



## **HPTN Study Operations Report**

**June 2011**

**PTN Executive Summary Report**  
**8 June 2011**  
**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

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	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1681	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	88	105%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	175	104%	29.4	6	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	1693	101%	34.7	48.8	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.2	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.8	2.6	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.4	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.7	2.6	
058	China – Guangxi – Heng County	24Dec2008	405	356	88%	29.9	11.9	81%
	China – Nanning	19May2010	350	113	32%	12.8	8.8	65%
	China – Xinjiang	23Dec2008	495	409	83%	29.9	13.7	81%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	1080	72%	49	22	
061	US – Atlanta	26Feb2010	201	116	58%	7	16.6	closed
	US – Boston	17Jul2009	403	237	59%	15.3	15.5	closed
	US – Decatur	16Sep2009	202	184	91%	12.2	15.1	closed
	US – Los Angeles	30Sep2009	403	283	70%	12.3	23	closed
	US – NY – Harlem Prevention Center	08Jan2010	201	154	77%	6.3	24.4	closed
	US – NY – New York Blood Center	01Oct2009	202	156	77%	10.7	14.6	closed
	US – San Francisco	13Aug2009	403	204	51%	13.6	15	closed
	US – Washington DC	28Jul2009	403	227	56%	14.2	16	closed
	Total		2418	1561	65%	15.3	102	
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	23	50%	13.6	1.7	62%

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	Total		46	23	50%	13.6	1.7	
063	Brazil – Rio de Janeiro	06Apr2011	300	19	6%	2.1	9	16%
	Thailand – Chiang Mai	01Apr2010	300	122	41%	14.4	8.5	57%
	Zambia – Lusaka – Matero Clinic	28Apr2011	200	9	5%	1.4	6.4	11%
	Total		800	150	19%	14.4	10.4	
064 (Women)	US – Atlanta	22Oct2009	200	215	108%	7	30.7	completed
	US – Baltimore	05Aug2009	200	210	105%	8.7	24.1	completed
	US – Chapel Hill	26May2009	200	210	105%	8.7	24.1	completed
	US – Decatur	27Aug2009	200	211	106%	11.1	19	completed
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	210	105%	7.4	28.4	completed
	US – Newark	05Jun2009	400	420	105%	10.5	40	completed
	US – Raleigh	11Aug2009	200	210	105%	5.7	36.8	completed
	US – Washington DC	17Jun2009	200	211	106%	10.3	20.5	completed
	Total			2000	2107	105%	14.2	148.4
064 (Men)	US – Decatur	10Mar2010	30	43	143%	4.9	8.8	completed
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	37	123%	3.2	11.6	completed
	US – Washington DC	02Apr2010	30	40	133%	2.8	14.3	completed
	Total			120	174	145%	10.3	16.9
066	US – Baltimore	28Feb2011	16	17	106%	3.3	5.2	164%
	US – Chapel Hill	07Feb2011	16	16	100%	4	4	148%
	Total		32	33	103%	4	8.3	
068	South Africa – Bushbuckridge – MRC/Wits	05Mar2011	2900	624	22%	3.2	195	9%
	Total		2900	624	22%	3.2	195	

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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	2426	2085	2280	86%	94%
	Tanzania – Dar Es Salaam	218	1307	1144	1227	88%	94%
	Uganda – Mulago Hospital	545	3204	3026	3014	94%	94%
	Zimbabwe – Harare/Chitungwiza	507	2998	2761	2819	92%	94%
	Total	1678	9935	9016	9340	91%	94%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4477	4161	4249	93%	95%
	Tanzania – Dar Es Salaam	219	2408	2184	2284	91%	95%
	Uganda – Mulago Hospital	562	6115	5949	5807	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5566	5251	5284	94%	95%
	Total	1700	18566	17545	17625	95%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	617	601	608	97%	99%
	Brazil – Porto Alegre	90	1065	1043	1038	98%	97%
	Brazil – Rio de Janeiro	184	2402	2361	2333	98%	97%
	India – Chennai – YRGCare	250	3145	2819	3059	90%	97%
	India – Pune	175	2192	2161	2130	99%	97%
	Kenya – Kisumu	60	407	401	402	99%	99%
	Malawi – Blantyre – Queen Elizabeth Central	230	2435	2281	2379	94%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	2788	2577	2721	92%	98%
	South Africa – Johannesburg – Witwatersrand	46	456	435	447	95%	98%
	South Africa – Soweto	50	352	340	348	97%	99%
	Thailand – Chiang Mai	106	1342	1326	1303	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2562	2414	2502	94%	98%
	Total	1759	19763	18759	19271	95%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
052 Combined (Partners)	Botswana – Gabarone	77	617	575	608	93%	99%
	Brazil – Porto Alegre	93	1065	987	1038	93%	97%
	Brazil – Rio de Janeiro	188	2402	2003	2333	83%	97%
	India – Chennai – YRGCare	250	3145	2558	3059	81%	97%
	India – Pune	175	2192	2109	2130	96%	97%
	Kenya – Kisumu	60	406	393	401	97%	99%
	Malawi – Blantyre – Queen Elizabeth Central	231	2435	1982	2379	81%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	2788	2272	2721	81%	98%
	South Africa – Johannesburg – Witwatersrand	46	456	404	447	89%	98%
	South Africa – Soweto	50	352	319	348	91%	99%
	Thailand – Chiang Mai	107	1342	1214	1303	90%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2562	2138	2502	83%	98%
	Total		1772	19762	16954	19270	86%
057 (Mothers)	Brazil – Belo Horizonte	12	67	67	65	100%	97%
	Brazil – Porto Alegre – Conceicao	10	55	54	54	98%	97%
	Brazil – Porto Alegre – Santa Casa	15	87	85	84	98%	97%
	Brazil – Rio de Janeiro	13	72	72	70	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	72	418	407	405	97%	97%
	Total		122	699	685	678	98%
057 (Infants)	Brazil – Belo Horizonte	12	75	75	72	100%	97%
	Brazil – Porto Alegre – Conceicao	10	62	61	60	98%	97%
	Brazil – Porto Alegre – Santa Casa	15	100	98	96	98%	96%
	Brazil – Rio de Janeiro	13	83	83	80	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	72	490	474	471	97%	96%
	Total		122	810	791	780	98%
058	China – Guangxi – Heng County	356	749	625	672	83%	90%
	China – Nanning	113	61	52	58	85%	94%
	China – Xinjiang	409	863	726	770	84%	89%
	Thailand – Chiang Mai University	202	903	793	775	88%	86%
	Total		1080	2576	2196	2273	85%

