



HPTN Study Operations Report

March 2011

PTN Executive Summary Report
9 March 2011
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	218	81%	10	21.8	closed
	Uganda – Mulago Hospital	23Jun2008	500	545	109%	19.2	28.4	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	507	101%	20.5	24.7	completed
	Total		1670	1678	100%	20.5	81.9	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	409	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	219	81%	10	21.9	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	1700	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

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	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	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 – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1681	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	88	105%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	174	104%	29.4	5.9	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	245	102%	26.5	9.2	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	40	50	125%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	97	99%	30.1	3.2	closed

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	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1692	101%	34.7	48.8	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.2	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.8	2.6	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.4	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.7	2.6	
058	China – Guangxi – Heng County	24Dec2008	405	323	80%	26.8	12.1	73%
	China – Nanning	19May2010	350	85	24%	9.8	8.7	50%
	China – Xinjiang	23Dec2008	495	366	74%	26.9	13.6	73%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	976	65%	46	21.2	
061	US – Atlanta	26Feb2010	201	116	58%	7	16.6	closed
	US – Boston	17Jul2009	403	237	59%	15.3	15.5	closed
	US – Decatur	16Sep2009	202	184	91%	12.2	15.1	closed
	US – Los Angeles	30Sep2009	403	283	70%	12.3	23	closed
	US – NY – Harlem Prevention Center	08Jan2010	201	154	77%	6.3	24.4	closed
	US – NY – New York Blood Center	01Oct2009	202	156	77%	10.7	14.6	closed
	US – San Francisco	13Aug2009	403	204	51%	13.6	15	closed
	US – Washington DC	28Jul2009	403	227	56%	14.2	16	closed
	Total		2418	1561	65%	15.3	102	
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	17	37%	10.6	1.6	

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	Total		46	17	37%	10.6	1.6	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	68	23%	11.4	6	94%
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	68	9%	11.4	6	
064 (Women)	US – Atlanta	22Oct2009	200	215	108%	7	30.7	completed
	US – Baltimore	05Aug2009	200	210	105%	8.7	24.1	completed
	US – Chapel Hill	26May2009	200	210	105%	8.7	24.1	completed
	US – Decatur	27Aug2009	200	211	106%	11.9	17.7	completed
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	210	105%	7.4	28.4	completed
	US – Newark	05Jun2009	400	420	105%	10.5	40	completed
	US – Raleigh	11Aug2009	200	210	105%	5.7	36.8	completed
	US – Washington DC	17Jun2009	200	211	106%	10.3	20.5	completed
	Total			2000	2107	105%	15	140.5
064 (Men)	US – Decatur	10Mar2010	30	43	143%	4.9	8.8	completed
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	37	123%	3.2	11.6	completed
	US – Washington DC	02Apr2010	30	40	133%	2.8	14.3	completed
	Total			120	174	145%	10.3	16.9
066	US – Baltimore	28Feb2011	16	1	6%	0.3	3.3	15%
	US – Chapel Hill	07Feb2011	16	7	44%	1	7	37%
	Total			32	8	25%	1	8

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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	2346	2030	2212	87%	94%
	Tanzania – Dar Es Salaam	218	1256	1100	1184	88%	94%
	Uganda – Mulago Hospital	545	3114	2943	2938	95%	94%
	Zimbabwe – Harare/Chitungwiza	507	2917	2688	2750	92%	94%
	Total	1678	9633	8761	9084	91%	94%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4396	4088	4180	93%	95%
	Tanzania – Dar Es Salaam	219	2357	2136	2241	91%	95%
	Uganda – Mulago Hospital	562	6024	5859	5730	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5485	5172	5216	94%	95%
	Total	1700	18262	17255	17367	94%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	540	529	533	98%	99%
	Brazil – Porto Alegre	90	973	954	950	98%	98%
	Brazil – Rio de Janeiro	184	2218	2184	2159	98%	97%
	India – Chennai – YRGCare	250	2893	2625	2820	91%	97%
	India – Pune	175	2016	1992	1963	99%	97%
	Kenya – Kisumu	60	346	343	343	99%	99%
	Malawi – Blantyre – Queen Elizabeth Central	230	2203	2076	2157	94%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	2534	2355	2478	93%	98%
	South Africa – Johannesburg – Witwatersrand	46	409	390	402	95%	98%
	South Africa – Soweto	50	300	287	297	96%	99%
	Thailand – Chiang Mai	106	1233	1219	1199	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2318	2194	2269	95%	98%
	Total	1759	17983	17148	17572	95%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard	
052 Combined (Partners)	Botswana – Gabarone	77	540	506	533	94%	99%	
	Brazil – Porto Alegre	93	973	910	950	94%	98%	
	Brazil – Rio de Janeiro	187	2218	1860	2159	84%	97%	
	India – Chennai – YRGCare	250	2893	2403	2820	83%	97%	
	India – Pune	175	2016	1946	1963	97%	97%	
	Kenya – Kisumu	60	346	336	343	97%	99%	
	Malawi – Blantyre – Queen Elizabeth Central	231	2203	1821	2157	83%	98%	
	Malawi – Lilongwe – Lilongwe Central Hospital	255	2534	2094	2478	83%	98%	
	South Africa – Johannesburg – Witwatersrand	46	409	364	402	89%	98%	
	South Africa – Soweto	50	300	274	297	91%	99%	
	Thailand – Chiang Mai	107	1233	1117	1199	91%	97%	
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2317	1957	2268	84%	98%	
	Total		1771	17982	15588	17571	87%	98%
	057 (Mothers)	Brazil – Belo Horizonte	12	64	64	62	100%	97%
Brazil – Porto Alegre – Conceicao		10	52	51	51	98%	97%	
Brazil – Porto Alegre – Santa Casa		15	86	83	83	97%	97%	
Brazil – Rio de Janeiro		13	71	71	69	100%	97%	
Malawi – Blantyre – Queen Elizabeth Central		72	416	405	403	97%	97%	
Total			122	689	674	668	98%	97%
057 (Infants)	Brazil – Belo Horizonte	12	72	72	70	100%	97%	
	Brazil – Porto Alegre – Conceicao	10	57	56	55	98%	97%	
	Brazil – Porto Alegre – Santa Casa	15	99	96	95	97%	96%	
	Brazil – Rio de Janeiro	13	78	78	75	100%	97%	
	Malawi – Blantyre – Queen Elizabeth Central	72	474	458	456	97%	96%	
	Total		122	780	760	752	97%	96%
058	China – Guangxi – Heng County	323	589	482	534	82%	91%	
	China – Nanning	85	36	30	34	83%	94%	
	China – Xinjiang	366	690	579	622	84%	90%	
	Thailand – Chiang Mai University	202	792	703	687	89%	87%	
	Total		976	2107	1794	1876	85%	89%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	116	97	73	92	75%	94%
	US – Boston	237	270	190	251	70%	93%
	US – Decatur	184	222	128	207	58%	93%
	US – Los Angeles	283	303	228	281	75%	93%
	US – NY – Harlem Prevention Center	154	165	153	155	93%	94%
	US – NY – New York Blood Center	156	191	162	178	85%	93%
	US – San Francisco	204	287	208	266	72%	93%
	US – Washington DC	227	247	197	230	80%	93%
	Total	1561	1782	1339	1660	75%	93%
062	Malawi – Lilongwe – Lilongwe Central Hospital	17	128	127	126	99%	98%
	Total	17	128	127	126	99%	98%
064 (Women)	US – Atlanta	215	392	356	362	91%	92%
	US – Baltimore	210	411	398	378	97%	92%
	US – Chapel Hill	210	323	299	300	93%	93%
	US – Decatur	211	347	307	321	88%	93%
	US – NY – Bronx–Lebanon Hospital Center	210	328	315	304	96%	93%
	US – NY – Harlem Prevention Center	210	362	320	335	88%	92%
	US – Newark	420	821	789	756	96%	92%
	US – Raleigh	210	411	384	379	93%	92%
	US – Washington DC	211	338	316	313	93%	93%
	Total	2107	3733	3484	3447	93%	92%
066	US – Baltimore	1	0	0	0	–	–
	US – Chapel Hill	7	13	11	13	85%	100%
	Total	8	13	11	13	85%	100%

