

不良事件常用术语评定标准

(Common Terminology Criteria for Adverse Events)

CTCAE V4.0

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We Innovate Healthcare

Common Terminology Criteria for Adverse Events v4.0 (CTCAE)

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Quick Reference

The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

Components and Organization

SOC

System Organ Class, the highest level of the MedDRA hierarchy, is identified by anatomical or physiological system, etiology, or purpose (e.g., SOC Investigations for laboratory test results). CTCAE terms are grouped by MedDRA Primary SOCs. Within each SOC, AEs are listed and accompanied by descriptions of severity (Grade).

CTCAE Terms

An Adverse Event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may *not* be considered related to the medical treatment or procedure. An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses. Each CTCAE v4.0 term is a MedDRA LLT (Lowest Level Term).

Definitions

A brief definition is provided to clarify the meaning of each AE term.

Grades

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

- 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.

A Semi-colon indicates 'or' within the description of the grade.

A single dash (-) indicates a grade is not available.

Not all Grades are appropriate for all AEs. Therefore, some AEs are listed with fewer than five options for Grade selection.

Grade 5

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.

Activities of Daily Living (ADL)

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

**Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

† CTCAE v4.0 incorporates certain elements of the MedDRA terminology. For further details on MedDRA refer to the MedDRA MSSO Web site (<http://www.meddramsso.com>).

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快速参考

不良事件常用术语评定标准是用于不良事件(AE)报告的描述性术语。每项不良事件都提供了分级(严重性)的尺度。

组成和结构

SOC

系统器官分类。是药事管理的标准医学术语集(MedDRA)分级的最高水平,根据解剖或生理学系统,病因学或目的(如对于实验室检测结果进行的SOC研究)而区分识别。CTCAE术语根据MedDRA主要SOCs进行分组。在SOC各分类中,不良事件被分类详述且附有严重程度级别描述。

CTCAE术语

不良事件是指不利的、不希望发生的体征(包括实验室结果异常),症状或疾病,暂时性伴随医学治疗或操作,被认为可能或可能与医学治疗或操作有关。不良事件是用于医学记录或科学分析的特定事件的独特的表述方法。各CTCAE v4.0术语属MedDRA L1L(最低水平术语)。

定义

简短的定义用于解释说明各个不良事件术语。

分级

分级是指不良事件的严重程度。CTCAE根据下面的总则介绍了每种不良事件1级到5级独特的临床描述:

- 1级 轻度;无症状或有轻度体征;仅有临床或诊断观察结果;无需介入治疗。
 - 2级 中度;需要最低程度、局部或非侵入性治疗;与年龄相适的工具性日常生活活动能力受限。
 - 3级 严重或临床显著意义但非即刻危及生命;住院或延长住院时间;致残;自理日常生活活动能力受限。
 - 4级 导致危及生命后果;需要紧急介入治疗。
 - 5级 导致死亡的不良事件。
- 分号在分级的描述中代表“或者”。
短破折号 (-) 表示分级不适用。

并非所有这些分级都适用于所有的不良事件。因此,有些列出的不良事件分级选项少于5个。

第5级

第5级(死亡)对有些不良事件不适用,因此不作为一个选项。

日常生活活动能力(ADL)

*工具性日常生活活动能力指可以备餐、购置杂货或衣物、使用电话、理财等。

**自理日常生活活动能力指可以洗浴、穿脱衣物、进食、如厕、服药和充卧床不起。

Blood and lymphatic system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 - 6.5 g/dL; <4.9 - 4.0 mmol/L; <80 - 65 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.					
Bone marrow hypocellular	Mildly hypocellular or <=25% reduction from normal cellularity for age	Moderately hypocellular or >25 - <50% reduction from normal cellularity for age	Severely hypocellular or >50 - <=75% reduction cellularity from normal for age	Aplastic persistent for longer than 2 weeks	Death
Definition: A disorder characterized by the inability of the bone marrow to produce hematopoietic elements.					
Disseminated intravascular coagulation	-	Laboratory findings with no bleeding	Laboratory findings and bleeding	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by systemic pathological activation of blood clotting mechanisms which results in clot formation throughout the body. There is an increase in the risk of hemorrhage as the body is depleted of platelets and coagulation factors.					
Febrile neutropenia	-	-	Present	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a decrease in neutrophils associated with fever.					
Hemolysis	Laboratory evidence of hemolysis only (e.g., direct antiglobulin test; DAT; Coombs'; schistocytes; decreased haptoglobin)	Evidence of hemolysis and >=2 gm decrease in hemoglobin, no transfusion	Transfusion or medical intervention indicated (e.g., steroids)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by laboratory test results that indicate widespread erythrocyte cell membrane destruction.					
Hemolytic uremic syndrome	Evidence of RBC destruction (schistocytosis) without clinical consequences	-	Laboratory findings with clinical consequences (e.g., renal insufficiency, petechiae)	Life-threatening consequences, (e.g., CNS hemorrhage or thrombosis/embolism or renal failure)	Death
Definition: A disorder characterized by a form of thrombotic microangiopathy with renal failure, hemolytic anemia, and severe thrombocytopenia.					
Leukocytosis	-	-	>100,000/mm3	Clinical manifestations of leucostasis; urgent intervention indicated	Death
Definition: A disorder characterized by laboratory test results that indicate an increased number of white blood cells in the blood.					
Lymph node pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in a lymph node.					
Spleen disorder	Incidental findings (e.g., Howell-Jolly bodies); mild degree of thrombocytosis and leukocytosis	Prophylactic antibiotics indicated	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder of the spleen.					
Thrombotic thrombocytopenic purpura	Evidence of RBC destruction (schistocytosis) without clinical consequences	-	Laboratory findings with clinical consequences (e.g., renal insufficiency, petechiae)	Life-threatening consequences, (e.g., CNS hemorrhage or thrombosis/embolism or renal failure)	Death
Definition: A disorder characterized by the presence of microangiopathic hemolytic anemia, thrombocytopenic purpura, fever, renal abnormalities and neurological abnormalities such as seizures, hemiplegia, and visual disturbances. It is an acute or subacute condition.					
Blood and lymphatic system disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

血液和淋巴系统病症					
不良事件	分级				
	1	2	3	4	5
贫血症	血红蛋白 (Hgb) <LLN-10.0 g/dL; <LLN - 6.2 mmol/L; <LLN -100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 - 6.5 g/dL; <4.9 - 4.0 mmol/L; <80 - 65 g/L; 需要输血治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为每 100ml 血液中血红蛋白量降低的病症。贫血的体征和症状包括皮肤及粘膜苍白、呼吸短促、心悸、轻度心脏收缩期杂音、嗜睡、易疲劳。					
骨髓细胞减少	细胞总数轻度减少或 与该年龄段的正常细胞 总数相比, 减少程度 ≤25%	细胞总数中度减少, 或 与该年龄段的正常细胞 总数相比, 减少程度 >25-≤50%	细胞总数重度减少, 或 与该年龄段的正常细胞 总数相比, 减少程度 >50-≤75%	再生障碍持续超过两周	死亡
定义: 特征为骨髓无法产生造血元素的病症。					
弥散性血管内凝血	-	有实验室表现, 无出血	有实验室表现, 且出血	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为由系统病理活性激活凝血机制而导致全身凝血形成的病症。由于机体的血小板和凝血因子减少所致, 出血风险会增加。					
热性嗜中性粒细胞减少症	-	-	存在	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为与伴随发热的嗜中性粒细胞减少的病症。					
溶血	仅出现溶血的实验室 证据 (如直接抗球蛋白 试验; 直接抗人球蛋白 试验; Coombs 试验; 裂红细胞; 触珠 蛋白减少)	溶血证据, 及血红蛋白 减少 ≥2gm, 不需输血 治疗	需要输血或医学介入治 疗 (如类固醇治疗)	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为实验室检测结果显示有广泛的红细胞膜破损的病症。					
溶血性尿毒性综合征	红细胞破坏的表现 (裂细胞症), 无临床 后果	-	有实验室表现, 伴临床 后果 (如肾功能不全, 瘀点)	危及生命的后果 (如 中枢神经系统出血或 血栓形成/栓塞或肾功 能衰竭)	死亡
定义: 特征为的血栓性微血管病的一种形式, 伴随肾衰竭、溶血性贫血和严重血小板降低。					
白细胞增多	-	-	>100,000/mm ³	临床表现白细胞增 多; 需要紧急介入治 疗	死亡
定义: 实验室检查结果表明, 血液中白细胞数量增加的病症。					
淋巴结疼痛	轻微疼痛	中度疼痛; 工具性 ADL 受限	严重疼痛; 自理 ADL 受 限	-	-
定义: 特征为淋巴结有显著性不适感的病症。					
脾症	偶然发现 (如豪周氏 小体); 轻度血小板增 多和白细胞增多	需要预防性抗生素治疗	-	危及生命的后果; 需要紧急介入治疗	死亡
定义: 脾脏的病症。					
血栓形成的血栓性血小板减少性紫癜	有红细胞破坏证据 (裂细胞症) 无临床 后果	-	有实验室表现和临床后 果 (如肾功能不全, 瘀 点)	危及生命的后果, (如 中枢神经系统出血或 血栓症/栓塞或肾衰 竭)	死亡
定义: 特征为出现微血管病性溶血性贫血, 血栓性血小板减少性紫癜、发热、肾异常和神经学异常, 如癫痫发作、半身不遂、视觉障碍。属急性或亚急性状况。					
血液和淋巴系统病症-其它, 指定	无症状或轻度症状; 仅有临床或诊断学观 察结果; 无需介入治 疗	中度; 需要最低程度、 局部或非侵入性治疗; 与年龄相适的工具性 ADL 受限	严重或具有临床显著意 义但非即刻危及生命; 住院或延长住院时间; 致残; 自理 ADL 受限	危及生命的后果; 需要紧急介入治疗	死亡

Cardiac disorders					
Adverse Event	Grade				
	1	2	3	4	5
Acute coronary syndrome	-	Symptomatic, progressive angina; cardiac enzymes normal; hemodynamically stable	Symptomatic, unstable angina and/or acute myocardial infarction, cardiac enzymes abnormal, hemodynamically stable	Symptomatic, unstable angina and/or acute myocardial infarction, cardiac enzymes abnormal, hemodynamically unstable	Death
Definition: A disorder characterized by signs and symptoms related to acute ischemia of the myocardium secondary to coronary artery disease. The clinical presentation covers a spectrum of heart diseases from unstable angina to myocardial infarction.					
Aortic valve disease	Asymptomatic valvular thickening with or without mild valvular regurgitation or stenosis by imaging	Asymptomatic; moderate regurgitation or stenosis by imaging	Symptomatic; severe regurgitation or stenosis by imaging; symptoms controlled with medical intervention	Life-threatening consequences; urgent intervention indicated (e.g., valve replacement, valvuloplasty)	Death
Definition: A disorder characterized by a defect in aortic valve function or structure.					
Asystole	Periods of asystole; non-urgent medical management indicated	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia without cardiac electrical activity. Typically, this is accompanied by cessation of the pumping function of the heart.					
Atrial fibrillation	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker), or ablation	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia without discernible P waves and an irregular ventricular response due to multiple reentry circuits. The rhythm disturbance originates above the ventricles.					
Atrial flutter	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker), or ablation	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with organized rhythmic atrial contractions with a rate of 200-300 beats per minute. The rhythm disturbance originates in the atria.					
Atrioventricular block complete	-	Non-urgent intervention indicated	Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with complete failure of atrial electrical impulse conduction through the AV node to the ventricles.					
Atrioventricular block first degree	Asymptomatic, intervention not indicated	Non-urgent intervention indicated	-	-	-
Definition: A disorder characterized by a dysrhythmia with a delay in the time required for the conduction of an electrical impulse through the atrioventricular (AV) node beyond 0.2 seconds; prolongation of the PR interval greater than 200 milliseconds.					
Cardiac arrest	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by cessation of the pumping function of the heart.					
Chest pain - cardiac	Mild pain	Moderate pain; limiting instrumental ADL	Pain at rest; limiting self care ADL	-	-
Definition: A disorder characterized by substernal discomfort due to insufficient myocardial oxygenation.					
Conduction disorder	Mild symptoms; intervention not indicated	Moderate symptoms	Severe symptoms; intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by pathological irregularities in the cardiac conduction system.					
Constrictive pericarditis	-	-	Symptomatic heart failure or other cardiac symptoms, responsive to intervention	Refractory heart failure or other poorly controlled cardiac symptoms	Death
Definition: A disorder characterized by a thickened and fibrotic pericardial sac; these fibrotic changes impede normal myocardial function by restricting myocardial muscle action.					
Heart failure	Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities	Symptoms with mild to moderate activity or exertion	Severe with symptoms at rest or with minimal activity or exertion; intervention indicated	Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support)	Death
Definition: A disorder characterized by the inability of the heart to pump blood at an adequate volume to meet tissue metabolic requirements, or, the ability to do so only at an elevation in the filling pressure.					

心脏病症					
不良事件	分级				
	1	2	3	4	5
急性冠状动脉综合征	-	有症状，进展性绞痛；心脏酶类正常；血液动力学稳定	有症状，不稳定绞痛和/或急性心肌梗死；心脏酶类异常；血液动力学稳定	有症状，不稳定绞痛和/或急性心肌梗死；心脏酶类异常；血液动力学不稳定	死亡
定义：特征为与急性缺血心肌继发性冠状动脉疾病有关的症状和体征的紊乱。临床表现为一系列心脏病症从不稳定型心绞痛到心肌梗死。					
主动脉瓣病变	无症状瓣膜增厚，伴随或未伴随影像学检查发现轻度瓣膜返流或狭窄	无症状；影像学检查发现中度返流或狭窄	有症状；影像学检查发现重度返流或狭窄；症状可用医学手段控制	危及生命的后果；需要紧急介入治疗（如瓣膜置换术，瓣膜成形术）	死亡
定义：特征为主动脉瓣功能或结构缺陷的病症。					
心脏停搏	阶段性心脏停搏；需要非紧急医学处理	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为不伴随心电图活动的节律障碍。通常是伴随着心脏泵血功能的停止。					
心房颤动	无症状，无需介入治疗	非紧急医学介入治疗	有症状，药物不能完全控制，或需使用装置控制(如起搏器)，或部分切除	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为节律紊乱没有可辨别的P波和由于多次折返回路产生不规则的心室反应。节律紊乱源于心室。					
心房扑动	无症状，无需介入治疗	非紧急医学介入治疗	有症状，药物不能完全控制，或需使用装置控制(如起搏器)，或部分切除	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为节律障碍伴随每分钟200-300次组织的节律性心房收缩。节律紊乱源于心房。					
完全性房室传导阻滞	-	非紧急医学介入治疗	有症状，药物不能完全控制，或需使用装置控制(如起搏器)	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为节律障碍伴随房室结对心室的心房电脉冲传导完全阻滞。					
I度房室传导阻滞	无症状，无需介入治疗	非紧急医学介入治疗	-	-	-
定义：特征为节律障碍伴随所需时间延迟用于传导电脉冲通过房室节超出0.2秒；延长PR间期大于200毫秒。					
心脏骤停	-	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为心脏泵血功能停止的病症。					
胸痛（心源性）	轻度疼痛	中度疼痛；工具性ADL受影响	静止时疼痛；自理ADL受影响	-	-
定义：特征为由于心肌充氧不足导致的胸骨下疼痛的病症。					
传导紊乱	轻度症状；无需介入治疗	中度症状	严重症状；需要介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为疾病引起的心脏传导系统的不规律。					
缩窄性心包炎	-	-	有症状心衰，或其他心脏病症状，对治疗有反应	难治疗的心衰或其他难以控制的心脏病症状	死亡
定义：特征为心包增厚及纤维化的病症；纤维化病变限制心肌活动阻碍正常心肌功能。					
心力衰竭	无症状，实验室（如B型钠尿肽）或心脏影像学检查异常	轻度至中度活动或劳累时产生症状	静止或最低程度活动或劳累时严重症状；需要介入治疗	危及生命的后果；需要紧急介入治疗（如持续静脉治疗或机械血液动力学支持治疗）	死亡
定义：特征为心脏无力泵出足够体积的血液供应组织代谢需要或，仅在充盈压高时才有能力完成。					

Cardiac disorders					
Adverse Event	Grade				
	1	2	3	4	5
Left ventricular systolic dysfunction	-	-	Symptomatic due to drop in ejection fraction responsive to intervention	Refractory or poorly controlled heart failure due to drop in ejection fraction; intervention such as ventricular assist device, intravenous vasopressor support, or heart transplant indicated	Death
Definition: A disorder characterized by failure of the left ventricle to produce adequate output despite an increase in distending pressure and in end-diastolic volume. Clinical manifestations may include dyspnea, orthopnea, and other signs and symptoms of pulmonary congestion and edema.					
Mitral valve disease	Asymptomatic valvular thickening with or without mild valvular regurgitation or stenosis by imaging	Asymptomatic; moderate regurgitation or stenosis by imaging	Symptomatic; severe regurgitation or stenosis by imaging; symptoms controlled with medical intervention	Life-threatening consequences; urgent intervention indicated (e.g., valve replacement, valvuloplasty)	Death
Definition: A disorder characterized by a defect in mitral valve function or structure.					
Mobitz (type) II atrioventricular block	Asymptomatic, intervention not indicated	Symptomatic; medical intervention indicated	Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with relatively constant PR interval prior to the block of an atrial impulse. This is the result of intermittent failure of atrial electrical impulse conduction through the atrioventricular (AV) node to the ventricles.					
Mobitz type I	Asymptomatic, intervention not indicated	Symptomatic; medical intervention indicated	Symptomatic and incompletely controlled medically, or controlled with device (e.g., pacemaker)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with a progressively lengthening PR interval prior to the blocking of an atrial impulse. This is the result of intermittent failure of atrial electrical impulse conduction through the atrioventricular (AV) node to the ventricles.					
Myocardial infarction	-	Asymptomatic and cardiac enzymes minimally abnormal and no evidence of ischemic ECG changes	Severe symptoms; cardiac enzymes abnormal; hemodynamically stable; ECG changes consistent with infarction	Life-threatening consequences; hemodynamically unstable	Death
Definition: A disorder characterized by gross necrosis of the myocardium; this is due to an interruption of blood supply to the area.					
Myocarditis	Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities	Symptoms with mild to moderate activity or exertion	Severe with symptoms at rest or with minimal activity or exertion; intervention indicated	Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support)	Death
Definition: A disorder characterized by inflammation of the muscle tissue of the heart.					
Palpitations	Mild symptoms; intervention not indicated	Intervention indicated	-	-	-
Definition: A disorder characterized by an unpleasant sensation of irregular and/or forceful beating of the heart.					
Paroxysmal atrial tachycardia	Asymptomatic, intervention not indicated	Symptomatic; medical management indicated	IV medication indicated	Life-threatening consequences; incompletely controlled medically; cardioversion indicated	Death
Definition: A disorder characterized by a dysrhythmia with abrupt onset and sudden termination of atrial contractions with a rate of 150-250 beats per minute. The rhythm disturbance originates in the atria.					
Pericardial effusion	-	Asymptomatic effusion size small to moderate	Effusion with physiologic consequences	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by fluid collection within the pericardial sac, usually due to inflammation.					
Pericardial tamponade	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an increase in intrapericardial pressure due to the collection of blood or fluid in the pericardium.					
Pericarditis	Asymptomatic, ECG or physical findings (e.g., rub) consistent with pericarditis	Symptomatic pericarditis (e.g., chest pain)	Pericarditis with physiologic consequences (e.g., pericardial constriction)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by irritation to the layers of the pericardium (the protective sac around the heart).					

心脏病症					
不良事件	分级				
	1	2	3	4	5
左心室收缩功能异常	-	-	由于射血分数下降引发症状，对治疗有反应	由射血分数下降导致的难治性或控制效果差的心力衰竭；需要左室辅助装置，注射血管加压药辅助或心脏移植治疗	死亡
定义：特征为尽管舒张压与舒张末期容积增加，左心室仍不能产生足够的输出。临床表现可能包括呼吸困难、端坐呼吸，其他体征和症状如肺充血和水肿。					
二尖瓣病变	无症状，瓣膜增厚，伴随或未伴随影像学检查发现轻度瓣膜返流或狭窄	无症状；影像学检查发现中度返流或狭窄	有症状；影像学检查发现重度返流或狭窄；症状可用医学手段控制	危及生命的后果；需要紧急介入治疗（如瓣膜置换术，瓣膜成形术）	死亡
定义：特征为二尖瓣功能或结构缺陷的病症。					
莫氏 II 型房室传导阻滞	无症状，无需介入治疗	有症状；需要医学介入治疗	有症状，药物不能完全控制，或需使用装置控制(如起搏器)	危及生命的后果；需要紧急介入治疗	死亡
定义：心房搏动阻滞之前，节律障碍伴随相对固定 PR 间期的病症。是心房电脉冲传导从房室结到心室的间歇性失效的结果。					
莫氏 I 型	无症状，无需介入治疗	有症状；需要医学介入治疗	有症状，药物不能完全控制，或需使用装置控制(如起搏器)	危及生命的后果；需要紧急介入治疗	死亡
定义：心房搏动阻滞之前，节律障碍伴随 PR 间期逐渐延长的病症。是心房电脉冲传导从房室结到心室的间歇性失效的结果。					
心肌梗死	-	无症状，心脏酶系最低程度异常，无局部缺血性 ECG 改变的证据	严重症状；心脏酶系异常；血液动力学稳定；ECG 改变与梗死形成一致	危及生命的后果；血液动力学不稳定	死亡
定义：特征为严重的心肌坏死，是由于该区域的血液供应中断。					
心肌炎	无症状，实验室（如 B 型钠尿肽）或心脏影像学检查异常	轻度至中度活动或劳累时产生症状	静止或微量活动或劳累时严重症状；需要介入治疗	危及生命的后果；需要紧急介入治疗（如持续静脉治疗或机械血液动力学支持治疗）	死亡
定义：特征为心脏的肌肉组织发炎的病症。					
心悸	轻度症状；无需介入	需要介入治疗	-	-	-
定义：特征为由心脏不规律和/或强烈的搏动引起不适感的病症。					
阵发性房性心动过速	无症状，无需介入治疗	有症状，需要医学处理	需要静脉注射给药	危及生命的后果；药物不能完全控制；需要心脏复律治疗	死亡
定义：特征为节律紊乱伴随心房收缩突然出现和突然终止，收缩频率为每分钟 150-250 次。节律紊乱起源于心房。					
心包积液	-	无症状积液，体积小至中等	伴生理变化的积液	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为心包内聚积液体的病症，通常由炎症所致。					
心包填塞	-	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为由心包内血液或流质的聚积导致的心包内压增长的病症。					
心包炎	无症状，ECG 或体检（摩擦音）时发现心包炎	有症状性心包炎（如胸痛）	心包炎伴生理改变（如心包缩窄）	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为心包层（包裹在心周围的保护囊）受到刺激的病症。					

Cardiac disorders					
Adverse Event	Grade				
	1	2	3	4	5
Pulmonary valve disease	Asymptomatic valvular thickening with or without mild valvular regurgitation or stenosis by imaging	Asymptomatic; moderate regurgitation or stenosis by imaging	Symptomatic; severe regurgitation or stenosis by imaging; symptoms controlled with medical intervention	Life-threatening consequences; urgent intervention indicated (e.g., valve replacement, valvuloplasty)	Death
Definition: A disorder characterized by a defect in pulmonary valve function or structure.					
Restrictive cardiomyopathy	-	-	Symptomatic heart failure or other cardiac symptoms, responsive to intervention	Refractory heart failure or other poorly controlled cardiac symptoms	Death
Definition: A disorder characterized by an inability of the ventricles to fill with blood because the myocardium (heart muscle) stiffens and loses its flexibility.					
Right ventricular dysfunction	Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities	Symptoms with mild to moderate activity or exertion	Severe symptoms, associated with hypoxemia, right heart failure; oxygen indicated	Life-threatening consequences; urgent intervention indicated (e.g., ventricular assist device); heart transplant indicated	Death
Definition: A disorder characterized by impairment of right ventricular function associated with low ejection fraction and a decrease in motility of the right ventricular wall.					
Sick sinus syndrome	Asymptomatic, intervention not indicated	Non-urgent intervention indicated	Severe, medically significant; medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with alternating periods of bradycardia and atrial tachycardia accompanied by syncope, fatigue and dizziness.					
Sinus bradycardia	Asymptomatic, intervention not indicated	Symptomatic, medical intervention indicated	Severe, medically significant, medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with a heart rate less than 60 beats per minute that originates in the sinus node.					
Sinus tachycardia	Asymptomatic, intervention not indicated	Symptomatic; non-urgent medical intervention indicated	Urgent medical intervention indicated	-	-
Definition: A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates in the sinus node.					
Supraventricular tachycardia	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates above the ventricles.					
Tricuspid valve disease	Asymptomatic valvular thickening with or without mild valvular regurgitation or stenosis	Asymptomatic; moderate regurgitation or stenosis by imaging	Symptomatic; severe regurgitation or stenosis; symptoms controlled with medical intervention	Life-threatening consequences; urgent intervention indicated (e.g., valve replacement, valvuloplasty)	Death
Definition: A disorder characterized by a defect in tricuspid valve function or structure.					
Ventricular arrhythmia	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Medical intervention indicated	Life-threatening consequences; hemodynamic compromise; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia that originates in the ventricles.					
Ventricular fibrillation	-	-	-	Life-threatening consequences; hemodynamic compromise; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia without discernible QRS complexes due to rapid repetitive excitation of myocardial fibers without coordinated contraction of the ventricles.					
Ventricular tachycardia	-	Non-urgent medical intervention indicated	Medical intervention indicated	Life-threatening consequences; hemodynamic compromise; urgent intervention indicated	Death
Definition: A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates distal to the bundle of His.					
Wolf-Parkinson-White syndrome	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Symptomatic and incompletely controlled medically or controlled with procedure	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the presence of an accessory conductive pathway between the atria and the ventricles that causes premature ventricular activation.					
Cardiac disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

心脏病症					
不良事件	分级				
	1	2	3	4	5
肺动脉瓣膜病	无症状瓣膜增厚，伴随或未伴随影像学检查发现轻度瓣膜返流或狭窄 定义：特征为肺动脉瓣机能或结构缺损的病症。	无症状；影像学检查发现中度返流或狭窄	有症状；影像学检查发现重度返流或狭窄；症状可用医学手段控制	危及生命的后果；需要紧急介入治疗（如瓣膜置换术，瓣膜成形术）	死亡
限制型心肌病	-	-	有症状的心力衰竭或其他心脏病症，对治疗有反应	难治性心力衰竭，或其他控制效果差的心脏病症	死亡
右心室机能障碍	无症状，实验室（如B型钠尿肽）或心脏影像学检查异常 定义：特征为右心室机能受损，射血分数低与右心室壁活力降低。	轻度至中度活动或劳累时产生症状	严重症状，伴随低氧血症、右心衰竭；需要输氧治疗	危及生命的后果；需要紧急介入治疗（如心室辅助装置）；需要心脏移植手术	死亡
病态窦房结综合征	无症状，无需介入治疗 定义：特征为节律紊乱伴随心动过缓和房性心动过速交替，伴有晕厥，疲劳和头晕。	需要非紧急介入治疗	严重，有医学显著意义；需要医学介入治疗	危及生命的后果；需要紧急介入治疗	死亡
窦性心动过缓	无症状，无需介入治疗 定义：特征为源于窦房结的心率低于每分钟60次的节律紊乱的病症。	有症状；需要医学介入治疗	严重，有医学显著意义；需要医学介入治疗	危及生命的后果；需要紧急介入治疗	死亡
窦性心动过速	无症状，无需介入治疗 定义：特征为源于窦房结的心率高于每分钟100次的节律紊乱的病症。	有症状，需要非紧急介入治疗	需要紧急医学介入治疗	-	-
室上性心动过速	无症状，无需介入治疗 定义：特征为源于心室的心率高于每分钟100次的节律紊乱的病症。	需要非紧急介入治疗	需要医学介入治疗	危及生命的后果；需要紧急介入治疗	死亡
三尖瓣病变	无症状性瓣膜增厚，伴随或未伴随影像学检查发现轻度瓣膜返流或狭窄 定义：特征为三尖瓣功能或结构缺陷的病症。	无症状；影像学检查发现中度返流或狭窄	有症状；影像学检查发现重度返流或狭窄；症状可用医学手段控制	危及生命的后果；需要紧急介入治疗（如瓣膜置换术，瓣膜成形术）	死亡
室性心律失常	无症状，无需介入治疗 定义：特征为源于心室的节律紊乱的病症。	需要非紧急介入治疗	需要医学治疗	危及生命的后果；血液动力学危害；需要紧急介入治疗	死亡
心室颤动	- 定义：特征为心室收缩不协调，快速重复激发心肌纤维，导致节律紊乱，不伴随可以辨识的QRS波群。	-	-	危及生命的后果；血液动力学危害；需要紧急介入治疗	死亡
室性心动过速	- 定义：特征为源于希氏束的心率高于每分钟100次的节律紊乱的病症。	需要非紧急介入治疗	需要医学治疗	危及生命的后果；血液动力学危害；需要紧急介入治疗	死亡
预激综合征	无症状，无需介入治疗 定义：特征为心房和心室间存在额外的传导通路，造成室性早搏激活的病症。	需要非紧急介入治疗	有症状，药物或操作不能完全控制	危及生命的后果；需要紧急介入治疗	死亡
心脏病症-其它，指定	无症状或有轻度体征；仅有临床或诊断观察结果；无需介入治疗。	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Congenital, familial and genetic disorders					
Adverse Event	Grade				
	1	2	3	4	5
Congenital, familial and genetic disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

先天性、家族的遗传疾病					
不良事件	分级				
	1	2	3	4	5
先天性、家族的遗传疾病-其它，指定	无症状或有轻度体征；仅有临床或诊断观察结果；无需介入治疗。	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡

Ear and labyrinth disorders					
Adverse Event	Grade				
	1	2	3	4	5
Ear pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the ear.					
External ear inflammation	External otitis with erythema or dry desquamation	External otitis with moist desquamation, edema, enhanced cerumen or discharge; tympanic membrane perforation; tympanostomy	External otitis with mastoiditis; stenosis or osteomyelitis; necrosis of soft tissue or bone	Urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation, swelling and redness to the outer ear and ear canal.					
External ear pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the external ear region.					
Hearing impaired	Adults enrolled on a monitoring program (a 1, 2, 3, 4, 6 and 8 kHz audiogram): threshold shift of 15 - 25 dB averaged at 2 contiguous test frequencies in at least one ear or subjective change in the absence of a Grade 1 threshold shift Pediatrics (a 1, 2, 3, 4, 6 and 8 kHz audiogram): >20 dB at any frequency tested and does not meet criteria for >Grade 2	Adults enrolled in monitoring program (a 1, 2, 3, 4, 6 and 8 kHz audiogram): threshold shift of >25 dB averaged at 2 contiguous test frequencies in at least one ear Adult not enrolled in monitoring program: hearing loss but hearing aid or intervention not indicated; limiting instrumental ADL Pediatrics (a 1, 2, 3, 4, 6 and 8 kHz audiogram): >20 dB at >4 kHz	Adults enrolled in monitoring program (a 1, 2, 3, 4, 6 and 8 kHz audiogram): threshold shift of >25 dB averaged at 3 contiguous test frequencies in at least one ear; therapeutic intervention indicated Adults not enrolled in monitoring program: hearing loss with hearing aid or intervention indicated; limiting self care ADL Pediatrics (a 1, 2, 3, 4, 6 and 8 kHz audiogram): hearing loss sufficient to indicate therapeutic intervention, including hearing aids; >20 dB at 3 kHz and above in one ear; additional speech-language related services indicated	Adults: profound bilateral hearing loss (>80 dB at 2 kHz and above); non-serviceable hearing Pediatric: audiologic indication for cochlear implant and additional speech-language related services indicated	-
Definition: A disorder characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures.					
Middle ear inflammation	Serous otitis	Serous otitis, medical intervention indicated	Mastoiditis; necrosis of canal soft tissue or bone	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation (physiologic response to irritation), swelling and redness to the middle ear.					
Tinnitus	Mild symptoms; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by noise in the ears, such as ringing, buzzing, roaring or clicking.					
Vertigo	Mild symptoms	Moderate symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation as if the external world were revolving around the patient (objective vertigo) or as if he himself were revolving in space (subjective vertigo).					
Vestibular disorder	-	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by dizziness, imbalance, nausea, and vision problems.					
Ear and labyrinth disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

耳和迷路病症					
不良事件	分级				
	1	2	3	4	5
耳痛	轻度疼痛	中度疼痛; 工具性 ADL 受限	重度疼痛; 自理 ADL 受限	-	-
定义: 特征为耳部有显著不适感的病症。					
外耳炎症	外耳炎伴红斑或干燥脱皮	外耳炎伴湿性脱皮、水肿、耳垢分泌物增多或排出; 鼓膜穿孔; 鼓膜穿孔术	外耳炎伴乳突炎; 狭窄或骨髓炎; 软组织或骨坏死	需要紧急手术介入治疗	死亡
定义: 特征为外耳和耳道区域有炎症、水肿、发红的病症。					
外耳痛	轻度疼痛	中度疼痛; 工具性 ADL 受限	重度疼痛; 自理 ADL 受限	-	-
定义: 特征为外耳区域有显著不适感的病症。					
听力受损	成人参加监测项目 (一个 1, 2, 3, 4, 6 和 8kHz 听力记录单): 至少单耳 2 个邻近测试频率下的平均阈移为 15-25dB 或无 1 级阈移时主观认为有变化 儿科 (一个 1, 2, 3, 4, 6 和 8 kHz 听力记录单): 在任一检测频率下阈移>20dB, 但不满足>2 级的标准	成人参加监测项目 (一个 1, 2, 3, 4, 6 和 8kHz 听力记录单): 至少单耳 2 个邻近测试频率下的平均阈移大于 25dB 成人未参加监测项目: 听力损失但无需听力辅助或介入; 工具性 ADL 受限 儿科 (一个 1, 2, 3, 4, 6 和 8 kHz 听力记录单): 在大于 4kHz 频率下阈移 >20dB	成人参加监测项目 (一个 1, 2, 3, 4, 6 和 8kHz 听力记录单): 至少单耳 3 个邻近测试频率下的平均阈移大于 25dB; 需要治疗介入 成人未参加监测项目: 听力损失需听力辅助或介入; 自理 ADL 受限 儿科 (一个 1, 2, 3, 4, 6 和 8 kHz 听力记录单): 听力受损严重需要介入治疗, 包括听力辅助; 单耳在 3kHz 或以上频率下阈移 >20dB; 需要额外语言相关服务	成人: 严重双侧听力损失 (2kHz 或以上频率下阈移>80dB); 非有用听力 儿科: 需要听觉治疗, 人工耳蜗植入和额外语言相关服务	-
定义: 病症特征为由耳结构损伤引起的部分或全部觉察声音的能力丧失。					
中耳炎	浆液性耳炎	浆液性耳炎, 需要医学介入治疗	乳突炎; 耳道软组织或骨坏死	危及生命的后果; 需要紧急介入治疗	死亡
定义: 病症特征为中耳红肿, 有炎症 (对刺激的生理反应)。					
耳鸣	轻度症状, 无需介入治疗	中度症状; 工具性 ADL 受限	严重症状; 自理 ADL 受限	-	-
定义: 病症特征为耳中听到杂音, 如清脆响声、蜂鸣声、吼声或碎裂声。					
眩晕	轻度症状	中度症状; 工具性 ADL 受限	严重症状; 自理 ADL 受限	-	-
定义: 病症特征为病人感觉周围的外部世界在旋转 (客观眩晕) 或自身在旋转 (主观眩晕)。					
前庭病症	-	有症状; 工具性 ADL 受限	严重症状; 自理 ADL 受限	-	-
定义: 特征为有眩晕、失衡、恶心和视觉问题的病症。					
耳和迷路病症-其它, 指定	无症状或有轻度体征; 仅有临床或诊断观察结果; 无需介入治疗。	中度; 需要最低程度、局部或非侵入性治疗; 与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命; 住院或延长住院时间; 致残; 自理 ADL 受限	危及生命的后果; 需要紧急介入治疗	死亡

Endocrine disorders					
Adverse Event	Grade				
	1	2	3	4	5
Adrenal insufficiency	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder that occurs when the adrenal cortex does not produce enough of the hormone cortisol and in some cases, the hormone aldosterone. It may be due to a disorder of the adrenal cortex as in Addison's disease or primary adrenal insufficiency.					
Cushingoid	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms, medical intervention or hospitalization indicated	-	-
Definition: A disorder characterized by signs and symptoms that resemble Cushing's disease or syndrome: buffalo hump obesity, striae, adiposity, hypertension, diabetes, and osteoporosis, usually due to exogenous corticosteroids.					
Delayed puberty	-	No breast development by age 13 yrs for females; testes volume of <3 cc or no Tanner Stage 2 development by age 14.5 yrs for males	No breast development by age 14 yrs for females; no increase in testes volume or no Tanner Stage 2 by age 16 yrs for males; hormone replacement indicated	-	-
Definition: A disorder characterized by unusually late sexual maturity.					
Growth accelerated	-	>= +2 SD (standard deviation) above mid parental height or target height	-	-	-
Definition: A disorder characterized by greater growth than expected for age.					
Hyperparathyroidism	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by an increase in production of parathyroid hormone by the parathyroid glands. This results in hypercalcemia (abnormally high levels of calcium in the blood).					
Hyperthyroidism	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thyroid suppression therapy indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by excessive levels of thyroid hormone in the body. Common causes include an overactive thyroid gland or thyroid hormone overdose.					
Hypoparathyroidism	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms; medical intervention or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a decrease in production of parathyroid hormone by the parathyroid glands.					
Hypothyroidism	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thyroid replacement indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; hospitalization indicated	Life-threatening consequences; urgent intervention indicated;	Death
Definition: A disorder characterized by a decrease in production of thyroid hormone by the thyroid gland.					
Precocious puberty	Physical signs of puberty with no biochemical markers for females <8 years and males <9 years	Physical signs and biochemical markers of puberty for females <8 years and males <9 years	-	-	-
Definition: A disorder characterized by unusually early development of secondary sexual features; the onset of sexual maturation begins usually before age 8 for girls and before age 9 for boys.					
Virilization	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by inappropriate masculinization occurring in a female or prepubertal male.					
Endocrine disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

内分泌紊乱					
不良事件	分级				
	1	2	3	4	5
肾上腺功能不足	无症状；仅有临床或诊断观察结果；无需介入治疗。	中度症状；需要医学介入治疗	严重症状；需要住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：当肾上腺皮质不能产生足够的激素皮质醇或一些情况下的醛固酮时发生的紊乱。可能由阿狄森症或原发性肾上腺功能不足导致。					
类库兴氏综合征	轻度症状；无需介入治疗	中度症状；无需医学介入治疗	严重症状，需要医学介入或住院治疗	-	-
定义：特征为体征和症状类似库兴氏综合征的病症：水牛背肥胖、条纹、肥胖、高血压、糖尿病、骨质疏松，通常由外源性皮质激素导致。					
青春期延迟	-	女性至13岁无乳房发育；男性至14.5岁睾丸容量<3cc，或无Tanner 2级发育	女性至14岁无乳房发育；男性至16岁睾丸容量<3cc，或无Tanner 2级发育；需要激素替代治疗	-	-
定义：特征为性成熟显著延后的病症。					
加速生长	-	超过中位双亲身高或目标身高 $\geq +2$ SD(标准差)	-	-	-
定义：特征为生长速度超过该年龄预期的速度					
甲状旁腺功能亢进症	轻度症状；无需介入治疗	中度症状；需要医学介入治疗	-	-	-
定义：特征为甲状旁腺分泌甲状旁腺激素增多的病症。导致高钙血症（血中钙水平异常升高）。					
甲状腺功能亢进症	无症状；仅有临床或诊断观察结果；无需介入治疗	有症状；需要甲状腺抑制治疗；工具性ADL受限	严重症状；自理ADL受限；需要住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为体内甲状腺激素水平过高的病症。常见原因包括甲状腺过度活跃或甲状腺激素过量。					
甲状旁腺功能减退症	无症状；仅有临床或诊断观察结果；无需介入治疗	中度症状；无需医学介入治疗	严重症状；需要医学或住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为甲状旁腺分泌甲状旁腺激素减少的病症。					
甲状腺功能减退症	无症状；仅有临床或诊断观察结果；无需介入治疗	有症状；需要甲状腺替代治疗；工具性ADL受限	严重症状；自理ADL受限；需要住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为甲状腺分泌甲状腺激素减少的病症。					
性早熟	女性<8岁，男性<9岁出现无生物化学标记的青春期特征	女性<8岁，男性<9岁出现生物化学标记的青春期特征	-	-	-
定义：病症特征为第二性征显著过早发育；此时性成熟通常开始于女孩8岁前和男孩9岁前。					
男性化	轻度症状；无需介入治疗	中度症状；需要医学治疗	-	-	-
定义：病症特征为女性或青春期前男性出现不当的男性化。					
内分泌紊乱-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Eye disorders					
Adverse Event	Grade				
	1	2	3	4	5
Blurred vision	Intervention not indicated	Symptomatic; limiting instrumental ADL	Limiting self care ADL	-	-
Definition: A disorder characterized by visual perception of unclear or fuzzy images.					
Cataract	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; moderate decrease in visual acuity (20/40 or better)	Symptomatic with marked decrease in visual acuity (worse than 20/40 but better than 20/200); operative intervention indicated (e.g., cataract surgery)	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by partial or complete opacity of the crystalline lens of one or both eyes. This results in a decrease in visual acuity and eventual blindness if untreated.					
Conjunctivitis	Asymptomatic or mild symptoms; intervention not indicated	Symptomatic; topical intervention indicated (e.g., antibiotics); limiting instrumental ADL	Limiting self care ADL	-	-
Definition: A disorder characterized by inflammation, swelling and redness to the conjunctiva of the eye.					
Corneal ulcer	-	Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL	Limiting self care ADL; declining vision (worse than 20/40 but better than 20/200)	Perforation or blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by an area of epithelial tissue loss on the surface of the cornea. It is associated with inflammatory cells in the cornea and anterior chamber.					
Dry eye	Asymptomatic; clinical or diagnostic observations only; mild symptoms relieved by lubricants	Symptomatic; multiple agents indicated; limiting instrumental ADL	Decrease in visual acuity (<20/40); limiting self care ADL	-	-
Definition: A disorder characterized by dryness of the cornea and conjunctiva.					
Extraocular muscle paresis	Asymptomatic; clinical or diagnostic observations only	Symptomatic; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by incomplete paralysis of an extraocular muscle.					
Eye pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the eye.					
Eyelid function disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; nonoperative intervention indicated; limiting instrumental ADL	Limiting self care ADL; operative intervention indicated	-	-
Definition: A disorder characterized by impaired eyelid function.					
Flashing lights	Symptomatic but not limiting ADL	Limiting instrumental ADL	Limiting self care ADL	-	-
Definition: A disorder characterized by a sudden or brief burst of light.					
Floaters	Symptomatic but not limiting ADL	Limiting instrumental ADL	Limiting self care ADL	-	-
Definition: A disorder characterized by an individual seeing spots before their eyes. The spots are shadows of opaque cell fragments in the vitreous humor or lens.					
Glaucoma	Elevated intraocular pressure (EIOP) with single topical agent for intervention; no visual field deficit	EIOP causing early visual field deficits; multiple topical or oral agents indicated; limiting instrumental ADL	EIOP causing marked visual field deficits (e.g., involving both superior and inferior visual fields); operative intervention indicated; limiting self care ADL	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by an increase in pressure in the eyeball due to obstruction of the aqueous humor outflow.					
Keratitis	-	Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL	Decline in vision (worse than 20/40 but better than 20/200); limiting self care ADL	Perforation or blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by inflammation to the cornea of the eye.					
Night blindness	Symptomatic but not limiting ADL	Limiting instrumental ADL	Limiting self care ADL	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by an inability to see clearly in dim light.					

