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

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July 11, 2008

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
		Grade				
Adverse Event	Short Name	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						Page 4 of 10
		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

		Grade				
Adverse Event	Short Name	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 ≥24 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 ≤25% reduction from normal cellularity for age	Moderately hypocellular or >25 – ≤50% reduction from normal cellularity for age	Severely hypocellular or >50 – ≤75% reduction cellularity from normal for age	—	Death
CD4 count	CD4 count	<LLN – 500/mm^3 <LLN – 0.5 x 10^9 /L	<500 – 200/mm^3 <0.5 – 0.2 x 10^9 /L	<200 – 50/mm^3 <0.2 x 0.05 – 10^9 /L	<50/mm^3 <0.05 x 10^9 /L	Death
Haptoglobin	Haptoglobin	<LLN	—	Absent	—	Death
Hemoglobin	Hemoglobin	<LLN – 10.0 g/dL <LLN – 6.2 mmol/L <LLN – 100 g/L	<10.0 – 8.0 g/dL <6.2 – 4.9 mmol/L <100 – 80g/L	<8.0 – 6.5 g/L <4.9 – 4.0 mmol/L <80 – 65 g/L	<6.5 g/dL <4.0 mmol/L <65 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 ≥2 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 x 10^9 /L	<3000 – 2000/mm^3 <3.0 – 2.0 x 10^9 /L	<2000 – 1000/mm^3 <2.0 – 1.0 x 10^9 /L	<1000/mm^3 <1.0 x 10^9 /L	Death
Lymphopenia	Lymphopenia	<LLN – 800/mm^3 <LLN x 0.8 – 10^9 /L	<800 – 500/mm^3 <0.8 – 0.5 x 10^9 /L	<500 – 200/mm^3 <0.5 – 0.2 x 10^9 /L	<200/mm^3 <0.2 x 10^9 /L	Death
Neutrophils/granulocytes (ANC/AGC)	Neutrophils	<LLN – 1500/mm^3 <LLN – 1.5 x 10^9 /L	<1500 – 1000/mm^3 <1.5 – 1.0 x 10^9 /L	<1000 – 500/mm^3 <1.0 – 0.5 x 10^9 /L	<500/mm^3 <0.5 x 10^9 /L	Death
Platelets	Platelets	<LLN – 75,000/mm^3 <LLN – 75.0 x 10^9 /L	<75,000 – 50,000/mm^3 <75.0 – 50.0 x 10^9 /L	<50,000 – 25,000/mm^3 <50.0 – 25.0 x 10^9 /L	<25,000/mm^3 <25.0 x 10^9 /L	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, superaordinate 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

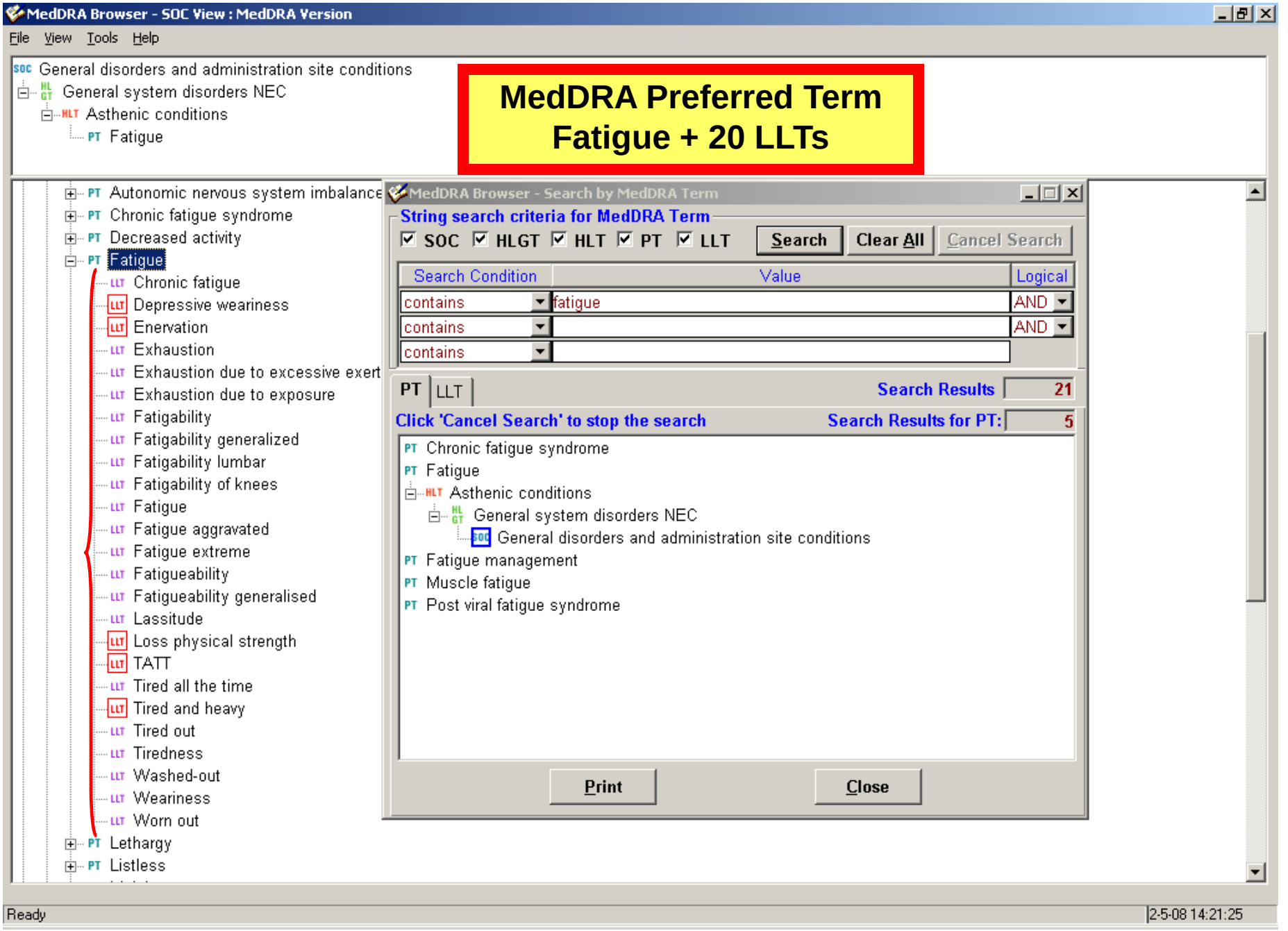
Multiple Concepts in one AE Term

CONSTITUTIONAL SYMPTOMS						Page 1 of 2
		Grade				
Adverse Event	Short Name	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


MedDRA Browser - SOC View : MedDRA Version
File View Tools Help
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 exert
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
Clear All
Cancel Search
Search Condition
Value
Logical
contains
fatigue
AND
contains
AND
contains
PT
LLT
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
Print
Close
Ready
2-5-08 14:21:25

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

Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10^9/L) – *Select* *'Select'* AEs appear at the end of the CATEGORY.	Infection (documented clinically) with Grade 3 or 4 ANC – *Select*	—	Localized, local intervention indicated	IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)	Death
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). ALSO CONSIDER: Neutrophils/granulocytes (ANC/AGC).						
Infection with normal ANC or Grade 1 or 2 neutrophils – *Select* *'Select'* AEs appear at the end of the CATEGORY.	Infection with normal ANC – *Select*	—	Localized, local intervention indicated	IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)	Death
Infection with unknown ANC – *Select* *'Select'* AEs appear at the end of the CATEGORY.	Infection with unknown ANC – *Select*	—	Localized, local intervention indicated	IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)	Death
REMARK: Infection with unknown ANC – *Select* is to be used in the rare case when ANC is unknown.						

