Subject Case Report Forms

MTN043_Version 6.0_PROD_BK_18DEC2020 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

MTN043_Version 6.0_PROD_BK_18DEC2020: ALL
Form: Follow-up Visit Summary
Generated On: 18 Dec 2020 22:06:21

Visit date	_____
Was study product permanently discontinued (scheduled or early) at this visit?	Yes ☐ No ☐
Was study product held at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations) should be recorded as concomitant medications.	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	Yes ☐ No ☐

Visit date	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	Yes ☐ No ☐

Visit date _____

Interim visit code _____

Was study product held at this visit? Yes ☐ No ☐

Was study product use permanently discontinued (scheduled or early) at this visit? Yes ☐ No ☐

Did the participant exit/terminate the study at this visit? Yes ☐ No ☐

Were any new adverse events (AEs) reported at this visit? Yes ☐ No ☐

Is the participant taking any concomitant medications that have not been previously reported? Yes ☐ No ☐

Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. Yes ☐ No ☐

Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations) should be recorded as concomitant medications.

Were any protocol deviations reported at this visit? Yes ☐ No ☐

Reason for interim visit (Select all that apply.)

- AE report or follow-up ☐
- Return of product or need new product ☐
- Completion of missed visit procedures ☐
  - If completion of missed visit procedures, for which visit are procedures being made up?
    - V3.0 - Week 1 ☐
    - V4.0 - Week 2 ☐
    - V5.0 - Month 1 ☐
    - V6.0 - Month 2 ☐
    - V7.0 - Month 3 (PUEV) ☐
    - V8.0 - 2 weeks after study product end ☐
    - Interim Visit ☐
- Other ☐
  - If other, specify _____

What study procedures were completed at this visit? Select all that apply.

- Behavioral Assessment - Follow Up ☐

Behavioral Assessment - Month 3 Follow Up	☐
Chemistry Panel	☐
COVID-19 Behavioral Assessment	☐
Edinburgh Postnatal Depression Scale	☐
Feeding Assessment	☐
Hematology	☐
HIV Test Results	☐
HIV Confirmatory Results	☐
IDI Tracking	☐
Pelvic exam	☐
Physical exam	☐
Pregnancy Test Results	☐
PrEP Provision and Returns	☐
Ring Adherence	☐
Ring Assessment	☐
Ring Insertion or Removal	☐
Seroconverter Results	☐
Social Impacts	☐
Specimen Storage	☐
STI Test Results	☐
Tablet Adherence	☐
Tablet Assessment	☐
Urine Test Results	☐
Vaginal Practices	☐
Vital signs	☐

Visit date	_____
Interim visit code	_____
Did the participant exit/terminate the study at this visit?	Yes ◯ No ◯
Were any new adverse events (AEs) reported at this visit?	Yes ◯ No ◯
Is the participant taking any concomitant medications that have not been previously reported?	Yes ◯ No ◯
Were any protocol deviations reported at this visit?	Yes ◯ No ◯
Reason for interim visit (Select all that apply.)	
AE report or follow-up	☐
Completion of missed visit procedures	☐
If completion of missed visit procedures, for which visit are procedures being made up?	V3.0 - Week 1 ◯ V4.0 - Week 2 ◯ V5.0 - Month 1 ◯ V6.0 - Month 2 ◯ V7.0 - Month 3 (PUEV) ◯ V8.0 - 2 weeks after study product end ◯ Interim Visit ◯
Other	☐
If other, specify	_____
What study procedures were completed at this visit? Select all that apply.	
Infant HIV Confirmatory Results	☐
Infant Ages and Stages Assessment	☐
Infant Specimen Storage	☐
Infant Vital Signs	☐
Physical Examination	☐
Seroconverter Results	☐

Screening visit date _____

Was this assessment performed?
- Yes
- No

Date of assessment _____

.We would like to know how you are feeling. Please select the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

1. - .I have been able to laugh and see the funny side of things.
   - As much as I always could (0).
   - Not quite so much now (1).
   - Definitely not so much now (2).
   - Not at all (3).

2. - .I have looked forward with enjoyment to things.
   - As much as I ever did (0).
   - Rather less than I used to(1).
   - Definitely less than I used to (2).
   - Hardly at all (3).

3. - .I have blamed myself unnecessarily when things went wrong.
   - Yes, most of the time (3).
   - Yes, some of the time (2).
   - Not very often (1).
   - No, never (0).

4. - .I have been anxious or worried for no good reason.
   - No, not at all (0).
   - Hardly ever (1).
   - Yes, sometimes (2).
   - Yes, very often (3).

5. - .I have felt scared or panicky for no very good reason.
   - Yes, quite a lot (3).
   - Yes, sometimes (2).
   - No, not much (1).
   - No, not at all (0).

6. - .Things have been getting on top of me.
   - Yes, most of the time I haven't been able to cope at all (3).
   - Yes, sometimes I haven't been coping as well as usual (2).
   - No, most of the time I have coped quite well (1).
   - No, I have been coping as well as ever (0).

7. - .I have been so unhappy that I have had difficulty sleeping.
   - Yes, most of the time (3).
   - Yes, sometimes (2).
   - Not very often (1).
   - No, not at all (0).

8. - .I have felt sad or miserable.
   - Yes, most of the time (3).
   - Yes, quite often (2).
   - Not very often (1).

	No, not at all (0). ☐
9. - .I have been so unhappy that I have been crying.	Yes, most of the time (3). ☐ Yes, quite often (2). ☐ Only occasionally (1). ☐ No, never (0). ☐
10. - .The thought of harming myself has occurred to me.	Yes, quite often (3). ☐ Sometimes (2). ☐ Hardly ever (1). ☐ Never (0). ☐
Following completion of this questionnaire, was the mother subsequently referred for further evaluation and/or management?	Yes ☐ No ☐
If no, why was this participant not referred?	_____
EPDS Score	_____

1 Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. British Journal of Psychiatry 150:782-786

2 Source: K. L. Wisner, B. L. Parry, C. M. Piontek, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

FOR INFANT ONLY:

If infant, has this participant enrolled in the study?
- Yes ☐
- No ☐

Date of infant enrollment: _____

If Infant, end of form.

FOR MOTHER ONLY:

Treatment arm
- DPV vaginal ring ☐
- Truvada oral tablet ☐

HIV Status
- Positive ☐
- Negative ☐

Pregnancy Status
- Positive ☐
- Negative ☐

Was the participant invited to participate in IDI?
- Yes ☐
- No ☐

Will this participant participate in IDI?
- Yes ☐
- No ☐

Geenius HIV-1/2 confirmatory test

Was Geenius HIV-1/2 confirmatory test collected for testing?
- Yes
- No

If "No", skip to "Was HIV RNA PCR testing completed?"

Geenius HIV-1/2 confirmatory test collection date _____

Geenius HIV-1/2 confirmatory test
- HIV negative
- HIV-1 indeterminate
- HIV-2 indeterminate
- HIV-1 positive
- HIV-2 positive
- HIV-2 positive with HIV-1 cross-reactivity
- HIV positive undifferentiated (untypeable)

HIV RNA PCR

Was HIV RNA PCR testing completed?
- Yes
- No

If "No", skip to "Were Absolute CD4+ collected for testing?"

HIV RNA PCR collection date _____

HIV RNA PCR
- Greater than
- Equal to
- Less than

HIV RNA PCR — Fixed Unit: viral copies/mL _____

OR

Target not detected ☐

HIV RNA PCR kit lower limit of detection

HIV RNA PCR kit
- Abbott M2000
- Roche TaqMan
- Gene Xpert

HIV RNA PCR kit lower limit of detection — Fixed Unit: viral copies/mL
- 20
- 40

OR

HIV RNA PCR kit lower limit of detection — Fixed Unit: viral copies/mL _____

Absolute CD4+

Were Absolute CD4+ collected for testing?
- Yes
- No

If "No", skip to "Final HIV Status".

Absolute CD4+ collection date _____

Absolute CD4+	Fixed Unit: cells/mm^3
OR	
Unable to analyze	☐
CD4 %	
CD4 % not available	☐
OR	
CD4 %	Fixed Unit: %
Final HIV status	
Final HIV status	HIV uninfected HIV infected pending
Plasma	
Was plasma for confirmatory testing collected?	Yes No
If "Yes" please fill out Specimen Storage form.	
Plasma for HIV confirmatory testing collection date	

HIV RNA PCR

Was HIV RNA PCR testing completed? Yes ◯ No ◯

If "No", skip to "Was HIV DNA PCR testing completed?"

HIV RNA PCR collection date _____

HIV RNA PCR Greater than ◯ Equal to ◯ Less than ◯

HIV RNA PCR Fixed Unit: viral copies/mL _____

OR

Target not detected ☐

HIV RNA PCR kit lower limit of detection

HIV RNA PCR Kit Abbott M2000 ◯ Roche TaqMan ◯ Gene Xpert ◯

HIV RNA PCR Kit Fixed Unit: viral copies/mL

Lower limit of detection 20 ◯ 40 ◯

OR

HIV RNA PCR Kit Fixed Unit: viral copies/mL

Lower limit of detection _____

HIV DNA PCR

Was HIV DNA PCR testing completed? Yes ◯ No ◯

If "No", skip to "Final HIV status"

HIV DNA PCR collection date _____

HIV DNA PCR Positive/reactive ◯ Negative/non-reactive ◯ Equivocal/Indeterminate ◯

Were any additional tests besides RNA or DNA performed? Yes ◯ No ◯

If "Yes", specify _____

Final HIV status

Final HIV status HIV uninfected ◯ HIV infected ◯ pending ◯

If "Final HIV status" is "HIV infected", Plasma for storage is required. Please refer to the Infant Specimen Storage form for recording purposes.

Rapid HIV test 1

Was Rapid HIV test sample 1 collected for testing?
- Yes
- No

If "No", skip to Rapid HIV test 2.

Rapid HIV test 1 Kit
- Alere/Abbot HIV Combo/Ultra
- Oraquick ADVANCE HIV-1/2
- Uni-Gold Recombigen HIV-1/2
- Alere/Abbot Determine
- Other

If "Other", specify: _____

Rapid HIV test 1 collection date _____

Rapid HIV test 1
- Antibody positive
- Antigen positive
- Antibody and antigen positive
- Negative

Rapid HIV test 2

Was Rapid HIV test sample 2 collected for testing?
- Yes
- No

If "No", end of form.

Rapid HIV test 2 Kit
- Alere/Abbot HIV Combo/Ultra
- Oraquick ADVANCE HIV-1/2
- Uni-Gold Recombigen HIV-1/2
- Alere/Abbot Determine
- Other

If "Other", specify: _____

Rapid HIV test 2 collection date _____

Rapid HIV test 2
- Antibody positive
- Antigen positive
- Antibody and antigen positive
- Negative

If at least one Rapid HIV tests is positive, complete the HIV Confirmatory Test Result form.

