

CTCAE v3.0 Revision Project Working Group Information for Getting Started

Prepared by:

Ann Setser, BSN, MEd

NCI Center for Bioinformatics

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Outline

- CTCAE v3.0 As-is
- MedDRA Fundamentals
- CTCAE v3.0 Relationship to MedDRA
- Content revision
 - 100% MedDRA single concepts
 - CTEP, FDA, CBITT, Industry, Others
 - Understandability, Reproducibility, Usability
- Instructions for Excel Documents

CTCAE v3.0 Components

- Adverse Event Term
- Supra-ordinate Term
- Grading Scale
- Also Consider
- Navigation Notes
- Mapped to MedDRA LLT (imperfect)

CTCAE v3.0 Components

AE Term

CARDIAC GENERAL							Page 1 of 3
Adverse Event	Short Name	Grade					
		1	2	3	4	5	
Hypertension	Hypertension	Asymptomatic, transient (<24 hrs) increase by >20 mmHg (diastolic) or to >150/100 if previously WNL; intervention not indicated Pediatric: Asymptomatic, transient (<24 hrs) BP increase >ULN; intervention not indicated	Recurrent or persistent (≥24 hrs) or symptomatic increase by >20 mmHg (diastolic) or to >150/100 if previously WNL; monotherapy may be indicated Pediatric: Recurrent or persistent (≥24 hrs) BP >ULN; monotherapy may be indicated	Requiring more than one drug or more intensive therapy than previously Pediatric: Same as adult	Life-threatening consequences (e.g., hypertensive crisis) Pediatric: Same as adult	Death	

REMARK: Use age and gender-appropriate normal values >95th percentile ULN for pediatric patients.

Adverse Event Term

- Mapped where possible to MedDRA LLT

CTCAE v3.0 Components

Supra-ordinate Terms

GASTROINTESTINAL						
		Grade				
Adverse Event	Short Name	1	2	3	4	5
Fistula, GI – Select: – Abdomen NOS – Anus – Biliary tree – Colon/cecum/appendix – Duodenum – Esophagus – Gallbladder – Ileum – Jejunum – Oral cavity – Pancreas – Pharynx – Rectum – Salivary gland – Small bowel NOS – Stomach	Fistula, GI – Select	Asymptomatic, radiographic findings only	Symptomatic; altered GI function (e.g., altered dietary habits, diarrhea, or GI fluid loss); IV fluids indicated <24 hrs	Symptomatic and severely altered GI function (e.g., altered dietary habits, diarrhea, or GI fluid loss); IV fluids, tube feedings, or TPN indicated ≥24 hrs	Life-threatening consequences	Death

Supra-ordinate term

- Is a grouping term based on disease process, signs, symptoms, or diagnosis
- Is accompanied by specific AEs that are all related to the Supra-ordinate term
- Provides clustering and consistent representation of Grade (severity descriptions) for related AEs
- Are not AEs, are not mapped to a MedDRA LLT term
- Cannot be used for reporting

CTCAE v3.0 Components

AE Grading Scale

		CARDIAC GENERAL					Page 1 of 3
Adverse Event	Short Name	Grade					
		1	2	3	4	5	
Hypertension	Hypertension	Asymptomatic, transient (<24 hrs) increase by >20 mmHg (diastolic) or to >150/100 if previously WNL; intervention not indicated Pediatric: Asymptomatic, transient (<24 hrs) BP increase >ULN; intervention not indicated	Recurrent or persistent (≥24 hrs) or symptomatic increase by >20 mmHg (diastolic) or to >150/100 if previously WNL; monotherapy may be indicated Pediatric: Recurrent or persistent (≥24 hrs) BP >ULN; monotherapy may be indicated	Requiring more than one drug or more intensive therapy than previously Pediatric: Same as adult	Life-threatening consequences (e.g., hypertensive crisis) Pediatric: Same as adult	Death	

REMARK: Use age and gender-appropriate normal values >95th percentile ULN for pediatric patients.

Grading/severity scale

- Unique for each AE term

CTEP, NCI CTCAE v3.0

General Descriptions of Grade

0	No adverse event or within normal limits
1	Mild Adverse Event (minor; no specific medical intervention; asymptomatic laboratory findings only, radiographic findings only; marginal clinical relevance)
2	Moderate Adverse Event (minimal intervention; local intervention; noninvasive intervention [packing, cautery])
3	Severe and undesirable Adverse Event (significant symptoms requiring hospitalization or invasive intervention; transfusion; elective interventional radiological procedure; therapeutic endoscopy or operation)
4	Life-threatening or disabling Adverse Event (complicated by acute, life-threatening metabolic or cardiovascular complications such as circulatory failure, hemorrhage, sepsis. Life-threatening physiologic consequences; need for intensive care or emergent invasive procedure; emergent interventional radiological procedure, therapeutic endoscopy or operation)
5	Fatal adverse event

CTCAE v3.0

General Descriptions of Grade used as a *guide* for defining CTCAE term-specific severity grading scale

Dysphagia (difficulty swallowing)

1	Symptomatic, able to eat regular diet
2	Symptomatic and altered eating/swallowing (e.g., altered dietary habits, oral supplements); IV fluids indicated <24 hrs
3	Symptomatic and severely altered eating/swallowing (e.g., inadequate oral caloric or fluid intake); IV fluids, tube feedings or TPN indicated \geq24 hrs
4	Life-threatening consequences (e.g., obstruction, perforation)

BLOOD/BONE MARROW

		Grade				
Adverse Event	Short Name	1	2	3	4	5
Bone marrow cellularity	Bone marrow cellularity	Mildly hypocellular or $\leq 25\%$ reduction from normal cellularity for age	Moderately hypocellular or $>25 - \leq 50\%$ reduction from normal cellularity for age	Severely hypocellular or $>50 - \leq 75\%$ reduction cellularity from normal for age	—	Death
CD4 count	CD4 count	$<LLN - 500/mm^3$ $<LLN - 0.5 \times 10^9 /L$	$<500 - 200/mm^3$ $<0.5 - 0.2 \times 10^9 /L$	$<200 - 50/mm^3$ $<0.2 \times 0.05 - 10^9 /L$	$<50/mm^3$ $<0.05 \times 10^9 /L$	Death
Haptoglobin	Haptoglobin	$<LLN$	—	Absent	—	Death
Hemoglobin	Hemoglobin	$<LLN - 10.0 \text{ g/dL}$ $<LLN - 6.2 \text{ mmol/L}$ $<LLN - 100 \text{ g/L}$	$<10.0 - 8.0 \text{ g/dL}$ $<6.2 - 4.9 \text{ mmol/L}$ $<100 - 80 \text{ g/L}$	$<8.0 - 6.5 \text{ g/dL}$ $<4.9 - 4.0 \text{ mmol/L}$ $<80 - 65 \text{ g/L}$	$<6.5 \text{ g/dL}$ $<4.0 \text{ mmol/L}$ $<65 \text{ g/L}$	Death
Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis)	Hemolysis	Laboratory evidence of hemolysis only (e.g., direct antiglobulin test [DAT, Coombs'] schistocytes)	Evidence of red cell destruction and $\geq 2 \text{ gm}$ decrease in hemoglobin, no transfusion	Transfusion or medical intervention (e.g., steroids) indicated	Catastrophic consequences of hemolysis (e.g., renal failure, hypotension, bronchospasm, emergency splenectomy)	Death
ALSO CONSIDER: Haptoglobin; Hemoglobin.						
Iron overload	Iron overload	—	Asymptomatic iron overload, intervention not indicated	Iron overload, intervention indicated	Organ impairment (e.g., endocrinopathy, cardiopathy)	Death
Leukocytes (total WBC)	Leukocytes	$<LLN - 3000/mm^3$ $<LLN - 3.0 \times 10^9 /L$	$<3000 - 2000/mm^3$ $<3.0 - 2.0 \times 10^9 /L$	$<2000 - 1000/mm^3$ $<2.0 - 1.0 \times 10^9 /L$	$<1000/mm^3$ $<1.0 \times 10^9 /L$	Death
Lymphopenia	Lymphopenia	$<LLN - 800/mm^3$ $<LLN \times 0.8 - 10^9 /L$	$<800 - 500/mm^3$ $<0.8 - 0.5 \times 10^9 /L$	$<500 - 200/mm^3$ $<0.5 - 0.2 \times 10^9 /L$	$<200/mm^3$ $<0.2 \times 10^9 /L$	Death
Neutrophils/granulocytes (ANC/AGC)	Neutrophils	$<LLN - 1500/mm^3$ $<LLN - 1.5 \times 10^9 /L$	$<1500 - 1000/mm^3$ $<1.5 - 1.0 \times 10^9 /L$	$<1000 - 500/mm^3$ $<1.0 - 0.5 \times 10^9 /L$	$<500/mm^3$ $<0.5 \times 10^9 /L$	Death
Platelets	Platelets	$<LLN - 75,000/mm^3$ $<LLN - 75.0 \times 10^9 /L$	$<75,000 - 50,000/mm^3$ $<75.0 - 50.0 \times 10^9 /L$	$<50,000 - 25,000/mm^3$ $<50.0 - 25.0 \times 10^9 /L$	$<25,000/mm^3$ $<25.0 \times 10^9 /L$	Death
Splenic function	Splenic function	Incidental findings (e.g., Howell-Jolly bodies)	Prophylactic antibiotics indicated	—	Life-threatening consequences	Death
Blood/Bone Marrow – Other (Specify, __)	Blood – Other (Specify)	Mild	Moderate	Severe	Life-threatening; disabling	Death

