

KEY ACTIONS
for patients and
consumers

Fact sheet 6: **National Clinical Trials Governance Framework –** **Information for patients and** **consumers**

Background

Clinical trials provide early access to new treatments and interventions for patients, and improve the overall standard of medical care provided in Australian hospitals.

To support the delivery of safe and high-quality clinical trial services for patients and consumers, the Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework (Governance Framework) for all Australian hospitals and day procedures with a clinical trial service.

About governance

Governance is the set of relationships and responsibilities established by a health service organisation between its state or territory department of health (for the public sector), governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It assures the community that systems are in place to deliver safe, high-quality health care that is continuously improving.

What is the National Clinical Trials Governance Framework?

The Commission has developed the 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 has been 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.



The Clinical Governance Standard (Standard 1) aims to implement governance for clinical trial services to ensure patients and consumers receive safe and high-quality clinical trial services.

Partnering with Consumers Standard (Standard 2) ensures that:

- Consumers are partners in the planning, design, delivery, measurement and evaluation of systems to deliver clinical trial services
- Trial participants and patients are partners in their own care.

Accreditation to Standards 1 and 2 is already in place in all hospitals and day procedure services across Australia and following the pilot, it is anticipated that, it will also apply to health services with a clinical trial service. Accreditation assures the community that clinical trial services meet expected patient safety and quality standards.

What does it mean for you?

Patients and consumers are at the centre of the Governance Framework which ensures that:

- Clinical trial services are patient-centred and meet community needs
- Trial participants, carers and their families are supported and encouraged to be partners in their own care
- Patients, their carers and families are supported to be partners in the design and governance of clinical trial services
- Patients and consumers have the opportunity to ask for more information about clinical trials information in different formats
- The health service organisation communicates with consumers and patients in a way that is respectful and supports effective partnerships.

Why is it important?

Patients and consumers play an important role in ensuring an acceptable standard for the conduct of clinical trials. As patients and consumers are the most affected by the success and failures of clinical trials, their feedback, complaints and experience can be used to improve the quality of clinical trial service provision.

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 \(second edition\)](#)

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

