



Bellberry Limited supporting research and ethics

POSITION DESCRIPTION & JOB SPECIFICATION

Early Phase Clinical Trial Manager

Position Groups	Bellberry Limited	Location Site	129 Glen Osmond Rd, Eastwood, 5063 or alternative
Position Title	Early Phase Clinical Trial Manager	Other Locations	Interstate travel required on a regular basis
Reports To	CEO/Operations	Date issued	December 2018

Total Job Specification Approval

Acknowledgement by Occupant/..... /.....

Bellberry Chief Executive/..... /.....

1. Organisational Profile

Bellberry is a private, independent Not-for-Profit organisation founded in 2004 with the dual aims of protecting the welfare of human research participants and improving the quality, efficiency and effectiveness of research in Australia.

Bellberry Human Research Ethics Committees (HREC), are NHMRC-certified. Bellberry has grown to the stage where at least two Bellberry HREC meetings are held every week of the year (except Christmas shutdown). Bellberry has eight committees, based in Adelaide and Queensland, with a pool of over 100 Committee members. Bellberry has an expert and professional review process, diverse skills base and significant scale for review.

Bellberry operates using an electronic submission process and dedicated virtual collaboration environment via eProtocol. eProtocol acts as an archive of the ethics review process into the future, and may be used to support regulatory inspections in the case of successful developments, it also provides a fully traceable history of the review process, any approval documentation, adverse events, amendments, annual reports and status changes.

2. Purpose of the Position

The Early Phase Clinical Trial Manager will provide dedicated resource for the support of Early Phase Clinical Trial sites and studies, and relationship management activities with partner Institutions.

Following the appointment of Bellberry as specialist Adult Early Phase Clinical Trials HREC for NSW Health, the Early Phase Clinical Trial Manager will be responsible for the establishment, transition and ongoing support of the project. This will include working closely with NSW Health Department and NSW Institutions to develop and implement systems and solutions needed to provide high quality, efficient and effective trial review. Anticipated elements include Institutional reporting, governance interactions and planning, contractual arrangements, education support, investigator helpdesk and triage, study support and site auditing.

The Early Phase Clinical Trial Manager will be required to engage internal and external stakeholders to build relationships, ensure Bellberry services meet customer expectations, and build business opportunities. Priorities for the role will be multi-faceted, but the welfare of participants will always be paramount.

The Early Phase Clinical Trial Manager will be required to:

- Provide a point of focus within Bellberry for Early Phase clinical trials;
- Project manage the implementation of the agreed framework, and associated governance and management processes required to fulfil the service agreement with NSW Health (November 2018);
- Build relationships with internal and external Stakeholders. Support existing users. Respond to and generate business development leads to develop new users;
- Build relationships and work together with regulatory bodies to ensure the welfare of clinical trial participants and the security and attractiveness of the Australian early phase clinical trial environment;
- Build suitable consultation processes;
- Ensure appropriate analytical capabilities are in place to support the metrics and reporting required to meet and exceed institutional client expectations;
- Provide advice and support for Early Phase clinical trial applications;
- Work with the Operations Manager and HREC Administration team to ensure appropriate triage and support is in place pre-submission, and provide oversight throughout the review process;
- Work with the Quality Manager to ensure the Quality Manual reflects best practice for early phase clinical trials;
- Work with the Quality Manager and Site Monitoring Team to ensure the conduct of trials meets the approvals of the HREC;
- Work with internal and external stakeholders to ensure a culture and practice of continuous improvement in the development and conduct of early phase clinical trials;
- Work with the Communications Officer to develop and deliver a branding and communications plan, including publication strategies to support the Early Phase trial space and individual projects (such as NSW Health Nov 2018) ;
- Manage project budgets;
- Work with Committee Manager to assist with recruitment of required early phase trial review expertise.

While the initial focus of the Early Phase Clinical Trial Manager will be to support the NSW Health initiative, it is anticipated that the role will also support existing Early Phase users and future developments in the space. The Early Phase Clinical Trial Manager may also be asked to manage other projects or programmes directed at the objectives of Bellberry, subject to workload.

The Early Phase Clinical Trial Manager will join the Bellberry Leadership Team and will share in the strategic direction and leadership of the Bellberry organisation. The Early Phase Clinical Trial Manager will be expected to partner with other members of the Leadership Team to identify improvement opportunities in each function. The Early Phase Clinical Trial Manager is expected to be required to report to the Board of Bellberry on a regular basis (approximately twice per year).

