Strategic Roadmap for Research Infrastructure

NHMRC CLINICAL TRIALS CENTRE
Comments on Discussion Paper

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The NHMRC Clinical Trials Centre, an academic research organisation with 20 years of experience in the design, development, management and analysis of investigator-initiated clinical trials (IITs) nationally and internationally, takes this opportunity to comment on the Strategic Roadmap for Research Infrastructure 2011 of the Department of Innovation, Industry, Science and Research. The focus of our comments relate to the area of ‘Promoting and Maintaining Good Health’.

The Promoting and Maintaining Good Health National Research Priority (NRP) is aimed at promoting good health and well being for all Australians: including priority goals in a Healthy start to life; Ageing well, ageing productively; Preventive healthcare; and Strengthening Australia’s social and economic fabric.

In promoting and maintaining good health, the development of effective preventative and treatment strategies aimed at improving health practice and health policy is key to achieving and maintaining better health outcomes. This research effort involves the translation of new scientific discoveries into better treatment strategies, determining which strategies represent real advances in effective health care though well conducted clinical research trials and maximising the use of solid trial evidence in informing best practice and policy.

Consequently, research infrastructure to support clinical trials research effort and the translational research sciences are essential to maximise potential health gains from new discoveries and new trial evidence. This includes building and maintaining capacity in special areas of expertise (such as biostatistics, bioinformatics, health economics, clinical epidemiology, clinical trial operations) as well as specialised infrastructure in linked databases across clinical trials, biological data and clinical outcomes.

Clinical trials research that is of national importance should include evaluations addressing key public health questions in key therapeutic areas & populations including those testing
promising, low-cost, unpatented or out-of-patent drugs or interventions in common conditions, otherwise unlikely to receive commercial investment. These trials would be large randomised clinical trials requiring significant investment but with the potential to provide highly cost-effective solutions to health care.

What are your views on the key future directions identified and are there other key areas that have not been included? What are your views on research infrastructure capability areas identified, including relative priority and their ability to support the current and future research needs?

With the explosion of new health technologies and in the face of finite resources, for Australia to be at the forefront of research and knowledge we need to be able to i) identify optimal treatments and to develop therapeutic strategies from basic science discoveries and ii) ensure effective treatments are translated into best practice. For this, we need:

- Specialists in clinical epidemiology, biostatistics, translational research sciences,
- Critical mass in these areas to ensure cross fertilisation of ideas and experience
- Capacity building and training programmes to increase the skills and knowledge
- Integrated networks across disciplines and institutions.

National Biobanking

We support a National biobank consisting of biospecimens from patients participating in clinical trials, across all therapeutic areas including cardiovascular disease, diabetes and oncology. The strength lies in the accompanying detailed and high quality clinical data, far greater than the minimum clinical data sets typically obtained with non-trial patient samples. The biospecimens (including tissue, blood samples) would be available for peer-reviewed research. The biobank would consist of:

(a) Physical Biobanks – to store biospecimens
(b) Virtual Biobank - to provide a ‘one-stop-shop’ where information can be found on the type of biological material (eg fresh tissue, formalin-fixo paraffin embedded blocks, serum, plasma etc) and the extent of linked clinical information for that clinical trial patient for samples stored at multiple sites

What are your views on eResearch infrastructure identified including relative priority and ability to support current and future eResearch needs?

- An e-research infrastructure to facilitate and accelerate researchers to setup and conduct investigator-initiated clinical trials across Australasia would be beneficial. These types of clinical trials complement those that are run and sponsored by commercial entities.
- Access nationally for all investigators of simple user friendly software specific for clinical trials data collection and management in addition to providing hosting facilities for these studies and simple national registration process for access rights
- In addition, enabling research-based access to medical records for downloading of patient data (rather than transcription which is the current inefficient & error-prone practice) for which patient consent has been obtained
What are your views on cross disciplinary requirements identified including their relative priority and ability to support current and future needs?

- We agree that the research groups listed in the Strategic Roadmap for Research Infrastructure 2011 ie biomedical, clinical, population and public health researchers are very important in clinical research.

- We propose that significant infrastructure support should also encompass biostatisticians, clinical epidemiologists, clinical investigators, health economists and translational health scientists and their technologies.

- There is a need for support for large research centres of excellence encompassing groups with cross-disciplinary expertise to facilitate the intellectual exchange necessary to achieve this goal.

These research personnel are important for:

- The critical assessment of where the gaps in current medical research are and which areas will have the most potential for impact, requiring greater investment. This requires investment in health economics, clinical trials design, access to information on what current is being conducted and where.

- The design of clinical studies to define the optimal use of technologies including molecular, genomic and other ‘–omic’ research, and to identify the most suitable patients for therapeutic treatments. These are rapidly expanding fields and capacity building in these areas is critical if Australia is to remain at the forefront of this research.