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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>
061	US – Atlanta	116	159	119	148	75%	93%
	US – Boston	237	362	277	335	77%	93%
	US – Decatur	184	290	188	268	65%	93%
	US – Los Angeles	283	404	323	374	80%	93%
	US – NY – Harlem Prevention Center	154	252	228	233	90%	92%
	US – NY – New York Blood Center	156	232	190	215	82%	93%
	US – San Francisco	204	338	257	312	76%	92%
	US – Washington DC	227	345	289	320	84%	93%
	Total	1561	2382	1871	2206	79%	93%
062	Malawi – Lilongwe – Lilongwe Central Hospital	23	174	171	171	98%	98%
	Total	23	174	171	171	98%	98%
064 (Women)	US – Atlanta	215	392	358	362	91%	92%
	US – Baltimore	210	411	398	378	97%	92%
	US – Chapel Hill	210	323	299	300	93%	93%
	US – Decatur	211	346	309	320	89%	93%
	US – NY – Bronx–Lebanon Hospital Center	210	328	315	304	96%	93%
	US – NY – Harlem Prevention Center	210	362	323	335	89%	92%
	US – Newark	420	821	789	756	96%	92%
	US – Raleigh	210	411	387	379	94%	92%
	US – Washington DC	211	337	315	312	93%	93%
	Total	2107	3731	3493	3446	94%	92%
066	US – Baltimore	17	81	67	81	83%	99%
	US – Chapel Hill	16	98	95	97	97%	99%
	Total	33	179	162	178	91%	99%

# 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 2011

### I. 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 NTFs/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. BOTH PREVIOUSLY REPORTED June study ops
  - b. Dar es Salaam – Protocol Deviation form issued 26/May/2010 describing that plasma and DBS storage were not requested by the clinic. PREVIOUSLY REPORTED June study ops
  - c. Dar es Salaam – 8 Protocol Deviation forms received on 6/30/10 They describe the failure of the physician to request DBS or breast milk storage. Discovered during retrospective chart reviews. PREVIOUSLY REPORTED August study ops
  - d. UZ-UCSF – NTF issued Sep 22<sup>nd</sup> describing the movement of the DBSCards from the laboratory (temperature monitored) to a storage area for the laboratory. The lab recently started monitoring temperatures in the area. A list of PTIDs involved is still pending.
  - e. UZ-UCSF - Pending NTF regarding another power problem that affected the freezers at the off site location
  - f. UZ-UCSF – NTF regarding outage of WB kits in October, delaying resulting of 1 participant.

#### B. Site Specific

1. Harare - Site is working on the validation of a new chemistry analyzer. Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory.
2. Kampala - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
3. Durban - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
4. Dar es Salaam - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

#### C. Shipping / QA Status

1. All samples requested at this time for QA have been shipped and tested.
2. Shipping lists for resistance testing samples have been sent to the sites. Samples from Tanzania and South Africa have been received at the NL. Documentation to allow the shipment of samples from Uganda and Zimbabwe sites is being prepared.
3. Mark Mirochnick and SCHARP have selected samples required for PK studies. Lists have been sent to the sites for shipping to the NL. Samples from Tanzania and South Africa have been received and are at the Network Lab.

Specimens will be forwarded from the NL to a non-Network affiliated lab (Dr Caparelli) for testing.

