Australia & New Zealand Breast Cancer Trials Group

Glossary of Terms

from the 2011-2012 ANZBCTG Annual Report

ACCRUAL TARGET (RECRUITMENT TARGET): The number of participants planned to be enrolled in the trial.

ADJUVANT THERAPY: Additional treatment used to improve the effects of surgical treatment. In cancer, adjuvant therapy may include chemotherapy, hormonal or radiation therapy after surgery, which is aimed at killing any remaining cancer cells.

ADVANCED BREAST CANCER: Cancer that has spread from the original site in the breast (metastasised) to other organs or tissues in the body. Also known as secondary breast cancer or metastatic breast cancer.

ANGIOGENIC: Blood vessel formation, which usually accompanies the growth of malignant tissue.

ANTIANGIOGENIC MOLECULE: An orally delivered small-molecule formulation with antiangiogenic and anticancer activity.

AROMATASE INHIBITORS (AI) (examples: anastrozole, exemestane and letrozole): A class of drugs used in the treatment of breast cancer in postmenopausal women. Some cancers require oestrogen to grow. Aromatase is an enzyme that synthesises oestrogen. Aromatase inhibitors block the synthesis of oestrogen. This lowers the oestrogen level, and slows the growth of cancers.

AXILLA: The underarm or armpit.

AXILLARY DISSECTION: Surgery to remove lymph nodes from the armpit. The procedure can be performed either at the same time as breast surgery or as a separate operation.

AXILLARY LYMPH NODES: Lymph nodes in and near the armpit.

BIOPSY: The removal of a small sample of tissue or cells from the body to help diagnose a disease.

BREAST CONSERVING SURGERY: Surgery to remove part of the breast. Also called a lumpectomy or a wide local excision.

CHEMOTHERAPY (examples: cyclophosphamide, doxorubicin, docetaxel and capecitabine): The use of medications (drugs) that are toxic to cancer cells. These drugs kill the cells, or prevent or slow their growth. The standardised combination of such drugs in the treatment of cancer is referred to as a 'treatment regimen'.

CLINICAL TRIAL: Research conducted with the participant's consent which usually involves a comparison of two or more treatments or diagnostic methods. Clinical trials are conducted to gain a better understanding of the underlying disease process and/or methods to treat or prevent it. The clinical trial process includes Phase I, II, and III trials.

DIMERISATION INHIBITOR: An antibody that prevents a compound or unit being produced by the combination of two like molecules.

DOUBLE-BLIND TRIAL: A clinical trial in which neither the participating individual nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo or another therapy.

DUCTAL CARCINOMA IN SITU (DCIS): Abnormal cells in the breast ducts, which over time could develop into invasive breast cancer.

ELIGIBILITY CRITERIA: Participant eligibility criteria for clinical trials can range from general (age, type of cancer) to specific (prior treatment, tumour characteristics, blood cell counts, organ function). Eligibility criteria may also vary with the stage of the disease.

ENDOCRINE-RESPONSIVE: Another name for hormone-responsive, or hormone receptor-positive breast cancer. Refer also to "hormone (endocrine) treatment".

GOOD CLINICAL PRACTICE (GCP): An international standard for the design, conduct, performance, recording and reporting of clinical trials; that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.

GRADE (TUMOUR GRADE): The degree of similarity of the cancer cells to normal cells. Grade is assessed by a pathologist. Grade 1 carcinoma is well differentiated and is associated with a better prognosis. Grade 2 carcinoma is moderately differentiated and is associated with an intermediate prognosis. Grade 3 carcinoma is poorly differentiated and is generally associated with a worse prognosis.

HER2-POSITIVE (HER2-amplified): HER2 stands for Human Epidermal Growth Factor Receptor 2. In HER2-positive breast cancer, the cancer cells have an abnormally high number of HER2 genes per cell. When this happens, too much HER2 protein appears on the surface of these cancer cells. This is called HER2 protein over expression or amplified. Too much HER2 protein is thought to cause cancer cells to grow and divide more quickly.

HER SIGNALLING PATHWAYS: One of the many complex processes associated with cell communication and action. The role of specific molecules in a cell which, via a cascade effect, inhibit or allow particular cell functions. Drugs being developed to inhibit these pathways might lead to new ways to block cancer cell growth and kill cancer cells.

HORMONE (ENDOCRINE) TREATMENT: Hormone (endocrine) treatment is used to treat breast cancers that are hormone receptor-positive, also known as hormone-responsive or endocrine-responsive. These cancers have receptors for the hormones oestrogen and/or progesterone; they are called ER and/or PR-positive cancers. There are several different types of hormone treatments. Some are taken as tablets (tamoxifen or aromatase inhibitors) and some are treatments to turn off or remove the ovaries (injections, surgery and sometimes radiotherapy).

HORMONE RECEPTORS: Proteins in a cell which bind to specific hormones. This stimulates the cell to act in a particular way.

