

HPTN 035

Participant Retention: Follow-up Plan, Retention Targets and Retention Plans

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HPTN 035 Follow-Up Plan

<i>Study Month</i>	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19-30	
<i>No. Enrolled Per Month Non-US</i>	70	105	140	140	175	175	175	175	175	175	175	175	175	175	175	175	175	170	0	
<i>No. Enrolled Per Month US</i>	10	15	15	20	20	20	20	20	20	20	20	20	20	20	15	15	15	15	0	
<i>Total No. Enrolled Per Month</i>	80	120	155	160	195	195	195	195	195	195	195	195	195	195	190	190	190	185	0	
<i>Cumulative No. Enrolled</i>	80	200	355	515	710	905	1100	1295	1490	1685	1880	2075	2270	2465	2655	2845	3035	3220	3220	
<i>Cumulative No. Exposed (a)</i>	40	100	178	258	355	453	550	648	745	843	940	1038	1135	1233	1328	1423	1518	1610	1610	
<i>Cumulative % Exposed (b)</i>	2%	6%	11%	16%	22%	28%	34%	40%	46%	52%	58%	64%	70%	77%	82%	88%	94%	100%	100%	
Phase II/IIb Screening	→																			
Phase II Enrollment	→																			
Phase II/IIb Follow-up										→										
Phase II Data Cleaning and DSMB Review											→									
Phase IIb Enrollment							→													
Phase IIb Follow-up								→												
Interim Phase IIb DSMB Reviews (c)																				

HPTN 035 Follow-Up Plan

- ◆ **Phase II:**
 - **First three months of follow-up among Phase II participants**
- ◆ **Phase IIb:**
 - **Phase II follow-up + all subsequent follow-up among Phase II and Phase IIb participants**

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<i>No. Enrolled Per Month Non-US</i>	70	105	140	140	175	175	175	175	175	175	175	175	175	175	175	175	175	170	0	
<i>No. Enrolled Per Month US</i>	10	15	15	20	20	20	20	20	20	20	20	20	20	20	15	15	15	15	0	
<i>Total No. Enrolled Per Month</i>	80	120	155	160	195	195	195	195	195	195	195	195	195	195	190	190	190	185	0	
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HPTN 035 Follow-Up Plan

- ◆ Each participant will be followed through the study end date or for a maximum of 30 months, whichever occurs first
- ◆ The study will end when a total of 192 HIV infections have been observed
- ◆ The Protocol Team will manage the accrual process such that accrual is discontinued 12 months before the targeted number of HIV infections will be observed
- ◆ Individual participants will be followed for a minimum of 12 months and a maximum of 30 months, depending on when they enroll in the study and when the targeted number of infections is observed

HPTN 035 Retention Targets

- ◆ HPTN 035 annual retention target:

HPTN 035 Retention Targets

- ◆ HPTN 035 annual retention target:

95%

HPTN 035 Retention Targets

- ◆ 95% per year translates to:

Month of Study	Target % Retained
1	99.58
2	99.17
3	98.75
4	98.33
5	97.92
6	97.50
7	97.08
8	96.67
9	96.25
10	95.83
11	95.42
12	95.00
13	94.58
14	94.17
15	93.75

Month of Study	Target % Retained
16	93.33
17	92.92
18	92.50
19	92.08
20	91.67
21	91.25
22	90.83
23	90.42
24	90.00
25	89.58
26	89.17
27	88.75
28	88.33
29	87.92
30	87.50

HPTN 035 Retention Targets

- ◆ **95% per year translates to:**
 - **If enroll 415 participants, need to retain at least 364 to meet end of study target**
 - **If enroll 320 participants, need to retain at least 280 to meet end of study target**

HPTN 035 Retention Definitions

- ◆ **During the study:**
 - Retention is defined based on whether participants complete scheduled monthly follow-up visits within the allowable visit window (± 2 weeks)
 - Participants who complete scheduled visits within the allowable window are considered “retained” for those visits
 - Participants who miss a scheduled visit, but then complete the next scheduled visit, will be considered “not retained” for the missed visit, but “retained” for the next visit
 - Retention rates can fluctuate over time and across visits
 - Retention shortfalls can be made up by ensuring that participants return for subsequent visits after missed visits

HPTN 035 Retention Definitions

- ◆ **After the study:**
 - **Retention is defined based on whether participants complete HIV testing at a scheduled study exit visit**
 - **Although every effort must be made to complete the exit visit within the allowable visit window, exit visits will be allowed to take place until the study end date at each site**
 - **Participants who complete a scheduled exit visit prior to the study end date, and undergo HIV testing at that visit, will be considered retained at the end of the study**

HPTN 035 Retention Tracking

- ◆ On-Site Tracking
- ◆ Cross-Site Tracking

HPTN 035 Retention Tracking

◆ On-Site Tracking

- All sites will track actual retention versus the study target locally
 - How will this be done at your site?
 - Who is responsible for oversight and management?
 - SOPs and tracking tools
 - Participant Tracking Database

