HPTN 084 - Open Label Extension Questionnaire

<div style="border:1px solid">1%</div>

Collection: LOGIN
Contains: PTID, CASIID, VISIT, PREGNANT

HPTN 084 - Open Label Extension Questionnaire

Question: PTID
Required

Please enter the participant's 9-digit PTID with no hyphens or spaces (for example: 999000111):

Question: CASIID
Required

Please enter the 5-7 digit CASI ID assigned to this participant (for example EX001):

Question: VISIT
Required

Scale Summary		
Code	Label	Show-If
55.0	V55.0 - Step 4a - Day 0	
56.0	V56.0 - Step 4b - Day 0	
57.0	V57.0 - Step 4c-CAB LA - Week 0	
58.0	V58.0 - Step 4c-CAB LA - Week 8	
59.0	V59.0 - Step 4c-CAB LA - Week 16	
60.0	V60.0 - Step 4c-CAB LA - Week 24	
61.0	V61.0 - Step 4c-CAB LA - Week 32	
62.0	V62.0 - Step 4c-CAB LA - Week 40	
63.0	V63.0 - Step 4c-CAB LA - Week 48	
64.0	V64.0 - Step 4c-TDF/FTC - Week 0	
65.0	V65.0 - Step 4c-TDF/FTC - Week 8	
66.0	V66.0 - Step 4c-TDF/FTC - Week 16	
67.0	V67.0 - Step 4c-TDF/FTC - Week 24	
68.0	V68.0 - Step 4c-TDF/FTC - Week 32	
69.0	V69.0 - Step 4c-TDF/FTC - Week 40	
70.0	V70.0 - Step 4c-TDF/FTC - Week 48	
71.0	V71.0 - Step 5-TDF/FTC - Day 0	

72.0	V72.0 - Step 5-TDF/FTC - Week 12	
73.0	V73.0 - Step 5-TDF/FTC - Week 24	
74.0	V74.0 - Step 5-TDF/FTC - Week 36	
75.0	V75.0 - Step 5-TDF/FTC - Week 48	
76.0	V76.0 - Step 4d - Week 0	
77.0	V77.0 - Step 4d - Week 4	
78.0	V78.0 - Step 4d - Week 8	
79.0	V79.0 - Step 4d - Week 12	
80.0	V80.0 - Step 4d - Week 16	
81.0	V81.0 - Step 4d - Week 20	
82.0	V82.0 - Step 4d - Week 24	
83.0	V83.0 - Step 4d - Week 28	
84.0	V84.0 - Step 4d - Week 32	
85.0	V85.0 - Step 4d - Week 36	
86.0	V86.0 - Step 4d - Week 40	
87.0	V87.0 - Step 4d - Week 2 PP	
88.0	V88.0 - Step 4d - Week 4 PP	
89.0	V89.0 - Step 4d - Week 8 PP	
90.0	V90.0 - Step 4d - Week 16 PP	
91.0	V91.0 - Step 4d - Week 24 PP	
92.0	V92.0 - Step 4d - Week 32 PP	
93.0	V93.0 - Step 4d - Week 44 PP	
94.0	V94.0 - Step 4d - Week 48 PP	

What visit is this?

Please select the visit from the drop down menu.

-- Select One -- ▾

Question: PREGNANT
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	

Is participant currently pregnant?

○ Yes

○ No

Collection: SITE_STAFF_QUESTIONS
Contains: LANGUAGE, COMPLETEDBY, FRSTVIS, PRODSW, OLE_QORRES29, STDYEXV

Question: LANGUAGE
Required

Scale Summary		
Code	Label	Show-If
1033	English	
1106	Shona	
2098	Setswana	
1134	Luganda	
1077	Zulu	
1076	Xhosa	
1089	Swahili	
1108	Luo	
1116	Chichewa	
1078	Afrikaans	
1072	Sotho	
1053	Siswati	

Language:
- ◉ English
- ◯ Shona
- ◯ Setswana
- ◯ Luganda
- ◯ Zulu
- ◯ Xhosa
- ◯ Swahili
- ◯ Luo
- ◯ Chichewa
- ◯ Afrikaans
- ◯ Sotho
- ◯ Siswati

Question: COMPLETEDBY
Required

Scale Summary		
Code	Label	Show-If
1	Participant is completing questionnaire	
2	Interviewer is administering questionnaire	

Is this questionnaire being completed by the participant directly or is an interviewer from the site staff reading the questionnaire to the participant and entering participant's responses?
- ◯ Participant is completing questionnaire
- ◯ Interviewer is administering questionnaire

Auto Page Break

Question: FRSTVIS
Required
Show if: (VISIT = 55.0:[V55.0 - Step 4a - Day 0]) or (VISIT = 56.0:[V56.0 - Step 4b - Day 0]) or (VISIT = 57.0:[V57.0 - Step 4c-CAB LA - Week 0]) or (VISIT = 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0]) or (VISIT = 71.0:[V71.0 - Step 5-TDF/FTC - Day 0]) or (VISIT = 76.0:[V76.0 - Step 4d - Week 0])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	

Is this the first visit (transition) in Open label extenstion part of the study.

○ Yes
○ No

Question: PRODSW
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	

Did the participant switch study product at this visit?

○ Yes
○ No

Question: OLE_QORRES29
Required

Scale Summary		
Code	Label	Show-If
1	CAB	
2	TDF/FTC	
3	None	

Which study product is the participant is taking at this visit?

○ CAB
○ TDF/FTC
○ None

Question: STDYEXV
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	

Is this study exit visit?

○ Yes
○ No

Page Break

- -

| **Collection:** INTRODUCTION |
| **Contains:** |

Thank you for joining this study. The following survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about behavior that you may consider to be private or confidential. We are asking these questions because your answers could help us to understand whether the study product could help to slow the spread of HIV in your community. The information you provide is an important contribution to this study and will be kept confidential.

You can skip any question that makes you feel uncomfortable or stop taking the survey at any time.

Page Break

Some questions will ask you about your behavior during a specific time period (for example, "in the past month"). Please pay close attention to the time period and only tell us about your behavior during that specific time.

Please do not use the browser back button to move through this survey as it may cause your answers to be lost. Only use the survey "Previous" and "Next" buttons at the bottom of each page to move through the survey.

If you have questions or need assistance, please let a member of the study staff know.

