

KEY ACTIONS
for accrediting
agencies

Fact sheet 10: National Clinical Trials Governance Framework – Information for accrediting agencies

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 towards the 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 carers. 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.

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 purpose of the Governance Framework is 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 National Safety and Quality Health Service (NSQHS) Standards for hospital and day procedure service accreditation, in particular, Standard 1: Clinical Governance and Standard 2: Partnering with Consumers.

Clinical Governance Standard

Clinical Governance is an integrated component of corporate governance of health service organisations. This means that, leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their clinical trial services, and for ensuring that they are patient centred, safe and effective. The Clinical Governance Standard has four components:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care.



Clinical trials governance is the set of relationships and responsibilities established by a health service organisation between its department of health (for the public sector), its governing body, executive, clinical trial workforce, sponsors, clinical and non-clinical managers, patients and consumers to ensure good clinical outcomes. It ensures that everyone, including frontline trial investigators and members of governing bodies is accountable to patients and the community for assuring the delivery of clinical trials is high quality, integrated into clinical care and continuously improving.

Partnering with Consumers Standard

The Partnering with Consumers Standard focuses on supporting patients, carers, families and consumers to be involved in the planning, design, measurement and evaluation of clinical trial services.

This Standard aims to ensure leaders of a health service organisation develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement and evaluation of care.

The Partnering with Consumers Standard has four components:

- Clinical governance and quality improvement systems to support partnering with consumers
- Partnering with patients in their own care
- Health literacy
- Partnering with consumers in organisational design and governance.

Assessment to the actions identified in the Governance Framework

The Governance Framework lists the actions against which health service organisations will be assessed, suggests strategies to help meet the actions within the NSQHS Standards and provides examples of evidence clinical trial services may use to demonstrate they have met the actions within the NSQHS Standards. It is mandatory for all public and private Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards for clinical service provision. Therefore, actions within the NSQHS Standards will also be mandatory for health service organisations that provide a clinical trial service.

The Commission is piloting the Governance Framework in hospitals and day procedure units throughout 2020. Insights gained from the pilot will inform the approach to the implementation of the Governance Framework.

Following the pilot, it is anticipated 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.

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.

Services not required to be assessed to the NSQHS Standards can voluntarily opt to apply the Governance Framework, for best practice and quality improvement purposes.

The Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme

The AHSSQA Scheme sets out the responsibilities of accrediting agencies in relation to implementation of the NSQHS Standards. The AHSSQA Scheme was endorsed by Health Ministers in 2010 and implemented in state and territory public health systems. Private and non-government health service organisations also are subject to the AHSSQA Scheme.

Under the AHSSQA Scheme, it is the Commission's responsibility to approve accrediting agencies seeking to assess health service organisations against the NSQHS Standards.



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](#)

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

