

Subject Case Report Forms

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023 - ALL

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

1. - Did the participant complete this visit? Yes

No

1a. - Visit Date \_\_\_\_\_

1b. - Weight \_\_\_\_\_

Fixed Unit: kg

OR not done

1d. - Systolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1e. - Diastolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1f. - Pulse \_\_\_\_\_

Fixed Unit: beats/min

1g. - Did the participant complete the CASI questionnaire for this visit? Yes

No

2. - Did the participant have any additional procedures at this visit? Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

3. - Did the participant exit/terminate the study at this visit? Yes

No

4. - Is the participant moving to a different visit schedule? Yes

No

4a. - If yes, please indicate which schedule.

Pregnancy visit schedule

Yearly visit schedule

1. - Did the participant complete this visit? Yes

No

1a. - Visit Date \_\_\_\_\_

1b. - Weight \_\_\_\_\_

Fixed Unit: kg

Or not done

1d. - Systolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1e. - Diastolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1f. - Pulse \_\_\_\_\_

Fixed Unit: beats/min

1g. - Did the participant complete the CASI questionnaire for this visit? Yes

No

2. - Did the participant have any additional procedures at this visit? Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

3. - Did the participant exit/terminate the study at this visit? Yes

No

4. - Is the participant moving to a new step or visit schedule? Yes

No

4a. - If yes, please indicate which step or visit schedule.

Pregnancy visit schedule

Seroconverter visit schedule

Step 3

Open label Truvada schedule

Yearly visit schedule

Week 5 Visit Only

5. - Date of participant's last dose of oral study product \_\_\_\_\_

6. - Time of participant's last dose of oral study product \_\_\_\_\_

1. - Did the participant complete this visit? Yes

No

1a. - Visit Date \_\_\_\_\_

1b. - Weight \_\_\_\_\_

Fixed Unit: kg

Or not done

1d. - Systolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1e. - Diastolic blood pressure \_\_\_\_\_

Fixed Unit: mmHg

1f. - Pulse \_\_\_\_\_

Fixed Unit: beats/min

1g. - Did the participant complete the CASI questionnaire for this visit? Yes

No

2. - Did the participant have any additional procedures at this visit? Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

3. - Did the participant exit/terminate the study at this visit? Yes

No

4. - Is the participant moving to a seroconverter visit schedule? Yes

No

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1. - Did the participant complete this visit? Yes   
No

---

1a. - Visit Date \_\_\_\_\_

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2. - Did the participant have any additional procedures at this visit? Yes   
No

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If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

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3. - Did the participant exit/terminate the study at this visit? Yes   
No

---

1. - Did the participant complete this visit? Yes

No

1a. - Visit Date \_\_\_\_\_

1b. - Weight \_\_\_\_\_

OR not done

1d. - Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

1e. - Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

1f. - Pulse \_\_\_\_\_ Fixed Unit: beats/min

1g. - Did the participant complete the CASI questionnaire for this visit? Yes

No

2. - Did the participant have any additional procedures at this visit? Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

3. - Did the participant exit/terminate the study at this visit? Yes

No

4. - Is the participant moving to a different step or visit schedule? Yes

No

4a. - If yes, please indicate which step or visit schedule. Seroconverter visit schedule

Back to Step 2

5. - Was the participant referred for an ultrasound at this visit? Yes

No

Please assign a sequential number to this sub-study pregnancy. Pregnancy 1

Only the pregnancies during the sub-study should be counted. Pregnancy 2

Pregnancy 3

Pregnancy 4

Pregnancy 5

Did the participant complete this visit? Yes

No

Visit Date

Weight

Fixed Unit: kg

OR Not Done

Systolic blood pressure Fixed Unit: mmHg

Diastolic blood pressure Fixed Unit: mmHg

Pulse Fixed Unit: beats/min

Did the participant change the OLE regimen at this visit? Yes

No

If yes, select the new OLE regimen

CAB LA

TDF/FTC

None

What is current OLE regimen at this visit

CAB LA

TDF/FTC

None

How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?

0

1

2

3

4

5

6

Did the participant complete the CASI questionnaire for this visit? Yes

No

If yes, when was the CASI survey done?

Before pregnancy testing (or not pregnant)

After pregnancy confirmed

Both

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Date of Visit - Pregnancy OLE**  
**Generated On: 19 Jan 2023 01:09:25**

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Did the participant have any additional procedures at this visit? Yes   
No

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If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

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Did the product get held/discontinued at this visit? Product Hold   
Product Discontinued   
No

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

---

Is the participant moving to a different step or visit schedule? Yes   
No

---

If yes, please indicate which step or visit schedule

Oral CAB (Step 4a)   
Loading Dose (4-week interval)   
CAB-LA (Step 4b)   
TDF/FTC (Step 4c)   
TDF/FTC (Step 5)   
Pregnancy and Infant Sub-Study   
Step 6

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HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Date of Visit - Yearly Visit

Generated On: 19 Jan 2023 01:09:25

Did the participant complete a yearly visit? Yes

No

Weight

Fixed Unit: kg

OR Not Done

Visit Date

Visit Code

V50.0 - Yearly Visit 1

V51.0 - Yearly Visit 2

V52.0 - Yearly Visit 3

V53.0 - Yearly Visit 4

V54.0 - Yearly Visit 5

Did the participant have any additional procedures at this visit?

Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Did the participant exit/terminate the study at this visit?

Yes

No

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_  
Visit Code V201 - Open Label Truvada Day 0   
V202 - Open Label Truvada Week 12   
V203 - Open Label Truvada Week 24   
V204 - Open Label Truvada Week 36   
V205 - Open Label Truvada Week 48

Weight \_\_\_\_\_ Fixed Unit: kg

OR Not Done

Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Pulse \_\_\_\_\_ Fixed Unit: beats/min

Did the participant complete the CASI questionnaire for this visit? Yes   
No

Did the participant have any additional procedures at this visit? Yes   
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

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

Is the participant moving to a yearly visit schedule? Yes   
No

Is the participant moving to a seroconverter visit schedule? Yes   
No

Is the participant moving to the Pregnancy Schedule? Yes   
No

Is the participant moving Back to Step 2? Yes   
No

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Date of Visit - OLE

Generated On: 19 Jan 2023 01:09:25

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_  
Weight \_\_\_\_\_ Fixed Unit: kg

OR Not Done

Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Pulse \_\_\_\_\_ Fixed Unit: beats/min

How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?  
0   
1   
2   
3   
4   
5   
6

Did the participant complete the CASI questionnaire for this visit? Yes   
No

If yes, when was the CASI survey done? Before pregnancy testing (or not pregnant)   
After pregnancy confirmed   
Both

Did the participant have any additional procedures at this visit? Yes   
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Did the study product get held/discontinued at this visit? Product Hold   
Product Discontinued   
No

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

Is the participant moving to a new step or visit schedule? Yes   
No

If yes, please indicate which step or visit schedule. Oral CAB (Step 4a)   
Loading Dose (4-week interval)   
CAB-LA (Step 4b)

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Form: Date of Visit - OLE

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TDF/FTC (Step 4c)

TDF/FTC (Step 5)

Pregnancy and Infant Sub-Study

Step 6

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**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Additional Procedures Y/N**

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Did the participant have any additional procedures at this visit?

Yes

No

---

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

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**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Adverse Event Y/N**

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Has the participant experienced an Adverse Event during the study?

Yes

No

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If yes, complete the Adverse Event Log.

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**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Adverse Event - Infant Y/N**

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Has the infant experienced an Adverse Event during the study?

Yes

No

If yes, complete the Adverse Event - Infant Log.

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1. - Was a sample collected for urine tests? Yes   
No

2. - Date of collection: \_\_\_\_\_

3. - Protein (Urine) neg   
trace   
1+   
2+   
3+   
4+

4. - Protein (Urine) Severity Grade Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

5. - Protein (Urine) Adverse Event \_\_\_\_\_

6. - Glucose (Urine) neg   
trace   
1+   
2+   
3+   
4+

7. - Glucose (Urine) Severity Grade Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

8. - Glucose (Urine) Adverse Event \_\_\_\_\_

Lab Name: \_\_\_\_\_

1. - Were samples collected for chemistry testing? Yes   
No

2. - Date of Collection \_\_\_\_\_

3. - BUN \_\_\_\_\_

4. - Urea \_\_\_\_\_

5. - Creatinine \_\_\_\_\_

Creatinine Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

Creatinine Adverse Event \_\_\_\_\_

6. - Calculated Creatinine Clearance \_\_\_\_\_

Calculated Creatinine Clearance Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

Creatinine Clearance Adverse Event \_\_\_\_\_

7. - CPK \_\_\_\_\_

CPK Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

CPK Adverse Event \_\_\_\_\_

8. - Calcium \_\_\_\_\_

Calcium Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

Calcium Adverse Event \_\_\_\_\_

9. - Phosphorus (Phosphate) \_\_\_\_\_

Phosphorus (Phosphate) Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe

Lab Name: \_\_\_\_\_

- Grade 4 – Potentially life-threatening
- Not gradable

Phosphorus (Phosphate) Adverse Event

10. - Glucose

Glucose Severity Grade

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Not gradable

Glucose Adverse Event

11. - Amylase

Amylase Severity Grade

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Not gradable

Amylase Adverse Event

12. - Lipase

Lipase Severity Grade

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Not gradable

Lipase Adverse Event

13. - Albumin

Albumin Severity Grade

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Not gradable

Albumin Adverse Event

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Form: Counseling

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Did a counseling session occur at this visit? Yes   
No

Indicate which topic areas were covered during this session. Mark all that apply.

- |                                  |                          |
|----------------------------------|--------------------------|
| Adherence goal setting           | <input type="checkbox"/> |
| Adherence reminder strategies    | <input type="checkbox"/> |
| Barriers to adherence            | <input type="checkbox"/> |
| Communication skills             | <input type="checkbox"/> |
| Product Storage                  | <input type="checkbox"/> |
| Disclosing product use to others | <input type="checkbox"/> |
| Planning for future PrEP use     | <input type="checkbox"/> |
| Pill or injection education      | <input type="checkbox"/> |
| Problem solving                  | <input type="checkbox"/> |
| Social Support                   | <input type="checkbox"/> |
| Pregnancy and/or Contraception   | <input type="checkbox"/> |
| Other                            | <input type="checkbox"/> |

If other, please specify: \_\_\_\_\_

Indicate which adherence barriers/challenges were explored during this session. Mark all that apply or only "None could be identified".

- |   |                          |
|---|--------------------------|
| None could be identified  | <input type="checkbox"/> |
| Barriers to return for study visits (e.g., money, transportation, time) | <input type="checkbox"/> |
| Disruption in routine (for example, travel away from home)              | <input type="checkbox"/> |
| Forgetting/no pills available   | <input type="checkbox"/> |
| Job/School commitments  | <input type="checkbox"/> |
| Lack of privacy   | <input type="checkbox"/> |
| Medication side effects   | <input type="checkbox"/> |
| Negative reactions (family, friends, partner)                           | <input type="checkbox"/> |
| Partying/drugs/alcohol  | <input type="checkbox"/> |
| Side effects  | <input type="checkbox"/> |
| Other   | <input type="checkbox"/> |

If other, please specify: \_\_\_\_\_

1 - Visit

- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0

- V202 - Open Label Truvada   
Week 12
- V203 - Open Label Truvada   
Week 24
- V204 - Open Label Truvada   
Week 36
- V205 - Open Label Truvada   
Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 116 Pregnancy 1 - Week 192
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108

- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180
- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive

Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1

3b - Select from the drop-down list 2

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1

5b - If yes, select from the drop-down list 2

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1

6b - If yes, select from the drop-down list 2

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89

- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72

- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 116 Pregnancy 1 - Week 192
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180
- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144

- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

1 - Visit V2.0 - Day 0/Enrollment   
V3.0 - Step 1 Week 2

- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24

- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 116 Pregnancy 1 - Week 192
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132

- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180
- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1

3b - Select from the drop-down list 2

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1

5b - If yes, select from the drop-down list 2

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1

6b - If yes, select from the drop-down list 2

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113

- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108

- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 116 Pregnancy 1 - Week 192
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180
- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180

V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6

- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48

- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 116 Pregnancy 1 - Week 192
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168

- V 115 Pregnancy 2 - Week 180
- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

Form: Contraception

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3b - Select from the drop-down list 2  
If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1

5b - If yes, select from the drop-down list 2

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1

6b - If yes, select from the drop-down list 2

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137

- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144

- V 113 Pregnancy 1 - Week 156
  - V 114 Pregnancy 1 - Week 168
  - V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

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2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

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2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

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2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- 
- V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153
  - V29.0 - Step 2 Week 161
  - V30.0 - Step 2 Week 169
  - V31.0 - Step 2 Week 177
  - V32.0 - Step 2 Week 185
  - V33.0 - Step 3 Day 0
  - V34.0 - Step 3 Week 12
  - V35.0 - Step 3 Week 24
  - V36.0 - Step 3 Week 36
  - V37.0 - Step 3 Week 48
  - V201 - Open Label Truvada Day 0
  - V202 - Open Label Truvada Week 12
  - V203 - Open Label Truvada Week 24
  - V204 - Open Label Truvada Week 36
  - V205 - Open Label Truvada Week 48
  - V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

Generated On: 19 Jan 2023 01:09:25

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- 
- V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153
  - V29.0 - Step 2 Week 161
  - V30.0 - Step 2 Week 169
  - V31.0 - Step 2 Week 177
  - V32.0 - Step 2 Week 185
  - V33.0 - Step 3 Day 0
  - V34.0 - Step 3 Week 12
  - V35.0 - Step 3 Week 24
  - V36.0 - Step 3 Week 36
  - V37.0 - Step 3 Week 48
  - V201 - Open Label Truvada Day 0
  - V202 - Open Label Truvada Week 12
  - V203 - Open Label Truvada Week 24
  - V204 - Open Label Truvada Week 36
  - V205 - Open Label Truvada Week 48
  - V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

Generated On: 19 Jan 2023 01:09:25

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- 
- V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153
  - V29.0 - Step 2 Week 161
  - V30.0 - Step 2 Week 169
  - V31.0 - Step 2 Week 177
  - V32.0 - Step 2 Week 185
  - V33.0 - Step 3 Day 0
  - V34.0 - Step 3 Week 12
  - V35.0 - Step 3 Week 24
  - V36.0 - Step 3 Week 36
  - V37.0 - Step 3 Week 48
  - V201 - Open Label Truvada Day 0
  - V202 - Open Label Truvada Week 12
  - V203 - Open Label Truvada Week 24
  - V204 - Open Label Truvada Week 36
  - V205 - Open Label Truvada Week 48
  - V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

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2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
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Form: Contraception

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2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

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1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
- V 110 Pregnancy 2 - Week 120
- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

Generated On: 19 Jan 2023 01:09:25

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form.