Page Break

Collection: PRODUCT_CHOICE
Contains: ATT_TOWARD_PREP_FU, C1

Collection: ATT_TOWARD_PREP_FU
Contains: INJLIKES, INJCONCERN, INJCHANGE, INCONVINJ, DISCMFINJ, ORALLIKES, ORALCONCRN, INCONVORAL, DISCMFORAL, OLE_QORRES1, OLE_QORRES2, OLE_QORRES3, OLE_QORRES4, OLE_QORRES5, OLE_QORRES6, OLE_QORRES7, OLE_QORRES8
Show if: (FRSTVIS = 1:[Yes]) and (PRODSW = 1:[Yes])

Question: INJLIKES
Minimum checks: 1
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0: [V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36]) and (OLE_QORRES29 = 1:[CAB]))

▶ What did/do you like about an injectable method? *Mark all that apply.*

- ☐ Nothing
- ☐ May protect against HIV
- ☐ Easier to use than other methods (i.e., don't have to remember to take pills; easier than condoms)
- ☐ May provide longer-term protection than other methods
- ☐ Can be used discreetly, without a partner's knowledge
- ☐ Is administered by a healthcare provider
- ☐ Does not interrupt sex
- ☐ Other, specify: [_____]
- ☐ Prefer not to answer

Page Break

Question: INJCONCERN
Minimum checks: 1

What concerns do you have about an injectable HIV prevention method? *Mark all that apply.*

- ☐ None
- ☐ May not protect against HIV
- ☐ May be painful
- ☐ May cause harmful side effects
- ☐ Once injected, it cannot be reversed immediately
- ☐ Cannot be used discreetly, without a partner's knowledge
- ☐ Cost may be unaffordable
- ☐ Other, specify: [_____]
- ☐ Prefer not to answer

Page Break

Question: INJCHANGE
Minimum checks: 1

If it were possible to change the way the injectable was given, what kind of changes would you recommend? *Mark all that apply.*

☐ None
☐ Reduce the volume of injectable
☐ Increase the duration of protection offered by the injectable (i.e., make it work for longer period of time)
☐ Receive the injection in the arm, instead of the buttock (bum)
☐ Receive the injection in the thigh, instead of buttock (bum)
☐ Other, specify: _____
☐ Prefer not to answer

Page Break

On a scale of 0 to 6, where 0 is none of the time and 6 is all of the time, please rate your responses to these questions.

Question: INCONVINJ
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0:[V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36] or 86.0:[V86.0 - Step 4d - Week 40] or 87.0:[V87.0 - Step 4d - Week 2 PP] or 88.0:[V88.0 - Step 4d - Week 4 PP] or 89.0:[V89.0 - Step 4d - Week 8 PP] or 90.0:[V90.0 - Step 4d - Week 16 PP] or 91.0:[V91.0 - Step 4d - Week 24 PP] or 92.0:[V92.0 - Step 4d - Week 32 PP] or 93.0:[V93.0 - Step 4d - Week 44 PP] or 94.0:[V94.0 - Step 4d - Week 48 PP]) and (OLE_QORRES29 = 1:[CAB]))

Scale Summary		
Code	Label	Show-If
0	None of the time 0	
1	1	
2	2	
3	Half of the time 3	
4	4	
5	5	
6	All of the time 6	
99	Prefer not to answer	

How often do you find it inconvenient or difficult to receive your injection as recommended?

None of the time 0	1	2	Half of the time 3	4	5	All of the time 6	Prefer not to answer
○	○	○	○	○	○	○	○

Page Break

On a scale of 0 to 6, where 0 is no discomfort at all and 6 is a very great deal of discomfort, please rate your responses to these questions.

Question: DISCMFINJ
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0:[V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36] or 86.0:[V86.0 - Step 4d - Week 40] or 87.0:[V87.0 - Step 4d - Week 2 PP] or 88.0:[V88.0 - Step 4d - Week 4 PP] or 89.0:[V89.0 - Step 4d - Week 8 PP] or 90.0:[V90.0 - Step 4d - Week 16 PP] or 91.0:[V91.0 - Step 4d - Week 24 PP] or 92.0:[V92.0 - Step 4d - Week 32 PP] or 93.0:[V93.0 - Step 4d - Week 44 PP] or 94.0:[V94.0 - Step 4d - Week 48 PP]) and (OLE_QORRES29 = 1:[CAB]))

Scale Summary		
Code	Label	Show-If
0	None at all 0	
1	1	
2	2	
3	Moderate discomfort 3	
4	4	
5	5	
6	A very great deal 6	
99	Prefer not to answer	

How much pain or discomfort have you experienced with your injection?

None at all 0	1	2	Moderate discomfort 3	4	5	A very great deal 6	Prefer not to answer
○	○	○	○	○	○	○	○

Page Break

Question: ORALLIKES
Minimum checks: 1
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0:[V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36] or 86.0:[V86.0 - Step 4d - Week 40] or 87.0:[V87.0 - Step 4d - Week 2 PP] or 88.0:[V88.0 - Step 4d - Week 4 PP] or 89.0:[V89.0 - Step 4d - Week 8 PP] or 90.0:[V90.0 - Step 4d - Week 16 PP] or 91.0:[V91.0 - Step 4d - Week 24 PP] or 92.0:[V92.0 - Step 4d - Week 32 PP] or 93.0:[V93.0 - Step 4d - Week 44 PP] or 94.0:[V94.0 - Step 4d - Week 48 PP]) and (OLE_QORRES29 = 2:[TDF/FTC]))

What did/do you like about an oral pill method? *Mark all that apply.*

- ☐ Nothing
- ☐ May protect against HIV
- ☐ Easier to use than other methods (e.g., condoms)
- ☐ Can be used discreetly, without a partner's knowledge
- ☐ Does not interrupt sex
- ☐ Easily reversible
- ☐ Other, specify: [ ]
- ☐ Prefer not to answer

Page Break

Question: ORALCONCRN
Minimum checks: 1

What concerns do you have about an **oral** HIV prevention method? *Mark all that apply.*

- ☐ None
- ☐ May not protect against HIV
- ☐ May cause harmful side effects
- ☐ Requires taking a daily pill
- ☐ Cannot be used discreetly, without a partner's knowledge
- ☐ Cost may be unaffordable
- ☐ Other, specify: _____
- ☐ Prefer not to answer

Page Break

On a scale of 0 to 6, where 0 is none of the time and 6 is all of the time, please rate your responses to these questions.

