

MTN-017 List of
Documents to be updated

per The Letter of
Amendment





Study-Specific Procedure (SSP) Manual

- **SSP Section 1 (Introduction)**– Include LoA #1
- **Section 2 (Documentation Requirements)**
 - **Protocol Deviations:** Update to reflect process for communicating about questions regarding protocol deviations



Study-Specific Procedure (SSP) Manual

- **Section Appendix 2-1 (Source Documentation of Study Procedures):** Add Real-time PK specimen's source documentation. This includes laboratory results and documentation of counseling.
- **Section Appendix 2-2 (CRFs Used as Source Documents):** Update with new PK data convergence non-DataFax CRF.



Study-Specific Procedure (SSP) Manual

- **Section 5 (Study Procedures)** – Include any procedures related to Real Time PK testing and counseling.
- **SSP Section 6 (Counseling and Behavioral Considerations)** – Add PK counseling procedures, including process for providing results to participant, how to conduct counseling, when do conduct it, and any other relevant information.



Study-Specific Procedure (SSP) Manual

- **Section 10 (Laboratory Considerations)** – To include process for collection, documentation, sample shipment for PK samples



Visit Checklists

- **Mid Study Period**
- **End Period Visit**
 - Add collection of PK samples and PK counseling



Other Implementation Tools

- Informed Consent Comprehension Checklists
 - Add question related to PK testing
- Source Documentation SOP
- Activation Checklist
 - Add approval of LoA #1
- Informed Consent per LoA #1
- Counseling Manual



Next Steps

- Management Team
 - Update SSP manual and other implementation tools
 - Post final SSP manual on MTN website
- Sites
 - Provide any additional comments/edits to management team
 - Update ICFs, IC Comprehension Checklist, relevant SOP

Questions?

