



## **HPTN Study Operations Report**

**January 2010**

**PTN Executive Summary Report**  
**13 January 2010**  
**Enrollment Summary**

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
027	Uganda – Mulago Hospital	12Oct2006	60	60	100%	7.1	8.5	completed
	Total		60	60	100%	7.1	8.5	
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	405	101%	18	22.5	83%
	Tanzania – Dar Es Salaam	28Jan2009	270	214	79%	11.7	18.3	76%
	Uganda – Mulago Hospital	23Jun2008	500	531	106%	19	27.9	84%
	Zimbabwe – Harare/Chitungwiza	14May2008	500	503	101%	20.3	24.8	85%
	Total		1670	1653	99%	20.3	81.4	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	408	102%	18	22.7	83%
	Tanzania – Dar Es Salaam	28Jan2009	270	218	81%	11.7	18.6	76%
	Uganda – Mulago Hospital	23Jun2008	500	551	110%	19	29	84%
	Zimbabwe – Harare/Chitungwiza	14May2008	500	507	101%	20.3	25	85%
	Total		1670	1684	101%	20.3	83	
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

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	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	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	65	50	77%	9.1	5.5	78%
	Brazil – Porto Alegre	26Nov2007	93	80	86%	26	3.1	91%
	Brazil – Rio de Janeiro	14Nov2007	185	159	86%	26.4	6	91%
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	190	144	76%	31	4.6	92%
	Kenya – Kisumu	03Nov2009	45	13	29%	2.4	5.4	48%
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	215	197	92%	24.3	8.1	90%
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	240	224	93%	25.6	8.8	91%
	South Africa – Johannesburg – Witwatersrand	20May2008	55	42	76%	20.1	2.1	89%
	South Africa – Soweto	11Jun2009	30	17	57%	7.2	2.4	74%
	Thailand – Chiang Mai	11Oct2007	90	90	100%	26.6	3.4	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	220	192	87%	26.7	7.2	91%
	Total		1668	1448	87%	31	46.7	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	65	50	77%	9.1	5.5	78%
	Brazil – Porto Alegre	26Nov2007	93	82	88%	26	3.2	91%
	Brazil – Rio de Janeiro	14Nov2007	185	159	86%	26.4	6	91%
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	190	144	76%	31	4.6	92%
	Kenya – Kisumu	05Nov2009	45	13	29%	2.3	5.7	47%
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	215	197	92%	24.3	8.1	90%
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	240	228	95%	25.6	8.9	91%
	South Africa – Johannesburg – Witwatersrand	20May2008	55	42	76%	20.1	2.1	89%
	South Africa – Soweto	11Jun2009	30	17	57%	7.2	2.4	74%
	Thailand – Chiang Mai	11Oct2007	90	91	101%	26.6	3.4	completed

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Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	220	191	87%	26.7	7.2	91%
	Total		1668	1454	87%	31	46.9	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	9	8	89%	29.6	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	4	5	125%	19.2	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	11	13	118%	28.2	0.5	completed
	Brazil – Rio de Janeiro	17Apr2008	4	7	175%	21.2	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	56	56	100%	37.1	1.5	completed
	Total		80	89	111%	37.1	2.4	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	9	8	89%	29.6	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	4	5	125%	19.2	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	11	13	118%	28.2	0.5	completed
	Brazil – Rio de Janeiro	17Apr2008	4	7	175%	21.2	0.3	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	56	56	100%	37.1	1.5	completed
	Total		80	89	111%	37.1	2.4	
058	China – Guangxi – Heng County	24Dec2008	400	193	48%	12.8	15.1	35%
	China – Xinjiang	23Dec2008	490	209	43%	12.9	16.2	35%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	604	40%	32	18.9	
061	US – Atlanta	–	201	–	–	0	–	
	US – Boston	17Jul2009	403	89	22%	6	14.8	34%
	US – Decatur	16Sep2009	202	38	19%	4	9.5	25%
	US – Los Angeles	30Sep2009	403	88	22%	3.5	25.1	23%
	US – NY – Harlem Prevention Center	–	201	–	–	0	–	
	US – NY – New York Blood Center	01Oct2009	202	35	17%	3.5	10	23%
	US – San Francisco	13Aug2009	403	96	24%	5.1	18.8	30%
	US – Washington DC	28Jul2009	403	61	15%	5.6	10.9	32%
	Total		2418	407	17%	6	67.8	
064 (Women)	US – Atlanta	22Oct2009	210	35	17%	2.8	12.5	45%
	US – Baltimore	05Aug2009	210	74	35%	5.4	13.7	88%
	US – Chapel Hill	26May2009	210	200	95%	4	50	closed
	US – Decatur	27Aug2009	210	34	16%	4.6	7.4	76%

