

Select any additional forms completed at this visit.

ACASI Tracking ②

Chemistry Testing ③

Counseling ④

Fasting Lipid Test Results ⑤

Hematology ⑥

Hepatitis B Vaccination ⑦

Hepatitis Test Results ⑧

HIV Test Results ⑨

Hormone Tests ⑩

Participant Receipt ⑪

Participant Transfer ⑫

Patient Health Questionnaire ⑬

Physical Exam ⑭

PK Dose Time 15

PK Specimen Collection 16

Specimen Collection 17

STI Tests 18

Supplemental HIV Results 19

Urinalysis 20

Vital Signs 21

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Additional Study Procedures
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
② ACASIT	1	ACASI Tracking			ACASIT
③ LBCHEM	1	Chemistry Testing			LBCHEM
④ CNSL	1	Counseling			CNSL
⑤ LBLIPID	1	Fasting Lipid Test Results			LBLIPID
⑥ LBHEM	1	Hematology			LBHEM
⑦ HPBVAC	1	Hepatitis B Vaccination			HPBVAC
⑧ LBHEP	1	Hepatitis Test Results			LBHEP
⑨ LBHIV	1	HIV Test Results			LBHIV
⑩ LB7	1	Hormone Tests			LB7
⑪ RECEIPT	1	Participant Receipt			RECEIPT
⑫ TRANSFER	1	Participant Transfer			TRANSFER
⑬ PHQ	1	Patient Health Questionnaire			PHQ

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Additional Study Procedures
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
14 PE	1	Physical Exam			PE
15 PKEX	1	PK Dose Time			PKEX
16 PKSPEC	1	PK Specimen Collection			PKSPEC
17 BSYN	1	Specimen Collection			BSYN
18 LBSTI	1	STI Tests			LBSTI
19 HIVSUPP	1	Supplemental HIV Results			HIVSUPP
20 LBURINE	1	Urinalysis			LBURINE
21 VS	1	Vital Signs			VS

Did the participant complete this visit?

Yes **1**
No

Visit Date _____ **2**

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

Yes **3**
No

Did participant have any changes or updates to their PrEP at this visit?

Yes **4**
No

If "Yes", please complete the Pre-exposure Prophylaxis Log.

Did participant have any changes or updates to their GAHT at this visit?

Yes **5**
No

If "Yes", please complete the Gender Affirming Hormone Therapy Log.

Were any new adverse events (AEs) reported at this visit?

Yes **6**
No

Is the participant taking any concomitant medications that have not been previously reported?

Yes **7**
No

Have any protocol deviations been reported at this visit?

Yes **8**
No

Did the participant have any additional procedures at this visit?

Yes **9**
No

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

HPTN091_Version_4.0_PROD_02NOV2022: ALL**Form: Date of Visit****Generated On: 04 Nov 2022 01:44:33**

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① FUYN	\$1	Did the participant complete this visit?		Y = Yes N = No	FUYN
② FUDAT	dd MMM yyyy	Visit Date			FUDAT
③ DOVTER	\$1	Did the participant exit/terminate the study at this visit?		Y = Yes N = No	DOVTER
④ DOVPREP	\$1	Did participant have any changes or updates to their PrEP at this visit?		Y = Yes N = No	DOVPREP
⑤ DOVGAHT	\$1	Did participant have any changes or updates to their GAHT at this visit?		Y = Yes N = No	DOVGAHT
⑥ DOVAEYN	\$1	Any AE		Y = Yes N = No	DOVAEYN
⑦ DOVCMYN	\$1	Any CM		Y = Yes N = No	DOVCMYN
⑧ DOVDVYN1	\$1	Any protocol deviations		Y = Yes N = No	DOVDVYN1

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Date of Visit

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
⑨ ADDYN	\$1	Did the participant have any additional procedures at this visit?		Y = Yes N = No	ADDYN

Did the participant complete this visit?

Yes ①
No

Visit Date _____ ②

Were any new adverse events (AEs) reported at this visit?

Yes ③
No

Is the participant taking any concomitant medications that have not been previously reported?

Yes ④
No

Have any protocol deviations been reported at this visit?

Yes ⑤
No

Did the participant have any additional procedures at this visit?

Yes ⑥
No

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

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Date of Visit - Seroconverter Schedule
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SVYN	\$1	Did the participant complete this visit?		Y = Yes N = No	SVYN
② SVSTDTC	dd MMM yyyy	Visit Date			SVSTDTC
③ DOV1AEYN	\$1	New AE reported		Y = Yes N = No	DOV1AEYN
④ DOV1CMYN	\$1	New CM reported		Y = Yes N = No	DOV1CMYN
⑤ DOV1DVYN	\$1	Any protocol deviations		Y = Yes N = No	DOV1DVYN
⑥ ADDYN	\$1	Did the participant have any additional procedures at this visit?		Y = Yes N = No	ADDYN

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Enrollment
Generated On: 04 Nov 2022 01:44:33

Treatment arm

1

Will this participant participate in DHI Sub-Study?

Yes

2

No

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Enrollment

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① ENTXARM	\$30	Treatment arm			ENTXARM
② ENDHIS	\$1	Will this participant participate in DHI Sub-Study?		Y = Yes N = No	ENDHIS

Interim visit date _____ **1**

Interim visit code _____ **2**

Was study product use permanently discontinued (scheduled or early) at this visit? **3**
Yes
No
If "Yes", please complete the appropriate study product log CRF.

Did the participant exit/terminate the study at this visit? **4**
Yes
No
If "Yes", please complete the Study Termination CRF.

Did participant have any changes or updates to their PrEP at this visit? **5**
Yes
No
If "Yes", please complete the Pre-exposure Prophylaxis Log.

Did participant have any changes or updates to their GAHT at this visit? **6**
Yes
No
If "Yes", please complete the Gender Affirming Hormone Therapy Log.

Were any new adverse events (AEs) reported at this visit? **7**
Yes
No
If "Yes", please complete the Adverse Event Log.

Is the participant taking any concomitant medications that have not been previously reported? **8**
Yes
No
If "Yes", please complete the Concomitant Medications Log.

Have any protocol deviations been reported at this visit? **9**
Yes
No
If "Yes", please complete the Protocol Deviations Log.

Reason for interim visit (Mark all that apply)

AE report or follow-up **11**

Report social harm 12
If checked, please complete the Social Impact Log.

Additional laboratory testing 13

Other 14

If other, specify: _____ 15

Were vital signs (such as weight) taken at this visit? Yes 16
No

Mark all forms completed at this visit.

ACASI Tracking 18

Chemistry Panel 19

Counseling 20

Fasting Lipid Test Results 21

Hematology 22

Hepatitis B Vaccination 23

Hepatitis Test Results 24

HIV Test Results 25

Hormone Tests 26

Participant Receipt 27

Participant Transfer 28

Patient Health Questionnaire 29

Physical Exam 30

PK Dose Time 31

PK Specimen Collection 32

Specimen Collection and Storage 33

STI Test Results 34

Supplemental HIV Results 35

Urinalysis 36

Vital Signs 37

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Interim Visit

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SVSTDTC1	dd MMM yyyy	Interim visit date			SVSTDTC1
② INTERIMCD	5.2	Interim visit code			INTERIMCD
③ SUPSTPROD	\$1	Study product permanently discontinued		Y = Yes N = No	SUPSTPROD
④ SUPPTER	\$1	Participant exit/terminate		Y = Yes N = No	SUPPTER
⑤ INTPREPU	\$1	Did participant have any changes or updates to their PrEP at this visit? If "Yes", please complete the Pre-exposure Prophylaxis Log.		Y = Yes N = No	INTPREPU
⑥ INTGAHTU	\$1	Did participant have any changes or updates to their GAHT at this visit? If "Yes", please complete the Gender Affirming Hormone Therapy Log.		Y = Yes N = No	INTGAHTU
⑦ INTAEYN	\$1	Any new AE reported		Y = Yes N = No	INTAEYN

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Form: Interim Visit

Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
8	INTCMYN	\$1	Any new CM reported		Y = Yes N = No	INTCMYN
9	INTDVYN	\$1	Any protocol deviations		Y = Yes N = No	INTDVYN
11	INTAE	1	AE report or follow-up			INTAE
12	INTSI	1	Report social harm			INTSI
13	INTLB	1	Additional laboratory testing			INTLB
14	INTOTH	1	Other			INTOTH
15	INTOSP	\$200	If other, specify:			INTOSP
16	VSPERF_YN	\$1	Were vital signs (such as weight) taken at this visit?		Y = Yes N = No	VSPERF_YN
18	ACASI	1	ACASI Tracking			ACASI
19	LBCHEM	1	Chemistry Testing			LBCHEM
20	CNSL	1	Counseling			CNSL

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Interim Visit

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
21 LBLIPID	1	Fasting Lipid Test Results			LBLIPID
22 LBHEM	1	Hematology			LBHEM
23 HPBVAC	1	Hepatitis B Vaccination			HPBVAC
24 LBHEP	1	Hepatitis Test Results			LBHEP
25 LBHIV	1	HIV Test Results			LBHIV
26 LB7	1	Hormone Tests			LB7
27 RECEIPT	1	Participant Receipt			RECEIPT
28 TRANSFER	1	Participant Transfer			TRANSFER
29 PHQ	1	Patient Health Questionnaire			PHQ
30 PE	1	Physical Exam			PE
31 PKEX	1	PK Dose Time			PKEX
32 PKSPEC	1	PK Specimen Collection			PKSPEC

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Interim Visit

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
33 BSYN	1	Specimen Collection			BSYN
34 LBSTI	1	STI Tests			LBSTI
35 HIVSUPP	1	Supplemental HIV Results			HIVSUPP
36 LBURINE	1	Urinalysis			LBURINE
37 VS	1	Vital Signs			VS

Target Visit Date _____

1

Reason visit was missed

- Unable to contact participant
- Participant unable to schedule visit within window
- Participant refused visit
- Participant incarcerated
- Participant admitted to healthcare facility
- Participant withdrew from study
- Participant deceased
- Other

2

If "Other", specify: _____

3

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Missed Visit

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SVSTDAT	dd MMM yyyy	Target Visit Date			SVSTDAT
② SVRSNMSD	2	Reason Visit Missed		1 = Unable to contact participant 2 = Participant unable to schedule visit within window 3 = Participant refused visit 4 = Participant incarcerated 5 = Participant admitted to healthcare facility 6 = Participant withdrew from study 7 = Participant deceased 99 = Other	SVRSNMSD
③ SVRSNMSDOS P	\$200	Reason Visit Missed Other Specify			SVRSNMSDOS P

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Identifier
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Participant ID:

1

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Identifier
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SUBJID	\$9	Subject Identifier			SUBJID

Name of receiving study site

- Bridge HIV CRS (764) ①
- Harlem Prevention Center CRS (745)
- Penn Prevention CRS (863)
- Houston AIDS Research Team (HART) CRS (853)
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)

Name of transferring study site

- Bridge HIV CRS (764) ②
- Harlem Prevention Center CRS (745)
- Penn Prevention CRS (863)
- Houston AIDS Research Team (HART) CRS (853)
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)

Date informed consent signed at receiving site

_____ ③

Date participant received at receiving site

_____ ④

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Participant Receipt

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1 RECSITENM	1	Name of receiving study site		1 = Bridge HIVRECSITENM CRS (764) 2 = Harlem Prevention Center CRS (745) 3 = Penn Prevention CRS (863) 4 = Houston AIDS Research Team (HART) CRS (853) 5 = Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)	
2 TRNSFSITENM	1	Name of transferring study site		1 = Bridge HIVTRNSFSITENM CRS (764) 2 = Harlem Prevention Center CRS (745) 3 = Penn Prevention CRS (863) 4 = Houston AIDS Research Team (HART) CRS (853) 5 = Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)	
3 RECICDAT	dd MMM yyyy	Date informed consent signed at receiving site			RECICDAT

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Receipt
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
④ RECDAT	dd MMM yyyy	Date participant received by site			RECDAT

Name of transferring study site

- Bridge HIV CRS (764) ①
- Harlem Prevention Center CRS (745)
- Penn Prevention CRS (863)
- Houston AIDS Research Team (HART) CRS (853)
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)

Name of receiving study site

- Bridge HIV CRS (764) ②
- Harlem Prevention Center CRS (745)
- Penn Prevention CRS (863)
- Houston AIDS Research Team (HART) CRS (853)
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)

Visit of last completed contact with participant

- V1 - Screening ③
- V2 - Enrollment
- V3 - Week 13
- V4 - Week 26
- V5 - Week 39
- V6 - Week 52
- V7 - Week 65
- V8 - Week 78
- Interim Visit
- V201 - GAHT Initiation Visit
- V202 - DHI Day 8 Post Visit
- V301 - Seroconversion
- Termination Visit
- V401 - GAHT Safety Visit

If "Interim visit", specify Interim visit code

_____ ④

Date participant's records were sent to receiving study site

_____ ⑤

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Participant Transfer

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① TRNSFSITENM	1	Name of transferring study site		1 = Bridge HIV TRNSFSITENM CRS (764) 2 = Harlem Prevention Center CRS (745) 3 = Penn Prevention CRS (863) 4 = Houston AIDS Research Team (HART) CRS (853) 5 = Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)	
② RECSITENM	1	Name of receiving study site		1 = Bridge HIV RECSITENM CRS (764) 2 = Harlem Prevention Center CRS (745) 3 = Penn Prevention CRS (863) 4 = Houston AIDS Research Team (HART) CRS (853) 5 = Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721)	
③ TRNSFVISIT	2	Visit code of last completed contact with participant		1 = V1 - Screening 2 = V2 - Enrollment 3 = V3 - Week 13	TRNSFVISIT

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Transfer
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				4 = V4 - Week 26 5 = V5 - Week 39 6 = V6 - Week 52 7 = V7 - Week 65 8 = V8 - Week 78 9 = Interim Visit 10 = V201 - GAHT Initiation Visit 11 = V202 - DHI Day 8 Post Visit 12 = V301 - Seroconversion Termination Visit 13 = V401 - GAHT Safety Visit	
4 INTERIMCD	5.2	Interim Visit Code			INTERIMCD
5 RECRDSNTDAT	dd MMM yyyy	Date participant's records were sent to receiving study site			RECRDSNTDAT

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Screening Date of Visit
Generated On: 04 Nov 2022 01:44:33

Screening visit date

1

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Screening Date of Visit
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SVSTDAT	dd MMM yyyy	Screening visit date			SVSTDAT

Date of study exit _____ **1**

- Primary reason for completion/discontinuation
- Scheduled exit visit/end of study **2**
 - Death
 - Participant refused further participation
 - Participant is unwilling or unable to comply with required study procedures
 - Lost to follow-up (remove for HVTN)
 - Investigator decision
 - Participant refused further study product use
 - HIV infection
 - Early study closure
 - Protocol deviation
 - Adverse event
 - Withdrawal of consent by participant
 - Study terminated by sponsor
 - One or more reactive HIV test results or acute HIV infection suspected
 - Participant unable to adhere to visit schedule
 - Other, specify

