



HPTN Study Operations Report

February, 2010

**PTN Executive Summary Report
10 February 2010
Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
046 V2 (Mothers)	Uganda – Mulago Hospital	08Feb2007	190	190	100%	8.2	23.2	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	347	100%	8.8	39.4	
046 V2 (Infants)	Uganda – Mulago Hospital	08Feb2007	190	193	102%	8.2	23.5	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	350	101%	8.8	39.8	
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	408	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	217	80%	10	21.7	closed
	Uganda – Mulago Hospital	23Jun2008	500	545	109%	19.2	28.4	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	506	101%	20.5	24.7	completed
	Total		1670	1676	100%	20.5	81.8	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	409	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	218	81%	10	21.8	closed
	Uganda – Mulago Hospital	23Jun2008	500	562	112%	19.2	29.3	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	510	102%	20.5	24.9	completed
	Total		1670	1699	102%	20.5	82.9	
052 Run-in (Indexes)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	10	100%	6.9	1.4	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
Total		86	82	95%	18	4.6		
052 Run-in (Partners)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed

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	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gabarone	16Apr2009	65	56	86%	10	5.6	86%
	Brazil – Porto Alegre	26Nov2007	93	82	88%	26.9	3	94%
	Brazil – Rio de Janeiro	14Nov2007	185	163	88%	27.3	6	94%
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	190	151	79%	31.9	4.7	95%
	Kenya – Kisumu	03Nov2009	45	20	44%	3.3	6.1	67%
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	215	205	95%	25.2	8.1	94%
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	240	240	100%	26.6	9	94%
	South Africa – Johannesburg – Witwatersrand	20May2008	55	42	76%	21	2	93%
	South Africa – Soweto	11Jun2009	30	27	90%	8.1	3.3	83%
	Thailand – Chiang Mai	11Oct2007	90	92	102%	28.2	3.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	220	198	90%	27.6	7.2	94%
	Total		1668	1516	91%	31.9	47.5	
052 Full Study (Partners)	Botswana – Gabarone	16Apr2009	65	57	88%	10	5.7	86%
	Brazil – Porto Alegre	26Nov2007	93	84	90%	26.9	3.1	94%
	Brazil – Rio de Janeiro	14Nov2007	185	162	88%	27.3	5.9	94%
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	190	151	79%	31.9	4.7	95%
	Kenya – Kisumu	05Nov2009	45	21	47%	3.2	6.6	66%
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	215	205	95%	25.2	8.1	94%
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	240	244	102%	26.6	9.2	94%
	South Africa – Johannesburg – Witwatersrand	20May2008	55	42	76%	21	2	93%
	South Africa – Soweto	11Jun2009	30	25	83%	8.1	3.1	83%
	Thailand – Chiang Mai	11Oct2007	90	93	103%	28.2	3.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	220	198	90%	27.6	7.2	94%
	Total		1668	1522	91%	31.9	47.7	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	9	8	89%	30.6	0.3	completed

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	Brazil – Porto Alegre – Conceicao	15Jun2008	4	5	125%	20.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	11	13	118%	29.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	4	7	175%	22.1	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	56	56	100%	38.1	1.5	completed
	Total		80	89	111%	38.1	2.3	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	9	8	89%	30.6	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	4	5	125%	20.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	11	13	118%	29.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	4	7	175%	22.1	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	56	56	100%	38	1.5	completed
	Total		80	89	111%	38	2.3	
058	China – Guangxi – Heng County	24Dec2008	400	208	52%	13.8	15.1	37%
	China – Xinjiang	23Dec2008	490	224	46%	13.8	16.2	38%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	634	42%	32.9	19.3	
061	US – Atlanta	–	201	–	–	0	–	
	US – Boston	17Jul2009	403	96	24%	6.9	13.9	39%
	US – Decatur	16Sep2009	202	65	32%	4.9	13.3	31%
	US – Los Angeles	30Sep2009	403	103	26%	4.4	23.4	29%
	US – NY – Harlem Prevention Center	08Jan2010	201	10	5%	1.1	9.1	9%
	US – NY – New York Blood Center	01Oct2009	202	48	24%	4.4	10.9	29%
	US – San Francisco	13Aug2009	403	110	27%	6	18.3	36%
	US – Washington DC	28Jul2009	403	72	18%	6.6	10.9	38%
	Total		2418	504	21%	6.9	73	
064 (Women)	US – Atlanta	22Oct2009	200	82	41%	3.7	22.2	61%
	US – Baltimore	05Aug2009	200	98	49%	6.3	15.6	103%
	US – Chapel Hill	26May2009	200	200	100%	4	50	completed
	US – Decatur	27Aug2009	200	56	28%	5.6	10	91%
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	207	104%	7.3	28.4	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	70	35%	3.6	19.4	61%
	US – Newark	05Jun2009	400	315	79%	8.3	38	137%

