

Supplemental Table S1. Adverse Event and Serious Adverse Event Reporting Categories

MedDRA Primary SOC

Blood and lymphatic system disorders

Cardiac disorders

Congenital, familial and genetic disorders

Ear and labyrinth disorders

Endocrine disorders

Eye disorders

Gastrointestinal disorders

General disorders and administration site conditions

Hepatobiliary disorders

Immune system disorders

Infections and infestations

Injury, poisoning and procedural complications

Investigations

Metabolism and nutrition disorders

Musculoskeletal and connective tissue disorders

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Nervous system disorders

Pregnancy, puerperium and perinatal conditions

Psychiatric disorders

Renal and urinary disorders

Reproductive system and breast disorders

Respiratory, thoracic and mediastinal disorders

Skin and subcutaneous tissue disorders

Social circumstances

Surgical and medical procedures

Vascular disorders

MedDRA=Medical Dictionary for Regulatory Activities; SOC=System Organ Class, from the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0

Supplemental Table S2. Adverse Event and Serious Adverse Event Grading and Relationship Structure	
CTCAE Grade	Description
Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL.
Grade 4	Life-threatening consequences; urgent intervention indicated.
Grade 5	Death related to AE.
Relationship to AE	Relationship Group
Unrelated	Unrelated
Unlikely	
Possible	Related
Probable	
Definite	
CTCAE=Common Terminology Criteria for Adverse Events, Version 5.0; ADL=activities of daily living; AE=adverse event	