

Glossary of Terms

A glossary of terms that may be used in gastro-intestinal clinical trials research.

A.

Aberrant – Deviating from normal

Ablation, hormonal – In cancer, various techniques to reduce the level of hormones in the blood to as low as possible.

Adenocarcinoma – A cancerous growth arising from a subtype of epithelial cells known as glandular epithelium.

Adjuvant therapy – Therapy given to augment or simulate some other form of treatment such as surgery or radiation therapy. It can be administered before or after the primary treatment.

Agranulocytosis – Disorder involving a severe acute deficiency in certain blood cells – neutrophils – as a result of damage to the bone marrow by toxic drugs or chemicals; characterized by fever, ulceration of mouth and throat, and sudden death.

Agonist – This refers to a characteristic of some types of drug, which means they act by triggering the normal activity of specific cells in the body.

Allele – Variant forms of the same gene. Different alleles produce variations in inherited characteristics, such as eye colour or blood type.

Alopecia – Baldness.

Amino acid – The building blocks that make up proteins. There are 20 different amino acids; the body can create 11, and 9 must be obtained through the diet. These nine are known as essential amino acids.

Amplification – An increase in the number of copies of a specific DNA fragment; can occur either *in vivo* or *in vitro*.

Anemia – Reduction of the quality of the oxygen carrying pigment, hemoglobin, in the blood; systems include shortness of breath after exertion, fatigue, tiredness, pallor, poor resistance to infection.

Aneuploid – The characteristic of having either fewer or greater than the normal number of chromosomes in a cell. Usually this indicates an abnormal cell.

Angiogenesis – The development of new blood vessels.

Antagonist – A drug that binds to a cellular receptor without producing any physiological effects and that blocks the binding by any other substance to that receptor.

Antibody – Immunoglobulin molecule that has a specific amino acid sequence that causes it to interact only with the antigen that induced its synthesis or with an antigen closely related to it in an immune response. Antibodies are classified according to their mode of action as agglutinins, bacteriolysins, hemolysins, opsonins, precipitins, etc.

Antibody specificity – The property of antibodies, which enables them to react with some antigenic determinants and not with others.

Antigen – Any substance capable of inducing a specific immune response, and of reacting with the products of that response. They may be foreign proteins, toxins, bacteria, or viruses.

Antineoplastic – Literally, against neoplasm, which is any new or abnormal growth or any benign or malignant tumour, chemotherapy is therefore antineoplastic by definition, since it is targeted to destroy tumour cells.

Antisense – The strand of double-stranded DNA that is complementary to the sense strand.

Apoptosis – One of the two mechanisms by which cell death occurs. This is characterized by cell shrinkage, DNA condensation, and DNA degradation.

Arm – Any of the treatment groups in a randomized trial. Most randomized trials have two “arm”, but some three “arm”, or even more.

Assay – The determination of the amount, purity, or potency of a substance.

Atypia – Used to describe cells with have lost their normal appearance but are not as abnormal as cancer cells.

Autosome – Any ordinary paired chromosome, as distinguished from a sex chromosome. Human cells contain 22 pairs of autosomes.

B.

Bacteriophage – A virus that lyses (destroys) bacteria.

Base pairs – The two complementary, nitrogen-rich molecules held together to form double-stranded DNA. Two strands of DNA are held together in the shape of a double helix by the bonds between their base pairs.

Basement membrane – A thin, delicate membrane lying at the base of an epithelium; composed of protein fibres.

Bias – Any deviation of results or inferences from the truth, or processes leading to such deviation.

Bioassay – Quantitative determination of the potency of a substance through the measurement of its effects on tissue, cells, living experimental animals, or humans.

Biobank – A repository of tissue and blood samples that can be used for genetic research.

Biomarker – A cellular or molecular indicator of exposure, health effects, or susceptibility.

Biopsy – Removal of a small piece of living tissue from an organ or body part for microscopic examination; important means of diagnosing cancer by examining a fragment of tumour.

Blinded study – A research study in which the subject and/or observers are not told to which experimental group subjects are assigned. When subjects and observers are not informed, the study is considered double-blinded/masked. When study analysts or statisticians are unaware of group assignments, the study is considered triple-blinded/masked. Also know as masked study.