If "Other", specify (max. 200 characters): _____ **3**

If "Death", enter date of death. _____ **4**

If "Adverse event", select applicable adverse event. _____ **5**

Does participant have a desire for future co-located Gender Affirming Hormone Therapy? Yes **6**
No
Unable to contact participant

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Study Termination
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① DSSTDAT	dd MMM yyyy	Date of study exit			DSSTDAT
② DSTERM	2	Primary reason for completion/dis continuation		1 = Scheduled exit visit/end of study 2 = Death 3 = Participant refused further participation 4 = Participant is unwilling or unable to comply with required study procedures 5 = Lost to follow-up (remove for HVTN) 6 = Investigator decision 7 = Participant refused further study product use 9 = HIV infection 10 = Early study closure 11 = Protocol deviation 12 = Adverse event 14 = Withdrawal of consent by participant 15 = Study terminated by sponsor	

HPTN091_Version_4.0_PROD_02NOV2022: ALL
 Form: Study Termination
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				16 = One or more reactive HIV test results or acute HIV infection suspected 17 = Participant unable to adhere to visit schedule 99 = Other, specify	
3 DSTERMOSP	\$200	If "Other", specify (max. 200 characters):			DSTERMOSP
4 DTHDAT	dd MMM yyyy	If "Death", enter date of death.			DTHDAT
5 DSAE	\$215	If "Adverse event", select applicable adverse event.			DSAE
6 GAHTFYN	\$2	Does participant have a desire for future co-located Gender Affirming Hormone Therapy?		Y = Yes N = No UA = Unable to contact participant	GAHTFYN

ACASI collection date _____ **1**

ACASI ID _____ **2**

Which questionnaire was completed? Enrollment **3**
Week 13
Week 26
Week 39
Week 52
Week 65
Week 78/Termination

Were there any problems or issues related to the administration or completion of the questionnaire? Yes **4**
No

If yes, please describe _____ **5**

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: ACASI Tracking

Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	QSDAT	dd MMM yyyy	ACASI collection date			QSDAT
2	QSCASIID	\$7	ACASI ID			QSCASIID
3	QSVER	1	Questionnaire completed		1 = Enrollment 2 = Week 13 3 = Week 26 4 = Week 39 5 = Week 52 6 = Week 65 7 = Week 78/Terminatio n	QSVER
4	SUPPQSCOMPP\$1 RO		Any problems or issues with administering questionnaire		Y = Yes N = No	SUPPQSCOMPP RO
5	SUPPDESCRIB \$200 E		If yes, please describe			SUPPDESCRIB E

Date of completion _____ **1**

Were any of the following topics discussed at this visit? Yes **2**
No

Mark all that apply.

PrEP Adherence goal setting **4**

PrEP Adherence reminder strategies **5**

Barriers to PrEP adherence **6**

Planning for future PrEP use **7**

GAHT Adherence goal setting **8**

GAHT Adherence reminder strategies **9**

Barriers to GAHT adherence **10**

Planning for future GAHT **11**

Communication skills **12**

Product Storage **13**

Disclosing product use to others 14

HIV prevention counseling 15

Problem solving 16

Other 17

If other, please specify: _____ 18

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Counseling

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① CNSLDAT	dd MMM yyyy	Date of completion			CNSLDAT
② QSYN_CNSL	\$1	Were any of the following topics discussed at this visit?		Y = Yes N = No	QSYN_CNSL
④ CNSL_QSORRE 1 S1		PrEP Adherence goal setting			CNSL_QSORRE S1
⑤ CNSL_QSORRE 1 S2		PrEP Adherence reminder strategies			CNSL_QSORRE S2
⑥ CNSL_QSORRE 1 S3		Barriers to PrEP adherence			CNSL_QSORRE S3
⑦ CNSL_QSORRE 1 S4		Planning for future PrEP use			CNSL_QSORRE S4
⑧ CNSL_QSORRE 1 S5		GAHT Adherence goal setting			CNSL_QSORRE S5
⑨ CNSL_QSORRE 1 S6		GAHT Adherence reminder strategies			CNSL_QSORRE S6

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Form: Counseling

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
10 CNSL_QSORRE 1 S7		Barriers to GAHT adherence			CNSL_QSORRE S7
11 CNSL_QSORRE 1 S8		Planning for future GAHT			CNSL_QSORRE S8
12 CNSL_QSORRE 1 S9		Communicatio n skills			CNSL_QSORRE S9
13 CNSL_QSORRE 1 S10		Product Storage			CNSL_QSORRE S10
14 CNSL_QSORRE 1 S11		Disclosing product use to others			CNSL_QSORRE S11
15 CNSL_QSORRE 1 S12		HIV prevention counseling			CNSL_QSORRE S12
16 CNSL_QSORRE 1 S13		Problem solving			CNSL_QSORRE S13
17 QSORRES_TPC 1 OTH		Other			QSORRES_TPC OTH
18 QSORRES_TPC \$200 OSP		If other, please specify:			QSORRES_TPC OSP

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Little interest or pleasure in doing things

Not at all 2
Several days
More than half the days
Nearly every day

Feeling down, depressed, or hopeless

Not at all 3
Several days
More than half the days
Nearly every day

Trouble falling or staying asleep, or sleeping too much

Not at all 4
Several days
More than half the days
Nearly every day

Feeling tired or having little energy

Not at all 5
Several days
More than half the days
Nearly every day

Poor appetite or overeating

Not at all 6
Several days
More than half the days
Nearly every day

Feeling bad about yourself - or that you are a failure or have let yourself or your family down

Not at all 7
Several days
More than half the days

Nearly every day

Trouble concentrating on things, such as reading the newspaper or watching television

Not at all **8**
Several days
More than half the days
Nearly every day

Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual

Not at all **9**
Several days
More than half the days
Nearly every day

Thoughts that you would be better off dead, or of hurting yourself

Not at all **10**
Several days
More than half the days
Nearly every day

PHQ Calculated Total

_____ **11**

If you mentioned any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all **12**
Somewhat difficult
Very difficult
Extremely difficult

In the past year, have you felt depressed or sad most days, even if you felt OK sometimes?

Yes **13**
No

Has there been a time in the past month when you have had serious thoughts about ending your life?

Yes **14**
No

Have you ever, in your whole life, tried to kill yourself or made a
suicide attempt?

Yes 15
No

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Patient Health Questionnaire
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
② PHQ01	1	Little interest or pleasure in doing things		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ01
③ PHQ02	1	Feeling down, depressed, or hopeless		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ02
④ PHQ03	1	Trouble falling or staying asleep, or sleeping too much		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ03
⑤ PHQ04	1	Feeling tired or having little energy		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ04
⑥ PHQ05	1	Poor appetite or overeating		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ05

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Patient Health Questionnaire
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
7 PHQ06	1	Feeling bad about yourself - or that you are a failure or have let yourself or your family down		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ06
8 PHQ07	1	Trouble concentrating on things, such as reading the newspaper or watching television		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ07
9 PHQ08	1	Moving or speaking so slowly that other people could have noticed. Or the opposite - being so figety or restless that you have been moving around a lot more than usual		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ08
10 PHQ09	1	Thoughts that you would be better off dead, or of hurting yourself		1 = Not at all 2 = Several days 3 = More than half the days 4 = Nearly every day	PHQ09
11 PHQCALC	2	PHQ Calculated Total			PHQCALC

HPTN091_Version_4.0_PROD_02NOV2022: ALL
 Form: Patient Health Questionnaire
 Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
12 PHQ10	1	If you mentioned any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?		1 = Not difficult at all 2 = Somewhat difficult 3 = Very difficult 4 = Extremely difficult	PHQ10
13 PHQ11	\$1	In the past year, have you felt depressed or sad most days, even if you felt OK sometimes?		Y = Yes N = No	PHQ11
14 PHQ12	\$1	Has there been a time in the past month when you have had serious thoughts about ending your life?		Y = Yes N = No	PHQ12
15 PHQ13	\$1	Have you ever, in your whole life, tried to kill yourself or made a suicide attempt?		Y = Yes N = No	PHQ13

Date of encounter _____ **1**

Visit Log completed at

V1 - Screening **2**

V2 - Enrollment

V3 - Week 13

V4 - Week 26

V5 - Week 39

V6 - Week 52

V7 - Week 65

V8 - Week 78

Interim Visit

V201 - GAHT Initiation Visit

V202 - DHI Day 8 Post Visit

V301 - Seroconversion Termination Visit

V401 - GAHT Safety Visit

If "Interim visit", specify Interim visit code _____ **3**

Was this encounter a PHN Session? Yes **4**
No

Type of Encounter

In-person **5**

Email

Text

Phone

Video Encounter

Duration of Encounter

10 minutes or less **6**

11-30 minutes

31-60 minutes

More than an hour

Number of Encounters (number of contacts on a given day) _____ **7**

Encounter initiated by Participant **8**
 Peer Health Navigator

Content of Encounter **9**
Mark all that apply

PrEP Adherence

PrEP Concerns **10**

GAHT Adherence **11**

GAHT Concerns **12**

Coordinating Care **13**

Study Appointments **14**

Barriers to access **15**

Linkage to follow-up services **16**

Referral to gender-affirming social services **17**

Referral to gender-affirming health services 18

Transgender community 19

Housing 20

Other 21

If "Other", specify: _____ 22

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① PHNTDAT	dd MMM yyyy	Date of completion			PHNTDAT
② PHNTVISIT	2	Visit Log completed at		1 = V1 - Screening 2 = V2 - Enrollment 3 = V3 - Week 13 4 = V4 - Week 26 5 = V5 - Week 39 6 = V6 - Week 52 7 = V7 - Week 65 8 = V8 - Week 78 9 = Interim Visit 10 = V201 - GAHT Initiation Visit 11 = V202 - DHI Day 8 Post Visit 12 = V301 - Seroconversion Termination Visit 13 = V401 - GAHT Safety Visit	PHNTVISIT
③ PHNTINT	5.2	Interim Visit Code			PHNTINT
④ PHTNSN	\$1	Was this encounter a PHN Session?		Y = Yes N = No	PHTNSN

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
5 PHNTTYP	1	Type of Encounter		1 = In-person 2 = Email 3 = Text 4 = Phone 5 = Video Encounter	PHNTTYP
6 PHNTDUR	1	Duration of Encounter		1 = 10 minutes or less 2 = 11-30 minutes 3 = 31-60 minutes 4 = More than an hour	PHNTDUR
7 PHNTNOC	3	Number of Encounters (number of contacts on a given day)			PHNTNOC
8 PHNTIB	1	Encounter initated by		1 = Participant 2 = Peer Health Navigator	PHNTIB
9 PHNTRES_1	1	PrEP Adherence			PHNTRES_1
10 PHNTRES_2	1	PrEP Concerns			PHNTRES_2
11 PHNTRES_3	1	GAHT Adherence			PHNTRES_3
12 PHNTRES_4	1	GAHT Concerns			PHNTRES_4

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13 PHNTRES_5	1	Coordinating Care			PHNTRES_5
14 PHNTRES_6	1	Study Appointments			PHNTRES_6
15 PHNTRES_7	1	Barriers to access			PHNTRES_7
16 PHNTRES_8	1	Linkage to follow-up services			PHNTRES_8
17 PHNTRES_9	1	Referral to gender-affirmi ng social services			PHNTRES_9
18 PHNTRES_10	1	Referral to gender-affirmi ng health services			PHNTRES_10
19 PHNTRES_11	1	Transgender community			PHNTRES_11
20 PHNTRES_12	1	Housing			PHNTRES_12
21 PHNTRESOTH	1	Other			PHNTRESOTH
22 PHNTTERMOSP\$200		If "Other", specify:			PHNTTERMOSP

Is the participant engaging with Peer Health Navigation?

Yes **1**
No

If "Yes", update the Peer Health Navigation Tracking log.

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking Y/N
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① PHNYN	\$1	Is the participant engaging with Peer Health Navigation?		Y = Yes N = No	PHNYN

Date reported to site _____ **1**

Concisely describe social impact (max. 200 characters). _____ **2**

Onset date _____ **3**

Reported at visit code _____ **4**

- V1 - Screening
- V2 - Enrollment
- V3 - Week 13
- V4 - Week 26
- V5 - Week 39
- V6 - Week 52
- V7 - Week 65
- V8 - Week 78
- Interim Visit
- V201 - GAHT Initiation Visit
- V202 - DHI Day 8 Post Visit
- V301 - Seroconversion
- Termination Visit
- V401 - GAHT Safety Visit

If "Interim visit", specify interim visit code. _____ **5**

Social impact _____ **6**

- Personal Relationships
- Travel/Immigration
- Employment
- Education
- Medical/Dental
- Health Insurance/Medical
- Aid/Hospital Plan
- Life Insurance/Funeral Coverage
- Housing
- Military/Other Government
- Agency

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Social Impact

Generated On: 04 Nov 2022 01:44:33

Involuntary Disclosure of gender identity

Other - Had other problems not covered in the list above.

If "Other", specify (max. 200 characters):

7

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Social Impact

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SIDAT	dd- MMM yyyy	Date Social Impact Reported to Site			SIDAT
② SITERM	\$200	Description of Social Impact			SITERM
③ SISTDAT	dd- MMM yyyy	Social Impact Start Date			SISTDAT
④ SIVISIT	2	Social Impact Reported Visit		1 = V1 - Screening 2 = V2 - Enrollment 3 = V3 - Week 13 4 = V4 - Week 26 5 = V5 - Week 39 6 = V6 - Week 52 7 = V7 - Week 65 8 = V8 - Week 78 9 = Interim Visit 10 = V201 - GAHT Initiation Visit 11 = V202 - DHI Day 8 Post Visit 12 = V301 - Seroconversion Termination Visit 13 = V401 - GAHT Safety Visit	SIVISIT

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Social Impact

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
5 INTERIMCD	5.2	Interim Visit Code			INTERIMCD
6 SIDECOD	2	Social Impact Code		01 = Personal Relationships 02 = Travel/Immigration 03 = Employment 04 = Education 05 = Medical/Dental 06 = Health Insurance/Medical Aid/Hospital Plan 07 = Life Insurance/Funeral Coverage 08 = Housing 09 = Military/Other Government Agency 10 = Involuntary Disclosure of gender identity 99 = Other - Had other problems not covered in the list above.	SIDECOD
7 SIDECODOSP	\$200	Social Impact Other Specify			SIDECODOSP

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Social Impact Y/N

Generated On: 04 Nov 2022 01:44:33

Has the participant experienced any social impacts related to study participation?

Yes 1
No

If "Yes", update the Social Impact log.

