



The National Clinical Trials Governance Framework case study

Royal Darwin Hospital

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.

Royal Darwin Hospital at a glance

State/territory	Northern Territory
Metropolitan/regional	Regional
Public/private	Public
Single/multi-site	Single
Population covered	200,450
No. clinical trials	< 100
Description of the organisation	<ul style="list-style-type: none"> ■ The Top End Health Services region includes: Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove Hospital, Top End Mental Health Services and numerous remote health clinics ■ The population represents 82% of the Northern Territory population ■ Around 26% of the population is from Aboriginal or Torres Strait Islander origin ■ The Royal Darwin Hospital is a university teaching hospital with 360-bed ■ Executive Leadership Team is the governing body and reports directly to the Department of Health ■ Some Committees established by the Executive Leadership Team include the Health Advisory Committee, the Safety and Quality Committee, the Clinical Innovation and Research Committee, the Aboriginal Health Committee.
Approach to implementation	<ul style="list-style-type: none"> ■ Small internal working party established to oversee implementation of the Governance Framework ■ Working party focuses on engaging all relevant stakeholders ■ Strong and effective support from executive ■ Risk safety and quality team engaged early in the implementation process ■ Educational opportunities identified early to increase awareness of the Governance Framework requirements across the organisation ■ Broad engagement across the organisation during the pilot accreditation assessment.

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Implementation of the Clinical Trials Governance Framework	Clinical Governance Standard	<ul style="list-style-type: none"> ■ Research incorporated in the strategic plan and organisational structure ■ Roles and responsibilities for safety and quality in clinical trials are included in clinical trials coordinator positions ■ Clinical Innovation and Research Committee is chaired by an Executive member and reports to the Executive Leadership Team ■ Operational data and trial findings discussed at Clinical Trial Unit quarterly meetings ■ Quality improvement activities, risks and incidents reported through Riskman ■ Collection of patient experience through community meetings, patient surveys, Talk to Us Program, online form or feedback cards.
	Partnering with Consumers Standard	<ul style="list-style-type: none"> ■ Health Advisory Committees and Consumer Advisory Group established to promote and facilitate community consultation and engagement to shape the delivery of services ■ Participant satisfaction surveys appropriate to the different language groups of the Royal Darwin Hospital catchment area conducted ■ Participant Experience and Consumer Engagement and Stakeholder Communication Strategy established ■ Communication resources provide clinicians guidance and contact details for support services.
	Aboriginal and Torres Strait Islander specific actions	<ul style="list-style-type: none"> ■ Collaborative partnership with Aboriginal Community Controlled Health Services and the primary health network ■ Aboriginal key performance indicators (KPIs) developed and reports monitored through the Aboriginal Health Committee ■ Reconciliation Action Plan and Northern Territory Health Aboriginal Cultural Security Framework have been established ■ Cultural awareness training provided to the workforce at orientation and repeated annually ■ A number of senior staff identify as Aboriginal and Torres Strait Islander.

Note: Top End Health Services as an entity has changed following an organisational restructure in July 2021.

The Royal Darwin Hospital is within the Top End Health Services region (TEHS). The TEHS region includes Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove Hospital, Top End Mental Health Services and numerous remote health clinics. The population in the region is estimated at 200,450 which is around 82% of the Northern Territory population. Around 26% of the population is from Aboriginal or Torres Strait Islander origin. The median age of the population is 33 years compared with the national median age of 37 years.

The Royal Darwin Hospital is a university teaching hospital with 360-bed and provides a broad range of services in all specialty areas.

The Executive Leadership Team is the governing body of Royal Darwin Hospital that leads and manages the business operations of TEHS (see Figure 1 and 2). The Executive Leadership Team reports directly to the Department of Health.

