

Clinical Biomarker Operations Manger

Job ID: 201909-125881

Job Function

Research

Location

South San Francisco
California
United States of America

Schedule

Full time

Job type

Regular

Company/Division

Pharmaceuticals

Job Level

Individual contributor

The Position

Position Purpose:

- Provides biomarker operational expertise and guidance to multiple cross-functional global Protocol Execution Teams (PETs), to implement scientifically driven clinical development plans. Single point of contact on Biomarker Sub Team (BMST), Companion Diagnostic Joint Project team (CDx JPT), Clinical Sub Team (CST), PET and with CRO partners on all aspects of biomarker operations
- Ensures the timely and efficient delivery of all biomarker operational aspects of gRED clinical studies, including company collaboration and academic collaboration studies across all stages (start-up, conduct and close-out), in accordance with the appropriate quality standards including ICH/GCP and applicable regulations.

Main Responsibilities and Accountabilities:

Provides biomarker operational expertise and guidance to global Protocol Execution Teams (PETs)

- Accountable for executing exploratory and companion diagnostic biomarker strategy, including planning, coordinating, and overseeing all operational activities required to manage the lifecycle of biomarker samples (collection, processing, analysis, data delivery process and final sample disposition).
- Authors biomarker portions of key clinical documents including Clinical Study Protocols, Informed Consents and Laboratory Reference Manuals.
- Develops and maintains effective working relationships with team members, with particular focus on the BMST, operational team, diagnostic partners (Roche DIA), external CRO and Central Lab (for outsourced teams), and external biomarker vendors, where applicable. Close collaboration with Biomarker Scientists, CDx Project Leaders and Clinical Trial Leaders. Core, standing member of multiple teams.
- Builds and maintains effective and efficient high performing biomarker sample analysis

& data delivery. Supports relevant stakeholders including Clinical Data Management, Biometrics, Biostatistics in their accountabilities, responsibilities and deliverables, including data analysis for go/no go decision making, filing of the clinical study report (CSR). Manage data delivery timelines in accordance with internal decision making/governance meetings (OBRF, DxRF, DRC, etc).

- Responsible for the identification, validation and selection of biomarker vendors in collaboration with the Biomarker Scientist and GPPS; ensuring appropriate cross-functional input is incorporated into the scope of work. Partner with Biomarker Scientist for biomarker assay development at vendors, leading operations of assay development and ensuring assay readiness in accordance with clinical sample testing timelines.
- Liaise with internal CDx function and external CDx partners to facilitate companion diagnostic development as needed and serve as a member of the CDx Joint Project Team
- Ensure collection, delivery and analysis of biosamples under the highest standards of quality, ethics, and informed consent at study level

Manages the development and oversight of the biomarker analysis timelines, budget, risk and quality plans

- Ensures biomarker operational tracking and project management tools are utilized to meet the needs of the operations team
- Supports the development of the biomarker analysis budget and manages it on a study level. Communicates variances in the budget as appropriate.
- Establishes biomarker sample analysis and data delivery milestones and ensures accurate tracking and reporting of Biomarker sample metrics.
- Provides study level updates to stakeholders, clinical study teams and biomarker teams including sample collection, assay status and analysis updates

Provides clinical biomarker operations expertise to ensure operational feasibility and delivery

- Responsible for assessing feasibility for biomarker operations plans on clinical studies across related functions
- Leads the development and finalization of the Biomarker Management Plan (BMP) based on input from scientific and
- operational stakeholders to execute biomarker operational strategies
- Reviews and provides recommendations into all study related documentation (including protocol, informed consent form, and amendments) and processes.
- Participates in Investigator and Pathologist meetings, monitor training, CRO kick-off meetings, as applicable, to deliver presentations and in-depth trainings to internal and external stakeholders on biomarker and companion diagnostic sample collection and handling procedures
- Contributes to HA exchanges specifically by providing responses to biomarker sample related questions or issues from Health Authorities or Ethics Committees.
- Co-develops protocol feasibility questionnaires to ensure sites can meet sample-handling needs for the study
- Provides input into the development of PET goals.

Delivers the operational elements of the biomarker management plan

- Proactively manages biomarker sample analysis and data delivery timelines and communicates any variances to the PET, BMST and CST and implements contingencies in consultation with key stakeholders.
- Primary contact for internal and external stakeholders to maintain oversight of

biomarker vendor performance, issues, their resolution and coordinates any corrective action in collaboration with GPPS.

- Coordinates data requirements with reference labs and internal data management groups to ensure all aspects of data collection are executed with high quality, including data formatting and transfer specifications and eCRF page design. Actively partners with Data Acquisition Specialists and Data Management to oversee and coordinate biomarker data format and delivery timelines
- Serves as the single point of contact for status of clinical trial samples and biomarker data

Provides the day-to-day operational management of biomarker vendors to ensure delivery against contracted scope of work

- Partners with internal/external stakeholders in the central lab set up, providing sample collection and processing instructions, kit contents, shipping conditions and logistics for biomarker samples
- Performs ongoing biomarker vendor management including development and oversight of scope of work, budgets (invoice review & reconciliation) and performance management
- Serves as primary point of contact for laboratories performing biomarker analysis and hence supports the biomarker outsourcing process through effective vendor management

Identifies areas of best practice and process improvements

- Participates in cross-functional initiatives and programs as assigned.
- May lead or be a representative on functional groups goals, initiatives and work-streams

Ensures study adherence to ICH/GCP and SOPs

Qualifications:

- Life sciences degree (Bachelor or Masters) in Scientific, Medical or Healthcare subject area required. Further qualification, e.g. PhD and/or project management certification is desirable.
- 3+ years related professional experience in a clinical research setting, clinical/diagnostic laboratory, or pharmaceutical/biotechnology R&D environment

Skills & Knowledge:

Experience

- Extensive clinical development experience with evidence of working in teams running clinical studies
- Pharmaceutical industry experience or experience working as a clinical trial coordinator within a clinical trial setting is a plus
- Clinical or biological laboratory experience with evidence of involvement in the processing and/or analysis of biological samples
- Project management skills
- Critical reasoning skills including the identification and resolution of complex problems
- Detail oriented with the ability to work independently and manage multiple competing priorities
- Planning, organizational and time management skills
- Highly flexible in a fast pace global matrix environment
- Professional interpersonal skills, excellent oral/written communication and influencing

skills

- Proven leadership skills, ability to successfully achieve results within a multi-cultural and geographically diverse team
- Creates team culture and promotes team spirit.
- Global Vendor Management experience preferred
- Good knowledge of ICH GCP

Competencies

- Technical and Business Expertise
- Teamwork and Collaboration
- Communication
- Achieving Results

Other:

- Mobile: Some travel may be required

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Who We Are

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