



## Cancer Therapy Evaluation Program

### Common Terminology Criteria for Adverse Events - Mapping Document (Version 2.0 to 3.0)

Public Health Service  
National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

CTCAE Version From 2.0	CTCAE Version To 3.0		
Category : ALLERGY/IMMUNOLOGY			
Adverse Event	Category	Adverse Event	Other Specify
Allergic reaction/hypersensitivity (including drug fever)	ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)	
Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	
Autoimmune reaction	ALLERGY/IMMUNOLOGY	Autoimmune reaction	
Serum sickness	ALLERGY/IMMUNOLOGY	Serum sickness	
Vasculitis	ALLERGY/IMMUNOLOGY	Vasculitis	
Allergy-Other (Specify,____)	ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, __)	



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CTCAE Version From 2.0	CTCAE Version To 3.0		
Category : AUDITORY/HEARING			
Adverse Event	Category	Adverse Event	Other Specify
External Auditory Canal	AUDITORY/EAR	Otitis, external ear (non-infectious)	
Inner ear/hearing	AUDITORY/EAR	Hearing: patients without baseline audiogram and not enrolled in a monitoring program	
Middle ear/hearing	AUDITORY/EAR	Otitis, middle ear (non-infectious)	
Auditory/Hearing-Other (Specify, _____)	AUDITORY/EAR	Auditory/Ear - Other (Specify, __)	



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CTCAE Version From 2.0	CTCAE Version To 3.0		
<b>Category</b> : Appendix IV RTOG/EORTC Late Radiation Morbidity Scoring Scheme (Use for adverse events occurring greater than 90 days after radiation therapy.)			
Adverse Event	Category	Adverse Event	Other Specify
Bladder- Late RT Morbidity Scoring  COMMENTS <i>v2.0 Bladder- Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Bladder- Late RT Morbidity Scoring (90004114)
Bone - Late RT Morbidity Scoring  COMMENTS <i>v2.0 Bone - Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Bone - Late RT Morbidity Scoring (90004112)
Brain- Late RT Morbidity Scoring  COMMENTS <i>v2.0 Brain- Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Brain- Late RT Morbidity Scoring (90004130)
Esophagus- Late RT Morbidity Scoring  COMMENTS <i>v2.0 Esophagus- Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Esophagus- Late RT Morbidity Scoring (90004128)
Eye- Late RT Morbidity Scoring  COMMENTS <i>v2.0 Eye- Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Eye- Late RT Morbidity Scoring (90004104)



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<b>Category</b> : Appendix IV RTOG/EORTC Late Radiation Morbidity Scoring Scheme (Use for adverse events occurring greater than 90 days after radiation therapy.)			
Adverse Event	Category	Adverse Event	Other Specify
Heart- Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Heart- Late RT Morbidity Scoring (90004116)
COMMENTS <i>v2.0 Heart- Late RT Morbidity Scoring deleted.</i> <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Joint- Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Joint- Late RT Morbidity Scoring (90004126)
COMMENTS <i>v2.0 Joint- Late RT Morbidity Scoring deleted.</i> <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Kidney-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Kidney-Late RT Morbidity Scoring (90004118)
COMMENTS <i>v2.0 Kidney-Late RT Morbidity Scoring deleted.</i> <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Larynx-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Larynx-Late RT Morbidity Scoring (90004124)
COMMENTS <i>v2.0 Larynx-Late RT Morbidity Scoring deleted.</i> <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Liver-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Liver-Late RT Morbidity Scoring (90004096)
COMMENTS <i>v2.0 Liver-Late RT Morbidity Scoring deleted.</i> <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Lung-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Lung-Late RT Morbidity Scoring (90004122)



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Adverse Event	Category	Adverse Event	Other Specify
COMMENTS <i>v2.0 Lung-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Mucous membrane-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Mucous membrane-Late RT Morbidity Scoring (90004098)
COMMENTS <i>v2.0 Mucous membrane-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Salivary glands-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Salivary glands-Late RT Morbidity Scoring (90004120)
COMMENTS <i>v2.0 Salivary glands-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Skin-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Skin-Late RT Morbidity Scoring (90004108)
COMMENTS <i>v2.0 Skin-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			
Small/Large intestine-Late RT Morbidity Scoring	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Small/Large intestine-Late RT Morbidity Scoring (90004110)
COMMENTS <i>v2.0 Small/Large intestine-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>			



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<b>Category</b> : Appendix IV RTOG/EORTC Late Radiation Morbidity Scoring Scheme (Use for adverse events occurring greater than 90 days after radiation therapy.)			
Adverse Event	Category	Adverse Event	Other Specify
Spinal cord-Late RT Morbidity Scoring  COMMENTS <i>v2.0 Spinal cord-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Spinal cord-Late RT Morbidity Scoring (90004100)
Subcutaneous tissue-Late RT Morbidity Scoring  COMMENTS <i>v2.0 Subcutaneous tissue-Late RT Morbidity Scoring deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Subcutaneous tissue-Late RT Morbidity Scoring (90004102)
Radiation-Other(Specify,_____)  COMMENTS <i>v2.0 Radiation-Other (Specify,_____) deleted.</i>  <i>v3.0 Site/organ specific criteria relevant to loco-regional therapy trials are integrated into one document without distinguishing between acute, late, chronic, or permanent AEs.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Radiation-Other(Specify,_____) (90004106)



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<b>Category</b> : Appendix VI BMT Complex/Multicomponent Events			
Adverse Event	Category	Adverse Event	Other Specify
Failure to engraft  COMMENTS <i>v2.0 Failure to engraft deleted.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Failure to engraft (90004134)
Graft versus host disease  COMMENTS <i>v2.0 Graft versus host disease deleted.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Graft versus host disease (10018651)
Stem cell infusion complications  COMMENTS <i>v2.0 Stem cell infusion complications deleted.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Stem cell infusion complications (90004132)
Veno-Occlusive Disease (VOD)  COMMENTS <i>v2.0 Veno-Occlusive Disease (VOD) deleted.</i>	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	Veno-Occlusive Disease (VOD) (10052612)