- Infrastructure investment is also required for the development of economic models to provide information on the budgetary impacts of new interventions in the Departments of Health and other portfolios.

- Biostatisticians, Health Economists and Epidemiologists are critical to the conduct and interpretation of high quality clinical research. For example, with new health technologies and expensive drugs being developed and becoming available, greater demands are placed on government to fund these. With limited financial resources, assessment must be made not only of whether the treatment is clinically effective but also whether it is cost-effective and in what circumstances, thus placing health economics in an integral part of translating innovations into widest clinical practice. Infrastructure to support this work and capacity building for greater expertise in this area is needed.

- Equally, there are also substantial gains to be made to be made through low cost interventions which may be highly cost effective and lead to significant improvements in population health, some with potential savings over current treatment and the flow-on benefits of improved health to other sectors through gains in productivity.
The idea of a nationally structured and networked clinical research structure which has a nationally coordinated focus and culture is particularly relevant in Australia with its relatively small population. Many Institutes and Centres are currently functioning in isolation, in competition and/or within University or Hospital structures which are not primarily focussed on facilitating national or international health research priorities. A similar Australian model of the USA’s National Institutes would provide the opportunity to create and nurture a national focus on identifying and conducting the best research, in an organisational culture which has a singular objective and is not constrained by competition or conflicting organisational cultures. Knowledge and expertise could be networked through infrastructure investment which would add value across all research centres nationally.

Such a network would require policy and funding support at the institutional, state and federal level. Infrastructure investment would include communications networks, high powered computers, national software. This would have the express purpose of sharing expertise, developing improved methodologies, sharing data sets and ideas and generating high quality national and international research and reports to meet national priorities for the benefit of government, industry, clinical practitioners and the Australian public.

The potential benefits of an increasingly skilled national network of expertise are many and include; higher levels of cross disciplinary and cross functional cooperation and the positioning of Australia as an attractive ‘one stop shop’ clinical research hub offering flexible and wide ranging resources for national and international initiatives. For example, the Biostatistics Collaboration of Australia offers a national Masters in Biostatistics which is administered nationally across a number of Universities, and demonstrates that there is the potential for national cooperation.

**National collection of minimum clinical data sets**

- We support the collection of clinical information on patients in priority clinical areas, including patient treatment, and the better use of eHealth systems to monitor treatments and outcomes and evaluating this information in the context of clinical trials
- And nationalised cancer and other morbidity registers (adequately staffed and supported by appropriate hardware & software) to facilitate access for national studies, rather than current hospital/state based approaches which are not fully standardised.
- And infrastructure investment to enhance the national clinical trial registry to ensure optimal use and strategic planning of clinical trials research

**Linkages between research disciplines**
We support expanding linkages across disciplines and across institutions eg for clinical trial registries and biological data. More detailed comments have been made in the Clinical Trials Action Group report.
APPENDIX – What is the NHMRC Clinical Trials Centre?

The NHMRC Clinical Trials Centre (CTC) has a 20 year history in designing and leading investigator initiated international clinical trials research with collaborating partners throughout Australia and overseas. Increasingly this research involves translating new discoveries and new ideas into better treatments and translating the evidence of clinical trials into better clinical practice and health policy.

The NHMRC CTC aims to bring together research conducted in multiple areas at the laboratory bench, clinical research and translating evidence in to clinical practice, such that the each area can inform future research in those other areas too.

The NHMRC CTC has research capabilities include:

1. The Australian New Zealand Clinical Trials Registry (ANZCTR), the first national clinical trials registry, was established by the CTC and is managed and hosted here. It is well placed to use to monitor gaps in the clinical trials space.
2. Expertise in biostatistics in the design and analysis of clinical trials
3. Expertise to oversee, monitor, review and provide advice on clinical trials research
4. Track record in investigator-initiated trial design and coordination. Over the past 20 years, the NHMRC CTC has conducted 65 trials, recruiting a total of 68,000 patients in therapeutic areas of cardiovascular disease, diabetes, neonatology and oncology.
5. Proven track record of clinical trials changing clinical practice.
6. Capacity to personalise care based on new technologies (from bench to bedside).
7. Expertise to incorporate health economic assessment into clinical trial design and the clinical research program
8. Expertise and capacity to evaluate trial evidence through systematic reviews and guide clinical practice and health policy

The CTC also contributes to research training and education effort through online post graduate degrees including: Masters in Biostatistics (G08); Masters in Clinical Trials (commencing 2011).

It works closely with national and international research collaborators including several oncology collaborative groups (AGITG, ANZGOG, ANZUP, ALTG, COGNO, ANZBCTG, PC4) and many international groups in oncology, cardiovascular disease, diabetes and neonatal medicine.

Further details are available at www.ctc.usyd.edu.au