Clinical Business Manager – ACCISS (CBMA)

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 Research Institute.

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 purpose of the Clinical Business Manager - ACCISS (CBMA) is to provide clinically applied leadership and administrative co-ordination for the Australian Centre for Complex Integrated Surgical Solutions (ACCISS). This will facilitate the provision of clinical services, quality clinical trial services for investigator initiated and industry sponsored clinical trials, quality management systems for medical device manufacture and co-ordination in preparation of collaborative research grants, including the supervision of early career researchers in preparation and submission of grant applications.

4. Key Accountabilities

The Clinical Business Manager will be responsible for the following:

Clinical Leadership

- Provide clinical operations leadership to ensure the provision of quality services in the manufacture and delivery of clinically applied digital innovations.
- Oversee the interactions between engineers, clinicians, junior doctors, students, academics and administrators.
- Ensure at all times that patient's interests are being served first and foremost
- Oversee the collection and management of clinical case data, including the preparation of clinical service reports that demonstrate meeting Key Performance Indicators.

Clinical Trial Support and Development

- Provide clinical advice on operational planning for clinical trials from feasibility assessment through to trial closeout in consultation with the TRI Translational Trials team.
- Ensure that all clinical research trial activities undertaken under the auspices of ACCISS are conducted in accordance with project specific documentation, applicable SOPs, ICH GCP guidelines and other regulatory and legal requirements.
- Manage Good Clinical Practice (GCP) training requirements for clinical trials staff ensuring they are GCP certified
- Facilitate liaison with industry sponsors and academic collaborators in clinical trials.

Grant Applications

- Identify relevant internal and external grant opportunities.
- Prepare and/or co-ordinate collaborative grant applications.
- Support junior staff in preparation of early career grant applications.

Quality Management

- Maintain an up to date understanding of relevant guidelines and policy changes specific to the manufacture of medical devices.
- Assist in the design and establishment of a robust, auditable quality management system for the manufacture of Class II medical devices.
- Assist in the maintenance of ACCISS compliance with regulatory guidelines for the manufacture of medical devices.

5. Reporting Relationships

The Clinical Business Manager - ACCISS (CMBA) reports to directly the Director of Clinical Translation and indirectly to the Director of ACCISS. Together, they report to the ACCISS Directorate who oversee ACCISS activities globally. ACCISS is owned by Metro South Health Service (MSHS) within the Division of Surgery but funded by both MSHS and TRI.

6. Experience, Knowledge, Skills, Abilities and Qualifications

Experience and Qualifications

- Tertiary qualification(s) in a clinical health discipline
- Qualification/experience in the coordination and management of clinical research projects.
- Experience in preparation of national and local grants for research funding
- Experience in quality management systems, ideally in medical device manufacturing

Knowledge, Skills and Abilities

- Relevant experience in a clinical research trial setting;
- Understanding of clinical trial processes with knowledge and understanding of ethics, governance, privacy and ICH-GCP principles;
- High level administrative skills with proven experience and excellent attention to detail;
- Skills in the management of clinical data and clinically themed Key Performance Indicators including cost-effectiveness;
- Excellent computer skills (i.e. Word, Excel, PowerPoint, Outlook, Adobe, Zoom/Teams etc.);
- Proven effective communication skills (written and verbal) across multiple disciplines and levels of seniority;
- Strong interpersonal and change management skills;
- Ability to work flexibly, autonomously and within a small team and with a wide range of internal and external stakeholders;
- Knowledge of the Ethical Research Management (ERM) system and CTM systems;
- Excellent organisational and time management skills, with proven focus on quality of work.