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Social Impact Y/N

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① SIYN	\$1	Any Social Impact		Y = Yes N = No	SIYN

Was a physical exam performed?

Yes 1
No

Date of exam _____ 2

BODY SYSTEM

HEENT

Not done 4
Normal
Abnormal

If "Abnormal", specify: _____ 5

Neck

Not done 6
Normal
Abnormal

If "Abnormal", specify: _____ 7

Lymph Nodes

Not done 8
Normal
Abnormal

If "Abnormal", specify: _____ 9

Heart/Cardiovascular

Not done 10
Normal
Abnormal

If "Abnormal", specify: _____ 11

Lung/Respiratory

Not done **12**
Normal
Abnormal

If "Abnormal", specify: _____

Abdomen

Not done **14**
Normal
Abnormal

If "Abnormal", specify: _____

Genitourinary

Not done **16**
Normal
Abnormal

If "Abnormal", specify: _____

Extremities

Not done **18**
Normal
Abnormal

If "Abnormal", specify: _____

Neurological

Not done **20**
Normal
Abnormal

If "Abnormal", specify: _____

Skin

Not done **22**
Normal
Abnormal

If "Abnormal", specify: _____

23

General appearance

Not done **24**
Normal
Abnormal

If "Abnormal", specify: _____

25

Other system finding

Not done **26**
Normal
Abnormal

If "Other system", specify system: _____

27

If "Abnormal", specify: _____

28

Comments (max. 200 characters): _____

29

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Physical Exam
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① PEPERF	\$1	Physical Examination Performed		Y = Yes N = No	PEPERF
② PEDAT	dd MMM yyyy	Date of Physical Examination			PEDAT
④ PERES_HEENT 2		HEENT Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_HEENT
⑤ PEDESC_HEEN T	\$200	HEENT Abnormal Description			PEDESC_HEEN T
⑥ PERES_NECK 2		Neck Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_NECK
⑦ PEDESC_NECK H	\$200	Neck Abnormal Description			PEDESC_NECK
⑧ PERES_LYMPH 2		Lymph Nodes Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_LYMPH
⑨ PEDESC_LYMP H	\$200	Lymph Nodes Abnormal Description			PEDESC_LYMP H
⑩ PERES_CARDI O	2	Heart/Cardio Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_CARDI O

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Physical Exam

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
11 PEDESC_CARD IO	\$200	Heart/Cardio Abnormal Description			PEDESC_CARD IO
12 PERES_LUNG	2	Lung/Resp Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_LUNG
13 PEDESC_LUNG	\$200	Lung/Resp Abnormal Description			PEDESC_LUNG
14 PERES_ABD	2	Abdomen Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_ABD
15 PEDESC_ABD	\$200	Abdomen Abnormal Description			PEDESC_ABD
16 PERES_GEN	2	Genitourinary Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_GEN
17 PEDESC_GEN	\$200	Genitourinary Abnormal Description			PEDESC_GEN
18 PERES_EXT	2	Extremities Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_EXT
19 PEDESC_EXT	\$200	Extremities Abnormal Description			PEDESC_EXT


HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Physical Exam

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
20 PERES_NEURO	2	Neurological Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_NEURO
21 PEDESC_NEUR O	\$200	Neurological Abnormal Description			PEDESC_NEUR O
22 PERES_SKIN	2	Skin Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_SKIN
23 PEDESC_SKIN	\$200	Skin Abnormal Description			PEDESC_SKIN
24 PERES_APP	2	General Appearance Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_APP
25 PEDESC_APP	\$200	General Appearance Abnormal Description			PEDESC_APP
26 PERES_OTHER	2	Physical Exam Other System Verbatim Finding		97 = Not done 2 = Normal 3 = Abnormal	PERES_OTHER
27 PETEST_OTHE R	\$200	Physical Exam Other System			PETEST_OTHE R
28 PEDESC_OTHE R	\$200	Other System Verbatim Finding Description			PEDESC_OTHE R

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Physical Exam
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
 PECOMM	\$200	Physical Exam Comments			PECOMM

Were vital signs done?

Yes ①
No

Date of assessment _____ ②

Height _____

Fixed Unit: cm ③

Weight _____

Fixed Unit: kg ④

Body temperature _____

Fixed Unit: C ⑤

Systolic blood pressure _____

Fixed Unit: mmHg ⑥

Diastolic blood pressure _____

Fixed Unit: mmHg ⑦

Blood pressure severity grade

Not gradable ⑧
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Calculated Blood Pressure Severity Grade

Not gradable ⑨
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Blood Pressure adverse event, if applicable _____ (10)

Not reportable as an adverse event (11)

Pulse _____ Fixed Unit: beats/min (12)

Rate of respiration _____ Fixed Unit: breaths/min (13)

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Vital Signs

Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	VSPERF	\$1	Vital Signs Performed		Y = Yes N = No	VSPERF
2	VSDAT	dd MMM yyyy	Vital Signs Date			VSDAT
3	HEIGHT_VSOR RES	4.1	Height			HEIGHT_VSOR RES
4	WEIGHT_VSO RRES	4.1	Weight			WEIGHT_VSO RRES
5	TEMP_VSORRE S	3.1+	Temperature			TEMP_VSORRE S
6	SYSBP_VSORR ES	3	Systolic Blood Pressure			SYSBP_VSORR ES
7	DIABP_VSORR ES	3	Diastolic Blood Pressure			DIABP_VSORR ES
8	BP_LBTOXGR	2	Blood Pressure Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	BP_LBTOXGR

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Vital Signs

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
9 BPSEV CALC	2	Calculated Blood Pressure Severity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	BPSEV CALC
10 LBAE_BP	\$215	Blood Pressure Adverse Event			LBAE_BP
11 LBNR_BP	1	Not reportable as an adverse event			LBNR_BP
12 PULSE_VSORRES	3	Pulse Rate			PULSE_VSORRES
13 RESP_VSORRES	2	Respiratory Rate			RESP_VSORRES

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: CD4 Test Results/Viral Load

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

CD4+

Was CD4+ specimen collected for testing?

Yes 2

No

Specimen collection date _____ 3

Unable to analyze 4

Absolute CD4+

Fixed Unit: cells/mm3 5

CD4 % _____ 6

HIV RNA

Was HIV RNA PCR testing completed?

Yes 8

No

Specimen collection date _____ 9

Operator

> 10

<

=

HIV RNA PCR

Fixed Unit: viral copies/mL 11

HIV RNA PCR target not detected 12

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: CD4 Test Results/Viral Load

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Detected, less than LLQ or LLD



Detected, greater than the upper limit of quantification



Additional CD4 Test Results or Viral Load data collected



Check this box if another CD4 form is needed to capture additional testing data

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: CD4 Test Results/Viral Load

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	LBYN_CD4	\$1	Any CD4 Sample Collected		Y = Yes N = No	LBYN_CD4
3	LBDAT_CD4	dd MMM yyyy	CD4 Collection Date			LBDAT_CD4
4	LBREASND_CD 4		CD4 Unable to Analyze			LBREASND_CD 4
5	LBORRES_CD4 4		CD4 Result			LBORRES_CD4
6	LBORRES_CD4 3 LY		CD4/Lymphocy tes Result			LBORRES_CD4 LY
8	MBYN_HIV1RN A	\$1	Any HIV-1 RNA PCR Testing Done		Y = Yes N = No	MBYN_HIV1RN A
9	MBDAT_HIV1R NA	dd MMM yyyy	HIV-1 RNA PCR Collection Date			MBDAT_HIV1R NA
10	MBORRES_HIV 1 1RNAOP		HIV-1 RNA PCR Result Operator		1 = > 2 = < 3 = =	MBORRES_HIV 1 1RNAOP
11	MBORRES_HIV 1 1RNA	\$9	HIV-1 RNA PCR Plasma Result			MBORRES_HIV 1 1RNA
12	MBORRES_HIV 1 1RNATND		HIV RNA PCR target not detected			MBORRES_HIV 1 1RNATND

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: CD4 Test Results/Viral Load

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13 MBLLOQ_HIV1 1 RNATXT		Detected, less than LLQ or LLD			MBLLOQ_HIV1 RNATXT
14 MBLLOQU_HIV 1 1RNA		Detected, greater than the upper limit of quantification			MBLLOQU_HIV 1RNA
15 MBPERF_HIV1 1 RNA		Additional CD4 Test Results or Viral Load data collected			MBPERF_HIV1 RNA

Lab Name: _____

Was a sample collected for serum chemistries?

Yes ①
No

Specimen collection date _____ ②

LIVER FUNCTION TESTS

Alkaline Phosphatase result _____ ④

Alkaline Phosphatase severity grade

Not gradable ⑤
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Alkaline Phosphatase severity grade - calculated

Not gradable ⑥
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Alkaline Phosphatase adverse event _____ ⑦

Not reportable as an adverse event ⑧

AST (SGOT) result _____ ⑨

AST (SGOT) severity grade

Not gradable ⑩
Grade 1 (Mild)

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

AST (SGOT) severity grade - calculated

- Not gradable **11**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

AST (SGOT) adverse event _____ **12**

Not reportable as an adverse event **13**

ALT (SGPT) result _____ **14**

ALT (SGPT) severity grade

- Not gradable **15**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

ALT (SGPT) severity grade - calculated

- Not gradable **16**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

ALT (SGPT) adverse event _____

17

Not reportable as an adverse event

18

Total Bilirubin result _____

19

Total Bilirubin severity grade

Not gradable 20

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Total Bilirubin severity grade - calculated

Not gradable 21

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Total Bilirubin adverse event _____

22

Not reportable as an adverse event

23

RENAL FUNCTION TESTS

Creatinine result _____

25

Creatinine severity grade

Not gradable 26

Grade 1 (Mild)

Grade 2 (Moderate)

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Creatinine severity grade - calculated

Not gradable **27**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Creatinine adverse event _____ **28**

Not reportable as an adverse event **29**

Creatinine Clearance result _____ **30**

Creatinine Clearance severity grade

Not gradable **31**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Creatinine Clearance severity grade - calculated

Not gradable **32**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Creatinine Clearance adverse event _____ **33**

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Not reportable as an adverse event **34**

Urea result _____ **35**

BUN result _____ **36**

OTHER CHEMISTRIES

Albumin result _____ **38**

Albumin severity grade **39**
Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Albumin severity grade - calculated **40**
Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Albumin adverse event _____ **41**

Not reportable as an adverse event **42**

Potassium result _____ **43**

Potassium severity grade **44**
Not gradable

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

-
- Grade 1 (Mild)
 - Grade 2 (Moderate)
 - Grade 3 (Severe)
 - Grade 4 (Potentially life-threatening)

Potassium severity grade - calculated

- Not gradable **45**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Potassium adverse event

_____ **46**

Not reportable as an adverse event

47

Comments (max. 200 characters):

_____ **48**

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① LBYN	\$1	Any Serum Chemistry Sample Collected		Y = Yes N = No	LBYN
② LBDAT	dd MMM yyyy	Chemistry Specimen Collection Date			LBDAT
④ LBORRES_ALP 4		Alkaline Phosphatase Result			LBORRES_ALP
⑤ LBTOXGR_ALP 2		Alkaline Phosphatase Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_ALP
⑥ ALPSEVCALC 2		Alkaline Phosphatase Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	ALPSEVCALC

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Chemistry Panel

Generated On: 04 Nov 2022 01:44:33

Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
7 LBAE_ALP	\$215	Alkaline Phosphatase Adverse Event			LBAE_ALP
8 LBNR_ALP	1	Not reportable as an adverse event			LBNR_ALP
9 LBORRES_AST	4	Aspartate Aminotransfera se Result			LBORRES_AST
10 LBTOXGR_AST	2	Aspartate Aminotransfera se Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_AST
11 ASTSEV CALC	2	Aspartate Aminotransfera se Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	ASTSEV CALC

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
12) LBAE_AST	\$215	Aspartate Aminotransferase Adverse Event			LBAE_AST
13) LBNR_AST	1	Not reportable as an adverse event			LBNR_AST
14) LBORRES_ALT	4	Alanine Aminotransferase Result			LBORRES_ALT
15) LBTOXGR_ALT	2	Alanine Aminotransferase Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_ALT
16) ALTSEV CALC	2	Alanine Aminotransferase Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	ALTSEV CALC

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	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
17	LBAE_ALT	\$215	Alanine Aminotransferase Adverse Event			LBAE_ALT
18	LBNR_ALT	1	Not reportable as an adverse event			LBNR_ALT
19	LBORRES_BILI	8.5	Total Bilirubin Result			LBORRES_BILI
20	LBTOXGR_BILI	2	Total Bilirubin Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_BILI
21	BILISEV CALC	2	Total Bilirubin Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	BILISEV CALC
22	LBAE_BILI	\$215	Total Bilirubin Adverse Event			LBAE_BILI

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
23 LBNR_BILI	1	Not reportable as an adverse event			LBNR_BILI
25 LBORRES_CRE AT	7.5	Creatinine Result			LBORRES_CRE AT
26 LBTOXGR_CRE AT	2	Creatinine Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_CRE AT
27 CREATSEV CAL C	2	Creatinine Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	CREATSEV CAL C
28 LBAE_CREAT	\$215	Creatinine Adverse Event			LBAE_CREAT
29 LBNR_CREAT	1	Not reportable as an adverse event			LBNR_CREAT

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
30 LBORRES_CRE 4.1 ATCLR		Creatinine Clearance Result			LBORRES_CRE ATCLR
31 LBTOXGR_CRE 2 ATCLR		Creatinine Clearance Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_CRE ATCLR
32 CREATCLRSEV 2 CALC		Creatinine Clearance Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	CREATCLRSEV CALC
33 LBAE_CREATC \$215 LR		Creatinine Clearance Adverse Event			LBAE_CREATC LR
34 LBNR_CREATC 1 LR		Not reportable as an adverse event			LBNR_CREATC LR
35 LBORRES_URA 7.5 TE		Urea Result			LBORRES_URA TE

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
36 LBORRES_URE 3 ANBL		Blood Urea Nitrogen Result			LBORRES_URE ANBL
38 LBORRES_ALB 7.5		Albumin Result			LBORRES_ALB
39 LBTOXGR_ALB 2		Albumin Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_ALB
40 ALBSEV CALC 2		Albumin Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	ALBSEV CALC
41 LBAE_ALB	\$215	Albumin Adverse Event			LBAE_ALB
42 LBNR_ALB	1	Not reportable as an adverse event			LBNR_ALB

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
43 LBORRES_K	7.5	Potassium Result			LBORRES_K
44 LBTOXGR_K	2	Potassium Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_K
45 KSEV CALC	2	Potassium Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	KSEV CALC
46 LBAE_K	\$215	Potassium Adverse Event			LBAE_K
47 LBNR_K	1	Not reportable as an adverse event			LBNR_K
48 LBCOMM	\$200	Comments (max. 200 characters):			LBCOMM

Lab Name: _____

SERUM LIPID

Was a fasting sample collected for the lipid profile?