HORMONE REPLACEMENT THERAPY (HRT): Drug therapy that supplies the body with hormones that it is no longer able to produce; usually to relieve menopausal symptoms.

HORMONE-RESPONSIVE: Also known as hormone receptor-positive or endocrine-responsive breast cancer.

HUMAN RESEARCH ETHICS COMMITTEE (HREC): The Human Research Ethics Committee's function is to review proposed research in order to ensure that the subject's rights are protected and that risk of harm is minimised.

HYPOTHESIS: Provides a suggested solution based on evidence.

IMMUNOHISTOCHEMISTRY (or IHC): Used to identify tissue components (e.g. abnormal cells in a cancerous tumour, different parts of biological tissue) by using a marker such as a fluorescent dye or an enzyme. The marker is attached to a type of protein (antigen) that finds another type of protein (antibody) and reacts to colour the target cells.

INDEPENDENT DATA SAFETY AND MONITORING COMMITTEE (IDSMC): An independent group of experts or adequately qualified individuals who monitor participant safety and treatment effectiveness data while a clinical trial is ongoing.

INFORMED CONSENT: Informed consent is a process whereby a person gives consent based on a clear understanding of the facts, any implications and possible future consequences. In the case of a clinical trial, these facts, implications and consequences are conveyed in the Participant Information Sheet and any associated materials.

IPSILATERAL: On or affecting the same side of the body.

ISOFORM: Any of two or more functionally similar proteins that may have a similar but not identical amino acid sequence, for example, there are two known isoforms of the oestrogen receptor, alpha (α) and beta (β).

LOCALLY ADVANCED BREAST CANCER: Breast cancer that has one or more of the following features: may be large (typically bigger than 5 cm); may have spread to several lymph nodes in the armpit (axilla) or other areas near the breast; and may have spread to other tissues around the breast such as the skin, muscle or ribs.

LUMPECTOMY: Also called "Breast Conserving Surgery".

LYMPHOEDEMA: Swelling caused by a build-up of lymph fluid, as a result of lymph nodes being removed or not working properly.

MAGNETIC RESONANCE IMAGING (MRI): A medical imaging device using a strong magnetic field and radio frequency to produce detailed images of internal body parts and structures. MRI is especially useful for imaging soft tissue like the brain, heart, muscles and tumours.

MAMMOGRAM: An x-ray of the breast.

MASTECTOMY: The surgical removal of the whole breast.

METASTATIC BREAST CANCER: Cancer that has spread from the original site in the breast to other organs or tissues in the body. Also known as secondary breast cancer or advanced breast cancer.

MICROMETASTASES: Small cancer cells that have spread (metastases) beyond the primary tumour and can only be detected by microscopic evaluation.

MONOCLONAL ANTIBODIES (examples: trastuzumab and bevacizumab): A treatment designed to specifically target a cell within the body, particularly cancer cells. Different cancer types can be targeted with different monoclonal antibodies.

MORBIDITY: The relative incidence of a particular disease within a defined population.

NEOADJUVANT: Treatment given prior to surgery or further treatment for cancer.

NODAL STATUS: Whether a breast cancer has spread (node-positive) or has not spread (node-negative) to lymph nodes in the armpit (axillary nodes). The number and site of positive axillary nodes can help predict the risk of cancer recurrence.

OESTROGEN: The main female sex hormone produced mostly by the ovaries.

OESTROGEN RECEPTOR (ER): A protein that may be present on certain cells to which oestrogen molecules can attach. The term "ER-positive" refers to tumour cells that contain the oestrogen-receptor protein. These cells are generally sensitive to hormone therapy.

OESTROGEN RECEPTOR ALPHA (ERα): One of two specific Oestrogen Receptor (ER) proteins. In standard clinical practice ERα is the primary ER protein assessed when determining if a tumour is "ER-positive".

OESTROGEN RECEPTOR BETA (ERβ): One of two specific Oestrogen Receptor (ER) proteins. ERβ is the less common variation of the ER protein and is not routinely assessed in standard clinical practice.

ONCOLOGIST: A doctor who specialises in treating cancer.

ONCOLOGY: A branch of medicine that deals with cancer.

OOPHORECTOMY: The surgical removal of an ovary or ovaries.

OPEN-LABEL TRIAL: A clinical trial in which doctors and participants know which drug or treatment is being administered.

OSTEOPOROSIS: A disease characterised by low bone mass and deterioration of bone architecture, which increases the susceptibility to fractures.

PARTICIPANT INFORMATION SHEET: A document designed to provide participants with relevant information and facts relating to the proposed clinical trial in order for the participant to make an informed decision regarding their participation in the trial.

PARTICIPATING INSTITUTION: Any public or private hospital or facility where ANZBCTG clinical trials are conducted.

PHASE II CLINICAL TRIAL: The second stage of the evaluation of a new drug in humans; these trials evaluate drug safety and preliminary efficacy (effectiveness) in a large number of participants (up to several hundred).

