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| **Position Title** | BEAT CF Project Manager | **Level** | B |
| **Reports to (role)** | Business Manager |
| **Team** | Infectious Diseases Implementation Research |
| **Location** | Telethon Kids Institute, Perth Children’s Hospital, 15 Hospital Ave, Nedlands(Negotiable, depending on candidate selected) |

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| **PURPOSE OF POSITION** |
| BEAT CF is a national multi-centre randomised controlled platform trial utilising Bayesian adaptive methods. The aim of the trial is to improve the management of pulmonary exacerbations in children and adults with Cystic Fibrosis. The BEAT CF Project Manager works as part of a national team and utilises specialist knowledge and highly developed management skills to oversee and deliver high-quality research services. The Project Manager oversees and manages a range of significant and complex research activities that play a critical role in supporting and achieving the trial’s outcomes. These activities include development of research protocols and procedures, providing expert advice and training, operational planning, writing complex procedures and guidelines, and managing sites at which recruitment of participants occurs. The Project Manager provides leadership to the trial in the delivery of high-level and professional research services and effective achievement of the trial’s priorities and provides expert advice at both strategic and operational levels.  |

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| **KEY RESPONSIBILITIES** |

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| **Key Responsibilities** | **Tasks required to achieve Key Responsibilities** | **Measures** |
| **Project Management of Clinical Trials** | * Contribute to strategic and operational planning and the achievement of goals for the BEAT CF research program
* Coordination and day-to-day management of BEAT CF, problem solving and ensuring the Principal Investigators are up to date with all matters
* Coordinate and supervise the set-up and continual running of BEAT CF across multiple sites, including monitoring of study metrics e.g. CRF completion, recruitment and overall tracking of the project
* Effective communication with trial sites to ensure compliance with good clinical practice (GCP) and local standards
* Database management and communication with database supplier
* Monitor study progress at clinical study sites and implement strategies to ensure compliance with the study protocol
* Effective coordination of meetings and communications with collaborators as required including DSMC, Investigators, and stakeholders
* Participation in continuous quality improvement and good clinical practice compliance activities
 | * BEAT CF delivered on time and within budget
* Study team and stakeholder feedback
* Feedback from Principal Investigator
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| **Project Delivery** | * Contribute to protocol development
* Development and management of trial documentation – ensure essential documents are filed and kept up-to-date, as per Good Clinical Practice and other applicable regulatory guidelines
* Preparation and submission of regulatory applications
* Creation of manuals/charters e.g. DSMC charter, monitoring plans
* Coordination of stakeholder input into documentation e.g. protocol review
* Monitoring of data quality and adherence to regulations across research projects including on-site monitoring, site initiation and closeout
* Safety monitoring including reporting of safety events to relevant authorities with input from investigators and data monitoring committees where applicable
 | * Projects completed to the standards required by regulation
* Project outcomes met
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| **Team Membership** | * Working cohesively and collaboratively with others - both internal (direct team members) and external (other Telethon Kids staff and collaborators)
* Organise and participate in regular BEAT-CF and IDIR team meetings
* Provide regular performance feedback to direct reports
* Share knowledge and expertise with IDIR team, formally and informally
 | * Positive feedback from team members and collaborators
* Harmonious and motivated work environment
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| Other | * Other duties as directed by the Business Manager or Team Leader
 | * Feedback from Team Leader and Business Manager
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| **Workplace** **Safety** | * Take reasonable care for your own safety and health and avoid harming the safety and health of others through any act or omission at work.
* Identify and assess workplace hazards and apply hazard controls.
* Report every workplace injury, illness or near miss, no matter how insignificant they seem.
* Abide by Telethon Kids Institute policies and procedures.
 | * Responsibilities are embedded in work practices.
* Hazards are effectively

managed or reported. * Accidents and incidents are reported in a timely manner.
* All applicable safety policies and procedures are sought, understood and implemented.
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| **ESSENTIAL CRITERIA** |

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| **Qualifications:** *(what are the minimum educational, technical or* *professional qualifications required to perform the role)* | Bachelor degree in biological sciences, allied health, nursing or other relevant discipline OR equivalent work experience |
| **Essential Skills, Knowledge & Experience:**  | 1. Experience in a clinical research environment, preferably across different phases of development
2. Working knowledge of GCP and applicable regulatory guidelines
3. Ability to work independently, take initiative, communicate and work within a team
4. Ability to be highly organised, with a proven ability to prioritise tasks appropriately in a busy working environment
5. Excellent interpersonal, verbal and written communication skills
6. Evidence of well-developed problem-solving ability
7. Evidence of desire to seek best practice and continuously learn
8. Ability to apply meticulous attention to detail
9. A high level of computer literacy including word processing, spreadsheets and databases
10. Ability to be flexible with working hours and travel interstate/overseas depending on study requirements
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| **DIRECT REPORTS***List by job title any positions to be supervised by this role* | BEAT CF Consumer Engagement OfficerBEAT CF Research Assistant*Negotiable depending on candidate selected* |

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| **Approved by:** | *Signature of the person with the authority to approve the job description and job title* |  |
| **Date approved:** | *Date upon which the job* *description was approved* |  |
| **Reviewed by P&C:** | *Date when the job description was last reviewed by People & Culture* |  |

