

Townsville Hospital and Health Service

Clinical Trials Unit
Multi-Specialties Team

Facilities and Capabilities – Sponsor Guide

Queensland Government

This Sponsor Guide provides an overview of the facilities, capabilities, governance requirements, and operational assumptions for multispecialty clinical trials conducted at Townsville Hospital and Health Service (THHS). It is intended to support sponsors and Contract Research Organisations (CROs) during site feasibility, selection, and study start-up.

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1. About Townsville Hospital and Health Service

Townsville Hospital and Health Service (THHS) is the largest tertiary health service in Northern Australia, delivering comprehensive healthcare across a wide geographical region. THHS supports high-quality, ethically conducted clinical research aligned with patient safety, scientific integrity, and regulatory compliance.

- Network of 21 facilities across regional and remote locations.
- Serves North Queensland's ~238,614 residents across ~148,000 km².
- Catchment extends from Mackay to the Torres Strait Islands and west to the Northern Territory border with a combined >80 facilities
- One of the region's largest healthcare providers and employers.

Townsville University Hospital (TUH) is Northern Australia's only tertiary referral centre with a level 6 emergency department (24/7), 15 operating theatres, and 18 inpatient units including neonatal, paediatric, and adult ICUs. It provides comprehensive care across all medical and surgical specialties.
Location: Townsville University Hospital, 100 Angus Smith Dr, Douglas QLD 4814, Australia. Pharmacy, Laboratory and Medical Imaging are onsite at the same address.

2. Clinical Trials Unit Overview

The TUH Clinical Trials Unit (CTU) is a multi-specialty service supporting investigator-initiated and sponsor-led clinical trials across a range of therapeutic areas.

2.1 Key Functions

- Trial feasibility and site selection support
- Study start-up and governance coordination
- Trial coordination and data management
- Onsite and remote monitoring support
- Quality and compliance oversight

2.2 Staffing and Expertise

Our Clinical Trials Team is a skilled, multidisciplinary group committed to advancing research and delivering innovative treatment options. We ensure the highest standards of clinical trial conduct, regulatory compliance, and patient care.

Current Principal Investigators and Specialties

Specialty	Investigators
Cardiology	Dr Udaya Ponangi; Dr Jaishanker Raman
Endocrinology	Dr Kunwarjit Sangla
Neurology	Dr Ravindra Urkude
Respiratory	Dr Pradeep Rajagopalan; Dr Helen Whitford
Sexual Health	Dr Arun Menon
Gastroenterology	Dr Ei Phyu Phyu Swe

We are open to engaging in trials from other specialties which are not mentioned above.

Trial Managers / Start-Up Specialists

Two trial managers oversee trial initiation, strategic planning, and operational management.

Clinical Trial Coordinators (CTCs)

Provide expert coordination and patient support across gastroenterology, respiratory, neurology, sexual health, endocrine, and rheumatology trials, including data management.

Governance and Regulatory Support

Ensure adherence to ethical and regulatory standards throughout the trial lifecycle.

Pharmacy Support

Three specialist clinical trials pharmacists and one pharmacy assistant manage investigational products and ensure safe handling of medications.
Staffing levels align to approved Full-Time Equivalent (FTE) allocations and the study portfolio.

3. Multi-Specialties Clinical Trial Capability

THHS supports multi-specialty clinical trials across a broad range of disciplines. Final capability is subject to investigator availability, departmental capacity, credentialling, and governance approval.

3.1 Key Capabilities

- Rapid start-up: accelerated ethics approval and contract execution for swift initiation.
- Therapeutic expertise: cardiology, gastroenterology, endocrinology, neurology, rheumatology, sexual health, and respiratory specialties; experience with early-phase, international, and multi-centre trials.
- Patient access: broad, diverse population supported by robust referral networks.
- Regulatory excellence: compliance with ICH-GCP, TGA, FDA, and EMA standards.
- Advanced infrastructure: infusion suites, onsite laboratory, secure IP storage.
- Technology integration: remote monitoring, secure EHR connectivity. Hybrid eISF (original-signature documents hardcopy; other study docs in secure network drive with download access for monitoring).

