



HPTN Study Operations Report

August 2010

PTN Executive Summary Report
11 August 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

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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	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 – Gaborone	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

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	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%	36.6	0.2	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	6	75%	26.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	35.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	10	125%	28.2	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	72	101%	44.1	1.6	completed
	Total		80	109	136%	44.1	2.5	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	36.6	0.2	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	6	75%	26.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	35.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	10	125%	28.2	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	72	101%	44.1	1.6	completed
	Total		80	109	136%	44.1	2.5	
058	China – Guangxi – Heng County	24Dec2008	405	261	64%	19.8	13.2	54%
	China – Nanning	19May2010	350	35	10%	2.8	12.5	14%
	China – Xinjiang	23Dec2008	495	283	57%	19.9	14.2	54%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	781	52%	39	20	
061	US – Atlanta	26Feb2010	201	85	42%	5.5	15.5	54%
	US – Boston	17Jul2009	403	183	45%	13	14.1	73%
	US – Decatur	16Sep2009	202	154	76%	11	14	70%
	US – Los Angeles	30Sep2009	403	219	54%	10.5	20.9	69%
	US – NY – Harlem Prevention Center	08Jan2010	201	154	77%	7.2	21.4	60%
	US – NY – New York Blood Center	01Oct2009	202	156	77%	10.5	14.9	69%
	US – San Francisco	13Aug2009	403	183	45%	12.1	15.1	72%
	US – Washington DC	28Jul2009	403	184	46%	12.6	14.6	73%
	Total		2418	1318	55%	13	101.4	
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	7	15%	3.6	1.9	

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	Total		46	7	15%	3.6	1.9	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	61	20%	4.4	13.9	36%
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	61	8%	4.4	13.9	
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	209	105%	11.1	18.8	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	2105	105%	14.2	148.2
064 (Men)	US – Decatur	10Mar2010	30	43	143%	5.1	8.4	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	36	120%	3.5	10.3	
	US – Washington DC	02Apr2010	30	40	133%	4.4	9.1	
	Total			120	173	144%	10.5	16.5

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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	2049	1800	1954	88%	95%
	Tanzania – Dar Es Salaam	218	1002	902	964	90%	96%
	Uganda – Mulago Hospital	545	2699	2558	2577	95%	95%
	Zimbabwe – Harare/Chitungwiza	507	2561	2371	2441	93%	95%
	Total	1678	8311	7631	7937	92%	95%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4047	3775	3875	93%	96%
	Tanzania – Dar Es Salaam	219	2100	1922	2019	92%	96%
	Uganda – Mulago Hospital	562	5501	5350	5271	97%	96%
	Zimbabwe – Harare/Chitungwiza	510	5057	4774	4841	94%	96%
	Total	1700	16705	15821	16006	95%	96%
052 Combined (Indexes)	Botswana – Gaborone	77	355	348	352	98%	99%
	Brazil – Porto Alegre	90	757	743	743	98%	98%
	Brazil – Rio de Janeiro	184	1793	1760	1754	98%	98%
	India – Chennai – YRGCare	250	2314	2122	2267	92%	98%
	India – Pune	174	1606	1593	1571	99%	98%
	Kenya – Kisumu	58	198	191	197	96%	100%
	Malawi – Blantyre – Queen Elizabeth Central	230	1654	1569	1627	95%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	1952	1834	1917	94%	98%
	South Africa – Johannesburg – Witwatersrand	46	302	293	298	97%	99%
	South Africa – Soweto	50	185	174	184	94%	99%
	Thailand – Chiang Mai	106	991	979	968	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1752	1669	1722	95%	98%
	Total	1756	13859	13275	13601	96%	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	355	332	352	94%	99%
	Brazil – Porto Alegre	92	757	719	743	95%	98%
	Brazil – Rio de Janeiro	186	1793	1517	1754	85%	98%
	India – Chennai – YRGCare	250	2314	1972	2267	85%	98%
	India – Pune	175	1609	1560	1574	97%	98%
	Kenya – Kisumu	60	204	192	203	94%	100%
	Malawi – Blantyre – Queen Elizabeth Central	231	1654	1395	1627	84%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	1952	1666	1917	85%	98%
	South Africa – Johannesburg – Witwatersrand	46	302	279	298	92%	99%
	South Africa – Soweto	50	185	170	184	92%	99%
	Thailand – Chiang Mai	107	991	903	968	91%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1752	1503	1722	86%	98%
	Total		1769	13868	12208	13610	88%
057 (Mothers)	Brazil – Belo Horizonte	8	48	48	46	100%	97%
	Brazil – Porto Alegre – Conceicao	6	32	31	31	97%	97%
	Brazil – Porto Alegre – Santa Casa	13	78	76	75	97%	97%
	Brazil – Rio de Janeiro	10	48	45	47	94%	97%
	Malawi – Blantyre – Queen Elizabeth Central	72	376	349	365	93%	97%
	Total		109	582	549	564	94%
057 (Infants)	Brazil – Belo Horizonte	8	56	56	54	100%	96%
	Brazil – Porto Alegre – Conceicao	6	37	36	36	97%	96%
	Brazil – Porto Alegre – Santa Casa	13	91	89	87	98%	96%
	Brazil – Rio de Janeiro	10	55	52	53	95%	96%
	Malawi – Blantyre – Queen Elizabeth Central	72	432	399	416	92%	96%
	Total		109	671	632	646	94%
058	China – Guangxi – Heng County	261	303	242	280	80%	93%
	China – Nanning	35	0	0	0	–	–
	China – Xinjiang	283	362	277	333	77%	92%
	Thailand – Chiang Mai University	202	587	522	519	89%	88%
	Total		781	1252	1041	1133	83%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	85	0	0	0	–	–
	US – Boston	183	80	45	76	56%	94%
	US – Decatur	154	40	16	38	40%	94%
	US – Los Angeles	219	83	51	78	61%	94%
	US – NY – Harlem Prevention Center	154	1	1	1	100%	94%
	US – NY – New York Blood Center	156	36	32	34	89%	94%
	US – San Francisco	183	92	75	87	82%	94%
	US – Washington DC	184	56	42	53	75%	94%
	Total	1318	388	262	367	68%	94%
064 (Women)	US – Atlanta	215	46	43	43	93%	94%
	US – Baltimore	210	81	78	77	96%	94%
	US – Chapel Hill	210	243	212	227	87%	94%
	US – Decatur	209	40	38	38	95%	94%
	US – NY – Bronx–Lebanon Hospital Center	210	248	238	232	96%	94%
	US – NY – Harlem Prevention Center	210	54	47	51	87%	94%
	US – Newark	420	337	320	316	95%	94%
	US – Raleigh	210	193	163	182	84%	94%
	US – Washington DC	211	225	208	211	92%	94%
	Total	2105	1467	1347	1378	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