Blood count – A laboratory test to measure the number of red blood cells (RBC's), white blood cells (WBC) and platelets (Plts) in a blood sample.

B-Lymphocytes – B cells, the cells primarily responsible for humoral immunity, the precursors of antibody-producing cells (plasma cells).

Bone marrow – The soft tissue filling the cavities of bones. Bone marrow exists in two types, yellow and red. Yellow marrow is found in the large cavities of large bones and consists mostly of fat cells and a few primitive blood cells. Red marrow is a hemopoietic tissue and is the site of production of erythrocytes (red blood cells) and granular leukocytes. Bone marrow is made-up of a framework of connective tissue containing branching fibres, with the frame being filled with marrow cells.

C.

CD3, CD4, and CD8 – Three of a number of lymphocytes surface proteins (markers) that promote the activities of T cells.

Carcinogen – Any substance that can initiate or promote the development of cancer.

Carcinoma – A malignant new growth made up of epithelial cells tending to infiltrate the surrounding tissues and give rise to metastases.

Carcinoma *in situ* – A neoplastic entity wherein the tumour cells are confined to the epithelium of origin, without invasion of the basement membrane.

Case-control study – A type of epidemiologic study that compares persons with a disease to persons without the same disease on the basis of their past exposure to a suspected risk factor. Cases and controls are matched to resemble each other in

sex and age. Same as a retrospective study.

Cell – Small, watery membrane-bound compartment filled with chemicals; the basic unit of any living organism.

Cell line – Cells from a person or animal that can be grown in a culture dish (in vitro). These cells can be either normal or cancerous.

Cellular – Related to or consisting of cells.

Chemical base – An essential building block. DNA contains four complementary bases – adenine paired with thymine and cytosine paired with guanine. In RNA, thymine is replaced by uracil.

Chemokines – Class of pro-inflammatory cytokines that have the ability to attract and activate leukocytes.

Chemotherapy – Drug treatment to kill cancer cells. Chemotherapy may be taken by mouth, or it may be put into the body by a needle into a vein, artery, or muscle.

Chimera – An organism composed of two genetically distinct types of cells.

Chromatid – Single chromosome containing only one DNA duplex. Two daughter chromatids become visible at mitotic metaphase, though they are present throughout G₂.

Chromatin – Early stainable DNA attached to a protein in the cell nucleus – the carrier of genes in inheritance.

Chromosomes – A structure in the nucleus containing a linear thread of DNA, which transmits genetic information and is associated with RNA and histones; during cell division. Each organism of a species normally has a characteristic number of chromosomes in its somatic cells, 46 being the number normally present in man, including the two (XX or XY) that determine the sex of the organism.

Clinical trial – A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether a new drug or treatment is both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

Clone – A group of identical genes, cells, or organisms derived from a single ancestor.

Cloning – The process of making genetically identical copies.

Cohort – In epidemiology, a group of individuals with some characteristics in common.

Cohort studies – Prospective investigation of the factors that might cause a disorder in which a cohort of individuals, who do not have evidence of but who are exposed to the putative cause, are compared with a concurrent cohort who are also free of the disorder but not exposed to the putative cause. They are then followed to compare the incidence of the outcome of interest. Also called longitudinal and prospective study.

Combination chemotherapy – Use of two or more chemicals to achieve maximum damage to tumour cells.

Combined modality treatment – The integration of two or more forms of treatment to combat the cancer. For example: radiation and surgery; radiation and chemotherapy; surgery, radiation and chemotherapy.

Complementary DNA (cDNA) – DNA synthesized through viral reverse transcriptase that is complementary to RNA.

Control group – The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Core biopsy – Removal of a piece of a tumour or lump. The piece is then sent to the laboratory to determine if the tumour is benign or malignant.

Cycle – Chemotherapy is usually administered at regular intervals. A cycle is a course of chemotherapy followed by a period in which the body recovers.

Cyclin – Proteins (A & B forms known) whose levels in a cell varies markedly during the cell cycle, rising until mitosis, then falling abruptly to zero.

