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Clinical Operations Manager - FSP

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Company: Parexel

Location: Turkey

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When our values align, there's no limit to what we can achieve.

Position Purpose:

The Clinical Operations Manager (COM)/COM-Finance (COM-F)/COM-Regulatory (COM-R) is accountable for performance and compliance for assigned protocols inacountryincompliancewithICH/GCPandcountryregulations, Client policiesandprocedures,qualitystandardsandadverseeventreportingrequirementsinternallyandexterna

The COM/COM-F/COM-R, under the oversight of the Senior Clinical Operations Manager (SCOM) or Clinical Research Director (CRD),is responsible for budget/finance aspects, for execution and oversight of clinical trial country submissions and approvals and to ensure site ready.

Primary Duties:

General

Manages countrydeliverables,timelines,andresultsforassignedprotocolstomeetcountrycommitments including:

- Quality and compliance in assigned protocols in country

Coordinates and liaises with Clinical Research Managers (CRMs), Clinical Research Associates (CRAs) and Clinical Trial Coordinators (CTCs), Finance and Legal if appropriate to ensure country deliverables

are obtained for submissions, budgets, CTRAs and local milestones

Collaborates closely with Headquarter to align country timelines for assigned protocols

Provides support and oversight to local vendors as applicable

Oversees CTCs as applicable

Contributes to the development of local SOPs

Oversees and coordinates local processes,clinical and ancillary supplies, import and export requirements, supplies destruction, local electronic/hard copy filing, archiving and retention requirements, and insurance process management

- Enters and updates country information in clinical and finance systems
Contributes or leads initiatives and projects adding value to the business

Contributes strongly to the COM team and other Country Operations roles knowledge by acting as process Subject Matter Expert (SME), sharing best practices, making recommendations for continuous improvement, and providing training as appropriate/required

Contributes to COM team and other Country Operations roles' knowledge by acting as a buddy/mentor and as a process Subject matter Expert (SME), sharing best practices, making recommendations for continuous improvement, and providing training as appropriate/required

Completes training assigned by Client and/or EP, as necessary, including general training requirements, SOPs, and system and process related training

Adheres to EP and Client SOPs and processes

Finance:
Has ownership of country and site budgets including:

- Development, negotiation, and completion of Clinical Trial Research Agreements (CTRA)
- Oversight and tracking of clinical research related payments
- Payment reconciliation at study close out
- Oversight of Foreign Corrupt Practices Act (FCPA), Denied Party Screening/Office of Foreign Assets Control (DPS/OFAC) and maintenance of financial systems
- Financial forecasting in conjunction with SCOM, CRDand other roles
Influences investigators, external partners, and country operations to adhere to budget targets

and agreed payment timelines.

Regulatory:
Executes and oversees clinical trial country submissions and approvals for assigned protocols including:

Development of local language materials including local language Informed Consents and translatio

Interactions with IRB/IEC and Regulatory Authority for assigned protocols

Skills and Education:
Bachelor's Degreein Business Finance/ Administration/ Life Science or equivalent
Health Care related experience required

5 7 years clinical research or combined experience in Clinical Research and Finance/Businessrequired

Expertise of core clinical systems, tools, and metrics

Excellent verbal and written influencing and training/mentoring skills, in local language and English

Strong coordination and organizational skills

Skilled knowledge of budget and contract negotiations, local regulatory environment and submission and approval processes, and understanding of how these impact study start-up

Able to indirectly influence investigators, vendors, external partners, and country managers to addre SCOM or manager.

Ability to make decisions independently with limited oversight from SCOM or manager

Requires a strong understanding of local regulatory environment

Ability to proactively develop risk management and mitigation plans in the country and resolve issues locally

Ability to lead a team of CTCs as applicable

Problem solving is essential

Ability to proactively identify issues and risks, analyze root cause and propose solutions and escalate as applicable

Effective and efficient time management, organizational and interpersonal skills, and conflict management skills

High sense of accountability and urgency to prioritize deliverables

Expertise of core clinical, regulatory, and financial systems, tools, andmetrics,

Strong communication, leadership, and negotiation skills as well as excellent influencing and trainin

Ability to focus on multiple deliverables and protocols simultaneously

Requires that the individual has ability to work effectively also in a remote virtual environment with a wide range of people

Positive mindset, growth mindset, capable of working independently and self - driven

Ability to directly influence site staff

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