



Australian Government

Clinical Trials Action Group

Discussion Paper Two

Developing Key Performance Measures for Clinical Trials

November 2009

© Commonwealth of Australia 2009
ISBN 978 0 642 72543 1

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth. Requests and inquiries concerning reproduction and rights should be addressed to:

Commonwealth Copyright Administration
Attorney-General's Department
3-5 National Circuit
BARTON ACT 2600

Or posted at:

<http://www.ag.gov.au/cca>

DISCLAIMER

While all reasonable care has been taken in the preparation of the material in this document, the Department of Innovation, Industry, Science and Research and its officers and employees (DIISR) accept no responsibility or liability for any errors, misrepresentations or omissions it may contain, whether caused by negligence or otherwise, or for any loss, expense, payment or liability, caused directly or indirectly, which you may suffer, incur or become liable for as a result of relying on the information provided. The material is provided as a guide only and you should seek further independent advice before relying on the information.

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:

General Manager
Pharmaceuticals, Health Industries and Enabling Technologies Branch
Department of Innovation, Industry, Science and Research
GPO Box 9839
Canberra ACT 2601

Or emailed to: pharmaceutical@innovation.gov.au

For inquiries, please call:

Mike Phelan

Pharmaceuticals, Health Industries and Enabling Technologies Branch
Department of Innovation, Industry, Science and Research
02 6276 1508

While you may lodge your submission electronically or by post, the Department of Innovation, Industry, Science and Research (DIISR) prefers electronic lodgement. For accessibility reasons, please email responses in a Word or RTF format. You are welcome to submit an additional PDF version.

Confidentiality and publication of submissions

All information (including name and address details) contained in submissions may be made available to the public on the DIISR website unless you indicate that you would like all or part of your submission to remain in confidence. Automatically generated confidentiality statements in emails do not suffice for this purpose. Respondents who would like part of their submission to remain in confidence should provide this information marked as such in a separate attachment. A request made under the *Freedom of Information Act 1982* (Commonwealth) for a submission marked 'confidential' to be made available will be determined in accordance with that Act.

Developing key performance measures for Clinical Trials

Purpose - an investigation of the development of appropriate performance measures for clinical trials.

In considering this issue, the focus should be on the establishment of appropriate performance measures to allow benchmarking of Australian clinical trials efficiency and productivity, and the development of mechanisms for ongoing data collection in order to facilitate and support clinical research. This allows proper comparisons to be made with other clinical trials destinations and Australia's performance over time. This information would be useful to governments, industry and other stakeholders for future consideration in funding and other arrangements. Relevant international performance measures will also be considered.

Key Clinical Trial Performance Indicators

'When deciding whether to include a specific country in a global clinical trial, sponsors typically consider a number of factors, including medical professionals' level of interest in the relevant study; the size of the medical market; the influence of clinical investigators; and the necessary costs.'¹

'In 2004-05, the Research and Development Taskforce (RDTF) of the Pharmaceuticals Industry Council developed a "Four Pillar Model" – the pillars being quality, timeliness, value (cost), and capacity – to describe the key factors determining a country's attractiveness to global decision makers as a site for conducting clinical trials.'²

Findings from studies undertaken by the RDTF to establish Australia's performance against these four pillars include:

- The 2008 Global Competitiveness Benchmarking Survey - found that Australia's overall global clinical trial competitiveness is perhaps better than or similar to North America and Western Europe, but less than Eastern Europe. (But note that Canada and many countries in Western Europe are also facing a loss of trials.)
- Australia faces a challenging future with cost competitive locations emerging in the AsiaPacific region and Central/Eastern Europe. Global companies are reviewing their distribution of clinical trials in various countries to strike a balance between countries with more capacity and lower cost against countries that can provide more rapid start-up and greater scientific capability (with reasonable performance on cost and recruitment capability). Traditional locations for global trials (such as Western Europe) are losing ground to newer locations for trials (such as Asia and Eastern Europe) unless they can ensure they are meeting key performance indicators for clinical trials used by pharmaceutical companies.
- From 2008 figures, long times to start up clinical trials in Australia are evident – 30% of clinical trials sponsored by North American and 33% by European headquartered companies took greater than 6 months.

