

# National Clinical Trials Governance Framework

The Australian Commission on Safety and Quality in Health Care, on behalf of all jurisdictions, developed the **National Clinical Trials Governance Framework** as the first step towards a nationally consistent approach to the accreditation of health services for the conduct of clinical trials.



Assessments commence in **May 2023**

## Mandatory for

health service organisations conducting clinical trials, including:

- public & private hospitals
- day procedure services
- public dental services



Assessed against 27 identified actions under the Governance Framework aligned with the NSQHS Standards, in particular the

- **Clinical Governance Standard**
- **Partnering with Consumers Standard**

For health service organisations to demonstrate they have met the actions within the NSQHS Standards

**for their clinical trial service provision**



## ACHS will work with you throughout the Assessment Process in two stages

### First three-year accreditation cycle

- Allow time for you to implement the Governance Framework
- Assessed against a **maturity scale**: Initial systems, Growing systems, Established systems

### Beyond the first three-year accreditation cycle

- Transition fully to the assessment of your clinical trial services under the Australian Health Service Safety and Quality Accreditation Scheme
- Assessed as either having **met** or **not met** the actions within the NSQHS Standards Clinical Governance Standard and Partnering with Consumers Standard (as provided in the Governance Framework)

For organisations that are already accredited to the NSQHS Standards with ACHS, assessment against the Governance Framework will occur in alignment with the NSQHS Standards assessment.

## Next Steps →

If your health service organisation conducts clinical trials, contact your Customer Services Manager via [csm@achs.org.au](mailto:csm@achs.org.au) or **02 9281 9955** to discuss when your health service will be assessed to the National Clinical Trials Governance Framework and what information you will need to provide in relation to the clinical trials being conducted by your health service.

## Ongoing Support For Our Members

Our dedicated Customer Services Team is here to provide ongoing support throughout the accreditation program and answer your questions regarding the assessment of the Clinical Trials Governance Framework.

### FAQs

#### **? Does my organisation need to be assessed under the Clinical Trials Governance Framework**

The actions in the National Clinical Trials Governance Framework are mandatory for health service organisations that provide a clinical trial service.

#### **? What is a clinical trial**

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Clinical trials include but are not limited to: Surgical and medical treatments and procedures, Experimental drugs and diagnostics, Biological products, Medical devices, Health-related service changes, Health-related preventative strategies and Health-related educational interventions.

#### **? What is the assessment process for the National Clinical Trials Governance Framework**

For the first three-year assessment cycle, clinical trials services will be assessed using a maturity scale for each action to provide a description of success.

Beyond the first three-year accreditation cycle, health service organisations 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.

#### **? What do I need to do in preparation for the assessment of the Clinical Trials Governance Framework**

Speak to your ACHS Customer Services Manager. Prior to assessment you will be required to submit information to ACHS about the clinical trials being conducted in your health service.

## Resources Available

We encourage you to access a range of resources developed by the Commission to assist health service organisations with the implementation of the National Clinical Trials Governance Framework.

These resources include a **self-assessment tool** and an **operational metrics tool** developed by The Australian Commission on Safety and Quality in Health Care.

**Scan QR code to find a summary of these resources and learn more about the National Clinical Trials Governance Framework.**



## Next Steps →

If your health service organisation conducts clinical trials, contact your Customer Services Manager via **cs@achs.org.au** or **02 9281 9955** to discuss when your health service will be assessed to the National Clinical Trials Governance Framework and what information you will need to provide in relation to the clinical trials being conducted by your health service.