Was an in-depth interview completed?	Yes ☐ No ☐
Date of completion	_____

Was the Ages and Stages Assessment completed? Yes ☐ No ☐

Date of completion _____

Communication total _____

Were any communication abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

Gross Motor total _____

Were any gross motor abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

Fine Motor total _____

Were any fine motor abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

Problem solving total _____

Were any problem solving abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

Personal-Social total _____

Were any personal-social abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

Were any other abnormalities observed? Yes ☐ No ☐

If "Yes", explain: _____

If no abnormalities observed, end of form.

Were any AEs related to these abnormalities reported at this visit? Yes ☐ No ☐

Adverse event _____

Tablet Bottle Return	
No tablet bottle(s) returned	☐
OR	
Date tablet bottle(s) returned by participant	_____
Number of tablet bottle(s) returned at this study visit	1 ☐ 2 ☐
Tablet Bottle Provision	
No tablet bottle(s) provided	☐
OR	
Date tablet bottle(s) provided	_____
Number of tablet bottle(s) provided	1 ☐ 2 ☐

Date when study product hold was initiated	_____
Visit when study product hold was initiated	V3.0 - Week 1 ☐ V4.0 - Week 2 ☐ V5.0 - Month 1 ☐ V6.0 - Month 2 ☐ Interim Visit ☐
If 'Interim visit' is chosen, provide interim visit code:	_____
Why is study product being held?	A reactive rapid HIV test ☐ Adverse Event ☐ Infant adverse event ☐ Participant unable/unwilling to comply with required study procedures, or o/w might be put at undue risk to their safety and well-being by continuing product use according to judgment of IoR/designee ☐ Other ☐
If "Infant adverse event", record infant adverse event number	_____
If "Other", specify:	_____
Adverse Event:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Date of last study product use:	_____
Was the participant instructed to resume study product use?	Yes ☐ No - hold continuing for another reason ☐
If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form.	No - early termination ☐ No - Hold continuing at scheduled PUEV ☐ No - permanently discontinued ☐
Date study product resumed	_____
Date study product hold continuing for another reason	_____

1. - Date of Assessment _____

2. - Did the participant attempt to insert a ring herself?
- Yes ☐
- No ☐

If Yes, go to Item 3.

2a. If “No”, please describe the reason.
- Participant refused to insert ring ☐
- Participant unable to insert ring ☐
- Other ☐

2b. If "Other", specify. _____

If the answer to item 2 is "No" end of form.

3. - Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the vaginal ring today in the clinic?
- Very difficult ☐
- Difficult ☐
- Easy ☐
- Very easy ☐
- N/A ☐

If "Easy" or "Very easy", go to item 5.

4. - Did the participant experience any of the following difficulties? (Mark Y/N for each)

a. - Required more than one attempt
- Yes ☐
- No ☐

b. - Physical discomfort while inserting the ring
- Yes ☐
- No ☐

c. - Reluctance to insert the ring herself
- Yes ☐
- No ☐

d. - Difficulty folding and gripping ring
- Yes ☐
- No ☐

e. - Difficulty inserting the ring far enough
- Yes ☐
- No ☐

f. - Unable to reach vagina
- Yes ☐
- No ☐

g. - Other
- Yes ☐
- No ☐

If "Other", specify: _____

5. - Did the participant require any help from the clinician to insert the vaginal ring?
- Yes, specify ☐
- Clinician inserted ☐
- Other ☐
- No ☐

If "Yes", specify: _____

6. - Did study staff verify that the ring was in place?
- Yes ☐

	No ☐ Not applicable ☐
If "No", specify:	
7. - If "Yes", upon verifying, was the ring correctly inserted by the participant?	Yes ☐ No ☐ Not applicable ☐
If "No", specify:	

Date of assessment	_____
RING PROVISION	
No ring provided	☐
OR	
Date ring provided	_____
If no rings were provided at this visit, skip to the RING RETURN section of this form.	
Number of rings provided	1 ◯ 2 ◯
Was a ring inserted at this visit?	Yes ◯ No ◯
Date of insertion	_____
Time of insertion	_____
If ring was not inserted, specify reason:	_____
RING RETURN	
Did the participant have a ring in place at the start of the visit?	Yes ◯ No ◯
Ring not returned	☐
If ring not returned, end of form.	
Date ring(s) returned	_____
Number of rings returned at this study visit	1 ◯ 2 ◯
Date returned ring #1 was provided to the participant	_____
Date of removal of ring #1	_____
Time of removal of ring #1	_____
Date returned ring #2 was provided to the participant	_____
Date of removal of ring #2	_____
Time of removal of ring #2	_____

T CELL SUBSETS

Were T Cell Subsets collected for testing? Yes ☐ No ☐

If "No", skip to "Were Absolute CD4+ collected for testing?"

T CELL SUBSETS collection date _____

Absolute CD4+

Were Absolute CD4+ collected for testing? Yes ☐ No ☐

If "No", skip to "Was HIV RNA PCR testing completed?"

Absolute CD4+ collection date _____

Absolute CD4+ Fixed Unit: cells/mm3 _____

OR

Unable to analyze ☐

CD4 %

CD4 % not available ☐

OR

CD4 % Fixed Unit: % _____

HIV RNA PCR

Was HIV RNA PCR testing completed? Yes ☐ No ☐

If "No", skip to "Was seroconverter plasma collected for storage?"

HIV RNA PCR collection date _____

HIV RNA PCR Greater than ☐ Equal to ☐ Less than ☐

HIV RNA PCR Fixed Unit: viral copies/mL _____

OR

Target not detected ☐

HIV RNA PCR kit lower limit of detection

HIV RNA PCR Kit Abbott M2000 ☐ Roche TaqMan ☐ Gene Xpert ☐

HIV RNA PCR Kit Lower limit of detection Fixed Unit: viral copies/mL 20 ☐ 40 ☐

OR

HIV RNA PCR Kit Lower limit of detection	Fixed Unit: viral copies/mL

Seroconverter Plasma Storage

Was seroconverter plasma collected for storage?	Yes ☐ No ☐
Seroconverter Plasma storage collection date	
Seroconverter Plasma storage	Stored ☐ Not Stored ☐
Seroconverter Plasma storage reason not stored	

Date of Completion	_____
.At any time during your study participation, have you experienced a negative change, event, or experience in your life related to your study participation?	Yes. ☐ No. ☐
If "Yes", complete a Social Impact Log form.	

Date reported to site	_____
Concisely describe social impact:	_____
Onset Date	_____
Reported at visit:	V3.0 - Week 1 ☐ V4.0 - Week 2 ☐ V5.0 - Month 1 ☐ V6.0 - Month 2 ☐ V7.0 - Month 3 (PUEV) ☐ V8.0 - 2 weeks after study product end ☐ Interim Visit ☐
If Interim visit, specify Interim visit code	_____
Social Impact	Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school ☐ Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work ☐ Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing ☐ Medical/Dental - Been refused medical or dental treatment, or treated negatively by a health care provider ☐ Personal Relationships - Had negative experiences with family (excluding partner) ☐ Personal Relationships - Had negative experiences with significant other, spouse, or sex partner ☐ Personal Relationships (Other) - Had negative experiences with friends, neighbors or other community members ☐ Travel/Immigration - Had problems obtaining formal permission to travel or enter another country, such as being denied a visa, or had a problem with immigration/naturalization ☐ Other - Had other problems not covered in the list above ☐
Did this involve physical harm to the participant?	Yes ☐

	No ☐
If "Yes", select Adverse Event #1	_____
If "Yes", select Adverse Event #2, if applicable	_____
If "Yes", select Adverse Event #3, if applicable	_____
Did this involve physical or other harm to participant's child(ren)?	Yes ☐ No ☐
If "Yes", was physical harm or other harm inflicted on the baby she is currently breastfeeding?	Yes ☐ No ☐
If "was physical harm or other harm inflicted on the baby she is currently breastfeeding?" is "Yes", record infant adverse event number.	_____
What impact did this situation have on the participant's quality of life?	Minimal disturbance ☐ Moderate disturbance; no significant impact ☐ Major disturbance with significant impact ☐
Describe what was done by staff and participant to address social impact	
Participant:	_____
Staff:	_____
Current status	Unresolved ☐ Unresolved at end of study ☐ Unable to resolve; no further action taken ☐ Resolved ☐
If either "Unable to resolve; no further action" or "Resolved" is marked:	
Closure date	_____

Was vaginal pH done? Yes ☐ No ☐

Date of collection _____

Vaginal pH _____

Was a vaginal wet prep sample collected? Yes ☐ No ☐

If no, skip to "Was a sample collected for Syphilis testing?"

Date of collection: _____

Homogenous vaginal discharge Positive ☐ Negative ☐ Not done ☐

Whiff test Positive ☐ Negative ☐ Not done ☐

Clue cells greater or equal to 20% Positive ☐ Negative ☐ Not done ☐

Trichomonas vaginalis Positive ☐ Negative ☐ Not done ☐

Buds and/or hyphae (yeast) Positive ☐ Negative ☐ Not done ☐

Was a sample collected for Syphilis testing? Yes ☐ No ☐

If no, skip to "Was a vaginal sample collected for NAAT for GC/CT/Trich testing?"

Date of collection _____

Syphilis screening test Non-reactive ☐ Reactive ☐ Not reported ☐

If Syphilis screening test is 'non-reactive', skip to "Was a sample collected for NAAT for GC/CT/Trich testing?"

Syphilis titer _____

Syphilis confirmatory test Positive ☐ Negative ☐ Indeterminate ☐ Not done ☐

Was a vaginal sample collected for NAAT for GC/CT/Trich testing? Yes ☐

	No ☐
If no, skip to "Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?"	
Date of collection	_____
N. gonorrhea	Positive ☐ Negative ☐ Not done ☐
C. trachomatis	Positive ☐ Negative ☐ Not done ☐
Trichomonas test	Positive ☐ Negative ☐ Not done ☐
Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Surface Antigen (HBsAG)	Positive ☐ Negative ☐

MTN043_Version 6.0_PROD_BK_18DEC2020: ALL
Form: Tablet Assessment
Generated On: 18 Dec 2020 22:06:21

1. - Date of Assessment _____

2. - Did the participant attempt to swallow a pill under direct observation at the clinic?
- Yes ☐
- No ☐

If "Yes", go to item 4.

2a. - If "No", specify reason:
- Participant refused to swallow pill ☐
- Participant unable to swallow pill ☐
- Other ☐

2b. - If "Other", specify. _____

3. - Explain the response for the reason provided why the participant's first pill dose was not directly observed at the clinic.

