SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PRE (012)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 01

Participant ID

x x x - x x x x x - x

Site Number | Participant Number | Chk

☐ No pre-existing conditions reported or observed. Staff Initials/Date

→ End of form. Submit to DF/Net.

Pre-existing Conditions

1

Condition: Dysuria

Onset Date (MMM yy): MAY 15

Staff Initials/Date: jmb 19may15

Comments: Participant has symptoms of burning with urination, treated presumtively with bactrim.

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: 2 or ☐ not gradable

2

Condition

Leave this item blank at Screening.

Onset Date (MMM yy):

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

3

Condition:

Onset Date (MMM yy):

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

4

Condition:

Onset Date (MMM yy):

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

jmb 17may15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 SLR-2 (145)

Visit Code 01.0

Participant ID

XXX-XXXXX-X

Site Number – Participant Number – Chk

Safety Laboratory Results

	Not done/ Not collected	Alternate Collection Date (dd MMM yy)	Severity Grade if applicable	AE Log Page #	Not reportable as an AE
2. SERUM CHEMISTRIES	☐ → *Go to item 3.*				
2a. AST (SGOT)	Not reported ☐	0021 U/L	☐	☐☐☐	OR ☐
2b. ALT (SGPT)	☐	0048 U/L	☐	☐☐☐	OR ☐
2c. Creatinine	☐	00.8 mg/dL	☐	☐☐☐	OR ☐
2c1. Calculated creatinine clearance		111 mL/min			

	Not done/ Not collected	Alternate Collection Date (dd MMM yy)	negative	positive
3. DIPSTICK URINALYSIS TESTS	☐ → *End of form.*			
3a. Leukocyte esterase (LE)	Not done ☐		☐	X
3b. Nitrates	Not done ☐		☐	X

Comments: _____

JMB 28 APR 15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 CM (423)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 01

Participant ID

XXX - XXXXX - X

Site Number | Participant Number | Chk

☐ Nonmedications taken at Screening/Enrollment — Staff Initials/ Date _____

☐ Nonmedications taken throughout study. — Staff Initials/ Date _____

→ End of form. Submit to DF/Net.

Concomitant Medications Log

1

Medication Name: **Bactrim**

Staff Initials/ Log Entry Date: JMB 19/5/15

Indication: **urinary tract infection**

Taken for a reported AE? ☐ yes ☒ no

AE Log page(s): ☐☐ ☐☐ ☐☐ ☐☐

Date Started: 19 MAY 15 (dd / MMM / yy)

Date Stopped: ☐☐ / ☐☐☐ / ☐☐ (dd / MMM / yy) OR ☐ Continuing at end of study

Dose/Units: 1 tablet daily

Frequency *Mark only one.*

prn ☒ | qd ☐ | tid ☐ | qhs ☐ | once ☐ | bid ☐ | qid ☐ | other, specify ☐ _____

Route *Mark only one.*

PO ☒ | IM ☐ | IV ☐ | TOP ☐ | IHL ☐ | VAG ☐ | REC ☐ | SC ☐ | other, specify ☐ _____

2

Medication Name:

Staff Initials/ Log Entry Date:

Indication:

Taken for a reported AE? ☐ yes ☐ no

AE Log page(s): ☐☐ ☐☐ ☐☐ ☐☐

Date Started: ☐☐ / ☐☐☐ / ☐☐ (dd / MMM / yy)

Date Stopped: ☐☐ / ☐☐☐ / ☐☐ (dd / MMM / yy) OR ☐ Continuing at end of study

Dose/Units:

Frequency *Mark only one.*

prn ☐ | qd ☐ | tid ☐ | qhs ☐ | once ☐ | bid ☐ | qid ☐ | other, specify ☐ _____

Route *Mark only one.*

PO ☐ | IM ☐ | IV ☐ | TOP ☐ | IHL ☐ | VAG ☐ | REC ☐ | SC ☐ | other, specify ☐ _____

JMB 19 may 15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PRE (012)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # ☐☐

Participant ID

XXX – XXXXX – X

Site Number | Participant Number | Chk

☐ No pre-existing conditions reported or observed. Staff Initials/Date _____

→ End of form. Submit to DF/Net.