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	US – Raleigh	11Aug2009	200	207	104%	5.7	36.3	completed
	US – Washington DC	17Jun2009	200	201	101%	4.9	41	completed
	Total		2000	1436	72%	8.7	165.1	
064 (Men)	US – Decatur	–	30	–	–	0	–	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	30	100%	2.3	13	completed
	US – Raleigh	–	30	–	–	0	–	
	US – Washington DC	–	30	–	–	0	–	
	Total		120	30	25%	4.4	6.8	

PTN Executive Summary Report
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Retention Summary

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
046 V2 (Mothers)	Uganda – Mulago Hospital	190	1140	1057	1071	93%	94%
	Zimbabwe – Harare/Chitungwiza	157	942	821	885	87%	94%
	Total	347	2082	1878	1956	90%	94%
046 V2 (Infants)	Uganda – Mulago Hospital	193	2123	1997	2015	94%	95%
	Zimbabwe – Harare/Chitungwiza	157	1727	1611	1639	93%	95%
	Total	350	3850	3608	3654	94%	95%
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	408	1595	1429	1545	90%	97%
	Tanzania – Dar Es Salaam	217	782	723	763	92%	98%
	Uganda – Mulago Hospital	545	2050	1947	1985	95%	97%
	Zimbabwe – Harare/Chitungwiza	506	2011	1888	1942	94%	97%
	Total	1676	6438	5987	6235	93%	97%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	3277	3022	3168	92%	97%
	Tanzania – Dar Es Salaam	218	1609	1488	1566	92%	97%
	Uganda – Mulago Hospital	562	4290	4160	4148	97%	97%
	Zimbabwe – Harare/Chitungwiza	510	4078	3864	3938	95%	97%
	Total	1699	13254	12534	12821	95%	97%
052 Combined (Indexes)	Botswana – Gabarone	56	162	151	161	93%	99%
	Brazil – Porto Alegre	87	568	558	559	98%	98%
	Brazil – Rio de Janeiro	176	1406	1384	1380	98%	98%
	India – Chennai – YRGCare	250	1799	1668	1768	93%	98%
	India – Pune	161	1228	1221	1205	99%	98%
	Kenya – Kisumu	20	23	15	23	65%	100%
	Malawi – Blantyre – Queen Elizabeth Central	215	1152	1098	1136	95%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	250	1406	1321	1384	94%	98%
	South Africa – Johannesburg – Witwatersrand	42	201	194	199	97%	99%
	South Africa – Soweto	27	32	27	32	84%	100%
	Thailand – Chiang Mai	102	769	758	753	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	208	1217	1162	1199	95%	99%
	Total	1594	9963	9557	9800	96%	98%
	052 Combined (Partners)	Botswana – Gabarone	57	162	146	161	90%
Brazil – Porto Alegre		89	568	541	559	95%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
	Brazil – Rio de Janeiro	175	1406	1215	1380	86%	98%
	India – Chennai – YRGCare	250	1799	1568	1768	87%	98%
	India – Pune	161	1228	1194	1205	97%	98%
	Kenya – Kisumu	21	21	17	21	81%	100%
	Malawi – Blantyre – Queen Elizabeth Central	216	1152	983	1136	85%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	254	1406	1214	1384	86%	98%
	South Africa – Johannesburg – Witwatersrand	42	201	188	199	94%	99%
	South Africa – Soweto	25	30	23	30	77%	100%
	Thailand – Chiang Mai	103	769	703	753	91%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	208	1217	1056	1199	87%	99%
	Total	1601	9959	8848	9796	89%	98%
057 (Mothers)	Brazil – Belo Horizonte	8	48	48	46	100%	97%
	Brazil – Porto Alegre – Conceicao	5	30	30	29	100%	97%
	Brazil – Porto Alegre – Santa Casa	13	78	75	75	96%	97%
	Brazil – Rio de Janeiro	7	42	42	41	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	56	336	325	325	97%	97%
	Total	89	534	520	516	97%	97%
057 (Infants)	Brazil – Belo Horizonte	8	56	56	54	100%	96%
	Brazil – Porto Alegre – Conceicao	5	35	35	34	100%	96%
	Brazil – Porto Alegre – Santa Casa	13	91	89	87	98%	96%
	Brazil – Rio de Janeiro	7	49	49	47	100%	96%
	Malawi – Blantyre – Queen Elizabeth Central	56	392	376	376	96%	96%
	Total	89	623	605	598	97%	96%
058	China – Guangxi – Heng County	208	102	81	96	79%	94%
	China – Xinjiang	224	151	125	142	83%	94%
	Thailand – Chiang Mai University	202	385	338	346	88%	90%
	Total	634	638	544	584	85%	91%

