



## **HPTN Study Operations Report**

**May 2010**

**PTN Executive Summary Report**  
**12 May 2010**  
**Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
046 V2 (Mothers)	Uganda – Mulago Hospital	08Feb2007	190	190	100%	8.2	23.2	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	347	100%	8.8	39.4	
046 V2 (Infants)	Uganda – Mulago Hospital	08Feb2007	190	193	102%	8.2	23.5	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	350	101%	8.8	39.8	
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	408	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	218	81%	10	21.8	closed
	Uganda – Mulago Hospital	23Jun2008	500	545	109%	19.2	28.4	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	507	101%	20.5	24.7	completed
	Total		1670	1678	100%	20.5	81.9	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	409	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	219	81%	10	21.9	closed
	Uganda – Mulago Hospital	23Jun2008	500	562	112%	19.2	29.3	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	510	102%	20.5	24.9	completed
	Total		1670	1700	102%	20.5	82.9	
052 Run-in (Indexes)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	10	100%	6.9	1.4	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
Total		86	82	95%	18	4.6		
052 Run-in (Partners)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed

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	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gabarone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	59	100%	5.4	10.9	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	219	100%	26.6	8.2	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	49	100%	10.2	4.8	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1678	101%	34.3	48.9	
052 Full Study (Partners)	Botswana – Gabarone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	87	104%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	173	103%	29.4	5.9	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	05Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	219	100%	27.3	8	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	49	123%	10.2	4.8	completed
	Thailand – Chiang Mai	11Oct2007	98	97	99%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1688	101%	34.7	48.6	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	33.6	0.2	completed

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	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	23.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	32.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	25.2	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	58	82%	41.1	1.4	completed
	Total		80	91	114%	41.1	2.2	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	8	67%	33.6	0.2	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	5	63%	23.2	0.2	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	13	87%	32.2	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	7	88%	25.2	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	58	82%	41.1	1.4	completed
Total		80	91	114%	41.1	2.2		
058	China – Guangxi – Heng County	24Dec2008	400	234	59%	16.8	13.9	46%
	China – Nanning	–	350	–	–	0	–	
	China – Xinjiang	23Dec2008	490	250	51%	16.8	14.9	46%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	686	46%	35.9	19.1	
061	US – Atlanta	26Feb2010	201	19	9%	2.5	7.6	24%
	US – Boston	17Jul2009	403	140	35%	10	14	56%
	US – Decatur	16Sep2009	202	118	58%	7.9	14.9	50%
	US – Los Angeles	30Sep2009	403	159	39%	7.5	21.2	49%
	US – NY – Harlem Prevention Center	08Jan2010	201	92	46%	4.1	22.4	35%
	US – NY – New York Blood Center	01Oct2009	202	88	44%	7.4	11.9	49%
	US – San Francisco	13Aug2009	403	146	36%	9.1	16	54%
	US – Washington DC	28Jul2009	403	137	34%	9.6	14.3	55%
Total		2418	899	37%	10	89.9		
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	2	4%	0.5	4	
	Total		46	2	4%	0.5	4	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	17	6%	1.4	12.1	11%
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	17	2%	1.4	12.1	

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<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>
064 (Women)	US – Atlanta	22Oct2009	200	199	100%	6.7	29.7	110%
	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	143	72%	8.6	16.6	140%
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	165	83%	6.6	25	113%
	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	1978	99%	11.7	169.1
064 (Men)	US – Decatur	10Mar2010	30	26	87%	2.1	12.4	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	12	40%	0.4	30	
	US – Washington DC	02Nov2009	30	28	93%	6.4	4.4	424%
	Total			120	120	100%	7.5	16

