



HPTN Study Operations Report

July 2010

**PTN Executive Summary Report
14 July 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	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
	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	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	164	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	58	98%	6	9.7	closed
	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	1678	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gabarone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	87	104%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	173	103%	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
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1690	101%	34.7	48.7	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	35.7	0.2	completed

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	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	25.3	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	34.3	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	27.3	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	68	96%	43.2	1.6	completed
	Total		80	101	126%	43.2	2.3	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	35.7	0.2	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	25.3	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	34.3	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	27.3	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	68	96%	43.2	1.6	completed
Total		80	101	126%	43.2	2.3		
058	China – Guangxi – Heng County	24Dec2008	405	253	62%	18.9	13.4	51%
	China – Nanning	19May2010	350	31	9%	1.9	16.3	9%
	China – Xinjiang	23Dec2008	495	270	55%	18.9	14.3	51%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	756	50%	38	19.9	
061	US – Atlanta	26Feb2010	201	57	28%	4.6	12.4	45%
	US – Boston	17Jul2009	403	158	39%	12.1	13.1	68%
	US – Decatur	16Sep2009	202	138	68%	10	13.8	64%
	US – Los Angeles	30Sep2009	403	198	49%	9.6	20.6	63%
	US – NY – Harlem Prevention Center	08Jan2010	201	152	76%	6.2	24.5	52%
	US – NY – New York Blood Center	01Oct2009	202	142	70%	9.5	14.9	63%
	US – San Francisco	13Aug2009	403	166	41%	11.2	14.8	66%
	US – Washington DC	28Jul2009	403	172	43%	11.7	14.7	67%
Total		2418	1183	49%	12.1	97.8		
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	6	13%	2.6	2.3	
	Total		46	6	13%	2.6	2.3	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	61	20%	3.5	17.4	28%
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	61	8%	3.5	17.4	

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Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
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	188	94%	10.7	17.6	174%
	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	2084	104%	13.8	151
064 (Men)	US – Decatur	10Mar2010	30	27	90%	4.2	6.4	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	17	57%	2.5	6.8	
	US – Washington DC	02Apr2010	30	40	133%	3.4	11.8	
	Total			120	138	115%	9.6	14.4

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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	2001	1759	1912	88%	96%
	Tanzania – Dar Es Salaam	218	952	859	920	90%	97%
	Uganda – Mulago Hospital	545	2619	2481	2505	95%	96%
	Zimbabwe – Harare/Chitungwiza	507	2503	2315	2389	92%	95%
	Total	1678	8075	7414	7727	92%	96%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	3980	3712	3816	93%	96%
	Tanzania – Dar Es Salaam	219	2031	1855	1957	91%	96%
	Uganda – Mulago Hospital	562	5394	5245	5174	97%	96%
	Zimbabwe – Harare/Chitungwiza	510	4973	4683	4765	94%	96%
	Total	1700	16378	15495	15712	95%	96%
052 Combined (Indexes)	Botswana – Gaborone	77	332	322	330	97%	99%
	Brazil – Porto Alegre	90	730	718	717	98%	98%
	Brazil – Rio de Janeiro	184	1733	1698	1696	98%	98%
	India – Chennai – YRGCare	250	2237	2058	2193	92%	98%
	India – Pune	174	1561	1547	1528	99%	98%
	Kenya – Kisumu	58	184	179	183	97%	100%
	Malawi – Blantyre – Queen Elizabeth Central	230	1590	1509	1565	95%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	1878	1762	1845	94%	98%
	South Africa – Johannesburg – Witwatersrand	46	284	275	281	97%	99%
	South Africa – Soweto	50	173	161	172	93%	100%
	Thailand – Chiang Mai	106	960	949	938	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1685	1604	1657	95%	98%
	Total	1756	13347	12782	13105	96%	98%
052 Combined (Partners)	Botswana – Gaborone	77	332	307	330	92%	99%
	Brazil – Porto Alegre	92	730	691	717	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	186	1733	1470	1696	85%	98%
	India – Chennai – YRGCare	250	2237	1917	2193	86%	98%
	India – Pune	175	1563	1512	1530	97%	98%
	Kenya – Kisumu	60	190	180	189	95%	100%
	Malawi – Blantyre – Queen Elizabeth Central	231	1590	1343	1565	84%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	1878	1599	1845	85%	98%
	South Africa – Johannesburg – Witwatersrand	46	284	262	281	92%	99%
	South Africa – Soweto	50	173	158	172	91%	100%
	Thailand – Chiang Mai	107	960	876	938	91%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1685	1449	1657	86%	98%
	Total	1769	13355	11764	13113	88%	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	76	75	97%	97%
	Brazil – Rio de Janeiro	7	42	42	41	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	68	360	338	349	94%	97%
	Total	101	558	534	540	96%	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	68	416	390	400	94%	96%
	Total	101	647	619	622	96%	96%
058	China – Guangxi – Heng County	253	261	211	242	81%	93%
	China – Nanning	31	0	0	0	–	–
	China – Xinjiang	270	327	249	302	76%	92%
	Thailand – Chiang Mai University	202	554	492	492	89%	89%
	Total	756	1142	952	1037	83%	91%
061	US – Atlanta	57	0	0	0	–	–
	US – Boston	158	71	37	67	52%	94%
	US – Decatur	138	27	12	26	44%	94%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
064 (Women)	US – Los Angeles	198	58	37	55	64%	94%
	US – NY – Harlem Prevention Center	152	0	0	0	–	–
	US – NY – New York Blood Center	142	27	24	26	89%	94%
	US – San Francisco	166	75	62	71	83%	94%
	US – Washington DC	172	47	38	44	81%	94%
	Total	1183	305	210	288	69%	94%
	US – Atlanta	215	26	25	25	96%	94%
	US – Baltimore	210	74	69	70	93%	94%
	US – Chapel Hill	210	211	185	199	88%	94%
	US – Decatur	188	31	30	29	97%	94%
	US – NY – Bronx–Lebanon Hospital Center	210	209	202	197	97%	94%
	US – NY – Harlem Prevention Center	210	34	27	32	79%	94%
	US – Newark	420	258	246	243	95%	94%
US – Raleigh	210	168	138	159	82%	94%	
US – Washington DC	211	203	189	192	93%	94%	
Total	2084	1214	1111	1145	92%	94%	