Question: INCONVORAL
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0:[V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36] or 86.0:[V86.0 - Step 4d - Week 40] or 87.0:[V87.0 - Step 4d - Week 2 PP] or 88.0:[V88.0 - Step 4d - Week 4 PP] or 89.0:[V89.0 - Step 4d - Week 8 PP] or 90.0:[V90.0 - Step 4d - Week 16 PP] or 91.0:[V91.0 - Step 4d - Week 24 PP] or 92.0:[V92.0 - Step 4d - Week 32 PP] or 93.0:[V93.0 - Step 4d - Week 44 PP] or 94.0:[V94.0 - Step 4d - Week 48 PP]) and (OLE_QORRES29 = 2:[TDF/FTC]))

Scale Summary		
Code	Label	Show-If
0	None of the time 0	
1	1	
2	2	
3	Half of the time 3	
4	4	
5	5	
6	All of the time 6	
99	Prefer not to answer	

How often do you find it inconvenient or difficult to take your oral study medication (i.e. the tablets) as recommended?

None of the time 0	1	2	Half of the time 3	4	5	All of the time 6	Prefer not to answer
○	○	○	○	○	○	○	○

Page Break

- -

On a scale of 0 to 6, where 0 is no discomfort at all and 6 is a very great deal of discomfort, please rate your responses to these questions.

Question: DISCMFORAL
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) or ((VISIT is-any-of 77.0:[V77.0 - Step 4d - Week 4] or 78.0:[V78.0 - Step 4d - Week 8] or 79.0:[V79.0 - Step 4d - Week 12] or 80.0:[V80.0 - Step 4d - Week 16] or 81.0:[V81.0 - Step 4d - Week 20] or 82.0:[V82.0 - Step 4d - Week 24] or 83.0:[V83.0 - Step 4d - Week 28] or 84.0: [V84.0 - Step 4d - Week 32] or 85.0:[V85.0 - Step 4d - Week 36] or 86.0:[V86.0 - Step 4d - Week 40] or 87.0:[V87.0 - Step 4d - Week 2 PP] or 88.0:[V88.0 - Step 4d - Week 4 PP] or 89.0:[V89.0 - Step 4d - Week 8 PP] or 90.0:[V90.0 - Step 4d - Week 16 PP] or 91.0:[V91.0 - Step 4d - Week 24 PP] or 92.0:[V92.0 - Step 4d - Week 32 PP] or 93.0:[V93.0 - Step 4d - Week 44 PP] or 94.0:[V94.0 - Step 4d - Week 48 PP]) and (OLE_QORRES29 = 2:[TDF/FTC]))

Scale Summary		
Code	Label	Show-If
0	None at all 0	
1	1	
2	2	
3	Moderate discomfort 3	
4	4	
5	5	
6	A very great deal 6	
99	Prefer not to answer	

How much discomfort have you experienced with your oral study medication (i.e. the tablets)?

None at all 0	1	2	Moderate discomfort 3	4	5	A very great deal 6	Prefer not to answer
○	○	○	○	○	○	○	○

Page Break

Question: OLE_QORRES1
Required

Scale Summary		
Code	Label	Show-If
1	Continue CAB LA	
2	Continue TDF/FTC	
3	Change to CAB LA with an oral lead in (4a)	
4	Change to CAB LA with direct to injection (4b)	
5	Stop CAB LA and start oral TDF/FTC	
6	No prevention method	

▶ What is your product choice today?

- ○ Continue CAB LA
- ○ Continue TDF/FTC
- ○ Change to CAB LA with an oral lead in (4a)
- ○ Change to CAB LA with direct to injection (4b)
- ○ Stop CAB LA and start oral TDF/FTC
- ○ No prevention method

Page Break

Question: OLE_QORRES2
Required

Scale Summary		
Code	Label	Show-If
1	No-one – it was my decision	
2	The study staff	
3	My mother	
4	My sibling/s	
5	My partner	
6	My best friend	
7	More than one of my friends	
8	Others	

When making your choice about which PrEP method to use, who did you speak with to help you make the decision?

- ○ No-one – it was my decision
- ○ The study staff
- ○ My mother
- ○ My sibling/s
- ○ My partner
- ○ My best friend
- ○ More than one of my friends
- ○ Others

Page Break

Question: OLE_QORRES3
Required

Scale Summary		
Code	Label	Show-If
1	This method suits my lifestyle best	
2	This method feels safest for me	
3	I want to get pregnant	
4	I do not want my partner, family or friends to know that I am taking PrEP	
5	Easier to use than other methods (e.g., condoms)	
6	Does not interrupt sex	
7	Easily reversible	
8	Other, specify:	
99	Prefer not to answer	

What were the main reasons for making the choice you did today?

- ○ This method suits my lifestyle best
- ○ This method feels safest for me
- ○ I want to get pregnant
- ○ I do not want my partner, family or friends to know that I am taking PrEP
- ○ Easier to use than other methods (e.g., condoms)
- ○ Does not interrupt sex
- ○ Easily reversible
- ○ Other, specify: [   ]
- ○ Prefer not to answer

Page Break

- -

Question: OLE_QORRES4
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) and (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	want to become pregnant at this time, or	
2	want to wait a bit before becoming pregnant, or	
3	did not want to get pregnant at all.	

When you became pregnant this time, did you
- ○ want to become pregnant at this time, or
- ○ want to wait a bit before becoming pregnant, or
- ○ did not want to get pregnant at all.

Page Break

Question: OLE_QORRES5
Required
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0:[V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48] or 76.0:[V76.0 - Step 4d - Week 0]) and (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
2	No	

Were you taking any of the study medicines when you became pregnant?

○ Yes

○ No

Page Break

Question: OLE_QORRES6
Required
Show if: (PREGNANT = 1:[Yes]) and (OLE_QORRES5 = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Never worried	
2	Sometimes worried	
3	Often worried	
99	Prefer not to answer	

If Yes, how often were you worried that the medicines would affect the <u>pregnancy</u>?

○ Never worried
○ Sometimes worried
○ Often worried
○ Prefer not to answer

Page Break

Question: OLE_QORRES7
Required
Show if: (PREGNANT = 1:[Yes]) and (OLE_QORRES5 = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Never worried	
2	Sometimes worried	
3	Often worried	
99	Prefer not to answer	

If Yes, how often were you worried that the medicines would affect the <u>baby</u>?

