

Common Terminology Criteria for Adverse Events

Version 3.0

Glossary of Terms

Cancer Therapy Evaluation Program
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Common Terminology Criteria for Adverse Events (CTCAE) - Glossary Report

-- A --

accentuation

To weaken; reduction in force, amount, or degree.

achalasia

Failure of normal relaxation of the lower esophageal sphincter associated with uncoordinated contractions of the thoracic esophagus, resulting in functional obstruction and difficulty swallowing. SYN: cardiospasm.

acrocyanosis

A circulatory disorder in which the hands, and less commonly the feet, are persistently cold and blue; some forms are related to Raynaud's phenomenon.

acute infusion reaction

A constellation of symptoms (chills, fever, headache, nausea, and vomiting, nephrotoxicity) that occur during or immediately following infusion.

ADD

An abbreviation for Attention Deficit Disorder: A diagnosable, treatable, biologically based condition characterized by developmentally inappropriate level of attention, concentration, activity, distractability, and impulsivity.

ADH

An abbreviation for antidiuretic hormone.

ADL

An abbreviation for Activities of Daily Living. The performance of the basic activities of self care; getting in and out of bed, dressing, eating, and getting around inside, dressing, bathing and using the toilet.

Assessment of ADL include identification of how a patient's symptoms affect his/her ability to care for self based from the perspective of physical, mental, or social ability to carry on the normal activities of life. How do the symptoms affect his/her ability to care for self, to move about, to do what he/she would do if able?

Relative to the neurologic exam, for example, interpretation of ADL is based on the impact of neurological disability on such functions as understanding, communicating, remembering, seeing, speaking, feeling, moving, walking, and integrated regulatory functions such as elimination. Assessment of ADLs

ADL

should be viewed in terms of capacity disabilities rather than dysfunction of component parts of the body.

Adverse Event (AE)

Any unfavorable or unintended symptom, sign, or disease (including abnormal lab) temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure. Such effects can be intervention related, dose related, route related, patient related, caused by an interaction with another drug.

aerodigestive tract

The passage leading from the mouth to the anus through the pharynx, esophagus, stomach, and intestine.

Alcohol Intolerance Syndrome

Abnormal metabolism, excretion, or other disposition of an alcohol or alcohol-like substance. Sulfonyleureas and other medications may cause an alcohol intolerance syndrome. Within 10 to 30 minutes of drinking a beverage or medication containing alcohol, some people get headaches, develop flushing or tingling in the face, and they may feel nauseated and lightheaded. These symptoms may last up to one hour and even relatively small amounts of alcohol--a half glass of wine, can cause a reaction.

aliment

To nourish.

ALSO CONSIDER

Indicates either (1) additional AEs that are to be graded if they are clinically significant, or (2) an alternate AE that may more precisely describe the event.

ALT

An abbreviation for alanine aminotransferase, an enzyme used in clinical diagnosis of viral hepatitis and myocardial infarction. SYN: SGPT (serum glutamic-pyruvic transaminase).

altered GI function

Impairment of the actions and physiologic properties of the stomach and intestines.

amenorrhea

Absence or abnormal cessation of the menses. Secondary amenorrhea is the absence of menstrual periods for 6 months in a woman whose menstrual

accentuation - amenorrhea



-- A --

amenorrhea

periods had previously been regular, or for 12 months in a woman who had irregular menstrual periods.

AML

An abbreviation for acute myelocytic leukemia, a group of malignant disorders characterized by the replacement of normal bone marrow with abnormal, primitive hematopoietic cells.

anastomosis

The surgical connection of separate or severed tubular hollow organs to form a continuous channel, as between two parts of the intestine. A communication between or coalescence of blood vessels; the surgical union of parts and especially hollow tubular parts.

ANC

An abbreviation for Absolute Neutrophil Count.

anejaculation

Dysfunction of inhibited orgasm characterized by ejaculation failure.

ankylose

Fixation and immobility of a joint.

anovulatory

A sexual cycle in which no ovum is discharged.

Antabuse-like Syndrome

Antabuse (disulfiram) adverse effects include fatigue, garlic breath, metallic taste, acne, and rare neurologic sequelae. Signs and symptoms of Antabuse with alcohol reaction include headache, nausea, vomiting, large red hot puritic rash, shortness of breath, cardiac arrest, seizure, coma, death.

aphasia

Aphasia is loss of communication skills previously learned and commonly occurs following strokes or in people with brain tumors or degenerative diseases that affect the language areas of the brain. This term does not apply to children who have never developed communication skills. Aphasia refers to the loss of ability to communicate verbally, whether by speech or reading-writing.

arachnoiditis

Acute or chronic inflammation of the arachnoid membrane of the meninges

arachnoiditis

most often involving the spinal cord or base of the brain. This term generally refers to a persistent inflammatory process characterized by thickening of the arachnoid membrane and dural adhesions. Associated conditions include prior surgery, infections, trauma, subarachnoid hemorrhage and chemical irritation. Clinical features vary with the site of inflammation, but include cranial neuropathies, radiculopathies, and myelopathies. SYN: leptomeningitis.

ARDS

An abbreviation for Adult Respiratory Distress Syndrome. Acute lung injury from a variety of causes, characterized by interstitial and/or alveolar edema and hemorrhage as well as perivascular pulmonary edema associated with hyaline membrane, proliferation of collagen fibers, and swollen epithelium.

arthralgia

Pain in a joint.

arthritis

Inflammation of a joint or a state characterized by inflammation of joints.

arthrodesis

Immobilization of a joint by fusion of joint surfaces promoting proliferation of bone cells; joint fusion. The stiffening of a joint by operative (surgical) means.

AST

An abbreviation for aspartate aminotransferase, an enzyme diagnostic aid in viral hepatitis and in myocardial infarctions. SYN: SGOT.

asterixis

Involuntary jerking movements, especially in the hands, best elicited by having the patient extend the arms, dorsiflex the wrists, and spread the fingers; due to arrhythmic lapses of sustained posture; seen primarily with various metabolic and toxic encephalopathies, especially hepatic encephalopathy.

asymptomatic

Having no signs or symptoms of adverse effects or disease.

ataxia

Loss of muscle coordination; inability to coordinate muscle activity during voluntary movement, so that smooth movements occur. Most often due to disorders of the cerebellum or the posterior columns of the spinal cord; may involve the limbs, head, or trunk. SYN: incoordination.

attribution



-- A --

attribution

In general, AEs in CTCAE have been developed to capture events associated with, but not necessarily attributable to a therapy. It is important to note that in general, attribution or casualty is a judgment outside of the domain of the CTCAE, and therefore attribution should not be part of the classification and grading of adverse events. However, there are exceptional cases in which the CTCAE development team has chosen to include association with an intervention in the categorization of the adverse event. For example, "Catheter-related infection" includes an association in the AE itself, but this does not imply that the catheter or those who placed the catheter are responsible for the adverse event. In these cases the categorization should still be thought of as associative rather than causative for reporting purposes.

audiogram

The graphic record drawn from the results of hearing tests with the audiometer. It charts the threshold of hearing at various frequencies against sound intensity in decibels.

avascular necrosis

A disease resulting from the temporary or permanent loss of the blood supply to the bones. Without blood, the bone tissue dies and causes the bone to collapse. If the process involves the bones near a joint, it often leads to collapse of the joint surface. Although it can happen in any bone, avascular necrosis most commonly affects the ends (epiphysis) of long bones such as the femur, the bone extending from the knee joint to the hip joint. The disease may affect just one bone, more than one bone at the same time, or more than one bone at different times. SYN: osteonecrosis, aseptic necrosis, and ischemic bone necrosis.

azoospermia

Absence of living spermatozoa in the semen; failure of spermatogenesis.

attribution - azoospermia



-- B --

Babinski sign

An abnormal reflex consisting of dorsiflexion of the great toe and abduction of the other toes in response to cutaneous stimulation of the plantar surface of the foot. Extension of the great toe and abduction of the other toes instead of the normal flexion reflex to plantar stimulation, considered indicative of pyramidal tract involvement ("positive" Babinski).

banding

A treatment for hemorrhoids. A rubber band is placed around the base of the hemorrhoid inside the rectum. The band cuts off circulation and the hemorrhoid withers away within a few days.

baseline

Clinical observations documented prior to medical intervention used for comparison or a control. Many AEs are graded based on an increase or decrease from baseline. If the baseline abnormalities are not documented the physician is responsible for indicating how baseline is to be determined.

blood patch

The injection of autologous blood into the epidural space either as a prophylactic treatment immediately following an epidural puncture or for treatment of headache as a result of an epidural puncture.

