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Senior Project Manager, Early phase (Poland)

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Company: Innovaderm

Location: Poland

Category: business-and-financial-operations

Senior Project Manager, Early phase (Poland)

Poland

CRO - Project Management

Full-time

Senior Projects Managers are crucial to the success of Clinical Trials managed by Innovaderm. They are the main point of contact internally as well as externally, ensuring all activities and deliverables are completed on time, on budget, and as expected.
Great project managers go further than creating project plans and following up on tasks. They show leadership to help project teams focus on objectives and deliver results.

This role will be perfect for you if:

You are a hands-on project manager who enjoys working on multi-site early phase projects including Phase I, Phase IIA / proof of concept as well as Investigator-Initiated studies.

You enjoy helping look for ways to improve and simplify processes to better respond the needs of Early phase projects in a regulated environment.

You wish to work for a mid-sized CRO that works on significant multisite trials, including Global Phase III projects.

You are looking to position themselves in an environment where you can grow your career alongside of a growing company.

IMPACT AND RESPONSIBILITIES

Client interactions

Serve as primary contact for the Sponsor

Provide efficient and timely updates on trial progress

Lead client calls effectively

Project planning

Oversee and actively participates in the preparation of project deliverables such as; study plans, protocol, informed consent form, electronic case report form (eCRF), tables/listings/figures (TLFs), clinical study report.

Participate in the planning and conduct of the Investigator's Meeting.

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

Quality and risk management

Ensure assigned studies are "audit ready" at all times.

Monitor the quality of study deliverables, (including vendor and SubCRO deliverables) and address issues as they arise.

Manage risk and control measures to assure project quality.

Analyze discrepancies between planned and actual results.

Review and approve responses to quality assurance audits.

Project budget and timelines

Control the project budget, with particular attention to internal hours allocated to all activities.

Identify out of scope activities for change orders.

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

Communicate effectively with study team members, functional departments, and senior

management.

Manage and report on recruitment status and highlight initiatives needed to meet recruitment timelines.

Project team leadership

Lead the core project team which may include: Associate Project Managers, Project Coordinators, Project Assistants.

Ensure all team members have adequate training on the project.

Work closely with vendors and the following internal teams to ensure all tasks and deliverables are completed on time, according to plans and according to applicable standards: Site Selection, Regulatory Affairs, Data Management, Clinical Monitoring, Biostatistics, Scientific Affairs.

Department oversight support

Support the Director of Early Phase and Translational Research for the operational strategy (key operational success factors, gaps from both vendors and internal factors, risk identification and mitigation, project timeline, target countries, number of sites, outsourcing vendor needs, etc.) in proposals sent to prospective clients for new business opportunities.

Support the Director of Early Phase and Translational Research in department oversight, including development and tracking of KPIs.

IDEAL PROFILE

Education

in a related field of study to clinical research

or an asset

Experience

At least years industry experience;

At least - years of clinical project management experience, including management of all projects phases from start up to closure, management of all functional services, vendor management.

Experience leading multi-centered, multinational phase III clinical trials including project budget financial tracking and forecasting

Experience in one or more of the following considered an asset: study start up, regulatory submission, resource management, supervisory experience, CRA, data management, medical writing, or vendor management

Experience managing dermatology trials

Experience in SAD-MAD studies is an asset

Experience in clinical site operations is an asset

Knowledge and skills

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

Excellent knowledge of Microsoft Office suite;

Fluency in English with excellent oral and written skills, required

Bilingualism (English and French) 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;

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

Permanent full-time position

Vacation, PPK, health allowance

Home-based position with teleworking allowance

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 Poland.

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