Yes **2**
No

Did the participant fast for at least 8 hours prior to blood collection?

Yes **3**
No

Date of collection: _____

4

Total Cholesterol result _____

5

Total Cholesterol severity grade

Not gradable **6**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Total Cholesterol severity grade - calculated

Not gradable **7**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Total Cholesterol adverse event _____

8

Not reportable as an adverse event

9

HDL Cholesterol result _____

10

Lab Name: _____

Triglycerides result _____ **11**

Triglycerides severity grade

- Not gradable **12**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Triglycerides severity grade - calculated

- Not gradable **13**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Triglycerides adverse event _____ **14**

Not reportable as an adverse event **15**

LDL Cholesterol result _____ **16**

LDL Cholesterol severity grade

- Not gradable **17**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

LDL Cholesterol severity grade - calculated

- Not gradable **18**
- Grade 1 (Mild)
- Grade 2 (Moderate)

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Lab Name: _____

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

LDL Cholesterol adverse event _____

19

Not reportable as an adverse event

20

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2 LBFAST_LIP	\$1	Was a fasting sample collected for the lipid profile?		Y = Yes N = No	LBFAST_LIP
3 LBCOND_LIP	\$1	Did the participant fast for at least 8 hours prior to blood collection? (lipids)		Y = Yes N = No	LBCOND_LIP
4 LBDAT_LIPID	dd MMM yyyy	Date of collection:			LBDAT_LIPID
5 LBORRES_CHO3 L		Total Cholesterol Result			LBORRES_CHO L
6 LBTOXGR_CH OL	2	Total Cholesterol Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening))	LBTOXGR_CH OL
7 CHOLSEV CALC 2		Total Cholesterol severity grade - calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate)	CHOLSEV CALC

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	
8 LBAE_CHOL	\$215	Total Cholesterol Adverse Event			LBAE_CHOL
9 LBNR_CHOL	1	Not reportable as an adverse event			LBNR_CHOL
10 LBORRES_HDL	3	HDL Cholesterol Result			LBORRES_HDL
11 LBORRES_TRI G	4	Triglycerides Result			LBORRES_TRI G
12 LBTOXGR_TRI G	2	Triglycerides Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_TRI G

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13 TRIGSEVCALC	2	Triglycerides severity grade - calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	TRIGSEVCALC
14 LBAE_TRIG	\$215	Triglycerides Adverse Event			LBAE_TRIG
15 LBNR_TRIG	1	Not reportable as an adverse event			LBNR_TRIG
16 LBORRES_LDL	3	LDL Cholesterol Result			LBORRES_LDL
17 LBTOXGR_LDL	2	LDL Cholesterol Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_LDL

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
18 LDLSEV CALC	2	LDL Cholesterol severity grade - calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LDLSEV CALC
19 LBAE_LDL	\$215	LDL Cholesterol Adverse Event			LBAE_LDL
20 LBNR_LDL	1	Not reportable as an adverse event			LBNR_LDL

Lab Name: _____

HEMOGRAM

Was a hematology sample collected?

Yes 2

No

Hematology collection date _____ 3

Has this participant had 6+ consecutive months of GAHT? 4

Hemoglobin _____ 5

Hemoglobin severity grade

Not gradable 6

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Hemoglobin severity grade - calculated

Not gradable 7

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Hemoglobin adverse event, if applicable _____ 8

Not reportable as an adverse event 9

Hematocrit _____ 10

Lab Name: _____

MCV _____ **11**

Platelets _____ **12**

Platelets severity grade

- Not gradable **13**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Platelets severity grade - calculated

- Not gradable **14**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Platelets adverse event, if applicable _____ **15**

Not reportable as an adverse event **16**

WBC _____ **17**

WBC severity grade

- Not gradable **18**
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

WBC severity grade - calculated

Not gradable **19**

Lab Name: _____

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

WBC adverse event, if applicable _____ **20**

Not reportable as an adverse event **21**

DIFFERENTIAL

Was a differential done? Yes **23**
No

Differential collection date _____ **24**

Neutrophils _____ **25**

Neutrophils severity grade Not gradable **26**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Neutrophils severity grade - calculated Not gradable **27**
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Lab Name: _____

Neutrophils adverse event, if applicable _____

28

Not reportable as an adverse event

29

Lymphocytes _____

30

Lymphocytes severity grade

Not gradable

31

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Lymphocytes severity grade - calculated

Not gradable

32

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Lymphocytes adverse event, if applicable _____

33

Not reportable as an adverse event

34

Monocytes _____

35

Eosinophils _____

36

Basophils _____

37

Atypical lymphocytes _____

38

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Form: Hematology

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Lab Name: _____

Comments (max. 200 characters): _____

39

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Form: Hematology

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Lab Name: _____

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
2	LBYN_HEM	\$1	Hematology Sample Collected		Y = Yes N = No	LBYN_HEM
3	LBDAT_HEM	dd MMM yyyy	Hematology Collection Date			LBDAT_HEM
4	GAHT_HGB	1	Has this participant had 6+ consecutive months of GAHT?			GAHT_HGB
5	LBORRES_HGB	8.5	Hemoglobin Result			LBORRES_HGB
6	LBTOXGR_HGB	2	Hemoglobin Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_HGB
7	HGBSEV CALC	2	Hemoglobin Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe)	HGBSEV CALC

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				4 = Grade 4 (Potentially life-threatening)	
8 LBAE_HGB	\$215	Hemoglobin Adverse Event			LBAE_HGB
9 LBNR_HGB	1	Not reportable as an adverse event			LBNR_HGB
10 LBORRES_HCT	7.5	Hematocrit Result			LBORRES_HCT
11 LBORRES_MCV	8.5	Ery. Mean Corpuscular Hemoglobin Result			LBORRES_MCV
12 LBORRES_PLA T	8.2	Platelets Result			LBORRES_PLA T
13 LBTOXGR_PLA T	2	Platelets Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_PLA T

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
14 PLATSEVCALC	2	Platelets Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	PLATSEVCALC
15 LBAE_PLAT	\$215	Platelets Adverse Event			LBAE_PLAT
16 LBNR_PLAT	1	Not reportable as an adverse event			LBNR_PLAT
17 LBORRES_WB C	7.2	WBC Result			LBORRES_WB C
18 LBTOXGR_WB C	2	WBC Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_WB C
19 WBCSEVCALC	2	WBC Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild)	WBCSEVCALC

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	
20 LBAE_WBC	\$215	WBC Adverse Event			LBAE_WBC
21 LBNR_WBC	1	Not reportable as an adverse event			LBNR_WBC
23 LBYN_DIFF	\$1	Differential Performed		Y = Yes N = No	LBYN_DIFF
24 LBDAT_DIFF	dd MMM yyyy	Differential Collection Date			LBDAT_DIFF
25 LBORRES_NEU T	7	Neutrophils Result			LBORRES_NEU T
26 LBTOXGR_NEU T	2	Neutrophils Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_NEU T

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
27 NEUTSEV CALC 2		Neutrophils Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	NEUTSEV CALC
28 LBAE_NEUT	\$215	Neutrophils Adverse Event			LBAE_NEUT
29 LBNR_NEUT	1	Not reportable as an adverse event			LBNR_NEUT
30 LBORRES_LYM 6		Lymphocytes Results			LBORRES_LYM
31 LBTOXGR_LYM 2		Lymphocytes Toxicity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	LBTOXGR_LYM
32 LYMSEV CALC 2		Lymphocytes Severity Grade Calculated		95 = Not gradable 1 = Grade 1 (Mild)	LYMSEV CALC

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Form: Hematology

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Lab Name: _____

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	
33 LBAE_LYM	\$215	Lymphocytes Adverse Event			LBAE_LYM
34 LBNR_LYM	1	Not reportable as an adverse event			LBNR_LYM
35 LBORRES_MO NO	6	Monocytes Result			LBORRES_MO NO
36 LBORRES_EOS	4	Eosinophils Result			LBORRES_EOS
37 LBORRES_BAS O	4	Basophils Result			LBORRES_BAS O
38 LBORRES_LYM AT	4	Lymphocytes Atypical Result			LBORRES_LYM AT
39 LBCOMM	\$200	Comments (max. 200 characters):			LBCOMM

Is participant vaccinated for Hepatitis B?

Yes **1**
No

Date of vaccination

_____ **2**

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Form: Hepatitis B Vaccination Tracking
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1 HPBVACV	\$1	Is participant vaccinated for Hepatitis B?		Y = Yes N = No	HPBVACV
2 HPBVACDAT	dd- MMM- yyyy	Date of vaccination			HPBVACDAT

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?

Yes 1
No

Date of collection _____ 2

Hepatitis B Surface Antigen (HBsAG)

Positive 3
Negative
Indeterminate

Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing?

Yes 4
No

Date of collection _____ 5

Hepatitis B Surface Antibody (HBsAb)

Positive 6
Negative
Indeterminate

Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing?

Yes 7
No

Date of collection _____ 8

Hepatitis B Core Antibody (HBcAb)

Positive 9
Negative
Indeterminate

Was a sample collected for Hepatitis C Antibody (HcAb) testing?

Yes 10
No

Date of collection _____

11

Hepatitis C Antibody (HCAb)

Positive 12
Negative
Indeterminate

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Form: Hepatitis Test Results

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① LBYN_HBSAG	\$1	Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?		Y = Yes N = No	LBYN_HBSAG
② LBDAT_HBSAG	dd MMM yyyy	Date of collection			LBDAT_HBSAG
③ LBORRES_HBS AG	1	Hepatitis B Surface Antigen (HBsAG)		1 = Positive 2 = Negative 3 = Indeterminate	LBORRES_HBS AG
④ LBYN_HBSAB	\$1	Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing?		Y = Yes N = No	LBYN_HBSAB
⑤ LBDAT_HBSAB	dd MMM yyyy	Date of collection			LBDAT_HBSAB
⑥ LBORRES_HBS AB	1	Hepatitis B Surface Antibody (HBsAb)		1 = Positive 2 = Negative 3 = Indeterminate	LBORRES_HBS AB
⑦ LBYN_HBCAG	\$1	Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing?		Y = Yes N = No	LBYN_HBCAG

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
8 LBDAT_HBCAG	dd MMM yyyy	Date of collection			LBDAT_HBCAG
9 LBORRES_HBC AG	1	Hepatitis B Core Antibody (HBcAb)		1 = Positive 2 = Negative 3 = Indeterminate	LBORRES_HBC AG
10 LBYN_HCAB	\$1	Was a sample collected for Hepatitis C Antibody (HcAb) testing?		Y = Yes N = No	LBYN_HCAB
11 LBDAT_HCAB	dd MMM yyyy	Date of collection			LBDAT_HCAB
12 LBORRES_HCA B	1	Hepatitis C Antibody (HcAb)		1 = Positive 2 = Negative 3 = Indeterminate	LBORRES_HCA B

Specimen Collection Date _____ **1**

Was this sample collected for additional testing? Yes **2**
No

HIV Rapid test result Reactive/Positive **3**
Non-Reactive/Negative
Invalid
Not Done

HIV Laboratory based immunoassay test result Reactive/Positive **4**
Non-Reactive/Negative
Invalid
Not Done

HIV RNA-1 Qualitative test result Reactive/Positive **5**
Non-Reactive/Negative
Invalid
Not Done

Was a viral load done? Yes **6**
No

Final HIV status Reactive/Positive **7**
Non-Reactive/Negative
Additional testing required

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Form: HIV Test Results

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① LBDAT_HIV	dd MMM yyyy	Specimen Collection Date			LBDAT_HIV
② LBHIVCNFM	\$1	Was this sample collected for additional testing?		Y = Yes N = No	LBHIVCNFM
③ LBORRES_HIV 1 RT1		HIV Rapid test result		1 = Reactive/Positi ve 2 = Non-Reactive/ Negative 3 = Invalid 4 = Not Done	LBORRES_HIV RT1
④ LBORRES_HIV 1 RT2		HIV Laboratory based immunoassay test result		1 = Reactive/Positi ve 2 = Non-Reactive/ Negative 3 = Invalid 4 = Not Done	LBORRES_HIV RT2
⑤ LBORRES_HIV 1 QUAL		HIV RNA Qualitative test result		1 = Reactive/Positi ve 2 = Non-Reactive/ Negative 3 = Invalid 4 = Not Done	LBORRES_HIV QUAL
⑥ LBYN_VL	\$1	Was a viral load done?		Y = Yes N = No	LBYN_VL

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Form: HIV Test Results

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
⑦ LBORRES_FNL 1 HIV		Final HIV status		1 = Reactive/Positi ve 2 = Non-Reactive/ Negative 3 = Additional testing required	LBORRES_FNL HIV

Was a serum total testosterone sample collected?

Yes ①
No

Date of collection:

_____ ②

Total testosterone

Fixed Unit: ng/dL ③

Symbol

< ④
=

Was a serum estradiol sample collected?

Yes ⑤
No

Date of collection:

_____ ⑥

Estradiol

Fixed Unit: pg/mL ⑦

Symbol

< ⑧
=

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Hormone Tests

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① LBYN_TESTOS \$1		Was a serum total testosterone sample collected?		Y = Yes N = No	LBYN_TESTOS
② LBDAT	dd MMM yyyy	Date of collection			LBDAT
③ TTESTOS_LBO RRES 6.2		Total testosterone			TTESTOS_LBO RRES
④ TESTOSYM_LB ORRESU \$1		symbol		1 = < 2 = =	TESTOSYM_LB ORRESU
⑤ LBYN_ESTRDI OL \$1		Was a serum estradiol sample collected?		Y = Yes N = No	LBYN_ESTRDI OL
⑥ LBDAT_ESTRD IOL	dd MMM yyyy	Date of collection:			LBDAT_ESTRD IOL
⑦ LBORRES_EST RDIOL 6.2		Estradiol			LBORRES_EST RDIOL
⑧ LBORRES_EST RDIOLOP \$1		Symbol		1 = < 2 = =	LBORRES_EST RDIOLOP

DOT day

Day 1 ①
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed?

Yes ②
No

If "No", record reason why dose was not observed (max. 200 characters).

③

Observed Dose date

④

Observed Dose time

⑤

DOT day

Day 1 ①
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed?

Yes ②
No

If "No", record reason why dose was not observed (max. 200 characters).

③

Observed Dose date

④

Observed Dose time

⑤

DOT day

Day 1 ①
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed?

Yes ②
No

If "No", record reason why dose was not observed (max. 200 characters).

③

Observed Dose date

④

Observed Dose time

⑤

DOT day

Day 1 ①
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed?

Yes ②
No

If "No", record reason why dose was not observed (max. 200 characters).