Cytokines – Nonantibody proteins secreted by inflammatory leukocytes and some nonleukocytic cells that act as intercellular mediators. Not really different from hormones, but the term tends to be used as a convenient generic shorthand for interleukins, lymphokines and several related signaling molecules such as TNF and interferons.

Cytokinesis – Process in which cytoplasm of a cell is divided after nuclear division (mitosis) is complete.

Cytology – The microscopic study of individual cells that have been sloughed off, cut out, or scraped off organs to be examined for signs of cancer.

Cytoplasm – The cellular substance outside the nucleus, in which the cell's organelles are suspended.

Cytotoxic – A cytotoxic drug is one that damages or destroys cells and is used to treat cancer.

D.

Data Safety and Monitoring Board – An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. The Board may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

Dendrites – Thread-like or tree branch-like extensions, such as the receptive surface of a new cell that branches off from the cell body.

Dendritic cells – Cells that are branched like a tree and convey antigens.

Deoxyribonucleic acid (DNA) – One of two nucleic acids found in the nucleus of all cells. DNA contains genetic information on cell growth, division, and function.

Dimer – A molecule which consists of two similar subunits.

Disease-Free Survival – Period after successful treatment in which there is no appearance of the symptoms or effects of the disease.

Dominant allele – A gene that is expressed, regardless of whether its counterpart allele on the other chromosome is dominant or recessive.

Doubling time – The time required to double the number of cells in a group of cells or in a tumour. A short doubling time (under 100 days) indicates a fast-growing tumour

Down-regulate – This refers to the reduction or suppression of the natural response to stimulation by a chemical in the body.

Duration of response – This is a measure of how effective a cancer treatment is and represents the period of time that a drug will continue to be effective and the disease continues to respond to the treatment.

E.

ECOG – Eastern Cooperative Oncology Group. A group of American oncologists which conducts trials on cancer treatments.

Effector cell – A terminally differentiated leukocyte that performs one or more specific functions.

Efficacy – The extent to which, under ideal conditions, an intervention, procedure, or regimen produces a benefit.

Endogenous – Developing or originating within the organisms or arising from causes within the organism.

Endpoint – Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

Enzyme – Any protein that acts as a catalyst, increasing the rate of a chemical reaction. Enzyme names often end with the suffix *ase*.

EORTC – European Organisation for Research and Treatment of Cancer. A group which carries out clinical trials on cancer therapies.

Epidemiology – Study of the determinants, distribution, and outcomes of health conditions, including diseases, within a population.

Epigenetics – The study of mechanisms involved in the production of phenotypic

complexity in morphogenesis. (1) The study of heritable changes in gene sequences. Epigenetics is reshaping the way scientists look at traditional genetics. This includes the study of how environmental factors affecting a parent can result in changes in the way genes are expressed in the offspring.

Epitope – In a complex antigenic molecule, the simplest form of an antigenic determinant.

Etiology – Cause of disease or the study of causes of disease.

Eukaryotic – A type of cell with a nucleus. A Eukaryotic cell is also known as eukaryote.

Experimental drug – A drug that is not licensed for use in humans, or as a treatment for a particular condition.

F.

Fibroblast – A connective tissue cell that differentiates into fibrous tissue.

Fibrosis – The development of tissue that is composed of fibers.

Flow cytometry – A technique for counting fluorescent-labeled cells or for separating selected populations of the cells for subsequent study; examines large numbers of cells and allows the separation of populations with, for example, particular surface properties.

Founder effect – The principle that when a smaller subgroup of a larger population establishes itself as a separate and isolated entity, the gene pool carries only a fraction of the genetic diversity of the parent population. This may result in an increased frequency of certain diseases in the subgroup, especially those diseases known to be autosomal recessive.

G.

GTPase – An energy-transferring enzyme.

Gamma Knife – A form of radiation therapy that uses a highly focused beam.

Gap 2 (G2) – In the somatic cell cycle, a pause between completion of synthesis and the onset of cell division.

Gene – Segment of a DNA molecule that contains all information for synthesis of a product (e.g. RNA molecule). The biological unit of heredity, each gene has a specific position (locus) on the chromosome map.

