



MTN-025 (HOPE) Operational Guidance #4: Updates to MTN-025 Safety Lab Results Calculator

The MTN-025 management team provides an Excel “*Safety Lab Results Calculator*” to assist Clinical Research Sites in calculating DAIDS Toxicity Table Grading for Adverse Event reporting. In addition, SCHARP has programmed lab severity grading checks to ensure that site entered severity grades are correct per the DAIDS Toxicity Table, version 2.0. As of 21 April 2017, Medidata was updated to allow for entry of non-rounded laboratory results (i.e. two digits after the decimal point for Creatinine), however, the *Safety Lab Results Calculator* was not updated concurrently. The *Safety Lab Results Calculator* has now been updated to version 1.2 and validated to align with current SCHARP lab severity grading checks.

The following provides instructions on implementation of the updated Safety Lab Results Calculator, version 1.2:

- Do NOT retrospectively update any laboratory values already entered in the Medidata database, including baseline creatinine values.
- For participants who have already completed PUEV, no action is needed. Maintain the current version 1.1 of the Safety Lab Calculator Tool.
- For participants who have not yet had their PUEV, complete a new Safety Lab Results Calculator, version 1.2 at their PUEV visit. Sites should complete this tool using the current baseline creatinine values in Medidata.
 - For some participants, this result will be a rounded value (e.g. 0.7). Enter this rounded value when completing the updated tool.
 - For some participants, this result will be a non-rounded value which aligns with the number of significant digits on your site lab reports (e.g. 0.65). Enter this non-rounded value when completing the updated tool.
- The other fields in the calculator should also be reentered based on baseline measurements and lab upper limits of normal (ULN), as appropriate. These fields include PTID, staff initials, date, AST ULN, ALT ULN, Creatinine ULN and baseline participant weight.
- All updated tools should be printed and filed in the participant chart. Reference the updated safety lab calculator tool, version 1.2 to grade lab results from PUEV samples.

All Operational Guidance documents must be printed and filed with regulatory documentation.

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Date