

# Council of Australian Governments (COAG) Health Council Revitalised Clinical Trials Agenda

## *Advancing the Clinical Trials Environment in Australia*

**Rationale:** At the 8 April 2016 COAG Health Council meeting, Health Ministers agreed to develop models/options to organise sites to better support and streamline clinical trials processes in Australia. COAG Health Council tasked the now Clinical Trials Project Reference Group (CTPRG), via AHMAC and CPC to:

*Develop options for next steps to stimulate the clinical trials sector to improve administrative efficiencies, better engage sponsors and improve trial start up times and outcomes.*

**Vision:** To improve health outcomes and contribute to the innovation economy and a self-improving health system by creating sustainable efficiencies within the clinical trials sector.

**Objective:** To support regional redesign to streamline and expedite start-up, enhance recruitment and retention and embed quality clinical trials systems in health care.

## **Principles**

Jurisdictions and the Commonwealth agree that the following principles will underpin new approaches that are practical and implementable to stimulate the clinical trials sector in Australia.

1. The **patient is at the centre** of clinical trials.
2. Research and clinical trials are **essential health system activities**.
3. Clinical trials foster a **culture of quality, safety and innovation**.
4. Access for patients **must be made easier** – participation, navigation and delivery.
5. **Partnerships and collaboration** are at the core of any success.
6. **Workforce support is central** - capacity, capability and predictability, career pathways.
7. **Knowledge and transparency** – KPIs, data, accountability, value offer.

## **Priority Action Areas**

Jurisdictions agreed that the following priority action areas should be highlighted. Implementation of priority action areas will vary between jurisdictions, recognising the different health care structures in place and the various stages of clinical trial system development.

Priority action areas are not mutually exclusive and jurisdictions may seek to serve one or more priority areas through identified mechanisms. For example, clinical trial coordination units (Area 1) may play a key role in enhancement of data and knowledge systems (Area 3). Through the CTPRG, jurisdictions agree to seek to harmonise approaches to the maximum extent possible in order to facilitate common or compatible clinical trials processes.

### **1. Coordination Units**

Jurisdictions agree to explore new models to centralise and coordinate management of clinical trials (e.g. via system redesign to support clinical trial coordination units). Noting that jurisdiction health service structures vary, it was agreed that the Local Health Network (LHN) or equivalent health service organising structure would be the minimum unit of organisation appropriate for such models (noting that clusters or larger groups may be more appropriate in some circumstances). Coordination units will:

- play a key 'gateway' role for sponsors, investigators, referrers and participants accessing and navigating trials;
- reduce the administrative load on trial sites through the provision and/or facilitation of key trial operational functions (e.g., feasibility assessment, ethics clearance, site authorisation, trial governance, insurance and contract management);
- act as central points for communication, training and education; and

- support the clinical trial workforce through building capacity and capability, ensuring quality control and pooling resources to provide career pathways and professional development.

Through the establishment of coordination units and increased collaboration across sites, jurisdictions will continue to work towards a standard approach to all elements of clinical trials governance and conduct.

## **2. Networks and Partnerships**

Jurisdictions agree to employ new approaches and build on existing approaches to develop, engage with, and capitalise on networks and partnerships to harness relationships and available infrastructure to drive and support coordinated, transformational change and improvements across the clinical trials sector. This may include partnerships with existing clinical trial networks as well as with communities of expertise/practice (e.g., oncology, working with Aboriginal and Torres Strait Islander groups) and registries. Arrangements may be both intra and inter-jurisdictional and cross/multi-discipline. Effective consumer engagement will be a key element of such partnerships as will engagement of the broader health system (e.g., general practice). Networks and partnerships should contribute to knowledge brokerage services and targeted consumer engagement and recruitment strategies.

## **3. Enhancement of data and knowledge systems**

Jurisdictions agree to enhance or develop approaches to ensure quality clinical trial data is gathered to inform systems improvement and contribute to better sector knowledge, recruitment and overall performance. This will include:

- fast-tracking agreed metrics collection; and
- facilitation of improved data linking capability.

Clinical trial coordination units may have a key role in specialised data and statistical analysis support or other specialist partnerships (i.e., universities, Advanced Health Translation Centres, etc). Jurisdictions agree that the use of data and knowledge to articulate the value offer of clinical trials will be emphasised. There will be opportunities for jurisdictions more advanced in trial data and knowledge systems to mentor other jurisdictions. Jurisdictions agree to seek to harmonise data collections, establish benchmarks where appropriate and identify and participate in linkage opportunities as they arise via My Health Record.

## **4. Research as essential health system business**

Jurisdictions agree to seek opportunities to promote health research as core business through embedding research and clinical trials into core hospital governance arrangements. This may include development and use of KPIs in corporate governance mechanisms and performance agreements. Similar mechanisms could be deployed in clinical governance arrangements (e.g., feasible participation targets). This priority is designed to send a strong message that research and clinical trials are central to quality health care and require attention in terms of corporate governance and resources to support conduct of trials.

## **5. Introduce clinical trials governance into ACSQHC Standards**

Research is part of the way a good health system is designed and it is a component of all parts of that system. This approach takes advantage of the well-established processes and structures of the Australian Commission on Safety and Quality in Health Care (ACSQHC), to create a clinical trials 'governance framework' covering the full spectrum of clinical trials in public hospitals and to ensure governance processes are robust and meet appropriate standards. Jurisdictions agree to development of a governance framework with a view to incorporation of a future clinical trials governance standard as part of the ACSQHC's National Safety and Quality Standards.

In addition to the above five priority action areas, CTPRG further agrees to consider standard care in the context of clinical trials, to inform development of streamlined ethical and governance approval processes for comparative-effectiveness and lower-risk trials.

CTPRG also agrees to consider the feasibility of developing national clinical trials participation levels. This would recognise and promote clinical trials and their central role in the development and delivery of quality health care.