

FACT SHEET
for accrediting
agencies

National Clinical Trials Governance Framework – Maturity rating for clinical trial service assessment

AHSSQA Scheme

Under the National Health Reform Act 2011, the Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for the formulation of standards relating to health care safety and quality matters. This includes formulating and coordinating the Australian Health Service Safety and Quality Accreditation Scheme (the AHSSQA Scheme), which provides for the national coordination of the accreditation process.

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 AHSSQA Scheme. That is, health service organisations will be assessed concurrently for clinical and corporate services and clinical trial service provision.

Implementation will commence 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, met with recommendations or not met the actions within the NSQHS Standards Clinical Governance Standard and Partnering with Consumers Standard (as provided in the Governance Framework).

The Maturity Scale

The Governance Framework recognises that clinical trial services are at different stages of maturity in their ability to implement the actions in relation to clinical governance and partnering with consumers. The maturity scale is a guide for progressive improvements to meet each action within the Governance Framework.

For the first assessment cycle, each action is to be rated in accordance with the maturity rating score. The mean score is used to determine the overall maturity rating for clinical trial service provision.

Calculating the mean maturity score

For each action, determine its maturity score:

Maturity rating	Rating score
Initial systems	1.0–1.99
Growing systems	2.0–2.99
Established systems	3.0



Determine the mean maturity score:

$$\text{Mean maturity score} = \frac{\text{Total rating score for Clinical Governance Standard} + \text{Total rating score for Partnering with Consumers Standard}}{\text{Total number of actions}}$$

An example of calculations is provided at **Attachment 1**.

Maturity rating	Mean maturity score	Description
Established systems	3.0	The accreditation assessment team reviews evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation.
Growing systems	2.0–2.99	The accreditation assessment team reviews 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	1.0–1.99	The evidence reviewed by the accreditation assessment team demonstrates that the requirements of the action are yet to be commenced or implemented.

Process for rating actions 'Growing systems'

In their reports to the health service organisation and the Commission on assessment outcomes, assessors are to provide a clear and concise explanation of the following for all actions rated as 'Growing systems':

- The minor part of the action that have not been fully met
- The specific unit or location in the service the rating applies to.

Requirements for the action to be fully met.

Process for rating actions 'Initial systems'

At the summation meeting following the first accreditation assessment, assessors are to specify any actions they have rated as 'Initial systems' and provide an explanation for the rating.

A summary report on the initial assessment, including a list of all actions rated as 'Initial systems', is to be provided to the health service organisation within five business days. This report should include a written explanation for all 'Initial systems' ratings and requirements for the actions to be fully met.

Relevant resources

- [National Clinical Trials Governance Framework and User Guide for Health Service Organisations](#)
- [National Clinical Trials Governance Framework Pilot Report – Executive Summary](#)
- [Fact sheet 4: Rating scale for assessment](#)
- [Policy – Approval under the Australian Health Service Safety and Quality Accreditation \(AHSSQA\) Scheme to conduct assessments](#)

Questions?

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



Attachment 1: Example of calculation of the mean maturity score

For Hospital X, the maturity score for each action was determined:

Standard	Component	Action	Score	Rating
Clinical Governance Standard	Governance, leadership and culture	1.1	2	Growing
	Management and executive leadership	1.3	2	Growing
		1.4	2	Growing
		1.5	2	Growing
	Clinical leadership	1.6	2	Growing
	Policies and procedures	1.7	2	Growing
	Quality improvement	1.8	2	Growing
		1.9	2	Growing
	Risk management	1.10	2	Growing
	Incident management systems and open disclosure	1.11	2	Growing
		1.12	2	Growing
	Feedback and complaints management	1.13	2	Growing
		1.14	2	Growing
	Diversity and high-risk groups	1.15	2	Growing
	Healthcare records	1.16	3	Growing
Safety and quality training	1.20	2	Growing	
Safe environment	1.29	2	Growing	
	1.33	2	Growing	
Partnering with Consumers Standard	Integrating governance systems into clinical trial service provision	2.1	2	Growing
	Applying quality improvement systems	2.2	2	Growing
		2.3	3	Established
	Healthcare rights and informed consent	2.4	3	Established
		2.5	2	Growing
	Communication that supports effective partnerships	2.8	2	Growing
		2.9	2	Growing
		2.10	2	Growing
Partnering with consumers in organisational design and governance	2.14	2	Growing	

Mean maturity score:

Total rating score for Clinical Governance Standard	37
Total rating score for Partnering with Consumers Standard	20
Total number of actions	27
Mean maturity score — $(37+20) \div 27$	2.11
Overall maturity rating	Growing