

KEY ACTIONS
for health service
organisations

Fact sheet 2: National Clinical Trials Governance Framework – **Clinical Governance Standard 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 towards implementing the National Safety and Quality Health Service (NSQHS) Standards and achieving accreditation of health services for the conduct of clinical trials.

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 is based on the NSQHS Standard 1: Clinical Governance Standard and Standard 2: Partnering with Consumers.

Since 2013, it is mandatory for all public and private hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards.

Following 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.

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.

What is the 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 its services including clinical trials services, and for ensuring that they are patient centred, and undertaken in a safe environment. The Clinical Governance Standard has four criteria:

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



As with corporate and clinical governance, clinical trials governance is the set of relationships and responsibilities established by a health service organisation between its department of health, its governing body, executive, clinical trial workforce, sponsors, human research ethics committees, those undertaking site-specific assessment, 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 of high quality, integrated into clinical care and continuously improving.

Implementing this Standard

Implementing the Governance Framework in a health service organisation or trial site involves governing bodies, clinicians, clinical and non-clinical managers, patients, consumers, clinical trial workforce and sponsors as well as, well-designed systems to deliver, monitor and account for the quality of clinical trial service provision.

Accreditation to the Standard requires that:

- Clinical trial services are integrated into clinical and corporate governance systems for improved safety and quality of clinical trial service provision
- Managers and the clinical trial workforce have the right qualifications, skills and supervision to provide safe, high-quality clinical trial services to patients
- The environment in which clinical trials are conducted is safe and promotes high-quality clinical trial service provision

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 tools and resources.
2. Following the pilot, it is anticipated that when your organisation accreditation next occurs, your clinical trials service will also be assessed to the actions identified in the Governance Framework using a maturity scale.

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.