If "Did the participant attempt to swallow the first pill under direct observation at the clinic?" is "No", end of form. _____

4. - Based on your assessment and her feedback, how easy or difficult was it for the participant to swallow the pill today in the clinic?
- Very difficult ☐
- Difficult ☐
- Easy ☐
- Very easy ☐
- N/A ☐

If "Easy" or "Very easy", end of form.

5. - Did she find it difficult to swallow for any of the following reasons? (Mark Y/N for each)
- Yes ☐
- No ☐

a. Because of the size of the pill?

b. - Because of pain?
- Yes ☐
- No ☐

c. - Because it was making her gag?
- Yes ☐
- No ☐

d. - Other
- Yes ☐
- No ☐

If "Other", specify: _____

DIPSTICK URINALYSIS

Was a specimen collected for dipstick urinalysis?
- Yes ☐
- No ☐

If "No", skip to "Urine culture".

Specimen collection date _____

Leukocyte esterase (LE)
- Neg ☐
- Trace ☐
- Small + ☐
- Moderate ++ ☐
- Large +++ ☐
- Not done ☐

Nitrites
- Positive ☐
- Negative ☐
- Not done ☐

Protein
- Neg ☐
- Trace ☐
- 1+ ☐
- 2+ ☐
- 3+ ☐
- 4+ ☐

Protein severity grade
- Grade 1 - Mild ☐
- Grade 2 - Moderate ☐
- Grade 3 - Severe ☐
- Not gradable ☐

Protein adverse event _____

Not reportable as an adverse event ☐

Glucose
- Neg ☐
- Trace ☐
- 1+ ☐
- 2+ ☐
- 3+ ☐
- 4+ ☐

Glucose severity grade
- Grade 1 - Mild ☐
- Grade 2 - Moderate ☐
- Grade 3 - Severe ☐
- Not gradable ☐

Glucose adverse event _____

Not reportable as an adverse event ☐

URINE CULTURE

Was a specimen collected for urine culture? Yes ☐ No ☐

If "No", end of form.

Specimen collection date _____

Date reported _____

Since the last study visit (or in the past 30 days if completed at the Screening visit), has the participant put any of the following inside her vagina?

Water only	Yes ☐ No ☐
Water plus soap	Yes ☐ No ☐
Materials such as paper, cloth, cotton or wool	Yes ☐ No ☐
Materials such as ashes or powders	Yes ☐ No ☐
Fingers, to clean or insert something (other than the vaginal ring)	Yes ☐ No ☐
Other	Yes ☐ No ☐

If "Other", specify _____

Which product is participant currently assigned to use?

Completed by administrator

- DPV vaginal ring.
- Oral Truvada.
- Not currently using a product.

1. - .In general, how worried are you about the effect of [product] on your own health?

- Very worried.
- A little worried.
- Not worried at all.

2. - .In general, how worried are you about the effect of using [product] on your baby's health?

- Very worried.
- A little worried.
- Not worried at all.

3. - .Have you received breastfeeding or feeding-related advice or care from any of the following people?

Check all that apply

- a. - .The father of your baby
- b. - .If different than the father of your baby, your primary partner
- c. - .Your mother
- d. - .Another family member, specify
- e. - .A friend
- f. - .Your doctor or clinician
- g. - .Your baby's pediatrician
- h. - .Traditional birth attendant [insert local term]
- i. - .Other traditional healer [insert local term]
- j. - .A religious leader [insert local term]
- k - .Other, specify

.If another family member, specify _____

.If Other, specify _____

4. - .Besides yourself, who has the most influence on your decisions about feeding the baby?

- Your primary partner.
- If different than your primary partner, the father of your baby.
- Your mother.
- Another family member, specify.
- A friend.
- Your doctor or clinician.
- Your baby's pediatrician.
- Traditional birth attendant [insert local term].
- Other traditional healer [insert local term].
- A religious leader [insert local term].

Other, specify. ☐

a. - .If another family member, specify _____

b. - .If Other, specify _____

5. - .Now I will ask you whether important people in your life support your product use. Are the following people supportive, not supportive or don't know about your use of [product]?

a. - .Is your primary partner…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

b. - .If different than your primary partner, is the father of your baby…? (if they are the same, check "N/A")
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

c. - .Is your mother…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

d. - .Is your father…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

e. - .Is your clinician…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

f. - .Is your baby's pediatrician…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

g. - .Is your religious leader/priest…?
- Supportive. ☐
- Not supportive. ☐
- Doesn't know about product. ☐
- N/A. ☐

h. - .Is there another important person in your life?
- Yes. ☐
- No. ☐

.If yes, specify _____

.If yes, is this person…?
- Supportive. ☐

Not supportive. ☐
Doesn't know about product. ☐
N/A. ☐

6. - .I am now going to read you some statements about how often you receive support from people around you. By "support" I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.

a. - .I have good friends who support me
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

b. - .My family is there for me
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

c. - .My primary partner helps me

If "N/A (no primary partner)" skip to item 7.
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐
- N/A (no primary partner). ☐

d. - .There is conflict with my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

e. - .I feel controlled by my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

f. - .I feel loved by my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

.I am now going to ask you some questions regarding mental health. Please answer "Yes" or "No" to the following.

7. - .Has a doctor, nurse, or other professional ever talked with you about depression (or problems with emotions, nerves or mental health)?
Yes. ☐
No. ☐

If no, skip to item 9.

8. - .When did the health professional talk to you about depression (or problems with emotions, nerves or mental health)?
Check all that apply

a. - .During my recent pregnancy ☐
b. - .Since I have had my baby ☐
c. - .During a previous pregnancy ☐
d. - .When I was breastfeeding after a prior pregnancy ☐
e. - .When I was not pregnant ☐

9. - .Have you ever wanted help for depression (or problems with emotions, nerves or mental health) from a doctor, nurse, or other professional?
Yes. ☐
No. ☐

10. - .Has a doctor, nurse, or other professional told you that you had depression (or problems with emotions, nerves or mental health)?
Yes. ☐
No. ☐

If "No", end of form.

11. - .When did the health professional tell you that you had depression (or problems with emotions, nerves or mental health)?

Check all that apply

a. - .Since I have had my baby ☐
b. - .During a previous pregnancy ☐
c. - .When I was breastfeeding after a prior pregnancy ☐
d. - .When I was not pregnant ☐

12. - .Did you get counseling or any other treatment for your depression (or problems with emotions, nerves or mental health)?
Yes. ☐
No. ☐

Were infant vital signs done?	Yes ☐ No ☐
Date of Assessment	
Length	Fixed Unit: cm
Head circumference	Fixed Unit: cm
Weight	Fixed Unit: kg
Body Temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min
Rate of Respiration	Fixed Unit: breaths/min

What additional study procedures were completed at this visit?

- Behavioral Assessment - Follow Up ☐
- Behavioral Assessment - Month 3 Follow Up ☐
- Chemistry Panel ☐
- COVID-19 Behavioral Assessment ☐
- Edinburgh Postnatal Depression Scale ☐
- Feeding Assessment ☐
- Feeding Inventory ☐
- Hematology ☐
- HIV Confirmatory Results ☐
- HIV Test Results ☐
- IDI Tracking ☐
- Pelvic Exam ☐
- Physical Examination ☐
- Pregnancy Test Results ☐
- PrEP Provision and Returns ☐
- Ring Adherence ☐
- Ring Assessment ☐
- Ring Insertion and Removal ☐
- Seroconverter Results ☐
- Social Impacts ☐
- Specimen Storage ☐
- STI Test Results ☐
- Tablet Adherence ☐
- Tablet Assessment ☐
- Urine Test Results ☐
- Vaginal Practices ☐
- Vital Signs ☐

What additional study procedures were completed at this visit?

Infant HIV Confirmatory Results	☐
Infant Ages and Stages Assessment	☐
Infant Specimen Storage	☐
Infant Vital Signs	☐
Physical Examination	☐
Seroconverter Results	☐

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

At which visit was this AE first reported?
- V3.0 - Week 1
- V4.0 - Week 2
- V5.0 - Month 1
- V6.0 - Month 2
- V7.0 - Month 3 (PUEV)
- V8.0 - 2 weeks after study product end
- Interim Visit

If "Interim visit", specify Interim visit code _____

Is the AE still ongoing?
- Yes
- No

If "No", outcome date _____

Severity grade
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Grade 5 (Death)

Relationship to study product
- Related
- Not related

Record rationale or alternative etiology in Comments text field below.

If “related” to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?
- Drug (dapivirine)
- Device (ring)
- Cannot distinguish between drug-device components

Action taken with study product
- Dose not changed
- Dose reduced
- Dose increased
- Drug withdrawn
- Drug interrupted
- Not applicable

Other actions
Mark "None" or all that apply.
None ☐

Medication(s) ☐

Therapeutic procedure/surgery ☐

Diagnostic procedure ☐

Referral	☐
Other	☐
If "Other", specify (max. 200 characters):	_____
Status/outcome	Recovered/resolved ☐ Recovering/resolving ☐ Recovered/resolved with sequelae ☐ Not recovered/not resolved ☐ Fatal ☐ Severity/frequency increased ☐
Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.	Yes ☐ No ☐
Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Has or will this AE be reported as an EAE? If "Yes", provide EAE number below.	Yes ☐ No ☐
EAE number Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces).	_____
SAE/EAE onset date	_____
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐
Comments (max. 450 characters):	_____

Medication name _____

Indication _____

Date started _____

Date stopped

Or _____

Ongoing ☐

Dose _____

Dose units
- Grams ☐
- Micrograms ☐
- Milligrams ☐
- Milliliters ☐
- Capsules ☐
- Drops ☐
- Puffs ☐
- Sachets ☐
- Suppository ☐
- Tablets ☐
- Units ☐
- Unknown ☐
- Other ☐

If "Other", specify: _____

Frequency
- As needed ☐
- Daily ☐
- Twice per day ☐
- Three times per day ☐
- Four times per day ☐
- Once in the morning ☐
- Every hour ☐
- Once ☐
- Other ☐

If "Other", specify: _____

Route
- Oral ☐
- Intramuscular ☐
- Intravenous ☐
- Topical ☐
- Inhalation ☐
- Vaginal ☐
- Rectal ☐

	Subcutaneous ☐ Other ☐
If "Other", specify:	_____
If contraceptive, was it dispensed at research center?	Yes ☐ No ☐
Taken for a reported AE?	Yes ☐ No ☐
If "Yes", select Adverse Event #1	_____
If "Yes", select Adverse Event #2, if applicable	_____
If "Yes", select Adverse Event #3, if applicable	_____

1. - Date of birth _____

2. - Age Fixed Unit: Years _____

3. - Sex at birth
- Male ☐
- Female ☐

4. - Ethnic group or tribe:
- Acholi ☐
- Baganda ☐
- Bagisu ☐
- Bakiga ☐
- Banyankore ☐
- Banyaruanda ☐
- Banyoro ☐
- Basoga ☐
- Batoro ☐
- Chewa ☐
- Colored ☐
- Indian ☐
- Iteso ☐
- Karamojong ☐
- Lango ☐
- Lomwe ☐
- Lugbara ☐
- Ndebele ☐
- Shona ☐
- Sotho ☐
- Tumbuka ☐
- White ☐
- Xhosa ☐
- Yao ☐
- Zulu ☐
- Other African tribe ☐
- Other ☐

.If other, specify: _____

5. - .Do you have a primary partner? By this I mean a husband, boyfriend, or steady partner with whom you regularly have sex.
- Yes. ☐
- No. ☐

If "No", skip to item 10.