Gene amplification – A process of DNA duplication that results in a chromosome having more than one copy of a gene or genes and that can lead to inappropriate gene activation. It is a common mechanism of activation of oncogenes .

Gene deletion – The total loss or absence of a gene.

Gene expression – The process by which a gene's coded information is translated into the structures present and operating in the cell (either proteins or RNAs).

Gene markers – Landmarks for a target gene either by detectable traits that are inherited along with the gene, or distinctive segments of DNA.

Gene therapy – Treating disease by replacing, manipulating, or supplementing nonfunctional or abnormal genes.

Genome – All the genetic material in all the chromosomes of a particular organism.

Genotype – The entire genetic constitution of an individual, or the alleles present at specific loci.

Germ cells – The reproductive cells of the body, either egg or sperm cells, and their precursors.

Germline – The cell line from which gametes are derived.

Grade – The degree of similarity of the cancer cells to normal cells. This is assessed by a pathologist. A grade 1 carcinoma is well differentiated and is associated with a good prognosis. A grade 2 carcinoma is moderately differentiated and is associated with an intermediate prognosis. A grade 3 carcinoma is poorly differentiated and is associated with a poor prognosis.

Growth factors – Hormones that regulate the division of cells. Disturbances of growth factor production or the response to growth factor are important in neoplastic transformation.

Guanosine Triphosphatase-activating Proteins (GAP) – A family of proteins that suppress tumours in certain cancers. GAPs are similar in structure to a part of neurofibromin.

H.

Haploid – The chromosome number of a normal gamete, with only one member of each chromosome pair. In humans, the haploid number is 23.

Haplotype – A group of alleles from closely linked loci, usually inherited as a unit. A set of restriction fragments lengths closely linked to one another and to a gene of interest.

Heat Shock Proteins 70 – A class of molecular chaperones found in both prokaryotes and in several compartments of eukaryotic cells.

Heat Shock Protein 90 – A class of molecular chaperones whose members act in the mechanism of signal transduction by steroid receptors.

Hepatocyte Growth Factor (HGF) – Mitogen shown to cause cell division in hepatocytes (liver cells).

HER-2/neu – An oncogene which may help determine resistance to hormone and chemotherapy.

Heterozygous – Having different alleles for a given gene.

Heterodimeric – A dimer in which two subunits are different. I.e. tubulin.

Histology – That department of anatomy that deals with the minute structure, composition, and function of the tissues; also called microscopical anatomy.

Histone – A simple protein, soluble in water and insoluble in ammonia, associated with DNA in chromatin. Histone is found in urine in leukemia and febrile conditions.

Homologous transplantation – Transplantation of tissue between genetically dissimilar animals of the same species. Also known as allogenic transplantation.

Homologue – A member of the same species, but different genotype, or having a similar structure or position.

Homozygous – Having identical alleles for a given gene.

Hormone – Chemicals secreted by various organs in the body that help regulate growth, metabolism, and reproduction. Some hormones are used as treatment for breast, ovarian and prostate cancers.

Hormone receptors – Proteins in a cell, which bind to specific hormones. This binding stimulates the cell to act in a certain way.

Hormonal therapy – Treatment of cancer by alteration of the hormonal balance. Some cancers will only grow in the presence or absence of certain hormones.

HOX-Homobox – Conserved DNA sequences originally detected by DNA hybridization in many of the genes that give rise to homeotic and segmentation mutants in drosophila.

Human Genome – The full collection of genes comprising a human being's genetic and physical characteristics.

Humoral immunity – A form of immunity whereby B lymphocytes and plasma cells produce antibodies to foreign agents (antigens) and stimulate T lymphocytes to attack them. These antibodies also stimulate the release of chemical mediators, which enhance antigen destruction.

Hyperplasia – An abnormal, excessive growth of cells that are benign.

Hypothesis – A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

I.

Immune system – Cellular and molecular components having the primary function of distinguishing self from non-self and providing defense against foreign organisms or substances. The primary cellular components are lymphocytes and macrophages, and the primary molecular components are antibodies and lymphokines.

