High Level Summary of Changes for the
Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric
Adverse Events, Version 2.0

The Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0 contains a number of changes detailed below when compared with the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 1.0 – December 2004 (Clarification dated August 2009). In addition, an introduction has been added, and the Glossary and Acronym and Instructions for Use sections have been expanded.

Section Heading Changes

Deleted
- Infection (and the one parameter [see Parameters Removed])
- Genitourinary (and three of the four parameters [see Parameters Removed])
- Ocular/Visual (moved the two parameters to Sensory [see New below])

Renamed
- Injection Site Reactions to Site Reactions to Injections and Infusions
- Skin – Dermatological to Dermatologic

New
- Pregnancy, Puerperium, and Perinatal
- Psychiatric
- Sensory (incorporates Ocular/Visual parameters)
- Urinary (incorporates one parameter [see Parameters Modified] in the former Genitourinary heading)

Parameter (i.e., Adverse Event) Groupings Created
- Amylase-related laboratory values (i.e., Pancreatic and Total)
- Blood pressure abnormalities (i.e., Hypertension and Hypotension)
- Lipid disorders (i.e., Fasting Cholesterol, LDL, and Triglycerides)
- Seizures (i.e., New Onset Seizure and Pre-existing Seizure)

Parameters Modified
- Abnormal Fat Accumulation changed to Lipohypertrophy
- Bone Mineral Loss changed to Osteoporosis
- Hemoglobin categorized by age and sex
- Injection Site Reactions categorized by age, erythema or redness, and induration or swelling
- Insomnia moved to the new section heading called Psychiatric Conditions
- Unintentional Weight Loss changed to Weight Loss
- Urinary Tract Obstruction moved to the new section heading called Urinary
- Uveitis moved to the new section heading called Sensory
- Visual Changes moved to the new section heading called Sensory
- Vertigo moved to the new section heading called Sensory
- WBC, decreased categorized by age
Parameters Added

Cardiovascular Section
- Heart Failure

Dermatologic Section
- Bruising
- Cellulitis
- Petechiae

Gastrointestinal Section
- Bloating or Distention
- Gastrointestinal Bleeding
- Perforation (colon or rectum)
- Rectal Discharge

Musculoskeletal Section
- Osteopenia

Pregnancy, Puerperium, and Perinatal Section
- Fetal Death or Stillbirth
- Preterm Delivery
- Spontaneous Abortion or Miscarriage

Psychiatric Section
- Psychiatric Disorders
- Suicidal Ideation or Attempt

Sensory Section
- Hearing Loss
- Tinnitus

Systemic Section
- Cytokine Release Syndrome
- Serum Sickness
- Underweight

Chemistries Section
- Direct Bilirubin, High
- Calcium (ionized), High and Low
- Creatinine Clearance or eGFR, Low

Urinalysis Section
- Glycosuria

Appendix A
- Total Bilirubin Table for Term and Preterm Neonates

Parameters Removed

Cardiovascular Section
- Pericardial Effusion
- Ventricular Dysfunction
- Vasovagal Episode

Infection Section
- Infection

Neurologic Section
- Alternation in Personality- Behavior or in Mood

Urinary (previously Genitourinary) Section
- Cervicitis (clinical exam)
- Cervicitis (symptoms)
- Inter-menstrual Bleeding
- Vulvovaginitis (clinical exam)
- Vulvovaginitis (symptoms)

Chemistries Section
- Cardiac Troponin T

Urinalysis Section
- Proteinuria, 24 hour collection