6. - .Does your primary partner know that you may enroll in this study?
- Yes. ☐

	No. ☐
7. - .Does your primary partner know you will be using an HIV prevention product?	Yes. ☐ No. ☐
8. - .Is your primary partner the father of the baby you are currently breastfeeding?	Yes. ☐ No. ☐ Don't know. ☐
9. - .Do you believe your primary partner has sexual partners other than you? (Read responses)	Yes, I know. ☐ Yes, I suspect. ☐ No. ☐ Don't know. ☐
10. - .How many sex partners have you had in your lifetime?	_____
11. - .Since you started breastfeeding this baby how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	Never. ☐ Monthly or less. ☐ 2 - 4 times a month/1 time per week. ☐ 2 - 3 times a week. ☐ 4 or more times a week. ☐
12. - .Since you started breastfeeding this baby how many sex partners have you had in total? Please include ALL male sex partners with whom you had vaginal, anal or oral sex. If "0", skip to item 14.	_____
13. - .We are interested in different kinds of sexual activity during breastfeeding. While breastfeeding this baby have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus.	Yes. ☐ No. ☐
14. - .In the last 12 months, did you have a sexual relationship with a man mainly in order to get money, gifts, or other things that are important for yourself or your family?	Yes. ☐ No. ☐
15. - .What methods have you ever used to prevent HIV? Mark all that apply.	
.Male condom	☐
.Female condom	☐
.Oral PrEP	☐
.Vaginal ring, specify	☐
.Other, specify	☐
.None	☐
.If "Vaginal ring", specify which study:	_____
.If "Other", specify	_____
16. - .How satisfied were you with this method for preventing HIV?	
.Male condom	Very satisfied. ☐

	Satisfied. ☐
	Neutral. ☐
	Dissatisfied. ☐
	Very dissatisfied. ☐
	N/A. ☐
.Female condom	Very satisfied. ☐
	Satisfied. ☐
	Neutral. ☐
	Dissatisfied. ☐
	Very dissatisfied. ☐
	N/A. ☐
.Oral PrEP	Very satisfied. ☐
	Satisfied. ☐
	Neutral. ☐
	Dissatisfied. ☐
	Very dissatisfied. ☐
	N/A. ☐
.Vaginal ring	Very satisfied. ☐
	Satisfied. ☐
	Neutral. ☐
	Dissatisfied. ☐
	Very dissatisfied. ☐
	N/A. ☐
.Other (specified above)	Very satisfied. ☐
	Satisfied. ☐
	Neutral. ☐
	Dissatisfied. ☐
	Very dissatisfied. ☐
	N/A. ☐

.I am now going to ask you some questions about alcohol use and smoking since you started breastfeeding. For these questions, please think of the period of time since you started breastfeeding this baby.

17. - .Since you started breastfeeding, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.	Monthly or less. ☐
	2-4 times a month. ☐
	2-3 times a week. ☐
	4 or more times a week. ☐
If "Never", skip to item 20.	Participant declined to answer. ☐
	Never. ☐

18. - .How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2. ☐ 3 or 4. ☐ 5 or 6. ☐ 7 to 9. ☐ 10 or more. ☐ Participant declined to answer. ☐
19. - .How often do you have six or more drinks on one occasion?	Never. ☐ Less than monthly. ☐ Monthly. ☐ Weekly. ☐ Daily or almost daily. ☐ Participant declined to answer. ☐
20. - .How many cigarettes do you smoke per day?	_____

Date of birth _____

Age _____ Fixed Unit: days

Sex at birth
- Male ☐
- Female ☐

Ethnic group or tribe:
- Acholi ☐
- Baganda ☐
- Bagisu ☐
- Bakiga ☐
- Banyankore ☐
- Banyaruanda ☐
- Banyoro ☐
- Basoga ☐
- Batoro ☐
- Chewa ☐
- Colored ☐
- Indian ☐
- Iteso ☐
- Karamojong ☐
- Lango ☐
- Lomwe ☐
- Lugbara ☐
- Ndebele ☐
- Shona ☐
- Sotho ☐
- Tumbuka ☐
- White ☐
- Xhosa ☐
- Yao ☐
- Zulu ☐
- Other African tribe ☐
- Other ☐

If other, specify: _____

Informed consent date	_____
Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐

Lab Name: _____

HEMOGRAM

Was a hematology sample collected? Yes ☐ No ☐

Hematology collection date _____

Hemoglobin _____

Hemoglobin severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

Hemoglobin adverse event, if applicable _____

Not reportable as an adverse event ☐

Hematocrit _____

MCV _____

Platelets _____

Platelets severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

Platelets adverse event, if applicable _____

Not reportable as an adverse event ☐

WBC _____

WBC severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

WBC adverse event, if applicable _____

Not reportable as an adverse event ☐

DIFFERENTIAL

Was a differential done? Yes ☐ No ☐

Differential collection date _____

Neutrophils _____

Neutrophils severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐

	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Not gradable ☐
Neutrophils adverse event, if applicable	
Not reportable as an adverse event	☐
Lymphocytes	
Lymphocytes severity grade	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Not gradable ☐
Lymphocytes adverse event, if applicable	
Not reportable as an adverse event	☐
Monocytes	
Eosinophils	
Basophils	

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐
If eligible, but participant did not enroll, specify reason:	_____
Was the participant enrolled into MTN-043?	Yes ☐ No ☐
If "Eligible and enrolled", or “Incomplete screening”, end of form.	
Select reason(s) why participant is ineligible.	I1. Age 18 years or older at Screening, as verified per site Standard Operating Procedures (SOPs). ☐ I2. At Enrollment, between 6 to 12 weeks postpartum (verified by birth records and/or similar supportive documentation and defined as between 42 – 84 days after delivery, inclusive). ☐ I3. By participant report at Screening and Enrollment, currently exclusively breastfeeding one infant and willing and able to continue exclusively breastfeeding that infant for the duration of their participation in the study. ☐ I4. Consistently using an effective method of contraception per participant report at Enrollment, and intending to continue use of an effective method for the duration of study participation. Effective methods include contraceptive implants, intrauterine device, injectable progestin, oral contraceptive pills, and surgical sterilization. ☐ I5. Able and willing to comply with all study requirements and complete all study procedures. ☐ I6a. Written informed consent to be screened for and to take part in the study. ☐ I6b. Written informed consent for the breastfed infant to be screened for and take part in the study. ☐

I7. Intention to stay within study catchment area for study duration and willingness to give adequate locator information, as defined in site SOPs. ☐

I8. At Screening and Enrollment, HIV-uninfected based on HIV testing performed by study staff (per algorithm in Appendix III). ☐

I9. At Screening and Enrollment, willing to be randomized at time of enrollment to either of the study products, and to continue study product use for at least 12 weeks. ☐

E1. At Screening or Enrollment, breastfeeding infant ineligible for enrollment in the study. ☐

E2a. Known adverse reaction to any of the study products (ever). ☐

E2b. Known adverse reaction to latex and polyurethane (ever). ☐

E2c. Post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to Enrollment. ☐

E2d. Use of vaginal medications(s) or other vaginal products within five days prior to Enrollment. ☐

E2e. Non-therapeutic injection drug use in the 12 months prior to Enrollment. ☐

E2f. History of exposure to any investigational drug(s) during pregnancy, including participation in MTN-042. ☐

E3. At Screening or Enrollment, has a positive HIV test. ☐

E4. At Screening or Enrollment, Grade 2 or higher breast or genitourinary findings. ☐

E5. At Screening or Enrollment, has a positive urinary pregnancy test. ☐

E6a. Positive for hepatitis B surface antigen (HBsAg). ☐

E6b. Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) $\geq$ Grade 2. ☐

E6c. Creatinine $\geq$ Grade 1. ☐

E6d. Estimated creatinine clearance $\geq$ Grade 2 (Cockcroft Gault formula). ☐

E7. Diagnosed with urinary tract infection (UTI), pelvic inflammatory disease (PID), STI or reproductive tract infection (RTI), requiring treatment per WHO Guidelines. ☐

	E8. As determined by the IoR/designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease. ☐
	E9. Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives. ☐
	E10a. Participation in any research study involving drugs, vaccines, or medical devices 30days or less prior to enrollment. ☐
	E10b. Currently participating in other research studies involving drugs, vaccines, or medical devices. ☐
	E10c. Expected to participate in other research studies involving drugs, vaccines, or medical devices during study participation. ☐
If "E9. Has a condition that, per IoR/designee…" (Investigator decision) , specify (max. 200 characters):	_____

Was a pregnancy test done?	Yes ☐ No ☐
Collection date	_____
Collection time	_____
Pregnancy test result	Positive ☐ Negative ☐

Date medical history collected	_____
Description of medical history condition/event	_____
Is condition/event gradable?	Yes ☐ No ☐
Severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Start date of medical history condition/event	_____
Is the condition ongoing?	Yes ☐ No ☐
Date medical history/condition ended/resolved	_____

Was a physical exam performed? Yes ☐ No ☐

Date of exam _____

For each organ system or body part evaluated, indicate whether the finding(s) were normal or abnormal. If abnormal, describe the finding(s) in the text field provided. If an organ system or body part is not evaluated, select “Not Done".

