Parameter Level Summary of Changes for the Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Corrected Version 2.1, July 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. Version 2.1 provided needed clarifications sought by site investigators, Operations Offices, Statistical and Data Management Centers, and Medical Officers within the Division for some of the parameters. After the release of Version 2.1 in March 2017, the need for further updates were noted by some DAIDS stakeholders, leading to the release of this current corrected version 2.1 (July 2017). The clarifications and updates have been highlighted within the body of the Table for convenience.

Please note that the link to the corrected version 2.1 of the table is the same as the link to version 2.1. Release of the corrections in this format should minimize any effects of this change related to protocol and CRF development. Please be advised that all protocols in development must use the updated, corrected version 2.1 of the table. Use of the corrected 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 corrected table is now posted on the RSC web page (http://rsc.tech-res.com/clinical-research-sites/safety-reporting/daids-grading-tables).

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

Changes to note in this corrected version 2.1 of the Severity Grading Table are parameter specific and are highlighted below in green. Non-highlighted items below also appear in the March 2017, version 2.1 and show the changes made to version 2.0.

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 Weight-for-height* 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 Weight-for-length* 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" soas 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, Removed "with other signs and symptoms of hepatotoxicity" *
  - Row 11, Column 5, Removed "with life-threatening consequences (e.g., signs and symptoms of liver failure)". *
- 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 are defined as sex 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).”

- Page 29, Footnote 17:
  - Updated first sentence to: “The most commonly used conversion factor to convert g/dL to mmol/L is 0.6206.”
- 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.

The highlighted areas show changes made to the March 2017, version 2.1 of the Severity Grading Table.