Medical Dictionary for Regulatory Activities – MedDRA

Background

- Is a clinically validated international [medical terminology](#) used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation.
- Is the [adverse event](#) classification dictionary endorsed by the [International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use](#) (ICH).

MedDRA

- Is used in the [US](#), [European Union](#), and [Japan](#). Its use is currently mandated in Europe and Japan for safety reporting.
- Is managed by the MSSO (Maintenance and Support Services Organization), an organization that reports to the [International Federation of Pharmaceutical Manufacturers and Associations](#) (IFPMA).

MedDRA Structure

System, Organ, Class	SOC	Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose	26
High Level Group Term	HLGT	Subordinate to SOC, supraordinate descriptor for one or more HLTs	332
High Level Term	HLT	Subordinate to HLGT, supraordinate descriptor for one or more PTs	1,688
Preferred Term	PT	Represents a single medical concept	18,075
Lowest Level Term	LLT	Lowest level of the terminology, related to a single PT as a synonym, lexical variant, or quasi-synonym (Note: All PTs have an identical LLT)	66,135

MedDRA

- In addition, the MedDRA dictionary includes Standardized MedDRA Queries (SMQs). SMQs are groupings of terms that relate to a defined medical condition or area of interest.
- MedDRA translations
 - Dutch
 - English
 - French
 - German
 - Italian
 - Japanese
 - Portuguese
 - Spanish

CTCAE v3.0 & MedDRA

- CTCAE & MedDRA
 - MedDRA is used by the biopharmaceutical industry and regulatory agencies within the ICH regions
- CTCAE use by Industry
 - CTCAE is widely used in oncology and HIV clinical research
 - To facilitate data exchange within internal databases using MedDRA and with regulatory authorities for the purpose of SAE reporting, must establish a mechanism to 'translate' or 'convert' CTCAE terms from investigators to MedDRA terms.
 - CTCAE mapping to MedDRA (imperfect)

Comparison

MedDRA

List of terms

>86,000

Content: Comprehensive

Hierarchy: 5 levels

Medically validated

CTCAE v3.0

List of terms

1,059

Content: Oncology

Severity Scale

Hierarchy: 2 levels

CTCAE v3.0 Issues & MedDRA

- CTCAE v3.0 Terms
 - Multiple concepts
 - One/many element of Grade description is critical AE concept
 - Not all MedDRA terms
 - 72% CTCAE = mapped to a single MedDRA term/code
 - 28% CTCAE = CTEP-only code (leading 9's with meaning to no one outside CTEP)

CTCAE v3.0

Multiple Concepts in one AE Term

CONSTITUTIONAL SYMPTOMS							Page 1 of 2
Adverse Event	Short Name	Grade					
		1	2	3	4	5	
Fatigue (asthenia, lethargy, malaise)	Fatigue	Mild fatigue over baseline	Moderate or causing difficulty performing some ADL	Severe fatigue interfering with ADL	Disabling	—	

Mapped to MedDRA: Fatigue 10016256

Fatigue, Asthenia, Lethargy, Malaise

- Are unique concepts in MedDRA (PTs)
- Are not
 - related to a single Preferred Term
 - synonyms, lexical variants, or quasi-synonyms

- SOC General disorders and administration site conditions
 - HLGT General system disorders NEC
 - HLT Asthenic conditions
 - PT Fatigue

MedDRA Preferred Term Fatigue + 20 LLTs

- PT Autonomic nervous system imbalance
- PT Chronic fatigue syndrome
- PT Decreased activity
- PT **Fatigue**
 - LLT Chronic fatigue
 - LLT Depressive weariness
 - LLT Enervation
 - LLT Exhaustion
 - LLT Exhaustion due to excessive exertion
 - LLT Exhaustion due to exposure
 - LLT Fatigability
 - LLT Fatigability generalized
 - LLT Fatigability lumbar
 - LLT Fatigability of knees
 - LLT Fatigue
 - LLT Fatigue aggravated
 - LLT Fatigue extreme
 - LLT Fatigueability
 - LLT Fatigueability generalised
 - LLT Lassitude
 - LLT Loss physical strength
 - LLT TATT
 - LLT Tired all the time
 - LLT Tired and heavy
 - LLT Tired out
 - LLT Tiredness
 - LLT Washed-out
 - LLT Weariness
 - LLT Worn out
- PT Lethargy
- PT Listless

MedDRA Browser - Search by MedDRA Term

String search criteria for MedDRA Term

SOC
 HLGT
 HLT
 PT
 LLT

Search Condition	Value	Logical
contains	fatigue	AND
contains		AND
contains		

Search Results: **21**

Click 'Cancel Search' to stop the search Search Results for PT: **5**

- PT Chronic fatigue syndrome
- PT Fatigue
 - HLT Asthenic conditions
 - HLGT General system disorders NEC
 - SOC General disorders and administration site conditions
 - PT Fatigue management
 - PT Muscle fatigue
 - PT Post viral fatigue syndrome

CTCAE Revision

Fatigue (asthenia, lethargy, malaise)

- List separately in CTCAE
- List in format of CTCAE '*Select*'?
 - General system disorders NEC
 - Fatigue
 - Asthenia
 - Lethargy
 - Malaise
- If listed separately and/or as '*Select*' is grading scale appropriate?

CTCAE v3.0

Critical concept listed in Grade only – not as AE Term

ALLERGY/IMMUNOLOGY							Page 1 of 1
		Grade					
Adverse Event	Short Name	1	2	3	4	5	
Allergic reaction/ hypersensitivity (including drug fever)	Allergic reaction	Transient flushing or rash; drug fever <38°C (<100.4°F)	Rash; flushing; urticaria; dyspnea; drug fever ≥38°C (≥100.4°F)	Symptomatic bronchospasm, with or without urticaria; parenteral medication(s) indicated; allergy-related edema/angioedema; hypotension	Anaphylaxis	Death	
REMARK: Urticaria with manifestations of allergic or hypersensitivity reaction is graded as Allergic reaction/hypersensitivity (including drug fever).							
ALSO CONSIDER: Cytokine release syndrome/acute infusion reaction.							

CTCAE Revision

Allergic reaction/hypersensitivity (including drug fever)

Allergic reaction/hypersensitivity

1. Transient flushing or rash; drug fever <38 C (<100.4 F)
2. Rash; flushing; urticaria; dyspnea; drug fever ≥ 38 C (≥ 100.4 F)
3. Symptomatic bronchospasm, with or without urticaria; parenteral medication(s) indicated; allergy-related edema/angioedema; hypotension
4. ?
5. ?