Figure 1: Royal Darwin Hospital organisational structure

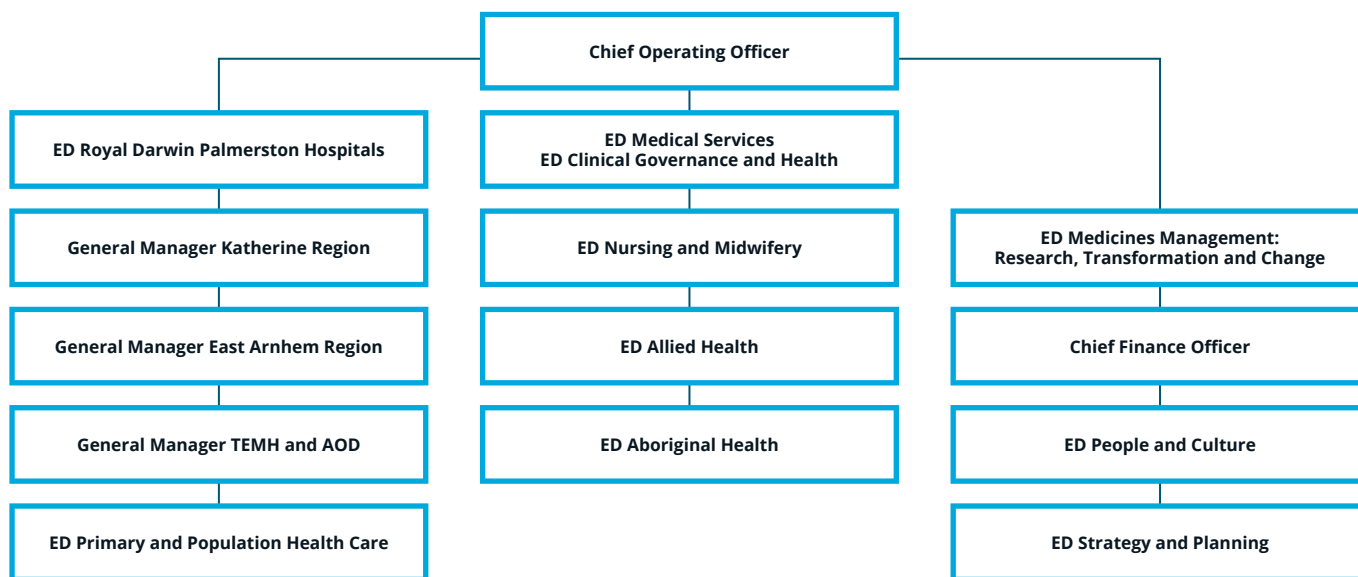
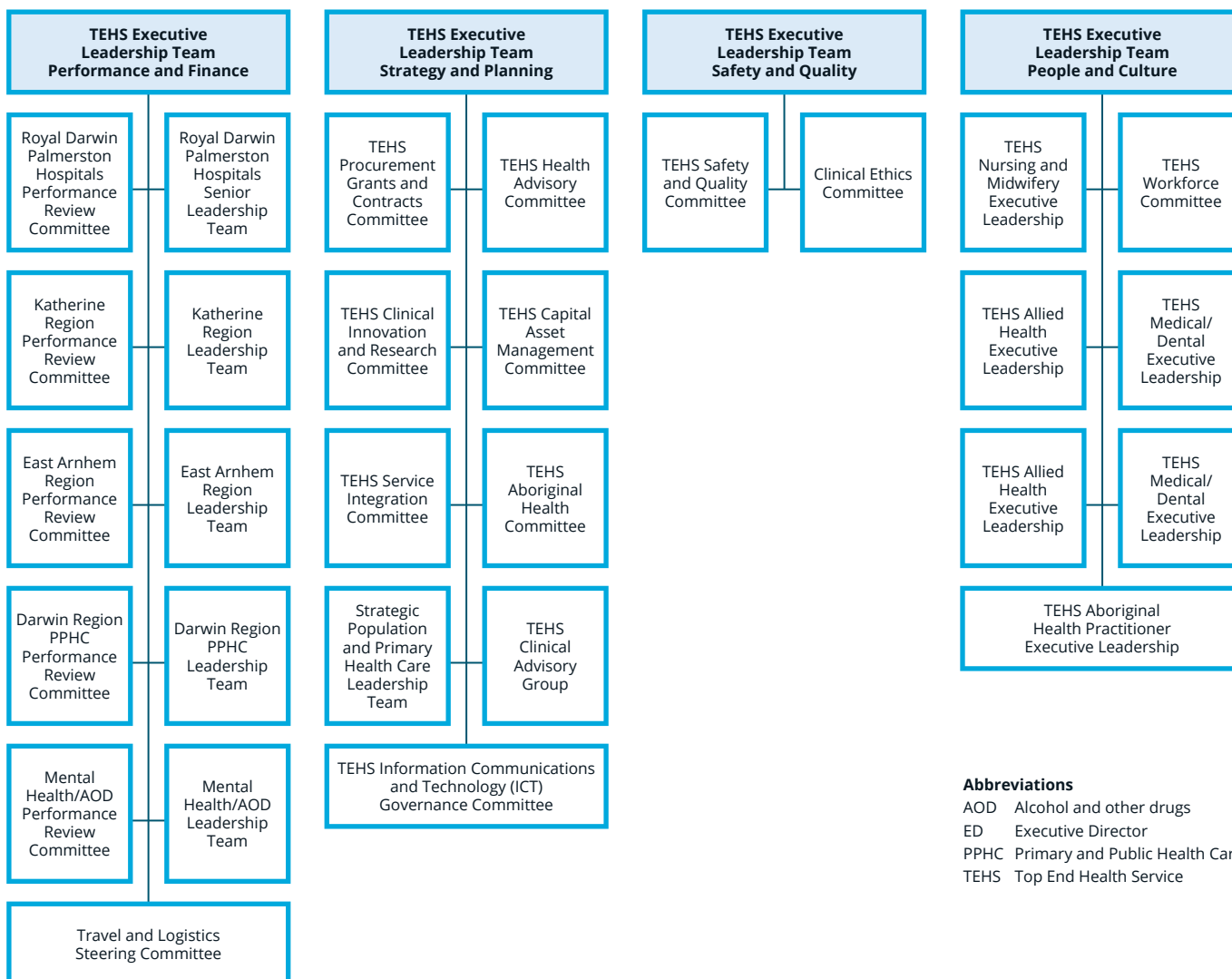