眼部病症					
不良事件	分级				
	1	2	3	4	5
视力模糊	无需介入治疗	有症状；工具性 ADL 受限	自理 ADL 受限	-	-
定义：特征为视力不清或图像模糊不清的病症。					
白内障	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；视敏度中度降低（20/40 或更高）	有症状，视敏度显著降低（低于 20/40 高于 20/200）；需要手术介入治疗（如白内障外科手术）	受感染眼部失明（20/200 或更低）	-
定义：特征为双目或单目部分或全部晶状体浑浊的病症。如果未经治疗会导致视敏度降低和最终失明。					
结膜炎	无症状或轻度症状，无需介入治疗	有症状；需要局部介入治疗（如抗生素）；工具性 ADL 受限	自理 ADL 受限	-	-
定义：特征为眼结膜出现红肿、炎症的病症。					
角膜溃疡	-	有症状；需要医学介入治疗（如局部制剂）；工具性 ADL 受限	自理 ADL 受限；视力下降（低于 20/40 高于 20/200）	受感染眼部穿孔或失明（20/200 或更低）	-
定义：特征为角膜表面的一定面积的上皮组织损失。与角膜和前房中的炎性细胞有关。					
干眼症	无症状；仅有临床或诊断学观察结果；可用润滑剂缓解轻度症状	有症状；需要多种药物治疗；工具性 ADL 受限	视敏度下降（<20/40）；自理 ADL 受限	-	-
定义：特征为角膜和结膜干燥的病症。					
眼外肌局部麻痹	无症状；仅有临床或诊断学观察结果	有症状；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为眼外肌不完全麻痹的病症。					
眼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为眼部有显著不适感的病症。					
眼睑功能障碍	无症状，仅有临床或诊断学观察结果；无需介入治疗	有症状，无需手术治疗；工具性 ADL 受限	自理 ADL 受限；需要手术治疗	-	-
定义：特征为眼睑机能受损的病症。					
闪光	有症状，ADL 未受限	工具性 ADL 受限	自理 ADL 受限	-	-
定义：特征为看到突然或短暂闪光的病症。					
漂浮物	有症状，ADL 未受限	工具性 ADL 受限	自理 ADL 受限	-	-
定义：特征为患者可以看到独立的漂浮斑点在眼前的病症。斑点是玻璃体或晶体不透明的细胞碎片阴影。					
青光眼	眼内压升高，可单一局部用药治疗；无视野缺失	眼内压升高使早期视野缺失；需多种局部或口服药物治疗；工具性 ADL 受限	眼内压升高使视野明显缺失（如同时包括上下视野）；需要手术治疗；自理 ADL 受限	受感染眼部失明（20/200 或更低）	-
定义：特征为由于房水流出阻塞，导致眼球压升高的病症。					
角膜炎	-	有症状；需要医学介入治疗（如局部用药）；工具性 ADL 受限	视力降低（低于 20/40 高于 20/200）；自理 ADL 受限	受感染眼部穿孔或失明（低于 20/200）	-
定义：特征为眼角膜有炎症的病症。					
夜盲症	有症状，ADL 未受限	工具性 ADL 受限	自理 ADL 受限	受感染眼部失明（低于 20/200）	-
定义：特征为在微光下的不能看清楚视的病症。					

Eye disorders					
Adverse Event	Grade				
	1	2	3	4	5
Optic nerve disorder	Asymptomatic; clinical or diagnostic observations only	Limiting vision of the affected eye (20/40 or better);	Limiting vision in the affected eye (worse than 20/40 but better than 20/200)	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by involvement of the optic nerve (second cranial nerve).					
Papilledema	Asymptomatic; no visual field defects	Symptomatic decline in vision; visual field defect present sparing the central 20 degrees	Marked visual field defect (worse than 20/40 but better than 20/200)	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by swelling around the optic disc.					
Photophobia	Symptomatic but not limiting ADL	Limiting instrumental ADL	Limiting self care ADL	-	-
Definition: A disorder characterized by fear and avoidance of light.					
Retinal detachment	Asymptomatic	Exudative and visual acuity 20/40 or better	Rhegmatogenous or exudative detachment; operative intervention indicated; decline in vision (worse than 20/40 but better than 20/200)	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by the separation of the inner retina layers from the underlying pigment epithelium.					
Retinal tear	-	Laser therapy or pneumopexy indicated	Vitreoretinal surgical repair indicated	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by a small laceration of the retina, this occurs when the vitreous separates from the retina. Symptoms include flashes and floaters.					
Retinal vascular disorder	-	Topical medication indicated	Intravitreal medication; operative intervention indicated	-	-
Definition: A disorder characterized by pathological retinal blood vessels that adversely affects vision.					
Retinopathy	Asymptomatic; clinical or diagnostic observations only	Symptomatic with moderate decrease in visual acuity (20/40 or better); limiting instrumental ADL	Symptomatic with marked decrease in visual acuity (worse than 20/40); disabling; limiting self care ADL	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder involving the retina.					
Scleral disorder	Asymptomatic; clinical or diagnostic observations only	Symptomatic, limiting instrumental ADL; moderate decrease in visual acuity (20/40 or better)	Symptomatic, limiting self care ADL; marked decrease in visual acuity (worse than 20/40)	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by involvement of the sclera of the eye.					
Uveitis	Asymptomatic; clinical or diagnostic observations only	Anterior uveitis; medical intervention indicated	Posterior or pan-uveitis	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by inflammation to the uvea of the eye.					
Vitreous hemorrhage	Asymptomatic or mild symptoms; clinical or diagnostic observations only	Symptomatic; limiting instrumental ADL	Limiting self care ADL; vitrectomy indicated	Blindness (20/200 or worse) in the affected eye	-
Definition: A disorder characterized by blood extravasation into the vitreous humor.					
Watering eyes	Intervention not indicated	Intervention indicated	Operative intervention indicated	-	-
Definition: A disorder of excessive tearing in the eyes; it can be caused by overproduction of tears or impaired drainage of the tear duct.					
Eye disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately sight-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Sight-threatening consequences; urgent intervention indicated; blindness (20/200 or worse) in the affected eye	-

眼部病症					
不良事件	分级				
	1	2	3	4	5
视神经病变	无症状；仅有临床或诊断学观察结果 定义：特征为涉及视神经（第二脑神经）的病症。	受感染眼部视力受限（20/40或更高）	受感染眼部视力受限（低于20/40高于20/200）	受感染眼部失明（20/200或更低）	-
视神经乳头水肿	无症状；无视野缺失 定义：特征为视神经乳头周围肿胀的病症。	有视力下降的症状；视野缺失，中心存在20度的盲区	显著视野缺失（低于20/40高于20/200）	受感染眼部失明（20/200或更低）	死亡
畏光	无症状，ADL未受限 定义：特征为害怕和躲避光的病症。	工具性ADL受限	自理ADL受限	-	-
视网膜脱离	无症状 定义：特征为内层视网膜层与底层的色素上皮分离的病症。	渗出性，视敏度20/40或更高	孔源性或渗出性剥离，需要手术介入治疗；视力下降（低于20/40高于20/200）	受感染眼部失明（20/200或更低）	-
视网膜撕裂	- 定义：疾病特征为视网膜有小裂口，在玻璃体与视网膜分离时产生。症状包括闪光和漂浮物。	需要激光或充气性视网膜固定术治疗	需要手术修复玻璃体视网膜	受感染眼部失明（20/200或更低）	-
视网膜血管病变	- 定义：病症特征为视网膜血管病变，对视力产生不利影响。	需要局部药物治疗	玻璃体内药物治疗；需要手术介入治疗	-	-
视网膜病变	无症状；仅有临床或诊断学观察结果 定义：涉及视网膜的病症。	有症状，视敏度中度下降（20/40或更高）；工具性ADL受限	有症状，视敏度显著下降（低于20/40）；致残；自理ADL受限	受感染眼部失明（20/200或更低）	-
巩膜病变	无症状；仅有临床或诊断学观察结果 定义：特征为涉及眼巩膜的病症。	有症状，工具性ADL受限；视敏度中度下降（20/40或更高）	有症状，自理ADL受限；视敏度显著下降（低于20/40）	受感染眼部失明（20/200或更低）	-
葡萄膜炎	无症状；仅有临床或诊断学观察结果 定义：特征为眼部葡萄膜有炎症的病症。	前葡萄膜炎，需要医学介入治疗	后或全葡萄膜炎	受感染眼部失明（20/200或更低）	-
玻璃体出血	无症状或轻度症状；仅有临床或诊断学观察结果 定义：特征为血液渗溢到玻璃体液中的病症。	有症状；工具性ADL受限	自理ADL受限；需要进行玻璃体切割术治疗	受感染眼部失明（20/200或更低）	-
流泪症	无需介入治疗 定义：特征为眼中有过多泪液的病症；可由过多分泌泪液或泪小管引流受损引起。	需要介入治疗	需要手术治疗	-	-
眼部病症-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及视觉；住院或延长住院时间；致残；自理ADL受限	危及视力的后果；需要紧急介入治疗；受感染眼部失明（20/200或更低）	-

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Abdominal distension	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe discomfort; limiting self care ADL	-	-
Definition: A disorder characterized by swelling of the abdomen.					
Abdominal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the abdominal region.					
Anal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the opening in the anal canal to the perianal skin.					
Anal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the anal region.					
Anal mucositis	Asymptomatic or mild symptoms; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the mucous membrane of the anus.					
Anal necrosis	-	-	TPN or hospitalization indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the anal region.					
Anal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the anal region.					
Anal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Symptomatic and severely altered GI function; non-emergent operative intervention indicated; TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the anal canal.					
Anal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the anal canal.					
Ascites	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by accumulation of serous or hemorrhagic fluid in the peritoneal cavity.					
Bloating	No change in bowel function or oral intake	Symptomatic; decreased oral intake; change in bowel function	-	-	-
Definition: A disorder characterized by subject-reported feeling of uncomfortable fullness of the abdomen.					
Cecal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the cecum.					
Cheilitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; intervention indicated	-	-
Definition: A disorder characterized by inflammation of the lip.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
腹胀	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；工具性 ADL 受限	严重不适；自理 ADL 受限	-	-
定义：特征为腹部膨胀的病症。					
腹痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为在腹部区域有显著不适感的病症。					
肛瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	严重改变 GI 功能；需要管饲饮食，全胃肠外营养或住院治疗；选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肛管的开口处与肛门周围皮肤之间有异常通道的病症。					
肛门出血	轻度，无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在肛门区域有出血的病症。					
肛门粘膜炎症	无症状性或轻度症状；无需介入治疗	有症状；需要医学治疗；工具性 ADL 受限	严重症状；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在肛门粘膜有炎症的病症。					
肛门坏死	-	-	需要全胃肠外营养或住院治疗；需要影像学、内镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在肛门区域发生坏死进程的病症。					
肛门疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为在肛门区域有显著不适感的病症。					
肛门狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	有症状，GI 功能严重改变；需要非紧急手术治疗；需要全胃肠外营养或住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肛管腔缩窄的病症。					
肛门溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	GI 功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为在肛管粘膜表面有局限的炎性和坏死糜烂性病灶。					
腹水	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要侵入性治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为腹膜腔内浆液或血液积聚。					
胃气胀	肠功能或经口摄食未改变	有症状，经口摄食减少；肠功能改变	-	-	-
定义：特征为病人报告胃有不适饱胀感的病症。					
盲肠出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为盲肠有出血的病症。					
唇炎	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限；需要介入治疗	-	-
定义：特征为唇部有炎症的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Colitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Abdominal pain; mucus or blood in stool	Severe abdominal pain; change in bowel habits; medical intervention indicated; peritoneal signs	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the colon.					
Colonic fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; bowel rest, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the large intestine and another organ or anatomic site.					
Colonic hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the colon.					
Colonic obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Hospitalization indicated; elective operative intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the intestinal contents in the colon.					
Colonic perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a rupture in the colonic wall.					
Colonic stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the colon.					
Colonic ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the colon.					
Constipation	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL	Obstipation with manual evacuation indicated; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by irregular and infrequent or difficult evacuation of the bowels.					
Dental caries	One or more dental caries, not involving the root	Dental caries involving the root	Dental caries resulting in pulpitis or periapical abscess or resulting in tooth loss	-	-
Definition: A disorder characterized by the decay of a tooth, in which it becomes softened, discolored and/or porous.					
Diarrhea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by frequent and watery bowel movements.					
Dry mouth	Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min	Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min	Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva <0.1 ml/min	-	-
Definition: A disorder characterized by reduced salivary flow in the oral cavity.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
结肠炎	无症状；仅有临床或诊断学观察结果；无需介入治疗	腹痛；粪便有粘液或出血	严重腹痛；肠排便习惯改变；需要医学治疗；有腹膜征兆	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为结肠有炎症的病症。					
结肠瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	严重改变 GI 功能；肠需要静养，全胃肠外营养或住院治疗；选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在大肠和其它器官或解剖部位之间有异常通道的病症。					
结肠出血	轻度，无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为结肠有出血的病症。					
结肠梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	需要住院治疗；选择性手术介入治疗；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为结肠中正常流量的肠内容物受到阻碍的病症。					
结肠穿孔	-	有症状；需要医学治疗	需要住院治疗；选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在结肠壁有破裂的病症。					
结肠狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	GI 功能严重改变；需要管饲饮食或住院治疗；选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为结肠内腔缩窄的病症。					
结肠溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	GI 功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在结肠粘膜表面有局限的炎性和坏死糜烂性病灶。					
便秘	偶尔或间歇性症状；可以偶尔使用大便软化剂、泻药、饮食调整或灌肠	持续的症状与有规律的使用泻药或灌肠；工具性 ADL 受限	顽固性便秘需要用手排空；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肠排空困难、不规律和粪便稀少的病症。					
龋齿	一或多颗龋齿，未伤牙根	龋齿伤及牙根	龋齿导致牙髓炎或根尖周脓肿或牙齿脱落	-	-
定义：病症特征为牙齿腐烂，导致软化、变色和/或多孔。					
腹泻	每日排便较基线增加小于 4 次；与基线相比造瘘术排泄物轻度增长	每日排便多于基线 4-6 次；与基线比较造瘘术排泄物中度增长	每日排便多于基线 7 次；失禁；需要住院治疗；与基线比较造瘘术排泄物重度增长；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为频繁的水样粪便排出。					
口干	有症状（如干燥或唾液浓稠）无显著饮食改变；非刺激性唾液流量>0.2ml/min	中度症状；经口摄食改变（如大量的水，其他润滑剂，饮食局限于酱汁和/或软、湿的食品）；非刺激性唾液流量为 0.1-0.2ml/min	不能口服足够食物；需要管饲饮食或全胃肠外营养；非刺激性唾液流量<0.1ml/min	-	-
定义：特征为口腔唾液流量减少的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Duodenal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the duodenum and another organ or anatomic site.					
Duodenal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the duodenum.					
Duodenal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Hospitalization or elective operative intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of stomach contents through the duodenum.					
Duodenal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the duodenal wall.					
Duodenal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding; hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the duodenum.					
Duodenal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the duodenal wall.					
Dyspepsia	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms; surgical intervention indicated	-	-
Definition: A disorder characterized by an uncomfortable, often painful feeling in the stomach, resulting from impaired digestion. Symptoms include burning stomach, bloating, heartburn, nausea and vomiting.					
Dysphagia	Symptomatic, able to eat regular diet	Symptomatic and altered eating/swallowing	Severely altered eating/swallowing; tube feeding or TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by difficulty in swallowing.					
Enterocolitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Abdominal pain; mucus or blood in stool	Severe or persistent abdominal pain; fever; ileus; peritoneal signs	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the small and large intestines.					
Enterovesical fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; noninvasive intervention indicated	Severe, medically significant; medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the urinary bladder and the intestine.					
Esophageal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the esophagus and another organ or anatomic site.					
Esophageal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the esophagus.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
十二指肠痿	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	严重改变GI功能；需要管饲饮食，全胃肠外营养或住院治疗；选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为十二指肠与其他器官或解剖部位之间有异常通道的病症。					
十二指肠出血	轻度，无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为在十二指肠有出血的病症。					
十二指肠梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	需要住院治疗或选择性手术介入治疗；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃正常流量的内容物通过十二指肠时受到阻碍的病症。					
十二指肠穿孔	-	有症状；需要医学治疗	严重症状；选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为在十二指肠肠壁破裂的病症。					
十二指肠狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要管饲饮食；住院治疗；选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为十二指肠内腔缩窄的病症。					
十二指肠溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；需要医学治疗；工具性ADL受限	GI功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在十二指肠肠壁粘膜表面有局限的炎性和坏死糜烂性病灶。					
消化不良	轻度症状；无需介入治疗	中度症状；需要医学治疗	严重症状；需要外科手术	-	-
定义：病症特征为胃部不适，常有痛感，由消化不良引起。症状包括胃烧、胀气、灼热、恶心和呕吐。					
吞咽困难	无症状；可以吃普通膳食	有症状，进食/吞咽改变	进食/吞咽严重改变；需要管饲饮食或全胃肠外营养或住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为吞咽困难的病症。					
小肠结肠炎	无症状；仅有临床或诊断学观察结果；无需介入治疗	腹痛；粪便有粘液或血	严重或持续性腹痛；发热；肠梗阻；腹膜征兆	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为小肠与大肠发炎的病症。					
肠膀胱痿	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要非侵入性治疗	严重，具有临床显著意义；需要医学治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为膀胱与肠之间有异常通道的病症。					
食道痿	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；GI功能改变	GI功能严重改变；需要管饲饮食、全胃肠外营养或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为食道与其他器官或解剖部位之间有异常通道的病症。					
食道出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为食道有出血的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Esophageal necrosis	-	-	Inability to aliment adequately by GI tract; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the esophageal wall.					
Esophageal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the contents in the esophagus.					
Esophageal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the esophageal region.					
Esophageal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the wall of the esophagus.					
Esophageal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding; hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the esophagus.					
Esophageal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the esophageal wall.					
Esophageal varices hemorrhage	-	Self-limited; intervention not indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from esophageal varices.					
Esophagitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered eating/swallowing; oral supplements indicated	Severely altered eating/swallowing; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation of the esophageal wall.					
Fecal incontinence	Occasional use of pads required	Daily use of pads required	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by inability to control the escape of stool from the rectum.					
Flatulence	Mild symptoms; intervention not indicated	Moderate; persistent; psychosocial sequelae	-	-	-
Definition: A disorder characterized by a state of excessive gas in the alimentary canal.					
Gastric fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; bowel rest; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the stomach and another organ or anatomic site.					
Gastric hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the gastric wall.					
Gastric necrosis	-	-	Inability to aliment adequately by GI tract; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the gastric wall.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
食道坏死	-	-	不能由 GI 管道充分消化；需要影像学，内窥镜或手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为食道壁发生坏死进程的病症。					
食道梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变；工具性 ADL 受限	需要住院治疗；需要选择性手术治疗；自理 ADL 受限；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为食道正常流量的内容物受到阻碍的病症。					
食道疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为在食道区域有显著不适感的病症。					
食道穿孔	-	有症状；需要医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为在食道壁有破裂的病症。					
食道狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	GI 功能严重改变；管饲饮食；需要住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为食道内腔缩窄的病症。					
食道溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变；工具性 ADL 受限	GI 功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；自理 ADL 受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在食道粘膜表面有局限的炎性和坏死糜烂性病灶。					
食道静脉曲张出血	-	自限性；无需介入治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为食道静脉曲张有出血的病症。					
食道炎	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；进食/吞咽改变；需要口服补充剂	进食/吞咽严重改变；需要管饲饮食，全胃肠外营养或住院治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为食道壁有炎症的病症。					
大便失禁	偶尔需要使用衬垫	每日需要使用衬垫	严重症状；需要选择性手术治疗	-	-
定义：特征为不能控制粪便由直肠溢出的病症。					
肠胃气胀	轻度症状；无需介入治疗	中度；持久；有心理后遗症	-	-	-
定义：特征为消化道有过量气体的病症。					
胃瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	GI 功能严重改变；肠需静养；管饲饮食；全胃肠外营养或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃与其他器官或解剖部位之间有异常通道的病症。					
胃出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胃壁有出血的病症。					
胃坏死	-	-	不能经胃肠道充分进食；需要放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃壁发生坏死进程的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Gastric perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the stomach wall.					
Gastric stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding; hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the stomach.					
Gastric ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the stomach.					
Gastritis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; medical intervention indicated	Severely altered eating or gastric function; TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation of the stomach.					
Gastroesophageal reflux disease	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms; surgical intervention indicated	-	-
Definition: A disorder characterized by reflux of the gastric and/or duodenal contents into the distal esophagus. It is chronic in nature and usually caused by incompetence of the lower esophageal sphincter, and may result in injury to the esophageal mucosal. Symptoms include heartburn and acid indigestion.					
Gastrointestinal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between any part of the gastrointestinal system and another organ or anatomic site.					
Gastrointestinal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the gastrointestinal region.					
Gastroparesis	Mild nausea, early satiety and bloating, able to maintain caloric intake on regular diet	Moderate symptoms; able to maintain nutrition with dietary and lifestyle modifications; may need pharmacologic intervention	Weight loss; refractory to medical intervention; unable to maintain nutrition orally	-	-
Definition: A disorder characterized by an incomplete paralysis of the muscles of the stomach wall resulting in delayed emptying of the gastric contents into the small intestine.					
Gingival pain	Mild pain	Moderate pain interfering with oral intake	Severe pain; inability to aliment orally	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the gingival region.					
Hemorrhoidal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the hemorrhoids.					
Hemorrhoids	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; banding or medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	-	-
Definition: A disorder characterized by the presence of dilated veins in the rectum and surrounding area.					
Ileal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the ileum and another organ or anatomic site.					
Ileal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the ileal wall.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
胃穿孔	-	有症状；无需医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃壁破裂的病症。					
胃狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；管饲饮食；需要住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃内腔缩窄的病症。					
胃溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；需要医学治疗；工具性ADL受限	GI功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在胃粘膜表面有局限的炎性和坏死糜烂性病灶。					
胃炎	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；进食/吞咽改变；需要医学介入	进食/胃机能严重改变；需要管饲饮食，全胃肠外营养或住院治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃有炎症的病症。					
胃食管反流病	轻度症状；无需介入治疗	中度症状；需要医学治疗	严重症状；需要外科手术介入治疗	-	-
定义：特征为胃和/或十二指肠内容物返流回末端食管。是慢性疾病，通常由下食管括约肌关闭不全引起，可能导致食管黏膜损伤。症状包括胃灼热和酸性消化不良。					
胃肠道瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要管饲饮食，全胃肠外营养或住院治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃肠道与其他器官或解剖部位之间有异常通道的病症。					
胃肠疼痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为胃肠区域有显著不适感的病症。					
胃轻瘫	轻度恶心，早期饱和感和腹胀，能够维持热量摄取和进食普通膳食	中度症状；能通过饮食维持营养摄取，需要改变生活方式；需要药物治疗	体重减轻；医学治疗无效；不能经口维持营养摄取	-	-
定义：特征为胃壁肌肉不完全瘫痪导致胃内容物进入小肠排空延迟的病症。					
牙龈疼痛	轻度疼痛	中度疼痛，影响经口摄食	严重疼痛；不能经口摄食	-	-
定义：特征为牙龈部位有显著不适感的病症。					
痔疮出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为痔疮有出血的病症。					
痔疮	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要包扎或医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	-	-
定义：特征为直肠和其周边区域出现静脉扩张的病症。					
回肠瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；管饲饮食；需要全胃肠外营养或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为回肠与其他器官或解剖部位之间有异常通道的病症。					
回肠出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为回肠壁有出血的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Ileal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the intestinal contents in the ileum.					
Ileal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the ileal wall.					
Ileal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the ileum.					
Ileal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the ileum.					
Ileus	-	Symptomatic; altered GI function; bowel rest indicated	Severely altered GI function; TPN indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by failure of the ileum to transport intestinal contents.					
Intra-abdominal hemorrhage	-	Medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding in the abdominal cavity.					
Jejunal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the jejunum and another organ or anatomic site.					
Jejunal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the jejunal wall.					
Jejunal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the intestinal contents in the jejunum.					
Jejunal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the jejunal wall.					
Jejunal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the jejunum.					
Jejunal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the jejunum.					
Lip pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort of the lip.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
回肠梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；工具性ADL受限	需要住院治疗；需要选择性手术治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为回肠正常流量的内容物受到阻碍的病症。					
回肠穿孔	-	有症状；需要医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为在回肠壁有破裂的病症。					
回肠狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；管饲饮食或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为回肠内腔缩窄的病症。					
回肠溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；工具性ADL受限	GI功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在回肠粘膜表面有局限的炎性和坏死糜烂性病灶。					
肠梗阻	-	有症状；GI功能改变；肠需要静养	GI功能严重改变；需要全胃肠外营养治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为回肠无法输送肠内容物的病症。					
腹腔内出血	-	需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为腹腔有出血的病症。					
空肠痿	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要全胃肠外营养或住院治疗；选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为空肠与其他器官或解剖部位之间有异常通道的病症。					
空肠出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为空肠有出血的病症。					
空肠梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；工具性ADL受限	需要住院治疗；需要选择性手术治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为空肠正常流量的内容物受到阻碍的病症。					
空肠穿孔	-	有症状；需要医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为空肠壁破裂的病症。					
空肠狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；管饲饮食或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为空肠内腔缩窄的病症。					
空肠溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；全胃肠外营养治疗；选择性手术或内窥镜介入；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在空肠粘膜表面有局限的炎性和坏死糜烂性病灶。					
唇痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为唇部有显著不适感的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Lower gastrointestinal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the lower gastrointestinal tract (small intestine, large intestine, and anus).					
Malabsorption	-	Altered diet; oral intervention indicated	Inability to aliment adequately; TPN indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inadequate absorption of nutrients in the small intestine. Symptoms include abdominal marked discomfort, bloating and diarrhea.					
Mucositis oral	Asymptomatic or mild symptoms; intervention not indicated	Moderate pain; not interfering with oral intake; modified diet indicated	Severe pain; interfering with oral intake	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the oral mucosal.					
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-	-
Definition: A disorder characterized by a queasy sensation and/or the urge to vomit.					
Obstruction gastric	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the contents in the stomach.					
Oral cavity fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the oral cavity and another organ or anatomic site.					
Oral dysesthesia	Mild discomfort; not interfering with oral intake	Moderate pain; interfering with oral intake	Disabling pain; tube feeding or TPN indicated	-	-
Definition: A disorder characterized by a burning or tingling sensation on the lips, tongue or entire mouth.					
Oral hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the mouth.					
Oral pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the mouth, tongue or lips.					
Pancreatic duct stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the pancreatic duct.					
Pancreatic fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the pancreas and another organ or anatomic site.					
Pancreatic hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the pancreas.					
Pancreatic necrosis	-	-	Tube feeding or TPN indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the pancreas.					
Pancreatitis	-	Enzyme elevation or radiologic findings only	Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional support)	Life-threatening consequences; urgent intervention indicated	Death

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
下消化道出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为下消化道有出血的病症（小肠、大肠和肛门）。					
吸收不良	-	改变饮食；需要口服给药治疗	不能经口摄取充足食物；需要全胃肠外营养	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为小肠营养吸收不足的病症。症状包括腹部显著不适，胀气和腹泻。					
口腔粘膜炎	无症状或轻度症状；无需介入治疗	中度疼痛；未影响经口摄食；需要调整饮食	严重疼痛；影响经口摄食	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为口腔粘膜发炎的病症。					
恶心	无食欲，未改变饮食习惯	经口摄食减少无显著体重减轻，脱水或营养不良	经口摄入热量或液体不足；需要管饲饮食，全胃肠外营养或住院治疗	-	-
定义：特征为有催吐感和/或呕吐冲动的病症。					
胃梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；工具性ADL受限	需要住院治疗；选择性手术介入治疗；自理ADL受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胃正常流量的内容物被阻塞的病症。					
口腔瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要全胃肠外营养或住院治疗；选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为口腔与其他器官或解剖部位之间有异常通道的病症。					
口腔触物痛感	轻度不适；未影响经口摄食	中度疼痛；影响经口摄食	致残性疼痛；需要管饲饮食或全胃肠外营养	-	-
定义：特征为唇，舌或整个口腔有灼热或刺痛感的病症。					
口腔出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为口腔出血的病症。					
口腔疼痛	轻度疼痛	中度疼痛；ADL受限	重度痛；自理ADL受限	-	-
定义：特征为口，舌或唇有显著不适感的病症。					
胰管狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要管饲饮食或住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胰管内腔缩窄的病症。					
胰瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变	GI功能严重改变；需要管饲饮食或全胃肠外营养或住院；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胰腺与其他器官或解剖部位之间有异常通道的病症。					
胰脏出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胰脏出血的病症。					
胰脏坏死	-	-	需要管饲饮食或全胃肠外营养治疗；放射、内窥镜，或手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胰脏发生坏死进程的病症。					
胰腺炎	-	仅有酶升高或放射学发现	严重疼痛；呕吐；需要医学治疗（如止痛、营养支持）	危及生命的后果；需要紧急介入治疗	死亡

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by inflammation of the pancreas.					
Periodontal disease	Gingival recession or gingivitis; limited bleeding on probing; mild local bone loss	Moderate gingival recession or gingivitis; multiple sites of bleeding on probing; moderate bone loss	Spontaneous bleeding; severe bone loss with or without tooth loss; osteonecrosis of maxilla or mandible	-	-
Definition: A disorder in the gingival tissue around the teeth.					
Peritoneal necrosis	-	-	Tube feeding or TPN indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the peritoneum.					
Proctitis	Rectal discomfort, intervention not indicated	Symptoms (e.g., rectal discomfort, passing blood or mucus); medical intervention indicated; limiting instrumental ADL	Severe symptoms; fecal urgency or stool incontinence; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the rectum.					
Rectal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the rectum and another organ or anatomic site.					
Rectal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the rectal wall and discharged from the anus.					
Rectal mucositis	Asymptomatic or mild symptoms; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation of the mucous membrane of the rectum.					
Rectal necrosis	-	-	Tube feeding or TPN indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the rectal wall.					
Rectal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the intestinal contents in the rectum.					
Rectal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the rectal region.					
Rectal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the rectal wall.					
Rectal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the rectum.					
Rectal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function (e.g. altered dietary habits, vomiting, diarrhea)	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the rectum.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
定义：特征为胰腺有炎症的病症。					
牙周病	牙龈退缩或牙龈炎； 探针发现有限出血； 轻度局部骨丢失	中度牙龈退缩或牙龈炎； 探针发现多位点出血； 中度骨丢失	自发性出血；严重骨丢失伴或不伴牙齿损伤； 上颌骨或下颌骨坏死	-	-
定义：牙齿周围牙龈组织的病症。					
腹膜炎	-	-	需要管饲饮食或全胃肠外营养； 需要放射、内窥镜，或手术治疗	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为发生在腹膜坏死进程的病症。					
直肠炎	直肠不适，无需介入治疗	有症状（如直肠不适， 流血或黏液）； 需要医学治疗； 工具性 ADL 受限	严重症状； 粪便紧迫或大便失禁； 自理 ADL 受限	危及生命的后果； 需要紧急介入治疗	死亡
定义：特征为直肠有炎症的病症。					
直肠瘘	无症状； 仅有临床或诊断学观察结果； 无需介入治疗	有症状； GI 功能改变	GI 功能严重改变； 需要全胃肠外营养或住院治疗； 需要选择性手术治疗	危及生命的后果； 需要紧急介入治疗	死亡
定义：特征为直肠与其他器官或解剖部位之间有异常通道的病症。					
直肠出血	轻度； 无需介入治疗	中度症状； 需要医学或少量烧灼术治疗	需要输血、放射、 内窥镜或选择性手术介入	危及生命的后果； 需要紧急介入治疗	死亡
定义：特征为直肠壁出血并从肛门排出的病症。					
直肠黏膜炎	无症状或轻度症状； 无需介入治疗	有症状； 需要医学治疗； 工具性 ADL 受限	严重症状； 自理 ADL 受限	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为直肠黏膜有炎症的病症。					
直肠坏死	-	-	需要管饲饮食或全胃肠外营养治疗； 需要放射、内窥镜或手术介入	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为直肠壁发生坏死进程的病症。					
直肠梗阻	无症状； 仅有临床或诊断学观察结果； 无需介入治疗	有症状； GI 功能改变； 工具性 ADL 受限	需要住院治疗； 需要选择性手术治疗； 自理 ADL 受限； 致残	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为直肠正常流量的内容物受到阻碍的病症。					
直肠疼痛	轻度疼痛	中度疼痛； 工具性 ADL 受限	严重疼痛； 自理 ADL 受限	-	-
定义：特征为直肠区域有显著不适感的病症。					
直肠穿孔	-	有症状； 需要医学治疗	严重症状； 需要选择性手术治疗	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为直肠壁破裂的病症。					
直肠狭窄	无症状； 仅有临床或诊断学观察结果； 无需介入治疗	有症状； GI 功能改变	GI 功能严重改变； 管饲饮食或住院治疗； 需要选择性手术治疗	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：特征为直肠内腔缩窄的病症。					
直肠溃疡	无症状； 仅有临床或诊断学观察结果； 无需介入治疗	有症状； GI 功能改变（如饮食习惯改变， 呕吐，腹泻）	GI 功能严重改变； 需要全胃肠外营养治疗； 需要选择性手术或内窥镜介入治疗； 自理 ADL 受限； 致残	危及生命的后果； 需要紧急手术介入治疗	死亡
定义：病症特征为在直肠黏膜表面有局限的炎性和坏死糜烂性病灶。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Retroperitoneal hemorrhage	-	Self-limited; intervention indicated	Transfusion, medical, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the retroperitoneal area.					
Salivary duct inflammation	Slightly thickened saliva; slightly altered taste (e.g., metallic)	Thick, ropy, sticky saliva; markedly altered taste; alteration in diet indicated; secretion-induced symptoms; limiting instrumental ADL	Acute salivary gland necrosis; severe secretion-induced symptoms (e.g., thick saliva/oral secretions or gagging); tube feeding or TPN indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the salivary duct.					
Salivary gland fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; tube feeding indicated	Severely altered GI function; hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between a salivary gland and another organ or anatomic site.					
Small intestinal mucositis	Asymptomatic or mild symptoms; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe pain; interfering with oral intake; tube feeding, TPN or hospitalization indicated; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the mucous membrane of the small intestine.					
Small intestinal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Hospitalization indicated; elective operative intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the intestinal contents.					
Small intestinal perforation	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the small intestine wall.					
Small intestinal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Symptomatic and severely altered GI function; tube feeding, TPN or hospitalization indicated; non-emergent operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the small intestine.					
Small intestine ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; limiting instrumental ADL	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the mucosal surface of the small intestine.					
Stomach pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the stomach.					
Tooth development disorder	Asymptomatic; hypoplasia of tooth or enamel	Impairment correctable with oral surgery	Maldevelopment with impairment not surgically correctable; disabling	-	-
Definition: A disorder characterized by a pathological process of the teeth occurring during tooth development.					
Tooth discoloration	Surface stains	-	-	-	-
Definition: A disorder characterized by a change in tooth hue or tint.					
Toothache	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the tooth.					

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
腹膜后出血	-	自限性；需要介入治疗	需要输血、放射、内窥镜或选择性手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为腹膜后区域有出血的病症。					
涎腺导管炎症	唾液轻微粘稠；轻度改变味觉（如金属味）	唾液粘稠；味觉明显改变；需要改变饮食；分泌诱发症状；工具性 ADL 受限	急性唾液腺坏死；严重的分泌诱导症状（如唾液粘稠/口腔分泌物或作呕）；需要管饲饮食或全胃肠外营养治疗；自理 ADL 受限；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涎腺导管有炎症的病症。					
唾液腺瘘	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变；需要管饲饮食	GI 功能严重改变；需要住院治疗；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为唾液腺与其他器官或解剖部位之间有异常通道的病症。					
小肠粘膜炎	无症状或轻度症状；无需介入治疗	有症状；需要医学治疗；工具性 ADL 受限	严重疼痛；影响经口进食；需要管饲饮食，全胃肠外营养或住院治疗；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为小肠粘膜有炎症的病症。					
小肠梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变；工具性 ADL 受限	需要住院治疗；需要选择性手术治疗；自理 ADL 受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为正常流量的肠内容物受到阻碍的病症。					
小肠穿孔	-	有症状；需要医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为小肠壁破裂的病症。					
小肠狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变	有症状，GI 功能严重改变；需要管饲饮食、全胃肠外营养或住院治疗；需要非紧急手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为小肠内腔缩窄的病症。					
小肠溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI 功能改变；工具性 ADL 受限	GI 功能严重改变；需要全胃肠外营养治疗；需要选择性手术或内窥镜介入治疗；自理 ADL 受限；致残	危及生命的后果；需要紧急手术介入治疗	死亡
定义：病症特征为在小肠粘膜表面有局限的炎性和坏死糜烂性病灶。					
胃痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为胃有显著不适感的病症。					
牙发育疾病	无症状；牙齿或釉质发育不全	需要口腔外科手术进行损伤矫正	外科手术不能矫正发育不良伴随损伤；致残	-	-
定义：特征为牙齿发育时发生病理性进程的病症。					
牙齿变色	表面污渍	-	-	-	-
定义：特征为牙齿色泽改变的病症。					
牙痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为牙齿有显著不适感的病症。					

Gastrointestinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Typhlitis	-	-	Symptomatic (e.g., abdominal pain, fever, change in bowel habits with ileus); peritoneal signs	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation of the cecum.					
Upper gastrointestinal hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention or minor cauterization indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the upper gastrointestinal tract (oral cavity, pharynx, esophagus, and stomach).					
Vomiting	1 - 2 episodes (separated by 5 minutes) in 24 hrs	3 - 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth.					
Gastrointestinal disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

胃肠道病症					
不良事件	分级				
	1	2	3	4	5
盲肠炎	-	-	有症状（如腹痛，发热，肠梗阻伴随排便习惯改变）；腹膜征兆	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为盲肠有炎症的病症。					
上消化道出血	轻度；无需介入治疗	中度症状；需要医学或少量烧灼术治疗	需要输血、放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为上消化道有出血的病症（口腔，咽，食管和胃）。					
呕吐	24小时内发作1-2次（间隔5分钟）	24小时内发作3-5次（间隔5分钟）	24小时内发作≥6次（间隔5分钟）；需要管饲饮食，全胃肠外营养或住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为将胃内容物从口喷出的反射行为。					
胃肠道病症-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

General disorders and administration site conditions					
Adverse Event	Grade				
	1	2	3	4	5
Chills	Mild sensation of cold; shivering; chattering of teeth	Moderate tremor of the entire body; narcotics indicated	Severe or prolonged, not responsive to narcotics	-	-
Definition: A disorder characterized by a sensation of cold that often marks a physiologic response to sweating after a fever.					
Death neonatal	-	-	-	-	Death
Definition: A disorder characterized by cessation of life occurring during the first 28 days of life.					
Death NOS	-	-	-	-	Death
Definition: A cessation of life that cannot be attributed to a CTCAE term associated with Grade 5.					
Edema face	Localized facial edema	Moderate localized facial edema; limiting instrumental ADL	Severe swelling; limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to excessive fluid accumulation in facial tissues.					
Edema limbs	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10 - 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to excessive fluid accumulation in the upper or lower extremities.					
Edema trunk	Swelling or obscuration of anatomic architecture on close inspection	Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	Gross deviation from normal anatomic contour; limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to excessive fluid accumulation in the trunk area.					
Facial pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the face.					
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest; limiting self care ADL	-	-
Definition: A disorder characterized by a state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.					
Fever	38.0 - 39.0 degrees C (100.4 - 102.2 degrees F)	>39.0 - 40.0 degrees C (102.3 - 104.0 degrees F)	>40.0 degrees C (>104.0 degrees F) for <=24 hrs	>40.0 degrees C (>104.0 degrees F) for >24 hrs	Death
Definition: A disorder characterized by elevation of the body's temperature above the upper limit of normal.					
Flu like symptoms	Mild flu-like symptoms present.	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by a group of symptoms similar to those observed in patients with the flu. It includes fever, chills, body aches, malaise, loss of appetite and dry cough.					
Gait disturbance	Mild change in gait (e.g., wide-based, limping or hobbling)	Moderate change in gait (e.g., wide-based, limping or hobbling); assistive device indicated; limiting instrumental ADL	Disabling; limiting self care ADL	-	-
Definition: A disorder characterized by walking difficulties.					
Hypothermia	-	35 - >32 degrees C; 95 - >89.6 degrees F	32 - >28 degrees C; 89.6 - >82.4 degrees F	<=28 degrees C ; 82.4 degrees F; life-threatening consequences (e.g., coma, hypotension, pulmonary edema, acidemia, ventricular fibrillation)	Death
Definition: A disorder characterized by an abnormally low body temperature. Treatment is required when the body temperature is 35C (95F) or below.					

