Healthcare Glossary of Terms

Summit therapeutics

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Term	Definition
Accelerated Approval	Accelerated approval regulations in the US allow drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint. Using a surrogate endpoint enabled the FDA to approve these drugs faster [1]
Added Clinical Benefit	A positive additional effect of a therapeutic intervention compared to other therapies (e.g. prolongation of life, reduction in pain, improvement in function, increased sense of well-being) [2]
Adjuvant Therapy	Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back [3]
Adverse Event (AE)	An adverse event is any undesirable experience associated with the use of a medical / investigational product in a patient [4]
Breakthrough Therapy Designation	Breakthrough Therapy designation is a process by the FDA designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s) [5]
Class	A set of medications and other compounds that have similar chemical structures, the same mechanism of action (i.e., binding to the same biological target), a related mode of action, and / or are used to treat the same disease [6]
Clinical Trial	Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments [7]
Cohort Study	A research study that compares a particular outcome (for example lung cancer) in groups of individuals who are alike in many ways but differ by a certain characteristic (for example, female nurses who smoke compared with those who do not smoke) [8]
Consent Form	A document with important information about a medical procedure or treatment, a clinical trial, or genetic testing. It also includes information on possible risks and benefits. If a person chooses to take part in the treatment, procedure, trial, or testing, he or she signs the form to give official consent [9]
Diagnostic Test	A type of test used to help diagnose a disease or condition [10]
Eligibility Criteria	In clinical trials, requirements that must be met for a person to be included in a trial. These requirements help make sure that participants in a trial are like each other in terms of specific factors such as age, type and stage of cancer, general health, and previous treatment. When all participants meet the same eligibility criteria, it is more likely that results of the study are caused by the intervention being tested and not by other factors or by chance [11]
European Medicines Agency (EMA)	The European Medicines Agency facilitates development, access and supervision of medicines for human and animal usage across the European Union [12]

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European Society for Medical Oncology (ESMO)	The European Society for Medical Oncology is a leading professional organisation for medical oncology. With more than 25,000 members representing oncology professionals from over 160 countries worldwide, ESMO was founded in 1975 [13]
Fast Track Designation	Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions [14]
First-in-Class	An indicator of a drugs potential for strong positive impact on the health of patients. These drugs often have mechanisms of action different from those of existing therapies [15]
First-line Therapy	The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation [16]
Guidelines	Information intended to advise people on how something should be done or what something should be[17]
Informed Consent	A process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment, genetic testing, or a clinical trial. This is to help them decide if they want to be treated, tested, or take part in the clinical trial [18]
Mechanism of Action	How a drug or other substance produces an effect in the body. A drug's mechanism of action could be how it affects a specific target in a cell, such as an enzyme, or a cell function, such as cell growth. Knowing the mechanism of action of a drug may help provide information about the safety of the drug and how it affects the body. It may also help identify which patients are most likely to respond to treatment [19]
Observational Study	Researcher observes study participants and records the effects of the treatment. Observational studies tend to be less involved for participants, who might need to complete questionnaires [20]
Orphan Drug	A drug used to treat, prevent, or diagnose an orphan disease. An orphan disease is a rare disease or condition that affects fewer than 200,000 people in the United States. Orphan diseases are often serious or life threatening [21]
Second-line Therapy	Treatment that is given when initial treatment (first-line therapy) doesn't work or stops working [22]
Standard of Care (SOC)	Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy [23]
Unmet Need	Unmet need for healthcare can be seen as covering a spectrum of healthcare needs that are not optimally met [24]
U.S. Food and Drug Administration (FDA)	The Food and Drug Administration is a U.S. federal agency in the Department of Health and Human Services that is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices [25]

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