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

March 2011

I. HPTN 027

A. General Comments

1. Protocol Version - 2.0 dated 20th May 2005
2. SSP version – 2.0
3. Enrollment Status – Closed.
4. Date of last SMC call –29th September 2008
5. Communiques/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related Notes to File/deviations issued since preparation of SMC report: None
7. Miscellaneous
 - a. Results for Hepatitis B Surface Antibody, polio, tetanus and HIB have been submitted to SCHARP.
 - b. Manuscripts are currently being prepared

B. Site Specific

Kampala - Stored samples have been moved from the JCRC to MU-JHU. There should be no samples remaining at the JCRC, the site is confirming this and will update LDMS records accordingly.

C. Shipping / QA Status

All requested samples have been shipped and received by the HPTN NL

II. HPTN 046

A. General Comments

1. Protocol Version - 3.0 dated 26 Sept, 2007
2. SSP version – 5.0 dated 9th April 2008
3. Enrollment Status - closed
4. Date of last SMC call – May 17, 2010
5. Communiques/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related Notes to File/deviations issued since preparation of SMC report
 - a. Dar es Salaam – NTF issued May 19th describing the delay in the testing of one sample for DNA PCR – resolved. Dar es Salaam – Protocol Deviation form issued 26th May 2010 describing that a cell pellet storage was not requested by the clinic. BOTH PREVIOUSLY REPORTED June study ops
 - b. Dar es Salaam – Protocol Deviation form issued 26/May/2010 describing that plasma and DBS storage were not requested by the clinic. PREVIOUSLY REPORTED June study ops
 - c. Dar es Salaam – 8 Protocol Deviation forms received on 6.30.10 They describe the failure of the physician to request DBS or breast milk storage. Discovered during retrospective chart reviews. PREVIOUSLY REPORTED August study ops
 - d. UZ-UCSF – NTF issued Sep 22nd describing the movement of the DBSCards from the laboratory (temperature monitored) to a storage area for the laboratory. The lab recently started monitoring temperatures in the area. A list of PTIDs involved is still pending.
 - e. UZ-UCSF pending NTF regarding another power problem that affected the freezers at the off site location
 - f. UZ-UCSF –NTF regarding outage of WB kits in October, delaying resulting of 1 participant.

B. Site Specific

1. Harare - No new updates. Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory.
2. Kampala - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
3. Durban - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

The BARC KZN Laboratory is running out of freezer space for plasma and breast milk for the HPTN 046 trial. Samples will be relocated to the BARC Jhb Biobanking Repository. All samples will be QC'd during this process and electronic shipping (relocation) and storage of the samples will be done using the LDMS. The samples will be relocated in batches. IATA regulations and good cold chain management processes will be followed at all times.

Any further breast milk and plasma samples collected by BARC for this study will still be stored short-term at BARC KZN (-70°C). They will then be shipped to the Biobanking Repository on a regular basis.

4. Dar es Salaam - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

1. All samples requested at this time for QA have been shipped and tested.
2. Shipping lists for resistance testing samples are being prepared by SCHARP.

III. HPTN 052

A. General Comments

1. Protocol Version 3.0 dated 20 Nov 06
2. SSP version 1.6 dated 9 Jan 09
3. Enrollment Status - closed
4. Date of last SMC call – scheduled for March 2011
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab related Notes to File/deviations issued since preparation of SMC report
 - a. HNSC NTF regarding validation of urinalysis instrument.
7. Miscellaneous - The NL is continuing to work on the QA activity regarding partner seroconversions, genotyping and ARV testing.