Immunohistochemistry (IHC) – Application of antigen-antibody interactions to histochemical techniques (antibody labeled with a fluorescent dye).

Immunophilin – Generic term for intracellular protein that binds immunosuppressive

drugs.

Immunotherapy – A treatment that stimulates the body's own defense mechanisms to combat diseases such as cancer.

Imprinting – A biochemical phenomenon that determines for certain genes which one of the pair of alleles, the mother's or the father's, will be active in that individual.

Incidence (rate) – The rate of new cases of a disease or event in a specified population during a specified time period.

Inclusion/exclusion criteria – The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

Induration – An area of abnormal hardness.

Infarct – Tissue death, resulting from too little blood flow or oxygen.

Infiltrating cancer – Cancer that has grown from the site in which it originated and into surrounding tissues.

Informed consent – Voluntary authorization, given to the physician or an investigator, by the patient, with full comprehension of the risks involved, for diagnostic or investigative procedures and medical and surgical treatment.

In situ – In place, localized and confined to one area; a very early stage of cancer.

Integrins – Family of proteins that are located on the cell surface and that are involved in binding to components outside the cell.

Intron – A sequence of DNA that is spliced out before a protein is made.

In vitro – Within a test tube or other outside of a living organism.

In vivo - Within a human or animal body.

Ipsilateral – On or affecting the same side of the body.

Isogenic – Of the same genotype.

K.

Karyotype – The complete set of chromosomes of a cell or organism. Used especially for the display prepared from photographs of mitotic chromosomes arranged in homologous pairs.

Kinase – Widely used abbreviation for phosphokinase, an enzyme catalyzing transfer of phosphate from ATP to a second substrate usually specified in less abbreviated name, for example creatine phosphokinase (creatine kinase), protein kinase.

Knockout mouse – Mouse in which a specific gene has either been modified or eliminated so that it no longer functions normally (the gene has been knocked out). This allows scientists to trace the role of the gene in the mouse's development process, especially as it relates to the development of a disease.

L.

Lesion – Area of tissue with impaired function because of damage from injury or disease; examples of primary lesions are ulcers, abscesses, and tumours.

Leukocytes – White blood cells. These include granular leukocytes (basophils, eosinophils, and neutrophils) as well as non-granular leukocytes (lymphocytes and monocytes)

Leukopenia – Reduction of leukocytes in the blood.

Ligand – A molecule that binds to and interacts with a large molecule to cause some change. For example a hormone or growth factor may bind to a receptor to activate a signaling pathway.

LIGHT – LIGHT gene is a member of the TNF superfamily of ligands and signals similarly.

Linear accelerator – A machine that produces high energy x-ray beams to destroy cancer cells during radiation therapy.

Linkage map – A map of the relative positions of genetic loci on a chromosome

determined on the basis of how often the loci are inherited together.

Liposome – Microscopic spherical membrane-enclosed sacs 20-30 nm in diameter, made artificially in a laboratory; the membrane resembles a cell membrane and the liposome resembles a cell organelle, enabling them to be incorporated into living cells, which is how they are able to transport toxic drugs into cancer cells to exert maximum effect.

Local recurrence – Return of the cancer in the affected area.

Lump – Any kind of abnormal mass in the body.

Lymph – A clear fluid circulating throughout the body in the lymphatic system; contains white blood cells and antibodies.

Lymphatic system – A system of vessels which drains fluid, out of the head, neck and limbs and returns it to the general circulation – a filtering system.

Lymphoedema – A swelling caused by excess fluid that collects after the lymph nodes have been removed by surgery or affected by radiation treatments.

Lysis – Dissolution or destruction of cells; loosening or unbinding. The suffix –lytic appears at the end of many words to describe a process that destroys cells.

M.

Malignant – Describing a tumour that invades and destroys tissue in which it originates, which can spread to other sites of the body via lymph system and blood.

Macrophage – An amoeba-like white blood cell that acts as a phagocyte (a cell eating organism).

MAPK (MAP Kinase) – Mitogen activated protein kinase, also called externally regulated kinases (ERKs); a protein that phosphorylates targets within the cell transmits numerous types of signals including many that promote cell survival.

