ACTR Australian Clinical Trials Degistry

Australian Clinical Trials Registry

1. From the ACTR Manager



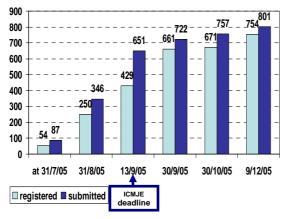
Welcome to the first issue of the Australian Clinical Trials Registry (ACTR) newsletter! We hope you enjoy this short summary of our activities in 2005.

Lisa Askie

2. Overview of the ACTR

The Australian Clinical Trials Registry has been established at the NHMRC Clinical Trials Centre, University of Sydney, with funding from the Australian Government, through a National Health and Medical Research Council (NHMRC) Enabling Grant.

The ACTR includes trials from the full spectrum of therapeutic areas including pharmaceuticals, surgical procedures. preventive measures. lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. lt has trials nationwide coverage all clinical involving Australian researchers or Australian participants. Trials that do not involve Australian researchers or participants are also accepted.



3. Number of trials registered

Table of contents

- 1. From the ACTR Manager
- 2. Overview of the ACTR
- 3. Number of trials registered
- 4. Website and database improvements
- 5. International developments
- 6. Trial registration and Ethics approvals
- 7. Proposed developments in 2006
- 8. Contact us

4. Website and database improvements

The initial version of the ACTR was developed within a very limited timeframe in order to meet the <u>International</u> <u>Committee of Medical Journal Editors</u> (<u>ICMJE</u>) deadlines for registering new and ongoing trials (see previous graph). A more stable database system has now been implemented. ACTR "version 2" has improved the search functionality and user-friendliness of the website.

The ACTR database and website have received very positive feedback from key groups internationally. Papers presented at two major conferences (International Congress in Peer Review, Chicago USA, and Cochrane Colloquium, Melbourne) assessed various trials registries worldwide and indicated that the ACTR was the only registry that technically complies with the ICMJE requirements. The ACTR's quality control processes to ensure the accuracy and completeness of registered data are held in high regard.

5. International developments

During 2005 there have been considerable efforts internationally to standardise the content and quality of trials registries. This has been led by the WHO International Clinical Trials Registry Platform (ICTRP). The main components of the ICTRP involve standards for trial registration, a proposal for a universal, unique trial reference number, membership criteria for network of registers, and а the development of a one-stop search portal for searching registers worldwide.

The ACTR has taken a leading role in this initiative with Davina Ghersi being invited to join the ICTRP Scientific Advisory Group (SAG) which met in Geneva in November 2005. At that meeting the SAG re-considered the minimum data items for trial registration. Once finalised, the SAG meeting report will be posted on the ICTRP website.

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

6. Trial registration and Ethics approvals

Many Australian Ethics Committees now include a question about prospective trial registration on their application forms. Notably, such a question is included on the statewide Victorian Department of Human Services Human Research Ethics Committee common application form used by most hospitals in Victoria, and by Queensland Health.

Similarly, Sydney South West Area Health Service's revised Ethics Committee application form also includes a question regarding trial registration.

If you know of other Ethics Committees that ask about trial registration on their application forms, please let us know.

7. Proposed developments in 2006

The direction of the ACTR in 2006 will be overseen by an external Advisory Board once its membership is finalised. This 13 member Board will consist of a wide variety of stakeholders representing researchers, clinicians, consumers, government, journal editors, regulators, funders and industry. The first Board meeting will take place in early 2006.

The following developments have been proposed by the ACTR management for discussion and possible implementation in 2006:

- further database / website improvements (such as more advanced searching, improved 'Help' system, establishing procedures for updating trial information)
- potential linkage to specialty registers
- development of a detailed communications / dissemination / promotion strategy
- extensive stakeholder consultations regarding design and access to the ACTR.

We would appreciate any feedback you can give us regarding opportunities for stakeholder consultation. If you have any suggestions regarding groups, institutions, organisation or individuals who would be interested in talking to us about the use of the ACTR, please contact us at the ACTR feedback site:

http://www.actr.org.au/feedback.aspx

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

Please visit our web site at: www.actr.org.au

Finally

2005 has seen major steps forward in the establishment of a comprehensive, national, on-line prospective registry of all clinical trials in Australia, but much work is still to be done to complete the final version of the Australian Clinical Trials Registry.

We would like to thank everyone who has contributed to the success of the ACTR over the past year and wish you all the best for 2006.

The ACTR Team



Back row, L-R: Lisa Askie (Project Manager), Jenny Chow (Executive Officer), Davina Ghersi (Director), Emma Smith (Project Officer).

Front row, L-R: Nicole Holcroft (Project Officer), Fergus Tai (Research Assistant), Opal Thongyoo (Research Assistant).