Pre-existing Conditions

1

Condition: ~~Dysuria~~ Urinary Tract Infection

Onset Date: MMM MAY yy 15

Staff Initials/Date: jmb 17may15

Comments: Participant has symptoms of burning with urination, treated presumptively with bactrum. Urine culture and microscopy results positive for urinary tract infection. jmb 20may15

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: 2 or ☐ not gradable

2

Condition: Proteinuria

Onset Date: MMM MAY yy 15

Staff Initials/Date: jmb 20may15

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: 1 or ☐ not gradable

3

Condition:

Onset Date: MMM ___ yy ___

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

4

Condition:

Onset Date: MMM ___ yy ___

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

Staff Initials/Date _____

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 CM (423)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 01

Participant ID

XXX - XXXXX - X

Site Number | Participant Number | Chk

☐ Nonmedications taken at Screening/Enrollment — Staff Initials/ Date _____

☐ Nonmedications taken throughout study. — Staff Initials/ Date _____

→ End of form. Submit to DF/Net.

Concomitant Medications Log

1

Medication Name: **Bactrim**

Staff Initials/ Log Entry Date: JMB 19/5/15

Indication: **urinary tract infection**

Taken for a reported AE? ☐ yes ☒ no

AE Log page(s): ☐☐ ☐☐ ☐☐ ☐☐

Date Started: 19 MAY 15 (dd / MMM / yy)

Date Stopped: 29 MAY 15 (dd / MMM / yy) OR ☐ Continuing at end of study

Dose/Units: 1 tablet daily

Frequency *Mark only one.*

prn ☒ | qd ☐ | tid ☐ | qhs ☐ | once ☐ | bid ☐ | qid ☐ | other, specify ☐ _____

Route *Mark only one.*

PO ☒ | IM ☐ | IV ☐ | TOP ☐ | IHL ☐ | VAG ☐ | REC ☐ | SC ☐ | other, specify ☐ _____

2

Medication Name:

Staff Initials/ Log Entry Date:

Indication:

Taken for a reported AE? ☐ yes ☐ no

AE Log page(s): ☐☐ ☐☐ ☐☐ ☐☐

Date Started: ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

Date Stopped: ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy) OR ☐ Continuing at end of study

Dose/Units:

Frequency *Mark only one.*

prn ☐ | qd ☐ | tid ☐ | qhs ☐ | once ☐ | bid ☐ | qid ☐ | other, specify ☐ _____

Route *Mark only one.*

PO ☐ | IM ☐ | IV ☐ | TOP ☐ | IHL ☐ | VAG ☐ | REC ☐ | SC ☐ | other, specify ☐ _____

JMB 28 apr 15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PRE (012)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # ☐☐

Participant ID

X X X – X X X X X X – X

Site Number – Participant Number – Chk

☐ No pre-existing conditions reported or observed. _____ Staff Initials/Date

→ End of form. Submit to DF/Net.

Pre-existing Conditions

1

Condition: ~~Dysuria~~ Urinary Tract Infection

Onset Date: MMM M A Y yy 1 5

Staff Initials/Date: jmb 17may15

Comments: Participant has symptoms of burning with urination, treated presumptively with bactrum. Urine culture and microscopy results positive for urinary tract infection. jmb 20may15 Resolved jmb 02june15

Ongoing at Enrolment? yes ☐ no ☒ jmb 02jun15

Severity Grade: 2 or ☐ not gradable

2

Condition: Proteinuria

Onset Date: MMM M A Y yy 1 5

Staff Initials/Date: jmb 20may15

Comments:

Ongoing at Enrolment? yes ☒ no ☐ jmb 02jun15

Severity Grade: 1 or ☐ not gradable

3

Condition:

Onset Date: MMM yy

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

4

Condition:

Onset Date: MMM yy

Staff Initials/Date:

Comments:

Ongoing at Enrolment? yes ☐ no ☐

Severity Grade: ☐ or ☐ not gradable

_____ Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 ECI (023)

Participant ID

X X X - X X X X X - X

Site Number | Participant Number | Chk

Form Completion Date

02 JUN 15

dd | MMM | yy

Eligibility Criteria

1. Does this participant meet all eligibility criteria? yes [X] no [ ] → *If no, go to item 2*

1a. Obtain signature _____ 02JUN15

Signature of Principal Investigator (or designee) | *Date*

1b. Obtain signature _____ 02JUN15

Signature of second staff member verifying eligibility | *Date*

2. Was the participant enrolled? yes [ ] no [X] → *If yes, end of form.*

3. Why was the participant not enrolled?

- [ ] participant did not complete all screening procedures → *End of form.*
- [ ] eligible but declined enrollment → *End of form.*
- [X] not eligible

4. Reason(s) for ineligibility *Mark all that apply.*

- [ ] 4a. participant < 18 or > 45 years old
- [ ] 4b. plans for relocation/travel
- [ ] 4c. participant is pregnant or planning to become pregnant within the next 3 months
- [ ] 4d. participant is breastfeeding
- [ ] 4e. participant unwilling to refrain from receptive sexual activity
- [ ] 4f. participant has enrolled in another research study in the
- [ ] 4h. PEP or PrEP exposure in the last 6 months
- [ ] 4i. participant is HIV-positive
- [ ] 4j. participant declines effective method of contraception
- [ ] 4k. participant has a grade 1 or higher pelvic exam finding
- [X] 4l. participant does not meet laboratory eligibility criteria. Specify or provide test results: positive for chlamydia infection

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 FVS (121)

Visit Code 05.0

Participant ID: XXX-XXXXX-X (Site Number - Participant Number - Chk)

Visit Date: 11 JUL 15 (dd MMM yy)

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.*** Alternate Collection Date (dd MMM yy)

   ☐ 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
   ☐ Ring Collection and Insertion
   ☐ Pharmacokinetics
   ☐ Specimen Storage
   ☐ Safety Laboratory Results
   ☐ Pelvic Exam
   ☐ STI Test Results
   ☐ HIV Results
   ☐ Physical Exam
   ☐ 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: _____

7/11/15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

PKD (164)

Visit Code 05.0

Participant ID: XXX-XXXXX-X (Site Number – Participant Number – Chk)

Specimen Collection Date: 13 JUL 15 (dd MMM yy)

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

1. Last menstrual period: ☐ None

Start Date: 08 JUL 15 (dd MMM yy)

Stop Date: 12 JUL 15 (dd MMM yy) OR ☐ ongoing

Not done/ Not collected	Specimen	Stored	Not Stored	If not stored, specify:	Was blood visible on swab?
☐	2. Single time-point blood draw:	☒	☐		
☐	3. Single time-point vaginal fluid for PK:	☒	☐		☐ Yes ☒ No
	3a. Number of vaginal swabs collected: 2				

Comments:

Version 1.0, 01-APR-15

7/13/15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 FVS (121)

Visit Code 0 6 . 1

Participant ID: X X X - X X X X X - X (Site Number - Participant Number - Chk)

Visit Date: 23 MAY 15 (dd MMM yy)

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.* Alternate Collection Date (dd MMM yy)

   ☒ 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
   - ☒ Ring Collection and Insertion
   - ☐ Pharmacokinetics
   - ☒ Specimen Storage
   - ☐ Safety Laboratory Results
   - ☐ Pelvic Exam
   - ☐ STI Test Results
   - ☐ HIV Results
   - ☐ Physical Exam
   - ☐ 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

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

RCI (135)

Visit Code 0 6 . 1

Participant ID

X X X - X X X X X - X

Site Number | Participant Number | Chk

Visit Date

2 3 M A Y 1 5

dd | MMM | yy

Ring Collection and Insertion

1 Did the participant have a ring in place at the start of the visit? ☐ Yes ☒ No

→ *If yes, go to item 2.*

1a. When was the ring last in place? 2 2 M A Y 1 5 (dd | MMM | yy) OR ☐ Not applicable (ring not in place since last visit)