Anaphylaxis

- 1.
- 2.
- 3.
4. ?
5. ?

Drug fever?

CTCAE Issue

Non-MedDRA Terms + CTEP-Only Codes

INFECTION CATEGORY

<p>Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10³/L) – <i>Select</i> ←</p> <p>'Select' AEs appear at the end of the CATEGORY.</p>	<p>Infection (documented clinically) with Grade 3 or 4 ANC – <i>Select</i></p>	<p>—</p>	<p>Localized, local intervention indicated</p>	<p>IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated</p>	<p>Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)</p>	<p>Death</p>
<p>REMARK: Fever with Grade 3 or 4 neutrophils in the absence of documented infection is graded as Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection).</p> <p>ALSO CONSIDER: Neutrophils/granulocytes (ANC/AGC).</p>						
<p>Infection with normal ANC or Grade 1 or 2 neutrophils – <i>Select</i> ←</p> <p>'Select' AEs appear at the end of the CATEGORY.</p>	<p>Infection with normal ANC – <i>Select</i></p>	<p>—</p>	<p>Localized, local intervention indicated</p>	<p>IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated</p>	<p>Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)</p>	<p>Death</p>
<p>Infection with unknown ANC – <i>Select</i> ←</p> <p>'Select' AEs appear at the end of the CATEGORY.</p>	<p>Infection with unknown ANC – <i>Select</i></p>	<p>—</p>	<p>Localized, local intervention indicated</p>	<p>IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated</p>	<p>Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)</p>	<p>Death</p>
<p>REMARK: Infection with unknown ANC – <i>Select</i> is to be used in the rare case when ANC is unknown.</p>						

INFECTION – SELECT

AUDITORY/EAR

- External ear (otitis externa)
- Middle ear (otitis media)

CARDIOVASCULAR

- Artery
- Heart (endocarditis)
- Spleen
- Vein

DERMATOLOGY/SKIN

- Lip/perioral
- Peristomal
- Skin (cellulitis)
- Ungual (nails)

GASTROINTESTINAL

- Abdomen NOS
- Anal/perianal
- Appendix
- Cecum
- Colon
- Dental-tooth
- Duodenum
- Esophagus
- Ileum
- Jejunum
- Oral cavity-gums (gingivitis)
- Peritoneal cavity
- Rectum
- Salivary gland
- Small bowel NOS
- Stomach

GENERAL

- Blood
- Catheter-related
- Foreign body (e.g., graft, implant, prosthesis, stent)
- Wound

HEPATOBIILIARY/PANCREAS

- Biliary tree
- Gallbladder (cholecystitis)
- Liver
- Pancreas

LYMPHATIC

- Lymphatic

MUSCULOSKELETAL

- Bone (osteomyelitis)
- Joint
- Muscle (infection myositis)
- Soft tissue NOS


NEUROLOGY

- Brain (encephalitis, infectious)
- Brain + Spinal cord (encephalomyelitis)
- Meninges (meningitis)
- Nerve-cranial
- Nerve-peripheral
- Spinal cord (myelitis)

OCULAR

- Conjunctiva
- Cornea
- Eye NOS
- Lens

PULMONARY/UPPER RESPIRATORY

- Bronchus
- Larynx
- Lung (pneumonia)
- Mediastinum NOS
- Mucosa
- Neck NOS 
- Nose
- Paranasal
- Pharynx
- Pleura (empyema)
- Sinus
- Trachea
- Upper aerodigestive NOS
- Upper airway NOS

RENAL/GENITOURINARY

- Bladder (urinary)
- Kidney
- Prostate
- Ureter
- Urethra
- Urinary tract NOS

SEXUAL/REPRODUCTIVE FUNCTION

- Cervix
- Fallopian tube
- Pelvis NOS
- Penis
- Scrotum
- Uterus
- Vagina
- Vulva

**Count of 77 INFECTION terms
99% map to MedDRA**

INFECTION CATEGORY

- Infection with unknown ANC – **Conjunctiva**
– **MedDRA: Conjunctivitis infective -10010742**

9
codes

- Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC $<1.0 \times 10^9/L$) – **Conjunctiva**
- Infection with normal ANC or Grade 1 or 2 neutrophils - **Conjunctiva**

SURGERY/INTRA-OPERATIVE INJURY

		Grade				
Adverse Event	Short Name	1	2	3	4	5

NAVIGATION NOTE: Intra-operative hemorrhage is graded as Hemorrhage/bleeding associated with surgery, intra-operative or postoperative in the HEMORRHAGE/BLEEDING CATEGORY.

Intra-operative injury – <i>Select Organ or Structure</i> *Select* AEs appear at the end of the CATEGORY. REMARK: The *Select* AEs are defined as significant, unanticipated injuries that are recognized at the time of surgery. These AEs do not refer to additional surgical procedures that must be performed because of a change in the operative plan based on intra-operative findings. Any sequelae resulting from the intra-operative injury that result in an adverse outcome for the patient must also be recorded and graded under the relevant CTCAE Term.	Intraop injury – <i>Select</i>	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated	Life threatening consequences; disabling	—
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Intra-operative Injury – <i>Other (Specify, ___)</i>	Intraop Injury – <i>Other (Specify)</i>	Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated	Life threatening consequences; disabling	—
------------------------------------------------------	-----------------------------------------	-----------------------------------------------------	--------------------------------------------------------	---------------------------------------------------------------------------	------------------------------------------	---

REMARK: Intra-operative Injury – Other (Specify, ___) is to be used only to report an organ/structure not included in the *Select* AEs found at the end of the CATEGORY. Any sequelae resulting from the intra-operative injury that result in an adverse outcome for the patient must also be recorded and graded under the relevant CTCAE Term.

AUDITORY/EAR – Inner ear – Middle ear – Outer ear NOS – Outer ear-Pinna CARDIOVASCULAR – Artery-aorta – Artery-carotid – Artery-cerebral – Artery-extremity (lower) – Artery-extremity (upper) – Artery-hepatic – Artery-major visceral artery – Artery-pulmonary – Artery NOS – Heart – Spleen – Vein-extremity (lower) – Vein-extremity (upper) – Vein-hepatic – Vein-inferior vena cava – Vein-jugular – Vein-major viscoeral vein – Vein-portal vein – Vein-pulmonary – Vein-superior vena cava – Vein NOS DERMATOLOGY/SKIN – Breast – Nails – Skin ENDOCRINE – Adrenal gland – Parathyroid – Pituitary	ENDOCRINE (continued) – Thyroid HEAD AND NECK – Gingiva – Larynx – Lip/perioral area – Face NOS – Nasal cavity – Nasopharynx – Neck NOS – Nose – Oral cavity NOS – Parotid gland – Pharynx – Salivary duct – Salivary gland – Sinus – Teeth – Tongue – Upper aerodigestive NOS GASTROINTESTINAL – Abdomen NOS – Anal sphincter – Anus – Appendix – Cecum – Colon – Duodenum – Esophagus – Ileum – Jejunum – Peritoneal cavity – Rectum – Small bowel NOS	GASTROINTESTINAL (continued) – Stoma (GI) – Stomach HEPATOBIILIARY/ PANCREAS – Biliary tree-common bile duct – Biliary tree-common hepatic duct – Biliary tree-left hepatic duct – Biliary tree-right hepatic duct – Biliary tree NOS – Gallbladder – Liver – Pancreas – Pancreatic duct MUSCULOSKELETAL – Bone – Cartilage – Extremity-lower – Extremity-upper – Joint – Ligament – Muscle – Soft tissue NOS – Tendon NEUROLOGY – Brain – Meninges – Spinal cord NERVES: – Brachial plexus – CN I (olfactory) – CN II (optic) – CN III (oculomotor) – CN IV (trochlear)	NEUROLOGY (continued) NERVES: – CN V (trigeminal) motor – CN V (trigeminal) sensory – CN VI (abducens) – CN VII (facial) motor-face – CN VII (facial) sensory-taste – CN VIII (vestibulocochlear) – CN IX (glossopharyngeal) motor pharynx – CN IX (glossopharyngeal) sensory ear-pharynx-tongue – CN X (vagus) – CN XI (spinal accessory) – CN XII (hypoglossal) – Cranial nerve or branch NOS – Lingual – Lung thoracic – Peripheral motor NOS – Peripheral sensory NOS – Recurrent laryngeal – Sacral plexus – Sciatic – Thoracodorsal OCULAR – Conjunctiva	PULMONARY/UPPER RESPIRATORY – Bronchus – Lung – Mediastinum – Pleura – Thoracic duct – Trachea – Upper airway NOS RENAL/GENITOURINARY – Bladder – Cervix – Fallopian tube – Kidney – Ovary – Pelvis NOS – Penis – Prostate – Scrotum – Testis – Ureter – Urethra – Urinary conduit – Urinary tract NOS – Uterus – Vagina – Vulva
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**141 Site-specific terms
<10% MedDRA**