## II. HPTN 052

### A. General Comments

1. Protocol Version - 3.0 dated 20 Nov 06
2. SSP version - 1.6 dated 9 Jan 09
3. Enrollment Status - closed
4. Date of last SMC call – scheduled for March 2011
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - none
6. Lab-related NTFs/deviations issued since preparation of SMC report:
  - a. HNSC NTF regarding validation of urinalysis instrument. Previously reported
  - b. HNSC – NTF regarding the usage of expired FBS Previously reported
  - c. COM Blantyre – NTF regarding correction of lab report with correct DOB, visit code and date Previously reported
  - d. Botswana – NTF regarding backup arrangements for the PBMC processing Previously reported
  - e. COM Blantyre – NTF regarding the validation of the urine pregnancy kit that was in use. Previously reported
  - f. UNC Lilongwe – NTF (several) regarding samples lost in the lab. Previously reported
  - g. UZ-UCSF - Protocol deviation submitted regarding delayed TAT for phosphate
7. Miscellaneous - The NL is continuing to work on the QA activity regarding partner seroconversions, genotyping and ARV testing as well as the hepatitis sub-study.

### B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site has prepared the validation documents. Site has finalized the validation of the back-up instrument and is working on finalizing other validation documents. Have not submitted their LDMS reconciliations, have not submitted their QC for review, but have submitted their inventory.
2. Harare - Pending an update on their ordering / inventory SOP. Site is working on the validation of a new chemistry analyzer. Did submit their LDMS reconciliations late, submitted their QC for review, and submitted their inventory.
3. Chennai – Did not have any LDMS queries, did not submit their QC for review, but submitted their inventory
4. Blantyre – Have submitted their LDMS reconciliations late, did submit their QC for review, and submitted their inventory
5. Porto Alegre - Did submit their LDMS reconciliations, submitted their QC for review and submitted their inventory.
6. Rio sites – Did submit their LDMS reconciliations late, have submitted their QC for review, and did submit their inventory.
7. Lilongwe - Did submit their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai – Have submitted their LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg--WITs –Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory

10. Soweto – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and Soweto have not submitted their inventory
11. Botswana - Did not submit their LDMS reconciliations , have not submitted their QC for review, and have not submitted their inventory
12. Kenya – Have submitted their LDMS reconciliations, have not submitted their QC for review, and have submitted their inventory

**C. Shipping / QA Status**

Pending a shipment from NARI Pune.

**III. HPTN 057**

**A. General Comments**

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 – Fully enrolled
4. Date of last SMC call – 21<sup>st</sup> February 2008.
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - Clarification memo issued 7/15/2010 clarifying that CK total protein and glucose are not required in HPTN 057 (they had been indicated in section Appendix 1B) PREVIOUSLY REPORTED ON STUDY OPS REPORT

**B. Site Specific**

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

**C. Shipping / QA Status**

Some specimens were missing from the list SCHARP sent to the sites for PK. New lists have been sent to the sites.

**IV. HPTN 058**

**A. General Comments**

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 – 24<sup>th</sup> January 2011
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report - None
6. Lab-related NTFs/deviations issued since preparation of SMC report - None

**B. Site Specific**

1. Thailand - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory. The lab can no longer receive a supply of one of the HCV assays they were using. The Architect HCV assay at the Maharaj Hospital will be used as the second HCV assay for HPTN 058. Validations have been performed and reviewed by the HPTN NL.

2. Xinjiang Site - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and has not submitted their inventory.
3. Guangxi - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and has not submitted their inventory.

**C. Shipping / QA Status**

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

**V. HPTN 061**

**A. General Comments**

1. Protocol Version – Version 2.0, April 2<sup>nd</sup> 2009
2. SSP Version – Section 11 Version 5.0 December 9<sup>th</sup> 2010.
3. Enrollment status – All sites have completed enrollment
4. Date of last SMC call – March 30<sup>th</sup> 2011
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report - Data communiqué 9 issued on May 5<sup>th</sup> 2011. Appendix D of SSP released for procedures for co-enrolled 061 participants with HVTN 505.
6. Lab-related notes to file/deviations issued since preparation of SMC report:
  - a. Atlanta – NTF received for rectal swab misplaced by lab. Previously reported NTFs received for 2 PIDs, one who did not return for 2<sup>nd</sup> WB; one who did after 4 weeks at 6 month visit. Previously reported NTF received for 2 PIDs who are lost to follow since enrollment and have not completed Syphilis confirmatory testing, 2 PIDs who completed syphilis confirmatory testing at visit 2.0 and for 9 PIDs who only had one WB per SCHARP's report (3 had completed and CRF were being refaxed)
  - b. Fenway – NTFs received for 5 PIDs plasma storage QNS. Previously reported NTF received for PID who returned for interim visit and HIV testing but no plasma was stored. Previously reported NTF received for 3 PIDs that have not had their 2<sup>nd</sup> WB as yet and are outside the 4 week window.
  - c. GWU - Previously reported Protocol Deviation received for PID enrolled who was under age. NTFs received for 2 PIDs who have refused HIV testing but allowed Syphilis testing and plasma storage. Previously NTF received for 2 PIDs; one 2<sup>nd</sup> WB collected after 4 week window, one outside 4 week window not yet collected.
  - d. NYBC - Previously reported--None
  - e. UCLA - Previously reported NTF received for freezer downtime as freezer was being repaired. Previously reported NTFs received for 3 PIDs for whom a 2<sup>nd</sup> WB was not completed.
  - f. Harlem - Previously reported--None.
  - g. San Francisco - Previously reported NTF received for PID who did not have 2<sup>nd</sup> WB within the 4 week window and no plasma stored at visit 2.0. Previously reported 5 NTFs received, two for which no plasma was stored, one the confirmatory Syphilis testing was not done, one for QNS plasma storage and one for specimens for plasma storage left out over 3 day weekend and had to be redrawn.

