Director of Clinical Research Operations

InGeneron, Inc. - Houston, TX

Position Summary:

Responsible for the overall execution of clinical trials (projects), accountable for the study start-up activities, budget and timeline management, organization, administration and execution of the clinical trial from start to finish, compliance with GCP, IHC, SOPs, internal/departmental guidelines. Works collaboratively with individuals cross-functionally across the organization. Primary contact for sponsors/CRO, clinical sites and vendors. Prioritizes activities with competing deadlines and provides strategic input to projects to ensure goals are met. Recommends leads and implements tactical process improvements. Responsible for contributing to a culture of process improvement, performance measures, project prioritization, and developing successful solutions Provides clear direction, with timelines for supporting members of the project (budget, contracts, regulatory, pricing, network operations, others). Provides supporting members with information they need to successfully complete their job for InGeneron.

Key Responsibilities

- Manage the study start- up process including site list delivery, team process report completion, project map with clear timelines for the project and all supporting team members accountable to the project. Responsible to outline expectations to internal teams and sponsor/vendors to ensure successful study implementation.

- Protocol Review: review clinical trials for scientific merit as well as operational review. Review protocol procedures for standard of care vs. research related charges. Provide all supporting team members with the information and contacts they need in order to complete their tasks.

- Responsible for managing, implementing and executing the day-to-day operations, functional activities and deadlines of the InGeneron Inc. clinical trials.
- Directs, oversees, trains, mentors and leads internal and external clinical teams.
- Makes appropriate strategic decisions to prioritize, operationalize and drive performance.
- Participates in the development of the short- and long-term strategic plan to support the objectives and goals of the Company's clinical studies.
- Demonstrates commitment and subject matter expertise to accelerate and improve study start-up processes, timelines and work flows.
- Promotes and maintains organizational efficiency and effectiveness. Measures performance and provides management with regular status updates on productivity, progress of the trials and alliances; and identifies opportunities for improvement.
- Develops and maintains standard and administrative operating procedures (SOPs and AOPs) and other business-related tools.
- Identifies new clinical trials and strategic opportunities

- Participates in strategic planning and resource allocation decisions including interviewing, hiring and on-boarding of selected candidates. Identifies mentoring/training needs and promotes staff development opportunities.
- Maintains up-to-date knowledge of scientific and clinical literature in relevant therapeutic areas including key clinical development topics.

Qualifications and Skills:

- Clinical trial operations and advanced management skills
- Proven leadership, mentoring and supervisory skills
- Superior organizational and change management skills
- Advanced public speaking, writing, presentation and negotiating skills
- Ability to delegate tasks appropriately, influence behavior and drive performance
- Advanced working knowledge of study start-up activities (i.e., feasibility, budget development, contract negotiation and regulatory affairs)
- Advanced computer skills, including Microsoft Office suite (including MS Project, Excel, and PowerPoint), and clinical trial management systems
- Ability to travel
- Accountable, proactive, passionate, strategic, innovative, open, mature and flexible

Experience and Education:

- Advanced life sciences degree or combination of equivalent education and experience
- CRO/Device company experience managing multi-site clinical trials
- 5+ years of clinical research operations management-level experience
- Excellent knowledge of ICH GCP guidelines; CRA/CRC certification preferred
- Strong project and change management skills required; lean six sigma training a plus
- CRO/Device Industry and/or start-up environment experience preferred
- Orthopedic Device experience- preferred

Job Type: Full-time

Job Location:

•Houston, TX

Required experience:

•project and/or change management: 3 years
•management-level clinical research operations: 5 years
•CRO/Medical Device: 5 years