

KEY ACTIONS
for health service
organisations

Fact sheet 1:

National Clinical Trials Governance Framework and accreditation overview

Background

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework (Governance Framework) as a first step toward implementing the National Safety and Quality Health Service (NSQHS) Standards and achieving accreditation of health services for the conduct of clinical trials.

In 2016, Australian health ministers noted that while states and territories have worked to improve the environment for clinical trials, there remained issues of fragmentation and inefficiencies that impact on Australia's attractiveness as a preferred location for trials. In 2017, the COAG Health Council agreed to strengthen Australia's clinical trial sector through a new revitalised clinical trials agenda. As part of this agenda, the Commission has developed the Governance Framework in collaboration with the Australian Government Department of Health, states and territories, clinical trial experts, the private sector, executives and managers, patients and consumers.

The Governance Framework is underpinned by a literature review, a mapping exercise of national and state and territory regulation, legislation, clinical trial policies and processes, and feedback received from national sector-wide consultation.

What is the aim of the National Clinical Trials Governance Framework?

The Governance Framework aims 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. The Governance Framework supports health services to reduce trial start up times, optimise pre-approval and participant recruitment time-frames, better engage trial sponsors and improve consistency in trial service delivery.

The Governance Framework is based on the Commission's existing NSQHS Standards, in particular, Standard 1: Clinical Governance and Standard 2: Partnering with Consumers. The Governance Framework lists the actions within the NSQHS Standards, suggests strategies that health services may implement to meet the actions, and provides examples of evidence clinical trial services may use to demonstrate they have met the actions when being assessed for accreditation.

It is anticipated that, assessment of health service organisations to the Governance Framework will strengthen governance arrangements for hospital administrators, health services that deliver clinical trials, private companies, trial sponsors, trial investigators and governments. Importantly, it will do so in a way that reduces duplication and increases efficiency and productivity across the clinical trials sector.



Accreditation to the National Clinical Trials Governance Framework

Accreditation is an evaluation process that involves assessment of a health service organisation's compliance with the safety and quality standards by an external agency.

Assessment to the Governance Framework is governed by rules set out in the Australian Health Service Safety and Quality Accreditation Scheme (AHSSQA). The Governance Framework provides the actions specific to clinical trial services as part of the NSQHS Standards.

Other services wishing to ensure best practice and ongoing quality improvement can choose to apply the Governance Framework within their organisations.

Under the AHSSQA Scheme, it is intended the Governance Framework will:

- Strengthen governance arrangements for clinical trial services
- Provide clarity to those responsible for delivering clinical trials, including health services, hospital administrators, clinicians, trial sponsors and patients, governing bodies and consumers
- Reduce duplication and increase efficiency, cohesion and productivity across the clinical trials sector.

Next Steps

1. In early 2020, the Commission will pilot the Governance Framework in hospitals and day procedure units. Insights gained from the pilot will inform the approach to implementing the Governance Framework and, the refinement of supporting resources.
2. Subject to the outcome of the pilot, it is anticipated that clinical trial services will be assessed using a maturity scale for each action within the Governance Framework to provide a description of success. That is, the Commission recognises that health services will be at different stages of maturity in their ability to implement the actions provided in the Governance Framework. It is expected that improvements should be achievable over a planning cycle of three years, although this will depend on the health service organisation.

3. The maturity scale is a guide for progressive improvements in each of the criteria within the Governance Framework including: demonstration that initial systems are in place; the health service organisation is growing systems and the health service organisation has established systems.
4. For health service organisations providing clinical trial services, following the pilot in 2020, it is anticipated that the next scheduled organisation-wide accreditation visit will involve assessment against the NSQHS Standards including the actions in the Governance Framework.

Find out more

Information on the Governance Framework is available on the Commission website at safetyandquality.gov.au/clinical-trials

Relevant information and documents:

[National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials](#)

[National Clinical Trials Governance Framework introductory video](#)

[National Clinical Trials Governance Framework fact sheets](#)

[NSQHS Standards \(second edition\)](#)

[National Model Clinical Governance Framework](#)

[NSQHS Standards User Guide for Governing Bodies](#)

You can also email the clinical trials project team at: CTgovernance@safetyandquality.gov.au or call 02 9123 3600.

