

Subject Case Report Forms

HPTN084_Version_21.1_AUX_EC_19MAY2022 - 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

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Date of Visit - Step 2

Generated On: 21 Jun 2022 23:43:45

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

1. - Did the participant complete this visit? Yes

No

1a. - Visit Date _____

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

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

After pregnancy confirmed

Both

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Date of Visit - Pregnancy OLE

Generated On: 21 Jun 2022 23:43:45

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 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 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

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

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Date of Visit - Open Label Truvada

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Date of Visit - OLE

Generated On: 21 Jun 2022 23:43:45

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
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)
TDF/FTC (Step 4c)

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Date of Visit - OLE

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TDF/FTC (Step 5)

Pregnancy and Infant Sub-Study

HPTN084_Version_21.1_AUX_EC_19MAY2022: 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.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Adverse Event Y/N

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Has the participant experienced an Adverse Event during the study?

Yes

No

If yes, complete the Adverse Event Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Adverse Event - Infant Y/N

Generated On: 21 Jun 2022 23:43:45

Has the infant experienced an Adverse Event during the study?

Yes

No

If yes, complete the Adverse Event - Infant Log.

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

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Counseling

Generated On: 21 Jun 2022 23:43:45

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

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
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- 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
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- V 114 Pregnancy 2 - Week 168
- V 115 Pregnancy 2 - Week 180
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- 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
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 - V 105 Pregnancy 1 - Week 60
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- 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 _____

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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
-

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
-

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
-

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
-

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
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- 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
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- V25.0 - Step 2 Week 129
- V26.0 - Step 2 Week 137
- V27.0 - Step 2 Week 145
- V28.0 - Step 2 Week 153
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- 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
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- V 112 Pregnancy 1 - Week 144
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- 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
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- V 106 Pregnancy 2 - Week 72
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- 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
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- 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
-

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: 21 Jun 2022 23:43:45

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
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 - 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
-

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: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Consent - Pregnancy Infant Sub-study
Generated On: 21 Jun 2022 23:43:45

For which OLE regimen did the participant consent during pregnancy?	CAB LA <input type="radio"/>
	TDF/FTC <input type="radio"/>
	None <input type="radio"/>

Did the participant consent to having her sample collected during pregnancy?	Yes <input type="radio"/>
	No <input type="radio"/>

If yes, did the participant consent to having her sample stored for future testing during pregnancy?	Yes <input type="radio"/>
	No <input type="radio"/>

Did the participant consent to having her infant's sample collected after pregnancy?	Yes <input type="radio"/>
	No <input type="radio"/>

If yes, did the participant consent to having her infant's sample stored for future testing during pregnancy?	Yes <input type="radio"/>
	No <input type="radio"/>

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_21.1_AUX_EC_19MAY2022: ALL

Form: Hematology

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Injection Administration

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Infant Breastmilk Feeding Assessment
Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: HIV Test Results Y/N

Generated On: 21 Jun 2022 23:43:45

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)
4th Generation Abbott tests (non-FDA approved)
Alere Determine (3rd generation)

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)
4th Generation Abbott tests (non-FDA approved)
Alere Determine (3rd generation)

5. - HIV EIA or CMIA Non-reactive/Negative
Reactive/Positive
Not Done

6. - HIV-1 RNA Qualitative Non-reactive/Negative
Reactive/Positive
Not Done

7. - Was a viral load done? Yes
No

8. - Date of collection _____

9. - Operator _____ >
<
=

10. - HIV RNA PCR (plasma) Fixed Unit: viral copies/mL

10a. - Target not detected

10b. - Detected, under lower limit of quantification

10c. - Detected, greater than the upper limit of quantification

11. - Final HIV status Negative
Positive
Additional testing needed

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 _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Plasma Storage

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Plasma Storage- Contraceptive Sub-study
Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Pregnancy Test Results

Generated On: 21 Jun 2022 23:43:45

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 second independent sample on same day? Yes
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 Infant Sub-Study? Yes
No

8. - Select if additional pregnancy test results form is required.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Dried Blood Spot Storage

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: STI Test Results

Generated On: 21 Jun 2022 23:43:45

Or select if not done



HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Infant Assessment

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Infant Assessment

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Sub-study Infant PTID

Generated On: 21 Jun 2022 23:43:45

Is this PTID for an Infant?

Yes

No

If Yes, what is the associated Mother's PTID

Form: Adverse Event

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Adverse Event

Generated On: 21 Jun 2022 23:43:45

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	_____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Adverse Event - Infant

Generated On: 21 Jun 2022 23:43:45

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
- Interim Visit

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

Early study closure

Other, specify

3. - Date of death _____

4. - Specify _____

5. - Was termination associated with an Adverse Event? Yes

No

5a. - If yes, please specify AE _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Concomitant Medications Y/N

Generated On: 21 Jun 2022 23:43:45

Were any concomitant medications taken?