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

July 2010

I. HPTN 027

A. General Comments

1. Protocol Version - 2.0 dated 20th May 2005
2. SSP version –
3. Enrollment Status – Closed.
4. Date of last SMC call –29th September 2008
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report:
6. None
7. Lab related notes to file/deviations issued since preparation of SMC report:
None
8. Miscellaneous
 - a. Specimens for polio, tetanus and HIB have been sent for testing.
 - b. The contract for the Hepatitis B Surface Antibody assays is being finalized.

B. Site Specific

Kampala--No new updates

C. Shipping / QA Status

All requested samples have been shipped

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. 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. Dar es Salaam – NTF issued May 19th describing the delay in the testing of one sample for DNA PCR – resolved.
 - b. Dar es Salaam – Protocol Deviation form issued 26th May 2010 describing that a cell pellet storage was not requested by the clinic. Previously reported June study ops
 - c. Dar es Salaam – Protocol Deviation form issued 26/May/2010 describing that plasma and DBS storage were not requested by the clinic. Previously report - June study ops
7. Miscellaneous

B. Site Specific including LDMS reports / inventory reports/QC review

1. Harare - NL and site have been having calls regarding the movement of samples and have met at the Annual Meeting to discuss the way forward. Site is formalized the specimen movement plan and working on the CD4 backup plan. Hematology SOP for the new analyser has been sent and comments have been provided back to the site. 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. 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.
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. Maternal QA shipments from all sites have been received at the Network Lab and have been tested.
2. Infant QA samples have been received by the HPTN Network Lab. Testing is pending on the Uganda samples as well as the DBS.
3. A further shipment of infant samples from the Dar site, as requested by the SMC, is 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 – 13 Apr 09
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: Notification to the FACScout users that they should not be utilizing the BD conversion formula supplied by BD.
6. Lab related notes to file/deviations issued since preparation of SMC report
 - a. IPEC resumed urinalysis testing previously reported June study ops.
 - b. UZ-UCSF moved samples to off-site freezer location without notifying the network lab previously reported June study ops.
 - c. UZ-UCSF ran out of the validated FBS and provided a list of PTIDs/VID that were processed with Hyclone FBS. Previously reported June study ops.
 - d. NARI Pune discovered a sample switch at storage between index and partner when reviewing the low viral load lists provided by SCHARP. Previously reported June study ops. HGNI and IPEC reported a delay in testing VLs due to shortage of Roche PCR kits in Brazil. Samples being sent to JHU for testing. This is continuing to occur.
 - e. Lilongwe – CTNG not ordered on a participant as scheduled. Previously reported June study ops.
 - f. Lilongwe – Cervical sample lost in the lab. NEW
7. Miscellaneous - The NL is continuing to work on QAing the viral loads from enrollment samples (<1000 copies/mL) as well as the ARV testing.