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes  No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a  No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a  No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9

- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1

- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

---

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168
- V 115 Pregnancy 1 - Week 180
- V 101 Pregnancy 2 - Week 12
- V 102 Pregnancy 2 - Week 24
- V 103 Pregnancy 2 - Week 36
- V 104 Pregnancy 2 - Week 48
- V 105 Pregnancy 2 - Week 60
- V 106 Pregnancy 2 - Week 72
- V 107 Pregnancy 2 - Week 84
- V 108 Pregnancy 2 - Week 96
- V 109 Pregnancy 2 - Week 108
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- V 111 Pregnancy 2 - Week 132
- V 112 Pregnancy 2 - Week 144
- V 113 Pregnancy 2 - Week 156
- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180

- V 116 Pregnancy 2 - Week 192
- V 101 Pregnancy 3 - Week 12
- V 102 Pregnancy 3 - Week 24
- V 103 Pregnancy 3 - Week 36
- V 104 Pregnancy 3 - Week 48
- V 105 Pregnancy 3 - Week 60
- V 106 Pregnancy 3 - Week 72
- V 107 Pregnancy 3 - Week 84
- V 108 Pregnancy 3 - Week 96
- V 109 Pregnancy 3 - Week 108
- V 110 Pregnancy 3 - Week 120
- V 111 Pregnancy 3 - Week 132
- V 112 Pregnancy 3 - Week 144
- V 113 Pregnancy 3 - Week 156
- V 114 Pregnancy 3 - Week 168
- V 115 Pregnancy 3 - Week 180
- V 116 Pregnancy 3 - Week 192

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2  
If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

- 1 - Visit
- V2.0 - Day 0/Enrollment
  - V3.0 - Step 1 Week 2
  - V4.0 - Step 1 Week 4
  - V5.0 - Step 2 Week 5
  - V6.0 - Step 2 Week 6
  - V7.0 - Step 2 Week 9
  - V8.0 - Step 2 Week 13
  - V9.0 - Step 2 Week 17
  - V10.0 - Step 2 Week 21
  - V11.0 - Step 2 Week 25
  - V12.0 - Step 2 Week 33
  - V13.0 - Step 2 Week 41
  - V14.0 - Step 2 Week 42
  - V15.0 - Step 2 Week 49
  - V16.0 - Step 2 Week 57
  - V17.0 - Step 2 Week 65
  - V18.0 - Step 2 Week 73
  - V19.0 - Step 2 Week 81
  - V20.0 - Step 2 Week 89
  - V21.0 - Step 2 Week 97
  - V22.0 - Step 2 Week 105
  - V23.0 - Step 2 Week 113
  - V24.0 - Step 2 Week 121
  - V25.0 - Step 2 Week 129
  - V26.0 - Step 2 Week 137
  - V27.0 - Step 2 Week 145
  - V28.0 - Step 2 Week 153

- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5
- Interim visit
- Pregnancy visit

1a - If 'Interim visit', provide interim visit code

1b - If 'Pregnancy visit', select visit code

- V 101 Pregnancy 1 - Week 12
- V 102 Pregnancy 1 - Week 24
- V 103 Pregnancy 1 - Week 36
- V 104 Pregnancy 1 - Week 48
- V 105 Pregnancy 1 - Week 60
- V 106 Pregnancy 1 - Week 72
- V 107 Pregnancy 1 - Week 84
- V 108 Pregnancy 1 - Week 96
- V 109 Pregnancy 1 - Week 108
- V 110 Pregnancy 1 - Week 120
- V 111 Pregnancy 1 - Week 132
- V 112 Pregnancy 1 - Week 144
- V 113 Pregnancy 1 - Week 156
- V 114 Pregnancy 1 - Week 168

- V 115 Pregnancy 1 - Week 180
  - V 116 Pregnancy 1 - Week 192
  - V 101 Pregnancy 2 - Week 12
  - V 102 Pregnancy 2 - Week 24
  - V 103 Pregnancy 2 - Week 36
  - V 104 Pregnancy 2 - Week 48
  - V 105 Pregnancy 2 - Week 60
  - V 106 Pregnancy 2 - Week 72
  - V 107 Pregnancy 2 - Week 84
  - V 108 Pregnancy 2 - Week 96
  - V 109 Pregnancy 2 - Week 108
  - V 110 Pregnancy 2 - Week 120
  - V 111 Pregnancy 2 - Week 132
  - V 112 Pregnancy 2 - Week 144
  - V 113 Pregnancy 2 - Week 156
  - V 114 Pregnancy 2 - Week 168
  - V 115 Pregnancy 2 - Week 180
  - V 116 Pregnancy 2 - Week 192
  - V 101 Pregnancy 3 - Week 12
  - V 102 Pregnancy 3 - Week 24
  - V 103 Pregnancy 3 - Week 36
  - V 104 Pregnancy 3 - Week 48
  - V 105 Pregnancy 3 - Week 60
  - V 106 Pregnancy 3 - Week 72
  - V 107 Pregnancy 3 - Week 84
  - V 108 Pregnancy 3 - Week 96
  - V 109 Pregnancy 3 - Week 108
  - V 110 Pregnancy 3 - Week 120
  - V 111 Pregnancy 3 - Week 132
  - V 112 Pregnancy 3 - Week 144
  - V 113 Pregnancy 3 - Week 156
  - V 114 Pregnancy 3 - Week 168
  - V 115 Pregnancy 3 - Week 180
  - V 116 Pregnancy 3 - Week 192
-

Form: Contraception

Generated On: 19 Jan 2023 01:09:25

2 - What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- None
- Oral Contraceptive pill
- Intrauterine Device (IUD)
- Injectable
- Contraceptive Patch
- Contraceptive Vaginal Ring
- Implant
- Other Contraceptive
- Sterilization (Tubal ligation / hysterectomy)

If Sterilization at Enrollment visit, end of form. If not, go to Question 4.

3 - If Enrollment visit, select Concomitant Medication Log line.

3a Select from the drop-down list 1 \_\_\_\_\_

3b - Select from the drop-down list 2 \_\_\_\_\_

If Enrollment visit, End of form. \_\_\_\_\_

4 - Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

4a - If yes, Date of procedure \_\_\_\_\_

5 - Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes If Yes, proceed to item 5a   
No If No, proceed to item 6

5a - If yes, select from the drop-down list 1 \_\_\_\_\_

5b - If yes, select from the drop-down list 2 \_\_\_\_\_

6 - Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes If Yes, proceed to item 6a   
No If No, End of form

6a - If yes, select from the drop-down list 1 \_\_\_\_\_

6b - If yes, select from the drop-down list 2 \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Consent - Pregnancy Infant Sub-study**  
**Generated On: 19 Jan 2023 01:09:25**

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Date of consent for Pregnancy and Infant sub-study \_\_\_\_\_

---

For which OLE regimen did the participant consent during pregnancy? CAB LA   
TDF/FTC   
None

---

Did the participant consent to having her sample collected during pregnancy? Yes   
No

---

If yes, did the participant consent to having her sample stored for future testing during pregnancy? Yes   
No

---

Did the participant consent to having her infant's sample collected after pregnancy? Yes   
No

---

If yes, did the participant consent to having her infant's sample stored for future testing during pregnancy? Yes   
No

---

Did the contraception method change since last visit? Yes

No

What type of birth control method is the participant currently using? None

Please update the Concomitant Medications form as appropriate.

Oral Contraceptive pill

Intrauterine Device (IUD)

Injectable

Contraceptive Patch

Contraceptive Vaginal Ring

Implant

Other Contraceptive

Sterilization (Tubal ligation /  
hysterectomy)

Condoms

Other

If "Other" Specify \_\_\_\_\_

Onset Date / Date of Procedure \_\_\_\_\_

Concomitant Medication Log Line \_\_\_\_\_

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 \_\_\_\_\_

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 \_\_\_\_\_

WBC \_\_\_\_\_

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

WBC Adverse Event \_\_\_\_\_

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 \_\_\_\_\_

Lymphocytes \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Hematology

Generated On: 19 Jan 2023 01:09:25

Lab Name: \_\_\_\_\_

Lymphocytes Severity Grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially  
life-threatening)

Not gradable

Lymphocytes Adverse Event \_\_\_\_\_

Monocytes \_\_\_\_\_

Eosinophils \_\_\_\_\_

Basophils \_\_\_\_\_

Atypical lymphocytes \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Injection Administration

Generated On: 19 Jan 2023 01:09:25

Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit must be confirmed negative/nonreactive prior to injection/dispensing of study product. In addition, pregnancy test results from the same visit day must be confirmed negative prior to injection/dispensing of study product.

1. - Was an injection given at this visit? Yes   
No

If injection was given:

Open label injection (active CAB LA)

2. - Injection date \_\_\_\_\_

3. - Needle gauge 21 G   
23 G   
25 G   
Other

3a. - If other needle gauge, specify: \_\_\_\_\_

4. - Needle length 1 in   
1 1/2 in   
2 in   
Other

4a. - If other needle length, specify: \_\_\_\_\_

5. - Was a full dose of 3ml given? Yes   
No

5a. - If no, what volume was given? Fixed Unit: ml \_\_\_\_\_

6. - Location of injection Right buttock   
Left buttock

7. - Time of preparation for injection \_\_\_\_\_

8. - Time of injection \_\_\_\_\_

If injection was not given:

9. - Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided. Injection missed   
Injection refused   
Injection schedule on hold or permanently discontinued   
Unblinded, active Truvada participant (no longer receiving placebo injection)   
Other, specify

9a. - If Other, specify \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Infant Breastmilk Feeding Assessment**  
**Generated On: 19 Jan 2023 01:09:25**

---

Infant PTID \_\_\_\_\_

---

Was a feeding assessment completed? Yes

No

---

Date of assessment \_\_\_\_\_

---

Has the infant ever been fed breastmilk? Yes

No

---

Is the infant currently fed breastmilk? Yes

No

---

Date infant last received breast milk \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: HIV Test Results Y/N

Generated On: 19 Jan 2023 01:09:25

---

Was an HIV test performed?

Yes

No

---

---

1. - Specimen Collection Date \_\_\_\_\_

---

2. - Was this sample collected for confirmatory testing? Yes   
No

---

3. - HIV Rapid 1 Non-reactive/Negative   
Reactive/Positive   
Not Done

---

3a. - Kit Code Rapid 1 OraQuick ADVANCE Rapid HIV-1/2   
Uni-Gold Recombigen HIV   
Reveal G-3 Rapid HIV-1   
Clearview HIV-1/2 STAT-PAK   
Clearview COMPLETE HIV-1/2   
INSTI HIV-1 Antibody Test   
SURE CHECK HIV 1/2 Assay   
4th Generation Abbott tests (FDA-approved): Determine HIV 1/2 Ag/Ab Combo   
4th Generation Abbott tests (non-FDA approved): Determine HIV Early Detect (HIV 1/2 Combo)   
Alere Determine (3rd generation)   
Advance Quality

---

4. - HIV Rapid 2 Non-reactive/Negative   
Reactive/Positive   
Not Done

---

4a. - Kit Code Rapid 2 OraQuick ADVANCE Rapid HIV-1/2   
Uni-Gold Recombigen HIV   
Reveal G-3 Rapid HIV-1   
Clearview HIV-1/2 STAT-PAK   
Clearview COMPLETE HIV-1/2   
INSTI HIV-1 Antibody Test   
SURE CHECK HIV 1/2 Assay   
4th Generation Abbott tests (FDA-approved): Determine HIV 1/2 Ag/Ab Combo   
4th Generation Abbott tests (non-FDA approved): Determine HIV Early Detect (HIV 1/2 Combo)   
Alere Determine (3rd generation)   
Advance Quality

---

---

5. - HIV EIA or CMIA	Non-reactive/Negative <input type="radio"/>
	Reactive/Positive <input type="radio"/>
	Not Done <input type="radio"/>

---

6. - HIV-1 RNA Qualitative	Non-reactive/Negative <input type="radio"/>
	Reactive/Positive <input type="radio"/>
	Not Done <input type="radio"/>

---

7. - Was a viral load done?	Yes <input type="radio"/>
	No <input type="radio"/>

---

8. - Date of collection	<input type="text"/>
-------------------------	----------------------

---

9. - Operator	> <input type="radio"/>
	< <input type="radio"/>
	= <input type="radio"/>

---

10. - HIV RNA PCR (plasma)	Fixed Unit: viral copies/mL
----------------------------	-----------------------------

---

10a. - Target not detected	<input type="checkbox"/>
10b. - Detected, under lower limit of quantification	<input type="checkbox"/>
10c. - Detected, greater than the upper limit of quantification	<input type="checkbox"/>

---

11. - Final HIV status	Negative <input type="radio"/>
	Positive <input type="radio"/>
	Additional testing needed <input type="radio"/>

---

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done

OR

Specimen Collection Date

Assay Result

Assay result not provided

HIV Negative

HIV-1 Positive

HIV-2 Positive

HIV-2 Positive with HIV-1  
Cross-Reactivity

HIV-1 Positive, Untypable

HIV-1 Indeterminate

HIV-2 Indeterminate

HIV Indeterminate

Other

Other assay result:

Comments (max. 200 characters)

HIV DNA

Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:

Not performed/Not reported by Lab (add comment)

OR

Specimen Collection Date

DNA Result

Detectable DNA result (record below)

Detectable DNA , but below limit of detection (<4.09 copies per million cells)

Detectable DNA, above the reportable range of the assay (>100 copies per million cells)

Undetectable DNA, below limit of detection (<4.09 copies per million cells )

Detectable DNA result:

Fixed Unit: copies per million cells

Comments (max. 200 characters)

Lab Name: \_\_\_\_\_

1. - Was a sample collected for liver function testing? Yes   
No

2. - Date of collection \_\_\_\_\_

3. - Alkaline phosphatase \_\_\_\_\_

Alkaline phosphatase Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

Alkaline phosphatase Adverse Event \_\_\_\_\_

4. - AST (SGOT) \_\_\_\_\_

AST (SGOT) Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

AST (SGOT) Adverse Event \_\_\_\_\_

5. - ALT (SGPT) \_\_\_\_\_

ALT (SGPT) Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

ALT (SGPT) Adverse Event \_\_\_\_\_

6. - Total bilirubin \_\_\_\_\_

Total bilirubin Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

Total bilirubin Adverse Event \_\_\_\_\_

1. - Was a plasma sample collected for storage? Yes

No

1a. - If no, record reason why plasma sample was not collected. \_\_\_\_\_

2. - Specimen collection date: \_\_\_\_\_

3. - Time plasma sample collected: \_\_\_\_\_

4. - Was plasma stored? Stored

Not Stored

4a. - If no, record reason why plasma sample was not stored. \_\_\_\_\_

Select if additional plasma storage form required.

