



Australian Government

Clinical Trials Action Group

Discussion Paper Four

Strategies to Improve Patient Recruitment

November 2009

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Consultation process

The Government is seeking feedback and comments on options outlined in this paper. The options have not received Government approval and are not law. Feedback and comments received will help to inform the Government's proposed approach on the way forward.

Making a submission:

Submissions on this paper are requested by: Friday, 12 February 2010

Submissions can be sent to:

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Strategies to improve patient recruitment

Purpose - the development of strategies to increase patient recruitment for clinical trials.

Background

‘Australia faces difficulties in recruitment for late stage clinical trials, including inefficient access to potential volunteers, often due to a lack of strong referral networks.’¹ Furthermore it is not uncommon for a few or no patients to be recruited to a site that has been granted approval to conduct a clinical trial.

There are clinical trial networks around Australia that could be used to attract patients to participate in clinical trials (see **Attachment 4A**). The Victorian Clinical Trials site, the NSW Cancer Trials Network and the Queensland Clinical Trials Network are some examples of state based efforts to inform the public of clinical trials. The National Health and Medical Research Council (NHMRC) have funded clinical trial networks for particular therapeutic areas (e.g. the Australasian Sleep Trials Network, TROG Cancer Research Network) but patient recruitment has not been their primary role. Clinical trial networks are generally established around a particular therapeutic area and may have dedicated infrastructure and support staff.

In recent years public clinical trial registers have been more commonly used, for example the Australia and New Zealand Clinical Trials Registry (ANZCTR) and clinicaltrials.gov. These registers have the potential to be used primarily for patient recruitment for clinical trials. Web based clinical trial recruitment agencies whose primary function is recruitment have also emerged (e.g. Clinical Trials Connect and Rewards for Research) which list clinical trials that are being conducted in Australia.

Additionally, it may also be useful for health professionals, such as general practitioners and clinicians, to have access to a system that will inform them of trials that are recruiting in their area to increase the referral of relevant patients to clinical trials.

What are the effective patient recruitment mechanisms in Australia? Can they be expanded? What are the lessons to be learnt from existing patient referral networks?

Are there other ways to increase patient recruitment? Are there effective international patient recruitment mechanisms that can be tailored for Australia?

Is it feasible to better link existing clinical trial sites from the same therapeutics area or capability?

What are the effective mechanisms for patients to register their interest for involvement in a clinical trial? Do they exist in Australia?

Do general practitioners need to be better engaged in clinical trials? If so, how?

¹ Pharmaceuticals Industry Strategy Group final report, December 2008 (p. 44)

Way forward

The Pharmaceuticals Industry Strategy Group (PISG) report recommended the establishment of co-ordinated patient referral networks. 'Some States have existing patient referral networks in particular therapeutic areas, but there is not sufficient collaboration between the partners or between the networks and the States to create a sufficient benefit or increase patient referrals to industry initiated clinical trials.'²

Industry believes that co-ordinated recruitment networks would increase Australia's capacity to conduct clinical trials and avoid costly recruitment delays. Such networks could function as:

- A co-ordination mechanism for companies seeking to conduct trials in Australia; and
- Referral networks for accommodating specialised subsets of diseases and/or priorities in public health.

It has been suggested that patient referral networks be established by therapeutic area, recognising the differences in patients, doctors and trial designs in different areas. Several stakeholders have recommended developing a national patient referral network initially in a single therapeutic area and then moving into other areas as success in the first is realised. Networks will work best in disease states that are very difficult to treat, e.g. cancer and multiple sclerosis, where current options have limited efficacy as clinical trials can provide increased options for treatment. It has also been suggested by industry that patient referral networks should align with national health priorities. The establishment of GP involvement in a patient referral network is seen as essential by many industry stakeholders.

Some stakeholders have suggested Australia should follow the UK National Institute of Health Research Clinical Research Network (NIHR CRN) (www.ukcrn.org.uk) approach for the development of networks in Australia. The NIHR CRN Coordinating Centre works with key partners in Scotland, Wales and Northern Ireland to aid the transformation of the clinical research environment across the whole of the UK. The NIHR CRN focuses on developing clinical research infrastructure as well as promoting the importance of clinical trials to doctors and the public, and is part of the broader development of the medical research environment in the UK. However, other stakeholders have questioned the appropriateness of an NIHR CRN model in Australia, where a state-based health system exists.