_____ ③

Observed Dose date

_____ ④

Observed Dose time

_____ ⑤

DOT day

Day 1 ①
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed?

Yes ②
No

If "No", record reason why dose was not observed (max. 200 characters).

3

Observed Dose date

4

Observed Dose time

5

DOT day

Day 1 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

PK Collection Day

Was dose observed?

Yes 2

No

If "No", record reason why dose was not observed (max. 200 characters).

3

Observed Dose date

4

Observed Dose time

5

DOT day

Day 1 1

Day 2

Day 3

Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed? Yes **2**
No

If "No", record reason why dose was not observed (max. 200 characters). _____ **3**

Observed Dose date _____ **4**

Observed Dose time _____ **5**

DOT day Day 1 **1**
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
PK Collection Day

Was dose observed? Yes **2**
No

If "No", record reason why dose was not observed (max. 200 characters). _____ **3**

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: PK Dose Time

Generated On: 04 Nov 2022 01:44:33

Observed Dose date

4

Observed Dose time

5

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: PK Dose Time

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1 DODY	1	DOT day		1 = Day 1 2 = Day 2 3 = Day 3 4 = Day 4 5 = Day 5 6 = Day 6 7 = Day 7 8 = PK Collection Day	DODY
2 PKDTYN	\$1	Was dose observed?		Y = Yes N = No	PKDTYN
3 PKDTNR	\$200	If "No", record reason why sample was not collected (max. 200 characters).			PKDTNR
4 OBDTD	dd MMM yyyy	Observed Dose date			OBDTD
5 OBDOT	HH:nn	Observed Dose time			OBDOT

PK Specimen type

- Pre-dose Plasma storage ①
 - Pre-dose DBS storage
 - 1 hour post-dose plasma
 - 1 hour post-dose PBMC
 - 4 hour post-dose plasma
 - 4 hour post-dose PBMC
 - Pre-dose PBMC storage
 - Serum storage
-

Was specimen collected?

- Yes ②
 - No
-

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

③

Specimen collection date

④

Specimen collection time

⑤

Was sample stored?

- Stored ⑥
 - Not stored
-

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

⑦

PK Specimen type

- Pre-dose Plasma storage ①
 - Pre-dose DBS storage
 - 1 hour post-dose plasma
-

- 1 hour post-dose PBMC
- 4 hour post-dose plasma
- 4 hour post-dose PBMC
- Pre-dose PBMC storage
- Serum storage

Was specimen collected? Yes **2**
No

If "No", record reason why sample was not collected (max. 200 characters). _____ **3**

Specimen collection date _____ **4**

Specimen collection time _____ **5**

Was sample stored? Stored **6**
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____ **7**

- PK Specimen type
- Pre-dose Plasma storage **1**
 - Pre-dose DBS storage
 - 1 hour post-dose plasma
 - 1 hour post-dose PBMC
 - 4 hour post-dose plasma
 - 4 hour post-dose PBMC
 - Pre-dose PBMC storage
 - Serum storage

Was specimen collected?

Yes 2
No

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

3

Specimen collection date

4

Specimen collection time

5

Was sample stored?

Stored 6
Not stored

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

7

PK Specimen type

Pre-dose Plasma storage 1
Pre-dose DBS storage
1 hour post-dose plasma
1 hour post-dose PBMC
4 hour post-dose plasma
4 hour post-dose PBMC
Pre-dose PBMC storage
Serum storage

Was specimen collected?

Yes 2
No

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

3

Specimen collection date _____ **4**

Specimen collection time _____ **5**

Was sample stored? Stored **6**
Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____ **7**

PK Specimen type Pre-dose Plasma storage **1**
Pre-dose DBS storage
1 hour post-dose plasma
1 hour post-dose PBMC
4 hour post-dose plasma
4 hour post-dose PBMC
Pre-dose PBMC storage
Serum storage

Was specimen collected? Yes **2**
No

If "No", record reason why sample was not collected (max. 200 characters). _____ **3**

Specimen collection date _____ **4**

Specimen collection time _____ **5**

Was sample stored? Stored **6**

Not stored

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

7

PK Specimen type

Pre-dose Plasma storage 1

Pre-dose DBS storage

1 hour post-dose plasma

1 hour post-dose PBMC

4 hour post-dose plasma

4 hour post-dose PBMC

Pre-dose PBMC storage

Serum storage

Was specimen collected?

Yes 2

No

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

3

Specimen collection date

4

Specimen collection time

5

Was sample stored?

Stored 6

Not stored

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

7

PK Specimen type

- Pre-dose Plasma storage ①
- Pre-dose DBS storage
- 1 hour post-dose plasma
- 1 hour post-dose PBMC
- 4 hour post-dose plasma
- 4 hour post-dose PBMC
- Pre-dose PBMC storage
- Serum storage

Was specimen collected?

- Yes ②
- No

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

③

Specimen collection date

④

Specimen collection time

⑤

Was sample stored?

- Stored ⑥
- Not stored

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

⑦

PK Specimen type

- Pre-dose Plasma storage ①
- Pre-dose DBS storage
- 1 hour post-dose plasma
- 1 hour post-dose PBMC
- 4 hour post-dose plasma

4 hour post-dose PBMC

Pre-dose PBMC storage

Serum storage

Was specimen collected?

Yes 2

No

If "No", record reason why sample was not collected (max. 200 characters). _____ 3

Specimen collection date _____ 4

Specimen collection time _____ 5

Was sample stored?

Stored 6

Not stored

If "No", record reason why sample was not stored (max. 200 characters). _____ 7

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Specimen Collection
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1 PKSPECT	1	PK Specimen type		1 = Pre-dose Plasma storage 2 = Pre-dose DBS storage 3 = 1 hour post-dose plasma 4 = 1 hour post-dose PBMC 5 = 4 hour post-dose plasma 6 = 4 hour post-dose PBMC 7 = Pre-dose PBMC storage 8 = Serum storage	PKSPECT
2 PKSPECYN	\$1	Any Specimen Collected		Y = Yes N = No	PKSPECYN
3 PKSPECNR	\$200	Reason Sample Not Collected			PKSPECNR
4 PKSPECDAT	dd MMM yyyy	Specimen collection date			PKSPECDAT
5 PKSPECTM	HH:nn	Specimen Collection Time			PKSPECTM
6 PKSAMS	1	Sample Stored		1 = Stored 2 = Not stored	PKSAMS
7 PKSAMSNR	\$200	Reason Sample Not Stored			PKSAMSNR

Specimen type

Plasma ①
Serum storage
DBS storage

Was specimen collected?

Yes ②
No

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

③

Specimen collection date

④

Specimen collection time

⑤

Was sample stored?

Stored ⑥
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

⑦

Specimen type

Plasma ①
Serum storage
DBS storage

Was specimen collected?

Yes ②
No

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

3

Specimen collection date

4

Specimen collection time

5

Was sample stored?

Stored 6
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

7

Specimen type

Plasma 1
Serum storage
DBS storage

Was specimen collected?

Yes 2
No

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

3

Specimen collection date

4

Specimen collection time

5

Was sample stored?

Stored 6
Not stored

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Specimen Collection
Generated On: 04 Nov 2022 01:44:33

If "Not stored", record reason why sample was not stored (max. 200 characters).

7

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Specimen Collection
Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	BSSPEC	1	Specimen Type		1 = Plasma 2 = Serum storage 3 = DBS storage	BSSPEC
②	BSCOLL	\$1	Any Specimen Collected		Y = Yes N = No	BSCOLL
③	BSREASC	\$200	Reason Sample Not Collected			BSREASC
④	BSDAT	dd MMM yyyy	Specimen Collection Date			BSDAT
⑤	BSTIM	HH:nn	Specimen Collection Time			BSTIM
⑥	BSSTORE	1	Sample Stored		1 = Stored 2 = Not stored	BSSTORE
⑦	BSREASNS	\$200	Reason Sample Not Stored			BSREASNS

Was a pharyngeal sample collected for N. gonorrhoea and C. trachomatis testing?

Yes 1
No

Collection date _____ 2

N. gonorrhoea - Pharyngeal test result

Detected 3
Non-detected
Equivocal
Invalid

C. trachomatis - Pharyngeal test result

Detected 4
Non-detected
Equivocal
Invalid

Was a urine sample collected for N. gonorrhoea and C. trachomatis testing?

Yes 5
No

Collection date _____ 6

N. gonorrhoea - URINE test result

Detected 7
Non-detected
Equivocal
Invalid

C. trachomatis - URINE test result

Detected 8
Non-detected
Equivocal
Invalid

Was a rectal swab sample collected for N. gonorrhea and C. trachomatis testing?

Yes **9**
No

Collection date _____

10

N. gonorrhea - RECTAL SWAB test result

Detected **11**
Non-detected
Equivocal
Invalid

C. trachomatis - RECTAL SWAB test result

Detected **12**
Non-detected
Equivocal
Invalid

Was a sample collected for Syphilis testing?

Yes **13**
No

Collection date _____

14

Algorithm used

Traditional **15**
Reverse

Treponemal

Not done **16**
Not detected/Negative
Positive/Reactive
Invalid
Indeterminate

Non-Treponemal

- Not done 17
- Not detected/Negative
- Positive/Reactive
- Invalid
- Indeterminate

Syphilis titer if indicated _____

18

Or

19

N/A

Second Treponemal test

- Not done 20
- Not detected/Negative
- Positive/Reactive
- Invalid
- Indeterminate

Second Non-Treponemal test

- Non-reactive 21
- Reactive
- Not reported
- Not done

Syphilis titer _____

22

Third Treponemal test

- Positive 23
- Negative
- Indeterminate
- Not done

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: STI Tests

Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	MBYN_PG	\$1	Pharyngeal sample collected for GC/CT		Y = Yes N = No	MBYN_PG
2	MBDAT_PG	dd MMM yyyy	Date of pharyngeal specimen collection			MBDAT_PG
3	MBORRES_NG 1 ONPG		GC pharyngeal test result		1 = Detected 2 = Non-detected 3 = Equivocal 4 = Invalid	MBORRES_NG ONPG
4	MBORRES_CTR1 ACHPG		CT pharyngeal test result		1 = Detected 2 = Non-detected 3 = Equivocal 4 = Invalid	MBORRES_CTR ACHPG
5	MBYN_UR	\$1	Urine sample collected for GC/CT		Y = Yes N = No	MBYN_UR
6	MBDAT_UR	dd MMM yyyy	Date of urine specimen collection			MBDAT_UR
7	MBORRES_NG 1 ONUR		GC urine test result		1 = Detected 2 = Non-detected 3 = Equivocal 4 = Invalid	MBORRES_NG ONUR
8	MBORRES_CTR1 IGAABUR		CT urine test result		1 = Detected	MBORRES_CTR IGAABUR

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: STI Tests

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				2 = Non-detected 3 = Equivocal 4 = Invalid	
9 MBYN_RS	\$1	Rectal sample collected for GC/CT		Y = Yes N = No	MBYN_RS
10 MBDAT_RS	dd MMM yyyy	Date of rectal specimen collection			MBDAT_RS
11 MBORRES_NG 1 ONRS		GC rectal test result		1 = Detected 2 = Non-detected 3 = Equivocal 4 = Invalid	MBORRES_NG ONRS
12 MBORRES_CTR1 IGAABRS		CT rectal test result		1 = Detected 2 = Non-detected 3 = Equivocal 4 = Invalid	MBORRES_CTR IGAABRS
13 MBYN_SYPH	\$1	Sample collected for syphilis		Y = Yes N = No	MBYN_SYPH
14 MBDAT_SYPH	dd MMM yyyy	Date of syphilis specimen collection			MBDAT_SYPH
15 MBALG	1	Algorithm used		1 = Traditional MBALG 2 = Reverse	

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: STI Tests

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
16 TREP_MBORRE2 S		Syphilis confirmatory test result		97 = Not done 1 = Not detected/Nega tive 2 = Positive/Reacti ve 3 = Invalid 4 = Indeterminate	TREP_MBORRE S
17 NONTREP_MB 2 ORRES		Syphilis screening test result		97 = Not done 1 = Not detected/Nega tive 2 = Positive/Reacti ve 3 = Invalid 4 = Indeterminate	NONTREP_MB ORRES
18 RPR_MBORRES\$6		Syphilis titer			RPR_MBORRES
19 NA_MBORRES 1		titer N/A			NA_MBORRES
20 TREP2_MBORR2 ES		Second Treponemal test		97 = Not done 1 = Not detected/Nega tive 2 = Positive/Reacti ve 3 = Invalid 4 = Indeterminate	TREP2_MBORR ES
21 NONTREP2_M 1 BORRES		Syphilis screening test result		1 = Non-reactive 2 = Reactive	NONTREP2_M BORRES

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: STI Tests

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				3 = Not reported 4 = Not done	
22 RPR2_MBORRE\$6 S		Syphilis titer			RPR2_MBORRE S
23 SYCT_MBORRE1 S		Syphilis confirmatory test result		1 = Postive 2 = Negative 3 = Indeterminate 4 = Not done	SYCT_MBORRE S

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done **3**

OR

Specimen Collection Date _____ **5**

Assay Result

Assay result not provided **6**

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: _____ **7**

Comments (max. 200 characters) _____ **8**

Laboratory Reported HIV Interpretation

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported **11**

OR

Interpretation

- HIV Negative **13**
- HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.
- HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.
- HIV-1 Positive
- HIV-2 Positive
- HIV-2 Positive - This result is distinct from HIV Positive, Untypable.
- HIV Positive
- Acute HIV-1 Positive
- HIV-1 Negative, HIV-2 inconclusive
- Inconclusive
- Other

Other interpretation: _____ **14**

Comments (max. 200 characters) _____ **15**

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) **18**

OR

Specimen Collection Date _____ **20**

DNA Result

- Detectable DNA result (record below) 21
- 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 22

Comments (max. 200 characters)

23

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Supplemental HIV Results
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
3 LBPERFN_HIV AS	1	Not Done			LBPERFN_HIV AS
5 LBDAT_HIVAS	dd MMM yyyy	HIV 1/2 Collection Date			LBDAT_HIVAS
6 LBORRES_HIV AS	2	Assay Result		1 = Assay result not provided 2 = HIV Negative 3 = HIV-1 Positive 4 = HIV-2 Positive 5 = HIV-2 Positive with HIV-1 Cross-Reactivit y 6 = HIV-1 Positive, Untypable 7 = HIV-1 Indeterminate 8 = HIV-2 Indeterminate 9 = HIV Indeterminate 99 = Other	LBORRES_HIV AS
7 LBORRES_HIV ASOTH	\$200	Other assay result			LBORRES_HIV ASOTH
8 LBCOMM_HIVA S	\$200	Comments			LBCOMM_HIVA S
11 LBPERFN_HIVL B	1	Not Reported			LBPERFN_HIVL B

HPTN091_Version_4.0_PROD_02NOV2022: ALL
 Form: Supplemental HIV Results
 Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
13 LBORRES_HIV 2 LB		Interpretation		1 = HIV Negative 2 = HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection. 3 = HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. 4 = HIV-1 Positive 5 = HIV-2 Positive 6 = HIV-2 Positive - This result is distinct from HIV Positive, Untypable. 7 = HIV Positive 8 = Acute HIV-1 Positive 9 = HIV-1 Negative, HIV-2 inconclusive 10 = Inconclusive 99 = Other	LBORRES_HIV LB
14 LBORRES_HIV \$20 LBOTH		Other interpretation			LBORRES_HIV LBOTH
15 LBCOMM_HIVL \$200 B		Comments			LBCOMM_HIVL B

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Supplemental HIV Results
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
18 LBPFRFN_DNA 1		Not performed/Not reported by Lab			LBPFRFN_DNA
20 LBDAT_DNA	dd MMM yyyy	HIV DNA Collection Date			LBDAT_DNA
21 LBORRES_DNA 1		DNA Result		1 = Detectable LBORRES_DNA DNA result (record below) 2 = Detectable DNA , but below limit of detection (<4.09 copies per million cells) 3 = Detectable DNA, above the reportable range of the assay (>100 copies per million cells) 4 = Undetectable DNA, below limit of detection (<4.09 copies per million cells)	
22 LBDET_DNA	5.2	Detectable DNA result			LBDET_DNA
23 LBCOMM_DNA	\$200	Comments			LBCOMM_DNA

Was a sample collected for urine tests?

