

HPTN 035

Participant Accrual: Timelines, Targets and Plans

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HPTN 035 Accrual Targets

- ◆ Initial targets based on participant accrual, retention, and HIV seroincidence rates assumed in the protocol

	Non US	US	Total
Phase II	700	100	800
Phase IIb	2200	220	2420
Total	2900	320	3220

HPTN 035 Accrual Timeline

Study Month	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 Accrual Targets

- ◆ **Phase II targets are fixed:**
 - 100 US
 - 700 non-US, ideally 100 from each site
 - Capped at 350 per site
 - Depending on timing of study activation, some non-US sites may not enroll any Phase II participants

HPTN 035 Accrual Targets

- ◆ Phase IIb targets may be adjusted based on actual accrual, retention, and HIV seroincidence rates
- ◆ If protocol assumptions are correct:
 - 220 US
 - 2420 non-US, ideally 315 per site
 - No cap per site, but monthly cap across sites prior to first DSMB review (20 US and 175 non-US)

HPTN 035 Accrual Targets

Study Month	NON-US SITES									US SITE		TOTAL	
	Blantyre	Chitungwiza-Harare	Durban-Hlabisa	Lilongwe	Lusaka	Moshi	Pune	Total Non-US	Total Cumulative Non-US	Philadelphia	Total Cumulative US	TOTAL	CUMULATIVE TOTAL
1	10	10	10	10	10	10	10	70	70	10	10	80	80
2	15	15	15	15	15	15	15	105	175	15	25	120	200
3	20	20	20	20	20	20	20	140	315	15	40	155	355
4	20	20	20	20	20	20	20	140	455	20	60	160	515
5	25	25	25	25	25	25	25	175	630	20	80	195	710
6	25	25	25	25	25	25	25	175	805	20	100	195	905
7	25	25	25	25	25	25	25	175	980	20	120	195	1100
8	25	25	25	25	25	25	25	175	1155	20	140	195	1295
9	25	25	25	25	25	25	25	175	1330	20	160	195	1490
10	25	25	25	25	25	25	25	175	1505	20	180	195	1685
11	25	25	25	25	25	25	25	175	1680	20	200	195	1880
12	25	25	25	25	25	25	25	175	1855	20	220	195	2075
13	25	25	25	25	25	25	25	175	2030	20	240	195	2270
14	25	25	25	25	25	25	25	175	2205	20	260	195	2465
15	25	25	25	25	25	25	25	175	2380	15	275	190	2655
16	25	25	25	25	25	25	25	175	2555	15	290	190	2845
17	25	25	25	25	25	25	25	175	2730	15	305	190	3035
18	25	25	24	24	24	24	24	170	2900	15	320	185	3220

HPTN 035 Accrual Management

- ◆ Each quarter, Protocol Team will review actual performance indicators and HIV seroincidence rates
- ◆ Goal is to conduct the study as efficiently as possible and discontinue accrual 12 months before targeted number of HIV infections will be observed
- ◆ Findings and recommendations from Protocol Team reviews will be communicated to all sites
- ◆ Some sites may enroll fewer than 415 participants, some may enroll more than 415

HPTN 035 Accrual Tracking

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

HPTN 035 Accrual Tracking

◆ On-Site Tracking

- All sites will track actual accrual versus site-specific targets locally
 - How will this be done at your site?
 - Who is responsible for oversight and management?
 - SOPs and tracking tools
 - Participant Tracking Database
 - Screening and Enrollment Log
- All sites will report the number of participants screened for and enrolled in the study to the HPTN CORE on a weekly basis

HPTN 035 Accrual Tracking

HPTN 035 Screening and Enrollment Report

Month	Participants Screened	Participants Enrolled
May 2004	1	1
July 2004	12	8
August 2004	3	2
Totals	16	11

HPTN 035 Accrual Tracking

◆ Cross-Site Tracking

- HPTN CORE will consolidate site-reported screening and enrollment numbers and issue a weekly cross-site report
- HPTN SDMC will issue cross-site enrollment reports based on data received and entered into the study database
- SDMC reported numbers will lag site-reported numbers, but differentials should be small

HPTN 035 Accrual Tracking

◆ Recruitment Yield

- **Combination on-site and cross-site tracking**
- **Sites will determine the “recruitment source” of each participant who screens for the study (e.g., STD clinic, flyer, community-based outreach location)**
- **Recruitment source codes will be recorded locally and on DataFax forms**
- **SCHARP receives data for enrolled participants only**
- **Site can calculate and monitor “yield” of eligible participants from each recruitment source**
- **SDMC can calculate and report “yield” of enrolled participants from each recruitment source**

HPTN 035 Accrual Plans

Each site will establish an SOP for participant accrual and will update the SOP, and recruitment efforts undertaken, if needed, to meet site-specific accrual goals.

The SOP should specify:

- ◆ Site-specific accrual goals
- ◆ Methods for tracking actual accrual versus accrual goals
- ◆ Recruitment methods and venues
- ◆ Methods for identifying the recruitment source of participant who present to the site for screening
- ◆ Methods for timely evaluation of the utility of recruitment methods and venues

HPTN 035 Accrual Plans

Accrual SOP (continued):

- ◆ Pre-screening procedures (if any)
- ◆ 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)

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Questions?