¹ Dr Harold E Glass, "The world's your clinical research oyster", *SCRIP*, 09 April 2009

² Report on the Pharmaceuticals Industry Council R&D Taskforce 4th Forum, March 2009, <http://www.pharmacouncil.com.au/resources.php>

- Comparing Australian start-up times with European and North American headquartered companies, European headquartered companies were 44% slower in Australia and North American headquartered companies were 36% much slower/slower in Australia.³
- For the 2006-08 period, set-up costs in Australia have increased. The main drivers for the increase in Australian set-up costs are institutional overheads, closely followed by governance and Human Research Ethics Committee fees.
- In 2008 an inaugural survey of investigator perceptions on the value of sponsored clinical research was conducted by the RDTF. The conclusions that can be drawn from the results of the survey are that industry funded trials create significant direct and indirect (spillover) benefits as reported by 187 researchers. To retain these benefits, Australian researchers, health administrators, government, and industry must focus on improving our global competitiveness.⁴

What clinical trial performance information should be collected? How, when and by whom?
How should this information be used to improve Australia's attractiveness as a destination for international clinical trial investment?

The National Healthcare Agreement (NHA) Reporting Structure

In November 2008, the Council of Australian Governments (COAG) endorsed a new Intergovernmental Agreement on Federal Financial Relations (IGA). The IGA provides an overarching framework for the Commonwealth's financial relations with the States and Territories.

The National Healthcare Agreement (NHA) is one of six agreements incorporated into the IGA. It is a single agreement between the Australian and all state and territory governments, and took effect on 1 July 2009. It will be reviewed every four to five years. The NHA extends across preventative, primary, sub-acute, acute and aged care and is intended to incorporate private sector services where relevant. 'Hospital and Related Care' is one of seven outcomes under the NHA, with the COAG Reform Council responsible for monitoring and performance assessment.

Hospital and related care assessment is based on a number of performance indicators. These performance indicators cover issues such as waiting times, adverse events, readmissions and cancer survival rates. There has been further work done to develop these indicators but it has not yet been released.

The National Health Performance Framework (NHPF) was developed by the National Health Performance Committee (NHPC) to report on the performance of the Australian health system at a national level. The NHPF focuses on overall health system performance, including acute patient services, community health, general practice and public health. However, some of the functions of the NHPF have since been taken over by the National Health Information Standards and Statistics Committee (NHSSC) which was formed in August 2008. The

³ <http://www.pharmacouncil.com.au/resources.php>, 'Forum Report March 2009, *Clinical Research in Crisis, Preparing Ourselves for Survival*' p16

⁴ *ibid*, Report on the Pharmaceuticals Industry Council R&D Taskforce 4th Forum, March 2009

NHISSC is a standing committee of the National e-Health and Information Principal Committee (NEHIPC). NEHIPC is one of several principal committees that report to the Australian Health Ministers' Advisory Council (AHMAC) and AHMAC provides support to the Australian Health Ministers' Conference (AHMC) under the Ministerial Council's arrangements for the Council of Australian Governments (COAG).⁵

According to the NHHRC final report, there is a *critical need to develop a credible and well resourced national health data system for monitoring and comparing performance in both private and public settings*. The report further notes that *even when data are collected, we lack a framework for making it 'smart' – comparing, analysing and reporting it back to clinicians, health services and consumers in a user-friendly format*.⁶

What scope is there to include clinical trial performance information into the hospital and related care in health system performance indicators?

International initiatives to improve performance measurement of clinical trials

- In the US, the Clinical Trials Transformation Initiative (CTTI) is a collaboration between government, industry, academia and patient groups. It aims to improve the quality and efficiency of clinical trials. The CTTI is to research methods or strategies to improve the design or operations of clinical trials; conduct consensus panels or expert meetings to assess current practice or develop recommendations for best practice; and develop models for improvement.
- The US Food and Drug Administration and the European Medicines Agency have embarked on a pilot programme to collaborate and share information on good clinical practice (GCP) inspections. 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.⁷

What other examples are there of clinical trials performance measures? What possible lessons or implications are there for the clinical trials environment in Australia?

⁵ From *Private and Public Hospitals*, Productivity Commission, Discussion Draft 2009

⁶ NHHRC *A Healthier Future for All Australians: Final Report* (p 56)

⁷ *Scrip: World Pharmaceutical News*, 'FDA and EMEA to co-operate on clinical trial inspections', 5th August 2009