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

HEPATOBILIARY/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 x 10e9/L) – Conjunctiva
- Infection with normal ANC or Grade 1 or 2 neutrophils - Conjunctiva

SURGERY/INTRA-OPERATIVE INJURY

Adverse Event	Short Name	Grade 1	Grade 2	Grade 3	Grade 4	Grade 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 – *Select Organ or Structure* *'Select'* AEs appear at the end of the CATEGORY.	Intraop injury – *Select*	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: 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.						
Intra-operative Injury – Other (Specify, __)	Intraop Injury – Other (Specify)	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 visceral 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
- Oral
- Peritoneal cavity
- Rectum
- Small bowel NOS

GASTROINTESTINAL (*continued*)
- Stoma (GI)
- Stomach

HEPATOBILIARY/ 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

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

ALLERGY_AsIs | ALLERGY_Rev | SOC_Immune | AdEERS_CDUS_Rpt | AutoCode | AdEERS_CDUS_ALL_AEs

dy

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: Anyphylaxis 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

Rows inserted with potential revision MedDRA terms.

Comments column

ALLERGY_AsIs | ALLERGY_Rev | SOC_Immune | AdEERS_CDUS_Rpt | AutoCode | AdEERS_CDUS_ALL_AEs

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

Worksheet #3

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

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

ALLERGY_AsIs | ALLERGY_Rev | SOC_Immune | AdEERS_CDUS_Rpt | AutoCode | AdEERS_CDUS_ALL_AEs

Worksheet #1

dy

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

ALLERGY_AsIs / ALLERGY_Rev / **SOC_Immune** / AdEERS_CDUS_Rpt / AutoCode / AdEERS_CDUS_ALL_AEs /

Worksheet #3

dy

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(SEAONAL)	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, __)	ALLERGY	1
ALLERGY/IMMUNOLOGY	Allergy/Immunology - Other (Specify, __)	ALLERGY - ITHCY 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

ALLERGY_AsIs | ALLERGY_Rev | SOC_Immune | **AdEERS_CDUS_Rpt** | AutoCode | AdEERS_CDUS_ALL_AEs

dy

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	
	Allergy/Immunology - Other				

ALLERGY_AsIs | ALLERGY_Rev | SOC_Immune | AdEERS_CDUS_Rpt | **AutoCode** | AdEERS_CDUS_ALL_AEs

dy

Working Group Information Only:

MedDRA autoencoding of 'Other, specify' verbatim:

Algorithm; Match; Uncoded

Worksheet #5

AdEERS CTCAE V3.0 CATEGORY	Count	AdEERS % of Total Count by CATEGORY
Grand Total	**65,996**	
GASTROINTESTINAL	11382	17.25%
BLOOD/BONE MARROW	7570	11.47%
INFECTION	7272	11.02%
METABOLIC/LABORATORY	7110	10.77%
NEUROLOGY	4867	7.37%
PULMONARY/UPPER RESPIRATORY	4746	7.19%
PAIN	4152	6.29%
CONSTITUTIONAL SYMPTOMS	3388	5.13%
DEATH	2696	4.09%
CARDIAC GENERAL	2643	4.00%
VASCULAR	2205	3.34%
HEMORRHAGE/BLEEDING	1655	2.51%
CARDIAC ARRHYTHMIA	1078	1.63%
DERMATOLOGY/SKIN	1059	1.60%
MUSCULOSKELETAL/SOFT TISSUE	1003	1.52%
RENAL/GENITOURINARY	943	1.43%
HEPATOBILIARY/PANCREAS	435	0.66%
COAGULATION	392	0.59%
LYMPHATICS	343	0.52%
ALLERGY/IMMUNOLOGY	328	0.50%
OCULAR/VISUAL	251	0.38%
ENDOCRINE	199	0.30%
SYNDROMES	183	0.28%
SEXUAL/REPRODUCTIVE FUNCTION	30	0.05%
AUDITORY/EAR	25	0.04%
SURGERY/INTRA-OPERATIVE INJURY	21	0.03%
SECONDARY MALIGNANCY	20	0.03%

CDUS CTCAE V3.0 CATEGORY	Count	CDUS % of Total Count by CATEGORY
Grand Total	**383,676**	
METABOLIC/LABORATORY	72184	18.81%
BLOOD/BONE MARROW	67076	17.48%
GASTROINTESTINAL	64871	16.91%
CONSTITUTIONAL SYMPTOMS	39166	10.21%
DERMATOLOGY/SKIN	30834	8.04%
PAIN	30580	7.97%
NEUROLOGY	20608	5.37%
PULMONARY/UPPER RESPIRATORY	14212	3.70%
INFECTION	7259	1.89%
CARDIAC GENERAL	6464	1.68%
HEMORRHAGE/BLEEDING	4407	1.15%
LYMPHATICS	3860	1.01%
MUSCULOSKELETAL/SOFT TISSUE	2902	0.76%
OCULAR/VISUAL	2672	0.70%
DEATH	2449	0.64%
COAGULATION	2306	0.60%
ALLERGY/IMMUNOLOGY	2265	0.59%
ENDOCRINE	2118	0.55%
RENAL/GENITOURINARY	2074	0.54%
CARDIAC ARRHYTHMIA	1785	0.47%
VASCULAR	1178	0.31%
AUDITORY/EAR	848	0.22%
SYNDROMES	663	0.17%
SEXUAL/REPRODUCTIVE FUNCTION	559	0.15%
HEPATOBILIARY/PANCREAS	259	0.07%
SURGERY/INTRA-OPERATIVE INJURY	32	0.01%
SECONDARY MALIGNANCY	30	0.01%
GROWTH AND DEVELOPMENT	15	0.004%

