Translational Trials Coordinator

Translational Research Institute, Brisbane

1. Background

The Translational Research Institute (TRI) is a leading Australian innovative medical research development and translation facility. It is home to a range of cutting-edge technologies including interventions to prevent and treat human diseases and provide diagnosis of early disease.

Supported by grants from the Australian and Queensland Governments, situated in the Princess Alexandra Hospital precinct, TRI combines the research intellect and capability of Queensland Health, The University of Queensland, Queensland University of Technology, and the Mater Hospital.

TRI houses over 1,000 leading researchers and support scientists who interface with clinicians on the hospital campus and at other Brisbane-based hospitals. It has two clinical trial facilities, one based at the PA Hospital and the other at the Centre for Children's Health Research next to the Children's Hospital. TRI licenses space to six start-up companies and space in an adjacent building to the biopharmaceutical manufacturer Thermo Fisher.

As a Translation Research Institute, TRI is charged with partnering scientific development with the commercial sector to ensure innovations move rapidly to improve patient outcomes and commercial return. To this end, TRI is at the interface of science, medicine and industry.

2. TRI Vision and Values

TRI will be a global leader in effective translation of research and innovation into improved healthcare and increased income and jobs for Australia. The TRI vision is achieved through a values-driven corporate culture focused on collaboration to achieve excellence. Our values are:

Leadership:	*Our actions will shape a healthier world*
Integrity:	*We do the right thing. Always*
Knowledge:	*Through sharing, we empower innovation*
Excellence:	*We strive for exceptional outcomes*
Collaboration:	*Together we're better*

We LIKE Collaboration

3. Position Purpose

The Translational Trials Coordinator will be accountable for the management, and coordination of assigned clinical research projects, from start-up through to close out. The purpose of the role is to ensure high quality outcomes for patients and study teams, supporting both investigator initiated, and industry sponsored clinical research projects.

4. Key Accountabilities

All activities must be conducted in accordance with project specific documentation, applicable SOPs, ICH GCP and regulatory requirements. The duties and responsibilities of the Translational Trials Coordinator include but are not limited to:

Study Start-up

- Participate in the evaluation and feasibility of new projects.
- Participate in protocol reviews, develop site-specific participant information and consent forms and other documentation required for submission to an ethics committee.
- Development of required documentation (e.g., recruitment plan, data management plan, budget and financials) for projects, as required.
- Undertake Human Ethics and Research Governance submissions for new projects using the ERM electronic system in accordance with site specific policies and procedures.
- Act as liaison with the site Research Ethics Coordinator and Research Governance Officer and other research staff in matters pertaining to the conduct of clinical research in humans.
- Identify specific resources required to establish, conduct, and coordinate a project in accordance with the study protocol and budgetary framework.
- Utilise project management tools to effectively coordinate trial start-up, ensuring timely management of activities and key milestones to meet required deadlines.
- Ensure vendor services, equipment, and supplies are available to meet specific project requirements.
- Ensure all agreements and/or approvals are in place in compliance with international, national, and local regulatory requirements prior to project initiation.

