



## **HPTN Study Operations Report**

**September 2011**

**PTN Executive Summary Report**  
**14 September 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	156	99%	7.8	20	closed
	Total		347	349	101%	8.8	39.7	
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

**PTN Executive Summary Report  
14 September 2011  
Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
	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	221	101%	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

**PTN Executive Summary Report**  
**14 September 2011**  
**Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1694	102%	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	480	402	84%	33.1	12.1	90%
	China – Nanning	19May2010	263	153	58%	16.1	9.5	82%
	China – Xinjiang	23Dec2008	555	466	84%	33.2	14	90%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	1223	82%	52.3	23.4	
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	27	59%	16.9	1.6	77%

**PTN Executive Summary Report**  
**14 September 2011**  
**Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
	Total		46	27	59%	16.9	1.6	
063 (Part 1)	Thailand – Chiang Mai	01Apr2010	61	61	100%	3	20.3	completed
	Total		61	61	100%	3	20.3	
063 (Part 2)	Brazil – Rio de Janeiro	06Apr2011	300	46	15%	5.4	8.5	41%
	Thailand – Chiang Mai	21Feb2011	239	120	50%	6.8	17.6	47%
	Zambia – Lusaka – Matero Clinic	28Apr2011	200	69	35%	4.6	15	38%
	Total		739	235	32%	6.8	34.6	
064 (Women)	US – Atlanta	22Oct2009	200	215	108%	7	30.7	completed
	US – Baltimore	05Aug2009	200	210	105%	8.7	24.1	completed
	US – Chapel Hill	26May2009	200	210	105%	8.7	24.1	completed
	US – Decatur	27Aug2009	200	211	106%	11.1	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	19	119%	6.6	2.9	325%
	US – Chapel Hill	07Feb2011	16	19	119%	7.3	2.6	267%
	Total		37	38	103%	7.3	5.2	
068	South Africa – Bushbuckridge – MRC/Wits	05Mar2011	2900	1670	58%	6.4	260.9	18%
	Total		2900	1670	58%	6.4	260.9	

**PTN Executive Summary Report**  
**14 September 2011**  
**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	156	1727	1611	1639	93%	95%
	Total	349	3850	3608	3654	94%	95%
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	408	2448	2105	2298	86%	94%
	Tanzania – Dar Es Salaam	218	1308	1145	1228	88%	94%
	Uganda – Mulago Hospital	545	3270	3088	3070	94%	94%
	Zimbabwe – Harare/Chitungwiza	507	3042	2800	2856	92%	94%
	Total	1678	10068	9138	9453	91%	94%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4499	4183	4268	93%	95%
	Tanzania – Dar Es Salaam	219	2409	2185	2285	91%	95%
	Uganda – Mulago Hospital	562	6182	6018	5864	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5610	5291	5322	94%	95%
	Total	1700	18700	17677	17739	95%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	702	678	690	97%	98%
	Brazil – Porto Alegre	90	1161	1138	1129	98%	97%
	Brazil – Rio de Janeiro	184	2601	2555	2521	98%	97%
	India – Chennai – YRGCare	250	3423	3052	3322	89%	97%
	India – Pune	175	2379	2348	2307	99%	97%
	Kenya – Kisumu	60	473	467	466	99%	99%
	Malawi – Blantyre – Queen Elizabeth Central	230	2685	2514	2618	94%	97%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	3065	2823	2984	92%	97%
	South Africa – Johannesburg – Witwatersrand	46	507	488	496	96%	98%
	South Africa – Soweto	50	409	394	403	96%	99%
	Thailand – Chiang Mai	106	1463	1447	1417	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2832	2662	2760	94%	97%
	Total	1759	21700	20566	21112	95%	97%

