FACT SHEET
for health service organisations

National Clinical Trials Governance Framework –

Roles and functions of managers (clinical and non-clinical)

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.

The aims of the Governance Framework are to support the delivery of high-quality clinical trial services and to ensure that clinical trials are conducted in a safe environment. The Governance Framework is based on the National Safety and Quality Health Services (NSQHS) Clinical Governance Standard and Partnering with Consumers Standard.

In February 2022, all jurisdictions agreed to implement the Governance Framework in health service organisations as an embedded under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme. That is, health service organisations will be assessed concurrently for clinical and corporate services and clinical trial service provision.

To give health services time to implement the Governance Framework, for the first three-year accreditation cycle, they will be assessed against a maturity scale. That is, health service organisations will be assessed as either having 'Established systems', 'Growing systems', or 'Initial systems' in place to meet the NSQHS Standards (as provided in the Governance Framework) for clinical trial service provision.

Beyond the first three-year accreditation cycle, health services will transition fully to the assessment of their clinical trial services under the AHSSQA Scheme and be assessed as either having met or not met the actions within the Governance Framework and receive 60 business days to remediate.

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 role of managers (clinical and non-clinical)?

Clinical and non-clinical managers including heads of clinical departments, business, finance and human resource managers advise and inform the governing body, and operate clinical trial services within the strategic and policy parameters endorsed by the governing body. They are primarily responsible for ensuring the systems that support the clinical trial service delivery are well designed and perform well.

Clinical Governance Standard

The Clinical Governance Standard aims to ensure 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 ensuring that they are patient centred, safe and effective. There are four criteria within this Standard. The roles and functions of managers (clinical and non-clinical) that apply to each criteria are listed below.

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Governance, leadership, culture

- Advise and inform the governing body on matters related to clinical trials
- Operate clinical trial services within the strategic and policy parameters endorsed by the governing body
- Ensure the systems that support clinical trial service delivery are well designed and perform well
- Lead the development of business plans, strategic plans, and organisational policies and procedures relevant to safety and quality
- Integrate safety and quality processes into organisational plans, policies and procedures
- Set up effective relationships with relevant individuals across the health service organisation to support good clinical trial operational outcomes
- Model the safety and quality values of the health service organisation in all aspects of management
- Support clinicians who embrace clinical trial leadership roles
- Create opportunities for the workforce to receive education in Good Clinical Practice in the conduct of clinical trials

Patient safety and quality improvement systems

- Coordinate and oversee the design of systems for the delivery of clinical trial services
- Engage with clinicians and study teams on all clinical trial system design issues
- Allocate appropriate resources to implement well-designed clinical trial systems of care
- Respond to identified concerns about the design of systems
- Periodically and systematically review the design of systems for high-quality clinical trial services that promote and maximise safety
- Ensure availability of data and information to clinical trial teams to support quality assurance and improvement
- Ensure that safety and quality systems for undertaking clinical trials reflect the role of the health service organisation within a wider network of other health services and providers
- Implement and resource effective systems for management of quality improvement and measurement; safety reporting; risk management; incident management; open disclosure; feedback and complaints
- Systematically monitor performance across all safety and quality systems relating to the conduct of clinical trials

Clinical performance and effectiveness

- Set up an operational policy and procedure framework for delivering clinical trial services, including training requirements
- Maintain records of professional skills, competence and performance in the conduct of clinical trials
- Implement and resource effective systems for management of credentialing and defining scope of clinical trial practice including: education and training and performance monitoring
- Respond in a prompt and effective way to indications of clinical trial operations underperformance
- Systematically monitor safety and quality performance across all clinical trial services

Safe environment for the delivery of care

- Coordinate and oversee planning and development of the clinical trial service to support safety and quality within the health service organisation
- Engage with clinicians in clinical trial services within the health service organisation
- Allocate appropriate resources to ensure that the environment supports safety and quality in the conduct of clinical trials
- Respond to identified concerns about the clinical trial environment within the health service organisation

Partnering with Consumers Standard

The Partnering with Consumers 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, measurement and evaluation of care. The functions of managers (clinical and non-clinical) that apply to Standard 2 for the conduct of clinical trials are:

- Understand the barriers for patients and consumers to understand and use health services, and develop strategies to improve the health literacy environment of the health service organisation
- Ensure that patients and consumers have access to high-quality, easy-to-understand information about health care and clinical trials
- Set up organisational systems to enable consumers to fully engage in planning and sharing decisions about their own health care planning and participation in clinical trials
- Collect and review patient experience information as part of quality improvement processes
- Create opportunities for consumer involvement in relevant operational committees and, planning, designing, and evaluating clinical trial services
- When appropriate, set up specific consumer advisory committee.

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.