

FACT SHEET
for health service
organisations

National Clinical Trials Governance Framework – **Process for accreditation to the National Clinical Trials Governance Framework**

About the National Clinical Trials Governance Framework

The Commission, on behalf of all jurisdictions, developed the National Clinical Trials Governance Framework (Governance Framework) as the first step towards a nationally consistent approach to the accreditation of health services for the conduct of clinical trials.

In February 2022, all jurisdictions agreed to implement the Governance Framework in health service organisations as an embedded approach 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.

Implementation commences in early 2023, in alignment with assessment of health service organisations to the National Safety and Quality Health Service (NSQHS) Standards.

For the first assessment cycle, health service organisations will be assessed against a maturity scale. 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 within the NSQHS Standards Clinical Governance Standard and Partnering with Consumers Standard (as provided in the Governance Framework).

About accreditation

Accreditation is the outcome of an independent assessment process undertaken to verify a health service organisation's implementation of the Governance Framework. Assessment and the awarding of accreditation provides assurances to the community that a health service organisation has the systems and processes in place to meet expected patient safety and quality standards of health care. It is mandatory for all public and private Australian hospitals, day procedure services and public dental services to be assessed through an independent accreditation process to determine whether they have implemented the actions within the Governance Framework.

Preparing for an assessment

Familiarise yourself with the Governance Framework

The National Clinical Trials Governance Framework and [user guide for health service organisations conducting clinical trials](#) provides:

- The roles and functions for identified positions relating to clinical trial service provision within a health service organisation
- The actions against which health service organisations with a clinical trial service will be assessed for accreditation



- Suggested strategies health service organisations may implement to meet the actions within the NSQHS Standards
- Examples of evidence health service organisations may provide that demonstrate they have met the actions within the NSQHS Standards for clinical trial service provision.

Use your existing committees or establish a working group responsible for strategic planning

This group should be set up in consultation with your senior management and include members of the clinical trials workforce, consumers and trial sponsors.

They will work with the organisation's management to implement the Governance Framework, allocate resources and develop mechanisms to report on and review operational performance on a regular basis. The governing body has ultimate responsibility for safety and quality and ensuring the actions as provided in the Governance Framework are met.

Conducting a self-assessment

Conducting a self-assessment, will help you identify areas where your health service organisation meets the actions in the Governance Framework and areas where improvement is required.

Use the [clinical trials portal self-assessment tool](#) to help determine how well your health service organisation meet the actions in the Governance Framework and monitor progress towards full conformance. The tool enables you to:

- Determine whether your health service organisation meets the actions
- Document the evidence that demonstrates each action has been met
- Create an action plan of any tasks to meet the actions, including allocating a person responsible for completing the tasks.

Actions within the Governance Framework are aligned with the NSQHS Standards. Speak with your safety and quality officer about the systems and processes currently in place to meet the actions within the NSQHS Standards and use the tool to assess your clinical trial service.

Sampling

Sampling of **all** clinical trial services and the trial they conduct within a health service organisation is required prior to being assessed against the actions in the Governance Framework.

The sample is based on the clinical department or area of specialisation conducting the trial; the phase of trial; sponsor type; and number of recruited trial participants.

Sampling the whole service ensures a representative sample of trials are assessed.

Your accreditation agency will require the following information ahead of assessment:

- List of all departments or specialisations (for example neurology, oncology, endocrinology)
- List of all clinical trials name
- For all clinical trials
 - clinical trial phase (I, II, III, IV)
 - Sponsor (for example commercial, university, hospital) and sponsor name
 - principal investigator (name and position)
 - number of staff allocated to the trial
 - number of patients in the trial
 - number of Aboriginal and Torres Strait Islander patients in the trial.



Overview of the assessment process

Implementation of the Governance Framework will occur in two stages.

