



Table of contents

1. From the ANZCTR Manager
2. Trial registration milestones in 2008
3. WHO ICTRP interactions continue
4. Current statistics
5. Survey of Australian HRECs
6. Australian Cancer Trials Online project
7. ANZCTR plans for 2009
8. Contact us

1. From the ANZCTR Manager

Welcome to the fourth 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 2008.

Lisa Askie

2. Trial registration milestones during 2008

There were several important milestones that occurred during 2008 that have highlighted the increasing recognition of the need for prospective trial registration.

- **Declaration of Helsinki revised**

The revised [Declaration of Helsinki](#), released in October 2008, now states that "Every clinical trial must be registered in a publicly accessible data base before recruitment of the first subject." (paragraph 19). This is clear statement from World Medical Association that it considers prospective trial registration as an ethical principle in all medical research.

- **Registration question now on NEAF**

Version 2 of the [National Ethics Application Form](#) (NEAF) now contains a question (9.1.8.4) which requests trial registration details be completed at the time of ethics application.

- **Registration of NHMRC funded trials**

The National Health and Medical Research Council (NHMRC) announced in their [8th August 2008 "Tracker" newsletter](#) that all clinical trials funded by the NHMRC must be registered with the ANZCTR.

3. WHO International Clinical Trial Registry Platform (ICTRP) - ongoing interactions

The ANZCTR continued its association with the WHO International Clinical Trials Registry Platform (ICTRP) in 2008 as a Primary Registry.

- **Data provider for the ICTRP Search Portal**

The ANZCTR provides an updated version of our registry's data to the [WHO's ICTRP](#) each week so that when the [ICTRP portal](#) is searched, up-to-date information is available. The ICTRP Search Portal now contains data from seven Primary Registries: see www.who.int/ictrp/en/

- **Improved linkage of records displayed on the ICTRP Search Portal**

On December 10th the ICTRP Search introduced a new method of displaying trials which allows records linked by common registration numbers from any of the participating Primary registers to be displayed in groups. This will make for easier identification of trials that have been registered more than once in different registries.

- **Establishing minimum standards for trial registries**

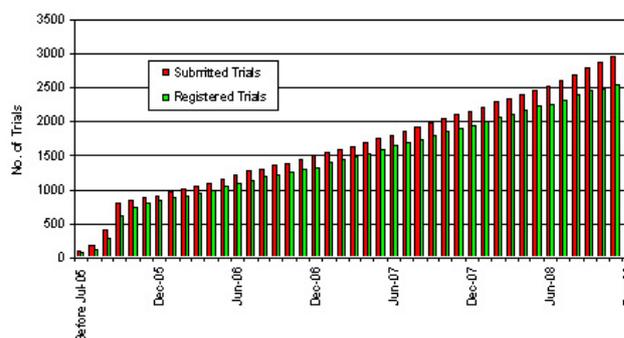
The ANZCTR Manager, Dr Lisa Askie, attended a meeting of the Best Practice Group (BPG) at the WHO in Geneva on 29-30th September 2008. Representatives from registries based in the USA, UK, South America, Germany, India, China, Japan, the Netherlands and Australia and New Zealand attended. Over two days the BPG members established several minimum standards to which registries should adhere.

- **Commentary published in the *Lancet***

A commentary on the role and importance of national registries was published in 2008: Grobler L, Siegfried N, **Askie L**, Hooft L, Tharyan P, Antes G. National and multinational prospective trial registers. *Lancet* 2008; 372: 1201-1202.

4. Current statistics

The past year has seen a sharp increase in the number of new trials submitted for registration with an average of 73 new trials being submitted each month - an increase from the 2006 average of 47 and the 2007 average of 54 per month.



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

The increased number of new trials being submitted, in addition to an average of 69 trials per month being updated, has meant that some registrants have experienced delays in having their trial approved for registration.

We intend to help address this in 2009 with the recruitment of a new staff member (to replace Emma Smith who left us in August). However, we advise that Registrants submit their trial well in advance of needing a registration number to ensure that deadlines such as ethics submissions or trial commencement dates are not missed.

Since our website counter commenced in September 2007, over 30,000 unique users have accessed the ANZCTR website. Since September 2008 we have been collecting information about the type of ANZCTR users and their satisfaction with the site. The Registry is being used for a wide variety of reasons including looking for trials to participate in, accessing information to include in a systematic review, as well as people looking for general information about clinical trials. This data collection is ongoing.

5. Survey of Australian HRECs

Recently, we have written to all Australian Human Research Ethics Committees (HRECs) to find out information about ways in which they promote prospective registration of clinical trials submitted for ethics approval. To date we have received 65 replies. In the new year we will be contacting the HRECs that have not yet responded to complete the data collection process.

6. Australian Cancer Trials Online consumer website project

Work commenced this year on the Australian Cancer Trials Online (ACTO) consumer website project. We are collaborating with colleagues from Cancer Australia and the School of Public

Lastly and once again

We would like to take this opportunity to thank all our stakeholders, funders and collaborators for your continued support during 2008 and wish you all a very happy holiday season & all the best for the New Year.

The ANZCTR Team



Davina Ghersi <i>Director</i>	Lisa Askie <i>Manager</i>	Emma Smith <i>Project Officer</i>	Jenny Chow <i>Executive Officer</i>	Nicole Holcroft <i>Project Officer</i>	Fergus Tai <i>Research Assistant</i>	Suchaya Thongyoo <i>Research Assistant</i>	Thuyen Vu <i>IT Officer</i>
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Health at the University of Sydney to assist in the development and evaluation of 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 is being evaluated via a cluster randomised trial before making the website accessible to the general public. For more information about this project, please contact: + 61 (0)2 9351 6171 or audiotrial@health.usyd.edu.au

7. ANZCTR plans for 2009

Major ANZCTR plans for 2009 include:

- taking steps to decrease the proportion of trials registered after the first participant is enrolled (as such trials do not fulfil the ICMJE requirement of *prospective* trial registration);
- undertaking comprehensive stakeholder consultations to assess our performance to date and plan for future needs; and
- establishing increased links and data transfer procedures with several partner registries.

8. 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:

- Phone:** +61 2 9562 5333
- Fax:** +61 2 9565 1863
- Website:** www.anzctr.org.au