Margin – The area of normal tissue surrounding a tumour when it is surgically removed.

Mast cell – Resident cell of connective tissue that contains many granules rich in histamine and heparan sulphate. Two types of mast cells are now recognized, those from connective tissue and a distinct set of mucosal mast cells, the activities of the latter are T-cell dependent.

Messenger RNA (mRNA) – RNA that carries the genetic code (DNA) from the nucleus of the cell to the cytoplasm.

Meta-Analysis – Quantitative procedures for summarizing, integrating, and combining the findings from a literature review of a subject under study. It uses summary statistics from primary analyses of studies, and is therefore a synthesis of results.

Metastasis – The spread of cancer from one part of the body to another through the lymphatic system or the bloodstream. The cells in the new cancer location are the same type as those found in the original sites.

Micrometastases – Small undetectable deposits of cancer which grow later.

Mitogen – An agent that induces mitosis and lymphocyte transformation.

Mitosis – The process of cell division. The number of mitoses indicates the number of tumour cells replicating.

Modality – A type or class of therapy, such as chemotherapy, surgery, and radiotherapy.

Modulation – A cell's ability to adapt to an environment.

Moiety – An equal part; any part or portion, as a portion of a molecule.

Molecule – A group of atoms arranged to interact in a particular way; one molecule of any substance is the smallest physical unit of that particular substance.

Monoclonal – used of a cell line whether within the body or in culture to indicate that it has a single clonal origin.

Monoclonal antibody – Antibody molecules that have a single binding site.

Because of this specificity, monoclonal antibodies react only with the antigen that spawned their production, and none other.

Morbidity – Disease rate in a given population.

Mortality – Incidence of death within a population in a given period of time.

Mutagen – An external agent that when applied to cells or organisms can increase the rate of mutation. Some kinds of radiation, many chemicals, and certain viruses can act as mutagens.

Mutation – A change in the number, arrangement, or molecular sequence of a gene.

Myelosuppression – Reduction in production of blood cells by bone marrow, commonly occurring after chemotherapy; may result in infection, anemia, and abnormal bleeding.

N.

Necrosis – The death of an individual cell or groups of cells in living tissue that is sometimes seen in carcinomas.

Neoadjuvant therapy – Chemotherapy given prior to the treatment of a primary tumour with the goals of improving results of surgery or radiotherapy and preventing metastasis.

Neoplasm – Any abnormal growth. Neoplasms may be benign or malignant, but the term most often is used to describe a cancer.

Neuraminidase – Enzyme catalyzing cleavage of neuraminic acid residues from oligosaccharide chains of glycoproteins and glycolipids. Used as a laboratory reagent.

Nodule – A small, solid mass.

Northern blot – A method of separating and identifying RNA by gel electrophoresis, transfer to a filter (blotting), and hybridization to radioactively labeled RNA or DNA.

Nucleotide – A subunit of DNA or RNA, consisting of one chemical base plus a phosphate molecule and a sugar molecule.

Nucleus – The cell structure that houses the chromosomes.

Neoplasm – Any new and abnormal growth.

Neutropenia – A decrease in the number of neutrophils, a type of white blood cell.

O.

Oligoadenylate synthetases – A family of interferon-induced enzymes that bind double-stranded RNA.

Oligonucleotide – Short DNA/RNA strand with linear sequence of up to 20 nucleotides bonded together. Above this length, the term *polynucleotide* is used.

Oligopeptide – Short peptide strand with linear sequence of up to 20 amino acids bonded together. Above this length, the term *polypeptide* is used.

Oncogenes – Genes that normally play a role in the growth of cells but, when overexpressed or mutated, can foster the growth of cancer.

Oncolytic – Pertaining to, characterized by or causing oncolysis which is the destruction of tumour cells.

Oncolysis – Destruction of a neoplasm; sometimes used with reference to the reduction of any swelling or mass.

Organelle – A structurally discrete component of a cell.

Overall survival – The time from the primary treatment of the cancer to death.

P.

Pathogenesis – The biochemical structural, and physiologic changes that occur during progression of disease.

Peptide – A compound of two or more amino acids, the building blocks of proteins.