Yes 1
No

Date of collection:

_____ 2

Protein (Urine)

Negative 3
Trace
1+
2+
3+
4+
30 mg/dL
100 mg/dL
300 mg/dL
2000 mg/dL or more

Protein (Urine) Severity Grade

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

Protein (Urine) severity grade - calculated

Not gradable 5
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially
life-threatening)

Protein (Urine) Adverse Event

_____ 6

Not reportable as an adverse event

7

Glucose (Urine)

- Negative 8
- Trace
- +1
- +2
- +3
- +4
- 250 mg/dL
- 500 mg/dL
- 1000 mg/dL
- 2000 mg/dL or more
- 1/10 g/dL (%)
- 1/4 g/dL (%)
- 1/2 g/dL (%)
- 1 g/dL (%)
- 2 g/dL (%) or more

Glucose (Urine) Severity Grade

- Not gradable 9
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

Glucose (Urine) severity grade - calculated

- Not gradable 10
- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Urinalysis
Generated On: 04 Nov 2022 01:44:33

Glucose (Urine) Adverse Event

11

Not reportable as an adverse event

12

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Urinalysis

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① LBYN_URINE	\$1	Was a sample collected for urine tests?		Y = Yes N = No	LBYN_URINE
② LBDAT_URINE	dd MMM yyyy	Date of collection:			LBDAT_URINE
③ LBORRES_PRO T	2	Protein (Urine)		1 = Negative 2 = Trace 3 = 1+ 4 = 2+ 5 = 3+ 6 = 4+ 7 = 30 mg/dL 8 = 100 mg/dL 9 = 300 mg/dL 10 = 2000 mg/dL or more	LBORRES_PRO T
④ LBTOXGR_PRO T	2	Protein (Urine) Severity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening))	LBTOXGR_PRO T
⑤ PROUSEV CALC	2	Protein (Urine) severity grade - calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe)	PROUSEV CALC

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Urinalysis

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				4 = Grade 4 (Potentially life-threatening)	
⑥ LBAE_PROT	\$215	Protein (Urine) Adverse Event			LBAE_PROT
⑦ LBNR_PROT	1	Not reportable as an adverse event			LBNR_PROT
⑧ LBORRES_GLU C	2	Glucose (Urine)		1 = Negative 2 = Trace 3 = +1 4 = +2 5 = +3 6 = +4 7 = 250 mg/dL 8 = 500 mg/dL 9 = 1000 mg/dL 10 = 2000 mg/dL or more 11 = 1/10 g/dL (%) 12 = 1/4 g/dL (%) 13 = 1/2 g/dL (%) 14 = 1 g/dL (%) 15 = 2 g/dL (%) or more	LBORRES_GLU C
⑨ LBTOXGR_GLU C	2	Glucose (Urine) Severity Grade		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate)	LBTOXGR_GLU C

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Urinalysis

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	
10 GLUUSEV CALC 2		Glucose (Urine) severity grade - calculated		95 = Not gradable 1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	GLUUSEV CALC
11 LBAE_GLUC	\$215	Glucose (Urine) Adverse Event			LBAE_GLUC
12 LBNR_URGLUC 1		Not reportable as an adverse event			LBNR_URGLUC

Therapy name

- Estradiol Tablets ①
- Estradiol Transdermal
- Estradiol Injectable
- Spirolactone
- Cyproterone Acetate
- Finasteride
- Other

If "Other", specify:

_____ ②

Dose

_____ ③

Dose units

- Grams ④
- Micrograms
- Milligrams
- Milliliters
- Capsules
- Drops
- Puffs
- Sachets
- Suppository
- Tablets
- Units
- Unknown
- Other

If "Other", specify:

_____ ⑤

Frequency

- PRN ⑥
- QD
- BID

- TID
- QID
- QM
- QH
- ONCE
- Other

If "Other", specify: _____

7

Route

- Oral
- Intramuscular
- Intravenous
- Topical
- Inhalation
- Vaginal
- Rectal
- Subcutaneous
- Other

8

If "Other", specify: _____

9

How was GAHT obtained?

- Study Clinic
- Private doctor
- Nonprescription
- Other

10

If "Other", specify: _____

11

Date started _____

12

Ongoing

13

What kind of product stoppage is being reported?

- Product Hold **14**
- Permanent Discontinuation
- Participant Reported

Please complete the relevant section below

Participant Reported

15

Date of product stoppage as reported by participant : _____

Why was product stopped?

- Lost product **16**
- Product damaged
- Ran out of product
- Participant requested temporary "drug holiday"
- Other

If "Other" is selected, please specify: _____

17

Date participant resumed study product: _____

18

Product Hold

19

Date when this study product hold was initiated: _____

Why is the study product being held?

- Reported of use of prohibited concomitant medications **20**
- One or more reactive HIV test results or expresses concern about having acute HIV infection
- Receiving PEP for potential HIV exposure
- Adverse Event
- Hepatitis B infection

- Participant unable/unwilling to comply with the required study procedures
- Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee
- Other

If "Other" is selected, please specify: _____ **21**

If product hold was associated with an adverse event, select the applicable AE1: _____ **22**

If product hold was associated with an adverse event, select the applicable AE2: _____ **23**

If product hold was associated with a new or updated concomitant medication, select applicable medication(s): _____ **24**

Date participant resumed study product: _____ **25**

Is this a permanent discontinuation? _____ **26**

Date stopped _____

- Primary reason for ending study product use
- Scheduled study product use period completed **27**
 - Death
 - Participant is unwilling or unable to comply with required study procedures
 - Lost to follow-up
 - Investigator decision
 - Participant refused further study product use
 - HIV infection

- Early study closure
- Protocol deviation
- Adverse event
- Withdrawal of consent by participant
- Study terminated by sponsor
- One or more reactive HIV test results or acute HIV infection suspected
- Participant unable to adhere to visit schedule
- Participant switched to clinic-provided study product
- Change made to study product prescription
- Other, specify

If "Other", specify: _____ **28**

If "Investigator decision", specify: _____ **29**

If "Adverse event", select applicable adverse event # 1 _____ **30**

If "Adverse event", select applicable adverse event # 2 _____ **31**

Is this a permanent discontinuation from study product? Yes **32**
No

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① GAHTTRT	2	Therapy name		1 = Estradiol Tablets 2 = Estradiol Transdermal 3 = Estradiol Injectable 4 = Spironolactone 5 = Cyproterone Acetate 6 = Finasteride 99 = Other	GAHTTRT
② GAHTTOS	\$200	If "Other", specify:			GAHTTOS
③ GAHTDOSE	\$20	Dose			GAHTDOSE
④ GAHTDOU	\$11	Dose units		g = Grams ug = Micrograms mg = Milligrams ml = Milliliters CAPSULE = Capsules gtt = Drops PUFF = Puffs SACHET = Sachets SUPPOSITORY = Suppository TABLET = Tablets UNIT = Units UNKNOWN = Unknown OTHER = Other	GAHTDOU

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
5 GAHTDOSP	\$200	If "Other", specify:			GAHTDOSP
6 GAHTDOFRQ	\$5	Frequency		PRN = PRN QD = QD BID = BID TID = TID QID = QID QM = QM QH = QH ONCE = ONCE Other = Other	GAHTDOFRQ
7 GAHTFRQOSP	\$200	If "Other", specify:			GAHTFRQOSP
8 GAHTROUTE	\$5	Route		PO = Oral IM = Intramuscular IV = Intravenous TOP = Topical IHL = Inhalation VAG = Vaginal REC = Rectal SC = Subcutaneous OTHER = Other	GAHTROUTE
9 GAHTROUTEO SP	\$200	If "Other", specify:			GAHTROUTEO SP
10 GAHTOBT	2	How was GAHT obtained?		1 = Study Clinic 2 = Private doctor 3 = Nonprescriptio n	GAHTOBT

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				99 = Other	
11 GAHTOBTOSP	\$200	If "Other", specify:			GAHTOBTOSP
12 GAHTSTDAT	dd- MMM- YYYY	Date started			GAHTSTDAT
13 GAHTONGO	1	Concomitant Meds Ongoing			GAHTONGO
14 GAHTPHO	1	Is this a product hold or permanent discontinuation ?		1 = Product Hold 2 = Permanent Discontinuation 3 = Participant Reported	GAHTPHO
15 GAHTPRDS	dd MMM yyyy	Date of product stoppage as reported by participant :			GAHTPRDS
16 GAHTPRR	2	Why was product stopped?		1 = Lost product 2 = Product damaged 3 = Ran out of product 4 = Participant requested temporary "drug holiday" 99 = Other	GAHTPRR

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
17 GAHTPRRO	\$200	If "Other" is selected, please specify:			GAHTPRRO
18 GAHTPRDR	dd MMM yyyy	Date participant resumed study product:			GAHTPRDR
19 GAHTPHDS	dd MMM yyyy	Date when this study product hold was initiated:			GAHTPHDS
20 GAHTPHR	2	Why is the study product being held?		1 = Reported of use of prohibited concomitant medications 2 = One or more reactive HIV test results or expresses concern about having acute HIV infection 3 = Receiving PEP for potential HIV exposure 4 = Adverse Event 5 = Hepatitis B infection 6 = Participant unable/unwilling to comply with the required study procedures	GAHTPHR

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				21 = Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee 99 = Other	
21 GAHTPHRO	\$200	If "Other" is selected, please specify:			GAHTPHRO
22 GAHTPHAE1	\$215	If product hold was associated with an adverse event, select the applicable AE1:			GAHTPHAE1
23 GAHTPHAE2	\$215	If product hold was associated with an adverse event, select the applicable AE2:			GAHTPHAE2
24 GAHTCM	\$215	If product hold was associated with a new or updated concomitant medication, select applicable medication(s):			GAHTCM

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
25 GAHTPHDR	dd MMM yyyy	"Date participant resumed study product:"			GAHTPHDR
26 GAHTENDAT	dd- MMM yyyy	Date stopped			GAHTENDAT
27 GAHTTERM	2	Primary reason for ending study product use		1 = Scheduled study product use period completed 2 = Death 4 = Participant is unwilling or unable to comply with required study procedures 5 = Lost to follow-up 6 = Investigator decision 7 = Participant refused further study product use 9 = HIV infection 10 = Early study closure 11 = Protocol deviation 12 = Adverse event 14 = Withdrawal of consent by participant 15 = Study terminated by sponsor	GAHTTERM

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				16 = One or more reactive HIV test results or acute HIV infection suspected 17 = Participant unable to adhere to visit schedule 18 = Participant switched to clinic-provided study product 19 = Change made to study product prescription 99 = Other, specify	
28 GAHTTERMOS P	\$200	If "Other", specify:			GAHTTERMOS P
29 GAHTTERMINV	\$200	If "Investigator decision", specify:			GAHTTERMINV
30 GAHTAE	\$215	If "Adverse event", select applicable adverse event #1			GAHTAE
31 GAHTAE2	\$215	If "Adverse event", select applicable adverse event #2			GAHTAE2

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
32 GAHTPERM	\$1	Is this a permanent discontinuation ?		Y = Yes N = No	GAHTPERM

Is the participant using GAHT?

Yes 1
No

If "Yes", update the Gender Affirming Hormone Therapy log.

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Y/N
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① GAHTYN	\$1	Any GAHT		Y = Yes N = No	GAHTYN

Medication name

- Descovy ①
- Truvada
- Cabotegravir
- Other

If "Other", specify: _____

How was PrEP obtained?

- Study Clinic ③
- Private doctor
- Nonprescription
- Other

If "Other", specify: _____

Date started _____

Ongoing ⑥

What kind of product stoppage is being reported?

- Product Hold ⑦
- Permanent Discontinuation
- Participant Reported

Please complete the relevant section below

Participant Reported _____

Date of product stoppage as reported by participant : _____

Why was product stopped?

- Lost product ⑨
- Product damaged
- Ran out of product

Participant requested temporary "drug holiday"
Other

If "Other" is selected, please specify: _____ **10**

Date participant resumed study product: _____ **11**

Product Hold _____ **12**

Date when this study product hold was initiated: _____

Why is the study product being held?