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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>
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	210	206	98%	6.5	31.7	closed
	US – NY – Harlem Prevention Center	26Oct2009	210	47	22%	2.6	18.1	
	US – Newark	05Jun2009	420	260	62%	7.4	35.1	121%
	US – Raleigh	11Aug2009	210	169	80%	5.2	32.5	84%
	US – Washington DC	17Jun2009	210	201	96%	4.9	41	closed
	Total		2100	1226	58%	7.7	159.2	
064 (Men)	US – Decatur	–	30	–	–	0	–	
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	30	100%	2.3	13	completed
	US – Raleigh	–	30	–	–	0	–	
	US – Washington DC	–	30	–	–	0	–	
	Total		120	30	25%	3.5	8.6	

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**Retention Summary**

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
027	Uganda – Mulago Hospital	60	900	885	836	98%	93%
	Total	60	900	885	836	98%	93%
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	405	1511	1358	1466	90%	97%
	Tanzania – Dar Es Salaam	214	714	656	698	92%	98%
	Uganda – Mulago Hospital	531	1902	1802	1844	95%	97%
	Zimbabwe – Harare/Chitungwiza	503	1899	1780	1837	94%	97%
	Total	1653	6026	5596	5845	93%	97%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	408	3097	2897	2997	94%	97%
	Tanzania – Dar Es Salaam	218	1492	1388	1455	93%	98%
	Uganda – Mulago Hospital	551	3993	3862	3865	97%	97%
	Zimbabwe – Harare/Chitungwiza	507	3832	3632	3704	95%	97%
	Total	1684	12414	11779	12021	95%	97%
052 Combined (Indexes)	Botswana – Gabarone	50	134	131	133	98%	100%
	Brazil – Porto Alegre	85	540	527	532	98%	99%
	Brazil – Rio de Janeiro	172	1344	1319	1320	98%	98%
	India – Chennai – YRGCare	250	1698	1577	1670	93%	98%
	India – Pune	154	1179	1173	1157	99%	98%
	Kenya – Kisumu	13	8	4	8	50%	100%
	Malawi – Blantyre – Queen Elizabeth Central	207	1086	1034	1071	95%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	234	1329	1246	1309	94%	98%
	South Africa – Johannesburg – Witwatersrand	42	182	177	181	97%	99%
	South Africa – Soweto	17	20	15	20	75%	100%
	Thailand – Chiang Mai	100	732	723	717	99%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	202	1149	1089	1133	95%	99%
	Total	1526	9401	9015	9250	96%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
052 Combined (Partners)	Botswana – Gabarone	50	134	127	133	95%	100%
	Brazil – Porto Alegre	87	540	509	532	94%	99%
	Brazil – Rio de Janeiro	172	1344	1161	1320	86%	98%
	India – Chennai – YRGCare	250	1698	1486	1670	88%	98%
	India – Pune	154	1179	1149	1157	97%	98%
	Kenya – Kisumu	13	7	5	7	71%	100%
	Malawi – Blantyre – Queen Elizabeth Central	208	1088	924	1073	85%	99%
	Malawi – Lilongwe – Lilongwe Central Hospital	238	1329	1143	1309	86%	98%
	South Africa – Johannesburg – Witwatersrand	42	182	169	181	93%	99%
	South Africa – Soweto	17	20	16	20	80%	100%
	Thailand – Chiang Mai	101	732	671	717	92%	98%
	Zimbabwe – Harare – Parirenyatwa Hospital	201	1146	992	1130	87%	99%
	<b>Total</b>		<b>1533</b>	<b>9399</b>	<b>8352</b>	<b>9248</b>	<b>89%</b>
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	75	75	96%	97%
	Brazil – Rio de Janeiro	7	42	42	41	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	56	336	325	325	97%	97%
	<b>Total</b>		<b>89</b>	<b>534</b>	<b>520</b>	<b>516</b>	<b>97%</b>
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	56	392	376	376	96%	96%
	<b>Total</b>		<b>89</b>	<b>623</b>	<b>605</b>	<b>598</b>	<b>97%</b>
058	China – Guangxi – Heng County	193	78	62	74	79%	94%
	China – Xinjiang	209	124	103	117	83%	94%
	Thailand – Chiang Mai University	202	352	315	318	89%	90%
	<b>Total</b>		<b>604</b>	<b>554</b>	<b>480</b>	<b>508</b>	<b>87%</b>

# 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 January 2010**

### **HPTN 027 (Uganda only)**

Specimens for antibody testing are being tested at the Johns Hopkins Medical Institute.