Note: Site files are not compatible with full remote monitoring.

4. Facilities and Infrastructure

The Clinical Trials Office provides a secure, efficient, and collaborative environment for managing clinical research, with infrastructure supporting all aspects of trial operations.

4.1 Clinical Facilities

- Outpatient clinics with nursing support, Monday–Friday, 8:00 am–4:00 pm
- Inpatient wards; procedural and treatment areas
- Telehealth services; interpreter and cultural liaison support
- Critical care ICU and 24/7 Emergency Department

4.2 Pharmacy Services

Investigational product (IP) storage, handling, and dispensing follow Queensland Health standards with temperature monitoring and full accountability.

Area	Details
IP Storage	2–8°C refrigeration with min/max monitoring, backup power, alarms, calibration; −70 to −80°C freezers; room-temperature storage with controlled access.
IP Handling	Secure on-site/off-site destruction as required.
Preparation & Administration	Laminar flow cabinets for hazardous/non-hazardous prep; negative pressure isolator for monoclonal antibody preparation.
Monitoring	Remote and onsite pharmacy monitoring available.

4.3 Pathology and Laboratory

Accredited pathology services and onsite laboratory (Pathology Queensland)

Feature	Details
Refrigerator	Min/max temperature monitoring, backup power, alarms, calibration.
−20°C Freezer	Min/max monitoring, backup power, regular calibration.
−80°C Freezer	Min/max monitoring, backup power, alarms, regular calibration.
Liquid Nitrogen	Available for snap-frozen sampling.
Shipping (Category B)	Coordinators and lab technicians trained. Lab techs support routine spin/aliquot/freeze.
Centrifuge maintenance	Department maintains specific records for clinical centrifuges.

4.4 Imaging

Medical imaging includes PET, CT, HRCT, MRI, bone scans, X-ray, ultrasound, and CT-guided biopsies. ARTnet accreditation in place for clinical trial compliance.

4.5 Information Systems

- ieMR (Cerner) as the primary source documentation system
- Secure Queensland Health IT infrastructure

4.6 Compactus Storage System

Secure, organised storage for laboratory kits and study equipment.

4.7 Dedicated Monitoring Spaces

- Meeting rooms for onsite monitoring with confidentiality assured
- Remote monitoring via secure access to ieMR for efficient off-site SDV

4.8 Clinical Equipment & Accreditation

All clinical equipment (e.g., observation machines, infusion pumps, ECG monitors) is registered under a quality management system in accordance with ISO 9004:2015.

- Australian Commission on Safety and Quality in Health Care (NSQHS) accreditation until 2028

- Royal Australasian College of Physicians (RACP) Principal Training Program Level 2 accreditation until Feb 2030
- Diagnostic Imaging Accreditation Scheme compliance (LSPN 002137) valid until 2027
- Medicare certification as an accredited pathology laboratory (Health Insurance Act 1973) until July 2028
- NATA scope of accreditation for Pathology Queensland – Townsville (ISO 15189) until July 2028

4.9 Clinical Trials Assessment Capabilities

Capability	Details
Serial sampling	Outpatient setting Monday–Friday for PK, ADA, PD, biomarkers, ECG, vitals; up to 6 hours post oral IP and post-infusion (IP infusion ≤ 60 minutes).
Sample collection deadlines	Ambient samples by 2:00 pm Mon–Thu and 12:00 pm Fri.
Visiting support	Able to support CXD1 to CXD4 visits.

5. Collaboration with External Health Partners and Decentralised Trial Delivery

To ensure timely and efficient delivery of study activities, THHS may collaborate with external healthcare providers and facilities based on study-specific requirements and capacity. These partners form part of the standard care network and adhere to Australian industry standards for routine care. Engagement is via established processes including private referrals and service requests.

5.1 When and Why We Use External Partners

- Manage high demand on public services and maintain study timelines
- Support diagnosis and work-up; results are integrated into screening
- Standard-of-care services delivered externally do not require HREC or RGO approval; documentation is recorded in ieMR
- External partners are not delegated to study-specific activities, do not require GCP certification, and do not store/administer study supplies

Accreditation and Compliance

All external partners are accredited by the Australian Council on Healthcare Standards (ACHS).

