

Precision Medicine Director

Job ID
REQ-10039749
Feb 21, 2025
Regno Unito

Sommario

The Precision Medicine Director (PMD) develops the Precision Medicine strategy and plans for a given program. The PMD leads and oversees all aspects of implementation and execution of the program PM strategy, supporting GCT/GPT including development of clinical biomarker assays with a medical purpose and (companion) diagnostics to support patient selection and stratification ensuring regulatory approval, technical market access and optimised commercial value. Acts as Precision Medicine Subject Matter Expert within the GCT/GPT.

About the Role

Major accountabilities:

- Develops the assigned program Precision medicine strategy aligned to the disease area strategy in support of a GCT/GPT and ensures seamless execution for the success of the program.
- Leads cross functional biomarker sub teams for molecular epidemiology, assay development for patient selection/stratification, data analyses/interpretation and data reporting.
- Serves as core member of the BDST and may lead BDST. Serves as subject matter expert at the Global Clinical Team (GCT) and/or Clinical trial team (CTT) as applicable.
- Contributes to the Dx target product profile (DxTPP), and the overall IVD/ CDx development strategy and plan.
- Avoids strategic and operational crises by proactively identifying and managing potential risks to the program(s).
- Authors the biomarker/CDx portions of key clinical documents including Clinical Development Plan, Investigator Brochures, Clinical study protocols and Study Reports
- Supports regulatory submissions by acting as biomarker/clinical Dx subject matter expert within the GPT team.
- May Support exploratory/scientific external academic collaborations to support biomarker data generation.
- Ensures 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.

Minimum Requirements:

Work Experience:

- 6 years industry experience
- 3+ years multi/cross functional leadership experience within either or Oncology, Immunology, Neuroscience, Cardiometabolic business unit.
- Excellent knowledge of diagnostics and associated regulatory requirements.

- Expert leadership skills demonstrated in cross functional teams.
- Strong interpersonal and communication skills for bridging scientific and business participants, for negotiating timelines and for effective international collaboration.
- Outstanding verbal and written communications
- Results driven

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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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Divisione

Development

Business Unit

Universal Hierarchy Node

Posizione

Regno Unito

Sito

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1

Dublin (NOCC), Irlanda

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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