Pharmacokinetics – The study of the movement of drugs through the body (absorption, distribution, excretion).

Phase I Trials – They are primarily intended to see how toxic the treatment is, to determine the maximally tolerated dose of a compound, its major side effects, and to test the best means of administering the treatment.

Phase II Trials – They are intended to determine whether a treatment is effective against cancer, they cannot determine whether the new treatment is any better than the standard treatment.

Phase III Trials – They are intended to see whether a new treatment is any better

than the current standard treatments by making direct comparisons with those treatments.

Phase IV – Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

Phenotype – The observed biochemical physiological and morphological characteristics of an individual, as determined by his or her genotype and the environment in which it is expressed.

Phosphate – The molecule forming the backbone of a DNA molecule. It contains atoms of phosphorus and oxygen.

Phosphatase – An enzyme that removes phosphates from nucleic acids or proteins.

Placebo – An inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments, such as with the breast cancer prevention trials, are often compared with placebos to assess the treatment's effectiveness.

Ploidy – The number of chromosome sets in a cell; an increase in ploidy in the cells of a malignant tumour usually indicates greater aggressiveness and invasiveness.

Polymerase Chain Reaction (PCR) – *In vitro* method for producing large amounts of specific DNA or RNA fragments of defined length and sequence from small amounts of short Oligonucleotide flanking sequence (primers). The reaction is efficient, specific, and extremely sensitive. Uses for the reaction include disease diagnosis, detection of difficult-to-isolate pathogens, mutation analysis, genetic testing, DNA sequencing, and analyzing evolutionary relationships.

Polymorphic – Presenting many changes in form.

PR – Progesterone receptors. A receptor inside the cell that binds progesterone. Tumours with plenty of PR are less aggressive and more responsive to hormone therapy than those without.

Prevalence – Measure of current sickness within a population at a particular time (point prevalence) or over a set period (period prevalence); can be expressed as a number of persons or as a rate, such as number of persons per 1,000.

Prolactin – protein expressed during S-phase of the cell cycle, and therefore potentially a marker of cellular proliferation.

Protease – An enzyme that hydrolyzes (splits bonds) proteins into their constituent peptides.

Protein – A large, complex molecule composed of amino acids. The sequence of the amino acids-and thus the function of the protein-is determined by the sequence of the base pairs in the gene that encodes it. Proteins are essential to the structure, function, and regulation of the body. Examples are enzymes, antibodies, and some hormones.

Proteolysis – Cleavage of proteins by protease.

Protocol – A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

Q.

Quality of Life (QOL) Trials – refers to trials that explore ways to improve comfort and quality of life for individuals with a chronic illness.

Quiescent cell – A cell at rest; not replicating or actively secreting.

R.

Rad – An old unit of radiation dose now superseded by the gray (1 gray = 100 rads)

Radioisotope – An unstable atom that decays to a stable state by emitting radiation and that is used to kill cancer cells by damaging their DNA. Some also are used to visualise particular organs.

Radiotherapy – The use of radiation, usually x-rays or gamma rays, to kill tumour

cells.

Randomisation – Whenever a clinical trial has an active control or a placebo control, a patient has no choice about which group or arm of the study he/she is assigned to. Neither does the doctor, or the primary investigator. Instead, a computer randomly assigns patients to one arm of the study or another. Used mainly in Phase III trials, never in Phase I and almost never in Phase II.

Recessive Allele – A gene that is expressed only when its counterpart allele of the matching chromosome is also recessive. Autosomal recessive disorders develop in people who receive two copies of the mutant gene, one from each parent who is a carrier.

Recombinant DNA – A combination of DNA molecules formed from two or more different sources.

Recurrence – Reappearance of cancer after a period of remission.

Retrovirus – Any of a group of RNA-containing viruses that produce reverse transcriptase (DNA is formed from RNA, not vice versa as in normal transcription) and are incorporated into the genetic material of infected cells. Such viruses are known to cause tumours.

Ribonuclease (RNase) – An enzyme that cleaves RNA.

Ribonucleic Acid (RNA) – A molecular structure formed in the nucleus of all living cells that plays a role in transferring information from DNA to the protein-forming system of the cell.

