



HPTN Study Operations Report

November 2009

**PTN Executive Summary Report
11 November 2009
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 | 374 | 94% | 15.9 | 23.5 | 74% |
| | Tanzania – Dar Es Salaam | 28Jan2009 | 270 | 213 | 79% | 9.6 | 22.2 | 63% |
| | Uganda – Mulago Hospital | 23Jun2008 | 500 | 469 | 94% | 16.9 | 27.8 | 75% |
| | Zimbabwe – Harare/Chitungwiza | 14May2008 | 500 | 449 | 90% | 18.2 | 24.7 | 76% |
| | Total | | 1670 | 1505 | 90% | 18.2 | 82.7 | |
| 046 V3 (Infants) | South Africa – Durban – Prince Mshiyeni Hospital | 22Jul2008 | 400 | 372 | 93% | 15.9 | 23.4 | 74% |
| | Tanzania – Dar Es Salaam | 28Jan2009 | 270 | 214 | 79% | 9.6 | 22.3 | 63% |
| | Uganda – Mulago Hospital | 23Jun2008 | 500 | 484 | 97% | 16.9 | 28.6 | 75% |
| | Zimbabwe – Harare/Chitungwiza | 14May2008 | 500 | 450 | 90% | 18.2 | 24.7 | 76% |
| | Total | | 1670 | 1520 | 91% | 18.2 | 83.5 | |
| 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) | ***Add site to report format*** | 03Nov2009 | – | 1 | – | 0.3 | 3.3 | |
| | Botswana – Gabarone | 16Apr2009 | 100 | 38 | 38% | 7 | 5.4 | 81% |
| | Brazil – Porto Alegre | 26Nov2007 | 93 | 77 | 83% | 23.9 | 3.2 | 93% |
| | Brazil – Rio de Janeiro | 14Nov2007 | 182 | 155 | 85% | 24.3 | 6.4 | 94% |
| | India – Chennai – YRGCare | 05Jul2007 | 240 | 220 | 92% | 28.7 | 7.7 | 95% |
| | India – Pune | 28Jun2007 | 190 | 139 | 73% | 28.9 | 4.8 | 95% |
| | Malawi – Blantyre – Queen Elizabeth Central | 16Jan2008 | 180 | 186 | 103% | 22.2 | 8.4 | 93% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 06Dec2007 | 240 | 208 | 87% | 23.5 | 8.9 | 93% |
| | South Africa – Johannesburg – Witwatersrand | 20May2008 | 75 | 38 | 51% | 18 | 2.1 | 92% |
| | South Africa – Soweto | 11Jun2009 | 90 | 6 | 7% | 5.1 | 1.2 | 75% |
| | Thailand – Chiang Mai | 11Oct2007 | 90 | 84 | 93% | 25.4 | 3.3 | 94% |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 05Nov2007 | 190 | 180 | 95% | 24.6 | 7.3 | 94% |
| | Total | | 1670 | 1332 | 80% | 28.9 | 46.1 | |
| 052 Full Study (Partners) | ***Add site to report format*** | 05Nov2009 | – | 1 | – | 0.2 | 5 | |
| | Botswana – Gabarone | 16Apr2009 | 100 | 38 | 38% | 7 | 5.4 | 81% |
| | Brazil – Porto Alegre | 26Nov2007 | 93 | 79 | 85% | 23.9 | 3.3 | 93% |
| | Brazil – Rio de Janeiro | 14Nov2007 | 182 | 155 | 85% | 24.3 | 6.4 | 94% |
| | India – Chennai – YRGCare | 05Jul2007 | 240 | 220 | 92% | 28.7 | 7.7 | 95% |
| | India – Pune | 28Jun2007 | 190 | 139 | 73% | 28.9 | 4.8 | 95% |
| | Malawi – Blantyre – Queen Elizabeth Central | 16Jan2008 | 180 | 185 | 103% | 22.2 | 8.3 | 93% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 06Dec2007 | 240 | 211 | 88% | 23.5 | 9 | 93% |
| | South Africa – Johannesburg – Witwatersrand | 20May2008 | 75 | 38 | 51% | 18 | 2.1 | 92% |
| | South Africa – Soweto | 11Jun2009 | 90 | 6 | 7% | 5.1 | 1.2 | 75% |
| | Thailand – Chiang Mai | 11Oct2007 | 90 | 84 | 93% | 25.4 | 3.3 | 94% |

