

## Principal Scientist

Job ID  
REQ-10002651

Apr 24, 2024

India

### Summary

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

Your responsibilities include, but are not limited to:

- Independently provide operational support to Biomarker Study Experts and clinical studies focusing on biomarkers and including reviews of clinical study protocol, site operations

manuals, informed consent forms, sample collection table, instruction manual, central lab protocol/manual, and eCRF and other biomarker sample operation logistics and coordination including study setup, sample tracking/reconciliation, assay and vendor set up, sample/data upload and study closure

- Partners with Biomarker Study Experts and BMD SME to set up, implement and monitor biomarker assays at external service providers (ESP) in one or more biomarker modalities (e.g. Immunoassay, LC-MS, Flow cytometry, genetics, tissues, digital endpoints etc.) in TM clinical studies
  - Support 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 troubleshooting, 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 other TM, BMD and GCO functions
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- Operational knowledge of clinical trials: clinical study set up, clinical sample management, clinical sample analysis and managing external service provider (ESP) including central laboratories and/or specialized vendors
  - Laboratory background and knowledge immunoassay and/or bioanalysis
  - Knowledge of the drug development process, clinical biomarkers and working with translation clinical research.
  - Strong project and time management skills, problem solving, communication and leadership skills.
  - Knowledge of regulatory requirements e.g. ICH/GCP, GLP, etc.

## 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!

### Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team 's representative of the patients and communities we serve.

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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>

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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>

Division  
Biomedical Research

Business Unit  
Pharma Research

Location  
India

Site  
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

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