

# National Clinical Trials Governance Framework – Frequently asked questions

## What is 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 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.

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 time frames and improve collaboration across health service organisations.

The Governance Framework describes the actions that are essential for health service organisations to achieve integrated corporate and clinical governance systems for clinical trial services.

## How will the Governance Framework assist hospital administrators to drive efficiencies in clinical trial service provision?

The cost of delays in trial start-up impact on clinical trial budgets and are frequently related to strategic and operational barriers. Improved organisational governance of trial services enables health administrators to oversight trial operations including (complex) contract negotiation (including financial schedules), use of national forms and standard contracts, determine work force arrangements and optimise organisational strategic planning to deliver clinical trial services. It is anticipated that, accreditation to the actions within the Governance Framework will remove barriers to the following clinical trial processes.

- Trial site feasibility assessment
- Timely ethical and site specific assessment approval timeframes
- Participant screening and recruitment activities
- Trial management
- Workforce planning and staff training
- Trial related financial management and reporting.



Systems and processes currently in place in health service organisations that underpin strategic planning to deliver clinical trial services include: organisational leadership; policies and procedures; risk management; incident management and open disclosure; workforce safety and quality training and infrastructure to deliver clinical trials.

The Commission has developed resources to support health services implement the Governance Framework. Once implemented, health service administrators will have visibility of trial related activity within their organisation. Clinical trial operations will be measured and reported by trial; trial site; health service organisation and jurisdiction. Measures of operational efficiency will align with the National Aggregate Statistics (NAS) currently reported only at the jurisdictional level for public health organisations.

## **How will accreditation against the actions in the Governance Framework fit with my current accreditation processes?**

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.

Health service organisations will continue to select their accrediting agency, from among approved agencies, to assess their performance.

## **How can I access the Governance Framework?**

Once endorsed by the COAG Health Council, the Governance Framework will be publically available via the Commission's website. A national pilot of the Governance Framework and supporting resources will be undertaken throughout the first half of 2020.

Further information about accessing the Governance Framework, the resources to support the pilot and implementation are available on the Commission website [safetyandquality.gov.au/our-work/clinical-trials/project-information](https://safetyandquality.gov.au/our-work/clinical-trials/project-information).

## **How does the Governance Framework align with the NSQHS Standards?**

The Governance Framework builds on the NSQHS Standards, providing information about the roles and functions of those people involved in providing clinical trial services within a health service organisation or trial site. The Governance Framework advises on the actions and suggests strategies a health service organisation or trial site may implement to meet the actions. Examples of evidence a health service organisation may provide to accreditation assessors to demonstrate they have met the actions are also available in the Governance Framework.

Accreditation of clinical trial services under the AHSSQA embeds clinical trials into routine health service provision, optimises organisational strategic planning to deliver clinical trial services and delivers measureable efficiencies in trial operations including:

- Trial site feasibility assessment
- Pre-recruitment activities (ethics and local site review and approval timeframes)
- Participant recruitment
- Trial management
- Workforce management
- Trial related financial management.

This approach intends to:

- Strengthen governance arrangements for clinical trial services
- Provide clarity to those responsible for delivering clinical trials, including patients, clinicians, trial sponsors and hospital administrators
- Reduce duplication and increase efficiency, cohesion and productivity across the clinical trials sector.

## **Why is there a National Clinical Trials Governance Framework?**

In April 2016, the COAG Health Council noted that, while jurisdictions have worked to improve the environment for clinical trials, issues of fragmentation and inefficiency remain that impact on Australia's attractiveness as a preferred location for clinical trials.

The Australian Health Ministers' Advisory Council (AHMAC) was tasked to work up options for the development of models of best practice to organise sites and to improve administered efficiencies, better

engage sponsors and improve trial start up times. The full AHMAC response was developed on its behalf by the (now) Clinical Trials Project Reference Group (CTPRG) and included a recommendation for a national Governance Framework. The CTPRG is the expert advisory sub-group within the Clinical Principal Committee under AHMAC who are tasked with progressing the COAG Health Council revitalised clinical trials agenda.

In 2017, the Commission was engaged by the Australian Government Department of Health on behalf of all states and territories to undertake a project to develop the Governance Framework under the Encouraging More Clinical Trials in Australia initiative. In April 2018, an **expert Steering Committee** was convened to advise on the development of the Governance Framework which was underpinned by a literature review; a mapping exercise of national and jurisdictional regulation, legislation, clinical trial policies and processes and national sector-wide consultation.