Stakeholder groups have said that the Australian public has a negative perception of clinical trials due to a lack of understanding and interest. It is suggested that direct promotion and advertising of clinical trials by pharmaceutical companies would be received poorly by the public, and therefore there may be a role for government or health professionals in raising awareness of clinical trials on a national level.

Since 2005, the Australian, state and territory governments have been investing in key building blocks for a national e-Health platform. E-Health will facilitate an electronic data capture, storage and management system to make health related information and statistical data more accessible. The proposed Individual Electronic Health Record (IEHR) may have opportunities for consent based referral systems. E-Health could

² Pharmaceuticals Industry Strategy Group final report, December 2008 (p. 77)

also capture epidemiological data which could assist in directing health research and patient recruitment.³

What is the scope for improving patient recruitment through the introduction of e-Health?

Possible approaches to improving patient referral and recruitment in Australia incorporating lessons from international models may include:

1. Establish clinical trials networks with a patient referral function:

- Conduct further research into existing clinical trials networks and the possibilities of grouping or linking them to form national networks; and
- Consider an enhanced role for the NHMRC in funding and establishing clinical trials patient referral systems.

2. Improve public awareness and develop a comprehensive trial database for self referral, which may include:

- Development and promotion of a clinical trials public awareness website;
- Development and promotion of a comprehensive database of clinical trials conducted in Australia; and
- Explore how self-referral databases can be integrated into e-Health record databases.

3. How can e-Health, privacy and standards be combined?

- Understand the technical possibilities (or limitations) of an electronic clinical trials patient referral system, taking into consideration the different standards in the various jurisdictions;
- Simplify and standardise e-Health related and statistical data throughout Australia; and
- Privacy Commissioner to provide advice on access to patient data for trial feasibility and recruitment.

³ <http://www.nehta.gov.au/>

ATTACHMENT 4A

Clinical Trials/Patient Referral Networks by Australian, State & Territory Governments

Federal

The NHMRC (www.nhmrc.gov.au) Clinical Trials Centre (CTC) was established in 1988 as a research unit of the National Health and Medical Research Council (NHMRC). It is affiliated with the Faculty of Medicine, University of Sydney.

The Australian New Zealand Clinical Trials Registry (ANZCTR) is an on-line register of clinical trials being undertaken in Australia and New Zealand (www.anzctr.org.au).

National

Rewards for Research Pty Ltd (www.rewardsforresearch.com) is a national clinical trial recruitment consultancy servicing organisations conducting clinical trials.

Australia New Zealand Breast Cancer Trials Group (www.anzbctg.org).

QLD

The **Queensland Clinical Trials Network Inc.** (QCTN) is the primary point of contact for domestic and international organisations seeking to undertake preclinical and clinical research in Australia (www.qctn.com.au). The QCTN was set up with funding by the QLD Government.

NSW

The **NSW Clinical Trials Business Development Centre** (ClinicalTrialsNSW) was created in 2007 and is an initiative of the NSW Government (www.clinicaltrials.org.au).

The **NSW Cancer Trials Network** (NSW CTN) was established by the NSW Government to provide NSW cancer patients with access to clinical trials. **Cancer Trials NSW** falls under the NSW CTN.

The **Multiple Sclerosis Research Australia Clinical Trials Network** (MSRACTN) was established by MS Research Australia (MSRA).

Victoria

Nucleus Network (www.nucleusnetwork.com.au) is funded by Clinical Trials Victoria (www.business.vic.gov.au). **Cancer Trials Australia** (www.cancertrialsaustralia.com) is part of the Nucleus Network.

Victorian Cancer Trials Link (www.cancervic.org.au/trials) is run by the non-profit organisation Cancer Council Victoria (www.cancervic.org.au) and the Victorian Cooperative Oncology Group. Both received funding from the Victorian Cancer Agency (Victorian Government) for this project.

WA

The **Western Australia Cancer Clinical Trials Registry** (WACCTR) was established by the Cancer Council WA and the Western Australian Clinical Oncology Group. It is an online register listing cancer clinical trials open in Western Australian hospitals (www.cancerwa.asn.au/patients/clinicaltrials/wacctr).

University of Queensland Clinical Trials Centre (www.uq.edu.au/qctc).

SA

The South Australian arm of the Cancer Council Australia has a national data base to search for clinical trials. It is not clear where the data is derived from (www.cancersa.org.au).