B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site has prepared the validation documents. Site has finalized the validation of the back-up instrument and is working on finalizing other validation documents. Have not submitted their LDMS reconciliations, have not submitted their QC for review, but have submitted their inventory.
2. Harare – A call was held with the lab regarding the recent problems with notifying the NL on the freezer problems A report on the number of samples affected has been received. The site is working with FSTRF to indicate this in their LDMS. Some samples have had multiple freeze/thaws. Once the LDMS has been updated, it will be useful to identify these samples. The call also addressed inventory issues. Pending an update on their ordering / inventory SOP. :Did not submit their LDMS reconciliations, submitted their QC for review, and submitted their inventory.
3. Chennai – Did submit their LDMS reconciliations, did not submit their QC for review, but submitted their inventory.

4. Blantyre – Having problems with their chemistry analyzer and utilizing the back-up lab. Have submitted their LDMS reconciliations, did submit their QC for review, and submitted their inventory
5. Porto Alegre - Did submit their LDMS reconciliations, submitted their QC for review and submitted their inventory.
6. Rio sites – Did submit their LDMS reconciliations, have submitted their QC for review, and did submit their inventory.
7. Lilongwe - Did submit their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai –Had no LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg – WITs--Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory
10. Soweto – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and Soweto have not submitted their inventory
11. Botswana –.Have submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory
12. Kenya – Have submitted their LDMS reconciliations, have not submitted their QC for review, and have submitted their inventory

C. Shipping / QA Status

Pending a shipment from NARI Pune. New QA lists for HIV genotyping and QA testing have gone out to the sites

IV. HPTN 057

A. General Comments

1. Protocol Version - 2.0 dated 28th October 2009
2. SSP version – 4.0 lab section dated 11th March 2010
3. Enrollment Status – Fully enrolled
4. Date of last SMC call – 21st February 2008.
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: Clarification memo issued 7.15.2010 clarifying that CK total protein and glucose are not required in HPTN 057 (they had been indicated in section Appendix 1B) PREVIOUSLY REPORTED ON STUDY OPS REPORT
6. Lab related Notes to File/deviations issued since preparation of SMC report:
 - a. Blantyre is using their back up laboratory for chemistry testing.

B. Site Specific

1. Blantyre - Lab is utilizing back up for chemistry analytes. Site are completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have submitted their inventory.
2. Santa Casa, Porto Alegre - No outstanding issues. Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
3. UFMG - No outstanding issues –. Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
4. HSE Rio - No outstanding issues. Site is completing LDMS reconciliations in a timely manner. No testing is done on site for this protocol.
5. HNSC Porto Alegre - Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

1. Specimens have been received from Blantyre and testing is currently underway. Further samples will be needed and SCHARP are working on this request.
2. Shipping lists have been sent to the Brazil sites. Samples from 3 sites have been received at the NL, the shipment from the UFMG site is expected.

V. HPTN 058

A. General Comments

1. Protocol Version – 2.0 dated 16th September 2008
2. SSP Version – 2.0 dated 5th December 2008
3. Enrollment status – open
4. Date of last SMC call – 24th January 2011
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report: None
6. Lab related Notes to File/deviations issued since preparation of SMC report: None

B. Site Specific

1. Thailand-. Site is completing the LDMS reconciliations in a timely, submitted their QC for review, and submitted their inventory. The lab can no longer receive a supply of one of the HCV assays they were using. The Architect HCV assay at the Maharaj Hospital will be used as the second HCV assay for HPTN 058. Validations have been performed and reviewed by the HPTN NL.
2. Xinjiang Site-. Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.
3. Guangxi-. Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

1. No outstanding shipments or requests. QA samples from China have not been requested at this time. Shipment of samples out of China remains problematic. NL will investigate the possibility of performing QA testing at the site labs using USA FDA approved methodologies.

VI. HPTN 061

A. General Comments

1. Protocol Version – Version 2.0, April 2nd 2009
2. SSP Version – Section 11 Version 5.0 December 9th 2010.
3. Enrollment status – All sites have completed enrollment
4. Date of last SMC call – November 8th 2010
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report: Notification of Change to SSP lab section 11 version 5.0 date 9 December 2010.
6. Lab related Notes to File/deviations issued since preparation of SMC report:
 - a. Atlanta – Note to Files received for 3 PIDs for whom blood for plasma storage was not drawn, during blood draw. . Previously Reported Note to File received for Participant who did not have rapid test done, since there were no controls and the urine and rectal swab that were collected were not picked up by the courier; participant returned for blood draw but refused the collection of urine and rectal swab again. PREVIOUSLY REPORTED
 - b. Fenway – Note to File received for QNS plasma storage
 - c. GWU - Notes to File received for 2 PIDs for whom plasma was not stored. Previously Reported received previously mentioned note to File-Waiting on Note to File for mislabeled rectal swab and stored plasma. Previously Reported Note to File received for participant for whom no plasma was stored due to a hard stick, site will try to bring participant back for redraw. PREVIOUSLY REPORTED
 - d. NYBC - None. Previously reported Note to File received for participant who requested rectal swab at visit 2.0. Note to File received for participant who after multiple sticks on multiple days only blood for rapid was able to be drawn.
 - e. UCLA - None. Previously reported Note File received for incorrect test ordered, HIV-1 Genotype instead of HIV-1 RNA Quant; NL gave permission to send

aliquot for the RNA Quant. Previously Reported Note to File received for ppt who refused rectal swab at visit 3.0 (ppt had also refused at visit 1.0)

- f. Harlem- None. Previously reported Note to File received for participant who did not return for 2nd WB. Previously Reported Note to File received for participant who was a hard stick, so there was no Syphilis test drawn and also no plasma was stored; participant has not returned for redraw. PREVIOUSLY REPORTED
- g. San Francisco- None. Previously reported Note to File received for plasma storage sample that was left out over weekend; sample processed and stored with comments in LDMS. Also note to File received for aliquot labeled with invalid PID on site label but valid PID on LDMS label. Previously Reported Note to File received for ppt who had a short blood draw and upon participant return RA did not collect plasma storage or 2nd confirmatory WB.