2 Number of **used** rings collected: ☐ None ☒ 1 → *If "1," go to item 3.*

2a. If none, specify reason: _____

3 Number of **new** rings dispensed to participant: ☐ None ☒ 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: _____

→ *End of form.*

4 Was a new ring inserted at this visit? ☒ Yes ☐ No → *If no, go to item 5.*

4a. Time new ring was inserted: 1 3 : 2 0 (24-hour clock) (hh | mm)

4b. Who inserted the new ring? ☐ Participant ☒ Study staff

5 Was a ring in place at the end of the visit? ☒ Yes ☐ 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: _____

JMB 28APR15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

SS (149)

Visit Code 0 6 . 1

Participant ID

X X X - X X X X X - X

Site Number | Participant Number | Chk

Initial Specimen Collection Date

2 3 M A Y 1 5

dd | MMM | yy

Specimen Storage

Not done/ Not collected		Alternate Collection Date (dd / MMM / yy)	stored	not stored	Reason not stored
X	1. Vaginal smear for gram stain		☐	☐	
X	2. Quantitative vaginal culture		☐	☐	
X	3. Vaginal swab for biomarkers:		☐	☐	
	3a. Was blood visible on the swab? yes ☐ no ☐				
X	4. Cervical cytobrush		☐	☐	
☐	5. Used vaginal ring	Alternate Collection Date:	☐	☐	

Collection Time (24-hour clock): hh 1 1 : mm 3 0

Comments: _____

Version 1.0, 01-APR-15

JMB 28APR15

Staff Initials/Date

Participant ID: x x x - x x x x x - x (Site Number - Participant Number - Chk)

Date AE Reported to Site: 22 may 15 (dd MMM yy)

Adverse Experience Log

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

2 Onset date: 22 MAY 15 (dd MMM yy)

3 At which visit was this AE first reported? 06.1 visit code

4 Severity: [X] 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: [ ] continuing [X] 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.")*: 23 MAY 15 (dd MMM yy)

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

8 Treatment *Mark "none" or all that apply.* [X] none → If none, go to item 9. [ ] new/prolonged hospitalization *Comment below.* [ ] medication(s) *(Report on CM)* [ ] procedure/surgery *Comment below.* [ ] other, specify *Comment below.* _____

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 - discomfort abated once removed

jmb 23may15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 RA (170)

Visit Code 07.0

Participant ID: xxx-xxxxx-x (Site Number – Participant Number – Chk)

Visit Date: 29 MAY 15 (dd MMM yy)

Ring Adherence

1	Date and visit code this form was last completed for this participant?	22 MAY 15 (dd MMM yy) Visit Code 06.0
2	Since this form was last completed, has the ring been out at any time?	[X] 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.

	Date ring out (dd-MMM-yy)	Duration ring was out (days hours minutes)	Removal/ Expulsion code	If other, specify:
3a.	22 MAY 15	00 23 15	10	
3b.				
3c.				
3d.				
3e.				

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: 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.

jmb 27apr15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

FVS (121)

Visit Code 0 8 . 0

Participant ID

x x x - x x x x x - x

Site Number | Participant Number | Chk

Visit Date

0 1 J U N 1 5

dd | MMM | yy

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.*

   Alternate Collection Date: dd ____ MMM ____ yy ____

   ☐ *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
   ☐ Ring Collection and Insertion
   ☐ Pharmacokinetics
   ☐ Specimen Storage
   ☐ Safety Laboratory Results
   ☐ Pelvic Exam
   ☐ STI Test Results
   ☐ HIV Results
   ☐ Physical Exam
   ☐ other, specify: _____

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PE (138)

Scenario 4a

Visit Code 0 8 . 0

Participant ID: x x x - x x x x x - x (Site Number - Participant Number - Chk)

Visit Date: 0 1 JUN 15 (dd MMM yy)

