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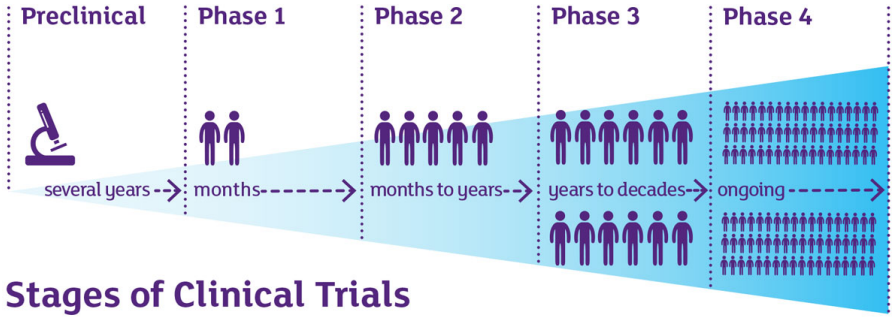
WHAT ARE CLINICAL TRIALS?

Clinical trials are undertaken to test whether a proposed new therapy is safe and effectiveness. It is a very important part of clinical research. Results from clinical trials are shared so that the broader medical, scientific and patient communities can benefit from this knowledge.

Clinical Trial phases:

Clinical trials are in four phases. The first three phases must be successful before the product or treatment is eligible for regulatory approval.

- **Phase I** – is the first testing of a new drug, treatment or clinical device on a small group of people (about 6-80) to evaluate safety. Phase I research studies can include drugs or treatments that have been tested in animals but never in humans.
- **Phase II** – generally involves a larger group of patients to further evaluate safety and explore the efficacy of the intervention. This usually involves one group of patients receiving the experimental drug, while a second 'control' group will receive a standard treatment or placebo. Often these studies are double blinded.
- **Phase III** – continues to investigate the efficacy of the intervention in larger groups of people (up to several thousand) by comparing against other similar treatments for the same condition, while monitoring for undesired effects. Once a Phase III study is successfully completed, regulatory approval can be sought for the drug or therapy to be made available for use in clinical practice. Often more than one phase III trial is required for regulatory approval.
- **Phase IV** – once the intervention has obtained regulatory approval and it is available for use, further studies are performed to monitor effectiveness and collect more information regarding undesired effects. Late Phase III/Phase IV studies often compare an investigational drug or therapy with one already available.



Stages of Clinical Trials

Image courtesy of the Cancer Institute NSW.

Experimental controls:

Some clinical trials may divide the trial participants into two or more groups to compare the results between the groups. The first is often referred to as the **experimental arms** where the participants receive the treatment under investigation; the **control arm** where participants receive no treatment; the **placebo arm** where an ineffective treatment is offered; or a **comparative arm** where participants are given an alternative treatment.

Depending on how the trial is designed, the participants may be aware of which group they have been allocated to which is referred to as a **non-blinded** or **unmasked** trial, or they may not know how what treatment they receive which is known as a **blinded** or **masked** trial. Some trials are designed so that even the investigators are not aware of which group is receiving the experimental intervention. These trials are often referred to as being **double blinded** or **masked trials**.

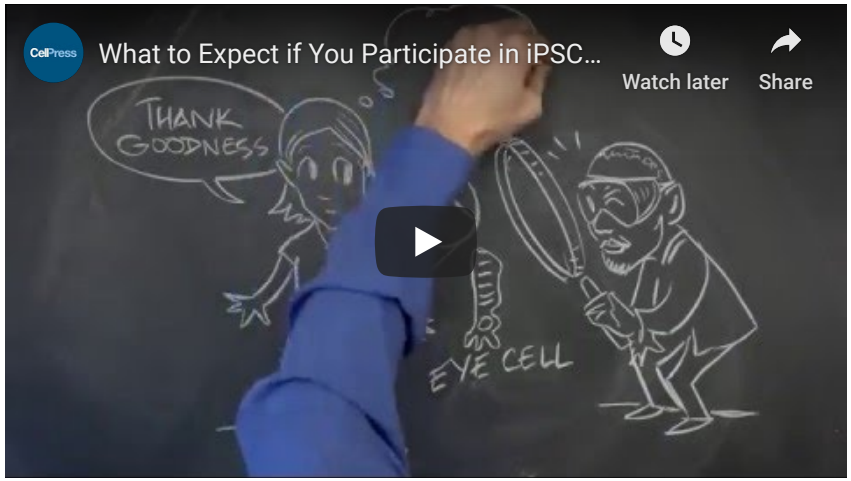
Ethical regulations:

Clinical trials in Australia are regulated by laws and codes of conduct that aim to protect trial participants and the integrity of the research. All clinical research projects in Australia must be approved by a Human Research Ethics Committee (HREC), which checks that the research conforms to the requirements of the National Statement on Ethical Conduct in Human Research.

Anyone taking part in a trial must be fully informed about the objectives of the research, what is expected of them and any risks and potential inconveniences that may be experienced during and after the trial. If you are thinking of being part of a trial, you should be given a participant information and consent form that contains details of the trial and your participation as part of the process of informed consent.

Visit the Australian Clinical Trials website to find out more about clinical trials.

What to expect when you participate in iPSC research:



Credit: University of Melbourne

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