MEMORANDUM

DATE:	19 APR 2006
TO:	Study Operations Group
FROM:	Deborah Donnell
RE:	Summary of HPTN and MTN Enrollment and Recruitment
CC:	

These tables are based on the same data as the protocol specific enrollment and retention reports routinely sent out by SCHARP to each of the protocol teams.

Enrollment Summary

The Enrollment Summary describes the number of participants enrolled in each study based on the data received and entered at SCHARP. The report lists the date of **First Enrollment**, the **Target Number** of participants, and the **Total Number** enrolled to date for each site in each study. The percentage of target already enrolled is:

$$\text{Target Enrollment} = \frac{\text{Total Enrolled}}{\text{Target Number}}$$

As a guide to the sites' progress in enrollment, the percentage **Enrollment Period** elapsed is calculated - this is the elapsed proportion of the accrual period specified in the protocol.

Retention Summary

The Retention Summary is based on study visits. The table reports the number of **Expected Visits** for each site on each protocol - this is a calculation of all visits that should have occurred to date assuming no missed visits or loss to followup. **Completed Visits** are the number of these expected visits that have actually occurred (based on data received and entered at SCHARP). **Protocol Expectations** calculates the number of visits that should have occurred to date assuming the protocol specified acceptable loss to followup rate. Currently the report uses a retention standard of 10% annual loss to followup for HPTN035, HPTN037, and HPTN039 (i.e., Phase IIb and III trials), and 0% for the safety run-in phase of HPTN052.

Retention is simply the proportion of expected visits that have been completed:

$$\text{Retention} = \frac{\text{Completed}}{\text{Expected}}$$

As a guide for performance, the **Protocol Expected Standard** is calculated as the percentage of **Protocol Expected** visits that have occurred:

$$\text{Protocol Expected Standard} = \frac{\text{Protocol Expected}}{\text{Expected}}$$

The network evaluation committee has defined adequate performance as within 90% of the protocol expected standard.

Questions about this report may be directed to Deborah Donnell (deborah@scharp.org; (206) 667-5661).

HPTN Network Laboratory Update February 2010

HPTN 027 (Uganda only)

Specimens for antibody testing are being tested at the Johns Hopkins Medical Institute.

HPTN 046

A. General Comments

1. Version 3.0 dated 26 Sept, 2007
2. Enrollment at all sites has been stopped.

B. Site Specific

1. Harare - No new updates
2. Kampala- No new updates
3. Durban - No new updates
4. Dar es Salaam - No new updates

HPTN 052

A. General Comments

The NL is working on the hepatitis substudy. This is pending due to some IRB revisions needed at some sites to allow for the shipment of samples for hepatitis testing. The NL is working on QAing the viral loads from enrollment samples (<1000 copies/mL). A new QA list including samples for ARV testing and genotyping was sent out to the sites. Several sites are pending shipment to the NL.

There was a recent communication to the labs regarding a problem with the Gemini Fetal Bovine Serum expiration date. Gemini has extended the expiration date and a note has been circulated to the sites regarding this issue.

B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site is preparing the validation documents for the NL to review.
2. Harare - The site is working on the action plan from the NL November visit
3. Chennai - No new updates
4. Blantyre - The NL is working with the site on updates to their action plan from the previous NL visit.
5. Porto Alegre - the site has had a delay in receiving HIV EIA FDA approved kits. The kits were ordered several months ago.
6. Rio sites – No new updates
7. Lilongwe – Inventory has not been received for several months. Reminders have been sent
8. Chiang Ma – No new updates
9. Johannesburg--WITs – No new updates
10. Soweto – No new updates.
11. Botswana – No new updates
12. Kenya – No new updates

HPTN 057

A. General Information

Cohort 4 has been added to the protocol. Labs have been asked to prepare documentation for Cohort 4.

