ACTR
Australian Clinical Trials Registry

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1. From the ACTR Manager

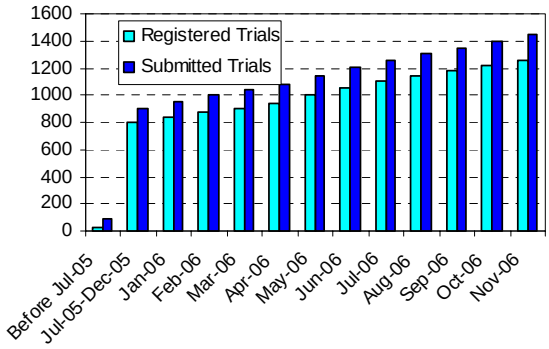
Welcome to the second issue of the ACTR newsletter. There are a number of significant events and achievements to report on since our previous posting. We hope you enjoy this short summary of our activities during 2006.

Lisa Askie

2. Milestone reached

The "1000th registered trial" mark was reached on 13th June 2006 with a study entitled: "A randomised controlled trial of exercise interventions in breast cancer patients: measuring feasibility and effect on recovery". This trial is funded by the National Breast Cancer Foundation and is being carried out by the research team led by Dr Sandi Hayes at the Institute of Health and Biomedical Innovation, Queensland University of Technology (ACTRN012606000233527).

We have seen a steady growth in the number of trials registered over the past year with, on average, 42 new trials registered each month. At the beginning of December 2006 there were 1280 trials registered on the ACTR.



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

The median time from trial submission to registration is 6 calendar days. During this period, the most common questions the ACTR staff need to ask Registrants relate to providing more detailed descriptions of the trial intervention(s) and outcomes, such as drug dosage and mode of administration, as well as outcome timepoints. Our main aim is to make sure that the trial meets the criteria of the WHO and the ICMJE.

3. International developments

There has been considerable activity internationally this year on progressing trial registration activities around the world. ACTR staff have been at the forefront of these activities.

Davina Ghersi

In September 2006, ACTR director, Davina Ghersi (left), took up the position of Coordinator of the WHO's International Clinical Trials Registry Platform (ICTRP).

Davina will be responsible for establishing a coordinated international network of trial registers. The ACTR will be actively involved in the development and implementation of this network of Registers.

The ICTRP is also making progress on developing a one-stop search portal for searching registers worldwide, and developing standards for trial registers.

ACTR contribution recognised

In an article published in the Lancet on 20th May 2006, Dr Richard Horton, editor of the journal, recognised the important contribution of the ACTR to the establishment of WHO registry platform (R Horton. Trial registers: protecting patients, advancing trust. *Lancet* 2006, 367:1633-5)

"Scientific Challenges in Trial Registration" meeting

In November, ACTR Manager, Lisa Askie, along with Davina Ghersi in her capacity as ICTRP Coordinator, were invited to a meeting in Virginia, USA, hosted by Clinicaltrials.gov. The meeting was attended by many key stakeholders including representatives from other registers in the USA, UK, Europe, South America and Israel as well as editors of major journals and representatives from the US National Library of Medicine, FDA, Institute of Medicine and others.

There was also a meeting of the ICTRP's Scientific Advisory Group and Registers Working Group in Kobe, Japan, in December.

Back row (left to right)
Prathap Tharyan, Toshiro Tango, John Cai, Rebecca Kush, Marc Taylor, Janet Wale, Luis-Gabriel Cuervo, Karmela Krleza-Jeric, Chris Chute, Gassan Karam, Gerd Antes, William Harlan, Frank Rockhold, Daisaku Sato, Nick Ide

Front row (left to right)
Esther Awit, David Moher, Elizabeth Wager, Davina Ghersi, Kay Dickersin, Soichiro Iwao, Richard Horton, Ida Sim, An-Wen Chan, Hélène Faure, Jeffrey Drazen

WHO ICTRP Scientific Advisory Group, Kobe Japan, Dec 2006

The keys issues discussed at either of these two meetings included possible mechanisms for:

- minimising (unplanned) duplicate trial entries both within, and across, registers
- ensuring data entered onto trials registers are valid and comply with the journal editors and WHO requirements
- ensuring registers are able to comprehensively capture all relevant trials within their constituency
- sharing data across registers
- results reporting

The issue of access to trial results and results reporting has been a topic hotly debated this year, particularly in the USA. In August, US Senators Mike Enzi and Edward Kennedy introduced legislation which, if enacted, would mandate trial registration and the public disclosure of trial results (the Enzi-Kennedy Bill). Several US States, including Maine and New Jersey, have also introduced regulations that would require drug companies to make the results of the trials they undertake publicly available if they wish to sell their products in that state. The reporting of adverse events is of particular concern to the public and these proposed laws are seeking to address this issue.