Working Group Information Only

CTCAE v3.0 AEs reported by CATEGORY

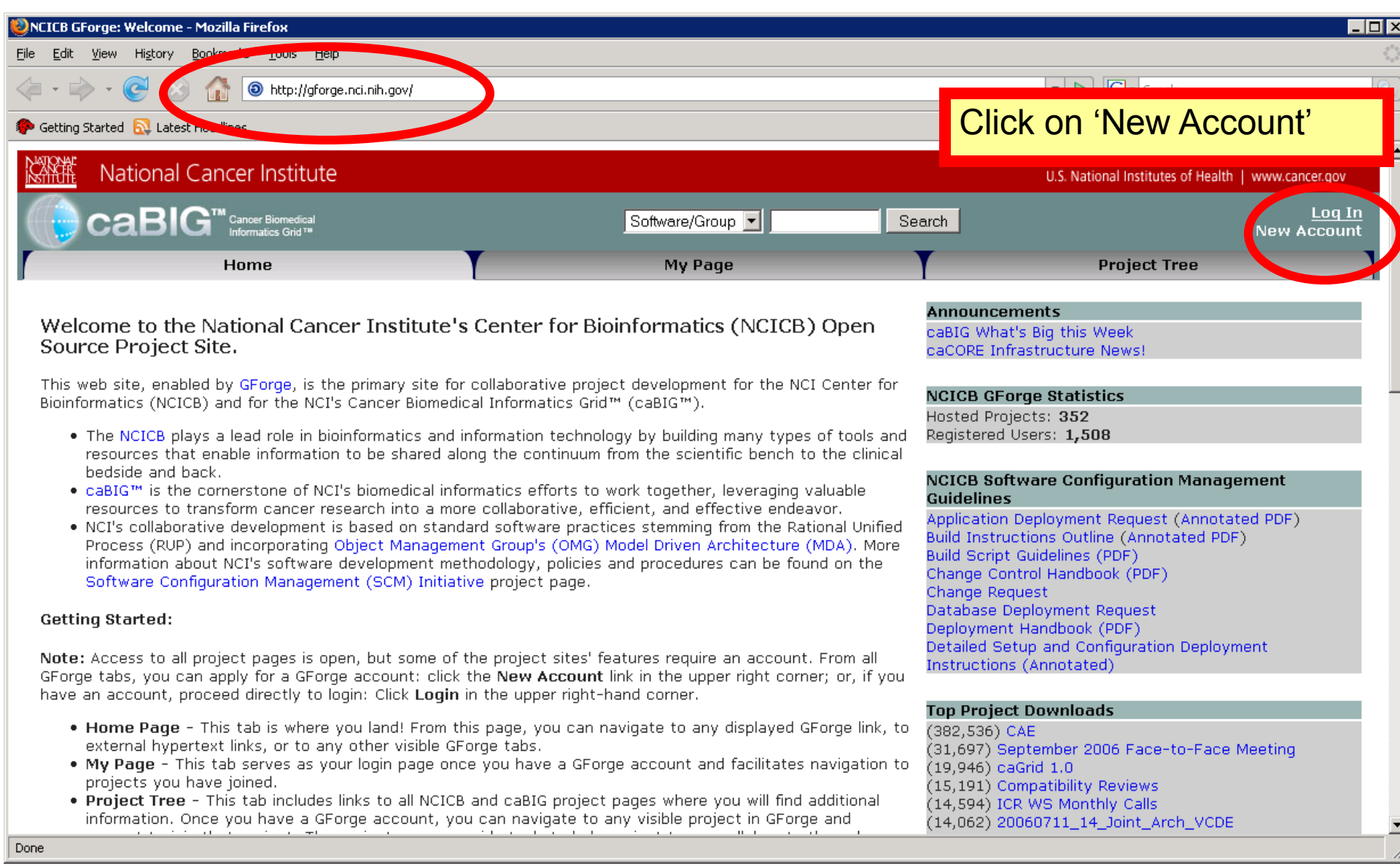
1.1.2004 – 4.1.208

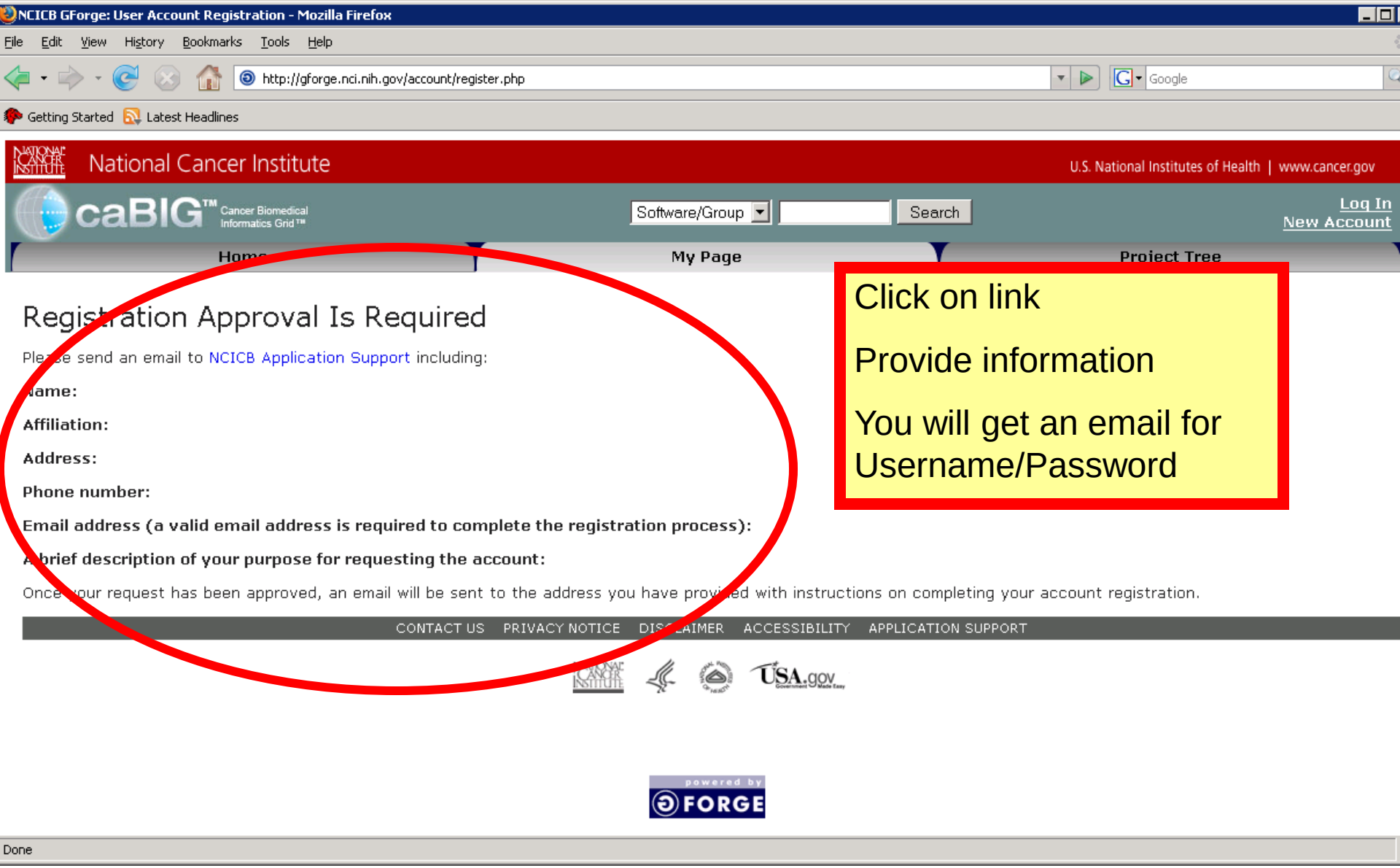
AutoCode | AdEERS_CDUS_ALL_AEs

Worksheet #6

gForge
Excel Documents + Instructions

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

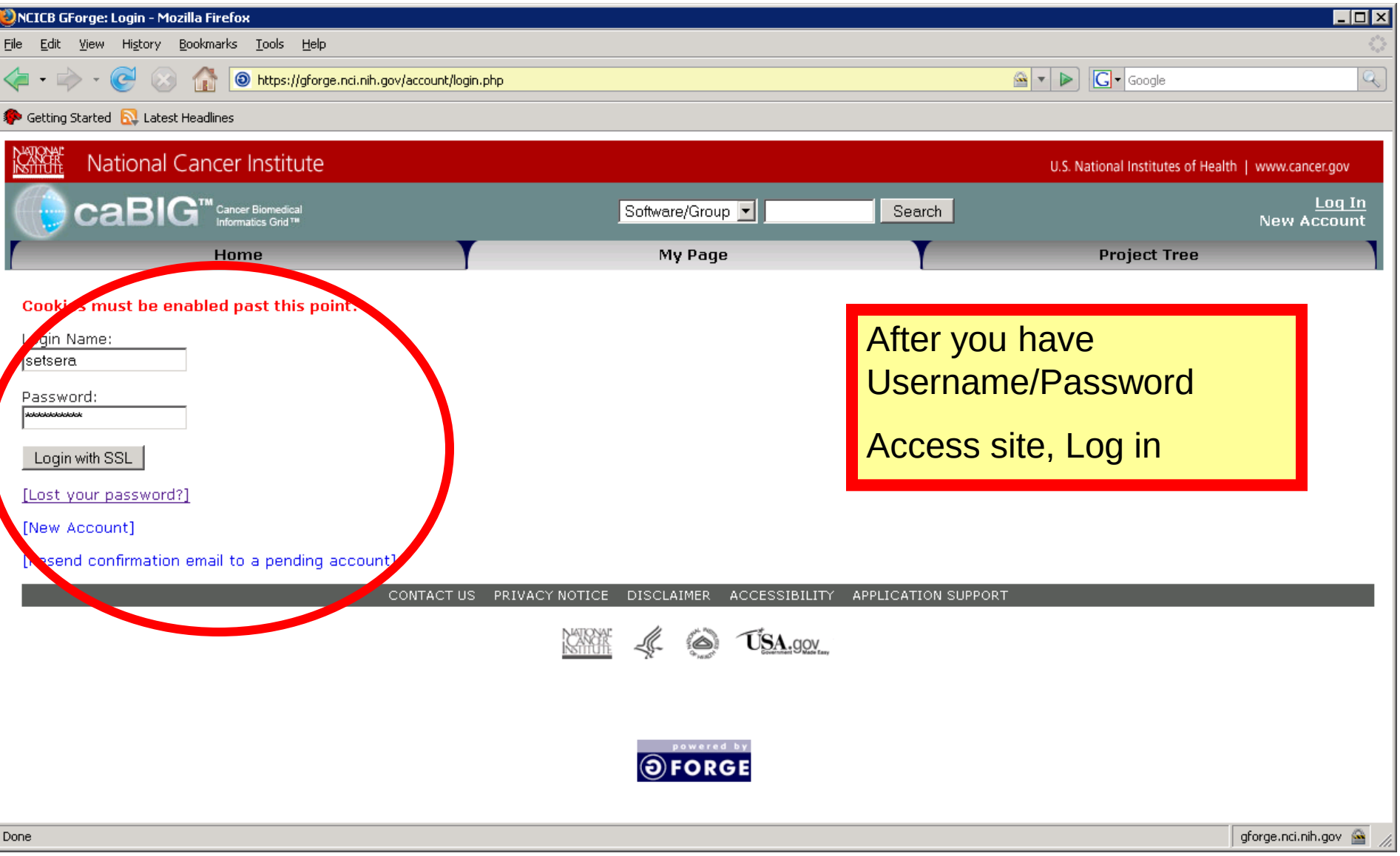

NCICB GForge: Welcome - Mozilla Firefox
File Edit View History Bookmarks Tools Help
http://gforge.nci.nih.gov/
Getting Started
Click on 'New Account'
National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov
caBIG™ Cancer Biomedical Informatics Grid™
Software/Group
Search
Log In
New Account
Home
My Page
Project Tree
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
Done



