POSITION DESCRIPTION

Position Title: Clinical Trials Manager, Queensland Drug Repurposing Initiative
Organisation Unit: UQ Centre For Clinical Research (UQCCR)
Position Number:
Type of Employment: Full Time - Fixed Term for 3 years
Classification: HEW Level 8

THE UNIVERSITY OF QUEENSLAND

The University of Queensland (UQ) contributes positively to society by engaging in the creation, preservation, transfer and application of knowledge. UQ helps shape the future by bringing together and developing leaders in their fields to inspire the next generation and to advance ideas that benefit the world. UQ strives for the personal and professional success of its students, staff and alumni. For more than a century, we have educated and worked with outstanding people to deliver knowledge leadership for a better world.

UQ ranks in the world’s top universities, as measured by several key independent ranking, including the Performance Ranking of Scientific Papers for World Universities (43), the US News Best Global Universities Rankings (52), QS World University Rankings (47), Academic Ranking of World Universities (55), and the Times Higher Education World University Rankings (60). UQ again topped the nation in the prestigious Nature Index and our Life Sciences subject field ranking in the Academic Ranking of World Universities was the highest in Australia at 20.

UQ has an outstanding reputation for the quality of its teachers, its educational programs and employment outcomes for its students. Our students remain at the heart of what we do. The UQ experience – the UQ Advantage – is distinguished by a research enriched curriculum, international collaborations, industry engagement and opportunities that nurture and develop future leaders. UQ has a strong focus on teaching excellence, winning more national teaching excellence awards than any other in the country and attracting the majority of Queensland's highest academic achievers, as well as top interstate and overseas students.

UQ is one of Australia’s Group of Eight, a charter member of edX and a founding member of Universitas 21, an international consortium of leading research-intensive universities.

Our 50,000-plus strong student community includes more than 13,000 postgraduate scholars and more than 12,000 international students from 144 countries, adding to its proud 240,000-plus alumni. The University has about 7,000 academic and professional staff and a $1.8 billion annual operating budget. Its major campuses are at St Lucia, Gatton and Herston, in addition to teaching and research sites around Queensland and Brisbane city. The University has six Faculties and four University-level Institutes. The Institutes, funded by government and industry grants, philanthropy and commercialisation activities, have built scale and focus in research areas in neuroscience, biomolecular and biomedical sciences, sustainable minerals, bioengineering and nanotechnology, as well as social science research.
UQ has an outstanding track-record in commercialisation of our innovation with major technologies employed across the globe and integral to gross product sales of $11billion+ (see http://uniqest.com.au/our-track-record).

UQ has a rapidly growing record of attracting philanthropic support for its activities and this will be a strategic focus going forward.

Faculty of Medicine

The University of Queensland’s Faculty of Medicine is an internationally recognised provider of world-class education and research. The research-intensive Faculty has a gross budget of almost $300 million, employs approximately 1000 continuing and fixed-term staff (headcount), has a community of more than 4000 non-salaried academic appointees and around 3200 students (headcount).

The Faculty of Medicine offers Australia’s largest medical degree program for graduates and school-leavers. Undergraduate and postgraduate programs are available in the disciplines of Medicine, Health Sciences, E-Health, Mental Health, Biomedical Sciences and Public Health.

The Faculty possesses enormous strengths spanning research, teaching, industry engagement and clinical practice in disciplines ranging from the basic sciences, biomedical research and development, to clinical trials and public health. Research projects within the Faculty have already led to discoveries with far-reaching social and economic impacts, including the revolutionary Gardasil (TM) vaccine for cervical cancer (Professor Ian Frazer) and a drug discovery EMA401 (Professor Maree Smith), a first-in-class oral treatment for chronic pain which through Spinafex Pharmaceuticals led to Australia’s largest biotechnology commercialisation deal. Faculty staff include three highly cited authors, one Fellow of the Royal Society (FRS), three Fellows of the Australian Academy of Science (FAA) and 12 Fellows of the Academy of Health and Medical Sciences (AAHMS). The Faculty is a core member of Brisbane Diamantina Health Partners, the Brisbane-wide academic health science system.

Educational offerings in biomedical sciences, medicine and public health are informed and supported by research activity across a range of fundamental and clinical areas of importance including recognised strengths in cancer, skin diseases, brain and mental health, maternal and child health and genomics. Cutting-edge facilities such as the Herston Imaging Research Facility (HIRF), the UQ Centre for Clinical Research (UQCCR), our laboratories in the Translational Research Institute (TRI) and the new Centre for Children’s Health Research (CCHR) enable outstanding research outcomes and sharpen our understanding of cancer, autoimmunity, mental disorders, infectious diseases and neurological disease. Further details are available at www.medicine.uq.edu.au.

UQ Centre for Clinical Research

The University of Queensland Centre for Clinical Research (UQCCR) is a $70 million purpose-built facility sponsored by Atlantic Philanthropies, the Queensland Government (Smart State funding) and UQ. The building, completed in early 2008, is located at the Royal Brisbane and Women’s Hospital site at Herston, Brisbane. The RBWH is the largest teaching hospital in Australia and the site also houses a basic medical research institute (QIMR), and a significant Faculty of Medicine presence, including the Schools of Public Health. The UQCCR has capacity for 320 staff with affiliation guided by research strengths, assessed by defined research quality indicators.

