Introduction

In February 2022, all jurisdictions agreed to implement the National Clinical Trials Governance Framework (Governance Framework) in health service organisations under the Australian Health Service Safety and Quality Accreditation Scheme. For the first three-year accreditation cycle, health service organisations will be assessed against a maturity scale: that is, as either having Established systems, Growing systems, or Initial systems in place to meet the National Safety and Quality Health Service Standards (as provided in the Governance Framework) for clinical trial service provision. Beyond the first three-year accreditation cycle, health service organisations will transition fully to the assessment of their clinical trial services and be assessed as either having met or not-met the actions within the Governance Framework and, receive 60 days to remediate.

Pilot of the Governance Framework

From September 2020 to March 2021, the Australian Commission on Safety and Quality in Health Care (the Commission) conducted a pilot implementation of the Governance Framework in 33 health service organisations nationally. The aim of the pilot was to familiarise the clinical trial workforce with the accreditation process and to assess the capacity of each health service organisation to meet the actions within the Governance Framework using a maturity scale. That is, whether the health service organisation had:

- **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.

Development of case studies

The Commission has developed case studies of participating health service organisations that demonstrated a successful integration of clinical trial services into existing corporate and clinical governance systems. These case studies describe the strategies used by health service organisations to implement the Clinical Governance Standard and Partnering with Consumers Standard, and may serve as a guide for other health service organisations in understanding what successful implementation could look like.
### Ramsay Health Care at a glance

<table>
<thead>
<tr>
<th>State/territory</th>
<th>National</th>
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<tbody>
<tr>
<td>Metropolitan/regional</td>
<td>Metropolitan</td>
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<tr>
<td>Public/private</td>
<td>Private</td>
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<tr>
<td>Single/multi-site</td>
<td>Multi-site</td>
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<tr>
<td>Population covered</td>
<td>&gt;1 million</td>
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<tr>
<td>No. clinical trials</td>
<td>300+</td>
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#### Description of the organisation
- Ramsay's global network covers ten countries
- Ramsay Australia has 72 private hospitals and day surgery
- Ramsay Australia admits more than one million patients annually
- Ramsay Australia employs more than 31,000 people
- National Clinical Trial Network established including 14 clinical trials units around Australia
- Ramsay Australia is governed by the Risk Management Committee which reports to the Ramsay Global Board.

#### Approach to implementation
- Project officer appointed to undertake a gap analysis, progress work with the clinical trials network and support engagement across sites
- Planning led by a small team with representation from risk safety and quality, clinical trials and the project officer
- Clinical Governance Committee responsible for overseeing implementation
- Education opportunities identified across Ramsay Australia to understand functions of clinical trials and the accreditation process.

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<table>
<thead>
<tr>
<th>Implementation of the Clinical Trials Governance Framework</th>
<th>Clinical Governance Standard</th>
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<tr>
<td>■ Strategic and business planning processes capture strategies and initiatives to deliver safe and quality clinical trial services</td>
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<tr>
<td>■ Regular report presented to Risk Management Committee including pre-determined KPIs, Riskman report, summary report on research specific policies</td>
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<td>■ Clinical Policy and Forms Framework defines the governance structure and principles for developing, approving, reviewing and managing policies, guidelines and forms</td>
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<td>■ Position descriptions for clinical trials identified positions include reporting line, position summary and skill requirements</td>
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<td>■ Patient Safety and Clinical Quality Framework in place</td>
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<td>■ Comprehensive risk management framework and clinical trial safety reporting policy in place</td>
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<td>■ Clinical trial safety events collated and reported quarterly to facility Chief Executives. Chief Executives report incidents to the Medical Advisory Committee and the Patient Care Review Committee.</td>
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<th>Partnering with Consumers Standard</th>
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<td>■ Consumer Engagement Framework in place to assist facilities establish, maintain and enhance consumer engagement</td>
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<td>■ Consumer Engagement Policy provides guidance on the engagement of consumers in broad operational and strategic decisions</td>
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<td>■ Consumers included in the Board membership and various committees</td>
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<td>■ Consumers participate in risk management and quality improvement activities</td>
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<td>■ Pamphlets and videos regularly developed to orientate and inform participants about trials they may participate in.</td>
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<th>Aboriginal and Torres Strait Islander specific actions</th>
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<td>■ National Learning and Development Orientation and Mandatory Learning Framework includes mandatory training on Aboriginal and Torres Strait Islander Cultural Awareness</td>
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<tr>
<td>■ Cultural Diversity, Sensitivity and Responsiveness Policy comprises requirements for awareness of, and sensitivity to, the diverse needs of the patient populations</td>
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<td>■ Aboriginal Support officer available at each facility.</td>
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Ramsay Health Care (Ramsay) provides health care through a global network of clinical practice, teaching and research. Ramsay’s global network covers ten countries in over 500 locations.

