

Trial Master File Oversight Manager

Job ID
REQ-10080249
Июн. 11, 2026
Испания

Сводка

Job Title: Trial Master File Oversight Manager

#LI-Hybrid

Location: Barcelona Gran Via, Spain

Relocation Support: This role is based in Barcelona Gran Via, Spain. Novartis is unable to offer relocation support: please only apply if accessible.

When you bring structure to complexity, you unlock better outcomes for patients. As a Trial Master File (TMF) Oversight Manager, you will play a critical role in ensuring the quality, integrity, and readiness of clinical trial documentation across a global portfolio. Working at the heart of clinical operations, you'll collaborate with cross-functional teams to strengthen governance, elevate standards, and drive continuous improvement in TMF processes—helping Novartis deliver high-quality research and transform patient care worldwide.

About the Role

Key Responsibilities

- Provide oversight for the assessment of quality and completeness of Trial Master Files across a global portfolio
- Identify and communicate trends, risks, and gaps in documentation and implement effective remediation plans
- Lead vendor Trial Master File oversight activities, monitor performance metrics, and optimize operating models
- Act as escalation point for Trial Master File quality issues and drive timely resolution
- Serve as subject matter expert on Trial Master File processes, tools, and training materials
- Support audit and inspection readiness through proactive quality reviews and preparation activities
- Contribute to root cause analysis and develop corrective and preventive action plans
- Drive continuous improvement in document management processes to enhance Trial Master File quality
- Lead or support innovation initiatives to advance Trial Master File systems and assessment approaches
- Support resource planning, forecasting, and prioritization of Trial Master File high-risk and critical studies

Essential Requirements

- Bachelor's degree or equivalent with relevant experience in the pharmaceutical or clinical research industry
- Minimum of five years' experience in clinical research and development, including clinical documentation or records management
- Proven ability to plan and execute cross-functional projects in a complex, global environment
- Strong influencing and presentation skills with the ability to communicate clearly at all organizational levels
- Experience working in multidisciplinary teams across different cultures and geographies
- Strong organizational awareness with the ability to manage multiple priorities effectively
- Demonstrated problem solving, negotiation, and conflict resolution skills
- Ability to build and maintain trusted relationships with internal and external stakeholders

Desirable Requirements

- People Management experience

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.

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: Learn about all the ways we'll help you thrive personally and professionally.
[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Development
Business Unit
Development
Место
Испания
Сайт
Barcelona Gran Vía

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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