**MTN-025 Study Specific Training Phase 1 – Screening & Enrolment**

*\*Sites are encouraged to follow this order for HOPE study specific training, but timing of breaks and number of days is per site discretion.*

*\*Study documents listed under references available on the MTN-025 website (with the exception of the IB). Printing of CRFs and other documents is optional/per site discretion, but recommend having at minimum electronic access. Slides and webinar recordings for each session can be found on the MTN-025 website.*

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| **Day 1** | | | |
| **Time** | **Presentation Topic** | **Presenter** | **References/Materials\*** |
| 10-10:45am | 1. [**HOPE Protocol Overview**](https://vimeo.com/175241400)  * Study Objectives * Study Design & Population * LoA#1 Key Updates * Resources/Communication | FHI 360 | * HOPE Protocol v2.0 * LoA#1 |
| 10:45-11am | 1. [**Participant Accrual (Overview)**](https://vimeo.com/175241625)  * Study Accrual Plan * Recruitment/Pre-Screening Procedures | FHI 360 | * SSP Section 4 (Accrual, Screening and Enrollment) * Site-specific accrual SOP |
| 11-11:15am | **Break** | | |
| 11:15-11:30am | 1. [**Recruitment/Prescreening Documentation**](http://www.mtnstopshiv.org/sites/default/files/attachments/03_HOPE_Recruitment_Prescr%20Doc_SCHARP%20w%20audio.pptx)  * Site recruitment lists * Pre-screening ID Assignment * Pre-screening Outcome CRF | SCHARP (recorded) | * Prescreening CRF ***(recommend printing hardcopy)*** |
| 11:30am-12pm | 1. [**Decliner Population**](https://vimeo.com/175241672)  * Decliner Population Overview * Decliner Visit Procedures * Eligibility Criteria * Off-site Decliner Visit Considerations * Documentation Requirements | FHI 360 | * SSP Section 2 (Decliner Population) * Decliner Visit Checklist * Decliner IC Comprehension Checklist * Decliner Behavioral Eligibility Worksheet * Decliner Eligibility Checklist * Decliner Screening & Enrollment Log |
| 12-12:45pm | **Lunch Break** | |  |
| 12:45-1:15pm | 1. [**Screening Visit Procedures**](https://vimeo.com/175241792)  * Screening Procedures Overview * Eligibility Criteria * PTID Assignment/Linkage Log * S&E Logs * Screen Failures | FHI 360 | * Protocol Sections: 5.2, 5.3, 7.2 * SSP Section 4 (Accrual, Screening and Enrollment) * Screening Visit Checklist * Screening Behavioral Eligibility Worksheet * Screening & Enrollment Log |
| 1:15-1:45pm | 1. [**Informed Consent**](https://vimeo.com/175241837)  * Informed Consent Types/Procedures * Supporting Materials and Documentation * Ongoing Informed Consent | FHI 360 | * SSP Section 5 (Informed Consent) * HOPE study factsheets * IC Coversheet * IC Comprehension Checklist * ICFs for your site |
| 1:45-2pm | **Break** | |  |
| 2-2:30pm | 1. [**HIV Testing for HOPE**](https://vimeo.com/175241912)  * New HIV Rapid and Confirmatory Tests * HOPE HIV Screening and Follow-Up Algorithms * HIV Testing Notification and Query Form | LC | * MTN-025 SSP Section 13 (Laboratory Considerations) * MTN-025 Protocol: Appendix II & III * MTN HIV Testing Notification & Query Form |
| 2:30-3:15pm | 1. [**HIV Counseling and Testing**](https://vimeo.com/175241975)  * HIV Pre- and Post-Test Counseling * HIV Counseling Messages for HIV results * Risk Reduction Counseling (Screening) | FHI 360 | * SSP tables 12-1, 12-2 and 12-3 (Counseling Considerations) * HIV Counseling worksheet (if in use at your site) |
| 3:15-4pm | 1. [**Lab Considerations**](https://vimeo.com/175242009)  * Overview and General Guidance * Labeling/Documentation/LDMS * Urine Testing * Blood Testing/Storage * Vaginal Specimens * Self-Collected Swabs | LC | * SSP Section 13 (Laboratory Considerations) |

