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Cancer Trials Unit

Site Profile

About Us

The Cancer Trials Unit (CTU) at Princess Alexandra Hospital (PAH), a major tertiary health care centre, providing care in most major adult specialities and leading academic and research centre, has over 20 years of experience in the conduct of oncology and haematology clinical trials. Operating within the Division of Cancer Services (DoCS), CTU adheres to the principles of the Declaration of Helsinki, ICH GCP, and all relevant national and international regulatory guidelines.

Clinical trial activities are conducted under established Standard Operating Procedures (SOPs) to ensure consistency, regulatory compliance, and the highest standards of research quality. Through strong collaborations with multinational pharmaceutical companies, biotechnology firms, contract research organizations (CROs), national research networks, and innovative investigators, CTU delivers a diverse and robust clinical trial portfolio across medical oncology, haematology and radiation oncology. This work is supported by an experienced multidisciplinary team and comprehensive infrastructure.

All trials are overseen by highly experienced Principal Investigators (PIs) based at PAH, who have extensive expertise in delivering standard of care treatment and seamlessly integrating clinical trials alongside routine clinical practice. PIs and CTU staff work closely together to ensure rigorous protocol compliance, patient safety and high-quality data generation. To further strengthen compliance and data integrity, PAH utilizes an integrated electronic Medical Record (ieMR) system aligned with ICH GCP Section 4.9, enabling secure and efficient source data verification during both onsite and remote monitoring visits.

CTU is committed to excellence in clinical research through robust governance, highly experienced staff and comprehensive education programs. All team members complete mandatory ICH-GCP training and Research Integrity training alongside protocol-specific competency assessments. This is supported by structured onboarding and ongoing participation in research education initiatives, ensuring high-quality trial conduct and patient care.

Clinical Trial Capabilities

CTU conducts a comprehensive range of Phase I–IV clinical trials across haematological and oncological malignancies in neoadjuvant, adjuvant and palliative settings. Our portfolio extends beyond interventional studies to include translational research, registries and treatment audits, driving innovation from bench to bedside. Trials encompass diverse and advanced treatment modalities, including chemotherapy, targeted and biological agents, autologous and allogeneic immune cell therapies, radiation and surgical interventions—reflecting CTU's commitment to delivering cutting-edge cancer care and research excellence.

CTU benefits from a substantial oncology patient population within the Metro South Hospital and Health Services (HHS), which is further complemented by referrals from other Queensland HHS, the private sector and interstate patients where trials are not locally available. Trials are offered to both inpatient and outpatient participants, supported by this extensive patient base, well-established referral networks and strong multidisciplinary collaboration.

Staff

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 within DoCS.

Clinical Trial Coordinator (CTC)

Specialised research professional working with and under the direction of the PI to support, facilitate and coordinate daily clinical trial activities, playing a critical role study conduct. CTCs collaborate with the PI, department, sponsor and institution to ensure compliance and manage administrative, financial, personnel and other related aspects of the trial. Coordinators within CTU hold nursing or allied health qualifications with backgrounds such as scientists, radiation therapists, and pharmacists, bringing diverse expertise to the unit. The team is structure into three streams haematology, medical oncology, and radiation oncology, with coordinators specialising in one of these streams, each led by a Team Leader. Trials are allocated to a lead CTC with additional backup support to ensure continuity and quality across all studies.

Clinical Trial Assistant (CTA)

Provides essential support to CTCs in the day-to-day conduct of clinical trials. Responsibilities include, but are not limited to, assisting with the collection and management of patient trial-specific data, preparing for onsite and remote monitoring visits and supporting the preparation of patient trial visits. The CTA works collaboratively with, and under the supervision of, CTCs to ensure smooth trial operations and compliance with study requirements.

CTU Clinical Trial Nurse (CTN)

The CTU nursing team works collaboratively with CTCs and study investigators to provide direct clinical care to trials patients. This may include supporting the informed consent process, educating patients, performing clinical observations and collecting protocol specific samples collections and health data. Nurses monitor for adverse effects and facilitate care transitions between outpatient clinics, oncology daycare and inpatient wards as required. In addition CTNs provide education and training to the oncology daycare and ward staff related to trial protocol treatments, potential side effects and general trial requirements in collaboration with CTCs.

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): The E&G team are responsible for preparing, coordinating and submitting regulatory documentation to the relevant regulatory bodies such as the relevant Human Research and Ethics Committee (HREC) and Metro South Research Governance Office (RGO). E&G liaise with sponsors, CTCs, vendors, PIs and HREC and RGO teams to ensure that submissions meet regulatory requirements and that appropriate approvals are in place prior to trial commencement and throughout its duration at this site. The team has proven capability in managing submissions for both lead site responsibilities and participating site requirements, ensuring compliance and timely activation across a wide range of studies.

Revenue/Finance Team: The Revenue Team oversees all financial transactions associated with CTU trial activities. Their responsibilities include negotiating trial budgets with sponsors in alignment with the CTU’s

established schedule of fees and reconciling payments received 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: Nathan Cornick
Hours: 8 am to 4 pm, Monday to Friday
t. 07 3176 7327
pah-ctu@health.qld.gov.au

Director: Stephanie Airey
Enquires: PAH-CTU@health.qld.gov.au

Haematology
Team Leader: Jason Kelly
Enquiries: haem-feasibility@health.qld.gov.au

Medical Oncology
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. All treatment areas are equipped with calibrated vital signs monitors, infusion pumps, emergency trolleys, oxygen supply and ECG machines, ensuring readiness for trial procedures and patient safety.

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

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

Oncology Day Treatment

- Two treatment units located across level 2E, with 16 chairs and 2 beds, and ground floor, with 11 chairs and 1 bed within the main hospital. In addition, a two-bed apheresis unit on level 2E provides both stem cell and therapeutic services.

Clinical Research Facility (CRF)

- The CRF offers specialised services and resources to support research and clinical trials. Housed on Levels 4 and 5 of the PAH R Wing, with direct access to PAH facilities and emergency response teams. 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 for processing and storing 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, the autologous transplant program and both allogenic and autologous Chimeric Antigen Receptor (CAR) T-cells programs 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), SPECT (including SPECT-CT), 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 certified Human Research Ethics Committee (HREC) responsible for the ethical and scientific review of research projects. Metro South HREC (MSHREC) assesses both the ethical and scientific validity of proposed research within Metro South Health. Under the National Health and Medical Research Council (NHMRC) National Mutual Acceptance scheme, the MSHREC is authorised to review research projects conducted across Queensland, New South Wales, Victoria, Western Australia, Australian Capital Territory and South Australia. MSHREC reviews 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 conducted at the site. SSA authorisation is a distinct process, separate from ethical review focusing on site-specific considerations. MSH-RGO reviews only documents that have a direct 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.