BMD

An abbreviation for Bone Mineral Density. The amount of mineral per square centimeter of bone is the definition used in clinical practice. Actual bone density would be expressed in grams per milliliter. It is most frequently measured by photon absorptiometry or x-ray computed tomography.

BMI

An abbreviation for body mass index.

BP

An abbreviation for blood pressure.

BSA

An abbreviation for body surface area.

bullae

A large blister appearing as a circumscribed area of separation of the epidermis from the subepidermal structure or as a circumscribed area of separation of epidermal cells caused by the presence of serum, or occasionally by an injected substance. ADJ: Bullous

Babinski sign - bullae



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-- C --

Calcium, ionized calcium

The quantity or concentration of calcium in the blood that exists as a free ion, not protein bound. Ionized calcium is added to CTCAE and provides an option for grading calcium.

canalicular stenosis

Narrowing or obstructive disorders of the lacrimal system of the eye causing impedence to the outflow of tears. Epiphora (insufficient drainage of tears) because of punctal and canalicular stenosis is a side effect of some antineoplastic agents.

capital femoral epiphysis

Slipped capital femoral epiphysis is a hip problem that starts if part of the growing end (the epiphysis) of the thigh bone (the femur) slips off from the top of the thigh bone.

cardiomyopathy

Cardiomyopathy is a disease of the heart muscle. The heart loses its ability to pump blood and, in some instances, heart rhythm is disturbed, leading to irregular heartbeats.

CATEGORY

A broad classification of adverse events based on anatomy and/or pathophysiology. Within each CATEGORY adverse events are listed alphabetically accompanied by their descriptions of severity (Grade).

causality

Reporting and grading AEs does not imply causality to intervention or error in administration. There are multiple causes of AEs: pre-existing conditions (e.g., hypertension, diabetes); concomitant medications (anticoagulants, steroids); other causes (e.g., transfusion reactions, accidental injuries). Reporting and grading an AE simply indicates that an event occurred. The physician must assign attribution of the event, either to the intervention or to something else.

cauterization

The application of a caustic substance, a hot instrument, an electric current, or other agent to sear or destroy tissue.

chelitis

Inflammation of the lips or of a lip. Cheilosis is an abnormal condition of the lips characterized by scaling of the surface and by the formation of fissures in the corners of the mouth.

chemosis

Edema of the bulbar conjunctiva, forming a swelling around the cornea; bulbar conjunctiva is the part of the conjunctiva covering the anterior surface of the sclera and the surface epithelium of the cornea.

CHF

An abbreviation for congestive heart failure, a condition in which the heart is not pumping as it should be. Causes can be clogged arteries, high blood pressure, a defect in the muscular walls or valves, other medical conditions, or medical interventions. CHF symptoms include weakness, fatigue, shortness of breath, and a buildup of fluid in body tissues.

chondrosarcoma

A primary malignant tumor derived from cartilage cells.

chylothorax

The presence of milky lymphatic fluid in the pleural space secondary to leakage from the thoracic duct or one of its main tributaries.

chylous

Relating to chyle, a turbid white or pale yellow fluid taken up by the lacteals from the intestine during digestion and carried by the lymphatic system via the thoracic duct into the circulation. The milky appearance is due to chylomicrons in the lymph.

clostridium difficile

A species of bacteria found to be a cause of pseudomembranous colitis and is associated with a number of intestinal diseases that are linked to antibiotic therapy. It is also the chief cause of nosocomial (associated with being in a hospital) diarrhea.

CN I

The 1st cranial nerve (olfactory nerve) conveys the sense of smell.

CN II

The 2nd cranial nerve (optic nerve) carries messages from the retina to the brain; vision, visual acuity.

CN III

The third cranial nerve (oculomotor nerve) supplies muscles of the eye (elevation of upper eyelid and extra ocular movement) and controls pupillary constriction and accommodation.

CN IV

Calcium, ionized calcium - CN IV



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-- C --

CN IV

The 4th cranial nerve (trochlear nerve) controls downward, inward movement of the eye.

CN IX

The 9th cranial nerve (glossopharyngeal nerve) controls motor movement of the pharynx and sensation of the ear, pharynx, and tongue.

CN V

The 5th cranial nerve (trigeminal nerve) controls motor movement of jaw muscles (mastication) and sensation of the face.

CN VI

The 6th cranial nerve (abducens) controls lateral movement of the eye.

CN VII

The 7th cranial nerve (facial nerve) controls motor movement of the face and sensation of taste.

CN VIII

The 8th cranial nerve (vestibulochoclear) controls hearing and balance.

CN X

The 10th cranial nerve (vagus nerve) controls motor movement of the palate, pharynx, and larynx. Sensory innervation of pharynx.

CN XI

The 11th cranial nerve (spinal accessory nerve) controls motor movement of the trapezius (shoulder) muscles and sternomastoid (sternum, clavicle, and mastoid process) muscles.

CN XII

The 12th cranial nerve (hypoglossal nerve) controls motor movement of the tongue.

CNS

An abbreviation for central nervous system (the brain and spinal cord).

coagulopathy

A disease affecting the clotting functions of the blood; hemorrhagic and thrombotic disorders as a consequence of abnormalities in blood coagulation.

colectomy

An operation to remove all or part of the colon.

complete resection

Removal of tissue, body part, or all of an organ by surgery.

confluent

Joining; running together; denoting certain skin lesions which become merged, forming a patch; denoting a disease characterized by lesions which are not discrete, or distinct one from the other.

conjunctivitis

Inflammation of the conjunctiva (the mucous membrane that lines the inner surface of the eyelids and is continued over the forepart of the eyeball). SYN: blennophthalmia, an excessive secretion and discharge of mucus.

contracture

Static muscle shortening due to tonic spasm or fibrosis, or to loss of muscular balance.

cor pulmonale

A complication of disorders that slow or block blood flow in the lungs, resulting from raised blood pressure in the lungs. Cor Pulmonale presents as right heart failure, which is defined by a sustained increase in right ventricular pressures combined with an inability to balance the cardiac output in response to exercise or other stimuli.

CPAP

An abbreviation for continuous positive airway pressure.

cranial nerve

The nerves that emerge from, or enter, the cranium or skull, in contrast to the spinal nerves, which emerge from the spine or vertebral column. The twelve paired cranial nerves are the olfactory, optic, oculomotor, trochlear, trigeminal, abducens, facial, vestibulochoclear, glossopharyngeal, vagal, accessory, and hypoglossal nerves.

CVA

An abbreviation for cerebrovascular accident. A sudden, non-convulsive loss of neurologic function due to an ischemic or hemorrhagic intracranial vascular event. In general, cerebrovascular accidents are classified by anatomic location in the brain, vascular distribution, etiology, age of the affected individual, and hemorrhagic vs. non-hemorrhagic nature.

cytokine release syndrome

An idiosyncratic inflammatory reaction produced by cells of the immune system seen during or immediately after infusion of an agent. Symptoms

CN IV - cytokine release syndrome



-- C --

cytokine release syndrome

include chills, high fever, hypotension, abdominal pain, nausea and sometimes diarrhea.

cytokine release syndrome - cytokine release syndrome



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-- D --

DAT

An abbreviation for direct antiglobulin test.