Comparison

MedDRA

List of standard terms

>86,000

Content: Comprehensive

Hierarchy: 5 levels

Medically validated

CTCAE v4.0

List of MedDRA standard terms

~1000?

Content: Subset of MedDRA appropriate for oncology

Severity Scale

Hierarchy: 2 – 3 levels?

CTCAE v4.0

1. Will **not** require sites to learn MedDRA
2. Will **not** require sites to code MedDRA
3. Will **not** be a clone of MedDRA
4. Will **not** be replace MedDRA

CTCAE v4.0

1. Will list a small subset of MedDRA standard terms that are common in oncology practice
2. CTCAE v4.0/MedDRA terms are recognized by the ICH community as practice standards

Working Group Assignments

Excel Documents

- Provide specific information by CTCAE v3.0 CATEGORY and by SOC
- 6 Worksheets per Excel File
- Not for comments, edits, additions, deletions, etc.
 - All work will be done on the Wiki
- Are available on gForge

CTCAE v3.0 CATEGORY	CTCAE v3.0 supra-ordinate term	CTCAE v3.0 Select AE	MedDRA LLT (v100)	MedDRA Code(v10.0)/ CTEP Code	PT	HLT	HLGT	SOC
ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)		Hypersensitivity	10020751	Hypersensitivity	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)		Allergic rhinitis	10001723	Rhinitis allergic	Nasal congestion and inflammations	Upper respiratory tract disorders (excl infections)	Respiratory, thoracic and mediastinal disorders
ALLERGY/IMMUNOLOGY	Autoimmune reaction		Autoimmune disorder	10061664	Autoimmune disorder	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders
ALLERGY/IMMUNOLOGY	Serum sickness		Serum sickness	10040400	Serum sickness	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/IMMUNOLOGY	Vasculitis		Vasculitis	10047115	Vasculitis	Vasculitides NEC	Vascular inflammations	Vascular disorders
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)		Immune system disorder	10021425	Immune system disorder	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders

For Working Group Background Information ONLY
Excel Files by CTCAE v3.0 CATEGORY with 6 Worksheets



Worksheet #1

CTCAE v3.0 CATEGORY	AE Count Indicator	Identifier/ Action	CTCAE v3.0 supra-ordinate term	CTCAE v3.0 Select AE	MedDRA LLT (v10.0)	MedDRA Code(v10.0)/ CTEP Code	PT	HLT	HLGT	SOC	Comments
ALLERGY/IMMUNOLOGY	A-1	Original	Allergic reaction/hypersensitivity (including drug fever)		Hypersensitivity	10020751	Hypersensitivity	Allergic conditions NEC	Allergic conditions	Immune system disorders	Reviewers: When original CTCAE term is split, discuss Grading scale for new terms. Use CTCAE v3.0 model of 'Supra-ordinate terms' with Select? Group with HLT as 'Supraordinate'?
ALLERGY/IMMUNOLOGY	A-1	Revision?	Allergic reaction				Hypersensitivity				Allergic reaction is LLT for PT Hypersensitivity
ALLERGY/IMMUNOLOGY	A-1	Revision?	Drug fever								Drug fever is LLT for PT Pyrexia.
ALLERGY/IMMUNOLOGY	A-1	Revision?	Anaphylaxis				Anaphylaxis			Immune system disorders	Original Grade 4: Anaphylaxis Consider listing separately & draft Grading Scale
ALLERGY/IMMUNOLOGY	A-2	Original	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)		Allergic rhinitis	10001723	Rhinitis allergic	Nasal congestion and inflammations	Upper respiratory tract disorders (excl infections)	Respiratory, thoracic and mediastinal disorders	Original = 4 PTs; SOC relocation
ALLERGY/IMMUNOLOGY	A-2	Revision?	Allergic rhinitis								
ALLERGY/IMMUNOLOGY	A-2	Revision?	Sneezing				Sneezing			and mediastinal disorders	SOC relocation
ALLERGY/IMMUNOLOGY	A-2	Revision?	Nasal congestion		Nasal stuffiness		Nasal congestion			Respiratory, thoracic and mediastinal disorders	Nasal congestion is often reported as Other, specify Respiratory

Rows inserted with potential revision MedDRA terms. Comments column

Worksheet #2

CTCAE v3.0 CATEGORY	CTCAE v3.0 supra-ordinate term	CTCAE v3.0 Select AE	MedDRA LLT (v100)	MedDRA Code(v10.0)/CTEP Code	PT	HLT	HLGT	SOC
ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)		Hypersensitivity	10020751	Hypersensitivity	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, __)		Immune system disorder	10021425	Immune system disorder	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders
ALLERGY/IMMUNOLOGY	Autoimmune reaction		Autoimmune disorder	10061664	Autoimmune disorder	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders
ALLERGY/IMMUNOLOGY	Serum sickness		Serum sickness	10040400	Serum sickness	Allergic conditions NEC	Allergic conditions	Immune system disorders
SYNDROMES	Cytokine release syndrome/acute infusion reaction		Cytokine release syndrome	10001598	Cytokine release syndrome	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders

CTCAE v3.0 ALLERGY CATEGORY

Majority of AEs reside in MedDRA SOC – Immune system disorders

SOC Immune systems disorders Worksheet displays all CTCAE v3.0 AEs that reside in Immune systems SOC

CTCAE v3.0 CATEGORY	CTCAE v3.0 supra-ordinate term	CTCAE v3.0 Select AE	MedDRA LLT (v100)	MedDRA Code(v10.0)/ CTEP Code	PT	HLT	HLGT	SOC
ALLERGY/ MMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)		Hypersensitivity	10020751	Hypersensitivity	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/ MMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)		Allergic rhinitis	10001723	Rhinitis allergic	Nasal congestion and inflammations	Upper respiratory tract disorders (excl infections)	Respiratory, thoracic and mediastinal disorders
ALLERGY/ MMUNOLOGY	Autoimmune reaction		Autoimmune disorder	10061664	Autoimmune disorder	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders
ALLERGY/ MMUNOLOGY	Serum sickness		Serum sickness	10040400	Serum sickness	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/ MMUNOLOGY	Vasculitis		Vasculitis	10047115	Vasculitis	Vasculitides NEC	Vascular inflammations	Vascular disorders
ALLERGY/ MMUNOLOGY	Allergy/Immunology - Other (Specify, __)		Immune system disorder	10021425	Immune system disorder	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders

CTCAE v3.0 ALLERGY CATEGORY AEs actually reside in 3 different MedDRA SOC

ALLERGY AsIs

Worksheet #1

CTCAE v3.0 CATEGORY	CTCAE v3.0 supra-ordinate term	CTCAE v3.0 Select AE	MedDRA LLT (v100)	MedDRA Code(v10.0)/ CTEP Code	PT	HLT	HLGT	SOC
ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)		Hypersensitivity	10020751	Hypersensitivity	Allergic conditions NEC	Allergic conditions	Immune system disorders
ALLERGY/IMMUNOLOGY	Allergy/immunology - Other (Specify, ___)		Immune system disorder	10021425	Immune system disorder	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders
ALLERGY/IMMUNOLOGY	Autoimmune reaction		Autoimmune disorder	10061664	Autoimmune disorder	Autoimmune disorders NEC	Autoimmune disorders	Immune system disorders
ALLERGY/IMMUNOLOGY	Serum sickness		Serum sickness	10040400	Serum sickness	Allergic conditions NEC	Allergic conditions	Immune system disorders
SYNDROMES	Cytokine release syndrome/acute infusion reaction		Cytokine release syndrome	10001598	Cytokine release syndrome	Immune and associated conditions NEC	Immune disorders NEC	Immune system disorders

All CTCAE v3.0 AE Terms that appear in CTCAE v4.0 and all new CTCAE v4.0 terms will be listed with their associated MedDRA SOCs

CTCAE v3.0 CATEGORY	CTCAE v3.0 term	Other Specify	Count
ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitivity (including drug fever)		906
ALLERGY/IMMUNOLOGY	Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)		1517
ALLERGY/IMMUNOLOGY	Autoimmune reaction		76
ALLERGY/IMMUNOLOGY	Serum sickness		4
ALLERGY/IMMUNOLOGY	Vasculitis		20
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGIC RESPONSE TO OXALIPLATIN-RESP DISTRESS, CHOKING, STRIDOR	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGIC TO PENICILLIN	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGIC TO PREVACID	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGIES	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGRES(SEASONAL)	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY - ITCHY EYES	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY - OTHER [MILK INTOLERANCE]	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY SEAFOOD & IODINE	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	allergy to antibiotics	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY TO ANTIBIOTICS SPECIFIED IN SAE REPORT	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY/IMMUNOLOGY OTHER: ASBESTOS	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY/IMMUNOLOGY OTHER: CODEINE	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY/IMMUNOLOGY OTHER: FIBERGLASS	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY/IMMUNOLOGY:ALLERGY-OTHER	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY_-_OTHER	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY_-SWOLLEN LIP/THROAT TIGHT	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY-OTHER	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY-OTHER [MILK INTOLERANCE]	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY-OTHER [THROAT IRRITATION]	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY-OTHER: DRUG RASH	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, ___)	ALLERGY-OTHER-NASAL DRYNESS	1

Working Group Information Only:

Historical data - CTCAE v3.0 AE terms reported to CTEP, NCI

Worksheet #4

CTCAE v3.0 CATEGORY	CTCAE v3.0 term	Other Specify	Count	LLT	Autocode
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY - OTHER [MILK INTOLERANCE]	1	Milk allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY SEAFOOD & IODINE	1	Seafood allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	allergy to antibiotics	1	Allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY TO ANTIBIOTICS SPECIFIED IN SAE REPORT	1	Allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY/IMMUNOLOGY OTHER: ASBESTOS	1	Allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY/IMMUNOLOGY OTHER: CODEINE	1	Allergy	Algorithm
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY/IMMUNOLOGY OTHER: FIBERGLASS	1	Allergy	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY/IMMUNOLOGY:ALLERGY-OTHER	1	Allergy	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY-OTHER [MILK INTOLERANCE]	1	Milk allergy	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ALLERGY-OTHER: DRUG RASH	1	Drug allergy	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	ANXIETY - OTHER [MILK INTOLERANCE]	1	Anxiety	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	BURNING/ITCHING EYES	1	Itch burning	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	FLUSHING NECK	1	Flushing	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	Generalized severe cyanosis	1	Cyanosis	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	Infusion reaction	1	Infusion	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	NASAL ALLERGY	6	Allergy	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	NASAL CAVITY [SNEEZING]	1	Sneezing	
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other specify	SEASONAL ALLERGIES-ALLERGY/IMMUNOLOGY	1	Seasonal allergy	Algorithm
	Allergy/Immunology - Other				

Working Group Information Only:
 MedDRA autoencoding of 'Other, specify' verbatim:
 Algorithm;
 Match;
 Uncoded

AdEERS CTCAE V3.0 CATEGORY	Count	AdEERS % of Total Count by CATEGORY	CDUS CTCAE V3.0 CATEGORY	Count	CDUS % of Total Count by CATEGORY
<i>Grand Total</i>	65,996		<i>Grand Total</i>	383,676	
GASTROINTESTINAL	11382	17.25%	METABOLIC/LABORATORY	72184	18.81%
BLOOD/BONE MARROW	7570	11.47%	BLOOD/BONE MARROW	67076	17.48%
INFECTION	7272	11.02%	GASTROINTESTINAL	64871	16.91%
METABOLIC/LABORATORY	7110	10.77%	CONSTITUTIONAL SYMPTOMS	39166	10.21%
NEUROLOGY	4867	7.37%	DERMATOLOGY/SKIN	30834	8.04%
PULMONARY/UPPER RESPIRATORY	4746	7.19%	PAIN	30580	7.97%
PAIN	4152	6.29%	NEUROLOGY	20608	5.37%
CONSTITUTIONAL SYMPTOMS	3388	5.13%	PULMONARY/UPPER RESPIRATORY	14212	3.70%
DEATH	2696	4.09%	INFECTION	7259	1.89%
CARDIAC GENERAL	2643	4.00%	CARDIAC GENERAL	6464	1.68%
VASCULAR	2205	3.34%	HEMORRHAGE/BLEEDING	4407	1.15%
HEMORRHAGE/BLEEDING	1655	2.51%	LYMPHATICS	3860	1.01%
CARDIAC ARRHYTHMIA	1078	1.63%	MUSCULOSKELETAL/SOFT TISSUE	2902	0.76%
DERMATOLOGY/SKIN	1059	1.60%	OCULAR/VISUAL	2672	0.70%
MUSCULOSKELETAL/SOFT TISSUE	1003	1.52%	DEATH	2449	0.64%
RENAL/GENITOURINARY	943	1.43%	COAGULATION	2306	0.60%
HEPATOBIILIARY/PANCREAS	435	0.66%	ALLERGY/IMMUNOLOGY	2265	0.59%
COAGULATION	392	0.59%	ENDOCRINE	2118	0.55%
LYMPHATICS	343	0.52%	RENAL/GENITOURINARY	2074	0.54%
ALLERGY/IMMUNOLOGY	328	0.50%	CARDIAC ARRHYTHMIA	1785	0.47%
OCULAR/VISUAL	251	0.38%	VASCULAR	1178	0.31%
ENDOCRINE	199	0.30%	AUDITORY/EAR	848	0.22%
SYNDROMES	183	0.28%	SYNDROMES	663	0.17%
SEXUAL/REPRODUCTIVE FUNCTION	30	0.05%	SEXUAL/REPRODUCTIVE FUNCTION	559	0.15%
AUDITORY/EAR	25	0.04%	HEPATOBIILIARY/PANCREAS	259	0.07%
SURGERY/INTRA-OPERATIVE INJURY	21	0.03%	SURGERY/INTRA-OPERATIVE INJURY	32	0.01%
SECONDARY MALIGNANCY	20	0.03%	SECONDARY MALIGNANCY	30	0.01%
			GROWTH AND DEVELOPMENT	15	0.004%