### **HPTN 046**

#### **A. General Comments**

1. Version 3.0 dated 26 Sept, 2007
2. Screening at all sites has been stopped. Enrollment is continuing.

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

1. Harare - No new updates
2. Kampala - No new updates
3. Durban - No new updates
4. Dar es Salaam - No new updates

### **HPTN 052**

#### **A. General Comments**

1. The NL is working on the hepatitis sub-study. This is pending due to some IRB revisions needed at some sites to allow for the shipment of samples for hepatitis testing. The NL is working on QAing the viral loads from enrollment samples (<1000 copies/mL). There are a few sites that are pending shipment to the NL. The NL is also working on testing ARV levels for participants with low viral loads.
2. There was a recent communication to the labs regarding a problem with the Gemini Fetal Bovine Serum expiration date. We are currently working with the sites on this issue.

#### **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 has had a recent issue with their VQA RNA panel. The site has decided to recertify.
3. Chennai - No new updates
4. Blantyre - The NL is working with the site on updates to their action plan from the previous NL visit.
5. Porto Alegre - No new updates
6. Rio sites – No new updates
7. Lilongwe – Inventory has not been received.
8. Chiang Ma – No new updates
9. Johannesburg--WITs – No New updates
10. Soweto – No new updates.
11. Botswana – No new updates
12. Kenya – No new updates

### **HPTN 057**

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

1. Cohort 4 has been added to the protocol. Labs have been asked to prepare documentation for Cohort 4.
2. A new version of the SSP is being written to include Cohort 4.

## **B. Site Specific**

1. Blantyre - No outstanding issues.
2. Santa Casa. Porto Alegre.- No outstanding issues.
3. UFMG. Belo Horizonte.- No outstanding issues.
4. HSE Rio.- No outstanding issues
5. HNSC. Porto Alegre - No outstanding issues.

## **HPTN 058**

### **A. Site Specific**

1. Thailand - No new updates
2. China sites.
  - a. Xinjiang Site - Clinic has been moved to a new location while renovations are being made. All relevant validations have been performed.
  - b. Guangxi - An additional clinic will be added in Nanning. All relevant validations have been performed.
3. An additional site in Vietnam is being considered.

## **HPTN 061 and 064**

### **A. 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.

### **B. 061 Site Specific**

1. Fenway - Site activated. As of Dec 4 approximately 76 enrolled.
2. George Washington University - Site activated. As of Dec 4 approximately 54 enrolled
3. San Francisco - Site activated. As of Dec 4 approximately 76 enrolled.
4. Harlem - Site activated by Network Lab. Still awaiting activation by FHI. .
5. Atlanta - Hope and Ponce CRS have been activated by NL. As of Dec 4 approximately 27 enrolled
6. New York Blood Center - Site activated. As of Dec 4 approximately 29 enrolled
7. UCLA - Site activated. As of Dec 4 approximately 54 enrolled.

### **C. 064 Site Specific**

1. North Carolina - The Durham site has enrolled 200 participants, and the Wake site has enrolled 169 participants.
2. New Jersey - The Newark North site has enrolled 116 participants, and the Newark South site has enrolled 126 participants.
3. Washington DC - Site has enrolled 201 participants.
4. Bronx - Site has enrolled 205 participants.
5. Baltimore - Site has enrolled 74 participants.
6. Harlem - Site has enrolled 39 participants.
7. Atlanta - The Hope site has enrolled 30 participants, and the Ponce site has enrolled 28 participants.

## **QC update**

The following sites have been submitting their monthly QC reports:

- MUJHU
- RIHES
- Guangxi
- Xinjiang
- Lilongwe
- NARI
- YRG Care
- Blantyre

**NL updates**

- The NL is working on the incidence testing for both HPTN 043 and the domestic trials.
- The specimen management training video has been sent to the sites.

**Travel Updates**

- Estelle and Vanessa will be at the upcoming 063 training in January for Thailand and will visit the Bangkok 067 site.
- Estelle will accompany the DAIDS group on a site visit to Dar in January.
- Vanessa will visit the Blantyre site this winter to prepare for 062.
- Trip reports are pending for the India sites.

