

# CTCAE v.6: Highlights of Changes

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  - Already enrolled to the [Quality Assurance Webinar December 12, 2025 - Navigating Adverse Events: What's New in CTCAE v6](#) course in ExpertusOne.
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Note: For site staff who were unable to attend the entire webinar: 1 hour CEU will also be offered via review of the webinar recording and completion of the post-course evaluation within a forthcoming SWOG: Navigating Adverse Events: What's New in CTCAE v6 course posted in the CTSU CLASS learning management system. When available in CLASS, the link to the post-meeting enduring course will be accessible from: [SWOG Quality Assurance Live Webinar Series](#) and the online CTSU CLASS catalog. The Disclosure for Enduring Course Participants will be posted under the "Resources" tab of the forthcoming course in CLASS.
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- This nursing continuing professional development activity was approved by the Georgia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.  
**Georgia Nurses Association Approval Code: Webinar: 203353688; Enduring Posting (in CLASS): 203353697.**
- The expiration date of this activity is **December 7, 2027.**

# Agenda

- Adverse event review
- CTCAE timeline
- CTCAE v6 overview
- Specific term additions and removals per SOC
- Other highlighted clarifications
- Implementation
- Resources

# Have you looked at CTCAEv6?

- No
- Glanced at pdf booklet
- Glanced at the track change spreadsheet
- In depth review of AE terms that impact my practice

# Summary Definition

Any unwanted sign, symptom, or disease that was not seen before individual's research participation, or worsening of baseline symptom, **REGARDLESS OF EXPECTEDNESS OR RELATIONSHIP TO RESEARCH.**

# Purposes of Adverse Event Monitoring

- Identify events that may have immediate effect on the safety of the participant
- Inform regulators, investigators, and others of new and important information about events
- Provide a summary of adverse experiences in order to develop the drug or regimen toxicity profile

# Data Standards for AE Terminology

- Medical Dictionary for Regulatory Activities (MedDRA)
- Common Terminology Criteria for Adverse Events (CTCAE)

# Medical Dictionary for Regulatory Activities (MedDRA)

- Clinically validated international medical terminology
- Classifies AE information associated with the use of biopharmaceuticals and other medical products
- Developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- Managed by the MSSO (Maintenance and Support Services Organization)
- Available in 27 languages with 5 in development (version 28.1)

# MedDRA Structure

System, Organ, Class	SOC	Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose	27*
High Level Group Term	HLGT	Subordinate to SOC, superordinate descriptor for one or more HLTs	337*
High Level Term	HLT	Subordinate to HLGT, superordinate descriptor for one or more PTs	1,739*
Preferred Term	PT	Represents a single medical concept	26,920*
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)	89,774*

# CTCAE Timeline



- 18 Categories
- 49 Terms
- 24 Categories
- 295 Terms
- 28 Categories
- >900 Terms
- 26 SOCs
- 790 Terms
- 26 SOCs
- 790 Terms
- 26 SOCs
- 790 Terms

*NOTE: CTCAE doesn't include the Product issues SOC*

# How many versions of CTCAE have you worked with?

- Only one, version 5
- Two, versions 4 and 5
- Three, versions 3, 4 and 5
- More than three

# How to Read the CTCAE

- Set up in a table format
- Terms are grouped by MedDRA Primary System Organ Class (SOC) and listed alphabetically
- Within each SOC, AEs are listed and accompanied by descriptions of severity: grades 1–5
- AE term is a MedDRA Lowest Level Term (LLT)
- Each SOC has an “Other, specify” options for reporting text terms not listed in CTCAE
- Semicolon indicates “or” within the description of the grade
- Em dash (—) indicates a grade is not available

# CTCAE v6 Overview

- Every CTCAE term is precisely mapped to a MedDRA v28.0 Lowest Level Term (LLT)
  - Benefit: Reduces ambiguity when integrating with safety signal processing, AE coding, or cross-study meta-analyses
- **Each** term has a definition, navigational notes, and grade descriptions
- Version 6.0 is the final version
- Future adjustments or additions will wait until version 7.0, expected between 2027–2030