**B. Site Specific**

1. Fenway - No new updates
2. George Washington University - No new updates
3. San Francisco - Preliminary report about previous allegations; freezers are fine, no way to follow up about plasma processing concerns as yet. Allegations made by RA about lab specimen processing SOP not being

followed and freezer and fridge concerns. Investigation currently being conducted at site. Investigation still pending, RA involved has extended disability leave.

4. Harlem - Employee at site will now take over shipping and LDMS duties, has completed IATA training and will be attending LDMS training at FSTRF facility.
5. Atlanta - No new updates
6. New York Blood Center - No new updates
7. UCLA - No new updates

**C. Shipping / QA Status**

1. Enrollment QA testing has been completed and data forwarded to SCHARP.
2. Due to discrepant QA results a 2<sup>nd</sup> set of QA is being done at Harlem and Fenway.

**VI. HPTN 063**

**A. General Comments**

1. Protocol Version - Version 1.0 dated 15 September 2008
2. SSP version - Version 1.0 dated 26<sup>th</sup> March 2010 (update in process)
3. Enrollment Status - All sites enrolling.
4. Date of last SMC call - None
5. Communiqués/Notifications of Change to SSP issued since preparation of last SMC report - None
6. Lab-related Notes to File/Deviations issued since preparation of SMC report - None

**B. Site Specific**

1. Thailand - No new updates
2. Brazil - No new updates.
3. Zambia - Site informed of LDMS errors and lab SOP not being followed for plasma processing, protocol deviation pending.

**VII. HPTN 064**

**A. General Comments**

1. Protocol Version - 1.0 dated 20 February 2010
2. SSP Version - 2.0 dated 12 May 2010
3. Enrollment Status - All sites have completed enrollment.
4. Date of last SMC call - 01 November 2010  
Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
5. Lab-related notes to file/deviations issued since preparation of SMC report:
  - a. Johns Hopkins University - NL informed that the confirmatory WB was sent to the incorrect lab and was not completed. Site informed to use stored plasma for the confirmatory WB. NTF received. PREVIOUSLY REPORTED April study ops. NL informed plasma wasn't stored for a participant due to a lab accident. NTF received. PREVIOUSLY REPORTED November study ops.
  - b. Emory - NL informed plasma (for one participant) wasn't stored within the allotted timeframe. NTF received. PREVIOUSLY REPORTED. NL informed that an enrolled participant used falsified information. NTF and Protocol Deviation received. PREVIOUSLY REPORTED December study ops.
  - c. Harlem - Incorrect PID and VID entered into LDMS on two participants. NTF received. PREVIOUSLY REPORTED March study ops.
  - d. GWU - NL informed that a 6-month participant was mistakenly extended to 12 month. NTF pending. NTF received. PREVIOUSLY REPORTED April study ops.

**B. Site Specific**

1. Bronx - No new updates.
2. Harlem - As of June 1<sup>st</sup>, the study coordinator will no longer be with the study.
3. Newark - No new updates.
4. Johns Hopkins University - No new updates.
5. George Washington University - No new updates.
6. University of North Carolina - No new updates.
7. Emory - No new updates.

**C. Shipping / QA Status**

1. All enrollment QA testing has been completed and the data forwarded to SCHARP.
2. All endpoint and incidence samples have been received.

**VIII. HPTN 066****A. General Comments**

1. Protocol Version - 2.0 dated 29<sup>th</sup> November 2010
2. SSP version – Version 1.0
3. Enrollment Status – UNC and JHU sites are actively screening and enrolling participants. Enrollment is almost complete.
4. Date of last SMC call – None
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - Lab Communique #1 issued 8<sup>th</sup> March 2011 stating that if possible, the blood sample on Day 35 needs to be drawn according to the following criteria: (1) As close as possible to the same time of day as the prior dose of study drug. (2) Within 3 hours of the tissue/luminal sample collection.
6. Lab-related notes to file/deviations issued since preparation of SMC report - None
7. Miscellaneous - PBMCs in this study are being used for PK analysis and will follow an SOP developed specifically for this purpose. This study is not storing viable PBMCs and will not follow the Cross-Network PBMC Processing SOP

**B. Site Specific**

1. UNC - None
2. JHU - The site enrolled a participant into the study was ineligible according to the HIV screening algorithm. The site has submitted NTF to FHI.