B. Site Specific including LDMS reports / inventory reports/QC review

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. Site is finalizing the validation of the back-up instruments. June: Had no LDMS reconciliations to perform, have not submitted their QC for review, but have submitted their inventory.
2. Harare – The site is working on the action plan from the NL November visit. NL and site have been having calls regarding the movement of samples and have met at the Annual Meeting to discuss the way forward. Site is formalized the specimen movement plan and working on the CD4 backup plan. Hematology SOP for the new analyser has been sent and comments have been provided back to the site. June: Have submitted their LDMS

reconciliations past the due date, submitted their QC for review, and submitted their inventory.

3. Chennai – The site is in the process of moving part of the laboratory. NL has reviewed the hematology and flow validations. The chemistry instrument has not been moved. The new back up chemistry instrument is being validated. June - did not submit their LDMS reconciliations or their QC for review, but submitted their inventory
4. Blantyre – The NL is working with the site on some processing issues. June - Have not submitted their LDMS reconciliations, or their QC for review, but submitted their inventory.
5. Porto Alegre – The site has had a delay in receiving HIV EIA FDA approved kits. The site plans on validating the OraQuick FDA cleared rapid test. Site has about one month's worth of VL testing available and will ship to JHU while they await the receipt of new kits. June - Have submitted their LDMS reconciliations, submitted their QC for review, and submitted their inventory
6. Rio sites – The site has been having some difficulty importing the Roche kit for Viral Load. This issue is being raised with Roche international and is being discussed on the cross network Lab Focus Group. Site is currently sending VL to JHU for testing. June - Have not submitted their LDMS reconciliations submitted their QC for review, and did submit their inventory.
7. Lilongwe - The site is planning on moving their PCR area to a new location and will move the PBMC processing area into the PCR area. No move plans have been submitted. June - Have submitted their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai – June - Had no LDMS reconciliations, submitted their QC for review, and submitted their inventory.
9. Johannesburg – WITs –June - Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory.
10. Soweto – June- Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and Soweto have not submitted their inventory.
11. Botswana –The lab is using the back-up laboratory for chemistry. ACTG reported that the site went to their hematology back up instrument. Site did not submit any NTF. Confirmation from site pending. June- Have submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory.
12. Kenya – June - Have submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

1. Shipments pending from Soweto and Kisumu for QA testing
2. New lists have gone out for genotyping and QA.

IV. HPTN 057

A. General Information

1. Protocol Version - 2.0 dated 28th October 2009
2. SSP version – 4.0 lab section dated 11th March 2010
3. Enrollment Status – open
4. Date of last SMC call – 21st February 2008.

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
- B. Site Specific including LDMS reports / inventory reports/QC review**
1. Blantyre - No outstanding issues. Site has started to enroll into Cohort 4. 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 have had no LDMS reconciliations to review, have not submitted their QC for review, and have not submitted their inventory. There is currently no testing being performed at this site.
 3. Central lab corrective action plan has many outstanding items. Site have had no LDMS reconciliations to review, have not submitted their QC for review, and have not submitted their inventory. There is currently no testing being performed at this site.
 4. HSE Rio.- No outstanding issues. Site had no LDMS reconciliations to review. No testing is done on site for this protocol.
 5. HNSC. Porto Alegre - No outstanding issues. Site have had no LDMS reconciliations to review, have not submitted their QC for review, and have not submitted their inventory. There is currently no testing being performed at this site.
- C. Shipping / QA Status**
- No outstanding shipments or requests

V. HPTN 058

A. General Information

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 – 26th January 2010
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
7. Guangxi – Protocol Deviation form issued 18th March 2010 describing that 9 female participants did not have a pregnancy test prior to signing the enrollment consent form. Staff have been retrained.
8. Miscellaneous

B. Site Specific including LDMS reports / inventory reports/QC review

1. Thailand - Screening specimens for QA have been tested. Site is completing the LDMS reconciliations in a timely, submitted their QC for review, and submitted their inventory.
2. Xinjiang Site - No new updates. Site is completing the LDMS reconciliations in a timely manner. Submitted their QC for review, and have not submitted their inventory.
3. Guangxi. - No new updates. Site is completing the LDMS reconciliations in a timely manner. Submitted their QC for review, and have not submitted their inventory.
4. An additional site in Vietnam is still being considered. Network Lab has received permission from DAIDS to travel to the site in Vietnam. Awaiting further information from FHI about this trip.

