yy stored not stored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Was blood visible on the swab? yes no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>X</strong> 4. Cervical cytobrush</td>
<td>dd MMM yy stored not stored</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>X</strong> 5. Used vaginal ring</td>
<td>dd MMM yy stored not stored</td>
<td>10:15</td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**
<table>
<thead>
<tr>
<th>Specimen</th>
<th>Stored</th>
<th>Not Stored</th>
<th>If not stored, specify</th>
<th>Was blood visible on swab?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Single time-point blood</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>draw:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Single time-point vaginal</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fluid for PK:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Number of vaginal swabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>collected:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Experience Log

1. **Adverse Experience (AE)** Record diagnosis (in English) if available. Include anatomical location, if applicable.

   **Vaginal erythema**

2. **Onset date**
   - **dd**
   - **MMM**
   - **yy**
   - 01jun15

3. **At which visit was this AE first reported?**
   - **08.0**
   - visit code

4. **Severity**
   - □ Grade 1—mild
   - □ Grade 3—severe
   - □ Grade 5—death
   - ✔ Grade 2—moderate
   - □ Grade 4—potentially life-threatening

5. **Relationship to study product**
   - ✔ related
   - □ not related
   - Record rationale or alternative etiology in Comments.

6. **Study product administration**
   - □ no change
   - □ held
   - □ permanently discontinued
   - □ N/A

7. **Status or Outcome of AE**
   - ✔ continuing
   - □ resolved
   - □ death
   - □ severity/frequency increased (report as new AE)
   - □ continuing at end of study participation

   **7a. Status/Outcome Date** (Leave blank if item 7 is "continuing" or "continuing at end of study participation.")
   - 04jun15
   - dd
   - MMM
   - yy
   - jmb-04jun15
   - If severity/frequency increased, record the new AE page #

8. **Treatment**
   - ✔ none
   - □ new/prolonged hospitalization
     - Comment below
   - □ medication(s)
     - (Report on CM)
   - □ procedure/surgery
     - Comment below
   - □ other, specify
     - ______________

9. **Is this an SAE according to ICH guidelines?**
   - □ yes
   - ✔ no

10. **Has or will this AE be reported as an EAE?**
    - □ yes
    - ✔ no

11. **Was this AE a worsening of a pre-existing condition?**
    - □ yes
    - ✔ no

**Comments:**

Temporal relationship and biologically plausible
**Adverse Experience Log**

1. **Adverse Experience (AE)**: Record diagnosis (in English) if available. Include anatomical location, if applicable.
   
   **Vaginal erythema**

2. **Onset date**: 04 JUN 15
   
   **At which visit was this AE first reported?**: 08.1

3. **Severity**
   - [ ] Grade 1—mild
   - [ ] Grade 2—moderate
   - [X] Grade 3—severe
   - [ ] Grade 4—potentially life-threatening
   - [ ] Grade 5—death

4. **Relationship to study product**
   - [X] related
   - [ ] not related
   
   Record rationale or alternative etiology in Comments.

5. **Study product administration**
   - [ ] no change
   - [X] held
   - [ ] permanently discontinued
   - [ ] N/A

6. **Status or Outcome of AE**
   - [X] continuing
   - [ ] resolved
   - [ ] death
   - [ ] severity/frequency increased (report as new AE)
   - [ ] continuing at end of study participation

7a. **Status/Outcome Date**

   (Leave blank if item 7 is "continuing" or "continuing at end of study participation").