**PTN Executive Summary Report**  
**14 September 2011**  
**Retention Summary**

<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>	
052 Combined (Partners)	Botswana – Gabarone	77	702	647	690	92%	98%	
	Brazil – Porto Alegre	93	1161	1066	1129	92%	97%	
	Brazil – Rio de Janeiro	188	2601	2147	2521	83%	97%	
	India – Chennai – YRGCare	250	3423	2752	3322	80%	97%	
	India – Pune	175	2379	2296	2307	97%	97%	
	Kenya – Kisumu	60	473	453	466	96%	99%	
	Malawi – Blantyre – Queen Elizabeth Central	232	2685	2160	2618	80%	97%	
	Malawi – Lilongwe – Lilongwe Central Hospital	255	3065	2446	2984	80%	97%	
	South Africa – Johannesburg – Witwatersrand	46	507	450	496	89%	98%	
	South Africa – Soweto	50	409	366	403	89%	99%	
	Thailand – Chiang Mai	107	1463	1320	1417	90%	97%	
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2832	2335	2760	82%	97%	
	<b>Total</b>		<b>1773</b>	<b>21700</b>	<b>18438</b>	<b>21112</b>	<b>85%</b>	<b>97%</b>
	057 (Mothers)	Brazil – Belo Horizonte	12	68	68	66	100%	97%
Brazil – Porto Alegre – Conceicao		10	58	56	56	97%	97%	
Brazil – Porto Alegre – Santa Casa		15	88	86	85	98%	97%	
Brazil – Rio de Janeiro		13	77	77	74	100%	97%	
Malawi – Blantyre – Queen Elizabeth Central		72	432	421	417	97%	97%	
<b>Total</b>			<b>122</b>	<b>723</b>	<b>708</b>	<b>699</b>	<b>98%</b>	<b>97%</b>
057 (Infants)	Brazil – Belo Horizonte	12	80	80	77	100%	96%	
	Brazil – Porto Alegre – Conceicao	10	68	66	65	97%	96%	
	Brazil – Porto Alegre – Santa Casa	15	102	99	98	97%	96%	
	Brazil – Rio de Janeiro	13	90	90	86	100%	96%	
	Malawi – Blantyre – Queen Elizabeth Central	72	504	487	484	97%	96%	
	<b>Total</b>		<b>122</b>	<b>844</b>	<b>822</b>	<b>811</b>	<b>97%</b>	<b>96%</b>
058	China – Guangxi – Heng County	402	905	746	806	82%	89%	
	China – Nanning	153	116	98	108	84%	93%	
	China – Xinjiang	466	1030	864	914	84%	89%	
	Thailand – Chiang Mai University	202	980	861	834	88%	85%	
	<b>Total</b>		<b>1223</b>	<b>3031</b>	<b>2569</b>	<b>2661</b>	<b>85%</b>	<b>88%</b>

**PTN Executive Summary Report**  
**14 September 2011**  
**Retention Summary**

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	116	216	170	199	79%	92%
	US – Boston	237	414	310	382	75%	92%
	US – Decatur	184	334	229	308	69%	92%
	US – Los Angeles	283	464	369	428	80%	92%
	US – NY – Harlem Prevention Center	154	298	274	274	92%	92%
	US – NY – New York Blood Center	156	284	238	261	84%	92%
	US – San Francisco	204	378	297	348	79%	92%
	US – Washington DC	227	400	341	369	85%	92%
	Total	1561	2788	2228	2570	80%	92%
062	Malawi – Lilongwe – Lilongwe Central Hospital	27	216	207	212	96%	98%
	Total	27	216	207	212	96%	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	19	126	110	125	87%	99%
	US – Chapel Hill	19	127	123	126	97%	99%
	Total	38	253	233	251	92%	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 September 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 notes to file (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. Shipping lists for resistance testing samples have been sent to the sites. Samples from Tanzania, South Africa, and Uganda have been received at the NL. Shipment of samples from Zimbabwe is being prepared.
2. 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 all sites have now been received at the HPTN Network Lab.

3. 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. SP version - 1.6 dated 9 Jan 09
3. Enrollment Status - Closed
4. Date of last SMC call – March 2011
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report:
6. Lab-related NTF/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. Previously reported
  - h. IPEC - RNA run needed to be re-read due to incorrect global id numbers entered. Previously reported
  - i. Botswana – Plasma samples not stored. Previously reported
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 is completing the last instrument validation for Model Colony. 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. Have submitted their LDMS reconciliations, submitted their QC for review, and submitted their inventory.
3. Chennai – Have submitted their LDMS queries, did not submit their QC for review, but submitted their inventory
4. Blantyre – Have submitted their LDMS reconciliations, did submit their QC for review, and submitted their inventory
5. Porto Alegre - Have submitted their LDMS reconciliations, submitted their QC for review and submitted their inventory.
6. Rio sites – Have submitted their LDMS reconciliations, have submitted their QC for review, and did submit their inventory.
7. Lilongwe - Have submitted their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai – Did not have any LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg, WITs – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory

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

**C. Shipping / QA Status**

Pending a shipment from NARI Pune and YRGcare.