- ○ Never worried
- ○ Sometimes worried
- ○ Often worried
- ○ Prefer not to answer

Page Break

Question: OLE_QORRES8
Required
Show if: (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Not at all	
2	A little	
3	A lot	
99	Prefer not to answer	

Has being pregnant changed how much you feel at risk of getting infected with HIV?

○ Not at all
○ A little
○ A lot
○ Prefer not to answer

Page Break

- -

Collection: C1
Contains: Q12, OLE_QORRES10

Question: Q12
Required

Scale Summary		
Code	Label	Show-If
1	CAB	
2	TDF/FTC	
3	Unsure	

Which treatment option do you prefer? Please select one.

- ○ CAB
- ○ TDF/FTC
- ○ Unsure

Page Break

Question Block: OLE_QORRES10
Contains: OLE_QORRES11, OLE_QORRES12, OLE_QORRES13, OLE_QORRES14, OLE_QORRES15, OLE_QORRES16, OLE_QORRES17, OLE_QORRES18, OLE_QORRES19, OLE_QORRES20, OLE_QORRES21, OLE_QORRES22, OLE_QORRES23, OLE_QORRES24, OLE_QORRES25, OLE_QORRES26
Required

Scale Summary		
Code	Label	Show-If
0	Strongly Agree	
1	Agree	
2	Neither Agree Nor Disagree	
3	Disagree	
4	Strongly Disagree	

Considering the option you prefer, please answer the following questions:

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
I know which options are avaialable to me.	○	○	○	○	○
I know the benefits of each option.	○	○	○	○	○
I know the risks and side effects of each option.	○	○	○	○	○
I am clear about which benefits matter most to me.	○	○	○	○	○
I am clear about which risks and side effects matter most to me.	○	○	○	○	○
I am clear about which is more important					

to me (the benefits or the risks and side effects).	○	○	○	○	○
I have enough support from others to make a choice.	○	○	○	○	○
I am choosing without pressure from others.	○	○	○	○	○
I have enough advice to make a choice.	○	○	○	○	○
I am clear about the best choice for me.	○	○	○	○	○
I feel sure about what to choose.	○	○	○	○	○
This decisions is easy for me to make.	○	○	○	○	○
I felt I have made an informed choice.	○	○	○	○	○
My decision shows what is important to me.	○	○	○	○	○
I expect to stick to	○	○	○	○	○

my decision.					
I am satisfied with my decision.	○	○	○	○	○

Page Break

- -

Collection: SOCIAL_AND_ECONOMIC
Contains: RELSTAT, REGPLACE, NUMNIGHTS, LASTNIGHT, LIVEWITH, NOFOOD, COMMSEX, SEXWORKER

We'd like to ask you some questions about yourself, your household and your living circumstances.

Question: RELSTAT
Required

	Scale Summary	
Code	Label	Show-If
1	Married	
2	Not married, have a regular partner and live with him	
3	Not married, have a regular partner but do not live with him	
4	Sexually active, but no regular partner	
5	Not sexually active currently	
99	Prefer not to answer	

How would you describe your current relationship status?
Note: Mark the response that best describes your situation.

- ○ Married
- ○ Not married, have a regular partner and live with him
- ○ Not married, have a regular partner but do not live with him
- ○ Sexually active, but no regular partner
- ○ Not sexually active currently
- ○ Prefer not to answer

Question: REGPLACE
Required

	Scale Summary	
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Do you have a regular place or home where you stay and store your things?

- ○ Yes
- ○ No
- ○ Prefer not to answer

Auto Page Break

Question: NUMNIGHTS
Required
Show if: (REGPLACE = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Number of nights	
99	Prefer not to answer	

On average, how many nights do you sleep in your regular place or home every **week**?

○ Number of nights [ ]

○ Prefer not to answer

Question: LASTNIGHT
Required
Show if: (REGPLACE = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Is the place you stayed last night your regular place or home?

○ Yes

○ No

○ Prefer not to answer

Page Break

Question: LIVEWITH
Minimum checks: 1

With whom do you live? *Mark all that apply.*

- ☐ Alone
- ☐ Partner
- ☐ Parent(s)
- ☐ Sibling(s)
- ☐ With own children
- ☐ Roommate(s)
- ☐ Other, specify: [   ]
- ☐ Prefer not to answer

Page Break

- -

Question: NOFOOD
Required

Scale Summary		
Code	Label	Show-If
0	Never worried	
1	Sometimes worried	
2	Often worried	
99	Prefer not to answer	

In the past **6 months**, how frequently did you worry that your household would not have enough food?

○ Never worried
○ Sometimes worried
○ Often worried
○ Prefer not to answer

Page Break

Question: COMMSEX
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the last **month**, have you ever been paid for sex?

○ Yes
○ No
○ Prefer not to answer

Page Break

Question: SEXWORKER
Required
Show if: (COMMSEX = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Do you identify yourself as a sex worker?

○ Yes
○ No
○ Prefer not to answer

Page Break

Collection: DISCL_AND_SUPPORT_FU
Contains: TOLDABTSTDY, TOLDABTPROD, WHO_TOLD, SUPPORTIVE
Show if: (VISIT is-any-of 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0])

We are now going to ask you questions about the people whom you might have talked to about this research.

Question: TOLDABTSTDY
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

▶ Since your last visit, have you told anyone that you are taking part in this study?

○ Yes
○ No
○ Prefer not to answer

Page Break

- -

Question: TOLDABTPROD
Required
Show if: (TOLDABTSTDY = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Did you specifically tell anyone that you are taking or using the study pills or injections?

○ Yes
○ No
○ Prefer not to answer

Page Break

Question Block: WHO_TOLD
Contains: TOLDSP, TOLDPARENT, TOLDSIBLING, TOLDOTHFAM, TOLDFRIEND, TOLDNEIGHBR, TOLDRNMD, TOLDOTH
Show if: (TOLDABTSTDY = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
2	Unsure	
88	Not applicable	
99	Prefer not to answer	

If you have told anyone you are participating in this study or taking or using the study pills or injections, answer "yes" or "no" for each person(s) you told in the list below.