Deep tissue fibrosis

Deep connective tissue refers to the layer below the superficial fat and includes muscle, fascia, and all connective tissue down to bone. Potential consequences of deep tissue fibrosis include reducing muscle strength. Also Consider Muscle weakness (specify muscle or muscle group), and nerve compression. Also Consider Neuropathy, sensory.

dehiscence

A bursting open, splitting, or gaping along natural or sutured lines.

desquamation

Detachment and shedding of superficial cells of an epithelium or from any tissue surface. Scaling or shedding of the horny layer of epidermis, this varies in amount from minute quantities to shedding the entire integument.

DIC

An abbreviation for disseminated intravascular coagulation. A hemorrhagic syndrome which occurs following the uncontrolled activation of clotting factors and fibrinolytic enzymes throughout small blood vessels; fibrin is deposited, platelets and clotting factors are consumed, and fibrin degradation products inhibit fibrin polymerization, resulting in tissue necrosis and bleeding.

diplopia

The condition in which a single object is perceived as two objects; double vision.

disabling

Signs or symptoms that cause physical or mental disabilities that affect or limit the ability of a person to perform activities of daily living (eating, ambulation, toileting, etc.)

DKA

An abbreviation for diabetic ketoacidosis; a state of absolute or relative insulin deficiency aggravated by hyperglycemia, dehydration, and acidosis-producing derangements in intermediary metabolism. The most common causes are underlying infection, disruption of insulin treatment, and new onset of diabetes.

DM

An abbreviation for diabetes mellitus.

DVT

An abbreviation for deep vein thrombosis.

dysarthria

Dysarthria is difficult, poorly articulated speech, such as slurring and is imperfect speech articulation due to disturbances of muscular control. Dysarthria is generally apparent in daily conversation where there is difficulty expressing certain sounds or words.

dysgeusia

A condition characterized by alterations of the sense of taste which may range from mild to severe, including gross distortions of taste quality. Altered taste perception can be to any one of the four taste qualities (sweet, salt, sour, bitter).

dyspareunia

Occurrence of pain during sexual intercourse.

dyspepsia

Means "bad" (dys) "digestion" (pepsia); a term which is often used to describe a set of symptoms which are believed to have their cause somewhere in the upper part of the gastrointestinal tract; upset stomach.

dysphagia

Difficulty swallowing and/or pain while swallowing. Some people may be completely unable to swallow or may have trouble swallowing liquids, foods, or saliva. Eating then becomes a challenge. Dysphagia may make it difficult to take in enough calories and fluids.

dysphasia

Dysphasia (sometimes called aphasia) is a disorder of language; complete or partial loss of ability to understand, speak, read and write. Lack of coordination in speech, and failure to arrange words in an understandable way.

DAT - dysphasia



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-- E --

ECG

An abbreviation for electrocardiogram, a graphic record of the heart's integrated action currents obtained with the electrocardiograph. SYN: EKG.

ectropion

The medical term used to describe sagging and outward turning of the lower eyelid and eyelashes. The margin of the eyelid and the eyelashes evert (turn out). This rubbing can lead to excessive tearing, crusting of the eyelid, mucous discharge and irritation of the eye.

EF

An abbreviation for ejection fraction; generally refers to left ventricular ejection fraction.

EIOP

An abbreviation for elevated intraocular pressure; the pressure (usually measured in millimeters of mercury) of the intraocular fluid within the eye is usually measured by means of a manometer.

embolism

A plug composed of a detached thrombus or vegetation, mass of bacteria, or other foreign body, occluding a vessel. The resulting event can be a stroke, pneumonia, abscess, gangrene, shock, etc.

encephalopathy

Any disorder of the brain that can be caused by disease, injury, drugs, or chemicals. Symptoms include mental confusion, ataxia, oculomotor abnormalities.

end organ dysfunction

The special structure containing the terminal of a nerve fiber in peripheral tissue such as muscle, tissue, skin, mucous membrane, or glands.

endoscopy

The use of a lighted tube (called an endoscope) linked to a camera/video display to examine the inside of the body (e.g., the esophagus, stomach, colon, ureters).

enophthalmos

Inward depression of the eyeball within the orbit, i.e. the opposite of the exophthalmos. It is due either to bony anomalies, such as maxillary sinus atelectasis and midface depression following sinonasal chronic inflammatory conditions, or traumatic injury to the orbit as the result of orbital fat herniating

enophthalmos

through the orbital walls. Enophthalmos may not be evident immediately owing to the presence of orbital edema. Recession of the eyeball within the orbit due to atrophy of orbital tissue, trauma, surgery, or radiation.

enteral nutrition

Nutritional support given via the alimentary canal or any route connected to the gastrointestinal system (i.e., the enteral route). This includes oral feeding and tube feeding using nasogastric, gastrostomy, and jejunostomy tubes.

enteritis

Inflammation of the intestine, especially of the small intestine that can cause abdominal pain, cramping, diarrhea, fever, and dehydration.

entropion

Entropion is the medical term used to describe rolling inward of the lower eyelid and eyelashes towards the eye. The skin of the eyelid and the eyelashes rub against the cornea (the front part of the eye) and conjunctiva (the mucous membrane that protects the eye). This rubbing can lead to excessive tearing, crusting of the eyelid, mucous discharge, a feeling that something is in the eye, irritation of the cornea, and impaired vision.

enucleation

Removal of an entire structure (such as an eyeball or tumor).

epiphysiodesis

Premature union of the epiphysis with the diaphysis, resulting in cessation of growth. An operative procedure that partially or totally destroys an epiphysis and may incorporate a bone graft to produce fusion of the epiphysis or premature cessation of its growth; generally undertaken to equalize leg length.

erythema

Redness of the skin.

erythroderma

A nonspecific designation for intense and usually widespread reddening of the skin from dilatation of blood vessels, often preceding, or associated with exfoliation (peeling, flaking).

etiology

The cause or origin of a sign, symptom, disease.

evisceration

Protrusion of omentum and/or intestine through an opening in the abdominal

ECG - evisceration



-- E --

evisceration

wall.

exfoliative

A condition of the skin characterized by scaling, itching (pruritus), skin redness, peeling.

exostosis

A bony outgrowth or lump that results from a disorder of the growth-plate in which some growth takes place sideways, away from the bone, instead of in the normal direction along its length. As the bone grows, the tip of the exostosis remains more or less where it was but the base stays attached to the bone. The exostosis either becomes a spur, pointing back towards middle of the bone, or is filled in, becoming a lump close to the end. Sometimes the lump is irregular. One of the most common places to develop an exostosis is around the knee, an area of maximum growth. They are also common at the shoulder, the wrist and on the ribs. SYN: osteochondroma or bony spur.

expressive dysphasia

Communication disorder characterized by impairment of expressive language (speech, writing, signs) and relative preservation of receptive language abilities (i.e., comprehension). Characteristics: (1) the patient understands but cannot answer appropriately; (2) the patient has difficulty finding words; (3) there is a reduced rate of word production - non-fluent dysphasia. In this form of dysphasia the patient should be asked to talk about something - the choice of subject will vary from patient to patient. The patient might use elaborate descriptions to get around their inability to find a particular word - circumlocution, and they may substitute words whose meaning is not quite correct.

extrapyramidal/involuntary movement

Movement that is not under the control of the brain. Occasionally involuntary movement happens so often that it interferes with the ability to function. Extrapyramidal movement is a disorder of the brain (striate body/basal ganglia), its associated structures (substantia nigra; subthalamic nucleus), and its descending connections with the midbrain that results in decreased ability to initiate and direct voluntary movements. Shaking, trembling.

exudative

Material, such as purulent and nonpurulent fluid, cells, or cellular debris, which has escaped from blood vessels and has been deposited in tissues or on tissue surfaces, usually as a result of inflammation.

evisceration - exudative



-- F --

fascia

A sheet of fibrous tissue that envelops the body beneath the skin, encloses muscles and groups of muscles, and separates their several layers or groups.

