Global Biomarker Diagnostic Associate Director " >

Job ID
324642BR
Aug 02, 2021
USA

Job Description

2005! That’s the year that Novartis began exploring Precision Medicine to extend and improve the lives of patients, by enabling the regulatory approval and commercial sale of transformative therapies.

Precision Medicine (PM) is an approach for prevention, diagnosis, treatment, and monitoring of disease that considers individual variability in biology, environment, and lifestyle for each person (source: NIH). Patient biomarker data and diagnostic assays drive healthcare decision-making by helping physicians identify patients for the right treatment and monitor their disease. Beyond biomarkers and companion diagnostics, precision medicine supports the Novartis pipeline by facilitating clinical trial design and execution, accelerating drug development, and informing early pipeline choices. By using advances in biology, technology, and data & digital solutions, Novartis Precision Medicine continues to innovate in our quest to disrupt treatment paradigms and reimagine medicine.

The Global Biomarker Diagnostic Associate Director (GBDaD), supports the Disease Area Global Biomarker Diagnostic Leader (GBDL) by, contributing to the execution of the Oncology Precision Medicine Strategy for a given disease area GPT. The GBDaD contributes to the implementation and execution of the disease area Precision Medicine strategy, with predominant focus on timely execution of biomarker activities to support decision making in the GPT and ensuring regulatory approval, of any CDx assays in collaboration with the CDx Regulatory team.

Key Responsibilities:

• Contributes to the implementation & execution of the precision medicine strategy
• Ensures timely execution of assay development for patient selection, stratification, pharmacodynamics, correlative studies and CDx development for clinical trials by working with internal stakeholders (global line functions) and external partners (clinical research organizations, Academic Labs, clinical labs and diagnostic partners) for assigned program(s) with limited oversight
• Contributes input to the PML and clinical team for assay development, molecular epidemiology, and other research-related activities with other internal stakeholders. Contributes to the target test profile, and the overall CDx development strategy and plan
• Contributes to companion diagnostic development as needed, and serves as a member of PML core team and International Clinical Team (ICT) and other teams where implemented.
• In collaboration with TCO/NIBR, identify and validate external laboratories involved in CTAs for clinical trials and companion diagnostic development.
• Authors the biomarker/CDx portions of key clinical documents including Clinical Development Plan, Clinical Study Protocols, Investigator Brochures, and Clinical Study Reports (CSRs)
• Supports regulatory submissions by acting as subject matter expert within the team. Contributes scientific

and technical sections of key regulatory documents including INDs, FDA briefing books, and submission documents (including NDAs, IDEs & PMAs). Coordinates data requirements with reference labs to support submission.
• Partners with Biomarker Trial Heads (BTHs) and other internal stakeholders to ensure all aspects of data collection are executed with high quality, including correlative science analysis plan, data formatting and transfer specifications, eCRF page design, and monitoring plans for correlative study samples.
• Actively educates other team members through knowledge sharing. Contributes to the development and implementation of processes supporting patient pre-selection and stratification, pharmacodynamic monitoring,correlative studies & requirements for CDx development
• Acts as core member of the International Clinical Team
• Avoids strategic and operational crises by proactively identifying and managing potential risks to the program(s). In case issues cannot be avoided, ensures that they are being resolved employing the full technical and strategic expertise and experience of the organization thus limiting negative impact on the program(s)
• Compliance to applicable US and international Medical Device regulations and standards including, but not limited to, 21 CFR 820, ISO 13485, 93/42/EEC, 98/79 EC, and the requirements of the Novartis CDx Quality Management System.

This role will be onsite at either our East Hanover, NJ or Cambridge, MA locations.

Diversity & Inclusion / EEO

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Minimum Requirements

What you'll bring to the role:

• 3 years industry experience
• 3+ years multi/cross functional leadership experience within an Oncology business unit.
• Expert leadership skills demonstrated in GPT, or in other organizational assignments. Expert skills to facilitate/optimize contribution of team members as individuals and members of cohesive team.
• Strong interpersonal and communication skills for bridging scientific and business participants, for negotiating timelines and for effective international collaboration.
• Diagnostic experience is an advantage
• Results driven

Education
(minimum desirable)
MD or Ph.D OR MD/PhD with minimum of 5 years of correlative science in Oncology, including biomarkers, of which a minimum of 1 years must be in Pharmaceutical industry.

MD must have a minimum of 2 years' experience in development & implementation of patient selection and other correlative strategies for clinical programs and/or oncology clinical trial experience.
Ph.D in Molecular Biology, Oncology, Molecular Pathology, Lab Medicine, Life Sciences or
MSc/MBA with equivalent experience in life sciences, Molecular Biology, Oncology, Molecular Pathology, Lab Medicine

Languages

Fluent English (written and oral),
Division
Global Drug Development
Business Unit
OHD GDD
Location
USA
Site
East Hanover, NJ
Company / Legal Entity
NIBRI
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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