

Australasian Kidney Trials Network NEWSLETTER

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Australasian Kidney Trials
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Message from the Chair of the Operations Secretariat— NHMRC SUCCESS!

Dear Colleagues,

Welcome to the 2nd edition of the AKT Network Newsletter.

We are pleased to announce that we have been successful in obtaining funding through an NHMRC enabling grant. This is very exciting as it will provide us with the resources required to better pursue our goal of facilitating clinical trials in kidney research.

Since the commencement of the trials' network we have had 9 trial proposals submitted for consideration by the Network. The majority of these submissions have requested AKT Network Coordination. The trials have been in the fields of dialysis (5), and chronic kidney disease diagnosis and treatment (4). Two of these trials have been voted on to progress to the next phase of full protocol development. In order to protect the intellectual property of the proposer, specific trial details will not be available until the trials have progressed further. I would like to take this opportunity to further encourage members of the Network to submit protocols for consideration

We are also pleased that we now have a full complement of members of our Advisory Board & Scientific committee. As always, I am always happy to hear from you to discuss any issues relating to the Network's operations.



Dr Carmel Hawley

Chair, Operations Secretariat

Clinical Trial Education Workshop at ANZSN

The AKT Network will be holding a Clinical Trial Education Session preceding the ANZSN Annual Scientific Meeting in Wellington this September.

The Workshop will be held from the morning of September the 3rd until the afternoon of September the 4th at the Duxton Hotel in downtown Wellington.

Sessions will be presented by experienced researchers with expertise in the running of clinical trials in kidney disease. This course is designed for anyone interested in becoming more involved in clinical trials, or someone wanting to update their knowledge.

A program can be accessed on the AKT Network website.

The low cost of \$55NZ will be charged for AKT Network members. For non-members, the cost of the course will be \$550. For more information please contact Daniel Francis.

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AKT Network website—www.aktn.org.au

The AKT Network website is finally up and running at www.aktn.org.au. The members section is still under construction, however you can find plenty of useful information on the networks aims, processes and functions.

If you have any questions about how the network works or want to check up on a current AKT Network policy, this is the place to go.

There are also links to submission forms for proposing your trials to the network.

As the network grows, the website will be continually updated so keep a lookout for any changes. If you have any questions, or comments please contact Daniel Francis at d.francis@uq.edu.au.

Clinical Trial Registration

In April, editors of six journals of kidney diseases, dialysis and transplantation (JASN, Nephrology Dialysis Transplantation, The American Journal of Transplantation, The American Journal of Kidney Diseases, Kidney International, and Transplantation) published a policy outlining requirements for clinical trial registration as a condition of consideration for publication in their various journals (Couser et al 2005). This follows a September 2004 statement by the International Committee of Medical Journal Editors, mostly representing general medical journals, requiring registration of clinical trials for consideration in their journals (De Angelis et al 2004).

These steps are aimed at reducing the selective publication of trials, a phenomenon that distorts the body of evidence available for clinical decision making. Registration of clinical trials, will place them in the public record and hopefully improve access to results of trials regardless of the outcomes.

Each trial must therefore be registered in a registry that meets six criteria outlined in the statements;

- 1) Accessible to the public at no charge
- 2) Searchable by standard, electronic (internet-based) methods
- 3) Open to all prospective registrants free of charge or at minimal cost
- 4) Validates registered information
- 5) Identifies trials with a unique number.
- 6) The registries must include information on: the investigator(s), research question or hypothesis, methodology, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date of last follow up, target number of subjects, status (anticipated, ongoing or closed) and funding source(s)

A number of such registries exist. It will be AKT Network policy to register our trials with the Cochrane Renal Group registry. Information on this registry and a trial submission form can be found at <http://www.cochrane-renal.org/trialsubmissionform.php>

Jonathan Craig
Daniel Francis

References

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DNT workshop

The Scientific Committee of the AKT Network met at the DNT workshop held at Couran Cove in March. A number of important issues were on the agenda to help ensure that the network can act with maximum effectiveness in facilitating clinical trials in kidney disease.

A number of policies have since been adopted and these can be viewed on the AKT network website at <http://www.aktn.org.au/index.html?page=27243>.

A major issue for the network is the differentiation between coordinated and endorsed trials and what this means in terms of network responsibility and resources. Details of this policy are outlined below.

Dr. Carmel Hawley, Chair of the Operations Secretariat was given the opportunity to present on the Tuesday morning of the workshop. Her presentation outlined the aims and objectives of the network, the roles and responsibilities of the three committees, and our policies regarding endorsed and coordinated trials and the protection of intellectual property. We are grateful to the DNT subcommittee for this opportunity to present on the AKT network.

The powerpoint slides of this presentation can be found at <http://www.uq.edu.au/aktn/index.html?page=31124&pid=27242>.

Endorsed or Coordinated Trials

One of the issues discussed by the Scientific Committee at the DNT workshop was the differences between these two categories of AKT network trials. These differences are summarised below.

Coordinated trials will utilise network resources to develop and run the trial. A coordinated trial may be proposed by any member of the AKT network. The proposal will proceed through the trial review process (see page 4) and will have the full resources of the network available to develop and run the trial. Data is generally managed, or coordinated centrally. A trial management committee will be formed to develop and run the trial to the rigorous standards of the AKT network. Assuming the trial proposer wishes to act as the equivalent of a principle investigator, they will be chair of the trial management committee.

In Endorsed trials, the network will offer assistance in some aspects of trial design, but will not run the trial, or manage the data. In endorsing a trial, the network indicates its support for the aims and objectives of the trial. Typically, support will be in the form of trial design, bio-statistical advice, or aid in bringing together a network of trial collaborators.

More information, including policies relating to publication and authorship of endorsed and coordinated trials can be found on the AKT Network website at www.aktn.org.au,

Trial Approval Process

The AKT Network seeks to facilitate the conduct of high quality clinical trials in kidney research. To ensure that trials are developed to the high standard expected of the AKT Network, that they are clinically relevant, that trials and trial proposers are treated fairly, and that AKT Network resources are spent in the most efficient means possible, a trial approval process has been developed. The process for an AKTN coordinated trial is shown graphically in the figure below.

As can be seen there are three phases to the process. At the Concept Phase preliminary information on a trial idea is submitted to the Network with the Scientific Committee voting on whether or not this idea should be pursued. The idea of this phase is to avoid enormous amounts of time and resources being invested into a trial that has little chance of being accepted for initiation. The Development Phase involves the development of a full protocol. Based on this, the Scientific Committee will then decide on whether the trial is to go ahead. An approved trial then moves into the Initiation phase when the trial is conducted. More details of this process can be found on our website.

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