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**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>
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	1861	1644	1787	88%	96%
	Tanzania – Dar Es Salaam	218	881	811	856	92%	97%
	Uganda – Mulago Hospital	545	2418	2304	2325	95%	96%
	Zimbabwe – Harare/Chitungwiza	507	2315	2164	2221	93%	96%
	Total	1678	7475	6923	7189	93%	96%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	3769	3517	3625	93%	96%
	Tanzania – Dar Es Salaam	219	1892	1749	1831	92%	97%
	Uganda – Mulago Hospital	562	5039	4907	4850	97%	96%
	Zimbabwe – Harare/Chitungwiza	510	4693	4439	4510	95%	96%
	Total	1700	15393	14612	14816	95%	96%
052 Combined (Indexes)	Botswana – Gabarone	77	262	254	260	97%	99%
	Brazil – Porto Alegre	90	662	651	651	98%	98%
	Brazil – Rio de Janeiro	184	1600	1573	1568	98%	98%
	India – Chennai – YRGCare	250	2063	1908	2025	92%	98%
	India – Pune	175	1421	1410	1392	99%	98%
	Kenya – Kisumu	59	115	110	115	96%	100%
	Malawi – Blantyre – Queen Elizabeth Central	229	1409	1333	1388	95%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	1698	1600	1670	94%	98%
	South Africa – Johannesburg – Witwatersrand	46	250	241	247	96%	99%
	South Africa – Soweto	49	118	108	118	92%	100%
	Thailand – Chiang Mai	106	882	871	863	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1481	1415	1458	96%	98%
	Total	1756	11961	11474	11754	96%	98%
052 Combined (Partners)	Botswana – Gabarone	77	262	240	260	92%	99%
	Brazil – Porto Alegre	92	662	631	651	95%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
	Brazil – Rio de Janeiro	186	1601	1367	1569	85%	98%
	India – Chennai – YRGCare	250	2063	1785	2025	87%	98%
	India – Pune	175	1421	1377	1392	97%	98%
	Kenya – Kisumu	60	115	106	115	92%	100%
	Malawi – Blantyre – Queen Elizabeth Central	230	1408	1190	1387	85%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	1698	1465	1670	86%	98%
	South Africa – Johannesburg – Witwatersrand	46	250	227	247	91%	99%
	South Africa – Soweto	49	118	108	118	92%	100%
	Thailand – Chiang Mai	107	882	804	863	91%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	1481	1274	1458	86%	98%
	Total	1767	11961	10574	11754	88%	98%
057 (Mothers)	Brazil – Belo Horizonte	8	48	48	46	100%	97%
	Brazil – Porto Alegre – Conceicao	5	30	30	29	100%	97%
	Brazil – Porto Alegre – Santa Casa	13	78	76	75	97%	97%
	Brazil – Rio de Janeiro	7	42	42	41	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	58	336	325	325	97%	97%
	Total	91	534	521	516	98%	97%
057 (Infants)	Brazil – Belo Horizonte	8	56	56	54	100%	96%
	Brazil – Porto Alegre – Conceicao	5	35	35	34	100%	96%
	Brazil – Porto Alegre – Santa Casa	13	91	89	87	98%	96%
	Brazil – Rio de Janeiro	7	49	49	47	100%	96%
	Malawi – Blantyre – Queen Elizabeth Central	58	393	377	377	96%	96%
	Total	91	624	606	599	97%	96%
058	China – Guangxi – Heng County	234	191	156	178	82%	93%
	China – Nanning	–	–	–	–	–	–
	China – Xinjiang	250	258	198	239	77%	93%
	Thailand – Chiang Mai University	202	490	430	438	88%	89%
	Total	686	939	784	855	83%	91%
061	US – Atlanta	19	0	0	0	–	–
	US – Boston	140	35	23	33	66%	94%
	US – Decatur	118	8	3	8	38%	94%

