FAQs - Frequently asked questions

GENERAL

What is the Australian New Zealand Clinical Trials Registry (ANZCTR)?

The ANZCTR is an online public registry of clinical trials, held at the NHMRC Clinical Trials Centre, University of Sydney. It is a Primary Registry in the World Health Organization (WHO) Registry Network, which means that it fulfils certain criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration.

The ANZCTR accepts both interventional and observational studies for registration from all countries and from the full spectrum of therapeutic areas including trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.

The registry was established in 2005 with $1.5 million in funding from the Australian Government, through a National Health & Medical Research Council Enabling Grant. The ANZCTR 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.

Who funds the ANZCTR?

The ANZCTR receives funding from Australian Government - Department of Health, Therapeutic Innovation Australia, National Collaborative Research Infrastructure Strategy, and the Health Research Council of New Zealand.

What is the purpose of the ANZCTR and why it is important?

The ANZCTR is part of the worldwide initiative to make public all clinical trials being conducted. The purposes of this are as follows:

- To improve research transparency: Making details of all trials publicly available improves research transparency and helps to overcome publication bias and selective reporting, thereby enabling clinicians and consumers to make more informed decisions.
- To facilitate trial participation: People interested in participating in a clinical trial and doctors investigating relevant trials for their patients have access to a reputable and comprehensive on-line register showing what trials are occurring across all areas of health, which may facilitate recruitment.
- To avoid duplication: Improving awareness of similar or identical trials will make it possible for researchers and funding agencies to avoid unnecessary duplication.
- To identify potential research areas: Describing clinical trials in progress can make it easier to identify gaps in clinical trials research.
- To promote research collaboration: Enabling researchers and health care practitioners to identify trials in which they may have an interest could result in more effective collaboration among researchers.
- To improve trial quality: Registries checking data as part of the registration process may lead to improvements in the quality of clinical trials by making it possible to identify potential problems (such as problematic randomisation methods) early in the research process.

How can I access the registry?

The ANZCTR is freely available at www.anzctr.org.au

How do I search the registry?

Please refer to the 'How to search' page.

How can I volunteer for a clinical trial?

Please refer to the 'How to get involved' page

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

The ANZCTR is the only Primary Registry in the WHO Registry Network in Australia/New Zealand. The ANZCTR has imported data from, and exported data to, various alliance organisations, including the Cochrane Renal Group and Multiple Sclerosis Research Australia (MSRA). The ANZCTR is also the primary data source for clinical trial information displayed on the consumer-friendly Australian Clinical Trials website (www.australianclinicaltrials.gov.au) managed by the Australian government and the Australian Cancer Trials website (www.australiancancertrials.gov.au) managed by Cancer Australia.

Other Australian and New Zealand groups maintain independent registers on specific disease areas, including:

- Australian and New Zealand Breast Cancer Trials Group Register (ANZBCTG)
- Victorian Cancer Trials Link (Cancer Council Victoria and Victorian Cooperative Oncology Group)

In addition, the Therapeutic Goods Administration (TGA) maintains an independent register of ongoing trials on therapeutic goods in Australia.

Are there other international registries?

Yes. There are currently 15 Primary Registries in the World Health Organization Registry Network. For a full list, please see: http://www.who.int/ictrp/network/primary/en/

In August 2005 the World Health Organization (WHO) launched its International Clinical Trial Registry Platform (ICTRP). 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 2007, the ICTRP launched its global search portal (http://www.who.int/trialsearch). The 15 Primary Registries plus the US-based registry, ClinicalTrials.gov, all contribute data to the search portal. From the portal, users can search for trials across all of these registries as well as link back to the original record in the primary registry.

Can I advertise on your website?

The ANZCTR website does not host or receive funding from advertising.

Can I download registration information?

Search results can be downloaded into XML format by selecting the most appropriate option from the drop-down menu in the top right hand corner of the 'Search results' page as follows, and clicking 'DOWNLOAD':

- *Download ALL trials* – Information from all fields on the ANZCTR registration form for every trial listed in the current search results will be downloaded in XML format contained in a zip file.
- *Download selected trials(s)* – Select the trial(s) for which you would like to download trial information by clicking the 'Select for download' button in the top right hand corner of the relevant trial summary boxes. After clicking the 'Download' button, information from all fields on the ANZCTR registration form for the selected trials will download in XML format contained in a zip file.
- *Download selected trial(s) summary* – Select the trial(s) for which you would like to download summary information by clicking the 'Select for download' button in the top right hand corner of the relevant trial summary boxes. After clicking the 'Download' button, summary information for selected trials including Request number, Scientific title, ACTRN and Anticipated start date will be downloaded into an XML file. To display the trial summary XML in a more user friendly version, you can open the downloaded XML trial summary file using Microsoft Excel.