**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.
6. Lab-related notes to file/deviations issued since preparation of SMC report - None

**B. Site Specific**

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

**C. Shipping / QA Status**

All requested shipments have been received.

**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 notes to file/deviations issued since preparation of SMC report - None

**B. Site Specific**

1. Thailand - Site completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory.
2. Xinjiang Site - Site completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.

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

**C. Shipping / QA Status**

No outstanding shipments or requests. NL has performed QA testing at the site labs using USA FDA-approved methodologies. Results are being compiled for submission to SCHARP.

**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 PID for which a tube was received with no rectal swab in it. NTF received for PID who was so difficult to stick no blood obtained, only rectal swab and urine collected. Previously reported NTF received for rectal swab misplaced by lab. Previously reported NTF received for 2 PIDs, one who did not return for 2<sup>nd</sup> WB; one who did after 4 weeks at 6-months visit. Previously reported NTFs 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 – Previously reported NTF 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 - NTF for flood in Ross Hall and freezer move pending. 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 reported 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 two NTFs received for 2 PIDs who refused sample collection. 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 - NTF received for PID due to difficult stick at 2 visits had no plasma stored. Previously reported Protocol Deviation submitted for specimen mix-up with a HVTN 505 participant and a HPTN 061 participant. 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 - Had flood in location of freezer; samples not compromised.
3. San Francisco - No new updates.
4. Harlem - No new updates
5. Atlanta - Investigation of rectal swab mislabel on going.
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. NL investigating discrepant QA results from 2<sup>nd</sup> set of QA 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 1.1 dated 4<sup>th</sup> August 2011
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 NTFs/protocol deviations issued since preparation of SMC report – Zambia - Previously reported protocol deviation received for lab SOP and SSP not being followed for plasma processing.

**B. Site Specific**

1. Thailand - No new updates
2. Brazil- No new updates.
3. Zambia - No new updates

**VII. HPTN 064****A. General Comments**

1. Protocol Version - 1.0 dated 09 July 2008
2. SSP Version - 2.0 dated 12 May 2010
3. Enrollment Status - All sites have completed enrollment.
4. Date of last SMC call - 01 November 2010
5. 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. Johns Hopkins University - NTF received; confirmatory WB was sent to the incorrect lab and was not completed. Previously reported April study ops. NTF received; plasma wasn't stored for a participant due to a lab accident. Previously reported November study ops.
  - b. Emory - NTF received; plasma wasn't stored within the allotted timeframe. Previously reported. NTF and protocol deviation received; site enrolled a participant who used falsified information. Previously reported December study ops.
  - c. Harlem - NTF received for incorrect PID and VID entered into LDMS on two participants. Previously reported March study ops.
  - d. GWU - NTF regarding the flood in Ross Hall and the freezer move is pending. NTF received for 6-month participant was mistakenly extended to 12 month. 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 are being tested.

**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 – 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 Communiqué #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 - None.

**C. Shipping / QA Status**

1. A QA list for the JHU site has been prepared by SCHARP. NL is in the process of preparing these samples for testing.
2. A QA list for the UNC site will be prepared after enrollment has been completed.

**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 notes to file/deviations issued since preparation of SMC report -
  - a. NTF received for PID with no 10ml tube collected. Previously reported in August study ops.
  - b. Protocol deviation received for specimen mix-up.
  - c. Protocol deviation received for extra WBs collected.
  - d. NTF received for PIDs with less than 4 plasma aliquots stored.
  - e. Protocol deviation received--site did not follow the testing algorithm.

- f. NTF pending - for site not documenting invalid rapid test results.
- g. NTFs received for PIDs with less than 4 plasma aliquots stored. Previously reported August, July, June, May and April study ops.

**B. Site Specific**

**C. Shipping /QA status**

The NL requested a 100% QC of all samples collected. The samples were shipped and received in the NL.

**NL updates**

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

**Travel Updates**

Estelle will be attending the Cape Town HPTN 067 training and the Bangkok HPTN 067 training in September.

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

### **058**

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

### **061**

The site teams are focused on completing last visits and the study team as a whole is working on communications plans, which will include results dissemination plans. The study team decided that 09 Dec 2011 is the final date possible for follow up in 061, but individual sites may choose an earlier date for themselves if necessary.