UQCCR’s mission is to improve health outcomes for individuals and populations based on rigorous, high quality clinical research. This is achieved by facilitating research and training,
influencing patient care, and providing the translational linkages between basic and applied scientific research, the patient, and health outcomes. The current research themes are: Mothers, Babies and Lifelong Health; Infection and Immunity; Brain and Mental Health; and Cancer.

UQCCR is a University-level research Centre reporting to the Research Dean of the Faculty of Medicine. The centre’s postgraduate students are enrolled through partnering Schools.

Information for Prospective Staff

Information about life at UQ including staff benefits, relocation and UQ campuses is available at - [http://www.uq.edu.au/current-staff/working-at-uq](http://www.uq.edu.au/current-staff/working-at-uq)

DUTY STATEMENT

Primary Purpose of the Position

The primary purpose of the position is to manage the Queensland Drug Repurposing Initiative (QDRI), which is being established with funding from the Advance Queensland Innovation Partnership Program (AQIP). The candidate will be based at the UQ Centre for Clinical Research (UQCCR), located at the Royal Brisbane & Women's Hospital Campus in Herston, Brisbane.

The position will be responsible for the overall management and oversight of the QDRI clinical trials and clinical research projects which will be established at multiple trial sites across South East Queensland. The Clinical Trial Manager (CTM) will manage clinical trials and clinical research projects to ensure start up, monitoring and close out according to Good Clinical Practice guidelines (ICH-GCP), Standard Operating Procedures local regulatory requirements and study specific requirements including budget and financial responsibilities.

The position will liaise regularly with QDRI partners, collaborators and University staff.

Duties

Duties and responsibilities primarily include, but are not limited to:

- HREC submissions and governance approvals across multiple clinical trial sites.
- Writing and contributing to preparation of clinical protocols, amendments, informed consent forms, study guides, case report forms and other clinical research related documents.
- Oversight and management of patient recruitment and engagement activities.
- Oversight and management of clinical data collection at trial sites.
- Oversight and management of patient sample biorepositories and sample databases.
- Establishment and maintenance of clinical trial management systems.
- Trial Master File (TMF) tracking and reporting on progress of study including site activation, patient enrolment and monitoring visits.
- Oversight and management of clinical trial assessments in liaison with Chief Investigators, Clinicians, Research Nurses and Research Assistants.
- Oversight of the engagement and performance of external CROs to ensure compliance with relevant study protocols.
• Ensuring studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures.
• Monitoring performance of investigational sites for clinical studies.
• Management of relevant operational budgets and payments.
• Managing investigational product (IP) accountability and the reconciliation process.
• Performing clinical data review listings and summary tables, including query generation.
• Developing, reviewing and monitoring key study quality metrics (e.g., eligibility, primary endpoint data, etc.) and determining appropriate action in conjunction with the study team.
• Occasional travel to clinical trial sites will be required as part of this role.

Service and Engagement

• Foster QDRI and partner relationships with key stakeholders including the patient’s associations, industry, government departments, professional bodies and the wider community.
• Other duties as reasonably directed by supervisors.

Other

Ensure you are aware of and comply with legislation and University policy relevant to the duties undertaken, including:
• the University’s Code of Conduct
• requirements of the Queensland occupational health and safety (OH&S) legislation and related OH&S responsibilities and procedures developed by the University or Institute/School
• the adoption sustainable practices in all work activities and compliance with associated legislation and related University sustainability responsibilities and procedures
• requirements of the Education Services for Overseas Students Act 2000, the National Code 2007 and associated legislation, and related responsibilities and procedures developed by the University.

Organisational Relationships

The position reports jointly to QDRI project leaders Dr Richard Gordon and A/Prof John O’Sullivan at the UQ Centre for Clinical Research (UQCCR).

SELECTION CRITERIA

Essential

• Relevant tertiary qualifications, preferably a Bachelor’s or Masters in health, science or related field with significant management experience and training in clinical trials and clinical research.
• A Demonstrated knowledge of Australian and international regulatory requirements for clinical trials and clinical research.
• A demonstrated successful track record in managing or coordinating multicenter clinical trials and clinical research in collaboration with other health disciplines.
• Experience in feasibility analyses, budget development, site start up and all aspects of trial management including site close-out and archiving.
• Demonstrated high level written and verbal communication skills, interpersonal, negotiation along with delegation skills and leadership attributes.

• Demonstrated ability to develop and report individual and group performance to produce highly functioning teams.

• Demonstrated ability to analyse and interpret research data and direct research relevant to health outcomes.

• Demonstrated problem solving and strategic planning skills with the ability to design and implement appropriate departmental processes and systems to improve and maintain quality.

• Demonstrated ability to coordinate research training programs relevant to clinical trials staff.

• Proficiency with clinical trial management systems or an ability to acquire this knowledge quickly.

**Desirable**

• At least three to five years’ experience in clinical trials and/or clinical research management.

• Senior Clinical Research Associates, Project Managers and/or applicants with prior Contract Research Organisation experience would be highly regarded

• The University of Queensland values diversity and inclusion and actively encourages applications from those who bring diversity to the University. Please refer to the University’s Diversity and Inclusion webpage ([http://www.uq.edu.au/equity](http://www.uq.edu.au/equity)) for further information and points of contact if you require additional support.

• This role is a full-time position; however flexible working arrangements may be negotiated.

• Accessibility requirements and/or adjustments can be directed to the contact person listed in the job advertisement.