HPTN 035 Retention Tracking

Follow-up Visit Master Log [X]

Study ID: 123-44444-4 [Find Participant] [Follow-up Schedule]

Given Name: Ghi Family Name: Arumero Nicknames: []

Age: 27 Health Worker: Nancy Lamson Screening Date: 20-May-04 Enrollment Date: 01-Jun-04 Participant Status: Active

[Check Visit Target Date and Window]

Follow-up Visit	Month	Visit Code	Scheduled Visit Date	Scheduled Pelvic Exam	Scheduled HIV Test	Actual Visit Date	Missed Visit
▶	1	[]	01-Jul-04	<input type="checkbox"/>	<input type="checkbox"/>	01-Jul-04	<input type="checkbox"/>
	2	[]	03-Aug-04	<input type="checkbox"/>	<input type="checkbox"/>	03-Aug-04	<input type="checkbox"/>
	3	[]	01-Sep-04	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	[]	<input type="checkbox"/>
	4	[]	01-Oct-04	<input type="checkbox"/>	<input type="checkbox"/>	[]	<input type="checkbox"/>
*	[]	[]	[]	<input type="checkbox"/>	<input type="checkbox"/>	[]	<input type="checkbox"/>

Note: This is not a record of completed testing.

Record: [] 1 of 4

Record: [] 3 of 11

HPTN 035 Retention Tracking

Scheduled Follow-up Visits		Thursday, September 09, 2004 thru Thursday, September 23, 2004			
Study ID	Visit Number	Scheduled Visit Date	Days Away	Testing Scheduled	Contact Permission
123-66666-6	1	15-Sep-04	6	<input type="checkbox"/> Pelvic Exam <input type="checkbox"/> HIV Testing	<input type="checkbox"/> Home phone call OK <input checked="" type="checkbox"/> Home visit OK? <input type="checkbox"/> Work visit OK? <input checked="" type="checkbox"/> Mail OK?

HPTN 035 Retention Tracking

Participants Late for Scheduled Follow-up Visits as of Thursday, September 09, 2004

Study ID	Visit Number	Scheduled Visit Date	Days Left in Window	Testing Scheduled	Contact Permission
123-44444-4	3	01-Sep-04	6	<input checked="" type="checkbox"/> Pelvic Exam <input checked="" type="checkbox"/> HIV Testing	<input type="checkbox"/> Home phone call OK <input checked="" type="checkbox"/> Home visit OK? <input type="checkbox"/> Work visit OK? <input checked="" type="checkbox"/> Mail OK?
123-92222-2	1	01-Sep-04	6	<input type="checkbox"/> Pelvic Exam <input type="checkbox"/> HIV Testing	<input type="checkbox"/> Home phone call OK <input type="checkbox"/> Home visit OK? <input type="checkbox"/> Work visit OK? <input type="checkbox"/> Mail OK?

HPTN 035 Retention Tracking

HPTN 035 High-priority Retention Targets

Days	Participant ID	Visit Number	Scheduled Visit Date	Target Date	Window End Date
6	123-44444-4	3	01-Sep-04	01-Sep-04	15-Sep-04

HPTN 035 Retention Tracking

Monthly Scheduled HPTN 035 Follow-up Visits vs. Actual Visits

Month	Scheduled Visits	Actual Visits	Raw Follow-up Rate
July 2004	1	1	100.00%
August 2004	2	2	100.00%
September 2004	8	2	25.00%
October 2004	6	0	0.00%
Totals	17	5	29.41%

HPTN 035 Retention Tracking

- ◆ **Cross-Site Tracking**

- HPTN SDMC will issue retention reports based on visit completion data received and entered into the study database

HPTN 035 Retention Plans

Each site will establish an SOP for participant retention and will update the SOP, and recruitment efforts undertaken, if needed, to meet the study retention goal.

The SOP should specify:

- ◆ Retention targets
- ◆ Methods for tracking actual retention versus retention goals
- ◆ Procedures for completing and updating participant locator information
- ◆ Site-specific definition of “adequate” locator information
- ◆ Visit reminder methods and timeframes
- ◆ Methods and timeframes for identifying when a visit has been missed

HPTN 035 Retention Plans

Retention SOP (continued):

- ◆ **Planned retention methods, including outreach/locator efforts taken within 24 hours, 1-3 days, 1 week, 2 weeks, 3-4 weeks after a missed visit**
- ◆ **Methods for timely evaluation of the utility of retention methods**
- ◆ **Ethical and human subjects considerations**
- ◆ **Staff responsibilities (direct and supervisory)**
- ◆ **Staff training requirements (if not specified elsewhere)**
- ◆ **QC/QA procedures related to the above (if not specified elsewhere)**

HPTN 035 Retention Targets

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