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	US – Los Angeles	159	13	0	12	0%	94%
	US – NY – Harlem Prevention Center	92	0	0	0	–	–
	US – NY – New York Blood Center	88	7	6	7	86%	94%
	US – San Francisco	146	34	27	32	79%	94%
	US – Washington DC	137	18	13	17	72%	94%
	Total	899	115	72	109	63%	94%
064 (Women)	US – Atlanta	199	0	0	0	–	–
	US – Baltimore	210	40	37	38	93%	94%
	US – Chapel Hill	210	200	170	189	85%	94%
	US – Decatur	143	20	12	19	60%	94%
	US – NY – Bronx–Lebanon Hospital Center	210	194	181	183	93%	94%
	US – NY – Harlem Prevention Center	165	0	0	0	–	–
	US – Newark	420	154	150	145	97%	94%
	US – Raleigh	210	30	26	28	87%	94%
	US – Washington DC	211	167	148	158	89%	94%
	Total	1978	805	724	760	90%	94%

# MEMORANDUM

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

These tables are based on the same data as the protocol specific enrollment and retention reports routinely sent out by SCHARP to each of the protocol teams.

## Enrollment Summary

The Enrollment Summary describes the number of participants enrolled in each study based on the data received and entered at SCHARP. The report lists the date of **First Enrollment**, the **Target Number** of participants, and the **Total Number** enrolled to date for each site in each study. The percentage of target already enrolled is:

$$\text{Target Enrollment} = \frac{\text{Total Enrolled}}{\text{Target Number}}$$

As a guide to the sites' progress in enrollment, the percentage **Enrollment Period** elapsed is calculated - this is the elapsed proportion of the accrual period specified in the protocol.

## Retention Summary

The Retention Summary is based on study visits. The table reports the number of **Expected Visits** for each site on each protocol - this is a calculation of all visits that should have occurred to date assuming no missed visits or loss to followup. **Completed Visits** are the number of these expected visits that have actually occurred (based on data received and entered at SCHARP). **Protocol Expectations** calculates the number of visits that should have occurred to date assuming the protocol specified acceptable loss to followup rate. Currently the report uses a retention standard of 10% annual loss to followup for HPTN035, HPTN037, and HPTN039 (i.e., Phase IIb and III trials), and 0% for the safety run-in phase of HPTN052.

**Retention** is simply the proportion of expected visits that have been completed:

$$\text{Retention} = \frac{\text{Completed}}{\text{Expected}}$$

As a guide for performance, the **Protocol Expected Standard** is calculated as the percentage of **Protocol Expected** visits that have occurred:

$$\text{Protocol Expected Standard} = \frac{\text{Protocol Expected}}{\text{Expected}}$$

The network evaluation committee has defined adequate performance as within 90% of the protocol expected standard.

Questions about this report may be directed to Deborah Donnell (deborah@scharp.org; (206) 667-5661).

## HPTN Network Laboratory Update May 2010

### HPTN 027 (Uganda only)

Specimens for antibody assay are awaiting testing.

### HPTN 046

#### A. General Comments

- Version 3.0 dated 26 Sept, 2007
- Enrollment at all sites has been stopped.
- Maternal QA shipments from all sites have been received at the Network Lab and have been tested.
- Lists for infant QA shipments have been sent to the sites and shipments are being prepared.

#### B. Site Specific

1. Harare - The site has moved samples from HPTN 046 to an off site location. The NL was not informed and is in the process of following up with the site to get the details.
2. Kampala - No new updates
3. Durban - No new updates
4. Dar es Salaam - No new updates

### HPTN 052

#### A. General Comments

The NL is continuing to work on QAing the viral loads from enrollment samples (<1000 copies/mL) as well as the ARV testing. The IQA has requested a change in calculating the percentage CD4s for the FACScout users: Blantyre, Lilongwe and YRGcare.

