Genetic Support Network of Victoria

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Glossary

Adverse Reaction: an unwanted effect caused by the administration of a drug.

Approved Drugs: drugs or treatments that have been approved by the Therapeutic Goods Administration to be safe and efficient for human use.

Arm: a treatment group in a *randomised* trial. Many *randomised* trials have two arms; one test arm (given the new drug treatment) and one control arm (given the current standard drug or treatment).

Association studies: searching a large group of individuals with a condition and a large group of individuals without the condition for certain markers (for example particular gene changes) to give information about which markers are more likely associated with the condition.

Baseline: the initial measurement at the beginning of a clinical trial before the participant starts to receive the experimental treatment being tested. The efficiency of a treatment is determined by comparing changes from baseline values.

Bias: a point of view that prevents impartial judgement. Bias can be controlled by *blinding* and *randomisation*.

Blinding: where a *participant* does not know which *arm* of the trial they are in (whether they are receiving the test treatment or the control treatment).

Clinical Trial: medical research studies that trial experimental treatments, prevention methods, diagnostic or screening techniques. They aim to discover a better way of managing, treating or diagnosing a certain condition by assessing how people respond to different treatments. See *Phase 1, 2, 3* and *4.*

Cohort: a group of people with similar characteristics.

Confidentiality: a participants' right to have their personal identity remain anonymous in any publications and their medical information to be kept confidential.

Control Group: a group of patients who receive the current standard for treatment and to whom results from the group receiving the test treatment are compared.

Diagnostic Trial: a research study which aims to find better tests or procedures for diagnosing a particular condition.

Double Blind Study: research studies where neither participants nor researchers know which participant group is the control group and which is the test group. This is done so that the expectations of the researchers or participants do not affect the results.

Eligibility Criteria: used for participant selection. See *Inclusion/Exclusion Criteria.*

Empirical: results or figures based on what has been observed from past experimental data and not based on theory or estimates.

Ethics approval: all research conducted through a hospital or university is required to have submitted a formal application to justify that the research meets high ethical standards. Research conducted through a private company may or may not have been through the ethics approval process. Any offer made to you to participate in research should be accompanied by an ethics approval number, to ensure the research meets these high standards.

Experimental Drug: a drug that is not currently licensed for use in humans or as a treatment for a human condition.

Focus Group: a small mediated discussion group, used for the purpose of research. *See qualitative research.*

Genetic Testing: a way of determining certain changes in an individual's DNA that may or may not be associated with a condition.

Gold Standard: the current best standard for treating.

Human Research Ethics Committee (HREC): a group of people who determine what research should be carried out. Researchers have to submit and ethics application and gain approval from the appropriate HREC before commencing any research studies. For example each hospital in Australia has its own HREC.

Hypothesis: an assumption used as a guide for further investigation.

Inclusion/Exclusion Criteria: medical, physical or social characteristics that determine whether or not an individual can participate in a research study. Examples are age, gender, stage of disease, or previous treatment.

Informed Consent: Informed consent is both a legal and ethical requirement of participation in research. This is a written or verbal consent process to ensure the participant is:

1. well-informed about the research, including possible risks
2. acting under their own free will and not coerced in any way

The goal of informed consent is to ensure participants are making decisions in accordance with their own personal values.

National Statement: The National Statement on Ethical Conduct in Research Involving Humans is a comprehensive set of guidelines written by the Australian Government. All *Human Research Ethics Committees (HRECs)* use these guidelines as standard when deciding whether to approve new research.

Phase 1 clinical trial: the first time the treatment is given to humans. Usually, this involves giving the treatment to a small number of healthy volunteers to determine the best dosage.

Phase 2 clinical trial: the treatment is given to a small number of patients with the condition to monitor safety and side effects.

Phase 3 clinical trial: the treatment is given to a large group of patients with the condition and benefits and side effects are monitored.

Phase 4 clinical trial: the ongoing monitoring of the treatment *after* it has been approved to ensure long-term safety.

Placebo: an *inactive* treatment given to the participant. For example the treatment group may be given a painkiller while the control group is given a placebo (sugar pill). This ensures that any benefits measured from the treatment are more than psychological effects.

Plain Language Statement: a brief outline of the research you are being invited to participate in. The Plain Language Statement is written by the researcher and should be in clear, simple language.

Principal Investigator: the lead researcher running the research project. The principal investigator may be a medical doctor, a scientist, or another trained professional with expertise in research.

Qualitative research: Qualitative research is a type of social research where the researchers are interested in exploring issues, perceptions and phenomena. Data may be collected from one-one on interviews with the participant, either in person or on the telephone, small mediated group discussions ('focus groups'), or written responses to a questionnaire.

Randomisation: the allocation of participants to either the treatment group or the control group in a random way. This ensures any measured effects of the treatment are not influenced by who the treatment was assigned to.

Compiled by Amy Schneider and Emily Higgs, Masters of Genetic Counselling students

http://www.clinicaltrials.gov/ct2/info/glossary

Consumers Health Forum of Australia (2011). *Consumer Guide to Clinical Trials*, accessed from https://www.chf.org.au/pdfs/chf/CHF-Clinical-trials_COL__WEB.pdf