全身性病症和给药部位症状					
分级					
不良事件	1	2	3	4	5
发冷	轻度冷感；发抖；牙齿打颤	全身中度颤抖；需要用麻醉药	严重或长时期，对麻醉药无反应	-	-
定义：病症特征为感觉寒冷，通常发热后伴随出汗这一生理反应。					
新生儿死亡	-	-	-	-	死亡
定义：特征为出生后 28 天中生命停止的病症。					
死亡（未指定）	-	-	-	-	死亡
定义：生命停止，不可归类于 CTCAE 术语的 5 级。					
面部水肿	局限性面部浮肿	中度面部浮肿；工具性 ADL 受限	严重浮肿；自理 ADL 受限	-	-
定义：特征为过量液体积聚在面部组织引起水肿的病症。					
四肢水肿	最大的可见差别处有 5-10% 的肢体间体积或周长差异；近距离观察有肿胀或解剖学结构模糊	最大的可见差别处有 >10-30% 的肢体间体积或周长差异；非常明显的解剖学结构模糊；皮肤褶皱消失；明显偏离正常解剖学轮廓；工具性 ADL 受限	有 >30% 的肢体间体积差异；严重偏离正常解剖学轮廓；自理 ADL 受限	-	-
定义：特征为过量液体积聚在上下肢引起水肿的病症。					
躯干水肿	近距离观察有肿胀或解剖学结构模糊	非常明显的解剖学结构模糊；皮肤褶皱消失；明显偏离正常解剖学轮廓；工具性 ADL 受限	严重偏离正常解剖学轮廓；自理 ADL 受限	-	-
定义：特征为过量液体积聚在躯干区域引起水肿的病症。					
面部疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为面部有显著不适感的病症。					
疲乏	疲劳但休息可缓解	疲劳且休息不能缓解；工具性 ADL 受限	疲劳且休息不能缓解；自理 ADL 受限	-	-
定义：病症特征为全身乏力的状态，明显无法拿出足够精力完成日常活动。					
发热	38.0-39.0 摄氏度（100.4-102.2 华氏度）	>39.0-40.0 摄氏度（102.3-104.0 华氏度）	>40.0 摄氏度（>104.0 华氏度）持续时间 ≤ 24 小时	>40.0 摄氏度（>104.0 华氏度）持续时间 > 24 小时	死亡
定义：特征为体温高于正常上限的病症。					
流感样症状	表现轻度流感样症状	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为很多症状与流感病人可以观察的症状相似的病症。包括发热、发冷、身体疼痛、不适、无食欲和干咳					
步态障碍	步态轻度改变（如两足分开，跛行或蹒跚）	步态中度改变（如两足分开，跛行或蹒跚）；需要辅助装置；工具性 ADL 受限	致残；自理 ADL 受限	-	-
定义：特征为行走困难的病症。					
体温过低	-	35->32 摄氏度； 95->89.6 华氏度	32->28 摄氏度； 89.6->82.4 华氏度	<=28 摄氏度； <=82.4 华氏度；危及生命的后果（如昏迷；低血压，肺水肿，酸血症，心室颤动）	死亡
定义：特征为体温异常低的病症。当体温于 35 摄氏度(95 华氏度)或更低时需要治疗。					

CTCAE v4.0

General disorders and administration site conditions					
Adverse Event	Grade				
	1	2	3	4	5
Infusion related reaction	Mild transient reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for <=24 hrs	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by adverse reaction to the infusion of pharmacological or biological substances.					
Infusion site extravasation	-	Erythema with associated symptoms (e.g., edema, pain, induration, phlebitis)	Ulceration or necrosis; severe tissue damage; operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by leakage of a pharmacologic or a biologic substance from the infusion site into the surrounding tissue. Signs and symptoms include induration, erythema, swelling, burning sensation and marked discomfort at the infusion site.					
Injection site reaction	Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)	Pain; lipodystrophy; edema; phlebitis	Ulceration or necrosis; severe tissue damage; operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an intense adverse reaction (usually immunologic) developing at the site of an injection.					
Irritability	Mild; easily consolable	Moderate; limiting instrumental ADL; increased attention indicated	Severe abnormal or excessive response; limiting self care ADL; inconsolable	-	-
Definition: A disorder characterized by an abnormal responsiveness to stimuli or physiological arousal; may be in response to pain, fright, a drug, an emotional situation or a medical condition.					
Localized edema	Localized to dependent areas, no disability or functional impairment.	Moderate localized edema and intervention indicated; limiting instrumental ADL	Severe localized edema and intervention indicated; limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to excessive fluid accumulation at a specific anatomic site.					
Malaise	Uneasiness or lack of well being	Uneasiness or lack of well being; limiting instrumental ADL	-	-	-
Definition: A disorder characterized by a feeling of general discomfort or uneasiness, an out-of-sorts feeling.					
Multi-organ failure	-	-	Shock with azotemia and acid-base disturbances; significant coagulation abnormalities	Life-threatening consequences (e.g., vasopressor dependent and oliguric or anuric or ischemic colitis or lactic acidosis)	Death
Definition: A disorder characterized by progressive deterioration of the lungs, liver, kidney and clotting mechanisms.					
Neck edema	Asymptomatic localized neck edema	Moderate neck edema; slight obliteration of anatomic landmarks; limiting instrumental ADL	Generalized neck edema (e.g., difficulty in turning neck); limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to an accumulation of excessive fluid in the neck.					
Non-cardiac chest pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by discomfort in the chest unrelated to a heart disorder.					
Pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by the sensation of marked discomfort, distress or agony.					
Sudden death NOS	-	-	-	-	Death
Definition: An unexpected cessation of life that cannot be attributed to a CTCAE term associated with Grade 5.					
General disorders and administration site conditions - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

全身性病症和给药部位症状					
不良事件	分级				
	1	2	3	4	5
输液相关反应	轻度短暂反应；无需中断输液；无需介入治疗	需要中断治疗或输液，但对症治疗的反应迅速（如抗组胺药，非甾体抗炎药，麻醉品，静脉输液）；需要≤24小时的预防药物治疗	长时期的（如对症治疗和/或暂时中断输液无快速反应）；初步改善后症状再度出现；需要住院治疗临床后遗症	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为对药物或生物制品输液有不良反应的病症。					
输液部位外渗	-	红斑伴随症状（如水肿、疼痛、硬结、静脉炎）	溃疡或坏死；严重组织损害；需要手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为药物或生物制品由输液部位向周围组织渗出的病症。症状和体征包括输液部位出现硬结、红斑、肿胀、烧灼感和明显不适。					
注射部位反应	触痛或不伴随症状（例如热感、红斑、瘙痒）	疼痛；脂肪代谢障碍；水肿；静脉炎	溃疡或坏死；严重组织损害；需要手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为注射部位产生的强烈的不良反应（通常是免疫反应）。					
应激性	轻度；易恢复	中度；工具性 ADL 受限；需要增强关注	严重异常或过度反应；自理 ADL 受限；不能恢复	-	-
定义：病症特征为对刺激或生理唤醒有异常反应；可能是对疼痛、恐惧、一种药物、情感状况或医疗条件的反应。					
局限性水肿	局限于依赖区，没有致残或功能损伤	中度局限性水肿，需要治疗；工具性 ADL 受限	严重局限性水肿，需要治疗；自理 ADL 受限	-	-
定义：特征为过量液体聚集在特定解剖部位引起水肿的病症。					
不适	不安或不舒服	不安或不舒服；工具性 ADL 受限	-	-	-
定义：病症特征为全身不适的不安感，不悦的感觉。					
多器官衰竭	-	-	休克，伴有氮血症和酸碱紊乱；显著凝血异常	危及生命的后果（如血管加压依赖性和少尿或无尿或缺血性结肠炎或乳酸中毒）	死亡
定义：病症特征为肺、肝、肾和凝血机制的进展性恶化。					
颈部水肿	无症状，局限性颈部水肿	中度颈部水肿；略有解剖标志消失；工具性 ADL 受限	普遍性颈部水肿（如转头困难）；自理 ADL 受限	-	-
定义：病症特征为颈部过量液体聚集导致的水肿。					
非心源性胸痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为与心脏病无关的胸部不适的病症。					
疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为有显著不适，痛苦或疼痛感觉的病症。					
猝死（未指定）	-	-	-	-	死亡
定义：非预期的生命停止，不能归类于 CTCAE 术语的 5 级。					
全身性病症和给药部位症状-其它，指定	无症状或有轻度体征；仅有临床或诊断观察结果；无需介入治疗。	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡

Hepatobiliary disorders					
Adverse Event	Grade				
	1	2	3	4	5
Bile duct stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; IV fluids indicated <24 hrs	Severely altered GI function; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a narrowing of the lumen of the bile duct.					
Biliary fistula	-	Symptomatic and intervention not indicated	Severely altered GI function; TPN indicated; endoscopic intervention indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the bile ducts and another organ or anatomic site.					
Cholecystitis	-	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by inflammation involving the gallbladder. It may be associated with the presence of gallstones.					
Gallbladder fistula	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Symptomatic or severely altered GI function; TPN indicated; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the gallbladder and another organ or anatomic site.					
Gallbladder necrosis	-	-	-	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the gallbladder.					
Gallbladder obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; IV fluids indicated <24 hrs	Symptomatic and severely altered GI function; tube feeding, TPN or hospitalization indicated; non-emergent operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of the contents of the gallbladder.					
Gallbladder pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the gallbladder region.					
Gallbladder perforation	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a rupture in the gallbladder wall.					
Hepatic failure			Asterixis; mild encephalopathy; limiting self care ADL	Moderate to severe encephalopathy; coma; life-threatening consequences	Death
Definition: A disorder characterized by the inability of the liver to metabolize chemicals in the body. Laboratory test results reveal abnormal plasma levels of ammonia, bilirubin, lactic dehydrogenase, and alkaline phosphatase.					
Hepatic hemorrhage	Mild; intervention not indicated	Symptomatic; medical intervention indicated	Transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the liver.					
Hepatic necrosis	-	-	-	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the hepatic parenchyma.					
Hepatic pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the liver region.					
Perforation bile duct	-	-	Radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the wall of the extrahepatic or intrahepatic bile duct.					

肝胆管病症					
不良事件	分级				
	1	2	3	4	5
胆管狭窄	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；需要<24小时静脉输液治疗	GI功能严重改变；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆管内腔缩窄的病症。					
胆瘘	-	有症状；无需医学治疗	GI功能严重改变；需要全胃肠外营养治疗；需要内窥镜治疗；需要选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆管与其他器官或解剖部位之间有异常通道的病症。					
胆囊炎	-	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆囊有关炎症的病症。可能与胆结石生成有关。					
胆囊瘘	无症状，仅有临床或诊断学观察结果；无需介入治疗	有症状；无需医学治疗	有症状或GI功能严重改变；需要全胃肠外营养治疗；需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆囊与其他器官或解剖部位之间有异常通道的病症。					
胆囊坏死	-	-	-	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆囊发生坏死进程的病症。					
胆囊梗阻	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；GI功能改变；需要<24小时静脉输液治疗	有症状或GI功能严重改变；管饲饮食，全胃肠外营养或住院治疗；需要非紧急手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为胆囊正常流量的内容物受到阻碍的病症。					
胆囊疼痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为胆囊区域有显著不适感的病症。					
胆囊穿孔	-	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胆囊壁破裂的病症。					
肝衰竭	-	-	无保持固定姿势的能力；轻度脑病；自理ADL受限	中度到重度脑病；昏迷；危及生命的后果	死亡
定义：特征为肝无法代谢体内的化学物质的病症。化验结果显示血浆中氨、胆红素、乳酸脱氢酶和碱性磷酸酶水平异常。					
肝出血	轻度；无需介入治疗	有症状；需要医学治疗	需要输血	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肝出血的病症。					
肝坏死	-	-	-	危及生命的后果；需要紧急放射或手术介入治疗	死亡
定义：特征为肝实质发生坏死进程的病症。					
肝痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为肝部有显著不适感的病症。					
胆管穿孔	-	-	需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为肝外或肝内胆管壁破裂的病症。					

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Hepatobiliary disorders					
Adverse Event	Grade				
	1	2	3	4	5
Portal hypertension	-	Decreased portal vein flow	Reversal/retrograde portal vein flow; associated with varices and/or ascites	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an increase in blood pressure in the portal venous system.					
Portal vein thrombosis	-	Intervention not indicated	Medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the formation of a thrombus (blood clot) in the portal vein.					
Hepatobiliary disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

肝胆管病症					
不良事件	分级				
	1	2	3	4	5
门静脉高压	-	门静脉血流降低	门静脉血流倒转或逆行；伴随脉管曲张或腹水	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为门静脉系统血压升高的病症。					
门静脉血栓	-	无需介入治疗	需要医学治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为门静脉有血栓（血凝块）形成的病症。					
肝胆管病症-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Immune system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Allergic reaction	Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated	Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics); prophylactic medications indicated for <=24 hrs	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an adverse local or general response from exposure to an allergen.					
Anaphylaxis	-	-	Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an acute inflammatory reaction resulting from the release of histamine and histamine-like substances from mast cells, causing a hypersensitivity immune response. Clinically, it presents with breathing difficulty, dizziness, hypotension, cyanosis and loss of consciousness and may lead to death.					
Autoimmune disorder	Asymptomatic; serologic or other evidence of autoimmune reaction, with normal organ function; intervention not indicated	Evidence of autoimmune reaction involving a non-essential organ or function (e.g., hypothyroidism)	Autoimmune reactions involving major organ (e.g., colitis, anemia, myocarditis, kidney)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder resulting from loss of function or tissue destruction of an organ or multiple organs, arising from humoral or cellular immune responses of the individual to his own tissue constituents.					
Cytokine release syndrome	Mild reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for <=24 hrs	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)	Life-threatening consequences; pressor or ventilatory support indicated	Death
Definition: A disorder characterized by nausea, headache, tachycardia, hypotension, rash, and shortness of breath; it is caused by the release of cytokines from the cells.					
Serum sickness	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate arthralgia; fever, rash, urticaria, antihistamines indicated	Severe arthralgia or arthritis; extensive rash; steroids or IV fluids indicated	Life-threatening consequences; pressor or ventilatory support indicated	Death
Definition: A disorder characterized by a delayed-type hypersensitivity reaction to foreign proteins derived from an animal serum. It occurs approximately six to twenty-one days following the administration of the foreign antigen. Symptoms include fever, arthralgias, myalgias, skin eruptions, lymphadenopathy, chest marked discomfort and dyspnea.					
Immune system disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

免疫系统病症					
不良事件	分级				
	1	2	3	4	5
变态反应	短暂的面部发红或皮疹；药物热<38 摄氏度 (<100.4 华氏度)；无需介入	需要中断治疗或输液；对于对症治疗能快速反应（如抗组胺药，非甾体抗炎药，麻醉药）；需要≤24 小时预防性治疗	长时期的（如对于对症治疗和/或输液的短暂中断不能快速反应）；初步改善后症状再次出现；需要住院治疗临床后遗症（如肾功能损伤，肺浸润）	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为暴露于过敏原引起的局部或全身反应的病症。					
过敏反应	-	-	有症状，支气管痉挛或不伴荨麻疹；需要非肠道给药治疗；变态反应相关的水肿/血管性水肿；低血压	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为肥大细胞释放的组胺和组胺样物质产生急性炎症反应，引起超敏免疫反应。临床上表现为呼吸困难、头昏、低血压、紫绀和意识丧失，并可能导致死亡。					
自身免疫性疾病	无症状；血清学或其他自身免疫反应证据，器官功能正常；无需介入治疗	自身免疫反应证据，涉及一个非必要器官或功能（如甲状腺功能减退症）	自身免疫反应涉及主要器官（例如结肠炎、贫血、心肌炎、肾）	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为一个器官或多器官的功能缺失或组织破坏，来源于个体对自身组织成分的体液或细胞免疫应答。					
细胞因子释放综合征	轻度反应；无需输液中断；无需介入治疗	需要中断治疗或输液；对于对症治疗能快速反应（如抗组胺药、非甾体抗炎药、麻醉药、静脉输液）；需要≤24 小时预防性治疗	长时期的（如对于对症治疗和/或输液的短暂中断不能快速反应）；初步改善后症状再次出现；需要住院治疗临床后遗症（如肾功能损伤，肺浸润）	危及生命的后果；需要加压或辅助呼吸	死亡
定义：病症特征为恶心、头痛、心动过速、低血压、皮疹及呼吸急促；由细胞释放细胞因子造成。					
血清病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度关节痛；发热，皮疹，荨麻疹，需要抗组胺类治疗	严重的关节痛或关节炎；广泛皮疹；需要类固醇或静脉输液治疗	危及生命的后果；需要加压或辅助呼吸治疗	死亡
定义：病症特征是对来自动物血清的异质蛋白的迟发型超敏反应。在给予外来抗原后大约 6 至 21 天发生。症状包括发烧、关节痛、肌肉痛、斑疹、淋巴结病、胸部明显的不适和呼吸困难。					
免疫系统病症-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Abdominal infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the abdominal cavity.					
Anorectal infection	Localized; local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the anal area and the rectum.					
Appendicitis	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by acute inflammation to the vermiform appendix caused by a pathogenic agent.					
Appendicitis perforated	-	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by acute inflammation to the vermiform appendix caused by a pathogenic agent with gangrenous changes resulting in the rupture of the appendiceal wall. The appendiceal wall rupture causes the release of inflammatory and bacterial contents from the appendiceal lumen into the abdominal cavity.					
Arteritis infective	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving an artery.					
Biliary tract infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the biliary tract.					
Bladder infection	-	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the bladder.					
Bone infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the bones.					
Breast infection	-	Local infection with moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	Severe infection; axillary adenitis; IV antibacterial, antifungal, or antiviral intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the breast.					
Bronchial infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the bronchi.					
Catheter related infection	-	Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process that arises secondary to catheter use.					
Cecal infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
腹部感染	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为腹腔有感染进程的病症。					
肛门直肠感染	局部的; 需要局部治疗	需要口服药物治疗 (如抗生素, 抗真菌, 抗病毒药物)	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射、内窥镜或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为肛门区域和直肠有感染进程的病症。					
阑尾炎	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为由致病原造成阑尾急性炎症的病症。					
阑尾穿孔	-	有症状; 需要药物治疗	严重症状; 需要选择性手术治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 病症特征为由致病原造成阑尾急性炎症产生坏疽性改变, 导致阑尾壁穿孔。阑尾壁破裂使炎性和细菌性内容物从阑尾内腔释放进入腹腔。					
感染性动脉炎	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为动脉有感染进程的病症。					
胆道感染	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为胆道有感染进程的病症。					
膀胱感染	-	需要口服药物治疗 (如抗生素, 抗真菌, 抗病毒药物)	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射、内窥镜或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为膀胱有感染进程的病症。					
骨感染	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为骨有感染进程的病症。					
乳房感染	-	局部感染伴中度症状; 需要口服药物治疗 (如抗生素, 抗真菌, 抗病毒药物)	严重感染; 腋下淋巴结炎; 需要抗生素, 抗真菌, 或抗病毒药物输液治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为乳房有感染进程的病症。					
支气管感染	-	中度症状; 需要口服药物治疗 (如抗生素, 抗真菌, 抗病毒药物)	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 放射、内窥镜或手术介入	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为支气管有感染进程的病症。					
导管相关感染	-	局部的; 需要局部治疗; 需要口服药物治疗 (如抗生素, 抗真菌, 抗病毒药物)	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 病症特征为继发于导管使用产生的感染进程。					
盲肠感染	-	-	需要抗生素, 抗真菌, 或抗病毒药物输液治疗; 需要放射、内窥镜或手术介入治疗	危及生命的后果; 需要紧急介入治疗	死亡

CTCAE v4.0

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by an infectious process involving the cecum.					
Cervicitis infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the uterine cervix.					
Conjunctivitis infective	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the conjunctiva. Clinical manifestations include pink or red color in the eyes.					
Corneal infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the cornea.					
Cranial nerve infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving a cranial nerve.					
Device related infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the use of a medical device.					
Duodenal infection	-	Moderate symptoms; medical intervention indicated (e.g., oral antibiotics)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the duodenum.					
Encephalitis infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; severe changes in mental status; self-limited seizure activity; focal neurologic abnormalities	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the brain tissue.					
Encephalomyelitis infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the brain and spinal cord tissues.					
Endocarditis infective	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the endocardial layer of the heart.					
Endophthalmitis	-	Local intervention indicated	Systemic intervention or hospitalization indicated	Blindness (20/200 or worse)	-
Definition: A disorder characterized by an infectious process involving the internal structures of the eye.					

感染和寄生虫感染					
分级					
不良事件	1	2	3	4	5
定义：特征为盲肠有感染进程的病症。					
宫颈感染	-	局部的；需要局部治疗（如抗生素，抗真菌，或抗病毒药物局部用药）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为子宫颈有感染进程的病症。					
结膜感染	-	局部的；需要局部治疗（如抗生素，抗真菌，或抗病毒药物局部用药）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为结膜有感染进程的病症。临床表现包括眼睛呈粉红色或红色。					
角膜感染	-	局部的；需要局部治疗（如抗生素，抗真菌，或抗病毒药物局部用药）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为角膜有感染进程的病症。					
脑神经感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑神经有感染进程的病症。					
器械相关感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为与医疗器械使用有关的感染进程。					
十二指肠感染	-	中度症状；需要医学治疗（如口服抗生素）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为十二指肠有感染进程的病症。					
脑炎感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；精神状态严重改变；自限性癫痫发作；局部神经系统异常	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑组织有感染进程的病症。					
脑脊髓感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑和脊髓组织有感染进程的病症。					
心内膜炎感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为心内膜层有感染进程的病症。					
眼内炎	-	需要局部治疗	需要系统治疗或住院治疗	失明（20/200或更低）	-
定义：特征为眼内结构有感染进程的病症。					

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Enterocolitis infectious	-	Passage of >3 unformed stools per 24 hrs or duration of illness >48 hrs; moderate abdominal pain	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated; profuse watery diarrhea with signs of hypovolemia; bloody diarrhea; fever; severe abdominal pain; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the small and large intestines.					
Esophageal infection	-	Local intervention indicated (e.g., oral antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the esophagus.					
Eye infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated; enucleation	Death
Definition: A disorder characterized by an infectious process involving the eye.					
Gallbladder infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the gallbladder.					
Gum infection	Local therapy indicated (Swish and swallow)	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the gums.					
Hepatic infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the liver.					
Hepatitis viral	Asymptomatic, treatment not indicated	-	Symptomatic liver dysfunction; fibrosis by biopsy; compensated cirrhosis, reactivation of chronic hepatitis	Decompensated liver function (e.g., ascites, coagulopathy, encephalopathy, coma)	Death
Definition: A disorder characterized by a viral pathologic process involving the liver parenchyma.					
Infective myositis	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the skeletal muscles.					
Joint infection	-	Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, antiviral); needle aspiration indicated (single or multiple)	Arthroscopic intervention indicated (e.g., drainage) or arthrotomy (e.g., open surgical drainage)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving a joint.					
Kidney infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the kidney.					

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
小肠结肠炎	-	每 24 小时>3 次未成形粪便或病程>48 小时；中度腹痛	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射、内窥镜或手术介入治疗；极多水样腹泻伴血容量过低迹象；血样腹泻；发热；严重腹痛；需要住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为小肠和大肠有感染进程的病症。					
食管感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为食管有感染进程的病症。					
眼部感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；放射或手术介入	危及生命的后果；需要紧急介入治疗；摘出术	死亡
定义：特征为眼部有感染进程的病症。					
胆囊感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胆囊有感染进程的病症。					
牙龈感染	需要局部治疗（漱口与吞咽）	中度症状；需要医学治疗（如口服抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；放射或手术介入	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为牙龈有感染进程的病症。					
肝脏感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肝脏有感染进程的病症。					
病毒性肝炎	无症状；无需治疗	-	有症状的肝功能异常；活检有纤维化；代偿性肝硬化。恢复慢性肝炎。慢性肝炎复发	肝功能代偿失调（例如腹水、凝血紊乱、脑病、昏迷）	死亡
定义：特征为涉及肝实质的病毒性病理进程的病症。					
感染性肌炎	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为骨骼肌有感染进程的病症。					
关节感染	-	局部的；需要局部治疗；需要口服治疗（如抗生素，抗真菌，抗病毒药物）；需要（单或多次）针抽吸治疗	需要关节镜介入治疗（如引流）或关节切开术（如开放式手术引流）	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为关节有感染进程的病症。					
肾感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肾有感染进程的病症。					

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Laryngitis	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an inflammatory process involving the larynx.					
Lip infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	-	-
Definition: A disorder characterized by an infectious process involving the lips.					
Lung infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the lungs.					
Lymph gland infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the lymph nodes.					
Mediastinal infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the mediastinum.					
Meningitis	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated; focal neurologic deficit	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by acute inflammation of the meninges of the brain and/or spinal cord.					
Mucosal infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving a mucosal surface.					
Nail infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	-	-
Definition: A disorder characterized by an infectious process involving the nail.					
Otitis externa	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the outer ear and ear canal. Contributory factors include excessive water exposure (swimmer's ear infection) and cuts in the ear canal. Symptoms include fullness, itching, swelling and marked discomfort in the ear and ear drainage.					
Otitis media	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the middle ear.					
Ovarian infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the ovary.					

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
喉炎	-	中度症状；需要口服治疗（如抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为喉有炎症进程的病症。					
唇部感染	局部的；需要局部治疗	需要口服治疗（如抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	-	-
定义：特征为唇部有感染进程的病症。					
肺感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为肺有感染进程的病症。					
淋巴结感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为淋巴结有感染进程的病症。					
纵隔感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为纵隔有感染进程的病症。					
脑脊膜炎	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗；局灶性神经功能缺损	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑脊膜和/或脊髓有急性炎症的病症。					
粘膜感染	局部的；需要局部治疗	需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为粘膜表面有感染进程的病症。					
指甲感染	局部的；需要局部治疗	需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	-	-
定义：特征为指甲有感染进程的病症。					
外耳炎	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为外耳和耳道有感染进程的病症。形成因素包括过度暴露于水中（游泳致耳感染）和耳道刺伤。症状包括胀感、搔痒、肿胀和耳朵明显不适及耳朵引流。					
中耳炎	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为中耳有感染进程的病症。					
卵巢感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为卵巢有感染进程的病症。					

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Pancreas infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the pancreas.					
Papulopustular rash	Papules and/or pustules covering <10% BSA, which may or may not be associated with symptoms of pruritus or tenderness	Papules and/or pustules covering 10-30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; associated with psychosocial impact; limiting instrumental ADL	Papules and/or pustules covering >30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; limiting self-care ADL; associated with local superinfection with oral antibiotics indicated	Papules and/or pustules covering any % BSA, which may or may not be associated with symptoms of pruritus or tenderness and are associated with extensive superinfection with IV antibiotics indicated; life-threatening consequences	Death
Definition: A disorder characterized by an eruption consisting of papules (a small, raised pimple) and pustules (a small pus filled blister), typically appearing in face, scalp, and upper chest and back Unlike acne, this rash does not present with whiteheads or blackheads, and can be symptomatic, with itchy or tender lesions.					
Paronychia	Nail fold edema or erythema; disruption of the cuticle	Localized intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, antiviral); nail fold edema or erythema with pain; associated with discharge or nail plate separation; limiting instrumental ADL	Surgical intervention or IV antibiotics indicated; limiting self care ADL	-	-
Definition: A disorder characterized by an infectious process involving the soft tissues around the nail.					
Pelvic infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the pelvic cavity.					
Penile infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the penis.					
Periorbital infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the orbit of the eye.					
Peripheral nerve infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the peripheral nerves.					
Peritoneal infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the peritoneum.					
Pharyngitis	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the throat.					
Phlebitis infective	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
胰腺感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胰腺有感染进程的病症。					
丘疹脓疱性皮炎	丘疹和/或脓疱覆盖<10%体表面积，伴随或不伴随瘙痒或触痛症状	丘疹和/或脓疱覆盖10%-30%体表面积，伴随或不伴随瘙痒或触痛症状；有精神社会影响；工具性ADL受限	丘疹和/或脓疱覆盖>30%体表面积，伴随或不伴随瘙痒或触痛症状；自理ADL受限；伴随局部重复感染，需要口服抗生素治疗	丘疹和/或脓疱覆盖任何百分比的体表面积，伴随或不伴随瘙痒或触痛症状；伴随广泛重复感染，需要静脉给予抗生素治疗；危及生命的后果	死亡
定义：病症特征为包含（小的凸出的）丘疹和脓包（小的，浓汁充满的水疱）的皮疹，典型出现在面部，头皮，及上胸和背部，与痤疮不同，该皮疹不呈现白头或黑头，但有搔痒或触痛病灶的症状。					
甲沟炎	甲褶水肿或红斑；破坏角质层	需要局部治疗；需要口服治疗（如抗生素，抗真菌，抗病毒药物）；甲褶水肿或红斑伴疼痛；伴随流脓或指甲脱离；工具性ADL受限	需要外科或抗生素输液治疗；自理ADL受限	-	-
定义：特征为指甲周围软组织有感染进程的病症。					
骨盆感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为骨盆腔有感染进程的病症。					
阴茎感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为阴茎有感染进程的病症。					
眼眶周围感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为眼眶有感染进程的病症。					
外周神经感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为外周神经有感染进程的病症。					
腹膜感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为腹膜有感染进程的病症。					
咽炎	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为咽喉发炎的病症。					
静脉炎感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by an infectious process involving the vein. Clinical manifestations include erythema, marked discomfort, swelling, and induration along the course of the infected vein.					
Pleural infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the pleura.					
Prostate infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the prostate gland.					
Rash pustular	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	-	-
Definition: A disorder characterized by a circumscribed and elevated skin lesion filled with pus.					
Rhinitis infective	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	-	-	-
Definition: A disorder characterized by an infectious process involving the nasal mucosal.					
Salivary gland infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the salivary gland.					
Scrotal infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the scrotum.					
Sepsis	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the presence of pathogenic microorganisms in the blood stream that cause a rapidly progressing systemic reaction that may lead to shock.					
Sinusitis	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the mucous membranes of the paranasal sinuses.					
Skin infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the skin.					
Small intestine infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the small intestine.					
Soft tissue infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving soft tissues.					
Splenic infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
定义：特征为静脉有感染进程的病症。临床表现包括红斑、明显不适、肿胀，沿着受感染的静脉有硬结。					
胸膜感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为胸膜有感染进程的病症。					
前列腺感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为前列腺有感染进程的病症。					
皮疹脓疱	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	-	-
定义：病症特征为局部有隆起的充满脓液的皮损。					
鼻炎感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	-	-	-
定义：特征为鼻粘膜有感染进程的病症。					
唾液腺感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为唾液腺有感染进程的病症。					
阴囊感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为阴囊有感染进程的病症。					
败血病	-	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为血流中存在病原微生物导致迅速进展性全身反应，可能引起休克。					
鼻窦炎	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为鼻窦的粘膜有感染进程的病症。					
皮肤感染	局部的，需要局部治疗	需要口服给药治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为皮肤有感染进程的病症。					
小肠感染	-	中度症状；需要口服给药治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为小肠有感染进程的病症					
软组织感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为软组织有感染进程的病症。					
脾感染	-	-	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡

Infections and infestations					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by an infectious process involving the spleen.					
Stoma site infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving a stoma (surgically created opening on the surface of the body).					
Tooth infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving a tooth.					
Tracheitis	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the trachea.					
Upper respiratory infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the upper respiratory tract (nose, paranasal sinuses, pharynx, larynx, or trachea).					
Urethral infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the urethra.					
Urinary tract infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the urinary tract, most commonly the bladder and the urethra.					
Uterine infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the endometrium. It may extend to the myometrium and parametrial tissues.					
Vaginal infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the vagina.					
Vulval infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the vulva.					
Wound infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an infectious process involving the wound.					
Infections and infestations - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

感染和寄生虫感染					
不良事件	分级				
	1	2	3	4	5
定义：特征为脾有感染进程的病症。					
吻合口部位感染	局部的，需要局部治疗	需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为吻合口（外科手术在体表的开口）有感染进程的病症。					
牙齿感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为牙齿有感染进程的病症。					
气管炎	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为气管有感染进程的病症。					
上呼吸道感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为上呼吸道有感染进程的病症。（鼻、鼻窦、咽、喉或气管）					
尿道感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射，内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为尿道有感染进程的病症。					
泌尿道感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为泌尿道有感染进程的病症，最常发生于膀胱和尿道。					
子宫感染	-	中度症状；需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为子宫内膜有感染进程的病症。会扩展到子宫肌层和子宫旁组织。					
阴道感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为阴道有感染进程的病症。					
外阴感染	局部的，需要局部治疗	需要口服治疗（如抗生素，抗真菌，抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为外阴有感染进程的病症。					
伤口感染	-	局部的；需要局部治疗（如局部用抗生素，抗真菌，或抗病毒药物）	需要抗生素，抗真菌，或抗病毒药物输液治疗；需要放射或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为伤口有感染进程的病症					
感染和寄生虫感染-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适应的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Ankle fracture	Mild; non-surgical intervention indicated	Limiting instrumental ADL; operative intervention indicated	Limiting self care ADL; elective surgery indicated	-	-
Definition: A finding of damage to the ankle joint characterized by a break in the continuity of the ankle bone. Symptoms include marked discomfort, swelling and difficulty moving the affected leg and foot.					
Aortic injury	-	-	Severe symptoms; limiting self care ADL; disabling; repair or revision indicated	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A finding of damage to the aorta.					
Arterial injury	Asymptomatic diagnostic finding; intervention not indicated	Symptomatic (e.g., claudication); repair or revision not indicated	Severe symptoms; limiting self care ADL; disabling; repair or revision indicated	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A finding of damage to an artery.					
Biliary anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage of bile due to breakdown of a biliary anastomosis (surgical connection of two separate anatomic structures).					
Bladder anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage of urine due to breakdown of a bladder anastomosis (surgical connection of two separate anatomic structures).					
Bruising	Localized or in a dependent area	Generalized	-	-	-
Definition: A finding of injury of the soft tissues or bone characterized by leakage of blood into surrounding tissues.					
Burn	Minimal symptoms; intervention not indicated	Medical intervention; minimal debridement indicated	Moderate to major debridement or reconstruction indicated	Life-threatening consequences	Death
Definition: A finding of impaired integrity to the anatomic site of an adverse thermal reaction. Burns can be caused by exposure to chemicals, direct heat, electricity, flames and radiation. The extent of damage depends on the length and intensity of exposure and time until provision of treatment.					
Dermatitis radiation	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Definition: A finding of cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation.					
Esophageal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of an esophageal anastomosis (surgical connection of two separate anatomic structures).					
Fall	Minor with no resultant injuries; intervention not indicated	Symptomatic; noninvasive intervention indicated	Hospitalization indicated	-	-
Definition: A finding of sudden movement downward, usually resulting in injury.					
Fallopian tube anastomotic leak	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a fallopian tube anastomosis (surgical connection of two separate anatomic structures).					
Fallopian tube perforation	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated (e.g., organ resection)	Death
Definition: A finding of rupture of the fallopian tube wall.					
Fracture	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic but non-displaced; immobilization indicated	Severe symptoms; displaced or open wound with bone exposure; disabling; operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of traumatic injury to the bone in which the continuity of the bone is broken.					

