
One front door.
Every capability you need.



Hunter
New England
**Clinical
Trials**

Delivered in partnership with



Hunter New England
Local Health District



Hunter Medical
Research Institute

UNIVERSITY OF
NEWCASTLE
AUSTRALIA





Who we are

Clinical trials are complex, resource intensive, and highly dependent on selecting the right sites.

Challenges such as slower than expected recruitment, teams needing additional support with protocol requirements, or infrastructure not originally designed for trial delivery are not uncommon. While these aren't unusual, they can have a meaningful impact on whether a study progresses as planned or encounters delays.

Hunter New England Clinical Trials (HNECT) was established to support the delivery of a quality, high performing clinical trials. Operating across one of Australia's largest health districts, we bring together the clinical scale of a major health network, the research infrastructure of a specialist medical research institute, and the academic rigour of a leading university into a coordinated ecosystem.

For commercial sponsors, this integration provides a coordinated environment that supports smooth and dependable study delivery.

The partnership

HNECT is a joint initiative delivered through three institutional partners – Hunter New England Local Health District (HNELHD), Hunter Medical Research Institute (HMRI) and the University of Newcastle (UoN) – each contributing something essential.

This is not a symbolic partnership. It is an integrated clinical trial ecosystem built to operate as one.



**Hunter New England
Local Health District**

One of Australia's largest health districts, providing clinical scale across metropolitan, regional, rural, and remote communities. HNECT functions as an embedded component of the HNELHD partnership, enabling clinical trial delivery within the health district and across its diverse patient populations.



A leading translational medical research institute housing the HNECT purpose-built Clinical Trials Facility, specialist biomedical expertise, and the Clinical Trials Coordinating Centre.



Academic partner contributing a pipeline of research-active clinicians and emerging investigators across the Hunter New England region.





Clinical Trials Support Unit

For commercial sponsors and CROs, every interaction with HNECT begins here. The Clinical Trials Support Unit (CTSU) is our dedicated front door facilitated by a dedicated and experienced team who facilitate the process of sponsor engagement.

From your first feasibility inquiry through to site activation, the CTSU coordinates across organisations so you don't have to navigate institutional complexity. On behalf of PI's and teams, we actively manage budgets, contracts, ethics submissions, governance coordination, and operational planning. We move quickly, communicate clearly, and take ownership of outcomes.

What the CTSU provides

- Central point of contact for all clinical trial enquiries
- Dedicated Clinician Liaison Officer for feasibility completion and investigator identification and engagement activities
- Timely, coordinated feasibility and risk assessments across sites and clinical services
- Consistent budget development and contract negotiation
- Streamlined ethics and governance coordination for expedited start-up timelines
- Proactive engagement to support future study pipeline and long-term partnerships

Supporting study teams

The CTSU provides centralised, embedded operational support for Principal Investigators and study teams at trial sites particularly valuable for investigators stepping into PI roles for commercial studies, or experienced PIs seeking to reduce administrative burden during study setup and activation.

We work alongside trial site study teams from feasibility through activation: governance, regulatory submissions, budget coordination, and operational planning.

Our aim is to set sites up so well that trial delivery is straightforward from the moment the first participant walks through the door.

We offer:

- Study feasibility, site capability assessments, clinician support and trial selection support
- Ethics, governance, and regulatory submissions and lifecycle management
- Guidance on budgets, contracts, sponsor requirements, and study start-up
- Support in the coordination of trial resources, timelines, and operational planning
- Standardised processes and quality systems for consistent, high-quality trial conduct
- Tailored support for emerging PIs on sponsor expectations, PI responsibilities, and regulatory obligations





Clinical Trial Facility

Located on the John Hunter Hospital campus within the Hunter Medical Research Institute, the Clinical Trials Facility (CTF) is a purpose-built outpatient environment designed around the operational requirements of commercial clinical trials.

The CTF was designed from the ground up for trial delivery: standardised processes, sponsor-ready monitoring environments, dedicated participant assessment areas and treatment bay, and direct integration with JHH clinical departments. This is not repurposed clinical space. That distinction matters operationally, practically, and for participant experience.

Infrastructure and integration

The HNECT Facility is supported by immediate access to full clinical infrastructure. JHH Pharmacy manages investigational product receipt, storage, dispensing, accountability, and aseptic compounding. Pathology services are available on campus. Diagnostic imaging, including CT, MRI (1.5T and 3T), PET-CT, and interventional radiology, is minutes away. For trials where participant safety is paramount, a Level 1 Trauma Emergency Department and Medical Emergency Teams are located on the same campus.

Network reach

The CTF is part of the collective broader clinical network. Trials requiring inpatient delivery, specialist procedures, or expanded participant access can be supported across John Hunter Hospital clinical departments, Maitland Hospital, Belmont Hospital, and other HNELHD sites aligned to protocol and population needs.

Community and regional delivery is supported through collaboration with the Rural Regional and Remote Clinical Trials Enabling Program, providing access to rural and remote populations while maintaining consistent governance, safety, and quality standards across all participating sites.





Clinical Trials Coordinating Centre

The HMRI Clinical Trials Coordinating Centre (CTCC) operates alongside the CTSU as a central coordination partner for investigators, collaborative research groups, and sponsors managing studies that require specialist operational expertise.

The CTCC brings formal project management, rigorous governance, and deep regulatory experience to trial coordination capabilities particularly valuable for complex, multi-site, or early-phase studies that demand more than site-level management.

