Parameter Level Summary of Changes for the
Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Clarification Version 2.1, March 2017

The Division of AIDS Table for grading the severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table) is a collection of commonly encountered adverse events and their descriptive terminology utilized for severity grading. As part of its standard review processes, DAIDS reassessed the "DAIDS AE Grading Table, version 2.0" for accuracy and updated it (version 2.1) to be consistent with current NIAID (DAIDS) requirements. Moreover, this document (version 2.1) provides the needed clarifications sought by site investigators, Operations Offices, Statistical and Data Management Centers, and Medical Officers within the Division for some of the parameters. The clarifications and updates have been summarized in the introduction and are also highlighted within the body of the Table for convenience.

Please be advised that all protocols in development must use the updated, clarified version (2.1) of the table. Use of version 2.1 for ongoing studies will be at the discretion of DAIDS programs and protocol teams and can be implemented via a Clarification Memo. The clarified table is now posted on the RSC web page (https:// rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables)

This DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, version 2.1, March 2017 supersedes version 2.0 of the Table dated November, 2014.

Changes to note in this version of the Severity Grading Table are parameter specific and are highlighted below:

Major Clinical Conditions Category

Pregnancy, Puerperium, and Perinatal Section
- Page 17, Stillbirth:
  - Row 1, Column 1: Deleted "Fetal Death".
  - Row 1, Column 4: Changed "Fetal loss" to "Fetal death".
- Page 17, Preterm Birth
  - Row 2, Column 1: Changed "Preterm Delivery" to "Preterm Birth".
  - Row 2, Columns 2-5: Changed "Delivery" to "Live birth".
- Page 17, Footnote:
  - Deleted the Preterm Birth Parameter footnote.
- Page 17, Footnote 7:
  - Updated to "A pregnancy loss occurring at < 20 weeks gestational age".

Psychiatric Section
- Page 18, Insomnia:
  - Row 1, Column 2: Added "causing no or minimal interference with usual social & functional activities."
  - Row 1, Column 3: Added "causing more than minimal interference with usual social & functional activities."
  - Row 1, Column 4: Added "causing inability to perform usual social & functional activities requiring intervention or hospitalization."

Sensory Section
- Page 20, Uveitis:
  - Row 4, Column 3: Corrected typographical error "Medicamylasal" to "Medical."

Systemic Section
- Page 22, Underweight;
  - Row 1, Column 2: Changed "NA" to "WHO BMI z-score < -1 to -2" for consistency.
  - Row 1, Column 3: Changed "< -2 to ≤ -3" to "< -2 to -3" for consistency.
  - Row 2, Column 2: Changed "NA" to "WHO BMI z-score < -1 to -2" for consistency.
  - Row 2, Column 3: Changed "< -2 to ≤ -3" to "< -2 to -3" for consistency.
  - Row 3, Column 2: Changed "NA" to "WHO BMI z-score < -1 to -2" for consistency.
  - Row 3, Column 3: Changed "< -2 to ≤ -3" to "< -2 to -3" for consistency.
- Page 22, Weight Loss:
  - Row 4, Column 1: Changed "Weight Loss" to "Unintentional Weight Loss" so as to avoid confusion with intentional weight loss.

Laboratory Values Category

Chemistries Section
- Page 25, Laboratory Values title:
  - Added new footnote: "An asymptomatic abnormal laboratory finding without an accompanying AE should not be reported to DAIDS in an expedited time frame unless it meets protocol-specific reporting requirements."
- Page 25, Bilirubin:
  - Row 9, Column 4: Added "with other signs and symptoms of hepatotoxicity" for easy interpretation.
  - Row 11, Column 4: Added "with other signs and symptoms of hepatotoxicity" for easy interpretation.
  - Row 11, Column 5: Added "with life-threatening consequences (e.g., signs and symptoms of liver failure)" for easy interpretation.
- Page 26, Creatinine, High:
  - Row 9, Column 3: Changed "Increase of > 0.3 mg/dL above baseline" to "Increase to 1.3 to < 1.5 x participant's baseline" to make the equation a multiple of the participant's baseline AND to be consistent across the grades.
  - Row 9, Column 4-5: Changed "above baseline" to "participant's baseline".
- Page 26, Creatinine Clearance or eGFR, Low:
  - Row 10, Column 3-5: Changed "baseline" to "participant's baseline".
  - Row 10, Column 4: Changed "≥ 30 to < 50%" to "30 to < 50%".
- Page 26, Footnote 14:
  - Updated to "Use the applicable formula (i.e., Cockcroft-Gault in mL/min or Schwartz, MDRD, CKD-Epi in mL/min/1.73m2). Sites should choose the method defined in their study and when not specified, use the method most relevant to the study population."
- Page 26, Footnote:
  - Added a new footnote: "*Reminder: Choose the method that selects for the higher grade."
- Page 27, Phosphate, Low:
  - Row 11, Column 2: Changed "0.81 to < LLN" to "0.65 to < LLN"
  - Row 11, Column 3: Changed "0.65 to < 0.81" to "0.45 to < 0.65"
  - Row 11, Column 4: Changed "0.32 to < 0.65" to "0.32 to < 0.45"
- Page 28, Sodium, Low:
  - Row 2, Column 3: Changed "125 to < 135" to "125 to < 130"

Hematology Section
- Page 29, Footnote 16:
  - Updated to guide grading of hemoglobin among transgender participants: "Male and female sex as assigned at birth. For transgender participants ≥13 years of age who have been on hormone therapy for more than 6 consecutive months, grade hemoglobin based on the gender with which they identify (i.e., a transgender female should be graded using the female sex at birth hemoglobin laboratory values)."

- o Page 29, Footnote 17:
  - Updated first sentence to: "The most commonly used conversion factor to convert g/dL to mmol/L is 0.6206."
- o Page 30, Platelets, Decreased:
  - Row 9, Column 2: Changed "100,000 to < 124,999" to "100,000 to < 125,000" and "*100.000 x 10^9 to < 124.999 x 10^9*" to "*100.000 x 10^9 to < 125.000 x 10^9*" for uniformity.