损伤、中毒和医疗操作并发症					
不良事件	分级				
	1	2	3	4	5
踝关节骨折	轻度；无需外科治疗	工具性 ADL 受限；需要手术治疗	自理 ADL 受限；需要选择性外科手术治疗	-	-
定义：发现踝骨的连续性被破坏的踝关节受损，症状包括明显不适、肿胀与受影响的脚足移动困难。					
主动脉损伤	-	-	严重症状；自理 ADL 受限；致残；需要恢复或修正治疗	危及生命的后果；有终末器官损害的证据；需要紧急手术介入治疗	死亡
定义：发现大动脉损伤。					
动脉损伤	无症状，仅有诊断学观察结果；无需介入治疗	有症状（如跛行）；无需复原或修正治疗	严重症状；自理 ADL 受限；致残；需要复原或修正治疗	危及生命的后果；有终末器官损害的证据；需要紧急手术介入治疗	死亡
定义：发现动脉损伤。					
胆道吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于胆道吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的胆汁渗漏。					
膀胱吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于膀胱吻合（以外科手术连接两个分离的解剖学结构）断裂引起的尿液渗漏。					
擦伤	局部或相关区域	全身性	-	-	-
定义：发现特征为血液渗漏到外周组织的软组织或骨损伤。					
烧伤	最低程度的症状；无需介入治疗	需要医学治疗；最低程度的清创术	需要中度或大面积清创术或再造治疗	危及生命的后果	死亡
定义：发现解剖部位发生的不利热反应造成完整性的损伤。烧伤可由暴露于化学物质、直接高热、电、火焰与辐射引起。损害程度取决于暴露的时长和强度，及直到接受治疗所需时间。					
放射性皮炎	轻微红斑或干燥脱皮	中度至严重红斑；片状湿性脱皮，大多局限于皮肤褶皱和折痕；中度水肿	皮肤褶皱和折痕之外也有湿性脱皮；有轻微的外伤或擦伤引起出血	危及生命的后果；完整厚度的真皮皮肤坏死或溃疡；涉及位点自发性出血；皮肤移植	死亡
定义：发现由于暴露于生物学有效水平的电离辐射下导致的皮肤炎症反应。					
食管吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于食管吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
跌倒	微小没有产生连带的损伤；无需介入治疗	有症状；需要非侵入性治疗	需要住院治疗	-	-
定义：发现突然向下移动，通常导致损伤。					
输卵管吻合口渗漏	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于输卵管吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
输卵管穿孔	无症状，仅有诊断学观察结果；无需介入治疗	有症状，无需介入治疗	严重症状；需要选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗（如器官切除术）	死亡
定义：发现输卵管管壁破裂。					
骨折	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状但无骨移位；需要固定	严重症状；骨移位或伤口开放骨暴露；致残；需要手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现骨连续性被破坏，有创伤性损伤。					

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Gastric anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a gastric anastomosis (surgical connection of two separate anatomic structures).					
Gastrointestinal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a gastrointestinal anastomosis (surgical connection of two separate anatomic structures).					
Gastrointestinal stoma necrosis	-	Superficial necrosis; intervention not indicated	Severe symptoms; hospitalization or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of a necrotic process occurring in the gastrointestinal tract stoma.					
Hip fracture	-	Hairline fracture; mild pain; limiting instrumental ADL; non-surgical intervention indicated	Severe pain; hospitalization or intervention indicated for pain control (e.g., traction); operative intervention indicated	Life-threatening consequences; symptoms associated with neurovascular compromise	
Definition: A finding of traumatic injury to the hip in which the continuity of either the femoral head, femoral neck, intertrochanteric or subtrochanteric regions is broken.					
Injury to carotid artery	-	-	Severe symptoms; limiting self care ADL (e.g., transient cerebral ischemia); repair or revision indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the carotid artery.					
Injury to inferior vena cava	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the inferior vena cava.					
Injury to jugular vein	-	-	Symptomatic limiting self care ADL; disabling; repair or revision indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the jugular vein.					
Injury to superior vena cava	Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; repair or revision not indicated	Severe symptoms; limiting self care ADL; disabling; repair or revision indicated	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A finding of damage to the superior vena cava.					
Intestinal stoma leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage of contents from an intestinal stoma (surgically created opening on the surface of the body).					
Intestinal stoma obstruction	-	Self-limited; intervention not indicated	Severe symptoms; IV fluids, tube feeding, or TPN indicated >=24 hrs; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of blockage of the normal flow of the contents of the intestinal stoma.					
Intestinal stoma site bleeding	Minimal bleeding identified on clinical exam; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of blood leakage from the intestinal stoma.					
Intraoperative arterial injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to an artery during a surgical procedure.					
Intraoperative breast injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death

损伤、中毒和医疗操作并发症					
不良事件	分级				
	1	2	3	4	5
胃吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于胃吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
胃肠吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于胃肠吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
胃肠道口坏死	-	浅表性坏死；无需介入治疗	严重症状；需要住院或选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现胃肠道口有坏死进程。					
髌骨骨折	-	骨裂；轻度疼痛；工具性 ADL 受限；无需外科治疗	严重疼痛；需要住院或控制疼痛（如牵引）；需要手术介入治疗	危及生命的后果；伴随神经血管危害症状	
定义：发现髌骨的外伤性损害，股骨头、股骨颈、股骨间或股骨转子下区域之中任一连续性被破坏。					
颈动脉损伤	-	-	严重症状；自理 ADL 受限（如短暂性脑缺血）；需要复原或修正治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现颈动脉有损伤。					
下腔静脉损伤	-	-	-	危及生命的后果；需要紧急介入治疗	死亡
定义：发现下腔静脉有损伤。					
颈静脉损伤	-	-	有症状，自理 ADL 受限；致残；需要复原或修正治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现颈静脉有损伤。					
上腔静脉损伤	无症状，仅有诊断学观察结果；无需介入治疗	有症状；无需复原或修正治疗	严重症状；自理 ADL 受限；致残；需要修复治疗	危及生命的后果；有终末器官损伤证据；需要紧急手术介入治疗	死亡
定义：发现上腔静脉有损伤					
肠口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现内容物从肠口（外科手术在体表的开口）渗漏。					
肠口梗阻	-	自限性；无需介入治疗	严重症状；需要静脉输液，管饲饮食，或全胃肠外营养治疗 >=24 小时；需要选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现肠口正常流量的内容物受阻。					
肠吻合口处出血	临床检查发现最低程度的出血；无需介入治疗	中度出血；需要医学治疗	严重出血；需要输血；需要放射或内窥镜治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现肠吻合口处出血渗漏。					
术中动脉损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中引起动脉损伤					
术中乳房损伤	需要一期修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构	危及生命的后果；需要紧急介入治疗	死亡

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A finding of damage to the breast parenchyma during a surgical procedure.					
Intraoperative cardiac injury	-	-	Primary repair of injured organ/structure indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the heart during a surgical procedure.					
Intraoperative ear injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection of injured organ/structure indicated; disabling (e.g., impaired hearing; impaired balance)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the ear during a surgical procedure.					
Intraoperative endocrine injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the endocrine gland during a surgical procedure.					
Intraoperative gastrointestinal injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the gastrointestinal system during a surgical procedure.					
Intraoperative head and neck injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the head and neck during a surgical procedure.					
Intraoperative hemorrhage	-	-	Postoperative radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of uncontrolled bleeding during a surgical procedure.					
Intraoperative hepatobiliary injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the hepatic parenchyma and/or biliary tract during a surgical procedure.					
Intraoperative musculoskeletal injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the musculoskeletal system during a surgical procedure.					
Intraoperative neurological injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the nervous system during a surgical procedure.					
Intraoperative ocular injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the eye during a surgical procedure.					
Intraoperative renal injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the kidney during a surgical procedure.					
Intraoperative reproductive tract injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death

损伤、中毒和医疗操作并发症					
分级					
不良事件	1	2	3	4	5
定义：发现手术操作中乳房实质受损。					
术中心脏损伤	-	-	需要初步修复受损器官/结构	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中心脏受损。					
术中耳损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残（如听力受损；平衡感受损）	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中耳受损。					
术中内分泌损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中内分泌腺受损。					
术中胃肠损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中胃肠系统受损。					
术中头和颈损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中头和颈受损。					
术中出血	-	-	需要术后放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中无法控制的出血。					
术中肝胆管损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中肝实质和/或胆道受损。					
术中肌肉与骨骼损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中肌与骨骼系统受损。					
术中神经损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中神经系统受损。					
术中眼损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中眼受损。					
术中肾脏损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中肾脏受损。					
术中生殖道损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A finding of damage to the reproductive organs during a surgical procedure.					
Intraoperative respiratory injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the respiratory system during a surgical procedure.					
Intraoperative skin injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the skin during a surgical procedure.					
Intraoperative splenic injury	-	Primary repair of injured organ/structure indicated	Resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the spleen during a surgical procedure.					
Intraoperative urinary injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to the urinary system during a surgical procedure.					
Intraoperative venous injury	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of damage to a vein during a surgical procedure.					
Kidney anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage of urine due to breakdown of a kidney anastomosis (surgical connection of two separate anatomic structures).					
Large intestinal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of an anastomosis (surgical connection of two separate anatomic structures) in the large intestine.					
Pancreatic anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a pancreatic anastomosis (surgical connection of two separate anatomic structures).					
Pharyngeal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a pharyngeal anastomosis (surgical connection of two separate anatomic structures).					
Postoperative hemorrhage	Minimal bleeding identified on clinical exam; intervention not indicated	Moderate bleeding; radiologic, endoscopic, or operative intervention indicated	Transfusion indicated of ≥ 2 units (10 cc/kg for pediatrics) pRBCs beyond protocol specification; urgent radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of bleeding occurring after a surgical procedure.					
Postoperative thoracic procedure complication	-	Extubated within 24 - 72 hrs postoperatively	Extubated >72 hrs postoperatively, but before tracheostomy indicated	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A finding of a previously undocumented problem that occurs after a thoracic procedure.					
Prolapse of intestinal stoma	Asymptomatic; reducible	Recurrent after manual reduction; local irritation or stool leakage; difficulty to fit appliance; limiting instrumental ADL	Severe symptoms; elective operative intervention indicated; limiting self care ADL	Life-threatening consequences; urgent operative intervention indicated	Death

损伤、中毒和医疗操作并发症					
分级					
不良事件	1	2	3	4	5
定义：发现手术操作中生殖器官受损。					
术中呼吸系统损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中呼吸道系统受损。					
术中皮肤损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中皮肤受损。					
术中脾脏损伤	-	需要初步修复受损器官/结构	需要切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中脾脏受损。					
术中泌尿系统损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中泌尿系统受损。					
术中静脉损伤	需要初步修复受损器官/结构	需要部分切除受损器官/结构	需要完全切除或再造受损器官/结构；致残	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作中静脉受损。					
肾脏吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于肾脏吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
大肠吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于大肠吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
胰腺吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于胰腺吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
咽吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射，内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于咽吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
术后出血	临床检查发现最低程度的出血；无需介入治疗	中度出血；需要放射、内窥镜或手术介入治疗	除方案规定外，需要输注 ≥ 2 个单位的非自体浓缩红细胞（儿科患者为 10cc/kg ）；需要紧急放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现手术操作后出现出血。					
手术操作后胸部并发症	-	术后24-72小时内拔管	术后 >72 小时拔管，但之前需要做气管造口术	危及生命的气道损伤；需要紧急介入治疗（如气管切开术或气管插管）	死亡
定义：发现发生在胸部手术后先有无书面记录的问题。					
肠口下垂	无症状；可复位	手动复位后复发；局部刺激或粪便渗漏；难以适应器具；工具性ADL受限	严重症状；需要选择性手术治疗；自理ADL受限	危及生命的后果；需要紧急手术介入治疗	死亡

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A finding of protrusion of the intestinal stoma (surgically created opening on the surface of the body) above the abdominal surface.					
Prolapse of urostomy	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Local care or maintenance; minor revision indicated	Dysfunctional stoma; elective operative intervention or major stomal revision indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of displacement of the urostomy.					
Radiation recall reaction (dermatologic)	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Definition: A finding of acute skin inflammatory reaction caused by drugs, especially chemotherapeutic agents, for weeks or months following radiotherapy. The inflammatory reaction is confined to the previously irradiated skin and the symptoms disappear after the removal of the pharmaceutical agent.					
Rectal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a rectal anastomosis (surgical connection of two separate anatomic structures).					
Seroma	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; simple aspiration indicated	Symptomatic, elective radiologic or operative intervention indicated	-	-
Definition: A finding of tumor-like collection of serum in the tissues.					
Small intestinal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of an anastomosis (surgical connection of two separate anatomic structures) in the small bowel.					
Spermatic cord anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a spermatic cord anastomosis (surgical connection of two separate anatomic structures).					
Spinal fracture	Mild back pain; non-prescription analgesics indicated	Moderate back pain; prescription analgesics indicated; limiting instrumental ADL	Severe back pain; hospitalization or intervention indicated for pain control (e.g., vertebroplasty); limiting self care ADL; disability	Life-threatening consequences; symptoms associated with neurovascular compromise	Death
Definition: A finding of traumatic injury to the spine in which the continuity of a vertebral bone is broken.					
Stenosis of gastrointestinal stoma	-	Symptomatic; IV fluids indicated <24 hrs; manual dilatation at bedside	Severely altered GI function; tube feeding, TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of narrowing of the gastrointestinal stoma (surgically created opening on the surface of the body).					
Stomal ulcer	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by a circumscribed, inflammatory and necrotic erosive lesion on the jejunal mucosal surface close to the anastomosis site following a gastroenterostomy procedure.					
Tracheal hemorrhage	Minimal bleeding identified on clinical or diagnostic exam; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of bleeding from the trachea.					
Tracheal obstruction	Partial asymptomatic obstruction on examination (e.g., visual, radiologic or endoscopic)	Symptomatic (e.g., noisy airway breathing), no respiratory distress; medical intervention indicated (e.g., steroids); limiting instrumental ADL	Stridor; radiologic or endoscopic intervention indicated (e.g., stent, laser); limiting self care ADL	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A finding of blockage of the lumen of the trachea.					

损伤、中毒和医疗操作并发症					
分级					
不良事件	1	2	3	4	5
定义：发现腹部表面上方的肠吻合口（外科手术时在体表的开口）突出。					
尿道口下垂	无症状；仅有临床或诊断学观察结果；无需介入治疗	局部护理或维护；需要少许修正	吻合口功能性失调；需要选择性手术或大的吻合修复治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现尿道口移位。					
放射恢复反应（皮肤病学）	微弱的红斑或干脱皮	中度至严重红斑；片状湿性脱皮，大多仅限于皮肤褶皱和折痕；中度水肿	皮肤褶皱和折痕外的区域也有湿性脱皮；由轻微的外伤或擦伤引起出血	危及生命的后果；完整厚度的皮肤坏死或溃疡；牵涉位点自发性出血；需要皮肤移植	死亡
定义：发现由药物引起，尤其是放疗几周或几个月后的化疗用药造成的急性皮肤炎症反应。炎症反应限于之前受过照射的皮肤，症状在药物停用后消失。					
直肠吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于直肠吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
血清肿	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要简单抽吸治疗	有症状，需要选择性放射或手术治疗	-	-
定义：发现组织中有肿瘤的血清聚积。					
小肠吻合口渗漏	无症状，仅有诊断学观察结果；无需治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于小肠吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
精索吻合口渗漏	无症状，仅有诊断学观察结果；无需治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于精索吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
脊柱骨折	轻度背痛；需要非处方镇痛药治疗	中度背痛；需要处方镇痛药治疗；工具性ADL受限	严重背痛；需要住院或镇痛治疗（如椎体成形术）；自理ADL受限；致残	危及生命的后果；伴随神经血管危害症状	死亡
定义：发现脊椎外伤性损伤，椎骨的连续性被打破。					
胃肠道狭窄	-	有症状；需要<24小时输液治疗；床边手动扩张术	严重改变GI功能；需要管饲饮食，全胃肠外营养或住院治疗；需要选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现胃肠道（外科手术在体表的开口）变窄。					
吻合口溃疡	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要选择性手术介入治疗	-	-
定义：病症特征为胃肠造口吻合术操作后，在空肠粘膜表面靠近接合位点处有局限的炎性和坏死糜烂性病灶。					
气管出血	通过临床或诊断检查到最低程度的出血；无需介入治疗	中度出血；需要介入治疗	严重出血；需要输血；需要放射或内窥镜介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现气管出现出血。					
气管梗阻	经检查（如目测、放射学或内窥镜）发现部分无症状性梗阻	有症状（如气道呼吸有杂音），无呼吸疼痛；需要医学治疗（如类固醇）；工具性ADL受限了；	喘鸣；需要放射或内窥镜介入治疗（如移植片支架，激光）自理ADL受限	危及生命的气道损伤；需要紧急介入治疗（如气管切开术或气管插管）	死亡
定义：发现气管内腔发生阻塞。					

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Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Tracheostomy site bleeding	Minimal bleeding identified on clinical exam; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of blood leakage from the tracheostomy site.					
Ureteric anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a ureteral anastomosis (surgical connection of two separate anatomic structures).					
Urethral anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a urethral anastomosis (surgical connection of two separate anatomic structures).					
Urostomy leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage of contents from a urostomy.					
Urostomy obstruction	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; dilation or endoscopic repair or stent placement indicated	Altered organ function (e.g., sepsis or hydronephrosis, or renal dysfunction); elective operative intervention indicated	Life-threatening consequences; organ failure; urgent operative intervention indicated	Death
Definition: A finding of blockage of the urostomy.					
Urostomy site bleeding	Minimal bleeding identified on clinical exam; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A finding of bleeding from the urostomy site.					
Urostomy stenosis	-	Symptomatic but no hydronephrosis, no sepsis or no renal dysfunction; dilation or endoscopic repair or stent placement indicated	Symptomatic (e.g., hydronephrosis, or renal dysfunction); elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of narrowing of the opening of a urostomy.					
Uterine anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a uterine anastomosis (surgical connection of two separate anatomic structures).					
Uterine perforation	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a rupture in the uterine wall.					
Vaginal anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a vaginal anastomosis (surgical connection of two separate anatomic structures).					
Vas deferens anastomotic leak	Asymptomatic diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A finding of leakage due to breakdown of a vas deferens anastomosis (surgical connection of two separate anatomic structures).					
Vascular access complication	-	Device dislodgement, blockage, leak, or malposition; device replacement indicated	Deep vein or cardiac thrombosis; intervention indicated (e.g., anticoagulation, lysis, filter, invasive procedure)	Embolic event including pulmonary embolism or life-threatening thrombus	Death
Definition: A finding of a previously undocumented problem related to the vascular access site.					

损伤、中毒和医疗操作并发症					
不良事件	分级				
	1	2	3	4	5
气管造口术位点出血	临床检查有最低程度的出血；无需介入治疗	中度出血；需要医学治疗	严重出血；需要输血；需要放射或内窥镜介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现气管造口术位点有血液渗漏。					
输尿管吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于输尿管吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
尿道吻合口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于尿道吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
尿道口渗漏	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现尿道口内容物渗漏。					
尿道口梗阻	无症状；仅有诊断学观察结果；无需介入治疗	有症状；需要扩张术或内镜修补或安置支架	器官功能改变（如败血症或肾积水，或肾功能不全）；需要选择性手术介入	危及生命的后果；器官衰竭；需要紧急手术介入治疗	死亡
定义：发现尿道口阻塞。					
尿道口位点出血	通过临床检查发现最低程度的出血；无需介入治疗	中度出血；需要医学治疗	严重出血；需要输血；需要放射或内窥镜介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现尿道口位点出血。					
尿道口狭窄	-	有症状但无肾积水，没有败血症或肾功能不全；需要扩张术或内镜修补或安置支架	有症状（如肾盂积水，或肾功能不全）；需要选择性手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：发现尿道开口变窄。					
子宫吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于子宫吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
子宫穿孔	无症状，仅有诊断学观察结果；无需介入治疗	有症状，无需医学治疗	严重症状；需要选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为子宫壁破裂的病症。					
阴道吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现阴道吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
输精管吻合口渗漏	无症状，仅有诊断学观察结果；无需介入治疗	有症状；需要医学治疗	严重症状；需要放射、内窥镜或选择性手术介入治疗	危及生命的后果；需要紧急手术介入治疗	死亡
定义：发现源于输精管吻合口（以外科手术连接两个分离的解剖学结构）断裂引起的渗漏。					
血管通路并发症	-	装置移出、阻塞、渗漏或错位；需要更换装置	深静脉或心脏血栓形成；需要治疗（如抗凝、溶解、过滤、侵袭性操作	栓塞事件包括肺栓塞或危及生命的血栓	死亡
定义：发现与血管通路位点有关的之前未有记录的问题。					

Injury, poisoning and procedural complications					
Adverse Event	Grade				
	1	2	3	4	5
Venous injury	Asymptomatic diagnostic finding; intervention not indicated	Symptomatic (e.g., claudication); repair or revision not indicated	Severe symptoms; limiting self care ADL; repair or revision indicated; disabling	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A finding of damage to a vein.					
Wound complication	Incisional separation of <=25% of wound, no deeper than superficial fascia	Incisional separation >25% of wound; local care indicated	Hernia without evidence of strangulation; fascial disruption/dehiscence; primary wound closure or revision by operative intervention indicated	Hernia with evidence of strangulation; major reconstruction flap, grafting, resection, or amputation indicated	Death
Definition: A finding of development of a new problem at the site of an existing wound.					
Wound dehiscence	Incisional separation of <=25% of wound, no deeper than superficial fascia	Incisional separation >25% of wound with local care; asymptomatic hernia or symptomatic hernia without evidence of strangulation	Fascial disruption or dehiscence without evisceration; primary wound closure or revision by operative intervention indicated	Life-threatening consequences; symptomatic hernia with evidence of strangulation; fascial disruption with evisceration; major reconstruction flap, grafting, resection, or amputation indicated	Death
Definition: A finding of separation of the approximated margins of a surgical wound.					
Wrist fracture	Mild; non-surgical intervention indicated	Limiting instrumental ADL; operative intervention indicated	Limiting self care ADL; elective surgery indicated	-	-
Definition: A finding of traumatic injury to the wrist joint in which the continuity of a wrist bone is broken.					
Injury, poisoning and procedural complications - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

损伤、中毒和医疗操作并发症					
分级					
不良事件	1	2	3	4	5
静脉损伤	无症状，仅有诊断学发现；无需介入治疗	有症状（如跛行）；无需复原或修正治疗	严重症状；自理 ADL 受限；需要复原或修正治疗；致残	危及生命的后果；终末器官损伤证据；需要紧急手术介入治疗	死亡
定义：发现静脉有损伤。					
伤口并发症	伤口的切口分离≤25%，深度没有超过浅筋膜	伤口的切口分离>25%；需要局部护理	疝气没有梗塞证据；筋膜破裂/裂开；需要手术闭合或修正主要伤口	疝气有梗塞证据；需要大的皮瓣重建、移植、切除术或截肢	死亡
定义：发现已有伤口位点有新问题发生。					
伤口开裂	伤口的切口分离≤25%，深度没有超过浅筋膜	伤口的切口分离>25%；需要局部护理；无症状疝气或有症状疝气不伴梗塞证据	筋膜破裂/裂开不伴切口处凸出；需要手术闭合或修复主要伤口	危及生命的后果；有症状疝气伴随梗塞证据；筋膜破裂/裂开不伴切口处凸出；需要大的皮瓣重建、移植、切除术或截肢	死亡
定义：发现外科伤口邻近的边缘出现分离。					
腕骨骨折	轻度；需要非外科介入治疗	工具性 ADL 受限；需要手术治疗	自理 ADL 受限；需要选择性手术治疗	-	-
定义：发现腕关节有外伤性损伤，腕骨的连续性被打破。					
损伤、中毒和医疗操作并发症-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡

Investigations					
Adverse Event	Grade				
	1	2	3	4	5
Activated partial thromboplastin time prolonged	>1 - 1.5 x ULN	>1.5 - 2.5 X ULN	> 2.5 x ULN; hemorrhage	-	-
Definition: An abnormal laboratory test result in which the partial thromboplastin time is found to be greater than the control value. As a possible indicator of coagulopathy, a prolonged partial thromboplastin time (PTT) may occur in a variety of diseases and disorders, both primary and related to treatment.					
Alanine aminotransferase increased	>ULN - 3.0 x ULN	Asymptomatic with ALT >3.0 - 5.0 x ULN; >3 x ULN with the appearance of worsening of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, or eosinophilia	>5.0 - 20.0 x ULN; >5 x ULN for >2 weeks	>20.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in the level of alanine aminotransferase (ALT or SGPT) in the blood specimen.					
Alkaline phosphatase increased	>ULN - 2.5 x ULN	>2.5 - 5.0 x ULN	>5.0 - 20.0 x ULN	>20.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in the level of alkaline phosphatase in a blood specimen.					
Aspartate aminotransferase increased	>ULN - 3.0 x ULN	Asymptomatic with AST >3.0 - 5.0 x ULN; >3 x ULN with the appearance of worsening of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, or eosinophilia	>5.0 - 20.0 x ULN; >5 x ULN for >2 weeks	>20.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in the level of aspartate aminotransferase (AST or SGOT) in a blood specimen.					
Blood antidiuretic hormone abnormal	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Hospitalization indicated	-	-
Definition: A finding based on laboratory test results that indicate abnormal levels of antidiuretic hormone in the blood specimen.					
Blood bilirubin increased	>ULN - 1.5 x ULN	>1.5 - 3.0 x ULN	>3.0 - 10.0 x ULN	>10.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an abnormally high level of bilirubin in the blood. Excess bilirubin is associated with jaundice.					
Blood corticotrophin decreased	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Hospitalization indicated	-	-
Definition: A finding based on laboratory test results that indicate a decrease in levels of corticotrophin in a blood specimen.					
Blood gonadotrophin abnormal	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A finding based on laboratory test results that indicate abnormal levels of gonadotrophin hormone in a blood specimen.					
Blood prolactin abnormal	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	-	-	-
Definition: A finding based on laboratory test results that indicate abnormal levels of prolactin hormone in a blood specimen.					
Carbon monoxide diffusing capacity decreased	3 - 5 units below LLN; for follow-up, a decrease of 3 - 5 units (ml/sec/mm Hg) below the baseline value	6 - 8 units below LLN; for follow-up, an asymptomatic decrease of >5 - 8 units (ml/sec/mm Hg) below the baseline value	Asymptomatic decrease of >8 units drop; >5 units drop along with the presence of pulmonary symptoms (e.g., >Grade 2 hypoxia or >Grade 2 or higher dyspnea)	-	-
Definition: A finding based on lung function test results that indicate a decrease in the lung capacity to absorb carbon monoxide.					
Cardiac troponin I increased	Levels above the upper limit of normal and below the level of myocardial infarction as defined by the manufacturer	-	Levels consistent with myocardial infarction as defined by the manufacturer	-	-
Definition: A laboratory test result which indicates increased levels of cardiac troponin I in a biological specimen.					
Cardiac troponin T increased	Levels above the upper limit of normal and below the level of myocardial infarction as defined by the manufacturer	-	Levels consistent with myocardial infarction as defined by the manufacturer	-	-
Definition: A laboratory test result which indicates increased levels of cardiac troponin T in a biological specimen.					

检测					
不良事件	分级				
	1	2	3	4	5
活化部分凝血活酶时间延长 定义：实验室检测结果异常，部分凝血酶原时间比对照值长。作为可能的凝血障碍指标，延长的部分凝血活酶时间（PPT）可出现于多种疾病和病症，包括原发和与治疗相关。	>1-1.5 × ULN	>1.5-2.5 × ULN	>2.5 × ULN；出血	-	-
丙氨酸氨基转移酶升高 定义：发现基于实验室检测结果，表明血液样本中的丙氨酸氨基转移酶（ALT 或 SGPT）水平升高。	>ULN-3.0 × ULN	无症状，ALT>3.0-5.0 × ULN； >3 × ULN 且出现疲劳加重、恶心、呕吐、右上四分之一处疼痛或触痛、发热、皮疹或嗜曙红细胞过多	>5.0 - 20.0 × ULN； >5 × ULN 持续>2 周	>20.0 × ULN	-
碱性磷酸酶升高 定义：发现基于实验室检测结果，表明血液样本中的碱性磷酸酶水平升高。	>ULN - 2.5 × ULN	>2.5 - 5.0 × ULN	>5.0 - 20.0 × ULN	>20.0 × ULN	-
天冬氨酸氨基转移酶升高 定义：发现基于实验室检测结果，表明血液样本中的天冬氨酸转氨酶（AST 或 SGOT）水平升高。	>ULN-3.0 × ULN	无症状，ALT>3.0-5.0 × ULN； >3 × ULN 出现疲劳加重、恶心、呕吐、右上四分之一处疼痛或触痛、发热、皮疹或嗜曙红细胞过多	>5.0 - 20.0 × ULN； >5 × ULN 持续 >2 周	>20.0 × ULN	死亡
血管加压素异常 定义：发现基于实验室检测结果，表明血液样本中的血管加压素水平异常。	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗	需要住院治疗	-	-
血红素升高 定义：发现基于实验室检测结果，表明血液中胆红素水平异常高。过量胆红素会引发黄疸。	>ULN - 1.5 × ULN	>1.5 - 3.0 × ULN	>3.0 - 10.0 × ULN	>10.0 × ULN	-
促肾上腺皮质激素降低 定义：发现基于实验室检测结果，表明血液样本中的促肾上腺皮质激素水平降低。	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗	需要住院治疗	-	-
促性腺激素异常 定义：发现基于实验室检测结果，表明血液样本中的促性腺激素水平异常。	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；需要医学治疗；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
催乳素异常 定义：发现基于实验室检测结果，表明血液样本中的催乳素水平异常。	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	-	-	-
一氧化碳扩散量下降 定义：发现基于实验室检测结果，表明吸收一氧化碳的肺容量降低。	低于 LLN 3-5 个单位；随访发现在基线值下降低 3-5 单位（ml/sec/mm Hg）	低于 LLN6-8 单位；随访发现无症状，在基线值下降低>5-8 单位（ml/sec/mm Hg）	无症状，降低>8 单位；>5 单位降低伴随肺部症状（如>2 级缺氧或>2 级及更高的呼吸困难）	-	-
心肌肌钙蛋白 I 升高 定义：实验室检查结果表明生物样本中心肌肌钙蛋白 I 水平升高。	根据厂商的定义，水平高于正常上限低于心肌梗死时的水平	-	根据厂商的定义，水平与心肌梗死时一致	-	-
心肌肌钙蛋白 T 升高 定义：实验室检查结果表明生物样本中心肌肌钙蛋白 T 水平升高。	根据厂商的定义，水平高于正常上限低于心肌梗死时的水平	-	根据厂商的定义，水平与心肌梗死时一致	-	-

CTCAE v4.0

Investigations					
Adverse Event	Grade				
	1	2	3	4	5
CD4 lymphocytes decreased	<LLN - 500/mm ³ ; <LLN - 0.5 x 10e9 /L	<500 - 200/mm ³ ; <0.5 - 0.2 x 10e9 /L	<200 - 50/mm ³ ; <0.2 x 0.05 - 10e9 /L	<50/mm ³ ; <0.05 x 10e9 /L	-
Definition: A finding based on laboratory test results that indicate a decrease in levels of CD4 lymphocytes in a blood specimen.					
Cholesterol high	>ULN - 300 mg/dL; >ULN - 7.75 mmol/L	>300 - 400 mg/dL; >7.75 - 10.34 mmol/L	>400 - 500 mg/dL; >10.34 - 12.92 mmol/L	>500 mg/dL; >12.92 mmol/L	-
Definition: A finding based on laboratory test results that indicate higher than normal levels of cholesterol in a blood specimen.					
CPK increased	>ULN - 2.5 x ULN	>2.5 x ULN - 5 x ULN	>5 x ULN - 10 x ULN	>10 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in levels of creatine phosphokinase in a blood specimen.					
Creatinine increased	>1 - 1.5 x baseline; >ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 baseline; > 3.0 - 6.0 x ULN	>6.0 x ULN	-
Definition: A finding based on laboratory test results that indicate increased levels of creatinine in a biological specimen.					
Ejection fraction decreased	-	Resting ejection fraction (EF) 50 - 40%; 10 - 19% drop from baseline	Resting ejection fraction (EF) 39 - 20%; > 20% drop from baseline	Resting ejection fraction (EF) <20%	-
Definition: The percentage computed when the amount of blood ejected during a ventricular contraction of the heart is compared to the amount that was present prior to the contraction.					
Electrocardiogram QT corrected interval prolonged	QTc 450 - 480 ms	QTc 481 - 500 ms	QTc >= 501 ms on at least two separate ECGs	QTc >= 501 or >60 ms change from baseline and Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia	-
Definition: A finding of a cardiac dysrhythmia characterized by an abnormally long corrected QT interval.					
Fibrinogen decreased	<1.0 - 0.75 x LLN or <25% decrease from baseline	<0.75 - 0.5 x LLN or 25 - <50% decrease from baseline	<0.5 - 0.25 x LLN or 50 - <75% decrease from baseline	<0.25 x LLN or 75% decrease from baseline or absolute value <50 mg/dL	-
Definition: A finding based on laboratory test results that indicate an decrease in levels of fibrinogen in a blood specimen.					
Forced expiratory volume decreased	FEV1% (percentages of observed FEV1 and FVC related to their respective predicted values) 99 - 70% predicted	FEV1 60 - 69 %	50 - 59%	<= 49%	-
Definition: A finding based on test results that indicate a relative decrease in the fraction of the forced vital capacity that is exhaled in a specific number of seconds.					
GGT increased	>ULN - 2.5 x ULN	>2.5 - 5.0 x ULN	>5.0 - 20.0 x ULN	>20.0 x ULN	-
Definition: A finding based on laboratory test results that indicate higher than normal levels of the enzyme gamma-glutamyltransferase in the blood specimen. GGT (gamma-glutamyltransferase) catalyzes the transfer of a gamma glutamyl group from a gamma glutamyl peptide to another peptide, amino acids or water.					
Growth hormone abnormal	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	-	-	-
Definition: A finding based on laboratory test results that indicate abnormal levels of growth hormone in a biological specimen.					
Haptoglobin decreased	<LLN	-	-	-	-
Definition: A finding based on laboratory test results that indicate an decrease in levels of haptoglobin in a blood specimen.					
Hemoglobin increased	Increase in >0 - 2 gm/dL above ULN or above baseline if baseline is above ULN	Increase in >2 - 4 gm/dL above ULN or above baseline if baseline is above ULN	Increase in >4 gm/dL above ULN or above baseline if baseline is above ULN	-	-
Definition: A finding based on laboratory test results that indicate increased levels of hemoglobin in a biological specimen.					
INR increased	>1 - 1.5 x ULN; >1 - 1.5 times above baseline if on anticoagulation	>1.5 - 2.5 x ULN; >1.5 - 2.5 times above baseline if on anticoagulation	>2.5 x ULN; >2.5 times above baseline if on anticoagulation	-	-
Definition: A finding based on laboratory test results that indicate an increase in the ratio of the patient's prothrombin time to a control sample in the blood.					
Lipase increased	>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN	>2.0 - 5.0 x ULN	>5.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in the level of lipase in a biological specimen.					
Lymphocyte count decreased	<LLN - 800/mm ³ ; <LLN x 0.8 - 10e9 /L	<800 - 500/mm ³ ; <0.8 - 0.5 x 10e9 /L	<500 - 200 mm ³ ; <0.5 - 0.2 x 10e9 /L	<200/mm ³ ; <0.2 x 10e9 /L	-
Definition: A finding based on laboratory test results that indicate a decrease in number of lymphocytes in a blood specimen.					
Lymphocyte count increased	-	>4000/mm ³ - 20,000/mm ³	>20000/mm ³	-	-

检测					
不良事件	分级				
	1	2	3	4	5
CD4淋巴细胞减少	<LLN-500/mm ³ ; <LLN-0.5 × 10e9/L	<500-200/mm ³ ; <0.5-0.2 × 10e9/L	<200-50/mm ³ ; <0.2 × 0.05-10e9/L	<50/mm ³ ; <0.05 × 10e9/L	-
定义: 发现基于实验室检测结果, 表明血液样本中 CD4 淋巴细胞水平降低。					
胆固醇升高	>ULN-300 mg/dL; >ULN-7.75mmol/L	>300 - 400 mg/dL; >7.75 - 10.34mmol/L	>400 - 500 mg/dL; >10.34 - 12.92 mmol/L	>500 mg/dL; >12.92 mmol/L	-
定义: 发现基于实验室检测结果, 表明血液样本中的胆固醇高于正常水平。					
CPK 升高	>ULN 2.5 × ULN	>2.5 × ULN - 5 × ULN	>5 × ULN - 10 × ULN	>10 × ULN	-
定义: 发现基于实验室检测结果, 表明血液样本中的肌酸磷酸激酶水平升高。					
肌酐升高	>1 - 1.5 × 基线; >ULN - 1.5 × ULN	>1.5 - 3.0 × 基线; >1.5 - 3.0 × ULN	>3.0 基线; >3.0 - 6.0 × ULN	>6.0 × ULN	-
定义: 发现基于实验室检测结果, 表明生物样本中的肌酐水平升高。					
射血分数下降	-	静止时射血分数 50-40 %; 比基线下降 10-19%	静止时射血分数 39-20 %; 比基线下降 >20%	静止时射血分数 <20%	-
定义: 该分数是心脏室收缩时的射血量与收缩之前存在量相比的值。					
心电图 QT 间期校正间隔时间延长	QTc 450 - 480 ms	QTc 481-500ms	至少两个单独的心电图中 QTc ≥ 501 ms	QTc ≥ 501ms 或较基线改变 >60 ms, 尖端扭转型或多态性室性心动过速或严重心律失常征兆/症状	-
定义: 发现特征为异常长的校正 QT 间期的心律失常。					
纤维蛋白原降低	<1.0 - 0.75 × LLN 或较基线下降 <25%	<0.75 - 0.5 × LLN 或较基线下降 25 - <50%	<0.5 - 0.25 × LLN 或较基线下降 50 - <75%	<0.25 × LLN 或较基线下降 75% 或绝对值 <50mg/dL	-
定义: 发现基于实验室检测结果, 表明血液样本中的纤维蛋白原水平降低。					
强压呼气量降低	FEV1 % (观察的 FEV1 和 FVC 与他们相应的估计值的百分比) 估计为 99-70%	FEV1 60-69%	FEV1 50-59%	FEV1 ≤ 49%	-
定义: 发现检测结果表明在特定几秒内呼出的最大肺活量分数相对下降。					
GGT 升高	>ULN - 2.5 × ULN	>2.5 - 5.0 × ULN	>5.0 - 20.0 × ULN	>20.0 × ULN	-
定义: 发现基于实验室检测结果, 表明血液样本中的 γ-谷氨酰转氨酶高于正常水平。GGT (γ-谷氨酰转氨酶) 催化 γ-谷氨酰基从谷氨酰基转移至其他肽、氨基酸或水。					
生长激素异常	无症状; 仅有临床或诊断学观察结果; 无需介入	有症状; 需要医学治疗; 工具性 ADL 受限	-	-	-
定义: 发现基于实验室检测结果, 表明生物样本中生长激素水平异常。					
触珠蛋白降低	<LLN	-	-	-	-
定义: 发现基于实验室检测结果, 表明生物样本中触珠蛋白水平降低。					
血红蛋白升高	相比 ULN 升高 >0 - 2gm/dL 或如果基线值高于 ULN 时, 高于基线值	相比 ULN 升高 >2 - 4gm/dL 或如果基线值高于 ULN 时, 高于基线值	相比 ULN 升高 >4gm/dL 或如果基线值高于 ULN 时, 高于基线值	-	-
定义: 发现基于实验室检测结果, 表明生物样本中血红蛋白水平升高。					
国际标准化比率升高	>1 - 1.5 × ULN; 抗凝作用高于基线 >1.5 倍	>1.5 - 2.5 × ULN; 抗凝作用高于基线 >1.5-2.5 倍	>2.5 × ULN; 抗凝作用高于基线 >2.5 倍	-	-
定义: 发现基于实验室检测结果, 表明病人的凝血酶原时间与血液对照样品相比的比例升高。					
脂肪酶升高	>ULN - 1.5 × ULN	>1.5 - 2.0 × ULN	>2.0 - 5.0 × ULN	>5.0 × ULN	-
定义: 发现基于实验室检测结果, 表明生物样品中的脂肪酶水平升高。					
淋巴计数下降	<LLN-800/mm ³ ; <LLN × 0.8 - 10e9/L	<800 - 500/mm ³ ; <0.8 - 0.5 × 10e9/L	<500 - 200/mm ³ ; <0.5 - 0.2 × 10e9/L	<200/mm ³ ; <0.2 × 10e9/L	-
定义: 发现基于实验室检测结果, 表明血样中的淋巴细胞数目下降。					
淋巴计数升高	-	>4000/mm ³ -20000/mm ³	>20000/mm ³	-	-

Investigations					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A finding based on laboratory test results that indicate an abnormal increase in the number of lymphocytes in the blood, effusions or bone marrow.					
Neutrophil count decreased	<LLN - 1500/mm ³ ; <LLN - 1.5 x 10 ⁹ /L	<1500 - 1000/mm ³ ; <1.5 - 1.0 x 10 ⁹ /L	<1000 - 500/mm ³ ; <1.0 - 0.5 x 10 ⁹ /L	<500/mm ³ ; <0.5 x 10 ⁹ /L	-
Definition: A finding based on laboratory test results that indicate a decrease in number of neutrophils in a blood specimen.					
Pancreatic enzymes decreased	<LLN and asymptomatic	Increase in stool frequency, bulk, or odor; steatorrhea	Sequelae of absorption deficiency	-	-
Definition: A finding based on laboratory test results that indicate an decrease in levels of pancreatic enzymes in a biological specimen.					
Platelet count decreased	<LLN - 75,000/mm ³ ; <LLN - 75.0 x 10 ⁹ /L	<75,000 - 50,000/mm ³ ; <75.0 - 50.0 x 10 ⁹ /L	<50,000 - 25,000/mm ³ ; <50.0 - 25.0 x 10 ⁹ /L	<25,000/mm ³ ; <25.0 x 10 ⁹ /L	-
Definition: A finding based on laboratory test results that indicate a decrease in number of platelets in a blood specimen.					
Serum amylase increased	>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN	>2.0 - 5.0 x ULN	>5.0 x ULN	-
Definition: A finding based on laboratory test results that indicate an increase in the levels of amylase in a serum specimen.					
Urine output decreased	-	-	Oliguria (<80 ml in 8 hr)	Anuria (<240 ml in 24 hr)	-
Definition: A finding based on test results that indicate urine production is less relative to previous output.					
Vital capacity abnormal	90 - 75% of predicted value	<75 - 50% of predicted value; limiting instrumental ADL	<50% of predicted value; limiting self care ADL	-	-
Definition: A finding based on pulmonary function test results that indicate an abnormal vital capacity (amount of exhaled after a maximum inhalation) when compared to the predicted value.					
Weight gain	5 - <10% from baseline	10 - <20% from baseline	>=20% from baseline	-	-
Definition: A finding characterized by an increase in overall body weight; for pediatrics, greater than the baseline growth curve.					
Weight loss	5 to <10% from baseline; intervention not indicated	10 - <20% from baseline; nutritional support indicated	>=20% from baseline; tube feeding or TPN indicated	-	-
Definition: A finding characterized by a decrease in overall body weight; for pediatrics, less than the baseline growth curve.					
White blood cell decreased	<LLN - 3000/mm ³ ; <LLN - 3.0 x 10 ⁹ /L	<3000 - 2000/mm ³ ; <3.0 - 2.0 x 10 ⁹ /L	<2000 - 1000/mm ³ ; <2.0 - 1.0 x 10 ⁹ /L	<1000/mm ³ ; <1.0 x 10 ⁹ /L	-
Definition: A finding based on laboratory test results that indicate an decrease in number of white blood cells in a blood specimen.					
Investigations - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