**IX. HPTN 068****B. General Comments**

1. Protocol Version – 1.0 dated 06<sup>th</sup> October 2010
2. SSP Version – 1.0 dated 01 February 2011
3. Enrollment status – Enrolling
4. Date of last SMC call – None
5. Communiqués/Notification of Changes to SSP issued since preparation of last SMC report - None
6. Lab-related NTFs/deviations issued since preparation of SMC report -
  - a. The site informed the NL of discordant rapid results for a participant and misunderstanding of the algorithm. NTF pending.
  - b. The site informed the NL of invalid rapid tests results that weren't documented. NTF pending.
  - c. The site informed the NL of discrepant rapid and WB results. NTF pending.
  - d. NTFs received for PIDs with less than 4 plasma aliquots stored.
  - e. NTFs received for PIDs with less than 4 aliquots of plasma stored. PREVIOUSLY REPORTED May study ops.

- f. NTF received for PIDs with less than 4 aliquots of plasma stored.  
PREVIOUSLY REPORTED April study ops.

**C. Shipping /QA status**

The Network Laboratory and SCHARP are planning to request the quarterly QA shipment.

**NL updates**

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

**Travel Updates**

- Estelle and Paul will be visiting China in the summer for HPTN 058 site visit.
- Estelle will be attending the Cape Town HPTN 067 training in July and the Bangkok HPTN 067 training in August
- Estelle and Paul will be visiting NARI and YRGcare in June for HPTN 052.
- LeTanya will be visiting the Agincourt site in July.

## **Implementations Issues and Problems Summary June 2011**

### **058**

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

### **061**

Retention is the greatest concern in study implementation. The study teams continue to focus all efforts on improving retention and completing the study.

### **063**

The Zambia site had to pause enrollment on May 13, 2011 due to delays in the approval of an ICF change from the UNZA REC. The site used this time to review participant files, correct all QCs, review qualitative interview transcripts. The site received the appropriate approval from the UNZA REC on May 16, 2011 and resumed enrollment on May 16, 2011.

## 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: 14 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

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

Analysis of the 6 month endpoint data is complete. The team is currently working on a manuscript for publication.

#### **Accrual Status:**

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

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

Blinded study product has been discontinued in all infants.

#### **Retention Status:**

There have been no retention issues identified at this time.

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

No issues at this time.

## Report for HPTN Study Operations Group

### HPTN 052

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

*Based on available data through: 14 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

All sites listed above are operating under Version 3.0 of the protocol. Enrollment is closed as of April 2010. Follow-up is on-going.

The HPTN 052 DSMB met 28 April 2011 and issued the following recommendations:

1. The Board recommends that the results of the trial be announced as soon as possible.
2. The Board congratulates the team for a very well-done trial that definitively shows that immediate ART reduces transmission of HIV.

In response to the above recommendations, LoA#5 to V. 3.0, a "Dear Participant" letter, and the DSMB summary and recommendations have been provided to the study sites. The sites are currently submitting these documents to their IRBs/ECs for approval, and are providing the "Dear Participant" letter to the study participants.

The status of IRB/EC approvals, as well as the response by the participants to the "Dear Participant" letter are being tracked.

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: 14 June 2011*

#### Participating Study Sites:

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

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

- Irmandade Santa Casa de Misericordia de Porto Alegre, 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 was completed in November 2011. Follow-up is for 1 year. The expected study completion date is November - December 2011. Safety and pk analysis for Cohorts 1 – 3 is complete and a manuscript with Cohorts 1 – 3 data is in development. Analysis of cohort 4 pk data is underway and is expected to be completed in summer of 2011.

#### Accrual Status:

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

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

#### Status of Intervention Delivery:

There have been no reported significant problems with the dispensing of tenofovir to the mothers or infants.

**Retention Status:**

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

**Implementation Issues and Problems:** none.

## Report for HPTN Study Operations Group

### HPTN 058

## A Phase III Randomized Controlled Trial to Evaluate the Efficacy of Drug Treatment in Prevention of HIV Infection and Death Among Opiate dependent Injectors

*Based on data available through 2 June 2011*

#### Participating Study Sites:

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

#### Study Implementation Status:

Enrollment in Chiang Mai was capped at 202 participants in October 2009. Xinjiang has enrolled 410 participants. Heng County has enrolled 350 participants. Nanning has enrolled 109 participants.

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

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

#### Accrual Status:

	Chiang Mai	Nanning	Heng County	Xinjiang
<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	19-May-10	24-Dec-08	21-Dec-08
<b># Individuals Enrolled</b>	202	109	350	410

#### Status of Intervention Delivery:

Study drug has been generally well tolerated.

**Retention Status:**

All Sites	
Week 26	89%
Week 52	84%
Week 78	85%
Week 104	86%
Week 130	77%
Week 156	81%

**Implementation Issues and Problems:**

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

## 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: 31 May 2011*

#### Participating Study Sites:

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

#### Study Implementation Status:

All sites for the HPTN 061 protocol have finished enrolling and following participants. The last date of index partner (participant-referred) enrollment was 30 days after the last date of community recruitment.

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

**Final Site-Reported Total Enrollment:**

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

**Status of Intervention Delivery:**

Sites continue to provide HIV and STI testing and referral as well as Peer Health Navigation to enrolled participants. Sites are finishing the last of the 6 month visits and conducting 12 month visits. Individual interviews have been completed at most sites.

