



HPTN Study Operations Report

**August 2011
REVISED 07 September 2011**

**PTN Executive Summary Report
10 August 2011
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	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

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	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1681	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	88	105%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	175	104%	29.4	6	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	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

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	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	386	80%	32	12.1	87%
	China – Nanning	19May2010	263	136	52%	14.9	9.1	76%
	China – Xinjiang	23Dec2008	555	454	82%	32	14.2	87%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	1178	79%	51.1	23.1	
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%	15.7	1.7	71%

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	Total		46	27	59%	15.7	1.7	
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	35	12%	4.2	8.3	32%
	Thailand – Chiang Mai	21Feb2011	239	110	46%	5.7	19.3	39%
	Zambia – Lusaka – Matero Clinic	28Apr2011	200	44	22%	3.5	12.6	28%
	Total		739	189	26%	5.7	33.2	
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%	5.4	3.5	267%
	US – Chapel Hill	07Feb2011	16	18	113%	6.1	3	224%
	Total		37	37	100%	6.1	6.1	
068	South Africa – Bushbuckridge – MRC/Wits	05Mar2011	2900	1297	45%	5.3	244.7	14%
	Total		2900	1297	45%	5.3	244.7	

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Retention Summary

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
046 V2 (Mothers)	Uganda – Mulago Hospital	190	1140	1057	1071	93%	94%
	Zimbabwe – Harare/Chitungwiza	157	942	821	885	87%	94%
	Total	347	2082	1878	1956	90%	94%
046 V2 (Infants)	Uganda – Mulago Hospital	193	2123	1997	2015	94%	95%
	Zimbabwe – Harare/Chitungwiza	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	3267	3086	3068	94%	94%
	Zimbabwe – Harare/Chitungwiza	507	3041	2798	2855	92%	94%
	Total	1678	10064	9134	9449	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	6179	6015	5862	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5609	5289	5321	94%	95%
	Total	1700	18696	17672	17736	95%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	670	645	659	96%	98%
	Brazil – Porto Alegre	90	1124	1103	1094	98%	97%
	Brazil – Rio de Janeiro	184	2538	2487	2462	98%	97%
	India – Chennai – YRGCare	250	3324	2970	3228	89%	97%
	India – Pune	175	2315	2286	2246	99%	97%
	Kenya – Kisumu	60	447	440	441	98%	99%
	Malawi – Blantyre – Queen Elizabeth Central	230	2586	2410	2524	93%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	2967	2692	2891	91%	97%
	South Africa – Johannesburg – Witwatersrand	46	489	468	479	96%	98%
	South Africa – Soweto	50	387	374	382	97%	99%
	Thailand – Chiang Mai	106	1419	1403	1375	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2724	2565	2657	94%	98%
	Total	1759	20990	19843	20438	95%	97%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard	
052 Combined (Partners)	Botswana – Gabarone	77	670	617	659	92%	98%	
	Brazil – Porto Alegre	93	1124	1037	1094	92%	97%	
	Brazil – Rio de Janeiro	188	2538	2095	2462	83%	97%	
	India – Chennai – YRGCare	250	3324	2684	3228	81%	97%	
	India – Pune	175	2315	2235	2246	97%	97%	
	Kenya – Kisumu	60	447	426	441	95%	99%	
	Malawi – Blantyre – Queen Elizabeth Central	232	2586	2086	2524	81%	98%	
	Malawi – Lilongwe – Lilongwe Central Hospital	255	2967	2356	2891	79%	97%	
	South Africa – Johannesburg – Witwatersrand	46	489	434	479	89%	98%	
	South Africa – Soweto	50	387	350	382	90%	99%	
	Thailand – Chiang Mai	107	1419	1279	1375	90%	97%	
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2724	2257	2657	83%	98%	
	Total		1773	20990	17856	20438	85%	97%
	057 (Mothers)	Brazil – Belo Horizonte	12	68	68	66	100%	97%
Brazil – Porto Alegre – Conceicao		10	56	55	54	98%	97%	
Brazil – Porto Alegre – Santa Casa		15	88	86	85	98%	97%	
Brazil – Rio de Janeiro		13	74	74	72	100%	97%	
Malawi – Blantyre – Queen Elizabeth Central		72	431	419	417	97%	97%	
Total			122	717	702	694	98%	97%
057 (Infants)	Brazil – Belo Horizonte	12	79	79	76	100%	96%	
	Brazil – Porto Alegre – Conceicao	10	65	64	63	98%	96%	
	Brazil – Porto Alegre – Santa Casa	15	101	99	97	98%	96%	
	Brazil – Rio de Janeiro	13	87	87	84	100%	96%	
	Malawi – Blantyre – Queen Elizabeth Central	72	503	485	483	96%	96%	
	Total		122	835	814	803	97%	96%
058	China – Guangxi – Heng County	386	861	712	768	83%	89%	
	China – Nanning	136	109	93	101	85%	93%	
	China – Xinjiang	454	965	815	858	84%	89%	
	Thailand – Chiang Mai University	202	951	836	812	88%	85%	
	Total		1178	2886	2456	2539	85%	88%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	116	193	151	179	78%	93%
	US – Boston	237	386	291	357	75%	92%
	US – Decatur	184	308	209	284	68%	92%
	US – Los Angeles	283	436	348	403	80%	92%
	US – NY – Harlem Prevention Center	154	298	272	274	91%	92%
	US – NY – New York Blood Center	156	279	230	257	82%	92%
	US – San Francisco	204	355	277	328	78%	92%
	US – Washington DC	227	383	326	354	85%	92%
	Total	1561	2638	2104	2436	80%	92%
062	Malawi – Lilongwe – Lilongwe Central Hospital	27	200	191	196	96%	98%
	Total	27	200	191	196	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	125	109	124	87%	99%
	US – Chapel Hill	18	122	119	121	98%	99%
	Total	37	247	228	245	92%	99%