B. Site Specific

1. Fenway - No new updates
2. George Washington University - No new updates
3. San Francisco - Allegations made by RA about lab specimen processing SOP not being followed and freezer and fridge concerns. Investigation currently being conducted at site.
4. Harlem - No new updates
5. Atlanta - No new updates
6. New York Blood Center: No new updates
7. UCLA - Due to participants from this site being co-enrolled in HVTN 505 (vaccine trail), procedures are being looked at to determine how these participants (from this site and potentially other 061 sites) will be dealt with so that they are not un-blinded in the 505 study..

C. Shipping / QA Status

QA samples have been received and QA testing in process at NL. .

VII. HPTN 063

A. General Comments

1. Protocol Version: Version 1.0 dated 15 September 2008
2. SSP version: Version 1.0 dated 26th March 2010 (update in process)
3. Enrollment Status: Thailand resumed enrolling February 21st 2011. Brasil and Zambia still on hold.
4. Date of last SMC call: None
5. Communiques/Notifications of Change to SSP issued since preparation of last SMC report: None
6. Lab related Notes to File/Deviations issued since preparation of SMC report -None

B Site Specific

1. Thailand -Retraining was held on February 15th 2011
2. Brazil- Retraining scheduled for March 10th 2011
3. Zambia-Retraining scheduled for March 16th to March 17th 2011

VIII. HPTN 064

A. General Comments

1. Protocol Version: 1.0 dated 20 February 2010
2. SSP Version: 2.0 dated 12 May 2010
3. Enrollment Status: All sites have completed enrollment.
4. Date of last SMC call : 01 November 2010
5. Communiques/Notification of Change to SSP issued since preparation of last SMC report: None

6. Lab related Notes to File/deviations issued since preparation of SMC report:
 - a. Johns Hopkins University: NL informed plasma wasn't stored for a participant due to a lab accident. Note to File received. PREVIOUSLY REPORTED November study ops.
 - b. Emory: NL informed plasma (for one participant) wasn't stored within the allotted timeframe. Note to File received. NL informed that an enrolled participant used falsified information. Note to File and Protocol Deviation received. PREVIOUSLY REPORTED December study ops.
 - c. Harlem: Incorrect PID and VID entered into LDMS on two participants. Note to File received.

B. Site Specific

1. Bronx: No new updates.
2. Harlem: No new updates.
3. Newark: No new updates.
4. Johns Hopkins University: Reminder sent to the site for weekly LDMS reconciliation report.
5. George Washington University: Reminder sent to the site for a weekly LDMS reconciliation report.
6. University of North Carolina: No new updates.
6. Emory: No new updates.

C. Shipping / QA Status

All enrollment QA testing has been completed and the data forwarded to SCHARP.

IX. HPTN 066

A. General Comments

1. Protocol Version - 2.0 dated 29th November 2010
2. SSP version – Version 1.0
3. Enrollment Status – UNC and JHU sites are actively screening and enrolling participants.
4. Date of last SMC call – None
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab related Notes to File/deviations issued since preparation of SMC report - None
7. Miscellaneous - PBMCs in this study are being used for PK analysis and will follow an SOP developed specifically for this purpose. This study is not storing viable PBMCs and will not follow the Cross-Network PBMC Processing SOP

B. Site Specific

1. UNC- None
2. JHU- None

X. HPTN 068

B. General Comments

1. Protocol Version – 1.0 dated 06th October 2010
2. SSP Version – 1.0 dated 01 February 2011
3. Enrollment status – enrolling
4. Date of last SMC call – none
5. Communiqués/Notification of Changes to SSP issued since preparation of last SMC report - None

NL updates

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

Travel Updates

Estelle and Paul will be visiting China in the spring for HPTN 058 site visit.
Estelle and Paul will be visiting NARI and YRGcare in June for HPTN 052.
Vanessa will be attending the retraining for the HPTN 063 study in Brazil.

Implementations Issues and Problems Summary March 2011

052

The study team is in the process of informing all participants about the updated advice from the WHO that recommends that HIV-infected persons initiate ART at CD4 cell count < 350. This information is being conveyed via an information sheet that also informs participants of whether the local health and government authorities are adopting these new WHO guidelines. The study team is tracking the process until all participants have been informed. A slide is available upon request which summarizes the current CD4 threshold in each country where HPTN 052 is taking place and whether and when the WHO recommended threshold of CD4 < 350 will be implemented.

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

058

The team is continuing to explore ways to increase both medication and counseling adherence.

Greg Lucas will be visiting the Nanning site 13-15 March 2011 to conduct a clinical training. Dr. Shao will send an outreach worker to Nanning to help make it possible for all sites to compare their strategies in order for all 3 sites to jointly decide lessons learned and best strategies for high risk recruitment with the remaining time in the study.

061

Retention is right now the greatest concern in study implementation. Fortunately, the follow-up visit windows in 061 are large creating opportunity for bringing participants who have missed their target window in for their 6 or 12 month visits. Unfortunately, the windows are starting to close for the 6 month visit, meaning that retention for that timepoint will soon be fixed. The SMC will convene for an interim discussion on the issue of retention only at the end of March.

063

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 received an official announcement that on 24 September 2010 they received approval of Foreign Clearance (Number 14846 for HPTN 063).

After the Thai site reported problems with the original ACASI, the protocol team significantly revised and simplified the ACASI instrument and closely monitored the piloting of the new instrument to ensure a more representative sample of participants were piloted before it was finalized. All three sites piloted the new ACASI instrument and provided feedback before it was finalized.

The revised ACASI is being translated and the audio is being finalized. Brazil is expecting approval of the ACASI scripts from their local IRB by mid-March. Zambia's local IRB does not require approval of the ACASI script however, it has been submitted for informational purposes. Thailand received approval for the newest version of the ACASI on 28 January 2011.

Sites have procured touchscreen laptops, similar to what is being used in other network studies that are using an ACASI system for data collection. The touchscreen laptops were not initially budgeted for in this study budget so the team is revisiting the original budget and looking for ways to accommodate the additional cost.