Figure 2: Royal Darwin Hospital Committee structure



Abbreviations
 AOD Alcohol and other drugs
 ED Executive Director
 PPHC Primary and Public Health Care
 TEHS Top End Health Service

Governance, leadership and culture

The Royal Darwin Hospital has established a set of policies and procedures to guide the conduct of a high-quality clinical trials that is appropriate to the size and context of the organisation.

The organisational structure demonstrates a comprehensive reporting line from research to the Executive Leadership Team and the Northern Territory Department of Health (NT Health) in which clinical trials are embedded.

The Chief Operating Officer is the Chair of the Executive Leadership Team. As the peak governance and decision-making body, the Executive Leadership Team is responsible for ensuring safe and high-quality care is delivered. The Executive Leadership Team has established a number of committees including but not limited to:

- The Health Advisory Committee supports the decision-making processes of the health service through consultation with, and advocacy on behalf of the community.
- The Clinical Innovation and Research Committee provides research governance leadership and supports the implementation of the TEHS Research Governance Framework
- The Safety and Quality Committee provides oversight of and leadership on the provision of high quality, safe clinical care and services and clinical governance systems for all of programs and services
- The Aboriginal Health Committee supports implementation of the Northern Territory Aboriginal Health Plan and Reconciliation Action Plan and seeks guidance from peak Aboriginal and Torres Strait Islander professional bodies and stakeholders.