August 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: None
6. Lab related notes to file/deviations issued since preparation of SMC report: None
7. Miscellaneous
 - a. Results for polio, tetanus and HIB have been received at the HPTN NL.
 - b. The contract for the Hepatitis B Surface Antibody assays has been 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 REPORTED June study ops
 - d. 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.
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. 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 and have been tested.
3. A further shipment of infant samples from the Dar site, as requested by the SMC, has been sent to the site.
4. All infants are now at the 6 month stage. A request has been sent to SCHARP for any other samples that would need to be requested.

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. Communiques/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. PREVIOUSLY REPORTED July study ops.
 - g. Botswana – QNS plasma storage for 2 participants.
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. July - 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 July. Have submitted their LDMS reconciliations, 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. July - did submit their LDMS reconciliations, did not submit their QC for review, but submitted their inventory
4. Blantyre – The NL is working with the site on some processing issues. July - have submitted their LDMS reconciliations, did not submit their QC for review, but submitted their inventory
5. Porto Alegre the site plans on validating the OraQuick HIV assay (FDA cleared) and send their VLs to JHU for testing. July - 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. July - have submitted their LDMS reconciliations, have 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. Move plans have been submitted. July - Have submitted their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai – July - Had no LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg--WITs – July - Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory
10. Soweto – July - 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. July - 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 Yrgcare, 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: 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)
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. UFMG - 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 has started to enroll into Cohort 4. Site had no LDMS reconciliations to review. No testing is done on site for this protocol.
5. HNSC. Porto Alegre - No outstanding issues. Site has started to enroll into Cohort 4. Site have had no LDMS reconciliations to review, have not submitted their QC for review, and have not submitted their inventory.

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. 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: 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.
7. 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. Awaiting further instruction about the additional sites from FHI.

