Precision Medicine Associate Director

Job ID
REQ-10039745
Febr. 07, 2025
Vereinigtes Königreich

Zusammenfassung

The Precision Medicine Associate Director (PMaD) provides clinical drug development, scientific and technical expertise for successful implementation and execution of the Precision Medicine plans for clinical studies in a given program with a focus on ensuring timely execution to meet studies timelines.

About the Role

Major accountabilities:

- Serves as core member of the BDST and as subject matter expert at the Global Clinical Team (GCT) and/or Clinical trial team (CTT) as applicable. As well as externally e.g. steering committees.
- Contributes to the Dx target product profile (DxTPP), and the overall IVD/ CDx development strategy and plan.
- Authors the biomarker/CDx portions of the study protocols and clinical study reports.
- Avoids strategic and operational crises by proactively identifying and managing potential risks to the program(s) and communicate them timely to GCT/CTT to minimize impact on program.
- Supports regulatory submissions by acting as biomarker/clinical Dx subject matter expert within the GCT/CTT team.
- Partners with CBS and other internal stakeholders to ensure all aspects of data collection and analysis are executed with high quality including statistical analysis plan, data formatting and transfer specifications, eCRF page design, and monitoring plans for biomarker study samples.
- 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:

- Education: MD or Ph.D. OR MD/Ph.D. with minimum of 6 years of experience in the field of precision medicine including CDx/IVD and minimum of 3 years in the pharmaceutical industry.
- 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.
- Expert skills to facilitate/optimise contribution of team members as individuals and member of cohesive team.

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Abteilung
Development
Business Unit
Universal Hierarchy Node
Ort
Vereinigtes Königreich
Website
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Dublin (Country President Office (CPO)), Irland
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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