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Plasma Storage- Contraceptive Sub-study**  
**Generated On: 19 Jan 2023 01:09:25**

Was a plasma sample collected for storage? Yes   
No

If no, record reason why plasma sample was not collected. \_\_\_\_\_

Specimen collection date: \_\_\_\_\_

Time plasma sample collected: \_\_\_\_\_

Was plasma stored? Stored   
Not Stored

If no, record reason why plasma sample was not stored. \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Pregnancy Test Results

Generated On: 19 Jan 2023 01:09:25

---

1. - Was a pregnancy test done? Yes

No

Not applicable

---

If no, end of form.

---

2. - Date of pregnancy test \_\_\_\_\_

---

3. - Specimen type (Mark only one):

Urine

Plasma

Serum

---

4. - Test result

Positive

Negative

---

---

1. - Was a pregnancy test done? Yes   
No   
Not applicable

---

If no, end of form.

---

2. - Date of pregnancy test \_\_\_\_\_

---

3. - Specimen type (Mark only one): Urine   
Plasma   
Serum

---

4. - Test result Positive   
Negative

If Negative, end of form.

5. - If Test result is positive, was the pregnancy confirmed on a Yes   
second independent sample on same day? No   
If No, go to Question 6.

---

5a. - If Yes, Specimen type (Mark only one): Urine   
Plasma   
Serum

---

5b. - If Yes, Test result Positive   
Negative

---

6. - Is the participant eligible for Pregnancy and Infant Sub-Study? Yes   
No

---

7. - Did the participant consent to participate in Pregnancy and Yes   
Infant Sub-Study? No

---

8. - Select if additional pregnancy test results form is required.

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Dried Blood Spot Storage

Generated On: 19 Jan 2023 01:09:25

1. - Was a dried blood spot collected? Yes

No

1a. - If no, record reason why sample was not collected. \_\_\_\_\_

2. - Specimen collection date \_\_\_\_\_

3. - Time dried blood spot collected \_\_\_\_\_

4. - Was dried blood spot stored? Stored

Not Stored

4a. - If no, record reason why sample was not stored. \_\_\_\_\_

Syphilis

1. - Was a sample collected for syphilis testing? Yes

No

2. - Date of collection: \_\_\_\_\_

3. - Non-Treponemal test Reactive

Non-reactive

4. - Treponemal test Non-reactive/Negative

Reactive/Positive

Not Done

5. - Titer if indicated \_\_\_\_\_

Or select if N/A

GC/CT

6. - Was a urine sample collected for NAAT for GC/CT? Yes

No

7. - Date of collection: \_\_\_\_\_

8. - N. gonorrhoea – URINE Positive

Negative

9. - C. trachomatis – URINE Positive

Negative

10. - Was a vaginal swab collected for NAAT for GC/CT? Yes

No

11. - Date of collection: \_\_\_\_\_

12. - N. gonorrhoea – VAGINAL Positive

Negative

13. - C. trachomatis – VAGINAL Positive

Negative

TV

14. - Was a sample collected for TV? Yes

No

15. - Date of collection: \_\_\_\_\_

16. - Trichomonas vaginalis - Rapid Test Negative

Positive

Invalid

Or select if not done

17. - Trichomonas vaginalis - Wet prep Negative

Positive

Invalid

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: STI Test Results**

**Generated On: 19 Jan 2023 01:09:25**

---

Or select if not done



1. - How many live pregnancy outcomes had resulted from this pregnancy?

Complete one log line for each live outcome.

2. - Infant PTID

3. - Is the infant alive?

Yes

No

4. - Was an infant assessment done?

Yes

No

If No, end of form.

5. - Date of assessment

6. - Length

Fixed Unit: cm

7. - Weight

Fixed Unit: kg

8. - Head circumference

Fixed Unit: cm

9. - Abdominal circumference

10. - Were any previously unreported fetal/infant congenital anomalies identified?

Yes

No

If "Yes", mark all that apply.

Not assessed

If "No" or "Not assessed", end of form.

10a. - Central nervous system, cranio-facial

10b. - Central nervous system, spinal

10c. - Cardiovascular

10d. - Renal

10e. - Gastrointestinal

10f. - Pulmonary

10g. - Musculoskeletal/extremities

10h. - Physical defect

10i. - Skin

10j. - Genitourinary

10k. - Chromosomal

10l. - Cranio-facial (structural)

10m. - Hematologic

10n. - Infectious

10o. - Endocrine/metabolic

10p. - Other

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Infant Assessment**

**Generated On: 19 Jan 2023 01:09:25**

---

10q. - Describe congenital anomaly/defect (max. 200 characters): \_\_\_\_\_

---

10r. - If fetal/infant congenital anomalies were identified, select Adverse Event log line. \_\_\_\_\_

---

10s. - If additional fetal/infant congenital anomalies were identified, select Adverse Event log line. \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Sub-study Infant PTID

Generated On: 19 Jan 2023 01:09:25

---

Is this PTID for an Infant?

Yes

No

---

If Yes, what is the associated Mother's PTID

---

Form: Adverse Event

Generated On: 19 Jan 2023 01:09:25

1. - Date reported to site \_\_\_\_\_  
2. - Adverse Event (AE) \_\_\_\_\_  
3. - Onset Date \_\_\_\_\_  
4. - At which visit was this AE first reported? \_\_\_\_\_  
4a. - If 'Interim visit', provide interim visit code \_\_\_\_\_  
5. - Is the AE still ongoing? Yes   
No

6. - Outcome Date \_\_\_\_\_  
7. - Toxicity (Severity) Grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Grade 5 (Death)

8. - Relationship to study product Related   
Not Related

8a. - Alternate etiology \_\_\_\_\_  
9. - Action taken with study product: Dose not changed   
Dose reduced   
Dose increased   
Dose withdrawn   
Dose interrupted   
Not applicable

10. - Other action(s) taken (Select "none" or all that apply)   
None  
10a. - Medication(s)   
10b. -   
10c. - Therapeutic procedure/surgery   
10d. - Diagnostic procedure   
10e. - Other

10e1. - Specify other: \_\_\_\_\_  
11. - Status/Outcome Recovered/resolved   
Recovering/resolving   
Resolved with sequelae   
Not recovered/resolved   
Fatal

12. - Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? Yes   
If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply. No

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Adverse Event

Generated On: 19 Jan 2023 01:09:25

12a. - Results in death	<input type="checkbox"/>
12b. - Is life-threatening	<input type="checkbox"/>
12c. - Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/>
12d. - Results in persistent or significant disability/incapacity	<input type="checkbox"/>
12e. - Is a congenital anomaly/birth defect	<input type="checkbox"/>
12f. - Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	<input type="checkbox"/>
13. - Has or will this AE be reported as an EAE?	Yes <input type="radio"/>
	No <input type="radio"/>
13a. - If yes, EAE number	_____

1. - Infant PTID	
2. - Date reported to site	
3. - Adverse Event (AE)	
4. - Onset Date	
5. - At which visit was this AE first reported?	V55.0 - Step 4a - Day 0 <input type="radio"/>
	V56.0 - Step 4b - Day 0 <input type="radio"/>
	V57.0 - Step 4c-CAB LA - Week 0 <input type="radio"/>
	V58.0 - Step 4c-CAB LA - Week 8 <input type="radio"/>
	V59.0 - Step 4c-CAB LA - Week 16 <input type="radio"/>
	V60.0 - Step 4c-CAB LA - Week 24 <input type="radio"/>
	V61.0 - Step 4c-CAB LA - Week 32 <input type="radio"/>
	V62.0 - Step 4c-CAB LA - Week 40 <input type="radio"/>
	V63.0 - Step 4c-CAB LA - Week 48 <input type="radio"/>
	V64.0 - Step 4c-TDF/FTC - Week 0 <input type="radio"/>
	V65.0 - Step 4c-TDF/FTC - Week 8 <input type="radio"/>
	V66.0 - Step 4c-TDF/FTC - Week 16 <input type="radio"/>
	V67.0 - Step 4c-TDF/FTC - Week 24 <input type="radio"/>
	V68.0 - Step 4c-TDF/FTC - Week 32 <input type="radio"/>
	V69.0 - Step 4c-TDF/FTC - Week 40 <input type="radio"/>
	V70.0 - Step 4c-TDF/FTC - Week 48 <input type="radio"/>
	V71.0 - Step 5-TDF/FTC - Day 0 <input type="radio"/>
	V72.0 - Step 5-TDF/FTC - Week 12 <input type="radio"/>
	V73.0 - Step 5-TDF/FTC - Week 24 <input type="radio"/>
	V74.0 - Step 5-TDF/FTC - Week 36 <input type="radio"/>
	V75.0 - Step 5-TDF/FTC - Week 48 <input type="radio"/>
	V76.0 - Step 4d - Week 0 <input type="radio"/>
	V77.0 - Step 4d - Week 4 <input type="radio"/>
	V78.0 - Step 4d - Week 8 <input type="radio"/>
	V79.0 - Step 4d - Week 12 <input type="radio"/>
	V80.0 - Step 4d - Week 16 <input type="radio"/>
	V81.0 - Step 4d - Week 20 <input type="radio"/>
	V82.0 - Step 4d - Week 24 <input type="radio"/>
	V83.0 - Step 4d - Week 28 <input type="radio"/>
	V84.0 - Step 4d - Week 32 <input type="radio"/>

- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40
- V87.0 - Step 4d - Week 2 PP
- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP
- Delivery - OLE - V95.0
- Delivery - OLE - V96.0
- Delivery - OLE - V97.0
- Delivery - OLE - V98.0
- Delivery - OLE - V99.0
- Interim Visit
- V116.0 - Step 6-CAB LA - Week 56
- V117.0 - Step 6-CAB LA - Week 64
- V118.0 - Step 6-CAB LA - Week 72
- V119.0 - Step 4c-CAB LA - Week 80
- V120.0 - Step 4c-CAB LA - Week 88
- V121.0 - Step 4c-CAB LA - Week 96

5a. - If 'Interim Visit' is chosen, provide interim visit code.

6. - Is the AE still ongoing? Yes   
No

7. - Outcome Date

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

9. - Relationship to Study Product Related   
Not Related

9a. - Alternate etiology

10. - Action Taken with Study Product: Dose not changed   
Dose reduced

---

Dose increased

Dose withdrawn

Dose interrupted

Not applicable

---

11a. - Other action(s) taken (Select "none" or all that apply)

None

11b. - Medication(s)

11c. - Therapeutic procedure/surgery

11d. - Diagnostic procedure

11e. - Other

11e1. - Specify other: \_\_\_\_\_

12. - Status/Outcome

Recovered/resolved

Recovering/resolving

Resolved with sequelae

Not recovered/resolved

Fatal

---

13. - Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? Yes

No

If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.

13a. - Results in death

13b. - Is life-threatening

13c. - Requires inpatient hospitalization or prolongation of existing hospitalization

13d. - Results in persistent or significant disability/incapacity

13e. - Is a congenital anomaly/birth defect

13f. - Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

14. - Has or will this AE be reported as an EAE? Yes

No

14a. - If yes, EAE number \_\_\_\_\_

---

---

1. - Termination date \_\_\_\_\_

---

2. - Reason for termination

Scheduled exit visit/end of study

Death

Participant refused further participation, specify

Participant relocated, no follow-up planned

Investigator decision, specify

Unable to contact participant

HIV infection - Step 1

Inappropriate enrollment

Invalid ID due to duplicate screening/enrollment

Other, specify

Early study closure

Local access to CAB-LA

---

3. - Date of death \_\_\_\_\_

---

4. - Specify \_\_\_\_\_

---

5. - Was termination associated with an Adverse Event? Yes

No

---

5a. - If yes, please specify AE \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Concomitant Medications Y/N

Generated On: 19 Jan 2023 01:09:25

---

Were any concomitant medications taken?

Yes

No

---

If yes, complete the Concomitant Medications Log.

---

Form: Concomitant Medications

Generated On: 19 Jan 2023 01:09:25

Reminder: Anticoagulant and antiplatelet medications as outlined in the SSP manual are prohibited within 7 days before and 7 days after injections.

Medication Name \_\_\_\_\_

Indication \_\_\_\_\_

Mark if this medication is being taken for contraception.

If medication is being taken for contraception, select the type of contraception.

