

Job Description

Job Title	Clinical Project Manager
Reporting lines (reports to + direct reports)	- Reports to Director, Clinical operations - Direct reports: None
Job Purpose	Acting as the main point of contact for sponsors and study teams, the CPM proactively manages project level operational aspects of Clinical Trial including management of study timelines, budget, resources and vendors and provides efficient updates on trial progress to the Clinical Operations Director, the sponsor and the study team with respect to sites/vendor selection, project plans, trial budget and timeline management, quality standards and risk mitigation.
Key responsibilities	The List of Responsibilities described below is not exhaustive and will be adapted based on tasks delegated by the Sponsor to Medevis Consulting: • Act as the primary point of contact for sponsors, study teams, and internal stakeholders throughout the clinical trial lifecycle. • Lead the development, review, and coordination of core study documents including Clinical Investigation Plans, Informed Consent Forms, and Investigator's Brochures. • Ensure all study documents and activities comply with ISO standards, ICH-GCP guidelines, and local regulatory requirements. • Oversee or participate in the Site Qualification Visit and confirmation of site selection in collaboration with the sponsor • Manage the setup and execution of Clinical Trial Agreements (CTAs) with investigational sites. • Prepare and coordinate submissions to Ethics Committees (ECs) and Competent Authorities (CAs) per country-specific regulations. • Develop and maintain operational plans including communication, TMF, monitoring, reporting, CRF completion guidelines, Data-Management and site training materials • Monitor and manage study timelines, deliverables, resources, and budgets to ensure successful project execution • Oversee and/or perform site management and monitoring activities with CRAs according to the approved Monitoring Plan • Coordinate the logistics and distribution of clinical devices and site supplies to ensure readiness and compliance • Collaborate with Data Management teams on eCRF design, user acceptance testing (UAT), and ongoing data review. • Collaborate with the Clinical scientist for accurate data review and reporting • Track study progress, patient enrolment, site performance, and key milestones, providing regular updates to sponsors and leadership • Ensure appropriate study progress and safety reporting to the EC/CA as per local requirements. • Identify and mitigate potential trial risks

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	• Resolve protocol deviation issues and site non compliance issues • Collaborate with the Regulatory team (internal or sponsor) for technical and vigilance documentation • Ensure completeness and audit-readiness of the Trial Master File (TMF) throughout the study and define archiving procedures. • Support statistical planning activities and lead the coordination of final study report development and submission.
Desired knowledge, skills and abilities	• Ability to work with multiple clients in a timely manner with good intuition, quality control and management skills • Ability to acquire knowledge in different diseases and therapeutic areas, willing to upgrade skills and medical/ scientific knowledge base • A team player with good communication & leadership skills who is adept at acquiring new skills • Excellent verbal and written communication skills in English • Ability to process information, analyze data, and reach conclusions based on sound reasoning • Team player, ability to interact with individuals and groups in other functional areas as well as outside the company • Self-starter, conscientious • Technical skills including use of computers (modern office environment), other technical experience might include use of computer-generated reports and audio-visual equipment. • Ability to travel to clinical sites in Europe, as well as conferences in the US & Europe • Good knowledge of EU clinical study requirements, regulations and legislation
Desired education and/or experience	Minimum education: BS or equivalent scientific qualification, MS or advanced research experience preferred. 3-years work experience (excluding internships). Good clinical research experience, preferably in medical devices. Knowledge of regulatory requirements and information governance frameworks (e.g. MDR reg., ICH GCP, Good Clinical Data Management Practices, 21CFR11).