

MTN-042 Data Communiqué #12 – 23 June 2023

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATE

Lab Normal Range Calculation - Infants

Calculation of lab normal ranges is dependent on age and therefore on date of birth. The MTN042 study databases reference the V201.0 folder for infants' Demographics forms, thus fail to calculate lab normal ranges when V201.0 assessments are reported in interim visit folders. As such, Data Management will add Infant Demographics forms to all Visits 201.0 that have been or are missed going forward; sites will need to re-enter/enter demographics data there. Any Infant Demographics forms currently existing in interim visit folders will be inactivated.

Reporting Early Termination for Infants Whose Mothers Withdraw Consent

On the Study Termination form and included in the drop-down list of responses to "Primary reason for completion/discontinuation" are "Participant is unwilling or unable to comply with required study procedures" and "Withdrawal of consent by participant". As infants are able neither to provide nor withdraw consent, and there are no responses specific to a mother withdrawing consent for her infant, in this scenario, please select "Withdrawal of consent by participant" and specify that the mother withdrew consent for her infant.