- Oral contraceptive pill
- Intrauterine device (IUD)   
(hormonal)
- Intrauterine device (IUD)   
(non-hormone-releasing)
- Injectable - DMPA (Depo)
- Injectable - NET-EN (Noristerat)
- Injectable - Sayana Press, Lunelle, Cycloferm
- Injectable - Other (Specify)
- Contraceptive patch
- Contraceptive vaginal ring
- Implants
- Emergency contraception
- Other, specify

If other type of contraception, specify: \_\_\_\_\_

Date Started \_\_\_\_\_

Date Stopped \_\_\_\_\_

OR

Ongoing

Frequency

- PRN
- QD
- QH
- QAM
- QPM
- QHS
- BID
- TID
- QID
- ONCE
- Other

Specify other: \_\_\_\_\_

Route

- Oral
- Intramuscular

- Intravenous
- Topical
- IHL
- Vaginal
- Rectal
- Subcutaneous
- Other

Specify other: \_\_\_\_\_

Dose \_\_\_\_\_

Dose Units \_\_\_\_\_

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

Specify other: \_\_\_\_\_

Taken for a reported adverse event? \_\_\_\_\_

- Yes
- No

Applicable AE #1 \_\_\_\_\_

Applicable AE #2 \_\_\_\_\_

Taken for injection site reaction? \_\_\_\_\_

- Yes
- No

Applicable ISR #1 \_\_\_\_\_

Applicable ISR #2 \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Specimen Storage - Contraceptive Sub-Study**  
**Generated On: 19 Jan 2023 01:09:25**

---

Was a plasma sample collected for storage? Yes   
No

---

Specimen collection date: \_\_\_\_\_  
Time plasma sample collected: \_\_\_\_\_  
Was plasma stored? Stored   
Not Stored

---

Was a serum sample collected for storage? Yes   
No

---

Specimen collection date: \_\_\_\_\_  
Time serum sample collected: \_\_\_\_\_  
Was serum sample stored? Stored   
Not Stored

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Specimen Collection - Breast Milk

Generated On: 19 Jan 2023 01:09:25

Were breast milk samples collected? Yes

If no, end of form. No

Date breast milk samples collected by site \_\_\_\_\_

Specimen collection date \_\_\_\_\_

Specimen collection time \_\_\_\_\_

Specimen collection method Hand expression

Pump

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Infant Specimen Collection - Cord Blood**  
**Generated On: 19 Jan 2023 01:09:25**

Infant PTID \_\_\_\_\_

Was specimen collected? Yes

No

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

Specimen collection date \_\_\_\_\_

Specimen collection time \_\_\_\_\_

Was the minimum required volume obtained? Yes

No

If "No", record reason why minimum required volume was not obtained (max. 200 characters). \_\_\_\_\_

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Infant Specimen Collection - Blood (Plasma)**  
**Generated On: 19 Jan 2023 01:09:25**

Infant PTID \_\_\_\_\_

Was specimen collected? Yes

No

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

Specimen collection date \_\_\_\_\_

Specimen collection time \_\_\_\_\_

Was the minimum required volume obtained? Yes

No

If "No", record reason why minimum required volume was not obtained (max. 200 characters). \_\_\_\_\_

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). \_\_\_\_\_

---

1. - Date social impact reported \_\_\_\_\_

---

2. - Concisely describe social impact. \_\_\_\_\_

---

3. - Onset date \_\_\_\_\_

---

4. - Social impact type

Personal Relationships - Had negative experiences with family, friends, significant others, or sex partners.

Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.

Employment - Been turned down for a new job, lost a job, or experienced other problems at work.

Education - Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.

Medical/Dental - Been refused medical or dental treatment, or treated negatively by a health care provider.

Health Insurance - Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.

Life Insurance - Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.

Housing - Had trouble getting or keeping housing, or had other problems related to housing.

Military/Other Government Agency - Had a problem with the military or any other government agencies.

Other - Had other problems not covered in the codes above.

---

4a. - If other, specify: \_\_\_\_\_

---

1. - Date of Birth \_\_\_\_\_

2. - Age \_\_\_\_\_ Fixed Unit: years

3. - What was the participant's sex at birth? Female   
Male

4. - What is the participant's self-identified gender? Male   
Female   
Transgender male (female to male)   
Transgender female (male to female)   
Gender Queer   
Gender variant or gender non-conforming   
Self-identify, other   
Prefer not to answer

4a. - If "self-identify, other", specify: \_\_\_\_\_

5. - What is the participant's current marital status? married/civil union/legal partnership   
living with primary or main partner   
have primary or main partner, not living together   
single/divorced/widowed   
Other

5a. - If other, specify: \_\_\_\_\_

6. - What is the participant's current employment status? full-time employment   
part-time employment   
not employed

7. - What is the participant's highest level of education? no schooling   
primary school, not complete   
primary school, complete   
secondary school, not complete   
secondary school, complete   
technical training, not complete   
technical training, complete   
college/university or higher, not complete   
college/university or higher, complete

8. - Ethnicity Hispanic or Latino   
Not Hispanic or Latino

9. - Race \_\_\_\_\_

9a. - If other race, specify: \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Social Impact Y/N

Generated On: 19 Jan 2023 01:09:25

---

Has the participant reported a social impact during the study?

Yes

No

---

If yes, complete the Social Impact Log.

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Screening Liver Function Tests

Generated On: 19 Jan 2023 01:09:25

Lab Name: \_\_\_\_\_

1. - Was a sample collected for liver function testing? Yes   
No

2. - Date of collection: \_\_\_\_\_

3. - ALT \_\_\_\_\_

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

4. - Total bilirubin \_\_\_\_\_

Total bilirubin Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Screening Chemistries

Generated On: 19 Jan 2023 01:09:25

Lab Name: \_\_\_\_\_

1. - Was a sample collected for chemistry testing? Yes   
No

2. - Date of Collection \_\_\_\_\_

3. - Creatinine \_\_\_\_\_

Creatinine Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

4. - Calculated Creatinine Clearance \_\_\_\_\_

Calculated Creatinine Clearance Severity Grade  
Grade 1 - Mild   
Grade 2 - Moderate   
Grade 3 - Severe   
Grade 4 - Potentially life-threatening   
Not gradable

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Hepatitis B Test Results

Generated On: 19 Jan 2023 01:09:25

---

1. - Hepatitis B Surface Antigen (HBsAg)	Positive/Reactive <input type="radio"/>
	Negative/Non-reactive <input type="radio"/>
	Not Done <input type="radio"/>

---

2. - Hepatitis B Surface Antibody (HBsAb)	Positive/Reactive <input type="radio"/>
	Negative/Non-reactive <input type="radio"/>
	Not Done <input type="radio"/>

---

3. - Hepatitis B Core Antibody (HBCoreAb) Total	Positive/Reactive <input type="radio"/>
	Negative/Non-reactive <input type="radio"/>
	Not Done <input type="radio"/>

---

Specimen collection date \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Hepatitis C Test Results

Generated On: 19 Jan 2023 01:09:25

Anti-Hepatitis C Antibody (anti-HCV)

Positive/Reactive   
Negative/Non-reactive   
Not Done

Specimen collection date \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: xxRandomization**

**Generated On: 19 Jan 2023 01:09:25**

---

Please ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Please also ensure participant is NOT pregnant prior to randomization.

---

Is the participant ready to be randomized?

Yes

No

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Injection Site Reaction Y/N**

**Generated On: 19 Jan 2023 01:09:25**

---

Has the participant experienced any Injection Site Reactions?

Yes

No

---

If yes, complete the Injection Site Reaction Log.

---

1. - Date reported to site

2. - Event diagnosis

- Injection site abscess
- Injection site anesthesia
- Injection site bruising
- Injection site discoloration
- Injection site erosion
- Injection site hemorrhage
- Injection site itching
- Injection site induration
- Injection site swelling
- Injection site nodule
- Injection site pain
- Injection site tenderness
- Injection site erythema
- Injection site warmth
- Injection site hematoma

3. - Injection site side

Left

Right

4. - Onset date

5. - At which visit was this ISR first reported?

- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89

- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- Interim Visit
- V55.0 - Step 4a - Day 0
- V56.0 - Step 4b - Day 0
- V57.0 - Step 4c-CAB LA - Week 0
- V58.0 - Step 4c-CAB LA - Week 8
- V59.0 - Step 4c-CAB LA - Week 16
- V60.0 - Step 4c-CAB LA - Week 24
- V61.0 - Step 4c-CAB LA - Week 32
- V62.0 - Step 4c-CAB LA - Week 40
- V63.0 - Step 4c-CAB LA - Week 48
- V64.0 - Step 4c-TDF/FTC - Week 0
- V65.0 - Step 4c-TDF/FTC - Week 8
- V66.0 - Step 4c-TDF/FTC - Week 16
- V67.0 - Step 4c-TDF/FTC - Week 24
- V68.0 - Step 4c-TDF/FTC - Week 32
- V69.0 - Step 4c-TDF/FTC - Week 40
- V70.0 - Step 4c-TDF/FTC - Week 48

- V71.0 - Step 5-TDF/FTC - Day 0
- V72.0 - Step 5-TDF/FTC - Week 12
- V73.0 - Step 5-TDF/FTC - Week 24
- V74.0 - Step 5-TDF/FTC - Week 36
- V75.0 - Step 5-TDF/FTC - Week 48
- V76.0 - Step 4d - Week 0
- V77.0 - Step 4d - Week 4
- V78.0 - Step 4d - Week 8
- V79.0 - Step 4d - Week 12
- V80.0 - Step 4d - Week 16
- V81.0 - Step 4d - Week 20
- V82.0 - Step 4d - Week 24
- V83.0 - Step 4d - Week 28
- V84.0 - Step 4d - Week 32
- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40
- V87.0 - Step 4d - Week 2 PP
- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP
- Delivery - OLE
- V201 - Open Label Truvada Day 0
- V202 - Open Label Truvada Week 12
- V203 - Open Label Truvada Week 24
- V204 - Open Label Truvada Week 36
- V205 - Open Label Truvada Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5

---

5a. - If 'Interim Visit' is chosen, provide interim visit code.

---

6. - Is the reaction still ongoing? Yes   
No

6a. - If no, provide an outcome date \_\_\_\_\_

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

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

9. - Other action(s) taken (Select "none" or all that apply)

None

9a. - Medication(s)

9b. -

9c. - Therapeutic procedure/surgery

9d. - Diagnostic procedure

9e. - Other

9e1. - Other, specify: \_\_\_\_\_

10. - Status/Outcome  
Recovered/resolved   
Recovering/resolving   
Resolved with sequelae   
Not recovered/resolved   
Fatal

11. - Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? Yes   
No

If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.

11a. - Results in death

11b. - Is life-threatening

11c. - Requires inpatient hospitalization or prolongation of existing hospitalization

11d. - Results in persistent or significant disability/incapacity

11e. - Is a congenital anomaly/birth defect

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Form: Injection Site Reaction

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---

11f. - Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

---

12. - Has or will this AE be reported as an EAE? Yes   
No

---

12a. - If yes, EAE number \_\_\_\_\_

---

---

1. - Site awareness date \_\_\_\_\_

---

2. - Deviation date \_\_\_\_\_

---

3. - Has or will this deviation be reported to local IRB/EC? Yes   
No

---

4. - Has or will this deviation be reported to DAIDS as a critical event? Yes   
No

---

5. - Type of deviation

- Inappropriate enrollment
- Failure to follow trial randomization or blinding procedures
- Study product management deviation
- Study product dispensing error
- Conduct of non-protocol procedure
- Breach of confidentiality
- Physical assessment deviation
- Lab assessment deviation
- Use of non-IRB/EC-approved materials
- Informed assent/consent process deviation
- Incorrect study product given/taken
- Missed procedure
- Other

---

6. - Description of deviation: \_\_\_\_\_

---

7. - Plans and/or action taken to address the deviation: \_\_\_\_\_

---

8. - Plans and/or action taken to prevent future occurrences of the deviation: \_\_\_\_\_

---

9. - Deviation reported by (staff name): \_\_\_\_\_

---

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Protocol Deviation Log Y/N**

**Generated On: 19 Jan 2023 01:09:25**

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Have any protocol deviations occurred?

Yes

No

---

If yes, complete the Protocol Deviation Log.

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Product Choice - OLE

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Is the participant eligible for Open Label Extension? Yes   
No

If No, Reason (end of form) Seroconvertor Schedule previous version   
Open Label Truvada Schedule previous version (AE or Prohibited Conmed or CAB contraindicated)   
Annual Schedule previous version (AE or Prohibited Conmed or CAB contraindicated)

Will participant move to Open Label Extension (OLE)? Yes   
No

Date decision was made on whether to move to Open-label extension?

If No, Reason (end of form) Study participation too burdensome   
Already accessed TDF/FTC through another mechanism   
Relocating to area where study is not offered   
Annual Schedule previous version (AE or Prohibited Conmed or CAB contraindicated)   
Prefer not to answer   
Other

Other, specify \_\_\_\_\_

If Yes, Date of Informed Consent \_\_\_\_\_

Select OLE schedule participant will follow CAB (Steps 4a, 4b, 4c)   
TDF/FTC (Step 4c)   
Pregnancy and Infant Sub-Study (Step 4d)   
Seroconvertor Schedule previous version   
Open Label Truvada Schedule previous version (AE or Prohibited Conmed or CAB contraindicated)

If CAB, specify introductory schedule: Oral CAB (Step 4a)   
Loading Dose (4-week interval) CAB-LA (Step 4b)   
Standard Dose (8-week interval) CAB-LA (Step 4c - CAB/LA)

If CAB regimen selected, Reason Prefer injections and/or don't like pills   
CAB was shown to be superior to Truvada for HIV prevention   
Want to avoid potential side effects of Truvada   
Other

Other, specify \_\_\_\_\_

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Form: Product Choice - OLE

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If TDF/FTC regimen selected, Reason

Don't like injections and/or  
prefer pills

The potential side effects of  
Truvada are better understood  
than those of Cabotegravir

Concerned about resistance if  
injectable PrEP fails

Other

Other, specify \_\_\_\_\_

---

Name of transferring study site	Baylor Uganda	<input type="radio"/>
	Blantyre	<input type="radio"/>
	Cape Town - Emavundleni	<input type="radio"/>
	Desmond Tutu TB Centre	<input type="radio"/>
	Durban - Botha's Hill	<input type="radio"/>
	Durban - Isipingo	<input type="radio"/>
	Durban - Verulam	<input type="radio"/>
	Gabarone	<input type="radio"/>
	Harare - Parirenyatwa	<input type="radio"/>
	Harare - Seke South	<input type="radio"/>
	Harare - Spilhaus	<input type="radio"/>
	Johannesburg - Ward 21	<input type="radio"/>
	Kisumu	<input type="radio"/>
	Lilongwe	<input type="radio"/>
	Makerere, Kampala, Uganda	<input type="radio"/>
	St. Mary's Clinic	<input type="radio"/>
	Soweto HPTN CRS	<input type="radio"/>
	Swaziland Prevention	<input type="radio"/>
	UVRI-IAVI	<input type="radio"/>
	Zengeza Clinic	<input type="radio"/>

