Project Manager - Clinical Trials

Job ID
REQ-10051318

5月 09, 2025

USA

摘要

The Project Manager will manage assay development and/or clinical trial project lifecycles. This includes the day-to-day management of assigned assay development projects and clinical trials performed at Navigate BioPharma Services in support of drug, device and combination clinical trials. Managing assay development or clinical trial projects require ensuring on-time delivery of services and milestones, resolving issues, assuring the project remains within budget and adhering to Navigate ' s quality standards. This role is an essential bridge between the sponsor, external stakeholders, and the Navigate business, serving as the primary point of contact for each project.

About the Role

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Establish and maintain effective communication channels with relevant internal and external project stakeholders throughout entire project lifecycle. Disseminate project updates, issues,

and modifications to teams in a proactive and timely manner.
- Monitor project timelines to ensure on-time execution and completion of project deliverables and milestones. Collaborate with sponsor and internal team to accurately forecast project billables and complete billing.
- Control project scope to ensure project is staying within budget and identify scope changes to ensure modifications are captured appropriately in change orders.
- Proactively identify risk, develop mitigation plans, and resolve issues. Escalate critical problems to management and project stakeholders.
- Author study-specific documentation, including presentations; lead internal and external meetings, and develop agendas and minutes.
- Manage assay development projects that may have IDE or IVD requirements including those with product development under design control. Lead timeline management for assay development projects, coordinating and aligning stakeholders for joint success. Be able to manage a larger number of clinical trial projects and/or multiple project portfolios, clinical trials with higher complexity, including those that require partner lab set-up and testing, turn-around time expectations and real time sample incident resolution.
- Demonstrate critical thinking skills and strategic planning in project execution and risk management.

OTHER RESPONSIBILITIES

- Work in a GMP/GCP/GLP/CLIA regulated environment and be responsible for following all applicable regulations.
- Ensuring that Quality Events such as incidents and deviations are properly documented, and supporting/owning the immediate remediation and preventative actions
- Ensuring change requests are properly initiated, completed, and approved prior to the use of the assay, system, instrument, software, etc. being changed
- Maintaining up-to-date training records and ensuring training is complete prior to performing specific job functions
- Following approved and effective procedures to perform specific job functions, and ensuring procedures accurately reflect activities being performed

Essential Requirements

- Bachelor's degree in a science-related field (Related Project Management coursework and/or experience strongly desire).
- Minimum of three (3) years related project management experience in a relevant industry is preferred.
- A strong customer and service focus is essential.
- Strong communication skills are also required to ensure that project schedules and client expectations are met or exceeded.
- Demonstrated ability and success in fostering internal and external collaborations.
- Demonstrated success working in a team. Must be able to influence without authority.
- Must be able to work in a team setting, trouble shoot be adaptable and foster collaborations.
- Strong scientific background is essential.
- Strong organizational and program management skills.
- Knowledge of logistics and clinical trial operations.
- Knowledge of FDA regulation of clinical trials; GCP and 21 CFR is strongly recommended.

Product development under design control desired.
- Project management certification is a plus.
- Demonstrated understanding of, or experience with, financial modeling strongly desired.

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The pay range for this position at commencement of employment is expected to be between $98,700 to $183,300 per annum; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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Innovative Medicines

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USA

状态
California

站点
Carlsbad

Company / Legal Entity
U441 (FCRS = US441) Navigate BioPharma Services, Inc.

Functional Area
BD&L & Strategic Planning

Job Type
Full time

Employment Type
Regular

Shift Work
No

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