NOVARTIS

Principal Scientist, BMD Study Coordinator and BMD Study Expert (BSC/BSE) Biomarkers

Job ID
REQ-10072836
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Индия

Сводка

Laboratory Excellence and Operation (LEO) and Biomarker Science and Operation (BSO) team in India are the key global resources for Line functions (LF) and Translational Medicine (TM) Clinical Trial Teams for biomarkers including biomarker outsourcing, scientific biomarker monitoring, vendor management, biomarker logistics, clinical site communication and sample coordination. LEO/BSO are working in close collaboration with clinical teams, LF technology experts, Biomarker Leads (BMLs) as well as external service providers (ESP) including central labs and clinical sites.

About the Role

- 5+ years of clinical operations experiences and/or clinical bioanalysis and/or clinical biomarkers. Advanced degree with 3 years in clinical operations and/or clinical bioanalysis and/or clinical biomarkers.
- Independently provide end to end operational support to clinical studies focusing on**biomarkers** and PK samples, clinical study setup, sample tracking/reconciliation, assay and vendor set up, sample/data upload and study closure. Specific steps include independent review of clinical study protocols, site operations manuals, informed consent forms, sample collection tables, instruction manuals, **central lab protocol**/manual, eCRF and other biomarker sample operation logistics and coordination.
- Serve as a BMD Study Expert BSE and clinical team representative from BMD on selected clinical studies and/or at a project level. Partner with clinical teams and functions
- Independently set up central lab and central lab services (specifications, clinical sites, samples,**assays**), implements and monitors biomarker/PK sample flow across BM modalities (e.g. Immunoassay, LC-MS, Flow cytometry, genetics etc.) and PK assays
- Partners with BMD SME to set up, implement biomarker assays at specialized external service providers (ESP) including data transfer and data flows in LIMS and DTS (e.g. study creation, **data flow,** data transfer, etc.) for managed biomarkers and studies. Update study and project information in relevant reports and IT systems
- Identify, escalate and resolve assay and sample management issues, ESP, quality or performance issues and engage LF experts/SME, clinical trial leaders and data management as needed.
- Lead best practices, process and continuous improvement initiatives and innovations in sample, vendor, data and assay monitoring function
- Collaborate with across TM functions, lead site, central lab and vendors processes, drives continuous improvement initiatives and innovations in LEO

Key Performance Indicators

- Ensure sample and biomarker data deliverables according to timelines and quality, ensuring adherence to international and local regulations.
- Effective risk management and troubleshooting of samples and biomarker assays
- Feedback of external and internal customers.
- Adherence to Novartis Values and Behaviors

Number of associates

No direct reports. Matrix management and contribution to multi-disciplinary teams. Manage the interaction with external CRO partners.

Financial responsibility

Responsible for financial/resource decisions within scope of designed authority.

Impact on the organisation

Internal impact: Responsible for the availability of high-quality biomarker data according to agreed timelines and quality to enable no delays in decision making and drug registration.

External impact: Novartis perceived as a reliable business partner.

Requirements

Education (minimum/desirable):

Minimum: M.Sc. in Life Sciences (or equivalent)

Languages: Fluent in English as working language.

Experience / Professional

Requirement:

- Operational knowledge of *clinical trials: clinical study set up, clinical sample management, clinical data flows (e.g. DTS) clinical sample analysis and managing external service provider (ESP) including central laboratories and/or specialized vendors*
- Laboratory background and knowledge of immunoassays and/or bioanalysis and data flows are desired. Data management background and experience is a plus
- Knowledge of the drug development process, clinical biomarkers, clinical data management and working with translation clinical research.
- Experience working in a global organization and matrix environment (multiple roles/connections and stakeholders) is a plus.
- Strong global project management, proactive planning in clinical studies, problem solving, influencing, and communication skills.
- Knowledge of regulatory requirements e.g. ICH/GCP, GLP, etc.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Biomedical Research
Business Unit
Research
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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