---

Name of receiving study site	Baylor Uganda	<input type="radio"/>
	Blantyre	<input type="radio"/>
	Cape Town - Emavundleni	<input type="radio"/>
	Desmond Tutu TB Centre	<input type="radio"/>
	Durban - Botha's Hill	<input type="radio"/>
	Durban - Isipingo	<input type="radio"/>
	Durban - Verulam	<input type="radio"/>
	Gabarone	<input type="radio"/>
	Harare - Parirenyatwa	<input type="radio"/>
	Harare - Seke South	<input type="radio"/>
	Harare - Spilhaus	<input type="radio"/>
	Johannesburg - Ward 21	<input type="radio"/>
	Kisumu	<input type="radio"/>
	Lilongwe	<input type="radio"/>
	Makerere, Kampala, Uganda	<input type="radio"/>
	St. Mary's Clinic	<input type="radio"/>
	Soweto HPTN CRS	<input type="radio"/>
	Swaziland Prevention	<input type="radio"/>

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Participant Transfer

Generated On: 19 Jan 2023 01:09:25

UVRI-IAVI

Zengeza Clinic

Visit code of last completed contact with participant \_\_\_\_\_

If interim visit, record interim visit code here \_\_\_\_\_

Date participant records were sent to receiving study site \_\_\_\_\_

---

Name of receiving study site	Baylor Uganda	<input type="radio"/>
	Blantyre	<input type="radio"/>
	Cape Town - Emavundleni	<input type="radio"/>
	Desmond Tutu TB Centre	<input type="radio"/>
	Durban - Botha's Hill	<input type="radio"/>
	Durban - Isipingo	<input type="radio"/>
	Durban - Verulam	<input type="radio"/>
	Gabarone	<input type="radio"/>
	Harare - Parirenyatwa	<input type="radio"/>
	Harare - Seke South	<input type="radio"/>
	Harare - Spilhaus	<input type="radio"/>
	Johannesburg - Ward 21	<input type="radio"/>
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	Lilongwe	<input type="radio"/>
	Makerere, Kampala, Uganda	<input type="radio"/>
	St. Mary's Clinic	<input type="radio"/>
	Soweto HPTN CRS	<input type="radio"/>
	Swaziland Prevention	<input type="radio"/>
	UVRI-IAVI	<input type="radio"/>
	Zengeza Clinic	<input type="radio"/>

---

Name of transferring study site	Baylor Uganda	<input type="radio"/>
	Blantyre	<input type="radio"/>
	Cape Town - Emavundleni	<input type="radio"/>
	Desmond Tutu TB Centre	<input type="radio"/>
	Durban - Botha's Hill	<input type="radio"/>
	Durban - Isipingo	<input type="radio"/>
	Durban - Verulam	<input type="radio"/>
	Gabarone	<input type="radio"/>
	Harare - Parirenyatwa	<input type="radio"/>
	Harare - Seke South	<input type="radio"/>
	Harare - Spilhaus	<input type="radio"/>
	Johannesburg - Ward 21	<input type="radio"/>
	Kisumu	<input type="radio"/>
	Lilongwe	<input type="radio"/>
	Makerere, Kampala, Uganda	<input type="radio"/>
	St. Mary's Clinic	<input type="radio"/>
	Soweto HPTN CRS	<input type="radio"/>
	Swaziland Prevention	<input type="radio"/>

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Form: Participant Receipt

Generated On: 19 Jan 2023 01:09:25

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UVRI-IAVI

Zengeza Clinic

---

Date informed consent signed at receiving site \_\_\_\_\_

---

---

1. - Target visit date

---

2. - Reason visit was missed

- Unable to contact participant
- Unable to schedule
- appointment(s) within allowable
- window
- Participant refused visit
- Participant incarcerated
- Participant admitted to a health
- care facility
- Participant withdrew from study
- Participant deceased
- Participant on pregnancy visit
- schedule
- Participant on seroconverter visit
- schedule
- Participant on yearly visit
- schedule
- Participant on open label
- Truvada schedule
- Unblinded active Truvada
- participant, no longer receiving
- placebo injections
- Other

---

2a. - If other, specify

---

Form: Medical History

Generated On: 19 Jan 2023 01:09:25

1. - Date medical history collected \_\_\_\_\_

2. - Description of medical history condition/event \_\_\_\_\_

Mark if sterilization procedure

3. - Is condition/event gradable? Yes

No

3a. - Toxicity (Severity) Grade Grade 1 (mild)

Grade 2 (moderate)

Grade 3 (severe)

Grade 4 (potentially  
life-threatening)

4. - Date of medical history condition/event \_\_\_\_\_

5. - Is the condition ongoing? Yes

No

6. - Date medical history/condition ended/resolved \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Medical History Y/N**

**Generated On: 19 Jan 2023 01:09:25**

---

Does the participant have any medical history to report?

Yes

No

---

If yes, complete the Medical History Log.

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Interim Visit

Generated On: 19 Jan 2023 01:09:25

1. - Interim visit date	
2. - Interim visit code	
3. - Reason for interim visit (Mark all that apply)	
3a. - AE report or follow-up	<input type="checkbox"/>
3b. - ISR report or follow-up	<input type="checkbox"/>
3c. - Report social harm	<input type="checkbox"/>
3d. - Additional laboratory testing	<input type="checkbox"/>
3e. - Other	<input type="checkbox"/>
3e1. - If other, specify:	
4. - Weight	Fixed Unit: kg
OR not done	<input type="checkbox"/>
5. - Did the participant exit/terminate the study at this visit?	Yes <input type="radio"/> No <input type="radio"/>
6. - Is the participant moving to a new visit schedule?	Yes <input type="radio"/> No <input type="radio"/>
If yes, please indicate which step or visit schedule.	Pregnancy visit schedule <input type="radio"/> Seroconverter visit schedule <input type="radio"/> Step 3 <input type="radio"/> Open label Truvada schedule <input type="radio"/> Yearly visit schedule <input type="radio"/>
Mark all forms completed at this visit.	
AE Log	<input type="checkbox"/>
CD4/VL Results	<input type="checkbox"/>
Chemistry Testing	<input type="checkbox"/>
Counseling	<input type="checkbox"/>
Dried Blood Spot Storage	<input type="checkbox"/>
Fasting Lipid Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Hepatitis B Test Results	<input type="checkbox"/>
Hepatitis C Test Results	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
Liver Function Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Interim Visit**

**Generated On: 19 Jan 2023 01:09:25**

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Participant Transfer	<input type="checkbox"/>
Pill Dispensation - Step 2 and 3	<input type="checkbox"/>
Plasma Storage	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Product Hold Log	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Cell Pellet Storage	<input type="checkbox"/>
Pill Count Step 1	<input type="checkbox"/>
HIV Supplemental Results	<input type="checkbox"/>

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Interim Visit - OLE

Generated On: 19 Jan 2023 01:09:25

---

1. - Interim Visit date \_\_\_\_\_

---

2. - Interim visit code \_\_\_\_\_

---

3 - Reason for interim visit (Mark all that apply)

3a. - AE report or follow-up

---

3b. - ISR report or follow-up

---

3c. - Report social harm

---

3d. - Additional laboratory testing

---

3e. - Other

---

3e1. - If other, specify: \_\_\_\_\_

---

4. - Weight \_\_\_\_\_ Fixed Unit: kg

---

OR Not Done

---

5. - Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

---

6. - Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

---

7. - Pulse \_\_\_\_\_ Fixed Unit: beats/min

---

8. - How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit? 0   
1   
2   
3   
4   
5   
6

---

9. - Did the product get held/discontinued at this visit? Product Hold   
Product Discontinued   
No

---

10. - Did the participant exit/terminate the study at this visit? Yes   
No

---

11. - Is the participant moving to a new step or visit schedule? Yes   
No

---

11a. - If yes, please indicate which step or visit schedule. Oral CAB (Step 4a)   
Loading Dose (4-week interval)   
CAB-LA (Step 4b)   
TDF/FTC (Step 4c)   
TDF/FTC (Step 5)   
Pregnancy and Infant Sub-Study

Mark all forms completed at this visit.

AE Log	<input type="checkbox"/>
CD4/VL Results	<input type="checkbox"/>
Chemistry Testing	<input type="checkbox"/>
Counseling	<input type="checkbox"/>
Dried Blood Spot Storage	<input type="checkbox"/>
Fasting Lipid Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
HIV Supplemental Results	<input type="checkbox"/>
Infant Assessment	<input type="checkbox"/>
Infant Breastmilk Feeding Assessment	<input type="checkbox"/>
Infant Specimen Collection - Plasma	<input type="checkbox"/>
Liver Function Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Plasma Storage	<input type="checkbox"/>
Pregnancy Test Results - OLE	<input type="checkbox"/>
Product Hold Log - OLE	<input type="checkbox"/>
Specimen Collection - Breast Milk	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Ultrasound - OLE	<input type="checkbox"/>
Infant HIV Test Results	<input type="checkbox"/>
Infant - Dried Blood Spot Storage	<input type="checkbox"/>
Cell Pellet Storage	<input type="checkbox"/>

1. - Was a whole blood sample collected for storage? Yes

No

1a. - If no, record reason why whole blood was not collected. \_\_\_\_\_

2. - Specimen collection date: \_\_\_\_\_

3. - Time whole blood collected: \_\_\_\_\_

4. - Was whole blood stored? Stored

Not Stored

4a. - If no, record reason why whole blood was not stored. \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: VOICE Risk Score - Modified

Generated On: 19 Jan 2023 01:09:25

Answers are worth 0 points unless otherwise noted.

1. - Is the participant currently married or living with her primary sex partner? Yes   
No

If no, score +2

VOICE Risk Score for Item 1

2. - Does her husband or primary partner provide the participant with financial and/or material support? Yes   
No

If no, score +1

VOICE Risk Score for Item 2

3. - Does her husband or primary partner have any sex partners other than the participant? Yes   
No   
Don't know

If yes or don't know, score +2

VOICE Risk Score for Item 3

4. - In the past 3 months, what number of alcoholic drinks per week did the participant have on average?

If 1 or more drinks, score +1

VOICE Risk Score for Item 4

5. - Is the participant < 25 years of age? Yes   
No

If yes, score +2

VOICE Risk Score for Item 5

Total VOICE RISK Score:

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Study Step

Generated On: 19 Jan 2023 01:09:25

---

Is the participant moving to Step 2, Follow-up Phase? Yes

No

---

Is the participant moving to Step 3, Follow-up Phase? Yes

No

---

Is the participant moving to a yearly visit schedule? Yes

No

---

Is the participant moving to a seroconverter schedule? Yes

No

---

Is the participant moving to a schedule for pregnant women? Yes

No

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Step Y/N

Generated On: 19 Jan 2023 01:09:25

---

Is the participant moving to a new step or visit schedule?

Yes

No

---

If yes, complete the Study Step CRF.

---

1. - Date pregnancy reported

2. - At what visit was the pregnancy reported?

- V2.0 - Day 0/Enrollment
- V3.0 - Step 1 Week 2
- V4.0 - Step 1 Week 4
- V5.0 - Step 2 Week 5
- V6.0 - Step 2 Week 6
- V7.0 - Step 2 Week 9
- V8.0 - Step 2 Week 13
- V9.0 - Step 2 Week 17
- V10.0 - Step 2 Week 21
- V11.0 - Step 2 Week 25
- V12.0 - Step 2 Week 33
- V13.0 - Step 2 Week 41
- V14.0 - Step 2 Week 42
- V15.0 - Step 2 Week 49
- V16.0 - Step 2 Week 57
- V17.0 - Step 2 Week 65
- V18.0 - Step 2 Week 73
- V19.0 - Step 2 Week 81
- V20.0 - Step 2 Week 89
- V21.0 - Step 2 Week 97
- V22.0 - Step 2 Week 105
- V23.0 - Step 2 Week 113
- V24.0 - Step 2 Week 121
- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
- V29.0 - Step 2 Week 161
- V30.0 - Step 2 Week 169
- V31.0 - Step 2 Week 177
- V32.0 - Step 2 Week 185
- V33.0 - Step 3 Day 0
- V34.0 - Step 3 Week 12
- V35.0 - Step 3 Week 24
- V36.0 - Step 3 Week 36
- V37.0 - Step 3 Week 48
- Interim Visit

- V55.0 - Step 4a - Day 0
- V56.0 - Step 4b - Day 0
- V57.0 - Step 4c-CAB LA - Week 0
- V58.0 - Step 4c-CAB LA - Week 8
- V59.0 - Step 4c-CAB LA - Week 16
- V60.0 - Step 4c-CAB LA - Week 24
- V61.0 - Step 4c-CAB LA - Week 32
- V62.0 - Step 4c-CAB LA - Week 40
- V63.0 - Step 4c-CAB LA - Week 48
- V64.0 - Step 4c-TDF/FTC - Week 0
- V65.0 - Step 4c-TDF/FTC - Week 8
- V66.0 - Step 4c-TDF/FTC - Week 16
- V67.0 - Step 4c-TDF/FTC - Week 24
- V68.0 - Step 4c-TDF/FTC - Week 32
- V69.0 - Step 4c-TDF/FTC - Week 40
- V70.0 - Step 4c-TDF/FTC - Week 48
- V71.0 - Step 5-TDF/FTC - Day 0
- V72.0 - Step 5-TDF/FTC - Week 12
- V73.0 - Step 5-TDF/FTC - Week 24
- V74.0 - Step 5-TDF/FTC - Week 36
- V75.0 - Step 5-TDF/FTC - Week 48
- V76.0 - Step 4d - Week 0
- V77.0 - Step 4d - Week 4
- V78.0 - Step 4d - Week 8
- V79.0 - Step 4d - Week 12
- V80.0 - Step 4d - Week 16
- V81.0 - Step 4d - Week 20
- V82.0 - Step 4d - Week 24
- V83.0 - Step 4d - Week 28
- V84.0 - Step 4d - Week 32
- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40
- V87.0 - Step 4d - Week 2 PP

- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP
- Delivery - OLE
- V201 - Open Label Truvada Day   
0
- V202 - Open Label Truvada   
Week 12
- V203 - Open Label Truvada   
Week 24
- V204 - Open Label Truvada   
Week 36
- V205 - Open Label Truvada   
Week 48
- V50.0 - Yearly Visit 1
- V51.0 - Yearly Visit 2
- V52.0 - Yearly Visit 3
- V53.0 - Yearly Visit 4
- V54.0 - Yearly Visit 5

---

2a. - If 'Interim Visit' is chosen, provide interim visit code. \_\_\_\_\_

---

3. - First day of last menstrual period \_\_\_\_\_

---

4. - Estimated date of delivery \_\_\_\_\_

---

5. - What information was used to estimate the date of delivery?

