NOVARTIS

Principal Scientist I/II, BMD

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Китай

Сводка

Laboratory Excellence and Operation (LEO) is the key global functional resource for Translation Medicine China, Line functions (LF) and BR Clinical Trial Teams for bi-omarkers including biomarker outsourcing, scientific biomarker monitoring, vendor management, biomarker logistics, clinical site communication and sample coordination. LEO is working in close collaboration with clinical teams, LF technology experts, Bi-omarker Leads (BMLs) as well as specialized external service providers (ESP), central labs and clinical sites.

About the Role

Key Responsibilities:

- Serves as Biomarker Study Expert (BSE) in China and Global studies, lead clinical biomarker operational study strategy and biomarker study plan implementation in TM clinical studies including providing input and reviews of clinical synopsis, study protocols, and other biomarker study operations documentation.
- Represent BMD platforms and modalities in Global and China CTT including soluble, cellular, genetics, imaging and digital endpoints. Partner with BMD BML and SME and provide biomarker and operational expertise on all assigned clinical studies e.g. lead the BM setup, sample tracking/reconciliation, assay set up, data flow, vendor set up, biomarker sections of clinical study report and biomarker study closure
- Independently provide operational support to clinical teams and clinical studies (both global and China studies) focusing on biomarker samples and PK sample including reviews of clinical study protocol, preparing site operations manuals, informed consent forms, sample collection table, instruction manual, central lab protocol/manual, and eCRF and other biomarker and PK sample operation logistics and coordination including study setup, sample tracking/reconciliation, assay and vendor set up, sample/data upload and study closure
- Effectively engage and partner with BMD subteams and biomarker LF experts in China and Global teams to ensure on time internal and external (vendor) biomarker deliverables. Update study and project information in relevant meeting, reports and IT systems
- Serve as a scientific monitor i.e. assay set up, assay transfer and implementation, and monitor biomarker assays at external service providers in one or more biomarker modalities (e.g. Immunoassay, LC-MS, Flow cytometry, tissues, genetics, digital endpoint and devices, etc.)
- Serve as expert for relevant China-specific regulations and policies (e.g. HGRAC, bio-sample export/import). Conduct feasibility analysis before study allocating to China and provide China biomarker solutions to ensure timely study execution in China.
- Continuously strengthen China local biomarker vender capabilities based on the study needs to enable efficient bio-assay development transfer in China
- Collaborate with other TM and BMD functions and lead biomarker clinical operation processes, continuous improvement initiatives and innovations in LEO and BMD
- In collaboration with relevant BMD managers, contributes to talent and career development of LEO associates in China. Provide supervision and mentorship to colleagues in LEO and BMD.

Essential Requirements:

- MS in life science with 10 years of combined experiences or PhD in life science with 8 years of combined experience in clinical operations and clinical biomarker analysis (method development, validation and sample analysis) in CRO or industry
- Fluent in English as working language.
- Laboratory knowledge and experience with several biomarker modalities and platforms e.g. immunoassays, LC-MS/mass spectrometry, cellular biomarkers, genetics, tissue or digital endpoints/digital devices.
- Direct experience in troubleshooting of assays in CRO and assay transfer to CROs and sample analysis as well as managing relationship and performance of external service providers/CROs including specialized laboratories
- Deep knowledge of *clinical study set up and clinical operations, clinical sample analysis*
- Extensive and in-depth knowledge of the drug development process, biomarkers and working with clinical translation research or global clinical studies
- In depth/expert knowledge of regulatory requirements e.g. data integrity, GCP, GLP, etc. Knowledge of China regulation is a plus, e.g. HGRAC, sample exportation.
- Highly self-motivated and collaborative, with a demonstrated ability to work effectively in matrix teams.

Desirable Requirements:

- Emerging leader who is passionate about driving patient-centric operational innovation and partnership with external service providers/CROs and internal subject matter experts
- Experience working in a global organization and matrix environment (multiple roles/connections and stakeholders)
- Strong global project management, problem solving, influencing, communication and leadership skills. Concise oral and written communication skills
- Highly self-motivated and collaborative, with a demonstrated ability to work effectively in matrix teams.

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.
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Biomedical Research
Business Unit
Research
Место
Китай
Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
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.china@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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