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Project Manager (Argentina)

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Company: Innovaderm

Location: Argentina

Category: arts-design-entertainment-sports-and-media

Project Manager (Argentina)

Argentina

CRO - Project Management

Full-time

The project manager has the overall responsibility for the successful initiation, planning, execution, monitoring, controlling and closure of assigned clinical trials or its portion conducted in EU or APAC regions. The project manager oversees and coordinates study resources to ensure compliance with the study budget, project scope and timelines and in accordance with applicable standard operating procedures (SOPs), good clinical practices, regulatory and study-specific requirements. Project Manager acts as the main line of communication to relevant stakeholders and provides input to feasibility, study design, budget development and ensures progress reporting (resources, budget and timeline). In this role project manager may be also responsible for overseeing activities managed by subCROs, especially in terms of providing deliverables and assessing the overall performance.

This role will be perfect for you if:

Wish to work on multisite clinical trials, including Global Phase III projects.

You have at least years' industry experience, including a minimum ofyears leading multi-site clinical trials (Phase II-III).

You are looking to position yourself in an environment where you can grow your career

alongside of a growing company.

More specifically, the Project Manager must:

Serves as primary contact for the Sponsor, vendors and internal team throughout the study.

Ensures assigned studies are “audit ready” at all times (project team training records, central files, system validation, etc.).

Communicates effectively with sponsors, study team members, functional departments, and senior management.

Proactively, manages operational aspects of the clinical trial including trial timelines, budget, resources and vendors. Coordinates tasks and deliverables from all functional departments involved in the project.

Controls the project budget by ensuring that project team member understand the hours allocation for each task and review time billed to the study against the budget to control write-off and identify out of scope activities for change orders.

Provides efficient updates on trial progress to the internal and external stakeholders, with respect to site selection, vendor selection, project plans, trial budget and timeline management, quality standards and risk mitigation.

Leads study start-up process, including but not limited to conduct of the Trial Kick-off meeting the set-up of trial master file (TMF), site selection and finalization of site lists, site activation, management of vendor set up timelines and site contracting and budgeting.

Manages risk and control measures to assure project quality. Escalates issue appropriately to Innovaderm management, quality assurance and sponsor, when required.

Leads client calls, internal work groups, vendor status update meetings. Ensure meeting minutes are completed, distributed to team members and filed in the Trial Master File (TMF) in a timely manner.

Monitors the quality of study deliverables, (including vendor and SubCRO deliverables), addresses quality issues with the appropriate team member and identify opportunities to improve training, execution and quality control across the study team.

Analyzes discrepancies between planned and actual results and participates in the development and implementation of corrective actions to be taken as needed.

Ensures that project specific training matrix is customized to each study and maintained accurate through out the study.

Ensures all team members including contracted services providers have adequate training on the project by reviewing training records periodically during the trial.

Reviews and approves Innovaderm, site, and vendor responses to quality assurance audits for appropriateness, timeliness and accordance with company SOPs and regulatory requirements.

Ensures that study specific documents and project deliverables (, study plans, protocol, informed consent form, electronic case report form (eCRF), tables/listings/figures (TLFs), clinical study report, etc.) are developed on time and meet study requirements.

Ensures all project level study documentation is filed in the TMF in accordance with company SOPs/all regulatory requirements and provide oversight to the clinical team regarding TMF filing, maintenance and archival procedures.

Provides project status updates to external and internal stakeholders ensuring compliance with the study budget, project scope and timelines and in accordance with applicable standard operating procedures (SOPs), good clinical practices, regulatory and study-specific requirements.

Manages and reports on recruitment status and highlights initiatives needed to mitigate slippage in recruitment timelines.

Participates in the planning and conduct of Investigator’s Meeting.

Collaborate with the Regulatory Affairs group, to ensures submission to central are done on time and collection of required essential documents is complete prior to site initiation and maintained current throughout study duration. Ensures that the Trial Master File (TMF) is complete, accurate, and inspection ready at all times.

May oversee clinical monitoring activities for site qualification, initiation, routine and close-out visits (project-specific training of CRAs, reviewing monitoring visit reports and follow-up letters,

ensuring compliance with monitoring plan, escalation of site-related issues).

Supports the sites and ensures that each site has the necessary material to adequately perform the study (, investigational product, study supplies, special equipment, safety lab kits, etc.).

In collaboration with the data management group, ensures that the CRF complies with the protocol and Sponsor requirements and ensures queries resolution and data review process follow the study timelines until database lock.

Being assigned to the study having APAC component: oversees work of the subCRO ensuring all deliverables are provided on time, in a good quality and in line with binding KPIs.

Supports Director of Project Management in building and maintaining good and operative relationship with APAC subCRO partners.

May act as mentor for new staff or for more junior staff.

May provide technical, therapeutic and project management expertise in training and process improvement efforts for the department.

IDEAL PROFILE

Education

in a related field of study to clinical research

Experience

At least years industry experience and a minimum of years in Phase I-III clinical trial project management

Experience leading concurrent multi-centered clinical trials with budgets in excess of $M USD

Experience managing dermatology trials an asset

Proven experience in managing projects containing APAC component having in its scope at least Japan, Australia and South Korea

Proven experience in managing projects executed in partnership with subCRO(s)

Knowledge and skills

Very strong leadership, accountability and communication skills

Excellent knowledge of GCP and ICH standards, FDA and local country regulations

Excellent knowledge of Microsoft Office suite

Fluency in English with excellent oral and written skills, required

Bilingualism (English and local language) is an asset

Ability to work in a team environment and establish good relationships with colleagues and sponsors

Good problem-solving abilities

Strong ability to carry out different projects and work under pressure while meeting timelines

Good knowledge of ICH guideline, applicable European Medicines Agency (EMA), Health Canada and Food and Drug Administration (FDA) regulations/guidelines.

OUR COMPANY

The work environment

At Innovaderm, you will work with brilliant and driven colleagues. Our values are collaboration, innovation, reliability and responsiveness. We offer a stimulating work environment and attractive advancement opportunities.

In this position, you will be eligible for the following perks:

Flexible work schedule / work schedule

Home-based position

Ongoing learning and development

About Innovaderm

Innovaderm is a contract research organization (CRO) specialized in dermatology. Since its beginnings in , our organization has benefited from a solid reputation for the quality of its research and services exceeding the expectations of its clients. Based in Montreal, Innovaderm continues to grow and expand in North America and Europe.

Innovaderm is committed to providing equitable treatment and equal opportunity to

all individuals. As such, Innovaderm will provide accommodations throughout the recruitment and selection process to applicants with disabilities, upon request. Innovaderm only accepts applicants who can legally work in Argentina.

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