Click on link

Provide information

You will get an email for Username/Password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Latest Headlines
National Cancer Institute
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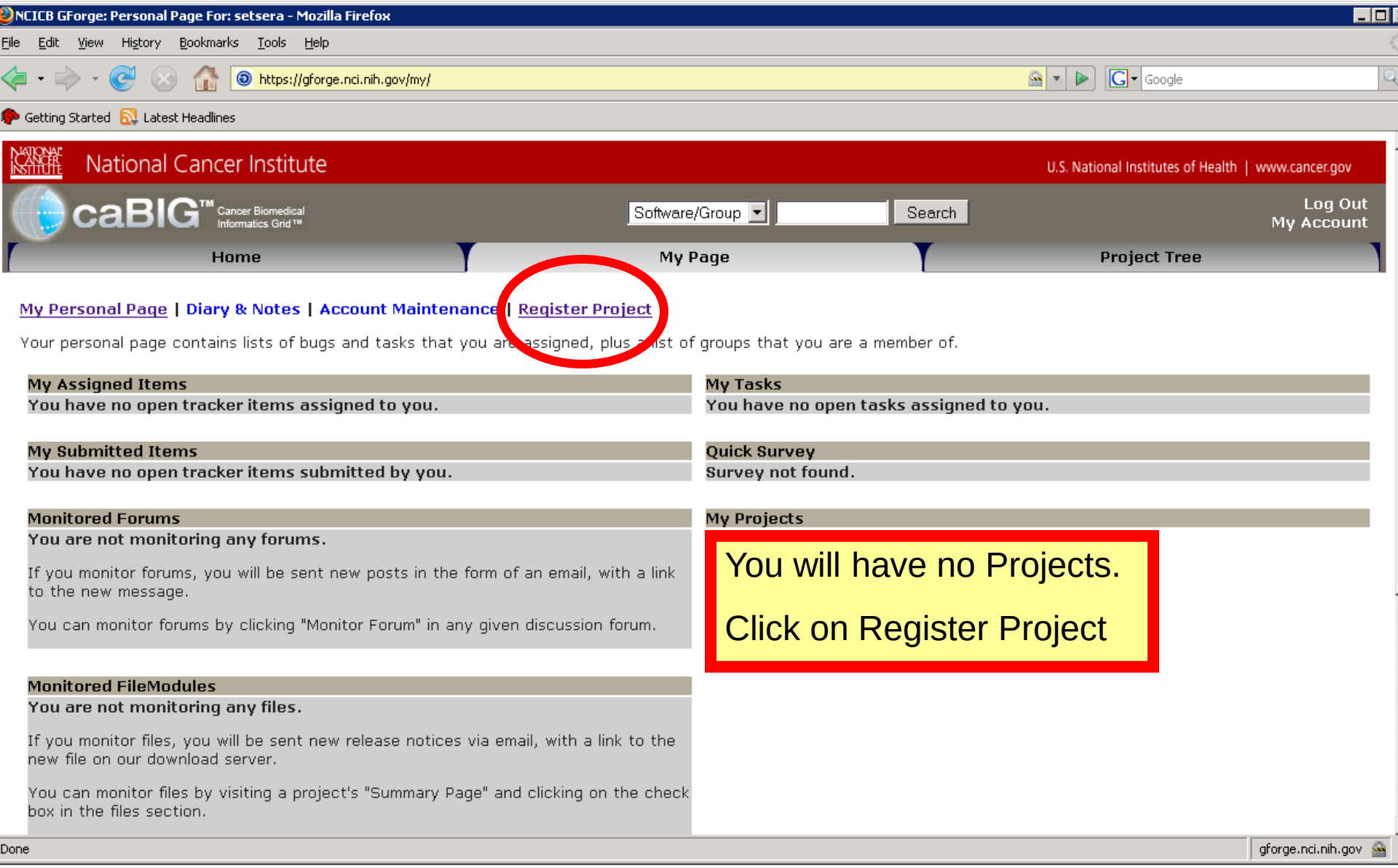
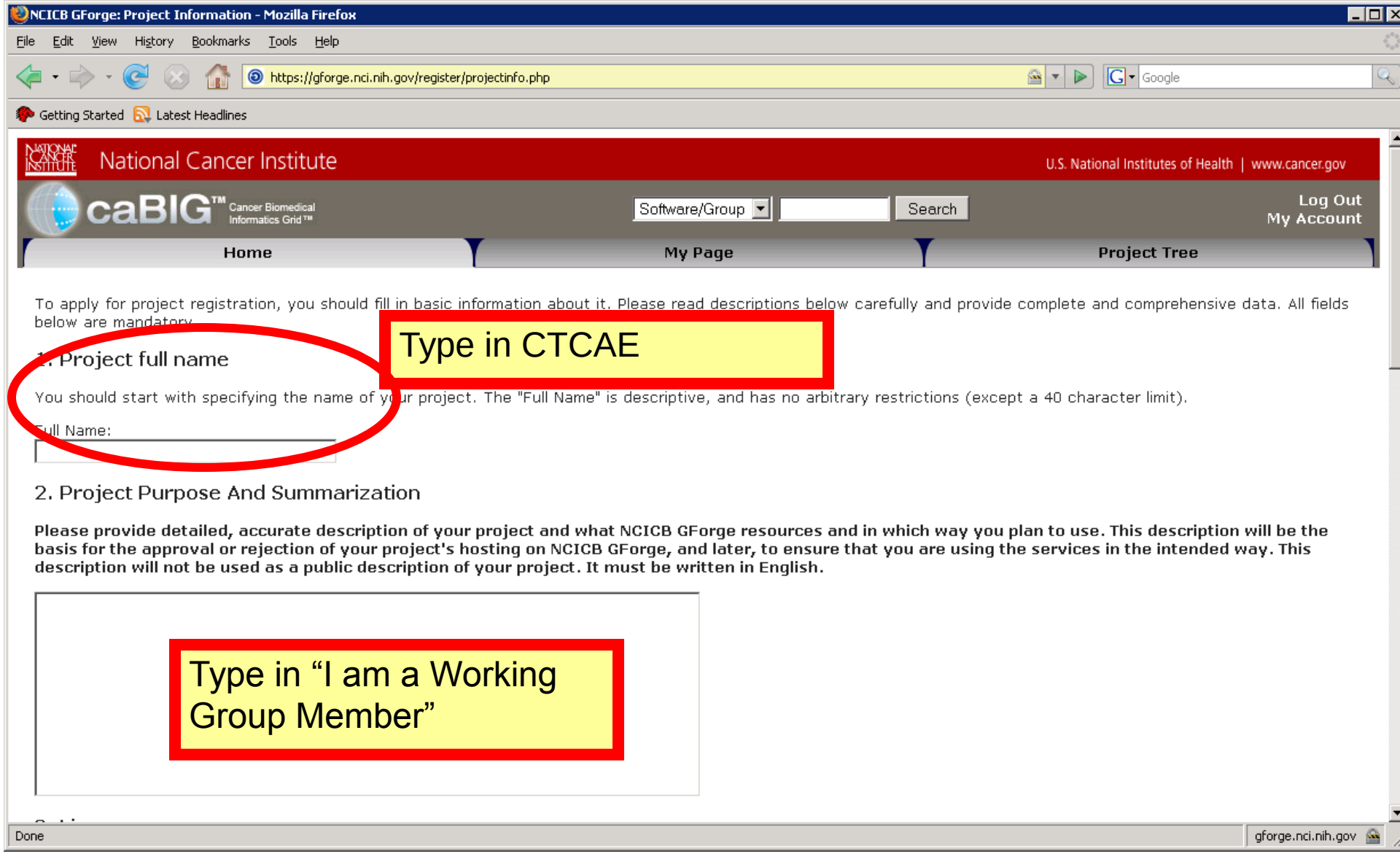
New Account
Home
My Page
Project Tree
Cookies must be enabled past this point.
Login Name:
setsera
Password:
Login with SSL
[Lost your password?]
[New Account]
[Resend confirmation email to a pending account]
After you have Username/Password
Access site, Log in
CONTACT US PRIVACY NOTICE DISCLAIMER ACCESSIBILITY APPLICATION SUPPORT
USA.gov
powered by FORGE
Done
gforge.nci.nih.gov


NCICB GForge: Personal Page For: setsera - Mozilla Firefox
File Edit View History Bookmarks Tools Help
https://gforge.nci.nih.gov/my/
Google
Getting Started
Latest Headlines
National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov
caBIG™ Cancer Biomedical Informatics Grid™
Software/Group
Search
Log Out
My Account
Home
My Page
Project Tree
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.
Done
gforge.nci.nih.gov