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| **Day 2** | | | |
| **Time** | **Presentation Topic** | **Presenter** | **References/Materials\*** |
| 10-10:15am | 1. [**Overview of Safety Data on Dapivirine Vaginal Ring**](https://vimeo.com/175242056)  * Information on key safety data from ASPIRE and The Ring Study | Safety MDs | * Dapivirine Ring Investigator’s Brochure V10.0 |
| 10:15-11:15am | 1. [**Overview of Key Clinical Considerations**](https://vimeo.com/175242159)  * Baseline Medical/Menstrual History * Concomitant Medications * PrEP Considerations * Physical Exams * Pelvic Exams * Contraceptive Counseling * PSRT | Safety MDs | * MTN-025 SSP Section 10 (Clinical Considerations) * Baseline medical history questions sheet * Pelvic Exam Checklist * Contraceptive Counseling Workshop (if in use at your site) * Site-specific PrEP SOP |
| 11:15-11:30am | **Break** | |  |
| 11:30-12pm | 1. [**Screening, Clinical, and Laboratory CRFs**](http://www.mtnstopshiv.org/sites/default/files/attachments/12_HOPE%20Screening%20Forms_SCHARP_17AUG2016.ppt)  * ECI CRFs (Decliner and Enroller) * Demographics CRF * Baseline Medical History Log * Concomitant Medications Log * Pelvic/Physical Exam/Vital Signs CRFs * Laboratory Results CRF * STI Test Results CRF * Screening QA/QC | SCHARP  (recorded) | * Screening CRF packet (recommend printing hardcopy) |
| 12-12:30pm | 1. [**Enrollment Visit Procedures**](https://vimeo.com/175242198)  * Enrollment Procedures Overview * Eligibility Determination * Overview of HIV Prevention Options Counseling * Ring Use Instructions/Important Information | FHI 360 | * Protocol Section 7.3 & Appendix 1 * SSP Section 4 (Accrual, Screening and Enrollment), and 12 (Counseling Considerations) * Enrollment Visit Checklist * Enrollment Behavioral Eligibility Worksheet * Eligibility Checklist * Ring Use Instructions/Important Information |
| 12:30-1:30pm | **Lunch Break** | |  |
| 1:30-2:30pm | 1. [**Study Product Considerations for Clinical Team**](https://vimeo.com/175242222)  * Initial Study Product Dispensing/Prescription Overview * Study Product COC * Ring Codes * Study Product Accountability * Study Product Resupply, Holds, Discontinuations, Participant Decline | MTN Pharmacist | * SSP Section 9 (Study Product Considerations) * Accountability Log and Used Ring Destruction Log * Prescription and Vaginal Ring Request Slip * RCI CRF and Ring Tracking Log (within Enrollment CRF packet) |
| 2:30-3pm | 1. [**Enrollment and Ring Related CRFs**](http://www.mtnstopshiv.org/sites/default/files/attachments/15_HOPE%20Enrollment%20Forms_SCHARP_17AUG2016.pptx)  * Enrollment CRF * Family Planning Log * Specimen Storage CRF * ACASI Tracking CRF * Ring Collection/Insertion CRF * Vaginal Ring Tracking Log * Baseline Behavior and Baseline Vaginal Practices Assessment CRFs * Enrollment QA/QC | SCHARP  (recorded) | * Enrolment CRF packet (recommend printing hardcopy) |
| 3-3:15pm | **Break** | |  |
| 3:15-3:45pm | 1. [**Administration of Behavioral CRFs (Baseline)**](https://vimeo.com/175242254)  * Guidance for administration of behavioral CRFs * Review of Baseline Forms, highlighting guidance for new or unique questions | BRWG | * SSP Section 7 (Behavioral Measures) * Behavioral & Demographic CRFs (within Screening and Enrollment CRF packets) |
| 3:45-4:00pm | 1. [**Protocol Deviations**](https://vimeo.com/175242293)  * Protocol Deviation Training | FHI 360 / SCHARP | * MTN Protocol Deviation Policy (on web) and SSP Section 3 (Source Documentation) * PD log CRF |

