

What is the Australian New Zealand Clinical Trials Registry?

The 'registry' or 'the ANZCTR' is a comprehensive, on-line register of all clinical trials being undertaken in Australia and New Zealand. The registry features the full spectrum of therapeutic areas including trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. It provides coverage of all clinical trials involving Australian/New Zealand researchers or participants.

The registry was established in 2005 at the [NHMRC Clinical Trials Centre](#), University of Sydney, with \$1.5 million in funding from the Australian Government, through a [National Health and Medical Research Council \(NHMRC\) Enabling Grant](#). The management team is led by Professor John Simes.

The registry is overseen by an Advisory Committee with wide representation from a variety of stakeholders including government, clinicians, the research community, journal editors, the pharmaceutical industry and regulator, and consumers.

What is the purpose of the registry?

Recently, there has been a worldwide initiative to make public all clinical trials being conducted.

With the establishment of the registry, Australians and New Zealanders, for the first time, will be able to find out which clinical trials are taking place across the countries in all areas of health - new drugs, treatments, therapies, surgical procedures and new medical devices.

People interested in participating in a clinical trial and doctors investigating relevant trials for their patients will have access to a reputable and comprehensive on-line register showing what trials are occurring throughout Australia and New Zealand.

Health professionals will be able to investigate the evidence behind new treatments, therapies or drugs arising from a trial listed by the registry.

The registry will help researchers identify gaps in their own research and prevent unnecessary duplication of clinical trials. Having access to information about trials under way across Australia and New Zealand will provide valuable insights for researchers.

Why is the registry important?

There is growing recognition internationally of the need to record the existence of clinical trials so that a true picture of the evidence for a particular new treatment, drug, medical device or therapy is publicly available.

The registry will help provide patients and health practitioners with access to information about trials that they may consider important for their future treatment choices or trials in which they may be interested to participate.

Prior registration is now a condition of publishing trials research. From 1st July 2005 the International Committee of Medical Journal Editors (ICMJE, which includes, among many others, editors of the *Medical Journal of Australia*, the *Lancet* and the *New England Journal of Medicine*) will not publish in their journals the results of any clinical trials not included on an authorised register at the trial's inception.

What are the benefits of a clinical trials registry?

A clinical trials register will increase the efficacy of the current clinical trial effort through:

- greater efficiency by reducing unnecessary duplication of research effort, because people planning a new trial will be aware of all the other trials that exist.
- potential for higher recruitment rates of clinical trial participants (especially for rare or life-threatening conditions), thereby increasing the chances of a successful outcome from some clinical trials.
- better compliance: a register identifies trials being conducted so that disclosure of results may be more timely.
- added value to research results, by providing a reliable and unbiased source of information about trials for systematic reviews, prospective meta-analyses and evidence-based guidelines.
- improving available evidence to inform treatment practice and health care.

How will the registry benefit patients?

- Patients and health professionals will have access to a searchable, accessible and comprehensive Australian New Zealand Clinical Trials Registry.
- For health professionals and patients the registry is a one-stop shop for all clinical trials and not just drugs and therapies. The registry also includes surgical and public health trials.
- The public will have a greater assurance that all clinical trials results are reported, including those with adverse findings.

How can I access the registry?

The registry website is: www.anzctr.org.au The list of registered trials can be accessed by clicking the Trial Search button, and more details of each trial can be viewed using the View button. Trials can be searched by listing a word from a text field in the Trial Search box and clicking Search.

What studies need to be registered?

All clinical trials involving Australian/New Zealand investigators or participants, in all areas of health and testing all forms of interventions should be registered. Clinical trials being conducted in other countries are also able to be registered on the ANZCTR.

Studies that meet the [WHO/ ICMJE 2008 definition](#) of a clinical trial should be registered. That is, any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Medical interventions include any intervention used to modify a health outcome and include drugs, surgical procedures, devices, behavioural treatments, etc. If in doubt about whether to register or not, registration is recommended.

When should studies be registered?

Trials should be registered before enrolment of the first patient.

Who is responsible for registering a trial?