HEENT Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neck Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lymph Nodes Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Heart/Cardiovascular Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lung/Respiratory Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Abdomen Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Extremities Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neurological Not done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Skin
- Not done ☐
- Normal ☐
- Abnormal ☐

If "Abnormal", specify: _____

General appearance
- Not done ☐
- Normal ☐
- Abnormal ☐

If "Abnormal", specify: _____

Other system finding
- Not done ☐
- Normal ☐
- Abnormal ☐

If "Other system finding", specify: _____

If "Abnormal", specify: _____

Answer the following question for mothers only

Breasts
- Not done ☐
- Normal ☐
- Abnormal ☐

If "Abnormal", specify: _____

Were vital signs done?	Yes ☐ No ☐
Date of assessment	_____
Height (only complete at Visit 1.0 - Screening)	Fixed Unit: cm _____
Weight	Fixed Unit: kg _____
Body temperature	Fixed Unit: C _____
Systolic blood pressure	Fixed Unit: mmHg _____
Diastolic blood pressure	Fixed Unit: mmHg _____
Blood pressure severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Blood pressure adverse event, if applicable	_____
Not reportable as an adverse event	☐
Pulse	Fixed Unit: beats/min _____
Rate of respiration	Fixed Unit: breaths/min _____

Date that study product use ended	_____
Visit that the study product use ended	V3.0 - Week 1 ☐ V4.0 - Week 2 ☐ V5.0 - Month 1 ☐ V6.0 - Month 2 ☐ V7.0 - Month 3 (PUEV) ☐ V8.0 - 2 weeks after study product end ☐ Interim Visit ☐
If "Interim Visit", specify Interim Visit code	_____
Primary reason for ending study product use	Scheduled study product use period completed ☐ Death ☐ Participant refused further participation ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Infant adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ Acquisition of hepatitis B infection (for Truvada group only). ☐ Allergic reaction to the study product. ☐ Reported use of PrEP for HIV prevention outside of the study ☐ Reported use of PEP for potential HIV exposure ☐ Non-therapeutic injection drug use ☐ Pregnancy ☐ Other ☐
If "Infant adverse event", record infant adverse event number	_____
If "Adverse event", select applicable adverse event.	_____
If "Other", specify:	_____

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Infant adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ Other, specify ☐
If Withdrawal of Consent by Participant, Investigator Decision, or Other, specify (max. 200 characters):	
If "Death", enter date of death.	
If "Adverse event" or "Death", select applicable adverse event.	

Date pregnancy history collected	_____
Number of full term live births (>=37 weeks)	_____
Number of premature live births (Less than 37 weeks)	_____
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	_____
Number of spontaneous abortions (Less than 20 weeks)	_____
Number of therapeutic/elective abortions	_____
Number of ectopic pregnancies	_____
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____

Date pregnancy reported to site	_____
Visit at which this pregnancy was reported	V3.0 - Week 1 ☐ V4.0 - Week 2 ☐ V5.0 - Month 1 ☐ V6.0 - Month 2 ☐ V7.0 - Month 3 (PUEV) ☐ V8.0 - 2 weeks after study product end ☐ Interim Visit ☐
If "Interim visit", specify Interim visit code.	_____
Date of onset of last menstrual period	_____
Or	
Amenorrhoeic for past 6 months	☐
Estimated date of delivery	_____
What primary information was used to estimate the date of delivery?	Last menstrual period ☐ Initial ultrasound <20 weeks ☐ Initial ultrasound >= 20 weeks ☐ Physical examination ☐ Conception date by assisted reproduction ☐ Other ☐
If "Other", specify:	_____
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete Pregnancy History form.	

Lab Name: _____

Was a sample collected for serum chemistries? Yes ☐ No ☐

Specimen collection date _____

LIVER FUNCTION TESTS

AST (SGOT) result _____

AST (SGOT) severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

AST (SGOT) adverse event _____

Not reportable as an adverse event ☐

ALT (SGPT) result _____

ALT (SGPT) severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

ALT (SGPT) adverse event _____

Not reportable as an adverse event ☐

RENAL FUNCTION TESTS

Creatinine result _____

Creatinine severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

Creatinine adverse event _____

Not reportable as an adverse event ☐

Creatinine Clearance result _____

Creatinine Clearance severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Not gradable ☐

Creatinine Clearance adverse event _____

Not reportable as an adverse event	☐

Site awareness date	
Deviation date	
Has or will this deviation be reported to local IRB/EC?	Yes ☐ No ☐
Has or will this deviation be reported to DAIDS as a critical event?	Yes ☐ No ☐
Type of deviation	Inappropriate enrollment ☐ Failure to follow randomization or blinding procedures ☐ Study product management deviation ☐ Study product dispensing error ☐ Study product use/non-use deviation ☐ Study product sharing ☐ Study product not returned ☐ Conduct of non-protocol procedure ☐ Improper AE/EAE ☐ Unreported AE ☐ Unreported EAE ☐ Breach of confidentiality ☐ Physical assessment deviation ☐ Lab assessment deviation ☐ Mishandled lab specimen ☐ Staff performing duties that they are not qualified to perform ☐ Questionnaire administration deviation ☐ Counseling deviation ☐ Use of non-IRB/EC-approved materials ☐ Use of excluded concomitant mediations, devices, or non-study products ☐ Informed consent process deviation ☐ Visit completed outside of window ☐ Other ☐
Description of deviation	
Plans and/or action taken to address the deviation	
Plans and/or action taken to prevent future occurrences of the deviation	
Deviation reported by	

Pelvic exam assessment	Not done ☐ No abnormal findings ☐ Abnormal findings ☐
Exam date	_____
If "Abnormal findings", select all that apply:	
VULVAR	
Vulvar edema	☐
Vulvar erythema	☐
Vulvar rash	☐
Vulvar tenderness	☐
Bartholin's or Skene's gland abnormality	☐
Vulvar ulcer	☐
Vulvar blister	☐
Vulvar pustule	☐
Vulvar peeling	☐
Vulvar ecchymosis	☐
VAGINAL	
Vaginal edema	☐
Vaginal erythema	☐
Vaginal masses (polyps, myomas, possible malignancy)	☐
Vaginal abrasions or lacerations	☐
Vaginal tenderness	☐
Vaginal ulcer	☐
Vaginal blister	☐
Vaginal pustule	☐
Vaginal peeling	☐
Vaginal ecchymosis	☐
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	☐
Cervical ulcer	☐
Cervical blister	☐
Cervical pustule	☐
Cervical peeling	☐
Cervical ecchymosis	☐
GENERAL/OTHER	
Odor (vaginal)	☐
Condyloma	☐
If "Condyloma", specify location:	_____
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	☐
Uterine masses (based on bimanual exam)	☐
Uterine tenderness	☐
Adnexal tenderness	☐
Abnormal blood or bleeding	☐
If "Abnormal blood or bleeding", specify:	_____
Other abnormal findings	☐
If "Other abnormal findings", specify:	_____
If "Other abnormal findings", specify anatomical location:	_____
Complete or update Baseline Medical Conditions Log or Adverse Event Log, as applicable.	
Were any new pelvic finding AEs reported at this visit?	Yes ○ No ○
If yes, please add AE(s)	
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____

Specimen type	Plasma for DPV drug levels ■ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ☐ Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ☐ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐

Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ■ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ☐ Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ☐ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐

	Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐
Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ■ Gram Stain of vaginal smear ☐ Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ☐ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐
Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ■ Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ☐ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐

	Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐
Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ☐ Vaginal Swab for biomarkers ■ Vaginal Swabs for microbiota ☐ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐
Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ☐

	Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ■ Plasma for archive ☐ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐ Both ☐
Specimen type	Plasma for DPV drug levels ☐ Dried blood spot for TFV-DP and FTC-TP drug level ☐ Breastmilk for drug concentration ☐ Gram Stain of vaginal smear ☐ Vaginal Swab for biomarkers ☐ Vaginal Swabs for microbiota ☐ Plasma for archive ■ Used vaginal ring #1 ☐ Used vaginal ring #2 ☐ Plasma for HIV Confirmatory Testing ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression ☐ Breast Pump ☐

Both

Specimen type

Plasma for DPV drug levels
Dried blood spot for TFV-DP and FTC-TP drug level
Breastmilk for drug concentration
Gram Stain of vaginal smear
Vaginal Swab for biomarkers
Vaginal Swabs for microbiota
Plasma for archive
Used vaginal ring #1
Used vaginal ring #2
Plasma for HIV Confirmatory Testing

Was specimen collected?

Yes
No

Specimen collection date

Was sample stored?

Stored
Not stored

If "No", record reason why sample was not stored (max. 200 characters).

If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?

Hand Expression
Breast Pump
Both

Specimen type

Plasma for DPV drug levels
Dried blood spot for TFV-DP and FTC-TP drug level
Breastmilk for drug concentration
Gram Stain of vaginal smear
Vaginal Swab for biomarkers
Vaginal Swabs for microbiota
Plasma for archive
Used vaginal ring #1
Used vaginal ring #2
Plasma for HIV Confirmatory Testing

Was specimen collected?

Yes
No

Specimen collection date

Was sample stored?	Stored Not stored
If "No", record reason why sample was not stored (max. 200 characters).	
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression Breast Pump Both
Specimen type	Plasma for DPV drug levels Dried blood spot for TFV-DP and FTC-TP drug level Breastmilk for drug concentration Gram Stain of vaginal smear Vaginal Swab for biomarkers Vaginal Swabs for microbiota Plasma for archive Used vaginal ring #1 Used vaginal ring #2 Plasma for HIV Confirmatory Testing
Was specimen collected?	Yes No
Specimen collection date	
Was sample stored?	Stored Not stored
If "No", record reason why sample was not stored (max. 200 characters).	
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	Hand Expression Breast Pump Both

Specimen type	Plasma for DPV drug levels ■ Dried Blood Spot for TFV-DP and FTC-TP drug levels ☐ Plasma for storage ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____

Specimen type	Plasma for DPV drug levels ☐ Dried Blood Spot for TFV-DP and FTC-TP drug levels ■ Plasma for storage ☐
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____

Specimen type	Plasma for DPV drug levels ☐ Dried Blood Spot for TFV-DP and FTC-TP drug levels ☐ Plasma for storage ■
Was specimen collected?	Yes ☐ No ☐
Specimen collection date	_____
Was sample stored?	Stored ☐ Not stored ☐
If "No", record reason why sample was not stored (max. 200 characters).	_____

Is the outcome of this pregnancy obtainable?

- Yes
- No

If "No", end of form.

How many pregnancy outcomes resulted from this reported pregnancy? _____

Outcome date _____

Place of delivery/outcome

- Home
- Hospital
- Clinic
- Unknown
- Other

If "Other", specify: _____

Specify outcome

- Full term live birth (greater than or equal to 37 weeks)
- Premature live birth (less than 37 weeks)
- Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)
- Spontaneous abortion (less than 20 weeks)
- Ectopic pregnancy
- Therapeutic/elective abortion
- Other

If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Method".

If "Other", specify: _____

Method

- Cesarean delivery
- Vaginal delivery - normal, unassisted
- Vaginal delivery - assisted (forceps, vacuum)
- Other

If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?"

Provide a brief narrative of the circumstances (max. 400 characters). _____

Were there any complications related to the pregnancy outcome?

- Yes
- No

If "No", skip to "Were any fetal/infant congenital anomalies identified?".

Delivery-related complications. Mark “None” or all that apply.