**MTN-025 Study Specific Training Phase 2 – Follow-Up**

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| **Day 3** | | | |
| **Time** | **Presentation Topic** | **Presenter** | **References/Materials\*** |
| 10-10:45am  *4-4:45am EST* | **1.** [**Follow-Up Visit Overview**](https://vimeo.com/179232146)   * Follow-up Visit Types & Procedures   + M1&2   + Quarterly   + PUEV/Term * Follow-up HIV Prevention Options Counseling * Minimum procedures required to dispense rings during f/u * Fast-tracking’ ring supply visits * Month 3 Considerations (transition to quarterly visits) | FHI 360 | * SSP Section 6 (Follow-up Procedures) * Protocol Section 7.4 and Appendix I * Follow-up Visit Checklist (Month 1 & 2/Quarterly) * SSP Section 12 (Counseling) |
| 10:45-11:45am  *4:45-5:45am EST* | **2.** [**Follow-Up Medical History & Adverse Events**](https://vimeo.com/182456510)   * Follow-up Medical/Menstrual History * AE/SAE/EAEs Definitions * AE Reporting and Terms | Safety MDs | * SSP Section 10 (Clinical Considerations) * SSP Section 11 (AE Reporting and Safety Monitoring) |
| 11:45am-12:15pm  *5:45-6:15am EST* | **3.** [**Product Use Management & Product Holds**](https://vimeo.com/179234444)   * Protocol Requirements for Product Holds/Discontinuations | Safety MDs | * SSP Section 10 (Clinical Considerations) * Protocol Section 9 * Product Use Management Flow Sheets |
| 12:15-1:00pm  *6:15-7am EST* | **Lunch Break** | | |
| 1-1:20pm  *7-7:20am EST* | **4.** [**Off-Site Visits**](https://vimeo.com/179235259)   * Off Site Visit Procedures and Documentation Considerations | FHI 360 | * SSP Section 2 (Decliners) * SSP Section 6 (Follow-up Procedures) * SSP Section 8 (Participant Retention) * SSP Section 9 (Study Product Considerations) * SSP Section 10 (Product Hold/Discontinuation) * SSP Section 12 (Counseling) |
| 1:20-1:40pm  *7:20-7:40am EST* | **5.** [**Participant Retention**](https://vimeo.com/179333300)   * Retention Definitions/Strategies * Participant Transfers * Termination/Withdrawals | FHI 360 | * SSP Section 5 (Informed Consent) * SSP Section 6 (Follow-up Procedures) * SSP Section 8 (Participant Retention) * Protocol Section 9 (Termination & Early Withdrawal) |
| 1:40-1:55 pm  *7:40-7:55am EST* | **6.** [**Participant Tracking Database**](https://vimeo.com/179464064)   * Overview of participant tracking database | SCHARP | * SSP Section 8 (Retention) * Participant Tracking Database User Manual |
| 1:55-2:10pm  *7:55-8:10am EST* | **7.** [**Follow-Up Visit Study Product Considerations**](https://vimeo.com/179336244)   * Product Considerations for Split/Missed/Off-site Visits * Review of Ring Resupply/Holds * Review of Ring Collection Procedures/Accountability Documentation | MTN Pharmacy | * SSP Section 9 (Study Product Considerations for Non-Pharmacy Staff) |
| 2:10-2:20pm  *8:10-8:20am EST* | **Break** | |  |
| 2:20-2:40pm  *8:20-8:40am EST* | **8.** [**Follow-Up Sample Collection**](https://vimeo.com/179341290)   * Hair Collection and Storage | LC | * SSP Section 13.9 (Laboratory Considerations) * SSP Section 12.7 (Counseling Considerations) |
| 2:40-2:55 pm  *8:40-8:55am EST* | **9.** [**Visit Scheduling & Missed/Split Visits**](https://vimeo.com/180078148)   * Review of Visit Windows/Targets * Missed/Split Visits/Interim Visits | SCHARP | * SSP Section 14 (Data Collection) |
| 2:55-3:15pm  *9:55-10:15am EST* | **10.** [**Management of Seroconverters**](https://vimeo.com/179353817)   * Care and Support for Seroconverters * Modified Procedures for Seroconverters * HIV Resistance Results/Counseling * MTN-015 Referral | FHI360 | * SSP Section 6.5 (Follow-up Procedures) * SSP Section 10.9 (Clinical Considerations) * Seroconverter Visit Checklist |
| 3:15-3:25pm  *9:15-9:25am EST* | **Break** | | |
| 3:25-3:45pm  *9:25-9:45am EST* | **11.** [**Management of Pregnancies**](https://vimeo.com/179464865)   * Clinical Management of Pregnancies * Modified Procedures for Pregnant Participants * MTN-016 Referral | FHI360 | * SSP Section 6 (Follow-up Procedures) * SSP Section 10 (Clinical Considerations) * Sample Pregnancy Management Worksheet |
| 3:45-4pm  *9:45-10am EST* | **12.** [**Follow-Up Behavioral CRFs**](https://vimeo.com/179356807)   * Review of follow-up behavioral CRFs, highlighting guidance for new or unique questions | BRWG | * SSP Section 7 (Behavioral Measures) |
| 4-5pm  *10-11am EST* | **13.** [**All CRFs: Follow-Up, AE Documentation, Product Hold, HIV, Pregnancy CRFs**](https://vimeo.com/179359924)   * Follow-up CRFs, including review of Social Harms/Benefits CRFs * AE and GAE CRFs * Product Hold CRFs * HIV CRFs * Pregnancy CRFs | SCHARP | * SSP Section 14 (Data Management) * MTN-025 Case Report Forms |