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|---------------|---|--------------------------|---------------|----------------|---------------------|----------------------|---------------------------------|---------------------|
| | Zimbabwe – Harare – Parirenyatwa Hospital | 05Nov2007 | 190 | 180 | 95% | 24.6 | 7.3 | 94% |
| | Total | | 1670 | 1336 | 80% | 28.9 | 46.2 | |
| 057 (Mothers) | Brazil – Belo Horizonte | 08Aug2007 | 9 | 8 | 89% | 27.5 | 0.3 | completed |
| | Brazil – Porto Alegre – Conceicao | 15Jun2008 | 4 | 5 | 125% | 17.1 | 0.3 | completed |
| | Brazil – Porto Alegre – Santa Casa | 19Sep2007 | 11 | 13 | 118% | 26.1 | 0.5 | completed |
| | Brazil – Rio de Janeiro | 17Apr2008 | 4 | 7 | 175% | 19.1 | 0.4 | completed |
| | Malawi – Blantyre – Queen Elizabeth Central | 26Dec2006 | 56 | 56 | 100% | 35 | 1.6 | completed |
| | Total | | 80 | 89 | 111% | 35 | 2.5 | |
| 057 (Infants) | Brazil – Belo Horizonte | 08Aug2007 | 9 | 8 | 89% | 27.5 | 0.3 | completed |
| | Brazil – Porto Alegre – Conceicao | 15Jun2008 | 4 | 5 | 125% | 17.1 | 0.3 | completed |
| | Brazil – Porto Alegre – Santa Casa | 19Sep2007 | 11 | 13 | 118% | 26.1 | 0.5 | completed |
| | Brazil – Rio de Janeiro | 17Apr2008 | 4 | 7 | 175% | 19.1 | 0.4 | completed |
| | Malawi – Blantyre – Queen Elizabeth Central | 27Dec2006 | 56 | 56 | 100% | 35 | 1.6 | completed |
| | Total | | 80 | 89 | 111% | 35 | 2.5 | |
| 058 | China – Guangxi – Heng County | 24Dec2008 | 400 | 157 | 39% | 10.7 | 14.7 | 29% |
| | China – Xinjiang | 23Dec2008 | 490 | 186 | 38% | 10.8 | 17.2 | 29% |
| | Thailand – Chiang Mai University | 30May2007 | 202 | 202 | 100% | 28.7 | 7 | completed |
| | Total | | 1500 | 545 | 36% | 29.9 | 18.2 | |
| 061 | US – Atlanta | – | 202 | – | – | 0 | – | |
| | US – Boston | 17Jul2009 | 403 | 53 | 13% | 3.9 | 13.6 | 22% |
| | US – Decatur | 16Sep2009 | 201 | 18 | 9% | 1.9 | 9.5 | 12% |
| | US – Los Angeles | 30Sep2009 | 403 | 32 | 8% | 1.4 | 22.9 | 9% |
| | US – NY – Harlem Prevention Center | – | 202 | – | – | 0 | – | pending |
| | US – NY – New York Blood Center | 01Oct2009 | 201 | 22 | 11% | 1.4 | 15.7 | 9% |
| | US – San Francisco | 13Aug2009 | 403 | 51 | 13% | 3 | 17 | 18% |
| | US – Washington DC | 28Jul2009 | 403 | 42 | 10% | 3.5 | 12 | 20% |
| | Total | | 2418 | 218 | 9% | 3.9 | 55.9 | |
| 064 (Women) | US – Atlanta | 22Oct2009 | 200 | 1 | 1% | 0.7 | 1.4 | 11% |
| | US – Baltimore | 05Aug2009 | 200 | 38 | 19% | 3.3 | 11.5 | 53% |
| | US – Chapel Hill | 26May2009 | 200 | 200 | 100% | 4 | 50 | completed |
| | US – Decatur | 27Aug2009 | 200 | 22 | 11% | 2.5 | 8.8 | 41% |