The Governance Framework is the first step towards a nationally consistent accreditation of health service organisations undertaking clinical trials and is highly anticipated by the jurisdictions and the clinical trials sector.

## **How was the Governance Framework developed and agreed?**

The development of the Governance Framework was based on broad consultation and in collaboration with representatives from all states and territories, technical experts and a wide range of stakeholders, including health professionals and consumers. The Governance Framework has been agreed by the AHMAC in October 2019 and by the COAG Health Council in November 2019.

## **What is the role of the Commission?**

The Commission oversees the implementation of the AHSSQA Scheme, including:

- Developing and maintaining the NSQHS Standards
- Advising Health Ministers on the scope of accreditation i.e. which health service organisations should be accredited
- Approving accrediting agencies to assess against the NSQHS Standards
- Liaising with regulators on opportunities to improve the NSQHS Standards and accreditation system
- Reporting to Health Ministers annually on matters relating to safety and quality in health care.

## **How is the Commission supporting the implementation of the Governance Framework?**

The Governance Framework and user guide provides detailed information and strategies to assist health service organisations with implementing the improvements required by the Governance Framework. Suggested strategies to meet the actions within the Governance Framework, and examples of evidence a health service might provide to demonstrate they have met the actions are also provided.

The Commission has also developed supporting resources (including a self-assessment tool, fact sheets, video tutorial and online operational metrics tool) to support implementation. These resources will also be available to all health services to use during the pilot process in early 2020.

The Commission has a NSQHS Standards Helpdesk as a national source of advice, support and, if required, mediation between health service organisations and surveyors during the survey. Support will be provided by telephone 1800 304 056 and email [accreditation@safetyandquality.gov.au](mailto:accreditation@safetyandquality.gov.au).

Additional support will be provided by the Commission to health service organisations throughout the pilot. This includes regular telephone contact, access to resources, support and expert information.

## **What happens if the health service organisation does not meet all the actions in the Governance Framework?**

Following the pilot, it is anticipated that, clinical trials services will be assessed using a maturity scale for each action to provide a description of success. That is, the Governance Framework recognises that health services will be at different stages of maturity in implementation of the actions. 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 NSQHS Standards for trial services including demonstration that initial systems are in place; the health service organisation is developing systems and the health service organisation has established systems.

**Figure 1: Maturity scale for trial site accreditation**



Subsequently, as with assessment to the NSQHS Standards, health service organisations will generally be given 90 days from the receipt of written notification of not met assessments (which may also be their survey report) to rectify any not met actions before a final determination is made on an accreditation award. This ensures consistency in the assessment process for all services (including clinical trial services) provided by health service organisations and day procedure facilities.

The benefit of the Governance Framework is a nationally consistent approach to organisational governance of all clinical trial services. It is anticipated that, assessment of health service organisations to the Governance Framework under the AHSSQA Scheme, 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 is embedded in the NSQHS Standards eliminating duplication in the accreditation assessment process.

## How will the Governance Framework impact investigator initiated-clinical trials?

One of the underpinning principles of the Governance Framework is equity. That is, health service organisations provide equitable access for the community to commercially sponsored clinical trials and investigator-initiated clinical trials in a timely manner.

The Governance Framework also provides guidance for health service organisations when they are the trial sponsor. 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 separates its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of sponsorship can be met.

## What is the role of clinical trial networks and Advanced Health Research and Translation Centres (AHRTCs) networks in supporting health service organisations implement the Governance Framework?

Clinical trial networks and ARHTCs could work with their member organisations to build capacity in a number of ways including, but not limited to: clinical trial education and training for the workforce and consumers; providing advice and support to trial investigators and researchers on good clinical trial practice relating to protocol development; data management and analytics; report writing; navigating ethical processes; participant recruitment and project management.

AHRTCs could also support health service organisations in the review of clinical trial outcomes and contribute to guideline development and evidence translation into clinical practice.

## Abbreviations

<u>AHMAC</u>	Australian Health Ministers' Advisory Council
<u>AHSSQA</u>	Australian Health Service Safety and Quality Accreditation
<u>ARHTCs</u>	Advanced Health Research and Translation Centres
<u>COAG</u>	Council of Australian Governments
<u>CTPRG</u>	Clinical Trials Project Reference Group
<u>NSQHS</u>	National Safety and Quality Health Service