# NEW: Pediatric ADLs

- Mild/moderate impact on age-appropriate normal daily activity
  - Similar to instrumental ADLs for adults
- Severe impact on age-appropriate normal daily activity
  - Similar to self-care ADLs for adults

# CTCAE 6 Lab AEs

- Laboratory-based AE grading is more patient-specific
  - Reflects where each subject starts rather than enforcing rigid thresholds
- Formalizes how to handle patients whose baseline lab values sit above the upper limit of normal (ULN)
  - **If baseline  $\leq$  ULN** → grade using the traditional method (multiples of ULN)
  - **If baseline  $>$  ULN** → grade based on proportion of change from the patient's own baseline, not from ULN

# Creatinine

- Lower-than-normal baseline values (common in pediatric or frail adult populations) are handled explicitly
- Even modest increases above LLN are now amplified in importance with LLN becoming a required reference in the grading algorithm

## Creatinine increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 3.0 x if baseline is below LLN; >1.5 - 3.0 x ULN	>3.0 x if baseline is below LLN; >3.0 - 6.0 x ULN	>6.0 x ULN	-

**Definition:** A finding based on laboratory test results that indicate increased levels of creatinine in a biological specimen.

**Navigational Note:** Consider Renal and urinary disorders: Acute kidney injury, Glomerulonephritis, Tubulointerstitial nephritis.

Creatinine increased <b>CTCAE version 5.0</b>	>ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 x baseline; >3.0 - 6.0 x ULN	>6.0 x ULN	-
<b>Definition:</b> A finding based on laboratory test results that indicate increased levels of creatinine in a biological specimen.					
<b>Navigational Note:</b> Also consider Renal and urinary disorders: Acute kidney injury					

# Lipase

- Grading cannot rely solely on numeric thresholds
- Presence or absence of pancreatitis symptoms must also factor in
- Consider both lab elevation *and* clinical symptoms to assign severity

## Lipase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 3.0 x ULN; >3.0 - 5.0 x ULN and asymptomatic	>3.0 - 5.0 x ULN with signs or symptoms; >5.0 x ULN and asymptomatic	>5.0 x ULN and with signs or symptoms	-

**Definition:** A finding based on laboratory test results that indicate an increase in the level of lipase in a biological specimen.

**Navigational Note:** Consider Gastrointestinal disorders: Pancreatitis.

Lipase increased <b>CTCAE version 5.0</b>	>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN; >2.0 - 5.0 x ULN and asymptomatic	>2.0 - 5.0 x ULN with signs or symptoms; >5.0 x ULN and asymptomatic	>5.0 x ULN and with signs or symptoms	-
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**Definition:** A finding based on laboratory test results that indicate an increase in the level of lipase in a biological specimen.

**Navigational Note:** -

# Alkaline Phosphatase (ALP)

- ALP abnormalities are capped at **Grade 1**
- Reflects accumulating evidence that isolated ALP elevation is not a reliable surrogate for liver damage

# Blood and lymphatic system disorder SOC

- Added terms
  - Aplastic anemia – grades 2-5
  - Hemolytic anemia – grades 1-5
  - Lymphopenia – grade 1 only as “present”
    - **NOTE:** Removed lymphocyte count decreased in the Investigations SOC
  - Thrombocytopenia – grades 1-5
    - **NOTE:** Removed platelet count decreased in the Investigations SOC with **value changes for grades 3 and 4**
  - Thrombocytosis – grade 1 only as “present”
  - Thrombotic microangiopathy- grades 2-5
- Removed terms: none

# Thrombocytopenia

## Thrombocytopenia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<LLN - 75,000/mm <sup>3</sup> ; <LLN - 75.0 x 10 <sup>9</sup> /L	<75,000 - 50,000/mm <sup>3</sup> ; <75.0 - 50.0 x 10 <sup>9</sup> /L	<50,000 - 10,000/mm <sup>3</sup> ; <50.0 - 10.0 x 10 <sup>9</sup> /L; transfusion indicated	<10,000/mm <sup>3</sup> ; 10.0 x 10 <sup>9</sup> /L; life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by a decrease in number of platelets in a blood specimen.