#### B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site is preparing the validation documents for the NL to review.
2. Harare - The site is working on the action plan from the NL November visit. The site has used non validated FBS in their PBMC preparations. The site is preparing a Note to File regarding this issue and will send a list of all samples involved. The site found 2 bottles of the validated FBS material in their freezers. The site has moved samples from HPTN 052 to an off site location. The NL was not informed and is in the process of following up with the site to get the details.
3. Chennai - The site is also planning to move part of the laboratory. The site has sent in the pre move plans for the lab.
4. Blantyre - The NL is working with the site on some processing issues.
5. Porto Alegre - The site has had a delay in receiving HIV EIA FDA approved kits. The kits were ordered several months ago. This is still pending. The site is running low on HIV RNA kits from Roche. This issue has been raised with the Roche International representative and is being discussed on the cross network Lab Focus Group.
6. Rio sites – The site does not have any Roche kits for Viral Load. This issue is being raised with Roche international and is being discussed on the cross network Lab Focus Group. The NL has continuously asked the site to send the samples out for testing.
7. Lilongwe – Inventory has been received for April.
8. Chiang Mai – No new updates

9. Johannesburg – WITs--No site/clinic inventory has been received.
10. Soweto – No site/clinic inventory has been received.
11. Botswana – The lab is using the back up laboratory for chemistry. No site/clinic inventory has been received.
12. Kenya – No new updates

#### **HPTN 057**

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

A new version of the SSP has been written to include Cohort 4. Lab section has been posted on the HPTN website.

##### **B. Site Specific**

1. Blantyre - No outstanding issues. Site has started to enroll. In cohort 4.
2. Santa Casa. Porto Alegre. - No outstanding issues.
3. UFMG. Belo Horizonte - Central lab corrective action plan has many outstanding items.
4. HSE Rio.- No outstanding issues. SOPs have been updated.
5. HNSC. Porto Alegre - No outstanding issues.

#### **HPTN 058**

##### **A. Site Specific**

1. Thailand - Screening specimens for QA have been received at the Network Lab.
2. China sites.
  - a. **Xinjiang Site** - No new updates.
  - b. **Guangxi** - No new updates.
3. An additional site in Vietnam is still being considered.  
Network Lab has still not received permission from DAIDS to communicate with the site.

#### **HPTN 061 and 064**

##### **General Information**

Team protocol trainings for 061 and 064 have been completed. DCLOT has agreed with the Network Lab proposals for rapid HIV testing which allows sites to follow local state regulations.

##### **A. 061 Site Specific**

1. Fenway - During the NL site visit in March, the NL noted that the site had not been virtually storing aliquots in the LDMS. The site is in the process of virtually storing the plasma aliquots for 061 in the LDMS
2. George Washington University - Moved to new site (processing lab did not move). CLIA certificates pending.
3. San Francisco - No new updates.
4. Harlem - No new updates.
5. Atlanta - Site visit pending.
6. New York Blood Center - Note to File for dual enrollment received.
7. UCLA - Updated SOPs for name based requisitions for specimens to be sent to the local lab submitted.

##### **B. 064 Site Specific**

1. North Carolina - Notes to File received on samples not processed within the six hour turnaround time.
2. New Jersey - A Note to File was received on a participant that did not return for a confirmatory WB.
3. Washington DC - New CLIA certificate pending. Note to File received for a disenrolled participant.
4. Bronx - No new updates

5. Baltimore - Site completed enrollment of 210 participants.
6. Harlem - No new updates.
7. Atlanta - Notes to File was received for two participants that haven't returned for a confirmatory WB.

#### **QC update**

The following sites have been submitting or have had active review of their monthly QC reports by the HPTN NL.:

UZ-UCSF  
RIHES  
Guangxi  
Xinjiang  
Lilongwe  
NARI  
YRG Care  
Blantyre  
HNSC  
IPEC

#### **NL updates**

The NL is working on the incidence testing for both HPTN 043 and the domestic trials. The NL is reformatting the Study Ops report and the new format will be available in June.

#### **Travel Updates**

Paul and Estelle are planning a visit to YRG Care in June. Estelle is planning a trip to Kenya during July.

## **Implementations Issues and Problems Summary May 2010**

### **052**

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

### **058**

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

### **061**

Recruitment lags behind target for all but the Atlanta and Harlem sites. Per SMC suggestion, the study team is considering what they will do if the recruitment period ends and the study is not fully recruited. The team is considering extending the enrollment period at some sites to allow full recruitment of the study.

