

Job Description : Clinical Trial Manager
Type : Full-time
Location : Australia – Melbourne preferably
Date : Immediate

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (“Telix”, the “Company”) is a Australian public Company (ASX:TLX) headquartered in Melbourne with operations in Europe, the US and Japan. Our mission is to be a leading, global biopharmaceutical Company in the field of “theranostic” radiopharmaceuticals and the Company is currently developing a mid-late stage pipeline of products in prostate, kidney and brain (GBM) cancer.

Description

The role is responsible for the operational planning, set up, conduct performance and closure of a clinical trial/study including data cleaning activities. This role ensures that those activities are conducted, in compliance with Telix quality standards and regulations, the forecasted timelines, milestones and budget.

The role is located in Melbourne (Australia) where the role will report to a Clinical Project Manager (based in Australia) and is expected to have extensive interaction with key staff in the USA and other international locations.

Key Objectives: To contribute to the achievement of the Group’s strategic clinical goals by working within the clinical team to assist in the organisation and management of the clinical trials of all Telix products.

Key Accountabilities:

- Implement all actions necessary for the successful start-up, execution and completion of clinical studies (Phase 1 to Phase 4) in accordance with company SOPs, CFR, ICH and GCP guidelines.
- Work collaboratively with the clinical team to develop work plans (Data Management Plan, Safety Plan, Monitoring Plan, Project Plan, etc).
- Create and implement study-specific clinical monitoring tools and clinical documents (Protocol, ICF, CRF, CSR).
- Create and manage the clinical trial budget.
- Identifying and organising meetings with appropriate trial investigators (clinicians) to ensure selection of the best clinical partners.
- Work collaboratively with the other clinical team members to identify, qualify, select and enlist clinical trial sites.
- Work with the clinical project manager to set study-specific objectives and timelines and ensure the clinical study is conducted in compliance with project goals.
- Manage clinical research organisations to start, execute and successfully complete clinical trials.
- Identify risks and issues, reporting to management, propose and implement corrective actions.
- Collect, process, organise and archive study documents.

Education and Experience:

- Bachelor's degree in nursing or in the lifesciences.
- Clinical Project Management experience.
- 4+ years' work experience in a similar role for a pharmaceutical/biotechnology company and/or clinical research organisation.
- Good working knowledge of the drug development process; clinical trial process, ICH GCP, local and international regulatory requirements.
- Strong understanding of phase I-IV clinical trials.
- Conflict/ issue resolution experience.
- Cross border stakeholder management experience essential.
- Flexibility to work hours that cater for international time zones across USA, Asia-Pacific and EMEA.
- Proficient with Microsoft Office Word and Excel.
- Available to travel.
- Fluent in English.

Personal Attributes:

- Commitment to the vision and mission of Telix.
- Ability to work under pressure and to tight timelines.
- Excellent interpersonal, communication and team participation skills.
- Possess good risk management and problem-solving skills.
- Ability to prioritise competitive priorities/ objectives.
- A conscientious attitude and prepared to work in a challenging environment.
- Ability and willingness to work collaboratively with global team members across multiple time zones.
- Must be detail orientated .
- Thrives on being part of a fast-paced but inclusive team, always keen to lend support to other team members when needed.

Contact

For further details and information pertaining to compensation for the role, as well as expressions of interest, please contact Telix People and Culture at employment@telixpharma.com



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