NOVARTIS

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

Job ID
REQ-10073629
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Индия

Сводка

Laboratory Excellence and Operation (LEO) is the key global resource for Line functions (LF) and BR Clinical Trial Teams for biomarkers including biomarker outsourcing, scientific biomarker monitoring, vendor management, biomarker logistics, clinical site communication, sample coordination and innovative solutions. LEO is working in close collaboration with clinical teams, LF technology experts, Biomarker Leads (BMLs), Data Management as well as specialized external service providers (ESP), central labs and clinical sites.

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

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)

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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

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

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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