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<b>Category : BLOOD/BONE MARROW</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Bone marrow cellularity	BLOOD/BONE MARROW	Bone marrow cellularity	
CD4 count	BLOOD/BONE MARROW	CD4 count	
Haptoglobin	BLOOD/BONE MARROW	Haptoglobin	
Hemoglobin	BLOOD/BONE MARROW	Hemoglobin	
Hemoglobin for leukemia studies or bone marrow infiltrative/ myelophthisic processes, if specified in the protocol.	BLOOD/BONE MARROW	Hemoglobin	
<b>COMMENTS</b> <i>v2.0 Hemoglobin for leukemia studies or bone marrow infiltrative/ myelophthisic processes, if specified in the protocol is deleted and merged into v3.0 Hemoglobin.</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			
Hemolysis (e.g., immune hemolytic anemia, drug related hemolysis, other)	BLOOD/BONE MARROW	Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis)	
Leukocytes (total WBC)	BLOOD/BONE MARROW	Leukocytes (total WBC)	
Leukocytes (total WBC) for BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Leukocytes (total WBC)	
<b>COMMENTS</b> <i>v2.0 Leukocytes (total WBC) for BMT studies, if specified in the protocol deleted and merged into v3.0 Leukocytes (total WBC).</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			
Leukocytes (total WBC) for pediatric BMT studies (using age, race and sex normal values), if specified in the protocol.	BLOOD/BONE MARROW	Leukocytes (total WBC)	
<b>COMMENTS</b> <i>v2.0 Leukocytes (total WBC) for pediatric BMT studies (using age, race and sex normal values), if specified in the protocol deleted and merged into v3.0 Leukocytes (total WBC).</i>			





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<b>Category : BLOOD/BONE MARROW</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
<p><b>COMMENTS</b></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Lymphopenia	BLOOD/BONE MARROW	Lymphopenia	
Lymphopenia for pediatric BMT studies (using age, race and sex normal values), if specified in the protocol.	BLOOD/BONE MARROW	Lymphopenia	
<p><b>COMMENTS</b></p> <p><i>v2.0 Lymphopenia for pediatric BMT studies (using age, race and sex normal values), if specified in the protocol is deleted and merged into v3.0 Lymphopenia.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Neutrophils/granulocytes (ANC/AGC)	BLOOD/BONE MARROW	Neutrophils/granulocytes (ANC/AGC)	
Neutrophils/granulocytes (ANC/AGC) for BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Neutrophils/granulocytes (ANC/AGC)	
<p><b>COMMENTS</b></p> <p><i>v2.0 Neutrophils/granulocytes (ANC/AGC) for BMT studies, if specified in the protocol deleted and merged into v3.0 Neutrophils/granulocytes (ANC/AGC).</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Neutrophils/granulocytes (ANC/AGC) for leukemia studies or bone marrow infiltrative/myelophthisic process, if specified in the protocol.	BLOOD/BONE MARROW	Neutrophils/granulocytes (ANC/AGC)	
<p><b>COMMENTS</b></p> <p><i>v2.0 Neutrophils/granulocytes (ANC/AGC) for leukemia studies or bone marrow infiltrative/myelophthisic process, if specified in the protocol deleted and merged into v3.0 Neutrophils/granulocytes (ANC/AGC).</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or</i></p>			



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<b>Category : BLOOD/BONE MARROW</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
<p>COMMENTS</p> <p><i>treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Platelets	BLOOD/BONE MARROW	Platelets	
Platelets for BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Platelets	
<p>COMMENTS</p> <p><i>v2.0 Platelets for BMT studies, if specified in the protocol deleted and merged into v3.0 Platelets.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Platelets for leukemia studies or bone marrow infiltrative/myelophthistic process, if specified in the protocol.	BLOOD/BONE MARROW	Platelets	
<p>COMMENTS</p> <p><i>v2.0 Platelets for leukemia studies or bone marrow infiltrative/myelophthistic process, if specified in the protocol deleted and merged into v3.0 Platelets.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Transfusion: Platelets	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	Transfusion: Platelets (10035543)
<p>COMMENTS</p> <p><i>v2.0 Transfusion: Platelets deleted. Transfusions are interventions not adverse events.</i></p>			
Transfusion: Platelets for BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	Transfusion: Platelets for BMT studies, if specified in the protocol. (90004004)
<p>COMMENTS</p>			



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<b>Category :</b> BLOOD/BONE MARROW			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
COMMENTS <i>v2.0 Transfusion: Platelets for BMT studies, if specified in the protocol deleted. Transfusions are interventions not adverse events.</i>			
Transfusion: pRBCs	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	Transfusion: pRBCs (10033359)
COMMENTS <i>v2.0 Transfusion: pRBCs deleted. Transfusions are interventions not adverse events.</i>			
Transfusion: pRBCs for BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	Transfusion: pRBCs for BMT studies, if specified in the protocol. (90004016)
COMMENTS <i>v2.0 Transfusion: pRBCs for BMT studies, if specified in the protocol deleted. Transfusions are interventions not adverse events.</i>			
Transfusion: pRBCs for pediatric BMT studies, if specified in the protocol.	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	Transfusion: pRBCs for pediatric BMT studies, if specified in the protocol. (90004012)
COMMENTS <i>v2.0 Transfusion: pRBCs for pediatric BMT studies, if specified in the protocol deleted. Transfusions are interventions not adverse events.</i>			
Blood/Bone Marrow-Other (Specify, _____)	BLOOD/BONE MARROW	Blood/Bone Marrow - Other (Specify, __)	



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<b>Category : CARDIOVASCULAR (ARRHYTHMIA)</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Conduction abnormality/Atrioventricular heart block	CARDIAC ARRHYTHMIA	Conduction abnormality/atrioventricular heart block <b>Select</b> Conduction abnormality NOS	
Nodal/junctional arrhythmia/dysrhythmia	CARDIAC ARRHYTHMIA	Supraventricular and nodal arrhythmia <b>Select</b> Nodal/Junctional	
Palpitations	CARDIAC ARRHYTHMIA	Palpitations	
Prolonged QTc interval (QTc > 0.48 seconds)	CARDIAC ARRHYTHMIA	Prolonged QTc interval	
COMMENTS			
<i>v3.0 Descriptions of Grade for Prolonged QTc interval are changed to measurable parameters.</i>			
Sinus bradycardia	CARDIAC ARRHYTHMIA	Supraventricular and nodal arrhythmia <b>Select</b> Sinus bradycardia	
Sinus tachycardia	CARDIAC ARRHYTHMIA	Supraventricular and nodal arrhythmia <b>Select</b> Sinus tachycardia	
Supraventricular arrhythmias (SVT/atrial fibrillation/flutter)	CARDIAC ARRHYTHMIA	Supraventricular and nodal arrhythmia <b>Select</b> Supraventricular arrhythmia NOS	
Vasovagal episode	CARDIAC ARRHYTHMIA	Vasovagal episode	
Ventricular arrhythmia (PVCs/bigeminy/trigeminy/ventricular tachycardia)	CARDIAC ARRHYTHMIA	Ventricular arrhythmia <b>Select</b> Ventricular arrhythmia NOS	
Cardiovascular/Arrhythmia-Other (Specify,____)	CARDIAC ARRHYTHMIA	Cardiac Arrhythmia - Other (Specify, __)	



