Public consultation

National Clinical Trials Governance Framework for health services conducting clinical trials

How to provide written feedback

Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) has been engaged by the Australian Department of Health on behalf of all states and territories to deliver the National Clinical Trials Governance Framework as a first step towards a nationally consistent approach to accreditation of health services undertaking clinical trials in Australia.

The draft National Clinical Trials Governance Framework has been developed based on findings from a literature review and mapping exercise, and is aligned with the National Model Clinical Governance Framework, the National Safety and Quality Health Service (NSQHS) Standards, second edition, as well as legislation and guidance material with which clinical trials must comply.

Who will the National Clinical Trials Governance Framework apply to?

It is mandatory for all Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards. Therefore, the Standards within the National Clinical Trials Governance Framework are also mandatory for those health service organisations that provide a clinical trials service.

What is the National Clinical Trials Governance Framework for?

The purpose of the National Clinical Trials Governance Framework is to ensure that clinical trials are conducted in a high quality manner for improved health outcomes for patients and the community. The National Clinical Trials Governance Framework describes the elements that are essential for health service organisations to achieve integrated clinical trial service delivery within routine health service provision. Through these systems, organisations and individuals are accountable to patients and the community for continuously improving the safety and quality of their clinical trial services.

What are the main issues?

A thriving clinical trials environment is essential for a robust healthcare system. Clinical trials provide early access to innovative treatments and interventions for patients, and improve the overall standard of medical care provided in Australian hospitals through the uptake of evidence into practice.

Recently, a number of reports have highlighted the barriers to conducting clinical trials in Australia. These barriers include long-standing variation in administrative...
practices between health services and jurisdictions, lengthy start-up times due to duplication and inconsistency in ethics and local site assessment processes, difficulties to retaining a reliable and skilled workforce and recruiting to target. The National Clinical Trials Governance Framework takes account of these report findings. It also reflects feedback from stakeholders, through work undertaken by the Commission on issues affecting good practice in the management and conduct of clinical trials.

When will the draft National Clinical Trials Governance Framework come into effect?

From 1st January 2020, Australian hospitals and day procedure facilities providing a clinical trials service will be assessed against the actions in the National Clinical Trials Governance Framework under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme.

The National Clinical Trials Governance Framework will be revised following the consultation process and published on the Commission website later in 2019.

How can I provide feedback on the National Clinical Trials Governance Framework?

You are invited to provide written feedback on the draft National Clinical Trials Governance Framework.

Included below are questions to guide your feedback, though you are not restricted to answering these questions and should feel free to offer additional suggestions. There is no word limit to your responses.

To receive a copy of the draft National Clinical Trials Governance Framework, including the supporting documents (the literature review and mapping exercise report), please email the Clinical Trials Governance Framework project team at: GTgovernance@safetyandquality.gov.au
Consultation questions
National Clinical Trials Governance Framework

1. Will the National Clinical Trials Governance Framework help health service organisations deliver efficient and effective clinical trial services?

2. Do you think the core principles of the National Clinical Trials Governance Framework appropriately express the expectation of the community for clinical trial services? If not, how could the core principles better articulate these expectations?

3. The suggested roles and functions for identified positions relating to the conduct of clinical trials are provided in the National Clinical Trials Governance Framework. Do you agree with the roles and the description of functions? Should other roles and functions be included?

   Please specify the roles you are commenting on e.g. patients and consumers, clinical trial site staff, trial investigators, clinical trial coordinators, managers, research governance officer, HREC executive officer, site-specific assessment officer, governing bodies, sponsors.

4. Health service organisations conducting clinical trials will be required to meet the actions outlined in the National Clinical Trials Governance Framework. Are these actions feasible and able to be met by health service organisations?

   If not, how could health service organisations be assessed against the governance standards?

5. What strategies would enable health service organisations to meet the actions outlined in the National Clinical Trials Governance Framework?

6. Do you think aligning the National Clinical Trials Governance Framework with clinical and corporate organisational governance will improve clinical trial service provision? If not, should other factors be considered to support embedding clinical trials into routine health service provision?

7. If you have comments on the language and/or terminology of the content, please provide suggested replacement text.

8. Do you have any other comments?
You can email your response to CTGovernance@safetyandquality.gov.au

You can also post your responses to:
Clinical Trials Governance Framework Consultation
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
Sydney NSW 2001

Our contact details

If you have any questions about the consultation, please contact:
Dr Bernadette Aliprandi-Costa on (02) 9126 3600 or
CTGovernance@safetyandquality.gov.au

The deadline for written responses is Friday 22 March 2019.