C. Shipping / QA Status

No outstanding shipments or requests. QA samples from China have not been requested at this time.

VI. HPTN 061

A. General Information

1. Protocol Version – Version 2.0, April 2nd 2009
2. SSP Version – Section 11 Version 3.0, April 7th 2010
3. Enrollment status – All sites are still enrolling. Sites were given the option of extending their recruitment beyond their 1 year anniversary date with the caveat that all recruitment must be done by September 25th 2010.
4. Date of last SMC call – April 12th 2010
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report: None
 - a. Lab-related notes to file/deviations issued since preparation of SMC report. GWU– Note to file was received for rectal swab that was mistakenly collected at the 26 week, visit 2.0 (rectal swabs are collected at enrollment and week 52.
 - b. Atlanta - Note to file received for rectal swab that was left out at room temperature over the weekend. Previously reported June study ops.

B. Site Specific including LDMS reports

1. Fenway: Storing of aliquot samples that were collected but never stored in LDMS was completed on 6/25/2010.
2. George Washington University: New CLIA certificate still pending.
3. San Francisco: The problems that the site was experiencing with LDMS from 6/4/2010 were finally resolved with FSTRF on 6/18/2010.
Note: San Francisco informed NL on June 4th 2010, site experiencing problems with LDMS. FSTRF currently working with site to resolve issues. Previously reported June study ops
4. Harlem - No new updates
5. Atlanta - NL site assessment visit was done on June 24th and 25th 2010 and action items have been completed
6. New York Blood Center - No new updates
7. UCLA- No new updates.

C. Shipping / QA Status

VII. HPTN 064

A. General Information

1. Protocol Version: Version 1.0 dated 20 February 2010
2. SSP version: Version 2.0 dated 12 May 2010
3. Enrollment Status: The Emory site is currently enrolling.
4. Date of last SMC call : February 22, 2010
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: Version 2.0 dated 12 May 2010
 - a. Lab-related notes to file/deviations issued since preparation of SMC report: Newark: Site informed the NL of an "imposter". Note to file is pending. Previously reported June study ops.
 - b. UNC - Site wasn't able to obtain the plasma for storage on two participants. Notes to file are pending.

B. Site Specific including LDMS reports

1. Bronx - No new updates.
2. Harlem - No new updates.

3. Newark - No new updates.
4. Johns Hopkins University - No new updates.
5. George Washington University - New CLIA certificate is pending.
6. University of North Carolina - No new updates.
6. Emory - SCHARP informed the site and the NL that one participant's sample is entered LDMS but not stored. The site is investigating the discrepancy.

C. Shipping / QA Status

No outstanding shipments or requests.

NL updates

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

Travel Updates

Estelle will be visiting the 043 sites in July/August (Soweto, Vulindlela-Barc, Harare and Dar es Salaam) as well as 046 site (Dar es Salaam) and 052 site (Kisumu)

Implementations Issues and Problems Summary July 2010

052

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

058

The number of participants incarcerated long-term will adversely affect retention.

061

Retention is right now the greatest concern in study implementation.

All sites are conducting six month visits and some sites are approaching 12 month (final) visits. Retention is not strong, with a study-wide average of 67% for the 6 month visit. Calls or visits have been conducted with the sites with the lowest retention (UCLA, Boston, Emory) to identify ways to improve retention and sites are working to improve their numbers.

062

Enrollment in CHAVI 001 is sporadic; hence, enrollment in 062 is likewise sporadic and will likely be unable to meet the 46 targeted participants before CHAVI 001 ends.

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 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, this approval must be in place in order to receive state department clearance.

The Zambia site received a non-approval letter from their MOH in February 2010. Zambian MOH approvals for all new studies were put on hold during this time pending review of their local regulations and guidelines regarding clinical research. On 01 June 2010, the MOH approved the study with the caveat that the final study report be cleared by the MOH before any publications or dissemination. The Zambia team has always taken this clause to mean that all study results should be provided to the MOH before dissemination although approval has never been sought to do so.