CTCC Services

- Research development support
- Central coordination and project management
- Risk-based operational oversight and issue escalation
- Quality management and compliance oversight
- Ethics and regulatory submissions and lifecycle management
- Site selection, activation, initiation, and ongoing site performance management
- Monitoring coordination and performance oversight
- Data management and health informatics
- Data oversight, reporting, and governance support
- Biostatistics and methodological expertise
- Health economics and health impact analysis
- Study closeout, reconciliation, and archiving





Therapeutic areas

HNECT supports the delivery of Phase I–IV commercial trials across a wide and growing range of therapeutic areas, reflecting both the specialist depth of a major tertiary hospital and the breadth of conditions seen in everyday clinical practice.

Our therapeutic capability spans adult and paediatric settings.

Oncology and haematology	Cardiology and vascular disease
Dermatology	Autoimmune and immunology
Respiratory medicine	Endocrinology and diabetes
Neurology and stroke	Gastroenterology
Renal and metabolic disease	Infectious diseases
Mental health	Women's health
Musculoskeletal and orthopaedics	Sexual Health

This breadth reflects the full scope of Hunter New England Health's clinical workforce and the research-active investigator community at HMRI and the University of Newcastle.

If your therapeutic area isn't listed, contact the CTSU we can identify appropriate investigator and site capability.





Facilities and capabilities

The following summarises key site capability across our ecosystem.

Area	Capability	Detail
Site Overview	Organisation	Hunter New England Clinical Trials (HNECT), delivered through Hunter New England Local Health District (HNELHD) in partnership with Hunter Medical Research Institute (HMRI) and the University of Newcastle (UoN)
	Network Model	Distributed, hospital-affiliated clinical research network spanning metropolitan, regional, and community settings
	Trial Experience	Phase I–IV commercial clinical trials across multiple therapeutic areas; outpatient, inpatient, and community environments
	Standards and Compliance	ICH-GCP, NHMRC National Statement, and National and state regulatory and governance requirements
Clinical Trials Facility	Purpose-Built Facility	Dedicated outpatient Clinical Trials Facility (CTF) on the John Hunter Hospital campus within HMRI
	Facility Capability	Standardised processes, on-site trial coordination, and sponsor-ready monitoring environments
	Integration	Fully integrated with JHH pharmacy, pathology, imaging, and emergency services
Clinical Trial Network	Hospital-Based Delivery	Trial delivery across John Hunter Hospital, Maitland Hospital, Belmont Hospital, and other HNELHD sites
	Community and Regional	Community and regional sites supported via the RRR Clinical Trials Enabling Program; decentralised and hybrid models available
Participant Infrastructure	Participant Care	Dedicated monitoring stations, private consultation rooms, and clinical assessment spaces across CTF, hospital, and community sites
	Secure Research Environments	Controlled-access research areas with sponsor-ready monitoring rooms and on-site coordination support
Digital and Data	Medical Records	Integrated district-wide EMR enabling real-time clinical data access across participating sites
	Monitoring Readiness	Electronic ISF with remote and hybrid monitoring capability aligned to sponsor and CRO requirements
Equipment and Safety	Core Clinical Equipment	12-lead ECG, vital signs monitoring, and calibrated clinical equipment across research and hospital settings
	Safety Capability	Research nurses and clinical staff trained in Advanced Life Support (ALS); established MET escalation and emergency response pathways
Pharmacy and Laboratory	Investigational Product	Full clinical trial pharmacy via JHH: IP receipt, storage, dispensing, accountability, and aseptic compounding
	Laboratory Services	On-site and networked phlebotomy, rapid pathology processing, biobanking, and histology including specialised specimen handling
Hospital Integration	Inpatient and Acute Care	24/7 inpatient beds, ICU, PICU, and Level 1 Trauma Emergency Department via John Hunter Hospital
Imaging	Diagnostic Imaging	X-ray, CT, Ultrasound, DEXA, MRI (1.5T & 3T), PET-CT, Nuclear Medicine, and Interventional Radiology
Research Ecosystem	Advanced Imaging	On-campus HMRI research MRI (3T and 7T) supporting advanced imaging and translational research
	Partner Organisations	HMRI, University of Newcastle, Hunter Imaging, and Calvary Mater Newcastle



Why choose Hunter New England Clinical Trials

The clinical trials landscape is highly competitive, and sponsors understandably look closely at indicators such as feasibility accuracy, screen failure rates, time from activation to first-patient-in, and protocol deviation rates. We understand the measures that matter and have developed our systems to support strong performance across them.

One contact, not three

The CTSU consolidates all sponsor engagement. You don't navigate institutional boundaries; we do that for you.

Diverse populations, real-world data

A catchment spanning from Newcastle's tertiary centre to remote communities delivers participant diversity that genuinely reflects intended treatment populations and generates data that holds up in the real world.

A facility built for trials, not adapted for them

The CTF was purpose-designed. That distinction matters for operational efficiency, monitoring access, investigational product management, and the overall sponsor experience.

Clinical depth on demand

24/7 emergency access, inpatient capability, and specialist imaging within one campus footprint, designed for trials where participant safety is non-negotiable.

ICH-GCP from the ground up

Our operations are built on GCP principles, not adapted to them. Standardised processes, a quality management system, and governance aligned to NSQHS standards and NSW Health requirements.

Three institutions. One team.

The HMRI/HNELHD/UoN partnership creates capability that no single organisation could replicate. Clinical scale, research infrastructure, and academic depth in one coordinated site.

Ready to start a conversation?

Contact our Clinical Trials Support Unit to discuss your study, explore site capability, or initiate a formal feasibility assessment.

info@hneclinicaltrials.com.au | hneclinicaltrials.com.au