PHASE III CLINICAL TRIAL: The most rigorous and extensive type of scientific clinical investigation of a new treatment. These trials are designed to determine the effectiveness of a treatment, often by comparing it to an existing standard therapy or a placebo, in a large number of participants (typically hundreds or thousands). A phase III trial is generally required before a drug would be approved by regulatory authorities for general use.

PLACEBO: An inert tablet (such as a sugar pill), liquid or powder that has no active ingredient. In clinical trials, experimental treatments are often compared with a placebo to assess the treatment's effectiveness.

PREDICTIVE FACTOR: A finding which assists a clinician to assess whether an individual's cancer will respond either positively or negatively to a particular treatment. For example, the presence of oestrogen receptors predicts for response to hormone treatment. This term is often confused with "prognostic factor".

PREVENTION TRIAL: A trial aiming to find better ways to prevent breast cancer in healthy women.

PRINCIPAL INVESTIGATOR (PI): The person responsible for overseeing all aspects of a clinical trial at an ANZBCTG participating institution; submitting the protocol for institutional review board approval; recruiting participants; obtaining informed consent; and collecting data.

PROGESTERONE RECEPTOR (PR): A protein that may be present on certain cells to which progesterone molecules can attach. The term "PR-positive" refers to tumour cells that contain the progesterone-receptor protein. These cells are generally sensitive to hormone therapy.

PROGNOSTIC FACTORS: The combination of a number of aspects of a person's general condition and disease diagnosis. General factors can include, but are not limited to, age, gender, lifestyle and medical history. Specific disease related factors can include disease diagnosis, stage, tumour size and location and treatment options. The combination of these factors can result in either a favourable or poor prognosis.

PROTOCOL: A written, detailed action plan for a clinical trial. The protocol provides the background, specifies the objectives, and describes the design and organisation of the trial.

QUALITY OF LIFE: An individual's overall appraisal of their situation and subjective sense of well-being.

RADIOTHERAPY: The use of radiation, usually x-rays or gamma rays, to kill cancer cells or damage them so they cannot grow and multiply.

RANDOMISATION: A method of preventing bias in research by 'randomly' assigning clinical trial participants to treatment groups. Randomisation ensures each treatment group has a similar range and number of participants, such that any differences between treatment groups at the end of the trial can be attributed to the trial treatments.

RANDOMISED TRIAL: A study in which participants are randomly assigned to one of two or more treatment arms of a clinical trial.

RECURRENCE: The return of breast cancer after a period of remission. During a recurrence, breast cancer cells which have evaded treatment may reappear at the original site or in another part of the body.

RECURRENCE SCORE: Obtained by the Onco*type* DX® Assay, is a numerical value between 0-100 representing the likelihood of recurrence to distant parts of the body at 10 years post diagnosis.

SELECTIVE ESTROGEN RECEPTOR MODULATOR (SERM) (examples: tamoxifen and raloxifen): A class of medication that acts on the oestrogen receptors of cells by blocking the effects of naturally produced oestrogen within the body. This form of treatment has been shown to be effective in hormone-sensitive breast cancers.

SENTINEL NODE: The hypothetical first lymph node or group of nodes reached by metastasising cancer cells from a primary tumour.

SENTINEL NODE BIOPSY: Sampling of the sentinel lymph node into which the primary tumour is draining first to determine if a full lymph node exploration is needed.

SIDE EFFECTS: Unwanted effects of a drug or treatment (e.g. nausea, headache, hair loss, etc). Side effects may be short or long term, ranging from minor inconveniences to serious adverse events.

STANDARD TREATMENT (THERAPY): The current best treatment known for a particular disease or condition.

STUDY CHAIR: An adequately qualified clinician assigned by the ANZBCTG to provide clinical advice and guidance for the development and ongoing conduct of a clinical trial.

STUDY COORDINATOR: A member of the research team at an ANZBCTG participating institution who takes responsibility for non-clinical aspects associated with the conduct of a clinical trial.

SYSTEMIC THERAPY: The use of chemotherapy, hormone therapy and/or targeted therapy or a combination of these to target the entire body to destroy any cancer cells that may have spread to distant body parts but are below the level of clinical detection.

TOXICITY: Harmful side effects from an agent being tested.

TREATMENT TRIALS: Treatment trials are designed to test the safety and effectiveness of new drugs, biological agents, techniques, or other interventions in people who have been diagnosed with cancer. These trials evaluate the new treatment against standard treatment, if there is one.

TRIPLE-NEGATIVE METASTATIC BREAST CANCER (TNBC): 'Triple-negative' is the term given to tumours which do not possess Oestrogen Receptor (ER) and Progesterone Receptor (PgR) proteins, and which do not over express the HER2 protein.

TYROSINE KINASE INHIBITOR (example: lapatinib): A drug that interferes with cell communication and growth and which may prevent tumour growth.