- ☐ None
- ☐ Intrapartum hemorrhage
- ☐ Postpartum hemorrhage

Non-reassuring fetal status	☐
Chorioamnionitis	☐
Other	☐
If "Other", specify:	_____
Non-delivery related complications. Mark “None” or all that apply.	☐
None	
Hypertensive disorders of pregnancy	☐
Gestational diabetes	☐
Other	☐
If "Other", specify:	_____
Were any fetal/infant congenital anomalies identified? Mark all that apply.	Yes ☐ No ☐ Not assessed ☐ Unknown ☐
If "No" or "Unknown", go to "Complete the infant items below for live birth only."	
Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Muscoloskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐
Chromosomal	☐
Cranio-facial (structural)	☐
Hematologic	☐
Infectious	☐
Endocrine/metabolic	☐
Other	☐
Describe congenital anomaly/defect (max. 200 characters).	_____

If "Yes", specify congenital anomaly/defect AE.

If Yes, complete AE Log and EAE Reporting form.

Complete the infant items below for live births only. Otherwise, end of form.

Infant sex — Male ☐ Female ☐

Infant birth weight — Fixed Unit: kg

Or

Infant birth weight unavailable ☐

Infant birth length — Fixed Unit: cm

Or

Infant birth length unavailable ☐

Infant birth head circumference — Fixed Unit: cm

Or

Infant birth head circumference unavailable ☐

Infant birth abdominal circumference — Fixed Unit: cm

Or

Infant birth abdominal circumference unavailable ☐

Infant gestational age by examination in weeks — Fixed Unit: Weeks

Infant gestational age by examination in days — Fixed Unit: Days

Or

Infant gestational age by examination unavailable ☐

If unavailable, end of form.

Method used to determine gestational age — Ballard ☐

Dubowitz ☐
Other ☐

If “Other”, specify (max. 200 characters): _____

Target visit date	_____
Reason visit was missed	Unable to contact participant ☐ Participant unable to schedule visit within window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to healthcare facility ☐ Participant withdrew from study ☐ Participant deceased ☐ Other ☐
If "Other", specify:	_____
Steps taken to address the missed visit (corrective action plan)	_____

Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization date and time	_____

Is this participant a mother or an infant?	Mother ☐ Infant ☐
If this participant is a mother, what is the infant's PTID?	_____
If "Mother", end of form.	
What is the mother's PTID?	_____
To which treatment arm was the mother assigned?	DPV vaginal ring ☐ Truvada oral tablet ☐

Date of assessment _____

1. - .Since your last visit, how comfortable have you been wearing the vaginal ring every day?
   - Usually/mostly comfortable. ☐
   - Sometimes uncomfortable. ☐
   - Usually/mostly uncomfortable. ☐

2. - .Since your last visit, how often have you had the vaginal ring out (of your vagina), even for just a minute?
   - Never. ☐
   - Rarely. ☐
   - Often. ☐

If "Never", end of form.

3. - .Since your last visit, how often was the vaginal ring removed for sex?
   - Never. ☐
   - Rarely. ☐
   - Often. ☐
   - N/A: I did not have sex (in the past 30 days). ☐

4. - .Since your last visit, how often was the vaginal ring out (of your vagina) for more than 12 hours in a row?
   - Never. ☐
   - Rarely. ☐
   - Often. ☐

5. - .What are the reason(s) why the vaginal ring(s) were removed?

Do not read response options out loud. Check all of the reasons that apply.

- .Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms ☐
- .Ring falling out: Ring was partially falling out ☐
- .Ring placement: Didn't feel the ring was correctly placed ☐
- .Ring presence: Wanted to look at the ring or see if the ring was still in place ☐
- .Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting ☐
- .Cleaned ring: Removed ring to clean it ☐
- .Cleaned vagina: Removed ring to clean vagina ☐
- .Felt sick: Felt sick/had non-genital side effects from the ring ☐
- .Emotional worries: Had emotional worries about the ring ☐
- .Partner ring knowledge: Did not want husband or primary sex partner to know about ring ☐
- .Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring ☐
- .Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring ☐
- .Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring ☐
- .Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place ☐

.Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex	☐
.Partner felt ring during sex: The sex partner feeling the ring during sex	☐
.Showed ring: Removed ring to show it to someone	☐
.Not having sex: Participant was not having sex so she decided to remove/stop using the ring	☐
.Interfered with sexual pleasure: The ring interfered with her sexual pleasure	☐
.Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure	☐
.Disliked ring: Removed ring because did not like the ring	☐
.Partner disliked ring: Removed ring because partner did not like the ring	☐
.Participant wanted to get pregnant	☐
.Partner wanted her to get pregnant	☐
.Product hold: Participant placed on product hold	☐
.Product permanently discontinued: Participant permanently discontinued from product	☐
.Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was not conducted at a regularly scheduled study visit	☐
.Delay in insertion of new ring: Ring removed between study visits and there was a delay in new ring insertion	☐
.Missed visit: Participant removed ring due to missed scheduled visit	☐
.Other	☐
.If "Other", specify:	_____

6. - .Did the ring come out on its own?

Yes ◯
No ◯

If No, end of form.

7. - .If yes, what are the reason(s) why the vaginal ring came out on its own?

Do not read response options aloud.

.Urination: During urination	Yes ◯ No ◯
.Bowel movement: Having a bowel movement	Yes ◯ No ◯
.Sex: Having sex or just finished sex	Yes ◯ No ◯
.Physical activity: Physical activity (other than sex), including lifting heavy objects	Yes ◯ No ◯

.Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)	Yes ☐ No ☐
.Menses related	Yes ☐ No ☐
.Other	Yes ☐ No ☐
.If Other, specify	_____

.Date of assessment _____

1. - .Since your last visit, how comfortable have you been taking a pill every day?
   - Usually/mostly comfortable. ☐
   - Sometimes uncomfortable. ☐
   - Usually/mostly uncomfortable. ☐

2. - .On average, how many times per week did you take the pill? _____

3. - .Since your last visit, how often have you skipped using the pills?
   - Never. ☐
   - Rarely. ☐
   - Often. ☐

If "Never", end of form.

4. - .What are the reason(s) why you skipped using the pills?

Do not read response options out loud. Check all of the reasons that apply.

- .Didn't have the pills with her ☐
- .Felt sick/was concerned about getting sick from the pills ☐
- .Ran out of or lost the pills ☐
- .Got tired of taking the pills every day ☐
- .Gave/sold/traded the tablets to someone else ☐
- .Had a change in her daily routine ☐
- .Forgot or was too busy ☐
- .Did not have sex/was not intending to have sex ☐
- .Had difficulty swallowing the pills ☐
- .Didn't like the pills/taste of the pills ☐
- .Someone else took/stole some of her pills ☐
- .Primary sex partner did not approve of her taking the pills ☐
- .Family member or friend did not approve of her taking the pills ☐
- .Other ☐
- .If "Other", specify: _____

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐
If eligible, but participant did not enroll, specify reason:	_____
Was the participant enrolled into MTN-043?	Yes ☐ No ☐
If "Eligible and enrolled", or "Incomplete screening", end of form.	
Select reason(s) why participant is ineligible.	I1. At Screening and Enrollment, infant is exclusively breastfed. ☐ I2. At Screening and Enrollment, the infant is generally healthy, according to the judgment of the IoR/designee. ☐ I3. At Enrollment, the infant is between the ages of 6 and 12 weeks postpartum (verified by birth records and/or similar supportive documentation with age defined as between 42 - 84 days after delivery, inclusive). ☐ E1. Has any condition that, in the opinion of the IoR/designee, would preclude eligibility, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives. ☐ E2a. Infants with birth weight less than 2000g. ☐ E2b. Participation in any research study involving drugs, vaccines, or medical devices since birth. ☐ E2c. Currently participating in other research studies involving drugs, vaccines, or medical devices. ☐ E2d. Expected to participate in other research studies involving drugs, vaccines, or medical devices for the duration of study participation. ☐
If "E1. Has a condition that, per IoR/designee…" (Investigator decision) , specify (max. 200 characters):	_____

Which product is participant currently assigned to use? Completed by administrator	DPV vaginal ring. ☐ Oral Truvada. ☐ Not currently using a product. ☐

1. - .Let's talk about your current comfort wearing the vaginal ring every day/ taking a pill every day….

a. - .Does it cause emotional discomfort? By this we mean the product causes you to feel unpleasant feelings like sadness or anger.	A little bit. ☐ A lot. ☐ Not at all. ☐
b. - .Does it cause physical discomfort? (if yes, complete AE if needed) By this we mean the product makes your body feel uncomfortable.	A little bit. ☐ A lot. ☐ Not at all. ☐
c. - .Does it cause sexual discomfort? (if yes, complete AE if needed)	A little bit. ☐ A lot. ☐ Not at all. ☐
d. - .Does it cause social discomfort? By this we mean discomfort or worry related to the reactions of people around you.	A little bit. ☐ A lot. ☐ Not at all. ☐
e. - .Does it cause any other issue?	Yes. ☐ No. ☐
.If yes, specify:	_____

If using the Truvada pill, skip to item 4.

2. - .How easy or difficult is it for you to insert the vaginal ring?	Very difficult. ☐ Difficult. ☐ Easy. ☐ Very easy. ☐ N/A: I didn't use the vaginal ring. ☐
3. - .How easy or difficult is it for you to remove the vaginal ring?	Very difficult. ☐ Difficult. ☐ Easy. ☐ Very easy. ☐ N/A: I didn't remove the vaginal ring. ☐

If using the vaginal ring, skip to item 7.

4. - .How easy or difficult is it for you to remember to take the pill?	Very difficult. ☐ Difficult. ☐ Easy. ☐ Very easy. ☐ N/A: I didn't use the pill. ☐

5. - .How easy or difficult is it for you to swallow the pill?
- Very difficult. ☐
- Difficult. ☐
- Easy. ☐
- Very easy. ☐
- N/A: I didn't use the pill. ☐

6. - .In the last 30 days, how often did you experience nausea or gagging after swallowing the pill?
- Never. ☐
- Rarely. ☐
- Often. ☐

7. - .In the last 30 days, how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.
- Never. ☐
- Monthly or less. ☐
- 2 - 4 times a month/1 time per week. ☐
- 2 - 3 times a week. ☐
- 4 or more times a week. ☐

8. - .In the last 30 days, have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus.
- Yes. ☐
- No. ☐

If "No", skip to item 10.

9. - .During the last act of anal sex that you had, was a male condom used?
- Yes. ☐
- No. ☐

10. - .In the last 30 days, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.
- Monthly or less. ☐
- 2-4 times a month. ☐
- 2-3 times a week. ☐
- 4 or more times a week. ☐
- Participant declined to answer. ☐
- Never. ☐

If "Never", skip to item 13.