	Yes	No	Unsure	Not applicable	Prefer not to answer
Your regular or primary sex partner?	○	○	○	○	○
Your mother or your father?	○	○	○	○	○
Your sister or your brother?	○	○	○	○	○
Other family members?	○	○	○	○	○
Friends?	○	○	○	○	○
Neighbors?	○	○	○	○	○
Nurse or doctor outside the study?	○	○	○	○	○
Other person(s)? Please specify:	○	○	○	○	○

Page Break

Question Block: SUPPORTIVE
Contains: SUPSP, SUPPARENT, SUPSIBLING, SUPOTHFAM, SUPFRIEND, SUPNEIGHBR, SUPRNMD, SUPOTH
Show if: (TOLDABTSTDY = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
2	Unsure	
88	Not applicable	
99	Prefer not to answer	

Was his/her/their reaction supportive?

	Yes	No	Unsure	Not applicable	Prefer not to answer
Your regular or primary sex partner?	○	○	○	○	○
Your mother or your father?	○	○	○	○	○
Your sister or your brother?	○	○	○	○	○
Other family members?	○	○	○	○	○
Friends?	○	○	○	○	○
Neighbors?	○	○	○	○	○
Nurse or doctor outside the study?	○	○	○	○	○
Other person(s)? Please specify: _____	○	○	○	○	○

Page Break

Collection: SOCIAL_SUPPORT
Contains: SOCIAL_SPPT_TABLE
Show if: (VISIT is-any-of 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48])

Here is a list of some things that other people do for us or give us that may be helpful or supportive.

Question Block: SOCIAL_SPPT_TABLE
Contains: CARE, LOVE, WORKPROBS, FAMPROBS, MONEY, INVITE, ADVICE, HELPSICK
Required

Scale Summary		
Code	Label	Show-If
5	5 As much as I would like	
4	4 Almost as much as I would like	
3	3 Some, but would like more	
2	2 Less than I would like	
1	1 Much less than I would like	
99	Prefer not to answer	

Please read each statement carefully and on a scale from 5 (meaning "As much as I would like") to 1 (meaning "Much less than I would like"), mark the response that is closest to your situation.

	5 As much as I would like	4 Almost as much as I would like	3 Some, but would like more	2 Less than I would like	1 Much less than I would like	Prefer not to answer
I have people who care what happens to me.	○	○	○	○	○	○
I get love and affection.	○	○	○	○	○	○
I get chances to talk to someone about problems at work or school or with my housework.	○	○	○	○	○	○
I get chances to talk to someone I trust about my personal or family problems.	○	○	○	○	○	○
I get chances to talk about money matters.	○	○	○	○	○	○
I get invitations to go out and do things with other people.	○	○	○	○	○	○
I get useful advice						

about important things in life.	○	○	○	○	○	○
I get help when I am sick.	○	○	○	○	○	○

Page Break

Collection: FERTILITY_CONTRACEP
Contains: NOTGETPREG, PREGWORRY, PREGCHANCE, OLE_QORRES28
Show if: (PREGNANT = 0:[No]) and (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 58.0:[V58.0 - Step 4c-CAB LA - Week 8] or 59.0: [V59.0 - Step 4c-CAB LA - Week 16] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 61.0:[V61.0 - Step 4c-CAB LA - Week 32] or 62.0:[V62.0 - Step 4c-CAB LA - Week 40] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 65.0:[V65.0 - Step 4c-TDF/FTC - Week 8] or 66.0:[V66.0 - Step 4c-TDF/FTC - Week 16] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 68.0:[V68.0 - Step 4c-TDF/FTC - Week 32] or 69.0:[V69.0 - Step 4c-TDF/FTC - Week 40] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 72.0:[V72.0 - Step 5-TDF/FTC - Week 12] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 74.0:[V74.0 - Step 5-TDF/FTC - Week 36] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48])

Now we'd like to ask some questions about your views on pregnancy.

Question: NOTGETPREG
Required

Scale Summary		
Code	Label	Show-If
0	Not important	
1	Somewhat important	
2	Very important	
99	Prefer not to answer	

How important is it to you to **NOT** get pregnant now?
- ○ Not important
- ○ Somewhat important
- ○ Very important
- ○ Prefer not to answer

Question: PREGWORRY
Required

Scale Summary		
Code	Label	Show-If
0	Not at all	
1	Somewhat	
2	A lot	
99	Prefer not to answer	

Compared to the other things in your life, how much do you worry about getting pregnant?
- ○ Not at all
- ○ Somewhat
- ○ A lot
- ○ Prefer not to answer

Question: PREGCHANCE
Required

Scale Summary		
Code	Label	Show-If
0	No chance at all	
1	Small chance	
2	Moderate chance	
3	Great chance	
99	Prefer not to answer	

How would you describe your chances of getting pregnant in the next 6 months?
- ○ No chance at all

○ Small chance
○ Moderate chance
○ Great chance
○ Prefer not to answer

Question: OLE_QORRES28
Required

Scale Summary		
Code	Label	Show-If
1	Never	
2	As Soon as possible	
3	Within next year	
4	Within 2-5 years	
5	Depends on circumstances	
6	Unsure	

▶ When do you think you might like to get pregnant?

○ Never
○ As Soon as possible
○ Within next year
○ Within 2-5 years
○ Depends on circumstances
○ Unsure

Page Break

Collection: HIV_RISK_PERCEP
Contains: PERSRISK, OWNBEHRISK, PTNRBEHRISK

Next, we will talk about how much you feel at risk of getting infected with HIV.

Question: PERSRISK
Required

Scale Summary		
Code	Label	Show-If
1	Not at all	
2	A little	
3	A lot	
99	Prefer not to answer	

How much do you personally feel at risk of getting infected with HIV?

- ○ Not at all
- ○ A little
- ○ A lot
- ○ Prefer not to answer

Question: OWNBEHRISK
Required

Scale Summary		
Code	Label	Show-If
1	Not at all	
2	A little	
3	A lot	
99	Prefer not to answer	

How much do you worry that your **own behaviors** put you at risk of getting infected with HIV?

- ○ Not at all
- ○ A little
- ○ A lot
- ○ Prefer not to answer

Question: PTNRBEHRISK
Required

Scale Summary		
Code	Label	Show-If
1	Not at all	
2	A little	
3	A lot	
99	Prefer not to answer	

How much do you worry that **your partner or partners' behaviors** put you at risk of getting infected with HIV?

