



Australian Government

Clinical Trials Action Group

Discussion Paper One

Developing a Clinical Trials Roadmap

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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Canberra ACT 2601

Or emailed to: pharmaceutical@innovation.gov.au

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Developing a clinical trials roadmap

Purpose - the development of a national clinical trials roadmap, which prioritises and co-ordinates the many initiatives and stakeholders involved in clinical trial operations, to best leverage the varied public investments in clinical research, including a definition of roles and responsibilities for the recommendations of the Action Group.

Background

From regulating to providing funding and infrastructure to universities, hospitals, research institutes and companies, Australian Governments at Commonwealth, State and Territory levels are involved across the spectrum of clinical trial activities. The purpose of developing a 'Clinical Trials Roadmap' is to co-ordinate the wide spectrum of public investments and interventions to ensure they maximise the sector's performance as well as to learn from relevant initiatives overseas.

Key success factors for the Australian clinical trial sector

In developing a Roadmap, the Action Group should analyse the major determinants of Australia's clinical trial competitiveness for the next decade, and make recommendations on the key areas for Government action. These would include taking note of the Pharmaceuticals Industry Strategy Group (PISG) report recommendations on timeliness of trial approval, e-Health and patient recruitment, which are examined more closely in other Action Group discussion papers.

Additional 'success factors' (or impediments to success) to consider might include:

- Ability to provide solutions to specific public health needs, in particular mental health, lifestyle diseases, indigenous health, improvements in current clinical practice;
- Development of centres of expertise in key medical research capabilities (for example: translational medicines capabilities linked to clinical services);
- The increasing trend to outsourcing research by biotechnology and pharmaceutical companies and associated growth in contract research organisations;
- Pressures on research budgets generally, the impact this will have on clinical trials and the opportunities provided through appropriate standardisation;
- Australia's regulatory regime in the context of overseas efforts to streamline drug approval timeliness;
- International trends towards transparency of clinical trial results and increased post-market regulatory scrutiny for medicines and devices;
- Planned healthcare reforms to hospital funding, as recommended by the National Health and Hospitals Reform Commission (NHHRC);
- Availability of skilled clinical staff, and associated training needs;
- National co-ordination of policy on clinical trials across the Australian, State and Territory governments; and

- Ensuring an ongoing process to monitor the environment for clinical trials to ensure Australia's efforts to improve global competitiveness remain effectively targeted or highlight new trends that need to be addressed.

Are there any other key success factors for clinical trials in Australia?

Existing initiatives of Australian Governments impacting on clinical trials

Regulatory

- *Ethical and Scientific Review* – initiatives to harmonise and streamline ethics review have been undertaken both within state jurisdictions and nationally. The National Health and Medical Research Council's (NHMRC's) Harmonisation of Multi-Centre Ethical Review (HoMER) initiative to harmonise ethics (including scientific merit) and parts of research governance review across Australia has been a major effort involving stakeholders from the Australian, State and Territory governments, institutions and industry. With the design of HoMER now largely determined, it will be progressively implemented over the next 12 months (for more information on the regulation of clinical trials, see **Attachment 1A**);
- *Privacy* – the Australian Government recently responded to the Australian Law Reform Commission's Report, *For your information: Australian Privacy Law and Practice*. These reforms will have implications for the collection of and access to patient health information. It is recommended that the Action Group undertake detailed and urgent examination of the proposed reforms to establish their impact on the future options for trial establishment and conduct. The group may consider seeking advice from the Privacy Commissioner to determine options for progressing privacy issues in clinical trials.
- *e-Health* – legislation will be required to enable the Unique Healthcare Identifiers and Shared Electronic Health Records. Similar to privacy reforms, the Action Group may wish to monitor and provide input to the development of this legislation, to ensure that the system will facilitate the more efficient conduct of clinical trials through better assessments of trial feasibility and improved patient recruitment.

Direct Government support initiatives

- Grants for the conduct of clinical trials are available from the NHMRC.
- Australian government \$7.5m 'Boost Cancer Research' program, which is dedicated to providing industry independent clinical trials research in cancer treatment and care.
- The NHMRC Clinical Trials Centre provides support for investigator initiated trials.
- R&D Tax Concession.
- State and Territory industry development initiatives, for example:
 - The NSW Clinical Trials Business Development Centre; NSW Cancer Trials Network and other research networks;
 - The Victorian Government's 'Biotechnology Bridges initiative'; Clinical Trials Victoria (an initiative of Business Victoria); Victorian Cancer Trials Link (received indirect funding from Victorian Government through the Victorian Cancer Agency);

- South Australia’s Bio Innovation SA;
- Western Australia’s Biotechnology Industry Development Strategy; and
- Queensland’s ‘Biotechnology Sector Action Plan’, Biotechnology Advisory Council and Clinical Trials Network (QTCN).