**Recruitment Status:**

*All recruitment has been completed. Total enrollment was 1558.*

**Retention Status:**

Retention for the 6 month visit is at 81%.

Retention for the 12 month (exit) visit is at 75%

**Implementation Issues and Problems:**

Retention is the greatest concern in study implementation. The study teams continue to focus all efforts on improving retention and completing the study.

## 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: 03 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

Lilongwe site was activated on 24 February 2010 and began enrolling in April 2010. Enrollment is dependent on identifying acutely infected people in the CHAVI 001 study, hence enrollment is sporadic. In-depth interviews have been conducted with both of the counselors to assess their perception of the acceptability and perceived impact of the counseling.

The team will meet during the HPTN Annual Meeting to discuss possible publications, qualitative analysis, and other business.

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

Twenty-two participants have been enrolled to date. One participant was enrolled who was later found to be not acutely infected. This participant was un-enrolled and a deviation memo was submitted to DAIDS and IRB.

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

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

#### **Retention Status:**

See the SCHARP report. To date only one participant has not returned for any visits since enrollment.

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

None.

## Report for HPTN Study Operations Group

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

*Based on data available through: 01 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

Version 1.0 of the protocol was approved on 16 September 2008 and distributed to sites upon notification of approval (17 September 2008). Letter of Amendment (LoA) #1 (Zambia only) dated 12 May 2010, was approved by DAIDS on 18 May 2010. LoA #2, dated 7 December 2010, was approved by DAIDS on 9 December 2010.

The Thai site was activated on 26 March 2010 and enrolled their first participant on 01 April 2010. Enrollment was paused on 22 June 2010 due to ACASI issues discussed during the 2010 HPTN Annual Meeting. The Thai site received DAIDS approval to resume screening/enrollment activities on 08 February 2011 after the ACASI was revised. Screening and enrollment activities resumed in Thailand on 14 February 2011.

The Brazil site was activated on 30 March 2011 and enrolled their first participant on 01 April 2011.

The Zambia site was activated on 19 April 2011 and enrolled their first participant on 20 April 2011.

#### **Accrual Status:**

Below is site-reported screening and enrollment data ending 01 June 2011. Refer also to the SCHARP enrollment summary.

**Retention Status:**

Refer to the SCHARP retention summary.

**HPTN-063 Cumulative Screening and Enrollment Report****Based on Site-Reported Information***June 1, 2011*

<b>Site (Quantitative Participants)</b>	<b>Date of First Screening</b>	<b>Date of First Enrollment</b>	<b>No. Pre- Screened</b>	<b>No. Report No Unprotected Sex</b>	<b>No. Not Receiving Care</b>	<b>Total No. Screened</b>	<b>Total No. Enrolled</b>
<b>Brazil: Rio de Janeiro (IPEC CRS)</b>	01-Apr-11	01-Apr-11					
Women			30	9	0	30	12
Heterosexual Men			7	0	0	7	2
MSM			36	4	0	34	7
<b>Thailand: Chiang Mai</b>	01-Apr-10	01-Apr-10					
Women			875	0	0	75	70
Heterosexual Men			612	0	0	29	26
MSM			130	0	0	4	24
<b>Zambia: Lusaka (Metero Clinic CRS)</b>	20-Apr-11	20-Apr-11					
Women			77	11	0	4	4
Heterosexual Men			20	1	0	5	6
<b>TOTAL</b>	<b>NA</b>	<b>NA</b>	<b>1787</b>	<b>25</b>	<b>0</b>	<b>188</b>	<b>151</b>

Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Thailand (Focus Groups)	Date of Focus Group	No. of Participants
Date of Interview	17-May-10	22-Jul-10	1-Oct-10	17-May-10	Session 1	17-Jun-10	8
	22-Jul-10	15-Sep-10	6-Oct-10	19-May-10	Session 2	27-Jan-11	11
	10-Sep-10	20-Apr-11	19-Oct-10	5-Aug-10	Session 3		
	20-Sep-10		17-Nov-10	18-Mar-10	Session 4		
	24-Mar-10		2-Dec-10		TOTAL	2	19
	21-Apr-11						
	12-May-11						
TOTAL	7	3	5	4			

Brazil (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Brazil (Focus Groups)	Date of Focus Group	No. of Participants
Date of Interview					Session 1		
					Session 2		
					Session 3		
					Session 4		
					TOTAL	0	0
TOTAL	0	0	0	0			

Zambia (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	Zambia (Focus Groups)	Date of Focus Group	No. of Participants
Date of Interview	10-May-11			Session 1		
				Session 2		
				Session 3		
				Session 4		
				<b>TOTAL</b>	<b>0</b>	<b>0</b>
<b>TOTAL</b>	<b>1</b>	<b>0</b>	<b>0</b>			

**Implementation Issues and Problems:**

The Zambia site had to pause enrollment on May 13, 2011 due to delays in the approval of an ICF change from the UNZA REC. The site used this time to review participant files, correct all QCs, review qualitative interview transcripts. The site received the appropriate approval from the UNZA REC on May 16, 2011 and resumed enrollment on May 16, 2011.