Study Maintenance

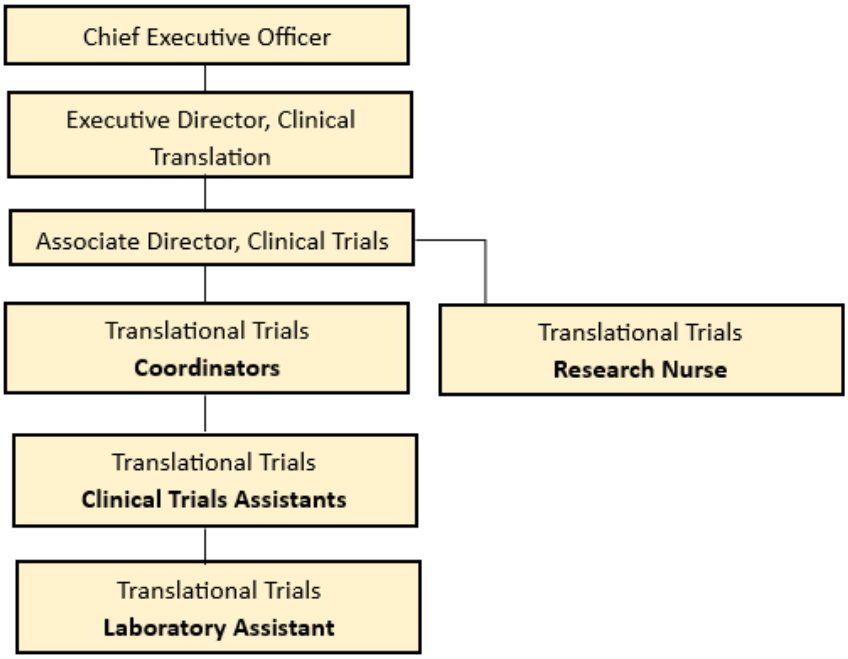
- Ensure ongoing study conduct and reporting requirements for Ethics and Research Governance are undertaken in compliance with ICH GCP, National Statement, National Standards and local policies and procedures.
- Provide support to the study team in all aspects of the day-to-day conduct of clinical research projects to ensure the quality and integrity of trials are maintained.
- Coordinate day-to-day activities of assigned projects, manage workload effectively, prioritise emerging and competing activities to ensure risk mitigation, and study protocol requirements are followed.
- Follow approved standard procedures to ensure the quality and safety of service provision.
- Assist in coordinating Translational Trials laboratory staff and logistics for processing of biospecimens in the CRF laboratory.
- Ensure Translational Trials policies and operating procedures relevant to the conduct of clinical research are followed ensuring standardisation and compliance with legal, ethical, and safety requirements.
- Use trial management systems to enter data and other information, as required, in a timely manner throughout the lifecycle of a project, ensuring accuracy and completeness.
- Participate in quality control activities for assigned projects to verify all project related activities have been completed, including monitoring visits, audit, and financials.
- Participate in project site close out activities, preparation of files for storage and archiving.

General Duties

- Assist the Translational Trials team to continue to grow clinical research activities in TRI's clinical research facilities.
- Assist with the development and review of Translational Trials policies and procedures for the operational conduct of clinical research, as required.
- Assist with the evaluation of the services provided by Translational Trials team to identify opportunities for improvement and prepare documentation for reporting purposes.
- Other duties as required.

5. Reporting Relationships

The Translational Trials Coordinator is an integral member of the Translational Trials team tasked with the facilitation and coordination of clinical trials for TRI. This role reports to the Associate Director Clinical Trials. The Translational Trials Coordinator will be expected to function independently following a period of induction and is familiar with the tasks of the role.



6. Key Objectives of Translational Trials

The specific objectives of TRI's Translational Trials team are to:

- Facilitate the development, activation and conduct of clinical research on the PAH campus and within TRI's TRIC facility located adjacent to the CHQ campus.
- Promote the awareness and availability of support services to researchers and external entities.
- Provide expert administrative/nursing, trial coordination, laboratory services and data management support for clinical research projects.
- Facilitate access for researchers to appropriately equipped and maintained research facilities.
- Provide budget advice and financial tracking services to facilitate reimbursement for activity.
- Coordinate education and training programs for members of the TRI clinical research teams.
- Promote patient safety, quality assurance, research compliance and adherence to Good Clinical Practice (GCP).
- Implement information technology solutions that will enable operational uniformity and transparency of clinical research activities.

7. Qualifications, Knowledge and Experience, Skills

Qualifications

- Tertiary qualifications in a health-related discipline
- Experience in oncology/haematology (highly desirable)
- Previous experience in Clinical Trials, and current TransCelerate endorsed ICH-GCP Certification

Knowledge and Experience

- Experience in the conduct and management of commercial clinical trials in a healthcare setting
- Demonstrated ability to plan effectively, problem solve, and ensure coordination of clinical research programs to the highest ethical and scientific standards, while demonstrating the ability to work well within a fast-paced team environment.
- Demonstrated success in developing collaborative processes dealing with a diverse group of internal and/or external clinical research stakeholders on complex research projects.
- Thorough knowledge and understanding of the requirements and procedures that must be followed that relate to research ethics, governance, privacy, ICH-GCP and regulatory compliance.
- Experience in training and mentoring junior staff in clinical research techniques and practices.
- Demonstrated experience in providing guidance on work activity, policies, and procedures.

Skills

- Ability to collaborate with a wide range of internal and external stakeholders and the capacity to work collaboratively within a multidisciplinary research team.
- Ability to use industry standard project management / coordination skills.
- Ability to understand technical, scientific, medical, and regulatory information.
- Experience in dealing efficiently with competing time demands, or unexpected events.
- Excellent computer skills (i.e., Word, Excel, PowerPoint).
- Strong project management, research coordination, reporting and presentation skills, understanding the need for attention to detail.
- Proven effective communication (written and verbal), problem solving, and interpersonal skills.