检测					
不良事件	分级				
	1	2	3	4	5
定义：发现基于实验室检测结果，表明血液、积液或骨髓中的淋巴细胞数目异常升高。					
中性粒细胞计数降低	<LLN - 1500/mm ³ ; <LLN - 1.5 × 10e9 /L	<1500 - 1000/mm ³ ; <1.5 - 1.0 × 10e9 /L	<1000 - 500/mm ³ ; <1.0 - 0.5 × 10e9 /L	<500/mm ³ ; <0.5 × 10e9 /L	-
定义：发现基于实验室检测结果，表明生物样本中的中性粒细胞数目降低。					
胰腺酶降低	<LLN, 无症状	大便次数增加、体积大或气味臭; 脂泻	吸收不足后遗症	-	-
定义：发现基于实验室检测结果，表明生物样本中的胰腺酶水平降低。					
血小板计数下降	<LLN - 75,000/mm ³ ; <LLN - 75.0 × 10e9 /L	<75,000 - 50,000/mm ³ ; <75.0 - 50.0 × 10e9 /L	<50,000-25,000/mm ³ ; <50.0 - 25.0 × 10e9 /L	<25,000/mm ³ ; <25.0 × 10e9 /L	-
定义：发现基于实验室检测结果，表明血液样本中的血小板数目下降。					
血清淀粉酶升高	>ULN - 1.5 × ULN	>1.5 - 2.0 × ULN	>2.0 - 5.0 × ULN	>5.0 × ULN	-
定义：发现基于实验室检测结果，表明血清样本中的淀粉酶水平升高。					
尿排泄量减少	-	-	少尿(8 小时内<80 ml)	无尿(24 小时内<240ml)	-
定义：发现基于检测结果，表明尿产量与之前排泄量相比有减少。					
肺活量异常	预测值的 90 - 75 %	预测值的<75 - 50 %; 工具性 ADL 受限	预测值的<50 %; 自理 ADL 受限	-	-
定义：发现基于肺功能检测结果，表明与预测值相比肺活量异常（最大吸入后的呼出量）。					
体重增加	高于基线 5<10 %	高于基线 10-<20 %	高于基线≥20 %	-	-
定义：发现特征为总体重增加；对于儿科，高于基线生长曲线。					
体重减轻	低于基线 5<10 %; 无需介入治疗	低于基线 10-<20 %; 需要营养支持	低于基线≥20 %; 需要管饲饮食或全胃肠外营养治疗	-	-
定义：发现特征为总体重减轻；对于儿科，低于基线生长曲线。					
白细胞降低	<LLN - 3000/mm ³ ; <LLN - 3.0 × 10e9 /L	<3000 - 2000/mm ³ ; <3.0 - 2.0 × 10e9 /L	<2000 - 1000/mm ³ ; <2.0 - 1.0 × 10e9 /L	<1000/mm ³ ; <1.0 × 10e9 /L	-
定义：发现基于实验室检测结果，表明血液样本中白细胞数目降低。					
检测-其它, 指定	无症状或轻度症状; 仅有临床或诊断学观察结果; 无需介入治疗	中度; 需要最低程度、局部或非侵入性治疗; 与年龄相适的工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命; 住院或延长住院时间; 致残; 自理 ADL 受限	危及生命的后果; 需要紧急介入治疗	死亡

Metabolism and nutrition disorders					
Adverse Event	Grade				
	1	2	3	4	5
Acidosis	pH <normal, but =>7.3	-	pH <7.3	Life-threatening consequences	Death
Definition: A disorder characterized by abnormally high acidity (high hydrogen-ion concentration) of the blood and other body tissues.					
Alcohol intolerance	-	Present	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an increase in sensitivity to the adverse effects of alcohol, which can include nasal congestion, skin flushes, heart dysrhythmias, nausea, vomiting, indigestion and headaches.					
Alkalosis	pH >normal, but <=7.5	-	pH >7.5	Life-threatening consequences	Death
Definition: A disorder characterized by abnormally high alkalinity (low hydrogen-ion concentration) of the blood and other body tissues.					
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a loss of appetite.					
Dehydration	Increased oral fluids indicated; dry mucous membranes; diminished skin turgor	IV fluids indicated <24 hrs	IV fluids or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by excessive loss of water from the body. It is usually caused by severe diarrhea, vomiting or diaphoresis.					
Glucose intolerance	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; dietary modification or oral agent indicated	Severe symptoms; insulin indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an inability to properly metabolize glucose.					
Hypercalcemia	>ULN - 11.5 mg/dL; >ULN - 2.9 mmol/L; ionized calcium >ULN - 1.5 mmol/L	>11.5 - 12.5 mg/dL ; >2.9 - 3.1 mmol/L; ionized calcium >1.5 - 1.6 mmol/L; symptomatic	>12.5 - 13.5 mg/dL ; >3.1 - 3.4 mmol/L; ionized calcium >1.6 - 1.8 mmol/L; hospitalization indicated	>13.5 mg/dL; >3.4 mmol/L; ionized calcium >1.8 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of calcium in blood.					
Hyperglycemia	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L	>250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization indicated	>500 mg/dL; >27.8 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of blood sugar. It is usually an indication of diabetes mellitus or glucose intolerance.					
Hyperkalemia	>ULN - 5.5 mmol/L	>5.5 - 6.0 mmol/L	>6.0 - 7.0 mmol/L; hospitalization indicated	>7.0 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of potassium in the blood; associated with kidney failure or sometimes with the use of diuretic drugs.					
Hypermagnesemia	>ULN - 3.0 mg/dL; >ULN - 1.23 mmol/L	-	>3.0 - 8.0 mg/dL; >1.23 - 3.30 mmol/L	>8.0 mg/dL; >3.30 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of magnesium in the blood.					
Hypernatremia	>ULN - 150 mmol/L	>150 - 155 mmol/L	>155 - 160 mmol/L; hospitalization indicated	>160 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of sodium in the blood.					
Hypertriglyceridemia	150 mg/dL - 300 mg/dL; 1.71 mmol/L - 3.42mmol/L	>300 mg/dL - 500 mg/dL; >3.42 mmol/L - 5.7 mmol/L	>500 mg/dL - 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L	>1000 mg/dL; >11.4 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of triglyceride concentration in the blood.					
Hyperuricemia	>ULN - 10 mg/dL; <=0.59 mmol/L without physiologic consequences	-	>ULN - 10 mg/dL; <=0.59 mmol/L with physiologic consequences	>10 mg/dL; >0.59 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate an elevation in the concentration of uric acid.					
Hypoalbuminemia	<LLN - 3 g/dL; <LLN - 30 g/L	<3 - 2 g/dL; <30 - 20 g/L	<2 g/dL; <20 g/L	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of albumin in the blood.					
Hypocalcemia	<LLN - 8.0 mg/dL; <LLN - 2.0 mmol/L; ionized calcium <LLN - 1.0 mmol/L	<8.0 - 7.0 mg/dL; <2.0 - 1.75 mmol/L; ionized calcium <1.0 - 0.9 mmol/L; symptomatic	<7.0 - 6.0 mg/dL; <1.75 - 1.5 mmol/L; ionized calcium <0.9 - 0.8 mmol/L; hospitalization indicated	<6.0 mg/dL; <1.5 mmol/L; ionized calcium <0.8 mmol/L; life-threatening consequences	Death

代谢与营养病症					
不良事件	分级				
	1	2	3	4	5
酸中毒	pH <正常值, 但 ≥7.3	-	pH <7.3	危及生命的后果	死亡
定义: 病症特征为血液和其他人体组织酸度异常高 (高氢离子浓度)。					
乙醇不耐受	-	存在	严重症状; 自理ADL受限	危及生命的后果; 需要紧急介入治疗	死亡
定义: 病症特征为对乙醇不良作用的敏感度增加, 包括鼻充血、皮肤潮红、心脏节律障碍、恶心、呕吐、消化不良和头痛。					
碱中毒	pH >正常值, 但 ≤7.5	-	pH >7.5	危及生命的后果	死亡
定义: 病症特征为血液和其他人体组织碱度异常高 (低氢离子浓度)。					
厌食症	没有食欲但未改变饮食习惯	经口摄食改变, 不伴体重明显减轻或营养不良; 需要口服营养补剂	伴体重明显减轻或营养不良 (如口服摄取热量和/或流质不足); 需要管饲饮食或全胃肠外营养治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为丧失食欲的病症。					
脱水	需要经口补充液体; 粘膜干燥; 皮肤肿胀减轻	需要静脉输液 <24 小时	需要输液或住院治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为体内身体水份过度丧失的病症。通常由腹泻、呕吐或出汗造成。					
葡萄糖耐受不良	无症状; 仅有临床或诊断学观察结果; 无需介入	有症状; 需要调整饮食习惯或口服试剂治疗	严重症状; 需要胰岛素治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义: 特征为不能正常代谢葡萄糖的病症。					
高钙血症	>ULN - 11.5 mg/dL; >ULN - 2.9mmol/L; 离子钙 >ULN - 1.5 mmol/L	>11.5 - 12.5 mg/dL; >2.9 - 3.1mmol/L; 离子钙 >1.5 - 1.6mmol/L; 有症状	>12.5 - 3.5mg/dL; >3.1 - 3.4mmol/L; 离子钙 >1.6-1.8mmol/L; 需要住院治疗	>13.5 mg/dL; >3.4 mmol/L; 离子钙 >1.8mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中钙浓度升高。					
高血糖症	空腹葡萄糖值 >ULN - 160mg/dL; 空腹葡萄糖值 >ULN - 8.9 mmol/L	空腹葡萄糖值 > 160 - 250mg/dL; 空腹葡萄糖值 >8.9-13.9 mmol/L	>250 - 500 mg/dL; >13.9 - 27.8mmol/L; 需要住院治疗	>500mg/dL; >27.8 mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血糖浓度升高, 通常是糖尿病或葡萄糖耐受不良的征兆。					
高钾血症	>ULN - 5.5 mmol/L	>5.5 - 6.0 mmol/L	>6.0 - 7.0 mmol/L; 需要住院治疗	>7.0 mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中钾浓度升高; 与肾衰或有时与利尿药使用有关。					
高镁血症	>ULN - 3.0 mg/dL; >ULN - 1.23mmol/L	-	>3.0 - 8.0 mg/dL; >1.23 - 3.30mmol/L	>8.0 mg/dL; >3.30 mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中镁浓度升高。					
高钠血症	>ULN - 150 mmol/L	>150 - 155 mmol/L	>155 - 160 mmol/L; 需要住院治疗	>160 mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中钠浓度升高。					
高甘油三酯血症	150 mg/dL - 300 mg/dL; 1.71mmol/L - 3.42mmol/L	>300 mg/dL - 500 mg/dL; >3.42mmol/L - 5.7 mmol/L	>500 mg/dL - 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L	>1000 mg/dL; >11.4 mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中甘油三酯浓度升高。					
高尿酸血症	>ULN - 10 mg/dL; ≤0.59 mmol/L 不伴生理学改变	-	>ULN - 10 mg/dL; ≤0.59mmol/L 不伴生理学改变	>10mg/dL; >0.59mmol/L; 危及生命的后果	死亡
定义: 病症特征为实验室检测结果表明血液中尿酸浓度升高。					
低白蛋白血症	<LLN - 3 g/dL; <LLN - 30 g/L	<3 - 2 g/dL; <30 - 20 g/L	<2 g/dL; <20 g/L	危及生命的后果; 需要紧急介入治疗	死亡
定义: 病症特征为实验室检测结果表明血液中白蛋白浓度降低。					
低钙血症	<LLN - 8.0 mg/dL; <LLN - 2.0mmol/L; 离子钙 <LLN - 1.0 mmol/L	<8.0 - 7.0 mg/dL; <2.0 - 1.75mmol/L; 离子钙 <1.0 - 0.9mmol/L; 有症状	<7.0 - 6.0mg/dL; <1.75 - 1.5mmol/L; 离子钙 <0.9 - 0.8mmol/L; 需要住院治疗	<6.0mg/dL; <1.5 mmol/L; 离子钙 <0.8 mmol/L; 危及生命的后果	死亡

CTCAE v4.0

Metabolism and nutrition disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by laboratory test results that indicate a low concentration of calcium in the blood.					
Hypoglycemia	<LLN - 55 mg/dL; <LLN - 3.0 mmol/L		<40 - 30 mg/dL; <2.2 - 1.7 mmol/L	<30 mg/dL; <1.7 mmol/L; life-threatening consequences; seizures	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of glucose in the blood.					
Hypokalemia	<LLN - 3.0 mmol/L	<LLN - 3.0 mmol/L; symptomatic; intervention indicated	<3.0 - 2.5 mmol/L; hospitalization indicated	<2.5 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of potassium in the blood.					
Hypomagnesemia	<LLN - 1.2 mg/dL; <LLN - 0.5 mmol/L	<1.2 - 0.9 mg/dL; <0.5 - 0.4 mmol/L	<0.9 - 0.7 mg/dL; <0.4 - 0.3 mmol/L	<0.7 mg/dL; <0.3 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of magnesium in the blood.					
Hyponatremia	<LLN - 130 mmol/L	-	<130 - 120 mmol/L	<120 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of sodium in the blood.					
Hypophosphatemia	<LLN - 2.5 mg/dL; <LLN - 0.8 mmol/L	<2.5 - 2.0 mg/dL; <0.8 - 0.6 mmol/L	<2.0 - 1.0 mg/dL; <0.6 - 0.3 mmol/L	<1.0 mg/dL; <0.3 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of phosphates in the blood.					
Iron overload	-	Moderate symptoms; intervention not indicated	Severe symptoms; intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by accumulation of iron in the tissues.					
Obesity	-	BMI 25 - 29.9 kg/m2	BMI 30 - 39.99 kg/m2, or 1 or 2 decimals should be used consistently over both grades	BMI >=40 kg/m2	-
Definition: A disorder characterized by having a high amount of body fat.					
Tumor lysis syndrome	-	-	Present	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by metabolic abnormalities that result from a spontaneous or therapy-related cytolysis of tumor cells.					
Metabolism and nutrition disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

代谢与营养病症					
不良事件	分级				
	1	2	3	4	5
定义：病症特征为实验室检测结果表明血液中钙浓度低。					
低血糖症	<LLN - 55 mg/dL; <LLN - 3.0 mmol/L		<40 - 30 mg/dL; <2.2 - 1.7 mmol/L	<30 mg/dL; <1.7 mmol/L; 危及生命的后果; 癫痫发作	死亡
定义：病症特征为实验室检测结果表明血液中葡萄糖浓度低。					
低钾血症	<LLN - 3.0 mmol/L	<LLN-3.0 mmol/L; 有症状; 需要治疗	<3.0-2.5 mmol/L; 需要住院治疗	<2.5mmol/L; 危及生命的后果	死亡
定义：病症特征为实验室检测结果表明血液中钾浓度低。					
低镁血症	<LLN - 1.2 mg/dL; <LLN - 0.5 mmol/L	<1.2 - 0.9 mg/dL; <0.5 - 0.4 mmol/L	<0.9 - 0.7 mg/dL; <0.4 - 0.3 mmol/L	<0.7 mg/dL; <0.3mmol/L; 危及生命的后果	死亡
定义：病症特征为实验室检测结果表明血液中镁浓度低。					
低钠血症	<LLN - 130 mmol/L	-	<130 - 120 mmol/L	<120 mmol/L; 危及生命的后果	死亡
定义：病症特征为实验室检测结果表明血液中钠浓度低。					
低磷酸盐血症	<LLN - 2.5 mg/dL; <LLN - 0.8 mmol/L	<2.5 - 2.0 mg/dL; <0.8 - 0.6 mmol/L	<2.0 - 1.0 mg/dL; <0.6 - 0.3 mmol/L	<1.0 mg/dL; <0.3 mmol/L; 危及生命的后果	死亡
定义：病症特征为实验室检测结果表明血液中磷酸盐浓度低。					
铁超负荷	-	中度症状; 无需介入治疗	严重症状; 需要治疗	危及生命的后果; 需要紧急介入治疗	死亡
定义：特征为组织中铁聚积的病症。					
肥胖	-	BMI 25 - 29.9 kg/m ²	BMI 30 - 39.99 kg/m ² , 在各分级中用1位或2位小数应保持一致	BMI ≥40 kg/m ²	-
定义：特征为身体脂肪量高的病症。					
肿瘤溶解综合症	-	-	存在	危及生命的后果; 需要紧急介入治疗	死亡
定义：病症特征为由自发性或治疗相关的肿瘤细胞溶解导致的代谢异常。					
代谢与营养病症-其它, 指定	无症状或轻度症状; 仅有临床或诊断学观察结果; 无需介入治疗	中度; 需要最低程度、局部或非侵入性治疗; 与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命; 住院或延长住院时间; 致残; 自理ADL受限	危及生命的后果; 需要紧急介入治疗	死亡

Musculoskeletal and connective tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Abdominal soft tissue necrosis	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the abdominal wall.					
Arthralgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in a joint.					
Arthritis	Mild pain with inflammation, erythema, or joint swelling	Moderate pain associated with signs of inflammation, erythema, or joint swelling; limiting instrumental ADL	Severe pain associated with signs of inflammation, erythema, or joint swelling; irreversible joint damage; disabling; limiting self care ADL	-	-
Definition: A disorder characterized by inflammation involving a joint.					
Avascular necrosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL, elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by necrotic changes in the bone tissue due to interruption of blood supply. Most often affecting the epiphysis of the long bones, the necrotic changes result in the collapse and the destruction of the bone structure.					
Back pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the back region.					
Bone pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the bones.					
Buttock pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the buttocks.					
Chest wall pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the chest wall region.					
Exostosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL, elective operative intervention indicated	-	-
Definition: A disorder characterized by non-neoplastic overgrowth of bone.					
Fibrosis deep connective tissue	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Definition: A disorder characterized by fibrotic degeneration of the deep connective tissues.					
Flank pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation on the lateral side of the body in the region below the ribs and above the hip.					
Generalized muscle weakness	Symptomatic; weakness perceived by patient but not evident on physical exam	Symptomatic; weakness evident on physical exam; weakness limiting instrumental ADL	Weakness limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of muscles in multiple anatomic sites.					
Growth suppression	Reduction in growth velocity by 10 - 29% ideally measured over the period of a year	Reduction in growth velocity by 30-49% ideally measured over the period of a year or 0 - 49% reduction in growth from the baseline growth curve	Reduction in growth velocity of >=50% ideally measured over the period of a year	-	-
Definition: A disorder characterized by of stature that is smaller than normal as expected for age.					

肌肉骨骼系统和结缔组织疾病					
不良事件	分级				
	1	2	3	4	5
腹部软组织坏死	-	局部伤口护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其它侵袭性介入治疗（例如组织再造、皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为腹壁软组织有坏死进程发生的病症。					
关节痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为关节有显著不适感的病症。					
关节炎	轻度疼痛伴炎症，红斑或关节肿胀	中度疼痛伴炎症迹象，红斑或关节肿胀；工具性ADL受限	严重疼痛伴炎症迹象，红斑或关节肿胀；不可逆的关节损伤；致残；自理ADL受限	-	-
定义：特征为关节有炎症的病症。					
无血管性坏死	无症状；仅有诊断学观察结果；无需介入治疗	有症状；工具性ADL受限	严重症状；自理ADL受限，需要选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为源于血液供给阻断的骨组织坏死变化的病症。常侵袭长骨骨髓，坏死改变导致骨结构的断裂和破坏。					
背痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为背部区域有显著不适感的病症。					
骨痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为骨有显著不适感的病症。					
臀痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为臀有显著不适感的病症。					
胸壁疼痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为胸壁区域有显著不适感的病症。					
外生骨疣	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；工具性ADL受限	严重症状；自理ADL受限，需要选择性手术介入治疗	-	-
定义：特征为非肿瘤性增生的骨。					
深层结缔组织纤维化	轻度硬化，能够在皮肤上平行于平面（滑动）及垂直于皮肤（捏挤）移动	中度硬化，能够滑动皮肤，不能捏挤皮肤；工具性ADL受限	严重硬化；不能滑动或捏挤皮肤；关节或孔口（如口，肛门）运动受限；自理ADL受限	全身性；伴随呼吸或饮食受损的体征或症状	死亡
定义：特征为深层结缔组织纤维化变性的病症。					
胁腹痛	轻度疼痛	中度疼痛；工具性疼痛	严重疼痛；自理ADL受限	-	-
定义：特征为身体侧边肋骨下髌骨上的区域有显著不适感的病症。					
全身肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；肌无力工具性ADL受限	肌无力自理ADL受限；致残	-	-
定义：特征为多个解剖部位肌肉强度减退的病症。					
生长抑制	与一年期间理论上测量生长速度相比降低10-29%	与一年期间理论上测量生长速度相比降低30-49%或比生长曲线基线降低0-49%	与一年期间理论上测量生长速度相比降低≥50%	-	-
定义：特征为身高小于正常年龄预期值的病症。					

Musculoskeletal and connective tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Head soft tissue necrosis	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the head.					
Joint effusion	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL; elective operative intervention indicated; disabling	-	-
Definition: A disorder characterized by excessive fluid in a joint, usually as a result of joint inflammation.					
Joint range of motion decreased	<=25% loss of ROM (range of motion); decreased ROM limiting athletic activity	>25 - 50% decrease in ROM; limiting instrumental ADL	>50% decrease in ROM; limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a decrease in joint flexibility of any joint.					
Joint range of motion decreased cervical spine	Mild restriction of rotation or flexion between 60 - 70 degrees	Rotation <60 degrees to right or left; <60 degrees of flexion	Ankylosed/fused over multiple segments with no C-spine rotation	-	-
Definition: A disorder characterized by a decrease in flexibility of a cervical spine joint.					
Joint range of motion decreased lumbar spine	Stiffness; difficulty bending to the floor to pick up a very light object but able to do athletic activity	Pain with range of motion (ROM) in lumbar spine; requires a reaching aid to pick up a very light object from the floor	<50% lumbar spine flexion; associated with symptoms of ankylosis or fused over multiple segments with no L-spine flexion (e.g., unable to reach to floor to pick up a very light object)	-	-
Definition: A disorder characterized by a decrease in flexibility of a lumbar spine joint.					
Kyphosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate accentuation; limiting instrumental ADL	Severe accentuation; operative intervention indicated; limiting self care ADL	-	-
Definition: A disorder characterized by an abnormal increase in the curvature of the thoracic portion of the spine.					
Lordosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate accentuation; limiting instrumental ADL	Severe accentuation; operative intervention indicated; limiting self care ADL	-	-
Definition: A disorder characterized by an abnormal increase in the curvature of the lumbar portion of the spine.					
Muscle weakness left-sided	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of the muscles on the left side of the body.					
Muscle weakness lower limb	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of the lower limb muscles.					
Muscle weakness right-sided	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of the muscles on the right side of the body.					
Muscle weakness trunk	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of the trunk muscles.					
Muscle weakness upper limb	Symptomatic; perceived by patient but not evident on physical exam	Symptomatic; evident on physical exam; limiting instrumental ADL	Limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a reduction in the strength of the upper limb muscles.					

肌肉骨骼系统和结缔组织疾病					
不良事件	分级				
	1	2	3	4	5
头部软组织坏死	-	局部伤口护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其它侵袭性介入治疗（例如组织再造、皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为头部软组织有坏死进程发生的病症。					
关节积液	无症状；仅有临床或诊断学观察结果；无需介入治疗	有症状；工具性 ADL 受限	严重症状；自理 ADL 受限；需要选择性手术治疗；致残	-	-
定义：特征为关节有过量液体的病症，通常引起关节炎。					
关节活动度降低	≤25%ROM（活动度）丧失；ROM 降低使体育活动受限	>25-50%ROM 降低；工具性 ADL 受限	>50%ROM 降低；自理 ADL 受限；致残	-	-
定义：特征为任何关节的灵活性降低的病症。					
颈椎关节活动度减少	60-70 度内旋转或弯曲轻度受限	<60°左右旋转；<60 度弯曲	多节僵硬或融合，颈椎棘突不能旋转	-	-
定义：特征为颈椎棘突关节灵活性降低的病症。					
腰椎关节运动活动度减少	四肢伸直；弯身在地上拿起很轻的物品有困难，但可以参加体育活动。	腰椎活动度疼痛；需要辅助工具才能从地上拿起很轻的物品	腰椎弯曲<50%；伴随多节僵硬或融合症状，腰椎不能旋转（如不能从地上拿起很轻的物品）	-	-
定义：特征为腰椎关节灵活性降低的病症。					
脊柱后凸	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度突出；工具性 ADL 受限	严重突出；需要手术治疗；自理 ADL 受限	-	-
定义：特征为脊柱的胸部曲率异常增加的病症。					
脊柱前凸	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度明显；工具性 ADL 受限	严重明显；需要手术治疗；自理 ADL 受限	-	-
定义：特征为脊柱的腰部曲率异常增加的病症。					
左侧肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为左侧身体肌肉强度减退的病症。					
下肢肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为下肢肌肉强度减退的病症。					
右侧肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为右侧身体肌肉强度减退的病症。					
躯干肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为躯干肌肉强度减退的病症。					
上肢肌无力	有症状；病人觉察到无力但体格检查无证据	有症状；体格检查有无力证据；工具性 ADL 受限	自理 ADL 受限；致残	-	-
定义：特征为上肢肌肉强度减退的病症。					

Musculoskeletal and connective tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Musculoskeletal deformity	Cosmetically and functionally insignificant hypoplasia	Deformity, hypoplasia, or asymmetry able to be remediated by prosthesis (e.g., shoe insert) or covered by clothing	Significant deformity, hypoplasia, or asymmetry, unable to be remediated by prosthesis or covered by clothing; disabling	-	-
Definition: A disorder characterized by of a malformation of the musculoskeletal system.					
Myalgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation originating from a muscle or group of muscles.					
Myositis	Mild pain	Moderate pain associated with weakness; pain limiting instrumental ADL	Pain associated with severe weakness; limiting self care ADL	-	-
Definition: A disorder characterized by inflammation involving the skeletal muscles.					
Neck pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the neck area.					
Neck soft tissue necrosis	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the neck.					
Osteonecrosis of jaw	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL	Severe symptoms; limiting self care ADL; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the bone of the mandible.					
Osteoporosis	Radiologic evidence of osteoporosis or Bone Mineral Density (BMD) t-score -1 to -2.5 (osteopenia); no loss of height or intervention indicated	BMD t-score <-2.5; loss of height <2 cm; anti-osteoporotic therapy indicated; limiting instrumental ADL	Loss of height >=2 cm; hospitalization indicated; limiting self care ADL	-	-
Definition: A disorder characterized by reduced bone mass, with a decrease in cortical thickness and in the number and size of the trabeculae of cancellous bone (but normal chemical composition), resulting in increased fracture incidence.					
Pain in extremity	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the upper or lower extremities.					
Pelvic soft tissue necrosis	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the pelvis.					
Scoliosis	<20 degrees; clinically undetectable	>20 - 45 degrees; visible by forward flexion; limiting instrumental ADL	>45 degrees; scapular prominence in forward flexion; operative intervention indicated; limiting self care ADL; disabling	-	-
Definition: A disorder characterized by a malformed, lateral curvature of the spine.					
Soft tissue necrosis lower limb	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the lower extremity.					
Soft tissue necrosis upper limb	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g. tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the soft tissues of the upper extremity.					

肌肉骨骼系统和结缔组织疾病					
不良事件	分级				
	1	2	3	4	5
肌肉骨骼畸形	外观性和功能性无临床显著意义的发育不全	畸形、发育不全或不对称能够修复补救（如加鞋垫）或衣物遮掩	明显畸形、发育不全或不对称，不能够修复补救或衣物遮掩；致残	-	-
定义：特征为肌肉骨骼系统有畸形的病症。					
肌痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为肌肉或肌肉群有显著不适感的病症。					
肌炎	轻度疼痛	中度疼痛伴随肌无力；疼痛使工具性ADL受限	疼痛伴严重肌无力；自理ADL受限	-	-
定义：特征为骨骼肌有炎症的病症。					
颈痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为颈部有显著不适感的病症。					
颈部软组织坏死	-	局部伤口护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其他侵袭性介入治疗（例如组织再造，皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为颈部软组织发生坏死性进程的病症。					
颌骨骨坏死	无症状；仅有临床或诊断观察结果；无需介入	有症状；需要医学治疗（如局部用药）；工具性ADL受限	严重症状；自理ADL受限；需要选择性手术治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为下颌骨发生坏死性进程的病症。					
骨质疏松症	有骨质疏松症放射学证据或骨密度（BMD）t值-1至-2.5（骨量减少）；高度未减，无需介入治疗	骨密度t值<-2.5；高度下降<2cm；需要抗骨质疏松治疗；工具性ADL受限	高度下降≥2cm；需要住院治疗；自理ADL受限	-	-
定义：病症特征为骨量减少，伴随皮层厚度与松质骨小梁的数量和大小减少（化学结构正常），从而增加骨折发生率。					
肢体疼痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为上下肢有显著不适感的病症。					
骨盆软组织坏死	-	局部护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其他侵袭性介入治疗（例如组织再造，皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为骨盆软组织发生坏死性进程的病症。					
脊柱侧凸	<20度；临床不能检测到	>20-45度；前屈时可看到；工具性ADL受限	>45度；肩胛骨突出前屈；需要手术治疗；自理ADL受限；致残	-	-
定义：特征为脊柱畸形、侧凸的病症。					
下肢软组织坏死	-	局部护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其他侵袭性介入治疗（例如组织再造，皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为下肢的软组织发生坏死性进程的病症。					
上肢软组织坏死	-	局部护理；需要医学治疗（如敷药包扎或局部用药）	需要手术清创或其他侵袭性介入治疗（例如组织再造，皮瓣或移植）	危及生命的后果；需要紧急手术介入治疗	死亡
定义：特征为上肢的软组织发生坏死性进程的病症。					

CTCAE v4.0

Musculoskeletal and connective tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Superficial soft tissue fibrosis	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Definition: A disorder characterized by fibrotic degeneration of the superficial soft tissues.					
Trismus	Decreased ROM (range of motion) without impaired eating	Decreased ROM requiring small bites, soft foods or purees	Decreased ROM with inability to adequately aliment or hydrate orally	-	-
Definition: A disorder characterized by lack of ability to open the mouth fully due to a decrease in the range of motion of the muscles of mastication.					
Unequal limb length	Mild length discrepancy <2 cm	Moderate length discrepancy 2 - 5 cm; shoe lift indicated; limiting instrumental ADL	Severe length discrepancy >5 cm; limiting self care ADL; disabling; operative intervention indicated	-	-
Definition: A disorder characterized by of a discrepancy between the lengths of the lower or upper extremities.					
Musculoskeletal and connective tissue disorder - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

肌肉骨骼系统和结缔组织疾病					
不良事件	分级				
	1	2	3	4	5
表面软组织纤维化	轻度硬化，能够在皮肤平行于面移动（滑动）及垂直于皮肤（捏挤）	中度硬化，能够滑动皮肤，不能捏挤；工具性ADL受限	严重硬化；不能滑动或捏挤皮肤；关节或孔口（如口，肛门）运动受限；自理ADL受限	全身性；伴随呼吸或饮食削弱的体征或症状	死亡
定义：特征为软组织表面有纤维化变性的病症。					
牙关紧闭	活动度下降，进食未受损	活动度下降，需要小口吃、软食物或酱汁	活动度下降，无法经口补充足够营养或水合物	-	-
定义：病症特征为由于咀嚼肌的活动度下降导致不能完全张开口。					
肢体不等长	轻度肢体差异<2cm	中度肢体差异2-5cm；需要垫高鞋子；工具性ADL受限	严重肢体差异>5cm；自理ADL受限；致残；需要手术治疗	-	-
定义：特征为上下肢长度有差异的病症。					
肌肉骨骼系统和结缔组织疾病-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Adverse Event	Grade				
	1	2	3	4	5
Leukemia secondary to oncology chemotherapy	-	-	-	Present	Death
Definition: A disorder characterized by leukemia arising as a result of the mutagenic effect of chemotherapy agents.					
Myelodysplastic syndrome	-	-	-	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by insufficiently healthy hematopoietic cell production by the bone marrow.					
Treatment related secondary malignancy	-	-	Non life-threatening secondary malignancy	Acute life-threatening secondary malignancy; blast crisis in leukemia	Death
Definition: A disorder characterized by development of a malignancy most probably as a result of treatment for a previously existing malignancy.					
Tumor pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort from a neoplasm that may be pressing on a nerve, blocking blood vessels, inflamed or fractured from metastasis.					
Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

良性，恶性和未界定肿瘤（含囊肿及息肉）					
不良事件	分级				
	1	2	3	4	5
肿瘤化疗继发白血病 定义：特征为由化疗制剂致突变作用引发白血病的病症。	-	-	-	存在	死亡
骨髓增生异常综合征 定义：特征为骨髓产生的健康造血细胞不足的病症。	-	-	-	危及生命的后果； 需要紧急介入治疗	死亡
治疗相关的继发性恶性肿瘤 定义：特征为由于对之前已存在恶性肿瘤的治疗引起恶性肿瘤进展的病症。	-	-	非危及生命的继发性恶性肿瘤	急性危及生命的继发性恶性肿瘤；白血病急性发作	死亡
肿瘤疼痛 定义：病症特征为肿瘤引起显著不适感，可能压迫神经、阻塞血管、转移引起发炎或骨折。	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
良性，恶性和未界定肿瘤（含囊肿及息肉）-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Nervous system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Abducens nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the abducens nerve (sixth cranial nerve).					
Accessory nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the accessory nerve (eleventh cranial nerve).					
Acoustic nerve disorder NOS	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the acoustic nerve (eighth cranial nerve).					
Akathisia	Mild restlessness or increased motor activity	Moderate restlessness or increased motor activity; limiting instrumental ADL	Severe restlessness or increased motor activity; limiting self care ADL	-	-
Definition: A disorder characterized by an uncomfortable feeling of inner restlessness and inability to stay still; this is a side effect of some psychotropic drugs.					
Amnesia	Mild; transient memory loss	Moderate; short term memory loss; limiting instrumental ADL	Severe; long term memory loss; limiting self care ADL	-	-
Definition: A disorder characterized by systematic and extensive loss of memory.					
Aphonia	-	-	Voicelessness; unable to speak	-	-
Definition: A disorder characterized by the inability to speak. It may result from injuries to the vocal cords or may be functional (psychogenic).					
Arachnoiditis	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation of the arachnoid membrane and adjacent subarachnoid space.					
Ataxia	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; mechanical assistance indicated	-	-
Definition: A disorder characterized by lack of coordination of muscle movements resulting in the impairment or inability to perform voluntary activities.					
Brachial plexopathy	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by regional paresthesia of the brachial plexus, marked discomfort and muscle weakness, and limited movement in the arm or hand.					
Central nervous system necrosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; corticosteroids indicated	Severe symptoms; medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a necrotic process occurring in the brain and/or spinal cord.					
Cerebrospinal fluid leakage	Post-craniotomy; asymptomatic; Post- lumbar puncture: transient headache; postural care indicated	Post-craniotomy: moderate symptoms; medical intervention indicated; Post- lumbar puncture: persistent moderate symptoms; blood patch indicated	Severe symptoms; medical intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by loss of cerebrospinal fluid into the surrounding tissues.					
Cognitive disturbance	Mild cognitive disability; not interfering with work/school/life performance; specialized educational services/devices not indicated	Moderate cognitive disability; interfering with work/school/life performance but capable of independent living; specialized resources on part time basis indicated	Severe cognitive disability; significant impairment of work/school/life performance	-	-
Definition: A disorder characterized by a conspicuous change in cognitive function.					
Concentration impairment	Mild inattention or decreased level of concentration	Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL	Severe impairment in attention or decreased level of concentration; limiting self care ADL	-	-
Definition: A disorder characterized by a deterioration in the ability to concentrate.					

神经系统疾病					
不良事件	分级				
	1	2	3	4	5
外展神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为牵涉外展神经（第六脑神经）的病症。					
副神经紊乱	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为牵涉副神经（第十一脑神经）的病症。					
听神经病症（未指明）	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为牵涉听觉神经（第八脑神经）的病症。					
静坐不能	轻度坐立不安或运动活动增加	中度坐立不安或运动活动增加；工具性 ADL 受限	严重坐立不安或运动活动增加；自理 ADL 受限	-	-
定义：病症特征为内心不安的不适感，不能静坐；是一些抗精神病药物的副作用。					
健忘症	轻度；短暂记忆缺失	中度；短时期的记忆缺失；工具性 ADL 受限	严重；长时期的记忆缺失；自理 ADL 受限	-	-
定义：特征为系统性和广泛的记忆缺失的病症。					
失声	-	-	发不出声；不能讲话	-	-
定义：特征为不能够讲话的病症。可能源于声带损伤或属功能性（心理性）。					
蛛网膜炎	轻度症状	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为蛛网膜和邻近蛛网膜下腔有炎症的病症。					
共济失调	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限；需要机械辅助	-	-
定义：特征为肌肉运动缺乏协调性造成损伤或不能完成随意活动的病症。					
臂丛神经病变	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限；	-	-
定义：病症特征为臂丛神经区域麻木，有明显的不适感和肌肉无力，手臂或手活动受限。					
中枢神经系统坏死	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；需要皮质激素治疗	严重症状；需要药物治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑和/或脊髓发生坏死进程的病症。					
脑脊液渗漏	颅骨切除术后：无症状；腰椎穿刺后：短暂头痛；需要体位护理	颅骨切除术后：中度症状；需要医学介入治疗；腰椎穿刺后：持续中度症状；需要充填血	严重症状；需要医学介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑脊液流失到周围组织的病症。					
认知障碍	轻度认知障碍；未影响工作/学校/生活表现；无需提供专门教育服务/设备	中度认识障碍；影响工作/学校/生活表现，但可以独立生活；需要兼职的特定资源	严重认识障碍；严重损害工作/学校/生活表现	-	-
定义：特征为认知功能有显著改变的病症。					
注意集中障碍	轻度注意力不集中或专心度下降	中度注意力减退或专心度降低；工具性 ADL 受限	严重注意力减退或专心度降低；自理 ADL 受限	-	-
定义：特征为注意力集中能力衰退的病症。					

Nervous system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Depressed level of consciousness	Decreased level of alertness	Sedation; slow response to stimuli; limiting instrumental ADL	Difficult to arouse	Life-threatening consequences	Death
Definition: A disorder characterized by a decrease in ability to perceive and respond.					
Dizziness	Mild unsteadiness or sensation of movement	Moderate unsteadiness or sensation of movement; limiting instrumental ADL	Severe unsteadiness or sensation of movement; limiting self care ADL	-	-
Definition: A disorder characterized by a disturbing sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking.					
Dysarthria	Mild slurred speech	Moderate impairment of articulation or slurred speech	Severe impairment of articulation or slurred speech	-	-
Definition: A disorder characterized by slow and slurred speech resulting from an inability to coordinate the muscles used in speech.					
Dysesthesia	Mild sensory alteration	Moderate sensory alteration; limiting instrumental ADL	Severe sensory alteration; limiting self care ADL	-	-
Definition: A disorder characterized by distortion of sensory perception, resulting in an abnormal and unpleasant sensation.					
Dysgeusia	Altered taste but no change in diet	Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste	-	-	-
Definition: A disorder characterized by abnormal sensual experience with the taste of foodstuffs; it can be related to a decrease in the sense of smell.					
Dysphasia	Awareness of receptive or expressive characteristics; not impairing ability to communicate	Moderate receptive or expressive characteristics; impairing ability to communicate spontaneously	Severe receptive or expressive characteristics; impairing ability to read, write or communicate intelligibly	-	-
Definition: A disorder characterized by impairment of verbal communication skills, often resulting from brain damage.					
Edema cerebral	-	-	-	Life-threatening consequences; urgent intervention indicated	-
Definition: A disorder characterized by swelling due to an excessive accumulation of fluid in the brain.					
Encephalopathy	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a pathologic process involving the brain.					
Extrapyramidal disorder	Mild involuntary movements	Moderate involuntary movements; limiting instrumental ADL	Severe involuntary movements or torticollis; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by abnormal, repetitive, involuntary muscle movements, frenzied speech and extreme restlessness.					
Facial muscle weakness	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by a reduction in the strength of the facial muscles.					
Facial nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the facial nerve (seventh cranial nerve).					
Glossopharyngeal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by involvement of the glossopharyngeal nerve (ninth cranial nerve).					
Headache	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in various parts of the head, not confined to the area of distribution of any nerve.					
Hydrocephalus	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; intervention not indicated	Severe symptoms or neurological deficit; intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal increase of cerebrospinal fluid in the ventricles of the brain.					
Hypersomnia	Mild increased need for sleep	Moderate increased need for sleep	Severe increased need for sleep	-	-
Definition: A disorder characterized by characterized by excessive sleepiness during the daytime.					