How do I cite an ANZCTR study record in a publication?

An example citation is:

Australian and New Zealand Clinical Trials Registry [Internet]: Sydney (NSW): NHMRC Clinical Trials Centre, University of Sydney (Australia); 2005 - Identifier ACTRN12605000004662. A multi-centre, randomised, double-blind, placebo-controlled clinical trial examining the efficacy and safety of low-dose aspirin after initial anticoagulation to prevent recurrent venous thromboembolism; 2005 Jul 12 [cited 2008 June 18]; [1 page]. Available from www.anzctr.org.au/ACTRN12605000004662.aspx.

REGISTRATION

Is registration of clinical trials mandatory in Australia or New Zealand?

Registration of clinical trials is not legally required in Australia or New Zealand. However, there are a number of initiatives that seek to encourage and enforce prospective registration:

- In 2004 the International Committee of Medical Journals Editors (ICMJE, including editors of the *Medical Journal of Australia, Lancet, New England Journal of Medicine* and others) declared that they would not consider a trial for publication without evidence that it had been registered in a publicly accessible trials registry prior to enrolment of the first participant.
- The Declaration of Helsinki now explicitly states that "every clinical trial must be registered in a publicly accessible database before recruitment of the first subject". The Declaration is the cornerstone document guiding the ethical conduct of research in humans by physicians.
- The World Health Organization (WHO) considers the registration of all interventional trials to be "a scientific, ethical and moral responsibility" (who.int/ictrp/en/).
- Australia has also endorsed prospective trial registration in two key documents which guide the conduct of Human Research Ethics Committees and the conduct of Australians undertaking research in humans.
    - The 2018 update to the National Statement on Ethical Conduct in Human Research (2007) contains paragraph 3.1.7 which states “For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.”

    - The 2007 revision of the Australian Code for the Responsible Conduct of Research which was jointly issued by the NHMRC, the Australian Research Council and Universities Australia also contains a clause regarding prospective trial registration. Clause 4.10 of this document states that "researchers must register clinical trials with a recognised register to promote access to information about all clinical trials."
- Ethics committees are increasingly requiring prospective registration as a requirement of ethical approval.

Who is responsible for registering a trial?

The trial's sponsor or an appropriate representative is responsible for registering a trial. The sponsor is defined by the NHMRC and Therapeutic Goods Administration (TGA) as "an individual, company or institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial". 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

What studies need to be registered?

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 intervention 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.

The ANZCTR also accepts observational studies for registration.

When should studies be registered?

In order to obtain prospective registration, trials must be registered before enrolment of the first participant.
In cases where retrospective registration is required (i.e. the trial has, at the time of registration, already begun recruitment, ended recruitment or has since been completed), the ANZCTR will allow registration, however registrants should double-check requirements with their respective Ethics Committees and be aware that some journals require prospective registration as a condition of publication.

** In order to fulfil this prospective registration requirement, we recommend that you commence the registration process at least three weeks prior to the anticipated recruitment start date.**

Please note that the ANZCTR prioritises submissions from Australian and New Zealand registrants and trials with recruitment sites in Australia or New Zealand. For international registrants, there is likely to be a delay in processing your trial submission and additional time should be allowed prior to enrolment of the first participant.

What does prospective registration mean?

Prospective registration means that the registration process for a trial was complete and the registration number was issued before enrolment of the first participant. A trial is not registered with ANZCTR until a registration number (ACTRN*) is issued. Once a trial is successfully registered ANZCTR will send an email to the registrant and Principal Investigator advising them of the allocated registration number.

*Note that the ACTRN is different from the request number issued at the time of submission.
Example request number: 371456
Example registration number: ACTRN12616001299494

What does retrospective registration mean?

Retrospective registration means that the trial was registered after the first participant was enrolled.

How do I register a trial?

Full instructions are available at the 'How to register a trial' page.