### **062**

Lilongwe will be the only site contributing participants to this study. Identification of acutely infected individuals relies on the CHAVI 001 study. CHAVI 001 is scheduled to end June 2012 which would necessitate ending recruitment 9 months prior to this date, approximately October-November 2011. It is not likely that the site will be able to identify 46 participants by this date. This situation was discussed with DAIDS and the study PIs on 29 April and all agreed that the site should continue enrolling as long as possible. The primary objective of the study—feasibility and acceptability of the intervention—can be achieved with a smaller sample.

### **063**

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, this approval must be in place in order to receive state department clearance.

### **064**

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met.

### **065**

There are some concerns among DC providers with regard to the study's design. The protocol chairs, Wafaa El-Sadr and Bernie Branson are working to address these concerns.

## 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: 03 May 2010*

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

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

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

Enrollment closed on 21 January. All infants have been randomized. The last infant will complete 6-month follow-up and complete study product dosing in July.

#### **Accrual Status:**

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

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

#### **Retention Status:**

There have been no retention issues identified at this time.

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

No issues at this time.

## Report for HPTN Study Operations Group

### HPTN 052

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

*Based on available data through: 11 May 2010*

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

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

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

All sites listed above are operating under Version 3.0 of the protocol. As of April 8, 2010, the study met its enrollment target of 1750 couples. Sites will continue to enroll couples who are in the screening pipeline. SCHARP will officially announce when enrollment has ended, along with the final total N of the study. To date, the enrollment is at 1761 couples.

On May 10, 2010, HPTN 052 was reviewed by its DSMB (Data Safety Monitoring Board) and the informal outcome is that the study will continue per the protocol until the next DSMB review scheduled in November 2010. Official feedback from the DSMB regarding their review will be sent to the team shortly.

**Accrual Status:**

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

<b>HPTN 052 Cumulative Screening and Enrollment Data</b>															
<b>Week Ending: 15 April 2010</b>															
	Lilon gwe	RIHE S	NARI	Blant yre	Brazil - FIOCR UZ	Brazil - HGNI	Brazil - HNSC	YRG CARE	Zimb abwe	WITS SA	Bots wana	Sowe to	Kenya	Indivi duals	Cou ples
<b>Date First Screened</b>	04- Apr- 05	13- Jun- 05	22- Jun- 05	16- Aug- 05	13- Sep-05	03- Oct- 05	04- Jan- 06	08- Nov- 05	07- Dec- 05	07- Apr- 08	11- Mar- 09	21- May- 09	21- Oct- 09		
<b>Date First Enrolled</b>	12- Apr- 05	24- Jun- 05	01- Jul-05	25- Aug- 05	14- Sep-05	13- Oct- 05	30- Jan- 06	10- Nov- 05	09- Jan-06	20- May- 08	16- Apr- 09	11- Jun- 09	03- Nov- 09		
<b># Screened*</b>	1494	564	714	1950	393	365	274	1106	2334	190	486	425	498	10831	n/a
<b># Enrolled - Individuals</b>	500	212	350	464	210	152	180	500	474	90	154	100	118	3518	n/a
<b># Enrolled - Couples</b>	250	106	175	232	105	76	90	250	237	45	77	50	59	n/a	1759
<b>Eligible</b>	508	212	388	464	212	152	180	600	518	90	156	98	118	3718	n/a
<b>Ineligible</b>	962	350	310	1462	178	212	94	498	1788	96	328	320	362	6976	3488
<b>Eligibility Unknown</b>	24	2	16	24	3	1	0	8	28	4	2	7	18	137	n/a
<b>Individuals # Screened/Individuals # Enrolled</b>	3.0	2.7	2.0	4.2	1.9	2.4	1.5	2.2	4.9	2.1	3.2	4.3	4.2	3.1	n/a

- \*One participant may have multiple screening attempts.
- \*\* Fenway and HSE have been phased out of participation in HPTN 052 and will no longer screen and enroll participants.
- \*\*\*Total enrollment numbers in above chart account for couples enrolled at both Fenway and HSE, though not shown. As such, the total number of couples is always going to be 7 more than what each individual site enrolled adds up to – this is explained in the table below.