- Last menstrual period
- Initial ultrasound <20 weeks
- Initial ultrasound >=20 weeks
- Physical exam
- Conception date by assisted reproduction
- Other

---

5a. - If other, specify: \_\_\_\_\_

---

Date pregnancy reported

At what visit was the pregnancy reported?

- V55.0 - Step 4a - Day 0
- V56.0 - Step 4b - Day 0
- V57.0 - Step 4c-CAB LA - Week 0
- V58.0 - Step 4c-CAB LA - Week 8
- V59.0 - Step 4c-CAB LA - Week 16
- V60.0 - Step 4c-CAB LA - Week 24
- V61.0 - Step 4c-CAB LA - Week 32
- V62.0 - Step 4c-CAB LA - Week 40
- V63.0 - Step 4c-CAB LA - Week 48
- V64.0 - Step 4c-TDF/FTC - Week 0
- V65.0 - Step 4c-TDF/FTC - Week 8
- V66.0 - Step 4c-TDF/FTC - Week 16
- V67.0 - Step 4c-TDF/FTC - Week 24
- V68.0 - Step 4c-TDF/FTC - Week 32
- V69.0 - Step 4c-TDF/FTC - Week 40
- V70.0 - Step 4c-TDF/FTC - Week 48
- V71.0 - Step 5-TDF/FTC - Day 0
- V72.0 - Step 5-TDF/FTC - Week 12
- V73.0 - Step 5-TDF/FTC - Week 24
- V74.0 - Step 5-TDF/FTC - Week 36
- V75.0 - Step 5-TDF/FTC - Week 48
- V76.0 - Step 4d - Week 0
- V77.0 - Step 4d - Week 4
- V78.0 - Step 4d - Week 8
- V79.0 - Step 4d - Week 12
- V80.0 - Step 4d - Week 16
- V81.0 - Step 4d - Week 20
- V82.0 - Step 4d - Week 24
- V83.0 - Step 4d - Week 28
- V84.0 - Step 4d - Week 32
- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40

- V87.0 - Step 4d - Week 2 PP
- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP
- Delivery - OLE - V95.0
- Delivery - OLE - V96.0
- Delivery - OLE - V97.0
- Delivery - OLE - V98.0
- Delivery - OLE - V99.0
- Interim Visit
- V116.0 - Step 6-CAB LA - Week 56
- V117.0 - Step 6-CAB LA - Week 64
- V118.0 - Step 6-CAB LA - Week 72
- V119.0 - Step 4c-CAB LA - Week 80
- V120.0 - Step 4c-CAB LA - Week 88
- V121.0 - Step 4c-CAB LA - Week 96

If 'Interim Visit' is chosen, provide interim visit code. \_\_\_\_\_

First day of last menstrual period \_\_\_\_\_

Estimated date of delivery \_\_\_\_\_

- What information was used to estimate the date of delivery?
- Last menstrual period
  - Initial ultrasound <20 weeks
  - Initial ultrasound >=20 weeks
  - Physical exam
  - Conception date by assisted reproduction
  - Other

If other, specify: \_\_\_\_\_

1. - Has the participant ever been pregnant before? Yes   
No

If no, end of form.

2. - Number of full term live births ( $\geq 37$  weeks) \_\_\_\_\_

3. - Number of premature live births (less than 37 weeks) \_\_\_\_\_

4. - Number of spontaneous fetal deaths and/or still births ( $\geq 20$  weeks) \_\_\_\_\_

5. - Number of spontaneous abortions (less than 20 weeks) \_\_\_\_\_

6. - Number of therapeutic/elective abortions \_\_\_\_\_

7. - Number of ectopic pregnancies \_\_\_\_\_

8. - Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? Yes   
No

8a. - If yes, specify: \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Pill Count Enrollment**

**Generated On: 19 Jan 2023 01:09:25**

---

Record the number of pills dispensed at the Enrollment Visit.

---

Cabotegravir (active or placebo)

---

TDF/FTC (active or placebo)

---

Comments (max. 400 characters)

---

Lab Name: \_\_\_\_\_

1. - Was a sample collected for the fasting lipid profile? Yes   
No

1a. - Date of collection \_\_\_\_\_

1b. - Did the participant fast for at least 8 hours prior to blood collection? Yes   
No

If participant did not fast do not record lipid results.

Total cholesterol \_\_\_\_\_

Total cholesterol Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

Total cholesterol Adverse Event \_\_\_\_\_

Triglycerides \_\_\_\_\_

Triglycerides Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

Triglycerides Adverse Event \_\_\_\_\_

LDL \_\_\_\_\_

LDL Direct or Calculated? Direct   
Calculated

LDL Severity Grade  
Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

LDL Adverse Event \_\_\_\_\_

HDL \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Enrollment Visit

Generated On: 19 Jan 2023 01:09:25

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1 - Date of Enrollment Visit	
2 - Height	Fixed Unit: cm
3 - Weight	Fixed Unit: kg
5 - Systolic blood pressure	Fixed Unit: mmHg
6 - Diastolic blood pressure	Fixed Unit: mmHg
7 - Pulse	Fixed Unit: beats/min
8 - Did the participant consent to having blood stored and used for future testing?	Yes <input type="radio"/> No <input type="radio"/>
9 - Did the participant consent to genetic testing?	Yes <input type="radio"/> No <input type="radio"/>
10 - Did the participant consent to participating in the Contraceptive Sub-study?	Yes <input type="radio"/> No <input type="radio"/> Not applicable <input type="radio"/>
11 - Did the participant consent to participate in the Qualitative Sub-study?	Yes <input type="radio"/> No <input type="radio"/> Not applicable <input type="radio"/>
12 - Did the participant consent to participating in the Pregnancy Sub-Study?	Yes <input type="radio"/> No <input type="radio"/> Not applicable <input type="radio"/>
13 - What is the CASI ID assigned to this participant?	
14 - Did the participant complete the enrollment CASI questionnaire?	Yes <input type="radio"/> No <input type="radio"/>

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: CD4/Viral Load Results

Generated On: 19 Jan 2023 01:09:25

CD4+

Was a CD4 done?

Yes

No

Date of collection:

Absolute CD4+

Fixed Unit: cells/mm<sup>3</sup>

Or select if unable to analyze

Viral Load

Was a viral load done?

Yes

No

Date of collection:

Operator

>

<

=

HIV RNA PCR (plasma)

Fixed Unit: viral copies/mL

Detected, less than LLQ or LLD

Detected, greater than the upper limit of quantification

Target not detected

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Additional Procedures**

**Generated On: 19 Jan 2023 01:09:25**

---

Select any additional forms completed at this visit.

---

CD4/Viral Load Results	<input type="checkbox"/>
Chemistry Testing	<input type="checkbox"/>
Dried Blood Spot Storage	<input type="checkbox"/>
Fasting Lipid Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Heptatitis B Test Results	<input type="checkbox"/>
Heptatitis C Test Results	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
Liver Function Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Pill Dispensation - Step 2 and 3	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Cell Pellet Storage	<input type="checkbox"/>
Supplemental HIV Results	<input type="checkbox"/>

---

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Additional Procedures - OLE**

**Generated On: 19 Jan 2023 01:09:25**

Select any additional forms completed at this visit.

CD4/Viral Load Results	<input type="checkbox"/>
Chemistry Testing	<input type="checkbox"/>
Counseling	<input type="checkbox"/>
Dried Blood Spot Storage	<input type="checkbox"/>
Fasting Lipid Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
HIV Supplemental Results	<input type="checkbox"/>
Infant Assessment	<input type="checkbox"/>
Infant Breastmilk Feeding Assessment	<input type="checkbox"/>
Infant Specimen Collection - Plasma	<input type="checkbox"/>
Liver Function Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Plasma Storage	<input type="checkbox"/>
Pregnancy Test Results - OLE	<input type="checkbox"/>
Specimen Collection - Breast Milk	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Ultrasound - OLE	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Infant HIV Test Results	<input type="checkbox"/>
Infant Dried Blood Spot Storage	<input type="checkbox"/>
Cell Pellet Storage	<input type="checkbox"/>

1. - Date of pill count \_\_\_\_\_

2. - Did the participant return any pills at this visit? Yes

If yes, record the number of pills returned at this visit. No

2a. - Cabotegravir (active or placebo) \_\_\_\_\_

2b. - TDF/FTC (active or placebo) \_\_\_\_\_

3. - Was the participant dispensed any additional pills at this visit? Yes

If yes, record the number of pills dispensed at this visit. No

3a. - Cabotegravir (active or placebo) \_\_\_\_\_

3b. - TDF/FTC (active or placebo) \_\_\_\_\_

Comments (max. 400 characters) \_\_\_\_\_

1. - Did this pregnancy have an obtainable outcome? Yes   
No

2. - If an outcome was not obtainable, please specify why:

END OF FORM.

3. - How many pregnancy outcomes resulted from this reported pregnancy? \_\_\_\_\_

4. - Pregnancy outcome date \_\_\_\_\_

5. - Place of delivery/outcome Home   
Hospital   
Clinic   
Unknown   
Other

5a. - If other, specify: \_\_\_\_\_

6. - Pregnancy outcome Full term live birth ( $\geq 37$  weeks)   
Premature term live birth ( $< 37$  weeks)   
Stillbirth/intrauterine fetal demise ( $\geq 20$  weeks)   
Spontaneous abortion ( $< 20$  weeks)   
Ectopic pregnancy   
Therapeutic/elective abortion   
Other

6a. - If other, specify: \_\_\_\_\_

6b. - If outcome was full-term or premature live birth, select delivery method. C-section   
Standard vaginal   
Delivery method Operative vaginal

7. - Provide a brief narrative of the circumstances. \_\_\_\_\_

8. - Were there any delivery-related complications? Yes   
If yes, select all delivery related complications that apply: No   
Unknown

8a. - Intrapartum hemorrhage

8b. - Postpartum hemorrhage

8c. - Non-reassuring fetal status

8d. - Chorioamnionitis

8e. - Other

8e1. - If other, specify: \_\_\_\_\_

9. - Were there any non-delivery-related complications? Yes   
If yes, select all non-delivery related complications that apply: No

	Unknown <input type="radio"/>
9a. - Hypertensive disorders of pregnancy	<input type="checkbox"/>
9b. - Gestational diabetes	<input type="checkbox"/>
9c. - Other	<input type="checkbox"/>
9c1. - If other, specify:	
10. - Were any fetal/infant congenital anomalies identified? If yes, please select all anomalies that apply:	Yes <input type="radio"/>
	No <input type="radio"/>
	Unknown <input type="radio"/>
10a. - Central nervous system, cranio-facial	<input type="checkbox"/>
10b. - Central nervous system, spinal	<input type="checkbox"/>
10c. - Cardiovascular	<input type="checkbox"/>
10d. - Renal	<input type="checkbox"/>
10e. - Gastrointestinal	<input type="checkbox"/>
10f. - Pulmonary	<input type="checkbox"/>
10g. - Musculoskeletal/extemities	<input type="checkbox"/>
10h. - Physical defect	<input type="checkbox"/>
10i. - Skin	<input type="checkbox"/>
10j. - Genitourinary	<input type="checkbox"/>
10k. - Chromosomal	<input type="checkbox"/>
10l. - Craniofacial (structural)	<input type="checkbox"/>
10m. - Hemotologic	<input type="checkbox"/>
10n. - Infectious	<input type="checkbox"/>
10o. - Endocrine/metabolic	<input type="checkbox"/>
10p. - Other	<input type="checkbox"/>
10p1. - If Other, describe the congenital anomaly/defect:	
11. - Complete the infant items below for live births only. Otherwise, end of form.	Male <input type="radio"/>
	Female <input type="radio"/>
Infant gender	Unknown <input type="radio"/>
12. - Infant birth weight	Fixed Unit: kg
Or select if unavailable	<input type="checkbox"/>
Infant birth weight unit	Fixed Unit: kg
13. - Infant birth length	Fixed Unit: cm

Or select if unavailable	<input type="checkbox"/>
Infant birth length unit	Fixed Unit: cm
14. - Infant birth head circumference	Fixed Unit: cm
Or select if unavailable	<input type="checkbox"/>
Infant birth head circumference unit	Fixed Unit: cm
15. - Infant birth abdominal circumference	Fixed Unit: cm
Or select if unavailable	<input type="checkbox"/>
Infant birth abdominal circumference unit	Fixed Unit: cm
16. - Infant gestational age by obstetric assessment	Fixed Unit: days
Or select if unavailable	<input type="checkbox"/>
Infant gestational age by examination in Days Unit	Fixed Unit: Days
17. - Classification of the newborn by birth weight and gestational age (obstetric or by examination):	Large for gestational age (> 90%) <input type="radio"/> Appropriate for gestational age <input type="radio"/> Small for gestational age (< 10%) <input type="radio"/> Intrauterine growth retardation (< 3%) <input type="radio"/> Classification not available <input type="radio"/>
18. - Infant Apgar score at 1 minute:	
Or select if unavailable	<input type="checkbox"/>
19. - Infant Apgar score at 5 minutes:	
Or select if unavailable	<input type="checkbox"/>
20. - Infant Apgar score at 10 minutes:	
Or select if unavailable	<input type="checkbox"/>

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL  
Form: Pregnancy Outcome Log - OLE  
Generated On: 19 Jan 2023 01:09:25

1. - Date pregnancy reported \_\_\_\_\_  
1a. - Did this pregnancy have an obtainable outcome? Yes   
No

1b. - If an outcome was not obtainable, please specify why:  
END OF FORM.