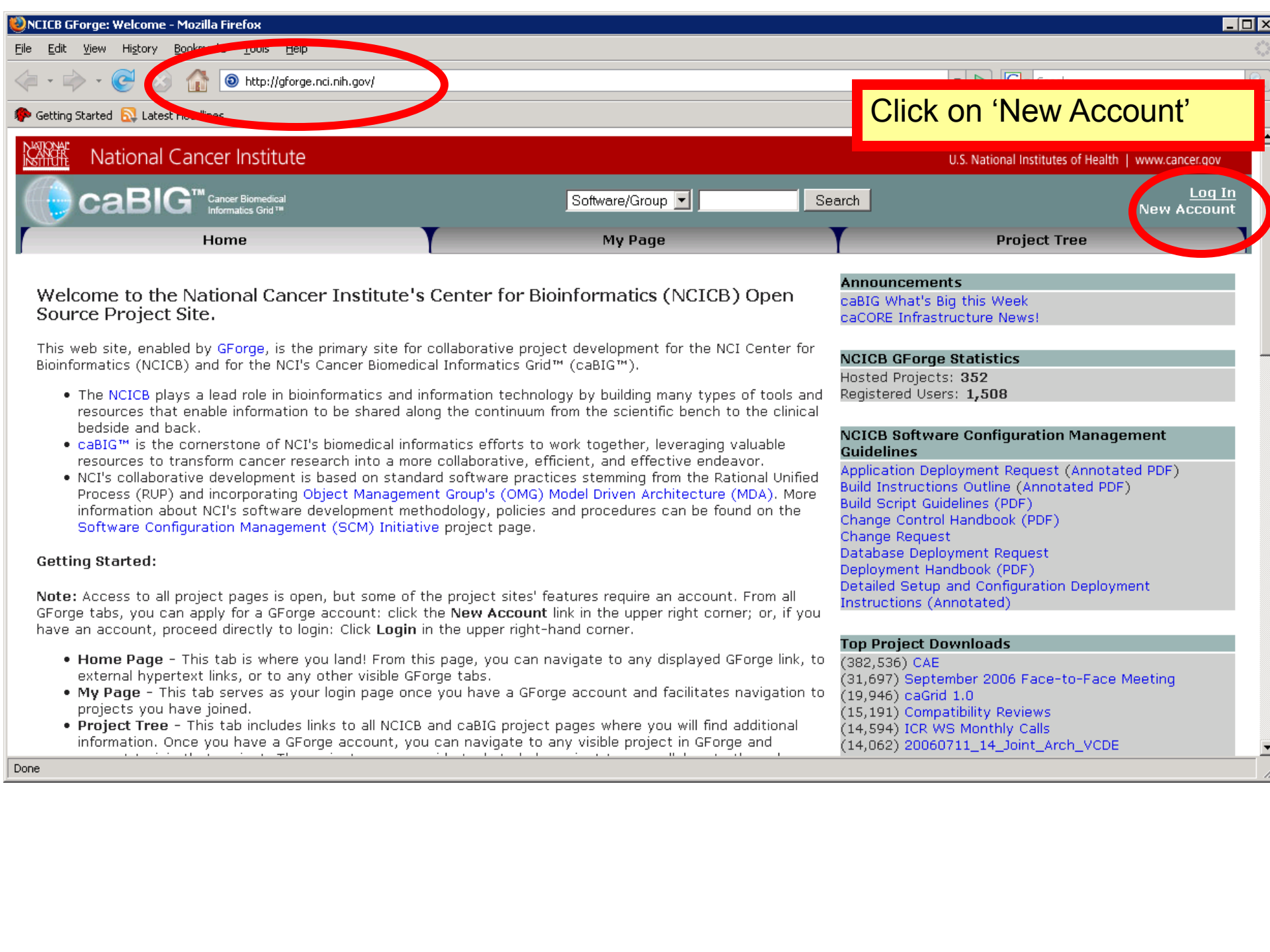
Working Group Information Only
CTCAE v3.0 AEs reported by CATEGORY
1.1.2004 – 4.1.208

Worksheet #6

gForge

Excel Documents + Instructions

<http://gforge.nci.nih.gov/>



Click on 'New Account'

Log In
New Account

Welcome to the National Cancer Institute's Center for Bioinformatics (NCICB) Open Source Project Site.

This web site, enabled by GForge, is the primary site for collaborative project development for the NCI Center for Bioinformatics (NCICB) and for the NCI's Cancer Biomedical Informatics Grid™ (caBIG™).

- The NCICB plays a lead role in bioinformatics and information technology by building many types of tools and resources that enable information to be shared along the continuum from the scientific bench to the clinical bedside and back.
- caBIG™ is the cornerstone of NCI's biomedical informatics efforts to work together, leveraging valuable resources to transform cancer research into a more collaborative, efficient, and effective endeavor.
- NCI's collaborative development is based on standard software practices stemming from the Rational Unified Process (RUP) and incorporating Object Management Group's (OMG) Model Driven Architecture (MDA). More information about NCI's software development methodology, policies and procedures can be found on the Software Configuration Management (SCM) Initiative project page.

Getting Started:

Note: Access to all project pages is open, but some of the project sites' features require an account. From all GForge tabs, you can apply for a GForge account: click the **New Account** link in the upper right corner; or, if you have an account, proceed directly to login: Click **Login** in the upper right-hand corner.

- **Home Page** - This tab is where you land! From this page, you can navigate to any displayed GForge link, to external hypertext links, or to any other visible GForge tabs.
- **My Page** - This tab serves as your login page once you have a GForge account and facilitates navigation to projects you have joined.
- **Project Tree** - This tab includes links to all NCICB and caBIG project pages where you will find additional information. Once you have a GForge account, you can navigate to any visible project in GForge and

Announcements

- [caBIG What's Big this Week](#)
- [caCORE Infrastructure News!](#)

NCICB GForge Statistics

Hosted Projects: **352**
Registered Users: **1,508**

NCICB Software Configuration Management Guidelines

- [Application Deployment Request \(Annotated PDF\)](#)
- [Build Instructions Outline \(Annotated PDF\)](#)
- [Build Script Guidelines \(PDF\)](#)
- [Change Control Handbook \(PDF\)](#)
- [Change Request](#)
- [Database Deployment Request](#)
- [Deployment Handbook \(PDF\)](#)
- [Detailed Setup and Configuration Deployment Instructions \(Annotated\)](#)

Top Project Downloads

- (382,536) [CAE](#)
- (31,697) [September 2006 Face-to-Face Meeting](#)
- (19,946) [caGrid 1.0](#)
- (15,191) [Compatibility Reviews](#)
- (14,594) [ICR WS Monthly Calls](#)
- (14,062) [20060711_14_Joint_Arch_VCDE](#)



Registration Approval Is Required

Please send an email to [NCICB Application Support](#) including:

- Name:
- Affiliation:
- Address:
- Phone number:
- Email address (a valid email address is required to complete the registration process):
- A brief description of your purpose for requesting the account:

Once your request has been approved, an email will be sent to the address you have provided with instructions on completing your account registration.



Click on link
Provide information
You will get an email for
Username/Password

Cookies must be enabled past this point.

Login Name:

Password:

[\[Lost your password?\]](#)

[\[New Account\]](#)

[\[Send confirmation email to a pending account\]](#)

After you have
Username/Password
Access site, Log in



[My Personal Page](#) | [Diary & Notes](#) | [Account Maintenance](#) | [Register Project](#)

Your personal page contains lists of bugs and tasks that you are assigned, plus a list of groups that you are a member of.

My Assigned Items

You have no open tracker items assigned to you.

My Tasks

You have no open tasks assigned to you.

My Submitted Items

You have no open tracker items submitted by you.

Quick Survey

Survey not found.

Monitored Forums

You are not monitoring any forums.

If you monitor forums, you will be sent new posts in the form of an email, with a link to the new message.

You can monitor forums by clicking "Monitor Forum" in any given discussion forum.

My Projects

You will have no Projects.

Click on Register Project

Monitored FileModules

You are not monitoring any files.

If you monitor files, you will be sent new release notices via email, with a link to the new file on our download server.

You can monitor files by visiting a project's "Summary Page" and clicking on the check box in the files section.

NCICB GForge: Project Information - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://gforge.nci.nih.gov/register/projectinfo.php

Getting Started Latest Headlines

NATIONAL CANCER INSTITUTE National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

caBIG™ Cancer Biomedical Informatics Grid™ Software/Group Search Log Out My Account

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To apply for project registration, you should fill in basic information about it. Please read descriptions below carefully and provide complete and comprehensive data. All fields below are mandatory.

1. Project full name

You should start with specifying the name of your project. The "Full Name" is descriptive, and has no arbitrary restrictions (except a 40 character limit).