Ramsay Australia has 72 private hospitals and day surgery units and is Australia’s largest private hospital operator. Ramsay Australia admits more than one million patients annually and employs more than 31,000 people.

Ramsay Australia has established a National Clinical Trial Network which currently includes 14 dedicated clinical trials units around Australia.

The Risk Management Committee is the peak committee for all Australian Ramsay hospitals and reports directly to the Ramsay Global Board.
**Governance, leadership and culture**

Ramsay Australia’s Clinical Trials Network shows a strong link between clinical trial unit managers, clinical trial coordinators, project manager, director of research operations, and Chief Executive (Figure 1).

**Figure 1:** Ramsay Australia’s Clinical Trials Network structure

[Diagram of the Clinical Trials Network structure is shown with various roles and locations, including Chief Executive Officer, Chief Operating Officer, Operations Executive Managers, Directors of Clinical Services, VMOs acting as Principal Investigators, External Clinical Trial Units, and abbreviations such as VMO (Visiting Medical Officer).]
Ramsay Australia strategic and business planning processes explicitly capture strategies and initiatives to deliver safe and quality clinical trial services across multiple therapeutic areas. Performance across these areas is closely monitored by the Risk Management Committee which is the peak committee reporting to the Ramsay Global Board. Appointed members of the Risk Management Committee are oriented to individual corporate areas including patient safety and quality. Comprehensive regular reports are presented to the Risk Management Committee and include:

- Riskman report
- Unsatisfactory outliers according to clinical indicators, by hospital
- Pre-determined key performance indicators (KPIs)
- Unresolved complaint outside the 31-day closure requirement
- Policies endorsed by the Clinical Governance Committee
- Clinical Governance summary report including complaints, credentialing, policies and guidelines, research specific policies, and Safe Operating Procedures
- Australian Risk Management Committee dashboard
- Net Promoter Score (NPS) Australian Hospital Patient Experience Question Set (AHPEQS).

Clinical trial risks or issues are reported in the regular report to the Risk Management Committee.

Strategic and operational risks are considered at least annually by all operating divisions as part of Ramsay Australia's annual strategic planning, forecasting, and budgeting process. Each facility is responsible for the development and maintenance of a risk management plan identifying material risks, developing strategies for dealing with those risks and developing and testing controls.

The Ramsay Australia Clinical Policy and Forms Framework defines the governance structure and principles for developing, approving, reviewing and management of its clinical policies, guidelines, and forms. The Ramsay Australia national Clinical Governance Unit is responsible for the development of all clinical policies, guidelines, and forms. Facilities do not develop clinical policies but adhere to the mandatory use of Ramsay Australia clinical policies with supporting guidelines, facility work instructions and standard operating procedures. All clinical trial sites use standardised operating procedures and a standardised process to establish trial activity. All clinical trials operate under an ethical and governance framework that complies with the Australian Code of Research Conduct, Good Clinical Practice and ethical standards.

Position descriptions for clinical trial identified positions include reporting line, position summary and skill requirements. Good Clinical Practice training is mandatory for the clinical trial workforce.

Ramsay Australia Patient Safety and Clinical Quality Framework represents the systems and process through which patient safety and quality care initiatives are managed. The Patient Safety and Clinical Quality Framework is person-centred and consists of four other key areas including safety, structure, culture, and a culture of continuous improvement.

Ramsay Australia has developed a comprehensive Clinical Governance Framework based on:

- Clinical risk management (making sure their services are safe and minimising risk of error)
- Clinical effectiveness (making sure that the clinical services they provide are effective)
- Effective workforce (making sure their staff are competent and up to date)
- Consumer participation (involving their patients and carers in their care).

**Patient safety and quality improvement system**

Ramsay Australia's Governance Framework ensures that clinical trial services provided are effective by ensuring:

- Quality and safety indicators are used to measure and monitor performance
- Quality plans are initiated when significant issues are flagged
- Quality and safety indicators are benchmarked nationally
- Serious clinical incidents are reported and investigated
- Clinicians are represented on the Governance Committee and expert clinical advisory panels
- High risk areas are audited on a regular basis
- Quality performance and safety issues are reported to the Board.