   [ ] dd
   [ ] MMM
   [ ] yy

8. **Treatment**
   - [X] none
   - [ ] if none, go to item 9
   - [ ] new/prolonged hospitalization
   - [ ] medication(s)
     - [ ] report on CMA
   - [ ] procedure/surgery
   - [ ] other, specify

9. **Is this an SAE according to ICH guidelines?**
   - [X] yes
   - [ ] no

10. **Has this AE been reported as an EAE?**
    - [X] yes
    - [ ] no

11. **Was this AE a worsening of a pre-existing condition?**
    - [X] yes
    - [ ] no

**Comments:**

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**Version 1.0. 01.APR-15**

**JMB 03JUN15**

Starts New Page
Clinical Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated:
   dd  MMM  yy  Visit code
   04  JUN  15  08.1

2. Why is study product being held?
   Mark only one per page.
   □ positive HIV test result
   □ adverse experience
   □ pregnancy
   □ use of prohibited medications
   □ breastfeeding
   □ report of PEP use for HIV exposure
   □ report of PrEP use for HIV exposure
   □ other, specify: __________________________
   Record on Concomitant Medications Log CRF.
   AE Log page # 002

3. Date of last study product use:
   dd  MMM  yy
   04  JUN  15

4. Was the participant instructed to resume study product use?
   □ yes  Date: __________________________
   □ no—hold continuing for another reason  Date: ____________
   □ no—early termination  Date: ____________
   □ no—hold continuing at the Day 28 visit  Date: ____________
   □ no—permanently discontinued  Date: ____________

Comments: __________________________________________
Pharmacokinetics Specimens—Day 28

1. Last menstrual period:  
   [ ] None
   [ ] Ongoing

   Start Date: 07 JUL 15
   Stop Date: 11 JUL 15

| Not done/Not collected | Specimen | Stored | Not Stored | If not stored, specify:
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. 0-hour blood draw:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. 1-hour blood draw:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. 2-hour blood draw:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. 4-hour blood draw:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. 6-hour blood draw:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaginal Fluid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. 0-hour vaginal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td>[ ] Yes [X] No</td>
</tr>
<tr>
<td></td>
<td>8. 1-hour vaginal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td>[X] Yes [ ] No</td>
</tr>
<tr>
<td></td>
<td>9. 2-hour vaginal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td>[X] Yes [ ] No</td>
</tr>
<tr>
<td></td>
<td>10. 4-hour vaginal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td>[ ] Yes [X] No</td>
</tr>
<tr>
<td></td>
<td>11. 6-hour vaginal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td>[ ] Yes [X] No</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12. Rectal fluid for PK:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13. Cervical biopsy for PK:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14. Cervical biopsy for PD:</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Monsel's solution used to stop bleeding during biopsy.

Version 1.0, 01-APR-15
Ring Collection and Insertion

1. Did the participant have a ring in place at the start of the visit?
   - Yes [x]
   - No [ ]
   → If yes, go to item 2.

   1a. When was the ring last in place?
   - dd [ ]
   - MMM [ ]
   - yy [ ]
   OR [ ] Not applicable (ring not in place since last visit)

2. Number of used rings collected:
   - None [ ]
   - 1 [x]
   → If “1,” go to item 3.

   2a. If none, specify reason: ________________________________

3. Number of new rings dispensed to participant:
   - None [ ]
   - 1 [x]
   → If “1,” go to item 4.

   3a. Reason ring not dispensed:
   - participant on clinical hold [ ]
   - participant has been permanently discontinued from product [ ]
   - participant declined study ring, specify: ________________________________
   - early termination [ ]
   - Day 28 ring removal visit [ ]
   - Other, specify: ________________________________
   → End of form.

4. Was a new ring inserted at this visit?
   - Yes [ ]
   - No [x]
   → If no, go to item 5.

   4a. Time new ring was inserted:
   - hh [ ]
   - mm [ ] (24-hour clock)

   4b. Who inserted the new ring?
   - Participant [ ]
   - Study staff [ ]

5. Was a ring in place at the end of the visit?
   - Yes [ ]
   - No [x]
   → If yes, end of form.

   5a. Reason ring not in place at end of visit:
   - participant declined to have ring inserted [ ]
   - participant had to leave before ring could be inserted [ ]
   - Other, specify: ________________________________

