MTAA Position Statement and Response to RDTF Discussion Paper: Proposed model for an Australian Coordinating Body for Clinical Trials

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1. Executive Summary

On December 4th, 2018, the Research & Development Taskforce (the RDTF) issued a draft Discussion Paper titled: *Proposed Model for an Australian Coordinating Body for Clinical Trials* which calls for a "dedicated, single point of ownership" to address the current "spread of responsibilities for different aspects of the clinical trials 'infrastructure' across various Commonwealth and State agencies, and an associated lack of ownership and accountability in implementing policies designed to encourage investment" in clinical trials.

The RDTF stemmed from the previous and since disbanded Pharmaceutical Industry Council (PIC). The RDTF Terms of Reference state that its role is to focus on:

a) providing expertise and guidance on issues relating to the clinical trials environment in Australia;
b) fostering better understanding of clinical trials and the contribution they make to advancing health outcomes for Australians;
c) identifying areas for the reform of the clinical trials regulatory environment;
d) proposing options that can help address identified areas in need of reform;
e) monitoring initiatives across all levels of government in Australia that are designed to enhance the clinical trials regulatory environment;
f) cultivating, with the approval of sponsor associations (i.e., Medicines Australia and the MTAA), relationships with key stakeholders, including relevant government officials, and the broader Australian medical research community; and
g) helping respond to ad hoc policy reviews and ongoing and emerging issues.

The RDTF Discussion Paper recommends that the Independent Hospital Pricing Authority (IHPA) is used as the model for the Australian Coordinating Body for Clinical Trials (ACBCT). The proposed governing model consists of a governing board that identifies priorities, establishes direction and specific tasks; and a separate operation office responsible for streamlining ethics and research governance processes between jurisdictions, building capacity and enhancing patient recruitment, adoption of health initiatives, marketing and communications, and quality assurance.

The Discussion Paper also outlines the proposed roles of various government bodies:

1) The role of the States and Territories would be to implement, manage and oversee nationally-harmonized processes for both ethics approvals and clinical trials governance processes; build capacity in staffing and infrastructure; and drive patient recruitment initiatives for clinical trials, particularly in the public healthcare system.

2) The role of the National Health and Medical Research Council (NHMRC) would remain to provide overarching policy around medical research in Australia. The Discussion Paper notes that the NHMRC has ceased all activities associated with clinical trial reform initiatives as of June 30th, 2017, and will not have a role in distributing any research related funding and grants.

3) The role of the Therapeutic Goods Administration (TGA), in the clinical trials context, would be to provide comprehensive metrics and dataset to the Australian Coordinating Body for Clinical Trials, collected via the eCTN process for reporting and monitoring clinical trial activity.

MTAA is supportive of establishing a national coordinating body for clinical trials. The desired state of running clinical trials in Australia needs to include:

- Nationally harmonized ethics approval and monitoring systems and processes, in accordance with international standard ISO 14155 *Clinical investigation of medical devices for human subjects – Good clinical practice*
- Timeliness and cost-effective set-up, recruitment and running of clinical trials
- Competitiveness in relation to other OECD countries

In the next section we provide detailed feedback to the draft Discussion Paper: *Proposed Model for an Australian Coordinating Body for Clinical Trials*.

2. Proposed model for an Australian Coordinating Body for clinical trials

The Discussion Paper proposes that the ACBCT is established using the IHPA model. MTAA agrees with the proposal to establish an ACBCT as a Statutory Authority operating under the Australian Public Service rules. We would like to better understand what checks and balances are proposed to be put in place to ensure **transparency and accountability** of the ACBCT.

IHPA is an independent government agency established under Commonwealth legislation on 15 December 2011 as part of the National Health Reform Agreement (NHRA) reached by the Council of Australian Governments (COAG) in August 2011. IHPA's primary function is to calculate and deliver an annual National Efficient Price (NEP). The NEP is a major determinant of the level of Australian Government funding for public hospital services and provides a price signal or benchmark for the efficient cost of providing public hospital services.[1]

The Discussion Paper also provides an outline of the proposed governance structure. The proposed composition of the Governing Board consists of:

- One member from the Federal Department of Health/ NHMRC
- One member from the Federal Department of Industry
- One representative of each of the State/Territory jurisdictions
- One representative from industry (commercial)
- One consumer representative
- One representative from academic research interests

The clinical trials for medicines and medical devices have significant differences that require specific knowledge and experience. Therefore, we recommend that **two industry representatives** be included in the Governing Board, one from Medicines Australia representing the pharmaceutical industry and one from MTAA representing the medical device industry.