FEV1

An abbreviation for forced expiratory volume; the maximal volume that can be expired in a specific time interval when starting from maximal inspiration.

fibrosis

Any condition where tough, fibrous (fiber-like) connective tissue invades any organ, usually as a consequence of inflammation or other injury. Fibrosis refers to the formation of fibrous tissue as a reparative or reactive process, as opposed to formation of fibrous tissue as a normal constituent of an organ or tissue.

fistula

An abnormal communication between the cavities of two internal structures or between a cavity of an internal structure and the surface of the skin.

fixation

Sometimes associated with deep tissue fibrosis, fixation is defined as no movement on adjacent tissue, usually fascia or bone.

flu-like syndrome

A constellation of symptoms characterized by inflammation of the nasal mucosa, the pharynx, and conjunctiva, and by headache and severe, often generalized, myalgia.

Folstein Mini-Mental Exam

This Mini-Mental Status Exam is a quick way to evaluate cognitive function. It is often used to screen for dementia or monitor its progression. SYN: MMSE.

function

The special action or physiologic property of an organ or other part of the body.

functional impairment

Any loss or abnormality of psychological, physiological or anatomical structure or function.

fascia - functional impairment



-- G --

galactorrhea

Any white discharge from the nipple that is persistent and looks like milk.

GFR

An abbreviation for glomerular filtration rate.

GGT

An abbreviation for gamma-glutamyl transferase .

Grade

In CTCAE, Grade refers to the severity of adverse events. Generally, Grade 1 events are mild; Grade 2 are moderate; Grade 3 are severe; Grade 4 are life-threatening or disabling; Grade 5 is death. CTCAE grading is by definition a 5-point scale generally corresponding to mild, moderate, severe, life-threatening and death. This grading system inherently places a value on the importance of an event, although, there is not necessarily "proportionality" among grades (a "2" is not necessarily twice as bad as a "1"). Some adverse events are difficult to "fit" into this 5 point schema, but altering the general guidelines of severity scaling would render the system useless for comparing results between trials, an important purpose of the system. Some AES do not have a value for every Grade (e.g., Grade 4 hiccups is blank).

Grade 0

In order to render the CTCAE readable and because Grade 0 is universally defined as absence of an AE or within normal limits, Grade 0 does not appear on the document. However, for the purposes of baseline documentation where required, Grade 0 is appropriate for each AE.

Grade 5

Grade 5 is routinely considered Death related to an adverse event. However, Death is inappropriate for many of the AEs listed in the CTCAE. The CTCAE document distinguishes this by including a Grade 5 column and specifying either Death or a 'Em dash' (-) for each AE.

GVHD

An abbreviation for Graft-versus-host disease. A reaction of donated bone marrow or peripheral stem cells against a recipient's tissue.



-- H --

hemodynamic collapse

Failure of the circulatory system to support vital functions.

hemodynamic instability

Inconsistent, fluctuating status of the circulatory system; unstable vital signs.

hemoptysis

The spitting of blood derived from the lungs or bronchial tubes as a result of pulmonary or bronchial hemorrhage.

hemostasis

The arrest of bleeding. The process which spontaneously arrests the flow of blood from vessels carrying blood under pressure. It is accomplished by contraction of the vessels, adhesion and aggregation of formed blood elements, and the process of blood or plasma coagulation.

honeycombing

Something resembling the structure of hexagonal, thin-walled cells in configuration or pattern; to form in or cover with a pattern-like that of a honeycomb.

hospitalization

Hospitalization includes any overnight stay in a healthcare facility, including the so-called "23 hour observation" status often used because of reimbursement issues. It does not include extended infusions or treatments in an outpatient facility. Evaluation and treatment in an emergency medical department is not per-se a hospitalization, but investigators should use good judgment when considering reporting guidelines and definitions for a patient treated for extended periods of time in emergency departments. Prolongation of hospitalization is defined as longer than expected and is to be a result of the AE itself or intervention or potential complications from the AE, including prevention/monitoring.

Howell-Jolly bodies

Spherical or ovoid eccentrically located granules, occasionally observed in circulating erythrocytes via a laboratory test. The significance of the bodies is not exactly known but they occur most frequently after splenectomy or in megaloblastic or severe hemolytic anemia.

HUS

An abbreviation for hemolytic uremic syndrome.

hyperbaric oxygen

Hyperbaric oxygen therapy is a medical treatment administered by delivering

hyperbaric oxygen

100% oxygen at pressures greater than atmospheric (sea level) pressure to a patient in an enclosed chamber. Hyperbaric oxygen acts as a drug, eliciting varying levels of response at different treatment depths, and dosages and has been proven effective as adjunctive therapy for specifically indicated conditions.

hyperosmolar non-ketotic coma

A complication seen in diabetes mellitus in which very marked hyperglycemia occurs (such as levels over 800 mg/dL) causing osmotic shifts in water in brain cells and resulting in coma. It can be fatal or lead to permanent neurologic damage. Ketoacidosis does not occur in these cases.

hypoplasia

Underdevelopment of a tissue or organ, usually due to a decrease in the number of cells. Atrophy due to destruction of some of the elements and not merely to their general reduction in size.

hemodynamic collapse - hypoplasia



-- | --

ICP

An abbreviation for intracranial pressure.

Indicated vs. Required

CTCAE uses the word 'indicated' rather than 'required' when describing grades in which interventions help define severity. In most cases the meaning is interchangeable, but there are situations when a procedure would be indicated, but not performed due to extenuating circumstances. Example: A patient develops a pleural effusion, requires supplemental oxygen, and the clinical situation merits thoracic chest tube placement, but the patient declines the procedure. In this case grading is based on the medical opinion of what should be done, not what was actually done. 'Required' would mean that if an action was not taken, then the AE could not be graded.

INR

An abbreviation for International Normalized Ratio. The INR is a standardized Prothrombin Time (PT), a system established by the World Health Organization and the International Committee on Thrombosis and Hemostasis for monitoring and reporting blood coagulation tests. Under this system, results are standardized using the International Sensitivity Index (ISI) for the particular test reagent/instrument combination used.

interfering with ADL

Signs or symptoms that create a hindrance or obstacle in the ability to perform Activities of Daily Living (eating, ambulating, toileting, etc.)

interfering with function

Signs or symptoms that either prevent a part of the body to perform its action, or that intervene/intrude upon the normal physiologic property of an organ or other part of the body.

intervention

CTCAE describes events that result from protocol interventions rather than effects that result from treatment for adverse events. CTCAE is not to be used for reporting effects of a treatment for adverse events.

interventional radiology

The use of fluoroscopy, CT, and ultrasound to guide percutaneous procedures such as performing biopsies, draining fluids, inserting catheters, or dilating or stenting narrowed ducts or vessels. Interventional Radiology includes angioplasty and vascular stenting, catheter embolization, vascular access procedures, ultrasound or x-ray guided biopsy.

Intra-operative injury

Damage or trauma to any of the tissues or organs of the body inflicted as the result of a surgical intervention.

Invasive procedure

A procedure that involves insertion of an instrument or device into the body through the skin (usually by cutting or puncturing) or a body orifice for diagnosis or treatment.

ischemic changes

Changes to tissues or organs of the body caused by inadequate circulation, often due to constriction or obstruction of the blood supply to the area.