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<b>Category : CARDIOVASCULAR (GENERAL)</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Acute vascular leak syndrome	VASCULAR	Acute vascular leak syndrome	
Cardiac-ischemia/infarction	CARDIAC GENERAL	Cardiac ischemia/infarction	
Cardiac left ventricular function	CARDIAC GENERAL	Left ventricular systolic dysfunction	
Cardiac troponin I (cTnI)	CARDIAC GENERAL	Cardiac troponin I (cTnI)	
Cardiac troponin T (cTnT)	CARDIAC GENERAL	Cardiac troponin T (cTnT)	
Edema	CARDIAC GENERAL	Cardiac General - Other (Specify, __)	Edema (10030114)
COMMENTS <i>v2.0 Edema deleted. Edema is not a CTCAE v3.0 term. Edema generally falls within two groups: 1). General or systemic, including CHF, hypoalbuminemia, and excessive renal retention of salt and water; and 2). Local, including venous stasis, lymphatic stasis, and prolonged dependency. Therefore depending on etiology, edema is graded in the CARDIAC GENERAL CATEGORY or LYMPHATICS CATEGORY.</i>			
Hypertension	CARDIAC GENERAL	Hypertension	
Hypotension	CARDIAC GENERAL	Hypotension	
Myocarditis	CARDIAC GENERAL	Myocarditis	
Operative injury of vein/artery	SURGERY/INTRA-OPERATIVE INJURY	Intra-operative injury <b>Select</b> Vein NOS	
COMMENTS <i>v2.0 Operative injury of vein/artery split into v3.0 Intra-operative injury -Vein NOS and v3.0 Intra-operative injury -Artery NOS.</i>			
Pericardial effusion/pericarditis	CARDIAC GENERAL	Pericardial effusion (non-malignant)	
COMMENTS <i>v2.0 Pericardial effusion/pericarditis split into v3.0 Pericardial effusion and v3.0 Pericarditis.</i>			
Peripheral arterial ischemia	VASCULAR	Peripheral arterial ischemia	
Phlebitis (superficial)	VASCULAR	Phlebitis (including superficial thrombosis)	
Thrombosis/embolism	VASCULAR	Thrombosis/thrombus/embolism	
COMMENTS <i>v2.0 Thrombosis/embolism split into v3.0 Thrombosis/embolism (vascular access-related) and v3.0 Thrombosis/thrombus/embolism.</i>			
Visceral arterial ischemia (non-myocardial)	VASCULAR	Visceral arterial ischemia (non-myocardial)	
Cardiovascular/General-Other (Specify,____)	CARDIAC GENERAL	Cardiac General - Other (Specify, __)	



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<b>Category : COAGULATION</b>			
Adverse Event	Category	Adverse Event	Other Specify
DIC (disseminated intravascular coagulation)	COAGULATION	DIC (disseminated intravascular coagulation)	
Fibrinogen	COAGULATION	Fibrinogen	
Fibrinogen for leukemia studies or bone marrow infiltrative/myelophthistic process, if specified in the protocol.	COAGULATION	Fibrinogen	
<p><b>COMMENTS</b></p> <p><i>v2.0 Fibrinogen for leukemia studies or bone marrow infiltrative/myelophthistic process, if specified in the protocol deleted and merged into v3.0 Fibrinogen.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Partial thromboplastin time (PTT)	COAGULATION	PTT (Partial Thromboplastin Time)	
Prothrombin time (PT)	COAGULATION	INR (International Normalized Ratio of prothrombin time)	
Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura/TTP or hemolytic uremic syndrome/HUS)	COAGULATION	Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura [TTP] or hemolytic uremic syndrome [HUS])	
Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura/TTP or hemolytic uremic syndrome/HUS) for BMT studies, if specified by the protocol.	COAGULATION	Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura [TTP] or hemolytic uremic syndrome [HUS])	
<p><b>COMMENTS</b></p> <p><i>v2.0 Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura/TTP or hemolytic uremic syndrome/HUS) for BMT studies, if specified by the protocol is deleted and merged into v3.0 Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura/TTP or hemolytic uremic syndrome/HUS).</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Coagulation-Other (Specify, _____)	COAGULATION	Coagulation - Other (Specify, ___)	



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<b>Category :</b> CONSTITUTIONAL SYMPTOMS			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Fatigue (lethargy, malaise, asthenia)	CONSTITUTIONAL SYMPTOMS	Fatigue (asthenia, lethargy, malaise)	
Fever (in the absence of neutropenia, where neutropenia is defined as AGC<1.0 x 10e9/L)	CONSTITUTIONAL SYMPTOMS	Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 x 10e9/L)	
Rigors, chills	CONSTITUTIONAL SYMPTOMS	Rigors/chills	
Sweating (diaphoresis)	CONSTITUTIONAL SYMPTOMS	Sweating (diaphoresis)	
Weight gain	CONSTITUTIONAL SYMPTOMS	Weight gain	
Weight gain - Veno-Occlusive Disease (VOD) for BMT studies if specified in the protocol.	CONSTITUTIONAL SYMPTOMS	Weight gain	
<p><b>COMMENTS</b></p> <p><i>v2.0 Weight gain - Veno-Occlusive Disease (VOD) for BMT studies if specified in the protocol is deleted and merged into v3.0 Weight gain.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Weight loss	CONSTITUTIONAL SYMPTOMS	Weight loss	
Constitutional Symptoms-Other (Specify,_____)	CONSTITUTIONAL SYMPTOMS	Constitutional Symptoms - Other (Specify, __)	