神经系统疾病					
不良事件	分级				
	1	2	3	4	5
意识水平压制	警戒水平降低	镇静；对刺激反应慢；工具性 ADL 受限	难以唤醒	危及生命的后果	死亡
定义：特征为认知和反应能力降低的病症。					
眩晕	轻度失稳或有移动感	中度失稳或有移动感；工具性 ADL 受限	严重失稳或有移动感；自理 ADL 受限	-	-
定义：病症特征为一种烦扰的头昏、不稳、眼花、旋转或摇摆感觉。					
发音困难	言语轻度模糊	中度发音清晰度受损或言语模糊	严重发音清晰度受损或言语模糊	-	-
定义：特征为由于不能协调用于讲话的肌肉造成讲话慢且含糊不清。					
感觉迟钝	轻度感觉改变	中度感觉改变；工具性 ADL 受限	严重感觉改变；自理 ADL 受限	-	-
定义：病症特征为感观知觉失真，导致感觉异常与不适。					
味觉障碍	味觉改变，但饮食未改变	味觉改变并改变饮食（如口服补充剂）；有腐败或令人厌恶的味觉；丧失味觉	-	-	-
定义：病症特征为对食品味道有异常的感觉；可能与嗅觉感觉降低有关。					
言语障碍	能意识到感知性或表达性的障碍特征；不损害沟通能力	中度感知性或表达性的障碍特征；损害自发沟通能力	重度感知性或表达性的障碍特征；损害读、写或沟通能力	-	-
定义：特征为语言沟通技能损害的病症，常由脑损伤导致。					
脑水肿	-	-	-	危及生命的后果；需要紧急介入治疗	-
定义：特征为由脑中积聚的过量液体导致肿胀的病症。					
脑病	轻度症状	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涉及脑的病理进程的病症。					
锥体外疾病	轻度无意识运动	中度无意识运动；工具性 ADL 受限	严重无意识运动或斜颈；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为异常的、反复的，非自主的肌肉运动，狂乱言语和极端不安。					
面部肌肉无力	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为面部肌肉强度减退的病症。					
面神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为涉及面神经的病症（第七脑神经）。					
舌咽神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涉及舌咽神经的病症（第九脑神经）。					
头痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为头部多部位有显著不适感的病症，不限于任一神经分布区域。					
脑积水	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性 ADL 受限；无需介入治疗	严重症状或神经功能缺损；需要治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脑室的脑脊液异常增多的病症。					
嗜睡	轻度睡眠需求增多	中度睡眠需求增多	严重睡眠需求增多	-	-
定义：特征为白天过度睡眠的病症。					

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Nervous system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Hypoglossal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the hypoglossal nerve (twelfth cranial nerve).					
Intracranial hemorrhage	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated	Ventriculostomy, ICP monitoring, intraventricular thrombolysis, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the cranium.					
Ischemia cerebrovascular	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms	-	-	-
Definition: A disorder characterized by a decrease or absence of blood supply to the brain caused by obstruction (thrombosis or embolism) of an artery resulting in neurological damage.					
IVth nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the trochlear nerve (fourth cranial nerve).					
Lethargy	Mild symptoms; reduced alertness and awareness	Moderate symptoms; limiting instrumental ADL	-	-	-
Definition: A disorder characterized by a decrease in consciousness characterized by mental and physical inertness.					
Leukoencephalopathy	Asymptomatic; small focal T2/FLAIR hyperintensities; involving periventricular white matter or <1/3 of susceptible areas of cerebrum +/- mild increase in subarachnoid space (SAS) and/or mild ventriculomegaly	Moderate symptoms; focal T2/FLAIR hyperintensities, involving periventricular white matter extending into centrum semiovale or involving 1/3 to 2/3 of susceptible areas of cerebrum +/- moderate increase in SAS and/or moderate ventriculomegaly	Severe symptoms; extensive T2/FLAIR hyperintensities, involving periventricular white matter involving 2/3 or more of susceptible areas of cerebrum +/- moderate to severe increase in SAS and/or moderate to severe ventriculomegaly	Life-threatening consequences; extensive T2/FLAIR hyperintensities, involving periventricular white matter involving most of susceptible areas of cerebrum +/- moderate to severe increase in SAS and/or moderate to severe ventriculomegaly	Death
Definition: A disorder characterized by diffuse reactive astrocytosis with multiple areas of necrotic foci without inflammation.					
Memory impairment	Mild memory impairment	Moderate memory impairment; limiting instrumental ADL	Severe memory impairment; limiting self care ADL	-	-
Definition: A disorder characterized by a deterioration in memory function.					
Meningismus	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by neck stiffness, headache, and photophobia resulting from irritation of the cerebral meninges.					
Movements involuntary	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by uncontrolled and purposeless movements.					
Myelitis	Asymptomatic; mild signs (e.g., Babinski's reflex or Lhermitte's sign)	Moderate weakness or sensory loss; limiting instrumental ADL	Severe weakness or sensory loss; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation involving the spinal cord. Symptoms include weakness, paresthesia, sensory loss, marked discomfort and incontinence.					
Neuralgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by intense painful sensation along a nerve or group of nerves.					
Nystagmus	-	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involuntary movements of the eyeballs.					
Oculomotor nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the oculomotor nerve (third cranial nerve).					
Olfactory nerve disorder	-	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the olfactory nerve (first cranial nerve).					

神经系统疾病					
不良事件	分级				
	1	2	3	4	5
舌下神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为涉及舌下神经的病症（第十二脑神经）。					
颅内出血	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；需要医学治疗	需要脑室造口术，颅内压监测，室内溶栓或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为所有出血的病症。					
缺血性脑血管病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状	-	-	-
定义：特征为由动脉阻塞（血栓症或栓塞）引起脑的供血减少或缺乏导致神经损伤。					
第四神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为涉及滑车神经的病症（第四脑神经）。					
昏睡症	轻度症状；警惕性和意识降低	中度症状；工具性ADL受限	-	-	-
定义：特征为意识降低，精神和身体惰性的病症。					
脑白质病	无症状；小病灶T2/FLAIR高信号；牵涉室周白质或<1/3大脑易感染区域+/-蛛网膜下腔轻度增加和/或轻度脑室扩大	中度症状；病灶T2/FLAIR高信号；牵涉室周白质扩展到半卵圆中央或1/3至2/3大脑易感染区域+/-蛛网膜下腔中度增加和/或中度脑室扩大	严重症状；广泛T2/FLAIR高信号；室周白质牵涉2/3或更多大脑易感染区域+/-蛛网膜下腔中至重度增加和/或中至重度脑室扩大	危及生命的后果；广泛T2/FLAIR高信号；室周白质牵涉大部分大脑易感染区域+/-蛛网膜下腔中至重度增加和/或中至重度脑室扩大	死亡
定义：特征为弥漫反应性星形细胞增多症伴随多区域无炎症的坏死病灶。					
记忆损伤	轻度记忆损伤	中度记忆损伤；工具性ADL受限	严重记忆损伤；自理ADL受限	-	-
定义：特征为记忆功能衰退的病症。					
假性脑膜炎	轻度症状	中度症状；工具性ADL受限	严重症状；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为刺激脑膜导致颈强直、头痛和畏光。					
非自主性移动	轻度症状	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为非控制性和无目的移动的病症。					
脊髓炎	无症状；轻度征兆（如巴宾斯基反射或莱尔米特征）	中度无力或感觉丧失；工具性ADL受限	严重无力或感觉丧失；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涉及脊髓发炎的病症。症状包括无力、感觉异常、感觉丧失、显著不适与失禁。					
神经痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为沿着一个或多个神经有强烈疼痛感的病症。					
眼球震颤	-	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为眼球非自主性运动的病症。					
动眼神经疾病	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为涉及动眼神经的病症（第三脑神经）。					
嗅神经疾病		中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为涉及嗅神经的病症（第一脑神经）。					

Nervous system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Paresthesia	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by functional disturbances of sensory neurons resulting in abnormal cutaneous sensations of tingling, numbness, pressure, cold, and warmth that are experienced in the absence of a stimulus.					
Peripheral motor neuropathy	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; assistive device indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation or degeneration of the peripheral motor nerves.					
Peripheral sensory neuropathy	Asymptomatic; loss of deep tendon reflexes or paresthesia	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation or degeneration of the peripheral sensory nerves.					
Phantom pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort related to a limb or an organ that is removed from or is not physically part of the body.					
Presyncope	-	Present (e.g., near fainting)	-	-	-
Definition: A disorder characterized by an episode of lightheadedness and dizziness which may precede an episode of syncope.					
Pyramidal tract syndrome	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by dysfunction of the corticospinal (pyramidal) tracts of the spinal cord. Symptoms include an increase in the muscle tone in the lower extremities, hyperreflexia, positive Babinski and a decrease in fine motor coordination.					
Radiculitis	Mild symptoms	Moderate symptoms; limiting instrumental ADL; medical intervention indicated	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation involving a nerve root. Patients experience marked discomfort radiating along a nerve path because of spinal pressure on the connecting nerve root.					
Recurrent laryngeal nerve palsy	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms	Severe symptoms; medical intervention indicated (e.g., thyroplasty, vocal cord injection)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by paralysis of the recurrent laryngeal nerve.					
Reversible posterior leukoencephalopathy syndrome	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; abnormal imaging studies; limiting instrumental ADL	Severe symptoms; very abnormal imaging studies; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by headaches, mental status changes, visual disturbances, and seizures associated with imaging findings of posterior leukoencephalopathy. It has been observed in association with hypertensive encephalopathy, eclampsia, and immunosuppressive and cytotoxic drug treatment. It is an acute or subacute reversible condition.					
Seizure	Brief partial seizure; no loss of consciousness	Brief generalized seizure	Multiple seizures despite medical intervention	Life-threatening; prolonged repetitive seizures	Death
Definition: A disorder characterized by a sudden, involuntary skeletal muscular contractions of cerebral or brain stem origin.					
Sinus pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort in the face, between the eyes, or upper teeth originating from the sinuses.					
Somnolence	Mild but more than usual drowsiness or sleepiness	Moderate sedation; limiting instrumental ADL	Obtundation or stupor	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by characterized by excessive sleepiness and drowsiness.					
Spasticity	Mild or slight increase in muscle tone	Moderate increase in muscle tone and increase in resistance through range of motion	Severe increase in muscle tone and increase in resistance through range of motion	Life-threatening; unable to move active or passive range of motion	Death
Definition: A disorder characterized by increased involuntary muscle tone that affects the regions interfering with voluntary movement. It results in gait, movement, and speech disturbances.					
Stroke	Asymptomatic or mild neurologic deficit; radiographic findings only	Moderate neurologic deficit	Severe neurologic deficit	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a sudden loss of sensory function due to an intracranial vascular event.					
Syncope	-	-	Fainting; orthostatic collapse	-	-
Definition: A disorder characterized by spontaneous loss of consciousness caused by insufficient blood supply to the brain.					

神经系统疾病					
分级					
不良事件	1	2	3	4	5
感觉异常	轻度症状	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：病症特征为感觉神经元功能紊乱造成刺痛、麻木、压迫、寒冷和温暖等无刺激时存在的异常皮肤感觉。					
周围运动神经病症	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限；需要辅助装置	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为周围运动神经有炎症或衰退的病症。					
周围感觉神经病症	无症状；深腱反射丧失或感觉异常	中度症状；工具性ADL受限	严重症状；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为周围感觉神经有炎症或衰退的病症。					
幻痛	轻度疼痛	中度疼痛；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：病症特征为与已经摘除或不属于身体部分的肢体或器官有关的显著不适感。					
昏厥前期	-	存在（如将近晕厥）	-	-	-
定义：病症特征为可能在晕厥发作之前出现的偶发头昏与眩晕。					
锥体束综合征	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限；	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为脊髓的皮质脊髓（锥体）束功能障碍的病症。症状包括下肢肌紧张增加、反射亢进，巴宾斯基阳性与精细运动协调能力降低。					
脊神经根炎	轻度症状	中度症状；工具性ADL受限；需要医学治疗	严重症状；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涉及神经根炎症病症。由于脊髓压迫连接的神经根，病人沿着神经通路有显著不适感。					
喉返神经麻痹	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状	严重症状；需要医学治疗（如甲状软骨成形术，声带注射）	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为喉返神经麻痹的病症。					
可逆性后脑白质病综合征	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；有异常影像学结果；工具性ADL受限	严重症状；影像学结果非常异常；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为头痛、精神状态改变、视力障碍、癫痫并伴随后脑白质病影像学结果。据观察它与高血压脑病、惊厥、免疫抑制和细胞毒性药物治疗有关。是一种急性或亚急性可逆性的疾病。					
癫痫发作	短暂的局部发作；没有丧失意识	短暂的全身性发作	医学治疗情况下仍多次发作	危及生命；长期反复复发	死亡
定义：特征为源于大脑或脑干的突然、非自主性的骨骼肌收缩的病症。					
窦痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为源于窦的面部、眼之间或上齿的显著不适。					
嗜睡	轻度但比一般困倦或睡意强烈	中度镇静；工具性ADL受限	迟钝或昏呆	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为过度睡意和困倦的病症。					
痉挛	肌肉紧张度轻度或微小增加	肌肉紧张度和对活动度的抵抗力中度增加	肌肉紧张度和对活动度的抵抗力严重增加	危及生命；不能有效移动或被动的活动度	死亡
定义：病症特征为非自主性肌肉紧张度增加，影响干扰自主性运动的区域。它导致步态、运动和言语障碍。					
中风	无症状或轻度神经功能缺损；仅有放射学发现	中度神经功能缺损	严重神经功能缺损	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为颅内血管事件导致感觉功能突然丧失。					
晕厥	-	-	昏晕；直立位虚脱	-	-
定义：病症特征为由于脑供血不足导致的自发性意识丧失。					

Nervous system disorders					
Adverse Event	Grade				
	1	2	3	4	5
Transient ischemic attacks	Mild neurologic deficit with or without imaging confirmation	Moderate neurologic deficit with or without imaging confirmation	-	-	-
Definition: A disorder characterized by a brief attack (less than 24 hours) of cerebral dysfunction of vascular origin, with no persistent neurological deficit.					
Tremor	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by the uncontrolled shaking movement of the whole body or individual parts.					
Trigeminal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by involvement of the trigeminal nerve (fifth cranial nerve).					
Vagus nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by involvement of the vagus nerve (tenth cranial nerve).					
Vasovagal reaction	-	-	Present	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a sudden drop of the blood pressure, bradycardia, and peripheral vasodilation that may lead to loss of consciousness. It results from an increase in the stimulation of the vagus nerve.					
Nervous system disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

神经系统疾病					
不良事件	分级				
	1	2	3	4	5
短暂性脑缺血发作	轻度神经功能缺损伴或不伴影像学确认	中度神经功能缺损伴或不伴影像学确认	-	-	-
定义：病症特征为源于血管的脑功能障碍短暂发作（小于24小时），不伴持久性神经功能缺损。					
震颤	轻度症状	中度症状；工具性ADL受限	严重症状；自理ADL受限；	-	-
定义：病症特征为整个身体或个别部位有不能控制的颤抖运动。					
三叉神经紊乱	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为涉及三叉神经的病症（第五脑神经）。					
迷走神经紊乱	无症状；仅有临床或诊断学观察结果；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为涉及迷走神经的病症（第十脑神经）。					
血管迷走反应	-	-	存在	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为血压突然下降，心搏过缓和周围血管舒张，可能导致意识丧失。由迷走神经兴奋增加所致。					
神经系统疾病-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Pregnancy, puerperium and perinatal conditions					
Adverse Event	Grade				
	1	2	3	4	5
Fetal death	-	-	-	-	Fetal loss at any gestational age
Definition: A disorder characterized by death in utero; failure of the product of conception to show evidence of respiration, heartbeat, or definite movement of a voluntary muscle after expulsion from the uterus, without possibility of resuscitation.					
Fetal growth retardation	-	<10% percentile of weight for gestational age	<5% percentile of weight for gestational age	<1% percentile of weight for gestational age	-
Definition: A disorder characterized by inhibition of fetal growth resulting in the inability of the fetus to achieve its potential weight.					
Premature delivery	Delivery of a liveborn infant at >34 to 37 weeks gestation	Delivery of a liveborn infant at >28 to 34 weeks gestation	Delivery of a liveborn infant at 24 to 28 weeks gestation	Delivery of a liveborn infant at 24 weeks of gestation or less	-
Definition: A disorder characterized by delivery of a viable infant before the normal end of gestation. Typically, viability is achievable between the twentieth and thirty-seventh week of gestation.					
Unintended pregnancy	-	-	Unintended pregnancy	-	-
Definition: A disorder characterized by an unexpected pregnancy at the time of conception.					
Pregnancy, puerperium and perinatal conditions - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate, local or noninvasive intervention indicated; limiting instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

妊娠，产后和围产期疾病					
不良事件	分级				
	1	2	3	4	5
胎儿死亡	-	-	-	-	在任何胎龄的胎儿死亡
定义：病症特征为胎死子宫中；妊娠产物从子宫娩出后没有呼吸、心跳或明确的自主性肌肉运动的证据，没有复生的可能性。					
胎儿生长迟缓	-	按胎龄算，<体重的10%	按胎龄算，<体重的5%	按胎龄算，<体重的1%	-
定义：病症特征为胎儿生长抑制，导致胎儿不能达到可能的重量。					
早产	在>34至37周妊娠生产成活婴儿	在>28至34周妊娠生产成活婴儿	在24至28周妊娠生产成活婴儿	在24周或更早妊娠生产成活婴儿	-
定义：特征为正常妊娠结束前产下存活的婴儿。通常在妊娠20和37周之间产下的婴儿有生存能力。					
非故意的妊娠	-	-	非故意的妊娠	-	-
定义：特征为受孕时产生非预期的妊娠。					
血管迷走反应	-	-	存在	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为血压突然下降，心搏徐缓和周围血管舒张，可能导致意识丧失。由迷走神经刺激增加所致。					
妊娠，产后和围产期疾病-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Psychiatric disorders					
Adverse Event	Grade				
	1	2	3	4	5
Agitation	Mild mood alteration	Moderate mood alteration	Severe agitation; hospitalization not indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a state of restlessness associated with unpleasant feelings of irritability and tension.					
Anorgasmia	Inability to achieve orgasm not adversely affecting relationship	Inability to achieve orgasm adversely affecting relationship	-	-	-
Definition: A disorder characterized by an inability to achieve orgasm.					
Anxiety	Mild symptoms; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; hospitalization not indicated	Life-threatening; hospitalization indicated	Death
Definition: A disorder characterized by apprehension of danger and dread accompanied by restlessness, tension, tachycardia, and dyspnea unattached to a clearly identifiable stimulus.					
Confusion	Mild disorientation	Moderate disorientation; limiting instrumental ADL	Severe disorientation; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a lack of clear and orderly thought and behavior.					
Delayed orgasm	Delay in achieving orgasm not adversely affecting relationship	Delay in achieving orgasm adversely affecting relationship	-	-	-
Definition: A disorder characterized by sexual dysfunction characterized by a delay in climax.					
Delirium	Mild acute confusional state	Moderate and acute confusional state; limiting instrumental ADL	Severe and acute confusional state; limiting self care ADL; hospitalization indicated	Life-threatening consequences; hospitalization indicated	Death
Definition: A disorder characterized by the acute and sudden development of confusion, illusions, movement changes, inattentiveness, agitation, and hallucinations. Usually, it is a reversible condition.					
Delusions	-	Moderate delusional symptoms	Severe delusional symptoms; hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by false personal beliefs held contrary to reality, despite contradictory evidence and common sense.					
Depression	Mild depressive symptoms	Moderate depressive symptoms; limiting instrumental ADL	Severe depressive symptoms; limiting self care ADL; hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by melancholic feelings of grief or unhappiness.					
Euphoria	Mild mood elevation	Moderate mood elevation	Severe mood elevation (e.g., hypomania)	-	-
Definition: A disorder characterized by an exaggerated feeling of well-being which is disproportionate to events and stimuli.					
Hallucinations	Mild hallucinations (e.g., perceptual distortions)	Moderate hallucinations	Severe hallucinations; hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by a false sensory perception in the absence of an external stimulus.					
Insomnia	Mild difficulty falling asleep, staying asleep or waking up early	Moderate difficulty falling asleep, staying asleep or waking up early	Severe difficulty in falling asleep, staying asleep or waking up early	-	-
Definition: A disorder characterized by difficulty in falling asleep and/or remaining asleep.					
Libido decreased	Decrease in sexual interest not adversely affecting relationship	Decrease in sexual interest adversely affecting relationship	-	-	-
Definition: A disorder characterized by a decrease in sexual desire.					
Libido increased	Mild increase in sexual interest not adversely affecting relationship	Moderate increase in sexual interest adversely affecting relationship	Severe increase in sexual interest leading to dangerous behavior	-	-
Definition: A disorder characterized by an increase in sexual desire.					
Mania	Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)	Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)	Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by excitement of psychotic proportions manifested by mental and physical hyperactivity, disorganization of behavior and elevation of mood.					
Personality change	Mild personality change	Moderate personality change	Severe personality change; hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death

精神疾病					
分级					
不良事件	1	2	3	4	5
精神躁动	轻度情绪改变	中度情绪改变	严重躁动；无需住院治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为有坐立不安的状态伴随烦躁和紧张不愉快的感觉。					
性快感缺失	无法达到高潮，未对关系产生不利影响	无法达到高潮，对关系产生不利影响	-	-	-
定义：特征为不能达到高潮的病症。					
焦虑	轻度症状；无需介入治疗	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限；无需住院治疗	危及生命；需要住院治疗	死亡
定义：病症特征为对危险的担忧和恐惧感，同时在无可清晰辨识的刺激下伴随坐立不安、紧张、心动过速和呼吸困难。					
意识错乱	轻度定向障碍	中度定向障碍；工具性 ADL 受限	严重定向障碍；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡
定义：病症特征为缺乏清楚和有序的思维和行为。					
性高潮延迟	推迟达到高潮，未对关系产生不利影响	推迟达到高潮，对关系产生不利影响	-	-	-
定义：病症特征为高潮延迟的性功能障碍。					
谵妄	轻度急性错乱状态	中度急性错乱状态；工具性 ADL 受限	严重急性错乱状态；自理 ADL 受限；需要住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：病症特征为错乱、幻觉、行为改变、注意迟钝、躁动和幻觉的急性或突然形成。通常是可逆状态。					
妄想	-	中度妄想症状	严重妄想症状；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：病症特征为不顾矛盾性证据和常识，个人信念与与现实背离。					
抑郁	轻度抑郁症状	中度抑郁症状；工具性 ADL 受限	严重抑郁症状；自理 ADL 受限；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：特征为有悲痛或不快的忧郁情绪病症。					
欣快	轻度情绪提高	中度情绪提高	情绪严重提高（如轻躁狂）	-	-
定义：病症特征为与事情和刺激不相符的夸张的快乐感。					
幻觉	轻度幻觉（如知觉扭曲）	中度幻觉	严重幻觉；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：特征为没有外部刺激时出现错误的感官知觉的病症。					
失眠	轻度入睡和保持睡眠困难，或早醒	中度入睡和保持睡眠困难，或早醒	严重入睡和保持睡眠困难，或早醒	-	-
定义：特征为入睡和/或保持睡眠困难。					
性欲减退	对性的兴趣轻度降低，未对关系产生不利影响	对性的兴趣中度降低，对关系产生不利影响	-	-	-
定义：特征为对性的欲望减退。					
性欲增强	对性的兴趣轻度增强，未对关系产生不利影响	对性的兴趣中度增强，对关系产生不利影响	对性的兴趣重度增强，导致危险行为	-	-
定义：特征为对性的欲望增强的病症。					
躁狂症	轻度躁狂症状（如情绪提高，思维迅速，言语快速，睡眠需求减少）	中度躁狂症状（如关系和工作困难；卫生状况差）	严重躁狂症状（如轻躁狂；重大的性或财务不慎）；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：病症特征为精神病患者的兴奋，表现为精神和身体的过度兴奋、行为混乱和情绪高涨。					
人格改变	轻度人格改变	中度人格改变	严重人格改变；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡

Psychiatric disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by a conspicuous change in a person's behavior and thinking.					
Psychosis	Mild psychotic symptoms	Moderate psychotic symptoms (e.g., disorganized speech; impaired reality testing)	Severe psychotic symptoms (e.g., paranoid; extreme disorganization); hospitalization not indicated	Life-threatening consequences; threats of harm to self or others; hospitalization indicated	Death
Definition: A disorder characterized by personality change, impaired functioning, and loss of touch with reality. It may be a manifestation of schizophrenia, bipolar disorder or brain tumor.					
Restlessness	Mild symptoms; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by an inability to rest, relax or be still.					
Suicidal ideation	Increased thoughts of death but no wish to kill oneself	Suicidal ideation with no specific plan or intent	Specific plan to commit suicide without serious intent to die which may not require hospitalization	Specific plan to commit suicide with serious intent to die which requires hospitalization	-
Definition: A disorder characterized by thoughts of taking one's own life.					
Suicide attempt	-	-	Suicide attempt or gesture without intent to die which may not require hospitalization	Suicide attempt with intent to die which requires hospitalization	Death
Definition: A disorder characterized by self-inflicted harm in an attempt to end one's own life.					
Psychiatric disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; disabling; limiting self care ADL	Life-threatening consequences; hospitalization or urgent intervention indicated	Death

精神疾病					
不良事件	分级				
	1	2	3	4	5
定义：病症特征为个人的行为和思维显著改变。					
精神病	轻度精神病症状	中度精神病症状（如言语混乱；对现实分辨受损	严重精神病症状；（如偏执；极度混乱）；无需住院治疗	危及生命的后果，对自身或他人有危害威胁；需要住院治疗	死亡
定义：病症特征为性格改变、机能受损和对现实的感知丧失。可能是精神分裂症、双相性精神障碍或脑肿瘤的表现。					
坐立不安	轻度症状；无需介入治疗	中度症状；工具性ADL受限	严重症状；自理ADL受限	-	-
定义：特征为不能休息、放松或静止的病症。					
自杀观念	对死亡的意向增长但无意自杀	有自杀的意念但无具体计划或意图	有自杀的具体计划不伴死亡的真正意图，或不需住院治疗	有自杀的具体计划伴严重的死亡意图，需要住院治疗	-
定义：特征为有结束自己生命意向的病症。					
自杀企图	-	-	有自杀企图或动作，不伴死亡意图，不需住院治疗	有自杀企图或动作，伴死亡意图，需要住院治疗	死亡
定义：病症特征为对自己伤害，企图结束生命。					
精神疾病-其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；与年龄相适的工具性ADL受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入治疗	死亡

Renal and urinary disorders					
Adverse Event	Grade				
	1	2	3	4	5
Acute kidney injury	Creatinine level increase of >0.3 mg/dL; creatinine 1.5 - 2.0 x above baseline	Creatinine 2 - 3x above baseline	Creatinine >3x baseline or >4.0 mg/dL; hospitalization indicated	Life-threatening consequences; dialysis indicated	Death
Definition: A disorder characterized by the acute loss of renal function and is traditionally classified as pre-renal (low blood flow into kidney), renal (kidney damage) and post-renal causes (ureteral or bladder outflow obstruction).					
Bladder perforation	-	Extraperitoneal perforation, indwelling catheter indicated	Intraperitoneal perforation; elective radiologic, endoscopic or operative intervention indicated	Life-threatening consequences; organ failure; urgent operative intervention indicated	Death
Definition: A disorder characterized by a rupture in the bladder wall.					
Bladder spasm	Intervention not indicated	Antispasmodics indicated	Hospitalization indicated	-	-
Definition: A disorder characterized by a sudden and involuntary contraction of the bladder wall.					
Chronic kidney disease	eGFR (estimated Glomerular Filtration Rate) or CrCl (creatinine clearance) < 60 ml/min/1.73 m ² or proteinuria 2+ present; urine protein/creatinine >0.5	eGFR or CrCl 59 - 30 ml/min/1.73 m ²	eGFR or CrCl 29 - 15 ml/min/1.73 m ²	eGFR or CrCl < 15 ml/min/1.73 m ² ; dialysis or renal transplant indicated	Death
Definition: A disorder characterized by gradual and usually permanent loss of kidney function resulting in renal failure.					
Cystitis noninfective	Microscopic hematuria; minimal increase in frequency, urgency, dysuria, or nocturia; new onset of incontinence	Moderate hematuria; moderate increase in frequency, urgency, dysuria, nocturia or incontinence; urinary catheter placement or bladder irrigation indicated; limiting instrumental ADL	Gross hematuria; transfusion, IV medications or hospitalization indicated; elective endoscopic, radiologic or operative intervention indicated	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death
Definition: A disorder characterized by inflammation of the bladder which is not caused by an infection of the urinary tract.					
Hematuria	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; urinary catheter or bladder irrigation indicated; limiting instrumental ADL	Gross hematuria; transfusion, IV medications or hospitalization indicated; elective endoscopic, radiologic or operative intervention indicated; limiting self care ADL	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death
Definition: A disorder characterized by laboratory test results that indicate blood in the urine.					
Hemoglobinuria	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	-	-	-	-
Definition: A disorder characterized by laboratory test results that indicate the presence of free hemoglobin in the urine.					
Proteinuria	1+ proteinuria; urinary protein <1.0 g/24 hrs	Adults: 2+ proteinuria; urinary protein 1.0	Adults: urinary protein >3.5 g/24 hrs; Pediatric urine P/C (Protein/Creatinine) >1.9	-	-
Definition: A disorder characterized by laboratory test results that indicate the presence of excessive protein in the urine. It is predominantly albumin, but also globulin.					
Renal calculi	Asymptomatic or mild symptoms; occasional use of nonprescription analgesics indicated	Symptomatic; oral antiemetics indicated; around the clock nonprescription analgesics or any oral narcotic analgesics indicated	Hospitalization indicated; IV intervention (e.g., analgesics, antiemetics); elective endoscopic or radiologic intervention indicated	Life-threatening consequences; urgent radiologic, endoscopic or operative intervention indicated	Death
Definition: A disorder characterized by the formation of crystals in the pelvis of the kidney.					
Renal colic	Mild pain not interfering with activity; nonprescription medication indicated	Moderate pain; limiting instrumental ADL; prescription medication indicated	Hospitalization indicated; limiting self care ADL	-	-
Definition: A disorder characterized by paroxysmal and severe flank marked discomfort radiating to the inguinal area. Often, the cause is the passage of kidney stones.					
Renal hemorrhage	Mild symptoms; intervention not indicated	Analgesics and hematocrit monitoring indicated	Transfusion, radiation, or hospitalization indicated; elective radiologic, endoscopic or operative intervention indicated	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death

肾及泌尿系统疾病					
分级					
不良事件	1	2	3	4	5
急性肾损伤	肌酐水平增高 >0.3mg/dL; 肌酐高于基线 1.5-2.0 倍	肌酐高于基线 2-3 倍	肌酐高于基线 3 倍或增高 >4.0mg/dL; 需要住院治疗	危及生命的后果; 需要透析治疗	死亡
定义: 病症特征为急性肾功能丧失, 传统上分为肾前性(低血流量入肾), 肾性(肾损害)和肾后性原因(输尿管或膀胱流出道梗阻)。					
膀胱穿孔	-	腹膜外穿孔, 需要留置导尿管	腹膜外穿孔; 需要选择性放射、内窥镜或手术介入治疗	危及生命的后果; 器官衰竭; 需要紧急手术介入治疗	死亡
定义: 特征膀胱壁有破裂的病症。					
膀胱痉挛	无需介入治疗	需要镇痛剂治疗	需要住院治疗	-	-
定义: 病症特征为膀胱壁突然的非自主性收缩。					
慢性肾病	eGFR(估计肾小球滤过率)或CrCl(肌酐清除率) <60ml/min/1.73 m ² 或存在蛋白尿 2+; 尿蛋白/肌酐>0.5	eGFR或CrCl 59 - 30 ml/min/1.73 m ²	eGFR或CrCl 29 - 15 ml/min/1.73 m ²	eGFR或CrCl < 15 ml/min/1.73 m ² ; 需要透析或肾移植	死亡
定义: 病症特征为肾功能逐渐且通常是永久丧失, 导致肾衰竭。					
非感染性膀胱炎	显微镜性血尿; 排尿频率、尿急、排尿困难或夜尿最低程度增加; 发生尿失禁	中度血尿; 排尿频率、尿急、排尿困难、夜尿或尿失禁中度增加; 需要安置导尿管或膀胱冲洗; 工具性 ADL 受限	肉眼血尿; 需要输血, 静脉注射药物或住院治疗; 需要选择性内窥镜、放射或手术介入治疗	危及生命的后果; 需要紧急放射或手术介入治疗	死亡
定义: 病症特征为膀胱发炎, 不是由于尿路感染引起					
血尿	无症状; 仅有临床或诊断学观察结果; 无需介入治疗	有症状; 需要安置导尿管或膀胱冲洗; 工具性 ADL 受限	严重血尿; 需要输血, 静脉注射药物或住院治疗; 需要选择性内窥镜、放射或手术介入治疗; 自理ADL受限	危及生命的后果; 需要紧急放射或手术介入治疗	死亡
定义: 特征为实验室结果显示尿中有血的病症。					
血红蛋白尿	无症状; 仅有临床或诊断学观察结果; 无需介入治疗	-	-	-	-
定义: 特征为实验室结果显示尿中有血红蛋白的病症。					
蛋白尿	蛋白尿 1+; 尿蛋白 <1.0g/24 小时	成人: 蛋白尿 2+; 尿蛋白 1.0	成人: 尿蛋白>3.5g/24 小时; 小儿尿 P/C (蛋白/肌酐) >1.9	-	-
定义: 特征为实验室结果显示尿中存在过量蛋白的病症。主要是白蛋白, 还有球蛋白。					
肾结石	无症状或轻度症状; 需要偶尔使用非处方镇痛药	有症状; 需要口服止吐药; 需要全天候非处方镇痛药或任何口服麻醉性镇痛药	需要住院治疗; 静脉注射治疗(如镇痛药, 止吐药); 需要选择性内窥镜或放射介入治疗	危及生命的后果; 需要紧急放射、内窥镜或手术介入治疗	死亡
定义: 特征为在肾盂处有结晶形成的病症。					
肾绞痛	轻度疼痛不妨碍活动; 需要非处方药物治疗	中度疼痛; 工具性 ADL 受限; 需要处方药物治疗	需要住院治疗; 自理 ADL 受限	-	-
定义: 病症特征为突发性严重肋腹有显著性不适感, 幅射至腹股沟区域。通常起因于肾结石通过。					
肾出血	轻度症状; 无需介入治疗	需要镇痛药治疗和血细胞比容监测	需要输血, 放射或住院治疗; 需要选择性放射, 内窥镜或手术介入治疗	危及生命的后果; 需要紧急放射或手术介入治疗	死亡

Renal and urinary disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by bleeding from the kidney.					
Urinary fistula	-	Noninvasive intervention indicated; urinary or suprapubic catheter placement indicated	Limiting self care ADL; elective radiologic, endoscopic or operative intervention indicated; permanent urinary diversion indicated	Life-threatening consequences; urgent radiologic or operative intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between any part of the urinary system and another organ or anatomic site.					
Urinary frequency	Present	Limiting instrumental ADL; medical management indicated	-	-	-
Definition: A disorder characterized by urination at short intervals.					
Urinary incontinence	Occasional (e.g., with coughing, sneezing, etc.), pads not indicated	Spontaneous; pads indicated; limiting instrumental ADL	Intervention indicated (e.g., clamp, collagen injections); operative intervention indicated; limiting self care ADL	-	-
Definition: A disorder characterized by inability to control the flow of urine from the bladder.					
Urinary retention	Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual	Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated	Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass	Life-threatening consequences; organ failure; urgent operative intervention indicated	Death
Definition: A disorder characterized by accumulation of urine within the bladder because of the inability to urinate.					
Urinary tract obstruction	Asymptomatic; clinical or diagnostic observations only	Symptomatic but no hydronephrosis, sepsis or renal dysfunction; urethral dilation, urinary or suprapubic catheter indicated	Symptomatic and altered organ function (e.g., hydronephrosis, or renal dysfunction); elective radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by blockage of the normal flow of contents of the urinary tract.					
Urinary tract pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the urinary tract.					
Urinary urgency	Present	Limiting instrumental ADL; medical management indicated	-	-	-
Definition: A disorder characterized by a sudden compelling urge to urinate.					
Urine discoloration	Present	-	-	-	-
Definition: A disorder characterized by a change in the color of the urine.					
Renal and urinary disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate, local or noninvasive intervention indicated; limiting instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

肾及泌尿系统疾病					
分级					
不良事件	1	2	3	4	5
定义：特征为肾有出血的病症。					
尿瘘	-	需要非侵袭性治疗；需要泌尿或耻骨上安置导尿管	自理 ADL 受限；需要选择性，放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急放射或手术介入治疗	死亡
定义：特征为在泌尿系统一部位和其它器官或解剖部位之间有异常通道的病症。					
尿频	存在	工具性 ADL 受限；需要医学处理	-	-	-
定义：特征为排尿间隔短的病症。					
尿失禁	偶尔（如咳嗽，喷嚏时等），无需用衬垫	自发性的；需要用衬垫；工具性 ADL 受限	需要介入治疗（如夹子，注射胶原）；需要手术介入治疗；自理 ADL 受限	-	-
定义：病症特征为无法控制尿从膀胱里溢出。					
尿潴留	无需在泌尿，耻骨上或间歇安置导尿管；少许残留可以排空	需要安置泌尿、耻骨上或间歇性导管；需要医学治疗	需要选择性手术或放射介入治疗；受感染的肾功能或质量有实质损失	危及生命的后果；器官衰竭；需要紧急手术介入治疗	死亡
定义：特征为因为无法排出，尿在膀胱内聚积的病症。					
尿路梗阻	无症状；仅有临床或观察结果	有症状但无肾积水、败血病或肾功能异常；需要尿道扩张术、泌尿或耻骨上导尿管	有症状，器官功能改变（如肾积水或肾功能异常）；需要选择性放射、内窥镜或手术介入治疗	危及生命的后果；需要紧急介入治疗	死亡
定义：特征为尿路正常流量的内容物被阻塞的病症。					
尿路疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	严重疼痛；自理 ADL 受限	-	-
定义：特征为尿路有显著性不适感的病症。					
尿急	存在	-	-	-	-
定义：特征为突然很急迫想排尿的病症。					
尿液变色	存在	-	-	-	-
定义：特征为尿的颜色改变的病症。					
肾及泌尿系统疾病—其它，指定	无症状或轻度症状；仅有临床或诊断学观察结果；无需介入治疗	中度；需要最低程度、局部或非侵入性治疗；工具性 ADL 受限	严重或具有临床显著意义但非即刻危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入治疗	死亡

Reproductive system and breast disorders					
Adverse Event	Grade				
	1	2	3	4	5
Azoospermia	-	-	Absence of sperm in ejaculate	-	-
Definition: A disorder characterized by laboratory test results that indicate complete absence of spermatozoa in the semen.					
Breast atrophy	Minimal asymmetry; minimal atrophy	Moderate asymmetry; moderate atrophy	Asymmetry >1/3 of breast volume; severe atrophy	-	-
Definition: A disorder characterized by underdevelopment of the breast.					
Breast pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the breast region.					
Dysmenorrhea	Mild symptoms; Intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by abnormally painful abdominal cramps during menses.					
Dyspareunia	Mild discomfort or pain associated with vaginal penetration; discomfort relieved with use of vaginal lubricants or estrogen	Moderate discomfort or pain associated with vaginal penetration; discomfort or pain partially relieved with use of vaginal lubricants or estrogen	Severe discomfort or pain associated with vaginal penetration; discomfort or pain unrelieved by vaginal lubricants or estrogen	-	-
Definition: A disorder characterized by painful or difficult coitus.					
Ejaculation disorder	Diminished ejaculation	Anejaculation or retrograde ejaculation	-	-	-
Definition: A disorder characterized by problems related to ejaculation. This category includes premature, delayed, retrograde and painful ejaculation.					
Erectile dysfunction	Decrease in erectile function (frequency or rigidity of erections) but intervention not indicated (e.g., medication or use of mechanical device, penile pump)	Decrease in erectile function (frequency/rigidity of erections), erectile intervention indicated, (e.g., medication or mechanical devices such as penile pump)	Decrease in erectile function (frequency/rigidity of erections) but erectile intervention not helpful (e.g., medication or mechanical devices such as penile pump); placement of a permanent penile prosthesis indicated (not previously present)	-	-
Definition: A disorder characterized by the persistent or recurrent inability to achieve or to maintain an erection during sexual activity.					
Fallopian tube obstruction	Diagnostic observations only; intervention not indicated	Mild symptoms; elective intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by blockage of the normal flow of the contents in the fallopian tube.					
Fallopian tube stenosis	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated (e.g., organ resection)	Death
Definition: A disorder characterized by a narrowing of the fallopian tube lumen.					
Female genital tract fistula	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between a female reproductive system organ and another organ or anatomic site.					
Feminization acquired	Mild symptoms; Intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by the development of secondary female sex characteristics in males due to extrinsic factors.					
Genital edema	Mild swelling or obscuration of anatomic architecture on close inspection	Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour	Lymphorrhoea; gross deviation from normal anatomic contour; limiting self care ADL	-	-
Definition: A disorder characterized by swelling due to an excessive accumulation of fluid in the genitals.					
Gynecomastia	Asymptomatic breast enlargement	Symptomatic (e.g., pain or psychosocial impact)	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by excessive development of the breasts in males.					
Hematosalpinx	Minimal bleeding identified on imaging study or laparoscopy; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death