Pelvic Exam

1 Vaginal pH: ☐ Not done 3 . 7 If > 4.5, mark Positive → ☐ Positive

2 Pelvic exam assessment: ☐ Not done → End of form. ☒ Abnormal findings ☐ No abnormal findings → End of form.

2a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ Vulvar edema	☐ Vaginal edema	☐ Cervical edema and/or friability	☐ Odor (vaginal)
☐ Vulvar erythema	☒ Vaginal erythema	☐ Cervical erythema	☐ Condyloma, specify location: _____
☐ Vulvar rash	☐ Vaginal masses (polyps, myomas, possible malignancy)	☐ Cervical masses (polyps, myomas, possible malignancy)	
☐ Vulvar tenderness	☐ Vaginal abrasions or lacerations	☐ Cervical motion tenderness	☐ Adnexal masses (based on bimanual exam; not pregnancy or infection-related)
☐ Bartholin's or Skene's gland abnormality	☐ Vaginal tenderness	☐ Cervical discharge	☐ Uterine masses (based on bimanual exam)
	☐ Abnormal vaginal discharge → ☐ slight ☐ moderate ☐ pooling		☐ Uterine tenderness
			☐ Adnexal tenderness
Vulvar lesions	**Vaginal lesions**	**Cervical lesions**	☐ Observed blood or bleeding, describe: _____
☐ Ulcer	☐ Ulcer	☐ Ulcer	
☐ Blister	☐ Blister	☐ Blister	
☐ Pustule	☐ Pustule	☐ Pustule	
☐ Peeling	☐ Peeling	☐ Peeling	
☐ Ecchymosis	☐ Ecchymosis	☐ 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 ☐ No → End of form.

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

0 0 1 | | | | | | | | | | | |

Version 1.0, 01-APR-15

JMB 01JUN15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PER (168)

Scenario 4a

Visit Code 0 8 . 0

Participant ID: X X X - X X X X X - X

Site Number | Participant Number | Chk

Exam Date: 0 1 J U N 1 5

dd | MMM | yy

Pelvic Exam Ring Assessment

1	Was the vaginal ring present in the vagina at the start of the exam?	[X] Yes [ ] No → *If no, go to item 3.*
2	Was the vaginal ring removed during the exam?	[X] Yes [ ] No → *If no, end of form.*
	2a. If yes, how long was the vaginal ring removed from the vagina?	0 0 *Hours* 1 0 *Minutes*
3	Was the vaginal ring rinsed prior to reinsertion?	[X] Yes [ ] No [ ] Not reinserted → *If yes or no, end of form.*
	3a. Specify reason ring not reinserted: _____	

JMB 01JUN15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 RA (170)

Visit Code 0 8 . 0

Scenario 4a

Participant ID: X X X - X X X X X - X (Site Number - Participant Number - Chk)

Visit Date: 0 1 J U N 1 5 (dd MMM yy)

Ring Adherence

1	Date and visit code this form was last completed for this participant?	2 3 M A Y 1 5 (dd MMM yy) Visit Code 0 7 . 0
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?	☐☐ → *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.	

	Date ring out *dd-MMM-yy*	Duration ring was out *days*	*hours*	*minutes*	Removal/ Expulsion code	If other, specify:
3a.	☐☐-☐☐☐-☐☐	☐☐	☐☐	☐☐	☐☐	
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: _____

JMB 01JUN15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 AE (460)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 0 1

Scenario 4a

Participant ID

X X X - X X X X X - X

Site Number — Participant Number — Chk

Date AE Reported to Site

0 1 J U N 1 5

dd MMM yy

Adverse Experience Log

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

Vaginal erythema

2 Onset date: 0 1 j u n 1 5 (dd MMM yy)

3 At which visit was this AE first reported? 0 8 . 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.")*

dd MMM yy

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

8 Treatment *Mark "none" or all that apply.*

- ☒ none → If none, go to item 9.
- ☐ new/prolonged hospitalization *Comment below.*
- ☐ medication(s) *(Report on CM)*
- ☐ procedure/surgery *Comment below.*
- ☐ other, specify _____ *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:

Temporal ralationship and biologically plausible

Participant ID: XXX-XXXX-X (Site Number – Participant Number – Chk)

Scenario 4c

Visit Date: 04 JUN 15 (dd MMM yy)