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 – Harlem and NYBC have completed enrollment.
4. Date of last SMC call – April 12th 2010
5. Communiques/Notification of change to SSP issued since preparation of last SMC report: Clarification Memo was issued on July 30th 2010 regarding how to enroll participants that sites were unable to obtain blood from after several attempts of phlebotomy. Lab-related notes to file/deviations issued since preparation of SMC report:

- a. San Francisco- Note to File received on samples that were destroyed since visit was conducted with incorrect PID.
- b. UCLA – Note to File received for participant who despite several attempts by the site, did not return for the 2nd confirmatory WB during the 4 week window.
- c. GWU– PREVIOUSLY REPORTED 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).
- d. 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 - No new updates.
- 2. George Washington University - New CLIA certificate still pending.
- 3. San Francisco - No new updates the problems that the site was experiencing with LDMS from 6/4/2010 were finally resolved with FSTRF on 6/18/2010.
 - a. 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 - No new updates
- 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. Lab-related notes to file/deviations issued since preparation of SMC report:
 - a. Newark - Site informed the NL of an “imposter”. Note to File received.
 - b. UNC - Note to File received site wasn’t able to obtain the plasma for storage on two participants. Note to File pending sample not processed within the 6 hour turnaround time.
 - c. Emory - Note to File received. Lab mishandled WB sample and not able to obtain a result.

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. Note to File received. Site staff will contact participant to return for collection of plasma storage samples

C. Shipping / QA Status

Shipments pending from UNC and Emory for QA testing.

NL updates

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

Travel Updates

Implementations Issues and Problems Summary 2010

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 should start taking ART at CD4 cell counts of 350 and below. This information is being conveyed via an information sheet that also informs participants of whether or not 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.

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.

062

Enrollment in CHAVI 001 is sporadic; hence, enrollment in 062 is likewise sporadic. However, enrollment has averaged one participant/month which is the expected rate.

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 just received verbal approval from their MOH so that state department clearance can be issued. It is not clear how long this process will take. Formal documentation will be received from the American Embassy.

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 16 June 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 22 June 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 22 June 2010. Sites were encouraged to maintain contact with already enrolled participants and to continue recruiting for the qualitative components. On 5 July 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). The protocol team received feedback on the newest version of the ACASI text and sent another version for piloting to the sites. Site feedback is expected at COB 4 August 2010.

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. The piloting is expected to begin mid-August 2010.

064

Accrual for the qualitative component 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 and the qualitative component progress.

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: 4 August 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:

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. PAB over the next couple of weeks will inform the site pharmacist of the procedures for study product destruction.

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: 6 August 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:

The study team is in the process of informing all participants about the updated advice from the WHO that recommends that HIV-infected persons should start taking ART at CD4 cell counts of 350 and below. This information is being conveyed via an information sheet that also informs participants of whether or not 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.

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 August 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. Half of the pairs will be enrolled in Blantyre and the other half will be enrolled across the four Brazil sites.

Enrollment is complete in Blantyre. Hospital do Servidores and Conceicao are open to accrual. The remaining Brazil sites are expected to open in August 2010.

Accrual Status:

Below is the site reported enrollment summary for Cohorts 1, 2, 3 and 4; refer also to the SCHARP 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, Porto Alegre Brazil	3	4	4	
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	
Conceicao, Porto Alegre Brazil	-	-	4	1
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	3
Total	30	21	30	19

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 03 August 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 280 participants. Heng County has enrolled 260 participants. Nanning has enrolled 33 participants. The clinic in Urumqi remains relocated to their satellite site due to orders from the Chinese authorities. Anticipated completion date of the renovations to the main clinic is September 2010.

David Celentano and Vu Minh Quan made a site assessment visit in Vietnam in mid July. After the visit the team consensus is that adding a site in Vietnam would be too costly with too long of a time period in addition to many other unknown parameters. The qualified reserve site in Tallin, Estonia under Anneli Uuskula will submit a revised application to the team.

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 shipment #4 has arrived in Beijing.

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 August 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	27 July 2010
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
178	181	237	178	213	155	154	1,296

Status of Intervention Delivery:

Sites continue to provide HIV and STI testing as well as Peer Health Navigation to enrolled participants. All sites except the Harlem and NYBC CRSs continue to enroll new community recruited participants. New York Blood Center completed their 125 participant target for community referred participants on 27 July and will continue to enroll index referred participants until 17 August.

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. All four of these sites plan to extend their recruitment to the last allowed deadline for community recruitment, 29 September 2010, and are working to reach their enrollment targets.

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 Study Team Call (22 July) was devoted to discussion of retention strategies. The protocol co-chairs will meet with each site team via teleconference in the month of August to discuss retention issues.

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: 04 August 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) is now being reviewed at RAB.

Accrual Status (completed at all sites):

Seven 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. Three participants have completed the enhanced counseling visits (intervention arm); three participants have completed the in-depth interview at week 12.

Retention Status:

N/A

Implementation Issues and Problems:

Enrollment in CHAVI 001 is sporadic; hence, enrollment in 062 is likewise sporadic. However, enrollment has averaged one participant/month which is the expected rate.