**Navigational Note:** -

Platelet count decreased <b>CTCAE version 5.0</b>	<LLN - 75,000/mm <sup>3</sup> ; <LLN - 75.0 x 10 <sup>9</sup> /L	<75,000 - 50,000/mm <sup>3</sup> ; <75.0 - 50.0 x 10 <sup>9</sup> /L	<50,000 - 25,000/mm <sup>3</sup> ; <50.0 - 25.0 x 10 <sup>9</sup> /L	<25,000/mm <sup>3</sup> ; <25.0 x 10 <sup>9</sup> /L	-
<b>Definition:</b> A finding based on laboratory test results that indicate a decrease in number of platelets in a blood specimen.					
<b>Navigational Note:</b> -					

# Cardiac Disorders SOC

- Added terms:
  - Left ventricular dysfunction – grades 1-3
  - Cyanosis grade 2
    - Note: removed from Vascular disorders SOC
- Added/removed grades
  - Asystole:
    - removed grade 1,
    - added grade 3
  - Hypertension: removed grade 1
  - Myocarditis: added grade 1
- Removed terms:
  - Conduction disorder
  - Left ventricular systolic dysfunction
  - Restrictive cardiomyopathy
  - Right ventricular dysfunction
  - Restrictive cardiomyopathy
  - Right ventricular dysfunction

# Left ventricular dysfunction

## Left ventricular dysfunction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Left ventricular ejection fraction (LVEF) $\geq 50\%$ <b>AND</b> one or more of the following: 1) New relative decline in Global Longitudinal Strain (GLS) $>15\%$ from baseline 2) New rise in cardiac biomarkers	LVEF 40 - 49% <b>AND</b> one or more of the following: 1) LVEF reduction by $\geq 10\%$ 2) New relative decline in GLS $>15\%$ from baseline 3) New rise in cardiac biomarkers	New LVEF reduction to $<40\%$	-	-

**Definition:** A disorder characterized by an **ASYMPTOMATIC** abnormality of cardiac function.

**Navigational Note:** If symptomatic, consider Cardiac disorders: Heart failure.

Ejection fraction decreased <b>CTCAE version 5.0</b>	-	Resting ejection fraction (EF) 50 - 40%; 10 - 19% drop from baseline	Resting ejection fraction (EF) 39 - 20%; $\geq 20\%$ drop from baseline	Resting ejection fraction (EF) $<20\%$	-
<b>Definition:</b> The percentage computed when the amount of blood ejected during a ventricular contraction of the heart is compared to the amount that was present prior to the contraction.					
<b>Navigational Note:</b> Also consider Cardiac disorders: Left ventricular systolic dysfunction. Report Cardiac disorders: Left ventricular systolic dysfunction if same grade event.					

# Congenital, familial and genetic disorders

- No changes, still just 1 AE term of “Other, specify”

# Ear and labyrinth disorders SOC

- Substantial clarification:
  - Hearing impaired: clarified grades 1-4 with criteria for adults and pediatrics

# Knowledge check

Participant has a lymphocyte count of  $100/\text{mm}^3$  with a lower limit of normal reference of  $1,800/\text{mm}^3$ . What is the grade of lymphopenia?

- A. Grade 1
- B. Grade 2
- C. Grade 3
- D. Grade 4

# Knowledge check

What grade is an Alkaline Phosphatase of 750 U/L with a normal reference range of 44-147 U/L?

- A. Grade 1
- B. Grade 2
- C. Grade 3
- D. Grade 4

# Endocrine disorders SOC

- Added terms
  - Added Hypogonadism - grades 1-5
  - Added Thyroiditis - grades 1-5
- Removed terms
  - Growth accelerated (moved to different SOC)

# Eye Disorders SOC

- Added terms
  - Decreased night vision: grades 1-4
- Removed terms
  - Night blindness

# Gastrointestinal SOC

- Added terms

- Hematemesis grades 1-5
- Hematochezia grades 1-5
- Melena grades 1-5
- Pancreatic insufficiency grades 1-3

- Removed terms

- Anal hemorrhage
- Colonic hemorrhage
- Lower gastrointestinal hemorrhage
- Rectal hemorrhage

# Diarrhea

## Diarrhea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Change in consistency or frequency	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric); change in consistency or frequency AND limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Increase of $\geq 7$ stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; requires IV intervention; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by an increase in frequency and/or loose or watery bowel movements.