Version 1.0, 01-APR-15
Specimen Storage

Not done/Not collected

1. Vaginal smear for gram stain
   Alternate Collection Date
   dd  MMM  yy
   stored  not stored
   Reason not stored

Not done/Not collected

2. Quantitative vaginal culture
   Alternate Collection Date
   dd  MMM  yy
   stored  not stored
   Reason not stored

Not done/Not collected

3. Vaginal swab for biomarkers:
   3a. Was blood visible on the swab?
      yes  no
   Alternate Collection Date
   dd  MMM  yy
   stored  not stored
   Reason not stored

Not done/Not collected

4. Cervical cytoplasm
   Alternate Collection Date
   dd  MMM  yy
   stored  not stored
   Reason not stored

Not done/Not collected

5. Used vaginal ring
   Alternate Collection Date
   Collection Time (24-hour clock)
   hh  mm
   stored  not stored
   hh: mm
   Reason not stored

Comments:

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Version 1.0, 01-APR-15

Staff Initials/Date
**Adverse Experience Log**

<table>
<thead>
<tr>
<th>1. Adverse Experience (AE)</th>
<th>Record diagnosis (in English) if available. Include anatomical location, if applicable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>InCREASED AST Result</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Onset date</th>
<th>02 SEP 15</th>
</tr>
</thead>
</table>

| 3. At which visit was this AE first reported? | 13.6 |

| 4. Severity                 | Grade 3—severe |

| 5. Relationship to study product | not related |

| 6. Study product administration | N/A |

| 7. Status or Outcome of AE    | continuing at end of study participation |

| 7a. Status/Outcome Date       | dd MMM yy |

If severity/frequency increased, record the new AE page #

| 8. Treatment                  | medication(s) |

Mark “none” or all that apply.

- none
- new/prolonged hospitalization
- procedure/surgery
- other, specify

If none, go to item 9.

Comment below.

| 9. Is this an SAE according to ICH guidelines? | yes no |

| 10. Has or will this AE be reported as an EAE? | yes no |

| 11. Was this AE a worsening of a pre-existing condition? | yes no |

Comments:

Version 1.0, 01-APR-15
### Adverse Experience Log

**Participant ID**: XXXX-XXXXXX-X

**Date AE Reported to Site**: 05SEP15

#### Adverse Experience (AE)
Record diagnosis (in English) if available. Include anatomical location, if applicable.

**Increased ALT result**

#### Onset date
**dd MMM yy**: 02SEP15

**At which visit was this AE first reported?**: 130

#### Severity
- [ ] Grade 1—mild
- [X] Grade 3—severe
- [ ] Grade 5—death
- [ ] Grade 2—moderate
- [ ] Grade 4—potentially lifethreatening

#### Relationship to study product
- [ ] related
- [X] not related

*Record rationale or alternative etiology in Comments.*

#### Study product administration
- [ ] no change
- [ ] held
- [ ] permanently discontinued
- [X] N/A

#### Status or Outcome of AE
- [ ] continuing
- [ ] resolved
- [ ] death
- [ ] severity/frequency increased
  (report as new AE)
- [X] continuing at end of study participation

#### Status/Outcome Date
(Leave blank if item 7 is
"continuing" or "continuing at end of study participation."

**dd MMM yy**:

If severity/frequency increased, record the new AE page #

#### Treatment
Mark "none" or all that apply.

- [ ] none
- [ ] new/prolonged hospitalization
  Comment below.
- [X] medication(s)
  (Report on CM)
- [ ] procedure/surgery
  Comment below.
- [ ] other, specify
  Comment below.

#### Is this an SAE according to ICH guidelines?
- [ ] yes
- [X] no

#### Has or will this AE be reported as an EAE?
- [ ] yes
- [X] no

#### Was this AE a worsening of a pre-existing condition?
- [ ] yes
- [X] no

**Comments:**

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*Version 1.0, 01-APR-15*