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|-----------------|---|---------------------------------|----------------------|-----------------------|----------------------------|-----------------------------|--|----------------------------|
| | US – NY – Bronx–Lebanon Hospital Center | 16Jun2009 | 200 | 202 | 101% | 4.4 | 45.9 | completed |
| | US – NY – Harlem Prevention Center | 26Oct2009 | 200 | 4 | 2% | 0.5 | 8 | |
| | US – Newark | 05Jun2009 | 400 | 171 | 43% | 5.3 | 32.3 | 87% |
| | US – Raleigh | 11Aug2009 | 200 | 54 | 27% | 3.1 | 17.4 | 50% |
| | US – Washington DC | 17Jun2009 | 200 | 189 | 95% | 4.9 | 38.6 | 80% |
| | Total | | 2000 | 881 | 44% | 5.6 | 157.3 | |
| 064 (Men) | US – Decatur | – | 30 | – | – | 0 | – | |
| | US – NY – Bronx–Lebanon Hospital Center | 30Sep2009 | 30 | 16 | 53% | 1.4 | 11.4 | 55% |
| | US – Raleigh | – | 30 | – | – | 0 | – | |
| | US – Washington DC | – | 30 | – | – | 0 | – | |
| | Total | | 120 | 16 | 13% | 1.4 | 11.4 | |

PTN Executive Summary Report
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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) | South Africa – Durban – Prince Mshiyeni Hospital | – | 1 | 1 | 1 | 100% | 99% |
| | Uganda – Mulago Hospital | 193 | 2123 | 1997 | 2015 | 94% | 95% |
| | Zimbabwe – Harare/Chitungwiza | 157 | 1727 | 1611 | 1639 | 93% | 95% |
| | Total | 350 | 3851 | 3609 | 3655 | 94% | 95% |
| 046 V3 (Mothers) | South Africa – Durban – Prince Mshiyeni Hospital | 374 | 1269 | 1149 | 1234 | 91% | 97% |
| | Tanzania – Dar Es Salaam | 213 | 562 | 522 | 553 | 93% | 98% |
| | Uganda – Mulago Hospital | 469 | 1568 | 1497 | 1524 | 95% | 97% |
| | Zimbabwe – Harare/Chitungwiza | 449 | 1569 | 1485 | 1523 | 95% | 97% |
| | Total | 1505 | 4968 | 4653 | 4834 | 94% | 97% |
| 046 V3 (Infants) | South Africa – Durban – Prince Mshiyeni Hospital | 372 | 2582 | 2424 | 2504 | 94% | 97% |
| | Tanzania – Dar Es Salaam | 214 | 1081 | 983 | 1060 | 91% | 98% |
| | Uganda – Mulago Hospital | 484 | 3308 | 3220 | 3208 | 97% | 97% |
| | Zimbabwe – Harare/Chitungwiza | 450 | 3216 | 3049 | 3115 | 95% | 97% |
| | Total | 1520 | 10187 | 9676 | 9887 | 95% | 97% |
| 052 Combined (Indexes) | ***Add site to report format*** | 1 | 0 | 0 | 0 | – | – |
| | Botswana – Gabarone | 38 | 95 | 95 | 95 | 100% | 100% |
| | Brazil – Porto Alegre | 82 | 472 | 461 | 465 | 98% | 99% |
| | Brazil – Rio de Janeiro | 168 | 1216 | 1200 | 1195 | 99% | 98% |
| | India – Chennai – YRGCare | 230 | 1505 | 1404 | 1481 | 93% | 98% |
| | India – Pune | 149 | 1059 | 1054 | 1040 | 100% | 98% |
| | Malawi – Blantyre – Queen Elizabeth Central | 196 | 914 | 875 | 902 | 96% | 99% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 218 | 1132 | 1068 | 1115 | 94% | 99% |
| | South Africa – Johannesburg – Witwatersrand | 38 | 149 | 140 | 148 | 94% | 99% |
| | South Africa – Soweto | 6 | 7 | 7 | 7 | 100% | 100% |
| | Thailand – Chiang Mai | 94 | 657 | 648 | 644 | 99% | 98% |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 190 | 971 | 926 | 957 | 95% | 99% |

