



## **HPTN Study Operations Report**

**June 2010**

**PTN Executive Summary Report  
9 June 2010  
Enrollment Summary**

<b>Protocol</b>	<b>Site</b>	<b>Date of First Enrollment</b>	<b>Target Number</b>	<b>Total Enrolled</b>	<b>% Target Enrollment</b>	<b>Months of Enrollment</b>	<b>Cumulative Enrollment Per Month</b>	<b>% Enrollment Period</b>
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	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	59	100%	6	9.8	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1680	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	05Nov2009	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%	34.5	0.2	completed

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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
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	24.1	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	33.1	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	26.1	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	59	83%	42	1.4	completed
	Total		80	92	115%	42	2.2	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	34.5	0.2	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	24.1	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	33.1	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	26.1	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	59	83%	42	1.4	completed
Total		80	92	115%	42	2.2		
058	China – Guangxi – Heng County	24Dec2008	400	241	60%	17.7	13.6	48%
	China – Nanning	19May2010	350	15	4%	0.7	21.4	4%
	China – Xinjiang	23Dec2008	490	259	53%	17.8	14.6	48%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	717	48%	36.9	19.4	
061	US – Atlanta	26Feb2010	201	45	22%	3.4	13.2	33%
	US – Boston	17Jul2009	403	151	37%	10.9	13.9	61%
	US – Decatur	16Sep2009	202	126	62%	8.9	14.2	56%
	US – Los Angeles	30Sep2009	403	163	40%	8.4	19.4	55%
	US – NY – Harlem Prevention Center	08Jan2010	201	127	63%	5.1	24.9	42%
	US – NY – New York Blood Center	01Oct2009	202	114	56%	8.4	13.6	55%
	US – San Francisco	13Aug2009	403	156	39%	10	15.6	59%
	US – Washington DC	28Jul2009	403	147	36%	10.5	14	61%
Total		2418	1029	43%	10.9	94.4		
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	6	13%	1.5	4	
	Total		46	6	13%	1.5	4	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	41	14%	2.3	17.8	19%
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	41	5%	2.3	17.8	

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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	160	80%	9.5	16.8	155%
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	209	105%	7.5	27.9	128%
	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	2055	103%	12.6	163.1
064 (Men)	US – Decatur	10Mar2010	30	27	90%	3	9	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	17	57%	1.4	12.1	
	US – Washington DC	02Apr2010	30	34	113%	2.3	14.8	
	Total			120	132	110%	8.4	15.7

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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	1935	1700	1854	88%	96%
	Tanzania – Dar Es Salaam	218	905	828	878	91%	97%
	Uganda – Mulago Hospital	545	2496	2375	2395	95%	96%
	Zimbabwe – Harare/Chitungwiza	507	2406	2231	2303	93%	96%
	Total	1678	7742	7134	7429	92%	96%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	3877	3613	3723	93%	96%
	Tanzania – Dar Es Salaam	219	1952	1798	1885	92%	97%
	Uganda – Mulago Hospital	562	5208	5070	5006	97%	96%
	Zimbabwe – Harare/Chitungwiza	510	4836	4551	4641	94%	96%
	Total	1700	15873	15032	15255	95%	96%
052 Combined (Indexes)	Botswana – Gabarone	77	305	298	303	98%	99%
	Brazil – Porto Alegre	90	697	683	685	98%	98%
	Brazil – Rio de Janeiro	184	1658	1632	1624	98%	98%
	India – Chennai – YRGCare	250	2132	1971	2091	92%	98%
	India – Pune	175	1482	1469	1451	99%	98%
	Kenya – Kisumu	59	152	145	151	95%	100%
	Malawi – Blantyre – Queen Elizabeth Central	230	1505	1428	1482	95%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	1771	1666	1742	94%	98%
	South Africa – Johannesburg – Witwatersrand	46	268	258	265	96%	99%
	South Africa – Soweto	50	146	133	145	91%	100%
	Thailand – Chiang Mai	106	913	902	893	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1581	1509	1556	95%	98%
	Total	1758	12610	12094	12388	96%	98%
052 Combined (Partners)	Botswana – Gabarone	77	305	280	303	92%	99%
	Brazil – Porto Alegre	92	697	660	685	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	1658	1416	1624	85%	98%
	India – Chennai – YRGCare	250	2132	1838	2091	86%	98%
	India – Pune	175	1482	1435	1451	97%	98%
	Kenya – Kisumu	60	154	145	153	94%	100%
	Malawi – Blantyre – Queen Elizabeth Central	231	1505	1273	1482	85%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	1771	1519	1742	86%	98%
	South Africa – Johannesburg – Witwatersrand	46	268	243	265	91%	99%
	South Africa – Soweto	50	146	130	145	89%	100%
	Thailand – Chiang Mai	107	913	833	893	91%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1581	1362	1556	86%	98%
	Total	1769	12612	11134	12390	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	59	342	328	331	96%	97%
	Total	92	540	524	522	97%	97%
057 (Infants)	Brazil – Belo Horizonte	8	56	56	54	100%	96%
	Brazil – Porto Alegre – Conceicao	5	35	35	34	100%	96%
	Brazil – Porto Alegre – Santa Casa	13	91	89	87	98%	96%
	Brazil – Rio de Janeiro	7	49	49	47	100%	96%
	Malawi – Blantyre – Queen Elizabeth Central	59	398	379	382	95%	96%
	Total	92	629	608	604	97%	96%
058	China – Guangxi – Heng County	241	222	178	206	80%	93%
	China – Nanning	15	0	0	0	–	–
	China – Xinjiang	259	293	223	271	76%	93%
	Thailand – Chiang Mai University	202	523	463	466	89%	89%
	Total	717	1038	864	944	83%	91%
061	US – Atlanta	45	0	0	0	–	–
	US – Boston	151	56	36	53	64%	94%
	US – Decatur	126	14	7	13	50%	94%