Risk-benefit ratio – The risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being tested.

rRna – A nucleic acid found in all living cells. Plays a role in transferring information from DNA to the protein-forming system of the cell.

S.

Scintigraphy – A body scan that maps the distribution of a radioactive tracer throughout the body; such a map aids the diagnosis of cancer. Example: lymphoscintigraphy, a nuclear imaging technique performed by administering a radiolabeled contrast agent into the lymphatic system to create an image of lymph nodes.

Sequencing – Determination of the order of nucleotides in a DNA or RNA molecule, or the order of amino acids in a protein.

Sentinel node – The single axillary lymph node that can be examined to determine if cancer has spread beyond the breast to other lymph nodes.

Side effects – Any undesired actions or effects of a drug or treatment. Experimental drugs must be evaluated for both immediate and long-term side effects.

Signal transduction – The process by which an extracellular signal (i.e. a hormone) interacts with a receptor at the cell surface, causing a change inside the cell that ultimately causes a change in the cell's functioning.

Somatic cells – All body cells except the reproductive cells.

Southern Blot – A blotting method in which DNA is separated by gel electrophoresis, transferred to a filter, and detected by hybridization to radioactively labeled RNA or DNA.

S Phase – Test performed to determine how many cells within the tumour are at a particular stage of division.

Squamous cell carcinoma – A cancerous growth arising from a subtype of epithelial cells known as squamous epithelium.

Standard treatment – A treatment currently in wide use and approved for use, considered to be effective in the treatment of a specific disease or condition.

Statistical significance – the probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.

Stem cell – One of the mitotically active somatic cells that serve to replenish those that die during the life of the metazoan organism.

Stroma – The soluble, aqueous phase within the chloroplast containing water-soluble enzymes.

Stromal – Relating to the stroma of an organ or other structure.

Study endpoint – A primary or secondary outcome used to judge the effectiveness of a treatment.

Substrate – A substance that is acted upon by an enzyme.

Suppressor gene – A gene that can reverse the effect of a specific type of mutation in other genes.

T.

Taq Polymerase – An enzyme that joins DNA base pairs together and is normally used in the polymerase chain reaction (PCR).

T cells – White blood cells that have several functionally distinct subsets, including helper T cells, cytotoxic T cells, and suppressor T cells.

Telomere – The end portion of a chromosome. This part does not contain any genes that code for proteins.

Thrombocytopenia – A reduction in the number of platelets in the blood, causing spontaneous bruising and prolonged bleeding following an injury.

Toxicity – Side-effects which are due to treatments.

Transcription – The process of copying information from DNA into new strands of messenger RNA (mRNA). The mRNA then carries this information to the cytoplasm, where it serves as the blueprint for the manufacture of a specific protein.

Transgenic – The presence of two genes on opposite chromosomes of a pair.

Tumour – Any abnormal swelling in or on a part of the body; the term is usually applied to any abnormal growth of tissue, whether benign or malignant.

Tumour suppressor genes – Genes responsible for regulating normal growth by inhibiting cell proliferation and tumour development; mutations that inactivate these genes may lead to the development of cancer;

Tyrosine – An amino acid present in most proteins.

Tyrosine kinase – An enzyme that catalyzes the transfer of energy to tyrosine.

U.

Ubiquitin – Small protein present in all eukaryotic cells. Can be linked to the lysine side chains of proteins by formation of an amide bond to its C terminal glycine in an ATP requiring process.

Ultrasound – High frequency sound waves used to locate a tumour inside the body. Helps determine if a breast lump is solid or filled with fluid.

V.

Variable – Any characteristic, quantity, attribute, phenomenon, or event that varies or that can have different values.

Vector – In infectious disease, an organism that transmits a pathogen from one organism to another. In molecular biology, a sequence of genetic material that can be used to introduce specific genes into the genome of an organism.

Viable – Able to live.

W.

Western Blotting – A blotting method in which proteins are transferred from a gel to a thin, rigid support and detected by binding of labeled antibody.

X.

Xenograft – A graft from one species to another.

Y.

Z.

