Clinical Data Manager

POSITION DESCRIPTION

Position Level
Level 7
Faculty/Division
Medicine / Clinical Research Unit (CRU)
Position Number
00186803
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Position Summary
The CRU has been established to support academic researchers to have the relevant expertise, systems and tools to allow efficient, high quality, impactful research to be conducted across UNSW and its affiliated networks.

The Clinical Data Manager is a member of the Clinical Research Unit (CRU) operations team and will be responsible for the design, development, maintenance and management of electronic data capture systems and processes to facilitate the conduct of high-quality clinical research projects across a broad range of therapeutic areas. The Clinical Data Manager will participate in the development of and adhere to Standard Operating Procedures (SOPs) to ensure data compliance, integrity and security.

The role will require stakeholder management with key groups within UNSW, affiliated Medical Research Institutes (MRIs) and across the UNSW network to ensure quality data management service delivery. Key stakeholders include Division of Research and Enterprise, UNSW IT, the Kirby Institute and The George Institute for Global Health.

The Clinical Data Manager will work closely with the Senior Clinical Data Manager and reports to the Program Operations Lead. The Clinical Data Manager has no direct reports.

Accountabilities
Specific accountabilities for this role include:

- Participate in CRU data management projects including: assessment of existing UNSW electronic data management solutions and evaluation of new technologies or commercial electronic data management systems against researcher, regulatory and UNSW requirements.
• Build study databases including electronic case report forms for the collection and analysis of study data in alignment with the study protocol, including laboratory and questionnaire data, incorporating coding and data validation rules to ensure consistency of data entry.

• Develop data management plans, training materials, user manuals and related resources that govern the study database design, building, testing and maintenance in collaboration with the project team.

• Participate in the development of CRU Data Management Standard Operating Procedures (SOPs) to ensure data collection, handling and record keeping is compliant with UNSW SOPs, the International Council for Harmonisation's Good Clinical Practice Guidelines and other relevant legislations and guidelines including The Australian Code for the Responsible Conduct of Research.

• Collaborate with the project team and database service providers to develop and maintain electronic database systems to meet the needs of users including continuous process improvement.

• Develop a thorough knowledge of the required datasets, manage the limitations, clean the data and adjust any required variables to ensure the data is validated for analysis.

• Participate and provide advice in the development of data analyses plans including liaising with study statisticians, Protocol Steering Committees and study teams.

• Design and produce both routine and complex customised study data reports for the management of studies for project team, Protocol Steering Committees and conference presentations.

• Participate in activities and attend and contribute to compulsory meetings of Clinical Research Unit as required.

• Perform other duties as assigned by Senior Clinical Data Manager and Program Operations Lead.

• Align with and actively demonstrate the UNSW Values in Action: Our Behaviours and the UNSW Code of Conduct.

• Cooperate with all health and safety policies and procedures of the university and take all reasonable care to ensure that your actions or omissions do not impact on the health & safety of yourself or others.

**Skills and Experience**

• Tertiary qualifications in a health-related field or computer qualifications.

• Comprehensive relevant experience (> 5 years) in clinical research data management, including experience in the development of clinical study databases and data management documentation such as SOPs / data management plans, preferably in an academic setting.

• Knowledge and experience with a wide range of clinical research electronic data capture platforms, software development life cycle, sprint methodologies and project management software.
• Extensive demonstrated knowledge of International Council for Harmonisation Good Clinical Practice Guidelines (ICH-GCP), Australian TGA, NHMRC and US FDA guidelines, cybersecurity and other regulatory compliances and their application to Good Clinical Data Management.

• Demonstrated high level critical thinking, analytical and problem-solving skills.

• Strong stakeholder management skills and demonstrated success working effectively with a range of people at different levels across various teams.

• Excellent communication skills with the ability to clearly convey ideas and information to a wide range of stakeholders through presentations, written communication and other means.

• Excellent organisational and time management skills and demonstrated ability to manage and respond to changing priorities and deadlines.

• An understanding of and commitment to UNSW’s aims, objectives and values in action, together with relevant policies and guidelines.

• Knowledge of health and safety responsibilities and commitment to attending relevant health and safety training.

About this document

This Position Description outlines the objectives, desired outcomes, key responsibilities, accountabilities, required skills, experience and desired behaviours required to successfully perform the role.

This template is not intended to limit the scope or accountabilities of the position. Characteristics of the position may be altered in accordance with the changing requirements of the role.