

About the National Clinical Trials Governance Framework

In 2017, the Australian Commission on Safety and Quality in Health Care (the Commission) undertook a project to develop the [National Clinical Trials Governance Framework](#) (the Governance Framework) on behalf of all states and territories, as a first step towards accrediting health services undertaking clinical trials. The Governance Framework is a key element of the COAG Health Council revitalised clinical trials agenda under the Encouraging More Clinical Trials in Australia initiative.

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.

Under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme, it is intended the Governance Framework will strengthen governance arrangements for hospital administrators, health services that deliver clinical trials, private companies, trial sponsors and trial investigators. Specifically, the Governance Framework supports health services to improve trial start-up times, optimise pre-approval and recruitment timeframes and improve collaboration across health service organisations.

The Commission have developed the following introductory video that explains what the Governance Framework is:



<https://www.youtube.com/watch?v=tGXmj9ReeLw>

Pilot of the National Clinical Trials Governance Framework

St Vincent's Health Network, Sydney and Melbourne has been selected as one of the 14 pilot sites for the pilot of the Governance Framework, with the pilot accreditation assessment planned for December 2020. The full list of pilot sites selected can be found [here](#).

Following the pilot, it is anticipated that, health service organisations accredited to the National Safety and Quality Health Service (NSQHS) Standards conducting clinical trials will be assessed against the actions in the Governance Framework.

For health service organisations that are already accredited to the NSQHS Standards, the accreditation process will remain unchanged. However, assessment against the actions in the Governance Framework will be included.

SVHM Departmental Requirements

The Research Directorate will be contacting all departments in the following weeks to ask for the completion of the 'National Clinical Trials Governance Framework: Departmental Feedback Form' to provide information on the departmental workforce, training, policies/procedures and operations.

Supporting Documents and Resources

The Governance Framework, Literature Review and Mapping Exercise

The Governance Framework is underpinned by a literature review, a mapping exercise of national and state and territory regulation, legislation, clinical trial policies and processes, and feedback received from national sector-wide consultation.

- [National Clinical Trials Governance Framework and User Guide](#)
- [National Clinical Trials Governance Framework Literature Review](#)
- [National Clinical Trials Governance Framework Mapping Exercise](#)

The documents listed above can be found at:

<https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide>

FAQs and Fact Sheets

- [FAQs - National Clinical Trials Governance Framework](#)
- [Fact sheet 1 - National Clinical Trials Governance Framework and accreditation overview](#)
- [Fact sheet 2 - National Clinical Trials Governance Framework - Clinical Governance Standard](#)
- [Fact sheet 3 - National Clinical Trials Governance Framework - Partnering with Consumers Standard](#)
- [Fact sheet 4 - National Clinical Trials Governance Framework - Roles and functions of the governing body](#)
- [Fact sheet 5 - National Clinical Trials Governance Framework - Roles and functions of managers \(clinical and non-clinical\)](#)
- [Fact sheet 6 - National Clinical Trials Governance Framework - Information for consumers](#)
- [Fact sheet 7 - National Clinical Trials Governance Framework - Roles and functions of clinical trial sponsors](#)
- [Fact sheet 8 - National Clinical Trials Governance Framework - Roles and functions for site principal investigators](#)
- [Fact sheet 9 - National Clinical Trials Governance Framework - Roles and functions for the clinical trial workforce](#)
- [Fact sheet 10 - National Clinical Trials Governance Framework - Information for accrediting agencies](#)

The documents listed above can be found at:

<https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-faqs-and-fact-sheets>

Questions

If you have any questions on the Governance Framework or pilot of the Governance Framework please contact:



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