

**Clinical Trials Jurisdictional
Working Group
Sydney and Melbourne Industry
Liaison Meetings
June 2015**

Acknowledgement

This document was prepared by the Commonwealth of Australia on behalf of the Clinical Trials Jurisdictional Working Group (CTJWG). The CTJWG comprises representatives from all Australian jurisdictions.

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Background

The benefits of clinical trials are multiple and diverse and are estimated to be worth about \$1 billion to the Australian economy each year. The environment in which clinical trials are conducted is complex with every study requiring ethics and site approval before it can commence.

A body of work is underway to improve the Australian clinical trials environment, with a view to improving health outcomes and increasing international investment in Australia.

A range of committees and stakeholders are working to progress improvements that will:

- enhance participation in clinical trials by both health practitioners and patients;
- continue to build a best practice, quality driven clinical trials sector;
- facilitate a predictable operating environment for clinical trials (in terms of, e.g. costs, time to obtain the necessary approvals, and time to recruit the required numbers of patients); and
- ensure that Australia's clinical trials capability and capacity is internationally competitive.

The Clinical Trials Jurisdictional Working Group (CTJWG) is one of the key committees established by Australian governments to achieve productive change in the clinical trials environment. The CTJWG was established under the auspices of the Council of Australian Governments Health Committee to identify and address barriers and enablers to multi-jurisdictional clinical trials. It involves senior officials from the Commonwealth, state and territory health departments, and the National Health and Medical Research Council (NHMRC). The CTJWG works in collaboration with other key stakeholders, including the NHMRC and the Clinical Trials Advisory Committee (CTAC), to progress its program of work.

To identify Australia's strengths and weaknesses in clinical trials and opportunities for investment in overall competitiveness the CTJWG held a 'Round Table' in Melbourne, on 3 February 2015, to discuss niche markets and potential opportunities for promoting Australia's competitive advantages. There was also discussion on ways in which to promote Australia as a preferred location for conducting clinical trials. Key themes emerging from the discussions informed development of the CTJWG Implementation Plan, which includes four priority areas:

- improving efficiency of clinical trial recruitment and accruals;
- enhancing national consistency for ethics and governance;
- establishing a metrics system and promoting ICT interoperability; and
- strategically positioning Australia as a preferred location for clinical trials.

The CTJWG subsequently convened meetings in Melbourne and Sydney on 25 and 30 June 2015 respectively, to share and test its identified priorities and work program. The purpose was to harness the experience and perspectives of contract research organisations (CROs) and front-line industry representatives and gain a better understanding of their current priorities for the clinical trials sector. Participants were given the opportunity to critique the CTJWG priorities and work program, and to highlight gaps, opportunities, challenges and

solutions. Participants were also invited to engage with NHMRC pilots to test a best practice model for research governance.

This document provides a summary of feedback received from these meetings.

CTJWG Clinical Trials Liaison Meetings

At the outset, participants were provided with information about work that is underway to improve the clinical trials environment in Australia. This included development of a Clinical Trials Framework for Action, which summarises activities underway by Australian governments (both state and federal) and how overall objectives will be achieved. Participants also received specific information about the CTJWG Implementation Plan, and activities underway within individual jurisdictions and by the NHMRC, the Department of Industry and Science and AusTrade. It was acknowledged that there are a multitude of players involved in clinical trials and that no one organisation/body controls the sector overall. In particular, clinical triallists and the participants of their trials ultimately drive the conduct of clinical trials, and health system managers and biotechnology, pharmaceutical and medical technology industries are pivotal to advancing the sector. Updates on other key initiatives included:

- Development and implementation of a framework for National Aggregated Statistics for clinical trials to provide governments with reliable information on clinical trial activity. This will standardise data collection across jurisdictions, provide a means of identifying gaps and barriers and facilitate a quality improvement approach to the sector.
- The conduct of pilot studies to test a best practice model of research governance at 16 sites around the country (NHMRC).
- Enhancement of the AustralianClinicalTrials.gov.au website in an effort to help boost patient participation in clinical trials (NHMRC). CTJWG is currently considering how best to enhance recruitment and is continuing to engage with stakeholders (including industry) on this and related issues.
- Re-development and costing of a standard list of clinical trial items that can be used as a starting point for negotiating clinical trial funding arrangements. The aim is to improve transparency and speed up contract negotiations between sponsors and trial sites (developed by the Independent Hospital Pricing Authority, NHMRC and Department of Health).

Participants were asked to comment on whether identified priorities and activities were appropriate, whether any key gaps existed, the types of collective action that could be taken in partnership with CROs and industry to progress improvements and/or address any identified gaps, and specific aspects that they would be prepared to contribute to. Participants were also asked to describe what a successful clinical trials environment would look like and to identify strategies to achieve this. Four key achievements were suggested as critical to overall success:

- Establishing benchmarks for clinical trial start-up timelines and approvals for both public and private institutions to drive improvements that would provide Australia with a competitive advantage in the global market.
- Improving Australia's capability for clinical trials feasibility assessments and promoting greater visibility of trials to improve efficiency and targeting of recruitment.

- Raising the profile of clinical trials and enhancing engagement with consumers, clinicians, GPs, health care professionals, hospital administrators and the general public.
- Collaborative partnerships with pharmaceutical companies and CROs with sharing of data to inform future improvements to the sector.

More detailed feedback is summarised according to the *Clinical Trials Framework for Action* themes as outlined below.