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.*

   Alternate Collection Date: dd ___ MMM ___ yy ___

   ☐ 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
   - ☒ Ring Collection and Insertion
   - ☒ Pharmacokinetics
   - ☒ Specimen Storage
   - ☐ Safety Laboratory Results
   - ☒ Pelvic Exam
   - ☐ STI Test Results
   - ☐ HIV Results
   - ☐ Physical Exam
   - ☐ other, specify: _____

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PE (138)

Visit Code 08.1

Participant ID: XXX-XXXXX-X (Site Number – Participant Number – Chk)

Visit Date: 04 JUN 15 (dd MMM yy)

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.*
→ *End of form.*

2a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ Vulvar edema	☐ Vaginal edema	☐ Cervical edema and/or friability	☐ Odor (vaginal)
☐ Vulvar erythema	☒ Vaginal erythema	☐ Cervical erythema	☐ Condyloma, specify location: _____
☐ Vulvar rash	☐ Vaginal masses (polyps, myomas, possible malignancy)	☐ Cervical masses (polyps, myomas, possible malignancy)	
☐ Vulvar tenderness	☐ Vaginal abrasions or lacerations	☐ Cervical motion tenderness	☐ Adnexal masses (based on bimanual exam; not pregnancy or infection-related)
☐ Bartholin's or Skene's gland abnormality	☐ Vaginal tenderness	☐ Cervical discharge	☐ Uterine masses (based on bimanual exam)
	☐ Abnormal vaginal discharge: slight ☐ moderate ☐ pooling ☐		☐ Uterine tenderness
			☐ Adnexal tenderness
Vulvar lesions	**Vaginal lesions**	**Cervical lesions**	☐ Observed blood or bleeding, describe: _____
☐ Ulcer	☐ Ulcer	☐ Ulcer	
☐ Blister	☐ Blister	☐ Blister	
☐ Pustule	☐ Pustule	☐ Pustule	
☐ Peeling	☐ Peeling	☐ Peeling	
☐ Ecchymosis	☐ Ecchymosis	☐ 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 ☒ No → *End of form.*

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

002 | | | |

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

RCI (135)

Scenario 4c

Visit Code 0 8 . 1

Participant ID

X X X – X X X X X – X

Site Number – Participant Number – Chk

Visit Date

0 4 J U N 1 5

dd MMM yy

Ring Collection and Insertion

1 Did the participant have a ring in place at the start of the visit? [X] Yes [ ] 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 [X] 1 → *If "1," go to item 3.*

2a. If none, specify reason: _____

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

3a. Reason ring not dispensed:

- [X] 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 → *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

→ *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: _____

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 SS (149)

Scenario 4c

Visit Code 0 8 . 1

Participant ID

Site Number – Participant Number – Chk

Initial Specimen Collection Date

dd: 0 4 | MMM: J u n | yy: 1 5

Specimen Storage

Not done/ Not collected

[X] 1. Vaginal smear for gram stain

Alternate Collection Date dd MMM yy

stored [ ] not stored [ ]

Reason not stored

Not done/ Not collected

[X] 2. Quantitative vaginal culture

Alternate Collection Date dd MMM yy

stored [ ] not stored [ ]

Reason not stored

Not done/ Not collected

[X] 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

[X] 4. Cervical cytobrush

Alternate Collection Date dd MMM yy

stored [ ] not stored [ ]

Reason not stored

Not done/ Not collected

[ ] 5. Used vaginal ring

Alternate Collection Date dd MMM yy

Collection Time (24-hour clock) hh : mm 1 0 : 1 5

stored [X] not stored [ ]

Reason not stored

Comments:

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 PKD (164)

Visit Code 08.1

Participant ID: XXX-XXXXX-X (Site Number – Participant Number – Chk)

Specimen Collection Date: 04 JUN 15 (dd MMM yy)

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

1. Last menstrual period: [X] None

Start Date: dd MMM yy

Stop Date: dd MMM yy

ongoing OR [ ]

