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Associate Project Manager (Spain)

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Associate Project Manager (Spain)

Spain

CRO - Project Management

Full-time

The Associate Project Manager ensures the successful initiation, planning, execution, monitoring, controlling and closure of assigned clinical research projects. The Associate Project Manager must 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.

This role will be perfect for you if:

We can count on you to deliver results while using a disciplined approach to project management.

You are knowledgeable about clinical research projects and looking to continue learning.

Working in an organization that is driven by science and innovation and completing meaningful work is important to you.

More specifically, the **Associate Project Manager:**

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

Coordinates tasks and deadlines between the different departments involved in the project.

Oversees project coordinators, SSU team members, RDA and RAC resources to ensure correct prioritization of site activation activities amongst team members.

Interacts with vendor management to ensure vendor supplies and services are coordinated for with site activation timelines.

Escalates to project manager when site activation timelines are at risk or cannot be maintained.

Assists with managing the needs and expectations of the Sponsor and other internal and external project stakeholders.

Assists with ensuring all team members are adequately trained on the project.

May plan the activities and resources (internal and external resources, equipment, etc.) required for the project.

Manages the quality of assigned work and deliverables.

Assists with providing project status updates to external and internal stakeholders.

Ensures assigned tasks are completed in 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.

Reconciles study trackers.

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

Assists with enforcing effective change control and risk management throughout the project.

Reviews and may assist in the drafting of project operational plans, processes, and manuals as applicable (, project management plan, monitoring plan, etc.).

Assists with ensuring that study specific documents and project deliverables (, protocol, informed consent form, electronic case report form (eCRF), tables/listings/figures (TLFs), clinical study report, etc.) meet applicable country requirements.

Oversee activities related to sites selection (feasibility questionnaires, sites selection, planning of site qualification visits).

Monitors patient recruitment, subject status, and follows up with sites on recruitment strategy plan.

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

In collaboration with the Regulatory Affairs group, may oversee activities related to central ethics and regulatory submissions.

Ensures collection of required essential documents from the sites prior to study initiation and maintains of currency of site level documentation throughout the study.

May assist the project manager with quality reviews and or audits of the Trial Master File (TMF) to ensure inspection readiness.

May support clinical monitoring activities, such as CRA training, visit report review, site letters, and escalated site issues.

May track site qualification, initiation, routine and close-out visits, project-specific training, monitoring visit reports and follow-up letters, compliance with monitoring plan, escalation of site-related issues.

Maintains the project specific training matrix and confirms project team members are fully training per the study matrix prior to team members performing study tasks.

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, may ensure 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.

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

Minimumyears of relevant industry experience in the pharmaceutical, biotechnology or CRO industry

At least years experience coordinating activities related clinical trial management

Knowledge and skills

Excellent knowledge of GCP and ICH standards, FDA and Canadian regulations

Excellent knowledge of Microsoft Office suite

Excellent oral and written skills in English

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

Good problem-solving abilities

Good organizational skills

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

Core Project Management competencies

Demonstrated ability to establish and deliver resource-based project plans

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

Company benefits package

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 Spain.

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