LoA #2 was distributed to sites on 10 December 2010 with instruction to submit it to their local IRBs/ECs for approval. Brazil and Thailand have received approval for LoA #2; Zambia has submitted the LoA but is still awaiting IRB review.

065

On September 28, 2010, FHI was informed that MedStar Health Research Institute (MHRI), the body that governs research at Washington Hospital Center (WHC), has declined to participate in the study. After several attempts by the study chair, co-chair, and the NIH to negotiate with MHRI and WHC, WHC made a final decision not to participate after a call with NIH in mid-February. WHC has now officially been removed from the list of potential HPTN 065 study sites.

067

The Clinical Trial Agreement is still pending with Gilead. The timeline for drug availability depends upon this agreement.

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: 1 March 2011

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:

All infants have now completed the 6 months study product dosing period. Follow-up will continue until the last infant completes the 18 month visit which is expected to occur around July 2011.

Analysis of the 6 month endpoint data is complete. An abstract discussing the details of the results is being presented CROI meeting. The team is currently working on a manuscript for publication.

Accrual Status:

The study enrolled 1678 mother-infant pairs [1700 infants in all].

Status of Intervention Delivery:

Blinded study product has been discontinued in all infants.

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: 9 March 2011

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. Enrollment is closed as of April 2010. Follow-up is on-going.

A full amendment is being drafted to include incorporation of all Letters of Amendment and Clarification Memos, and new information related to the EAE reporting system.

Retention Status:

Overall, 90% of all couples are retained in the study. 97% of all Index cases are retained in the study, with 6% of these Indexes retained without their partners. Refer to the SCHARP "Couples Status" retention summary available on Atlas for site-specific information.

Implementation Issues and Problems:

The study team is in the process of informing all participants about the updated advice from the WHO that recommends that HIV-infected persons initiate ART at CD4 cell count < 350. This information is being conveyed via an information sheet that also informs participants of whether the local health and government authorities are adopting these new WHO guidelines. The study team is tracking the process until all participants have been informed. A slide is available upon request which summarizes the current CD4 threshold in each country where HPTN 052 is taking place and whether and when the WHO recommended threshold of CD4 < 350 will be implemented.

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: 1 March 2011

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 was completed in November 2011. Follow-up is for 1 year. The expected study completion date is November - December 2011.

Accrual Status:

Below is the site reported enrollment summary for Cohorts 1, 2, 3 and 4; refer also to the SHARP enrollment summary.

Site	# Evaluable Mother/Infant Pairs Enrolled			
	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Queen Elizabeth Central Hospital, Blantyre Malawi	24	16	15	15
Santa Casa, Porte Alegre Brazil (pending drug import approval)	3	4	4	2
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	3
Conceicao, Porte Alegre Brazil	-	-	4	5
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	6
Total	30	21	30	31

Status of Intervention Delivery:

There have been 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: none.

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 4 March 2011

Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Heng County, 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 in October 2009. Xinjiang has enrolled 361 participants. Heng County has enrolled 320 participants. Nanning has enrolled 81 participants.

The Chinese team members continue to work on recruiting a higher risk cohort and improving retention and adherence (both counseling and medication).

A compassionate use mechanism is being explored via a rollover/compassionate use study between the site in Thailand and RB.

A DSMB call took place on 16 February 2011. The DSMB was complimentary of the sites' efforts to recruit higher risk participants and requested a feasibility focused review after October data is available.

Accrual Status:

	Chiang Mai	Nanning	Heng County	Xinjiang
Date First Screened	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
Date First Enrolled	30-May-07	19-May-10	24-Dec-08	21-Dec-08
# Individuals Screened	281	196	675	648
# Individuals Enrolled	202	81	320	361

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	89%
Week 52	84%
Week 78	85%
Week 104	87%
Week 130	83%
Week 156	82%

Implementation Issues and Problems:

The team is continuing to explore ways to increase both medication and counseling adherence.

Greg Lucas will be visiting the Nanning site 13-15 March 2011 to conduct a clinical training. Dr. Shao will send an outreach worker to Nanning to help make it possible for all sites to compare their strategies in order for all 3 sites to jointly decide lessons learned and best strategies for high risk recruitment with the remaining time in the study.

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: 28 February 2011

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 have finished enrolling and following participants. The last date of index partner (participant-referred) enrollment was 30 days after the last date of community recruitment.

Site	Date of Activation	Date of First Enrollment	Date of Completion of Community Recruitment
The Fenway Institute	06 July 2009	17 July 2009	29 Sept 2010
George Washington University	20 July 2009	28 July 2009	28 Sept 2010
San Francisco Vaccine and Prevention CRS	11 August 2009	13 August 2009	29 Sept 2010
New York Blood Center	24 August 2009	01 October 2009	27 July 2010
Hope Clinic CRS	04 September 2009	16 September 2009	16 Sept 2010
UCLA	25 September 2009	29 September 2009	29 Sept 2010
Ponce de Leon CRS	09 October 2009	26 February 2010	16 Sept 2010
Harlem Prevention Center	05 January 2010	08 January 2010	17 June 2010

Final Site-Reported Total Enrollment:

Fenway	GWU	Emory: Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
237	227	295	203	284	158	154	1,558

Status of Intervention Delivery:

Sites continue to provide HIV and STI testing and referral as well as Peer Health Navigation to enrolled participants. All sites have now completed enrollment (last date for enrollment was 29 October 2010). Individual interviews have been completed at most sites.

Recruitment Status:

All recruitment has been completed. Total enrollment was 1558.

Retention Status:

All sites are conducting six month visits and have conducted 12 month (final) visits. Retention for the 6 month visit is not strong, but improved slowly until this month, and now is at study-wide average of 77%. There is less disparity now between sites in their 6 month retention rate than previously, from a low of 67% (Emory) to a high of 93% (Harlem). Calls have been conducted between site staff and the protocol co-chairs on the topic of retention for each site and retention remains the primary focus of the monthly study team calls.