### **063**

Sites identified challenges recruiting men into HPTN 063 for various reasons. During the full team meeting at the 2011 HPTN Annual Meeting, the sites and protocol team explored different avenues of recruiting men in HPTN 063 and have proposed new recruitment methods. The protocol team has increased calls to bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. The HPTN 063 Protocol Team is also considering proposed changes to relax the HPTN 063 eligibility criteria to help in recruitment efforts. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs are distributed to the full protocol team and closely monitored.

### **068**

After an assessment visit at the end of July, there were irregularities noted in the informed consent documentation. Since that time, the site, the CTU, FHI 360 and DAIDS have worked in concert to ameliorate the issue. The site has worked to perform a 100% ICF QC, which should be completed by 16 September. The CTU has sent staff to the site to help in the QC and to work with the site to help improve their study process.

## 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 September 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 sites have completed follow-up.

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

Database lock will occur after all QCs have been addressed. Secondary manuscripts are being considered.

#### **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:**

NA

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

NA

## Report for HPTN Study Operations Group

### HPTN 052

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

*Based on available data through: 9 September 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 have submitted 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.

The team is discussing an amendment to the study for continued follow up of currently enrolled couples. Details are being considered.

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: 12 September 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 – Serviço de Doenças Infecciosas, Rio de Janeiro (HSD)
  - Hospital Nossa Senhora da Conceicao Serviço 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. Analysis of cohort 4 pk data is underway and is expected to be completed in summer of 2011. An abstract with Cohort 4 data will be submitted to CROI for March 2012 with the manuscript including data from Cohorts 1 – 4 published shortly after.

#### 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 13 September 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 466 participants. Heng County has enrolled 402 participants. Nanning has enrolled 153 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.

The latest SMC review took place on 2 September. They encouraged the sites to continue efforts of recruiting a higher risk population.

The JWG will be held in Beijing in early November and will also review data regarding high risk recruitment and retention.

DSMB call is scheduled for the end of September

#### 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 Screened</b>	281	349	846	863
<b># Individuals Enrolled</b>	202	153	402	466

#### 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	83%
Week 130	78%
Week 156	85%

**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: 12 September 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 are following participants.

Site	Date of Activation	Date of First Enrollment	Date of Completion of Community Recruitment
The Fenway Institute	06 July 2009	17 July 2009	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 focused on trying to bring in their last participants for 12 month visits over the next couple of months, if possible. All qualitative data collection and coding have been completed.

**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 79%

**Implementation Issues and Problems:**

The site teams are focused on completing last visits and the study team as a whole is working on communications plans, which will include results dissemination plans. The study team decided that 09 Dec 2011 is the final date possible for follow up in 061, but individual sites may choose an earlier date for themselves if necessary.

## **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: 06 September 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.

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

Twenty-seven 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. One social harm has been reported to FHI360 as well at the IRB.

### **Retention Status:**

See the SCHARP report.

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

None.

## Report for HPTN Study Operations Group

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

*Based on data available through: 07 September 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. LoA #3, dated 6 July 2011, was approved by DAIDS on 20 July 2011.

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 02 September 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

*September 02, 2011*

Site (Quantitative Participants)	Date of First Screening	Date of First Enrollment	No. Pre- Screened	No. Report No Unprotected Sex	No. Not Receiving Care	Total No. Screened	Total No. Enrolled
<b>Brazil: Rio de Janeiro (IPEC CRS)</b>	01-Apr-11	01-Apr-11					
Women			156	6	0	114	26
Heterosexual Men			71	3	0	37	5
MSM			76	8	0	52	16
<b>Thailand: Chiang Mai</b>	01-Apr-10	01-Apr-10					
Women			1211	0	0	106	99
Heterosexual Men			1244	2	0	52	45
MSM			225	0	0	37	36
<b>Zambia: Lusaka (Metero Clinic CRS)</b>	20-Apr-11	20-Apr-11					
Women			195	1	0	50	47
Heterosexual Men			64	1	0	21	20
<b>TOTAL</b>	<b>N/A</b>	<b>N/A</b>	<b>3242</b>	<b>21</b>	<b>0</b>	<b>469</b>	<b>294</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	14-Jul-11	17-Nov-10	18-Mar-10	Session 4		
	24-Mar-10		2-Dec-10	31-May-11	TOTAL	2	19
	21-Apr-11			26-Jun-11			
	12-May-11			3-Aug-11			
	23-Aug-11						
TOTAL	8	4	5	7			