A new version of the SSP is being written to include Cohort 4. Lab section has been completed and sent to FHI.

B. Site Specific

1. Blantyre - No outstanding issues.
2. Santa Casa. Porto Alegre.- No outstanding issues.
3. UFMG. Belo Horizonte - No outstanding issues.
4. HSE Rio - No outstanding issues
5. HNSC--Porto Alegre - No outstanding issues.

HPTN 058

A. Site Specific

1. Thailand - No new updates
2. China sites.
 - a. **Xinjiang Site.**
Clinic has been moved to a new location while renovations are being made. All relevant validations have been performed.
 - b. **Guangxi.**
An additional clinic will be added in Nanning. All relevant validations have been performed. NL has issued approval for this clinic to perform UDS, pregnancy and HIV rapid testing.
3. An additional site in Vietnam is being considered.

HPTN 061 and 064

A. General Information

Team protocol trainings for 061 and 064 have been completed. DCLOT has agreed with the Network Lab proposals for rapid HIV testing which allows sites to follow local state regulations.

B. 061 Site-Specific

1. Fenway - No new updates
2. George Washington University - Notes to File submitted regarding use of serum for Western Blots instead of plasma.
3. San Francisco - No new updates.
4. Harlem - Site recently activated No new updates
5. Atlanta - no new updates
6. New York Blood Center - Notes to File submitted for PTIDS for which Western Blots, CD4 and viral loads were not done. Protocol Deviation report requested.
7. UCLA - no new updates

C. 064 Site-Specific

1. North Carolina - The site submitted a note to file indicating the Western Blot had been cancelled by their lab.
2. New Jersey - No new updates
3. Washington DC - The site submitted note to files indicating serum was used for the Western Blot testing instead of plasma.
4. Bronx - No new updates
5. Baltimore - No New updates.
6. Harlem - No new updates
7. Atlanta - No new updates.

QC update

The following sites have been submitting their monthly QC reports:

- MUJHU
- RIHES
- Guangxi
- Xinjiang
- Lilongwe
- NARI
- YRG Care
- Blantyre

NL updates

The NL is working on the incidence testing for both HPTN 043 and the domestic trials.

The specimen management training video has been sent to the sites.

New IATA manuals and SaftPak shipping certifications DVDs have been sent to the sites that the NL is the PNL.

Travel Updates

- Trip reports are pending for the India sites.
- Estelle and LeTanya will be attending the HPTN 043 meeting in Chiang Mai in March.
- Vanessa will be attending the HPTN 063 training in Brazil in March.
- Paul is planning a site visit to Uganda and Tanzania in April.

Implementations Issues and Problems Summary February, 2010

052

Enrollment is expected to be completed by March/April 2010. The target enrollment of each site is listed below. Some target numbers have been amended since Blantyre and Zimbabwe have agreed to increase their enrollment targets.

Boston, MA (Fenway)	2
Lilongwe, Malawi (UNCP):	250
Blantyre, Malawi (JHP):	225
Harare, Zimbabwe (UZ-UCSF):	230
Rio de Janeiro, Brazil (IPEC and HGNI):	200
Porto Alegre, Brazil (HNSC):	98
Pune, India (NARI):	200
Chennai, India (YRG CARE):	250
Chiang Mai, Thailand (RIHES):	100
Johannesburg, South Africa (WITS):	55
Gaborone, Botswana:	65
Soweto, South Africa	30
Kenya	45
Total:	1750

RIHES and YRG CARE have both reached their enrollment targets of 100 and 250 couples, respectively.

058

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation. The study drug supply for this first shipment has an August 2010 expiry date.

061

Site reports and enrollment numbers show that the rate of acceptance of peer health navigation and success rate at having participants refer their sexual partners to the study is varying markedly between sites and lower than had been expected. To improve the number of index referrals, the study team have decided to expand "index" status to all participants who test HIV negative at enrollment. An LoA is being written to allow this to happen.

062

Removal of Blantyre site will require rapid and steady enrollment in Lilongwe to ensure 40+ participants within 24 months.

063

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now

waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, we must have this approval in order to receive state department clearance.

064

Accrual is currently being monitored very closely at all sites to ensure study targets are met.