Enhanced participation in clinical trials

This aim sets out to improve patient recruitment and expand participation in clinical trials across the health sector through better awareness amongst health practitioners and the public about the importance and benefits of clinical trials. Suggestions from meeting participants relevant to this aim include:

- Raise the profile of clinical trials and their benefits to consumers, patients, general practitioners, allied health workers and health administrators. Clinical trials could be promoted through major media including newspapers, science programmes and/or TV advertisements. There could be greater focus on recruitment and changing perceptions (both within the broader medical community and the public) so that clinical trials are considered as a viable and important option for patients. Opportunities for a major recruitment drive that focuses on public education in the media and the importance of participating in clinical trials should be explored. There must also be acknowledgement that healthy and non-hospitalised people participate in clinical trials, and efforts to remove negative connotations associated with clinical trial participation through media and government campaigns.
- There are opportunities to review current approaches to informed consent and its feasibility, and also to improve study design to facilitate recruitment.
- Strategies to obtain buy in from GPs and GP networks need to be identified to assist in gaining support from the GP community.
- Consider the role of primary care services as an alternative for hosting clinical trials and explore how they can support specialists.
- Consider training sessions for study coordinators.
- Ensure that training programs for all health workers includes a mandatory component on the importance of clinical trials for the individual and the community. This training should include an overview of clinical trials conduct - processes, ethics and access to patients. This is especially important to GPs as they can be a barrier to accessing patients.

A best practice, quality driven clinical trials sector

This aim seeks to build capacity and capability, and collaboration across the sector. A vibrant and active clinical research community, informative clinical trials, robust clinical networks, contract research organisations (CROs), high quality registries and effective translation of research into practice are central to a best practice, quality driven clinical trials sector. Fundamentally, they also underpin a continually self-improving health system. To this end, participants suggested:

- Embedding clinical research within the health system, potentially through incorporation of appropriate key performance indicators (KPIs) into performance agreements of hospital administrators and chief executive officers.
- Centralising resources for clinical research within institutions to increase efficiencies. Resources should be provided to investigators and study coordinators at the site level, and sharing of resources across departments should be enabled, which could also provide a single point of contact for trials.
- More transparent and consistent interpretation of governmental approval processes from an operational perspective (such as training requirements and documentation, site initiation etc), with standardisation of associated templates.
- Consider incorporation of clinical trial KPIs for local health areas/networks in order to embed clinical trials into service provision.
- Further engagement of clinical research professionals working locally within sponsor organisations or with CROs.

Predictable and efficient operating environment for clinical trials

Significant progress has been made to streamline the operating environment for clinical trials and further work is underway. Enhancing consistency and standardisation of processes to enable delivery of trials in a repeatable and predictable manner across sites and jurisdictions is essential to this aim. A set of strategic and organisational level metrics to increase transparency, reduce variation, and drive a quality improvement approach across the clinical trials sector are also critical. A summary of potential additional actions with respect to this aim as suggested by participants include:

- Given that consistency in clinical trials start-up times is critical, there is a need to achieve shorter start-up times than that of current competitors in the Asia-Pacific region without compromising quality of review. Establishing target approval timelines in Australia of 2-4 months for both public and private institutions would enable a more competitive advantage in the global market.
- Options for embedding improvements to governance processes should be explored. This work is ongoing and will incorporate findings from pilots of the good governance approach to research governance, as relevant and appropriate, once pilots are complete. A national governance framework should also be considered, as well as potential roles and incentives for governance officers to champion clinical trial approvals.
- The possibility of additional data collection through Human Research Ethics Committees (HRECs) and governance offices should be explored.
- Exploring data linkage capabilities and other data sources from non-public organisations, GP networks and other non-hospital and independent research groups may also be beneficial.
- Explore the potential of smaller sites to conduct more clinical trials in order to provide more choice for global sponsors.
- Promote transparency of costs at sites and identify reliable sites for recruitment.
- Improving accuracy and capability of feasibility assessments.
- Increase time investigators are involved in clinical trials.

Australia's clinical trial capacity is internationally competitive

This aim strives to position Australia as a preferred location for clinical trials through identification, utilisation and promotion of existing and potential future strengths. Engagement with CROs and industry, and leveraging connections with international decision-makers, are critical to success. Developing Australian clinical champions of clinical trials activities to promote improvements is another key element of the strategy. Participant suggestions against this aim include:

- Explore how to promote privately hosted clinical trial sites
- Change sponsor perceptions that Australia has slow trial start-up times (i.e. not all sites are slow to recruit).
- Promote the australianclinicaltrials.gov.au site internationally.
- Promote Australia's tax advantages.
- Establish a marketing strategy to raise Australia's profile to international sponsors and ensure that the same positive messages are being made by all.
- Ensure sponsors and CROs are consulted about improvements in clinical trials as they are the conduit to international sponsors.
- Promote Australia's niche market capacity for smaller studies in cutting edge technologies.
- Explore opportunities for knowledge translation of successful operating environments for clinical trials from international settings e.g. New Zealand, UK and Korea.

Future directions

The following actions are a summary of feedback on ways to work together to collectively promote and improve Australia's clinical trials operating environment:

- Share industry and CRO data on global competitiveness, start-up timelines and clinical trials conduct.
- Build on the CTJWG National Aggregate Statistics approach and broaden to all trial sponsors and single-site trials and seek data input from the private sector sites.
- Investigate opportunities to develop a data portal that CROs and pharmaceuticals could contribute data through.
- Explore opportunities for CROs/pharmaceuticals to share knowledge on issues relating to ethics, governance and recruitment.

Conclusion

There are a multitude of players involved in the success of attracting investment in clinical trials and ultimately improving health outcomes. In the absence of a single governing body for clinical trials, collaboration between all players is needed to drive improvements. Concluding remarks from Dr Tony Penna highlighted that the importance of a partnership approach between all key stakeholders involved in clinical trials. Mechanisms for achieving this included regular liaison meetings (approximately bi-annually) to provide updates on key initiatives and to test key bodies of work with stakeholders working at the frontline and in the delivery of clinical trials.