28 March 2019

Clinical Trials Governance Framework Project Team
Australian Commission on Safety and Quality in Health Care
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Dear Clinical Trials Governance Framework Project Team

Re: AusBiotech’s response to the Australian Commission on Safety and Quality in Health Care’s draft National Clinical Trials Governance Framework

AusBiotech is pleased to provide comments to the Australian Commission on Safety and Quality in Health Care (the Commission) on its draft National Clinical Trials Governance Framework.

All Australians have a vested interest in attracting more trials to Australia and in ensuring a healthy clinical trials environment.

Clinical trials make a critical contribution to the health and wellbeing of Australians, and bring significant economic benefits to this country. Commercial trials play an important role in this system, alongside Investigator Initiated Trials, and produce diagnostics and medical products that save lives as well as potential, cutting-edge alternative treatment pathways.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. We take a keen interest in clinical trials and within AusBiotech, the AusBiotech Clinical Trials Advisory Group provides expert advice on operational and policy-related clinical trial matters. Our response has been led by this group.

We applaud efforts to support the delivery of high-quality clinical trial services, which will further enhance Australia’s desirability as a destination for clinical trials. We therefore believe the intent of the Framework is to be commended.

Response to proposal

AusBiotech believes the overarching aims of the National Clinical Trials Governance Framework (the Framework) are laudable in principle, particularly that clinical research is considered routine clinical care, and is supportive of its general aims. We also have no obvious serious concerns with the proposed elements within the Framework.

We believe that realising the Framework’s stated purpose – ‘To ensure that clinical trials are conducted in a safe environment and in a high-quality manner for improved health outcomes for patients and the community’ – would help strengthen Australia’s reputation for high-quality clinical trials.
Possible implementation challenges with the Framework

However, the implementation of the Framework as currently articulated may have unintended negative consequences that would undermine its aims and ultimately its value. To maximise the economic benefits and health outcomes that clinical trials can deliver for Australians, a key focus and goal should be on increasing Australia’s attractiveness as a preferred destination to conduct trials. This is most readily facilitated through measures such as increasing recruitment, decreasing costs, and helping achieve shorter start-up times. We have identified several key challenges of the Framework that, once implemented, may adversely affect Australia’s ability to achieve this goal.

1. **Alignment with other initiatives.** Whilst the Framework references how it aligns with National Safety and Quality Health Service Standards, we also believe the Commission needs to articulate how the Framework aligns with other health strategies and programmes. For example, it should identify how it fits with the Therapeutic Goods Administration’s proposed Good Clinical Practice Inspections Program and National Health and Medical Research Council Guidelines. This would provide useful clarity on the role and purpose of these different initiatives, and provide confidence to the sector that there will not be duplication. Moreover, duplication and creating too many extra layers of requirements may affect start-up times and costs, decreasing Australia’s attractiveness as a place to conduct trials.

2. **Resourcing requirements.** The care taken in observing and collecting accurate data in clinical trials is at a level above routine clinical care, and resourcing is therefore already a key consideration. The Framework will require that the sector undertake additional activities that will require resourcing, for example, health care personnel will be needed to undertake the site accreditation, and training and proper career paths for personnel who go into these types of roles in order to attract and retain the appropriately qualified/experienced people. There may be the unintended consequence of existing trials units being underfunded as work gets underway on embedding trials across hospitals.

Whilst resourcing is not within the scope of the Commission’s contract, it is nonetheless a key issue that should be considered when finalising the Framework and the ‘Guide for Implementation’ (pending). Extra resourcing requirements may result in increased costs throughout the delivery chain, which may in turn decrease Australia’s attractiveness as a destination to conduct clinical trials.

Suggested edits to the Framework

Further, we also believe the Framework would benefit from several inclusions:

- **A defined list of key performance indicators (KPIs) across all stakeholders in order to increase accountability would be beneficial.** Without this, everyone will continue to operate to their own KPIs. These defined KPIs could include: Research Governance Officer (RGO) submission to site initiation; site initiation to first patient in; and recruitment to target. These are key indications that are important to local and international companies that are looking to conduct clinical trials in Australia. While these milestones are not solely driven by the RGO/site, they are in a position to play a significant role in influencing these timelines.

- **Timelines relating to RGO submission / approvals should include both initial approvals and interim trial submissions/approvals.** There is a current lack of consistency in the management of trial amendments (such as ethics approved protocol and informed consent forms) and timelines associated with the review of amended budgets. We suggest that similar expectations are placed on the oversight of initial submissions/approvals and interim submissions/approvals of amendments.

- **We would like the Framework to include governance of lead sites / coordinating investigators.** These are key roles that staff within a research site take on to support trial delivery across Australia. We believe that site governance should have a record of investigators who are taking on lead Principal Investigator (PI) responsibilities for mutual acceptance Human Research Ethics Committee submissions. We suggest that the Framework includes points of contact within site governance should issues arise with regard to lead PI/lead site responsibilities.
Framework guidance

In the past, we have seen a number of guidance documents released that allow for too much variability and interpretation. The guidance for the Framework needs to be specific and direct enough to avoid interpretation which will continue to create confusion and complexity. For example, in relation to accreditation, the Guide for Implementation (pending) could include:

- Clarification on whether a site that is already approved for a study, but is yet to be accredited, can still proceed
- The length of time it is anticipated the accreditation will take, and who determines the order/priority of accreditation
- An articulation of who will be responsible for assessing the site accreditation, and thus resourcing that activity.

When relevant, we would appreciate advance notice of implementation of the changes and the opportunity to comment on any subsequent amendments proposed.

All Australians have a vested interest in attracting more trials to Australia and in ensuring a healthy clinical trials environment. We applaud efforts to reduce variation in practices and reduce start-up times caused by duplication and inconsistency. We believe the Framework can help achieve this, and look forward to working with the Commission on behalf of our members in relation to further consultations on the Framework.

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