

Senior Scientist

Job ID
REQ-10078962
май 29, 2026
Индия

Сводка

Laboratory Excellence and Operation (LEO) and Biomarker Science and Operation (BSO) team in India are the key global resources for Line functions 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

Key Accountabilities

- Provide operational support to clinical studies focused on biomarkers, safety and PK samples, including clinical study setup, sample tracking/reconciliation, assay and vendor coordination, sample/data upload support and study closure activities. Responsibilities include supporting the re-view of clinical study protocols, site operations manuals, informed consent forms, sample collection tables, instruction manuals, central lab protocol/manual, eCRF-related content, and other biomarker sample operation logistics.
- Serve as a BMD Study Coordinator/ and clinical team representative from BMD on selected clinical studies and/or at a project level.
- Partner with clinical teams, data management, central labs, vendors, and internal functions to support biomarker and PK sample related activities. Independently set up central lab and central lab services (specifications, clinical sites, samples, assays),
- Implement and monitor biomarker/PK sample flow across BM modalities (e.g., Immunoassay, LC-MS, Flow cytometry, genetics etc.) and PK assays
- Maintain and update study and project information in relevant reports, trackers, dashboards, and IT systems.
- Identify and escalate sample management, assay, vendor, data, quality or performance-related issues and to senior team members, subject matter experts, clinical trial leaders, and data management teams as appropriate.
- Contribute to process improvements, best practices, process and continuous improvement initiatives within sample, vendor, data and assay monitoring activities.
- Collaborate across Translational Medicine functions, central lab, clinical sites, and vendors to support efficient study execution, aligning with defined LEO processes.

Essential Requirement

- Master's degree (M.Sc.) in Life Sciences or advanced degree in Clinical Operations, Clinical Bioanalysis, Biomarkers, or related field, with ~3+ years of relevant clinical operations experience.
- Operational knowledge of clinical trials: clinical study set up, central lab 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
- Knowledge of the drug development process, clinical biomarkers, clinical data management and working with translation clinical research 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

Desirable Requirement

- Laboratory background, knowledge of bioanalysis, are desired.
- Experience working in a global organization and matrix environment (multiple roles/connections and stakeholders) is a plus.

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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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