When is an ANZCTR record publicly viewable?

The date of registration, which is the date an ACTRN (registration number) is issued, is the date information in the form is made public. This is the same for both prospective and retrospective registration.

Once a study is registered it remains permanently publicly viewable on the website.

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

Is there a charge for registering studies on ANZCTR?

No. It is free to register studies on the ANZCTR.

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

Yes. The ANZCTR became an ICMJE acceptable registry in 2006.

My study is not yet approved by an ethics committee. Can I register it on ANZCTR?

Yes, you can obtain provisional registration (refer to the next FAQ for more information).

What does provisional registration mean?

Provisional registration is allocated to submissions which meet the requirements for registration, but do not yet have ethics approval. The study is still classified as 'Registered', and provisional registration is sufficient to meet the requirements of the International Committee of Medical Journal Editors (ICMJE) and ethics committee requests for registration. Provisional registration is indicated by:

- the letter 'p' appearing at the end of the registration ID, e.g. ACTRN12615000923540p;
- a 'Provisional' watermark on the registration record; and
- a 'Provisional registration' label at the top of the trial record summary.

Once ethics approval is obtained and the record is updated, this will be changed to full registration. This labelling mechanism applies from the 1st October 2015. Any studies registered on the ANZCTR prior to this date will have a 2 year grace period before this new labelling mechanism is applied.

Does the ANZCTR accept observational studies for registration?

Yes, the ANZCTR accepts both interventional and observational studies for registration. For observational studies, 'Observational' must be selected for the 'Study type' field.

Can I register a study after it has started, has closed to recruitment, or has been completed?

Studies should be registered before enrolment of the first participant, i.e. prospectively. In cases where retrospective registration is required (i.e. the trial has, at the time of registration, already begun recruitment, ended recruitment or has since been completed), the ANZCTR will allow registration. However, registrants should double-check requirements with their respective Ethics Committees and be aware that some journals require prospective registration as a condition of publication.

What is the UTN?

The Universal Trial Number (UTN) is a unique number which aims to facilitate the unambiguous identification of clinical trials registered in WHO Primary Registries and displayed on the WHO International Clinical Trials Registry Platform's (ICTRP) Search Portal. It is not a registration number. A UTN should be obtained early in the history of the trial and should:

- become permanently attached to the trial
- be used whenever information about the trial is communicated
- become part of the trial's identity
- be documented in the trial protocol
- be submitted every time the trial is registered

To obtain a UTN please go to http://apps.who.int/trialsearch/utn.aspx, and enter in your name, email and organisation. WHO will then send you an email with a link to confirm your request. Once confirmed you will receive a second email from WHO with your UTN details.

Should I register my clinical trial on the ANZCTR, ClinicalTrials.gov or other registries?

To meet the requirements of the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO) for transparency and publication, it is necessary that clinical trials are registered once on any Primary Registry in the WHO Registry Network or an ICMJE approved registry before the time of first participant enrolment. By prospectively registering your trial with the ANZCTR, ClinicalTrials.gov or another registry approved by the WHO Registry Network or ICMJE, you will be meeting these requirements. You will only need to register your clinical trial once on one of the approved registries unless directed otherwise by a local authority (e.g. Human Research Ethics Committees (HREC)).

** Please note that clinical trials with Australian and New Zealand recruitment sites registered on ClinicalTrials.gov are also displayed on the ANZCTR.**

My study is registered on ClinicalTrials.gov but I need to register it on ANZCTR also. Is there a way to automatically copy the details across from ClinicalTrials.gov to ANZCTR?

Yes, you can import some details across from the ClinicalTrials.gov record to a new ANZCTR record. To do this, please:

- Click on 'Register trial' from the home page
- Click 'PROCEED' under option "Register trial on ANZCTR that has already been registered elsewhere"
- Follow the steps until you get to the page that asks, "Has this trial been registered on any of the following clinical trials registries?"
- Select the box next to ClinicalTrials.gov and click on 'PROCEED'
- Enter the ClinicalTrials.gov registration ID and click on 'NEXT'
- Complete then submit the form for review

All data imported from ClinicalTrials.gov will be editable and the ANZCTR registration form must be completed in accordance with the data item definitions. Some fields may require additional details in order to meet ANZCTR registration standards (check 'i' icon next to each field for full details). Once approved, an ANZCTR registration number (ACTRN) will be issued.