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

### **052**

Enrollment is expected to be completed by March/April 2010. The target enrollment of each site is listed below. Some target numbers have been amended since Blantyre and Zimbabwe have agreed to increase their enrollment targets.

Boston, MA (Fenway)	2
Lilongwe, Malawi (UNCP):	250
Blantyre, Malawi (JHP):	225
Harare, Zimbabwe (UZ-UCSF):	230
Rio de Janeiro, Brazil (IPEC and HGNI):	200
Porto Alegre, Brazil (HNSC):	98
Pune, India (NARI):	200
Chennai, India (YRG CARE):	250
Chiang Mai, Thailand (RIHES):	100
Johannesburg, South Africa (WITS):	55
Gaborone, Botswana:	65
Soweto, South Africa	30
Kenya	45
Total:	1750

RIHES and YRG CARE have both reached their enrollment targets of 100 and 250 couples, respectively.

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

### **058**

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation, and until the site is registered with RCC. The study drug supply for this first shipment has an August 2010 expiry date.

### **061**

Site reports and enrollment numbers show that the rate of acceptance of peer health navigation and success rate at having participants refer their sexual partners to the study is varying markedly between sites. Initial speculation seems to be that the degree of services and support already available in the community influence how appealing these study components are to participants. The study team is currently reviewing what can be done to improve the rate of referral from index participants. Low rates of referral have the potential of lowering overall enrollment in the study substantially.

### **062**

The counseling training has been difficult to schedule. The protocol is being revised for the third time to allow for Blantyre to continue without CHAVI screening mechanism. Data collection burden is high and is under review now.

### **063**

The ACASI and CRFs took longer than anticipated to finalize. There is a long turn-around time for completing the ACASI translations and audio recordings so the anticipated date for

completion is 6 weeks after the Thailand training. The sites and protocol team have been very diligent about reviewing documents and providing comments.

**064**

Accrual is currently being monitored very closely at all sites to ensure study targets are met.

**Report for HPTN Study Operations Group**

**HPTN 027**

**A PHASE I STUDY TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF  
ALVAC-HIV vCP1521 IN INFANTS BORN TO HIV-1 INFECTED WOMEN IN  
UGANDA**

*Based on available data through: 13 January 2010*

**Participating Study Site:**

Makerere University-Johns Hopkins University Research Collaboration/Mulago Hospital  
Kampala, Uganda

**Study Implementation Status:**

24-month study follow-up is complete. Site has de-registered.

CRF Database was locked from any further submissions on 29 October.

Study samples are en route from the site to JHU for analysis. Some of the lab data assay data has been received from the Richmond Lab.

**Accrual Status:**

60 of 60 have been enrolled. Accrual is complete.

**Status of Intervention Delivery:**

N/A

**Retention Status:**

N/A

## 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: 13 January 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 is coming to completion. The sites will be told to stop enrollment as soon as SCHARP has information that 1670 mothers have been enrolled. As of January 12 there were 1662 enrollments.

Tanzania has been placed on Clinical Pause for non-compliance with DAIDS safety reporting and laboratory compliance issues. IMPAACT, DAIDS and OCSO representatives are currently at the site to determine whether or not the clinical pause will be removed which may allow the site to participate in future IMPAACT studies.

#### **Accrual Status:**

1662 mother-infants pairs have been enrolled under version 3.0 of the protocol. 1425 infants have been randomized.

#### **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: 8 January 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.

**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: 31 December 2009</b>															
	Lilongwe	RIHES	NARI	Blantyre	Brazil - FIOCRUZ	Brazil - HGNI	Brazil - HNSC	YRG CARE	Zimbabwe	WITS SA	Botswana	Soweto	Kenya	Individuals	Couples
<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>	1444	530	646	1766	366	326	262	1106	2048	178	382	239	140	9471	n/a
<b># Enrolled - Individuals</b>	464	204	308	420	200	138	168	500	398	84	96	38	36	3066	n/a
<b># Enrolled - Couples</b>	232	102	154	210	100	69	84	250	199	42	48	19	18	n/a	1533
<b>Eligible</b>	474	198	338	420	202	138	168	578	444	78	122	56	36	3274	n/a
<b>Ineligible</b>	796	328	292	1296	158	174	94	518	1580	94	258	172	94	5870	2935
<b>Eligibility Unknown</b>	174	4	16	50	6	14	0	10	24	6	2	11	10	327	n/a
<b>Individuals # Screened/Individuals # Enrolled</b>	3.1	2.6	2.1	4.2	1.8	2.4	1.6	2.2	5.1	2.1	4.0	6.3	3.9	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.

