Clinical Trials Governance Framework Consultation
Australian Commission on Safety and Quality in Health Care
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Consultation: National Clinical Trials Governance Framework for health services conducting clinical trials.

22 March 2019.

Dear Dr Aliprandi-Costa,

Medicines Australia welcomes the opportunity to provide comment on the Australian Commission on Safety and Quality in Health Care's Clinical Trials Governance Framework Consultation.

Our submission has been prepared with the expert input of Medicines Australia members as well as the joint sponsored Medicines Australia/Medical Technology Association of Australia/AusBiotech Research and Development Taskforce (RDTF). Members of the Taskforce are selected for their significant experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory and research and development (R&D) issues that stand to impact the MedTech sector.

Clinical trials are important in providing Australian patients with early access to new and innovative medicines as well as providing flow on benefits that raise the health and productivity of all Australians. They also attract significant local and overseas research funding. Because of this, there is considerable competition between countries for global clinical trials. Differences in research governance systems, including ethics approvals, and inconsistencies within and between states/territories in Australia, continue to hamper Australia's potential to attract new clinical trials from key trading partners.

The concept of a National Clinical Trials Governance Framework could be a first directional step towards a nationally consistent approach to Clinical Trials in Australia. This would help the clinical trials sector overall, as long as it does not create any extra burden or complexity. A key benefit could be harmonization of inter-state/territory differences in governance & process requirements. The Framework articulates well the fundamental principle that Clinical Trial participation should be embedded as Standard Care and required as part of Quality Standards. This is good news for patients, particularly in areas such as oncology, where access to trial participation is often limited to major centres – an issue in Australia given its size/geography. In addition, the emphasis of timeliness of clinical trial participation is advantageous towards Australia's involvement in global trials.

As there is currently no overarching long-term national plan to target areas of inefficiency and inconsistency in the clinical trials setting, Medicines Australia is supportive of any efforts leading to improvements that will ensure Australia's continued competitiveness in this area.

Members have expressed the following concerns;

• The framework does not address the current complexity in the governance and ethical standards in Australia to conduct multicentre clinical trials and the varying costs across States and territories;

• The Framework is not fit for purpose to differentiate the varying needs of clinical trial centres such as phase 1 units, thereby introducing complexity;

• There is a concern that smaller capable clinical trial units and private institutions will be burdened and inadequately resourced or skilled to complete the accreditation requirements, potentially resulting in the closure of these clinical trial units and limiting clinical trial opportunities for Australians;

• During the consultation workshops, significant concern was expressed by individuals representing the Health sector, and the administrative burden on resources the accreditation process will introduce;

• The framework does not specify defined metrics or measures of success to ensure Australia continues to be an attractive destination for globally sponsored clinical trials;

• The framework does not address how consistency in the interpretation of national ethical guidelines will be achieved across accredited sites;

• There is a concern, the framework will introduce additional complexity, limit the number of clinical trial sites including rural centres, limit improvement to clinical trial start up times and patient recruitment rates, and add additional quality and inspection requirements to an already fractured national approach to Clinical Trials in Australia.

• There is no mention of supporting innovative clinical trial practices such as teletrials – outreach of trial framework into rural/remote areas

• There is no mention of the need to support areas where trials are particularly challenging e.g. paediatrics, vulnerable populations etc

In addition, on page 64, it may be more appropriate for 2.5 to read “The health service organization has processes to ensure (rather than “identify”)”.

We are interested in maximising the potential effectiveness of the standard and we look forward to supporting the Commission during this present review.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments.

Please feel free to contact Betsy Anderson-Smith if you would like further clarification on any aspect of our submission (banderson-smith@medaus.com.au).

Yours sincerely

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