## **Report for HPTN Study Operations Group**

### **HPTN 064 Women's HIV SeroIncidence Study (ISIS)**

*Based on data available through: 01 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

HPTN 064 successfully completed enrollment July 26, 2010, enrolling 2098 women. All study visits were completed on February 28, 2011.

The qualitative sites have successfully completed all qualitative interviews and focus groups. The HPTN CORE has completed preliminary coding the qualitative interviews, female focus groups and male focus groups. The HPTN 064 Qualitative Working Group held a team analysis meeting in the Durham FHI office January 24-28, 2011. Several qualitative abstracts were submitted as a result of the meeting. Two abstracts were submitted and accepted at the upcoming International AIDS Society (IAS) Conference, and one abstract was submitted and accepted for the upcoming National HIV Prevention Conference (NHPC). Core members and community members recently presented a workshop based on preliminary qualitative data at the Aids Alliance sponsored VOICES conference in May, 2011.

The team will discuss publications and analysis planning during the 2011 HPTN Annual Meeting.

Additionally, the HPTN CORE is working closely with sites, SCHARP, NIH and the Network Lab to ensure proper study close out.

#### **Accrual Status:**

Completed.

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

N/A

#### **Retention Status:**

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

#### **Implementation Issues and Problems: N/A**

## Report for HPTN Study Operations Group

### HPTN 065

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

*Based on available data through: 2 June 2011*

### Participating Study Sites:

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

#### Bronx:

Eighteen test sites (including 9 hospitals) and 20 care sites are participating in the study. The team has completed all site contracts and IRB submissions for these sites. (Note that two hospitals have been combined into one entity for randomization.)

#### Washington, DC:

Nineteen test sites (including 7 hospitals) and 19 care sites are participating in the study. The team has completed all site contracts and IRB submissions for these sites.

### Study Implementation Status:

#### Expansion of HIV testing:

- Social Mobilization: The first social mobilization ads began on November 19, 2010 in DC on social networking and dating websites and in print. The NY DOH has approved the Bronx ad. The study team and ad agency have finalized a distribution plan, and the first ads were distributed on April 1, 2011.
- Expanded Testing in Hospitals: February 1, 2011 marked the official start of the Expanded Testing component in hospitals. The majority of DC (6 out of 7) and Bronx (7 out of 9) hospitals have begun submitting HIV testing data for the study. A second face-to-face meeting is being planned in DC for the summer of 2011 and conference calls are being planned for the Bronx hospitals. An Atlas-based data collection tool is almost complete and will be used to collect expanded HIV testing data soon.

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

- The Linkage-to-Care component began on April 1, 2011 for DC and Bronx test sites. To date, all but one test site in DC have been activated; 55% of Bronx test sites and 70% of DC test sites have begun dispensing coupons. As of June 2, 2011, a total of 35 coupons (10 in the Bronx and 25 in DC) have been dispensed.
- The Linkage-to-Care component began on April 1, 2011 for all DC and Bronx care sites. To date, 15% of the care sites in the Bronx have handed out 9 \$25 gift

cards and 7 \$100 gift cards. Forty-two percent of the care sites in DC have handed out 24 \$25 gift cards and 12 \$100 gift cards.

- The Viral Suppression component began at 10 DC care sites on February 1, 2011. The first gift card for viral suppression was distributed on February 9, 2011. The VS component began on March 1, 2011 at one Bronx care site and on April 1, 2011 at the remaining DC and Bronx care sites. To date, all DC and Bronx care sites have been activated; 50% of Bronx sites and 88% of DC sites have begun dispensing gift cards. As of June 2, 2011, a total of 673 (477 in DC and 196 in the Bronx) gift cards have been dispensed for VS.

#### Prevention for Positives (PfP):

- The team is in the process of selecting a subset of care sites to participate in the PfP component. To date, 12 sites have officially been invited, and 11 have officially agreed to participate in this component (6 in NY and 5 in DC). The team is negotiating with one additional site in DC.
- The team is proceeding with contract and IRB approval processes for the 11 sites that have already been selected for PfP.

#### Patient and Provider Surveys:

- The Provider Survey closed on May 2, 2011. The final response rate for this baseline survey was 60%, 53% in the Bronx and 71% in DC. The protocol team discussed the baseline data at the protocol team meeting at the HPTN annual meeting on June 7, 2011.

#### Site and DOH Surveys:

- A "first wave" of implementation of the care site survey was completed with 3 sites in the Bronx and 3 sites in DC in April 2011. Feedback from sites is being incorporated into the survey and the survey will be rolled out to all care sites by July 2011.
- Programming of the test site survey by SCHARP is complete; feedback from subgroup members is currently being incorporated into the survey. The test site survey is expected to be implemented beginning with a small group of test sites in July 2011.
- Programming of the DOH survey by SCHARP is still in progress. DOH surveys will be implemented on a rolling basis once programming is completed.