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| Protocol | Site | Total Enrolled | Expected Visits | Completed Visits | Protocol Expectations | Retention Rate | Protocol Expected Standard |
|-------------------------|---|----------------|-----------------|------------------|-----------------------|----------------|----------------------------|
| | Total | 1410 | 8177 | 7878 | 8050 | 96% | 98% |
| 052 Combined (Partners) | ***Add site to report format*** | 1 | - | - | - | - | - |
| | Botswana – Gabarone | 38 | 95 | 93 | 95 | 98% | 100% |
| | Brazil – Porto Alegre | 84 | 472 | 445 | 465 | 94% | 99% |
| | Brazil – Rio de Janeiro | 168 | 1216 | 1058 | 1195 | 87% | 98% |
| | India – Chennai – YRGCare | 230 | 1505 | 1330 | 1481 | 88% | 98% |
| | India – Pune | 149 | 1059 | 1033 | 1040 | 98% | 98% |
| | Malawi – Blantyre – Queen Elizabeth Central | 196 | 914 | 776 | 902 | 85% | 99% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 221 | 1132 | 980 | 1115 | 87% | 99% |
| | South Africa – Johannesburg – Witwatersrand | 38 | 149 | 136 | 148 | 91% | 99% |
| | South Africa – Soweto | 6 | 7 | 6 | 7 | 86% | 100% |
| | Thailand – Chiang Mai | 94 | 657 | 602 | 644 | 92% | 98% |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 190 | 971 | 846 | 957 | 87% | 99% |
| | Total | 1415 | 8177 | 7305 | 8050 | 89% | 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 | 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% |
| | Total | 89 | 534 | 520 | 516 | 97% | 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 | 56 | 392 | 376 | 376 | 96% | 96% |
| | Total | 89 | 623 | 605 | 598 | 97% | 96% |
| 058 | China – Guangxi – Heng County | 157 | 52 | 45 | 49 | 87% | 94% |
| | China – Xinjiang | 186 | 79 | 71 | 74 | 90% | 94% |
| | Thailand – Chiang Mai University | 202 | 288 | 259 | 261 | 90% | 91% |
| | Total | 545 | 419 | 375 | 384 | 89% | 92% |

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).

HPT Network Laboratory Update November 2009

HPTN 027 (Uganda only)

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

HPTN 046

- A. General Comments
Version 3.0 dated 26 Sept, 2007
- 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
The NL is working on the hepatitis substudy. The PI has been talking with the sites regarding the testing they will perform on site and the testing that will be done at the NL.
- 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 validating a new hematology instrument. The site has had a recent issue with their VQA RNA panel. NL is working with the site on this issue.
 3. Chennai - No new updates
 4. Blantyre - The site has had a recent issue with their VQA RNA panel. The NL is working with the site on this issue and updates to their action plan from the previous NL visit.
 5. Porto Alegre - No new updates
 6. Rio sites –No new updates
 7. Lilongwe – No new updates
 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
Plans to add an additional Cohort are under discussion.
- 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
Thailand - No new updates
- B. China sites.
 - 1. Xinjiang Site- Current clinic space will be moving temporarily while renovations are being made.
 - 2. Guangxi - An additional clinic will be added in Nanning
Paul was due to travel November 2nd but trip has been postponed because invitation letter (required for visa) was received too late.
- C. 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. 064 Site Specific
 - 1. North Carolina - The Durham site has enrolled 200 women. The Wake site is currently enrolling participants.
 - 2. New Jersey - Site activated and enrolling participants.
 - 3. Washington - Site activated and enrolling participants.
 - 4. Bronx Site - has enrolled 200 women.
 - 5. Baltimore- Site activated and enrolling participants...
 - 6. Harlem - Site recently met activation requirements for the laboratory.
 - 7. Atlanta - Hope and Ponce sites are activated and enrolling participants.
- C. 061 Site Specific
 - 1. Fenway - Site activated As of October 9th approximately 40 enrolled.
 - 2. George Washington University - Site activated. As of October 9th approximately 20 enrolled
 - 3. San Francisco - Site activated. As of October 9th approximately 40 enrolled.
 - 4. Harlem - Site recently activated. .
 - 5. Atlanta - Hope and Ponce CRS have been activated by NL . As of October 9th approximately 12 enrolled
 - 6. New York Blood Center - Site activated .Site has had an issue with their Brady printer and was unable to print LDMS labels. As of October 9th approximately 8 enrolled
 - 7. UCLA - Site activated. As of October 9th approximately 12 enrolled.

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.