Full Name:

2. Project Purpose And Summarization

Please provide detailed, accurate description of your project and what NCICB GForge resources and in which way you plan to use. This description will be the basis for the approval or rejection of your project's hosting on NCICB GForge, and later, to ensure that you are using the services in the intended way. This description will not be used as a public description of your project. It must be written in English.

Done gforge.nci.nih.gov

Type in CTCAE

Type in "I am a Working Group Member"

Summary

Working Group Next Steps

1. gForge Account

- Working Group Membership
- Excels + Instructions
- Calendar of Events & Timelines

2. BiomedGT Wiki Account

- Use Discuss feature to discuss changes as appropriate
- Enter recommendations for revision
- Correspond with others on Revision Project
- Wiki to be updated at conclusion of this phase

Working Group #1

SOCs

- Blood and lymphatic system disorders
- Immune system disorders
- Infections and infestations

Members

Community Participants

Mary Allen¹

Thomas J. Walsh, MD¹

Brett Loechelt

Richard Aplenc, MD

Lillian Sung MD, PhD

¹ Unconfirmed or awaiting
response

CTEP Participants

Naoko Takebe, MD

Igor Espinoza-Delgado, MD*

Richard Little, MD

Ann Setser, BSN, MEd

*Temporary WG Lead.
When WG convenes,
membership will name Lead

Working Groups

Members at Large

Anne Tompkins
Carol Andrist
Lisa Nastari
Shveta Tiwari
Kathy Sward
Krystal Sexton
Erin Hawkins
William Schelman
Eric Tate
Michael Apruzzese
Yukiko Watabe
Laurie Womak
Vikrant Deshmukh
Gwen Samuel
Others-

WG Leads will request participation from Members at Large, or M@L may request WG of interest

Provisions

CTCAE v.3 Revision Project Calendar - Timelines

- July 14 Working Groups being review
- July 16 Steering Committee Kick-off Meeting
 - **WG** Leads included
- July 25 Working Group first review period ends
- July 28 Steering Committee Meeting
 - **WG** Leads included
- July 29 Working Group Meeting (WG #s 1 – 6? TBD)
 - **WG** Leads provide input from Steering Committee Meeting
- July 30 Working Group Meeting (WG #s 7 - 12? TBD)
 - **WG** Leads provide input from Steering Committee Meeting

Steering Committee		
Lawrence Wright (Chair)		CBIIT, NCI
Alice Chen (co-chair)		IDB, CTEP, NCI
Ann Setser (co-chair)		CBIIT, NCI
Roberta Harris		TRI Contractor for CTEP, NCI
Shanda Finnigan		CTEP, NCI
Lois Nesbitt	Section Head, Medical Oversight	NSABP Biostatistical Center
Lynn B. Rufo	Manager, Medical Coding, Biometric s Operations	Cephalon, Inc.
Louis Frey		U of Utah
Stuart Turner		
Frank Hartel		CBIIT, NCI
Mike Riben		MD Anderson
Salvatore Mungal		Duke

Members of the CTCAE Advisory Board		
Frank Hartel		CBIIT, NCI
Rachel Humphrey	VP, Development Lead	BMS
Jean-Pierre Bizzari		Sanofi
Joanne Lager	Director Clinical Pharmacology Oncology Discovery Medicine Research & Development	GSK
Lesley Seymour		NCIC
Simon Voss	Associate Director/Medical Fellow I - Global Patient Safety - Oncology	Lilly
Nina Maris		Schering-Plough Research Institute
Chris Takimoto	Senior Director, Translational Medicine	Ortho Biotech Oncology R & D/Centocor
Jeff Summers	Duputy Director for Safety, Biologic Oncology Division	FDA
Andy Trotti		RTOG
Bob Kane		FDA
Alice Chen	Medical Officer	IDB, CTEP, NCI
Ann Setser		CBIIT, NCI
Percy Ivy	Associate Chief	IDB, CTEP, NCI
Ted Trimble	Medical Officer	CIB, CTEP, NCI
Linda Bressler	Director of Regulatory Affairs Cancer and Leukemia Group B (CALGB) Central Office	CALGB
Lori Minasian		DCP, NCI
James Nickas	Senior Director, Development Drug Safety	Genentech
Nathalie Dubois		EORTC
Anna Zhao-Wong	MedDRA MSSO	
J. Michael Hamilton	Chief Medical Officer	Avalon Pharmaceuticals
Anne Tompkins		

Find More Information about CTCAE v3.0

CTCAE Online Instructions and Guidelines

<http://ctep.cancer.gov/>

Go to CTEP website



- Resources
- Funding Opportunities
- Guidelines & Tools for Protocol Development
- Requisition of Agents
- Reporting Guidelines
- Monitoring of Clinical Trials
- Industry Collaborations
- Human Research Protections

Scroll down

[Resources](#)

- Clinical Trial Sources
- Clinical Trials Plan
- Cooperative Group Guidelines
- Community Clinical Oncology Program (CCOP)
- Investigator Resources
- Childhood Cancer Resources
- Research Resources
- Directory of Research Tools and Services
- CTEP Electronic Resources
- AIDS Malignancy
- Gynecologic Cancer Intergroup (GCIG)
- The Breast Cancer Intergroup of North America (TBCI)
- Related Links
- CTEP Semi-Annual Early Clinical Trials Meeting Information

[Funding Opportunities](#)

- Reading Room for RFP NO2-CM-37029-23, Clinical Trials and Information Management Support
- Grant Funding Resources and Assistance
- Quick Trials
- Program Announcements (PAs)
- Requests for Applications (RFAs)
- Notices (including availability of supplemental support)
- Requests for Proposals (RFPs)
- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR): Grants and Contracts Funding
- Plans and Priorities for Cancer Research

[Reporting Guidelines](#)

- Clinical Data Update System (CDUS)
- CTCAE (formerly known as CTC) v2.0 and v3.0
- Adverse Event Guidelines (AdEERS)
- Gender & Minority Accrual Data
- NCI Secondary AML/MDS Form

[Monitoring of Clinical Trials](#)

- Office for Human Research Protections - IRB Registration and Assurance Filing
- International Cooperative Project Assurance
- Guidelines for Monitoring of Clinical Trials for Cooperative Groups and CCOP Research Bases
- Multicenter Guidelines
- Data and Safety Monitoring (DSM)
- NCI Cooperative Group Monitoring Committee Policy
- Clinical Trials Monitoring Service (CTMS)/Theradex

[Industry Collaborations](#)

- CTEP Interaction with Industry
- Model Agreements
- NCI Cooperative Group - Industry Relation Guidelines
- Intellectual Property Option Policy
- CTEP Pharmacogenomics Guidelines

[Human Research Protections](#)

[About CTEP](#)

- Mission
- Personnel
- Branches
- Org. Charts

[NCI News](#)

[CTEP Highlights](#)

[NCI's Clinical Trials Cooperative Groups National Meetings Report - December 2007](#)

[CTEP Investigational Agents](#)

[NCI Clinical Announcement on Intraperitoneal Chemotherapy in Ovarian Cancer \(January 5, 2006\)](#)

[March 26-27, 2007 NCI Preoperative Therapy in Invasive Breast Cancer](#)

- Cooperative Group Common Budget Outline (MS Excel File Format)
- Cooperative Group Data Sharing Policy
- Cooperative Group Guidelines for Development, Conduct & Analysis of Clinical Trials with International Collaborating Institutions
- CTEP Conflict of Interest Policy for Cooperative Group Phase 3 Trials
- Investigational Drug Steering Committee (IDSC)

Cooperative Group Guidelines (New Guidelines Under Development)

[Cooperative Group Semi-Annual Meeting Schedule \(MS Word\)](#)

[CTEP Forms](#)

[Office of AIDS Malignancy Program](#)

[Inside PMB \(PMB newsletter\)](#)

Clinical Trial Resources:

- [List of Codes and Values](#)
- [\(AdEERS\): Adverse Event Expedited Reporting System](#)
- [CTCAE v3.0](#)
- [CTCAE/CTC Archive](#)
- [\(CDUS\): Clinical Data Update System](#)
- [\(CDE\): Common Data Elements](#)

[Clinical Trials Working Group](#)

[Coordinating Center for Clinical Trials](#)

Click on CTCAE v3.0

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Cancer Therapy Evaluation Program

NATIONAL CANCER INSTITUTE

CTEP

Resources Funding Opportunities Guidelines & Tools for Protocol Development Requisition of Agents Reporting Guidelines Monitoring of Clinical Trials Industry Collaborations

Developing Cancer Therapies

Go!