Examples of External Services

- Private ophthalmology and optometry
- Private audiology
- Pathology for safety bloods (including rural QH collection centres)
- Private cardiology imaging
- Private gastroenterology
- Private radiology

5.2 Telehealth Services at TUH

Telehealth via secure phone and video consultations enhances access for rural and remote patients, improves equity, and supports continuity of care.

Phone-based Telehealth

- AE and concomitant medication assessments (without physical exam)
- Wellness and healthcare resource utilisation checks
- Informed consent discussions (forms exchanged via email/mail for physician signature)
- Survival and long-term follow-up

Video-based Telehealth

- Vital signs monitoring and ECGs (where permissible)
- AE and concomitant medication assessments
- Wellness/resource utilisation checks; survival and long-term follow-up

Consultation Model & Standard of Care

Secure video consultations are conducted by delegated investigators at Townsville, with patients supported by clinical staff (e.g., nursing or GP) at Queensland Health outpatient facilities using accredited equipment.

Sponsor/CRO Restrictions

If telehealth is prohibited by the sponsor/CRO, this must be disclosed during site selection as it significantly impacts recruitment, retention, and equitable access.

5.3 Teletrials

Teletrials enable study activities at healthcare facilities other than the primary Townsville site where delegated staff are present, and study supplies are stored/administered. Primary and satellite sites collaborate under the supervision of the primary site. Some teletrials follow shared-care models where certain visits occur at the primary site and others at satellites.

Study Activities in Teletrials

- IP may be stored at primary or satellite sites or transferred as required
- Central labs stored/collected independently at each site
- Monitoring conducted at both primary and satellite sites
- Documentation archived at both primary and satellite sites

5.4 Standard Operating Procedures

THHS adheres to national and local guidelines to ensure the highest standards in clinical trial conduct.

- National Guidelines include ICH E6(R3)
- Good Clinical Practice; National SOPs for Clinical Trials (incl. Teletrials).
- National Clinical Trials Governance Framework.
- Australian Clinical Trials Handbook.
- Serious Breaches of GCP or Protocol (therapeutic goods).
- Safety Monitoring and Reporting in Clinical Trials.
- QH Guides to Informed Decision Making and Clinical Documentation.

Health Service–specific procedures include (non-exhaustive):

- THHSCOR160992 (Research Governance Review Pathway)
- THHSSCLI181210 (Interpreters and Translators)
- THHSSCLI050189 (Cold Chain Management)
- THHSCLI161079 (Cytotoxic Medications)
- THSSCOR100490 (Waste Management)
- THHSSCLI14070 (Clinical Incident Management)
- THHSCLI171191 (Consumer Feedback)
- THHSCLI181266 (Indigenous Hospital Liaison)
- THHSCOR161008 (Research Requirements Post-Authorisation)
- QH Retention and Disposal of Clinical Records
- THHSCLI241606 (Clinical Trials)
- THHSCLI211487v2 (Uploading to ieMR)
- Quick Reference Guide – Importing Clinical Documentation into ieMR.

6. Study Start-Up and Governance

A Confidentiality Disclosure Agreement (CDA) must be fully executed between the Sponsor (or CRO) and the site prior to the release of any study-related documents, including but not limited to the protocol, Investigator's Brochure (IB), and draft contract or budget.

For Townsville University Hospital and associated sites, CDAs are reviewed and executed through the **Research Governance Office (RGO)**. Sponsors/CROs are required to submit the CDA to the RGO for review and processing.

No study documents can be shared, and no formal feasibility, regulatory, or site selection activities can proceed until the CDA is fully executed.

