

MTN-003 Operational Walkthrough Agenda

Day 1
Tuesday, 11 November 2008

Time	Topic	Presenter/Leader
08.30	Welcome and Introductions	All
09.00	Overview and Purpose of Operational Walkthrough	MTN CORE (FHI)
09.15	Protocol Overview <ul style="list-style-type: none"> • Study Objectives • Key Study Design Specifications • Visit and Procedures Schedule • Product Dispensing and Returns • Safety Monitoring and Reporting • Protocol Q&A 	Protocol Co-Chair
10.30	Tea Break	All
11.00	Laboratory Considerations <ul style="list-style-type: none"> • Laboratory-Related Protocol Requirements • New Tests Used in VOICE • For Each Test: <ul style="list-style-type: none"> • Specimen Collection Requirements • Specimen Processing Requirements 	MTN NL
13.00	Lunch	All
14.00	Laboratory Considerations (continued) <ul style="list-style-type: none"> • Workflow and Overall Specimen Management • Abnormal Values • Specimen Storage, Shipping, and LDMS • Laboratory Activation Requirements 	MTN NL
15.00	HIV Testing Considerations and Study Procedures for Seroconverters	MTN CORE (FHI)
15.30	LDMS Specimen Tracking Sheet Seroconverter Laboratory Test Results form	MTN SDMC
16.00	Wrap-up and Review of Day 1 / Preview of Day 2	All
16.30	Adjourn	

MTN-003 Operational Walkthrough Agenda

Day 2 Wednesday, 12 November 2008

Time	Topic	Presenter/Leader
08.00	Q&A and Review of Day 1	All
	<p><i>Over the course of this day, all screening and enrollment visits and procedures will be discussed, as listed below. A tea break will occur at 10.30 and lunch will occur at 13.00.</i></p> <p>Screening Visits and Procedures:</p> <ul style="list-style-type: none"> • Eligibility Criteria <p>Screening Part 1 Visit:</p> <ul style="list-style-type: none"> • Protocol Requirements • SCHARP-Provided Forms • Source Documentation Considerations • Review of Visit Checklist / On-Site Participant/Specimen/Forms Flow <p>Screening Part 2 Visit:</p> <ul style="list-style-type: none"> • Protocol Requirements • SCHARP-Provided Forms • Source Documentation Considerations • Review of Visit Checklist / On-Site Participant/Specimen/Forms Flow <p>Enrollment Visit:</p> <ul style="list-style-type: none"> • Protocol Requirements • Randomization and Initial Product Dispensation • SCHARP-Provided Forms • Source Documentation Considerations • Review of Visit Checklist / On-Site Participant/Specimen/Product/Forms Flow 	<ul style="list-style-type: none"> • MTN CORE (FHI) • MTN CORE (FHI) • MTN SDMC • MTN CORE (FHI) • Site TBN • MTN CORE (FHI) • MTN SDMC • MTN CORE (FHI) • Site TBN • MTN CORE (FHI) • MTN SDMC • MTN SDMC • MTN CORE (FHI) • Site TBN
16.00	Wrap-up and Review of Day 2 / Preview of Day 3	All
16.30	Adjourn	

MTN-003 Operational Walkthrough Agenda

Day 3 Thursday, 13 November 2008

Time	Topic	Presenter/Leader
08.00	Q&A and Review of Day 2	All
08.30	Follow-up Visits: Months 1 and 2 <ul style="list-style-type: none"> • Protocol Requirements • Study Product Return and Re-Supply • SCHARP-Provided Forms • Source Documentation Considerations • Review of Visit Checklist / On-Site Participant/Specimen/Product/Forms Flow 	<ul style="list-style-type: none"> • MTN CORE (FHI) • MTN CORE (FHI) • MTN SDMC • MTN CORE (FHI) • Site TBN
10.30	Tea Break	
11.00	Follow-up Visits: Month 3 <ul style="list-style-type: none"> • Protocol Requirements • Study Product Return and Re-Supply • SCHARP-Provided Forms • Source Documentation Considerations • Review of Visit Checklist / On-Site Participant/Specimen/Product/Forms Flow 	<ul style="list-style-type: none"> • MTN CORE (FHI) • MTN CORE (FHI) • MTN SDMC • MTN CORE (FHI) • Site TBN
13.00	Lunch	
14.00	Considerations for Product Hold/Discontinuation <ul style="list-style-type: none"> • Protocol Requirements, Roles and Responsibilities, Documentation and Communication Flow • Study Product Request Slip • Product Hold/Discontinuation Case Report Form 	<ul style="list-style-type: none"> • MTN CORE (FHI) • MTN SDMC • MTN SDMC
14.45	Considerations for Adverse Event Reporting <ul style="list-style-type: none"> • Protocol Specifications • Source Documentation Considerations • AE Log Case Report Form 	<ul style="list-style-type: none"> • MTN CORE (FHI) • MTN CORE (FHI) • MTN SDMC
15.30	Wrap-up and Review of Day 3 / Re-Cap of Key Lessons Learned, Next Steps, and Action Items	All
16.30	Adjourn	