MEMORANDUM

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

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).

**Due to travel
conflicts, the lab
report for August is
not included in this
month's report. It
will be sent
separately.**

Implementations Issues and Problems Summary August 2011

Revised 07 September 2011

058

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

061

The site teams continue to focus efforts on improving 12 month retention. Sites are also working to figure out how to provide adequate staff resources for completing remaining study visits as the number of staff is drawn down, and determining site-specific plans for closing to follow up. The study team as a whole have 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. The study team is in the middle of completing their communications plan.

063

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

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 decided to increase calls bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs will be distributed and closely monitored.

Sites also noted that patients in regular care with well controlled disease often come for visits every 6 months as opposed to every 3 months. After consultation with the sites, the HPTN 063 Protocol Team submitted Letter of Amendment (LoA) #3 to DAIDS for approval to modify the inclusion criteria, defining "clinical care" as 2 visits in the last 9 months as opposed to 2 visits in the last 6 months. The team received DAIDS approval for LoA #3 on July 20, 2011. LoA #3 was distributed to the sites the same day. Sites are currently waiting for approval from local IRB and ethics committees on the letter of amendment.

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: 8 August 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.

Accrual Status:

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

Status of Intervention Delivery:

Blinded study product has been discontinued in all infants.

Retention Status:

There have been no retention issues identified at this time.

Implementation Issues and Problems:

No issues at this time.

Report for HPTN Study Operations Group

HPTN 052

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

Based on available data through: 5 August 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 August 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, Porte 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 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 a 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, Porte Alegre Brazil (pending drug import approval)	3	4	4	2
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	3
Conceicao, Porte Alegre Brazil	-	-	4	5
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	6
Total	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 12 August 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 460 participants. Heng County has enrolled 387 participants. Nanning has enrolled 138 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 JWG will be held in Beijing in early November and will also review data regarding high risk recruitment and retention.

SMC call is scheduled for 2 September.

DSMB call is scheduled for the end of September

Accrual Status:

	Chiang Mai	Nanning	Heng County	Xinjiang
Date First Screened	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
Date First Enrolled	30-May-07	19-May-10	24-Dec-08	21-Dec-08
# Individuals Screened	281	315	804	840
# Individuals Enrolled	202	138	387	460

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	89%
Week 52	84%
Week 78	86%
Week 104	83%
Week 130	80%
Week 156	86%

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: 01 August 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 78%

Implementation Issues and Problems:

The site teams continue to focus efforts on improving 12 month retention. Sites are also working to figure out how to provide adequate staff resources for completing remaining study visits as the number of staff is drawn down, and determining site-specific plans for closing to follow up. The study team as a whole have decided that 09 Dec 2011 is the final date possible for follow up in O61, but individual sites may choose an earlier date for themselves if necessary. The study team is in the middle of completing their communications plan.

Report for HPTN Study Operations Group

HPTN 062

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

Based on data available through: 03 August 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-five participants have been enrolled to date. One participant was enrolled who was later found to be not acutely infected. This participant was un-enrolled and a deviation memo was submitted to DAIDS and IRB.

Status of Intervention Delivery:

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

Retention Status:

See the SCHARP report.

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: 04 August 2011
REVISED 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.

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 29 July 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

August 1, 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
Brazil: Rio de Janeiro (IPEC CRS)	01-Apr-11	01-Apr-11					
Women			91	0	0	29	23
Heterosexual Men			33	5	0	29	3
MSM			53	2	0	24	9
Thailand: Chiang Mai	01-Apr-10	01-Apr-10					
Women			1196	0	0	100	94
Heterosexual Men			1063	0	0	47	42
MSM			198	0	0	34	34
Zambia: Lusaka (Metero Clinic CRS)	20-Apr-11	20-Apr-11					
Women			157	2	0	24	28
Heterosexual Men			33	1	0	20	16
TOTAL	NA	NA	2824	10	0	311	249

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						
TOTAL	7	4	5	6			

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		
				TOTAL	0	0
TOTAL	1	0	0			

Implementation Issues and Problems:

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

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 decided to increase calls bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs will be distributed and closely monitored.

