

The National Clinical Trials Governance Framework- Response to the Consultation

28 March 2019

Introduction

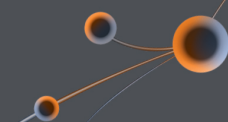
Research Australia is the national alliance representing the entire health and medical research pipeline, from the laboratory to patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

A member-based organisation, Research Australia's role is to:

- **Engage** Australia in a conversation about the health benefits and economic value of its investment in health and medical research.
- **Connect** researchers, funders and consumers to increase investment in health and medical research from all sources.
- **Influence** government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

Research Australia has participated in the consultation on the Draft Framework, attending the Melbourne workshop on 21 February, and is pleased to have this opportunity to make this submission.

We welcome the development of the National Clinical Trials Framework as an important initiative which can help advance the conduct of clinical trials in Australia. Our comments on the Framework are limited to some specific areas (roles, site authorisation and reporting) where we believe it can be improved.



Organisational Culture

Research Australia supports the Framework's recognition of the need to create an appropriate organisational culture.

On page 17 of the Framework, the Commission has identified a number of outcomes that such a culture needs to provide.

The first of these is

- *Strong strategic and cultural leadership of clinical trial services, that prioritises:*
 - *effective planning to enable development and improvement opportunities to be captured*
 - *selecting high quality clinical trials that will provide value to patients and consumers, improves the clinical evidence-base and supports continuous improvement in clinical trial service provision*
 - *allocating resources to support the delivery of high-quality clinical trial services*

While it is open to the Framework to do so, it has largely avoided stating the criteria an organisation should use to select clinical trials, focusing instead on the processes to be put in place. In the absence of any other statements on this subject, the highlighted section in the above text appears to provide high level criteria against which any prospective clinical trial should be assessed. When this possibility was raised in the workshop, the response from the Commission's representatives was that it was not intended to be interpreted in this way. Nonetheless, this would appear to be a reasonable interpretation of the text.

Research Australia submits that the final draft of the Framework should clarify the purpose of the above statement if it is retained, including whether the Framework is providing any criteria for the assessment of prospective clinical trials.

Roles and Functions

Roles versus capacity

Research Australia supports the approach of the Framework in identifying roles and functions that need to be performed without specifying that a particular position needs to be created or that a particular title needs to be applied to an individual within an organisation.

Notwithstanding the text to this effect on page 18 of the Framework document, Research Australia is aware that there is still some concern among our membership that the Framework will require organisations to employ additional staff and/or appoint staff to new positions.

Research Australia submits that the Commission should be cognisant of the concern about the need for additional staff, and emphasise that the Framework does not require the employment of people into particular positions, just that an organisation has individuals with the capacity to undertake the specified functions.

Standard 1- Decision maker

The Draft Framework is largely effective in describing the functions assigned to different roles.

Of note, however, the function of decision maker is largely absent. By decision maker, Research Australia is referring to the person/group responsible for making the decision as whether a proposed clinical trial will be hosted at the site in question.

Page 21 of the Framework states that one of the responsibilities of the CEO is to

- *'...(delegate) a person responsible for site-specific assessment and authorisation, and an escalation process for disputed local site-specific authorisation of clinical trials if required....'*

The paragraph appears to imply that a single person is to be responsible for both the site-specific assessment and site-specific authorisation.

Research Australia submits that this is not necessarily the case, and the Framework should explicitly recognise that the delegations for site-specific assessment and site-specific authorisation could be provided to different persons.

This issue is compounded by the failure of the Framework document to make any further reference to the function of site-specific authorisation.

Pages 21 to 27 of the Framework outline a range of different roles and activities for:

- Approving authorities,
- Managers,
- HREC,
- Research Governance Officer,
- Site Specific Assessment Officer (with pre-authorisation and post-authorisation activities)
- Clinical Trial Site Staff
- Site Clinical Trial Coordinator
- Sponsors and contract research organisations.

Page 23 of the Framework outlines the role of the Site-Specific Assessment Officer. The description includes pre-authorisation and post-authorisation activities, but does not address the actual activity/responsibility for making the decision. On none of these pages (21 to 27) is the role or activity of 'site-specific authorisation/authoriser' described or referenced. It is similarly absent from 'Standard 1 Clinical trials governance standard' and the roles and functions outlined in this table on pages 28 to 38.

While it is clear from the Framework that someone must be responsible for site specific authorisation, the absence of any description of this role or activity from the Framework seems a glaring omission.

At a minimum, the obligations/responsibilities of the site specific authoriser could include acting within their delegation, considering the site specific assessment, and recording and communicating their decision.

Research Australia submits that the Framework should explicitly describe the role and functions of the site-specific authoriser, and that Standard 1 should specially identify site specific authorisation as a Function.

Standard 1- External Reporting

One of the core principles of the Framework is

- ‘Transparency is measurable using key performance indicators to increase accountability and promote the value Australia offers as a destination for clinical trials.’ (page 9)

In a similar vein, the Mapping document (page 32) emphasises the importance of reporting.

‘The majority of participants identified site accreditation as a method for measuring the success of the Governance Framework. In order to obtain accreditation, it was generally agreed that metrics or key performance indicators (KPIs) should be required as part of the Governance Framework and therefore accreditation, and that audits should be carried out to ensure accurate reporting against those metrics (rather than self-reported metrics alone).’

Research Australia agrees that transparency is critical and that reporting of appropriate measures is essential if transparency is to be achieved. To this end, Research Australia believes the Framework needs to place greater emphasis on the importance of reporting. While there are some references in Standard 1 to adverse event reporting and to trials sponsors providing documents in a timely manner to support annual reporting, there is not a more comprehensive recognition of the importance of reporting. Nor is there identification of external reporting as a specific role or function.

Research Australia submits that Standard 1 should more clearly articulate, and assign responsibility for, reporting on each clinical trial to the governing body, and especially for external reporting to State and Territory Departments of Health.

Conclusion

Research Australia appreciates the opportunity to participate in the consultation and to make this submission.

Clinical Trials play a critical role in providing early access to innovative treatments and innovations, and improving the quality, effectiveness and efficiency of health care. An effective National Clinical Trials Framework can improve the effectiveness of clinical trials in Australia, bring both better health outcomes and economic benefits. We look forward to the next draft of the Framework and are pleased to assist in any way we can.

Lucy Clynes

General Manager, Research Australia

lucy.clynes@researchaustralia.org