Job Description

Job title	Snr Clinical Project Manager
Reports to	VP Clinical Operations
Department	Clinical Operations
Location	WFH & London
Date last updated	24 August 2022

Job Purpose (main purpose & function)

The Clinical Project Manager (CPM) will manage all aspects of assigned clinical trials from start up through to close-out, including managing the Leucid Study Management Team (SMT), and any CROs and other vendors engaged by Leucid to perform trial related activities.

The CPM is accountable for the strategic and technical trial activities ensuring high quality standards within agreed budget and timelines, and in line with appropriate regulations and guidelines.

This individual must have the ability to work and communicate efficiently with internal and external partners, and must possess strong verbal and written communication competencies as well as interpersonal skills with experience participating on project teams, coordinating safety activities, and adhering to tight timelines.

Core accountabilities / responsibilities:

- Accountable for all aspects of trial management including supply management, vendor selection and oversight, site initiation, training, monitoring, essential document management, closedown and archiving in accordance with current Standard Operating Procedures (SOPs) and ICH Good Clinical Practice (GCP) guidelines
- Oversight of trial conduct through all trial periods (start-up, enrolment, study conduct and close-out)
- Leads the cross-functional Leucid Study Management Team
- Prepares and reviews study-related and essential trial start-up documents (i.e, protocols, Informed consent forms, Investigator Brochures, ATIMP Manuals, Laboratory Manuals, Case Report Form (CRFs), and other relevant study plans and charters)
- Provides oversight and guidance of any delegated tasks to junior staff/contractors
- Participates in trial strategy development, Line Listing Review, and Clinical Study Report preparation, as appropriate.
- Manages the trial project plan, including timelines and budget
- Sponsor oversight of operational functional activities outsourced to CROs and other vendors
- Training of CROs and other trial vendors
- Works with CROs to develop and revise study specific plans and detailed timelines, and ensure that transferred obligations and performance expectations are met
- Reviews other trial documents (such as study tools/worksheets).
- Proactively identifies potential study issues/risks and recommends/implements solutions
- Creates and implements corrective action plans when performance expectations are not being met
- Prepares metrics and updates for management, as required.
- Organises and manages internal team meetings, and other trial-specific meetings
- Participates in the development, review and implementation of departmental SOPs and processes.
- Attends cross-functional meetings as needed to represent Clinical Operations and study-specific issues.
- May lead/support departmental initiatives
- Other duties as assigned.

These tasks are not intended to be an exhaustive list of all responsibilities, duties, and skills required of people assigned to this role, but are instead intended to describe the general nature and level of the work. Different levels of responsibilities and accountabilities may be assigned to take account of the skills capabilities and

experience of the individual.

Line Management responsibilities:

- None

Budgetary responsibilities:

- Management and accountability of trial budgets

Experience & knowledge:

- Bachelor's degree in life sciences, nursing or health related field required
- At least 5 years of related oncology clinical trial management experience
- At least 2 years ATIMP trial management experience, experience with CAR-T therapies desirable
- Extensive clinical research knowledge and a cross-functional understanding of clinical trial methodology
- Working knowledge of international regulatory and ICH GCP guidelines
- Ability to deal with time demands, incomplete information or unexpected events
- Ability to adjust workload based upon changing priorities
- Must display strong analytical and problem-solving skills
- Comfortable in a fast-paced, and dynamic small company environment
- High proficiency in IT literacy, including a thorough understanding of Microsoft Word and advanced skills in PowerPoint and Excel

Person Specification:

The individual will be highly motivated, pragmatic, and with good interpersonal skills. A high level of work organisation is required, with an ability to prioritise appropriately to meet timelines. The individual will be able to work independently/autonomously with strong professional integrity in a dynamic SME environment.

This job description is not designed to cover or contain a comprehensive listing of activities, duties, or responsibilities. Duties, responsibilities, and activities may change, or new ones may be assigned at any time with or without notice to reflect the changing needs of the business.

About Leucid Bio Ltd

Leucid Bio is a clinical stage biotech advancing CAR T-cell therapies for hard-to-treat cancers. Founded to translate 20 years of pioneering CAR-T research led by Dr John Maher at King's College London (King's), Leucid Bio has developed next generation cell therapies based upon Dr Maher's novel approach, in which the CAR structure has been redesigned to recapitulate the lateral distribution of signalling domains as observed in natural immune receptors. The technology gives properties to the CAR-Ts that enable them to consistently outperform previous generations of CAR-T therapies in pre-clinical studies; enhancing T-cell potency and generating a persistent long-term response with reduced toxicity.

APPROVAL SIGNATURES (print name and signature)	
Manager:	
CEO:	
Human Resources:	