FACT SHEET
for clinical
trial sponsors

National Clinical Trials Governance Framework –

Roles and functions of clinical trial sponsors

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.

Sponsors and contract research organisations

All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity. Sponsors of trials under the Therapeutic Goods Administration Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes may include individuals, companies, institutions, or organisations.

The trial sponsor is responsible for the initiation, management and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct.

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The quality and integrity of the clinical trial data is also the responsibility of the trial sponsor. The trial sponsor retains overall responsibility for all delegated functions in accordance with the Guideline for Good Clinical Practice and the International Organisation for Standardisation for trials under the CTN or CTX schemes. This also applies when a non-commercial trial sponsor delegates duties to a coordinating principal investigator, trial coordinating centre, clinical research organisation or health service organisation.

It is the responsibility of the sponsor to ensure appropriate approvals are obtained prior to the commencement of the clinical trial and that conditions of any approvals are adhered to during the course of the clinical trial. The trial sponsor also ensures that the ethical principles of research merit and integrity, justice, beneficence and respect are applied to the conduct of clinical trials.

Trial sponsors ensure that a trial is appropriately monitored for compliance with the protocol. Before initiating a trial, the trial sponsor should ensure that quality management systems are in place and that these systems are robust enough to fulfil all the requirements of the protocol and relevant regulatory requirements, including relevant state and territory legislation. For example, when designing a trial, the principles of Good Clinical Practice requires trial sponsors to use a multi-disciplinary team of qualified individuals (such as, biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process.

For investigator-initiated trials, the health service organisation or trial site that is the approving authority may also be the trial sponsor. In such cases, the governing body ensures that it delineates its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of sponsorship can be met.

Trial sponsors should have processes in place to ensure the risks associated with clinical trials and their conduct are identified and assessed, so that adequate trial monitoring and management plans can be developed to mitigate risk that may adversely impact on trial quality or participant safety.

Trial sponsors, or their delegate, are also required to:

- Retain clear, accurate, secure and complete records of all clinical trials including clinical trial data and primary materials. Allow access and reference to these by the regulator and interested parties, as appropriate
- Disseminate clinical trial findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner
- Disclose and manage actual, potential or perceived conflicts of interest
- Ensure that authors of clinical trial outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the clinical trial and its output, and that they agree to be listed as an author
- Acknowledge those who have contributed to the clinical trial, and cite and acknowledge other relevant work appropriately and accurately
- Report suspected breaches of the Australian Code for the Responsible Conduct of Research (the Code) to the relevant institution and/or authority.

Roles and functions of sponsors

The Governance Framework recognises the important role clinical trial sponsors have in contributing to the delivery of safe, high-quality clinical trial service provision. The Governance Framework outlines the functions of clinical trial sponsors under two criteria, patient safety and quality improvement systems and clinical performance and effectiveness.

Patient safety and quality improvement systems

- Ensure open and transparent communication with the trial site personnel including the principal investigator, clinical trial teams, site coordinating and authorising offices
- Conduct the trial according to the trial protocol and the conditions of the Human Research Ethics Committee (HREC) approval
- Provide required documents in a timely manner and support trial sites with document submission to the relevant office (HREC and Site-Specific Assessment Office) for adverse event and annual reporting
- Support quality processes and reporting as required on the conduct of clinical trials within the health service organisation or trial site

Clinical performance and effectiveness

If the health service organisation is the sponsor of a clinical trial, they have a responsibility for monitoring the conduct of a clinical trial for compliance with relevant regulations and requirements and should ensure they have sufficient resources to meet all of their monitoring obligations. In this case, the health service organisation should:

- Ensure that it exercises appropriate quality control over a clinical trial such that researchers or other staff over whom it has authority, conform to any contracts and agreements and comply with any relevant internal or applicable external policies
- Ensure that it has an opportunity to consider any changes to a research project that have implications for its capacity to support the conduct of the trial in accordance with any ethical and administrative requirements
- Have some role in protecting the safety and welfare of participants in the trial via notification of relevant information from appropriate parties
- Ensure that data collected is properly secured and that project records are properly kept
- Ensure that financial matters related to a research project are being properly managed
- Oversee the conduct of the project via receipt of progress reports on at least an annual basis (at a minimum) during the active phases of the research project
- Oversee the conduct of the project via receipt of final reports on the clinical trial
- Ensure that project closure proceeds in accordance with any contractual or internal site requirements
- Ensure that research outcomes that are published are notified to the institution
- Ensure that any complaints raised by participants in the trial, allegations of research misconduct or potential post-project authorisation conflicts of interest are properly investigated and that any resulting recommendations are implemented and, if appropriate, notified to the reviewing HREC and/or the NHMRC as appropriate
- Ensure that any special conditions that have been imposed at the time of project authorisation are met.

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.