HPTN Leadership sent a letter on June 16, 2010 to the MOH to acknowledge receipt of the Zambia approval letter. In this letter, Dr. Vermund assured the MOH that any study results would be reviewed by the MOH before submission to any conferences or publications. The HPTN CORE received a letter of receipt from the MOH on June 22, 2010.

After the HPTN annual meeting, the HPTN 063 protocol team decided that enrollment would be put on hold until the ACASI issues were resolved. Sites were notified of the pause in enrollment on June 22, 2010. Sites were encouraged to maintain contact with already enrolled participants and to continue recruiting for the qualitative components. On July 5,

2010, all follow-up visits were also put on hold to ensure that there was consistency in the ACASI survey for all future enrollment and follow-up visits.

The protocol team is actively working on rewording the questions of the ACASI to make them more understandable to participants. The team is also looking into modifying the computer interface so that is easier to use. The protocol team is working very closely with SCHARP to help identify potential new products to use (e.g. PC tablets). SCHARP provided the protocol team with a sample survey with all possible options for changes in programming (e.g. drop down menu, virtual keyboard, multiple choice). Suggested revisions to the ACASI questions will be sent to the sites for feedback within the next week.

The protocol team also decided that the new ACASI will be piloted with a more representative sample of participants to ensure clarity of the questions and understanding of the content before it is finalized. To ensure that the content is culturally appropriate, the protocol team has asked each site to translate the ACASI once all revisions to the English version are final.

064

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met. Weekly reports are collected from each site to monitor retention.

065

On July 6, 2010, the protocol team decided that only sites that obtain IRB approval will be randomized.

On June 23, FHI learned that learned that Springbok Services, the company we were trying to contract with for the Financial Incentives gift cards, filed a Chapter 11 bankruptcy petition. Springbok was a large, experienced business in this field and was vetted successfully by FHI's contracts and purchasing department; the bankruptcy petition was completely unexpected. FHI had not finalized the contract with so no money was lost. FHI is now working with our purchasing department to identify alternate vendors.

066

LoA #1 has been drafted to address 2 issues:

- 1) Minor miscommunication within the protocol team on how the study days were being counted. Enrollment is now on Day 0 as opposed to Day 1. Also, the weekly PK visits are now at the start of the following week as opposed to the end of the current week. This creates a 1-day shift in the PK visits.
- 2) Notice was received from the FDA on 06 July 2010, informing the team that HPTN 066 is IND-exempt. As such, all language pertaining to the IND, 1572, and FDA oversight has now been removed from the protocol and the sample informed consent.

LoA #1 will be submitted to DAIDS for review and approval on Monday, 12 July 2010. The time required for this review and approval and the time required for IRB review and approval of the LoA may result in a slight delay in the activation timeline. It is not expected that it will be a significant delay.

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: 9 July 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. All infants have been randomized. The last infant will complete 6 month follow-up and complete study product dosing in July.

The DSMB met on 15 June and determined that HPTN 046 should continue without change or intervention.

Accrual Status:

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

Status of Intervention Delivery:

As of this report 14 infants are still receiving the blinded study product.

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: 13 July 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. As of April 8, 2010, the study met its enrollment target of 1750 couples. SCHARP announced that the last enrollment took place on May 3, 2010. The total final enrollment was confirmed by SCHARP at 1763 couples.

Retention Status:

Refer to the SCHARP "Couples Status" retention summary available on Atlas.

Implementation Issues and Problems:

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: 8 July 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, Porto Alegre (Santa Casa)
- Hospital dos Servidores do Estado - Servico de Doencas Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Servico de Infectologia, Porto 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.

The protocol was amended to add a fourth cohort looking at a maternal dose during labor and daily infant dosing for 1 week. The target number of mother/infant pairs for enrollment into Cohort 4 is 30. It is anticipated that approximately half of the pairs will be enrolled in Blantyre and the other half will be enrolled across the four Brazil sites.

The Blantyre Site opened for accrual to Cohort 4 on 4 April 2010.

Hospital do Servidores opened for accrual on 30 June 2010. The remaining Brazil sites are expected to open for accrual in July 2010.