NCICB GForge: Project Information - Mozilla Firefox
File Edit View History Bookmarks Tools Help
https://gforge.nci.nih.gov/register/projectinfo.php
Google
Getting Started
Latest Headlines
National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov
caBIG™ Cancer Biomedical Informatics Grid™
Software/Group
Search
Log Out
My Account
Home
My Page
Project Tree
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:
Type in CTCAE
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.
Type in “I am a Working Group Member”
Done
gforge.nci.nih.gov

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 Allen[1]
Thomas J. Walsh, MD[1]
Brett Loechelt
Richard Aplenc, MD
Lillian Sung MD, PhD

CTEP Participants

Naoko Takebe, MD
Igor Espinoza-Delgado, MD*
Richard Little, MD
Ann Setser, BSN, MEd

[1] Unconfirmed or awaiting response

*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,Biometrics 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		

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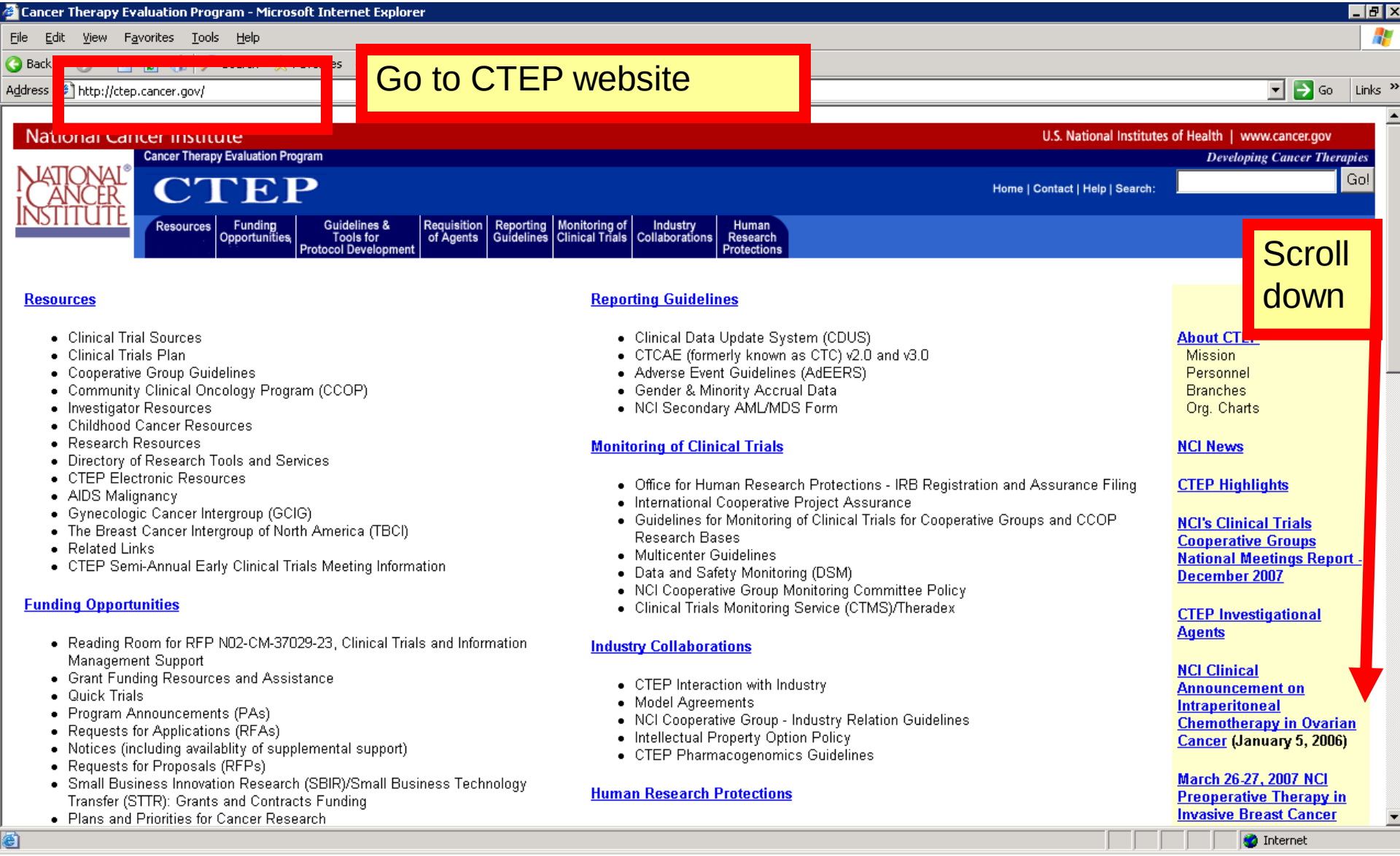
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NCI Clinical Announcement on Intraperitoneal Chemotherapy in Ovarian Cancer (January 5, 2006)
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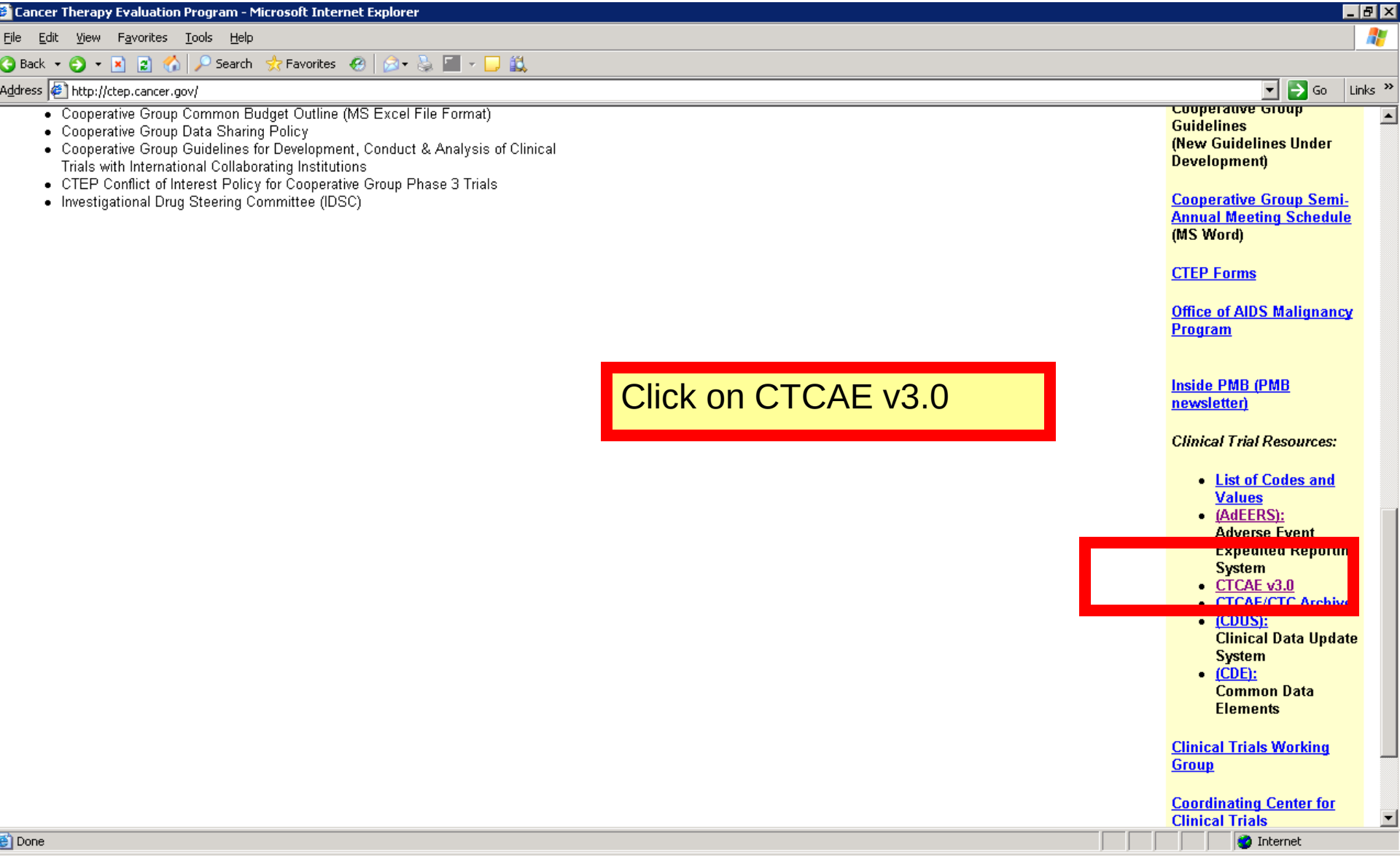