Stage 1 – Assessment against a maturity scale

For the first assessment cycle:

1. **Initial assessment** – assessors will
 - request the information required to enable sampling of clinical trials services
 - review evidence provided by health service organisations to demonstrate clinical trial services have implemented the relevant actions in the NSQHS Standards for clinical trial services as provided in the Governance Framework
 - develop a visit schedule and undertake an onsite or virtual site assessment to verify the evidence provided through observation and interviews with key personnel, trial sponsors and trial participants
 - provide the following reports
 - a. initial report assessing the health service to the NSQHS Standards for clinical service provision
 - b. report assessing the health service organisation to the actions in the Governance Framework
 - c. provide the maturity score card for clinical trial service provision
 - for the first assessment cycle, health service organisations will receive one of the following ratings
 - ▶ **Established systems:** Evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation
 - ▶ **Growing systems:** Evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps
 - ▶ **Initial systems:** Evidence to demonstrate that the requirements of the action are yet to be commenced or implemented
2. **Final report** – the accrediting agency will provide a final report within one month of the assessment
3. **Submission of data** – the Commission receives data on assessment outcomes from the accrediting agency
4. **Registration** – the Commission will enter the details of health service organisations who have been assessed on a register of assessed clinical trial service providers.

Assessment of health service organisations against the maturity scale recognises that health service organisations are at different stages of maturity in implementing the actions within the Governance Framework. It is expected that improvements should be achievable over a planning cycle of three years (one accreditation cycle).

Stage 2 – Assessment under the AHSSQA scheme

For the second and subsequent assessment cycles, health service organisations will be accredited if all actions in the Governance Framework are rated as 'met' or 'met with recommendation'.

For the second and subsequent accreditation cycles, the assessment process will involve:

1. **Initial assessment** – assessors will
 - request the information required to enable sampling of clinical trials services
 - review evidence provided by health service organisations to demonstrate clinical trial services have implemented the relevant actions in the NSQHS Standards for clinical trial services as provided in the Governance Framework
 - develop a visit schedule and undertake an onsite or virtual site assessment to verify evidence through observation and interviews with key personnel, trial sponsors and trial participants
 - advise health service organisations of any actions rated 'not met' at the time of assessment
 - provide an initial report to health service organisations within five business days of the conclusion of the initial assessment
2. **Remediation period** – where relevant actions assessed have been rated 'not met', health service organisations will be given 60 business days to implement changes to demonstrate the requirements of the specified actions have been met
3. **Final assessment** – the accrediting agency will conduct a final assessment within 65 business days of the initial assessment, to determine if actions rated 'not met' have been remediated, as well as whether any improvements have been made to actions rated 'met with recommendation'



4. **Determination of accreditation** – the accrediting agency will determine whether health service organisations have satisfied the requirements of the assessment. Health service organisation will be awarded accreditation if all relevant actions in the Governance Framework are rated as ‘met’ or ‘met with recommendation’. The period of accreditation awarded will be of three years
5. **Submission of data** – the Commission receives data on assessment outcomes from accrediting agency
6. **Registration** – the Commission will enter the details of health service organisations who are accredited on a register of assessed clinical trial service providers.

Accreditation is awarded for a period of three years. The date of commencement of the accreditation period is the date the accrediting agency formally notifies the health service organisation of the final outcome of the accreditation assessment.

The PICMoRS method

Assessors apply the PICMoRS methodology when reviewing a health service organisation for accreditation under the AHSSQA Scheme. PICMoRS is a mnemonic that stands for:

P	Process
I	Improvement strategies
C	Consumer participation
Mo	Monitoring
R	Reporting
S	Safety and quality systems

PICMoRS helps assessors to conduct a thorough evaluation of the safety and quality systems and clinical governance operations of a health service organisation. All six parts to the PICMoRS method must be completed to conduct a comprehensive assessment of the processes being examined.

Relevant resources

National Clinical Trials Governance Framework resources:

- [user guide for HSOs conducting clinical trials](#)
- [Pilot Report \(executive summary\)](#)
- [introductory video](#)
- [fact sheets](#)
- [case studies](#)

Questions?

For more information, please visit the [Commission’s website](#). You can also email the [Advice Centre](#) or call 1800 304 056.