ICP - ischemic changes



-- J --

jaundice

A condition in which the skin and the whites of the eyes become yellow, urine darkens, and the color of stool becomes lighter than normal. Jaundice occurs when the liver is not working properly or when a bile duct is blocked. Jaundice often results from an elevated bilirubin. Jaundice itself is not an AE, but is reported as bilirubin and/or liver dysfunction/failure.

joint-effusion

Accumulation of watery fluid in the cavity of a joint.

jaundice - joint-effusion



-- K --

keratinization

Formation or development of a tough, horny layer usually of an insoluble protein substance that is the chief structural constituent of hair and nails.

keratitis

A term used to define a wide variety of corneal infections, irritations, and inflammations. Symptoms of corneal infection include extreme pain and photophobia.

keratoconjunctivitis

Inflammation of the conjunctiva and of the cornea of the eye.

ketoacidosis

Diabetic ketoacidosis is a state of absolute or relative insulin deficiency aggravated by ensuing hyperglycemia, dehydration, and acidosis-producing derangements in intermediary metabolism. The most common causes are underlying infection, disruption of insulin treatment, and new onset of diabetes. Ketoacidosis typically is characterized by hyperglycemia over 300 mg/dL, low bicarbonate (<15 mEq/L), and acidosis (pH <7.30) with ketonemia and ketonuria.

kyphosis

A deformity of the spine characterized by extensive flexion in which there is a sharply angulated segment, the apex of the angle being posterior. SYN: hump or hunch.

keratinization - kyphosis



-- L --

lab values

Because many institutions have differences for normal ranges of metabolic, laboratory, and hematology values, the CTCAE often uses the terms 'Upper Limit of Normal (ULN)' and 'Lower Limit of Normal (LLN)' in lieu of actual numerical values. In some cases, an institution's LLN might be beyond the range specified for a Grade 1. In this case, the institutional limits of normal should take precedence over the CTCAE values. For example, if an institution's LLN of lymphocytes is 500/mm³, a lymphocyte count of 501 at that institution would be translated to a CTCAE Grade 0; a lymphocyte count of 499 would be translated to a CTCAE Grade 3. Because local laboratory values trump CTCAE v3.0's ranges, some Grade 1 and Grade 2 AEs will not exist for a local lab.

Laryngeal nerve

The laryngeal nerves attach to the voice box, or larynx. Laryngeal nerve damage can be caused by a variety of medical conditions. There are two laryngeal nerves—one on the right and one on the left. These nerves help move the vocal cords, allowing a person to talk. They also help prevent food from going into the windpipe, or trachea. Damage to these nerves usually produces symptoms: hoarseness, inhalation of food or bacteria into the lungs which causes aspiration pneumonia, difficulty breathing, or shortness of breath. Causes of laryngeal nerve damage include: injury, which may occur accidentally during surgery or other medical procedures; strokes; tumors, or growths, that can invade the nerve; infection, resulting in inflammation or destruction of the nerve; enlarged arteries, which may press on the nerve; diseases of the nervous system

laryngectomy

Surgical removal of the larynx, also called the voice box.

laryngismus

Throat tightness.

laryngitis

A weak, hoarse, gravelly voice, dry, sore throat, often fever, dry and nonproductive cough, a tickling in the back of the throat, and difficulty swallowing.

late effects

CTCAE grading is NOT based on duration (acute vs. chronic vs. late vs. permanent) of an AE. The duration of an AE is to be captured by serial evaluations over time. Modern multi-modality management involving the

late effects

interactions of sequential and concurrent modalities makes it increasingly difficult to designate an effect as acute, sub-acute or late. The '90-Day Rule' historically utilized by radiation oncologists is eliminated in CTCAE because the use of predetermined time-based limits for designating acute vs. late in an individual patient is no longer applicable. CTCAE does not address duration or any pre-determined definition of acute vs. late and therefore duration is not an intrinsic part of grading criteria for a given event. Designation of acute vs. late is to be a determination of the investigators upon review and interpretation of aggregate data, serial evaluations that permit investigators to evaluate a change in the severity (grade) as a function of time.

Leak (including anastomotic)

Anastomosis is the surgical connection of separate or severed tubular hollow organs to form a continuous channel, as between two parts of the intestine; a communication between or coalescence of blood vessels; the surgical union of parts and especially hollow tubular parts. Anastomotic leak refers to the escape, entry, or passage of fluid as the result of breakdown of a suture line (e.g., leakage of gastric or intestinal fluid following surgery involving joining stomach and bowel structures.

leukoencephalopathy

Leukoencephalopathy is the destruction of the myelin sheaths which cover nerve fibers. These sheaths, composed of lipoprotein layers, promote the transmission of a neural impulse along an axon. In cancer patients, especially leukemia patients, leukoencephalopathy is a rare side effect, caused by methotrexate and/or radiation. The symptoms of leukoencephalopathy include seizures, mental dysfunction, and ataxia. Leukoencephalopathy, also called multifocal demyelinating disease, is not unique to patients treated with chemotherapy and radiation, but can be associated with AIDS, local injury, ischemia, toxic agents, or metabolic disorders.

Lhermitte sign

A sensation similar to an electrical shock radiating from the back of the head down the spine as the neck is bent forward. Flexing of the neck produces electric shock-like sensations that extend down the spine and shoot into the limbs caused by trauma to the cervical portion of the spinal cord, multiple sclerosis, cervical cord tumor, cervical spondylosis, or even vitamin B12 deficiency.

Life-threatening

lab values - Life-threatening



-- L --

Life-threatening

An AE whose existence or immediate sequelae are associated with an imminent risk of death.

LLN

An abbreviation for Lower Limit of Normal, usually in reference to laboratory values.

LOC

An abbreviation for level of consciousness.

lordosis

A disorder defined by an excessive inward curve of the spine. It differs from the spine's normal curves at the cervical, thoracic, and lumbar regions, which are, to a degree, either kyphotic or lordotic. An abnormal extension deformity; anteroposterior curvature of the spine, generally lumbar with the convexity looking anteriorly. SYN: hollow back or saddle back.

lymphangiosarcoma

A malignant neoplasm derived from vascular tissue (i.e., an angiosarcoma) in which the neoplastic cells originate from the endothelial cells of lymphatic vessels, usually developing in the arm several years after radical mastectomy.

lymphedema

A condition in which excess fluid collects in tissue and causes swelling. It may occur in the arm or leg after lymph vessels or lymph nodes in the underarm or groin are removed or treated with radiation.

lymphorrhea

Lymphorrhea is an escape of lymph on the surface from ruptured, torn, or cut lymphatic vessels. SYN: Lymphorrhagia.

Life-threatening - lymphorrhea



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-- M --

macular

Referring to the macula of the eye, the center of the retina which contains a high concentration of photoreceptor cells which convert light into nerve signals. Because of the high concentration of photoreceptors, we are able to see fine details such as newsprint with the macula. At the very center of the macula is the fovea, the site of our sharpest vision of, relating to, or characterized by a spot or spots. Macular degeneration is a general term used to describe a number of diseases of the retina. Of these diseases, age-related macular degeneration is the most common, primarily affecting people over the age of 60.

madarosis

Loss of the eyelashes or of the hair of the eyebrows. It is not just a cosmetic problem but can be an indicator of something more serious, such as eye trauma, eyelid infections, cancer of the eyelid, or metabolic conditions such as hypothyroidism or pituitary insufficiency.

major organ

Any part of the body exercising an essential and specific function (e.g. the lung for respiration), so that removal of the body part could potentially result in serious health consequences.

maldevelopment

Abnormal growth or development.

mastoiditis

An infection of the mastoid bone of the skull. Mastoiditis is usually a consequence of a middle ear infection (acute otitis media). The infection may spread from the ear to the mastoid bone of the skull. The mastoid bone fills with infected materials and its honeycomb-like bone structure may deteriorate.

MDS

An abbreviation for myelodysplastic syndrome. MDS encompasses a diverse group of bone marrow disorders that share a common clonal defect of stem cells. These disorders are characterized by one or more cytopenias, despite a relatively hypercellular bone marrow. They are referred to as preleukemia because of their tendency to transform into acute myelogenous leukemia (AML). SYN: pre-leukemia or myelodysplastic syndrome.

medical intervention

Actions performed by medical professionals to dull, suppress or completely remove symptoms and/or disease by altering or removing malfunctions. Interventions include surgery, radiation, chemotherapy, stimulants, sedative

medical intervention

and suppressive drugs, dialysis, etc. Refers to more than drugs and may include physical therapy, specialized nursing care or exercise.

megacolon

A condition where the nerves to the large intestine do not work correctly and the colon becomes backed up with feces. The stool becomes larger than normal and also dries out, causing trouble passing stool and severe bloating. A condition of extreme dilation and hypertrophy of the colon.

meningismus

Pain due to irritation of the layers (meninges) surrounding the brain and spinal cord. A condition in which the symptoms simulate meningitis, but in which no actual inflammation of these membranes is present. A state of meningeal irritation with symptoms suggesting meningitis that often occurs at the onset of acute febrile diseases especially in children.