Brazil (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Brazil (Focus Groups)	Date of Focus Group	No. of participants
Date of Interview				18-Jul-11	Session 1		
					Session 2		
					Session 3		
					Session 4		
					TOTAL	0	0
TOTAL	0	0	0	1			

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:**

Sites identified challenges recruiting men into HPTN 063 for various reasons. During the full team meeting at the 2011 HPTN Annual Meeting, the sites and protocol team explored different avenues of recruiting men in HPTN 063 and have proposed new recruitment methods. The protocol team has increased calls to bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. The HPTN 063 Protocol Team is also considering proposed changes to relax the HPTN 063 eligibility criteria to help in recruitment efforts. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs are distributed to the full protocol team and closely monitored.

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

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

*Based on data available through: 07 September 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 2099 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 and presented as a result of the meeting:

- HPTN Core members and community members presented a workshop based on preliminary qualitative data at the Aids Alliance sponsored VOICES conference in May, 2011.
- Members from the HPTN 064 Protocol Team presented an oral presentation and a poster at the 6th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Rome in July, 2011.
- Members from the HPTN CORE presented an oral presentation at the 2011 National HIV Prevention Conference in Atlanta, GA in August, 2011.

The HPTN 064 Protocol Team is planning a one day face to face meeting on September 26, 2011 to discuss the primary analysis and future publications.

Data analysis and laboratory assessments are currently underway.

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: 9 September 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. (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.

### 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 social mobilization campaign began on April 1, 2011. Ads have been placed on dating sites, community blogs, and printed in magazines that target MSM.
- Posters in both English and Spanish were developed for distribution in the Bronx. Sites have begun placing ads in their clinics and around the Bronx.
- Appointment cards to encourage testing twice a year have been developed by the ad agency in DC and will be distributed by the DC DOH. As well, promotional items, such as water bottles, are being explored to further promote HIV testing.
- Expanded Testing in Hospitals: February 1, 2011 marked the official start of the Expanded Testing component in hospitals. All DC and the majority of Bronx (8 out of 9) hospitals have begun submitting HIV testing data for the study. A second face-to-face meeting took place on July 27, 2011 in DC, and a second round of conference calls has been held with all 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 test sites in DC and the Bronx have been activated; 60% of Bronx test sites and 100% of DC test sites have begun dispensing coupons. All care sites in the Bronx and DC have been activated to redeem coupons for gift cards.
- The Viral Suppression component began at 10 DC care sites on February 1, 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, and all have begun dispensing gift cards.

#### Prevention for Positives (PfP):

- A subset of 12 care sites (6 in NY and 6 in DC) have been invited and officially agreed to participate in the PFP study component. The team is proceeding with contract and IRB approval processes for the 12 sites. To date, 3 sites in DC have received IRB approval for this component.
- The anticipated start date for this component is late fall, 2011.

#### 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. A draft manuscript presenting these data is currently being reviewed by the study team.

#### Site and DOH Surveys:

- Programming of the test and care site surveys by SCHARP has been completed.
- All care sites and all test sites that have previously attended a TLC-Plus training have been invited to take the test and/or care site survey. Five sites in DC and 3 sites in the Bronx function as Standard of Care (SOC) Test Sites only, and have not as of yet attended any TLC-Plus training. Phone-based trainings for these sites are being planned now; the survey will be opened for these sites after they have attended a training which will cover how to access and complete the surveys.
- SCHARP has decided not to program the DOH survey using Atlas, but instead is in the process of developing a fillable pdf document to send to DOHs. DOH surveys will be implemented on a rolling basis once the document is finalized.

#### Training Update

- All sites, with the exception of SOC-only test sites, have been provided an operational training. The study team is providing refresher trainings for sites and new staff members via phone or in person, as needed or requested.
- A phone-based training for SOC-only test sites is currently being planned to take place at the end of September.

#### Reviews:

- The next DSMB review is tentatively scheduled for November 15, 2011.
- The study team has decided to undergo an SMC review which will be planned for late 2011.

