Clinical Document Management: Migration Team Lead

Job ID
393659BR
Juli 31, 2024
Schweiz

Summary

-Oversees the strategic and operational planning/ management from a clinical trial execution perspective. Oversight of budget and resource allocation within assigned trial. Enables operational excellence through process improvement and knowledge sharing across trials within program/franchise. Enables an empowered organization that can navigate in a matrix environment and adjust quickly to business needs.

About the Role

We are seeking a CDM Migration Team Lead to join our CDM team reimagining TMF at Novartis!

This position is accountable for leading business activities relating to data migrations in and out of Novartis electronic Document Management Systems (eDMS), ensuring effective planning, delivery and oversight of all business-related activities, partnering with business, IT and external collaborators complying with all GxP Quality standards.

Major Accountabilities
• Act as CDGM contact for key partners, collaborating with them to improve clinical documentation process, systems and capabilities across the organisation.
• Delivers excellence in service delivery, including optimisation and simplification in compliance with Novartis policies & regulatory requirements, responding in an agile way to new or evolving business priorities.
• Provide robust oversight of 3rd party vendor activities including monitoring sustainable performance against SLAs.
• Lead or contribute to cross functional initiatives or projects, including defining and gaining approval for projects or initiatives, and ensuring deliverables are achieved in line with agreed timeframes and budget.
• Embeds a risk-based attitude across the team and in service delivery, ensuring identification, evaluation and management of risks, including mitigation activities.
• Set priorities, manage schedules and develop robust resourcing model to support timely delivery of TMF services.
• Support CDGM and business teams in preparation for and during audits, inspections and migration activities. Own CAPAs arising from inspections/audits ensuring they are closed out on time.
• Leads team, recruits, retains, manages and develops associates through coaching and feedback, talent reviews and other available Novartis resources and tools, and fosters a safe environment for team dialogue and growth.

Required experience:

• Bachelor’s degree in life-sciences/healthcare/pharmacy and relevant industry experience

• Minimum of 8 years of 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.

• Proven experience in direct people management or matrix management of project/clinical teams.

• Deep understanding of drug development process, international drug approval procedures and standards (e.g., ICH-E3, ICH-E6, eCTD) and industry-wide
standards in clinical document management (e.g., DIA TMF reference model).

• Demonstrated success in planning and driving cross functional projects.

• Strong influencing and presentation skills. Ability to communicate effectively at all levels.

• Good organizational awareness, including experience working in multi-disciplinary teams, across cultures and geographies.

• Good negotiation, problem solving and conflict resolution skills; experience establishing positive 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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Site
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C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
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Job Type
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