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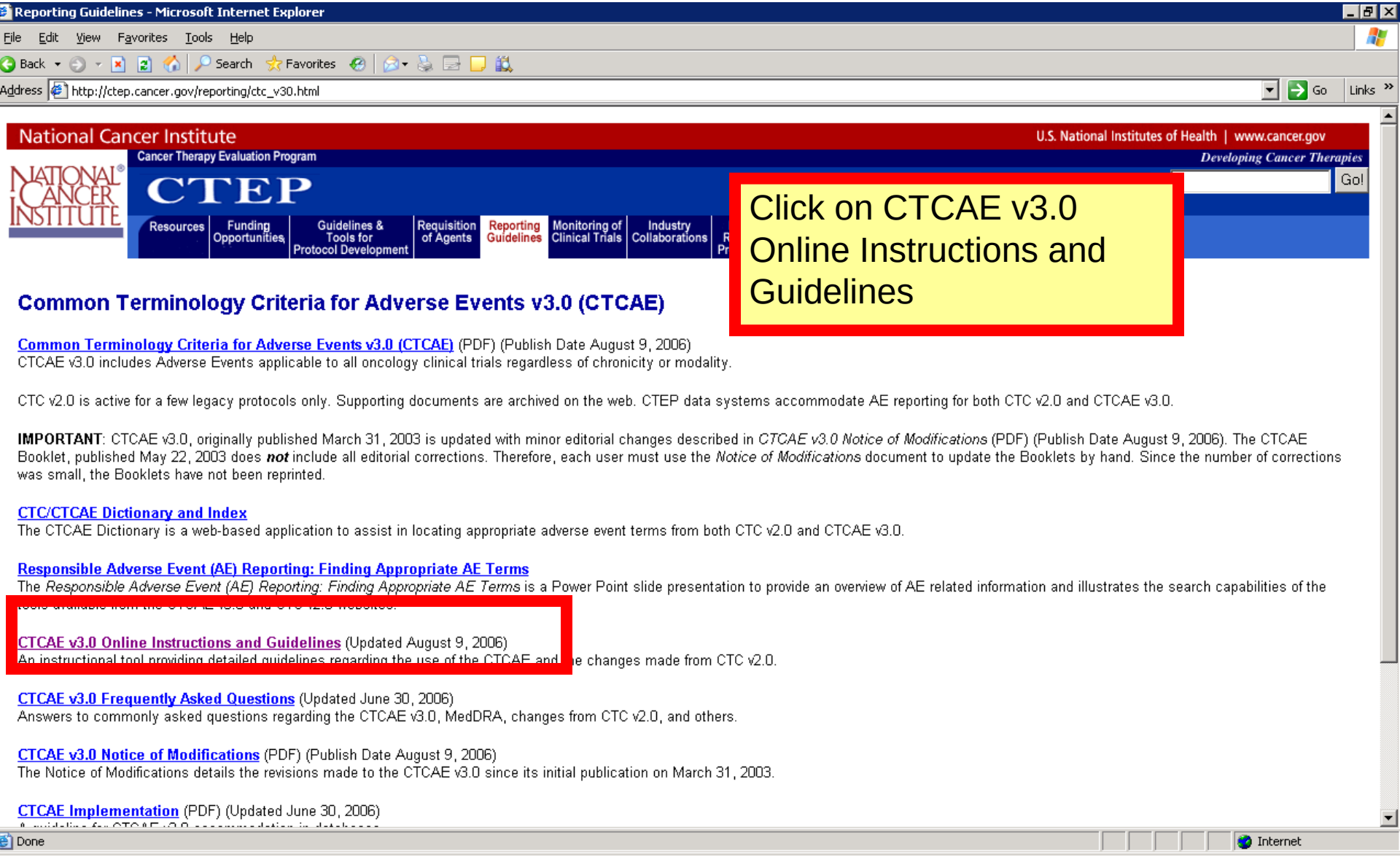

