MTN-042 Data Communiqué #11 – 4 May 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 Reporting Clarification

Any local lab result reported as being under the instrumentation's lower limit of detection should be entered into the database as the closest value possible to, but less than, the detectable lower limit (e.g. bilirubin reported as "less than 0.145 mg/dL" should be entered into the database as "0.14 mg/dL").

As a reminder, the CRF Completion Guidelines specify the following reporting parameters:

- AST/SGOT: U/L, report as a whole number
- ALT/SGPT: U/L, report as a whole number
- Creatinine: mg/dL, report up to 5 decimal places
- Calculated Creatinine Clearance: mL/min, report up to 2 decimal places
- Hemoglobin: g/dL, report up to 5 decimals
- MCV: fl, report up to 5 decimals
- Platelets: cells/mm3, report up to 5 decimals
- WBC: cells/mm3, report up to 5 decimals
- Neutrophils: cells/mm3, report as a whole number
- Lymphocytes: cells/mm3, report as a whole number
- Monocytes: cells/mm3, report as a whole number
- Eosinophils: cells/mm3, report as a whole number
- Basophils: cells/mm3, report as a whole number

Please refer to the CRF Completion Guidelines for additional information.

Infant Weight Grading Clarification

The infant weight grading tool provided to sites is intended to facilitate infant weight severity grading, but given the complexities of infant weight grading, cannot be completely accurate. In order to capture borderline cases, SCHARP employs an internal program specifically designed to provide greater precision in the grading of infant growth events. In the event that SCHARP's programming results in a severity grading mis-assessment, SCHARP will query with a weight calculation correction. If such a query results in a previously unidentified AE, the site awareness date will reflect the date of query placement.