The Alan Walker Cancer Care Centre, located at the Royal Darwin Hospital, is involved in national and international clinical trials and follows the Northern Territory Cancer Care Strategy. The strategy was developed by the Northern Territory Cancer Care Network on behalf of NT Health and provides a collaborative focus and direction for health care professionals, consumers and organisations involved to achieve improved patient experiences and optimal clinical outcomes for cancer patients. Clinical trials contribute to the key priority areas of quality and safety of the strategy:

STRATEGIC OBJECTIVE – Delivery of high-quality cancer care based on contemporary evidence and data collection, application of optimal care pathways and increased participation in clinical trials.

The Royal Darwin Hospital strategic and business planning processes capture strategies and initiatives to deliver safe and quality clinical trial services. The TEHS Strategic Plan aligns with the NT Health and includes clinical trials in its strategic directions. The TEHS Clinical Governance Framework describes the arrangements that ensure TEHS sets, manages, monitors, and improves the delivery of safe, high-quality healthcare. The TEHS Clinical Governance Framework aligns with the NT Health Clinical Governance Quality and Safety Framework and includes research and innovation.

Roles and responsibilities for safety and quality in clinical trials is included in clinical trials coordinator positions. A Clinical Innovation and Research Committee is chaired by an Executive member and reports to the Executive Leadership Team. Safety and quality priorities and initiatives are also communicated to the workforce during orientation and affirmed at annual essential training.

The Royal Darwin Hospital has specific key performance indicators that require reporting to the NT Health. The Research: Monitoring Procedure promotes the safety of research participants and best research practice through collection of quality research data, appropriate record keeping, access and storage of research records. The TEHS Safety and Quality Plan includes priority areas, measurable outcomes, time frame and responsible positions. Clinical trials routinely collect, operational outcomes and trial findings and monitor data for trends. Data is discussed at Clinical Trial Unit quarterly meetings.

Patient safety and quality improvement systems

The TEHS Governance Document Framework articulates the process for the development, approval, implementation, and review of all governance documents. NT Health sets policies and establishes the consultation and engagement around new and revised policy documents. Requests for additional policies and procedures go to the TEHS Clinical Innovation and Research Committee.

All quality improvement activities are maintained within the quality improvement module on Riskman. Quality improvement education sessions are conducted and clinical trials units are encouraged to report any serious incidents via Riskman. Reports are run and analysed by the Executive Leadership Team and outcomes reported as a quality improvement standing agenda item in committees.

The Royal Darwin Hospital identifies one of the strategic risk associated with clinical trials as the inability to initiate, coordinate and embed research to support contemporary models of care.

The Risk Management Policy and Framework is a practical reference tool and sets out the processes for proactive identification, management, and timely resolution of risks and incidents. A structured process is in place to report outcomes and adverse events up through clinical trials steering committees. The Royal Darwin Hospital involves the workforce in the review of incidents which are reported via Riskman. Incidents receive an incident severity rating and relevant operational managers, members of executive team, the Chief Operating Officer and NT Health are alerted to facilitate visibility and enable appropriate review, action and monitoring. Timely feedback on the analysis of incidents is provided to the governing body, the workforce, and consumers. Any information presented to consumers is deidentified.

Feedback from trial investigators, the clinical trial workforce, sponsors, trial participants, their families and carers is used to improve safety and quality. TEHS uses learnings from patient experiences to guide service delivery and assist in identifying areas for improvement. TEHS collects information on the experience of patients, carers and families through:

- Community meetings
- Patient surveys
- Feedback through the Talk to Us Program, the NT Health online form or feedback cards
- Consumer participation on a range of advisory or operational committees.

The clinical trial workforce receives training on complaint management at orientation and annual essential training. The TEHS Consumer Feedback Management Guideline provides an approach and framework to ensure all consumer feedback is promptly acknowledged, investigated, reported and recorded.

Consumer focused evaluation and quality monitoring processes encompass regular and ad hoc processes. A feedback forum is held annually with all stakeholders. Feedback is collated and reported up through the Committee structure to the Executive Leadership Team.