Retention at the 12 month (exit) visit is low at 70% and ranges from a site low of 49% to a site high of 100% at Harlem.

Implementation Issues and Problems:

Retention is right now the greatest concern in study implementation. Fortunately, the follow-up visit windows in 061 are large creating opportunity for bringing participants who have missed their target window in for their 6 or 12 month visits. Unfortunately, the windows are starting to close for the 6 month visit, meaning that retention for that timepoint will soon be fixed. The SMC will convene for an interim discussion on the issue of retention only at the end of March.

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: 3 March 2011

Participating Study Sites:

University of North Carolina Project, Kamuzu Central Hospital, Lilongwe, Malawi

Study Implementation Status:

Lilongwe site was activated on 24 February 2010 and began enrolling in April 2010. Enrollment is dependent on identifying acutely infected people in the CHAVI 001 study, hence enrollment is sporadic. The site has increased enrollment rate significantly in the past few months, due in part to the broader screening strategy implemented in September.

Accrual Status (completed at all sites):

Seventeen participants have been enrolled to date.

Status of Intervention Delivery:

Most study visits have been completed on time; retention is high. No social harms have been reported.

Retention Status:

See the SCHARP report.

Implementation Issues and Problems:

None

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: 03 March 2011

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 approved on 16 September 2008 and distributed to sites upon notification of approval (17 September 2008). Letter of Amendment (LoA) #1 (Zambia only) dated 12 May 2010, was approved by DAIDS on 18 May 2010. LoA #2, dated 7 December 2010, was approved by DAIDS on 9 December 2010.

The Thai site was activated on 26 March 2010 and enrolled their first participant on 01 April 2010.

Enrollment was paused on 22 June 2010 due to ACASI issues discussed during the 2010 HPTN Annual Meeting (see details below in the **Implementation Issues and Problems** section). However, the Thailand site still actively recruited and enrolled participants for the qualitative component. The Thai site received DAIDS approval to resume screening/enrollment activities on 08 February 2011. Screening and enrollment activities resumed in Thailand on 14 February 2011.

Sites are currently reviewing the drafts of version 2.0 of the SSP. The HPTN CORE is in the process of receiving feedback to make revisions before the final version is released.

Site activation activities are complete at all sites. The site training schedule was as follows: Thailand (25-29 January, 2010 - **Completed**), Zambia (21-27 October 2010 - **Completed**), and Brazil (1-5 March, 2010 - **Completed**). Refresher training for the Thailand site took place via conference call on 02 February 2011. Re-training for the Zambia site via conference call is scheduled for 10 March 2011. Members of the Protocol Team and HPTN CORE will travel to do retraining for the Brazil site on 16-17 March 2011.

Accrual Status:

Below is site-reported screening and enrollment data ending 03 March 2011. Refer also to the SCHARP enrollment summary.

Retention Status:

Refer to the SCHARP retention summary.

HPTN-063 Cumulative Screening and Enrollment Report							
Based on Site-Reported Information							
3 March, 2011							
Site (Quantitative Participants)	Date of First Screening	Date of First Enrollment	No. Pre-Screened	No. Report No Unprotected Sex	No. Not Receiving Care	Total No. Screened	Total No. Enrolled
Brazil: Rio de Janeiro (IPEC CRS)							
Women							
Heterosexual Men							
MSM							
Thailand: Chiang Mai		1 April 2010					
Women			506	0	0	36	36
Heterosexual Men			387	0	0	19	17
MSM			84	0	0	15	14
Zambia: Lusaka (Metero Clinic CRS)							
Women							
Heterosexual Men							
TOTAL	NA	NA	977	0	0	70	67

Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Thailand (FG)	Date of Focus Group	No. of participants
Date of Interview	17 May 2010	22 July 2010	1 Oct 2010	17 May 2010	Session 1	17 June 2010	8
	22 July 2010	15 Sept 2010	6 Oct 2010	19 May 2010	Session 2	27 Jan 2011	11
	10 Sept 2010		19 Oct 2010	5 Aug 2010	Session 3		
	20 Sept 2010		17 Nov 2010		Session 4		
			2 Dec 2010		TOTAL	2	19
	4	2	5	3			

Implementation Issues and Problems:

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 received an official announcement that on 24 September 2010 they received approval of Foreign Clearance (Number 14846 for HPTN 063).

After the Thai site reported problems with the original ACASI, the protocol team significantly revised and simplified the ACASI instrument and closely monitored the piloting of the new instrument to ensure a more representative sample of participants were piloted before it was finalized. All three sites piloted the new ACASI instrument and provided feedback before it was finalized.

The revised ACASI is being translated and the audio is being finalized. Brazil is expecting approval of the ACASI scripts from their local IRB by mid-March. Zambia's local IRB does not require approval of the ACASI script; however, it has been submitted for informational purposes. Thailand received approval for the newest version of the ACASI on 28 January 2011.

Sites have procured touchscreen laptops, similar to what is being used in other network studies that are using an ACASI system for data collection. The touchscreen laptops were not initially budgeted for in this study budget so the team is revisiting the original budget and looking for ways to accommodate the additional cost.

LoA #2 was distributed to sites on 10 December 2010 with instruction to submit it to their local IRBs/ECs for approval. Brazil and Thailand have received approval for LoA #2; Zambia has submitted the LoA but is still awaiting IRB review.

Report for HPTN Study Operations Group

HPTN 064 Women's HIV SeroIncidence Study (ISIS)

Based on data available through: 03 March 2011

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:

HPTN 064 successfully completed enrollment July 26, 2010 enrolling 2098 women.

The qualitative sites have successfully completed all qualitative interviews and focus groups. The HPTN CORE completed coding the qualitative interviews, female focus groups and male focus groups. The HPTN 064 Qualitative Working Group had a team analysis meeting in the Durham FHI office January 24-28, 2011. Several qualitative abstracts are being submitted by the protocol team and community members in the next coming months as a result of the meeting. The HPTN CORE is working closely with the Protocol Team to finalize the communication and publications plan.

