V2.2 Date: February 2025

Cancer Trials Unit

Site CV

About

The Cancer Trials Unit (CTU) has been in operation since the early 2000s and is dedicated to providing a high-quality service for the delivery of clinical research treatments for patients with cancer. CTU is part of the Division of Cancer Services (DoCS) within the Princess Alexandra Hospital (PAH). CTU has a wide portfolio of clinical research studies, spanning across medical oncology, haematology and radiation oncology disciplines and catering to a wide spectrum of cancer indications. The PAH utilises an integrated electronic Medical Record (ieMR) system which is compliant with all requirements as defined in ICH GCP Section 4.9.

Studies

CTU accepts clinical trial patient referrals from all Queensland Hospital and Health Services, as well as patients referred from the private sector and from any state within Australia if the trial is unavailable in their own geographical area. Clinical trials are offered to both inpatient and outpatient participants. Close working relationships are also maintained with the relevant surgical, medical, and multidisciplinary teams associated with the treatment of cancers such as (but not limited to) head and neck cancer, breast cancer, and melanoma. CTU participates in Phase 1, 2 ,3 and 4 trials for haematological and oncological malignancies in the neo-adjuvant, adjuvant, and palliative settings, along with an array of translational laboratory studies and treatment audit projects. Trials are sponsored by multinational pharmaceutical companies, smaller biotech companies, national study groups, or single investigators. Trial treatments may include chemotherapy, biological agents, autologous and allogeneic immune cell therapies, radiation and/or surgery.

Staff

CTU Director

The CTU Director operationally manages all staff employed by CTU. The CTU Director provides leadership in the development, implementation, and monitoring of clinical research management programs within CTU, DoCS, and Metro South Hospital and Health Service (MSHHS), and policies to support the continuum of care. The CTU Director applies well developed clinical knowledge and skills to contribute to the strategic direction of research management across DoCS and provide authoritative counsel to stakeholders. The CTU Director is also responsible for facilitating commercial sponsor, collaborative cancer group and local investigator-initiated research for DoCS.

Clinical Trial Coordinator

The Clinical Trial Coordinator (CTC) is a specialised research professional working with and under the direction of the Principal Investigator (PI) to support, facilitate and coordinate daily clinical trial activities, playing a critical role in the conduct of the study. By performing these duties, the CTC works with the PI, department, sponsor, and institution to support and provide guidance on the administration of compliance, financial, personnel and other related aspects of the clinical study. The CTCs employed within CTU have either a nursing or allied health qualification with backgrounds such as scientists, radiation therapists, and pharmacists, bringing unique skills and perspectives to the unit. There are three trial streams within the unit: haematology, medical oncology, and radiation oncology, with coordinators specialising in one of these streams, led by a Team Leader (TL) for each stream. Individual trials are allocated to a lead CTC and at least two backup CTCs. A CTC will be responsible for approximately 10-20 trials depending on current trial activity levels.

Clinical Trial Assistant

The Clinical Trial Assistant (CTA) supports CTCs with the day-to-day conduct of clinical trials. This may include but is not limited to assisting the CTC with submission and management of patient trial-specific data, preparation of monitor visits and submission of regulatory and procedural documentation to the relevant personnel regarding revenue and trial activity. The CTA works collaboratively and under the supervision of the CTCs.

CTU Clinical Trial Nurse

The CTU nursing team works collaboratively with CTCs and study investigators. They are primarily based in the oncology outpatient clinics where they provide direct clinical care for trials patients. This may include assistance towards the informed consent process, providing education to patients, undertaking clinical observations and sample collections as required of the protocol, collecting, and recording clinical information related to patient health, and monitoring patients for side effects. Clinical Trial Nurses (CTNs) will also facilitate handover of patient care from the outpatient setting to oncology daycare or ward staff as required. CTNs may be required to attend the ward or CRF to undertake trial specific observations/collections that are time sensitive and/or resource intensive and are considered outside "standard clinical care". CTNs provide education and training to the oncology daycare and ward staff related to trial protocol treatments, advise on side effects of investigation products, and give general trial information in collaboration with the CTC.

Scientist

The CTU scientist processes patient trial-specific samples. They are also responsible for providing expert knowledge and scientific advice when assessing the trial protocol related to pathology and processing requirements.

Operational Support

Administration Support Officer (ASO): The ASO supports the CTU team by completing general administrative duties as well as coordinating bookings for on-site visitors, liaising with CTC and study sponsors to arrange study site initiation visits and other such duties.

Ethics and Governance Team (E&G): E&G are responsible for the preparation, coordination, and submission of regulatory documentation to the relevant regulatory boards such as the relevant Human Research and Ethics Committee (HREC) and Metro South Research Governance Office (RGO). The E&G team liaise with sponsors, CTCs, vendors, PIs and HREC and RGO teams to ensure that submissions comply with regulatory requirements and appropriate approvals are received before a trial is able to be conducted and for the duration of the trial at this site.

Revenue/Finance Team: The Revenue Team oversees all financial transactions associated with CTU trial activities. Their responsibilities include negotiating trial budgets with sponsors and reconciling payments received by CTU for trial conduct. Additionally, the team supports CTU management in developing business plans to ensure the unit's financial and operational viability.

