Genentech
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Date: 11/07/19

Global Study Manager - PDG Oncology

Job ID: 201911-132059

Job Function
Clinical Development

Location
South San Francisco
California
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

Purpose:

- **Provides operational expertise and leadership to one or more cross-functional global Study Management Teams (SMTs)**
- **Ensures the timely and efficient delivery of all operational aspects of one or more studies through all phases (phase 1b-IV) and stages (start-up, conduct and close-down), in accordance with the appropriate quality standards including ICH/GCP and applicable regulations.**

Main Responsibilities and Accountabilities:

- **Provides direction and leadership to one or more global Study Management Teams (SMTs)**
  - **Develops operational plans including site monitoring strategies, risk mitigation strategies, trial budgets, site selection, and clinical supplies management**
  - **Builds and maintains effective and efficient high performing operations teams and ensures team members are aware of their accountabilities, responsibilities and deliverables**
  - **Creates team culture and promotes team spirit**
  - **Develops and maintains effective working relationships with Study Management Team (SMT) members, with particular focus on affiliate teams, external CRO (for outsourced teams) and co-development partner study teams**
  - **In collaboration with functional management, coaches, mentors, supports, and provides study specific direction to Study Management team members**
  - **Responsible for leading identification and selection of vendors; ensuring appropriate cross-functional input is incorporated into the scope of work**

    - **Responsible for assessing feasibility of and driving execution/adherence to protocol amendments or changes to clinical studies, across functions**
    - **Responsible for leading identification and selection of vendors; ensures appropriate cross-functional input into the scope of work**
- **Contributes to the development and management of the study timelines, budget, risk and quality plans**
    - **Ensures operational tracking tools are identified, including systems to meet the needs of the operations team and ensures reporting to the Global Studies Leader (GSL)**
    - **Develops and manages clinical study budgets (including HQ budget). Communicates variances in the budget and action plan for resolution to the GSL**
    - **Establishes study milestones and ensures accurate tracking and reporting of study metrics such as initial recruitment projections**
    - **Provides operational input into the development of protocol feasibility questionnaires**
- **Provides clinical operations expertise to ensure operational feasibility and delivery**
    - **Leads the development and finalization of site feasibility questionnaires**
    - **Leads the creation of the study level patient recruitment plan and retention strategies based on feasibility data and input from the affiliate teams and consultation with the GSL and Operational Program Leader (OPL)**
    - **Provides operational input and insight into all study related documentation (including protocol and informed consent form) and processes**
    - **Analyzes the feasibility data across countries with input from the affiliates and makes recommendations to the GSL for the strategic country and site distribution and patient numbers**
- **Oversees forecasting of clinical/non-clinical supplies**
    - **Designs drug assumption and supply chain process in partnership with Drug Supplies, affiliates and GSL**
    - **Oversees the forecasting and management of non-clinical supplies to ensure sites have supplies to run clinical study**
- **Delivers the operational elements of the study plan**
    - **Chairs operations team meeting and organizes investigator meetings, monitor training, CRO kick-off meetings**
    - **Ensures that reporting process of SUSARs is established and maintained for the duration of the study**
    - **Proactively manages actual study level recruitment versus planned patient recruitment status and communicates variance to the GSL and implements contingencies in consultation with key stakeholders**
    - **Primary contact with affiliates to maintain oversight of performance, issues, their resolution and coordinates any corrective action**
    - **Actively partner with Data Management and Clinical Science to oversee eCRF completion and data quality issues**
    - **Ensures the completion and finalization of any corrective and preventative action plans resulting from site audits, in conjunction with CCO, etc., as necessary**
    - **Oversees the maintenance of drug supplies and resolution of issues with input from the Drug Supplies**
    - **Coordinates responses to study questions or issues from Health Authorities**

    - **Provides operational input into the development and tracking of SMT goals**
- **Provides the day-to-day operational management of CROs and vendors to ensure delivery against contracted scope of work**
    - **Performs ongoing vendor management (e.g., CROs, Central Labs, IxRS, etc.), including negotiation of scope of work, budgets, performance management, and issue resolution**
    - **Develops and supports appropriate site and CRO/vendor audit and quality plans**
- **Identifies areas of best practice and process improvements**
    - **Participates in Product Development Global Operations initiatives and programs as assigned**
    - **Maintains oversight and ensures consistency of the operational aspects across studies within a project**
- **Ensures study adherence to ICH/GCP and SOPs**

Qualifications

Life sciences degree or nursing equivalent.

Skills & Knowledge:

Experience

- **Proven clinical development experience of the operational aspects of all stages of clinical studies preferably working in a Global environment and/or including monitoring or leading affiliate teams, working with vendors and/or CROs, drug supply management and planning operational activities to achieve database lock.**
- **Experience of project managing operational aspects of a clinical study including development and management of timelines and budgets.**
- **Good knowledge of ICH GCP**
- **Proven ability to successfully achieve results within a multi-cultural and geographically diverse team.**
- **Experience of working as part of a large team and leading small study or functional teams, with a proven ability to be an active member of the team and motivate and lead a small team to deliver against commitments.**
- **Well-developed written and verbal communication skills demonstrated by an ability to present clear instruction/direction to teams at the same level in the organization and influence at higher levels in the organization.**
- **Strong attention to detail**
- **Proficient computer skills**

Competencies

- **Technical and Business Expertise**
- **Teamwork and Collaboration**
- **Communication**

- **Achieving Results**

Other

- **Mobile: Some travel may be required**

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#LI-PDBA1

Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

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