Report for HPTN Study Operations Group

HPTN 027

A PHASE I STUDY TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF ALVAC-HIV vCP1521 IN INFANTS BORN TO HIV-1 INFECTED WOMEN IN UGANDA

Based on available data through: 2 February 2010

Participating Study Site:

Makerere University-Johns Hopkins University Research Collaboration/Mulago Hospital
Kampala, Uganda

Study Implementation Status:

- 24-month study follow-up is complete. Site has de-registered.
- CRF Database was locked from any further submissions on 29 October.
- Study samples are en route from the site to JHU for analysis. Some of the lab data assay data has been received from the Richmond Lab.

Accrual Status:

60 of 60 have been enrolled. Accrual is complete.

Status of Intervention Delivery:

N/A

Retention Status:

N/A

Report for HPTN Study Operations Group

HPTN 046

A phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical transmission during breastfeeding

Based on available data through: 2 February 2010

Participating Study Sites:

CAPRISA Umlazi; Durban, South Africa
Muhimbili Hospital; Dar es Salaam, Tanzania
Mulago Hospital; Kampala, Uganda
Chitungwiza Clinics; Chitungwiza, Zimbabwe

Study Implementation Status:

Enrollment closed on 21 January. Randomizations will continue until all eligible enrolled infants reach 6 weeks of age. Randomization should continue until early March.

Accrual Status:

The study enrolled 1674 mother-infant pairs [1699 infants in all].

Status of Intervention Delivery:

Retention Status:

There have been no retention issues identified at this time.

Implementation Issues and Problems:

No issues at this time.

Report for HPTN Study Operations Group

HPTN 052

A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples *Based on available data through: 5 February 2010*

Participating Study Sites:

Gaborone, Botswana
Porto Alegre and Rio de Janeiro, Brazil
Chennai, India
Pune, India
Blantyre, Malawi
Lilongwe, Malawi
Johannesburg, South Africa
Soweto, South Africa
Chiang Mai, Thailand
Harare, Zimbabwe
Kisumu, Kenya

Study Implementation Status:

All sites listed above are operating under Version 3.0 of the protocol.

Accrual Status:

Below is site-reported screening and enrollment data; refer also to the SCHARP enrollment summary.

HPTN 052 Cumulative Screening and Enrollment Data															
Week Ending: 31 December 2009															
	Lilongwe	RIHES	NARI	Blantyre	Brazil - FIOCRUZ	Brazil - HGNI	Brazil - HNSC	YRG CARE	Zimbabwe	WITS SA	Botswana	Soweto	Kenya	Individuals	Couples
Date First Screened	04-Apr-05	13-Jun-05	22-Jun-05	16-Aug-05	13-Sep-05	03-Oct-05	04-Jan-06	08-Nov-05	07-Dec-05	07-Apr-08	11-Mar-09	21-May-09	21-Oct-09		
Date First Enrolled	12-Apr-05	24-Jun-05	01-Jul-05	25-Aug-05	14-Sep-05	13-Oct-05	30-Jan-06	10-Nov-05	09-Jan-06	20-May-08	16-Apr-09	11-Jun-09	03-Nov-09		
# Screened*	1490	538	674	1808	372	334	266	1106	2146	180	418	325	270	9965	n/a
# Enrolled - Individuals	492	204	320	434	200	142	174	500	406	84	110	56	50	3066	n/a
# Enrolled - Couples	246	102	160	217	100	71	87	250	203	42	55	28	25	n/a	1593
Eligible	504	499	354	434	202	142	174	600	454	80	146	80	54	3445	n/a
Ineligible	812	330	298	1336	160	184	92	498	1640	94	256	210	148	6074	3037
Eligibility Unknown	174	9	22	38	10	8	0	8	52	6	16	35	68	446	n/a
Individuals # Screened/Individuals # Enrolled	3.0	2.6	2.1	4.2	1.9	2.4	1.5	2.2	5.3	2.1	3.8	5.8	5.4	3.1	n/a

- *One participant may have multiple screening attempts.
- ** Fenway and HSE have been phased out of participation in HPTN 052 and will no longer screen and enroll participants.
- ***Total enrollment numbers in above chart account for couples enrolled at both Fenway and HSE, though not shown.

Termination/Transfer Status of Couples at Fenway and HSE:

	HSE	Fenway
# Couples enrolled during run-in period	5	2
# Terminated couples	2	2
# Transferred couples to IPEC	3	N/A
Date of last terminated/transferred couple	26 July 2007	9 May 2007

Retention Status:

Refer to the SCHARP retention summary.

