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Clinical Research Project Director - Europe

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As a pharmaceutical support industry leader, **UBC** is devoted to **empowering health solutions for a better tomorrow**. We **take pride in improving patient outcomes and advancing healthcare**. At UBC, we provide services to enhance the entire drug development process and commercialization lifecycle - from clinical trial support to real-world evidence generation.

Embark on a **rewarding career journey with UBC** **grow** your career while making a meaningful **impact on the world** around you. **UBC** fosters a culture built on our Core Values of Respect, Accountability, Innovation, Quality, Integrity, and Collaboration. We believe in an **inclusive workplace** that fosters creativity.

If you are seeking a career that will **challenge inspire**, and **reward** you, join us at **UBC**!

Brief Description :

Project Director (PD) is responsible for engaging and delivering activities related to project operations, financial performance, business development, and department administration within the UBC Evidence Development Solutions Department.

The PD is responsible for providing operational leadership, oversight, and client relationship management for a broad range of UBC projects. The PD will have a leading role in overseeing the planning, implementation, direction, and completion of project work. The PD will be responsible for directing Project Managers and cross-functional teams to ensure satisfactory delivery of contracted services within the allocated timelines, budgets, and quality standards. Additionally, the PD will support business development opportunities,

conduct line management of Project Associates, Associate Project Managers, and Project Managers as required, and participate/lead departmental process initiatives.

Specific job duties:

- Project Leadership:

Provide strategic leadership, vision, and support to the project teams, ensuring alignment with the company's goals and client expectations.

Drive PM performance, project quality delivery, milestone timeline adherence, financial margin optimization, and customer satisfaction through efficient and effective directorship.

Ensure project teams prepare project plans to meet contracted services and timelines.

Engage in UBC cross-functional interactions to address project needs and drive problem resolution; facilitate the involvement of Senior Management as necessary

Attend/participate in project internal / external meetings, and audits as needed

- Project Team Productivity:

Lead and mentor multidisciplinary project teams, including Project Managers, Operations teams, vendors, and other functional staff, ensuring effective communication, collaboration, and performance of project deliverables according to contract terms.

Work with cross-functional managers to ensure projects are adequately staffed team members receive adequate training for specific job assignments.

Vendor Management: Select, contract, and manage external vendors and subcontractors, when necessary, while maintaining quality and cost-effectiveness.

- Financial Oversight:

Monitor delivery of projects per scope and budgets, and demonstrate strong oversight of financial health for assigned projects

Oversee project budgets, resource expenditures, and effectively drive compliance with forecasting, invoicing, revenue recognition, out-of-scope management, and contract modifications.

- Risk Management:

Proactive, ongoing identification of project risks and development of mitigating strategies to

minimize their impact on projects effectively.

Ensure development and maintenance of risk management plans and risk assessments and categorization tools.

- **Client Relationship Management:**

Serve as the UBC senior operational contact with clients for all project related items, maintaining strong relationships, addressing their needs, and providing regular project updates.

Ensure regular conduct of formal governance discussions to assess performance and drive issue resolution.

- **Quality Compliance Oversight:**

Implement quality control measures to maintain the highest standards of data integrity, patient safety, and protocol compliance.

Ensure activities on projects are delivered with adherence to project Plans, company policies and/or sponsor's SOPs.

Be familiar with and ensure that all projects adhere to relevant regulatory requirements, data privacy provisions, and international guidelines (e.g., FDA, EMA, EU Clinical Trials Directives, ICH-GCP, GDPR, HIPAA).

- **Reporting:**

Prepare, maintain, and deliver high quality project progress reports, metrics, and other outputs to clients and UBC senior management.

Ensure that project specific tracking metrics are developed, consistent with scope of work and project timelines.

Ongoing review of available dashboards and reports for assigned projects to ensure adherence to all required activities and operational / financial performance indicators

-**Business Development:**

Assist, as directed, on specific business development opportunities: capabilities presentations, RFP review, proposals/budget input, bid defence participation.

Work with UBC Business Development to develop and grow UBC client relationships and

maximum business opportunities.

Attend and present at conferences as required.

- **Department Administration**

Responsible for the development, implementation, and project management process compliance for global projects

Lead, innovate, and develop operational strategies that meet requirements and maximize project delivery success

Identify, develop, and implement improvements to UBC processes, quality, and overall project delivery

Engage in cross-functional collaborations with UBC leadership staff to optimize project delivery

Contribute to UBC meetings, training activities, and cross-functional activities as appropriate

Partake in ongoing assessment of project delivery resource needs, manage resource requests, and allocate staff to maintain target utilizations for roles.

Implement creative resourcing solutions to maximize productivity and utilization of the team.

Manage the process of identifying/tracking staffing requirements and liaise with Human Resources regarding strategy, hiring, and onboarding project management resources.

Identify and develop UBC process improvements

Prepare procedures, SOPs, guidelines and other standard materials for department

Ensure staff are adequately trained on applicable SOPs, processes, and systems

Ensure timely completion of timesheets and expense reporting by assigned staff

Ensure timely completion of required UBC and project specific training by assigned staff

Other duties as assigned by UBC Senior Leadership

- **Expected Project Load:**

PD Oversight of 4 to 6 projects, depending on scope

PD Oversight of 1 multi-study programs, depending on scope

Direct management of 1 to 2 projects, depending on scope

-Supervisory Responsibility:

Mentor, provide support, and direct supervision of Project Managers, Associate Project Managers, Project Associates, and other administrative staff.

Conduct interviews for internal/external project management and operational candidates

Conduct ongoing performance review of assigned staff and remediate deficiencies

Conduct annual employee performance evaluations

Desired Skills and Qualifications:

Bachelor's degree in in an appropriate discipline (Life Sciences, Healthcare, or Business) or equivalent industry experience. Advanced degree (Master's or Ph.D.) preferred.

Minimum 12 – 15 years of clinical research operations experience, within in a CRO, pharmaceutical, device/diagnostics or biotechnology company

Minimum 10 years of experience at increasing levels of project management or clinical research oversight responsibilities

Previous history as a Project Director or Director of Clinical Operations (related) within a CRO preferred

Minimum 5 years supervisory/management experience

Proven ability to lead, motivate, and manage cross-functional teams.

Strong understanding and experience in operational clinical operations and overall drug/biologic development processes

Strong knowledge of functional components of clinical drug development (e.g., clinical, data management, statistics and medical writing)

Comprehensive knowledge of ICH GCP and applicable international regulations (EU Clinical Trials Directives, FDA Guidelines, etc.)

Broad therapeutic experience a plus

Excellent understanding of and experience managing evidence development projects (e.g., Phase IV studies, RWE, Ph II – III clinical trials, expanded access programs, etc.) globally

Ability to drive operational strategy for global evidence development programs

Experience with proposal and budget development for evidence development programs

Client focused with strong leadership skills

Strong verbal, written, and interpersonal communication skills

Strong prioritization, time management, and project management skills

Strong negotiation, influencing, consensus building, and relationship management skills

Strong innovative, analytical, problem-solving and decision-making skills

Strong financial acumen and budget management experience.

Strong computer skills including MS Office

Proficiency in project management tools and software

Results driven and team-oriented, with the ability to influence outcomes as necessary

Demonstrated ability to manage staff to achieve company and client goals

Ability to handle multiple tasks in a fast-paced, deadline oriented environment

10% travel availability

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