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<b>Protocol</b>	<b>Site</b>	<b>Total Enrolled</b>	<b>Expected Visits</b>	<b>Completed Visits</b>	<b>Protocol Expectations</b>	<b>Retention Rate</b>	<b>Protocol Expected Standard</b>
	US – Los Angeles	163	33	10	31	30%	94%
	US – NY – Harlem Prevention Center	127	0	0	0	–	–
	US – NY – New York Blood Center	114	17	14	16	82%	94%
	US – San Francisco	156	51	42	48	82%	94%
	US – Washington DC	147	39	29	37	74%	94%
	Total	1029	210	138	198	66%	94%
064 (Women)	US – Atlanta	215	2	2	2	100%	94%
	US – Baltimore	210	54	51	51	94%	94%
	US – Chapel Hill	210	200	173	189	87%	94%
	US – Decatur	160	25	17	24	68%	94%
	US – NY – Bronx–Lebanon Hospital Center	210	200	189	189	95%	94%
	US – NY – Harlem Prevention Center	209	9	6	9	67%	94%
	US – Newark	420	182	176	172	97%	94%
	US – Raleigh	210	89	77	84	87%	94%
	US – Washington DC	211	201	185	190	92%	94%
	Total	2055	962	876	909	91%	94%

# MEMORANDUM

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

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 June 2010

### I. HPTN 027

#### A. General Comments

1. Protocol Version - 2.0 dated 20<sup>th</sup> May 2005
2. SSP version –
3. Enrollment Status – Closed.
4. Date of last SMC call –29<sup>th</sup> 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. 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

1. 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 9<sup>th</sup> 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 19<sup>th</sup> describing the delay in the testing of one sample for DNA PCR – resolved. Dar es Salaam – Protocol Deviation form issued 26<sup>th</sup> May 2010 describing that a cell pellet storage was not requested by the clinic.
  - b. Dar es Salaam – Protocol Deviation form issued 26/May/2010 describing that plasma and DBS storage were not requested by the clinic.

#### 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. Hematology SOP for the new analyser is pending. 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 has 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. No outstanding shipments or requests

## **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 FACScount 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.
  - b. UZ-UCSF moved samples to off-site freezer location without notifying the network lab.
  - c. UZ-UCSF ran out of the validated FBS and provided a list of PTIDs/VID that were processed with Hyclone FBS.
  - d. NARI Pune discovered a sample switch at storage between index and partner when reviewing the low viral load lists provided by SCHARP.
  - e. 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.
  - f. Lilongwe – CTNG not ordered on a participant as scheduled.
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.  
May - Had no LDMS reconciliations to perform, submitted their QC for review, and 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. Hematology SOP for the new analyser is pending.  
May: Had no LDMS reconciliations to perform, submitted their QC for review, and submitted their inventory.
3. Chennai – The site is in the process of moving part of the laboratory. NL is reviewing the validation information.  
May: Have submitted their LDMS reconciliations, submitted their QC for review, and submitted their inventory.
4. Blantyre – The NL is working with the site on some processing issues.  
May: Have submitted their LDMS reconciliations past the due date, submitted their QC for review, and submitted their inventory.
5. Porto Alegre – The site has had a delay in receiving HIV EIA FDA approved kits. The kits were ordered several months ago. This is still pending. Discussed validating the rapid test Oraquick in place of the EIA kit. Site has about one month's worth of VL testing available.

