NOVARTIS

Trial Master File (TMF) Compliance Lead

Job ID
REQ-10040063
fév 20, 2025
Etats-Unis

Résumé

#LI-Hybrid

Location: Cambridge, MA or East Hanover, NJ

The Trial Master File (TMF) Compliance Lead will be responsible for the Translational Clinical Oncology (TCO) strategy on 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 Global Drug Development (GDD), and Clinical Quality Assurance (CQA), leading TCO contribution to global workstreams and initiatives on TMF and DMS, driving change management and escalation of issues.

About the Role

Key Responsibilities:

- 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 Clinical Operations staff.

Essential Requirements:

- This position will be located at the Cambridge, MA or East Hanover, NJ site and will not have the ability to be located remotely. This position will require approximately 2 - 5% travel as defined by the business (domestic and/ or international).
- 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 TMF 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
- 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)

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The pay range for this position at commencement of employment is expected to be between: $185,500 and $344,500/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

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expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 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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