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			
	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Queen Elizabeth Central Hospital, Blantyre Malawi	24	16	15	11
Santa Casa, Porto Alegre Brazil	3	4	4	
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	
Conceicao, Porto Alegre Brazil	-	-	4	
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	
Total	30	21	30	11

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:

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 11 July 2010

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. Xinjiang has enrolled 271 participants. Heng County has enrolled 253 participants. Nanning has enrolled 29 participants. The clinic in Urumqi remains relocated to their proposed satellite site due to orders from the Chinese authorities. Anticipated completion date of the renovations to the main clinic is July 2010. DAIDS issued an approval for this temporary relocation. The ban on international communications in Xinjiang has been lifted.

Adding a site in Vietnam still remains a possibility and discussions are ongoing. A site visit is planned by study team members in mid July. There is a possibility that NIH will also travel in August to meet with the Vietnamese MOH.

The Chinese team members continue to work on recruiting among a higher risk cohort and improving retention. This focus has temporarily resulted in slower enrollment. To improve retention, the group is researching the feasibility of completing follow-up visits among participants who are incarcerated. This will require a protocol change and OHRP approval of the plan.

Discussions are under way to formulate a plan to allow Suboxone compassionate use for participants who have completed 058 follow-up.

Study drug has arrived in Beijing. After clearing through Customs, the study drug will be shipped to sites.

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		24-Dec-08	21-Dec-08
# Individuals Screened	281	57	548	510
# Individuals Enrolled	202	29	253	271

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	87%
Week 52	77%
Week 78	86%
Week 104	80%
Week 130	81%

Implementation Issues and Problems:

The number of participants incarcerated long-term will adversely affect retention.

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: 06 July 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	Date of Completion of Community Recruitment
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	26 February 2010	
Harlem Prevention Center	05 January 2010	08 January 2010	17 June 2010

Accrual Status (participants enrolled at each site) as of 07 July 2010:

Fenway	GWU	Emory :Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
160	170	202	166	191	134	151	1,174

Status of Intervention Delivery:

Sites continue to provide HIV and STI testing as well as Peer Health Navigation to enrolled participants. All sites except Harlem CRS continue to enroll new community recruited participants. Harlem completed their 125 participant target for community referred participants on 17 June and will continue to enroll index referred participants until 17 July. Individual interviews have begun (or will begin very soon) at all sites.

Recruitment Status:

Recruitment lags significantly behind target for the Boston, UCLA, GWU and San Francisco sites. Sites have been challenged to either complete enrollment by the target date or consider extending their enrollment period until September 29, 2010. At this time Boston is the only site that has confirmed that they will extend their enrollment period.

Retention Status:

All sites are conducting six month visits and some sites are approaching 12 month (final) visits. Retention is not strong, with a study-wide average of 67% for the 6 month visit. Calls or visits have been conducted with the sites with the lowest retention (UCLA, Boston, Emory) to identify ways to improve retention and sites are working to improve their numbers. The next Study Team Call (22 July) will be devoted to discussion of retention.

Implementation Issues and Problems:

Retention is right now the greatest concern in study implementation.

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: 8 July 2010

Participating Study Sites:

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

Study Implementation Status:

Version 2.0 of the protocol, dated 10 September 2009, was approved by DAIDS and distributed to the sites on 16 September 2009. All IRB approvals have been received.

Lilongwe site was activated on 24 February 2010 and began enrolling in April. A new amendment (proposed version 3) has gone through multiple revisions; it is hoped to be ready for Regulatory Review this month.

Accrual Status (completed at all sites):

Six participants have been enrolled to date.

Status of Intervention Delivery:

The visits are lengthy but all visits have been completed as scheduled, according to the staff reports.

Retention Status:

N/A

Implementation Issues and Problems:

Enrollment in CHAVI 001 is sporadic; hence, enrollment in 062 is likewise sporadic and will likely be unable to meet the 46 targeted participants before CHAVI 001 ends.

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: 02 July, 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 approved on 15 September 2008 and distributed to sites on the same day.

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

The Brazil site has received local and central IRB (CONEP) approvals and is currently awaiting state department clearance which has been significantly delayed due to delays in Ministry of Health (MOH) sign-off. The site has completed most of their site activation requirements but a number of items are still pending.

A site specific Letter of Amendment (LoA) was drafted and approved to remove specimen exportation from the protocol for the Zambia site only (in response to local regulations banning exportation of participant specimens). The Zambia site received UAB IRB approval for the site-specific LoA #1 on 24 May 2010. The site received approval of a **draft** of LoA #1 from the local IRB on 4 May 2010, and they are awaiting approval for the official LoA. Approval from the local Ministry of Health (MOH) was received on 01 June 2010. HPTN leadership sent a letter to the Zambia MOH to clarify some of the language in the approval letter (see details below in the **Implementation Issues and Problems** section). The site received a confirmation of receipt for this letter.