Travel Updates

- Estelle and Letanya will be visiting the Zimbabwe site in November.
- Estelle will be visiting the Botswana site in November and the India sites in December.
- Estelle will be at the upcoming 063 training in January for Thailand.,
- Paul will visit both China sites mid November 2009
- Vanessa will visit the Blantyre site in November.
- Someone from the NL will visit the Dar es Salaam in December

Implementations Issues and Problems Summary November 2009

HPTN 052:

Enrollment is expected to be completed by the end of March 2010. The target enrollment of each site is listed below. Some sites (e.g. Blantyre is at 191 as of mid-October 2009) have already or will go beyond their target. In such cases, these sites will continue to enroll until the study is fully enrolled.

| | |
|---|-----------|
| Boston, MA (Fenway) | 2 |
| Lilongwe, Malawi (UNCP): | 250 |
| Blantyre, Malawi (JHP): | 190 |
| Harare, Zimbabwe (UZ-UCSF): | 200 |
| Rio de Janeiro, Brazil (IPEC and HGNI): | 197 |
| Porto Alegre, Brazil (HNSC): | 98 |
| Pune, India (NARI): | 200 |
| Chennai, India (YRG CARE): | 250 |
| Chiang Mai, Thailand (RIHES): | 100 |
| Johannesburg, South Africa (WITS): | 75 |
| Gaborone, Botswana: | 82 |
| Soweto, South Africa | 68 |
| <u>Kenya</u> | <u>38</u> |
| Total: | 1750 |

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

HPTN 058:

The civil unrest in Urumqi has caused continued loss of all international communication lines in Xinjiang province. However, Dr. Yiming Shao's team in Beijing remains in close contact with the site in Urumqi. This problem is anticipated to last indefinitely.

HPTN 061:

Sites have had difficulty with the knowing how to classify certain participants at enrollment because of uncertainty about their prior HIV diagnosis or information revealed later in the visit that contraindicates information provided earlier. Guidance was distributed to the team in the revised SSP on how to address such issues.

HPTN 062:

It is uncertain if the Blantyre site can continue participation as is currently planned. Funding has not been confirmed for this site, and the future of CHAVI 001 at the site is questionable.

HPTN 063:

The ACASI and CRFs are taking 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.

HPTN 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: 6 November 2009

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: 6 November 2009

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:

As of 31 October there have been 1516 enrollments; 444 in Zimbabwe, 482 in Uganda, 372 in South Africa and 218 in Tanzania. There have been 1252 infants randomized; 368 in Zimbabwe, 411 in Uganda, 294 in South Africa and 179 in Tanzania. The target number of randomizations is 1500. HPTN 046 is anticipated to be fully enrolled by late 4th quarter 2009 or early 1st quarter 2010.

Tanzania has been placed on Clinical Pause for non-compliance with DAIDS safety reporting and laboratory compliance issues. Official notice went to the site on 28 August. The site may continue to enroll and randomize based on mothers that have already signed consents, but further screening is suspended until the site meets the terms of lifting of the clinical pause.

The SMC is to review HPTN 046 on 9 November. The DSMB meets on 4 December.

Accrual Status:

1516 infants have been enrolled under version 3.0 of the protocol. 1252 infants have been randomized.

Status of Intervention Delivery:

All sites have made the blinded study product exchange and should be using the "B" kits.

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 November 2009

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 activated to the protocol are screening and enrolling under Version 3.0 of the protocol.

The new site in Kisumu, Kenya was activated 19 October 2009.

The HPTN 052 DSMB meeting was held 3 November 2009, where the following recommendations and comments were made:

- 1) Expand efforts to complete enrollment as soon as possible.
- 2) Expand retention efforts for couples already enrolled.
- 3) Expand the testing for presence of ART to include a random sample of baseline specimens from both arms and a random sample of follow-up specimens in the delay arm in order to get a better idea of how prevalent it is that individuals are using ART without our knowledge.
- 4) Specific questions were raised regarding some neurological-related adverse events that we will explore further with the sites where these occurred.