Click on CTCAE v3.0
Online Instructions and
Guidelines

Common Terminology Criteria for Adverse Events v3.0 (CTCAE)

[Common Terminology Criteria for Adverse Events v3.0 \(CTCAE\)](#) (PDF) (Publish Date August 9, 2006)

CTCAE v3.0 includes Adverse Events applicable to all oncology clinical trials regardless of chronicity or modality.

CTC v2.0 is active for a few legacy protocols only. Supporting documents are archived on the web. CTEP data systems accommodate AE reporting for both CTC v2.0 and CTCAE v3.0.

IMPORTANT: CTCAE v3.0, originally published March 31, 2003 is updated with minor editorial changes described in *CTCAE v3.0 Notice of Modifications* (PDF) (Publish Date August 9, 2006). The CTCAE Booklet, published May 22, 2003 does **not** include all editorial corrections. Therefore, each user must use the *Notice of Modifications* document to update the Booklets by hand. Since the number of corrections was small, the Booklets have not been reprinted.

[CTC/CTCAE Dictionary and Index](#)

The CTCAE Dictionary is a web-based application to assist in locating appropriate adverse event terms from both CTC v2.0 and CTCAE v3.0.

[Responsible Adverse Event \(AE\) Reporting: Finding Appropriate AE Terms](#)

The *Responsible Adverse Event (AE) Reporting: Finding Appropriate AE Terms* is a Power Point slide presentation to provide an overview of AE related information and illustrates the search capabilities of the tools available from the CTCAE v3.0 and CTC v2.0 websites.

[CTCAE v3.0 Online Instructions and Guidelines](#) (Updated August 9, 2006)

An instructional tool providing detailed guidelines regarding the use of the CTCAE and the changes made from CTC v2.0.

[CTCAE v3.0 Frequently Asked Questions](#) (Updated June 30, 2006)

Answers to commonly asked questions regarding the CTCAE v3.0, MedDRA, changes from CTC v2.0, and others.

[CTCAE v3.0 Notice of Modifications](#) (PDF) (Publish Date August 9, 2006)

The Notice of Modifications details the revisions made to the CTCAE v3.0 since its initial publication on March 31, 2003.

[CTCAE Implementation](#) (PDF) (Updated June 30, 2006)

Guidelines for CTCAE v3.0 implementation in databases.

Click on Search

Welcome to the Common Terminology Criteria for Adverse Events (CTCAE) v3.0 Online Instructions and Guidelines

The CTCAE v3.0 Online Instructions and Guidelines is designed as an introduction to the NCI CTCAE v3.0. This tool can be used by investigators, nurses, and CRAs who are new to the CTCAE v3.0. For users familiar with version 2.0, it provides an explanation for the changes in v3.0 and will assist with the transition.

Information in the Online Instructions and Guidelines can be accessed using the Contents, Index, Search, or Glossary buttons at the top, left-hand side of this screen.

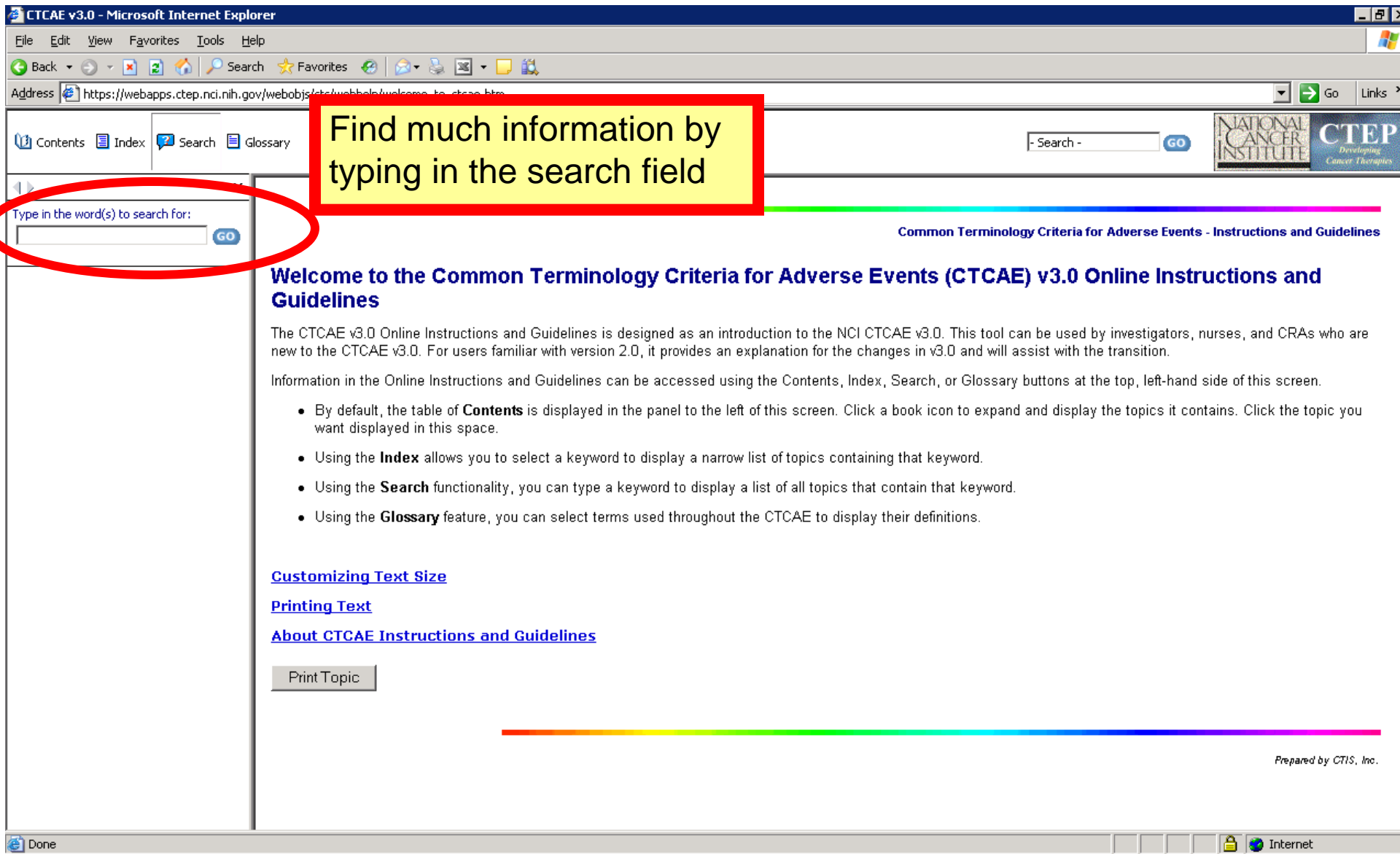
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- Using the **Index** allows you to select a keyword to display a narrow list of topics containing that keyword.
- Using the **Search** functionality, you can type a keyword to display a list of all topics that contain that keyword.
- Using the **Glossary** feature, you can select terms used throughout the CTCAE to display their definitions.

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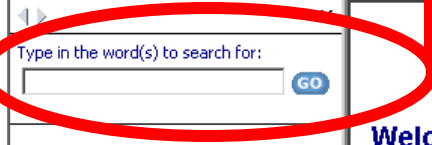
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Link to CTCAE v3.0 Revision Project Recorded Education Session

<https://webmeeting.nih.gov/p19665680>

Questions about project:
Ranjana Srivastava,
srivastava_ranjana@bah.com