**Navigational Note:** Consider Gastrointestinal disorders: Colitis, Enterocolitis.

Diarrhea  <b>CTCAE version 5.0</b>	Increase of $< 4$ stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL	Increase of $\geq 7$ stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
<p><b>Definition:</b> A disorder characterized by an increase in frequency and/or loose or watery bowel movements.</p> <p><b>Navigational Note:</b> -</p>					

# General Disorders SOC

- Added terms
  - Peripheral edema grades 1-3
  - Pneumatosis grades 1-5
- Removed terms
  - Neck edema

# Hepatobiliary Disorders SOC

- Added terms
  - Biliary obstruction grades 1-5
  - Hepatitis grades 2-5
- Removed terms: none

# Immune System Disorders SOC

- Added terms
  - Graft versus host disease grades 2-5
  - Secondary hemophagocytic lymphohistiocytosis grades 1-5
- Removed terms: none

# Infections and Infestations SOC

- Added terms

- Aseptic meningitis grades 3-5
- Candidiasis grades 1-5
- Encephalitis grades 3-5
- Encephalomyelitis grades 3-5
- Meningoencephalitis grades 3-5
- Pneumonia grades 2-5

- Removed terms

- Encephalitis infection
- Encephalomyelitis infection
- Lung infection
- Papulopustular rash
- Thrush

# Injury, Poisoning and Procedural Complications

- Added terms
  - Anesthetic complication grades 2-5
  - Nerve injury grades 2-5
  - Post biopsy bleeding grades 2-5
  - Systemic post-immunization reaction grades 1-5
  - Tissue injury grades 2-5
- Removed terms
  - Ankle fracture
  - Hip fracture
  - Spinal fracture
  - Vaccination complication
  - Wrist fracture

# Investigations SOC

- Added terms
  - Creatinine clearance decreased grades 2-3
  - HDL decreased grade 1
  - LDL increased grade 1
  - Neutrophil count increased grade 1
  - Urinary protein increased grades 1-3
  - Vitamin D decreased grade 1
- Added/removed grades
  - Alkaline phosphatase increased:  
removed grades 2, 3, 4
  - Blood gonadotrophin abnormal:  
removed grade 3
  - Forced expiratory volume decreased:  
removed grade 4
- Removed terms
  - Cardiac troponin I increased
  - Cardiac troponin T increased
  - CPK increased
  - Ejection fraction decreased
  - Electrocardiogram T wave abnormal
  - Lymphocyte count decreased
  - Pancreatic enzymes decreased
  - Platelet count decreased

# Neutrophil count decreased

**Neutrophil count decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<1500 - 1000/mm <sup>3</sup> ; <1.5 - 1.0 x 10 <sup>9</sup> /L	<1000 - 500/mm <sup>3</sup> ; <1.0 - 0.5 x 10 <sup>9</sup> /L	<500 - 100/mm <sup>3</sup> ; <0.5 - 0.1 x 10 <sup>9</sup> /L	<100/mm <sup>3</sup> ; <0.1 x 10 <sup>9</sup> /L	-

**Definition:** A finding based on laboratory test results that indicate a decrease in number of neutrophils (ANC) in a blood specimen.  
**Navigational Note:** -

Neutrophil count decreased <b>CTCAE version 5.0</b>	<LLN - 1500/mm <sup>3</sup> ; <LLN - 1.5 x 10e9 /L	<1500 - 1000/mm <sup>3</sup> ; <1.5 - 1.0 x 10e9 /L	<1000 - 500/mm <sup>3</sup> ; <1.0 - 0.5 x 10e9 /L	<500/mm <sup>3</sup> ; <0.5 x 10e9 /L	-
<b>Definition:</b> A finding based on laboratory test results that indicate a decrease in number of neutrophils in a blood specimen.					
<b>Navigational Note:</b> -					

