| Position Description | |
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| **POSITION TITLE** | Clinical Data Manager / Senior Clinical Data Manager |
| **CAREER STEP** | Independent / Specialist |
| **REPORTING RELATIONSHIP** | Head of Data Management |
| **TEAM** | Data Management |
| **EMPLOYMENT DURATION** | Permanent |
| **TYPE OF EMPLOYMENT** | Full-time |
| **DATE** | June 2022 |

## The George Institute for Global Health

The George Institute ('TGI') employs 700+ people, focused on improving the health of millions of people worldwide. As a medical research institute affiliated with leading universities and with projects in approximately 50 countries, we are challenging the status quo in healthcare to find the best ways to prevent and treat chronic disease and injury, and to influence policy and practice worldwide. Our innovative commercial enterprises help maximise our impact.

Here is a sample of the things we are doing to achieve our goal of having the greatest possible impact on global health:

- We are identifying better and safer treatments for our biggest killers like stroke, heart disease and high blood pressure
- In many countries, our award winning FoodSwitch smartphone app is helping people make healthy food choices when shopping
- In China, we ran a successful education and awareness program to reduce the amount of salt eaten by people by 25% each day
- In rural India, we have shown that mobile technology can help diagnose mental health, as well as help treat cardiovascular disease, and we're looking at similar approaches to treating chronic diseases in Indonesia and China
- Together with Aboriginal communities in NSW, Australia, we have developed an innovative community led program to assist young Aboriginal drivers attain their license, now implemented in a dozen of locations
- We are developing an affordable dialysis machine, with potential to save millions of lives each year and transform the way kidney disease is treated globally
- And much more…

## Context of the Role

The George Institute is looking to expand its data management team to better support and manage the increased data management needs across the diverse research projects conducted by staff and affiliates.

## The Role

The Clinical Data Manager is responsible for planning and implementing the set-up, programming, and ongoing maintenance of data management systems in support of George Institute research projects to ensure the collection of complete and accurate data for final analysis. Appointment to this role may be at a senior level based on the appointee's skills and experience.

**Reporting Relationships**

The Clinical Data Manager will report to the Head of Data Management.

The reporting status may have alterations as result of new structures emerging from TGI's development of new processes and resources to manage our academic research.

**Duties and Key Responsibilities**

**Data Management Systems & Processes**

- Ensure delivery of data management services for academic and commercial studies within pre-specified agreed targets and timelines.  This includes but is not limited to:
    - Liaise with stakeholders (internal and external) to determine study requirements
    - Write, or contribute to the preparation of data management documentation, for example Data Management Plans, Edit Check Specifications, DM SOPs
    - Design, or contribute to the design, testing and implementation of electronic data collection systems, integrations, and project reports
    - Provide training, expertise and guidance to team members delegated to perform other DM set-up, conduct, maintenance or close out activities
    - Ensure quality and accuracy of research data in development and maintenance of above systems
    - Track progress against budget and project plans
- Provide expertise on all aspects of data management for clinical trials and other research projects conducted at The George:
    - Provide evaluation of potential projects submitted for consideration by external collaborators or commercial clients
    - Interpretation of complex study protocols to guide data management workflows, CRF and EDC design
    - Preparation and input into RFPs, and development of costing estimates for new projects
    - Provide expert advice/ adhere to best data governance practice across all DM activities
- Provide expertise across a range of DM activities:
    - Act as expert user or super user for nominated DM systems and undertake training to develop expertise, knowledge and skills in the systems
    - Participate in the selection, implementation, validation and maintenance of new data management systems and processes as necessary
    - Act as the point of contact for users of DM systems, provide support and expertise to troubleshoot data and system issues
    - Be the DM system vendor contact person and manage contracts
    - Help develop and maintain data management SOPs and standards in relation to these systems

*As a Team Member:*
- Participate in special projects to improve processes, tools, systems, and organisation
- Take responsibility for personal learning and development and for setting achievable and meaningful work objectives and managing personal targets, meeting obligations of The Institute's Performance Management and Development Policy

- Demonstrate commitment to The Institute's organisational values, including performing to an exceptionally high ethical standard and focus on integrity, collaboration, and teamwork in all efforts.

## *Work, Health and Safety*
- Comply with Work Health and Safety legislation and operate in accordance with established Occupational Health and Safety practice and procedures at the Institute.
- Promote and contribute to a safe, secure environment for staff and visitors.


## Skills, Knowledge and Experience
### *Essential*
- Tertiary qualifications in science or related field
- Extensive data management experience in clinical and epidemiological research (including, but not limited to, clinical trials)
- Experience working with electronic data capture systems such as RedCap, including database design, validation, support, and maintenance
- Strong IT skills including SQL, reporting software, all MS Office applications, web-based databases, and strong conceptual ability to learn new software applications quickly
- Proven ability to handle large data sets, including reporting and other evaluation procedures
- Ability to liaise and interact with external vendors and suppliers
- A strong understanding of relevant Good Clinical Practice and regulatory guidelines, especially as connected with data quality and accuracy
- Ability to evaluate and recommend changes to existing processes and procedures for greater effectiveness
- Excellent time management and project management skills
- Excellent written and verbal communication skills
- High level problem solving, analytical, and strategic thinking skills
- Excellent interpersonal skills and the ability to work well and flexibly ie. autonomously, in small teams and with a wide range of varying stakeholders, including senior management
- Ability to see the big picture, whilst still maintaining a focus on detail and implementation
- Ability to be flexible and adaptable in the face of changing organisational priorities and ambiguous environments
- Strong focus on quality of work

### *Desirable*
- Experience with data governance processes and frameworks
- Experience with data sharing processes
- Understanding of data and privacy legislation, information security policies and standards including but not limited to the Privacy Act 1988 (Cth), GDPR, PIPL.