All study visits were completed on February 28, 2011. Additionally, the HPTN CORE is working closely with sites, SCHARP, NIH and the Network Lab to ensure proper study close out.

Accrual Status:

Completed.

Status of Intervention Delivery:

N/A

Retention Status:

Completed, final retention statistics are pending. Please see SCHARP Retention Report.

Implementation Issues and Problems:

N/A

Report for HPTN Study Operations Group

HPTN 065

TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States

Based on available data through: 4 March 2011

Participating Study Sites:

HPTN 065 includes two intervention communities (Washington, D.C. and the Bronx, New York) and four comparator communities (Miami, Florida; Philadelphia, Pennsylvania; Chicago, Illinois; and Houston, Texas). The team has identified a total of 76 sites (37 test sites and 39 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study.

Bronx:

The protocol team has finalized a list of 18 test sites (including 9 hospitals) and 20 care sites to participate in the study. The team has completed all site contracts and IRB submissions for these sites. (Note that two hospitals have been combined into one entity for randomization.)

Washington, DC.

The protocol team has finalized a list of 19 test sites (including 7 hospitals) and 19 care sites to participate in the study. The team has completed all site contracts and received all but one (Howard University) IRB approvals for these sites.

Study Implementation Status:

Overall Plan for Implementation:

1. Finalize site selection and notify sites - COMPLETED
2. Set up minimal subcontracts with all sites (using non-FI budgets) - COMPLETED
3. Obtain all IRB approvals – NEARING COMPLETION, ONLY 1 REMAINING
4. Begin Provider Survey component with Care Sites - COMPLETED
5. Randomize sites - NEARING COMPLETION, ONLY 1 REMAINING
6. Conduct operational trainings - BEGUN
7. Begin Expanded HIV Testing, Linkage-to-Care, and Viral Suppression study components – HIV TESTING AND VIRAL SUPPRESSION BEGUN
8. Select Prevention for Positive Sites – IN PROCESS
9. Begin Prevention for Positives and Patient Survey components

Randomization:

- DC Care sites Block 1 – October 14, 2010
- DC Care sites Block 2 – February 3, 2011 (excluding Howard University)
- DC Test sites (all) – February 9, 2011 (excluding Howard University)
- NY Care sites (all) – January 7, 2011
- NY Test sites (all) – February 10, 2011
- Howard University – pending IRB approval (expected mid-March)

Study Start Dates:

The study officially started on September 29, 2010, with the launch of the Provider Survey. The study has been registered in ClinicalTrials.gov with a start date of September 2010. The viral suppression study component started on February 1, 2011 for the 10 HIV care sites randomized in Washington, D.C., and will begin for the remaining 10 DC HIV care sites on April 1, 2011, one of the Bronx care sites on March 1, 2011, and the rest of the Bronx care sites on April 1, 2011. Expanded HIV testing in hospital in-patient and emergency departments began February 1, 2011. Linkage-to-care is expected to begin in all HIV test sites on April 1, 2011.

Protocol Status:

The protocol received final approval for V1.0 from DAIDS on March 16, 2010. Subsequently, Version 2.0 of the protocol received final approval from DAIDS on July 20, 2010.

IRB Update:

The protocol (V1.0) was submitted to a central IRB (Copernicus) for review, and was granted unconditional approval on May 21, 2010. Version 2.0 of the protocol was approved by Copernicus on July 27, 2010. The final Provider Survey and all associated participant materials were approved as an amendment by Copernicus on September 23, 2010.

All sites have the option of using their own local IRB or the central IRB. Given this choice, approximately 50% of the sites are using the central IRB and 50% of the sites are using their own local IRBs. All test and care sites in the Bronx have obtained IRB approval. In DC, 95% of the HIV test sites and 95% of the HIV care sites have obtained IRB approval (Howard is the only site remaining).

Contract Update:

The team has generated and sent contracts to all participating institutions in Washington, D.C. and the Bronx. All HIV test and care sites in both the Bronx and DC have finalized a contract with FHI. FHI is now in the process of amending contracts for those test and care sites randomized to the financial incentive arms of the study.

Expansion of HIV testing:

- Social Mobilization: The first social mobilization ads began on November 19, 2010 in DC on social networking and dating websites and in print. The ads will continue in various venues throughout DC through May 31, 2010. The NY DOH has approved the Bronx ad. The study team and ad agency have finalized a distribution plan, and the first ads will be distributed in March 2011.
- Expanded Testing in Hospitals: February 1, 2011 marked the official start of the Expanded Testing component in Hospitals. A face-to-face meeting took place in DC for all participating hospitals on February 17, 2011 in order to discuss how each institution will expand testing in their in-patient and ED settings and facilitate implementation of this. Conference calls for all participating hospitals in the Bronx in order to discuss how each institution will expand testing in their inpatient and ED settings have now been completed. Monthly follow-ups with each hospital is now underway.

Linkage-to-Care (L2C) and Viral Suppression (VS):

- The viral suppression component officially started in 10 DC care sites on February 1, 2011. The first gift cards for viral suppression were distributed on February 9, 2011.

- The Linkage-to-care component is expected to start by April 1 for DC and Bronx test sites.

Prevention for Positives (PfP):

- The study team is working to update the CARE+ program.
- The team is in the process of selecting a subset of care sites to participate in the PfP component.

Patient and Provider Surveys:

- Both the patient and provider surveys have been finalized and the patient survey has been translated into Spanish.
- The provider survey was launched on September 29, 2010, with care sites that have both a contract and IRB approval for the survey in place. To date, the survey has been sent to ART-prescribing providers at 17 out of 19 care sites in Washington, D.C., and 20 out of 20 care sites in the Bronx.
- The current response rate is 51%.
- In order to increase the response rate, we have re-opened the survey link to sites that had low response rates in the beginning phase of implementation. Providers from these sites who had not completed the survey have been sent another invitation email.