My trial is already registered with ClinicalTrials.gov. Can I add ANZCTR specific information to this record without registering the trial again?

Clinical trials with Australian and/or New Zealand recruitment sites registered on ClinicalTrials.gov are displayed on the ANZCTR. Data from ClinicalTrials.gov are imported and mapped to the corresponding ANZCTR field (where possible) for display on the ANZCTR. There are several ANZCTR fields for which data is either not available on the ClinicalTrials.gov record or cannot be extracted. The primary sponsor or an authorised representative of the primary sponsor for the trial registered with ClinicalTrials.gov can provide details for these additional 'missing' fields through the ANZCTR. To do this, please:

- Click on 'Register trial' from the home page
- Click 'PROCEED' under option "Add ANZCTR specific details to a ClinicalTrials.gov registration record"
- Once you acknowledge that you are authorised to provide further details for the trial and agree to 'Terms and conditions' you will be directed to a page where you can enter the existing ClinicalTrials.gov registration number
- Enter the ClinicalTrials.gov registration ID and click on 'PROCEED'
- Complete then submit the form for review

Data imported from ClinicalTrials.gov record will not be editable. The additional ANZCTR information that can be provided includes: Accrual to date, Australian recruitment details (hospitals, postcodes), funding source, primary and secondary sponsor, other collaborators, ethics approval committees and dates, Principal Investigator details, public and scientific contact details, and brief summary (if no data provided on ClinicalTrials.gov record). All these additional details are displayed in a separate marked section at the bottom of the trial record.

Note: The sponsor is defined as an individual, company or institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. An appropriate representative of a sponsor is any individual with delegated authority to agree to the conditions of providing additional trial information on ANZCTR on behalf of the sponsor.

Does the ANZCTR accept submissions from countries other than Australia and New Zealand?

The ANZCTR encourages registrants to use their local Primary Registry if available. For a full list of Primary Registries please go to www.who.int/ictrp/network/primary/en/. As the ANZCTR is funded by Australia and New Zealand we must prioritise submissions from these countries first, followed by submissions from countries that do not have their own primary registries, and then finally submissions which are from countries that do have their own primary registry in the WHO Registry Network. Accordingly, if you are applying from outside Australia or New Zealand and have no recruitment sites in Australia or New Zealand, then there may be a delay in processing your submission. All submissions must be written in clear and concise English, otherwise we have the right to reject them.

Can a trial be removed from the ANZCTR once it has been registered?

No. Once a study has been registered, it cannot be removed and remains publicly viewable.

Do I have to update any information after my trial has been registered?

Yes, the registrant is responsible for ensuring that the information provided in the registration record remains accurate and up-to-date. Full updating instructions are available at the 'How to update a trial' page.

My trial is already registered, but there are now two new steps (step 11 and step 12) on my registration page that appear empty. What are these?

From October 2018, the ANZCTR commenced collecting information on Individual Participant Data (IPD) sharing (Step 11) and study results (Step 12). These new steps are mandatory, and must be completed by the registrant, in order to comply with updates to the WHO minimum data set and ICJME policy.

You are able to add information to these fields by completing an 'update' of your trial. See 'How to update a trial' page for complete instructions on how to complete an update.

Once these new steps are adequately completed by the registrant, the date that they are approved by ANZCTR staff is displayed on the public view. This date is separate to the registration date and does not impact either the registration date or the 'prospectively registered'/'retrospectively registered' label of a trial.

How can a record be transferred to another user?

If a record needs to be transferred to another user, we will need to do this on your behalf. The current registrant needs to send an email to info@actr.org.au authorising the transfer. The email should include:

- the request number/registration ID of the record; and
- the email address linked to the ANZCTR user account of the person who the record needs to be transferred across to. If they do not yet have an ANZCTR user account, they will need to create one here.

Note that only the registrant of the study can make amendments to a record, i.e. the person who has the record linked to their account.

I submitted my application a number of days ago, why have I not heard anything back?

If you are from Australia or New Zealand, we will respond to your submission within four working days. If you have not heard from us within this time, please check that you have correctly submitted your application, i.e. the status of your submission should be 'Submitted' and you should also have received a confirmation email from us.
If you are from countries outside Australia and New Zealand there is likely to be a delay in processing your submission. Apologies for any inconvenience this may cause.