**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
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**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
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