MI

An abbreviation for myocardial infarction, death of an area of the heart muscle, usually as a result of occlusion of a coronary artery. SYN: cardiac infarction, heart attack.

mild

In the CTCAE, the general descriptions of Grade 1 are referred to as 'mild' in type or degree.

MMSE

An abbreviation for Mini-Mental Status Exam, a quick way to evaluate cognitive function. It is often used to screen for dementia or monitor its progression.

moderate

In the CTCAE, the general descriptions of Grade 2 are referred to as 'moderate', being within reasonable limits; not excessive or extreme; medium or average extent.

monotherapy

The use of a single agent to treat a particular disorder or disease.

MUGA

An abbreviation for multiple gated acquisition scan.

multiple AEs

Multiple events may be documented for some AEs. For example

macular - multiple AEs



-- M --

multiple AEs

'Hemorrhage': an ulcer that perforates and bleeds is reported as Ulcer, GI Specify--stomach; Perforation GI Specify-- stomach; Hemorrhage, GI Specify - stomach and then assign the appropriate grade for hemorrhage.

myxedema coma

Myxedema is severe hypothyroidism characterized by firm inelastic edema, dry skin and hair, and loss of mental and physical vigor. Myxedema coma, a rare, life-threatening condition, occurs in the progression of hypothyroidism and can be precipitated by infection, medication, environmental exposure, and other metabolic-related stresses.

multiple AEs - myxedema coma



-- N --

Navigation Note

A Navigation Note indicates the location of an AE term within the CTCAE document. It lists signs/symptoms alphabetically within a CATEGORY and the AE term will appear within the same CATEGORY unless the 'NAVIGATION NOTE' states differently.

neuroconstipation

Neurological disorders that may cause constipation; ileus.

neuropathic pain

Nerves themselves can generate pain, and with neuropathic pain the nerve fibers themselves may be damaged or injured. They then send incorrect signals to other pain centers. Neuropathic pain often seems to have no cause. It responds poorly to standard pain treatment and may get worse instead of better over time. For some people, it can lead to serious disability. An example of neuropathic pain is called "phantom limb syndrome" which occurs when an arm or a leg has been removed because of illness or injury, but the brain still gets pain messages from the nerves that originally carried impulses from the missing limb. These nerves now seem to misfire and cause troubling pain.

neuropathy

A condition of the nervous system that causes numbness, tingling, burning or weakness. It usually begins in the hands or feet, and can be caused by certain anticancer drugs.

non-autologous

Referring to having been derived or transferred from other than a particular individual's own body.

non-essential organ

Any part of the body exercising a specific but non-essential function (e.g., appendix, gallbladder), so that removal of the body part would not result in serious health consequences.

NOS

An abbreviation for not otherwise specified.

NSAIDS

An abbreviation for nonsteroidal anti-inflammatory drugs. A group of drugs that decrease fever, swelling, pain, and redness

nyctalopia

Decreased ability to see in reduced illumination. Occurs in patients with impaired rod function; often associated with a deficiency of vitamin A.

nystagmus

An involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed. It may result in some degree of visual loss.



-- O --

obstipation

Intestinal obstruction; severe constipation.

obtundation

A dulled or reduced level of alertness or consciousness.

oligospermia

A subnormal concentration of spermatozoa in the penile ejaculate.

operative intervention

Any treatment requiring direct physical intervention (e.g., surgery) usually carried out with instruments, but may be performed with the hands as in manipulation of a simple fracture. These interventions are usually performed in an operating room or equivalent setting.

ophthalmologic changes

Visual or anatomical eye abnormalities identified by eye examination.

ophthalmoplegia

Paralysis of one or more of the eye muscles.

oral nutritional supplements

Vitamins, minerals and other substances for oral consumption that provide nutrition.

osteomyelitis

Acute or chronic inflammation of the bone and its structures (marrow and adjacent bone). Osteomyelitis is secondary to infection with pyogenic organisms. The infection associated with osteomyelitis may be localized or it may spread through the periosteum, cortex and marrow.

osteonecrosis

Osteonecrosis is defined as cell death in components of bone (e.g., the marrow fat and mineralized tissue). It represents the final common pathway of several disease entities, which result in impaired blood supply to the bone tissue causing necrosis or death of the bone. Osteonecrosis may also be referred to as aseptic necrosis, bone necrosis, avascular necrosis, bone infarction, or ischemic necrosis.

osteopenia

Decreased calcification or density of bone; a descriptive term applicable to all skeletal systems in which such a condition is noted; reduced bone mass.

osteoporosis

osteoporosis

Osteoporosis is a disease in which bones become fragile and more likely to break. If not prevented or if left untreated, osteoporosis can progress painlessly until a bone breaks. These broken fractures occur typically in the hip, spine, and wrist.

obstipation - osteoporosis



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-- P --

palpebral conjunctival epithelial metaplasia

Abnormal transformation of the eyelid conjunctival tissue.

pancreas, exocrine enzyme deficiency

Three major groups of pancreatic digestive enzymes: (1) proteases [trypsin and chymotrypsin]; (2) lipase [hydrolysis of triglycerides]; (3) amylase [hydrolyses carbohydrates]. The pancreas produces a host of other digestive enzymes, including ribonuclease, deoxyribonuclease, gelatinase and elastase.

papillary formation

A small nipple-like projection, such as a protuberance on the skin, at the root of a hair as part of 'Dermal change lymphedema, phlebolymphe~~ma~~.'

papular

Small solid usually conical elevation of the skin caused by inflammation, accumulated secretion, or hypertrophy of tissue elements.

parenteral

By some other means than through the gastrointestinal tract; referring particularly to the introduction of substances by intravenous, subcutaneous, intramuscular, or intramedullary injection.

parenteral nutrition

The administering of nutrients for assimilation and utilization by a patient who cannot maintain adequate nutrition by enteral feeding alone. Nutrients are administered by a route other than the alimentary canal (e.g., intravenously).

pathologic finding

Abnormal finding related to disease or abnormal structural or functional changes.

PD

An abbreviation for progressive disease.

PE

An abbreviation for pulmonary embolus.

periodontal

Referring to around a tooth and/or gums.

peritoneal signs

Signs detected on physical examination of the abdomen (e.g., guarding, rebound tenderness) that may indicate irritation of the peritoneum and the possible need for surgical evaluation and/or treatment.

persistent

Existing or continuing for a long time. However, in CTCAE, 'persistent' generally refers to >24 hours, not to chronicity or duration of adverse events.

phantom limb pain

An example of neuropathic pain called "phantom limb syndrome" which occurs when an arm or a leg has been removed because of illness or injury, but the brain still gets pain messages from the nerves that originally carried impulses from the missing limb. These nerves now seem to misfire and cause troubling pain. The sensation of pain or other unpleasant feelings in the place of a missing (phantom) limb.

phlebolympathic cording

Irregularly firm, non-compressable blood or lymphatic vessels.

phlebolymphe~~ma~~

Fluid retention in tissues as a consequence of irregularities in blood or lymphatic vessels.

photophobia

A condition in which the eyes are more sensitive to light than normal.

phrenic nerve dysfunction

The diaphragm receives its sole muscular neurologic impulse from the phrenic nerve. Injury or damage to the phrenic nerve may cause diaphragmatic dysfunction which may induce atelectasis, dyspnea, and the need for prolonged mechanical ventilation.

physiologic consequences

Results related to the functioning of the body (i.e., the physical and chemical processes of cells, tissues, organs, and systems, including their interactions).