**Termination/Transfer Status of Couples at Fenway and HSE:**

	<b>HSE</b>	<b>Fenway</b>
# Couples enrolled during run-in period	5	2
# Terminated couples	2	2
# Transferred couples to IPEC	3	N/A
Date of last terminated/transferred couple	26 July 2007	9 May 2007

**Retention Status:**

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

**Implementation Issues and Problems:**

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

## Report for HPTN Study Operations Group

### HPTN 057

## A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants

Based on available data through: 3 May 2010

#### Participating Study Sites:

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

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

- Irmandade Santa Casa de Misericordia de Porto Alegre, Porto Alegre (Santa Casa)
- Hospital dos Servidores do Estado – Servico de Doencas Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Servico de Infectologia, Porte Alegre (Conceicao)

#### Study Implementation Status:

Enrollment into Cohorts 1, 2 and 3 was completed on Sept 16, 2008. A total of 81 evaluable mother/infant pairs were enrolled. Follow-up of participants in Cohorts 1, 2, and 3 is complete.

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

The Blantyre Site opened for accrual to Cohort 4 on 4 April 2010. The site has started screening and anticipates the first enrollment this month.

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

#### Accrual Status:

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

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

**Status of Intervention Delivery:**

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

**Retention Status:**

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

**Implementation Issues and Problems:**

## Report for HPTN Study Operations Group

### HPTN 058

## A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors

*Based on data available through 10 May 2010*

#### Participating Study Sites:

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

#### Study Implementation Status:

Enrollment in Chiang Mai was capped at 202 participants. Xinjiang has enrolled 249 participants. Heng County has enrolled 234 participants. The clinic in Urumqi remains relocated to their proposed satellite site due to orders from the Chinese authorities. Anticipated completion date of the renovations to the main clinic is June 2010. DAIDS issued an approval for this temporary relocation. The ban on international communications in Xinjiang has been partially lifted.

The Nanning site (also in Guangxi Province) received study drug and was activated. All staff received additional training 19-23 April 2010. The site began screening 6 May 2010 after the Chinese national holiday.

Adding a site in Vietnam still remains a possibility and discussions are ongoing.

Marek Chawarski has circulated a new draft of the Counseling Manual for review among team members. The team has continued regular conference calls with the counselors to address any questions they have about this component of the study. Several new counselors were trained by Marek during the 19-23 April training.

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

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

**Accrual Status:**

	<b>Chiang Mai</b>	<b>Nanning</b>	<b>Heng County</b>	<b>Xinjiang</b>
<b>Date First Screened</b>	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
<b>Date First Enrolled</b>	30-May-07		24-Dec-08	21-Dec-08
<b># Individuals Screened</b>	281	6	493	465
<b># Individuals Enrolled</b>	202		234	249

**Status of Intervention Delivery:**

Study drug has been generally well tolerated.

**Retention Status:**

All Sites	
Week 26	87%
Week 52	78%
Week 78	84%
Week 104	79%
Week 130	77%

**Implementation Issues and Problems:**

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

## Report for HPTN Study Operations Group

### HPTN 061

Feasibility study of a community-level, multi-component intervention for Black men who have sex with men in preparation for a community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black men who have sex with men

***Based on data available through: 04 May 2010***

#### Participating Study Sites:

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

#### Study Implementation Status:

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

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

#### Accrual Status (participants enrolled at each site) as of 01 March 2010:

Fenway	GWU	Emory :Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
133	132	160	143	155	78	82	883

#### Status of Intervention Delivery:

LoA #3 was disseminated to the team on April 7, 2010. Analysis of the focus group data is taking place at this time, with the first two rounds of coding and review completed. The

qualitative team has finalized the questionnaire for the qualitative interviews and some sites have begun conducting their interviews. The publications committee will be reviewing proposed papers on Friday, 07 May.