2. - How many pregnancy outcomes resulted from this reported pregnancy? \_\_\_\_\_

3. - Infant PTID \_\_\_\_\_

4. - Pregnancy outcome date \_\_\_\_\_

5. - Place of delivery/outcome Home   
Hospital   
Clinic   
Unknown   
Other

5a. - If other, specify: \_\_\_\_\_

6. - Pregnancy outcome Full term live birth ( $\geq 37$  weeks)   
Premature term live birth ( $< 37$  weeks)   
Spontaneous abortion ( $< 20$  weeks)   
Ectopic pregnancy   
Therapeutic/elective abortion   
Other   
Stillbirth   
Intrauterine fetal demise ( $\geq 20$  weeks)

6a. - If Stillbirth, Intrauterine fetal demise ( $\geq 20$  weeks) or Other, specify: \_\_\_\_\_

6b. - If outcome was full-term or premature live birth, select delivery methods. C-section   
Standard vaginal   
Operative vaginal   
Delivery method \_\_\_\_\_

7. - Provide a brief narrative of the circumstances. \_\_\_\_\_

8. - Were there any delivery-related complications? Yes   
No   
Unknown

If yes, select all delivery related complications that apply:  
8a. - Intrapartum hemorrhage   
8b. - Postpartum hemorrhage   
8c. - Non-reassuring fetal status   
8d. - Chorioamnionitis   
8e. - Other

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL  
Form: Pregnancy Outcome Log - OLE  
Generated On: 19 Jan 2023 01:09:25

8e1. - If other, specify: \_\_\_\_\_

9. - Were there any non-delivery-related complications? Yes   
No   
Unknown

If yes, select all non-delivery related complications that apply:

9a. - Hypertensive disorders of pregnancy

9b. - Gestational diabetes

9c. - Other

9c1. - Other, specify \_\_\_\_\_

10. - Were any fetal/infant congenital anomalies identified? Yes   
No   
Unknown

If yes, please select all anomalies that apply:

10a. - Central nervous system, cranio-facial

10b. - Central nervous system, spinal

10c. - Cardiovascular

10d. - Renal

10e. - Gastrointestinal

10f. - Pulmonary

10g. - Musculoskeletal/extremities

10h. - Physical defect

10i. - Skin

10j. - Genitourinary

10k. - Chromosomal

10l. - Craniofacial (structural)

10m. - Hematologic

10n. - Infectious

10o. - Endocrine/metabolic

10p. - Other

10p1. - If Other, describe the congenital anomaly/defect: \_\_\_\_\_

11. - Complete the infant items below for live births only. Otherwise, end of form. Male   
Female   
Unknown

Infant gender

12. - Infant birth weight Fixed Unit: KG

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Pregnancy Outcome Log - OLE**  
**Generated On: 19 Jan 2023 01:09:25**

Or select if unavailable	<input type="checkbox"/>
Infant birth weight unit	KG
13. - Infant birth length	Fixed Unit: cm
Or select if unavailable	<input type="checkbox"/>
Infant birth length unit	cm
14. - Infant birth head circumference	Fixed Unit: cm
Or select if unavailable	<input type="checkbox"/>
Infant birth head circumference unit	cm
15. - Infant birth abdominal circumference	Fixed Unit: cm
Or select if unavailable	<input type="checkbox"/>
Infant birth abdominal circumference unit	cm
16. - Infant gestational age by obstetric assessment	Fixed Unit: days
Infant gestational age by examination in Days Unit	days
Or select if unavailable	<input type="checkbox"/>
17. - Classification of the newborn by birth weight and gestational age (obstetric or by examination):	Large for gestational age (> 90%) <input type="radio"/> Appropriate for gestational age <input type="radio"/> Small for gestational age (< 10%) <input type="radio"/> Intrauterine growth retardation (< 3%) <input type="radio"/> Classification not available <input type="radio"/>
18. - Infant Apgar score at 1 minute:	
Or select if unavailable	<input type="checkbox"/>
19. - Infant Apgar score at 5 minutes:	
Or select if unavailable	<input type="checkbox"/>
20. - Infant Apgar score at 10 minutes:	
Or select if unavailable	<input type="checkbox"/>

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Product Hold Y/N**

**Generated On: 19 Jan 2023 01:09:25**

---

Is there a product hold or discontinuation to report?

Yes

No

---

If yes, complete the Product Hold/Discontinuation Log.

---

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Product Hold Y/N-OLE**

**Generated On: 19 Jan 2023 01:09:25**

---

Is there a product hold or discontinuation to report?

Yes

No

---

Which study product is being held?

- Oral CAB   
CAB-LA injection   
TDF/FTC

Date of last oral study product or CAB injection \_\_\_\_\_

Date when this study product hold or discontinuation was initiated: \_\_\_\_\_

At what visit was this product hold/discontinuation initiated?

- V55.0 - Step 4a - Day 0   
V56.0 - Step 4b - Day 0   
V57.0 - Step 4c-CAB LA - Week 0   
V58.0 - Step 4c-CAB LA - Week 8   
V59.0 - Step 4c-CAB LA - Week 16   
V60.0 - Step 4c-CAB LA - Week 24   
V61.0 - Step 4c-CAB LA - Week 32   
V62.0 - Step 4c-CAB LA - Week 40   
V63.0 - Step 4c-CAB LA - Week 48   
V64.0 - Step 4c-TDF/FTC - Week 0   
V65.0 - Step 4c-TDF/FTC - Week 8   
V66.0 - Step 4c-TDF/FTC - Week 16   
V67.0 - Step 4c-TDF/FTC - Week 24   
V68.0 - Step 4c-TDF/FTC - Week 32   
V69.0 - Step 4c-TDF/FTC - Week 40   
V70.0 - Step 4c-TDF/FTC - Week 48   
V71.0 - Step 5-TDF/FTC - Day 0   
V72.0 - Step 5-TDF/FTC - Week 12   
V73.0 - Step 5-TDF/FTC - Week 24   
V74.0 - Step 5-TDF/FTC - Week 36   
V75.0 - Step 5-TDF/FTC - Week 48   
V76.0 - Step 4d - Week 0   
V77.0 - Step 4d - Week 4   
V78.0 - Step 4d - Week 8   
V79.0 - Step 4d - Week 12   
V80.0 - Step 4d - Week 16   
V81.0 - Step 4d - Week 20   
V82.0 - Step 4d - Week 24

- V83.0 - Step 4d - Week 28
- V84.0 - Step 4d - Week 32
- V85.0 - Step 4d - Week 36
- V86.0 - Step 4d - Week 40
- V87.0 - Step 4d - Week 2 PP
- V88.0 - Step 4d - Week 4 PP
- V89.0 - Step 4d - Week 8 PP
- V90.0 - Step 4d - Week 16 PP
- V91.0 - Step 4d - Week 24 PP
- V92.0 - Step 4d - Week 32 PP
- V93.0 - Step 4d - Week 40 PP
- V94.0 - Step 4d - Week 48 PP
- Delivery - OLE - V95.0
- Delivery - OLE - V96.0
- Delivery - OLE - V97.0
- Delivery - OLE - V98.0
- Delivery - OLE - V99.0
- Interim Visit
- V116.0 - Step 6-CAB LA - Week 56
- V117.0 - Step 6-CAB LA - Week 64
- V118.0 - Step 6-CAB LA - Week 72
- V119.0 - Step 4c-CAB LA - Week 80
- V120.0 - Step 4c-CAB LA - Week 88
- V121.0 - Step 4c-CAB LA - Week 96

Interim visit code

Why is the study product being held or discontinued?

- One or more reactive HIV test results or acute HIV infection suspected
- Reported use of prohibited concomitant medication
- Participant is currently using or planning to use PrEP or PEP (other than study product)
- Clinical AE (protocol mandated)
- Laboratory AE (protocol mandated)
- Injection site reaction
- CMC recommendation based on a clinical event
- CMC recommendation based on a laboratory value

---

	CMC recommendation based on a psychosocial concern	<input type="checkbox"/>
	Other clinical reason	<input type="checkbox"/>
	Hepatitis B infection	<input type="checkbox"/>
	Positive pregnancy test result	<input type="checkbox"/>
	Participant request - injection intolerance	<input type="checkbox"/>
	Participant request - unwilling or unable to comply with required study procedures	<input type="checkbox"/>
	Participant request - other reason	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If "Other clinical reason", "Participant request - other reason" or "Other" is selected, please specify: \_\_\_\_\_

---

If product hold was associated with an adverse event, select the applicable AE: \_\_\_\_\_

---

If product hold was associated with an injection site reaction, select the applicable ISR: \_\_\_\_\_

---

If product hold was associated with a new or updated concomitant medication, select applicable medication(s): \_\_\_\_\_

---

Complete this section only if participant has either resumed or permanently discontinued study drug.

	Yes	<input type="checkbox"/>
	No (permanently discontinued)	<input type="checkbox"/>
	No (hold continuing/permanently discontinued for another reason)	<input type="checkbox"/>

---

Has the participant resumed study product?

---

Date participant resumed study product: \_\_\_\_\_

---

Date participant permanently discontinued study product: \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Product Hold/Discontinuation Log

Generated On: 19 Jan 2023 01:09:25

1. - Date of last oral study product use: \_\_\_\_\_

2. - Date of last injection: \_\_\_\_\_

3. - Date when this study product hold or discontinuation was initiated: \_\_\_\_\_

4. - At what visit was this product hold or discontinuation initiated? \_\_\_\_\_

4a. - Interim visit code \_\_\_\_\_

5. - Why is the study product being held or discontinued?
- One or more reactive HIV test results or acute HIV infection suspected
  - Reported use of prohibited concomitant medication
  - Participant is currently using or planning to use PrEP or PEP (other than study product)
  - Clinical AE (protocol mandated)
  - Laboratory AE (protocol mandated)
  - Injection site reaction
  - Low oral adherence - Step 1
  - CMC recommendation based on a clinical event
  - CMC recommendation based on a laboratory value
  - CMC recommendation based on a psychosocial concern
  - Other clinical reason
  - Hepatitis B infection
  - Positive pregnancy test result
  - Participant request - injection intolerance
  - Participant request - unwilling or unable to comply with required study procedures
  - Participant request - other reason
  - Other
  - Participant refused long acting contraception

5a. - If "Other clinical reason", "Participant request - other reason" or "Other" is selected, please specify: \_\_\_\_\_

6. - If product hold was associated with an adverse event, select the applicable AE: \_\_\_\_\_

7. - If product hold was associated with an injection site reaction, select the applicable ISR: \_\_\_\_\_

8. - If product hold was associated with a new or updated concomitant medication, select applicable medication(s): \_\_\_\_\_

9. - Will the participant resume study product?
- Yes
  - No (permanently discontinued)
  - No (hold continuing/permanently discontinued for another reason)

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Product Hold/Discontinuation Log**  
**Generated On: 19 Jan 2023 01:09:25**

---

9a. - Date participant resumed  
study product: \_\_\_\_\_

---

---

1. - Has the participant screened for the study before? Yes   
No

1a. - If yes, record the first Rave PTID assigned. \_\_\_\_\_

2. - Date the participant marked or signed the study screening and enrollment consent form: \_\_\_\_\_

3. - Did the participant meet all eligibility criteria? Yes   
No

3a. - If no, select the Inclusion Criteria that were NOT met, if applicable. Select all that apply.

Born female

18-45 years at the time of screening

Willing and able to provide informed consent

Willing and able to undergo all required study procedures

Non-reactive HIV test results at Screening and Enrollment

Sexually active

Score of  $\geq 5$  using a modified VOICE risk score

No plans to re-locate or travel away from the site for  $> 8$  consecutive weeks during study participation

Creatinine clearance  $\geq 60$  mL/min

HBsAg negative and accepts vaccination

ALT  $< 2x$  ULN and Tbili  $\leq 2.5 x$  ULN

HCV antibody negative

Is not pregnant

If of reproductive potential, willing to use a reliable form of contraception during the study

No medical condition that, in the opinion of the IoR, would interfere with the conduct of the study

No alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study

3b. - If no, select the Exclusion Criteria that WERE met, if applicable. Select all that apply.

One or more reactive HIV test results at Screening or Enrollment

Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study

Co-enrollment in any other HIV interventional research study

Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial

- Current or chronic history of liver disease or known hepatic or biliary abnormalities
- History of seizure disorder
- Clinically significant cardiovascular disease
- Inflammatory skin conditions that compromise the safety of IM injections, per the IoR
- Has a tattoo or other dermatological condition overlying the buttock region which, in the opinion of the IoR, may interfere with interpretation of ISRs
- Coagulopathy which would contraindicate IM injection
- Active or planned use of prohibited medications
- Known or suspected allergy to study product components (active or placebo)

4. - Will the participant enroll in the study? Yes   
No

4a. - If no, why did the participant not enroll? Not eligible   
Participant declined to receive study product   
Participant changed her mind   
Unable to contact participant/no show   
Other

4a1. - If other, specify: \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Randomization**

**Generated On: 19 Jan 2023 01:09:25**

---

Please ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Please also ensure participant is NOT pregnant prior to randomization. Lastly, please double check that you are randomizing the correct person (i.e. double check the PTID) prior to clicking "Yes" and saving the form.

---

Is the participant ready to be randomized?

Yes

No

---

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**

**Form: Open Label Truvada Y/N**

**Generated On: 19 Jan 2023 01:09:25**

---

Is the participant taking open label Truvada?

Yes

No

---

If yes, complete the Open Label Truvada Log.

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Open Label Truvada Log

Generated On: 19 Jan 2023 01:09:25

Reason for starting open label Truvada

- Participant is pregnant/breastfeeding
- Participant can no longer receive study injections due to an AE
- Participant no longer wants to receive study injections in Step 2
- Other

If "Other", specify:

Date started

Date stopped

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Early Unblinding

Generated On: 19 Jan 2023 01:09:25

Was the participant unblinded early? Yes   
No

If no, end of form.