Not done/ Not collected	Specimen	Stored	Not Stored	If not stored, specify:	Was blood visible on swab?
[ ]	2. Single time-point blood draw:	[X]	[ ]		
[ ]	3. Single time-point vaginal fluid for PK:	[X]	[ ]		[ ] Yes [X] No
	3a. Number of vaginal swabs collected: 1				

Comments:

Version 1.0, 01-APR-15

Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 AE (460)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 0 1

Scenario 4c

Participant ID

X X X - X X X X X - X

Site Number — Participant Number — Chk

Date AE Reported to Site

0 1 J U N 1 5

dd MMM yy

Adverse Experience Log

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

Vaginal erythema

2 Onset date: 0 1 j u n 1 5 (dd MMM yy)

3 At which visit was this AE first reported? 0 8 . 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~~
- jmb 04jun15
- ☐ resolved
- ☐ death
- jmb 04jun15 ☒ 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.")*

0 4 j u n 1 5 (dd MMM yy) jmb 04jun15

If severity/frequency increased, record the new AE page # AE page # 0 2

8 Treatment *Mark "none" or all that apply.*

- ☒ none → *If none, go to item 9.*
- ☐ new/prolonged hospitalization *Comment below.*
- ☐ medication(s) *(Report on CM)*
- ☐ procedure/surgery *Comment below.*
- ☐ other, specify *Comment below.* _____

jmb 04jun15

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 ralationship and biologically plausible

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 AE (460)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 0 2

Scenario 4c

Participant ID

X X X - X X X X X - X

Site Number — Participant Number — Chk

Date AE Reported to Site

0 4 j u n 1 5

dd MMM yy

Adverse Experience Log

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

Vaginal erythema

2 Onset date: 0 4 J U N 1 5 (dd MMM yy)

3 At which visit was this AE first reported? 0 8 . 1 *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

- ☒ 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.")*

dd MMM yy

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

8 Treatment *Mark "none" or all that apply.*

- ☒ none → If none, go to item 9.
- ☐ new/prolonged hospitalization *Comment below.*
- ☐ medication(s) *(Report on CM)*
- ☐ procedure/surgery *Comment below.*
- ☐ other, specify _____ *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:

JMB 04JUN15

Staff Initials/Date

Participant ID

Site Number	Participant Number	Chk
XXX	XXXXX	X

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 → 002 *AE Log page #*
- ☐ pregnancy
- ☐ use of prohibited medications → *Record on Concomitant Medications Log CRF.*
- ☐ breastfeeding
- ☐ report of PEP use for HIV exposure
- ☐ report of PrEP use for HIV exposure
- ☐ other, specify: _____

3. Date of last study product use:

dd	MMM	yy
04	JUN	15

4. Was the participant instructed to resume study product use?

	dd	MMM	yy
☐ 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: _____

SAMPLE: DO NOT FAX TO DATAFAX
(MTN 027) DF/Net 027

PKS (162)

Visit Code 09.0

Participant ID: XXX-XXXXX-X (Site Number - Participant Number - Chk)

Specimen Collection Date: 13 JUL 15 (dd MMM yy)

Pharmacokinetics Specimens—Day 28

1. Last menstrual period: ☐ None
Start Date: 07 JUL 15 (dd MMM yy)
Stop Date: 11 JUL 15 (dd MMM yy) OR ☐ ongoing

Not done/ Not collected	Specimen	Stored	Not Stored	If not stored, specify:	Was blood visible on swab?
	Blood				
☐	2. 0-hour blood draw:	☒	☐		
☐	3. 1-hour blood draw:	☒	☐		
☐	4. 2-hour blood draw:	☒	☐		
☐	5. 4-hour blood draw:	☒	☐		
☐	6. 6-hour blood draw:	☒	☐		
	Vaginal Fluid	**Stored**	**Not Stored**	**If not stored, specify:**	**Was blood visible on swab?**
☐	7. 0-hour vaginal fluid for PK:	☒	☐		☐ Yes ☒ No
☐	8. 1-hour vaginal fluid for PK:	☒	☐		☒ Yes ☐ No
☐	9. 2-hour vaginal fluid for PK:	☒	☐		☒ Yes ☐ No
☐	10. 4-hour vaginal fluid for PK:	☒	☐		☐ Yes ☒ No
☐	11. 6-hour vaginal fluid for PK:	☒	☐		☐ Yes ☒ No
	Other				
☐	12. Rectal fluid for PK:	☒	☐		
☐	13. Cervical biopsy for PK:	☒	☐		
☐	14. Cervical biopsy for PD:	☒	☐		

Comments: Monsels solution used to stop bleeding during biopsy.