11. - .How many drinks containing alcohol do you have on a typical day when you are drinking?
- 1 or 2. ☐
- 3 or 4. ☐
- 5 or 6. ☐
- 7 to 9. ☐
- 10 or more. ☐
- Participant declined to answer. ☐

12. - .How often do you have six or more drinks on one occasion?
- Never. ☐
- Less than monthly. ☐
- Monthly. ☐
- Weekly. ☐
- Daily or almost daily. ☐

Participant declined to answer. ☐

13. - .I am now going to read you some statements about how often you receive support from people around you. By “support” I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.

a. - .I have good friends who support me
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

b. - .My family is always there for me
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

c. - .My primary partner helps me

If "N/A (no primary partner)" skip to item 14.
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐
- N/A (no primary partner). ☐

d. - .There is conflict with my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

e. - .I feel controlled by my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

f. - .I feel loved by my primary partner
- Always. ☐
- Most of the time. ☐
- Some of the time. ☐
- Rarely. ☐
- Never. ☐

14. - .I am now going to ask you some questions regarding mental health. Please answer "Yes" or "No" to the following.

a. - .At any time since your last visit, has a doctor, nurse, or other professional talked with you about depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐
b. - .Since your last visit, has a doctor, nurse, or other health care worker told you that you had depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐
c. - .Did you get counseling or any other treatment for your depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐

Which product is participant currently assigned to use? Completed by administrator.	DPV vaginal ring. ☐ Oral Truvada. ☐ Not currently using a product. ☐

If the participant is using the vaginal ring skip to item 2.

1. - .Overall, how much do you like using the pill?	Dislike very much. ☐ Dislike. ☐ Neither like nor dislike. ☐ Like. ☐ Like very much. ☐
2. - .Overall, how much do you like using the vaginal ring?	Dislike very much. ☐ Dislike. ☐ Neither like nor dislike. ☐ Like. ☐ Like very much. ☐
3. - .Overall, how satisfied have you been with this method for preventing HIV?	Very satisfied. ☐ Satisfied. ☐ Neutral. ☐ Dissatisfied. ☐ Very dissatisfied. ☐

4. - .Let's talk about your current comfort wearing the vaginal ring every day/ taking a pill every day…

a. - .Does it cause emotional discomfort? By this we mean the product causes you to feel unpleasant feelings like sadness or anger.	A little bit. ☐ A lot. ☐ Not at all. ☐
b. - .Does it cause physical discomfort? (if yes, complete AE if needed) By this we mean the product makes your body feel uncomfortable.	A little bit. ☐ A lot. ☐ Not at all. ☐
c. - .Does it cause sexual discomfort? (if yes, complete AE if needed)	A little bit. ☐ A lot. ☐ Not at all. ☐
d. - .Does it cause social discomfort? By this we mean discomfort or worry related to the reactions of people around you.	A little bit. ☐ A lot. ☐ Not at all. ☐
e. - .Does it cause any other issue?	Yes. ☐ No. ☐
.If "Does it cause any other issue?" is yes, specify:	_____

5. - .Would you be willing to use [product] for HIV prevention when breastfeeding in the future?
- Yes. ☐
- No. ☐
- Not sure. ☐

6. - .Which method would you prefer to use for HIV prevention if breastfeeding?
- Vaginal ring. ☐
- Oral PrEP. ☐
- Male condom. ☐
- Other. ☐
- None of the above. ☐

.If other, specify: _____

6. - .If the vaginal ring or oral PrEP were available to you, which product would you prefer to use for HIV prevention?
- Vaginal ring. ☐
- Oral PrEP. ☐
- Either – I find either product acceptable. ☐
- Neither – I find neither product acceptable. ☐

7. - .If the [study product] were available to you, would you prefer to use [study product] or male condoms for HIV prevention?
- [study product]. ☐
- Male condoms. ☐
- Either – I find either product acceptable. ☐
- Neither – I find neither product acceptable. ☐

8. - .When you're not breastfeeding, would you be willing to use [product] for HIV prevention?
- Yes. ☐
- No. ☐
- Not sure. ☐

8. - .Which method would you prefer to use for HIV prevention when you are not breastfeeding?
- Vaginal ring. ☐
- Oral PrEP. ☐
- Male condom. ☐
- Other. ☐
- None of the above. ☐

. If 'Other', specify: _____

9. - .In general, how worried are you about the effect of [product] on your own health?
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

10. - .Some women may have worries about the effect of [product] on their own health or wellbeing. Are you worried [product] could…?

a. - .Cause infections or cancer?
- Yes. ☐
- No. ☐

b. - .Make you gain weight?
- Yes. ☐
- No. ☐

c. - .Affect your future fertility?
- Yes. ☐

	No. ☐
d. - .Result in people thinking you are HIV positive?	Yes. ☐ No. ☐
e. - .Impact the amount of milk you produce?	Yes. ☐ No. ☐
f. - .Impact the taste or thickness of your milk?	Yes. ☐ No. ☐
g. - .Delay the healing process from delivery?	Yes. ☐ No. ☐
h. - .Anything else related to [product]?	Yes. ☐ No. ☐
.If yes, please specify	_____
11. - .In general, how worried are you about the effect of using [product] on your baby's health?	Very worried. ☐ A little worried. ☐ Not worried at all. ☐
12. - .Some women may have worries about the effect of [product] on their baby's health. Are you worried [product] could…?	
a. - .Cause problems with your baby's physical growth?	Yes. ☐ No. ☐
b. - .Impact your baby's desire to breastfeed?	Yes. ☐ No. ☐
c. - .Cause problems with your baby's mental development?	Yes. ☐ No. ☐
d. - .Cause your baby to have other health problems later in life?	Yes. ☐ No. ☐
e. - .Cause you additional stress which could affect your baby's health?	Yes. ☐ No. ☐
f. - .Anything else related to [assigned product]?	Yes. ☐ No. ☐
.If yes, please specify:	_____
If using the pill, skip to 16.	
13. - .How easy or difficult is it for you to insert the vaginal ring?	Very difficult. ☐ Difficult. ☐ Easy. ☐ Very easy. ☐ N/A: I didn't use the vaginal ring. ☐

14. - .How easy or difficult is it for you to remove the vaginal ring?
- Very difficult. ☐
- Difficult. ☐
- Easy. ☐
- Very easy. ☐
- N/A: I didn't remove the vaginal ring. ☐

15. - .Did you mind wearing the vaginal ring…

a. - .After delivering your baby?
- Yes. ☐
- No. ☐
- N/A. ☐

b. - .During sex?
- Yes. ☐
- No. ☐
- N/A. ☐

c. - .When not sexually active?
- Yes. ☐
- No. ☐
- N/A. ☐

d. - .During menses?
- Yes. ☐
- No. ☐
- N/A. ☐

e. - .During daily activities?
- Yes. ☐
- No. ☐
- N/A. ☐

.If using the vaginal ring, skip to question 20.

16. - .Did you mind swallowing the pills daily…

a. - .While balancing other responsibilities with your baby?
- Yes. ☐
- No. ☐
- N/A. ☐

b. - .On days when you did not have sex?
- Yes. ☐
- No. ☐
- N/A. ☐

17. - .How easy or difficult is it for you to remember to take the pill?
- Very difficult. ☐
- Difficult. ☐
- Easy. ☐
- Very easy. ☐
- N/A: I didn't use the pill. ☐

18. - .How easy or difficult is it for you to swallow the pill?
- Very difficult. ☐
- Difficult. ☐

Easy. ◯
Very easy. ◯
N/A: I didn't use the pill. ◯

19. - .In the last 30 days, how often did you experience nausea or gagging after swallowing the pill?

Never. ◯
Rarely. ◯
Often. ◯

20. - .Have you received breastfeeding or feeding-related advice or care from any of the following people?

Check all that apply.

a. - .The father of your baby ☐
b. - .If different than the father of your baby, your primary partner ☐
c. - .Your mother ☐
d. - .Another family member (specify) ☐
e. - .A friend ☐
f. - .Your doctor or clinician ☐
g. - .Your baby's pediatrician ☐
h. - .Traditional birth attendant [insert local term] ☐
i. - .Other traditional healer [insert local term] ☐
j. - .A religious leader [insert local term] ☐
k. - .Other, specify ☐

.If another family member, specify _____
.If Other, specify _____

21. - .Besides yourself, who has the most influence on your decisions about feeding the baby?

Your primary partner. ◯
If different than your primary partner, the father of your baby. ◯
Your mother. ◯
Another family member, specify. ◯
A friend. ◯
Your doctor or clinician. ◯
Your baby's pediatrician. ◯
Traditional birth attendant [insert local term]. ◯
Other traditional healer [insert local term]. ◯
A religious leader [insert local term]. ◯
Other, specify. ◯

.If another family member, specify _____
.If Other, specify _____

22. - .Now I will ask you whether important people in your life support your product use. Are the following people supportive, not supportive or don't know about your use of [product]?

a. - .Is your primary partner…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
b. - .If different than your primary partner, is the father of your baby…? (if they are the same, tick N/A)?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
c. - .Is your mother…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
d. - .Is your father…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
e. - .Is your clinician…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
f. - .Is your baby's pediatrician…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
g. - .Is your religious leader/priest…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐
h. - .Is there another important person in your life?	Yes. ☐ No. ☐
.If yes, specify who	_____
.If yes, is this person…?	Supportive. ☐ Not supportive. ☐ Doesn't know about product. ☐ N/A. ☐

23. - .In the last 30 days how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.

- Never.
- Monthly or less.
- 2 - 4 times a month/1 time per week.
- 2 - 3 times a week.
- 4 or more times a week.

24. - .How many male sex partners have you had since joining the study, in total? Please include ALL male sex partners with whom you had vaginal, anal or oral sex.

_____

25. - .In the last 30 days, have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus.

- Yes.
- No.

If "No", skip to 27.

26. - .During the last act of anal sex that you had, was a male condom used?

- Yes.
- No.

27. - .In the last 30 days, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.

- Monthly or less.
- 2-4 times a month.
- 2-3 times a week.
- 4 or more times a week.
- Participant declined to answer.
- Never.

If "Never", skip to 30.

28. - .How many drinks containing alcohol do you have on a typical day when you are drinking?

- 1 or 2.
- 3 or 4.
- 5 or 6.
- 7 to 9.
- 10 or more.
- Participant declined to answer.

29. - .How often do you have six or more drinks on one occasion?

- Never.
- Less than monthly.
- Monthly.
- Weekly.
- Daily or almost daily.
- Participant declined to answer.

30. - .I am now going to read you some statements about how often you receive support from people around you. By “support” I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.

a. - .I have good friends who support me

- Always.
- Most of the time.
- Some of the time.
- Rarely.