Key Contacts

Administration Support Officer: Hitesh Sachdeva
Hours: 8 am to 4 pm, Monday to Friday
t. 07 3176 7327
pah-ctu@health.qld.gov.au

A/Director: Jason Kelly
Enquires: PAH-CTU@health.qld.gov.au

Haematology
A/Team Leader: David Barnes
Enquiries: haem-feasibility@health.qld.gov.au

Medical Oncology
A/Team Leader: Jillian Hung
Enquiries: MedOnc-Feasibility@health.qld.gov.au

Radiation Oncology

Team Leader: Angela Byron (Radiation Oncology Ipswich Road)
Team Senior: Narelle Wallace (Radiation Oncology Raymond Terrace)
Enquiries: PAH-CTU-ROPAIR@health.qld.gov.au *(Ipswich Road)*
PAH-CTU-ROPART@health.qld.gov.au *(Raymond Terrace)*

Ethics and Governance
Team Leader: Anne Hughes
Enquiries: PAH-CTU-Submissions@health.qld.gov.au

Revenue
Team leader: Selina Hudson
Enquiries: pah-ctu-revenue@health.qld.gov.au

Institution Details
PAH-CTU Essential Information for Contracts, Budgets & Indemnities document available on request.

Facilities and Internal Vendors

CTU have a wide network of available facilities and internal vendors who support clinical trials across the Princess Alexandra Hospital.

Oncology Outpatient Department

- Located on level 2E of the main hospital, it provides facilities to allow screening, review, and treatment of clinical trial patients. It includes reception and waiting area, twelve consulting rooms, and two nurse examination/phlebotomy rooms.
- Additionally, the Ground Level D Outpatients of the main hospital provides facilities to allow screening and reviews of trial patients, with ten consulting rooms and one examination/phlebotomy room.

Oncology Ward

- Located on level 2E of the main hospital, including 29 inpatient beds for haematology and oncology patients.

Oncology Day Treatment

- Includes two treatment units located across level 2E and ground floor of the main hospital, as well as a two-bed apheresis unit providing stem cell and therapeutic services.

Clinical Research Facility (CRF)

- The TRI CRF is located on levels 4 and 5 of the main hospital building (R-Wing) and is operated by MSHHS. Level 4 includes reception and clinical areas including a phlebotomy room (three chairs), two interview rooms, seven investigation rooms, a VECTRA scanner, four bed bay, eight treatment chairs, gym, and reception area. Level 5 holds office spaces and a laboratory (PC1).

CTU Sample Processing Centre

- The laboratory within CRF is utilised by CTU scientists for processing clinical trial samples. Available equipment includes refrigerated centrifuges, and temperature-monitored laboratory refrigerator (4°C), and freezers (-20°C, -30°C, and -80°C).

Oncology Pharmacy

- Located on the main floor of the main hospital, with an oncology satellite pharmacy on level 2E. Cancer Services pharmacy provides patient and professional education and advice. They have facilities for secure storage of study drugs and devices including temperature-monitored controlled ambient (15°C to 25°C), and 24-hour alarm-monitored refrigerator (2°C to 8°C) and freezer (-15°C to -25°C and -60°C to -80°C) storage of investigational product (IP). Pharmacy also has facilities for on-site sterile manufacture of medicines.

Pathology Queensland (PQ)

- PQ is a NATA-accredited laboratory and offers testing across all major pathology disciplines including anatomical pathology, chemical pathology, genetic pathology, haematology, immunology, and microbiology.

Special Investigations

- Within PAH PQ is Special Investigations, which provides support for services such as bone marrow biopsies and the autologous transplant program within the hospital. They are equipped with processing facilities for haematopoietic stem cells including annual HEPA filter certification program, particle size monitoring test, and three liquid nitrogen tanks with 24-hour temperature and liquid nitrogen level monitoring.

Radiology

- PAH radiology services include x-ray, ultrasound, CT (including PET-CT), MRI (including PET-MRI), image-guided procedures (e.g., biopsies), and interventional radiology procedures.

Cardiology

- Located on level 3 of the main hospital, the Cardiac Diagnostics Unit provides inpatient and outpatient services including echocardiography, holter monitoring, and exercise stress testing.

Regulatory

HREC

Metro South Health operates a Human Research Ethics Committee (HREC) which provides ethical and scientific review/clearance of research projects. Metro South HREC (MSHREC) considers both the ethical and scientific validity of proposed research within Metro South Health. Under the National Health and Medical Research Council (NHMRC) coordinated National Mutual Acceptance, the MSHREC can also review for research projects conducted in Queensland, New South Wales, Victoria, Western Australia, Australian Capital Territory and South Australia. MSHREC review applications for both greater than low risk, and low and negligible risk pathways. The MSHREC is certified by the NHMRC (registration number EC00167).

MSHREC relevant forms, committee members and meeting dates can be accessed via their website Human Research Ethics Committee | Metro South Health.

RGO

Site Specific Assessment (SSA) considers the legal compliance, financial management, accountability, and risk management associated with research. SSA authorisation provides a separate review and is distinctly different from the ethical clearance process. MSH-RGO only require review of documents that are considered to have a site impact i.e. CTRA, insurance certificates and indemnities. More information regarding MSH-RGO can be found here: Apply for research governance authorisation | Metro South Health.

Resources

Australian Clinical Trials

An Australian Government initiative to provide information and resources to participants, healthcare providers, researchers, and industry about taking part in, accessing and running clinical trials: Australian Clinical Trials.

ClinTrial Refer

ClinTrial Refer is an evidence-based digital health innovation developed by clinical researchers in Australia, to simplify access and accelerate recruitment to current clinical trials: Clin Trial Refer – ClinTrial Refer App connects doctors & patients to recruiting clinical trials.