#### Training Update:

- Study operational trainings for all test and care sites in D.C and the Bronx randomized to the SOC Care arm, Financial Incentive Care arm, and Financial Incentive test arm, were held between January, 2011 and March, 2011. In total, 12 operational trainings were held in order to train all sites.
- Additional Live Meeting web-based trainings have been held for one site in DC and two sites in the Bronx for site staff who were not able to attend the previous trainings or who have been newly hired at sites.
- An additional in-person training was held for one DC site for site staff who were not able to attend the previous training.
- HIV test sites in both DC and the Bronx randomized to the SOC arm will receive a live, web-based study training in July or August, 2011 (contingent on the completion of the HIV Test Site Survey).

Reviews:

- The study team presented the overall study design to the Prevention Trials Data Safety and Monitoring Board (DSMB) on December 9, 2010. The DSMB provided written comments and questions to the team. Responses to the comments from this DSMB review were submitted to the committee on May 2, 2011. The next DSMB review is scheduled of November 15, 2011.
- HPTN 065 was reviewed by the HPTN PMG on February 2, 2011. The review focused on the Monitoring Plan that is under development.
- The study team has decided to undergo an SMC review which will be planned for late 2011.

Protocol:

- A clarification memo (CM #1 to V2.0 of the protocol) was submitted to David Burns at DAIDS on May 31, 2011 to correct some minor issues in the Prevention for Positives informed consent form. DAIDS is currently reviewing the document.

**Accrual Status:** N/A

**Retention Status:** N/A

**Implementation Issues and Problems:**

None

## 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: 2 June 11*

#### Participating Study Sites:

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

#### Study Implementation Status:

Version 2.0 of the protocol was granted final approval on 29 November 2010 and was distributed to the sites 1 December 2010. Letter of Amendment (LoA) #1 to HPTN 066, Version 2.0 was approved by DAIDS on 16 December 2010. A clarification memo was drafted in May to address inclusion criteria and lab samples.

UNC activated on 21 January 2011 and has enrolled 14 participants. JHU activated on 17 February 2011 and has enrolled 9 participants.

#### Accrual Status:

	UNC	JHU
<b>Date First Screened</b>	24-Jan-2011	21-Feb-2011
<b>Date First Enrolled</b>	7-Feb-2011	28-Feb-2011
<b># Individuals Screened</b>	21	30
<b># Individuals Enrolled</b>	16	13

#### Retention Status:

Refer to the SCHARP retention summary.

#### Implementation Issues and Problems:

- None at this time

## Report for HPTN Study Operations Group

### HPTN 067

#### The ADAPT study:

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

*Based on data available through June 13, 2011*

#### Participating Study Sites:

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

#### Study Implementation Status:

Version 2.0 of the protocol dated February 18, 2011 received final RAB chief sign-off February 21<sup>st</sup> and was distributed to the team that same day. This full amendment was needed to incorporate the recent iPrEx results into the template Informed Consent Forms as well as other minor corrections and modifications.

The CASI, CRFs and Weekly Interview Guide are finalized. The CASI is in the process of being translated into Xhosa and the Thai version is being revised. The team has requested an additional CRF that is currently being drafted. Other implementation materials (including counseling materials and the SSP) are currently being drafted or under review. The Wisepill devices have been manufactured and are available for sites.

The Cape Town site submitted the protocol and Informed Consent Forms (ICFs) for both initial local IRB review and Medicines Control Council (MCC) review in November. The local IRB approved version 2.0 of the protocol on 30 March 2011. The local language version of the Informed Consent Forms was approved 20 May 2011. MCC approval was obtained 24 May 2011. The team has requested a revised letter from the MCC including the protocol version date and number. Once this letter is obtained, the site intends to apply for protocol registration. The site is currently working on meeting all data, lab, pharmacy and administrative site activation requirements. The study specific training is set for 25-29 July 2011 in Cape Town. Study drug has been requested from Gilead and will be shipped to Clinical Research Products Management Center (CPRMC).

The Bangkok site has submitted for Thai MOPH review and began the CDC Scientific Review process which will be followed by CDC IRB review. The site is hoping to obtain approvals from both the Thai MOPH IRB and the CDC by the summer. The site is currently working on meeting all data, lab, pharmacy and administrative site activation requirements.

The Clinical Trial Agreement between Gilead and DAIDS was approved by both parties 29 March 2011. Study drug is anticipated to arrive in Cape Town (pending protocol registration) in July.

**Accrual Status:**

Pending, no sites have been activated.

**Status of Intervention Delivery:**

Pending, no sites have been activated.

**Retention Status:**

Pending, no sites have been activated.

**Implementation Issues and Problems:**

None.

## Report for HPTN Study Operations Group

### HPTN 068

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

*Based on data available through: 14 June 2011*

#### **Participating Study Sites:**

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

#### **Study Implementation Status:**

Enrollment commenced 5 March 2011. The site has been increasing enrollment each week, just recently completing its 14th week of enrollment.

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

825 of 2,900 enrolled

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

No issues

#### **Retention Status:**

Not applicable.

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

None.

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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 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	Closed 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
<b>HPTN 067</b>	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	71,589	DAIDS	In Development