生殖系统和乳房病症					
不良事件	分级				
	1	2	3	4	5
无精子症 定义：特征为实验室检查结果证明精液中完全没有精子的一种病症。	-	-	精液无精子	-	-
乳房萎缩 定义：特征为乳房发育不全的病症。	最小程度的偏位和萎缩	中度的偏位和萎缩	偏位>乳房大小的1/3；严重萎缩	-	-
乳房疼痛 定义：特征为乳房区域具有明显不适感的症状。	轻度疼痛	中度疼痛；工具性ADL受限	重度疼痛；自理ADL受限	-	-
痛经 定义：特征为月经时出现异常腹部痛性痉挛的病症。	轻度症状，无需介入	中度症状；工具性ADL受限	重度症状；自理ADL受限	-	-
性交困难 定义：特征为性交困难或疼痛的病症。	阴道插入有轻度不适或疼痛；使用阴道润滑剂或雌激素后，不适缓解	阴道插入有中度不适或疼痛；使用阴道润滑剂或雌激素后，不适部分缓解	阴道插入有重度不适或疼痛；使用阴道润滑剂或雌激素后，不适无法缓解	-	-
射精障碍 定义：特征为射精相关问题的病症，包括早泄、射精延迟、逆行或疼痛。	射精减少	不射精或逆行射精	-	-	-
勃起功能障碍 定义：特征为在性交时，持续或复发的无法实现或维持勃起的病症。	勃起机能下降（勃起的频率和强度），但无需介入（药物治疗或使用机械装置如阴茎泵）	勃起机能下降（勃起的频率和强度），需要介入（药物治疗或使用机械装置如阴茎泵）	勃起机能下降（勃起的频率和强度），但介入无效（药物治疗或使用机械装置如阴茎泵），需要安装永久的人工阴茎（不是之前存在的）	-	-
输卵管阻塞 定义：特征为输卵管正常流量的内容物被阻断的病症。	仅作诊断观察，无需介入	中度症状，需要选择性介入	重度症状，需要选择性手术介入	-	-
输卵管狭窄 定义：特征为输卵管腔狭窄的病症。	无症状，仅有临床或诊断观察结果；无需介入	有症状；无需介入	症状严重；需要选择性手术介入	危及生命的后果；需要紧急手术介入（如器官切除术）	死亡
女性生殖道瘘 定义：特征为女性生殖系统器官和另一个器官或解剖部位有异常通道的病症。	无症状，仅有临床或诊断观察结果；无需介入	有症状；无需介入	症状严重；需要选择性手术介入	危及生命的后果；需要紧急介入	死亡
后天的男子女性化 定义：特征为由于外因引起男性的女性第二性征发育的病症。	轻度症状，无需介入	中度症状，需要医学介入	-	-	-
生殖器水肿 定义：特征为由于生殖器内液体过度累积导致肿胀的病症。	近距离观察可见轻微的肿胀和解剖学架构模糊	明显的解剖学架构模糊；皮肤褶皱消失；与正常解剖学外观有明显偏差	淋巴溢；与正常解剖学外观有巨大偏差；自理ADL受限	-	-
男子女性型乳房 定义：特征为男性乳房过度发育的病症。	无症状性乳房增大	有症状（疼痛或精神影响）	严重症状；需要选择性手术介入	-	-
输卵管积血	通过影像研究或腹腔镜检查出血极少，无需介入	出血量中等，需要医学介入	出血严重；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡

Reproductive system and breast disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by the presence of blood in a fallopian tube.					
Irregular menstruation	Intermittent menses with skipped menses for no more than 1 to 3 months	Intermittent menses with skipped menses for more than 4 to 6 months	Persistent amenorrhea for more than 6 months	-	-
Definition: A disorder characterized by irregular cycle or duration of menses.					
Lactation disorder	Mild changes in lactation, not significantly affecting production or expression of breast milk	Changes in lactation, significantly affecting breast production or expression of breast milk	-	-	-
Definition: A disorder characterized by disturbances of milk secretion. It is not necessarily related to pregnancy that is observed in females and can be observed in males.					
Menorrhagia	Mild; iron supplements indicated	Moderate symptoms; medical intervention indicated (e.g., hormones)	Severe; transfusion indicated; surgical intervention indicated (e.g., hysterectomy)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by abnormally heavy vaginal bleeding during menses.					
Nipple deformity	Asymptomatic; asymmetry with slight retraction and/or thickening of the nipple areolar complex	Symptomatic; asymmetry of nipple areolar complex with moderate retraction and/or thickening of the nipple areolar complex	-	-	-
Definition: A disorder characterized by a malformation of the nipple.					
Oligospermia	Sperm concentration >48 million/mL or motility >68%	Sperm concentration 13 - 48 million/mL or motility 32 - 68%	Sperm concentration <13 million/mL or motility <32%	-	-
Definition: A disorder characterized by a decrease in the number of spermatozoa in the semen.					
Ovarian hemorrhage	Minimal bleeding identified on imaging study or laparoscopy; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by bleeding from the ovary.					
Ovarian rupture	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by tearing or disruption of the ovarian tissue.					
Ovulation pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in one side of the abdomen between menstrual cycles, around the time of the discharge of the ovum from the ovarian follicle.					
Pelvic floor muscle weakness	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic, not interfering with bladder, bowel, or vaginal function; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a reduction in the strength of the muscles of the pelvic floor.					
Pelvic pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the pelvis.					
Penile pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the penis.					
Perineal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the area between the genital organs and the anus.					
Premature menopause	-	-	Present	-	-
Definition: A disorder characterized by ovarian failure before the age of 40. Symptoms include hot flashes, night sweats, mood swings and a decrease in sex drive.					
Prostatic hemorrhage	Minimal bleeding identified on imaging study; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death

生殖系统和乳房病症					
不良事件	分级				
	1	2	3	4	5
定义：特征为输卵管出血的病症。					
月经不调	间歇性月经伴随月经周期跳跃，不超过 1-3 月	间歇性月经伴随月经周期跳跃，超过 4-6 月	持续 6 个月无月经	-	-
定义：特征为不规则月经周期的病症。					
乳汁分泌紊乱	乳汁分泌有轻度变化，不会显著影响母乳产量和表达	乳汁分泌有变化，会显著影响母乳产量和表达	-	-	-
定义：特征为乳汁分泌紊乱的病症。与怀孕无必然联系，男性和女性中都能观察到。					
月经过多	轻度症状；需要补充铁剂	中度症状；需要医学介入（如激素）	重度症状；需要输血和外科手术（如子宫切除术）	危及生命的后果；需要紧急介入	死亡
定义：特征为月经时不正常的大量阴道出血的病症。					
乳头畸形	无症状；不对称伴有乳头乳晕复合体轻度萎缩和/或增厚	有症状；不对称伴有乳头乳晕复合体中度萎缩和/或增厚	-	-	-
定义：特征为乳头畸形的病症。					
少精液症	精子浓度 > 48 百万/毫升或活动能力 > 68%	精子浓度 13-48 百万/毫升或活动能力 32-68%	精子浓度 < 13 百万/毫升或活动能力 < 32%	-	-
定义：特征为精液中精子数量减少的病症。					
卵巢出血	通过影像学或腹腔镜检查，发现最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡
定义：特征为卵巢出血的病症。					
卵巢破裂	无症状，仅有临床或诊断观察结果；无需介入	有症状，不需要介入	需要输血、放射治疗、内窥镜检查或需要选择性手术介入	危及生命的后果；需要紧急介入	死亡
定义：特征为卵巢组织撕裂或破裂的病症。					
排卵痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为大约在卵巢中的卵子排出时间前后，月经周期之间腹部的一侧感到显著不适的病症。					
骨盆底肌无力	无症状；仅有临床或诊断观察结果；无需介入	有症状，但不影响膀胱、肠或阴道功能；工具性 ADL 受限	症状严重；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡
定义：特征为骨盆底肌肉强度降低的病症。					
骨盆痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为骨盆有显著不适感的病症。					
阴茎痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为阴茎有显著不适感的病症。					
会阴痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为生殖器官和肛门之间区域有显著不适感的病症。					
过早绝经	-	-	存在	-	-
定义：特征为 40 岁之前卵巢衰竭的病症。症状包括热潮红、盗汗、心境不稳和性欲下降。					
前列腺出血	通过影像学检查观察到最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡

Reproductive system and breast disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by bleeding from the prostate gland.					
Prostatic obstruction	Diagnostic observations only; intervention not indicated	Mild symptoms; elective intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by compression of the urethra secondary to enlargement of the prostate gland. This results in voiding difficulties (straining to void, slow urine stream, and incomplete emptying of the bladder).					
Prostatic pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the prostate gland.					
Scrotal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the scrotal area.					
Spermatic cord hemorrhage	Minimal bleeding identified on imaging study; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by bleeding from the spermatic cord.					
Spermatic cord obstruction	Diagnostic observations only; intervention not indicated	Mild symptoms; elective intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by blockage of the normal flow of the contents of the spermatic cord.					
Testicular disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic but not interfering with urination or sexual activities; intervention not indicated; limiting instrumental ADL	Severe symptoms; interfering with urination or sexual function; limiting self care ADL; intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by involvement of the testis.					
Testicular hemorrhage	Minimal bleeding identified on imaging study; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by bleeding from the testis.					
Testicular pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the testis.					
Uterine fistula	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the uterus and another organ or anatomic site.					
Uterine hemorrhage	Minimal bleeding identified on imaging study; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by bleeding from the uterus.					
Uterine obstruction	Diagnostic observations only; intervention not indicated	Mild symptoms; elective intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by blockage of the uterine outlet.					
Uterine pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the uterus.					
Vaginal discharge	Mild vaginal discharge (greater than baseline for patient)	Moderate to heavy vaginal discharge; use of perineal pad or tampon indicated	-	-	-
Definition: A disorder characterized by vaginal secretions. Mucus produced by the cervical glands is discharged from the vagina naturally, especially during the childbearing years.					
Vaginal dryness	Mild vaginal dryness not interfering with sexual function	Moderate vaginal dryness interfering with sexual function or causing frequent discomfort	Severe vaginal dryness resulting in dyspareunia or severe discomfort	-	-
Definition: A disorder characterized by an uncomfortable feeling of itching and burning in the vagina.					

生殖系统和乳房病症					
不良事件	分级				
	1	2	3	4	5
定义：特征为前列腺出血的病症。					
前列腺梗阻	仅需诊断观察；无需介入	轻度症状；需要选择性介入	重度症状；需要选择性手术介入	-	-
定义：特征为前列腺增大伴随尿道压迫的病症。将导致排泄困难（无法滤过、减慢尿液流速和膀胱排空不完全）。					
前列腺痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为前列腺有显著不适感的病症。					
阴囊痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为阴囊区域有显著不适感的病症。					
精索出血	通过影像学检查观察到最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡
定义：特征为精索出血的病症。					
精索梗阻	仅有诊断观察结果；无需介入	轻度症状；需要选择性介入	重度症状；需要选择性手术介入	-	-
定义：特征为精索正常流量的内容物被阻断的病症。					
睾丸病症	无症状，仅有临床或诊断观察结果；无需介入	有症状，但不影响排尿或性行为；无需介入；工具性 ADL 受限	严重症状；影响排尿或性行为；自理 ADL 受限；需要介入	危及生命的后果；需要紧急介入	死亡
定义：特征为牵涉睾丸的病症。					
睾丸出血	通过影像学检查观察到最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡
定义：特征为睾丸出血的病症。					
睾丸痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为睾丸有显著不适感的病症。					
子宫瘘	无症状，仅需临床或诊断观察；无需介入	有症状；无需介入	严重症状；可选择手术介入	危及生命的后果；需要紧急介入	死亡
定义：特征为子宫和另一个器官或解剖部位有异常通道的病症。					
子宫出血	通过影像学检查观察到最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡
定义：特征为子宫出血的病症。					
子宫梗阻	仅有诊断观察结果；无需介入	轻度症状；需要选择性介入	重度症状；需要选择性手术介入	-	-
定义：特征为子宫出口被阻塞的病症。					
子宫疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为子宫有显著不适感的病症。					
阴道分泌物增多	阴道轻度增多（比病人的基线水平多）	中到重度的阴道分泌物增多；需要使用会阴垫或棉球	-	-	-
定义：特征为与阴道分泌物相关的病症。子宫颈淋巴结产生的粘液从阴道自然地流出，尤其在育龄。					
阴道干燥	轻度的阴道干燥，不妨碍性交	中度的阴道干燥，妨碍性交或造成频繁的不适	严重的阴道干燥，导致性交困难或严重不适	-	-
定义：特征为阴道内有搔痒和灼热不适感的病症。					

CTCAE v4.0

Reproductive system and breast disorders					
Adverse Event	Grade				
	1	2	3	4	5
Vaginal fistula	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the vagina and another organ or anatomic site.					
Vaginal hemorrhage	Minimal bleeding identified on clinical exam or imaging study; intervention not indicated	Moderate bleeding; medical intervention indicated	Severe bleeding; transfusion indicated; radiologic or endoscopic intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Definition: A disorder characterized by bleeding from the vagina.					
Vaginal inflammation	Mild discomfort or pain, edema, or redness	Moderate discomfort or pain, edema, or redness; limiting instrumental ADL	Severe discomfort or pain, edema, or redness; limiting self care ADL; small areas of mucosal ulceration	Widespread areas of mucosal ulceration; life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation involving the vagina. Symptoms may include redness, edema, marked discomfort and an increase in vaginal discharge.					
Vaginal obstruction	Diagnostic observations only; intervention not indicated	Mild symptoms; elective intervention indicated	Severe symptoms; elective operative intervention indicated	-	-
Definition: A disorder characterized by blockage of vaginal canal.					
Vaginal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by a sensation of marked discomfort in the vagina.					
Vaginal perforation	Asymptomatic clinical or diagnostic observations only; intervention not indicated	Symptomatic and intervention not indicated	Severe symptoms; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a rupture in the vaginal wall.					
Vaginal stricture	Asymptomatic; mild vaginal shortening or narrowing	Vaginal narrowing and/or shortening not interfering with physical examination	Vaginal narrowing and/or shortening interfering with the use of tampons, sexual activity or physical examination	-	Death
Definition: A disorder characterized by a narrowing of the vaginal canal.					
Vaginismus	Mild discomfort or pain associated with vaginal spasm/tightening; no impact upon sexual function or physical examination	Moderate discomfort or pain associated with vaginal spasm/tightening; disruption in sexual function and physical examination	Severe discomfort or pain associated with vaginal spasm/tightening; unable to tolerate vaginal penetration or physical examination	-	-
Definition: A disorder characterized by involuntary spasms of the pelvic floor muscles, resulting in pathologic tightness of the vaginal wall during penetration such as during sexual intercourse.					
Reproductive system and breast disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

生殖系统和乳房病症					
不良事件	分级				
	1	2	3	4	5
阴道瘘	无症状，仅有临床或诊断观察结果；无需介入	有症状；无需介入	严重症状；可选择手术介入	危及生命的后果；需要紧急介入	死亡
定义：特征为阴道和另一个器官或解剖部位有异常通道的病症。					
阴道出血	通过临床或影像学检查观察到最低程度的出血；无需介入	中度出血；需要医学介入	严重出血；需要输血；需要放射或内窥镜介入	危及生命的后果；需要紧急手术介入	死亡
定义：特征为阴道出血的病症。					
阴道发炎	轻度不适或疼痛，水肿或发红	中度不适或疼痛，水肿或发红；工具性 ADL 受限	重度不适或疼痛，水肿或发红；自理 ADL 受限；小范围粘膜溃疡形成	大范围粘膜溃疡形成；危及生命的后果；需要紧急介入	死亡
定义：特征为阴道发炎的病症。症状可能包括发红、水肿、显著不适和增加阴道溢液。					
阴道梗阻	仅有诊断观察结果；无需介入	轻度症状；需要选择性介入	重度症状；需要选择性手术介入	-	-
定义：特征为阴道腔阻塞的病症。					
阴道疼痛	轻度疼痛	中度疼痛；工具性 ADL 受限	重度疼痛；自理 ADL 受限	-	-
定义：特征为阴道有显著不适感的病症。					
阴道穿孔	无症状，仅有临床或诊断观察结果；无需介入	有症状，无需介入；	严重症状；可选择手术介入	危及生命的后果；需要紧急介入	死亡
定义：特征为阴道壁破裂的病症。					
阴道狭窄	无症状；轻度的阴道缩短或变窄	阴道变窄和/或缩短，但不妨碍体检	阴道变窄和/或缩短，会妨碍使用棉球、性行为或体检		死亡
定义：特征为阴道腔狭窄的病症。					
阴道痉挛	与阴道痉挛/收紧有关的轻度不适或疼痛；不影响性功能或体检	与阴道痉挛/收紧有关的中度不适或疼痛；在性行为或体检中会破裂	与阴道痉挛/收紧有关的严重不适或疼痛；无法忍受阴道穿透或体检	-	-
定义：特征为骨盆底肌肉无意识痉挛的病症，导致阴道壁在穿透如性交时出现病理性紧缩。					
生殖系统和乳房病症—其它，指定	无症状或轻度症状，仅有临床或诊断观察结果；无需介入	中度症状；需要最低程度、局部或非侵入性介入；年龄适合的工具性 ADL 受限	重度症状或临床上具有显著意义，但不会立刻危及生命；需要住院或延长住院时间；残疾；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Adult respiratory distress syndrome	-	-	Present with radiologic findings; intubation not indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by progressive and life-threatening pulmonary distress in the absence of an underlying pulmonary condition, usually following major trauma or surgery.					
Allergic rhinitis	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by an inflammation of the nasal mucous membranes caused by an IgE-mediated response to external allergens. The inflammation may also involve the mucous membranes of the sinuses, eyes, middle ear, and pharynx. Symptoms include sneezing, nasal congestion, rhinorrhea and itching.					
Apnea	-	-	Present; medical intervention indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by cessation of breathing.					
Aspiration	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Altered eating habits; coughing or choking episodes after eating or swallowing; medical intervention indicated (e.g., suction or oxygen)	Dyspnea and pneumonia symptoms (e.g., aspiration pneumonia); hospitalization indicated; unable to aliment orally	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by inhalation of solids or liquids into the lungs.					
Atelectasis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., dyspnea, cough); medical intervention indicated (e.g., chest physiotherapy, suctioning); bronchoscopic suctioning	Oxygen indicated; hospitalization or elective operative intervention indicated (e.g., stent, laser)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by the collapse of part or the entire lung.					
Bronchial fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical management indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention with thoracoplasty, chronic open drainage or multiple thoracotomies indicated	Death
Definition: A disorder characterized by an abnormal communication between the bronchus and another organ or anatomic site.					
Bronchial obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., mild wheezing); endoscopic evaluation indicated; radiographic evidence of atelectasis/lobar collapse; medical management indicated (e.g., steroids, bronchodilators)	Shortness of breath with stridor; endoscopic intervention indicated (e.g., laser, stent placement)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by blockage of a bronchus passage, most often by bronchial secretions and exudates.					
Bronchial stricture	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., rhonchi or wheezing) but without respiratory distress; medical intervention indicated (e.g., steroids, bronchodilators)	Shortness of breath with stridor; endoscopic intervention indicated (e.g., laser, stent placement)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by a narrowing of the bronchial tube.					
Bronchopleural fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention with thoracoplasty, chronic open drainage or multiple thoracotomies indicated	Death
Definition: A disorder characterized by an abnormal communication between a bronchus and the pleural cavity.					
Bronchopulmonary hemorrhage	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the bronchial wall and/or lung parenchyma.					

呼吸、胸和纵隔病症					
不良事件	分级				
	1	2	3	4	5
成人呼吸窘迫综合症	-	-	X射线发现存在； 无需插管	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为进展性和危及生命的肺部疾病（肺部状态未知），通常发生在大的创伤或手术后。					
过敏性鼻炎	轻度症状；无需介入	中度症状；需要医学介入	-	-	-
定义：特征为IgE介导对外部致敏原的反应，导致鼻粘膜发炎的病症。此炎症也涉及鼻窦、眼、中耳和咽的粘膜。症状包括喷嚏、鼻塞、鼻涕溢和搔痒。					
呼吸暂停	-	-	存在；需要医学介 入	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为呼吸停止的病症。					
吸入异物	无症状，仅有临床或 诊断观察结果；无需 介入	改变饮食习惯；吃或咽后出 现咳嗽或气哽；需要医学介 入（如抽吸或吸氧）	呼吸困难和肺炎症 状（如吸入性肺 炎）；需要住院；无 法经口进食	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为肺中吸入固体和液体的病症。					
肺膨胀不全	无症状，仅有临床或 诊断观察结果；无需 介入	有症状（如呼吸困难，咳 嗽）；需要医学介入（如胸 部物理治疗，抽痰）；支气 管镜抽痰	需要吸氧；住院或 需要选择性手术介 入（如支架，激 光）	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为部分肺塌陷的病症。					
支气管瘘	无症状，仅有临床或 诊断观察结果；无需 介入	有症状，需要导管胸廓造口 术或医疗处理；工具性ADL 受限	严重症状；自理 ADL受限；需要内 窥镜检查或手术介 入（如支架或原发 性闭合）	危及生命的后 果；需要紧急手 术介入（胸廓成 形术）、慢性开放 引流或多重开胸 术	死亡
定义：特征为支气管和另一个器官或解剖部位有异常通道的病症。					
支气管梗阻	无症状，仅有临床或 诊断观察结果；无需 介入	有症状（如轻度喘鸣）；需 要内窥镜评价；肺膨胀不全 或塌陷的X线照片影像；需 要医疗处理（如类固醇， 支气管扩张剂）	呼吸急促伴随喘 鸣；需要内窥镜介 入（如激光，支架 安置）	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为支气管通路阻断的病症，通常由支气管分泌物或渗出液引起。					
支气管狭窄	无症状，仅有临床或 诊断观察结果；无需 介入	有症状（如鼾音或喘鸣）， 但没有呼吸性窘迫；需要医 学介入（如类固醇，支气 管扩张剂）	呼吸急促伴随喘 鸣；需要内窥镜介 入（如激光，支架 更换）	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为支气管狭窄的病症。					
支气管胸膜瘘	无症状，仅有临床或 诊断观察结果；无需 介入	有症状，需要导管胸廓造口 术或医疗处理；工具性ADL 受限	严重症状；自理 ADL受限；需要内 窥镜检查或手术介 入（如支架或原发 性闭合）	危及生命的后 果；需要紧急手 术介入（胸廓成 形术、慢性开放 引流或多重开胸 术）	死亡
定义：特征为支气管和胸膜腔之间有异常通道的病症。					
肺支气管出血	轻度症状；无需介入	中度症状；需要医学介入	需要输血、放射、 内窥镜或手术介入 （如出血位点的止 血）	危及生命的呼吸 或血液动力学损 伤；需要插管或 紧急介入	死亡
定义：特征为支气管壁和/或肺实质出血的病症。					

CTCAE v4.0

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Bronchospasm	Mild symptoms; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Limiting self care ADL; oxygen saturation decreased	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by a sudden contraction of the smooth muscles of the bronchial wall.					
Chylothorax	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thoracentesis or tube drainage indicated	Severe symptoms; elective operative intervention indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by milky pleural effusion (abnormal collection of fluid) resulting from accumulation of lymph fluid in the pleural cavity.					
Cough	Mild symptoms; nonprescription intervention indicated	Moderate symptoms, medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs and usually accompanied by a distinctive sound.					
Dyspnea	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an uncomfortable sensation of difficulty breathing.					
Epistaxis	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated (e.g., nasal packing, cauterization; topical vasoconstrictors)	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the nose.					
Hiccups	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe symptoms; interfering with sleep; limiting self care ADL	-	-
Definition: A disorder characterized by repeated gulp sounds that result from an involuntary opening and closing of the glottis. This is attributed to a spasm of the diaphragm.					
Hoarseness	Mild or intermittent voice change; fully understandable; self-resolves	Moderate or persistent voice changes; may require occasional repetition but understandable on telephone; medical evaluation indicated	Severe voice changes including predominantly whispered speech	-	-
Definition: A disorder characterized by harsh and raspy voice arising from or spreading to the larynx.					
Hypoxia	-	Decreased oxygen saturation with exercise (e.g., pulse oximeter <88%); intermittent supplemental oxygen	Decreased oxygen saturation at rest (e.g., pulse oximeter <88% or PaO2 <=55 mm Hg)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by a decrease in the level of oxygen in the body.					
Laryngeal edema	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated (e.g., dexamethasone, epinephrine, antihistamines)	Stridor; respiratory distress; hospitalization indicated	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by swelling due to an excessive accumulation of fluid in the larynx.					
Laryngeal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical management indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention indicated (e.g., thoracoplasty, chronic open drainage or multiple thoracotomies)	Death
Definition: A disorder characterized by an abnormal communication between the larynx and another organ or anatomic site.					
Laryngeal hemorrhage	Mild cough or trace hemoptysis; laryngoscopic findings	Moderate symptoms; medical intervention indicated	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by bleeding from the larynx.					
Laryngeal inflammation	Mild sore throat; raspy voice	Moderate sore throat; analgesics indicated	Severe throat pain; endoscopic intervention indicated	-	-
Definition: A disorder characterized by an inflammation involving the larynx.					

呼吸、胸和纵隔病症					
不良事件	分级				
	1	2	3	4	5
支气管痉挛	轻度症状；无需介入	有症状，需要医学介入；工具性 ADL 受限	自理 ADL 受限；氧饱和度降低	危及生命的呼吸或血液动力学损伤；需要插管或紧急介入	死亡
定义：特征为支气管壁的平滑肌收缩的病症。					
乳糜胸	无症状，仅有临床或诊断观察结果；无需介入	有症状；需要胸腔穿刺术或导管引流	严重症状；需要选择性手术介入	危及生命的呼吸或血液动力学损伤；需要插管或紧急介入	死亡
定义：特征为由于胸膜腔的淋巴液累积导致乳汁胸膜积液（液体的异常积聚）的病症。					
咳嗽	轻度症状；需要非处方药介入	中度症状，需要医学介入；工具性 ADL 受限	症状严重；自理 ADL 受限	-	-
定义：特征为胸腔突然的、常为反复痉挛性收缩的病症，会导致从肺中剧烈地释放空气，并伴随特别的声音。					
呼吸困难	中等体力劳动时呼吸急促	最低程度的体力劳动时呼吸急促；工具性 ADL 受限	休息时呼吸急促；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡
定义：特征为呼吸困难有不适感的病症。					
鼻出血	轻度症状；无需介入	中度症状；需要医学介入（如鼻填塞术、烧灼术、局部血管收缩）	需要输血、放射、内窥镜或手术介入（如出血位点的止血）	危及生命的后果；需要紧急介入	死亡
定义：特征为鼻子出血的病症。					
呃逆	轻度症状；无需介入	中度症状；需要医学介入；工具性 ADL 受限	严重症状；妨碍睡眠；自理 ADL 受限；	-	-
定义：特征为由于不自觉的打开和关闭声门引起反复呛声的病症，归因于膈膜痉挛。					
声嘶	轻度或间歇的嗓音改变；可以完全听懂；会自身缓解	中度或持续的嗓音改变；电话交流偶尔需要重复，但仍然可以理解；需要医学评估	严重的嗓音改变，包括大部分的耳语	-	-
定义：特征为来源或扩散至喉部，引起粗糙和刺耳嗓音的病症。					
缺氧	-	活动时氧饱和度降低（如脉搏血氧计 < 88%）；需要间歇的辅助供氧	休息时氧饱和度降低（如脉搏血氧计 < 88% 或 PaO ₂ <= 55 mmHg）	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为体内氧浓度下降的病症。					
喉头水肿	无症状，仅有临床或诊断观察结果；无需介入	有症状，需要医学介入（如地塞米松、肾上腺素、抗组胺类）	喘鸣；呼吸性窘迫；需要住院治疗	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为喉头内液体过度累积导致肿胀的病症。					
喉痿	无症状，仅有临床或诊断观察结果；无需介入	有症状，需要导管胸廓造口术或医疗处理；工具性 ADL 受限	严重症状；自理 ADL 受限；需要内窥镜检查或手术介入（如支架或原发性闭合）	危及生命的后果；需要紧急手术介入（如胸廓成形术、慢性开放引流或多重开胸术）	死亡
定义：特征为喉和另一个器官或解剖部位有异常通道的病症。					
喉出血	轻度咳嗽或痕量咯血；有喉镜检查结果	中度症状；需要医学介入	需要输血、放射、内窥镜或手术介入（如出血位点的止血）	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为喉出血的病症。					
喉发炎	轻度喉咙痛；嗓音粗糙	中度喉咙痛；需要镇痛药	严重喉咙痛；需要内窥镜检查介入	-	-
定义：特征为喉发炎的病症。					

CTCAE v4.0

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Laryngeal mucositis	Endoscopic findings only; mild discomfort with normal intake	Moderate discomfort; altered oral intake	Severe pain; severely altered eating/swallowing; medical intervention indicated	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by an inflammation involving the mucous membrane of the larynx.					
Laryngeal obstruction	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), but causing no respiratory distress; medical management indicated (e.g., steroids); limiting instrumental ADL	Limiting self care ADL; stridor; endoscopic intervention indicated (e.g., stent, laser)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by blockage of the laryngeal airway.					
Laryngeal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), but causing no respiratory distress; medical management indicated (e.g., steroids)	Limiting self care ADL; stridor; endoscopic intervention indicated (e.g., stent, laser)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a narrowing of the laryngeal airway.					
Laryngopharyngeal dysesthesia	Mild symptoms; no anxiety; intervention not indicated	Moderate symptoms; mild anxiety, but no dyspnea; short duration of observation and or anxiolytic indicated; limiting instrumental ADL	Severe symptoms; dyspnea and swallowing difficulty; limiting self care ADL	Life-threatening consequences	Death
Definition: A disorder characterized by an uncomfortable persistent sensation in the area of the laryngopharynx.					
Laryngospasm	-	Transient episode; intervention not indicated	Recurrent episodes; noninvasive intervention indicated (e.g., breathing technique, pressure point massage)	Persistent or severe episodes associated with syncope; urgent intervention indicated (e.g., fiberoptic laryngoscopy, intubation, botox injection)	Death
Definition: A disorder characterized by paroxysmal spasmodic muscular contraction of the vocal cords.					
Mediastinal hemorrhage	Radiologic evidence only; minimal symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the mediastinum.					
Nasal congestion	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Associated with bloody nasal discharge or epistaxis	-	-
Definition: A disorder characterized by obstruction of the nasal passage due to mucosal edema.					
Pharyngeal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an abnormal communication between the pharynx and another organ or anatomic site.					
Pharyngeal hemorrhage	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the pharynx.					
Pharyngeal mucositis	Endoscopic findings only; minimal symptoms with normal oral intake; mild pain but analgesics not indicated	Moderate pain and analgesics indicated; altered oral intake; limiting instrumental ADL	Severe pain; unable to adequately aliment or hydrate orally; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an inflammation involving the mucous membrane of the pharynx.					
Pharyngeal necrosis	-	-	Inability to aliment adequately by GI tract; tube feeding or TPN indicated; radiologic, endoscopic, or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death

呼吸、胸和纵隔病症					
不良事件	分级				
	1	2	3	4	5
喉粘膜炎	仅内镜检查可见；正常摄入时有轻度不适	中度不适；需要改变经口摄入方式	重度疼痛；极大地改变进食/吞咽方式；需要医学介入	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为喉粘膜发炎的病症。					
喉梗阻	无症状；仅有临床或诊断观察结果；无需介入	有症状（如气道呼吸有杂音），但不会引起呼吸性窘迫；需要医疗处理（如类固醇）；工具性 ADL 受限	自理 ADL 受限；喘鸣；需要内窥镜介入（如支架，激光）	危及生命的后果；需要紧急介入	死亡
定义：特征为喉气道阻塞的病症。					
喉狭窄	无症状，仅需临床或诊断观察；无需介入	有症状（如气道呼吸有杂音），但不会引起呼吸性窘迫；需要医疗处理（如类固醇）	自理 ADL 受限；喘鸣；需要内窥镜介入（如支架，激光）	危及生命的后果；需要紧急介入	死亡
定义：特征为喉气道狭窄的病症。					
咽喉触物感痛	轻度症状；无焦虑；无需介入	中度症状；轻度焦虑，无呼吸困难；需要短时间观察和/或抗焦虑剂；工具性 ADL 受限	严重症状；呼吸和吞咽困难；自理 ADL 受限	危及生命的后果	死亡
定义：特征为咽喉区域有持续不适感的病症。					
喉痉挛	-	暂时性发作；无需介入	重复发作；需要非侵入性介入（如呼吸技术，压点按摩）	持续或严重发作，伴有昏厥；需要紧急介入（如纤维光学喉镜检查、插管、注射 A 型肉毒毒素制剂）	死亡
定义：特征为声带间歇性肌肉收缩发作的病症。					
纵隔出血	仅有放射学证据；最低程度的症状；无需介入	中度症状；需要医学介入	需要输血、放射、内窥镜或可选择手术介入（如出血位点的止血）	危及生命的后果；需要紧急介入	死亡
定义：特征为纵隔出血的病症。					
鼻充血	轻度症状；无需介入	中度症状；需要医学介入	与鼻衄或鼻出血相关	-	-
定义：特征为由于粘膜水肿使鼻道阻塞的病症。					
咽痿	无症状，仅有临床或诊断观察结果；无需介入	有症状，需要导管胸廓造口术或医疗处理；工具性 ADL 受限	严重症状；自理 ADL 受限；需要内窥镜检查或手术介入（如支架或原发性闭合）	危及生命的后果；需要紧急介入	死亡
定义：特征为咽和另一个器官或解剖部位有异常通道的病症。					
咽出血	轻度症状；无需介入	中度症状；需要医学介入	输血、放射、内窥镜或手术介入（如出血位点的止血）	危及生命的呼吸或血液动力学损伤；需要插管或紧急介入	死亡
定义：特征为咽出血的病症。					
咽粘膜炎	仅内镜检查可见，正常经口摄入时有最低程度的不适；轻度疼痛但无需镇痛药	中度疼痛，需要镇痛药；改变经口摄入方式；工具性 ADL 受限	重度疼痛；无法经口足够地补充食物和水合物；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡
定义：特征为涉及咽粘膜发炎的病症。					
咽坏死	-	-	无法经胃肠道给予充足的食物；需要喂食管或全胃肠外营养；需要放射、内窥镜或手术介入	危及生命的后果；需要紧急手术介入	死亡

CTCAE v4.0

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by a necrotic process occurring in the pharynx.					
Pharyngeal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), but causing no respiratory distress; medical management indicated (e.g., steroids); limiting instrumental ADL	Limiting self care ADL; stridor; endoscopic intervention indicated (e.g., stent, laser)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by a narrowing of the pharyngeal airway.					
Pharyngolaryngeal pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the pharyngolaryngeal region.					
Pleural effusion	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; intervention indicated (e.g., diuretics or limited therapeutic thoracentesis)	Symptomatic with respiratory distress and hypoxia; surgical intervention including chest tube or pleurodesis indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by an increase in amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough and marked chest discomfort.					
Pleural hemorrhage	Asymptomatic; mild hemorrhage confirmed by thoracentesis	Symptomatic or associated with pneumothorax; chest tube drainage indicated	>1000 ml of blood evacuated; persistent bleeding (150-200 ml/hr for 2 - 4 hr); persistent transfusion indicated; elective operative intervention indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by bleeding from the pleural cavity.					
Pleuritic pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the pleura.					
Pneumonitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by inflammation focally or diffusely affecting the lung parenchyma.					
Pneumothorax	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; intervention indicated (e.g., tube placement without sclerosis)	Sclerosis and/or operative intervention indicated; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by abnormal presence of air in the pleural cavity resulting in the collapse of the lung.					
Postnasal drip	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by excessive mucous secretion in the back of the nasal cavity or throat, causing sore throat and/or coughing.					
Productive cough	Occasional/minimal production of sputum with cough	Moderate sputum production; limiting instrumental ADL	Persistent or copious production of sputum; limiting self care ADL	-	-
Definition: A disorder characterized by expectorated secretions upon coughing.					
Pulmonary edema	Radiologic findings only; minimal dyspnea on exertion	Moderate dyspnea on exertion; medical intervention indicated; limiting instrumental ADL	Severe dyspnea or dyspnea at rest; oxygen indicated; limiting self care ADL	Life-threatening respiratory compromise; urgent intervention or intubation with ventilatory support indicated	Death
Definition: A disorder characterized by accumulation of fluid in the lung tissues that causes a disturbance of the gas exchange that may lead to respiratory failure.					
Pulmonary fibrosis	Mild hypoxemia; radiologic pulmonary fibrosis < 25% of lung volume	Moderate hypoxemia; evidence of pulmonary hypertension; radiographic pulmonary fibrosis 25-50%	Severe hypoxemia; evidence of right-sided heart failure; radiographic pulmonary fibrosis >50 - 75%	Life-threatening consequences (e.g., hemodynamic/pulmonary complications); intubation with ventilatory support indicated; radiographic pulmonary fibrosis >75% with severe honeycombing	Death
Definition: A disorder characterized by the replacement of the lung tissue by connective tissue, leading to progressive dyspnea, respiratory failure or right heart failure.					
Pulmonary fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical management indicated; limiting instrumental ADL	Limiting self care ADL; endoscopic stenting or operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death

呼吸、胸和纵隔病症					
不良事件	分级				
	1	2	3	4	5
定义：特征为咽部发生坏死进程的病症。					
咽狭窄	无症状，仅需临床或诊断观察；无需介入	有症状（如气道呼吸有杂音），但不会引起呼吸性窘迫；需要医疗处理（如类固醇）；工具性ADL受限	自理ADL受限；喘鸣；需要内窥镜介入（如支架，激光）	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为咽导气管狭窄的病症。					
咽喉痛	轻度疼痛	中度疼痛；工具性ADL受限	严重疼痛；自理ADL受限	-	-
定义：特征为咽喉区域有显著不适感的病症。					
胸膜积液	无症状；仅需临床或诊断观察；无需介入	有症状；需要介入（如利尿剂或限制治疗的胸腔穿刺术）	呼吸性窘迫和缺氧症状；需要手术介入，包括胸管或胸膜固定术	危及生命的呼吸或血液动力学损伤；需要插管或紧急介入	死亡
定义：特征为胸膜腔内增加大量液体的病症。症状包括呼吸急促、咳嗽和显著的胸部不适。					
胸膜出血	无症状，胸腔穿刺术证实的轻度出血	有症状或与气胸相关；需要胸管引流	>1000 ml的血排出；持续出血（2-4小时，每小时150-200毫升）；需要持续输血；选择性手术介入	危及生命的呼吸或血液动力学损伤；需要插管或紧急介入	死亡
定义：特征为胸膜腔出血的病症。					
胸膜痛	轻度疼痛	中度疼痛；工具性ADL受限	重度疼痛；自理ADL受限	-	-
定义：特征为胸膜有显著不适感的病症。					
肺炎	无症状，仅需临床或诊断观察；无需介入	有症状；需要医学介入；工具性ADL受限	严重症状；自理ADL受限；需要吸氧	危及生命的呼吸损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为炎症局部或扩散影响肺实质的病症。					
气胸	无症状，仅需临床或诊断观察；无需介入	有症状；需要介入（如无硬化症的导管更换）	硬化症和/或手术介入；需要住院	危及生命的后果；需要紧急介入	死亡
定义：特征为胸膜腔存在异常气体导致肺萎陷的病症。					
后鼻滴涕	轻度症状；无需介入	中度症状；需要医学介入	-	-	-
定义：特征为鼻腔或咽后部出现过度粘液分泌，导致喉咙痛和/或咳嗽的病症。					
排痰性咳嗽	咳嗽时偶尔/最低程度生痰	中度生痰；工具性ADL受限	持续或大量生痰；自理ADL受限	-	-
定义：特征为咳嗽时咳出分泌物的病症。					
肺水肿	仅X射线片可发现；最低程度的劳力性呼吸困难	中度劳力性呼吸困难；需要医学介入；工具性ADL受限	严重呼吸困难或休息时呼吸困难；需要吸氧；自理ADL受限	危及生命的呼吸损伤；需要紧急介入或插管以支持通气	死亡
定义：特征为肺组织中液体累积致使气体交换紊乱，可能导致呼吸衰竭的病症。					
肺纤维化	轻度低血氧症；放射学肺纤维化小于肺容量的25%	中度低血氧症；肺动脉高压症的证据；放射学肺纤维化为肺容量的25%-50%	重度低血氧症；右侧心力衰竭的证据；放射学肺纤维化为肺容量的50%-75%	危及生命的后果（如血液动力学/肺并发症）；需要插管辅助呼吸；放射学肺纤维化大于肺容量75%，并呈严重的蜂窝样	死亡
特征为肺组织被结缔组织取代，导致进展性呼吸困难、呼吸衰竭或右心衰竭的病症。					
肺痿	无症状，仅有临床或诊断观察结果；无需介入	有症状；需要导管胸廓造口术或医疗处理；工具性ADL受限	自理ADL受限；需要内镜放置支架或手术介入	危及生命的后果；需要紧急手术介入	死亡

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Definition: A disorder characterized by an abnormal communication between the lung and another organ or anatomic site.					
Pulmonary hypertension	Minimal dyspnea; findings on physical exam or other evaluation	Moderate dyspnea, cough; requiring evaluation by cardiac catheterization and medical intervention	Severe symptoms, associated with hypoxemia, right heart failure; oxygen indicated	Life-threatening airway consequences; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by an increase in pressure within the pulmonary circulation due to lung or heart disorder.					
Respiratory failure	-	-	-	Life-threatening consequences; urgent intervention, intubation, or ventilatory support indicated	Death
Definition: A disorder characterized by impaired gas exchange by the respiratory system resulting in hypoxemia and a decrease in oxygenation of the tissues that may be associated with an increase in arterial levels of carbon dioxide.					
Retinoic acid syndrome	Fluid retention; <3 kg of weight gain; intervention with fluid restriction and/or diuretics indicated	Moderate signs or symptoms; steroids indicated	Severe symptoms; hospitalization indicated	Life-threatening consequences; ventilatory support indicated	Death
Definition: A disorder characterized by weight gain, dyspnea, pleural and pericardial effusions, leukocytosis and/or renal failure originally described in patients treated with all-trans retinoic acid.					
Sinus disorder	Asymptomatic mucosal crusting; blood-tinged secretions	Symptomatic stenosis or edema/narrowing interfering with airflow; limiting instrumental ADL	Stenosis with significant nasal obstruction; limiting self care ADL	Necrosis of soft tissue or bone; urgent operative intervention indicated	Death
Definition: A disorder characterized by involvement of the paranasal sinuses.					
Sleep apnea	Snoring and nocturnal sleep arousal without apneic periods	Moderate apnea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL	Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self care ADL	Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated	Death
Definition: A disorder characterized by cessation of breathing for short periods during sleep.					
Sneezing	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by the involuntary expulsion of air from the nose.					
Sore throat	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL; limiting ability to swallow	-	-
Definition: A disorder characterized by of marked discomfort in the throat					
Stridor	-	-	Respiratory distress limiting self care ADL; medical intervention indicated	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by a high pitched breathing sound due to laryngeal or upper airway obstruction.					
Tracheal fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention indicated (e.g., thoracoplasty, chronic open drainage or multiple thoracotomies)	Death
Definition: A disorder characterized by an abnormal communication between the trachea and another organ or anatomic site.					
Tracheal mucositis	Endoscopic findings only; minimal hemoptysis, pain, or respiratory symptoms	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe pain; hemorrhage or respiratory symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an inflammation involving the mucous membrane of the trachea.					
Tracheal stenosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), but causing no respiratory distress; medical management indicated (e.g., steroids)	Stridor or respiratory distress limiting self care ADL; endoscopic intervention indicated (e.g., stent, laser)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Definition: A disorder characterized by a narrowing of the trachea.					