The trial's Sponsor or an appropriate representative is responsible for registering a trial. This is "an individual, company or institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial" (as [defined by the NHMRC and TGA](#)). An appropriate representative of a Sponsor is any individual with delegated authority to agree to the conditions of registration on behalf of the Sponsor.

Sponsors include (as defined by [clinicaltrials.gov](#)):

- (Company) Sponsors legally responsible for conducting clinical trials
- Governmental or international agencies conducting or supporting clinical trials
- Lead principal investigators who are responsible for conducting and coordinating the overall clinical investigation. For multi-site studies, trial data should be submitted only once. (i.e. trial data should *not* be submitted from every study location).

The Sponsor is responsible for

- registering the trial
- the accuracy and completeness of registered data, and for indicating when selected non-mandatory items should be suppressed from public view
- ensuring that information on any one trial is submitted only once
- communicating with trial collaborators regarding the registration status of the trial, and the registration number
- ensuring information on the registered trial is kept up-to-date

How do I register a trial?

Trial registration can be completed online at: www.anzctr.org.au

First time users need to create a login name and password. Using the Register Trial button will take the registrant to the screens that need to be completed. This includes basic trial information such as the types of participants, the interventions being tested and the outcomes to be assessed. Other information required includes details of the study design, sample size and contact information. Each field has an information button to assist registrants in entering the correct data. Once each screen is completed, the registrant should click the Save and review button to save the information to the online registry database. Once all the mandatory information has been entered, the registrant should click the Submit button.

Following submission of the data, the ANZCTR staff will check the data submitted and query the contact person should anything need clarification. Once any queries are confirmed, trials are officially 'registered' and allocated a unique registration number. Both date of submission and date of registration are recorded. Information on each trial (including patient accrual, trial and publication status) is updated regularly.

What is recorded on the registry?

The registry records a trial's:

- objectives
- main design features
- sample size and recruitment status
- treatments under investigation
- outcomes being assessed
- principal investigators
- contact details for specific trial information

Does the registry meet the requirements of the International Committee of Medical Journal Editors (ICMJE)?

There is considerable pressure internationally to develop national clinical trials registers.

- Many of the editors of the most prestigious international journals have announced that from 1st July 2005 that they will not publish articles reporting on unregistered clinical trials.
- In response to this and the strongly negative public reaction to the lack of full disclosure of the adverse effects of some drugs, the Americans and British have recently developed national registries.
- The World Health Organisation is developing a clinical [trials portal](#) which link the national registers, providing an international resource on clinical trials.

The Australian New Zealand Clinical Trials Registry is consistent with the requirements set out by the ICMJE and WHO portal. In 2006, the ANZCTR became an [ICMJE acceptable registry](#) and in early 2007, the ANZCTR became one of the first [Primary Registers](#) in the WHO register network.

Will patients or health care providers have to pay to access the information or register a trial?

No, access is free to the trial information that is publicly available. There is no charge for registering a trial.

What are the future plans for the registry?

Currently, the registry has all the data and functionality needed to meet the ICMJE requirements. However, the registry will be further developed in phases over the next few years in order to improve various functions. The registry will be fully operational by 2008.

Planned phases of ANZCTR development***Phase 1***

This phase of development was completed by the end of June 2005 to ensure that Australian/New Zealand trialists were able to meet the ICMJE deadline of 1st July 2005. The web site and the "back end" database were developed within a very short period of time. Opportunities for consultation were limited and this site was compiled primarily to meet an immediate need. We are aware of problems and some simple modifications that need to be made to the web site and database. We are also developing a more sophisticated search screen and a "query" system to facilitate administration of the ANZCTR.

Phase 2

In November 2005 a meeting of the WHO ICTRP Advisory Board will be held at which it is anticipated decisions will be made regarding:

- the standardisation of the required items for registration
- certification of registers
- a globally unique trial numbering system
- a portal for searching registers worldwide
- The ANZCTR data fields will then be amended, if required, to comply with the agreed international standard.

Phase 3- Currently implemented

A detailed audit trail facility will be developed and implemented that will enable the registrants to log on and update selected fields, with a record kept of the field changed and the nature of the change.