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<b>Category : DERMATOLOGY/SKIN</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Alopecia	DERMATOLOGY/SKIN	Hair loss/alopecia (scalp or body)	
Bruising (in absence of grade 3 or 4 thrombocytopenia)	DERMATOLOGY/SKIN	Bruising (in absence of Grade 3 or 4 thrombocytopenia)	
Dry skin	DERMATOLOGY/SKIN	Dry skin	
Erythema multiforme (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis)	DERMATOLOGY/SKIN	Rash: erythema multiforme (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis)	
Flushing	DERMATOLOGY/SKIN	Flushing	
Hand-foot skin reaction	DERMATOLOGY/SKIN	Rash: hand-foot skin reaction	
Injection site reaction	DERMATOLOGY/SKIN	Injection site reaction/extravasation changes	
Nail changes	DERMATOLOGY/SKIN	Nail changes	
Photosensitivity	DERMATOLOGY/SKIN	Photosensitivity	
Pigmentation changes (e.g., vitiligo)	DERMATOLOGY/SKIN	Hypopigmentation	
<b>COMMENTS</b>			
<i>v2.0 Pigmentation changes (e.g., vitiligo) split into v3.0 Hypopigmentation and v3.0 Hyperpigmentation.</i>			
Pruritus	DERMATOLOGY/SKIN	Pruritus/itching	
Radiation dermatitis	DERMATOLOGY/SKIN	Rash: dermatitis associated with radiation <b>Select</b> Radiation	
Radiation recall reaction (reaction following chemotherapy in the absence of additional radiation therapy that occurs in a previous radiation port)	DERMATOLOGY/SKIN	Rash: dermatitis associated with radiation <b>Select</b> Chemoradiation	
Rash/desquamation	DERMATOLOGY/SKIN	Rash/desquamation	
Rash/dermatitis associated with high-dose chemotherapy or BMT studies.	DERMATOLOGY/SKIN	Rash/desquamation	
<b>COMMENTS</b>			
<i>v2.0 Rash/dermatitis associated with high-dose chemotherapy or BMT studies is deleted and merged into v3.0 Rash desquamation.</i>			
<i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			





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<b>Category : DERMATOLOGY/SKIN</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Rash/desquamation associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol.  COMMENTS <i>v2.0 Rash/desquamation associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol is deleted and merged into v3.0 Rash desquamation.</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>	DERMATOLOGY/SKIN	Rash/desquamation	
Urticaria (hives, welts, wheals)	DERMATOLOGY/SKIN	Urticaria (hives, welts, wheals)	
Wound-infectious	INFECTION	Infection with unknown ANC <b>Select</b> Wound	
Wound-non-infectious	DERMATOLOGY/SKIN	Wound complication, non-infectious	
Dermatology/Skin-Other (Specify, _____)	DERMATOLOGY/SKIN	Dermatology/Skin - Other (Specify, ___)	



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<b>Category : ENDOCRINE</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Cushingoid appearance (e.g., moon face, buffalo hump, centripetal obesity, cutaneous striae)	ENDOCRINE	Cushingoid appearance (e.g., moon face, buffalo hump, centripetal obesity, cutaneous striae)	
Feminization of male	ENDOCRINE	Feminization of male	
Gynecomastia	SEXUAL/REPRODUCTIVE FUNCTION	Gynecomastia	
Hot flashes/flushes	ENDOCRINE	Hot flashes/flushes	
Hypothyroidism	ENDOCRINE	Thyroid function, low (hypothyroidism)	
Masculinization of female	ENDOCRINE	Masculinization of female	
SIADH (syndrome of inappropriate antidiuretic hormone)	ENDOCRINE	Neuroendocrine: ADH secretion abnormality (e.g., SIADH or low ADH)	
Endocrine-Other (Specify, _____)	ENDOCRINE	Endocrine - Other (Specify, __)	



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<b>Category : GASTROINTESTINAL</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Anorexia	GASTROINTESTINAL	Anorexia	
Ascites (non-malignant)	GASTROINTESTINAL	Ascites (non-malignant)	
Colitis	GASTROINTESTINAL	Colitis	
Constipation	GASTROINTESTINAL	Constipation	
Dehydration	GASTROINTESTINAL	Dehydration	
Diarrhea patients without colostomy	GASTROINTESTINAL	Diarrhea	
COMMENTS <i>v2.0 Diarrhea patients without colostomy is deleted and merged into v3.0 Diarrhea.</i>			
Diarrhea patients with a colostomy	GASTROINTESTINAL	Diarrhea	
COMMENTS <i>v2.0 Diarrhea patients with a colostomy is deleted and merged into v3.0 Diarrhea.</i>			
Diarrhea associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol.	GASTROINTESTINAL	Diarrhea	
COMMENTS <i>v2.0 Diarrhea associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol is deleted and merged into v3.0 Diarrhea.</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			
Diarrhea for pediatric BMT studies, if specified in the protocol.	GASTROINTESTINAL	Diarrhea	
COMMENTS <i>v2.0 Diarrhea for pediatric BMT studies, if specified in the protocol is deleted and merged into v3.0 Diarrhea.</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			



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<b>Category : GASTROINTESTINAL</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Duodenal ulcer (requires radiographic or endoscopic documentation)	GASTROINTESTINAL	Ulcer, GI <b>Select</b> Duodenum	
Dyspepsia/heartburn	GASTROINTESTINAL	Heartburn/dyspepsia	
Dysphagia, esophagitis, odynophagia (painful swallowing)	GASTROINTESTINAL	Esophagitis	
Dysphagia-esophageal related to radiation	GASTROINTESTINAL	Dysphagia (difficulty swallowing)	
COMMENTS <i>v2.0 Dysphagia-esophageal related to radiation is deleted and merged into v3.0 Dysphagia (difficulty swallowing).</i>			
Dysphagia-pharyngeal related to radiation	GASTROINTESTINAL	Dysphagia (difficulty swallowing)	
COMMENTS <i>v2.0 Dysphagia-pharyngeal related to radiation is deleted and merged into v3.0 Dysphagia (difficulty swallowing).</i>			
Fistula-esophageal	GASTROINTESTINAL	Fistula, GI <b>Select</b> Esophagus	
Fistula-intestinal	GASTROINTESTINAL	Fistula, GI <b>Select</b> Small bowel NOS	
Fistula-pharyngeal	PULMONARY/UPPER RESPIRATORY	Fistula, pulmonary/upper respiratory <b>Select</b> Pharynx	
Fistula-rectal/anal	GASTROINTESTINAL	Fistula, GI <b>Select</b> Anus	
COMMENTS <i>v2.0 Fistula-rectal/anal split into v3.0 Fistula, GI-Anus and v3.0 Fistula, GI-Rectum.</i>			
Flatulence	GASTROINTESTINAL	Flatulence	
Gastric ulcer (requires radiographic or endoscopic documentation)	GASTROINTESTINAL	Ulcer, GI <b>Select</b> Stomach	
Gastritis	GASTROINTESTINAL	Gastritis (including bile reflux gastritis)	
Ileus (or neuroconstipation)	GASTROINTESTINAL	Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation)	
Mouth dryness	GASTROINTESTINAL	Dry mouth/salivary gland (xerostomia)	



