

Trial Master File Oversight Manager

Job ID

REQ-10080251

Jun 11, 2026

LOC_IE

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

Role Requirements

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 \(PDF 30 MB\)](#)

Division

DIV_GD

Business Unit

Development

Location

LOC_IE

Site
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
[Apply to Job](#)

Job ID
REQ-10080251

Trial Master File Oversight Manager

[Apply to Job](#)

Source URL: <https://prod1.jobapi.novartis.com.cn/req-10080251-trial-master-file-oversight-manager>

List of links present in page

1. <https://prod1.jobapi.novartis.com.cn/req-10080251-trial-master-file-oversight-manager>
2. <https://www.novartis.com/about/strategy/people-and-culture>
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Dublin-NOCC/Trial-Master-File-Oversight-Manager_REQ-10080251-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Dublin-NOCC/Trial-Master-File-Oversight-Manager_REQ-10080251-1