Yes

No

If yes, complete the Concomitant Medications Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Concomitant Medications

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Specimen Storage - Contraceptive Sub-Study
Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Specimen Collection - Breast Milk

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Infant Specimen Collection - Cord Blood
Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Infant Specimen Collection - Blood (Plasma)
Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Social Impact Y/N

Generated On: 21 Jun 2022 23:43:45

Has the participant reported a social impact during the study?

Yes

No

If yes, complete the Social Impact Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Screening Liver Function Tests

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Screening Chemistries

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Hepatitis B Test Results

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Hepatitis C Test Results

Generated On: 21 Jun 2022 23:43:45

Anti-Hepatitis C Antibody (anti-HCV)

Positive/Reactive
Negative/Non-reactive
Not Done

Specimen collection date _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: xxRandomization

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Injection Site Reaction Y/N

Generated On: 21 Jun 2022 23:43:45

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

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

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 _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Protocol Deviation Log

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Protocol Deviation Log Y/N

Generated On: 21 Jun 2022 23:43:45

Have any protocol deviations occurred?

Yes

No

If yes, complete the Protocol Deviation Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Product Choice - OLE

Generated On: 21 Jun 2022 23:43:45

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 _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Product Choice - OLE

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Participant Transfer

Generated On: 21 Jun 2022 23:43:45

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="checkbox"/>
	Blantyre	<input type="checkbox"/>
	Cape Town - Emavundleni	<input type="checkbox"/>
	Desmond Tutu TB Centre	<input type="checkbox"/>
	Durban - Botha's Hill	<input type="checkbox"/>
	Durban - Isipingo	<input type="checkbox"/>
	Durban - Verulam	<input type="checkbox"/>
	Gabarone	<input type="checkbox"/>
	Harare - Parirenyatwa	<input type="checkbox"/>
	Harare - Seke South	<input type="checkbox"/>
	Harare - Spilhaus	<input type="checkbox"/>
	Johannesburg - Ward 21	<input type="checkbox"/>
	Kisumu	<input type="checkbox"/>
	Lilongwe	<input type="checkbox"/>
	Makerere, Kampala, Uganda	<input type="checkbox"/>
	St. Mary's Clinic	<input type="checkbox"/>
	Soweto HPTN CRS	<input type="checkbox"/>
	Swaziland Prevention	<input type="checkbox"/>
	UVRI-IAVI	<input type="checkbox"/>
	Zengeza Clinic	<input type="checkbox"/>

Name of transferring study site	Baylor Uganda	<input type="checkbox"/>
	Blantyre	<input type="checkbox"/>
	Cape Town - Emavundleni	<input type="checkbox"/>
	Desmond Tutu TB Centre	<input type="checkbox"/>
	Durban - Botha's Hill	<input type="checkbox"/>
	Durban - Isipingo	<input type="checkbox"/>
	Durban - Verulam	<input type="checkbox"/>
	Gabarone	<input type="checkbox"/>
	Harare - Parirenyatwa	<input type="checkbox"/>
	Harare - Seke South	<input type="checkbox"/>
	Harare - Spilhaus	<input type="checkbox"/>
	Johannesburg - Ward 21	<input type="checkbox"/>
	Kisumu	<input type="checkbox"/>
	Lilongwe	<input type="checkbox"/>
	Makerere, Kampala, Uganda	<input type="checkbox"/>
	St. Mary's Clinic	<input type="checkbox"/>
	Soweto HPTN CRS	<input type="checkbox"/>
	Swaziland Prevention	<input type="checkbox"/>

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Participant Receipt

Generated On: 21 Jun 2022 23:43:45

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: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Medical History Y/N

Generated On: 21 Jun 2022 23:43:45

Does the participant have any medical history to report?

Yes

No

If yes, complete the Medical History Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Interim Visit

Generated On: 21 Jun 2022 23:43:45

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

No

6. - Is the participant moving to a new visit schedule? Yes

No

If yes, please indicate which step or visit schedule. Pregnancy visit schedule

Seroconverter visit schedule

Step 3

Open label Truvada schedule

Yearly visit schedule

Mark all forms completed at this visit.

AE Log

CD4/VL Results

Chemistry Testing

Counseling

Dried Blood Spot Storage

Fasting Lipid Test Results

Hematology

Hepatitis B Test Results

Hepatitis C Test Results

HIV Test Results

Injection Administration

Liver Function Test Results

Participant Receipt

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Interim Visit

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Interim Visit - OLE

Generated On: 21 Jun 2022 23:43:45

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. - 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 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/>
9. - Did the product get held/discontinued at this visit?	Product Hold <input type="radio"/> Product Discontinued <input type="radio"/> No <input type="radio"/>
10. - Did the participant exit/terminate the study at this visit?	Yes <input type="radio"/> No <input type="radio"/>
11. - Is the participant moving to a new step or visit schedule?	Yes <input type="radio"/> No <input type="radio"/>
11a. - If yes, please indicate which step or visit schedule.	Oral CAB (Step 4a) <input type="radio"/> Loading Dose (4-week interval) <input type="radio"/> CAB-LA (Step 4b) <input type="radio"/> TDF/FTC (Step 4c) <input type="radio"/> TDF/FTC (Step 5) <input type="radio"/> Pregnancy and Infant Sub-Study <input type="radio"/>

