NOVARTIS

Biomarker Scientific Coordinator

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Сводка

BMD China and Laboratory Excellence and Operation (LEO) are the key China and global resources for Line functions (LF) and Translational Medicine (TM) Clinical Trial Teams for biomarkers including biomarker outsourcing, sci-entific biomarker monitoring, vendor management, biomarker logistics, clinical site communication and sample coordination. We are working in close collabo-ration with global and China clinical teams, LF technology experts, Biomarker Leads (BMLs) as well as external service providers (ESP) including central labs and clinical sites.

About the Role

Major accountabilities:

- Independently provide operational support to Biomarker Study Experts, 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 co-ordination including study setup, sample tracking/reconciliation, assay and vendor set up, sample/data upload and study closure.
- Serve as a Biomarker Study Expert (BSE) and clinical team representative from BMD on selected clinical studies. Partner with clinical teams and functions including global and China teams.
- 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 cy-tometry, genetics etc.) and PK assays.
- Support specialized BM external service and providers including set up, 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.
- Independently identify and resolve sample management and sample dis-crepancy issues for biomarker and PK samples. Identify, and escalate issues, ESP, quality or performance issues and en-gage LF experts/SME, clinical trial leaders and data management as needed.
- Contribute to the best practices, process and continuous improvement ini-tiatives and innovations in sample management functions. Collaborate with across TM functions, lead site, central lab and vendors processes, drives continuous improvement initiatives and innovations in LEO.
- 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

Minimum Requirements:

- BS in life science with 4+ years of clinical operation experiences and/or clinical bioanalysis and/or clinical bi-omarkers. Advance degree with 2+ years in clinical operations and/or clin-ical bioanalysis and/or clinical bi-omarkers.
- Fluent in English as working language.
- Operational knowledge of clinical trials: clinical study set up, clinical sample management, clinical sample analysis and managing external service pro-vider (ESP) including central laboratories and/or specialized vendors.
- Laboratory or data management background and knowledge of immuno-assay and/or bioanalysis is a plus.
- Knowledge of the drug development process, clinical biomarkers and working with translational clinical research.
- Strong project and time management skills, problem solving, communica-tion and leadership skills.
- Knowledge of regulatory requirements e.g. ICH/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.

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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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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