

MTN-020 Data Communiqué #17 – May 22, 2015

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

UPDATES – none

CLARIFICATIONS –

1. Completion of Study Exit Assessment (SEV-1~5) CRF for Seroconverters

Per Operational Guidance 9, if a participant seroconverts at her Product Use End Visit (PUEV) or is in the middle of algorithm testing, she should be scheduled to complete a Study Exit Visit (SEV). When administering the Study Exit Assessment CRF at her SEV, please line through Item 8 on page 3 and mark “no data recorded” on pages 4 and 5 of the CRF as these questions are not applicable. Participants who have seroconverted prior to their scheduled PUEV will be terminated at the PUEV and will not complete the SEV-1~5 CRF.

REMINDERS – none

iDATAFAX CORNER – No updates