Implementation Issues and Problems:

Enrollment is expected to be completed by March/April 2010. The target enrollment of each site is listed below. Some target numbers have been amended since Blantyre and Zimbabwe have agreed to increase their enrollment targets.

Boston, MA (Fenway)	2
Lilongwe, Malawi (UNCP):	250
Blantyre, Malawi (JHP):	225
Harare, Zimbabwe (UZ-UCSF):	230
Rio de Janeiro, Brazil (IPEC and HGNI):	200
Porto Alegre, Brazil (HNSC):	98
Pune, India (NARI):	200
Chennai, India (YRG CARE):	250
Chiang Mai, Thailand (RIHES):	100
Johannesburg, South Africa (WITS):	55
Gaborone, Botswana:	65
Soweto, South Africa	30
Kenya	45
<hr/>	
Total:	1750

RIHES and YRG CARE have both reached their enrollment targets of 100 and 250 couples, respectively.

Refer to the Network Laboratory report for any issues and problems related to the clinical site laboratories.

Report for HPTN Study Operations Group

HPTN 057

A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants

Based on available data through: 5 Feb 2010

Participating Study Sites:

Malawi - Queen Elizabeth Central Hospital, Malawi College of Medicine-JHU Research Project, Blantyre (QECH)

Brazil - Federal University of Minas Gerais, Belo Horizonte (UFMG)

- Irmandade Santa Casa de Misericordia de Porto Alegre, Porte Alegre (Santa Casa)
- Hospital dos Servidores do Estado – Servico de Doencas Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Servico de Infectologia, Porte Alegre (Conceicao)

Study Implementation Status:

Enrollment into Cohorts 1, 2 and 3 was completed on Sept 16, 2008. A total of 81 evaluable mother/infant pairs were enrolled. Follow-up of participants in Cohorts 1, 2, and 3 is complete.

Accrual at all sites is temporarily closed pending protocol registration and site activation of protocol amendment Version 2.0, which will add a fourth cohort looking at a maternal dose during labor and daily infant dosing for 1 week.

The protocol amendment is final. Cohort 4 is anticipated to begin enrollment in early Q1 2010.

Study Drug is available for shipment to sites pending protocol registration

Accrual Status:

Below is the site reported enrollment summary for Cohorts 1, 2 and 3; refer also to the SHARP enrollment summary.

Site	# Evaluable Mother/Infant Pairs Enrolled (# c-section deliveries)		
	Cohort 1	Cohort 2	Cohort 3
Queen Elizabeth Central Hospital, Blantyre Malawi	24 (3)	16	15 (2)
Santa Casa, Porte Alegre Brazil	3 (2)	4	4 (2)
University of Minas Gerais, Belo Horizonte Brazil	3 (2)	1	2 (1)
Conceicao, Porte Alegre Brazil	-	-	4 (1)
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5 (5)
Total	30	21	30

Status of Intervention Delivery:

TDF dispensing is complete. There were no reported significant problems with the dispensing of tenofovir to the mothers or infants.

Retention Status:

Two mother/infant pairs for Cohorts 1 – 3 have been lost to follow-up.

Implementation Issues and Problems:

Report for HPTN Study Operations Group

HPTN 058

A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors

Based on data available through 5 February 2010

Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Heng County, Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Guangxi, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Nanning, Guangxi, China
- Research Institute for Health Sciences, Chiang Mai, Thailand

Study Implementation Status:

Enrollment in Chiang Mai was capped at 202 participants. Xinjiang has enrolled 221 participants. Heng County, Guangxi has enrolled 206 participants. The clinic in Urumqi remains relocated to their proposed satellite site due to orders from the Chinese authorities. DAIDS issued an approval for this temporary relocation. It is hoped that the ban on foreign communication in Xinjiang will soon be lifted.

The Nanning site (also in Guangxi Province) has been approved by NIH and the local authorities and the site is working towards site activation which will not occur until study drug is on site.

All sites have submitted LoA #1 to their local IRBs and registered with the RCC.

Adding a site in Vietnam still remains a possibility. The team held a Site Selection Committee on 3 February 2010. The team discussed approving the site for development predicated on the site being able to meet certain deadlines for obtaining all approvals. This request will be submitted to the EC.

Marek Chawarski is in the process of revising the Counseling Manual. The team has continued regular conference calls with the counselors to address any questions they have about this component of the study.

A Study Monitoring Committee (SMC) review occurred 26 January 2010. A DSMB review is anticipated 26 February 2010. The DSMB review will occur in Nanning and several members of the protocol team will attend. Trainings and assessments will therefore be held at both China sites.

