NOVARTIS

TMF Oversight Manager

Job ID
REQ-10043278
Apr 03, 2025
Switzerland

Summary

The TMF Oversight Manager is responsible for ensuring delivery and oversight of high quality and timely TMF Quality Review activities for a portfolio of internal, outsourced or BD&L studies. You will drive implementation of Clinical Document Governance Management initiatives, projects and process improvement activities to enhance clinical document management systems, processes and standards at Novartis.

About the Role

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

Your responsibilities include, but are not limited to

- - Responsible for timely assessment of quality and completeness of TMFs for an assigned portfolio of studies.
  - Identify and communicate TMF risks/trends/patterns and works with key stakeholders to define and implement pragmatic remediations.
  - Execute vendor oversight plan, monitors service metrics, and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
  - Serve as Subject Matter Expert on TMF training materials, formal and informal processes and tracking tools for TMF oversight activities in collaboration with CDM Process team and other key stakeholders
  - Provide Audit/Inspection readiness support by driving TMF quality reviews in preparation for audits/inspections, contributes to root cause analysis identification and creation/delivery of CAPAs.
  - Identify and implement improvements to document management processes to improve quality of TMFs. May act as business lead for innovation projects to enhance TMF quality assessment.
  - Support the forecasting and tracking of TMF Quality Review resource needs including proactive identification of resources to support TMF Quality Review activities for high-risk and priority projects.
  - Support definition and refinement of TMF management strategy for assigned portfolio of studies. Ensures clear expectations for TMF set up and maintenance, including contractual agreement with third parties, for outsourced studies.

- **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 Organisations) 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 organisational 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.

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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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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

Division
Development
Business Unit
Innovative Medicines
Location
Switzerland
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Alternative Location 1
Dublin (NOCC), Ireland
Alternative Location 2
London (The Westworks), United Kingdom
Functional Area
Research & Development
Job Type
Full time

Employment Type
Regular
Shift Work
No
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List of links present in page

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2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
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