- Reported of use of prohibited concomitant medications **13**
- One or more reactive HIV test results or expresses concern about having acute HIV infection
- Receiving PEP for potential HIV exposure
- Adverse Event
- Hepatitis B infection
- Participant unable/unwilling to comply with the required study procedures
- Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee
- Other

If "Other" is selected, please specify: _____ **14**

If product hold was associated with an adverse event, select the applicable AE1: _____ **15**

If product hold was associated with an adverse event, select the applicable AE2: _____ **16**

If product hold was associated with a new or updated concomitant medication, select applicable medication(s): _____

17

Date participant resumed study product: _____

18

Is this a permanent discontinuation? _____

19

Date stopped _____

Primary reason for ending study product use

- Scheduled study product use period completed 20
- Death
- Participant is unwilling or unable to comply with required study procedures
- Lost to follow-up
- Investigator decision
- Participant refused further study product use
- HIV infection
- Early study closure
- Protocol deviation
- Adverse event
- Withdrawal of consent by participant
- Study terminated by sponsor
- One or more reactive HIV test results or acute HIV infection suspected
- Participant unable to adhere to visit schedule
- Participant switched to clinic-provided study product
- Change made to study product prescription
- Other, specify

If "Other", specify: _____

21

If "Investigator decision", specify: _____ (22)

If "Adverse event", select applicable adverse event #1 _____ (23)

If "Adverse event", select applicable adverse event #2 _____ (24)

Is this a permanent discontinuation from study product? Yes (25)
No

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① PREPTRT	1	Medication name		1 = Descovy 2 = Truvada 3 = Cabotegravir 4 = Other	PREPTRT
② PREPTOS	\$200	If "Other", specify:			PREPTOS
③ PREPOBT	2	How was PrEP obtained?		1 = Study Clinic 2 = Private doctor 3 = Nonprescriptio n 99 = Other	PREPOBT
④ PREPOSP	\$200	If "Other", specify:			PREPOSP
⑤ PREPSTDAT	dd- MMM- YYYY	Date started			PREPSTDAT
⑥ PREPONGO	1	Ongoing			PREPONGO
⑦ PREPPHO	1	Is this a product hold or permanent discontinuation ?		1 = Product Hold 2 = Permanent Discontinuation 3 = Participant Reported	PREPPHO

HPTN091_Version_4.0_PROD_02NOV2022: ALL
 Form: Pre-exposure Prophylaxis Log
 Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
8 PREPPRDS	dd MMM yyyy	Date of product stoppage as reported by participant :			PREPPRDS
9 PREPPRR	2	Why was product stopped?		1 = Lost product 2 = Product damaged 3 = Ran out of product 4 = Participant requested temporary "drug holiday" 99 = Other	PREPPRR
10 PREPPRRO	\$200	If "Other" is selected, please specify:			PREPPRRO
11 PREPPRDR	dd MMM yyyy				PREPPRDR
12 PREPPHDS	dd MMM yyyy	Date when this study product hold was initiated:			PREPPHDS
13 PREPPHR	2	Why is the study product being held?		1 = Reported of use of prohibited concomitant medications	PREPPHR

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				2 = One or more reactive HIV test results or expresses concern about having acute HIV infection 3 = Receiving PEP for potential HIV exposure 4 = Adverse Event 5 = Hepatitis B infection 6 = Participant unable/unwilling to comply with the required study procedures 21 = Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee 99 = Other	
14 PREPPHRO	\$200	If "Other" is selected, please specify:			PREPPHRO

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
15 PREPPHAE1	\$215	If product hold was associated with an adverse event, select the applicable AE1:			PREPPHAE1
16 PREPPHAE2	\$215	If product hold was associated with an adverse event, select the applicable AE2:			PREPPHAE2
17 PREPCM	\$215	If product hold was associated with a new or updated concomitant medication, select applicable medication(s):			PREPCM
18 PREPPHDR	dd MMM yyyy	Date participant resumed study product:			PREPPHDR
19 PREPENDAT	dd- MMM yyyy	Date stopped			PREPENDAT
20 PREPTERM	2	Primary reason for ending study product use		1 = Scheduled study product use period completed 2 = Death	PREPTERM

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				4 = Participant is unwilling or unable to comply with required study procedures 5 = Lost to follow-up 6 = Investigator decision 7 = Participant refused further study product use 9 = HIV infection 10 = Early study closure 11 = Protocol deviation 12 = Adverse event 14 = Withdrawal of consent by participant 15 = Study terminated by sponsor 16 = One or more reactive HIV test results or acute HIV infection suspected 17 = Participant unable to adhere to visit schedule 18 = Participant switched to clinic-provided study product	

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				19 = Change made to study product prescription 99 = Other, specify	
21 PREPTERMOSP	\$200	If "Other", specify:			PREPTERMOSP
22 PREPTERMINV	\$200	If "Investigator decision", specify:			PREPTERMINV
23 PREPAE	\$215	If "Adverse event", select applicable adverse event #1			PREPAE
24 PREPAE2	\$215	If "Adverse event", select applicable adverse event #2			PREPAE2
25 PREPPERM	\$1	Is this a permanent discontinuation ?		Y = Yes N = No	PREPPERM

Is the participant taking PrEP?

Yes 1
No

If "Yes", update the Pre-exposure Prophylaxis log.

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Y/N
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① PPREPYN	\$1	Any PrEP		Y = Yes N = No	PPREPYN

Date AE reported to site _____ **1**

Adverse event (AE) _____ **2**

Onset date _____ **3**

At which visit was this adverse event first reported? **4**

- V1 - Screening
- V2 - Enrollment
- V3 - Week 13
- V4 - Week 26
- V5 - Week 39
- V6 - Week 52
- V7 - Week 65
- V8 - Week 78
- Interim Visit
- V201 - GAHT Initiation Visit
- V202 - DHI Day 8 Post Visit
- V301 - Seroconversion
- Termination Visit
- V401 - GAHT Safety Visit

If "Interim visit", specify interim visit code. _____ **5**

Is the AE still ongoing? Yes **6**
No

If "No", outcome date _____ **7**

Severity grade **8**

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)

Grade 4 (Potentially life-threatening)
Grade 5 (Death)

Relationship to study product

Related to PrEP 9

Record pertinent details for relationship assessment in comments

Related to GAHT

Related to both PrEP and GAHT

Not related

Action taken with study product

Dose not changed 10

Dose reduced

Dose increased

Drug withdrawn

Drug interrupted

Not applicable

Other actions

11

Mark "None" or all that apply.

None

Medication(s)

12

Therapeutic procedure/surgery

13

Diagnostic procedure

14

Other

15

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

16

Status/Outcome

If "Severity/Frequency increased" is selected, report as a new adverse event.

Recovered/Resolved

Recovering/Resolving

Recovered/Resolved with Sequelae

Not recovered/Not resolved

Fatal

Severity/frequency increased

17

If status or outcome is "Severity/Frequency increased", select adverse event. _____

18

Is this a serious adverse event according to ICH/GCP or protocol guidelines?

Yes

No

19

If "No", go to "Has or will this AE be reported as an EAE?".
If "Yes", check all that apply.

Results in death

20

Is life-threatening

21

Requires inpatient hospitalization or prolongation of existing hospitalization

22

Results in persistent or significant disability/incapacity

23

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

24

Has or will this AE be reported as an EAE?

Yes **25**

No

If "Yes", provide EAE number below. If "No", go to "Was this AE a worsening of a baseline medical condition?".

SAE/EAE number

26

Begin number with 4-digit year, followed by 6-digit SAE/EAE number (no dashes or spaces). _____

SAE/EAE onset date

_____ **27**

Comments (max. 450 characters):

_____ **28**

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Adverse Event

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① AEDAT	dd MMM yyyy	Date AE Reported to Site			AEDAT
② AETERM	\$200	Adverse Event Reported Term			AETERM
③ AESTDAT	dd- MMM yyyy	Start Date of Adverse Event			AESTDAT
④ AEVISIT	2	Visit AE Reported		1 = V1 - Screening 2 = V2 - Enrollment 3 = V3 - Week 13 4 = V4 - Week 26 5 = V5 - Week 39 6 = V6 - Week 52 7 = V7 - Week 65 8 = V8 - Week 78 9 = Interim Visit 10 = V201 - GAHT Initiation Visit 11 = V202 - DHI Day 8 Post Visit 12 = V301 - Seroconversion Termination Visit 13 = V401 - GAHT Safety Visit	AEVISIT

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Adverse Event

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
5 INTERIMCD	5.2	Interim Visit			INTERIMCD
6 AEONGO	\$1	Adverse Event Ongoing		Y = Yes N = No	AEONGO
7 AEENDAT	dd- MMM yyyy	End Date of Adverse Event			AEENDAT
8 AESEV	1	Adverse Event Severity/Inten sity		1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening) 5 = Grade 5 (Death)	AESEV
9 AEREL	1	Adverse Event Causality		1 = Related to AEREL PrEP 2 = Related to GAHT 3 = Related to both PrEP and GAHT 4 = Not related	
10 AEACN	2	Action Taken with Study Treatment		1 = Dose not changed 2 = Dose reduced 3 = Dose increased 4 = Drug withdrawn 5 = Drug interrupted	AEACN

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Adverse Event
Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				98 = Not applicable	
11 AETRNONE	1	Treatment None			AETRNONE
12 AETRTCM	1	Concomitant or Additional Trmmt Given			AETRTCM
13 AETRTPR	1	Treatment Thera Proc/Surg			AETRTPR
14 AERTDIAGPR	1	Treatment Diag Proc/Surg			AERTDIAGPR
15 AERTTOTH	1	Other Action Taken			AERTTOTH
16 AEACNOTH	\$200	Other Action Taken Specify			AEACNOTH
17 AEOUT	1	Outcome of Adverse Event MTN		1 = Recovered/Resolved 2 = Recovering/Resolving 3 = Recovered/Resolved with Sequelae 4 = Not recovered/Not resolved	AEOUT

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Adverse Event

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				5 = Fatal 6 = Severity/frequ ency increased	
18 AEOUTREFID	\$215	Severity Increase Selected AE			AEOUTREFID
19 AESER	\$1	Adverse Event Serious Event		Y = Yes N = No	AESER
20 AESDTH	1	Results in death			AESDTH
21 AESLIFE	1	Is Life Threatening			AESLIFE
22 AESHOSP	1	Initial or Prolonged Hospitalization			AESHOSP
23 AESDISAB	1	Disability or Permanent Damage			AESDISAB
24 AESMIE	1	Other Medically Important Serious Event			AESMIE
25 EAEYN	\$1	Adverse Event Expedited Adverse Event		Y = Yes N = No	EAEYN

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Adverse Event

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
26 AEREFID	10+	Expedited Adverse Event Number			AEREFID
27 SAEDAT	dd- MMM yyyy	SAE/EAE onset date			SAEDAT
28 AE_COVAL	\$450	Adverse Event Comments			AE_COVAL

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Adverse Event Y/N
Generated On: 04 Nov 2022 01:44:33

Has the participant experienced an adverse event during the study?

Yes 1
No

If "Yes", update the Adverse Event log.

HPTN091_Version_4.0_PROD_02NOV2022: ALL

Form: Adverse Event Y/N

Generated On: 04 Nov 2022 01:44:33

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① AEYN	\$1	Any Adverse Event		Y = Yes N = No	AEYN

Medication name _____ **1**

Indication _____ **2**

Check if this medication a statin **3**

Check if this medication an anti-hypertensive **4**

Date started _____ **5**

Date stopped _____ **6**

Or _____

Ongoing **7**

Dose _____ **8**

Dose units

- Grams **9**
- Micrograms
- Milligrams
- Milliliters
- Capsules
- Drops
- Puffs
- Sachets
- Suppository
- Tablets
- Units
- Unknown
- Other

If "Other", specify: _____

10

Frequency

- PRN 11
- QD
- BID
- TID
- QID
- QM
- QH
- ONCE
- Other

If "Other", specify: _____

12

Route

- Oral 13
- Intramuscular
- Intravenous
- Topical
- Inhalation
- Vaginal
- Rectal
- Subcutaneous
- Other

If "Other", specify: _____

14

Taken for a reported AE?

- Yes 15
- No

If "Yes", select adverse event. _____

16

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Concomitant Medications
Generated On: 04 Nov 2022 01:44:33

	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
①	CMTRT	\$200	Concomitant Medication Name			CMTRT
②	CMINDC	\$100	Concomitant Meds Indication			CMINDC
③	CMSTN	1	Check if this medication a statin			CMSTN
④	CMAHYP	1	Check if this medication an anti-hypertensi ve			CMAHYP
⑤	CMSTDAT	dd- MMM- yyyy	Concomitant Meds Start Date			CMSTDAT
⑥	CMENDAT	dd- MMM yyyy	Concomitant Meds End Date			CMENDAT
⑦	CMONGO	1	Concomitant Meds Ongoing			CMONGO
⑧	CMDOSE	\$20	Concomitant Meds Dose			CMDOSE
⑨	CMDOSU	\$11	Concomitant Meds Dose Unit		g = Grams ug = Micrograms mg = Milligrams ml = Milliliters	CMDOSU

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 Form: Concomitant Medications
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				CAPSULE = Capsules gtt = Drops PUFF = Puffs SACHET = Sachets SUPPOSITORY = Suppository TABLET = Tablets UNIT = Units UNKNOWN = Unknown OTHER = Other	
10 CMDOSUOSP	\$200	Concomitant Meds Dose Units Other Specify			CMDOSUOSP
11 CMDOSFRQ	\$5	Concomitant Meds Dosing Frequency per Interval		PRN = PRN QD = QD BID = BID TID = TID QID = QID QM = QM QH = QH ONCE = ONCE Other = Other	CMDOSFRQ
12 CMDOSFRQOS P	\$200	Concomitant Meds Dosing Freq per Interval Other Specify			CMDOSFRQOS P
13 CMROUTE	\$5	Concomitant Meds Route of Administration		PO = Oral IM = Intramuscular IV = Intravenous	CMROUTE

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				TOP = Topical IHL = Inhalation VAG = Vaginal REC = Rectal SC = Subcutaneous OTHER = Other	
14 CMROUTEOSP	\$200	Concomitant Meds Route of Administration Other Specify			CMROUTEOSP
15 CMYN_AE	\$1	Taken for Reported Adverse Event Y/N		Y = Yes N = No	CMYN_AE
16 CMAE	\$215	Adverse Event			CMAE

Were any concomitant medications taken?

Yes 1
No

If "Yes", update the Concomitant Medications log.

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Form: Concomitant Medications Y/N
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① CMYN	\$1	Any Concomitant Medications Taken		Y = Yes N = No	CMYN

Date of birth _____ **1**

Age _____ Fixed Unit: yrs **2**

Sex assigned at birth Male **3**
Female

Ethnicity Hispanic or Latino **4**
Not Hispanic or Latino
Not reported
Unknown

Race _____ **5**

If "Other", specify: _____ **6**

Gender

Mark all that apply.

Female **8**

Transgender Female/Transgender Woman **9**

Gender nonbinary/Genderfluid/Gender Nonconforming **10**

Another gender identity **11**

If "Another gender identity", specify: _____ **12**

Prefer not to answer

 13

How do you identify your sexual orientation?

- Bisexual 14
 - Gay/Lesbian/Homosexual
 - Queer
 - Straight/Heterosexual
 - Two Spirit
 - Additional identity
 - Not sure
 - Prefer not to answer
-

If "Additional identity", specify:

 15

What is the participant's current employment status?

- full-time employment 16
 - part-time employment
 - not employed
-

What is the participant's highest level of education?

- No schooling 17
 - 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
-

In the last 6 months, did you have enough money to pay for rent, food, or utilities (gas, electric, phone, etc)?