**Recruitment Status:**

Recruitment lags behind target for all but the Atlanta and Harlem sites. Per SMC suggestion, the study team is considering what they will do if the recruitment period ends and the study is not fully recruited. The team is considering extending the enrollment period at some sites to allow full recruitment of the study.

**Retention Status:**

The early-activating sites are beginning to conduct six month visits. The SMC was concerned, as are the study co-chairs, that retention of the first 10 or so participants seemed to be difficult. SCHARP is being asked to prepare a retention report for all sites and retention will be the focus of the study team call on 13 May.

**Implementation Issues and Problems:**

See above.

# Report for HPTN Study Operations Group

## HPTN 062

### *Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection*

***Based on data available through: 07 May 2010***

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

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

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

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

Lilongwe site was activated on 24 February 2010. The first two participants were enrolled the week of 27 April. The first participant was manually randomized because the site could not access the internet randomization system. A Protocol Deviation was written reporting this event. The second randomization was done per protocol without incident.

A Clarification Memo #1 which clarifies when “provider notification” will be offered at the site was issued on 28 April 2010.

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

Two participants have been enrolled to date

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

The first two participants have completed all visit requirements to date. The site reported that the Enrollment activities take 5-6 hours when combined with the CHAVI 001 visit.

#### **Retention Status:**

N/A

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

Lilongwe will be the only site contributing participants to this study. Identification of acutely infected individuals relies on the CHAVI 001 study. CHAVI 001 is scheduled to end June 2012 which would necessitate ending recruitment 9 months prior to this date, approximately October-November 2011. It is not likely that the site will be able to identify 46 participants by this date. This situation was discussed with DAIDS and the study PIs on 29 April and all agreed that the site should continue enrolling as long as possible. The primary objective of the study—feasibility and acceptability of the intervention—can be achieved with a smaller sample.

## 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: 03 May 2010*

#### Participating Study Sites:

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

#### Study Implementation Status:

Version 1.0 of the protocol was approved on 15 September 2008 and distributed to sites on the same day.

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

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

The Zambia site received local and UAB IRB approvals but received a non-approval letter from the MOH on 13 January 2010, due to a current ban on sample exportation. They have appealed the decision and are awaiting feedback.

Site activation activities are continuing at the Brazil and Zambia sites. The site training schedule is as follows: Thailand (25-29 January, 2010 - **Completed**), Zambia (8-12 March, 2010 - **Postponed**), and Brazil (1-5 March, 2010 – **Completed**).

**Accrual Status:**

Below is site-reported screening and enrollment data ending 30 May 2010; refer also to the SCHARP enrollment summary.

Site	Date of First Screening	Date of First Enrollment	Total No. Screened	No. Report No Unprotected Sex	No. Not Receiving Care	Total No. Enrolled
Brazil: Rio de Janeiro (IPEC CRS)						
Women						
Heterosexual Men						
MSM						
Thailand: Chiang Mai	01-Apr-10	01-Apr-10				
Women			11	0	0	11
Heterosexual Men			3	0	0	3
MSM			3	0	0	3
Zambia: Lusaka (Metero Clinic CRS)						
Women						
Heterosexual Men						
<b>TOTAL</b>	<b>NA</b>	<b>NA</b>	<b>17</b>	<b>0</b>	<b>0</b>	<b>17</b>

**Retention Status:**

Refer to the SCHARP retention summary.

**Implementation Issues and Problems:**

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, this approval must be in place in order to receive state department clearance.

**Report for HPTN Study Operations Group**  
**HPTN 064**  
**Women's Seroprevalence Study (ISIS)**  
*Based on data available through: 07 May 10*

**Participating Study Sites:**

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

**Study Implementation Status:**

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

Since the last update, the Johns Hopkins AIDS CRS successfully completed enrollment with a total of 210 women. The New Jersey Medical School CRS (El-Sadr CTU) also successfully completed enrollment, enrolling a total of 420 women. HPTN 064 now has seven communities that have completed enrollment. The other three sites have passed their half-way points for recruitment.

