

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

Job ID

REQ-10072836

Jun 15, 2026

LOC_IN

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.

Role Requirements

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 \(PDF 30 MB\)](#)

Division

DIV_RE

Business Unit

Research

Location

LOC_IN

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular
Shift Work

No

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List of links present in page

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