Trial Master File (TMF) Compliance Lead

Job ID
REQ-10040057

2月 18, 2025

Switzerland

摘要

More than 100,000 people across 140 countries are working for Novartis to discover, develop, and successfully market innovative products to prevent and cure diseases, ease suffering, and enhance the quality of life.

The TMF Compliance Lead will be responsible for the Translational Clinical Oncology (TCO) strategy on Trial Master File (TMF) and Document Management System (DMS) related topics to ensure compliance of global study TMFs in accordance with Novartis SOPs and ICH/GCP guidelines. The TMF Compliance Lead will represent TCO on all TMF and DMS related aspects, partnering with TMF governance, NIBR TM, with GDD, and CQA, leading TCO contribution to global workstreams and initiatives on TMF and DMS, driving change management and escalation of issues.

About the Role

Major accountabilities:

- Lead the TMF Compliance team, defining and implementing the TCO strategy for the management of study and program documentation within the Document Management Systems.
- Lead all TMF QC activities for TCO in accordance with TCO portfolio and Clinical Operations study milestones as applicable per Novartis SOPs and ICH/GCP guidelines.
- Liaise with partners in TMF governance, and other stakeholders to ensure alignment, and quality outcomes.
- Ensure tracking and reporting of key quality indicators (KQIs) and reinforce overall compliance to TMF process and regulations.
- Maintain up to date knowledge of the TMF Reference Model, industry best practices and regulatory considerations.
- Ensure TCO representation and serve as TCO representative on TMF/DMS process improvement initiatives, committees, work streams and governances.
- Lead the establishment and maintenance of TMF/DMS/ guidance documents, best practices, and training materials for TCO Clinical Operations. Contribute to the on-boarding and training of new ClinOps staff.

Minimum Requirements:
Work Experience:

- B.S. or advanced degree preferably in life sciences/healthcare or equivalent experience.
- A minimum 10 years of relevant experience in the Pharmaceutical Industry with broad experience in Trial Master File quality management at Global, Country or Site levels
- Demonstrated ability for leading initiatives with cross-functional teams and implementation of recommendations
- Developed or have participated in the development of SOPs, guidance documents, work practices and tracking tools

Skills:

- Experience working in matrix environment and in global teams
- Excellent interpersonal, problem-solving, negotiation and conflict resolution skills
- Excellent organizational skills
- Excellent communicator and presenter (oral and written)

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

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.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all

individuals. If, because of a medical condition or disability, you need a reasonable

accommodation for any part of the recruitment process, or in order to receive more detailed

information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

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部门

Biomedical Research

Business Unit
Pharma Research

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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