- May: Had no 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.  
May: Have submitted their LDMS reconciliations late (HGNI had none), submitted their QC for review, and did not submit their inventory.
  7. Lilongwe  
May: Have submitted their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
  8. Chiang Mai  
May: Had no LDMS reconciliations, submitted their QC for review, and submitted their inventory.
  9. Johannesburg – WITs  
May: Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory.
  10. Soweto  
May: 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.  
May: Have submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory.
  12. Kenya  
May: 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 will go out in June for genotyping and QA.

#### **IV. HPTN 057**

##### **A. General Information**

1. Protocol Version - 2.0 dated 28<sup>th</sup> October 2009
2. SSP version – 4.0 lab section dated 11<sup>th</sup> March 2010
3. Enrollment Status – open
4. Date of last SMC call – 21<sup>st</sup> February 2008.
5. Communiques/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related notes to file/deviations issued since preparation of SMC report:

##### **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 submitted their QC for review, and have submitted their inventory.
2. Santa Casa/Porto Alegre - No outstanding issues. Site has had no LDMS reconciliations to review, has not submitted their QC for review, and has 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 has had no LDMS reconciliations to review, has not submitted their QC for review, and has 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 has had no LDMS reconciliations to review, has not submitted their QC for review, and has 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 16<sup>th</sup> September 2008
2. SSP Version – 2.0 dated 5<sup>th</sup> December 2008
3. Enrollment status – open
4. Date of last SMC call – 26<sup>th</sup> 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: Guangxi – Protocol Deviation form issued 18<sup>th</sup> March 2010 describing that 9 female participants did not have a pregnancy test prior to signing the enrollment consent form. Staff has 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 manner, 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 has 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 has 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 about this trip 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 2<sup>nd</sup> 2009
2. SSP Version – Section 11 Version 3.0, April 7<sup>th</sup> 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 25<sup>th</sup> 2010.
4. Date of last SMC call – April 12<sup>th</sup> 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: Atlanta - Note to file received for rectal swab that was left out at room temperature over the weekend.

**B. Site-Specific including LDMS reports**

1. Fenway - Storing of aliquot samples that were collected but never stored in LDMS continues.
2. George Washington University - New CLIA certificate still pending.

3. San Francisco - Informed NL on June 4<sup>th</sup> 2010, site experiencing problems with LDMS. FSTRF currently working with site to resolve issues.
4. Harlem - No new updates.
5. Atlanta - NL site assessment visit schedule for June 24<sup>th</sup> to 25<sup>th</sup> 2010.
6. New York Blood Center - No new updates.
7. UCLA - No new updates.

**D. 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: Emory and Harlem are 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
6. Lab-related notes to file/deviations issued since preparation of SMC report:
  - a. Newark - Site informed the NL of an "imposter". Note to file is pending.
  - b. UNC- Site wasn't able to process a few samples within the 6-hour turnaround time. Note to files are pending.

**B. Site Specific including LDMS reports)**

1. Bronx - No new updates.
2. Harlem - No new updates.
3. Newark - Newark site informed the NL of an "imposter".
4. Johns Hopkins University - No new updates.
5. George Washington University - New CLIA certificate is pending.
6. University of North Carolina - No new updates.
7. Emory - SCHARP informed the NL of 3 samples that were entered into 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**

- Paul and Estelle are planning a visit to YRG Care in June.
- 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)
- Paul will be visiting the 046 site (Harare) and 052 sites (Malawi) in August.

## **Implementations Issues and Problems Summary June 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**

Recruitment lags behind target for all but the Atlanta and Harlem sites. Sites have been challenged to either complete enrollment by the target date or consider extending their enrollment period until September 25, 2010. At this time Boston and possibly GW may be the only sites that will extend their enrollment period.

Sites are conducting six month visits. Retention is not strong, with no sites retaining above 83%. Sites were alerted to the situation and it will be reviewed again on the next study call.