PJC

An abbreviation for Premature Junctional Contraction.

pleurodesis

A surgical procedure that causes the membranes around the lung to stick together and prevent the buildup of fluid in the space between the membranes. The production of adhesions between the parietal and visceral pleura. The procedure is used in the treatment of bronchopleural fistulas, malignant pleural effusions, and pneumothorax and often involves instillation of chemicals or other agents into the pleural space causing, in effect, a pleuritis that seals the space.

palpebral conjunctival epithelial metaplasia - plexopath



-- P --

plexopathy

Damage to a nerve or network of nerves that results in dysfunction in the affected area (e.g., decrease in movement or sensation).

plication

The tightening of stretched or weakened bodily tissues or channels by folding the excess in tucks and suturing (plication of the neck of the bladder). The folding of one part on and the fastening of it to another (as areas of the bowel freed from adhesions and left without normal serosal covering. A folding or putting together in pleats; an operation for reducing the size of a hollow viscus by taking folds or tucks in its walls.

PNC

An abbreviation for Premature Nodal Contraction.

pollakiuria

Frequency of urination or micturition at short intervals. It may result from increased urine formation, decreased bladder capacity, or lower urinary tract irritation.

post-infectious neuralgia

Following an infection, an acute paroxysmal pain radiating along the course of one or more nerves usually without demonstrable changes in the nerve structure.

pRBC

An abbreviation for packed Red Blood Cells.

proctalgia

Rectal pain.

pruritus

Itching.

pseudomembranes

Inflammation of mucous membranes due to radiation injury resulting in the formation of a thick exudate (i.e., pseudomembrane) covering the surface of the mucous membranes.

PT

An abbreviation for Prothrombin Time.

PTT

An abbreviation for Partial Thromboplastin Time. The time needed for plasma

PTT

to form a fibrin clot following the addition of calcium and a phospholipid reagent; used to evaluate the intrinsic clotting system.

PVCs

An abbreviation for Premature Ventricular Contractions.

pyramidal tract dysfunction

Nerve fibers which originate in the cerebral cortex, pass through the medullary pyramid, and terminate in the motor brain stem and spinal cord mediate direct cortical control and initiation of skilled movements. Symptoms include dysarthria, weakness, spasticity, gait abnormalities, and generalized hyper-reflexia.

plexopathy - pyramidal tract dysfunction



-- R --

radiculitis

Inflammation or irritation of the root of a spinal nerve. Radiculitis is characterized by pain that seems to radiate from the spine to extend outward to cause symptoms away from the source of the spinal nerve root irritation. The term radiculitis is used when symptoms demonstrate nerve root irritation but x-rays and other radiology examinations show no abnormalities. (Note: Radiculopathy is radiculitis caused by the nerve root being compressed by a compressed vertebral disk or arthritis).

radiographic findings

Results of imaging techniques used in clinical practice including x-rays, ultrasound, computed tomography, magnetic resonance, radionuclide scanning, thermography, etc.

RAEB

An abbreviation for Refractory Anemia with Excess Blasts.

receptive dysphasia

A language disorder involving difficulty processing spoken language, or difficulty expressing oneself orally. Many people with dyslexia also have some type of dysphasia. People with receptive dysphasia have difficulty distinguishing sounds that follow each other rapidly. People with receptive dysphasia need more time between sounds in order to comprehend them. Sensory aphasia is when there is impairment in the comprehension of spoken and written words, associated with effortless, articulated, but paraphrastic, speech and writing; malformed words, substitute words, and enologisms are characteristic. When severe, and speech is incomprehensible, it is called jargon aphasia. The patient often appears unaware of his deficit. SYN: fluent aphasia, impressive aphasia, posterior aphasia, psychosensory aphasia, receptive aphasia, Wernicke's aphasia.

REMARK

A 'REMARK' in CTCAE is a clarification of an AE.

Retinoic acid syndrome

Retinoic acid syndrome is the major adverse effect of tretinoin and it occurs in about 25% of treated APL patients in the absence of prophylactic measures and is often fatal. Generally, the retinoic acid syndrome is associated with increasing leucocyte counts and is probably caused by the release of several cytokines by maturing blast cells. The retinoic acid syndrome gives a clinical picture of bodyweight gain, respiratory distress, serous effusions and cardiac and renal failure.

rhegmatogenous

Derived from the Greek word rhegma, which means a discontinuity or a break. A rhegmatogenous retinal detachment occurs when a tear in the retina leads to fluid accumulation with a separation of the neurosensory retina from the underlying retina. This is the most common type of retinal detachment.

ROM

An abbreviation for range of motion.

RTA

An abbreviation for renal tubular acidosis.

radiculitis - RTA



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-- S --

SAS

An abbreviation for subarachnoid space, the space between the arachnoidea and pia mater, traversed by delicate fibrous trabeculae and filled with cerebrospinal fluid. Since the pia mater immediately adheres to the surface of the brain and spinal cord, the space is greatly widened wherever the brain surface exhibits a deep depression (for example, between the cerebellum and medulla). The large blood vessels supplying the brain and spinal cord lie in the subarachnoid space.

scleral melt

Loss of structural integrity of the scleral membrane of the eye.

scleral necrosis

Lack of blood supply or death of the sclera, commonly known as "the white of the eye" (the tough, opaque tissue that serves as the eye's protective outer coat).

sclerosis

A pathological condition in which a tissue has become hard and which is produced by overgrowth of fibrous tissue and other changes (as in arteriosclerosis) or by increase in interstitial tissue and other changes (as in multiple sclerosis). SYN: hardening.

scoliosis

Abnormal lateral curvature of the vertebral column. Depending on the etiology, there may be one curve, or primary and secondary compensatory curves; scoliosis may be "fixed" as a result of muscle and/or bone deformity or "mobile" as a result of unequal muscle contraction.

SD

An abbreviation for standard deviation.

Second Malignancy

The occurrence of a cancer that follows a previously treated malignant neoplasm but is not considered a metastasis of the initial neoplasm. This second malignancy may have the same or different histological type and can occur in the same or different organs as the previous neoplasm but in all cases arises from an independent oncogenic event. The development of the second neoplasm may or may not be related to the treatment for the previous neoplasm since genetic risk or predisposing factors may actually be the cause.

septic shock

septic shock

A life-threatening severe form of sepsis that usually results from the presence of gram-negative bacteria and their toxins in the bloodstream. It is characterized by decreased blood flow to organs and tissues, hypotension, organ dysfunction (as of the heart, kidneys, or lungs), impaired mental state, and often multiple organ failure.

sequelae

Symptoms and conditions which are the result of treatment.

serologic

Referring to the watery portion of an animal fluid remaining after coagulation; the clear yellowish fluid that remains from blood plasma after fibrinogen, prothrombin, and other clotting factors have been removed by clot formation. SYN: blood serum.

seroma

A fluid accumulation of serum within a tissue or organ.

severe

In the CTCAE, the general descriptions of Grade 3 are referred to as 'severe.'

SF

An abbreviation for shortening fraction.

SGOT

An abbreviation for serum glutamate oxaloacetate transaminase. SYN: AST.

SGPT

An abbreviation for serum glutamate pyruvate transaminase. SYN: ALT.

SIADH

An abbreviation for Syndrome of Inappropriate Anti-Diuretic Hormone.

sicca

Keratoconjunctivitis associated with decreased tears. SYN: dry eye syndrome.

standard deviation

Statistical index of the degree of deviation from central tendency, namely, of the variability within a distribution; the square root of the average of the squared deviations from the mean. A measure of dispersion or variation used to describe a characteristic of a frequency distribution.