7/13/15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

RCI (135)

Visit Code 09.0

Participant ID: XXX-XXXXX-X (Site Number - Participant Number - Chk)

Visit Date: 13 JUL 15 (dd MMM yy)

Ring Collection and Insertion

1 Did the participant have a ring in place at the start of the visit? ☒ Yes ☐ 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 → ***If "1," go to item 3.***

2a. If none, specify reason: _____

3 Number of **new** rings dispensed to participant: ☒ None ☐ 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: _____

→ ***End of form.***

4 Was a new ring inserted at this visit? ☐ Yes ☐ No → ***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 → ***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: _____

7/13/15 Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027 SS (149)

Visit Code 09.0

Participant ID: XXX-XXXXX-X (Site Number - Participant Number - Chk)

Initial Specimen Collection Date: 13 JUL 15 (dd MMM yy)

Specimen Storage

1. Vaginal smear for gram stain — Not done/Not collected ☐ — Alternate Collection Date: dd MMM yy — stored ☒ — not stored ☐ — Reason not stored: _____

2. Quantitative vaginal culture — Not done/Not collected ☐ — Alternate Collection Date: dd MMM yy — stored ☒ — not stored ☐ — Reason not stored: _____

3. Vaginal swab for biomarkers: — Not done/Not collected ☐ — Alternate Collection Date: dd MMM yy — stored ☒ — not stored ☐ — Reason not stored: _____

   3a. Was blood visible on the swab? yes ☐ no ☐

4. Cervical cytobrush — Not done/Not collected ☐ — Alternate Collection Date: dd MMM yy — stored ☒ — not stored ☐ — Reason not stored: _____

5. Used vaginal ring — Not done/Not collected ☐ — Alternate Collection Date: dd MMM yy — Collection Time (24-hour clock): hh mm 09:45 — stored ☒ — not stored ☐ — Reason not stored: _____

Comments: _____

JC 7/13/15
Staff Initials/Date

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

AE (460)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 0 1

Participant ID

X X X - X X X X X - X

Site Number *Participant Number* *Chk*

Date AE Reported to Site

0 5 SEP 1 5

dd *MMM* *yy*

Adverse Experience Log

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

Increased AST result

2 Onset date 0 2 SEP 1 5 (*dd* *MMM* *yy*)

3 At which visit was this AE first reported? 1 3 . 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.")*

dd *MMM* *yy*

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

8 Treatment *Mark "none" or all that apply.*

☐ *none* → ***If none, go to item 9.***

☐ *new/prolonged hospitalization* ***Comment below.***

☒ *medication(s) (Report on CM)*

☐ *procedure/surgery* ***Comment below.***

☐ *other, specify* ***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:

9/5/15

SAMPLE: DO NOT FAX TO DATAFAX

(MTN 027) DF/Net 027

AE (460)

Note: Number pages sequentially (01, 02, 03) for each participant. Page # 01

Participant ID

XXX - XXXXX - X

Site Number | Participant Number | Chk

Date AE Reported to Site

05 SEP 15

dd | MMM | yy

Adverse Experience Log

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

Increased ALT result

2 Onset date 02 SEP 15 (dd | MMM | yy)

3 At which visit was this AE first reported? 13.0 *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

- ☐ 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.")*

dd | MMM | yy

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

8 Treatment *Mark "none" or all that apply.*

- ☐ none → **If none, go to item 9.**
- ☐ new/prolonged hospitalization **Comment below.**
- ☒ medication(s) (Report on CM)
- ☐ procedure/surgery **Comment below.**
- ☐ other, specify **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:

9/5/15