### **062**

Enrollment in CHAVI 001 will end in late 2011, thus 062 enrollments will end then also. It is unlikely that the site will be able to identify and enroll 46 participants by that date.

### **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. DAIDS and HPTN leadership are currently discussing this issue and deciding on acceptability of this approval letter.

During the HPTN annual meeting, the Thai site expressed concern with the usability of the ACASI. More participants than originally expected, are unfamiliar with the use of computers and are having a difficult time using the system without assistance (approximately 60% are requiring assistance). In addition, the language in some of the questions has been difficult for participants to understand. It is expected that screening and enrollment will be put on hold in the coming days while the team devises a way to improve the ACASI platform and questions.

**064**

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met. A number of face-to-face meetings focusing on retention were held during the 2010 HPTN Annual Meeting.

**065**

During the face-to-face protocol team meeting held on June 8, 2010, the protocol team decided on the following strategy:

- Complete site identification and selection
- Obtain IRB approval from all participating sites
- Complete and inform sites of randomization
- Provide study-specific training
- Implement linkage-to-care and viral suppression interventions

## **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: 15 June 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 meets 15 June to evaluate HPTN 046.

#### **Accrual Status:**

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

#### **Status of Intervention Delivery:**

#### **Retention Status:**

There have been no retention issues identified at this time.

#### **Implementation Issues and Problems:**

No issues at this time.

## Report for HPTN Study Operations Group

### HPTN 052

#### **A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples**

*Based on available data through: 16 June 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, however, sites still had couples in the pipeline who agreed to be enrolled. SCHARP announced that the last enrollment took place on May 3, 2010. The final enrollment total is pending confirmation of enrollment figures from one site.

#### **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: 2 Jun 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.

The Brazil sites are expected to have all approvals in place and open for accrual in May 2010.

#### Accrual Status:

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

Site	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Queen Elizabeth Central Hospital, Blantyre Malawi	24	16	15	3
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	
<b>Total</b>	<b>30</b>	<b>21</b>	<b>30</b>	<b>3</b>

**Status of Intervention Delivery:**

There were no reported significant problems with the dispensing of tenofovir to the mothers or infants in Cohorts 1 – 3.

**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 1 June 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 260 participants. Heng County has enrolled 236 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 early 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.

The export permit has been applied for to ship a new supply of study drug to China. The team is hoping to have this permit in early June.

**Accrual Status:**

	<b>Chiang Mai</b>	<b>Nanning</b>	<b>Heng County</b>	<b>Xinjiang</b>
<b>Date First Screened</b>	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
<b>Date First Enrolled</b>	30-May-07		24-Dec-08	21-Dec-08
<b># Individuals Screened</b>	281	30	515	490
<b># Individuals Enrolled</b>	202	6	236	260

**Status of Intervention Delivery:**

Study drug has been generally well tolerated.

**Retention Status:**

<b>All Sites</b>	
Week 26	87%
Week 52	77%
Week 78	84%
Week 104	82%
Week 130	79%

**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: 15 June 2010*

#### Participating Study Sites:

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

#### Study Implementation Status:

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

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

#### Accrual Status (participants enrolled at each site) as of 04 June 2010:

Fenway	GWU	Emory Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
151	142	185	157	175	112	129	1,051

#### Status of Intervention Delivery:

All focus groups have been completed and the transcripts are being coded and reviewed at this time. The individual interviews have begun at some sites.

**Recruitment Status:**

Recruitment lags behind target for all but the Atlanta and Harlem sites. Sites have been challenged to either complete enrollment by the target date or consider extending their enrollment period until September 25, 2010. At this time Boston and possibly GW may be the only sites that will extend their enrollment period.

**Retention Status:**

Sites are conducting six month visits. Retention is not strong, with no sites retaining above 83%. Sites were alerted to the situation and it will be reviewed again on the next study call.

**Implementation Issues and Problems:**

See above.

## 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: 14 June 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. An amendment is drafted and will be ready for Regulatory Review within the month.

#### **Accrual Status (completed at all sites):**

Six participants have been enrolled to date.

#### **Status of Intervention Delivery:**

Staff reports that the visits are long and tiring, but so far all participants have been willing to return and complete the weekly visits. The first two enrollees are now moving into monthly visit schedule.

#### **Retention Status:**

N/A

#### **Implementation Issues and Problems:**

Enrollment in CHAVI 001 will end in late 2011, thus 062 enrollments will end then also. It is unlikely that the site will be able to identify and enroll 46 participants by that date.