- ○ Not at all
- ○ A little
- ○ A lot
- ○ Prefer not to answer

Page Break

- -

> **Collection:** SEX_BEH_AND_PARTNERS
> **Contains:** MAINPTNR, MAIN_PRIM_PARTNER, ALL_PARTNERS, VAGINAL_SEX, OLE_QORRES27, OLE_QORRES30, RECEP_ANAL_SEX, Q33, Q34, TRANSACT_SEX

The following questions are about times that you had different types of sex **because you wanted to**, not because you were forced or pressured to have sex.

Let's briefly go over the definitions of some terms so that you understand what is being asked. For vaginal sex, we mean when a man puts his penis into your vagina. For anal sex, we mean when a man puts his penis into your anus or buttocks (bum).

Please answer the following questions as honestly as you can. Remember that your answers are confidential.

Page Break

Question: MAINPTNR
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

At any time during the past **month,** have you had a primary partner? By primary partner, we mean a man you have sex with on a regular basis or who you consider to be your **main** or **regular partner.**

○ Yes
○ No
○ Prefer not to answer

Page Break

Collection: MAIN_PRIM_PARTNER
Contains: MPAGE, MPAGEUNK, MPTALKHIV, MPTESTHIV, MPHIVSTAT, MPART, MPOTHSEX
Show if: (MAINPTNR = 1:[Yes])

We'd like to know more about your relationship and the person that you have sex with regularly, i.e. your primary partner.

Question: MPAGE
Required

Scale Summary		
Code	Label	Show-If
1	Age in years	
77	Don't know	
99	Prefer not to answer	

How old, in years, is your primary partner? If you are unsure of the exact age, please take your best guess.

○ Age in years [____]

○ Don't know

○ Prefer not to answer

Page Break

Question: MPAGEUNK
Required
Show if: (MPAGE = 77:[Don't know])

Scale Summary		
Code	Label	Show-If
1	Much older	
2	Somewhat older	
3	About the same age	
4	Somewhat younger	
5	Much younger	
99	Prefer not to answer	

Compared to you, is your primary partner much older, somewhat older, about the same age, somewhat younger, or much younger?

- ○ Much older
- ○ Somewhat older
- ○ About the same age
- ○ Somewhat younger
- ○ Much younger
- ○ Prefer not to answer

Page Break

Custom Layout Question: MPTIME

How long have you been with your primary partner?

☐ Less than a month

☐ Months ☐ Years

☐ Prefer not to answer

Page Break

- -

Question: MPTALKHIV
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Have you talked with your primary partner about his HIV status?

○ Yes
○ No
○ Prefer not to answer

Page Break

Question: MPTESTHIV
Required
Show if: (MPTALKHIV = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Have you and your primary partner tested together for HIV?

○ Yes
○ No
○ Prefer not to answer

Question: MPHIVSTAT
Required
Show if: (MPTALKHIV = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	HIV negative	
2	HIV positive	
77	Don't know	
3	He doesn't know	
99	Prefer not to answer	

What is the HIV status of your primary partner?

○ HIV negative
○ HIV positive
○ Don't know
○ He doesn't know
○ Prefer not to answer

Page Break
- -

Question: MPART
Required
Show if: (MPTALKHIV = 1:[Yes]) and (MPHIVSTAT = 2:[HIV positive])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
77	Don't know	
99	Prefer not to answer	

Some people infected with the HIV virus are prescribed medication called antiretrovirals or ARVs by a doctor or a nurse to help them live longer. Is your primary partner taking ARVs?

○ Yes
○ No
○ Don't know
○ Prefer not to answer

Page Break

Question: MPOTHSEX
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
3	Unsure	
99	Prefer not to answer	

Do you think your primary partner had sex with anyone besides you in the past **month**?

○ Yes
○ No
○ Unsure
○ Prefer not to answer

Page Break

Collection: ALL_PARTNERS
Contains: NUMPTNRS, OPHIVSTAT, OPHIVPOS

Question: NUMPTNRS
Required

Scale Summary		
Code	Label	Show-If
1	Number of partners	
999	Prefer not to answer	

In the past **month**, approximately how many male sex partners did you have – *including your primary partner, if you have one?* By sex partner, we mean someone who you had vaginal or anal sex with.

○ Number of partners [   ]

○ Prefer not to answer

Auto Page Break
- -

Question: OPHIVSTAT
Required
Show if: (NUMPTNRS.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of partners	
999	Prefer not to answer	

Of these sex partners, approximately how many told you their HIV status?

○ Number of partners ⬚

○ Prefer not to answer

Page Break

Question: OPHIVPOS
Required
Show if: (OPHIVSTAT.TEXT > 0) and (NUMPTNRS.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of partners	
999	Prefer not to answer	

▶Of these sex partners who told you their HIV status, how many were HIV positive?

○ Number of partners [   ]

○ Prefer not to answer

Page Break

Collection: VAGINAL_SEX
Contains: NUMVS, VNOCOND, VHIVUNK, VHIVPOS

Now we will shift to the number of times you had sex. If you can't recall exact numbers, please give your best estimate.

Question: NUMVS
Required

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

In the past **month**, approximately how many times did you have vaginal sex?

○ Number of times [   ]

○ Prefer not to answer

Page Break

Question: VNOCOND
Required
Show if: (NUMVS.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

Of the times when you had vaginal sex in the past month, approximately how many times was it **without** a condom?

○ Number of times [   ]

○ Prefer not to answer

Page Break

Question: VHIVUNK
Required
Show if: (VNOCOND.TEXT > 0) and (NUMVS.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

Of these times that you had vaginal sex without a condom in the past month, approximately how many were with partners whose HIV status you **did not** know?

○ Number of times [   ]

○ Prefer not to answer

Page Break

Question: VHIVPOS
Required
Show if: (VHIVUNK.TEXT > 0) and (VHIVKNOWN ≠ 0) and (NUMVS.TEXT > 0) and (VNOCOND.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
77	Don't know	
999	Prefer not to answer	

That leaves times that you had vaginal sex without a condom with partners whose HIV status you **did** know in the past month. Of these times, approximately how many were with partners who were HIV positive?

○ Number of times [____]

○ Don't know

○ Prefer not to answer

Page Break

Question: OLE_QORRES27
Required
Show if: (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Increased	
2	Decreased	
3	Stayed the same	

Has the number of times you have vaginal or anal sex changed since you became pregnant?

○ Increased
○ Decreased
○ Stayed the same

Page Break

- -

Question: OLE_QORRES30
Required
Show if: (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Increased	
2	Decreased	
3	Stayed the same	

Has the number of times you used a condom during sex changed since you became pregnant?

