
GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this document. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“5-FU”	5-Fluorouracil, an antimetabolite chemotherapy agent that interferes with DNA synthesis
“ACS”	acute coronary syndrome, a group of heart conditions resulting from the sudden reduction of blood flow to the heart, which leads to shortness of breath and sudden chest pain
“ADR”	adverse drug reaction, unintended, harmful events attributed to the use of medicines
“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrence in a patient or subject receiving a drug or other pharmaceutical product in a clinical trial and which does not necessarily have a causal relationship with the treatment
“ALI”	acute lung injury, a clinical syndrome characterized by acute hypoxemic respiratory failure due to diffuse lung injury, commonly associated with conditions such as sepsis, pneumonia, trauma, or drug toxicity. It represents a less severe form of acute respiratory distress syndrome (ARDS)
“AML”	acute myeloid leukemia, a serious acute condition with poor prognosis
“ANDA”	Abbreviated New Drug Application, application for the approval of a generic version of an already approved brand-name drug
“API”	active pharmaceutical ingredient, the biologically active component in a pharmaceutical drug that produces the intended therapeutic effect
“ARDS”	acute respiratory distress syndrome, a life-threatening lung condition that occurs when fluid builds up in the alveoli (air sacs) of the lungs, preventing adequate oxygen from reaching the bloodstream. It is characterized by rapid onset of widespread inflammation in the lungs
“AUC”	area under the curve, a pharmacokinetic parameter that measures the body’s exposure to a drug, i.e., how much of the drug reaches a person’s bloodstream over a given period of time after a dose is administered
“avanafil”	a selective phosphodiesterase type 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction in adult men
“BPH”	benign prostatic hyperplasia, a non-cancerous enlargement of the prostate gland that commonly affects men as they age, potentially causing urinary symptoms

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“bronchiectasis”	a chronic respiratory condition characterized by abnormal widening and scarring of the airways, leading to persistent cough and recurrent infections
“CAGR”	compound annual growth rate
“cAMP”	cyclic adenosine monophosphate, a key intracellular signaling molecule that regulates various cellular processes
“CAP”	community-acquired pneumonia, an acute lung infection contracted outside healthcare settings
“CDMO”	contract development and manufacturing organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of development and manufacturing services outsourced on a contract basis
“C _{max} ”	the maximum observed concentration of a drug
“CMC”	chemistry, manufacturing and controls, also commonly referred to as process development, which covers the comprehensive documentation and processes that define the chemical composition, manufacturing procedures, and quality control measures for pharmaceutical products. CMC encompasses the development, scale-up, and validation of manufacturing methods to ensure consistent product quality and compliance with regulatory standards
“CMML”	chronic myelomonocytic leukemia
“CNS”	central nervous system, comprises the brain and spinal cord
“COPD”	chronic obstructive pulmonary disease, a chronic inflammatory lung disease that causes obstructed airflow from the lungs, with symptoms including breathing difficulty, cough and mucus production
“mCRC”	metastatic colorectal cancer, a type of cancer arising from the colon or rectum that has spread to other parts of the body
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CRS”	chronic rhinosinusitis, inflammation of the nasal cavity and sinuses lasting 12 weeks or longer
“CRSsNP”	chronic rhinosinusitis without nasal polyps

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“CTCAE Grade”	the standardized classification of the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE), developed by the U.S. National Cancer Institute (NCI). The CTCAE provides a grading scale from Grade 1 (mild) to Grade 5 (death related to AE) to ensure consistent assessment, documentation, and reporting of treatment-related toxicities across studies
“dienogest”	a synthetic progestin used primarily for the treatment of endometriosis
“DPNP”	diabetic peripheral neuropathic pain, nerve pain in the extremities caused by diabetes-related nerve damage
“DPP1”	dipeptidyl-peptidase 1, an enzyme involved in the activation of neutrophil serine proteases
“DVT”	deep vein thrombosis, a blood clot that forms in a deep vein
“endometriosis”	a condition where tissue similar to the uterine lining grows outside the uterus, causing pain and other symptoms
“GMP”	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards
“HYP”	hydroxyproline, an amino acid that is a major component of collagen and serves as a biomarker for collagen metabolism
“IBD”	a group of chronic, immune-mediated inflammatory conditions of the gastrointestinal tract, primarily including ulcerative colitis and Crohn’s disease
“IC ₅₀ ”	concentration at half maximal inhibition, a measure of the potency of a substance in inhibiting a specific biological or biochemical function
“IL-6”	interleukin-6, a pro-inflammatory cytokine that plays a key role in immune responses and inflammation
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“innovative drug”	Category 1 innovative drug or Category 2 modified new drug as classified by the NMPA in China, unless the context otherwise requires, and comparable designations in other jurisdictions
“inflammation”	a protective biological response of the body’s immune system to harmful stimuli such as infection, injury, or irritants, aimed at eliminating the cause and initiating tissue repair
“ <i>in vitro</i> ”	Latin for “within the glass”, studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules

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“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done <i>in vitro</i>
“levofolinic acid”	the biologically active L-isomer of folinic acid and an essential reduced form of folate. It plays critical roles in DNA synthesis and repair through its involvement in purine and pyrimidine nucleotide production as well as amino acid metabolism
“MAD”	multiple ascending dose, a clinical trial design in which drug doses are gradually increased to determine the tolerability and optimal dose of the study drug after multiple dosing
“Nav1.8”	voltage-gated sodium channel 1.8, a sodium channel protein primarily found in pain-sensing neurons
“nebulizer”	a medical device that converts liquid medication into a fine mist for inhalation therapy
“neutrophil elastase”	an enzyme released by neutrophils that plays a role in inflammation and tissue damage
“PALI”	postoperative acute lung injury, a severe respiratory condition that occurs following major surgical procedures
“PDE4B”	phosphodiesterase 4B, an enzyme belonging to the PDE4 family. It specifically hydrolyzes cAMP into its inactive form, thereby regulating intracellular levels of cAMP. PDE4B is expressed in various tissues, particularly in immune cells and the central nervous system, and plays an important role in modulating inflammatory responses, immune cell activity, and certain neurological processes. Dysregulation of PDE4B has been associated with inflammatory diseases, psychiatric disorders, and some cancers, making it a target for therapeutic intervention
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“pharmacodynamics” or “PD”	the study of a drug’s molecular, biochemical, and physiologic effects or actions
“pharmacokinetics” or “PK”	a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body
“Phase I clinical trial”	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness

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“Phase II clinical trial”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance and optimal dosage
“Phase III clinical trial”	a study in which a drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the product’s labeling
“pneumonia”	inflammation of the lung tissue, particularly the alveoli and surrounding tissues, usually caused by an infection from bacteria, viruses, fungi, or other microorganisms
“postoperative acute pain”	pain experienced immediately following surgical procedures
“PTE”	pulmonary thromboembolism, a blockage in one of the pulmonary arteries in the lung by a blood clot
“QT/QTc interval”	a measurement on an electrocardiogram that represents the time between ventricular depolarization and repolarization
“rivaroxaban”	a factor Xa inhibitor for the treatment and prevention of deep vein thrombosis and pulmonary thromboembolism in adults
“SAD”	single ascending dose, a study design in which single doses of a drug are gradually increased to evaluate safety and tolerability
“SAEs”	serious adverse events, adverse events occurring during clinical drug use that pose a significant threat to the patient’s health or life, including those leading to death, life-threatening conditions, the need for hospitalization or prolonged hospitalization, permanent or severe disability/loss of function, or congenital abnormalities/birth defects
“sepsis”	life-threatening organ dysfunction from dysregulated immune response to infection
“silodosin”	an alpha-1 adrenergic receptor antagonist used to treat benign prostatic hyperplasia
“sivelestat sodium”	a neutrophil elastase inhibitor used for the treatment of ARDS
“SIRS”	systemic inflammatory response syndrome, a widespread inflammatory response to various clinical insults
“ticagrelor”	an oral antiplatelet medication used to prevent cardiovascular events

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“ $T_{\max}$ ”	the time taken to reach the maximum plasma concentration ($C_{\max}$) of a drug following administration
“TNF- α ”	tumor necrosis factor alpha, a pro-inflammatory cytokine released by immune cells that can induce tumor cell death, regulate immune responses, and stimulate inflammation
“VTE”	venous thromboembolism, a condition that occurs when a blood clot forms in a vein