TMF Integration Oversight Manager

Job ID
REQ-10051615

5月 26, 2025

United Kingdom

摘要

Clinical Document Governance Management (CDGM) is accountable for strategy and delivery of clinical document management (CDM) systems, processes, standards and operations of CDM services (including Trial Master File management (TMF), clinical submission readiness, record retention and archiving, Good Documentation Practice capability build) across Novartis globally. In addition, CDGM is driving the transformation of TMF at Novartis, through the introduction and adoption of new technologies, processes and ways of working.

The TMF Oversight Integration Manager ensure successful planning and transition of TMF documentation to and from Novartis in support of Mergers & Acquisition (M&A) projects and Out licensing activities. Drives implementation of CDGM initiatives, projects and process improvement activities to enhance clinical document management systems, processes and standards at Novartis.

This is a hybrid role and can be based in London or Dublin offices. The expectation is to be in the office 12 days/month

About the Role

Job Description

Major accountabilities but not limited to:

- Act as CDGM point of contact for assigned portfolio of In-Licensing / Out-Licensing / Acquisition / Divestment Projects, collaborating with key stakeholders with CDGM teams, Development Informatics, Legal, Development Quality Assurance and Global Project Teams.
- Lead and/or Contribute to the development of TMF Transition Plans and ensure the successful transitions of TMF (paper and electronic) documentation outside of Novartis in support of out-licensing and divestment projects, and into Novartis in support of in-licensing and acquisition projects.
- Develop and maintain paper and electronic document processes & standards relating to M&A projects and Out licensing activities, in compliance with internal and external requirements & regulations.
- Identify and communicate risks/trends/patterns relating to TMF, M&A projects, Out licensing activities and work with key stakeholders to define and implement pragmatic remediations.
- Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
- Serves as Subject Matter Expert on TMF transition related training materials, formal and informal processes and tracking tools for TMF transition oversight activities in collaboration with CDM Process team and other key stakeholders
- Provides support for inspections/audits, contributes to root cause analysis identification and creation/delivery of CAPAs.
- Supports the TMF Integration Lead with respect to forecasting and planning of M&A projects.

Minimum Requirements:

- Bachelor ' s degree or equivalent and relevant industry experience
- Minimum of 5 years working in clinical research and development in the pharmaceutical industry (and/or Contract Research Organizations) with specific experience in clinical documentation and/or records & information management.
- Demonstrated success in planning and executing cross functional projects.
- Strong influencing and presentation skills. Ability to communicate effectively at all levels.
- High organizational awareness, including experience working in multi-disciplinary teams, across cultures and geographies.
- Good negotiation, problem solving and conflict resolution skills; experience establishing trusted relationships with internal and external stakeholders.
- Fluent in English

Why Novartis:
Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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

Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Development

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Dublin (NOCC), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10051615

TMF Integration Oversight Manager

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10051615-tmf-integration-oversight-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/careers/benefits-rewards
3. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/London-The-Westworks/TMF-Integration-Oversight-ManagerREQ-10051615-1
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/London-The-Westworks/TMF-Integration-Oversight-ManagerREQ-10051615-1