**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 retention summary.

**Implementation Issues and Problems:**

Enrollment is expected to be completed by March/April 2010. The target enrollment of each site is listed below. Some target numbers have been amended since Blantyre and Zimbabwe have agreed to increase their enrollment targets.

Boston, MA (Fenway)	2
Lilongwe, Malawi (UNCP):	250
Blantyre, Malawi (JHP):	225
Harare, Zimbabwe (UZ-UCSF):	230
Rio de Janeiro, Brazil (IPEC and HGNI):	200
Porto Alegre, Brazil (HNSC):	98
Pune, India (NARI):	200
Chennai, India (YRG CARE):	250
Chiang Mai, Thailand (RIHES):	100
Johannesburg, South Africa (WITS):	55
Gaborone, Botswana:	65
Soweto, South Africa	30
Kenya	45
<hr/>	
Total:	1750

RIHES and YRG CARE have both reached their enrollment targets of 100 and 250 couples, respectively.

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: 8 Jan 2010

#### Participating Study Sites:

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

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

- Irmandade Santa Casa de Misericordia de Porto Alegre, Porto Alegre (Santa Casa)

- Hospital dos Servidores do Estado – Servico de Doencas Infecciosas, Rio de Janeiro (HSD)

- Hospital Nossa Senhora da Conceicao Servico de Infectologia, Porto Alegre (Conceicao)

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

Accrual at all sites is temporarily closed pending protocol registration and site activation of protocol amendment Version 2.0, which will add a fourth cohort looking at a maternal dose during labor and daily infant dosing for 1 week.

The protocol amendment is final. Cohort 4 is anticipated to begin enrollment in early Q1 2010.

Study Drug is available for shipment to sites pending protocol registration

#### 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 (# c-section deliveries)		
	Cohort 1	Cohort 2	Cohort 3
Queen Elizabeth Central Hospital, Blantyre Malawi	24 (3)	16	15 (2)
Santa Casa, Porto Alegre Brazil	3 (2)	4	4 (2)
University of Minas Gerais, Belo Horizonte Brazil	3 (2)	1	2 (1)
Conceicao, Porto Alegre Brazil	-	-	4 (1)
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5 (5)
<b>Total</b>	<b>30</b>	<b>21</b>	<b>30</b>

**Status of Intervention Delivery:**

TDF dispensing is complete. There were no reported significant problems with the dispensing of tenofovir to the mothers or infants.

**Retention Status:**

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

**Implementation Issues and Problems:**

## Report for HPTN Study Operations Group

### HPTN 058

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

*Based on data available through 8 January 2010*

#### Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Heng County, Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, 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 209 participants. Heng County, Guangxi has enrolled 190 participants. The clinic in Urumqi remains relocated to their proposed satellite site due to orders from the Chinese authorities. DAIDS issued an approval for this temporary relocation. The ban on foreign communication in Xinjiang will soon be lifted.

The Nanning site (also in Guangxi Province) has been approved by NIH and the local authorities and the site is working towards site activation which will not occur until study drug is on site. It is anticipated that this will not take place prior to late January.

All sites have submitted LoA #1 to their local IRBs. The Heng County and Xinjiang sites have submitted LoA #1 approvals to the RCC.

Adding a site in Vietnam still remains a possibility. Discussions between NIH and the Vietnamese MOH continue.

Marek Chawarski is in the process of revising the Counseling Manual. The team has continued regular conference calls with the counselors to address any questions they have about this component of the study.

#### Accrual Status:

	Chiang Mai	Guangxi	Xinjiang
<b>Date First Screened</b>	11-Apr-07	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	398	381
<b># Individuals Enrolled</b>	202	190	209

**Status of Intervention Delivery:**

Study drug has been generally well tolerated.

**Retention Status:**

All Sites	
Week 26	89%
Week 52	89%
Week 78	80%
Week 104	80%
Week 130	100%

**Implementation Issues and Problems:**

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation, and until the site is registered with RCC. The study drug supply for this first shipment has an August 2010 expiry date.

## 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: 11 January 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 have now been activated to the protocol.