Mark all forms completed at this visit.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Interim Visit - OLE

Generated On: 21 Jun 2022 23:43:45

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"/>

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Whole Blood Storage

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: VOICE Risk Score - Modified

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Study Step

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Step Y/N

Generated On: 21 Jun 2022 23:43:45

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

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
- Interim Visit

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 (≥ 37 weeks) _____

3. - Number of premature live births (less than 37 weeks) _____

4. - Number of spontaneous fetal deaths and/or still births (≥ 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_21.1_AUX_EC_19MAY2022: ALL

Form: Pill Count Enrollment

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Enrollment Visit

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: CD4/Viral Load Results

Generated On: 21 Jun 2022 23:43:45

CD4+

Was a CD4 done?

Yes

No

Date of collection:

Absolute CD4+

Fixed Unit: cells/mm³

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_21.1_AUX_EC_19MAY2022: ALL

Form: Additional Procedures

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Additional Procedures - OLE

Generated On: 21 Jun 2022 23:43:45

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"/>

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 (≥ 37 weeks)
Premature term live birth (< 37 weeks)
Stillbirth/intrauterine fetal demise (≥ 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="checkbox"/>
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="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
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="checkbox"/>
	Female <input type="checkbox"/>
Infant gender	Unknown <input type="checkbox"/>
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_21.1_AUX_EC_19MAY2022: ALL
Form: Pregnancy Outcome Log - OLE
Generated On: 21 Jun 2022 23:43:45

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 (≥ 37 weeks)
Premature term live birth (< 37 weeks)
Spontaneous abortion (< 20 weeks)
Ectopic pregnancy
Therapeutic/elective abortion
Other
Stillbirth
Intrauterine fetal demise (≥ 20 weeks)

6a. - If Stillbirth, Intrauterine fetal demise (≥ 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_21.1_AUX_EC_19MAY2022: ALL
Form: Pregnancy Outcome Log - OLE
Generated On: 21 Jun 2022 23:43:45

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

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_21.1_AUX_EC_19MAY2022: ALL

Form: Product Hold Y/N

Generated On: 21 Jun 2022 23:43:45

Is there a product hold or discontinuation to report?

Yes

No

If yes, complete the Product Hold/Discontinuation Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Product Hold Y/N-OLE

Generated On: 21 Jun 2022 23:43:45

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
- Interim Visit

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
- 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

If "Other clinical reason", "Participant request - other reason" or "Other" is selected, please specify:

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Product Hold/Discontinuation-OLE

Generated On: 21 Jun 2022 23:43:45

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

No (permanently discontinued)

No (hold continuing/permanently discontinued for another reason)

Has the participant resumed study product? _____

Date participant resumed study product: _____

Date participant permanently discontinued study product: _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Product Hold/Discontinuation Log

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Product Hold/Discontinuation Log
Generated On: 21 Jun 2022 23:43:45

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 ≥ 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 ≥ 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_21.1_AUX_EC_19MAY2022: ALL

Form: Randomization

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Open Label Truvada Y/N

Generated On: 21 Jun 2022 23:43:45

Is the participant taking open label Truvada?

Yes

No

If yes, complete the Open Label Truvada Log.

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Open Label Truvada Log

Generated On: 21 Jun 2022 23:43:45

Reason for starting open label Truvada	Participant is pregnant/breastfeeding <input type="checkbox"/>
	Participant can no longer receive study injections due to an AE <input type="checkbox"/>
	Participant no longer wants to receive study injections in Step 2 <input type="checkbox"/>
	Other <input type="checkbox"/>

If "Other", specify:	_____
Date started	_____
Date stopped	_____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Early Unblinding

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Pill Dispensation - Step 2 and 3
Generated On: 21 Jun 2022 23:43:45

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) _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Ultrasound Results

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL

Form: Cell Pellet Storage

Generated On: 21 Jun 2022 23:43:45

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. _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Log Revisions

Generated On: 21 Jun 2022 23:43:45

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)

Will the participant resume study product? No (hold

continuing/permanently discontinued for another reason)

Date participant resumed study product: _____

The below fields should be updated for Open Label Truvada form only

Date Stopped _____

HPTN084_Version_21.1_AUX_EC_19MAY2022: ALL

Form: Long Term Consent Update

Generated On: 21 Jun 2022 23:43:45

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_21.1_AUX_EC_19MAY2022: ALL
Form: Infant Dried Blood Spot Storage
Generated On: 21 Jun 2022 23:43:45

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. _____