Phase 4

Stakeholder consultations will be undertaken to determine what the users of the ANZCTR want in their registry.

Phase 5

A detailed project plan will be developed based on the stakeholder consultations and feedback on Phases 1 to 4. Long term sustainable funding and management structures will be investigated and implemented.

Other initiatives involving the ANZCTR

It is anticipated that in the near future the World Health Organisation (WHO) will develop an international system for assigning a unique trial registration number (UTRN) which the ANZCTR will then incorporate in its system.

In May 2007, the WHO developed an international clinical trials [search portal](#). The Australian/New Zealand register is linked to this portal so that people can investigate what trials are occurring overseas. This will not only help researchers and health professionals get a better picture of what is happening in their area of expertise overseas, but will have important benefits for patients and their health care providers.

Are there any other Australian/New Zealand clinical trials registries?

Other Australian/New Zealand registers of information on specific disease areas are already available. However, these are not all comprehensive or interactively searchable. The registers include:

- National Clinical Trials Register (Clinical Trials Centre: cancer trials) - not publicly available
- [Perinatal Trials Register](#) (Clinical Trials Centre & Perinatal Society of Australia and New Zealand)
- [Australian and New Zealand Breast Cancer Trials Group Register](#) (ANZBCTG)
- [Cancer Trials NSW](#) (Cancer Council NSW)
- [Cancer Trials Victoria](#) (Cancer Council Victoria and Victorian Cooperative Oncology Group)

The information held by these registries will be incorporated into the new Australian New Zealand Clinical Trials Registry.

Are there other international registries?

The first call for comprehensive registration of clinical trials was made over 20 years ago. However, a recent major catalyst for action was the announcement by the International Committee of Medical Journal Editors (ICMJE) in September 2004 that all 11 ICMJE member journals would require, as a condition of consideration for publication, registration in a publicly accessible trials registry. Trials must be registered before the first subject is enrolled. This policy applies to any clinical trial starting enrolment after 1 st July 2005 . For trials that began enrolment prior to this date, the ICMJE member journals required registration by 13 th

September 2005 . The ICMJE has established specific criteria that registries are required to fulfil (<http://www.icmje.org/faq.pdf>) before they will be considered as an acceptable registry. At August 2007 the following seven trial registries were recognised by the ICMJE as acceptable registries:

1. Australian New Zealand Clinical Trial Registry (Australia) <http://www.anzctr.org.au>
2. ClinicalTrials.gov (USA) <http://www.clinicaltrials.gov>
3. ISRCTN Register (UK) <http://www.ISRCTN.org>
4. UMIN Clinical Trials Registry (Japan) <http://www.umin.ac.jp/ctr/index/htm>
5. Netherlands Trial Register (The Netherlands) <http://www.trialregister.nl>
6. Clinical Trials Registry (India) <http://www.ctri.in/>
7. Chinese Clinical Trials Register (China) <http://www.chictr.org/>

In parallel with the ICMJE initiatives, the World Health Organization (WHO) launched its International Clinical Trial Registry Platform (ICTRP) in August 2005. The ICTRP's main objectives are to ensure that all clinical trials are registered and can be easily found as well as settings standards for good registry practice.

In May 2006, the ICTRP recommended that research institutions and companies register all medical studies that test treatments on human beings, including the early phase studies, whether they involve patients or healthy volunteers. The ICTRP also recommended that a minimum 20 key details about a trial (WHO Trial Registration Data Set) be disclosed at the time studies are about to commence.

In May 2007, the ICTRP launched its global search portal (www.who.int/trialsearch). To date, five trials registries (ANZCTR, clinicaltrials.gov, ISRCTN, ChiCTR and CTRI) are contributing data to the search portal. From the portal, users can search for trials across these five registers as well as link back to the original record in the primary register. It is likely that more registers will contribute data to the portal in the near future.

Currently, there are many clinical trials registries around the world, often working in isolation. The ICTRP is seeking to bring participating registers together in a global network to assist them share their experiences, which will minimise duplication of effort, and to ensure common standards are adopted to make searching across registries easier.