Indirect Government support initiatives

- e-Health which has the potential to bring significant efficiencies in the running of clinical trials. For example in assessing the feasibility of clinical research projects or retrieving data from clinical trial participants.

Potential Additional Levers for future action

Government

- Australian Health Ministers Conference.
- COAG – for example: Better Competition and Regulation Working Group.

Industry

- How would industry be able to facilitate HoMER, e-Health, and patient referral networks?

Consumers

- Educate the general public about clinical trials and their value.
- Increase engagement with consumer groups and patient support groups.

Are there any other initiatives that support clinical trials in Australia?
 What other ways can Government, Industry, consumers and other stakeholders support clinical trials?

International activities to improve the operations of clinical trials

There are numerous initiatives from around the world aimed at improving the performance and attractiveness for investment. Some examples include:

- The UK National Institute of Health Research Clinical Research Network (NIHR CRN) (www.ukcrn.org.uk) aims to support clinical research and facilities throughout the UK in order to improve the research environment. 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 a broader renovation in the medical research investment environment in the UK. This initiative is working to improve the whole clinical trials environment in the UK including reducing approval times and providing support and guidance for clinical trials regulatory issues.
- Starting in December 2007, KoNECT is a Korean Government initiative that is spread across a number of relevant portfolios, established hospital research centres and networks.

It provides training programs for all levels of clinical research and funds the development of technologies that support clinical trials. The initiative is a collaboration between government, academia and industry. KoNECT aims at making Korea a global hub for clinical trials research. For more information see <http://www.konect.or.kr/eng/index.jsp>

- An assessment of the European Union's Clinical Trials Directive was announced in December 2008, to address issues of timeliness, cost and difficulty in conducting trials in member states. The European Commission has issued a Public Consultation Paper identifying key issues which include harmonising regulations across member states and ensuring compliance with good clinical practice (GCP) in trials performed in third countries. For more information see http://ec.europa.eu/enterprise/pharmaceuticals/clinicaltrials/clinicaltrials_key.htm
- The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have embarked on a pilot program to collaborate and share information on good clinical practice (GCP) inspections¹. The initiative is aimed at ensuring that clinical trials submitted in marketing applications in the US and the EU are conducted uniformly, appropriately and ethically. The partners outlined three objectives for the initiative: to conduct periodic information exchanges; to conduct collaborative inspections; and to share information on interpretation of GCPs.

What other examples are there? What are the possible lessons or implications for Australia?

¹ *Scrip: World Pharmaceutical News*, 'FDA and EMA to co-operate on clinical trial inspections', 5th August 2009

The Regulation of Clinical Trials

The *Therapeutic Goods Act, 1989* (the Act) requires most therapeutic goods (medicines and medical devices) to be approved and included on the Australian Register of Therapeutic Goods before they can be supplied in Australia. The legislation also allows access to therapeutic goods not included on the Australian Register of Therapeutic Goods through the conduct of clinical trials, subject to certain conditions under sections 18 and 19 of the Act. These sections provide for the operation of the Clinical Trial Notification (CTN) and Clinical Trial Exemption schemes.

The responsibilities of Human Research and Ethics Committees (HRECs) in relation to the CTN Scheme are set up under item 3 of schedule 5A of the Therapeutic Goods Regulations. Regulation 12AD sets out that the standard expected for all clinical trials are Good Clinical Practice as adopted by the International Conference for Harmonisation on Technical Requirements for Registration of Pharmaceuticals (ICH) and the Committee for Proprietary Medicines (CPMP), the protocol as approved by the HREC and the National Statement as adopted by the NHMRC.² In addition to the National Statement, the *Australian code for the responsible conduct of research 2007* has an essential role in promoting good research governance.³

State and Territory laws that may be relevant to human research include those relating to use of information held by state or territory authorities, use of human tissues, guardianship, and illegal and unprofessional conduct.⁴

² *Access to Unapproved Therapeutic Goods in Australia, Therapeutic Goods Administration, May 2001*

³ *National Statement on Ethical Conduct in Human Research, NHMRC, ARC and AVCC*

⁴ *ibid*