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<b>Category : GASTROINTESTINAL</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Mucositis due to radiation	GASTROINTESTINAL	Mucositis/stomatitis (clinical exam) <b>Select</b> Oral cavity	
Nausea	GASTROINTESTINAL	Nausea	
Pancreatitis	HEPATOBIILIARY/PANCR EAS	Pancreatitis	
Proctitis	GASTROINTESTINAL	Proctitis	
Salivary gland changes	GASTROINTESTINAL	Salivary gland changes/saliva	
Sense of smell	NEUROLOGY	Neuropathy: cranial <b>Select</b> CN I Smell	
Stomatitis/pharyngitis (oral/pharyngeal mucositis)	GASTROINTESTINAL	Mucositis/stomatitis (functional/symptomatic) <b>Select</b> Oral cavity	
Stomatitis/pharyngitis (oral/pharyngeal mucositis) for BMT studies, if specified in the protocol.	GASTROINTESTINAL	Mucositis/stomatitis (functional/symptomatic) <b>Select</b> Oral cavity	
<p><b>COMMENTS</b></p> <p><i>v2.0 Stomatitis/pharyngitis (oral/pharyngeal mucositis) for BMT studies, if specified in the protocol is deleted and merged into v3.0 Mucositis/stomatitis (functional/symptomatic)-Oral cavity.</i></p> <p><i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i></p>			
Taste disturbance (dysgeusia)	GASTROINTESTINAL	Taste alteration (dysgeusia)	
Typhlitis (inflammation of cecum)	GASTROINTESTINAL	Typhlitis (cecal inflammation)	
Vomiting	GASTROINTESTINAL	Vomiting	
Gastrointestinal-Other (Specify,____)	GASTROINTESTINAL	Gastrointestinal - Other (Specify, __)	



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CTCAE Version From 2.0	CTCAE Version To 3.0		
<b>Category : HEMORRHAGE</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia	HEMORRHAGE/BLEEDING G	Hemorrhage/Bleeding - Other (Specify, ___)	Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia (90004060)
COMMENTS <i>v2.0 Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia deleted.</i>			
Hemorrhage/bleeding without grade 3 or 4 thrombocytopenia	HEMORRHAGE/BLEEDING G	Hemorrhage/Bleeding - Other (Specify, ___)	Hemorrhage/bleeding without grade 3 or 4 thrombocytopenia (10018988)
COMMENTS <i>v2.0 Hemorrhage/bleeding without grade 3 or 4 thrombocytopenia deleted.</i>			
CNS hemorrhage/bleeding	HEMORRHAGE/BLEEDING G	Hemorrhage, CNS	
Epistaxis	HEMORRHAGE/BLEEDING G	Hemorrhage, pulmonary/upper respiratory <b>Select</b> Nose	
Hematemesis	HEMORRHAGE/BLEEDING G	Hemorrhage, GI <b>Select</b> Stomach	
Hematuria (in the absence of vaginal bleeding)	HEMORRHAGE/BLEEDING G	Hemorrhage, GU <b>Select</b> Bladder	
Hemoptysis	HEMORRHAGE/BLEEDING G	Hemorrhage, pulmonary/upper respiratory <b>Select</b> Respiratory tract NOS	
Hemorrhage/bleeding associated with surgery	HEMORRHAGE/BLEEDING G	Hemorrhage/bleeding associated with surgery, intra-operative or postoperative	
Melena/GI bleeding	HEMORRHAGE/BLEEDING G	Hemorrhage, GI <b>Select</b> Lower GI NOS	
Petechiae/purpura (hemorrhage/bleeding into skin or mucosa)	HEMORRHAGE/BLEEDING G	Petechiae/purpura (hemorrhage/bleeding into skin or mucosa)	
Rectal bleeding/hematochezia	HEMORRHAGE/BLEEDING G	Hemorrhage, GI <b>Select</b> Rectum	
Vaginal bleeding	HEMORRHAGE/BLEEDING G	Hemorrhage, GU <b>Select</b> Vagina	



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Category : HEMORRHAGE			
Adverse Event	Category	Adverse Event	Other Specify
Hemorrhage-Other (Specify, _____)	HEMORRHAGE/BLEEDING G	Hemorrhage/Bleeding - Other (Specify, ___)	