Clinical performance and effectiveness

The Royal Darwin Hospital has established an induction, orientation, mandatory training, and competency assessment relevant to clinical trials.

A programme for members of the workforce who are wanting to gain more experience in research is in place. The programme gives a general concept of research and provides opportunities to conduct research with guidance from senior roles and includes an annual forum for junior medical officers to present their projects.

Partnering with consumers

The Royal Darwin Hospital demonstrates a commitment to improve processes for partnering with consumers through the Health Advisory Committees. These committees have been established to promote and facilitate community consultation and engagement to shape the delivery of services. Members are appointed by the Minister for Health from a mix of background, skills and expertise to ensure appropriate local community input and engagement in health services planning.

The TEHS Consumer Advisory Group has been implemented and comprises a representative group of consumers, family members and carers to provide advice in the ongoing development of mental health services. An Indigenous Advisory Group has been established including Indigenous staff and consumer consultant to assist in the development of an Indigenous Consumer Advisory Group. TEHS currently has a consumer register which includes carers, family members and persons who wish to be involved, included and/or informed of developments and planning opportunities across the service.

Statistics are accessed to determine the demographics of the local population and to guide communication strategies to ensure the inclusion of all patients, consumers and clinical trials participants. The Executive Leadership Team ensures a culture of safety for staff and consumers and conducts participant satisfaction surveys appropriate to the different language groups of the Royal Darwin Hospital catchment area.

The Stakeholder Communication Strategy is a guide for the Research Governance Office in engaging with stakeholders. The Stakeholder Communication Strategy aligns with the NT Health and TEHS Strategic Plan and consumers are identified as one of the main target audience.

The Participant Experience and Consumer Engagement is a Framework which provide guidance to staff on how to build supportive relationships across the health service and support delivery of participant centred care.

Health literacy

Communication strategies are often determined by the sponsor. Trial information is only available in English, however interpreters are used when needed. Diagrams, pictures, and pictorial flowcharts are also used to aid discussions. Clinicians have access to communication resources that provide contact details for support services such as local consumer health advocates, interpreters, or cultural support and liaison services.

Aboriginal and Torres Strait Islander specific actions

An effective collaborative partnership exists between TEHS, Aboriginal controlled health services and the primary health network. The Royal Darwin Hospital is represented at these partnership committees where research is regularly discussed. In conjunction with Aboriginal controlled health services, the Royal Darwin Hospital reports against specific Aboriginal KPIs monitored through the Aboriginal Health Committee.

The TEHS Reconciliation Action Plan is in place which provides a holistic approach to create meaningful relationships, enhance respect and promote sustainable opportunities for Aboriginal people. The Northern Territory Health Aboriginal Cultural Security Framework focuses on the unique centrality of culture to health and the respect for Aboriginal people and culture necessary to enhance service access, equity, and effectiveness.

Cultural Awareness training is provided to the workforce at orientation and repeated at annual essential training. Additional interactive online modules are also being developed.

A number of senior staff identify as Aboriginal and Torres Strait Islander and work alongside Aboriginal and Torres Strait Islander people within Menzies School of Health Research who is a partner research organisation based on the Royal Darwin Hospital campus.

Approach to implementation

The Royal Darwin Hospital has established a small internal working party to oversee the implementation of the Governance Framework. The focus of the working party is on engaging all relevant stakeholders to embed clinical trial activity into current and new strategic and operational planning processes. There is a strong and effective involvement from the executive in leading engagement across organisation.

The risk safety and quality team has been engaged early in the implementation process and the requirements of the governance framework have been considered on multiple levels (across the Royal Darwin Hospital, TEHS and with research partners).

Educational opportunities have been identified early to increase awareness of the Governance Framework requirements across the organisation

The Royal Darwin Hospital ensured broad engagement during the pilot accreditation assessment. Clinical trial workforce, sponsors, managers, executives and clinical trials participants were interviewed.

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.