Date participant was unblinded: \_\_\_\_\_

Visit at which participant was unblinded: \_\_\_\_\_

If Interim visit, please provide interim visit number \_\_\_\_\_

Reason participant was unblinded early: Pregnancy

Emergency unblinding

DSMB directive

Other

If other, specify: \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Pill Dispensation - Step 2 and 3**  
**Generated On: 19 Jan 2023 01:09:25**

Was the participant dispensed any pills at this visit? Yes

If yes, record the number of pills dispensed at this visit. No

Date of pill dispensation \_\_\_\_\_

TDF/FTC (active or placebo) \_\_\_\_\_

Comments (max. 450 characters) \_\_\_\_\_

Was an ultrasound exam performed? If yes, go to exam date. Yes   
No

Reason ultrasound not performed. \_\_\_\_\_

End of form. \_\_\_\_\_

Exam Date \_\_\_\_\_

Estimated gestational age (at time of ultrasound): \_\_\_\_\_

Weeks \_\_\_\_\_

Days \_\_\_\_\_

If estimated gestational age is less than 14 weeks, complete crown-rump length and skip biparietal diameter and femur length. If estimated gestational age is greater than or equal to 14 0/7 weeks, skip crown-rump length and complete biparietal diameter and femur length.

Crown-rump length \_\_\_\_\_ Fixed Unit: cm

Biparietal diameter \_\_\_\_\_ Fixed Unit: cm

Femur length \_\_\_\_\_ Fixed Unit: cm

OR Not Done

Comments (max. 450 characters) \_\_\_\_\_

Anatomical Data

Intracranial

Face/Lip

Spine

Thorax

Four-chamber heart

Stomach

Kidneys

Bladder (urinary)

Cord insertion

Upper limbs

Lower limbs

Gender

Amniotic fluid

Result

Not visualized

Normal

Abnormal

If abnormal, please describe \_\_\_\_\_

Anatomical Data

Intracranial

Face/Lip

Spine

Thorax

---

	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input type="checkbox"/>
	Bladder (urinary)	<input type="checkbox"/>
	Cord insertion	<input type="checkbox"/>
	Upper limbs	<input type="checkbox"/>
	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input type="checkbox"/>

---

Result	Not visualized	<input type="checkbox"/>
	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

If abnormal, please describe \_\_\_\_\_

---

---

Anatomical Data	Intracranial	<input type="checkbox"/>
	Face/Lip	<input type="checkbox"/>
	Spine	<input checked="" type="checkbox"/>
	Thorax	<input type="checkbox"/>
	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input type="checkbox"/>
	Bladder (urinary)	<input type="checkbox"/>
	Cord insertion	<input type="checkbox"/>
	Upper limbs	<input type="checkbox"/>
	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input type="checkbox"/>

---

Result	Not visualized	<input type="checkbox"/>
	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

If abnormal, please describe \_\_\_\_\_

---

---

Anatomical Data	Intracranial	<input type="checkbox"/>
	Face/Lip	<input type="checkbox"/>
	Spine	<input type="checkbox"/>
	Thorax	<input checked="" type="checkbox"/>
	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input type="checkbox"/>

---

	Bladder (urinary)	<input type="radio"/>
	Cord insertion	<input type="radio"/>
	Upper limbs	<input type="radio"/>
	Lower limbs	<input type="radio"/>
	Gender	<input type="radio"/>
	Amniotic fluid	<input type="radio"/>

---

Result	Not visualized	<input type="radio"/>
	Normal	<input type="radio"/>
	Abnormal	<input type="radio"/>

---

If abnormal, please describe \_\_\_\_\_

---

Anatomical Data	Intracranial	<input type="radio"/>
	Face/Lip	<input type="radio"/>
	Spine	<input type="radio"/>
	Thorax	<input type="radio"/>
	Four-chamber heart	<input checked="" type="radio"/>
	Stomach	<input type="radio"/>
	Kidneys	<input type="radio"/>
	Bladder (urinary)	<input type="radio"/>
	Cord insertion	<input type="radio"/>
	Upper limbs	<input type="radio"/>
	Lower limbs	<input type="radio"/>
	Gender	<input type="radio"/>
	Amniotic fluid	<input type="radio"/>

---

Result	Not visualized	<input type="radio"/>
	Normal	<input type="radio"/>
	Abnormal	<input type="radio"/>

---

If abnormal, please describe \_\_\_\_\_

---

Anatomical Data	Intracranial	<input type="radio"/>
	Face/Lip	<input type="radio"/>
	Spine	<input type="radio"/>
	Thorax	<input type="radio"/>
	Four-chamber heart	<input type="radio"/>
	Stomach	<input checked="" type="radio"/>
	Kidneys	<input type="radio"/>
	Bladder (urinary)	<input type="radio"/>
	Cord insertion	<input type="radio"/>
	Upper limbs	<input type="radio"/>

---

	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input type="checkbox"/>
Result	Not visualized	<input type="checkbox"/>
	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

If abnormal, please describe \_\_\_\_\_

---

Anatomical Data	Intracranial	<input type="checkbox"/>
	Face/Lip	<input type="checkbox"/>
	Spine	<input type="checkbox"/>
	Thorax	<input type="checkbox"/>
	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input checked="" type="checkbox"/>
	Bladder (urinary)	<input type="checkbox"/>
	Cord insertion	<input type="checkbox"/>
	Upper limbs	<input type="checkbox"/>
	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input type="checkbox"/>

---

Result	Not visualized	<input type="checkbox"/>
	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

If abnormal, please describe \_\_\_\_\_

---

Anatomical Data	Intracranial	<input type="checkbox"/>
	Face/Lip	<input type="checkbox"/>
	Spine	<input type="checkbox"/>
	Thorax	<input type="checkbox"/>
	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input type="checkbox"/>
	Bladder (urinary)	<input checked="" type="checkbox"/>
	Cord insertion	<input type="checkbox"/>
	Upper limbs	<input type="checkbox"/>
	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input type="checkbox"/>

---

Result	Not visualized <input type="radio"/>
	Normal <input type="radio"/>
	Abnormal <input type="radio"/>

---

If abnormal, please describe \_\_\_\_\_

---

---

Anatomical Data	Intracranial <input type="radio"/>
	Face/Lip <input type="radio"/>
	Spine <input type="radio"/>
	Thorax <input type="radio"/>
	Four-chamber heart <input type="radio"/>
	Stomach <input type="radio"/>
	Kidneys <input type="radio"/>
	Bladder (urinary) <input type="radio"/>
	Cord insertion <input checked="" type="radio"/>
	Upper limbs <input type="radio"/>
	Lower limbs <input type="radio"/>
	Gender <input type="radio"/>
	Amniotic fluid <input type="radio"/>

---

Result	Not visualized <input type="radio"/>
	Normal <input type="radio"/>
	Abnormal <input type="radio"/>

---

If abnormal, please describe \_\_\_\_\_

---

---

Anatomical Data	Intracranial <input type="radio"/>
	Face/Lip <input type="radio"/>
	Spine <input type="radio"/>
	Thorax <input type="radio"/>
	Four-chamber heart <input type="radio"/>
	Stomach <input type="radio"/>
	Kidneys <input type="radio"/>
	Bladder (urinary) <input type="radio"/>
	Cord insertion <input type="radio"/>
	Upper limbs <input checked="" type="radio"/>
	Lower limbs <input type="radio"/>
	Gender <input type="radio"/>
	Amniotic fluid <input type="radio"/>

---

Result	Not visualized <input type="radio"/>
	Normal <input type="radio"/>
	Abnormal <input type="radio"/>

---

If abnormal, please describe

Anatomical Data

- Intracranial
- Face/Lip
- Spine
- Thorax
- Four-chamber heart
- Stomach
- Kidneys
- Bladder (urinary)
- Cord insertion
- Upper limbs
- Lower limbs
- Gender
- Amniotic fluid

Result

- Not visualized
- Normal
- Abnormal

If abnormal, please describe

Anatomical Data

- Intracranial
- Face/Lip
- Spine
- Thorax
- Four-chamber heart
- Stomach
- Kidneys
- Bladder (urinary)
- Cord insertion
- Upper limbs
- Lower limbs
- Gender
- Amniotic fluid

Result

- Not visualized
- Normal
- Abnormal

If abnormal, please describe

Anatomical Data

- Intracranial
- Face/Lip

---

	Spine	<input type="checkbox"/>
	Thorax	<input type="checkbox"/>
	Four-chamber heart	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Kidneys	<input type="checkbox"/>
	Bladder (urinary)	<input type="checkbox"/>
	Cord insertion	<input type="checkbox"/>
	Upper limbs	<input type="checkbox"/>
	Lower limbs	<input type="checkbox"/>
	Gender	<input type="checkbox"/>
	Amniotic fluid	<input checked="" type="checkbox"/>

---

Result	Not visualized	<input type="checkbox"/>
	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

If abnormal, please describe \_\_\_\_\_

---

1. - Was an ultrasound exam performed? If yes, go to exam date. Yes   
No

1a. - Reason ultrasound not performed. \_\_\_\_\_

2 - Exam Date \_\_\_\_\_

3. - Number of fetuses observed on ultrasound \_\_\_\_\_

4. - Estimated gestational age (at time of ultrasound) - Weeks \_\_\_\_\_

5. - Estimated gestational age (at time of ultrasound) - Days \_\_\_\_\_

6. - If estimated gestational age is less than 14 weeks, complete crown-rump length and skip biparietal diameter and femur length (Mark "Or Not done/not collected") . If estimated gestational age is greater than or equal to 14 0/7 weeks, skip crown-rump length (Mark "Or Not done/not collected") and complete biparietal diameter and femur length. Fixed Unit: cm

Crown-rump length

\_\_\_\_\_ Or Not done/not collected

7. - Biparietal diameter Fixed Unit: cm

\_\_\_\_\_ Or Not done/not collected

8. - Femur length Fixed Unit: cm

\_\_\_\_\_ Or Not done/not collected

9. - Intracranial Result Not visualized   
Normal   
Abnormal

\_\_\_\_\_ If abnormal, please describe \_\_\_\_\_

10. - Face/Lip Result Not visualized   
Normal   
Abnormal

\_\_\_\_\_ If abnormal, please describe \_\_\_\_\_

11. - Spine Result Not visualized   
Normal   
Abnormal

\_\_\_\_\_ If abnormal, please describe \_\_\_\_\_

12. - Thorax Result Not visualized   
Normal   
Abnormal

\_\_\_\_\_ If abnormal, please describe \_\_\_\_\_

13. - Four-chamber heart Result Not visualized

---

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

14. - Stomach Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

15. - Kidneys Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

16. - Bladder (urinary) Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

17. - Cord insertion Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

18. - Upper limbs Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

19. - Lower limbs Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

20. - Gender Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

21. - Amniotic fluid Result

Not visualized

Normal

Abnormal

---

If abnormal, please describe \_\_\_\_\_

---

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Cell Pellet Storage

Generated On: 19 Jan 2023 01:09:25

Was a cell pellet collected for storage? Yes   
No

If no, record reason why sample was not collected. \_\_\_\_\_

Specimen collection date \_\_\_\_\_

Time cell pellet collected \_\_\_\_\_

Was cell pellet stored? Stored   
Not Stored

If no, record reason why sample was not stored. \_\_\_\_\_

Form Name \_\_\_\_\_

Event Name \_\_\_\_\_

The below fields should be updated for Adverse Event or Injection site reaction forms only Yes   
No

Is the AE / reaction still ongoing? \_\_\_\_\_

Outcome Date \_\_\_\_\_

Status/Outcome Recovered/resolved   
Recovering/resolving   
Resolved with sequelae   
Not recovered/resolved   
Fatal

Action Taken with Study Product Dose not changed   
Dose reduced   
Dose increased   
Dose withdrawn   
Dose interrupted   
Not applicable

The below fields should be updated for Concomitant Medications form only

Date Stopped \_\_\_\_\_  
Or Ongoing

The below fields should be updated for Product Hold/Discontinuation form only Yes   
No (permanently discontinued)   
No (hold continuing/permanently discontinued for another reason)

Will the participant resume study product? \_\_\_\_\_  
Date participant resumed study product: \_\_\_\_\_

The below fields should be updated for Open Label Truvada form only

Date Stopped \_\_\_\_\_

HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL

Form: Long Term Consent Update

Generated On: 19 Jan 2023 01:09:25

---

Did the participant change their long term consent since enrollment? Yes

No

---

If Yes, indicate the current response for each of the below questions:

Did the participant consent to having blood stored and used for future testing? Yes

No

---

Date consent updated \_\_\_\_\_

Did the participant consent to genetic testing? Yes

No

---

Date consent updated \_\_\_\_\_

Infant PTID \_\_\_\_\_

HIV RNA PCR Yes

No

Was HIV RNA PCR testing completed? \_\_\_\_\_

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

Date of collection \_\_\_\_\_

Operator >

<

=

HIV RNA PCR (plasma) Fixed Unit: viral copies/mL

Target not detected

Detected, less than the lower limit of quantification

Detected, above the upper limit of quantification

HIV DNA PCR Yes

No

Was HIV DNA PCR testing completed? \_\_\_\_\_

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

Date of collection \_\_\_\_\_

HIV DNA PCR Result Negative/non-reactive

Positive/reactive

Equivocal/Indeterminate

Final HIV status Negative

Positive

Final HIV status Additional testing needed

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Infant Dried Blood Spot Storage**  
**Generated On: 19 Jan 2023 01:09:25**

Infant PTID \_\_\_\_\_

Was a dried blood spot collected? Yes

No

If no, record reason why sample was not collected. \_\_\_\_\_

Specimen collection date \_\_\_\_\_

Time dried blood spot collected \_\_\_\_\_

Was dried blood spot stored? Stored

Not Stored

If no, record reason why sample was not stored. \_\_\_\_\_

**HPTN084\_Version\_23.0\_PROD\_CE\_13JAN2023: ALL**  
**Form: Informed Consent - Version 4.0**  
**Generated On: 19 Jan 2023 01:09:25**

---

Did the participant consent for Protocol Version 4.0?

Yes

No

---

If Yes, Date of Informed Consent \_\_\_\_\_

---