

HPTN 082 - A Phase IV Randomized Multi-site Prospective Study to Assess PrEP Acceptance and Adherence Among HIV-uninfected Young Women
Report - February 13, 2019
Visit Cutoff Date: February 12, 2019
Table C - Screening Summary by Site

| | Overall | Spilhaus CRS | Emavundleni CRS | Ward 21 CRS |
|---|-----------------|-----------------|--------------------|-----------------|
| Screened | 646 | 213 | 183 | 250 |
| Enrolled | | | | |
| Yes | 451/646 (69.8%) | 148/213 (69.5%) | 141/183 (77.0%) | 162/250 (64.8%) |
| No | 195/646 (30.2%) | 65/213 (30.5%) | 42/183 (23.0%) | 88/250 (35.2%) |
| Reason Not Enrolled | | | | |
| Other | 66/195 (33.8%) | 13/65 (20.0%) | 23/42 (54.8%) | 30/88 (34.1%) |
| Reactive or positive HIV test result | 29/195 (14.9%) | 16/65 (24.6%) | 5/42 (11.9%) | 8/88 (9.1%) |
| Pregnant or planning to become pregnant during the next 12 months | 21/195 (10.8%) | 9/65 (13.8%) | 2/42 (4.8%) | 10/88 (11.4%) |
| Score < 5 on VOICE risk score tool | 10/195 (5.1%) | 5/65 (7.7%) | 3/42 (7.1%) | 2/88 (2.3%) |
| In the month prior to screening, no vaginal or anal intercourse reported | 6/195 (3.1%) | 1/65 (1.5%) | 2/42 (4.8%) | 3/88 (3.4%) |
| Hepatitis B (HBV) seropositive or unwilling to accept vaccination if HBV seronegative | 6/195 (3.1%) | 4/65 (6.2%) | 1/42 (2.4%) | 1/88 (1.1%) |
| Planning to relocate or absences >4 weeks required in the next 12 months | 5/195 (2.6%) | 0/65 (0.0%) | 5/42 (11.9%) | 0/88 (0.0%) |
| Not interested in PrEP | 2/195 (1.0%) | 1/65 (1.5%) | 0/42 (0.0%) | 1/88 (1.1%) |
| Lacks mobile phone access or SMS capacity | 2/195 (1.0%) | 0/65 (0.0%) | 1/42 (2.4%) | 1/88 (1.1%) |
| Has a health condition that may interfere with participation | 2/195 (1.0%) | 0/65 (0.0%) | 1/42 (2.4%) | 1/88 (1.1%) |
| Receiving therapy with other investigational agents or agents which may inhibit or compete for elimination via active | 1/195 (0.5%) | 0/65 (0.0%) | 1/42 (2.4%) | 0/88 (0.0%) |
| Not female at birth | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Younger than 16 or older than 25 | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Reported PrEP use within the last 12 months | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Participation in another clinical trial using investigational agents | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Prior participation in the active arm of an HIV vaccine trial | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Current use of ARV drugs for post-exposure prophylaxis (PEP) | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Completion of PEP regimen within 4 weeks prior to screening | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Current active and serious infections which could interfere with study participation | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Signs or symptoms of acute HIV infections | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Abnormal kidney function tests | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Allergy/sensitivity to the study drug or its components | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |
| Unable to complete Enrollment Visit within 45 days of blood collection at Screening Visit | 0/195 (0.0%) | 0/65 (0.0%) | 0/42 (0.0%) | 0/88 (0.0%) |

¹Reasons Not Enrolled are not mutually exclusive.

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Listing A - Listing of 'Other' Reasons by Site