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

On April 7, 2010, the HPTN EC approved the extension of follow-up. Sites are currently taking the steps necessary to implement these guidelines.

**Accrual Status:**

Please see SCHARP Enrollment Report.

**Status of Intervention Delivery:**

N/A

**Retention Status:**

Please see SCHARP Retention Report.

**Implementation Issues and Problems:**

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met.

## 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: 6 May 2010*

#### Participating Study Sites:

HPTN 065 includes two intervention communities (Washington, D.C. and the Bronx, New York) and four comparator communities (Miami, Florida; Philadelphia, Pennsylvania; Chicago, Illinois; and Houston, Texas). There will be a total of 80 sites (40 test sites and 40 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study. In each intervention location, there will be 20 test sites and 20 care sites.

#### Study Implementation Status:

The protocol received final approval for V1.0 on March 16, 2010. The protocol has been submitted to a central IRB (Copernicus) for review. Copernicus has granted conditional approval – they would like to see some revisions to the template ICF for the PfP (prevention for positives) subcomponent of the study. The protocol chairs have decided to move forward with a protocol amendment (to V2.0) to make these revisions, as well as other modifications to the protocol.

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

#### Expansion of HIV testing:

- Creative agencies in DC and the Bronx continue to work on the social mobilization efforts – they are creating ads that will be in line with the current Ask for the Test (DC) and the Bronx Knows (Bronx) testing campaign.
- Hospitals in DC and the Bronx have been approached to participate in the study. Conference calls continue to work out the details of their participation.

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

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

#### Prevention for Positives (PfP):

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

#### Patient and Provider Surveys:

- The patient and provider surveys are undergoing final development and pilot testing.

**Accrual Status:** N/A

**Retention Status:** N/A

#### Implementation Issues and Problems:

There are some concerns among DC providers with regard to the study's design. The protocol chairs, Wafaa El-Sadr and Bernie Branson are working to address these concerns.

**Table 1: Site Selection in Washington, D.C. and the Bronx, New York**

Community	Site Type	Expected # of Sites	# of Signed Lols	Details for Lols	Comments
DC	Test	20	14	5 hospitals 6 non-hospital test sites 3 test and care sites	<ul style="list-style-type: none"> <li>no sites have declined to participate</li> </ul>
	Care	20	11	5 hospitals 3 non-hospital care sites 3 test and care sites	<ul style="list-style-type: none"> <li>no sites have declined to participate</li> </ul>
Bronx	Test	20	12	4 hospitals 6 non-hospital test sites 2 test and care sites	<ul style="list-style-type: none"> <li>3 test sites have been eliminated because they no longer do HIV testing</li> </ul>
	Care	20	12	4 hospitals 6 non-hospital care sites 2 test and care sites	<ul style="list-style-type: none"> <li>1 care site has declined participation due to "limitations with our patient population" (per an email from the site).</li> <li>2 care site was eliminated due to an ongoing federal investigation (1 site) and no longer seeing HIV patients (1 site)</li> </ul>

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# Appendix: HPTN Protocols and INDs

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<b>Protocol #</b>		<b>IND</b>	<b>IND Sponsor</b>	<b>Study Status</b>
<b>HPTN 027</b>	A Phase I Study to Evaluate the Safety and Immunogenicity of ALVAC-HIV vCP1521 in Infants Born to HIV-1 Infected Women in Uganda	BB-IND 12023	DAIDS	Closed to Accrual
<b>HPTN 046</b>	Phase III Trial to Determine the Efficacy and Safety of an Extended Regimen of Nevirapine in Infants Born to HIV Infected Women to Prevent Vertical HIV Transmission During Breastfeeding	72,592	DAIDS	Closed to Accrual
<b>HPTN 052</b>	A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples	68,535	DAIDS	Enrolling
<b>HPTN 057</b>	A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants	72,531	DAIDS	Open to Accrual
<b>HPTN 058</b>	A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors	73,797	DAIDS	Enrolling