6.1 Ethics and Governance Approval

- Human Research Ethics Committee (HREC) approval
- Site-Specific Assessment (SSA)
- Compliance with the Queensland Health Research Governance Framework

6.2 Contracts and Budgeting

- Budget negotiation and approval
- Clinical Trial Research Agreements (CTRAs)
- Invoicing aligned to agreed milestones

6.3 Study Start-Up Timelines (Typical)

Activity	Typical timeframe	Responsibility
Feasibility assessment	2–4 weeks	Sponsor / CTU
Ethics submission	Sponsor-led	Sponsor
SSA submission	2–3 weeks	CTU
Contract execution	4–8 weeks	Sponsor / THHS
Site initiation	Post approvals	Sponsor / CTU

6.4 Start-Up Processes

Site Selection Visit (SSV)

- Scheduled within ~2 weeks of request and PI availability
- Format: 1-hour with PI; 1-hour with Clinical Trials Manager incl. site tour; 15-minute meeting with Trials Pharmacist
- Tour includes waiting areas, clinic rooms, nursing assessment rooms, imaging, and pathology

Start-Up Team

Role	Start-Up Duties	Contact
Clinical Trials Manager	Budget negotiations; internal quoting; protocol review; trial logistics; organising SIV; CTRA quality checks	Theresa Joseph **T:** 07 4433 0495 **E:** tsv-multispecialties-clinicaltrials-manager@health.qld.gov.au
Regulatory / Administration Officer	HREC document prep (if required); SSA preparation; localisation of study docs; RGO query resolution; set-up internal systems	Jordan Hoey **T:** 07 4433 0988 **E:** tsv-multispecialties-clinicaltrials@health.qld.gov.au
Finance Officer	Managing invoices	**E:** tsv-multispecialties-clinicaltrials-finance@health.qld.gov.au
Pharmacy	Internal quoting	via CT Manager at start-up
RGO	Reviewing applications	**E:** TSV-RGO@health.qld.gov.au

Note: The ongoing study team will be released to sponsors upon RGO submission only.

Study Start-Up Timeframes (Selection → Green Light)

Week	Sponsor actions	Site actions
1	Prepare for HREC: send budget, manuals, protocol, IB	Protocol review; send PI CV & GCP
2	Submit to Lead HREC; answer site questions	—
3	—	Prepare internal quotes
4		Update sponsor budget template with patient activity fees
5	Update budget with internal quote fees; send document pack; SSA to ERM	Return internal quotes to sponsor
6	Budget approved; send CTRA & Indemnity drafts	Quality check CTRA/Indemnity; request partial execution; localise documents
7	Approve localised docs (PICFs); send PE CTRA & Indemnity	Prepare SSA; request internal sign-offs
8	Send essential documents; set up access; ship supplies	Submit RGO SSA; send study team details; organise SIV; start essential docs
9–13	—	Respond to RGO queries; complete essential docs; system training; receive supplies
14	Conduct SIV	Complete delegation & training logs
15–16	Green Light	Commence recruitment

Milestones: Week 5 – HREC approval; Week 8 – RGO submission; Week 14 – SIV; Week 15–16 – Green Light.

HREC Matters

Townsville RGO accepts HREC approvals from any NHMRC-Certified HREC.
National Mutual Acceptance – HRECs, RGOs and Organisations contacts list.

Note: that we do not accept HREC approvals from Bellberry Limited.

CTN Details

Approving Authority: Townsville Hospital and Health Service
Contact Officer: Kieran Keyes (Health Service Chief Executive)
Phone: 07 4433 1358
Email: TSV-RGO@health.qld.gov.au

THHS Budget and Contracting Process

- THHS sets standardised clinical trial fees annually across the organisation, reviewed and adjusted based on wage rates and QH clinical trial network feedback.

Fee Schedule

- A detailed site fee schedule with justification is provided prior to site selection and should be incorporated into the sponsor's budget template before sending to site.
- RGO / HREC fees should be included in the CTRA as separate line items.

Budget Development

- Upon receipt of protocol and study manuals, the site prepares a patient fee quote covering all budget items and schedule of assessments according to the THHS fee schedule.
- Exceptions: central laboratory processing fees and pharmacy fees are quoted separately by their respective services.