SAS - Stevens-Johnson Syndrome



-- S --

Stevens-Johnson Syndrome

Recurrent or severe form of Erythema Multiforme. SYN: Toxic Epidermal Necrolysis, TEN, Lyell's Syndrome, Epidermolysis.

stop dates

Routine AE reporting associates AEs with the course or cycle of intervention. Serious and unexpected AEs are reported via AdEERS and the primary AE is associated with the date of onset. When resolution dates are important, document duration by serial assessments (e.g., Day 5 [Gr 4]; Day 10 [Gr 3], etc.). Interval assessments presuppose there is a stop date. When investigators are interested in consistently capturing duration of AEs, the protocol is to prospectively state specified intervals for AE assessment.

stricture/stenosis (including anastomotic)

An abnormal narrowing of a bodily passage (as from inflammation, cancer, or the formation of scar tissue).

stupor

A condition of greatly dulled or completely suspended sense or sensibility. A chiefly mental condition marked by absence of spontaneous movement, greatly diminished responsiveness to stimulation, and usually impaired consciousness.

Supra-ordinate

In CTCAE, a grouping term that provides a single set of grading criteria for related adverse events.

SVC

An abbreviation for Superior Vena Cava.

SVT

An abbreviation for supraventricular tachycardia.

symblepharon

Adhesion of one or both eyelids to the eyeball, partial or complete, resulting from burns or other trauma but rarely congenital.

syncope

Loss of consciousness and postural tone caused by diminished cerebral blood flow. SYN: Fainting.



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t-score

The result of a Bone Mineral Density Test (BMD), to determine thickness or density of bones; a test for osteoporosis.

Tanner Stage

A stage of puberty in the Tanner growth chart, based on pubic hair growth, development of genitalia in boys, and breast development in girls.

telangiectasia

The permanent enlargement of blood vessels, causing redness in the skin or mucous membranes.

tension pneumothorax

A variety of spontaneous pneumothorax in which air enters the pleural cavity and is trapped during expiration; intrathoracic pressure builds to values higher than atmospheric pressure, compresses the lung, and may displace the mediastinum and its structures toward the opposite side, with consequent disadvantageous effects on blood flow. A tension pneumothorax is a potentially life-threatening condition which can lead to dangerously low oxygen levels, shock, or death.

thombolysis

The breaking up of a blood clot.

thoracentesis

Removal of fluid from the pleural cavity through a needle inserted between the ribs.

thoracotomy sealant

A material (e.g., fibrin sealant or glue) used to effect an airtight closure to prevent or seal an airleak after thoracotomy.

threshold shift

Measurement of the degree of hearing loss or impairment in terms of a decibel shift from an individual's previous audiogram.

thyroid storm

Excessive functional activity of the thyroid gland resulting in increased metabolic rate, enlargement of the thyroid gland, rapid heart rate, and high blood pressure. Thyroid storm is a life threatening, abrupt exacerbation of hyperthyroidism caused by the sudden excessive release of thyroid gland hormones into the circulation.

-- T --

TIA

Abbreviation for transient ischemic attack, a sudden focal loss of neurological function with complete recovery usually within 24 hours; caused by a brief period of inadequate perfusion in a portion of the territory of the carotid or vertebral basilar arteries.

tinnitus

Noises (ringing, whistling, booming, etc.) in the ears.

TMJ

An abbreviation for temporomandibular joint.

Torsade de pointes

A ventricular tachycardia characterized by periodic twisting of the points of the QRS complexes and rates between 200 and 250 beats per minute. It may be self-limited or may progress to ventricular fibrillation.

torticollis

A contraction, often spasmodic, of the muscles of the neck, chiefly those supplied by the spinal accessory nerve; the head is drawn to one side and usually rotated so that the chin points to the other side.

toxic epidermal necrolysis

(TEN) is a severe mucocutaneous exfoliative disease with an uncertain pathogenesis and a high mortality rate. It can usually be distinguished from the morphologically similar, but more benign, staphylococcal scalded skin syndrome (SSSS) according to historical and epidemiologic factors. The primary manifestation of TEN is the appearance of an erythematous confluent morbilliform eruption that rapidly evolves into exfoliation of the skin at the dermal-epidermal junction, resulting in large sheets of necrotic epidermis and the underlying shiny, denuded dermal surface. This process seems to be immune-complex mediated.

TPN

An abbreviation for total parenteral nutrition, nutrition maintained entirely by intravenous injection or other non-gastrointestinal route.

transaminases

A subclass of enzymes of the transferase class that catalyze the transfer of an amino group from a donor (generally an amino acid) to an acceptor (generally a 2-keto acid). Most of these enzymes are pyridoxyl phosphate proteins.

transient

Short-lived; passing. In CTCAE, transient generally refers to <24 hours.

t-score - tresis



-- T --

tresis

Abnormal opening in a hollow organ or viscus.

trichiasis

A condition in which the hair adjacent to a natural orifice turns inward and causes irritation; e.g., in inversion of an eyelid (entropion), eyelashes irritate the eye. SYN: trichoma, trichomatosis.

trismus

Persistent contraction of the masseter muscles due to failure of central inhibition; often the initial manifestation of generalized tetanus. SYN: ankylostoma, lockjaw.

TSH

An abbreviation for thyroid stimulating hormone.

TTP

An abbreviation for thrombotic thrombocytopenic purpura.

tumor flare

A gradual tapering or spreading outward. A diffuse redness of the skin extending beyond the local reaction to the application of an irritant; it is due to dilation of the arterioles and capillaries; depends upon an axon reflex set up by the liberation of a histamine-like substance in skin when injured. SYN: triple response.

TURP

An abbreviation for transurethral resection of the prostate. Surgical procedure to remove tissue from the prostate using an instrument inserted through the urethra.

typhlitis

Inflammation of and/or necrosis of the cecum, appendix, and/or ileum. Typhlitis has been associated with aplastic anemia, lymphoma, AIDS, and immunosuppression following renal transplantation or during treatment of malignancy. The etiology of typhlitis is unknown, but its pathogenesis is multifactorial. Profound neutropenia, with total neutrophil counts of less than 1000/mm³, appears to be a universal predisposing factor. Mucosal injury from cytotoxic drugs plays an important role in the typhlitis observed during chemotherapy. SYN: Neutropenic Enterocolitis.

tresis - typhlitis



-- U --

ULN

An abbreviation for upper limits of normal, generally referred to in laboratory values.

uveitis

Intraocular inflammation of the uveal tract: iris, ciliary body, and choroids, and also comprises a large group of diverse diseases affecting not only the uvea but also the retina, optic nerve and vitreous.

ULN - uveitis



-- V --

valgus

Bent or twisted outward away from the midline or body; modern accepted usage, particularly in orthopedics, erroneously transposes the meaning of varus to valgus, as in genu valgum (knock-knee).

validity

CTCAE is not a medically validated tool. The evolution of the dictionary reflects compilation of adverse events commonly reported on oncology clinical trials and analysis of multiple, large adverse event databases. CTCAE grades are a composition of general consensus regarding acceptable and unacceptable severity.

varus

Bent or twisted inward toward the midline of the limb or body; modern accepted usage, particularly in orthopedics, erroneously transposes the meaning of valgus to varus, as in genu varum (bowleg).

vasculitis

Inflammation of a blood vessel.

venous stasis

Congestion and slowing of circulation in veins due to blockage by either obstruction or high pressure in the venous system, usually best seen in the feet and legs.

ventilatory support

Respiration assisted either manually or by a machine.

ventriculostomy

Establishment of an opening in a ventricle, usually from the third ventricle to the subarachnoid space to relieve hydrocephalus.

vesicular

A small (less than 0.5 cm) circumscribed elevation of the skin containing fluid. A bleb, blister, bulla. A small sac containing liquid or gas.

visual acuity

Acuteness or clearness of vision, especially of form vision, which is dependent mainly on the sharpness of the retinal focus.

visual field

The area simultaneously visible to one eye without movement; often measured by means of a bowl perimeter located 330 mm from the eye.

VOD

An abbreviation for Veno-Occlusive Disease.



-- W --

WBC

An abbreviation for white blood cell.

WNL

An abbreviation for within normal limits, generally referred to in laboratory values.

WPW

An abbreviation for Wolff-Parkinson-White Syndrome.

WBC - WPW



-- X --

xerostomia

Dry mouth; it occurs when the body is not able to make enough saliva.

xerostomia - xerostomia