Translational Trials Clinical Trials Assistant

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 Clinical Trials Assistant (CTA) will support the TRI Translational Trials initiative in growing collaborative research activities across TRI and its partners. The CTA will assist the Translational Trials Team and other members of the study team in the conduct of clinical trials from start-up through to close out for both investigator initiated, and industry sponsored clinical trials and specifically includes bio-specimen laboratory processing.

4. Key Accountabilities

All activities must be conducted in accordance with project specific documentation, laboratory manuals, applicable SOP's, ICH GCP and applicable regulatory requirements.
The duties and responsibilities of the Translational Trials Clinical Trials Assistant include but are not limited to:

Study Start-up

- Assist in the preparation of Human Ethics submissions and amendments for projects using the ERM electronic system in accordance with site specific policies and procedures;
- Assist in preparing SSA (Site Specific Assessment) and submissions to the Research Governance Office;
- Assist in the coordination of the study start up process;
- Assist with tracking the progress of patient recruitment, trial supplies, resources, vendor services, equipment and documentation to meet specific project requirements;
- Liaise with the Translational Trials team, Investigators and/or Sponsors;
- Update project tracking tools and systems related to the conduct of clinical trials;
- Assist with development of study related documentation (e.g., site related check lists and essential documents) as required;
- Utilise project management tools to assist the study team in the timely management of activities to meet required deadlines.

Study Maintenance

- Assist with the set up and maintenance of trial Master Files;
- Assist with the distribution of study documents to investigators and site staff;
- Assist with the planning and preparation of investigator and/or project meetings;
- Assist with the collection and tracking of essential regulatory documents and safety reports;
- Undertake appropriate training as required including GCP;
- Complete study related data entry accurately, in accordance with timelines;
- Maintain up to date site information, including contact details and trial related trackers;
- Track, monitor, progress and report on requests for invoice and authorised clinical trial payments, accurately and in a timely manner;
- Proactively identify study administrative issues and provide high level administrative support to the trial team to overcome issues;
- Assist with study recruitment tasks;
- Receipting, handling, processing, and preparing bio-specimen samples for transportation as required, according to specific standard operating procedures, laboratory manual and/or work instructions;
- Maintain appropriate standards of safety, cleanliness, and function within the laboratory as directed by TRI's quality system relative to the processing of bio-specimens.
- Ensure Translational Trials policies and operating procedures relevant to the conduct of clinical trials are followed ensuring standardisation and compliance with legal and ethical requirements;

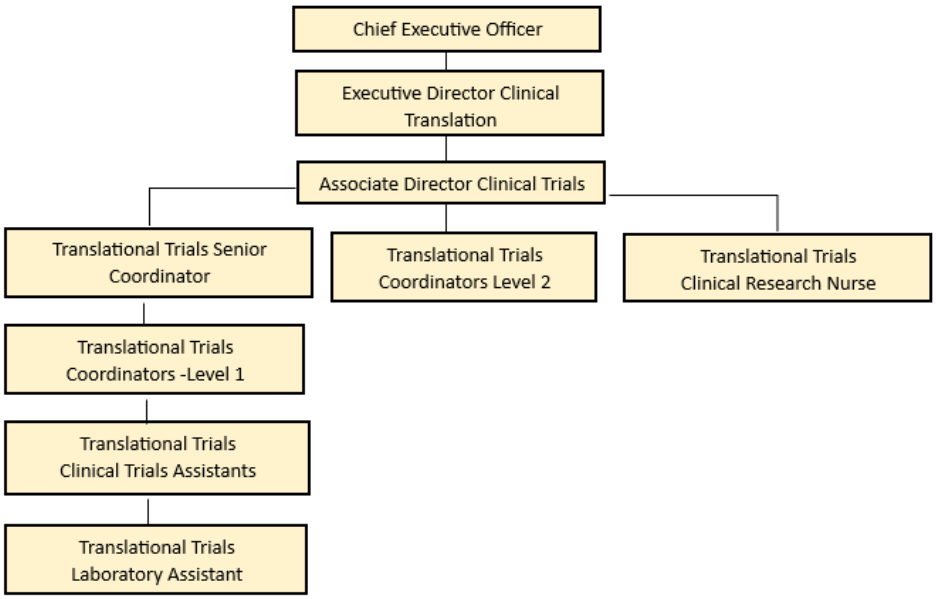
- Use trial management systems to enter data and other information, as required, in a timely manner throughout the lifecycle of a project ensuring accuracy and completeness.
- Participate in quality control activities for assigned projects to verify all project related activities have been completed;
- Assist with project site close out and archiving activities.

General Duties

- Provide general administrative support to the Translational Trials team where required;
- Assist with the preparation of study documentation, presentation materials, forms and the development of administrative filing systems and processes;
- Participate in the continuous improvement of processes tools and systems;
- Comply with TRI's Code of Conduct and WHS statement;
- Other duties as required.

5. Reporting Relationships

The position reports to the Senior Translational Trials Coordinator.



6. Key Objectives of Translational Trials

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

- Facilitate the conduct of clinical trials in the TRI Clinical Research Facility (CRF) on the PAH campus.
- Promote the awareness and availability of Translational Trials clinical trial support services to researchers and external entities.
- Provide expert administrative, nursing, trial coordination, laboratory services and data management support for clinical trials.
- Provide budget advice, financial tracking and management of clinical trial activity to facilitate timely reimbursements.

- Promote quality assurance, research compliance, and adherence to GCP.
- Implement information technology solutions to enable operational uniformity and transparency of clinical research activities.

7. Experience, Knowledge, Skills, Abilities and Qualifications

Experience

- Relevant experience in a clinical trials setting, similar research or healthcare related environment.

Knowledge, Skills and Abilities

- Laboratory experience;
- Understanding of medical terminology;
- Understanding of clinical trial processes with some knowledge and understanding of ethics, governance, privacy and ICH-GCP principles;
- High level administrative and computer skills (i.e. Word, Excel, PowerPoint, Outlook, Adobe, Zoom/Teams etc.), with proven experience and excellent attention to detail;
- Proven effective communication skills (written and verbal), and strong interpersonal skills;
- Ability to work flexibly, autonomously and within a small multidisciplinary team within a fast paced environment and collaborate with a wide range of internal and external stakeholders;
- Ability to quickly learn new computer systems such as the Ethical Research Management (ERM) system and other IT trial support systems;
- Experience in managing time demands in a fast-paced environment with competing priorities, and unexpected events;
- Excellent organisational skills, with a focus on the quality of work produced.

Desirable

- Current GCP certification;
- Demonstrated ability using project tracking tools and systems related to research trials;
- Demonstrated ability to develop and review procedures and related checklists;
- Ability to set up and maintain site information and trial related trackers;
- Ability to track, monitor progress, and report on financial aspects of a clinical trial;
- Demonstrated ability to proactively identify study administrative issues and actively contribute to working as a team to overcome issues;
- Demonstrated ability to conduct recruitment study tasks;
- Ability to prepare study-related presentation materials; and
- Ability to understand technical, scientific, medical, and regulatory information.

Qualifications

- Tertiary qualification(s) in a health/science discipline
- Relevant experience in research and a clinical laboratory environment