BMD Lead and Senior Principal Scientist

Job ID
REQ-10002650
Apr. 24, 2024
Indien

Zusammenfassung

Laboratory Excellence and Operation (LEO) and Biomarker Science and Operations team (BSO) in India are the key global resources for Line functions (LF) and BR TM Clinical Trial Teams for biomarkers including biomarker planning, outsourcing, scien-tific biomarker monitoring, vendor oversight, biomarker logistics, clinical site training and sample coordination. LEO/BSO is working in close collaboration with clinical teams (CTT), LF technology experts, Biomarker Leads (BML) as well as external ser-vice providers (ESP) including specialized vendors, central labs and clinical sites. Bi-omarker Study Expert/BMSE in Biomarker Development (BMD), Translational Medi-cine (TM) is a core member of TM clinical teams (CTT). BMSE partners with BML to translate BM strategy into executable BM plan. BMSE is accountable for the bi-omarker operational strategy, biomarker implementation and meeting operational ob-jectives of all assigned clinical studies. BSO lead will also perform local Biomarker Science and Operations team management activities and represents BMD in collaborations across TM groups in India. Acts as an ambassador for BMD in interactions with the wider Novartis organization in India, as well as local external partners and vendors. Advocates for and supports local associate development and shares knowledge of the changing clinical environment and talent pool in India with the wider TM organization.

About the Role

Your responsibilities include, but are not limited to:

- Partner with BMD Biomarker Leads (BML) and biomarker subteam SMEs and contribute to project and study biomarker strategy, co-lead (with BML) the efficient transition of biomarker strategy to biomarker study operational plan for assigned studies
- Lead clinical biomarker operational study strategy and biomarker study plan implementation in TM clinical studies including providing input and reviews of clinical synopsis, study protocols, and other biomarker study operations documentation.
- Represent all BMD platforms and modalities in CTT including soluble, cellular, genetics, imaging and digital endpoints. Partner with BMD BML and SME and provide biomarker and operational expertise on all assigned clinical studies e.g. lead the BM setup, sample tracking/reconciliation, assay set up, data flow, vendor set up, biomarker sections of clinical study report and biomarker study closure
- Effectively engage and partner with BMD subteams and biomarker LF experts to ensure on time internal and external (vendor) biomarker deliverables. Update study and project information in relevant meeting, reports and IT systems
- Serve as a scientific monitor i.e. assay set up, assay transfer and implementation, and monitor biomarker

assays at external service providers in one or more biomarker modalities (e.g. Immunoassay, LC-MS, Flow cytometry, tissues, genetics, digital endpoint and devices, etc.)

- Lead best practices, process and continuous improvement initiatives and innovations in sample, vendor, data flow and assay monitoring functions
- Contributes to talent and career development of Biomarker Science and Operations staff locally. In collaboration with the relevant BMD managers, contributes to the hiring/interview/onboarding and mentoring process for new hires in India
- Utilizes established networks and builds new network connections to bring new knowledge into the BMD department.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

- 7+ years in clinical trials and clinical biomarkers. Scientific and operational knowledge of *clinical trials, study set up and operations, clinical sample analysis and managing external service provider (ESP) including central laboratories and/or specialized vendors*
- Broad knowledge of clinical biomarkers including soluble, cellular, tissue, genetics, imaging and digital endpoints/devices. Track record of contributions to complex global early phase clinical trials and biomarker implementation
- Understanding of clinical data flow (e.g. DTS) and clinical data management principles. Laboratory background and knowledge of immunoassay and/or bioanalysis and/or cellular biomarkers or other biomarker platforms is highly desired
- Knowledge of the drug development process, biomarkers and working with translation clinical research.
- Knowledge of regulatory requirements e.g. ICH/GCP, GLP, etc.
- Strong project management, problem solving, communication and leadership skills.
- Track record of independent and team contributions, being flexible and adapting in a changing environment.

WHY NOVARTIS

769 million lives were touched by Novartis medicines in 2020, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

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