Accrual Status:

	Chiang Mai	Guangxi	Xinjiang
Date First Screened	11-Apr-07	19-Dec-08	19-Dec-08
Date First Enrolled	30-May-07	24-Dec-08	21-Dec-08
# Individuals Screened	281	429	407
# Individuals Enrolled	202	206	221

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	87%
Week 52	89%
Week 78	77%
Week 104	81%
Week 130	58%

Implementation Issues and Problems:

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation. The study drug supply for this first shipment has an August 2010 expiry date.

Report for HPTN Study Operations Group

HPTN 061

Feasibility study of a community-level, multi-component intervention for Black men who have sex with men in preparation for a community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black men who have sex with men

Based on data available through: 05 February 2010

Participating Study Sites:

- Ponce de Leon Center CRS (site 5802) and Hope Clinic CRS (site 31440) in Atlanta and Decatur, Georgia, respectively
- San Francisco Vaccine and Prevention CRS in San Francisco, California (site 30305)
- New York Blood Center (NYBC)/Union Square CRS (site 31605) and Harlem Prevention Center CRS (site 30276) in New York City, New York
- University of California at Los Angeles (UCLA) Vine Street CRS (site 31607) in Los Angeles, California
- The Fenway Institute CRS (site 31602) in Boston, Massachusetts
- George Washington University CRS (site 31608) in Washington, D.C.

Study Implementation Status:

All sites for the HPTN 061 protocol are enrolling and following participants.

Site	Date of Activation	Date of First Enrollment
The Fenway Institute	06 July 2009	17 July 2009
George Washington University	20 July 2009	28 July 2009
San Francisco Vaccine and Prevention CRS	11 August 2009	13 August 2009
New York Blood Center	24 August 2009	01 October 2009
Hope Clinic CRS	04 September 2009	16 September 2009
UCLA	25 September 2009	29 September 2009
Ponce de Leon CRS	09 October 2009	N/A
Harlem Prevention Center	05 January 2010	08 January 2010

Accrual Status (participants enrolled at each site) as of 01 Jan 2010:

Fenway	GWU	Emory: Ponce +Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
95	69	58	110	110	43	5	490

Status of Intervention Delivery:

Site reports and enrollment numbers show that the rate of acceptance of peer health navigation and success rate at having participants refer their sexual partners to the study is varying markedly between sites and lower than had been expected. To improve the number of index referrals, the study team have decided to expand "index" status to all participants who test HIV negative at enrollment. An LoA is being written to allow this to happen.

Retention Status:

The study team has discussed different ways to encourage retention, including compensating participants for periodically contacting the site with updated locator information. Sites have been encouraged to implement those strategies they deem to be most promising for ensuring retention. Only a few participants have been scheduled for follow-up visits at this time and they have been making their visits.

Implementation Issues and Problems:

See above in "Status of Intervention Delivery"

Report for HPTN Study Operations Group

HPTN 062

Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection

Based on data available through: 02 February 2010

Participating Study Site:

- Tidziwe Centre, Kamuzu Central Hospital, Lilongwe, Malawi

Study Implementation Status:

The Prevention Management Group met late January and determined that the cost of including Blantyre as a site in 062 was too high, and therefore, the site has been removed from this study. The expected 46 participants will be recruited from Lilongwe only.

Version 2.0 of the protocol, dated 10 September 2009, was approved by DAIDS and distributed to the sites on 16 September 2009. Lilongwe, FHI, and UNC IRBs have approved this version.

Protocol-specific training was completed 5-9 December 2009. The counselor training was conducted the week of 18 January 2010 when the 062 intervention counselors were trained by consultants from FHI, UNC, Michele Demers, and their graduate students. Kevin McKenna from FHI also participated in this training.

Activation in Lilongwe was anticipated to occur early February. However, a number of tasks still remain. These include: Several SOPs regarding qualitative data; staff roster and delegation of duties; testing randomization system; finishing Counseling Manual materials; "walkthroughs" of study visits, including counseling practice; and registration with DAIDS Protocol Registration Office. Activation is now expected late February.

Accrual Status (completed at all sites):

No sites have begun enrollment to date.

Status of Intervention Delivery:

N/A

Retention Status:

N/A

Implementation Issues and Problems:

Removal of Blantyre site will require rapid and steady enrollment in Lilongwe to ensure 40+ participants within 24 months.

