FACT SHEET
for health service organisations

National Clinical Trials Governance Framework –

Overview of the National Clinical Trials Governance Framework

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 a nationally consistent approach to 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 then Council of Australian Governments 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 and Aged Care, 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 polices 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.

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Overview of 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.

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.

Overview of the Partnering with Consumers Standard

- The Partnering with Consumers Standard requires health service organisations to establish partnerships with patients, carers, families and consumers in the design, and evaluation of all clinical services including clinical trial services
- Partnerships are necessary at all levels of the organisation to ensure that a health service organisation achieves the best possible outcomes for all parties. Delivering clinical trials that are based on partnerships provides many benefits for patients, consumers, clinicians, health service organisations and the health system. There is evidence of links between the existence of effective partnerships, with positive experience for patients, high-quality health care and improved safety.

The Partnering with Consumers Standard has four criteria:

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

This Standard requires health service organisations to:

- Establish mechanisms to form partnerships with patients, in their own care, including when participating in clinical trials
- Support patients, consumers and carers to actively participate in the organisational design and governance of clinical trial services
- Ensure that patients, trial participants and consumers are provided with information about their healthcare rights
- Ensure information on clinical trials is provided to trial participants, patients, carers and their families, and consumers.

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.

Relevant resources

- National Clinical Trials Governance Framework resources
  - **user guide for HSOs conducting clinical trials**
  - **introductory video**
  - **fact sheets**
  - **case studies**
- ***NSQHS Standards (second edition)***
- ***National Model Clinical Governance Framework***
- ***NSQHS Standards User Guide for Governing Bodies***

Questions?

For more information, please visit the **Commission's website**. You can also email the **Advice Centre** or call 1800 304 056.