Enrollment was paused on June 22m 2010 due to ACASI issues discussed during the 201 HPTN Annual Meeting (see details below in the **Implementation Issues and Problems** section).

Site activation activities are continuing at the Brazil and Zambia sites. 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 - **Completed**).

Accrual Status:

Below is site-reported screening and enrollment data ending 02 July 2010; refer also to the SCHARP enrollment summary.

HPTN-063 Cumulative Screening and Enrollment Report							
Based on Site-Reported Information							
July 2, 2010							
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							
Women			313	0	0	1	33
Heterosexual Men			229	0	0	1	16
MSM			55	0	0	1	12
Zambia: Lusaka (Metero Clinic CRS)							
Women							
Heterosexual Men							
TOTAL	NA	NA	597	0	0	3	61
Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Thailand (Focus Groups)	Date of Focus Group	No. of participants
Date of Interview	17-May-10			17-May-10	Session 1	17-Jun-10	8
				19-May-10	Session 2		
					Session 3		
					Session 4		
					TOTAL	1	8
TOTAL	1	0	0	0			

Retention Status:

Refer to the SCHARP retention summary.

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 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, this approval must be in place in order to receive state department clearance.

The Zambia site received a non-approval letter from their MOH in February 2010. Zambian MOH approvals for all new studies were put on hold during this time pending review of their local regulations and guidelines regarding clinical research. On 01 June 2010, the MOH approved the study with the caveat that the final study report be cleared by the MOH before any publications or dissemination. The Zambia team has always taken this clause to mean that all study results should be provided to the MOH before dissemination although approval has never been sought to do so.

HPTN Leadership sent a letter on June 16, 2010 to the MOH to acknowledge receipt of the Zambia approval letter. In this letter, Dr. Vermund assured the MOH that any study results would be reviewed by the MOH before submission to any conferences or publications. The HPTN CORE received a letter of receipt from the MOH on June 22, 2010.

After the HPTN annual meeting, the HPTN 063 protocol team decided that enrollment would be put on hold until the ACASI issues were resolved. Sites were notified of the pause in enrollment on June 22, 2010. Sites were encouraged to maintain contact with already enrolled participants and to continue recruiting for the qualitative components. On July 5, 2010, all follow-up visits were also put on hold to ensure that there was consistency in the ACASI survey for all future enrollment and follow-up visits.

The protocol team is actively working on rewording the questions of the ACASI to make them more understandable to participants. The team is also looking into modifying the computer interface so that is easier to use. The protocol team is working very closely with SCHARP to help identify potential new products to use (e.g. PC tablets). SCHARP provided the protocol team with a sample survey with all possible options for changes in programming (e.g. drop down menu, virtual keyboard, multiple choice). Suggested revisions to the ACASI questions will be sent to the sites for feedback within the next week.

The protocol team also decided that the new ACASI will be piloted with a more representative sample of participants to ensure clarity of the questions and understanding of the content before it is finalized. To ensure that the content is culturally appropriate, the protocol team has asked each site to translate the ACASI once all revisions to the English version are final.

Report for HPTN Study Operations Group
HPTN 064
Women's Seroprevalence Study (ISIS)
Based on data available through: 07 July 2010

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.

Since the last update, HPTN 064 now has nine communities that have completed enrollment. The other site has passed their half-way points for recruitment.

All qualitative sites have successfully completed all qualitative interviews and are actively recruiting and conducting focus groups.

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 and retention are both being monitored very closely at all sites to ensure study targets are met. Weekly reports are collected from each site to monitor retention.

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: 9 July 2010

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 is working to identify a total of 80 sites (40 test sites and 40 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study. The team intends to include 20 test sites and 20 care sites in each intervention location.

Bronx:

The protocol team has finalized a list of 19 test sites and 20 care sites to participate in the study. FHI is moving forward with site contracts and IRB submissions for these sites. At this time, a 20th test site has not been identified that fits the protocol criteria, despite the fact that 28 sites have been approached. The team is discussing the implications of randomizing only 19 test sites.

Washington, DC.