Site and DOH Surveys:

- Test site, care site, and DOH surveys developed by the sub-group have been approved by the study chair and co-chair.
- SCHARP is nearing completion of the care site survey programming. A "first wave" of implementation of the care site survey will begin with 3 sites in NY and 3 sites in DC in March 2011.
- Programming of the test site and DOH surveys by SCHARP is still in progress. Test and DOH surveys will be implemented on a rolling basis once programming is completed.

Training Update:

- A study operational training was held on January 11, 2011 for the 5 Washington, D.C. care sites randomized to use financial incentives to promote viral suppression.
- Study operational trainings for the NY care sites were held on February 23 and 24, 2011, and are planned for March 8 and 15, 2011.
- Study operational trainings for the NY test sites randomized to the Financial Incentive arm are being planned for March 16 and 28, 2011.
- Study operational trainings for the remaining DC FI care sites and all SOC care sites are being planned for March 9, 10, and 14, 2011.
- Study operational trainings for the DC test sites randomized to the Financial Incentive arm are being planned for March 17 and 30, 2011.
- HIV test sites in both DC and the Bronx randomized to the SOC arm will receive a live web-based study training in April.

Reviews:

- The study team presented the overall study design to the Prevention Trials Data Safety and Monitoring Board (DSMB) on December 9, 2010. The DSMB provided written comments and questions to the team; the protocol chair and co-chair is working with the team on a response to the queries. Response to the comments from this DSMB review will be submitted to the committee on May 2, 2011.

- HPTN 065 was reviewed by the HPTN PMG on February 2, 2011. The review focused on the Monitoring Plan that is under development.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems:

On September 28, 2010, FHI was informed that MedStar Health Research Institute (MHRI), the body that governs research at Washington Hospital Center (WHC), has declined to participate in the study. After several attempts by the study chair, co-chair, and the NIH to negotiate with MHRI and WHC, WHC made a final decision not to participate after a call with NIH in mid-February. WHC has now officially been removed from the list of potential HPTN 065 study sites.

Report for HPTN Study Operations Group

HPTN 066 Dose-Proportionality and Intra-Individual Variability of Intracellular Tenofovir Diphosphate and Emtricitabine Triphosphate in Healthy Volunteers

Based on data available through: 4 March 11

Participating Study Sites:

- Johns Hopkins University, Baltimore MD; USA
- University of North Carolina at Chapel Hill, Chapel Hill NC; USA

Study Implementation Status:

Version 2.0 of the protocol was granted final approval on 29 November 2010 and was distributed to the sites 1 December 2010. Letter of Amendment (LoA) #1 to HPTN 066, Version 2.0 was approved by DAIDS on 16 December 2010.

UNC activated on 21 January 2011 and has enrolled 5 participants. JHU activated on 17 February 2011 and has enrolled 1 participant.

Accrual Status:

	UNC	JHU
Date First Screened	24-Jan-2011	21-Feb-2011
Date First Enrolled	7-Feb-2011	28-Feb-2011
# Individuals Screened	10	5
# Individuals Enrolled	5	1

Retention Status:

Refer to the SCHARP retention summary.

Implementation Issues and Problems:

Both sites are currently active and enrolling participants.

Report for HPTN Study Operations Group

HPTN 067

The ADAPT study:

A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)

Based on data available through March 3, 2011

Participating Study Sites:

- The Thailand Ministry of Public Health–United States (U.S.) Centers for Disease Control (CDC) collaboration (TUC) Silom Community Clinic in Bangkok, Thailand (31681)
- The Emavundleni Centre, The Desmond Tutu HIV Foundation in Cape Town, South Africa (30346)

Study Implementation Status:

Version 2.0 of the protocol dated February 18, 2011 was approved February 21st and distributed to the team that same day. This full amendment was needed to incorporate the recent iPrEx results into the template Informed Consent Forms as well as other minor corrections and modifications.

The CASI and Weekly Interview Guide have been drafted and are in the process of being finalized. Other implementation materials (including counseling materials, CASI, CRFs and the SSP) are currently being drafted. The Wisepill devices are expected to be ready for study use in April.

The Cape Town site submitted the protocol and Informed Consent Forms (ICFs) for both initial local IRB review and Medicines Control Council (MCC) review in November. The University of Cape Town Research Ethics Committee requested several minor changes to the local informed consents which were incorporated into version 2.0. These changes were reviewed by the committee 25 February 2011 and the team is awaiting a response. The MCC responded to the team in late February with minor questions and the site expects a speedy approval upon receipt of their answers. The site is currently working on meeting all data, lab, pharmacy and administrative site activation requirements. The core team is currently reviewing dates for a study specific training in May.

The Bangkok site has submitted for Thai MOPH review and began the CDC Scientific Review process which will be followed by CDC IRB review. The site is hoping to obtain approvals from both the Thai MOPH IRB and the CDC by the summer. The site is currently working on meeting all data, lab, pharmacy and administrative site activation requirements. The site has a PPD Site Initiation Visit scheduled for March 10-11, 2011 which is required for OCSO clinical site approval.

Accrual Status:

Pending, no sites have been activated.

Status of Intervention Delivery:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

The Clinical Trial Agreement is still pending with Gilead. The timeline for drug availability depends upon this agreement.

Report for HPTN Study Operations Group

HPTN 068

Effects of cash transfer for the prevention of HIV in young South African women

Based on data available through: 1 March 2011

Participating Study Sites:

MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt)

Study Implementation Status:

The study was activated and was open for enrollment 1 March 2011. The site plans to start enrollment slowly and then build to a pace of 150 young women per week.

Accrual Status (completed at all sites):

Not applicable.

Status of Intervention Delivery:

Not applicable; study has not been activated.

Retention Status:

Not applicable.

Implementation Issues and Problems:

None

Appendix: HPTN Protocols and INDs

Protocol #		IND	IND Sponsor	Study Status
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	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
HPTN 067	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	71,589	DAIDS	In Development