Report for HPTN Study Operations Group

HPTN 063

Preparing for International Prevention Trials Involving HIV-Infected Individuals in Care Settings

Based on data available through: 04 February 2010

Participating Study Sites:

- Matero Clinic CRS; Lusaka, Zambia
- Chiang Mai University AIDS Prevention CRS; Chiang Mai, Thailand
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS; Rio de Janeiro, Brazil

Study Implementation Status:

Version 1.0 of the protocol was granted final approval on 15 September 2008 and distributed to sites on the same day. The English version of the CRFs and ACASI scripts are final. The ACASI and CRFs have been translated into all 4 local languages (Portuguese, Thai, Bemba, and Nyanja). The sites and protocol team are currently finalizing the translations. The audio recordings are expected to be final in February and March.

The qualitative assessments for HPTN 063 were final as of 26 March 2009 and have been translated by the sites.

Brazil submitted to their local IRB on 20 February 2009 and received approval on 17 April 2009. They received approval from their central IRB (CONEP) on 16 December 2009 (original submission was 04 May 2009). They are now awaiting state department clearance.

Zambia originally submitted to their IRB on 17 April 2009 and received approval on 25 August 2009. They submitted an update to the ICFs because of a change in investigator. The site received a non-approval letter from the Ministry of Health (MOH) on 13 January 2010, due to a current ban on sample exportation. They have appealed the decision and are awaiting feedback.

Chiang Mai submitted to their IRB on 02 September 2009 and submitted to the JHU IRB for November review. They require the final ACASI documents for final approval although they currently have provisional approval. They are submitting the ACASI document on 10 February 2010. Study specific training took place 25-29 January 2010. It is estimated that the site will be ready for activation in approximately 6 weeks.

Site activation activities are continuing at each site and site. The site training schedule is as follows: Thailand (25-29 January, 2010 - Completed), Zambia (8-12 March, 2010 - Postponed), and Brazil (1-5 March, 2010).

Accrual Status:

Pending, no sites have been activated.

Status of Intervention Delivery:

N/A

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, we must have this approval in order to receive state department clearance.

Report for HPTN Study Operations Group
HPTN 064
Women's Seroprevalence Study (ISIS)
Based on data available through: 05 February 10

Participating Study Sites:

- Emory University, Atlanta, Georgia (Ponce de Leon Center CRS and Hope Clinic CRS)
- Johns Hopkins Adult AIDS CRS, Baltimore, Maryland
- University of North Carolina-Chapel Hill, North Carolina (UNC AIDS CRS and Wake County Health and Human Services CRS)
- Columbia University, New York, New York (Bronx-Lebanon Hospital Center CRS and Harlem Prevention Center CRS)
- New Jersey Medical School Adult Clinical Trials Center, Newark, New Jersey
- George Washington University School of Public Health and Health Services, Washington D.C.

Study Implementation Status:

All HPTN 064 study sites have been activated and screening and enrollment is well underway.

Three of the ten study communities: the UNC AIDS CRS (Durham site), the Bronx-Lebanon Hospital Center (BLHC) CRS and the George Washington University School of Public Health and Health Services (GWU) CRS) that agreed to re-open enrollment activities have successfully started enrolling a total of 210 women at each CRS.

With accrual steady, we anticipate that Wake CRS will be closed to accrual by the end of next month.

The team is currently planning and preparing recruitment reports for its first SMC Review on February 22, 2010.

Accrual Status:

Please see SCHARP Enrollment Report.

Status of Intervention Delivery:

N/A

Retention Status:

Please see SCHARP Retention Report.

Implementation Issues and Problems:

Accrual is currently being monitored very closely at all sites to ensure study targets are met.

Appendix: HPTN Protocols and INDs

Protocol #		IND	IND Sponsor	Study Status
HPTN 027	A Phase I Study to Evaluate the Safety and Immunogenicity of ALVAC-HIV vCP1521 in Infants Born to HIV-1 Infected Women in Uganda	BB-IND 12023	DAIDS	Closed to Accrual
HPTN 046	Phase III Trial to Determine the Efficacy and Safety of an Extended Regimen of Nevirapine in Infants Born to HIV Infected Women to Prevent Vertical HIV Transmission During Breastfeeding	72,592	DAIDS	Closed to Accrual
HPTN 052	A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples	68,535	DAIDS	Enrolling
HPTN 057	A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants	72,531	DAIDS	Closed to Accrual
HPTN 058	A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors	73,797	DAIDS	Enrolling