	Never. ☐
b. - .My family is always there for me	Always. ☐ Most of the time. ☐ Some of the time. ☐ Rarely. ☐ Never. ☐
c. - .My husband/primary partner helps me a lot If "N/A (no primary partner)" skip to item 31.	Always. ☐ Most of the time. ☐ Some of the time. ☐ Rarely. ☐ Never. ☐ N/A (no primary partner). ☐
d. - .There is conflict with my husband/primary partner	Always. ☐ Most of the time. ☐ Some of the time. ☐ Rarely. ☐ Never. ☐
e. - .I feel controlled by my husband/primary partner	Always. ☐ Most of the time. ☐ Some of the time. ☐ Rarely. ☐ Never. ☐
f. - .I feel loved by my husband/primary partner	Always. ☐ Most of the time. ☐ Some of the time. ☐ Rarely. ☐ Never. ☐

31. - .I am now going to ask you some questions regarding mental health. Please answer "Yes" or "No" to the following.

a. - .At any time since your last visit, has a doctor, nurse, or other professional talked with you about depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐
b. - .Since your last visit, has a doctor, nurse, or other health care worker told you that you had depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐
c. - .Did you get counseling or any other treatment for your depression (or problems with emotions, nerves or mental health)?	Yes. ☐ No. ☐

32. - .Would any of the following keep you from asking for help with depression (or problems with emotions, nerves or mental health) if you thought you needed it?

a. - .Being embarrassed to talk about personal matters with others	Yes. ☐ No. ☐
b. - .Being afraid of what others might think	Yes. ☐ No. ☐
c. - .Family members might not approve	Yes. ☐ No. ☐
d. - .Cost of transport	Yes. ☐ No. ☐
e. - .Had no time	Yes. ☐ No. ☐
f. - .Other	Yes. ☐ No. ☐
.If 'Other', specify	_____

33. - .We are interested in learning more about women's wellbeing in their relationships. Some of the questions are sensitive. If anyone interrupts us, I will change the topic of conversation.

Remember that all your answers will be kept confidential, and that you do not have to answer any questions that you do not want to. May I continue?

The next questions are about your relationship with your primary sex partner or any other partners. Thinking about the period of time from when you first joined this study until now,
Has your primary sex partner or ANY other current or previous partner:

a. - .Insulted, ignored or humiliated you, yelled at you, or made you feel ashamed or bad about yourself?	Yes. ☐ No. ☐
b. - .Made you feel afraid, unsafe or in danger?	Yes. ☐ No. ☐
c. - .Slapped you, hit you with a fist or something else, or beaten you?	Yes. ☐ No. ☐
d. - .Kicked, dragged, pushed, pulled your hair, choked or burnt you?	Yes. ☐ No. ☐
34. - .Since joining this study, has your primary sex partner or ANY other current or previous partner ever forced you to have sex by holding you down or hurting you?	Yes. ☐ No. ☐
35. - .Since joining this study, has anyone else (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you?	Yes. ☐ No. ☐

1. - .In the past seven days, what has your baby been fed...? (select all the apply)

a. - .Breastmilk	☐
b. - .Formula	☐
c. - .Solid foods (porridge, cereal, mushed fruits and vegetables, soup, etc.)	☐
d. - .Water	☐
e. - .Other	☐
.If "Other", specify	_____

2. - .In how many months will you introduce solid foods, baby formula, water, or other foods into your baby's diet?

- 1 month or less. ☐
- 2 months. ☐
- 3 months. ☐
- 4 months. ☐
- 5 months. ☐
- 6 months or more. ☐
- Not sure. ☐

3. - .How many times per day do you breastfeed (or provide breast milk to) your baby? _____

Was a Feeding Assessment completed at this visit?	Yes. ☐ No. ☐

If "No", end of form.

1. - .What have you fed your baby since your last visit?	Breastmilk only. ☐ Other. ☐

Do not read response options out loud.

.If "Other", has your baby completely weaned from breast milk? (Defined as at least one week without breast milk and no intention of restarting)	Yes. ☐ No. ☐
2. - .Since your last visit, how many times per day on average were you breastfeeding (or providing breast milk to) your baby?	_____
3. - .In the last 24 hours, how many times did you breastfeed (or provide your breast milk to) your baby?	_____
.Date infant last received breast milk:	_____

.Since last visit, which of the following has the baby been fed?	Formula. ☐ Solid foods. ☐ Water. ☐ Juice. ☐ Other. ☐
.If "Other", specify (max. 200 characters).	_____
.Date infant first received since last visit:	_____
.On average, since your last visit, how often does baby receive?	Once. ☐ 1-2 times/week. ☐ 3-4 times/week. ☐ 5-6 times/week. ☐ Daily. ☐ 2-3 times/day. ☐ 4 or more times/day. ☐
.Main reason for introduction:	Mother questioned whether quantity of breast milk was sufficient for infant. ☐ Other person questioned whether quantity of breast milk was sufficient for infant. ☐ Mother returned to work/was separated from infant for some other reason. ☐ Questioned breast milk quality or nutritional content (including whether extra hydration necessary). ☐ Infant sick. ☐ Mother sick. ☐ Mother no longer wants to breastfeed. ☐ Infant no longer wants to breastfeed. ☐ Felt infant was developmentally ready. ☐ Other. ☐
.If "Other", specify (max. 200 characters).	_____
.Did any of the following people advise or encourage introducing this to the baby?	Mother's doctor. ☐ Baby's doctor. ☐ Partner and/or father of the baby. ☐ Family member. ☐ Friend. ☐ Traditional healer. ☐ Other. ☐
.If "Other", specify (max. 200 characters).	_____

1 - Date of assessment _____

.(Read at Enrollment only)

As you may know, there is an outbreak of respiratory disease caused by the novel coronavirus. The disease is called COVID-19. There are millions of confirmed cases and many deaths related to COVID-19, including here in [add country & COVID-19 relevant info (I.e., lockdown started in X month)].

2 - .How many people do you know personally who are (or have been) infected with COVID-19?

Please include both suspected and confirmed infections, do not count yourself, and give your best estimate if you do not know the exact number.

If completing at follow-up, only count those people who have been infected since you joined the study. _____

3 - .Were you infected (or suspected to be infected) with COVID-19? (If completing at follow-up, indicate if you've been infected since you joined the study)

(Do not read response options)

- Yes, tested and the result was positive. ☐
- Yes, suspected but not confirmed by a test. ☐
- No, tested and the result was negative. ☐
- No. ☐
- Not sure. ☐

4 - .Did you ever self-isolate or quarantine to prevent yourself from getting or transmitting COVID-19?

- Yes. ☐
- No. ☐

5 - .Now I'm going to ask you about some worries you might currently have. Please indicate how worried or concerned you are about the following things:

a - .Having enough food to eat
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

b - .Having a job
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

c - .Having money to cover basic expenses
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

d - .Getting the coronavirus (COVID-19)
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

e - .Getting HIV
- Very worried. ☐
- A little worried. ☐
- Not worried at all. ☐

6 - .Which of these concerns worries you the most? (pick one)	Having enough food to eat. ☐ Having a job. ☐ Having money to cover basic expenses. ☐ Getting the coronavirus (COVID-19). ☐ Getting HIV. ☐
7 - .Between getting COVID-19 and getting HIV, which is more concerning to you right now?	Getting COVID-19. ☐ Getting HIV. ☐ Both equally. ☐ Neither concerns me. ☐
8 - .How has COVID-19 influenced your interest in preventing HIV?	Decreased. ☐ Increased. ☐ No influence. ☐
9 - .How has COVID-19 influenced your interest in using [pills/ring]?	Decreased. ☐ Increased. ☐ No influence. ☐

.If Enrollment, skip to item 11.

10 - .Did you experience any of the following situations because of COVID-19 and the plans used to manage the outbreak?

(Read response options, select Yes or No as appropriate)

a - .Less privacy than usual	Yes. ☐ No. ☐
b - .Less access to clean water than usual	Yes. ☐ No. ☐
c - .Less access to toilet facilities than usual	Yes. ☐ No. ☐
d - .Being unable to conceal study product use from others	Yes. ☐ No. ☐
e - .Being unable to use your study product as directed	Yes. ☐ No. ☐
f - .Forgetting to use your study product	Yes. ☐ No. ☐
11 - .Do you think other people would judge you or treat you badly if you had COVID-19?	Yes. ☐ No. ☐

If Visit 7 - PUEV - Month 3, end of form

12 - .I'm going to ask you about several different aspects of your life that might have changed because of COVID-19 (and the plans used to manage it). For each one, please tell me if the following has decreased, increased, or not changed because of COVID-19.

a - .Your level of anxiety (nervous or on edge; not being able to stop or control worrying)	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
b - .Your feelings of depression (hopeless, little interest in doing things, feeling constantly sad)	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
c - .Your feeling of connection to family	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
d - .Your feeling of connection to friends	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
e - .How often you have sex	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
f - .Your access to condoms	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
g - .How often you use condoms when you have sex	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
h - .Violence in your household	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
i - .Your access to money for necessary items	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
j - .How much food you eat	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐

	Has not changed. ☐
k - .Your access to health care	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
l - .Your alcohol consumption	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
m - .Your feeling of connection to your primary partner If "N/A: No primary partner", skip to item 13.	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed/no different because of COVID-19. ☐ N/A: No primary partner. ☐ N/A: Don't know. ☐
n - .Your partner's alcohol consumption	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed/no different because of COVID-19. ☐ Don't know. ☐
13 - .Were you given any specific information about COVID-19 and pregnancy?	Yes. ☐ No. ☐
14 - .Were you given any specific information about COVID-19 and breastfeeding?	Yes. ☐ No. ☐
b - .Has this information impacted your feeding decisions at all?	Yes. ☐ No. ☐
15 - .We are curious to hear about how the coronavirus impacted you and your baby, if at all. Since the coronavirus pandemic started, please consider how you or your baby may have been impacted.	
a - .How much have you thought your life is (was) in danger because of the COVID-19 pandemic?	Not at all. ☐ Somewhat. ☐ Very much. ☐
b - .How much have you thought your baby's life was in danger because of the COVID-19 pandemic?	Not at all. ☐ Somewhat. ☐ Very much. ☐
c - .How much have you worried that exposure to COVID-19 would harm your baby?	Not at all. ☐ Somewhat. ☐ Very much. ☐

d - .How concerned have you been that you or your baby are not receiving the clinical care that you need?	Not at all. ☐ Somewhat. ☐ Very much. ☐
e - .How did the quality of your prenatal care change because of the COVID-19 pandemic?	Improved. ☐ Worsened. ☐ No change. ☐
f - .Did you deliver your baby somewhere other than a health facility because of COVID-19?	Yes. ☐ No. ☐
.If "Yes", specify	_____