Accrual Status:

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

| HPTN 052 Cumulative Screening and Enrollment Data | | | | | | | | | | | | | | | |
|--|-----------|-----------|-----------|-----------|------------------|---------------|---------------|-----------|-----------|-----------|-----------|-----------|-----------|-------------|---------|
| Week Ending: 31 October 2009 | | | | | | | | | | | | | | | |
| | Lilongwe | RIHES | NARI | Blantyre | Brazil - FIOCRUZ | Brazil - HGNI | Brazil - HNSC | YRG CARE | Zimbabwe | WITS SA | Botswana | Soweto | Kenya | Individuals | Couples |
| Date First Screened | 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 | | |
| Date First Enrolled | 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 | | | |
| # Screened* | 1342 | 508 | 606 | 1708 | 354 | 310 | 256 | 1015 | 1926 | 168 | 298 | 96 | 18 | 8625 | n/a |
| # Enrolled - Individuals | 428 | 190 | 296 | 392 | 194 | 136 | 162 | 452 | 374 | 76 | 74 | 8 | 0 | 2796 | n/a |
| # Enrolled - Couples | 214 | 95 | 148 | 196 | 97 | 68 | 81 | 226 | 187 | 38 | 37 | 4 | 0 | n/a | 1398 |
| Eligible | 436 | 190 | 318 | 394 | 196 | 136 | 164 | 514 | 422 | 78 | 90 | 30 | 2 | 2990 | n/a |
| Ineligible | 790 | 314 | 270 | 1248 | 150 | 162 | 92 | 480 | 1474 | 86 | 204 | 64 | 16 | 5350 | 2675 |
| Eligibility Unknown | 116 | 4 | 18 | 66 | 8 | 12 | 0 | 21 | 30 | 4 | 4 | 2 | 0 | 285 | n/a |
| Individuals # Screened/Individuals # Enrolled | 3.1 | 2.7 | 2.0 | 4.4 | 1.8 | 2.3 | 1.6 | 2.2 | 5.1 | 2.2 | 4.0 | 12.0 | 0.0 | 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:

| | HSE | Fenway |
|--|--------------|---------------|
| # 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 the end of March 2010. The target enrollment of each site is listed below. Some sites (e.g. Blantyre is at 191 as of mid-October 2009) have already or will go beyond their target. In such cases, these sites will continue to enroll until the study is fully enrolled.

| | |
|---|------|
| Boston, MA (Fenway) | 2 |
| Lilongwe, Malawi (UNCP): | 250 |
| Blantyre, Malawi (JHP): | 190 |
| Harare, Zimbabwe (UZ-UCSF): | 200 |
| Rio de Janeiro, Brazil (IPEC and HGNI): | 197 |
| Porto Alegre, Brazil (HNSC): | 98 |
| Pune, India (NARI): | 200 |
| Chennai, India (YRG CARE): | 250 |
| Chiang Mai, Thailand (RIHES): | 100 |
| Johannesburg, South Africa (WITS): | 75 |
| Gaborone, Botswana: | 82 |
| Soweto, South Africa | 68 |
| Kenya | 38 |
| <hr/> | |
| Total: | 1750 |

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: 10 Nov 09

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 maternal dosing and infant daily dosing for 1 week.

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

Study Drug will be available at the end of Nov 2009.

Accrual Status:

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

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

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 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 1 November 2009

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:

Chiang Mai has enrolled 202 participants, Xinjiang has enrolled 185 participants and Guangxi has enrolled 151 participants. The clinic in Urumqi has relocated into their proposed satellite site due to orders from the Chinese authorities. DAIDS has issued an approval for this temporary relocation.

The Nanning site (also in Guangxi Province as is the Heng County site) has been approved and the site is working towards site activation which will not occur until study drug is on site. It is anticipated that this will be late December or early January.

All sites have submitted LoA #1 to their local IRBs.

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.

Accrual Status:

| | Chiang Mai | Guangxi | Xinjiang |
|-------------------------------|------------|-----------|-----------|
| Date First Screened | 11-Apr-07 | 19-Dec-08 | 19-Dec-08 |
| Date First Enrolled | 30-May-07 | 24-Dec-08 | 21-Dec-08 |
| # Individuals Screened | 281 | 310 | 320 |
| # Individuals Enrolled | 202 | 151 | 185 |

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

| | |
|-----------|-----|
| All Sites | |
| Week 26 | 91% |
| Week 52 | 90% |
| Week 78 | 80% |
| Week 104 | 80% |

Implementation Issues and Problems:

The civil unrest in Urumqi has caused continued loss of all international communication lines in Xinjiang province. However, Dr. Yiming Shao's team in Beijing remains in close contact with the site in Urumqi. This problem is anticipated to last indefinitely.