We have received Letters of Intent (LoIs) for 17 test sites and 15 care sites and are in the process of collecting LoIs for the remainder. Once all LoIs are collected, the team will make the final decision with regard to participating sites and move forward with site contracts and IRB submissions.

Study Implementation Status:

Protocol Update:

The protocol received final approval for V1.0 on March 16, 2010. The protocol chair and co-chair have decided to move forward with a protocol amendment (to V2.0) to make minor modifications to the protocol and template ICF for the PfP (Prevention for Positives) subcomponent of the study. The study team submitted a full protocol amendment to DAIDS on June 24, 2010, and requested a waiver of the requirement for full PSRC review, given the non-substantive nature of the modifications. On July 1, 2010 the team was notified by David Burns that this request was granted. The full protocol amendment was submitted for RSC review on July 2, 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, after some minor revisions were made to the template ICF for the PfP (prevention for positives) subcomponent of the study. Once V2.0 of the protocol has been approved by DAIDS, the study team will move forward with submitting the amendment to the central IRB. The team is working to collect and submit required documents for those sites that will be using the central IRB. Sites not using the central IRB will be responsible for submitting version 2.0 of the protocol to their local IRBs.

Expansion of HIV testing:

- Ads that are in line with the current Ask for the Test (DC) campaign have been developed by a creative agency in DC, and ads in line with the Bronx Knows (Bronx) testing campaign are in the process of being developed by a creative agency in the Bronx and are nearing completion.
- Hospitals in DC and the Bronx have been approached to participate in the study. Conference calls continue to work out the details of their participation.

Linkage-to-Care (L2C) and Viral Load Suppression (VLS):

- The team is moving forward with site contracts and IRB submissions for the 19 test sites and 20 care sites in the Bronx. Once the DC site list has been finalized, the same will be done for these sites. The team has decided that sites must first obtain IRB approval before randomization will take place.

Prevention for Positives (PfP):

- The study team is working to update the CARE+ program.

Patient and Provider Surveys:

- The provider and patient surveys are undergoing final development.

Site and DOH Surveys:

- A subgroup was formed to develop a new survey tool that will collect information on current practices/programs/initiatives related to testing, linkage to care, and ART adherence both at the clinic level (targeting HIV test and care sites in DC and the Bronx) and at the city-level (targeting the DOHs in the intervention and comparator cities). The survey is under development.

Training Update:

- On June 16, 2010, the HIV Prevention, Diagnosis, and Treatment Best Practices Symposium was held in the Bronx. This symposium, sponsored by the Albert Einstein College of Medicine, in joint sponsorship with Jacobi Medical Center, reviewed the current guidelines for ART treatment. This event served as an HIV-provider training for HPTN 065. A webcast of the symposium will be posted on hptn.org soon.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems:

On July 6, 2010, the protocol team decided that only sites that obtain IRB approval will be randomized.

On June 23, FHI learned that learned that Springbok Services, the company we were trying to contract with for the Financial Incentives gift cards, filed a Chapter 11 bankruptcy petition. Springbok was a large, experienced business in this field and was vetted successfully by FHI's contracts and purchasing department; the bankruptcy petition was completely unexpected. FHI had not finalized the contract with so no money was lost. FHI is now working with our purchasing department to identify alternate vendors.

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: 09 July 10

Participating Study Sites:

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

Study Implementation Status:

Version 1.0 of the protocol was granted final approval on 7 June 2010 and distributed to the sites on the same day. Letter of Amendment (LoA) #1 to Version 1.0 of the protocol is being drafted and will be submitted for DAIDS review and approval shortly. (Details are below under **Implementation Issues and Problems.**)

Accrual Status:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

LoA #1 has been drafted to address 2 issues:

- 1) Minor miscommunication within the protocol team on how the study days were being counted. Enrollment is now on Day 0 as opposed to Day 1. Also, the weekly PK visits are now at the start of the following week as opposed to the end of the current week. This creates a 1-day shift in the PK visits.
- 2) Notice was received from the FDA on 06 July 2010, informing the team that HPTN 066 is IND-exempt. As such, all language pertaining to the IND, 1572, and FDA oversight has now been removed from the protocol and the sample informed consent.

LoA #1 will be submitted to DAIDS for review and approval on Monday, 12 July 2010. The time required for this review and approval and the time required for IRB review and approval of the LoA may result in a slight delay in the activation timeline. It is not expected that it will be a significant delay.

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	Closed to Accrual
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	Open 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