# Metabolism and Nutrition Disorders SOC

- Added terms
  - Diabetes mellitus grades 1-5
  - Failure to thrive grades 2,3
- Removed terms
  - Glucose intolerance
  - Obesity
- Added/removed grades
  - Hyperglycemia removed grade 5
  - Tumor lysis syndrome added grades 1-4

# Hyperglycemia

## Hyperglycemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L	>250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization indicated	>500 mg/dL; >27.8 mmol/L; life-threatening consequences	-

**Definition:** A condition characterized by laboratory test results that indicate a confirmed, short lasting and unexpected elevation in the concentration of blood sugar (glycemia).

**Navigational Note:** Consider Metabolism and nutrition disorders: Diabetes mellitus.

Hyperglycemia <b>CTCAE version 5.0</b>	Abnormal glucose above baseline with no medical intervention	Change in daily management from baseline for a diabetic; oral antiglycemic agent initiated; workup for diabetes	Insulin therapy initiated; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
<p><b>Definition:</b> A disorder characterized by laboratory test results that indicate an elevation in the concentration of blood sugar. It is usually an indication of diabetes mellitus or glucose intolerance.</p> <p><b>Navigational Note:</b> -</p>					

# Tumor lysis syndrome

## Tumor lysis syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory tumor lysis syndrome (LTLS) AND creatinine >ULN - 1.5 × ULN	LTLS AND creatinine >1.5 – 3.0 × ULN; cardiac arrhythmia managed medically; one brief generalized seizure; seizure(s) well controlled by anticonvulsants; infrequent focal motor seizures not limiting age-appropriate instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	LTLS AND creatinine >3.0 – 6.0 × ULN; cardiac arrhythmia controlled with device (e.g. defibrillator); seizure in which consciousness is altered; poorly controlled seizure disorder; breakthrough generalized seizures despite medical intervention	LTLS AND creatinine >6.0 × ULN; life-threatening cardiac arrhythmia or seizure	Death

**Definition:** A disorder characterized by metabolic abnormalities that result from a spontaneous or therapy-related cytolysis of tumor cells. Clinical tumor lysis syndrome (CTLS) requires one or more clinical manifestations along with criteria for laboratory tumor lysis syndrome (LTLS). LTLS is defined by two or more of the following laboratory abnormalities within 3 days before or 7 days after the initiation of chemotherapy: Uric acid  $\geq 476$   $\mu\text{mol/L}$  or 25% increase from baseline, Potassium  $\geq 6.0$   $\text{mmol/L}$  or 25% increase from baseline, Phosphorous  $\geq 2.1$   $\text{mmol/L}$  (children),  $\geq 1.45$   $\text{mmol/L}$  (adults) or 25% increase from baseline, Calcium  $\leq 1.75$   $\text{mmol/L}$  or 25% decrease from baseline.

**Navigational Note:** -

Tumor lysis syndrome <b>CTCAE version 5.0</b>	-	-	Present	Life-threatening consequences; urgent intervention indicated	Death
<b>Definition:</b> A disorder characterized by metabolic abnormalities that result from a spontaneous or therapy-related cytolysis of tumor cells.					
<b>Navigational Note:</b> -					

# Musculoskeletal and connective tissue disorders SOC

- Added terms
  - Growth accelerated grade 2
    - **NOTE:** Removed from Endocrine SOC
- Removed terms
  - Avascular necrosis

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

- Added terms
  - Differentiation syndrome grades 1-5
  - Keratoacanthoma grade 2
  - Retinoic acid syndrome
    - Note: Removed from Respiratory, thoracic and mediastinal disorders SOC
- Removed terms: none