[1]IHPA website, accessed on 12 April 2018: https://www.ihpa.gov.au/who-we-are

Considering the long history of difficulties in implementing reform measures we would like to recommend that **clear responsibilities and authorities** be defined between the coordinating role of the ACBCT and the implementation role of the States and Territories. Specifically, what recourse will be available to the ACBCT if States and Territories fail to implement reform measures?

3. National harmonization of systems and processes

One of the main issues raised by MTAA members is the current lack of **national harmonization** in the clinical trials space. Our members have clearly expressed the view that Australia needs to implement uniform systems and processes across medical institutions, States and Territories to ensure timely, transparent and efficient clinical research governance.

Furthermore, Australian best practices need to **align with international best practice**. For medical devices, the Good Clinical Practice is documented in the international standard ISO 14155 *Clinical investigation of medical devices for human subjects – Good clinical practice*, which is also recognized by the TGA[2].

The ACBCT should build up on the excellent work done by the NHMRC in the clinical trials space[3] to achieve an environment that encourages and supports internationally competitive, high quality clinical research.

4. Ethics committees

A step towards increased efficiency could be to **consolidate** the current plethora of Human Research Ethics Committees (HRECs) into a few that specialize in certain therapeutic areas. The HRECs would need to follow the **same (harmonized) process for ethics application, review and approval**, and use the **same forms and documentation processes**. The ACBCT should maintain a national registry of HRECs across States and Territories.

Membership of ethics committees typically include medical and ethics professionals, with little or no **engineering or scientific expertise** in the technologies being investigated for safety and effectiveness. Ethics committees are generally reluctant to reach out to technical experts within industry due to concerns about real or perceived conflict of interest.

A possible solution to the lack of specific engineering and scientific expertise within HRECs could be to reach out to the TGA statutory advisory committees[4] and other independent technical experts (non-TGA employees) that TGA uses to advise on specific engineering and scientific matters. That would require an appropriate level of cooperation between the ACBCT and the TGA. This could be beneficial in ensuring opinion consistency between HRECs and the TGA.

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[2] TGA Australian clinical trials handbook, March 2018: https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook-01.pdf

[3] NHMRC website, accessed on 12 April 2018: https://www.nhmrc.gov.au/research/clinical-trials/nhmrc-clinical-trials-initiatives

[4] TGA statutory advisory committees, website accessed on 12 April 2018: https://www.tga.gov.au/tga-statutory-advisory-committees

5. Cost effectiveness

In addition to harmonization of processes and a streamlined structure, cost effectiveness is another essential element for having viable and competitive clinical research in Australia.

IHPA's efforts in attempting to make the costing of clinical trials more **transparent** resulted in the 2015 table of standard costs.[5] While the IHPA list is a useful tool in benchmarking costs, the reality is that fees vary greatly depending on the services provided by the medical institutions, and some fees are significantly higher than in other OECD countries. For devices, there can be expensive medical procedures and tests such as MRIs, CT scans etc. that are charged to clinical trial sponsors.

It would be useful for ACBCT to maintain oversight of the list of standard costs. In addition, the costs charged in Australia should be **benchmarked** against comparable services in other OECD countries to monitor the cost-competitiveness of running clinical trials in Australia.

6. Appeals procedure

For clinical trials performed in public hospitals there should be an appeals procedure to allow compliance issues (e.g. deviations from harmonized procedures) and other grievances (e.g. excessive fees and charges) to be escalated and resolved in the spirit of **transparency and fairness**.

The ACBCT could potentially have a role in the appeals procedure.

[5] IHPA website, accessed on 12 April 2018: https://www.ihpa.gov.au/publications/development-table-standard-costs-conducting-clinical-trials-australia