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<b>Category : HEPATIC</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Alkaline phosphatase	METABOLIC/LABORATORY	Alkaline phosphatase	
Bilirubin	METABOLIC/LABORATORY	Bilirubin (hyperbilirubinemia)	
Bilirubin associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol.	METABOLIC/LABORATORY	Bilirubin (hyperbilirubinemia)	
<b>COMMENTS</b> <i>v2.0 Bilirubin associated with graft versus host disease (GVHD) for BMT studies, if specified in the protocol is deleted and merged into v3.0 Bilirubin (hyperbilirubinemia).</i>  <i>v2.0 BMT and leukemia AEs are deleted in CTCAE v3.0 for two reasons: 1. There was consensus that the grading schema used should be consistent and independent of disease or treatment type unless there are data to support such a difference. A Grade 3 platelet assessment should be independent of the cause of the AE, whether from chemotherapy, BMT, leukemia or solid tumor infiltration of the bone marrow; 2. Reporting of the same AE (e.g. platelets) was inconsistent. For example, in any one trial, data were often submitted under general platelet AE, BMT platelet AE, or leukemia platelet AE. The CTCAE development team judged this problem to be caused in part by the way CTC v2.0 leukemia and BMT criteria were set up. After review, the logical and efficient approach decided is to collapse the BMT and leukemia criteria into other existing AEs.</i>			
GGT (Gamma-Glutamyl transpeptidase)	METABOLIC/LABORATORY	GGT (gamma-Glutamyl transpeptidase)	
Hepatic enlargement	HEPATOBIILIARY/PANCREAS	Hepatobiliary/Pancreas - Other (Specify, __)	Hepatic enlargement (10019842)
<b>COMMENTS</b> <i>v2.0 Hepatic enlargement deleted.</i>			
Hypoalbuminemia	METABOLIC/LABORATORY	Albumin, serum-low (hypoalbuminemia)	
Liver dysfunction/failure (clinical)	HEPATOBIILIARY/PANCREAS	Liver dysfunction/failure (clinical)	
Portal vein flow	VASCULAR	Portal vein flow	
SGOT (AST) (serum glutamic oxaloacetic transaminase)	METABOLIC/LABORATORY	AST, SGOT(serum glutamic oxaloacetic transaminase)	
SGPT (ALT) (serum glutamic pyruvic transaminase)	METABOLIC/LABORATORY	ALT, SGPT (serum glutamic pyruvic transaminase)	
Hepatic-Other (Specify,____)	HEPATOBIILIARY/PANCREAS	Hepatobiliary/Pancreas - Other (Specify, __)	





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<b>Category</b> : INFECTION/FEBRILE NEUTROPENIA			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Catheter-related infection	INFECTION	Infection with unknown ANC <b>Select</b> Catheter-related	
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10e9/L, fever >=38.5 degrees C)	INFECTION	Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection)(ANC <1.0 x 10e9/L, fever >=38.5 degrees C)	
Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (ANC <1.0 x 10e9/L)	INFECTION	Infection - Other (Specify, __)	Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (ANC <1.0 x 10e9/L) (90004070)
COMMENTS <i>v2.0 Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (ANC &lt;1.0 x 10e9/L) is v3.0 supra-ordinate term with Select AEs.</i>			
Infection with unknown ANC	INFECTION	Infection - Other (Specify, __)	Infection with unknown ANC (90004066)
COMMENTS <i>v2.0 Infection with unknown ANC is v3.0 supra-ordinate term with Select AEs.</i>			
Infection without neutropenia	INFECTION	Infection - Other (Specify, __)	Infection without neutropenia (10021842)
COMMENTS <i>v2.0 Infection without neutropenia is v3.0 supra-ordinate term with Select AEs.</i>			
Infection/Febrile Neutropenia-Other (Specify,____)	INFECTION	Infection - Other (Specify, __)	



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Category : LYMPHATICS			
Adverse Event	Category	Adverse Event	Other Specify
Lymphatics	LYMPHATICS	Lymphatics - Other (Specify, __)	Lymphatics (10025222)
COMMENTS <i>v2.0 Lymphatics deleted.</i>			
Lymphatics-Other (Specify, __)	LYMPHATICS	Lymphatics - Other (Specify, __)	



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<b>Category : METABOLIC/LABORATORY</b>			
Adverse Event	Category	Adverse Event	Other Specify
Acidosis (metabolic or respiratory)	METABOLIC/LABORATORY	Acidosis (metabolic or respiratory)	
Alkalosis (metabolic or respiratory)	METABOLIC/LABORATORY	Alkalosis (metabolic or respiratory)	
Amylase	METABOLIC/LABORATORY	Amylase	
Bicarbonate	METABOLIC/LABORATORY	Bicarbonate, serum-low	
CPK (creatine phosphokinase)	METABOLIC/LABORATORY	CPK (creatine phosphokinase)	
Hypercalcemia	METABOLIC/LABORATORY	Calcium, serum-high (hypercalcemia)	
Hypercholesterolemia	METABOLIC/LABORATORY	Cholesterol, serum-high (hypercholestremia)	
Hyperglycemia	METABOLIC/LABORATORY	Glucose, serum-high (hyperglycemia)	
Hyperkalemia	METABOLIC/LABORATORY	Potassium, serum-high (hyperkalemia)	
Hypermagnesemia	METABOLIC/LABORATORY	Magnesium, serum-high (hypermagnesemia)	
Hypernatremia	METABOLIC/LABORATORY	Sodium, serum-high (hypernatremia)	
Hypertriglyceridemia	METABOLIC/LABORATORY	Triglyceride, serum-high (hypertriglyceridemia)	
Hyperuricemia	METABOLIC/LABORATORY	Uric acid, serum-high (hyperuricemia)	
Hypocalcemia	METABOLIC/LABORATORY	Calcium, serum-low (hypocalcemia)	
Hypoglycemia	METABOLIC/LABORATORY	Glucose, serum-low (hypoglycemia)	
Hypokalemia	METABOLIC/LABORATORY	Potassium, serum-low (hypokalemia)	
Hypomagnesemia	METABOLIC/LABORATORY	Magnesium, serum-low (hypomagnesemia)	



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Category : METABOLIC/LABORATORY			
Adverse Event	Category	Adverse Event	Other Specify
Hyponatremia	METABOLIC/LABORATORY	Sodium, serum-low (hyponatremia)	
Hypophosphatemia	METABOLIC/LABORATORY	Phosphate, serum-low (hypophosphatemia)	
Lipase	METABOLIC/LABORATORY	Lipase	
Metabolic/Laboratory-Other (Specify, _____)	METABOLIC/LABORATORY	Metabolic/Laboratory - Other (Specify, ___)	



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<b>Category : MUSCULOSKELETAL</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Arthritis	MUSCULOSKELETAL/SO FT TISSUE	Arthritis (non-septic)	
Muscle weakness (not due to neuropathy)	MUSCULOSKELETAL/SO FT TISSUE	Muscle weakness, generalized or specific area (not due to neuropathy) <b>Select</b> Whole body/generalized	
Myositis (inflammation/damage of muscle)	MUSCULOSKELETAL/SO FT TISSUE	Myositis (inflammation/damage of muscle)	
Osteonecrosis (avascular necrosis)	MUSCULOSKELETAL/SO FT TISSUE	Osteonecrosis (avascular necrosis)	
Musculoskeletal-Other (Specify, _____)	MUSCULOSKELETAL/SO FT TISSUE	Musculoskeletal/Soft Tissue - Other (Specify, ___)	