## 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: 11 June 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 are awaiting approval for the official LoA. Approval from the local Ministry of Health (MOH) was received on 01 June 2010. DAIDS and HPTN leadership are in discussion regarding some of the language in the approval letter (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 11 June 2010; refer also to the SCHARP enrollment summary.

Site (Quantitative Participants)	Date of First Screening	Date of First Enrollment	No. Report No Unprotected Sex	No. Not Receiving Care	Total No. Enrolled
<b>Brazil: Rio de Janeiro (IPEC CRS)</b>					
Women					
Heterosexual					
Men					
MSM					
<b>Thailand: Chiang Mai</b>	01-Apr-10	01-Apr-10			
Women			0	0	27
Heterosexual					
Men			0	0	14
MSM			0	0	9
<b>Zambia: Lusaka (Metero Clinic CRS)</b>					
Women					
Heterosexual					
Men					
<b>TOTAL</b>	<b>NA</b>	<b>NA</b>	<b>0</b>	<b>0</b>	<b>50</b>

Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders
<b>Date of Interview</b>	17-May-10	17-May-10	
		19-May-10	
<b>TOTAL</b>	<b>1</b>	<b>2</b>	

**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. DAIDS and HPTN leadership are currently discussing this issue and deciding on acceptability of this approval letter.

During the HPTN annual meeting, the Thai site expressed concern with the usability of the ACASI. More participants than originally expected, are unfamiliar with the use of computers and are having a difficult time using the system without assistance (approximately 60% are requiring assistance). In addition, the language in some of the questions has been difficult for participants to understand. It is expected that screening and enrollment will be put on hold in the coming days while the team devises a way to improve the ACASI platform and questions.

**Report for HPTN Study Operations Group**  
**HPTN 064**  
**Women's Seroprevalence Study (ISIS)**  
*Based on data available through: 14 June 10*

**Participating Study Sites:**

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

**Study Implementation Status:**

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

Since the last update, the Harlem Prevention Center and Ponce de Leon Ctr. CRS successfully completed enrollment with a total of 210 women. 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 for 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. A number of face-to-face meetings focusing on retention were held during the 2010 HPTN Annual Meeting.

## 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: 15 June 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). There will be 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. In each intervention location, there will be 20 test sites and 20 care sites.

### Study Implementation Status:

The protocol received final approval for V1.0 on March 16, 2010. The protocol 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. The protocol chairs have decided to move forward with a protocol amendment (to V2.0) to make these revisions, as well as other minor modifications to the protocol. The study team will request a waiver of the requirement for full PSRC review of the amendment, given the non-substantive nature of the modifications.

The study team is in the process of site selection for the 40 test sites and 40 care sites that will participate in the study. **Table 1** depicts a summary of progress to date.

### 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):

- HIV test and care sites are being selected to participate in these two study components.

### Prevention for Positives (PFP):

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

### Patient and Provider Surveys:

- The patient and provider surveys are undergoing final development.

On June 8, 2010, there was a face-to-face protocol team meeting held during the HPTN annual meeting.

**Accrual Status:** N/A

**Retention Status:** N/A

**Implementation Issues and Problems:**

During the face-to-face protocol team meeting held on June 8, 2010, the protocol team decided on the following strategy:

- Complete site identification and selection
- Obtain IRB approval from all participating sites
- Complete and inform sites of randomization
- Provide study-specific training
- Implement linkage-to-care and viral suppression interventions

**Table 1: Summary of Current Site Selection in Washington, D.C. and the Bronx, New York**  
(Data as of June 4, 2010)

Community	Site Type	# of Sites Needed for Study	# of Sites Approached	# of Signed LoIs	Details for LoIs
DC	Test	20	24	17	5 hospitals 7 non-hospital test sites 5 test and care sites
	Care	20	23	14	5 hospitals 4 non-hospital care sites 5 test and care sites
Bronx	Test	20	27	15	5 hospitals 6 non-hospital test sites 4 test and care sites
	Care	20	33	18	5 hospitals 9 non-hospital care sites 4 test and care sites

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# Appendix: HPTN Protocols and INDs

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<b>Protocol #</b>		<b>IND</b>	<b>IND Sponsor</b>	<b>Study Status</b>
<b>HPTN 027</b>	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
<b>HPTN 046</b>	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
<b>HPTN 052</b>	A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples	68,535	DAIDS	Enrolling
<b>HPTN 057</b>	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
<b>HPTN 058</b>	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