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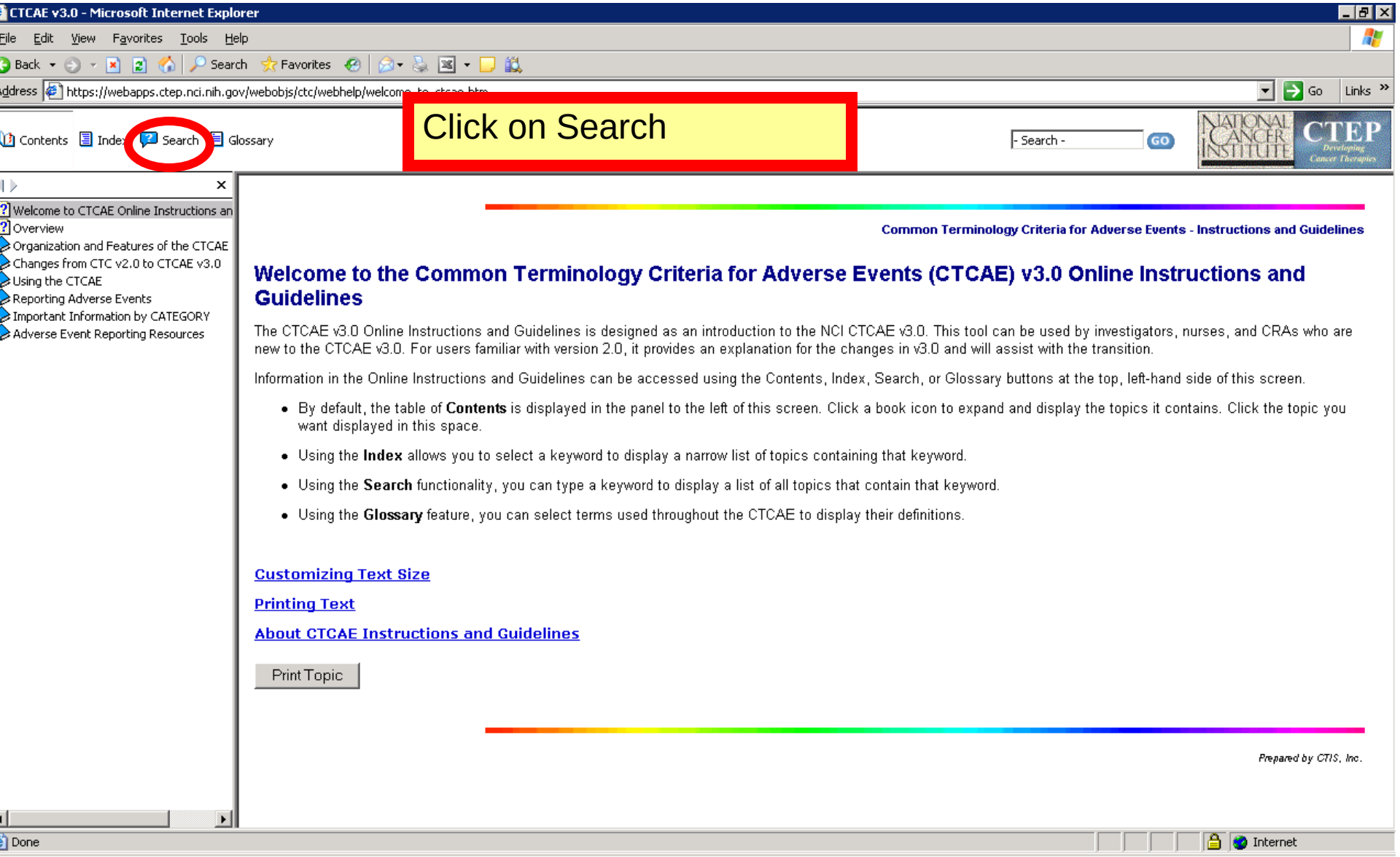
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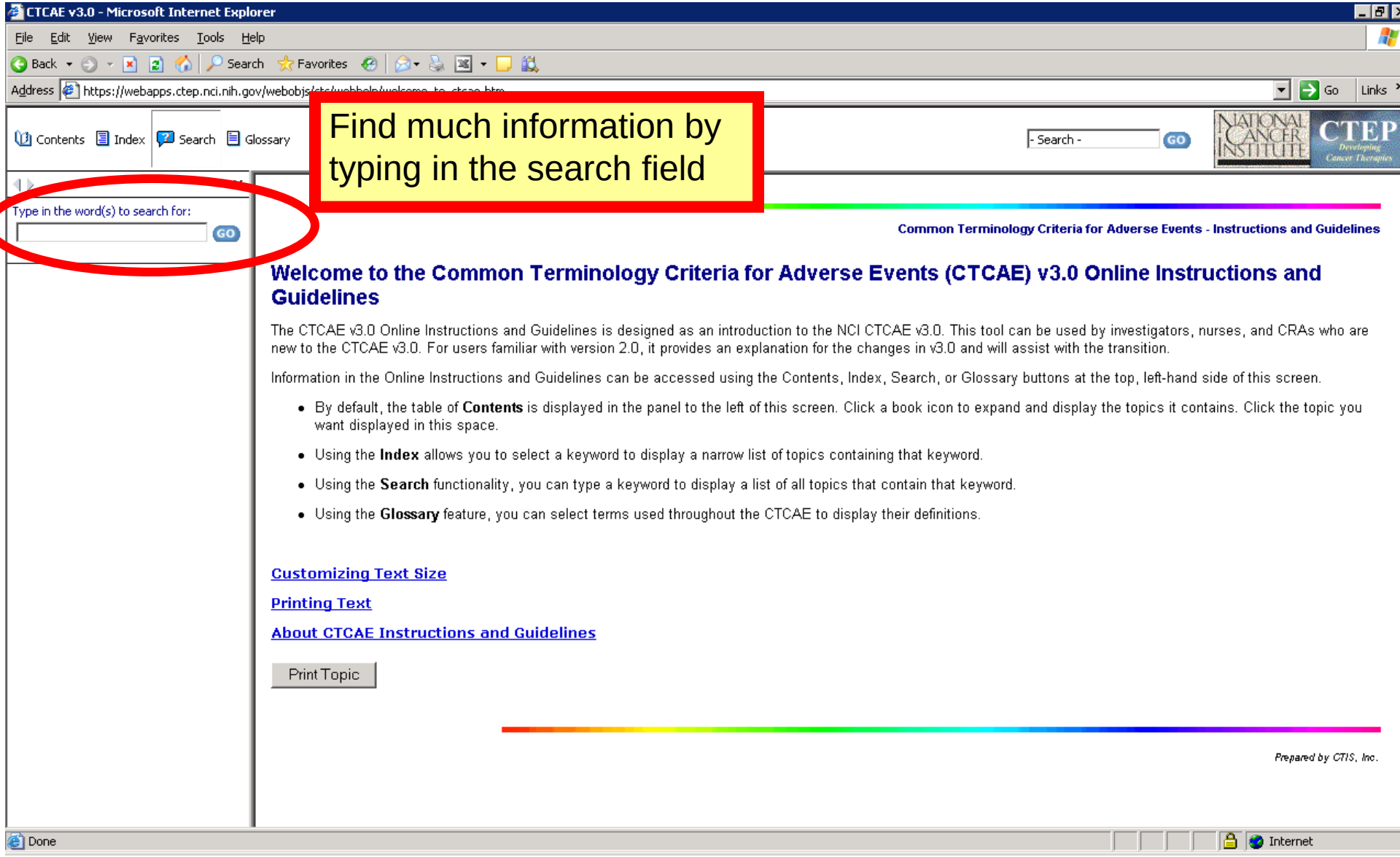
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Link to CTCAE v3.0 Revision Project Recorded Education Session

https://webmeeting.nih.gov/p19665680

Questions about project:

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