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<b>Category : NEUROLOGY</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Arachnoiditis/meningismus/radiculitis	NEUROLOGY	Arachnoiditis/meningismus/radiculitis	
Ataxia (incoordination)	NEUROLOGY	Ataxia (incoordination)	
CNS cerebrovascular ischemia	NEUROLOGY	CNS cerebrovascular ischemia	
Cognitive disturbance/learning problems (for pediatrics)	NEUROLOGY	Cognitive disturbance	
Confusion	NEUROLOGY	Confusion	
Delusions	NEUROLOGY	Psychosis (hallucinations/delusions)	
COMMENTS	<i>v2.0 Delusions and v2.0 Hallucinations merged to v3.0 Psychosis (hallucinations/delusions).</i>		
Depressed level of consciousness	NEUROLOGY	Somnolence/depressed level of consciousness	
Dizziness/lightheadedness	NEUROLOGY	Dizziness	
COMMENTS	<i>v2.0 Dizziness/lightheadedness and v2.0 Vertigo merged to v3.0 Dizziness.</i>		
Extrapyramidal/involuntary movement/restlessness	NEUROLOGY	Extrapyramidal/involuntary movement/restlessness	
Hallucinations	NEUROLOGY	Psychosis (hallucinations/delusions)	
COMMENTS	<i>v2.0 Hallucinations and v2.0 Delusions merged to v3.0 Psychosis (hallucinations/delusions).</i>		
Insomnia	CONSTITUTIONAL SYMPTOMS	Insomnia	
Irritability (children <3 years of age)	NEUROLOGY	Irritability (children <3 years of age)	
Leukoencephalopathy associated with radiological findings	NEUROLOGY	Leukoencephalopathy (radiographic findings)	
Memory loss	NEUROLOGY	Memory impairment	
Mood alteration-anxiety, agitation	NEUROLOGY	Mood alteration <b>Select</b> Anxiety	
Mood alteration-depression	NEUROLOGY	Mood alteration <b>Select</b> Depression	
Mood alteration-euphoria	NEUROLOGY	Mood alteration <b>Select</b> Euphoria	



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<b>Category : NEUROLOGY</b>			
Adverse Event	Category	Adverse Event	Other Specify
Neuropathy - cranial	NEUROLOGY	Neurology - Other (Specify, __)	Neuropathy - cranial (10048658)
COMMENTS <i>v2.0 Neuropathy-cranial deleted. All cranial nerves are v3.0 select AEs.</i>			
Neuropathy - motor	NEUROLOGY	Neuropathy: motor	
Neuropathy-sensory	NEUROLOGY	Neuropathy: sensory	
Nystagmus	OCULAR/VISUAL	Nystagmus	
Personality/behavioral	NEUROLOGY	Personality/behavioral	
Pyramidal tract dysfunction (e.g., increased tone, hyperreflexia, positive Babinski, decreased fine motor coordination)	NEUROLOGY	Pyramidal tract dysfunction (e.g., increased tone, hyperreflexia, positive Babinski, decreased fine motor coordination)	
Seizure(s)	NEUROLOGY	Seizure	
Speech impairment (e.g., dysphasia or aphasia)	NEUROLOGY	Speech impairment (e.g., dysphasia or aphasia)	
Syncope (fainting)	NEUROLOGY	Syncope (fainting)	
Tremor	NEUROLOGY	Tremor	
Vertigo	NEUROLOGY	Dizziness	
COMMENTS <i>v2.0 Vertigo and v2.0 Dizziness/lightheadedness merged into v3.0 Dizziness.</i>			
Neurology-Other (Specify, _____)	NEUROLOGY	Neurology - Other (Specify, __)	



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<b>Category : OCULAR/VISUAL</b>			
Adverse Event	Category	Adverse Event	Other Specify
Cataract	OCULAR/VISUAL	Cataract	
Conjunctivitis	OCULAR/VISUAL	Ocular surface disease	
Dry eye	OCULAR/VISUAL	Dry eye syndrome	
Glaucoma	OCULAR/VISUAL	Glaucoma	
Keratitis (corneal inflammation/corneal ulceration)	OCULAR/VISUAL	Keratitis (corneal inflammation/corneal ulceration)	
Tearing (watery eyes)	OCULAR/VISUAL	Watery eye (epiphora, tearing)	
Vision-blurred vision	OCULAR/VISUAL	Vision-blurred vision	
Vision-double vision (diplopia)	OCULAR/VISUAL	Ophthalmoplegia/diplopia (double vision)	
Vision-flashing lights/floaters	OCULAR/VISUAL	Vision-flashing lights/floaters	
Vision-night blindness (nyctalopia)	OCULAR/VISUAL	Night blindness (nyctalopia)	
Vision-photophobia	OCULAR/VISUAL	Vision-photophobia	
Ocular/Visual-Other (Specify, ___)	OCULAR/VISUAL	Ocular/Visual - Other (Specify, ___)	





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<b>Category : PAIN</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Abdominal pain or cramping	PAIN	Pain <b>Select</b> Abdomen NOS	
Arthralgia (joint pain)	PAIN	Pain <b>Select</b> Joint	
Bone pain	PAIN	Pain <b>Select</b> Bone	
Chest pain (non-cardiac and non-pleuritic)	PAIN	Pain <b>Select</b> Chest/thorax NOS	
Dysmenorrhea	PAIN	Pain - Other (Specify, __)	Dysmenorrhea (10013935)
COMMENTS <i>v2.0 Dysmenorrhea is graded as v3.0 Pain select-Uterus.</i>			
Dyspareunia	SEXUAL/REPRODUCTIVE FUNCTION	Vaginal dryness	
COMMENTS <i>v2.0 Dyspareunia is graded as v3.0 Vaginal dryness Grade 2.</i>			
Earache (otalgia)	PAIN	Pain <b>Select</b> Middle ear	
Headache	PAIN	Pain <b>Select</b> Head/headache	
Hepatic pain	PAIN	Pain <b>Select</b> Liver	
Myalgia (muscle pain)	PAIN	Pain <b>Select</b> Muscle	
Neuropathic pain (e.g., jaw pain, neurologic pain, phantom limb pain, post-infectious neuralgia, or painful neuropathies)	PAIN	Pain <b>Select</b> Neuralgia/peripheral nerve	
Pain due to radiation	PAIN	Pain <b>Select</b> Pain NOS	