- Never 18
 - Once in awhile
 - Fairly often
-

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Very often

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	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	BIRTHDAT	dd- MMM- YYYY	Date of Birth			BIRTHDAT
2	AGE	3	Age			AGE
3	SEX	\$1	Sex assigned at birth		M = Male F = Female	SEX
4	ETHNIC	2	Ethnicity		1 = Hispanic or Latino 2 = Not Hispanic or Latino 3 = Not reported 99 = Unknown	ETHNIC
5	RACE	\$100	Race			RACE
6	RACEOSP	\$200	If "Other", specify:			RACEOSP
8	SCORRES_GN DRF	1	Female			SCORRES_GN DRF
9	SCORRES_GN DRTGF	1	Transgender Female/Transg ender Woman			SCORRES_GN DRTGF
10	SCORRES_GN DRGV	1	Gender nonbinary/Gen derfluid/Gende r Nonconforming			SCORRES_GN DRGV

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Form: Demographics

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	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
11	SCORRES_GN DRSI	1	Another gender identity			SCORRES_GN DRSI
12	SCORRES_GN DRSIOSP	\$200	If "Another gender identity", specify:			SCORRES_GN DRSIOSP
13	SCORRES_GN DRNA	1	Prefer not to answer			SCORRES_GN DRNA
14	SCORRES_SEX ORIEN	1	How do you identify your sexual orientation?		1 = Bisexual 2 = Gay/Lesbian/H omosexual 3 = Queer 4 = Straight/Heter osexual 5 = Two Spirit 6 = Additional identity 7 = Not sure 8 = Prefer not to answer	SCORRES_SEX ORIEN
15	SCORRES_SEX ORIENOSP	\$200	If "Additional category", specify:			SCORRES_SEX ORIENOSP
16	SCJOBCLAS	1	What is the participant's current employment status?		1 = full-time employment 2 = part-time employment 3 = not employed	SCJOBCLAS

Field Name	Data Type	SAS Label	Units	Values	Include Field OID
17 SCTEDULEVEL	1	What is the participant's highest level of education?		1 = No schooling 2 = Primary school, not complete 3 = Primary school, complete 4 = Secondary school, not complete 5 = Secondary school, complete 6 = Technical training, not complete 7 = Technical training, complete 8 = College/university or higher, not complete 9 = College/university or higher, complete	SCTEDULEVEL
18 SCINCSEC	1	In the last 6 months, did you have enough money to pay for rent, food, or utilities (gas, electric, phone, etc)?		1 = Never 2 = Once in awhile 3 = Fairly often 4 = Very often	SCINCSEC

Has the participant screened before?

Yes 1
No

If Yes, enter the first RAVE PTID assigned _____

2

Did the participant meet all eligibility criteria?

Yes 3
No

Eligibility status

Eligible and enrolled 4
Eligible/Not enrolled
Ineligible
Incomplete screening

Date "Eligible and Enrolled" or "Incomplete screening" _____

5

If "Eligible and enrolled", or "Incomplete screening", end of form.

Date "Eligible/Not Enrolled" or "Ineligible" _____

7

Select reason(s) why participant is ineligible.

11. Eighteen years or older at the time of screening. 8
12. Willing and able to provide informed consent for the study.
13. Interest in oral PrEP – as defined in the SSP Manual.
14. Non-reactive HIV test results at Screening and at least one non-reactive test result at Enrollment.
15. Available to return for all study visits and within site catchment area, as defined per site's Standard Operating Procedures (SOP).
16. At risk for sexually acquiring HIV infection based on self-report of at least one of the following:

I6a. At risk for sexually acquiring HIV infection based on self-report of any anal or vaginal sex with one or more sexual partners in the previous 3 months, regardless of condom use.

I6b. At risk for sexually acquiring HIV infection based on self-report of anal or vaginal sex in exchange for money, food, shelter, or other goods or favors in the previous 3 months.

I6c. At risk for sexually acquiring HIV infection based on self-report of history of STI(s) in the past 6 months.

I7. Willing to undergo all required study procedures.

I8. General good health, as evidenced by the following laboratory values:

I8a. Calculated creatinine clearance \geq 60 mL/minute using the Cockcroft-Gault equation.

I8b. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and total bilirubin $<$ 2.5 times the upper limit of normal (ULN) (with the exception of Gilbert's syndrome).

I8c. HBV surface antigen (HBsAg) negative.

E1. Any reactive or positive HIV test result at Screening or at least one reactive/positive HIV test result at Enrollment, even if HIV infection is not confirmed.

E2. Plans to move away from the site area within the next 18 months.

E3. Co-enrollment in any other research study that may interfere with this study (as provided by self-report or other available documentation). Exceptions may be made after consultation with the Clinical Management Committee (CMC).

- E4. Significant hepatic dysfunction or end-stage liver disease, per the opinion of the site investigator and in consultation with the CMC. For participants using cyproterone acetate, please consult the CMC for any evidence of liver abnormalities.
- E5. History of deep vein thrombosis, pulmonary embolism, and/or clotting disorder.
- E6. Active or planned use of medications with significant drug interactions as described in the Package Insert for Truvada® or Descovy®, per clinician's discretion (provided by self-report or obtained from medical history or medical records). See Section 5.8 for a full list of drug interactions.
- E7. Any other condition, including but not limited to alcohol or substance abuse and uncontrolled medical condition and/or allergies, that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives would make the patient unsuitable for the study or unable/unwilling to comply with the study requirements.

If "Investigator decision", specify (max. 200 characters): _____ **9**

If eligible, but participant declined enrollment, specify reason: _____ **10**

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Form: Inclusion Exclusion Criteria
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① IEYN2	\$1	Screened previously		Y = Yes N = No	IEYN2
② IEPTID_TEXT	\$9	Previous PTID			IEPTID_TEXT
③ IEYN	\$1	Any Inclusion/ Exclusion Criteria Findings		Y = Yes N = No	IEYN
④ IESTATUS	1	Eligibility Status		1 = Eligible and enrolled 2 = Eligible/Not enrolled 3 = Ineligible 4 = Incomplete screening	IESTATUS
⑤ IEDAT	dd MMM yyyy	Screening Outcome Date			IEDAT
⑦ NENR_VISDAT	dd MMM yyyy	Date Eligible/Not Enrolled or Ineligible			NENR_VISDAT

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Form: Inclusion Exclusion Criteria
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
8 IETEST	2	Inclusion Exclusion Criteria Result		1 = I1. Eighteen years or older at the time of screening. 2 = I2. Willing and able to provide informed consent for the study. 3 = I3. Interest in oral PrEP – as defined in the SSP Manual. 4 = I4. Non-reactive HIV test results at Screening and at least one non-reactive test result at Enrollment. 5 = I5. Available to return for all study visits and within site catchment area, as defined per site's Standard Operating Procedures (SOP).	IETEST

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
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6 = I6. At risk for sexually acquiring HIV infection based on self-report of at least one of the following:
7 = I6a. At risk for sexually acquiring HIV infection based on self-report of any anal or vaginal sex with one or more sexual partners in the previous 3 months, regardless of condom use.
8 = I6b. At risk for sexually acquiring HIV infection based on self-report of anal or vaginal sex in exchange for money, food, shelter, or other goods or favors in the previous 3 months.

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Form: Inclusion Exclusion Criteria
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
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9 = I6c. At risk for sexually acquiring HIV infection based on self-report of history of STI(s) in the past 6 months.
10 = I7. Willing to undergo all required study procedures.
11 = I8. General good health, as evidenced by the following laboratory values:
12 = I8a. Calculated creatinine clearance ≥ 60 mL/minute using the Cockcroft-Gault equation.
13 = I8b. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and total bilirubin < 2.5 times the upper limit of normal (ULN) (with the exception of Gilbert's syndrome).

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Form: Inclusion Exclusion Criteria

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
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14 = I8c. HBV surface antigen (HBsAg) negative.
15 = E1. Any reactive or positive HIV test result at Screening or at least one reactive/positive HIV test result at Enrollment, even if HIV infection is not confirmed.
16 = E2. Plans to move away from the site area within the next 18 months.
17 = E3. Co-enrollment in any other research study that may interfere with this study (as provided by self-report or other available documentation). Exceptions may be made after consultation with the Clinical Management Committee (CMC).

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
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18 = E4.
Significant
hepatic
dysfunction or
end-stage liver
disease, per
the opinion of
the site
investigator
and in
consultation
with the CMC.
For
participants
using
cyproterone
acetate, please
consult the
CMC for any
evidence of
liver
abnormalities.
19 = E5.
History of deep
vein
thrombosis,
pulmonary
embolism,
and/or clotting
disorder.

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
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20 = E6.
Active or
planned use of
medications
with significant
drug
interactions as
described in
the Package
Insert for
Truvada® or
Descovy®, per
clinician's
discretion
(provided by
self-report or
obtained from
medical history
or medical
records). See
Section 5.8 for
a full list of
drug
interactions.

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Form: Inclusion Exclusion Criteria
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				21 = E7. Any other condition, including but not limited to alcohol or substance abuse and uncontrolled medical condition and/or allergies, that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives would make the patient unsuitable for the study or unable/unwilling to comply with the study requirements.	
 IETESTOSP	\$200	Investigator Decision Specify			IETESTOSP

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Form: Inclusion Exclusion Criteria
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
10 IEREASON	\$200	Eligible/not enrolled specify			IEREASON

Date informed consent signed _____ **1**

Consent type

Screening and Enrollment **2**

Specimen Storage

IDI Sub-study

DHI Sub-study

Other

Consent version _____ **3**

If "Other", specify _____ **4**

Did the participant consent to long-term specimen storage and future testing? Yes **5**

No

Not applicable

Did the participant consent to IDI Sub-study? Yes **6**

No

Not applicable

Did the participant consent to DHI Sub-study? Yes **7**

No

Not applicable

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Form: Informed Consent
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① RFICDAT	dd MMM yyyy	Date initial informed consent signed			RFICDAT
② CONTYP	1	Consent type		1 = Screening and Enrollment 2 = Specimen Storage 3 = IDI Sub-study 4 = DHI Sub-study 5 = Other	CONTYP
③ CONVER	\$20	Consent version			CONVER
④ OTHSPY	\$200	Other, specify			OTHSPY
⑤ LTSFTYN	\$2	Did the participant consent to long-term specimen storage and future testing?		Y = Yes N = No NA = Not applicable	LTSFTYN
⑥ IDIYN	\$2	Did the participant consent to IDI Sub-study?		Y = Yes N = No NA = Not applicable	IDIYN
⑦ DHISYN	\$2	Did the participant consent to DHI Sub-study?		Y = Yes N = No NA = Not applicable	DHISYN

Date medical history collected _____ **1**

Description of medical history condition/event _____ **2**

Is condition/event gradable? Yes **3**
No

Severity grade

Grade 1 (Mild) **4**
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Start date of pre-existing condition/event _____ **5**

Is the condition ongoing? Yes **6**
No

Date medical history/condition ended/resolved _____ **7**

Comments (max. 200 characters): _____ **8**

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Form: Medical History

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	Field Name	Data Type	SAS Label	Units	Values	Include Field OID
1	MHDAT	dd- MMM- YYYY	Date of Medical History Collection			MHDAT
2	MHTERM	\$200	Medical History Event Reported Term			MHTERM
3	MHYN_SEV	\$1	Medical History Event Gradable		Y = Yes N = No	MHYN_SEV
4	MHSEV	1	Medical History Event Severity/Inten sity		1 = Grade 1 (Mild) 2 = Grade 2 (Moderate) 3 = Grade 3 (Severe) 4 = Grade 4 (Potentially life-threatening)	MHSEV
5	MHSTDAT	dd- MMM- YYYY	Start Date of Medical History Event			MHSTDAT
6	MHONGO	\$1	Medical History Event Ongoing		Y = Yes N = No	MHONGO
7	MHENDAT	dd- MMM- YYYY	End Date of Medical History Event			MHENDAT
8	MHCOMM	\$200	Comments (max. 200 characters)			MHCOMM

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Does the participant have any medical history to report?

Yes 1
No

If "Yes", update the Medical History log.

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Form: Medical History Y/N

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① MHYN	\$1	Any Medical History Event		Y = Yes N = No	MHYN

Site awareness date _____ **1**

Deviation date _____ **2**

Has or will this deviation be reported to local IRB/EC? Yes **3**
No

Has or will this deviation be reported to DAIDS as a critical event? Yes **4**
No

Type of deviation

- Enrollment of an ineligible patient **5**
- Informed consent not obtained prior to performing protocol-specified procedures
- Non-compliance with study randomization and blinding procedures
- Breach of participant confidentiality
- A protocol-specified laboratory assay consistently not being performed
- A site-specific laboratory assay is deliberately added to protocol requirements by the investigator to be conducted for all participants
- Other

Description of deviation _____ **6**

Plans and/or action taken to address the deviation _____ **7**

Plans and/or action taken to prevent future occurrences of the deviation _____ **8**

Deviation reported by _____ **9**

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Form: Protocol Deviations
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① DVDAT	dd MMM yyyy	Site Awareness Date			DVDAT
② DVSTDAT	dd MMM yyyy	Start Date of Deviation			DVSTDAT
③ DVIRB	\$1	Deviation Reported to Local IRB/EC		Y = Yes N = No	DVIRB
④ DVDAIDS	\$1	Deviation Reported to DAIDS		Y = Yes N = No	DVDAIDS
⑤ DVDECOD	2	Deviation Dictionary-Deriv ed/Standardiz ed Term		1 = Enrollment of an ineligible patient 2 = Informed consent not obtained prior to performing protocol-specifi ed procedures 3 = Non-complianc e with study randomization and blinding procedures 4 = Breach of participant confidentiality 5 = A protocol-specifi ed laboratory assay consistently not being performed	DVDECOD

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Form: Protocol Deviations
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
				6 = A site-specific laboratory assay is deliberately added to protocol requirements by the investigator to be conducted for all participants 99 = Other	
⑥ DVTERM	\$600	Protocol Deviation Reported Term			DVTERM
⑦ DVPLNADRES	\$600	Plans Taken to Address This Deviation			DVPLNADRES
⑧ DVPLNPRVNT	\$600	Plans Taken to Prevent Future Deviations			DVPLNPRVNT
⑨ DVREPORT	\$100	Deviation Reported by Staff			DVREPORT

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Form: Protocol Deviations Y/N
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Have any protocol deviations been reported?

Yes 1
No

If "Yes", update the Protocol Deviations log.

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Form: Protocol Deviations Y/N
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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① DVYN	\$1	Any Protocol Deviations		Y = Yes N = No	DVYN

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Is the participant ready to be randomized?

Yes **1**
No

Randomization date and time

_____ **2**

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Form: Randomization

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Field Name	Data Type	SAS Label	Units	Values	Include Field OID
① RANDTRIG	\$1	Participant Randomized		Y = Yes N = No	RANDTRIG
② RANDOMIZED_ AT	dd MMM yyyy HH:nn:ss	Randomization Date and Time			RANDOMIZED_ AT