| Site | Date | Reason Given |
|-----------------|-----------|--|
| Spilhaus CRS | 05JAN2017 | Excluded per clinician's discretion, has drug depe |
| Spilhaus CRS | 12DEC2016 | uncontrolled type 1 diabetes mellitus |
| Spilhaus CRS | 29JAN2017 | screening window closed |
| Spilhaus CRS | 30JAN2017 | screening to enrollment window closed before enrol |
| Spilhaus CRS | 01FEB2017 | screening to enrollment window closed before enrol |
| Spilhaus CRS | 08FEB2017 | screening to enrollment window closed before enrol |
| Spilhaus CRS | 06MAR2017 | screening window closed |
| Spilhaus CRS | 17MAY2017 | likely breast feeding |
| Spilhaus CRS | 11JUL2017 | 10. R discretion |
| Spilhaus CRS | 17AUG2017 | questionable computer literacy difficulty completi |
| Spilhaus CRS | 21SEP2017 | did not return for enrolment |
| Spilhaus CRS | 26SEP2017 | did not return for enrollment |
| Spilhaus CRS | 26SEP2017 | did not return for enrolment |
| Emavundleni CRS | 11NOV2016 | screening window closed |
| Emavundleni CRS | 11NOV2016 | screening window closed |
| Emavundleni CRS | 14NOV2016 | not sexually active |
| Emavundleni CRS | 15NOV2016 | screening window closed |
| Emavundleni CRS | 16NOV2016 | screening window closed |
| Emavundleni CRS | 07JAN2017 | Screening window closed |
| Emavundleni CRS | 02DEC2016 | Screening window closed |
| Emavundleni CRS | 12DEC2016 | screening window closed |
| Emavundleni CRS | 18JAN2017 | screening window has closed. |
| Emavundleni CRS | 07FEB2017 | out of window due to work commitments |
| Emavundleni CRS | 07FEB2017 | not sexually active |
| Emavundleni CRS | 08FEB2017 | Screening window closed |
| Emavundleni CRS | 21FEB2017 | screening window closed |
| Emavundleni CRS | 08MAR2017 | participant did not return for enrolment. |
| Emavundleni CRS | 12APR2017 | screening window closed |
| Emavundleni CRS | 19APR2017 | investigator discretion |
| Emavundleni CRS | 02MAY2017 | screening window closed |
| Emavundleni CRS | 02MAY2017 | participant screening window has closed |
| Emavundleni CRS | 02MAY2017 | participant screening window closed |
| Emavundleni CRS | 03MAY2017 | investigator decision |
| Emavundleni CRS | 30MAY2017 | not sexually active |
| Emavundleni CRS | 31MAY2017 | study fully enrolled |
| Emavundleni CRS | 15JUN2017 | study fully enrolled |
| Ward 21 CRS | 06OCT2016 | Participant never came back to finish screening vi |
| Ward 21 CRS | 06OCT2016 | scared of needles, did not want to take bloods. |
| Ward 21 CRS | 20OCT2016 | did not return for enrolment |
| Ward 21 CRS | 25OCT2016 | Participant did not come back |

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| | | |
|-------------|-----------|--|
| Ward 21 CRS | 27OCT2016 | post 45 days |
| Ward 21 CRS | 01NOV2016 | Participant did not come back. |
| Ward 21 CRS | 02NOV2016 | participant did not come back |
| Ward 21 CRS | 24NOV2016 | past 45 days |
| Ward 21 CRS | 01DEC2016 | participant did not come back. |
| Ward 21 CRS | 01DEC2016 | participant did not come back. |
| Ward 21 CRS | 12DEC2016 | participant did not come back for enrollment, 4-5 |
| Ward 21 CRS | 13JAN2017 | participant is scored of needles. |
| Ward 21 CRS | 07MAR2017 | past 45 days on 29mar17 |
| Ward 21 CRS | 16JAN2017 | past 45 days on 19mar17 |
| Ward 21 CRS | 28MAR2017 | never came back to complete screening visit |
| Ward 21 CRS | 03APR2017 | participant not seen by clinician |
| Ward 21 CRS | 04APR2017 | not seen by clinician |
| Ward 21 CRS | 05APR2017 | not seen by clinician. |
| Ward 21 CRS | 22MAY2017 | never came back to complete screening visit |
| Ward 21 CRS | 30MAY2017 | never came back to complete screening visit |
| Ward 21 CRS | 26JUN2017 | enrolment target met |
| Ward 21 CRS | 04JUL2017 | Participant not willing to do vaginal swabs as one |
| Ward 21 CRS | 04JUL2017 | "enrollment targets met" |
| Ward 21 CRS | 03AUG2017 | enrolment target completed |
| Ward 21 CRS | 21JUL2017 | "Enrollment targets met" |
| Ward 21 CRS | 25JUL2017 | Enrolment target met |
| Ward 21 CRS | 28JUL2017 | "enrollment targets met." |
| Ward 21 CRS | 10AUG2017 | "enrollment targets met" |
| Ward 21 CRS | 16AUG2017 | "enrollment targets met." |
| Ward 21 CRS | 02OCT2017 | participant refused to do procedures. |