MTN-017 List of Documents to be updated per The Letter of Amendment
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?