Regulatory Diagnostics Manager

Job ID
REQ-10046819

4月 30, 2025

Ireland

摘要

The Regulatory Diagnostics Manager (RDM) for Precision Diagnostics is responsible for implementation of strategic plans for development of diagnostics, including companion diagnostics, as they pertain to the Novartis innovative medicines portfolio, including its marketed products. The RDM works with oversight of senior members of the RA Precision Diagnostics Team including the TA and Diagnostics Lead on strategies and submissions including companion diagnostics, in close collaboration with internal RA Disease Unit associates, associates of Digital, Data and Clinical Innovation (DDCI) at Novartis as well as Partner Companies that develop diagnostics and ensures adherence to regulatory requirements. The RDM will also provide regulatory support including tactical and technical regulatory direction for clinical trial assays to ensure compliance with regulations on diagnostics.

About the Role

Job Description

Major Accountabilities

Regulatory Strategy and Implementation

- Supports the diagnostics regulatory strategy for precision IVDs and CDx (e.g. US, EU, Japan, China).

- With support of the RA TA and Diagnostics Lead, responsible for submissions in the premarket as well as post-market space including investigational Device Exemptions (IDE), Significant Risk Determinations, Performance Study Applications (PsA) and pre-market authorization submissions

- With oversight of the RA TA and Diagnostics Lead, works to ensure diagnostic regulatory input for early development and late- stage programs is incorporated into the overall drug development strategy to ensure regulatory requirements pertaining to IVD, CDx and LDT regulations are met

- As needed, partner with RA country organizations to align on local regulatory requirements for precision IVDs and CDx and deliver timely submissions as appropriate including annual reports and notifications

- Facilitates preparation, filing, finalization of briefing books including coordination and planning for pre-Submission or other meetings with HAs related to precision diagnostics and CDx development. Participation in HA meetings as appropriate

- Develops, manages, and implements plans for timely response to HA requests and coordinates of any applicable follow-up activities.

- Member of RA subteam and Biomarker Development Subteam (BDST) as appropriate

Training and Compliance

Support compliance activities for Novartis clinical trials as they relate to global regulations on precision diagnostics and CDx, such as European IVDR Help ensure regulatory compliance of Partner companies for CDx development and IVD deliverables related to our portfolio, as appropriate and elevate to RA Diagnostic Lead where appropriate Support roll-out of new procedures, SOPs and working practices and training related to IVD and CDx development.

Performance Indicators

Successful implementation of regulatory diagnostics strategies with timely submissions for precision IVDs and CDx Full compliance with IVD and LDT rules for our clinical trials Identification of precision IVD and CDx needs for Novartis programs Strong partnership with RA Diagnostics Team members and the RA community Adherence to Novartis Policies and guidelines.

Experiences & Skills

- Minimum 2-4 years of experience in the pharmaceutical industry with relevant experience related to diagnostics, IVD or CDx development
- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MS, Ph D, PharmD) considered a plus.
- Demonstrated experience of successful contributions to a IVD/CDx regulatory project(s) and/or submission
- Experience in the diagnostic, IVD and/or CDx industry
- Understanding of IDE, MAA, NDA/BLA, 510(k), PMA submission(s)
- Understanding of assay validation and CLIA
- Understanding of clinical trials
- Strong interpersonal, communication and negotiation skills

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部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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