Pharmacy and Pathology Quotes

- Pharmacy: quotes provided directly by pharmacy service for inclusion in CTRA (non-negotiable pass-through costs).
- Pathology (central lab): quotes provided directly by pathology service (non-negotiable pass-through costs).

Budget Negotiation

- Once all fees are included, negotiation begins. On agreement, site requests a clean budget with final prices only and a draft CTRA for quality review prior to execution.

CTRA Document Process

- PI signature: wet ink.
- RGO signature: electronic preferred; no external e-signature audit trail (DocuSign/Adobe Sign not used).
- Wet-ink acceptable; if used, send three copies of the CTRA to site with return envelope.

Submission of Regulatory Documents for Site-Specific Approval (SSA)

- The site does not access sponsor portals to download study documents.

- To support local document management, version control, and regulatory record-keeping requirements, all study documents must be provided directly to the site/RGO.
- A partially executed Clinical Trial Research Agreement (CTRA) is required for Site-Specific Approval (SSA) submission.
- Please submit all required documents for SSA submission directly to the RGO Coordinator: **tsv-multispecialties-clinicaltrials@health.qld.gov.au**.

7. Study Conduct and Operations

Site Communication Guide

Many Clinical Trial Coordinators (CTCs) work part-time/flexible hours per health service policy. Please allow up to 5 working days for acknowledgement/action of emails and escalate after 7 working days. Use phone for urgent issues only. If not acknowledged after 5 days, escalate to the Clinical Trial Manager.

Clinical Trial Monitoring Guide

Contact the Primary CTC to book onsite or remote monitoring. Provide 4 weeks' notice for onsite, 2 weeks for remote. Visits occur Monday–Friday, 8:00 am–3:00 pm, aligned to PI availability.

- Onsite visits: access to eISF via hospital computer; daily 30-minute CTC meeting; 15–30 minutes with PI (pharmacy meeting arranged directly)
- Remote visits: 30-minute debrief with Primary CTC via MS Teams/phone
- CRAs: call IT (1800 198 175) 2 business days prior to reset password (if required); check remote access 5 days prior
- Unresolved issues to be documented in the monitoring report; allow up to 10 working days for CTC actions

Source Documentation

Source data are recorded within ieMR unless otherwise approved.

Decentralised and Telehealth Models

Supported where protocol-permitted and governance-approved.

Site Initiation Visit (SIV)

- Onsite and remote SIV options; scheduled at time of RGO submission to align with expected approval (approval at SIV cannot be guaranteed)
- CT Manager issues Outlook invitations for all relevant staff
- Staff training scheduled between RGO submission and SIV, aiming for completion before SIV

Standard SIV Agenda

- CTC training: ~2 hours for primary and secondary CTCs
- Pharmacy training: ~30 minutes
- Site tour and ISF review
- PI training: ~1 hour (with Sub-Is and other staff as available)

Delegation and Training Logs

Completed after SIV; a fully completed version is provided to the sponsor before research commences.

Ongoing Study Team (Roles & Access)

Role	Responsibilities	System access
Clinical Trials Manager	Point of contact from feasibility to SIV; escalation point for CRAs	EDC; IRT
Principal Investigator (PI)	Overall responsibility per GCP and site SOPs; ensures compliance	Training portal; Safety portal; EDC; others as required
Sub-Investigators	Assist PI; include doctors in the specialty	None (EDC for backup PI)
Primary CTC	Point of contact from SIV to last follow-up; leads patient activities; maintains files; coordinates monitoring	Training portal; EDC; IRT
Secondary CTC	Covers during primary CTC leave; visits; SAEs; data entry; queries; monitoring	EDC; IRT; others as required
Tertiary CTC	Coverage if secondary CTC on unplanned leave; support visits and SAEs	None
Regulatory Coordinator	Governance submissions and administration	None
Pharmacist(s)	Activities per delegation regarding pharmaceutical requirements	Training portal; IRT; other systems