Ramsay Australia has established a Risk Management Framework which includes comprehensive guidance on risk management and corporate governance, operational roles and responsibilities, risk escalation, risk management process and risk management tools. The process of managing risk is integrated into Ramsay Australia's overall governance, strategy, management, reporting process, policies, values and culture.
The Clinical Trial Safety Reporting Policy and Guideline provide comprehensive guidance to facilities on the management of safety monitoring and reporting requirements of clinical trials and includes clear definitions of multiple events and step by step management.

The number and severity of clinical trial safety events happening at a facility is collated and reported on a quarterly basis to the facility Chief Executive. The Chief Executive reports incidents to the Medical Advisory Committee and the Patient Care Review Committee.

The Patient Safety and Clinical Quality Framework also includes the garnering of patient and consumer feedback, involving consumers and patients in safety and quality, open disclosure, and complaints management. Ramsay Australia routinely collects and publishes data on patient and consumer experience. Action plans are developed from feedback received, and strategic and business planning are informed by patient and consumer experience. Ramsay Australia’s surveying of patient, families and carers is comprehensive and robust, however, clinical trial participants, their families and carers are not regularly surveyed.

**Partnering with consumers**

A Consumer Engagement Framework is in place and aims to assist facilities establish, maintain and enhance consumer engagement and participation at an individual, facility, governance and corporate level. The Consumer Engagement Policy provides guidance on the engagement of consumers in broad operational and strategic decisions. The Consumer Engagement Policy recognises that engaging consumers in the design, delivery and evaluation of health care can bring significant benefits to healthcare outcomes; the experience of care and the operations of delivering care.

Consumers are included in the Board membership and on various committees such as the Medical Advisory Committee.

Consumers participate in risk management and quality improvement activities and consumer feedback from patient satisfaction surveys informs strategic and business planning. Hospital volunteers are regularly consulted as consumers and any planned changes in business are often presented to consumers.

**Health literacy**

Pamphlets and videos are regularly developed to orientate and inform participants about trials they may participate in. The Resources Cultural Diversity, Sensitivity and Responsiveness Policy provides information for the workforce on participants’ culture and diversity.

**Aboriginal and Torres Strait Islander-specific actions**

Ramsay Australia’s National Learning and Development Orientation and Mandatory Learning Framework includes mandatory training on Aboriginal and Torres Strait Islander Cultural Awareness.

The Cultural Diversity, Sensitivity and Responsiveness Policy is in place and comprises requirements for awareness of, and sensitivity to, the diverse needs of the patient populations served in order to achieve safe and desired clinical care and outcomes. The document provides links to multiple videos, posters and podcasts.

An Aboriginal Support officer is available at each facility to support the participation of Aboriginal and Torres Strait Islander patients in clinical trials.
Actions assessed as Growing systems

- **Policies and procedures (Action 1.7)** – It was not always evident that policies and procedures were reviewed when due and clinical trials Standard Operating Procedures were not always formally approved and in current version.
- **Incident management systems (Action 1.11)** – There was some uncertainty in regards to reporting lines and process for adverse events and serious adverse events in the workforce interviewed.
- **Feedback (Action 1.13)** – Overall the organisation’s surveying of patient, families and carers is comprehensive and robust. However, there was insufficient evidence provided to confirm the survey of clinical trial participants, their families, carers and sponsors.
- **Safe environment (Action 1.29)** – Some equipment used for the care of clinical trial participants, were not serviced as required.

**Approach to implementation**

Ramsay Australia has engaged a project officer to undertake a gap analysis, progress work with the clinical trials network and support engagement across the sites. Planning is led by a small team with representation from risk safety and quality, clinical trials and the project officer.

Responsibility for overseeing the implementation of the National Clinical Trials Governance Framework sits with the Clinical Governance Committee.

Education opportunities have been identified across Ramsay Australia to understand functions of clinical trials and the accreditation process.

Resources

- The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials
- National Clinical Trials Governance Framework Frequently Asked Questions and fact sheets
- The National Clinical Trials Governance Framework Pilot: Executive Summary Report
- The Clinical Trials Portal
- Assessment to the National Safety and Quality Health Service Standards.

Find out more

For more information about The National Clinical Trials Governance Framework visit the Commission’s website or contact the Safety and Quality Advice Centre at AdviceCentre@safetyandquality.gov.au or phone 1800 304 056.