# Nervous system disorders SOC

- Added terms

- Autonomic neuropathy grades 1-5
- Brain fog grades 1, 2
- Cerebral venous sinus thrombosis grades 2-5
- Hemiparesis grades 1-3
- Immune effector cell-associated neurotoxicity syndrome grades 1-5
- Optic neuritis grades 1-4
- Tumor inflammation-associated neurotoxicity grades 1-5

- Removed terms

- Aphonia (moved to different SOC)
  - Ischemia cerebrovascular
  - Muscle weakness left-sided
  - Muscle weakness right-sided
- Added/removed grades
    - Dysphasia added grade 4
    - Edema cerebral added grade 1
    - Spinal cord compression added grades 1, 2
    - Vasovagal reaction added grade 2

# Pregnancy, puerperium and perinatal conditions SOC

- Added terms: none
- Removed terms: none

# Psychiatric disorders SOC

- Added terms: none
- Removed terms: none

# Renal and urinary disorders SOC

- Added terms
  - Glomerulonephritis grades 1-5
  - Nocturia grade 1
  - Tubulointerstitial nephritis grades 1-5
- Removed terms
  - Proteinuria

# Reproductive system and breast disorders SOC

- Added terms
  - Ovarian function insufficiency grades 1, 2
- Removed terms
  - Breast atrophy
  - Genital edema
  - Premature menopause

# Respiratory, thoracic and mediastinal disorders SOC

- Added terms
  - Aphonia grade 3
    - Note: removed from Nervous system disorders SOC
- Removed terms
  - Wheezing
  - Retinoic acid syndrome (moved to different SOC)
- Added/removed grades
  - Hypoxia added grade 1

# Skin and subcutaneous tissue disorders SOC

- Added terms
  - Dermatitis psoriasiform grades 1-3
  - Dermatositis bullous grades 1-5
  - Eczematous dermatitis grades 1-3
  - Exfoliative dermatitis grades 1-5
  - Lichenoid dermatitis grades 1-3
  - Papulovesicular rash grades 1-5
  - Pustular drug eruption grades 1-5
- Added/removed grades
  - Rash maculo-papular added grades 4, 5
- Removed terms
  - Bullous dermatitis
  - Eczema
  - Fat atrophy
  - Lipohypertrophy
  - Rash acneiform

# Vascular Disorders SOC

- Added terms
  - Venous thromboembolism grades 1-5
- Removed terms
  - Cyanosis(moved to different SOC)
  - Thromboembolic event

# Considering what you have heard so far, what concerns you the most?

# CTCAE Search Tools

- NCI Online CTCAE Dictionary Tool: [Safety Profiler](#)
- Apps:



# Implementation for NCI CTEP/DCP-supported Studies

- ALL new studies whose Rave study build begins after CTCAE v6 Rave AE Library Specification (ALS) 7.2 is released which tentatively is schedule for July 2026
- **NO** data conversion from CTCAE v5 to CTCAEv6

# Resources

- NCI CTEP CTCAE v6: [CTCAE and AE Reporting - NCI](#)
- MedDRA training materials: [Training Materials | MedDRA](#)

# Open Forum Discussion – Questions and Answers

# Prior QA Webinars Accessible for Review

Previous Webinars and Upcoming Webinar Information is posted at:

**[SWOG Quality Assurance Live Webinar Series | SWOG](#)**

CEU Courses posted in CLASS:

- **[Biospecimen Collection and Submission](#)**  
(1 contact hour)
- **[Cytogenetics](#)** (1 contact hour)
- **[Serious Adverse Event Reporting & Updates](#)**  
(1 contact hour)
- **[Workload Prioritization in Clinical Trials](#)**  
(1.5 contact hours)
- **[Disease Assessment in Solid Tumors](#)**  
(1 contact hour)
- **[Best Practices for Informed Consent](#)**  
(1 contact hour)
- **[Research Protocol Deviations vs Deficiencies](#)**  
(1 contact hour)

Non-CEU Courses posted in CLASS:

- **[Adverse Event Reporting](#)**
- **[SWOG Audits: Preparing for Success and Audit Process](#)**
- **[How to Develop a CAPA Plan](#)**

# Thank you