

Principal Scientist II (Biomarker Sample Management (BSM), Biomarkers Development (BMD))

Job ID

REQ-10073629

Mar 16, 2026

LOC_IN

About the Role

Major accountabilities:

- 8+ years of clinical operations and/or clinical data management or an advance degree with 6+ years in clinical operations and/or clinical data management
- Lead, develop, and implement innovative systems, IT solutions and processes/best practices for clinical sample management and clinical sample metadata flows in global clinical trials, covering exploratory and regulated biomarkers, PK samples, and more.
- Act as a global Subject Matter Expert (SME) for clinical sample processes and systems, driving consistent best practices and execution excellence
- Provide expert guidance to global clinical teams, biomarker experts, coordinators, and monitors for:
 - Clinical sample metadata setup with central labs and specialized CROs.
 - Operations manuals, paper/electronic requisition forms, and sample workflows.
 - Metadata mapping for LIMS, Data Transfer Specifications, and eCRFs.
 - In-study and final sample reconciliation.
- Update study and sample information across relevant IT systems (e.g., sample tracking platforms) following protocol amendments or reconciliation needs
- Oversee and contribute to managing bio-sample operational flows with CROs, external sample storage facility and internal stakeholders to ensure sample handling and processing steps for a range of analytical assays
- Provide operational support for clinical studies, including protocol review, biomarker- and PK-related logistics, site operations manuals, informed consent, central lab manuals, and sample tracking
- Partner with IT teams to enhance digital systems, and contribute to integration and automation projects supporting data handling and metadata quality

Key performance indicators:

- Effective, proactive planning of clinical sample-related operations.
- Timely and accurate implementation of systems and processes
- Strong feedback from internal and external partners regarding SME support
- Demonstrated adherence to Novartis Values and Behaviors.

Job Dimensions:

Number of associates

No direct reports: operates in matrix teams and manages interactions with external CRO partners.

Financial responsibility

Accountable for financial/resource decisions within assigned authority.

Impact on the organisation

Internal: Ensures availability of high-quality biomarker data enabling timely decision-making and regulatory submissions.

External: Contributes to Novartis being perceived as a reliable and innovative partner.

Minimum Requirements:

Education:

- Minimum: M. Sc. in Life Sciences.

Languages:

- Fluent in English as working language.

Experience / Professional Requirement:

1. Operational knowledge of clinical trials, including study setup, sample management, and clinical sample/data flow systems (e.g., DTS, LIMS, eCRF, eReq)
2. Clinical data management and data review experience highly desirable including knowledge of global clinical IT platforms (Medidata, Veeva, etc)
3. Track record of implementing innovative clinical systems, IT solutions, and digital process improvements is desired
4. Technical curiosity and an appetite for IT to support automation, digital workflow optimization, and effective integration across clinical data systems. Experience with programming (e.g., Python, SQL) or strong willingness to learn and apply programming to support workflow automation and data processes
5. Strong project management, planning, problem-solving, influencing, and communication skills. Experience working in a global, matrixed organization
6. Knowledge of drug development, clinical biomarkers and translational research. 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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