呼吸、胸和纵隔病症					
分级					
不良事件	1	2	3	4	5
定义：特征为肺和另一个器官或解剖部位有异常通道的病症。					
肺动脉高血压	最低程度的呼吸困难；体检或其它评估方法可发现	中度呼吸困难，咳嗽；需要心导管插入和医学介入进行评估	严重症状；与低氧血症、右心衰竭相关；需要吸氧	危及生命的气道后果；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为由于肺或心脏紊乱引起肺循环压力升高的病症。					
呼吸衰竭	-	-	-	危及生命的后果；需要紧急介入、插管或辅助呼吸	死亡
定义：特征为由于呼吸系统气体交换削弱引起低氧血症，以及和动脉二氧化碳水平升高相关的组织氧合作用降低的病症。					
维甲酸综合症	液体滞留；体重增加小于3公斤；需要限制液体和/或利尿剂介入	中度体征或症状；需要类固醇治疗	严重症状；需要住院治疗	危及生命的后果；需要辅助呼吸	死亡
定义：特征为全反式维甲酸治疗的病人出现体重增加、呼吸困难、胸膜和心包积液、白细胞增多和/或原发性肾衰竭的病症。					
窦紊乱	无症状，粘膜结痂；微血色的分泌物	有症状，狭窄或水肿/缩小，妨碍气流；工具性ADL受限	狭窄伴随严重的鼻阻塞；自理ADL受限	软组织或骨坏死；需要紧急手术介入	死亡
定义：特征为牵涉鼻窦的病症。					
睡眠性呼吸暂停	打鼾且夜里唤醒睡眠时没有窒息	中度呼吸暂停和氧去饱和；白天格外有睡意；需要医学评估；工具性ADL受限	氧去饱和；与高血压相关；需要医学介入；自理ADL受限	心血管或神经精神系统症状；需要紧急手术介入	死亡
定义：特征为睡觉时短时间呼吸暂停的病症。					
喷嚏	轻度症状；无需介入	中度症状；需要医学介入	-	-	-
定义：特征为不自觉地鼻子排出空气的病症。					
咽喉痛	轻度疼痛	中度疼痛；工具性ADL受限	重度疼痛；自理ADL受限；限制吞咽能力	-	-
定义：特征为咽喉有显著不适的病症。					
喘鸣	-	-	呼吸性窘迫，自理ADL受限；需要医学介入	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为由于喉或上气道梗阻引起高音调呼吸声音的病症。					
气管瘘	无症状；仅有临床或诊断观察结果；无需介入	有症状；需要导管胸廓造口术或医疗处理；工具性ADL受限	严重症状；自理ADL受限；需要内窥镜检查或手术介入（如支架或原发性闭合）	危及生命的后果；需要紧急手术介入（如胸廓成形术、慢性开放引流或重新开胸术）	死亡
定义：特征为气管和另一个器官或解剖部位有异常通道的病症。					
气管粘膜炎	仅内镜检查可见；最低程度的咯血、疼痛或呼吸症状	中度症状；需要医学介入；工具性ADL受限	严重疼痛；出血或呼吸症状；自理ADL受限	危及生命的后果；需要紧急介入	死亡
定义：特征为气管粘膜发炎的病症。					
气管狭窄	无症状，仅有临床或诊断观察结果；无需介入	有症状（如气道呼吸有杂音），但不会引起呼吸性窘迫；需要医疗处理（如类固醇）	喘鸣或呼吸性窘迫，自理ADL受限；需要内窥镜介入（如支架，激光）	危及生命的气道损伤；需要紧急介入（如气管切开术或插管）	死亡
定义：特征为气管狭窄的病症。					

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Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Voice alteration	Mild or intermittent change from normal voice	Moderate or persistent change from normal voice; still understandable	Severe voice changes including predominantly whispered speech; may require frequent repetition or face-to-face contact for understandability; may require assistive technology	-	-
Definition: A disorder characterized by a change in the sound and/or speed of the voice.					
Wheezing	Detectable airway noise with minimal symptoms	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Severe respiratory symptoms limiting self care ADL; oxygen therapy or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a high-pitched, whistling sound during breathing. It results from the narrowing or obstruction of the respiratory airways.					
Respiratory, thoracic and mediastinal disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

呼吸、胸和纵隔病症					
分级					
不良事件	1	2	3	4	5
噪音改变	与正常噪音有轻度或间歇的变化	与正常噪音有中度或持续的变化；仍然可理解	严重的噪音变化包括主要是耳语交谈时；可能需要频繁的面对面重复交流才能理解；可能需要助听技术	-	-
定义：特征为噪音的声音和/或速度变化的病症。					
哮喘	有最低程度症状的可检测到的气道杂音	中度症状；需要医学介入；工具性 ADL 受限	严重呼吸症状，自理 ADL 受限；需要吸氧治疗或住院	危及生命的后果；需要紧急介入	死亡
定义：特征为呼吸时有高音调哨声杂音的病症，由于呼吸气道缩窄或阻塞引起。					
呼吸、胸和纵隔病症—其它，指定	无症状或轻度症状，仅有临床或诊断观察结果；无需介入	中度症状；需要最低程度、局部或非侵入性介入；年龄适合的工具性 ADL 受限	重度症状或医学上具有显著意义但不会立即危及生命；需要住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡

Skin and subcutaneous tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Alopecia	Hair loss of up to 50% of normal for that individual that is not obvious from a distance but only on close inspection; a different hair style may be required to cover the hair loss but it does not require a wig or hair piece to camouflage	Hair loss of >50% normal for that individual that is readily apparent to others; a wig or hair piece is necessary if the patient desires to completely camouflage the hair loss; associated with psychosocial impact	-	-	-
Definition: A disorder characterized by a decrease in density of hair compared to normal for a given individual at a given age and body location.					
Body odor	Mild odor; physician intervention not indicated; self care interventions	Pronounced odor; psychosocial impact; patient seeks medical intervention	-	-	-
Definition: A disorder characterized by an abnormal body smell resulting from the growth of bacteria on the body.					
Bullous dermatitis	Asymptomatic; blisters covering <10% BSA	Blisters covering 10-30% BSA; painful blisters; limiting instrumental ADL	Blisters covering >30% BSA; limiting self care ADL	Blisters covering >30% BSA; associated with fluid or electrolyte abnormalities; ICU care or burn unit indicated	Death
Definition: A disorder characterized by inflammation of the skin characterized by the presence of bullae which are filled with fluid.					
Dry skin	Covering <10% BSA and no associated erythema or pruritus	Covering 10-30% BSA and associated with erythema or pruritus; limiting instrumental ADL	Covering >30% BSA and associated with pruritus; limiting self care ADL	-	-
Definition: A disorder characterized by flaky and dull skin; the pores are generally fine, the texture is a papery thin texture.					
Erythema multiforme	Target lesions covering <10% BSA and not associated with skin tenderness	Target lesions covering 10-30% BSA and associated with skin tenderness	Target lesions covering >30% BSA and associated with oral or genital erosions	Target lesions covering >30% BSA; associated with fluid or electrolyte abnormalities; ICU care or burn unit indicated	Death
Definition: A disorder characterized by target lesions (a pink-red ring around a pale center).					
Erythroderma	-	Erythema covering >90% BSA without associated symptoms; limiting instrumental ADL	Erythema covering >90% BSA with associated symptoms (e.g., pruritus or tenderness); limiting self care ADL	Erythema covering >90% BSA with associated fluid or electrolyte abnormalities; ICU care or burn unit indicated	Death
Definition: A disorder characterized by generalized inflammatory erythema and exfoliation. The inflammatory process involves > 90% of the body surface area.					
Fat atrophy	Covering <10% BSA and asymptomatic	Covering 10-30% BSA and associated with erythema or tenderness; limiting instrumental ADL	Covering >30% BSA; associated with erythema or tenderness; limiting self-care ADL	-	-
Definition: A disorder characterized by shrinking of adipose tissue.					
Hirsutism	In women, increase in length, thickness or density of hair in a male distribution that the patient is able to camouflage by periodic shaving, bleaching, or removal of hair	In women, increase in length, thickness or density of hair in a male distribution that requires daily shaving or consistent destructive means of hair removal to camouflage; associated with psychosocial impact	-	-	-
Definition: A disorder characterized by the presence of excess hair growth in women in anatomic sites where growth is considered to be a secondary male characteristic and under androgen control (beard, moustache, chest, abdomen)					
Hyperhidrosis	Limited to one site (palms, soles, or axillae); self care interventions	Involving >1 site; patient seeks medical intervention; associated with psychosocial impact	Generalized involving sites other than palms, soles, or axillae; associated with electrolyte/hemodynamic imbalance	-	-
Definition: A disorder characterized by excessive perspiration.					

皮肤和皮下组织病症					
不良事件	分级				
	1	2	3	4	5
脱发	与普通人的正常水平相比，脱发不超过 50%，远距离不明显，近距离观察可发现；可能需要不一样的发型遮盖缺发，但不需要假发或一片发掩饰	与普通人的正常水平相比，脱发超过 50%，其他人很容易发现；如果病人想彻底地掩饰脱发，有必要带假发或植发；会有精神社会影响	-	-	-
定义：特征为对于一定年纪的个人，在某个躯体部位的毛发密度相比正常值下降的病症。					
体臭	轻度气味；无需医生介入；需要自我护理	明显气味；有精神社会影响；需要病人就医	-	-	-
定义：特征为由于身体上细菌生长导致异常体味的病症。					
大疱性皮炎	无症状；大水疱面积小于体表面积的 10%	大水疱面积为体表面积的 10-30%；大水疱疼痛；工具性 ADL 受限	大水疱面积大于体表面积的 30%；自理 ADL 受限	大水疱面积大于体表面积的 30%；与体液或电解质异常有关；需要进重症监护室或烧伤病房	死亡
定义：特征为皮肤上存在充满液体的大水疱炎症的病症。					
干性皮肤	小于体表面积的 10%，无红斑或瘙痒	体表面积的 10-30%，有红斑或瘙痒；工具性 ADL 受限	大于体表面积的 30%，有瘙痒；自理 ADL 受限	-	-
定义：特征为薄片干燥皮肤的病症；通常毛孔完好，皮肤组织呈薄纸状。					
多形性红斑	目标病灶小于体表面积的 10%，皮肤无触痛感	目标病灶为体表面积的 10-30%，伴随皮肤触痛感	目标病灶大于体表面积的 30%，伴随口腔和生殖器糜烂	目标病灶大于体表面积的 30%；伴随体液或电解质异常；需要进重症监护室或烧伤病房	死亡
定义：特征为目标病灶的白色中心周围有粉红色-红色环的病症。					
红皮症	-	红斑面积超过体表面积的 90%，没有其它症状；工具性 ADL 受限	红斑面积超过体表面积的 90%，有伴随症状（如瘙痒或触痛感）；自理 ADL 受限	红斑面积超过体表面积的 90%，伴随体液或电解质异常；需要进重症监护室或烧伤病房	死亡
定义：特征为全身炎性红斑和皮肤脱落的病症。炎症区域超过体表面积的 90%。					
脂肪萎缩	面积小于体表面积的 10%，无症状	面积为体表面积的 10-30%，伴随红斑或触痛感；工具性 ADL 受限	面积超过体表面积的 30%，伴随红斑或触痛感；自理 ADL 受限	-	-
定义：特征为脂肪组织缩小的病症。					
妇女多毛症	发生在女性，毛发的长度、厚度或密度增加，并以男性的分布方式。病人能通过定期削减、漂白或剃除加以掩饰。	发生在女性，毛发的长度、厚度或密度增加，并以男性的分布方式。病人需要每天削减或持续破坏方式的剃除加以掩饰；伴随精神社会影响	-	-	-
定义：特征为女性解剖部位（胡须、髭、胸和腹部）的毛发存在过度生长的病症，毛发的生长具有男性第二性征，并受雄激素调控。					
多汗症	限于一个部位（掌、足底或腋窝）；需要自我护理	多于一个部位；需要病人就医；伴随精神社会影响	除了掌、足底或腋窝，还有全身其它部位出现；伴随电解质/血液动力学失调	-	-
定义：特征为出汗过量的病症。					

Skin and subcutaneous tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Hypertrichosis	Increase in length, thickness or density of hair that the patient is either able to camouflage by periodic shaving or removal of hairs or is not concerned enough about the overgrowth to use any form of hair removal	Increase in length, thickness or density of hair at least on the usual exposed areas of the body [face (not limited to beard/moustache area) plus/minus arms] that requires frequent shaving or use of destructive means of hair removal to camouflage; associated with psychosocial impact.	-	-	-
Definition: A disorder characterized by hair density or length beyond the accepted limits of normal in a particular body region, for a particular age or race.					
Hypohidrosis	-	Symptomatic; limiting instrumental ADL	Increase in body temperature; limiting self care ADL	Heat stroke	Death
Definition: A disorder characterized by reduced sweating.					
Lipohypertrophy	Asymptomatic and covering <10% BSA	Covering 10-30% BSA and associated tenderness; limiting instrumental ADL	Covering >30% BSA and associated tenderness and narcotics or NSAIDs indicated; lipohypertrophy; limiting self care ADL	-	-
Definition: A disorder characterized by hypertrophy of the subcutaneous adipose tissue at the site of multiple subcutaneous injections of insulin.					
Nail discoloration	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	-	-	-	-
Definition: A disorder characterized by a change in the color of the nail plate.					
Nail loss	Asymptomatic separation of the nail bed from the nail plate or nail loss	Symptomatic separation of the nail bed from the nail plate or nail loss; limiting instrumental ADL	-	-	-
Definition: A disorder characterized by loss of all or a portion of the nail.					
Nail ridging	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	-	-	-	-
Definition: A disorder characterized by vertical or horizontal ridges on the nails.					
Pain of skin	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the skin.					
Palmar-plantar erythrodysesthesia syndrome	Minimal skin changes or dermatitis (e.g., erythema, edema, or hyperkeratosis) without pain	Skin changes (e.g., peeling, blisters, bleeding, edema, or hyperkeratosis) with pain; limiting instrumental ADL	Severe skin changes (e.g., peeling, blisters, bleeding, edema, or hyperkeratosis) with pain; limiting self care ADL	-	-
Definition: A disorder characterized by redness, marked discomfort, swelling, and tingling in the palms of the hands or the soles of the feet.					
Periorbital edema	Soft or non-pitting	Indurated or pitting edema; topical intervention indicated	Edema associated with visual disturbance; increased intraocular pressure, glaucoma or retinal hemorrhage; optic neuritis; diuretics indicated; operative intervention indicated	-	-
Definition: A disorder characterized by swelling due to an excessive accumulation of fluid around the orbits of the face.					
Photosensitivity	Painless erythema and erythema covering <10% BSA	Tender erythema covering 10-30% BSA	Erythema covering >30% BSA and erythema with blistering; photosensitivity; oral corticosteroid therapy indicated; pain control indicated (e.g., narcotics or NSAIDs)	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an increase in sensitivity of the skin to light.					

皮肤和皮下组织病症					
不良事件	分级				
	1	2	3	4	5
多毛症	毛发的长度、厚度或密度增加，病人能通过定期削减、或剃除加以掩饰；或者病人对毛发过度生长并不非常关心，不会使用任何方式去毛。	至少在身体通常暴露的区域[脸(不限于胡须/髭区域)包括/不包括手臂]，毛发的长度、厚度或密度增加，需要频繁削减或持续破坏方式的剃除加以掩饰；伴随精神社会影响	-	-	-
定义：特征为对于一定的年龄和种族，某个特定身体区域的毛发密度或长度超过了正常可接受上限。					
少汗症	-	有症状；工具性 ADL 受限	体温增加；自理 ADL 受限	中暑	死亡
定义：特征为出汗减少的病症。					
脂质增生症	无症状；面积小于体表面积的 10%	面积为体表面积的 10-30%，伴随触痛感；工具性 ADL 受限	面积大于体表面积的 30%，伴随触痛感，需要麻醉药或非甾体抗炎药；脂质增生症；自理 ADL 受限	-	-
定义：特征为在多次注射胰岛素的位点，皮下脂肪组织肥大的病症。					
指甲变色	无症状；仅有临床或诊断观察结果；无需介入	-	-	-	-
定义：特征为指甲板的颜色改变的病症。					
指甲损失	无症状，指甲床从指甲板上分离或指甲损失	有症状，指甲床从指甲板上分离或指甲损失；工具性 ADL 受限	-	-	-
定义：特征为指甲的一部分或全部损失的病症。					
指甲脊皱	无症状；仅需临床或诊断观察；无需介入	-	-	-	-
定义：特征为指甲上有垂直或水平脊皱的病症。					
皮肤痛	轻度痛	中度痛；工具性 ADL 受限	重度痛；自理 ADL 受限；限制吞咽能力	-	-
定义：特征为皮肤有显著不适感的病症。					
掌足红肿触痛综合征	最低程度的皮肤变化或皮炎（如红斑、水肿或角质化过度），无疼痛	皮肤变化（如脱皮、大水疱、出血、水肿或过度角质化）伴随疼痛；工具性 ADL 受限	严重皮肤变化（如脱皮、大水疱、出血、水肿或过度角质化）伴随疼痛；自理 ADL 受限	-	-
定义：特征为手掌或足底发红、显著不适、肿胀和麻刺感的病症。					
眶周水肿	软或非凹陷性水肿	硬结或凹陷性水肿；需要局部介入	水肿伴随视觉障碍；眼内压升高，青光眼或视网膜出血；视神经炎；需要利尿剂；需要手术介入	-	-
定义：特征为脸框周围由于液体过度累积导致肿胀的病症。					
光过敏	无痛的红斑，面积小于体表面积的 10%	有触痛的红斑；面积为体表面积的 10-30%	红斑面积大于体表面积的 30%，伴随发疱；光敏感；需要口服皮质类固醇治疗；需要控制疼痛（如麻醉药或非甾体抗炎药）	危及生命的后果；需要紧急介入	死亡
定义：特征为皮肤对光敏感度增加的病症。					

Skin and subcutaneous tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Pruritus	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g. edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated	-	-
Definition: A disorder characterized by an intense itching sensation.					
Purpura	Combined area of lesions covering <10% BSA	Combined area of lesions covering 10-30% BSA; bleeding with trauma	Combined area of lesions covering >30% BSA; spontaneous bleeding	-	-
Definition: A disorder characterized by hemorrhagic areas of the skin and mucous membrane. Newer lesions appear reddish in color. Older lesions are usually a darker purple color and eventually become a brownish-yellow color.					
Rash acneiform	Papules and/or pustules covering <10% BSA, which may or may not be associated with symptoms of pruritus or tenderness	Papules and/or pustules covering 10-30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; associated with psychosocial impact; limiting instrumental ADL	Papules and/or pustules covering >30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; limiting self care ADL; associated with local superinfection with oral antibiotics indicated	Papules and/or pustules covering any % BSA, which may or may not be associated with symptoms of pruritus or tenderness and are associated with extensive superinfection with IV antibiotics indicated; life-threatening consequences	Death
Definition: A disorder characterized by an eruption of papules and pustules, typically appearing in face, scalp, upper chest and back.					
Rash maculo-papular	Macules/papules covering <10% BSA with or without symptoms (e.g., pruritus, burning, tightness)	Macules/papules covering 10-30% BSA with or without symptoms (e.g., pruritus, burning, tightness); limiting instrumental ADL	Macules/papules covering >30% BSA with or without associated symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by the presence of macules (flat) and papules (elevated). Also known as morbilliform rash, it is one of the most common cutaneous adverse events, frequently affecting the upper trunk, spreading centripetally and associated with pruritus.					
Scalp pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Definition: A disorder characterized by marked discomfort sensation in the skin covering the top and the back of the head.					
Skin atrophy	Covering <10% BSA; associated with telangiectasias or changes in skin color	Covering 10-30% BSA; associated with striae or adnexal structure loss	Covering >30% BSA; associated with ulceration	-	-
Definition: A disorder characterized by the degeneration and thinning of the epidermis and dermis.					
Skin hyperpigmentation	Hyperpigmentation covering <10% BSA; no psychosocial impact	Hyperpigmentation covering >10% BSA; associated psychosocial impact	-	-	-
Definition: A disorder characterized by darkening of the skin due to excessive melanin deposition.					
Skin hypopigmentation	Hypopigmentation or depigmentation covering <10% BSA; no psychosocial impact	Hypopigmentation or depigmentation covering >10% BSA; associated psychosocial impact	-	-	-
Definition: A disorder characterized by loss of skin pigment.					
Skin induration	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Definition: A disorder characterized by an area of hardness in the skin.					
Skin ulceration	Combined area of ulcers <1 cm; nonblanchable erythema of intact skin with associated warmth or edema	Combined area of ulcers 1 - 2 cm; partial thickness skin loss involving skin or subcutaneous fat	Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia	Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss	Death
Definition: A disorder characterized by circumscribed, inflammatory and necrotic erosive lesion on the skin.					

皮肤和皮下组织病症					
分级					
不良事件	1	2	3	4	5
搔痒症	轻度或局限性；需要局部介入	重度或分布广；间歇性；搔抓部位的皮肤有变化（如水肿、丘疹形成、剥皮、苔癬化、流脓/结硬皮）；需要口服给药；工具性 ADL 受限	重度或分布广；持续性；日常生活自理能力或睡眠受限；需要口服皮质类固醇或免疫抑制剂治疗	-	-
定义：特征为强烈痒觉的病症。					
紫癜	结合病灶区域小于体表面积的 10%	结合病灶区域为体表面积的 10-30%；外伤出血	结合病灶区域大于体表面积的 30%；自发出血	-	-
定义：特征为皮肤和粘膜区域出血的病症。新的病灶出现略带红色。老的病灶通常是暗紫色并且最终变为褐色-黄色。					
瘰疬样皮疹	丘疹和/或脓疱面积小于体表面积的 10%，可能伴随或不伴随搔痒或触痛症状	丘疹和/或脓疱面积为体表面积的 10-30%，可能伴随或不伴随搔痒或触痛症状；有精神社会影响；工具性 ADL 受限	丘疹和/或脓疱面积大于体表面积的 30%，可能伴随或不伴随搔痒或触痛症状；自理 ADL 受限；伴随局部重复感染，需要口服抗生素	丘疹和/或脓疱面积占体表面积的比例任意，可能伴随或不伴随搔痒或触痛症状，伴随广泛的重复感染，需要静脉给予抗生素；危及生命的后果	死亡
定义：特征为丘疹和脓疱爆发的病症，通常出现在脸、头皮、上胸和背部。					
斑丘疹	斑点/丘疹区域小于体表面积的 10%，伴随或不伴随症状（如搔痒、灼热、紧绷）	斑点/丘疹区域为体表面积的 10-30%，伴随或不伴随症状（如搔痒、灼热、紧绷）；工具性 ADL 受限	斑点/丘疹区域大于体表面积的 30%，伴随或不伴随相关症状；自理 ADL 受限	-	-
定义：特征为存在斑点（平的）和丘疹（隆起）的病症。也被称为麻疹样疹，是最常见的表皮不良事件之一，时常影响上躯干、向心扩散并伴随搔痒。					
头皮痛	轻度痛	中度痛；工具性 ADL 受限	中度痛；自理 ADL 受限	-	-
定义：特征为头顶和背面覆盖的皮肤有显著不适感的病症。					
皮肤萎缩	区域小于体表面积的 10%；伴有毛细血管扩张或肤色变化	区域为体表面积的 10-30%；伴有皮纹或皮肤附件结构损失	区域大于体表面积的 30%；伴有溃疡	-	-
定义：特征为表皮和真皮退化和变薄的病症。					
皮肤色素沉着	色素沉着区域小于体表面积的 10%；无精神社会影响	色素沉着区域大于体表面积的 10%；有精神社会影响	-	-	-
定义：特征为由于过量黑色素沉着导致皮肤变黑的病症。					
皮肤色素减退	皮肤色素减退或失色区域小于体表面积的 10%；无精神社会影响	皮肤色素减退或失色区域大于体表面积的 10%；有精神社会影响	-	-	-
定义：特征为皮肤色素损失的病症。					
皮肤硬结	轻度硬结，可以在皮肤平面上平行移动（滑动）以及垂直移动（挤捏）	中度硬结，皮肤能滑动，但无法捏皮肤；工具性 ADL 受限	重度硬结；无法滑动或捏皮肤；关节移动或孔口（如口、肛门）受限；自理 ADL 受限	全身性；伴随呼吸或饮食损伤的体征或症状	死亡
定义：特征为皮肤的一个区域硬化的病症。					
皮肤溃疡	溃疡结合区域小于 1cm；完整皮肤有非漂白性红斑，伴随热度和水肿	溃疡结合区域为 1-2cm；与皮肤或皮下脂肪相关的皮损局部变厚	溃疡结合区域大于 2cm；可能下伸至筋膜的涉及皮下组织损伤或坏死的皮损完全变厚	具有广泛破坏性、组织坏死或损伤肌肉、骨骼以及支持结构，伴随或不伴随皮损完全变厚的任何尺寸的溃疡	死亡
定义：特征为皮肤具有局部、炎性和坏死糜烂病灶的病症。					

Skin and subcutaneous tissue disorders					
Adverse Event	Grade				
	1	2	3	4	5
Stevens-Johnson syndrome	-	-	Skin sloughing covering <10% BSA with associated signs (e.g., erythema, purpura, epidermal detachment and mucous membrane detachment)	Skin sloughing covering 10 - 30% BSA with associated signs (e.g., erythema, purpura, epidermal detachment and mucous membrane detachment)	Death
Definition: A disorder characterized by less than 10% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes.					
Telangiectasia	Telangiectasias covering <10% BSA	Telangiectasias covering >10% BSA; associated with psychosocial impact	-	-	-
Definition: A disorder characterized by local dilatation of small vessels resulting in red discoloration of the skin or mucous membranes.					
Toxic epidermal necrolysis	-	-	-	Skin sloughing covering ≥30% BSA with associated symptoms (e.g., erythema, purpura, or epidermal detachment)	Death
Definition: A disorder characterized by greater than 30% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes.					
Urticaria	Urticarial lesions covering <10% BSA; topical intervention indicated	Urticarial lesions covering 10 - 30% BSA; oral intervention indicated	Urticarial lesions covering >30% BSA; IV intervention indicated	-	-
Definition: A disorder characterized by an itchy skin eruption characterized by wheals with pale interiors and well-defined red margins.					
Skin and subcutaneous tissue disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

皮肤和皮下组织病症					
不良事件	分级				
	1	2	3	4	5
史-约综合征	-	-	皮肤脱落范围小于体表面积的10%，伴有相关体征（如红斑、紫癜、表皮脱落和粘膜脱落）	皮肤脱落范围为体表面积的10-30%，伴有相关体征（如红斑、紫癜、表皮脱落和粘膜脱落）	死亡
定义：特征为身体总的皮肤区域中小于10%出现真皮分离的病症。此症状被认为是一种超敏复合物影响皮肤和粘膜。					
毛细血管扩张	毛细血管扩张区域小于体表面积的10%	毛细血管扩张区域大于体表面积的10%；伴随精神社会影响	-	-	-
定义：特征为小血管局部膨胀导致皮肤和粘膜变红的病症。					
中毒性表皮坏死溶解	-	-	-	皮肤脱落面积大于等于体表面积的30%，伴有症状（如红斑、紫癜或表皮脱落）	死亡
定义：特征为身体总的皮肤区域中大于30%出现真皮分离的病症。此症状被认为是一种超敏复合物影响皮肤和粘膜。					
荨麻疹	荨麻疹病灶区域小于体表面积的10%，需要局部介入	荨麻疹病灶区域为体表面积的10-30%，需要口服给药	荨麻疹病灶区域大于体表面积的30%，需要静脉给药	-	-
定义：特征为具有风疹块的皮肤痒疹病症，风疹块有白色内核与清晰的红色边界。					
皮肤和皮下组织病症—其它，指定	无症状或轻度症状；仅有临床或诊断观察结果；无需介入	中度症状；需要最低程度、局部或非侵入性介入；年龄合适的工具性ADL受限	严重症状或临床上具有显著意义但不会立即危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入	死亡

Social circumstances					
Adverse Event	Grade				
	1	2	3	4	5
Menopause	Menopause occurring at age 46 - 53	Menopause occurring at age 40 - 45	Menopause occurring before age 40 years of age	-	-
Definition: A disorder characterized by the permanent cessation of menses, usually defined by 12 consecutive months of amenorrhea in a woman over 45 years of age.					
Social circumstances - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

社会环境					
不良事件	分级				
	1	2	3	4	5
更年期	更年期发生在 46-53 岁	更年期发生在 40-45 岁	更年期发生在 40 岁之前	-	-
定义：特征为月经永久中止的病症，通常的定义是 45 岁以上妇女连续 12 个月无月经。					
社会环境— 其它，指定	无症状或轻度症状； 仅有临床或诊断观察 结果；无需介入	中度症状；需要最低程度、 局部或非侵入性介入；年龄 适合的工具性 ADL 受限	严重症状或临床上具有 显著意义但不会立即危 及生命；住院或延长住 院时间；致残；自理 ADL 受限	危及生命的后果；需 要紧急介入	死亡

Surgical and medical procedures					
Adverse Event	Grade				
	1	2	3	4	5
Surgical and medical procedures - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

手术和医疗程序					
不良事件	分级				
	1	2	3	4	5
手术和医疗程序—其它，指定	无症状或轻度症状；仅有临床或诊断观察结果；无需介入	中度症状；需要最低程度、局部或非侵入性介入；年龄适合的工具性 ADL 受限	严重症状或临床上具有显著意义但不会立即危及生命；住院或延长住院时间；致残；自理 ADL 受限	危及生命的后果；需要紧急介入	死亡

Vascular disorders					
Adverse Event	Grade				
	1	2	3	4	5
Capillary leak syndrome	-	Symptomatic; medical intervention indicated	Severe symptoms; intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by leakage of intravascular fluids into the extravascular space. This syndrome is observed in patients who demonstrate a state of generalized leaky capillaries following shock syndromes, low-flow states, ischemia-reperfusion injuries, toxemias, medications, or poisoning. It can lead to generalized edema and multiple organ failure.					
Flushing	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated; limiting instrumental ADL	Symptomatic, associated with hypotension and/or tachycardia; limiting self care ADL	-	-
Definition: A disorder characterized by episodic reddening of the face.					
Hematoma	Mild symptoms; intervention not indicated	Minimally invasive evacuation or aspiration indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel.					
Hot flashes	Mild symptoms; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by an uncomfortable and temporary sensation of intense body warmth, flushing, sometimes accompanied by sweating upon cooling.					
Hypertension	Prehypertension (systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg)	Stage 1 hypertension (systolic BP 140 - 159 mm Hg or diastolic BP 90 -99 mm Hg); medical intervention indicated; recurrent or persistent (>=24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg if previously WNL; monotherapy indicated. Pediatric: recurrent or persistent (>=24 hrs) BP >ULN; monotherapy indicated	Stage 2 hypertension (systolic BP >= 160 mm Hg or diastolic BP >=100 mm Hg); medical intervention indicated; more than one drug or more intensive therapy than previously used indicated. Pediatric: Same as adult	Life-threatening consequences (e.g. malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated. Pediatric: Same as adult	Death
Definition: A disorder characterized by a pathological increase in blood pressure; a repeatedly elevation in the blood pressure exceeding 140 over 90 mm Hg.					
Hypotension	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Medical intervention or hospitalization indicated	Life-threatening and urgent intervention indicated	Death
Definition: A disorder characterized by a blood pressure that is below the normal expected for an individual in a given environment.					
Lymph leakage		Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the loss of lymph fluid into the surrounding tissue or body cavity.					
Lymphedema	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by excessive fluid collection in tissues that causes swelling.					
Lymphocele	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	-	-
Definition: A disorder characterized by a cystic lesion containing lymph.					
Peripheral ischemia	-	Brief (<24 hrs) episode of ischemia managed non-surgically and without permanent deficit	Recurring or prolonged (>=24 hrs) and/or invasive intervention indicated	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A disorder characterized by impaired circulation to an extremity.					
Phlebitis	-	Present	-	-	-
Definition: A disorder characterized by inflammation of the wall of a vein.					
Superficial thrombophlebitis	-	Present	-	-	-
Definition: A disorder characterized by a blood clot and inflammation involving a superficial vein of the extremities.					

心血管病症					
不良事件	分级				
	1	2	3	4	5
毛细血管漏综合征	-	有症状；需要医学介入	严重症状；需要介入	危及生命的后果；需要紧急介入	死亡
定义：特征为血管内液体渗漏到血管外区域的病症。此症状可以在病人出现全身性毛细血管渗漏状态下观察到，并伴随休克综合征、低流量状态、局部缺血再灌注损伤、毒血症、药物治疗或中毒。可导致全身性水肿和多器官衰竭。					
潮红	无症状或轻度症状；仅需临床或诊断观察；无需介入	中度症状；需要医学介入；工具性 ADL 受限	有症状伴随低血压和/或心动过速；自理 ADL 受限	-	-
定义：特征为脸部片状发红的病症。					
血肿	轻度症状；无需介入	需要最低程度的侵袭性排出或抽吸	需要输血、放射、内窥镜或可选择手术介入	危及生命的后果；需要紧急介入	死亡
定义：特征为血液局部集中的病症，通常由于血管壁破裂导致血液凝结在一个器官、区域或组织。					
热潮红	轻度症状；无需介入	中度症状；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为不舒服的暂时强烈身体发热与潮红感觉的病症，有时还伴随出冷汗。					
高血压	高血压前期（收缩压为 120-139 mm Hg 或舒张压为 80-89 mm Hg）	一级高血压（收缩压为 140-159 mm Hg 或舒张压为 90-99 mm Hg）；需要医学介入；复发或持续（大于等于 24 小时）；症状加重通过舒张压加大超过 20 mm Hg 或之前血压正常但现在大于 140/90 mm Hg；需要单一疗法。儿科病人：复发或持续，血压超过正常上限大于等于 24 小时；需要单一疗法	二级高血压（收缩压大于等于 160 mm Hg 或舒张压大于等于 100 mm Hg）；需要医学介入；需要多于一个药的治疗或比之前更强烈的疗法。儿科病人：与成人相同	危及生命的后果（如恶性高血压，暂时或持续的神经功能缺失，高血压危象）；需要紧急介入。儿科病人：与成人相同	死亡
定义：特征为病理学上血压升高的病症。血压一再升高，并超过 140/90 mm Hg。					
低血压	无症状；无需介入	需要非紧急医学介入	需要医学介入或住院	危及生命，需要紧急介入	死亡
定义：特征为在特定环境下，个体的血压低于正常预期值的病症。					
淋巴漏	-	有症状；需要医学介入	严重症状；需要放射、内窥镜或可选择手术介入	危及生命的后果，需要紧急介入	死亡
定义：特征为淋巴液进入外周组织或体腔而损失的病症。					
淋巴水肿	痕量增厚或略微变色	明显变色；似皮革的皮肤组织；乳头状突起形成；工具性 ADL 受限	严重症状；自理 ADL 受限	-	-
定义：特征为组织内液体过度累积导致肿胀的病症。					
淋巴囊肿	无症状；仅有临床或诊断观察结果；无需介入	有症状；需要医学介入	严重症状；需要放射、内窥镜或可选择手术介入	-	-
定义：特征为包含淋巴的一个囊状病灶的病症。					
外周局部缺血	-	短暂的（小于 24 小时）局部缺血发作，需要非手术处理，不会持续性缺血	复发或延长（大于等于 24 小时）和/或需要侵入性介入	危及生命的后果；终末器官损伤的证据；需要紧急手术介入	死亡
定义：特征为肢体循环削弱的病症。					
静脉炎	-	存在	-	-	-
定义：特征为静脉壁发炎的病症。					
血栓性浅静脉炎	-	存在	-	-	-
定义：特征为肢体浅静脉发炎和血凝块的病症。					

CTCAE v4.0

Vascular disorders					
Adverse Event	Grade				
	1	2	3	4	5
Superior vena cava syndrome	Asymptomatic; incidental finding of SVC thrombosis	Symptomatic; medical intervention indicated (e.g., anticoagulation, radiation or chemotherapy)	Severe symptoms; multi-modality intervention indicated (e.g., anticoagulation, chemotherapy, radiation, stenting)	Life-threatening consequences; urgent multi-modality intervention indicated (e.g., lysis, thrombectomy, surgery)	Death
Definition: A disorder characterized by obstruction of the blood flow in the superior vena cava. Signs and symptoms include swelling and cyanosis of the face, neck, and upper arms, cough, orthopnea and headache.					
Thromboembolic event	Venous thrombosis (e.g., superficial thrombosis)	Venous thrombosis (e.g., uncomplicated deep vein thrombosis), medical intervention indicated	Thrombosis (e.g., uncomplicated pulmonary embolism [venous], non-embolic cardiac mural [arterial] thrombus), medical intervention indicated	Life-threatening (e.g., pulmonary embolism, cerebrovascular event, arterial insufficiency); hemodynamic or neurologic instability; urgent intervention indicated	Death
Definition: A disorder characterized by occlusion of a vessel by a thrombus that has migrated from a distal site via the blood stream.					
Vasculitis	Asymptomatic, intervention not indicated	Moderate symptoms, medical intervention indicated	Severe symptoms, medical intervention indicated (e.g., steroids)	Life-threatening; evidence of peripheral or visceral ischemia; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation involving the wall of a vessel.					
Visceral arterial ischemia	-	Brief (<24 hrs) episode of ischemia managed medically and without permanent deficit	Prolonged (>=24 hrs) or recurring symptoms and/or invasive intervention indicated	Life-threatening consequences; evidence of end organ damage; urgent operative intervention indicated	Death
Definition: A disorder characterized by a decrease in blood supply due to narrowing or blockage of a visceral (mesenteric) artery.					
Vascular disorders - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

心血管病症					
不良事件	分级				
	1	2	3	4	5
上腔静脉综合征	无症状；偶然发现上腔静脉血栓形成	有症状；需要医学介入（如抗凝、放射或化疗）	严重症状；需要多形式介入（如抗凝、化疗、放射和支架）	危及生命的后果；需要紧急多形式介入（如细胞裂解、血栓切除术、外科手术）	死亡
定义：特征为上腔静脉血流阻塞的病症。体征和症状包括脸、颈和上臂肿胀与发绀，咳嗽，端坐呼吸和头痛。					
血栓事件	静脉血栓形成（如浅表血栓）	静脉血栓形成（如不复杂的深静脉血栓），需要医学介入	血栓（如不复杂的肺栓塞[静脉]非栓塞心脏壁血栓[动脉]），需要医学介入	危及生命（如肺栓塞，脑血管事件，动脉供血不足）；血液动力学或神经系统不稳定；需要紧急介入	死亡
定义：特征为从远端部位进入血流的血栓阻塞血管的病症。					
血管炎	无症状，无需介入	中度症状，需要医学介入	严重症状，需要医学介入（如类固醇）	危及生命；外周或内脏局部缺血证据；需要紧急介入	死亡
定义：特征为血管壁发炎的病症。					
内脏动脉局部缺血	-	短暂的（小于24小时）局部缺血发作，需要医学处理，不会持续性缺血	长时的（大于等于24小时）或症状复发和/或需要侵入性介入	危及生命的后果；终末器官损伤的证据；需要紧急手术介入	死亡
定义：特征为由于内脏肠系膜动脉阻塞或狭窄导致血液供给减少的病症。					
心血管病症—其它，指定	无症状或轻度症状；仅有临床或诊断观察结果；无需介入	中度症状；需要最低程度、局部或非侵入性介入；年龄适合的工具性ADL受限	严重症状或临床上具有显著意义但不会立即危及生命；住院或延长住院时间；致残；自理ADL受限	危及生命的后果；需要紧急介入	死亡



Roche Product Development in Asia Pacific