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<b>Category : PAIN</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Pelvic pain	PAIN	Pain <b>Select</b> Pelvis	
Pleuritic pain	PAIN	Pain <b>Select</b> Pleura	
Rectal or perirectal pain (proctalgia)	PAIN	Pain <b>Select</b> Rectum	
Tumor pain (onset or exacerbation of tumor pain due to treatment)	PAIN	Pain <b>Select</b> Tumor pain	
Pain-Other (Specify,___)	PAIN	Pain - Other (Specify, __)	



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<b>Category : PULMONARY</b>			
<b>Adverse Event</b>	<b>Category</b>	<b>Adverse Event</b>	<b>Other Specify</b>
Adult respiratory distress syndrome (ARDS)	PULMONARY/UPPER RESPIRATORY	Adult Respiratory Distress Syndrome (ARDS)	
Apnea	NEUROLOGY	Apnea	
Carbon monoxide diffusion capacity (DL(co))	PULMONARY/UPPER RESPIRATORY	Carbon monoxide diffusion capacity (DL(co))	
Cough	PULMONARY/UPPER RESPIRATORY	Cough	
Dyspnea (shortness of breath)	PULMONARY/UPPER RESPIRATORY	Dyspnea (shortness of breath)	
FEV (1)	PULMONARY/UPPER RESPIRATORY	FEV(1)	
Hiccoughs (hiccups, singultus)	PULMONARY/UPPER RESPIRATORY	Hiccoughs (hiccups, singultus)	
Hypoxia	PULMONARY/UPPER RESPIRATORY	Hypoxia	
Pleural effusion (non-malignant)	PULMONARY/UPPER RESPIRATORY	Pleural effusion (non-malignant)	
Pneumonitis/pulmonary infiltrates	PULMONARY/UPPER RESPIRATORY	Pneumonitis/pulmonary infiltrates	
Pneumothorax	PULMONARY/UPPER RESPIRATORY	Pneumothorax	
Pulmonary fibrosis	PULMONARY/UPPER RESPIRATORY	Pulmonary fibrosis (radiographic changes)	
Voice changes/stridor/larynx (e.g., hoarseness, loss of voice, laryngitis)	PULMONARY/UPPER RESPIRATORY	Voice changes/dysarthria (e.g., hoarseness, loss or alteration in voice, laryngitis)	
Pulmonary-Other (Specify, ___)	PULMONARY/UPPER RESPIRATORY	Pulmonary/Upper Respiratory - Other (Specify, ___)	



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<b>Category : RENAL/GENITOURINARY</b>			
Adverse Event	Category	Adverse Event	Other Specify
Bladder spasms	RENAL/GENITOURINARY	Bladder spasms	
Creatinine	METABOLIC/LABORATORY	Creatinine	
Dysuria (painful urination)	PAIN	Pain <b>Select</b> Bladder	
Fistula or GU fistula (e.g., vaginal, vesicovaginal)	RENAL/GENITOURINARY	Fistula, GU <b>Select</b> Vagina	
Hemoglobinuria	METABOLIC/LABORATORY	Hemoglobinuria	
Incontinence	RENAL/GENITOURINARY	Incontinence, urinary	
Operative injury to bladder and/or ureter	SURGERY/INTRA-OPERATIVE INJURY	Intra-operative injury <b>Select</b> Bladder	
Proteinuria	METABOLIC/LABORATORY	Proteinuria	
Renal failure	RENAL/GENITOURINARY	Renal failure	
Ureteral obstruction	RENAL/GENITOURINARY	Obstruction, GU <b>Select</b> Ureter	
Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis)	RENAL/GENITOURINARY	Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis)	
Urinary frequency/urgency	RENAL/GENITOURINARY	Urinary frequency/urgency	
Urinary retention	RENAL/GENITOURINARY	Urinary retention (including neurogenic bladder)	
Urine color change (not related to other dietary or physiologic cause e.g., bilirubin, concentrated urine, hematuria)	RENAL/GENITOURINARY	Urine color change	
Vaginitis (not due to infection)	SEXUAL/REPRODUCTIVE FUNCTION	Vaginitis (not due to infection)	
Renal/Genitourinary-Other (Specify,____)	RENAL/GENITOURINARY	Renal/Genitourinary - Other (Specify, __)	



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Category : SECONDARY MALIGNANCY			
Adverse Event	Category	Adverse Event	Other Specify
Secondary Malignancy-Other (Specify,____) excludes metastasis from initial primary	SECONDARY MALIGNANCY	Secondary Malignancy - possibly related to cancer treatment (Specify, __)	



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<b>Category : SEXUAL/REPRODUCTIVE FUNCTION</b>			
Adverse Event	Category	Adverse Event	Other Specify
Erectile impotence	SEXUAL/REPRODUCTIVE FUNCTION	Erectile dysfunction	
Female sterility	SEXUAL/REPRODUCTIVE FUNCTION	Infertility/sterility	
COMMENTS <i>v2.0 Female sterility and v2.0 Male infertility merged into v3.0 Infertility/sterility.</i>			
Irregular menses (change from baseline)	SEXUAL/REPRODUCTIVE FUNCTION	Irregular menses (change from baseline)	
Libido	SEXUAL/REPRODUCTIVE FUNCTION	Libido	
Male infertility	SEXUAL/REPRODUCTIVE FUNCTION	Infertility/sterility	
COMMENTS <i>v2.0 Male infertility and v2.0 Female sterility merged into v3.0 Infertility/sterility.</i>			
Vaginal dryness	SEXUAL/REPRODUCTIVE FUNCTION	Vaginal dryness	
Sexual/Reproductive Function-Other (Specify, ___)	SEXUAL/REPRODUCTIVE FUNCTION	Sexual/Reproductive Function - Other (Specify, ___)	



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Category : SYNDROMES			
Adverse Event	Category	Adverse Event	Other Specify
Tumor flare	SYNDROMES	Tumor flare	
Tumor lysis syndrome	SYNDROMES	Tumor lysis syndrome	
Syndromes-Other (Specify, _____)	SYNDROMES	Syndromes - Other (Specify, ___)	