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1. From the ANZCTR Manager

Welcome to the third issue of the ANZCTR newsletter. The past year has seen many events and achievements and we hope you enjoy this summary of our activities during 2007.

Lisa Askie

2. ACTR is now ANZCTR

On October 31st, 2007 the Australian Clinical Trials Registry (ACTR), officially changed its name to the Australian New Zealand Clinical Trials Registry (ANZCTR). This is in recognition of funding support from the New Zealand Health Research Council. Please note that the new web address for the registry is www.anzctr.org.au so please change your book marks accordingly.

3. ANZCTR is a WHO Primary Register

In May 2007, the ANZCTR became one of the first Primary Registers in the WHO Register Network. This means that the ANZCTR fulfils all WHO requirements for a Primary Register (http://www.who.int/ictrp/network/contrib_registers/en/index.html) and contributes data to the WHO search portal: <http://www.who.int/ictrp/search/en/>

4. Major enhancements during 2007

The ANZCTR implemented several major enhancements to the Registry in August 2007. The improved functionality includes:

- **Updating trial information**
Trial information can now be updated at anytime in order to reflect a trial's current status or changes in trial protocol/information.
- **Data audit trail**
A detailed audit trail facility was implemented to coincide with the updating function. This allows a tracked history of all changes / updates made by registrants to be made publicly available. A trial's current information is displayed by default but with an ability for the information submitted at the time of registration to also be viewed.
- **Improved search function**
The ANZCTR search function is now more comprehensive. It includes an "advanced search" option which enable specific fields to

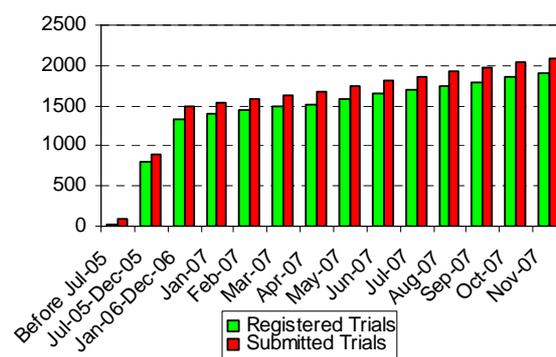
be searched as well as the ability to sort and print search results.

- **New trial registration format**

The improved functions required the addition of some new data items and re-formatting of the other data fields. The mandatory fields remain adherent to the WHO and journal editors' requirements.

5. Current statistics

The past year has seen a steady increase in the number of new trials registered with an average of 49 new trials registered each month - an increase from the 2006 average of 42 per month.



Once *submitted*, trials are checked for data quality, accuracy and duplication before being *registered*.

The median time from trial submission to registration remains at 6 calendar days. During this period, the most common questions the ANZCTR staff need to ask Registrants relate to providing specific time points for when Primary and Secondary Outcomes are measured. This also includes, specifying the appropriate tool or instrument used to measure the outcome, where applicable. Other information that often needs to be queried is the specific details for dose, duration and mode of administration for drug interventions.

Our main aim is to ensure that trial information provided by Registrants meets the WHO and journal editors' requirements before the trial is registered on the ANZCTR.

6. Cancer trials consumer website project

Funding has been committed from the NHMRC and Cancer Australia to develop and evaluate a consumer-focused website where all cancer trials being conducted in Australia can be easily accessed.

The project involves extracting up-to-date cancer trials information from the ANZCTR, requesting some additional data items relevant to cancer consumers, and making this information available on a separate website. The project will be evaluated via a cluster randomised trial before making the website accessible to the general public. A/Prof Alex Barratt from the University of Sydney is leading this project.

7. International Clinical Trials Symposium



The Third International Clinical Trials Symposium was held in Sydney on September 23-26, 2007. The symposium focused on the topic of improving health care in the new millennium.

The following presentations were given by ANZCTR staff at the Symposium:

International harmonisation: trials and tribulations - Dr Davina Gheri (ANZCTR Director / WHO International Clinical Trials Registry Platform Coordinator).

Australian Clinical Trials Registry: present and future - Dr Lisa Askie (ANZCTR Manager)

Australian Clinical Trials Registry: data quality audit - Suchaya Thongyoo (ANZCTR Research Assistant)

Lastly and once again

We would like to take this opportunity to thank all our stakeholders, funders and collaborators for your continued support during 2007 and wish you all a very happy holiday season and the best for the New Year.

The ANZCTR Staff



Davina Gheri Director Lisa Askie Manager Emma Smith Project Officer Jenny Chow Executive Officer Nicole Holcroft Project Officer Fergus Tai Research Assistant Suchaya Thongyoo Research Assistant Thuyen Vu I.T. Officer

8. Other meetings

The ANZCTR Manager, Dr. Lisa Askie attended a Registers Working Group Meeting at the WHO in Geneva on 29-30th November, 2007. Outcomes from this meeting will be reported on the ANZCTR website early in 2008.

9. New 'National Statement' and 'Code of Conduct' now have trial registration clauses

In March 2007 the NHMRC released the revised 'National Statement on Ethical Conduct in Human Research'. This Statement now includes Clause 3.3.12: "Before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible register." Access at: www.nhmrc.gov.au/publications/synopses/files/72.pdf

Similarly, the revised 'Australian Code for the Responsible Conduct of Research', released in June, also contains a clause that states: "4.10 Researchers must register clinical trials with a recognised register to promote access to information about all clinical trials." Download at: www.nhmrc.gov.au/publications/synopses/files/39.pdf

10. Contact Us

We welcome your questions, comments, suggestions and contributions on any matter relating to the Australian New Zealand Clinical Trials Registry.

Please send your message to: info@actr.org.au

Alternatively, you can contact us on:

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