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: 06 November 2009

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 but the Harlem site for the HPTN 061 protocol have been activated to the protocol. The Harlem site is expected to activate in November.

| 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 | N/A | N/A |

The Study Team had a face-to-face operations meeting in Washington D.C. on 14-15 October 2009 which was well attended and useful in letting sites discuss common challenges and successes with one another. The SSP sections have recently been updated to clarify and correct issues raised during implementation.

Accrual Status (participants enrolled at each site):

| Fenway | GWU | Emory - Ponce | Emory - Hope | San Fran | UCLA | NYBC | Harlem | TOTAL |
|--------|-----|---------------|--------------|----------|------|------|--------|-------|
| 49 | 35 | N/A | 19 | 49 | 28 | 16 | N/A | 196 |

Status of Intervention Delivery:

Some of the sites have had slow uptake of the health navigation component of the study and are developing materials and strategies to improve uptake. The most common reason that potential participants are ineligible is no unprotected anal intercourse in the last six months.

Retention Status:

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

Implementation Issues and Problems:

Sites have had difficulty with the knowing how to classify certain participants at enrollment because of uncertainty about their prior HIV diagnosis or information revealed later in the visit that contraindicates information provided earlier. Guidance was distributed to the team in the revised SSP on how to address such issues.

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 November 2009

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. Sites will submit to their respective IRBs this week.

Final CRFs, translations and back-translations are expected to be completed by December. The Counseling Manual and the qualitative interview guides are being drafted now.

Training will be in two parts; protocol-specific training is scheduled for 5-9 December 2009, and the counselor training is scheduled for the week of 18 January 2010. Two consultants from UNC, Michele Demers and Carol Golin, will be the trainers in January. Activation should occur shortly after the counselor training takes place.

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:

It is uncertain if the Blantyre site can continue participation as is currently planned. Funding has not been confirmed for this site, and the future of CHAVI 001 at the site is questionable.

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: 05 November 2009

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 content of the CRFs for 063 is final and SCHARP is currently programming the final English version. The content of the ACASI will be finalized in the coming weeks and SCHARP will begin the translations and audio recording during November and December.

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 will submit to the JHU IRB for November review. They will 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 are taking 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.

Additionally, Zambia has indicated that they are having administrative challenges with hiring at the moment and may not have some critical staff in place for the agreed upon training dates. We will receive an update from the site in 2-4 weeks and decide them if the training will need to be delayed until March.

Report for HPTN Study Operations Group

HPTN 064

Women's SeroIncidence Study (ISIS)

Based on data available through: 09 November 09

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.

Two of the ten study communities are fully enrolled. The UNC AIDS CRS (Durham site) is fully enrolled. The Bronx-Lebanon Hospital Center (BLHC) CRS is also fully enrolled. However, BLHC is also participating in the Qualitative Component of the study and is currently conducting focus groups with men and women. The George Washington University School of Public Health and Health Services (GWU) CRS is expected to complete enrollment of women by the end of November. GWU is also participating in the qualitative component and will continue with interviews and focus groups past enrollment.

The Prevention Management Group approved the reallocation of the Qualitative Component from the Johns Hopkins Adult AIDS (JHU) CRS to the George Washington University School of Public Health and Health Services (GWU) CRS on 23 September 09. The decision was communicated to sites by the Protocol Chair on 1 October 09. GWU has received IRB approval for this component and is in the process of submitting for RCC approval.

The JHU CRS was on voluntary pause from Friday, October 16 to Monday, November 2, 2009. The site has since re-initiated screening and enrollment for HPTN 064 and is working closely with the appropriate parties to ensure good implementation of the study.

FHI conducted site visits at the following HPTN 064 sites during October and November:

JHU CRS (October 5-6)
Emory CRSs (October 7-9)
GWU CRS (October 14)
UMDNJ CRS (November 2-3)
Harlem Prevention Center (November 4-5)
Bronx Lebanon Hospital CRS (November 6)

Accrual Status:

Please see SCHARP Screening and 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.

Appendix: HPTN Protocols and INDs

| Protocol # | | IND | IND Sponsor | Study Status |
|-----------------|--|--------------|-------------|-------------------|
| 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 | BB-IND 12023 | DAIDS | Closed to Accrual |
| HPTN 046 | 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 |
| 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 | Enrolling |
| 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 | 72,531 | DAIDS | Enrolling |
| 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 |