Sites also noted that patients in regular care with well controlled disease often come for visits every 6 months as opposed to every 3 months. After consultation with the sites, the HPTN 063 Protocol Team submitted Letter of Amendment (LoA) #3 to DAIDS for approval to modify the inclusion criteria, defining "clinical care" as 2 visits in the last 9 months as opposed to 2 visits in the last 6 months. The team received DAIDS approval for LoA #3 on July 20, 2011. LoA #3 was distributed to the sites the same day. Sites are currently waiting for approval from local IRB and ethics committees on the letter of amendment.

Report for HPTN Study Operations Group

HPTN 064 Women's HIV SeroIncidence Study (ISIS)

Based on data available through: 04 August July 2011

Participating Study Sites:

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

Study Implementation Status:

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

The qualitative sites have successfully completed all qualitative interviews and focus groups. The HPTN CORE has completed preliminary coding the qualitative interviews, female focus groups and male focus groups. The HPTN 064 Qualitative Working Group held a team analysis meeting in the Durham FHI office January 24-28, 2011. Several qualitative abstracts were submitted as a result of the meeting. HPTN Core members and community members recently 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.

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: 8 August 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 have recently been developed for distribution in the Bronx. FHI is working with the NY ad agency and the NY DOH to develop a dissemination plan for posters in MSM venues where Bronx residents frequent. Sites have agreed to place these posters within their clinics, as well as other locations around the Bronx, to encourage HIV testing.
- Palm appointment cards to encourage testing twice a year have been developed by the ad agency in DC. The DC DOH has agreed to distribute these palm cards to the various sites around DC, once they have been finalized.
- Expanded Testing in Hospitals: February 1, 2011 marked the official start of the Expanded Testing component in hospitals. The majority of DC (6 out of 7) and Bronx (7 out of 9) hospitals have begun submitting HIV testing data for the study. A second face-to-face meeting 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 90% 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, 1 site in DC has 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:

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

Training Update

- All 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 need be or requested.

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.

Protocol:

- A letter of amendment (LOA #1 to V2.0 of the protocol) was approved by the DAIDS RAB on July 18, 2011. The LOA corrected some minor issues in the Prevention for Positives informed consent form and revised the protocol team roster.

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: 2 August 11
REVISED 07 September 2011*

Participating Study Sites:

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

Study Implementation Status:

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

UNC activated on 21 January 2011 and has enrolled 18 participants. JHU activated on 17 February 2011 and has enrolled 13 participants.

Accrual Status:

	UNC	JHU
Date First Screened	24-Jan-2011	21-Feb-2011
Date First Enrolled	7-Feb-2011	28-Feb-2011
# Individuals Screened	24	31
# Individuals Enrolled	18	13

Retention Status:

Refer to the SCHARP retention summary.

Implementation Issues and Problems:

None at this time.

Report for HPTN Study Operations Group

HPTN 067

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

Based on data available through August 10, 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 English CASI is finalized. The CASI was translated into Xhosa and reviewed by the sites. It is currently being reprogrammed at SCHARP. The Thai version of the CASI is also being revised. The CRFs are being revised and are expected to be finalized by 12 August. Other implementation materials (including counseling materials, materials for the qualitative component and the SSP) are currently being drafted or under review. The Wisepill devices have been manufactured and are at the sites.

The Cape Town site training visit was held 25-29 July and the site is expected to be activated in the next week or two. "Dear Participant" letters will be provided to the Cape Town Site's IRB and participants after DAIDS review and approval in order to explain the results of recent PrEP study trials.

The Bangkok site has submitted for Thai MOPH review and CDC IRB review is scheduled for early September. The site is hoping to obtain approvals from the Thai MOPH IRB in August and the CDC in early September. The site is currently working on meeting all data, lab, pharmacy and administrative site activation requirements. The Study Specific training is currently set for 12-16 September 2011 in Bangkok.

The Clinical Trial Agreement between Gilead and DAIDS was approved by both parties 29 March 2011. Study drug was received by the Clinical Research Products Management Center (CPRMC) in June. Study drug will be shipped to the Cape Town site pending receipt of the VAT exception.

Accrual Status:

Pending, no sites have been activated.

Status of Intervention Delivery:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

None

Report for HPTN Study Operations Group

HPTN 068

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

Based on data available through: 8 August 2011

Participating Study Sites:

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

Study Implementation Status:

Enrollment commenced 5 March 2011. Through 21 weeks of enrollment the site has enrolled 1343 young women. 39 young women have been found to be HIV positive and 63 are HSV-2 positive.

Accrual Status (completed at all sites):

1,343 of 2,900 enrolled. 2660 negative young women need to be enrolled onto the study.

Status of Intervention Delivery:

No issues

Retention Status:

Not applicable.

Implementation Issues and Problems:

None.

Appendix: HPTN Protocols and INDs

Protocol #		IND	IND Sponsor	Study Status
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	68,535	DAIDS	Closed to Accrual
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	73,797	DAIDS	Enrolling
HPTN 067	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	71,589	DAIDS	In Development