The issues surrounding the reporting of trial results are complex. On the one hand, public disclosure of all the raw data from every clinical trial might solve the problems of lack of transparency. However, how these data are then used, interpreted, summarised and even re-analysed or re-published raises many potential dilemmas. Finding a balance between ensuring intellectual, academic and commercial interests, whilst still ensuring full public disclosure of trial results in an easily digestible format, will be difficult. It is an issue that will no doubt be further discussed in the coming months.

The ACTR is carefully watching the international debate on this issue, but at this stage there are no immediate plans to include results on our database. Various models could be considered from simple links to a trial's full citation, published paper or trial website to more complex options.

Another important development for trials registry activity around the world occurred on 19th May 2006, International Clinical Trials Day. At that time, Dr Tikki Pang, Director of Research Policy and Cooperation at the WHO, announced two key WHO policy positions regarding trial registration. These were that *all* interventional trials, including phases I and II trials, should be registered, and that all of the 20 minimum registration data items must be publicly disclosed at the time of registration. The WHO considered that there was no compelling evidence for delayed disclosure of some data items as had been advocated by some groups including the pharmaceutical industry. These policies decisions were made following an extensive debate amongst the ICTRP Scientific Advisory Group and other major stakeholders (Sim I, Chan A, Gülmezoglu AM, Evans T, Pang T. Clinical trial registration: transparency is the watchword. *Lancet* 2006; 367: 1631-3).

6. Australian developments regarding trial registration

During 2006, several key documents relating to the conduct of clinical trials in Australia were under revision, including the NHMRC's "National Statement on Ethical Conduct in Research Involving Humans" and the "Australian Code for the responsible conduct of research". The current draft of the revised "Australian Code" document now contains the following clause:
" 5.9 Register clinical trials
Researchers must register trials with a recognised register to promote access to the results of all clinical trials."

The ACTR has been asked to provide advice and assistance to several registers around the world during 2006. In addition, ACTR directors and staff were invited to give several presentations during the year regarding the ACTR's activities and trial registration issues in general, including:

- MS Research Australia (MSRA) Clinical Trials Workshop
- Association of Regulatory and Clinical Scientists (ARCS) Annual Scientific Meeting
- Australasian Health and Research Data Managers Association (AHRDMA) Annual Scientific Meeting
- Centre for Perinatal Health Services Research, University of Sydney, seminar

5. Citing your ACTR number

At the meeting held in Virginia in November (see page 1), Cathy de Angelis, Editor-in-chief of JAMA, discussed how journal editors are taking the matter of trial registration very seriously. She described how at manuscript meetings, the editors now routinely look up a trial's registration record via the website when they review manuscripts submitted for publication.

Hence, it is advisable to cite your ACTR number in all correspondence with journals and other relevant organisations.

6. ACTR Advisory Board

The direction of the ACTR is overseen by an external Advisory Board. The ACTR Advisory Board has 14 members which represent a wide variety of stakeholders including researchers, clinicians, consumers, academics, government, journal editors, regulators, funders and industry. Professor Terry Nolan, a member of the NHMRC Research Committee, is the Chair of the Board.

The inaugural ACTR Advisory Board meeting was held in Sydney on 10th July 2006 and a summary of that meeting will be placed on the ACTR website as soon as it is available.

7. Proposed plans for 2007

The ACTR Board endorsed the current Operational Plan at it's July meeting.

Further developments planned for 2007 include:

- database / website improvements (such as more advanced searching, improved 'Help' systems, establishing procedures for updating trial information)
- potential linkage to specialty registers
- extensive stakeholder consultations regarding design and access to the ACTR

8. Contact Us

We welcome your questions, comments, suggestions and contributions on any matter relating to the Australian 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.actr.org.au

Finally ……

We would like to take this opportunity to thank all our stakeholders, funders and collaborators for your continuing support during 2006, and wish you all the best for the new year.

The ACTR Staff

Back row, L-R : Nicole Holcroft (Project Officer), Lisa Askie (Manager), Fergus Tai (Research Assistant), Jenny Chow (Executive Officer).

Front row, L-R : Opal Thongyoo (Research Assistant), Emma Smith (Project Officer).