○ Increased
○ Decreased
○ Stayed the same

Page Break

Collection: RECEP_ANAL_SEX
Contains: NUMRA, RANOCOND, RAHIVUNK, RAHIVPOS

Question: NUMRA
Required

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

In the past **month**, approximately how many times did you have anal sex? By "anal sex", we mean when your partner puts his penis into your anus or buttocks (bum). If you have not had anal sex in the past month, please enter '0'.

○ Number of times [   ]

○ Prefer not to answer

Page Break

- -

Question: RANOCOND
Required
Show if: (NUMRA.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

Of the times when you had anal sex in the past month, approximately how many times was it **without** a condom?

○ Number of times ☐

○ Prefer not to answer

Page Break

Question: RAHIVUNK
Required
Show if: (RANOCOND.TEXT > 0) and (NUMRA.TEXT > 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
999	Prefer not to answer	

Of these times that you had anal sex without a condom in the past month, approximately how many were with partners whose HIV status you **did not** know?

○ Number of times [   ]

○ Prefer not to answer

Page Break

- -

Question: RAHIVPOS
Required
Show if: (RANOCOND.TEXT > 0) and (NUMRA.TEXT > 0) and (RAHIVUNK.TEXT > 0) and (RAHIVKNOWN ≠ 0)

Scale Summary		
Code	Label	Show-If
1	Number of times	
77	Don't know	
999	Prefer not to answer	

That leaves times that you had anal sex without a condom with partners whose HIV status you **did** know in the past month. Of these times, approximately how many were with partners who were HIV positive?

○ Number of times ☐

○ Don't know

○ Prefer not to answer

Page Break

Question: Q33
Required
Show if: (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Increased	
2	Decreased	
3	Stayed the same	

Has the number of times you have vaginal or anal sex changed since you became pregnant?

○ Increased
○ Decreased
○ Stayed the same

Page Break

Question: Q34
Required
Show if: (PREGNANT = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Increased	
2	Decreased	
3	Stayed the same	

Has the number of times you used a condom during sex changed since you became pregnant?

- ○ Increased
- ○ Decreased
- ○ Stayed the same

Page Break

Collection: TRANSACT_SEX
Contains: TRANSACTSX, PROVIDED

We as women often find ourselves in situations where we need someone to help us.

Question: TRANSACTSX
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Sometimes people give or receive something in return for having sex. In the last **month**, have you had sex with a man because he provided you with or you expected that he would provide you with food, clothes, a place to sleep, a cell phone, money or other support?

○ Yes

○ No

○ Prefer not to answer

Page Break

Question: PROVIDED
Minimum checks: 1
Show if: (TRANSACTSX = 1:[Yes])

What were you provided with in return for having sex? *Mark all that apply.*

- ☐ Food
- ☐ Clothes, shoes, accessories
- ☐ Cosmetics
- ☐ Cell phone
- ☐ Items for your child(ren) or family such as clothes, food, school fees
- ☐ Transport, tickets or money for transport
- ☐ Your own school fees or residence fees
- ☐ Somewhere to stay
- ☐ Cash
- ☐ Other, specify: _____
- ☐ Prefer not to answer

Page Break

Collection: VIOLENCE
Contains: HURT, INSULT, FORCED, UNSAFE
Show if: (VISIT is-any-of 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48])

Now we will ask you some questions about your relationships with any of your partners. We know that relationships can have good and bad moments. Some questions may be difficult to answer and we would like to remind you that your answers will be kept CONFIDENTIAL.

Question: HURT
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the **past 6 months**, have any of your partners punched, slapped, kicked, bit you, or caused you any type of physical harm?

○ Yes
○ No
○ Prefer not to answer

Question: INSULT
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the **past 6 months**, have any of your partners insulted, ignored or humiliated you, yelled at you, or made you feel ashamed or bad about yourself?

○ Yes
○ No
○ Prefer not to answer

Question: FORCED
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the **past 6 months**, have any of your partners forced you to have sex or perform any sexual act, or touched you sexually in any way that you did not want?

○ Yes
○ No
○ Prefer not to answer

Question: UNSAFE
Required

Scale Summary		
Code	Label	Show-If

1	Yes	
0	No	
99	Prefer not to answer	

In the **past 6 months**, have any of your partners made you feel afraid, unsafe or in danger?

○ Yes
○ No
○ Prefer not to answer

Page Break

Collection: MENTAL_HEALTH
Contains: MHEALTH, NIGHTMARE, AVOID, ONGUARD, NUMB

Question Block: MHEALTH
Contains: MHBOTHERED, MHUNFOCUSED, MHDEPRESSED, MHEFFORT, MHHOPEFUL, MHFEARFUL, MHRESTLESS, MHHAPPY, MHLONELY, MHGETGOING
Required

Scale Summary		
Code	Label	Show-If
1	Rarely or none of the time (less than 1 day)	
2	Some or a little of the time (1-2 days)	
3	Occasionally or a moderate amount of time (3-4 days)	
4	All of the time (5-7 days)	
99	Prefer not to answer	

We'd like to know more about the way you have felt or behaved in the past week. In the list below, please indicate how often you have felt this way during the past **week** by ticking the appropriate box for each question.

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)	Prefer not to answer
I was bothered by things that usually don't bother me.	○	○	○	○	○
I had trouble keeping my mind on what I was doing.	○	○	○	○	○
I felt depressed.	○	○	○	○	○
I felt that everything I did was an effort.	○	○	○	○	○
I felt hopeful about the future.	○	○	○	○	○
I felt fearful or afraid.	○	○	○	○	○
My sleep was restless.	○	○	○	○	○
I was happy.	○	○	○	○	○
I felt lonely.	○	○	○	○	○
I could not "get going", I did not feel motivated.	○	○	○	○	○

Page Break

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past **month**, you:

Question: NIGHTMARE
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Have had nightmares about it or thought about it when you did not want to?

○ Yes
○ No
○ Prefer not to answer

Question: AVOID
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

○ Yes
○ No
○ Prefer not to answer

Question: ONGUARD
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Were constantly on guard, watchful, or easily frightened?

○ Yes
○ No
○ Prefer not to answer

Question: NUMB
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Felt empty, numb or detached from others, activities, or your surroundings?