Key Information for Sponsors – Site Set-Up FAQs

- Safety portals: PI reviews DSUR/DIL and attends safety meetings where possible.
- Training portals: if mandatory, only PI, Primary CTC, and Pharmacist complete required modules.
- Training protocol: each new protocol/summary of changes is distributed to delegated staff on/before RGO approval; training recorded on paper log.
- Investigator Brochures: current versions provided to medical/pharmacy staff; training recorded on paper log.
- Other study documents: delegated staff are informed and review documents relevant to their role; formal documented training limited to protocols and IBs.
- Laboratory staff delegation: Routine laboratory procedures (e.g., sample receipt, processing, storage, freezing, and shipment) are performed by laboratory staff within their normal scope of practice and laboratory SOPs. As these are ancillary services and not investigator-delegated trial duties, laboratory staff are not listed on the study Delegation Log.
- New study staff: review current versions (protocol and IB), not historical versions.
- Patient devices/apps: do not install sponsor apps on patient personal devices; study devices may be provided; apps must not request personal identifiers.
- Recruitment: patients primarily identified via medical referrals or existing service patients.
- Screening logs: maintained by CTCs; shared with CRA if billable per CTRA.

Information Systems Used for Study Management

System	Purpose	Access	Training	Comments
Novell	Queensland Health network login	CRAs & auditors (1 per study at any time)	None	Used for authentication to QH systems
MyApps	Remote access to medical records for SDV	CRAs & auditors	Quick Reference Guide	Secure remote access for monitoring
ieMR (Cerner)	Primary medical record for documentation, results, consent, clinical measurements, patient diaries	Read-only for trial patients	Quick Reference Guide	FDA 21 CFR Part 11 compliant audit trail; access via Novell login; paper uploads per SOP

Study Documents Stored in the Study Office

- Original consent forms (also uploaded to ieMR)
- Site logs, delegation logs, training logs (also uploaded to MS Teams)
- Originally signed CTRAs (also uploaded to MS Teams)

Monitoring – Access & Logistics

Type	Details
Remote monitoring	ieMR access for one CRA for 1–3 days; 30-minute CTC meeting at conclusion; optional 15-minute PI meeting by request; instructions emailed before first visit
Onsite monitoring	ieMR access for one CRA for 1–3 days; daily 30-minute CTC meeting; 15–30-minute PI meeting
Contact information	Provide CRA name/mobile 6 weeks prior to first visit or at RGO submission to enable access set-up
Access duration	Access granted in 1-month or 6-month blocks per CTRA; CRA notified of expiry dates
Re-establishing access	Email TSV-MultiSpecialties-Clinical-Trials@health.qld.gov.au ≥ 5 working days prior to next visit if access expired
Booking a visit	Contact Primary CTC; 4 weeks' notice onsite / 2 weeks remote; new-patient monitoring within 2 weeks of enrolment if required; onsite Mon–Fri 8:00–15:00
Pharmacy monitoring	Plan directly with Pharmacy Team: tuh-trials-pharmacist@health.qld.gov.au

8. Standard Operating Assumptions

The following assumptions apply to all clinical trials at THHS. Any deviations must be agreed in writing prior to activation.

THHS will:

- Conduct trials per ICH-GCP, Queensland Health policies, and local SOPs
- Utilise ieMR as primary source system
- Support remote and onsite monitoring per site capability

- Implement telehealth and decentralised activities where protocol-permitted
- Provide pharmacy and pathology services consistent with QH practice

THHS will not:

- Permit storage of identifiable participant data on sponsor-managed systems
- Allow installation of sponsor software on personal or non-THHS devices
- Undertake procedures outside staff credentialling and scope of practice
- Conduct non-standard activities without documented agreement
- Guarantee participant recruitment numbers

Sponsor Obligations and Agreements

Sponsors are expected to review this guide during site selection. Any alternative or mutually agreed-upon processes that deviate from local practices must be documented in the Site Selection Letter and agreed prior to study activation.

9. Why Partner with THHS

- Large and diverse patient population
- Strong referral networks across Northern Queensland
- Experienced multidisciplinary research workforce
- Proven governance and compliance framework
- Commitment to high-quality data and participant safety
- Excellent track record of participant retention across multispecialty trials
- Consistent reliability, compliance, and quality performance aligned with sponsor expectations.

Contact Information

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