CENTRE FOR COMMUNITY-DRIVEN RESEARCH

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HOW CLINICAL TRIALS ARE REGULATED

Fact Sheet 005

Financing trials

There are several ways that we can ensure financial support for clinical trials. These may include federal or state funding through grants, funding through the pharmaceutical industry, funding through institutional grants and occasionally, funding through philanthropy.

In addition to sponsoring the trial from a financial point of view, the pharmaceutical industry often work collaboratively to provide the drug that is being tested to researchers outside of their own company.

Regulating clinical trials

To conduct a clinical trial in Australia there are a number of guidelines that need to be followed. All clinical trials must comply with the National Statement on Ethical Conduct in Human Research[1], the Australian Code for the Responsible conduct or research [2], as well as local, State and Territory guidelines. For clinical trials using goods that are not on the Australian Register of Therapeutic Goods, or use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval, there are two additional mechanisms used including the Clinical Trial Notification scheme (CTN) and Clinical Trial Exemption scheme (CTX).

Clinical trial notification

The majority of clinical trials receive approval to commence through the CTN. Through this notification scheme, Human Research Ethics Committess bear the responsibility of assessing ethical acceptability of the study and approving the trial protocol. Notification is sent to the CTN for each site where the study will be conducted. A study cannot commence until this process is complete.

Special access scheme

Therapeutic goods that have undergone an evaluation for quality safety and efficacy are listed on the Australian Register of Therapeutic Goods (ARTG). However, because there are circumstances where patients need to access treatments outside this system, the Therapeutic Goods Administration (TGA) manages the Special Access Scheme (SAS) on a case-by-case basis. Applications under the SAS are made to the TGA by registered medical practitioners, preferably the patient's treating doctor.

Clinical trial exemption

The Clinical Trial Exemption scheme (CTX) is not used often, but is available in situations where an application to conduct a clinical trial is submitted to the TGA for evaluation and comment (as opposed to notification through the CTN). The TGA decides whether or not the proposed usage of the therapy or device in the trial is within the guidelines for the product. If there are any objections or issues, the trial cannot commence until these have been resolved.

References

1. National Statment on Ethical Conduct in Human Research. 2007 (Updated May 2015), The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee.: Commonwealth of Australia, Canberra.
2. Australian Code for the responsible Conduct of research. National Health and Medical Research Council, the Australian Research Council and Universities Australia.

Next fact sheet in series: The Pharmaceutical Benefits Scheme