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 Jan 2010:

Fenway	GWU	Emory - Ponce	Emory - Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
88	57	N/A	38	93	81	34	N/A	392

#### Status of Intervention Delivery:

Site reports and enrollment numbers show that the rate of acceptance of peer health navigation and success rate at having participants refer their sexual partners to the study is varying markedly between sites. Initial speculation seems to be that the degree of services and support already available in the community influence how appealing these study

components are to participants. The study team is currently reviewing what can be done to improve the rate of referral from index participants. Low rates of referral have the potential of lowering overall enrollment in the study substantially.

**Retention Status:**

N/A: Retention will not be assessed until the first follow-up visits are due, in January 2010.

**Implementation Issues and Problems:**

See above in "Status of Intervention Delivery"

# 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 January 2010*

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

- Tidziwe Centre, Kamuzu Central Hospital, Lilongwe, Malawi
- Queen Elizabeth Hospital, Blantyre, 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. The Amendment includes: replacement of South Africa with Blantyre as a site; addition of observation of counseling intervention; new assessments added at each visit, and other minor changes to correct inconsistencies within the protocol and consent forms. Lilongwe IRB has approved the amendment; Blantyre and JHU are still pending.

As a result of the protocol training held in December, the team is now considering ways to cut the number of CRFs that is completed at enrollment and follow-up visits. During the mock walk-throughs of the enrollment visit, the site staff estimated that this visit would take 4-6 hours. Follow-up visits could take 2-3 hours, most of it devoted to data collection rather than patient care.

Now that CHAVI 001 has ceased in Blantyre, the 062 protocol is being revised to adjust the screening for acute infections. This revision, amendment 3, is pending final approval from DAIDS for the additional funds that will be needed if the screening lab work is shifted from CHAVI to HPTN.

The second part of the protocol training is scheduled for the week of 18 January 2010 when study counselors will be trained by consultants from UNC, Michele Demers and Carol Golin, and their graduate students. Activation in Lilongwe is expected soon thereafter.

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

No sites have begun enrollment to date.

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

N/A

#### **Retention Status:**

N/A

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

The counseling training has been difficult to schedule. The protocol is being revised for the third time to allow for Blantyre to continue without CHAVI screening mechanism. Data collection burden is high and is under review now.

## Report for HPTN Study Operations Group

### HPTN 063

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

*Based on data available through: 11 January 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 granted final approval on 15 September 2008 and distributed to sites on the same day. The English version of the CRFs and ACASI scripts are final. The ACASI and CRFs have been translated into all 4 local languages (Portuguese, Thai, Bemba, and Nyanja). The sites and protocol team are currently finalizing the translations. The audio recordings are expected to be final in February.

Brazil submitted to their local IRB on 20 February 2009 and received approval on 17 April 2009. They are now waiting for Central IRB approval. Zambia originally submitted to their IRB on 17 April 2009 and received approval on 25 August 2009. They have just submitted an update to the ICFs because of a change in investigator. Chiang Mai submitted to their IRB on 02 September 2009 and submitted to the JHU IRB for November review. They require the final ACASI documents for final approval.

The qualitative assessments for HPTN 063 are final as of 26 March 2009 and have been distributed to the sites for translation.

Site activation activities are underway at each site and site. The site training schedule is as follows: Thailand (25-29 January, 2010), Zambia (8-12 March, 2010), and Brazil (1-5 March, 2010).

#### **Accrual Status:**

Pending, no sites have been activated.

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

N/A

#### **Retention Status:**

Pending, no sites have been activated.

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

The ACASI and CRFs took longer than anticipated to finalize. There is a long turn-around time for completing the ACASI translations and audio recordings so the anticipated date for completion is 6 weeks after the Thailand training. The sites and protocol team have been very diligent about reviewing documents and providing comments.

**Report for HPTN Study Operations Group**  
**HPTN 064**  
**Women's Seroprevalence Study (ISIS)**  
*Based on data available through: 06 January 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.

Three of the ten study communities: the UNC AIDS CRS (Durham site), the Bronx-Lebanon Hospital Center (BLHC) CRS and the George Washington University School of Public Health and Health Services (GWU) CRS) that agreed to re-open enrollment activities have successfully started enrolling a total of 210 women at each CRS.

The team is currently planning for a Study Monitoring Committee (SMC) review that will most likely occur in February.

**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 is currently being monitored very closely at all sites to ensure study targets are met.

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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	Enrolling
<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	Enrolling
<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