#### Manuscripts under development:

- Clinician Practices and Attitudes Regarding Early Antiretroviral Therapy in the US - paper analyzing the baseline results of the provider survey: A. Kurth, K. Mayer, G. Beauchamp, L. McKinstry, J. Farrior, K. Buchacz, D. Donnell, B. Branson, W. El-Sadr for the HPTN 065 (TLC-Plus) Study Team
- Use of HIV Case Surveillance System to design and evaluate site-randomized interventions in an HIV prevention study: HPTN 065 (TLC-Plus Study): D. Donnell, I. Hall, T. Gamble, G. Beauchamp, A. Griffin, L. Torian, B. Branson, W. El-Sadr for the HPTN 065 (TLC-Plus) Study Team

Presentations:

- TLC-Plus: Design and Implementation of a Community-focused HIV Prevention Study in the U.S., El-Sadr, WM, Branson, BM, Donnell, D, Hall, HI, and King, GM. 2011 National HIV Prevention Conference, Aug. 14 - 17, 2011, Atlanta, GA.
- Using HIV Surveillance Data to Evaluate Outcome of Site Randomized Interventions in the TLC-Plus Study, Donnell, DJ, Hall HI, Yujiang Jia, Griffin, AB, Brady, KA, Grigg, RL, Sayegh, MA, Torian, LV and Wafaa El Sadr. 2011 National HIV Prevention Conference, Aug. 14 - 17, 2011, Atlanta, GA.

**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: 8 September 11*

#### Participating Study Sites:

- Johns Hopkins University (JHU), Baltimore MD; USA
- University of North Carolina at Chapel Hill (UNC), 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. Clarification Memo #1 to HPTN 066, Version 2.0 was approved by DAIDS on 15 June 2011.

UNC activated on 21 January 2011 and enrolled a total of 19 participants. 18 evaluable participants from UNC have completed the study so far. The final participant (#19) was enrolled at UNC on 30 August 2011. Follow-up should be complete on 18 October 2011. JHU activated on 17 February 2011 and enrolled a total of 19 participants. 13 evaluable participants from JHU completed the study. Accrual and follow-up activities have ended at JHU.

#### 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>	27	31
<b># Individuals Enrolled</b>	19	19
<b>Final # of evaluable participants</b>	18*	13

\* Note: There is one remaining participant in follow-up at UNC.

#### 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 September 12, 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:

The Cape Town site activated on 29 August and enrolled their first participant on 12 September.

The Bangkok site training visit is being held 13-16 September. The Thai ERC reviewed the protocol and granted approval with a few minor changes. The site is waiting to receive the approval letter from the Thai ERC to Protocol Version 1.0. CDC IRB review is scheduled for early September. The site is hoping to obtain approval from the CDC for this version in September. The team will then be able to finalize Protocol Version 3.0 in order to submit through the Thai review process, with activation anticipated in late 2011/ early 2012.

#### Accrual Status:

	Cape Town	Bangkok
<b>Date First Screened</b>	31-Aug-2011	
<b>Date First Enrolled</b>	12-Sept-2011	
<b># Individuals Screened</b>	10	
<b># Individuals Enrolled</b>	3	

#### Status of Intervention Delivery:

Pending

#### Retention Status:

Pending

#### 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 September 2011*

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

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

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

Through 27 weeks of enrollment the site has enrolled 1,666 young women. 53 young women have been found to be HIV positive and 76 are HSV-2 positive.

The South African Department of Education has ruled that no HIV testing can be completed on school property. The site is holding all its weekend camps at the Agincourt Labs for the time being until a new venue can be identified. In the short term this is beneficial as most of the recruiting is being completed close to the Agincourt Labs, but it would be better that the site find a more centralized location by the time follow-up commences.

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

1,666 of 2,900 enrolled. 2,660 negative young women need to be enrolled onto the study.

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

No issues. The cash transfers are properly being made to the accounts of the young women and their parents.

#### **Retention Status:**

Not applicable.

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

After an assessment visit at the end of July, there were irregularities noted in the informed consent documentation. Since that time, the site, the CTU, FHI 360 and DAIDS have worked in concert to ameliorate the issue. The site has worked to perform a 100% ICF QC, which should be completed by 16 September. The CTU has sent staff to the site to help in the QC and to work with the site to help improve their study process.

---

# Appendix: HPTN Protocols and INDs

---

<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	Open to Accrual