Forming networks for research: proposal for an Australian clinical trials alliance

A research network could improve outcomes through advocacy, identifying research gaps and providing shared infrastructure

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Research benefits from both competition and collaboration. Inefficiencies occur when researchers are engaged in similar research, often not realising that other groups in Australia are working in the same area. For example, it is possible that there are competing clinical trials in uncommon cancers, which will decrease the chance of any individual study recruiting adequate numbers of patients to answer the questions it poses. In May 2012, the *Medical Journal of Australia* hosted the *MJA* Clinical Trials Research Summit. This article was written on behalf of contributors to a working group discussion on networking held during that summit.

There are enormous advantages for clinical researchers working together in networks. Centralised coordination and accumulation of data will provide both greater statistical power to answer common research questions and opportunities to resolve uncertainties about hard clinical end points with the greatest impact on participants' lives. Centralising these functions allows clinical trials to be performed efficiently. Important roles for research networks are summarised in the Box.

It would be easiest to form and sustain networks if there were an umbrella group to help foster such networks, and a business case can be derived to support this.[1] Such an umbrella group could advocate for the importance of clinical research in improving health care for all Australians, provide the infrastructure to maintain local clinical research networks, and help foster and maintain new clinical trials sites. An umbrella group could help to leverage additional funding from government, community and commercial sources for worthwhile research projects. Additional funding could also assist in bringing groups in similar research fields together, in providing access to common resources and experienced staff, in enabling collaboration to develop standard operating procedures, and in helping groups to obtain access to databases and web-based (and e-health) functionality. Biostatisticians and methodologists could be shared between groups.

A central overview of the research proposals of research groups in the network may identify projects that would be best funded by project grants as opposed to those that could be part of larger program funding. Even in the short term, a coordinating group could help local researchers add value to their clinical trials by linking them with experts in building quality-of-life studies into phase III trials, or adding DNA or epigenetic substudies, which can add significant value when nested into the original study design. All these opportunities can only be realised by bringing together people whose work may otherwise be in very different arenas.

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Roles for a research network

- Networks of researchers formed will be more effective at promoting a research culture and securing sustained funding.
- An umbrella group should be responsible for:
  - providing centralised expertise
  - biostatistical support
  - adding value to clinical trials by identifying substudies
  - bringing the networks together to explore common interests. ◆

An umbrella group may help enable clinical data and pathology records to be linked with established blood, DNA, and tissue banks, and help to form new biobanking resources and expertise. The most common data linkage is between cancer registries and death registries so that incidence and survival data are linked. Tissue banks allow linkage of pathology specimens with clinical registry data to explore prognostic factors. These linkages must be governed by policies protecting the privacy of individual data, which should be de-identified in the final reports. There is also the opportunity to link existing disease-specific trials groups, such as in the Australasian Stroke Trials Network or the Australia and New Zealand Breast Cancer Trials Group.

An umbrella group could bring together networks for scientific meetings and meetings on topics of common interest around the funding, infrastructure and management of clinical research. For example, a significant area of interest is the translation of research not only from the laboratory to the clinic, but from the clinic into economic and public policy. An umbrella group could help networks make the connections necessary to facilitate these aspects too.

The alliance we propose is not designed to prescribe the composition or governance of groups. However, it should add value by facilitating the development of clinical research groups and helping to achieve long-term funding to resource and sustain them. Networks of research groups could, for example, be formed within a specialty college or by special interest groups, or within networks of hospitals or universities. Some of the funding to support the research would come from within such groupings. Multiple models of networks would evolve to best fit the clinical research activity and existing clinical and research relationships. The sustainability of groups would be predicated on sharing the role of principal investigator across the centres in the networks

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for different studies, and continuing to attract young investigators into the networks and mentor them.

As connections between groups become well established, clinical research groups could mentor newly established groups. This would enable experience, adaptable resource materials and even infrastructure to be shared, which could help to ensure a more rapid route to productivity and world-class-standard research work for new trials groups. The ability to share infrastructure and even experienced research staff could make new initiatives less costly to undertake.

An alliance or umbrella group could also identify where gaps exist in clinical research funding. For example, it could identify research that still needs to be undertaken by understanding where evidence is lacking from practice guidelines, and knowing what trials are ongoing from trials registries. Further, an alliance could identify deficiencies in funding for specific levels of research personnel, such as mid-career researchers.

In the longer term, it is possible to envisage such an umbrella group facilitating the development of accreditation standards for clinical trials groups and their investigators. It could liaise with consumer groups to strengthen consumer input into clinical trials for the mutual benefit of aligning research directions with consumer priorities as much as possible. Currently, this happens only sporadically.

Funding for an umbrella group is a key issue. The National Health and Medical Research Council would be an ideal body to consider this, and has previously had schemes such as enabling grants and program grants to fund large initiatives involving groups of researchers. What is needed is sustainable infrastructure funding to give stability to the clinical trials networks and their research teams, and to allow planning of not only Phase I to Phase IV clinical trials, but also larger longitudinal clinical studies, which are also necessary to inform clinical practice.[2] It would be unreasonable for one body to be expected to provide all of the funding required, so the umbrella group must be able to leverage funding from the spectrum of parties involved in clinical trials.

An important role for an umbrella group for clinical trials is advocacy, to encourage support for clinical research itself. This involves not only showing the clinically beneficial outcomes of trials that better inform health care for patients with similar conditions, but also the high return on investment that has already been shown by putting the results from clinical trials into practice. Highlighting the better outcomes that have been reported in patients participating in centres with trials programs is a major factor. Key partners in this advocacy are patients and their families, particularly those who have been involved with research and have personally experienced its benefits.

More than just advocating for funding, the umbrella group would be promoting a culture of research in all health care settings, including in primary care and in our hospitals, where the challenges of funding patient care in the short term can become all-consuming. Research not only leads to improved medical outcomes in those hospitals that participate in trials, but is cost-effective because even the control arm of a randomised trial often attracts funding that can save on routine care costs.[3,4]

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