○ Yes
○ No
○ Prefer not to answer

Page Break

Collection: ALCOHOL_DRUG_USE
Contains: ALCFREQ, ALCNUM, ALC6ORMORE, ALCBFRSX, DRUGBFRSX, SPDRUNK, DRUGUSE, INJECTEVER, INJECTMO
Show if: (VISIT is-any-of 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 60.0:[V60.0 - Step 4c-CAB LA - Week 24] or 63.0:[V63.0 - Step 4c-CAB LA - Week 48] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0] or 67.0:[V67.0 - Step 4c-TDF/FTC - Week 24] or 70.0:[V70.0 - Step 4c-TDF/FTC - Week 48] or 71.0:[V71.0 - Step 5-TDF/FTC - Day 0] or 73.0:[V73.0 - Step 5-TDF/FTC - Week 24] or 75.0:[V75.0 - Step 5-TDF/FTC - Week 48])

Now we would like to know more about your alcohol use. For alcohol, we mean beer, wine, home or local brews.

Question: ALCFREQ
Required

	Scale Summary	
Code	Label	Show-If
0	Never	
1	Monthly or less	
2	2 to 4 times a month	
3	2 to 3 times a week	
4	4 or more times a week	
99	Prefer not to answer	

How often do you have a drink containing alcohol?

○ Never
○ Monthly or less
○ 2 to 4 times a month
○ 2 to 3 times a week
○ 4 or more times a week
○ Prefer not to answer

Page Break

- -

Question: ALCNUM
Required
Show if: (ALCFREQ ≠ 0:[Never])

Code	Label	Show-If
	Scale Summary	
0	1 or 2	
1	3 or 4	
2	5 or 6	
3	7 to 9	
4	10 or more	
99	Prefer not to answer	

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

○ 1 or 2
○ 3 or 4
○ 5 or 6
○ 7 to 9
○ 10 or more
○ Prefer not to answer

Question: ALC6ORMORE
Required
Show if: (ALCFREQ ≠ 0:[Never])

Code	Label	Show-If
	Scale Summary	
0	Never	
1	Less than monthly	
2	Monthly	
3	Weekly	
4	Daily or almost daily	
99	Prefer not to answer	

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

○ Never
○ Less than monthly
○ Monthly
○ Weekly
○ Daily or almost daily
○ Prefer not to answer

Page Break
- -

Question: ALCBFRSX
Required
Show if: (ALCFREQ ≠ 0:[Never])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the past month, did you have a drink containing alcohol just before or during sex?

○ Yes

○ No

○ Prefer not to answer

Question: DRUGBFRSX
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the past month, did you use drugs just before or during sex?

○ Yes

○ No

○ Prefer not to answer

Question: SPDRUNK
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

In the past month, has your partner been drunk from alcohol?

○ Yes

○ No

○ Prefer not to answer

Page Break

- -

Now we'd like to ask you some questions about drug use. Don't include drugs that have been prescribed to you by a doctor or other health care provider.

Question Block: DRUGUSE
Contains: MARIJUANA, COCAINE, SPEED, INHALANT, SEDATIVE, HALLUCIN, OPIOID, RXDRUG, OTHDRUG
Required

Scale Summary		
Code	Label	Show-If
0	Never	
1	Less than monthly	
2	Monthly	
3	Weekly (At least once a week)	
4	Daily or almost daily	
99	Prefer not to answer	

In the past month, how often have you used each of the following substances?

	Never	Less than monthly	Monthly	Weekly (At least once a week)	Daily or almost daily	Prefer not to answer
Cannabis (Also called marijuana, pot, grass, dakka, dagga or hash)	○	○	○	○	○	○
Cocaine (Also called coke, crack, or snow)	○	○	○	○	○	○
Amphetamine-type stimulants (For example Tik/Crystal Meth, ecstasy, speed, or diet pills)	○	○	○	○	○	○
Inhalants (For example glue, petrol, paint thinner, nitrous)	○	○	○	○	○	○
Sedatives or sleeping pills (For example serepax, rohypnol, quaaludes/mandrax)	○	○	○	○	○	○
Hallucinogens (For example nyaope/whoonga, LSD, acid, mushrooms, PCP, Special K)	○	○	○	○	○	○
Opioids (For example heroin, morphine, methadone, etc.)	○	○	○	○	○	○

Prescription drugs for non-prescription purposes (For example codeine (including cough syrup), efavirenz, valium)	○	○	○	○	○	○
Other	○	○	○	○	○	○

Page Break

Question: INJECTEVER
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Have you ever used a needle to inject drugs?

○ Yes
○ No
○ Prefer not to answer

Page Break

Question: INJECTMO
Required
Show if: (INJECTEVER = 1:[Yes])

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Have you used a needle to inject drugs in the past month?

○ Yes
○ No
○ Prefer not to answer

Page Break

Collection: ATT_TOWARD_STUDY_PARTIC
Contains: PERCEIVED_BURDEN
Show if: (VISIT is-any-of 55.0:[V55.0 - Step 4a - Day 0] or 56.0:[V56.0 - Step 4b - Day 0] or 57.0:[V57.0 - Step 4c-CAB LA - Week 0] or 64.0:[V64.0 - Step 4c-TDF/FTC - Week 0])

We will now ask you some questions about your experience participating in this trial.

Collection: PERCEIVED_BURDEN
Contains: LOOKAT, ATTENDVIS

Question: LOOKAT
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

Did you ever feel that people looked at you different because you were using TDF/FTC and injections?

○ Yes
○ No
○ Prefer not to answer

Page Break

Question: ATTENDVIS
Required

Scale Summary		
Code	Label	Show-If
0	Not at all difficult	
1	A little more difficult than I might have thought	
2	Moderately difficult	
3	Quite difficult	
99	Prefer not to answer	

How difficult has it been for you to attend the study visits?

- ○ Not at all difficult
- ○ A little more difficult than I might have thought
- ○ Moderately difficult
- ○ Quite difficult
- ○ Prefer not to answer

Page Break

- -

Collection: END_SURVEY
Contains: NEED2TALK

Question: NEED2TALK
Required

Scale Summary		
Code	Label	Show-If
1	Yes	
0	No	
99	Prefer not to answer	

We have asked you a number of questions today. Some of them may have caused you to feel worried or sad. Would you like to talk to someone about any of your answers?

○ Yes
○ No
○ Prefer not to answer

Powered by DatStat