Report for HPTN Study Operations Group

HPTN 063 Preparing for International Prevention Trials Involving HIV-Infected Individuals in Care Settings

Based on data available through: 04 August, 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. The site received verbal Ministry of Health (MOH) approval on 22 July 2010. The MOH has sent this information to the American Embassy. The site has advised the HPTN CORE that any written documentation will be received from the American Embassy, not the MOH. 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 and received approval from the local IRB on 16 July 2010. Approval from the local MOH was received on 01 June 2010.

Enrollment was paused on 22 June 2010 due to ACASI issues discussed during the 201 HPTN Annual Meeting (see details below in the **Implementation Issues and Problems** section). However, the Thailand site is still actively recruiting and enrolling participants for the qualitative component.

Site activation activities are continuing at the Brazil and Zambia sites. Both the Zambia and Brazil sites will have all activation materials completed by 20 August 2010. 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 August 2010; refer also to the SCHARP enrollment summary.

**HPTN-063 Cumulative Screening and Enrollment Report
Based on Site-Reported Information**

*August 4,
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)							
Date of Interview	Women	Heterosexual Men	Stakeholders	MSM	Thailand (Focus Groups)	Date of Focus Group	No. of participants
	17-May-10	22-Jul-10		17-May-10	Session 1	17-Jun-10	8
	22-Jul-10			19-May-10	Session 2		
					Session 3		
					Session 4		
					TOTAL	1	8
TOTAL	2	1	0	2			

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 just received verbal approval from their MOH so that state department clearance can be issued. It is not clear how long this process will take. Formal documentation will be received from the American Embassy.

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 16 June 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 22 June 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 22 June 2010. Sites were encouraged to maintain contact with already enrolled participants and to continue recruiting for the qualitative components. On 5 July 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). The protocol team received feedback on the newest version of the ACASI text and sent another version for piloting to the sites. Site feedback is expected at COB 4 August 2010.

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. The piloting is expected to begin mid-August 2010.

Report for HPTN Study Operations Group
HPTN 064
Women's HIV Seroprevalence Study (ISIS)
Based on data available through: 02 August 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:

Since the last update, HPTN 064 successfully completed enrollment on 26 July 2010 enrolling 2,100 women.

The qualitative sites have successfully completed all qualitative interviews and are actively recruiting and conducting focus groups. The HPTN CORE staff completed coding the interviews and have started coding female focus groups from the Bronx-Lebanon site. A face-to-face meeting to discuss qualitative analysis is being planned for January 2011.

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 for the qualitative component 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 and the qualitative component progress.

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: 5 August 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 has identified a total of 79 sites (39 test sites and 40 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study. Site selection was based on surveillance data. Tests sites were ranked based on the volume of HIV+ cases identified in the previous year. Care sites were ranked based on the volume of HIV+ patients in care in the previous year

Bronx:

The protocol team has finalized a list of 19 test sites (including 9 hospitals) and 20 care sites to participate in the study. All sites have been notified and the team 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 were approached. The team has decided to move forward with randomizing only 19 test sites.

Washington, DC.

The protocol team has finalized a list of 20 test sites (including 8 hospitals) and 20 care sites to participate in the study. All sites have been notified and the team is moving forward with site contracts and IRB submissions for these sites.

Study Implementation Status:

Overall Plan for Implementation:

1. Finalize site selection and notify sites
2. Set up minimal subcontracts with all sites (using non-FI budgets)
3. Obtain all IRB approvals
4. Randomize sites
5. Conduct trainings
6. Begin Expanded HIV Testing, Linkage-to-Care, and Viral Suppression study components

Protocol Update:

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, after some minor revisions were made to the template ICF for the PFP (prevention for positives) subcomponent of the study. Version 2.0 of the protocol was approved by Copernicus on July 27, 2010. Approximately 60% of the sites are using the central IRB and 40% of the sites are using their own local IRBs

- Central IRB: The team is working to collect and submit required documents for those sites that will be using the central IRB. Submissions for 7 sites (5 DC sites and 2 Bronx sites) were made to the central IRB on August 5, 2010.
- Local IRBs: Materials for local IRB submissions have been provided to all DC sites and 90% of the Bronx sites that are not 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:

- Social Mobilization: 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.
- Expanded Testing in Hospitals: Eight hospitals in DC and nine in the Bronx have been selected to participate in this component of the study.

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, and the 20 test sites and 20 care sites in DC. 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 patient survey has been finalized and the provider survey is undergoing pilot testing.

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 is now posted on HTPN website.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems: None at this time.

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: 04 August 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 was granted approval by DAIDS on 22 July 2010 and distributed to the sites on the same day. Sites are currently submitting site activation items along with regulatory documents to fulfill activation requirements. Protocol training is expected to occur at the end of August.

Accrual Status:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

None.

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