3. Reporting/Working Relationships

- Reports to the CEO Bellberry;
- Works closely with the Bellberry Leadership Team comprising CEO, Operations Manager, Committee Manager, Quality Manager, Programme Manager, Innovation Manager and IT Business Partner;
- Works closely with external stakeholders and Bellberry clients (individual and institutional) with a focus on Early Phase Trial units;
- Works closely with a broad stakeholder base representing the research sector;
- Works with stakeholders in Commonwealth and State and Territory Governments, including collaborative working groups;
- Works with the Bellberry HREC Community to understand and explore opportunities in the HREC and review process;
- Interacts with peers from the Research sector;
- Provides programme reporting to the Board of Bellberry;
- Works with external specialist providers for project delivery;
- Other relationships as necessary to deliver on identified Projects and Programmes.

4. Special Conditions

- This role has been classified as a position of trust. The incumbent may be subject to a satisfactory criminal history/record check in line with Bellberry policies.
- Regular interstate travel with overnight absences is expected (approximately 2 per month).
- Occasional overseas travel may be required (approximately 1 per year).
- Occasional out of hours support for research related issues may be needed.
- A flexible working policy is in place, as well as the ability to build time in lieu for Christmas shutdown periods.
- Remote working is expected.

5. KEY AREAS OF RESPONSIBILITY AND PERFORMANCE INDICATORS

Key Area of Responsibility and Activities	Key Performance Indicators
5.1 Early Phase Clinical Trial Manager Leadership	
Provide a focus for Early Phase Clinical Trials within Bellberry	Agreed review KPIs are maintained.
Provide Executive function to the NSW Health Agreement	Effective delivery of NSW Health requirements.
Establish relationships with the Bellberry community and Stakeholder Organisations	Effective Stakeholder engagement processes are in place.
Early Phase Trial reviews	Provide oversight for individual early phase trials.
Contribute to Bellberry Communications	Deliver effective communications supporting the operations and delivery of early phase objectives.
Improvement areas	Undertake horizon scanning and review sector information to identify opportunities for improvement. Manage the delivery of improvement area projects.
Leadership	Act as a visible figurehead for Bellberry early phase activity, a champion for participants and a partner for stakeholders.
Bellberry Leadership Team	Act as part of the Bellberry Leadership Team
5.2 Ensure a safe working environment at all times by:	
Adopting procedures and practices which comply with the Work Health and Safety Act	100% of practices are compliant with the WHS Act.
Making proper use of all safeguards, safety devices and personal protective equipment (as required in undertaking the duties of the position)	Proper use is made of all relevant safety equipment.
Taking reasonable care to protect the health and safety of self and others	Always mindful of workplace safety as it pertains to self and others.
Ensuring that all accidents and incidents are reported	100% of accidents are reported within 24 hours.
Attending training programs to maintain knowledge and awareness of Work Health and Safety practices, as appropriate	Attendance at training programs as directed. The incumbent is responsible and accountable for working in an equitable manner and taking reasonable care to protect his/her own health, safety and welfare and avoiding adversely

	affecting the health and safety of others at work by complying with the SA Work Health and Safety Act 2012.
5.3 Adhere to Bellberry operating policies, and relevant legislative requirements including:	
<p>Policies outlined in the Bellberry Employee Handbook</p> <p>NHMRC National Statement on Ethical Conduct in Human Research 2007 and any updates</p>	Demonstrate a knowledge of and willingness to adhere and comply with all company policies and relevant legislative requirements of the position.

PERSON SPECIFICATION – ESSENTIAL REQUIREMENTS

1. QUALIFICATIONS:

- Tertiary qualification in a STEM related subject is preferred.
- Substantial experience in the Early Phase clinical research sector is essential.
- Experience in the broader research, Research Governance, Health or Medical fields will be valued, but is not essential.

2. PERSONAL SKILLS/ABILITIES/APTITUDES

- A detailed knowledge of early phase trial requirements is essential.
- Sound knowledge of the Australian research sector.
- Demonstrated ability to deliver projects.
- Demonstrated ability to meet services and project timeframes within a budget.
- Demonstrated highly effective communication and negotiation skills.
- Demonstrated ability to build positive stakeholder engagement and interactions.
- A personal commitment to continuous improvement will be highly regarded.
- Demonstrated ability to work with technical experts.
- Demonstrated ability to manage and deliver change.
- Personal drive for excellence, and motivation to support research that will help deliver better research and thus improve health outcomes.

3. EXPERIENCE

- Experience and understanding of research sector.
- Demonstrated ability to manage and lead team members and foster inter/intra team relationships.
- Demonstrated ability to manage multiple workstreams and competing priorities.