Biomarker Monitor and BMD Study Expert, Laboratory Excellence and Operations (LEO)

Job ID
REQ-10061694

9月 14, 2025

USA

摘要

#LI-Hybrid

Internal Title: Principal Scientist II

As a BMD Study Expert in LEO you will be driving patient-centric operational innovation and partnership with external service providers/CROs and internal subject matter experts. Laboratory Excellence and Operation (LEO) is the key global resource for Line functions (LF) and Biomedical Research (BR) Clinical Trial Teams for biomarkers including biomarker outsourcing, scientific bi-omarker monitoring, vendor management, biomarker logistics, clinical site communication and sample coordination. LEO is working in close collaboration with clinical teams, LF technology experts, Biomarker Leads (BMLs) as well as specialized external service providers (ESP), central labs and clinical sites.

About the Role

Key Responsibilities:

- Place, implement and monitor biomarker assays at external service providers (ESP) across several biomarker modalities (e.g. Immunoassay, LC-MS, Flow cytometry, genetics etc.) in Translational Medicine (TM) clinical studies. Support data transfer and data flow in LIMS and DTS (e.g. study creation, data flow, data transfer, etc.) for managed biomarkers and studies. Partner with ESP to ensure on time/quality deliverables
- Independently identify and resolve assay issues as well as ESP quality or performance issues. Engage partner LF SME, clinical trial leaders and data management and other teams in complex issue resolution and escalations
- Lead development of strategic ESPs, including on boarding, planning, communication, oversight, and act as a point of contact to ESP and SME at the BMD level. Lead the implementation of innovative and global external solutions with central labs, clinical sites and external service providers for BMs and lead best practices across BMD
- Serves as a Biomarker 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
- Provide input and review clinical study protocols, CSRs, site operations manuals, informed consent forms, sample collection table, instruction manuals, central lab protocol/manual, and eCRF and other sample/biomarker/assay/vendor setup, sample tracking/reconciliation, and data flows
- Collaborate with other TM and BMD functions and lead biomarker clinical operation processes, continuous improvement initiatives and innovations in LEO and BMD.
- Provide mentorship to colleagues in LEO and BMD.

Essential Requirements:

Education:

- Master ' s degree in life science with 10 years of combined experience or PhD in life sciences with 8 years of combined experience in clinical operations and clinical biomarker analysis (method development, validation and sample analysis) in CRO or industry. Relevant academic research experience may be included.

Professional Experience:

- Laboratory knowledge and experience with several biomarker modalities and platforms e.g. immunoassays, LC-MS/mass spectrometry, cellular biomarkers, genetics, tissue or digital endpoints/digital devices. Previous laboratory experience with a variety of immunoassay platforms or FACS are desired. Experience with multiplex assays and profiling platforms would be helpful
- Direct experience in troubleshooting of assays in CRO, assay transfers to CROs and sample analysis as well as managing relationship and performance of external service providers/CROs including specialized laboratories
- Deep knowledge of clinical study set up and clinical operations, clinical sample analysis and extensive knowledge of the drug development process. In depth/expert knowledge of

regulatory requirements e.g. data integrity, GCP, GLP, etc.
- Experience working in a global organization and matrix environment (multiple roles/connections and stakeholders). Strong global project management, problem solving, influencing, and communication skills.

Languages:

- Fluent in English as a working language.

The salary for this position is expected to range between $114,100 and $211,900 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards. US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Universal Hierarchy Node

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USA

状态
Massachusetts

站点
Cambridge (USA)

Company / Legal Entity
U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Functional Area
Research & Development

Job Type
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Employment Type
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Shift Work

No

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