NOVARTIS

Head, Clinical Document Management Integrated Systems Director

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Великобритания

Сводка

This position plays a critical leadership role in a complex matrix with all parts of the R&D organisation that contribute essential records for drug development and implement strategies that incorporate many systems that hold clinical trial data.

The Head, Clinical Document Management Integrated Systems Director drives initiatives in the Clinical Document Management tech space for example for: the implementation and embedding of regulatory, safety and site document exchange mechanisms in a sustainable way of working and integration of these capabilities into future clinical TMF strategies; the integration of existing systems and functionalities with future direction including AI/ML, genAI and automated workflows; support Non-Interventional study information management needs; incorporating clinical information from external sources contributing to the conduct of studies (e.g. CROs, BD&L inlicensed partners) including processes and automation, integration of these into the TMF strategies.

You would also be responsible for designing and developing new business processes and strategies while proactively identifying business risks and proposing and implementing strategies to manage the implications of these risks on the business.

About the Role

This position is a home worker / hybrid position based in the UK. Novartis can not offer relocation for this position. Please only apply if the country location suits you.

Key responsibilities but not limited to:

- Drive the implementation of the clinical records management systems innovation roadmap including ML/AI and relevant interfaces in partnership with GCO's Technology and AI, DDIT, QA and other relevant business functions
- Ensure efficient user support model for system related inquiries in a timely, efficient and resolutive manner
- Ensure effective business system ownership including maintenance of business rules, user requirements and metadata standards for digital data interoperability, transferability, reuse and preservation, and business administration (BA) activities
- Provide business leadership and support on GxP data/record migration and integration projects
- Foster thought leadership in the clinical operations tech space through proactive external network and industry associations (e.g. CDISC) contribution, keeping sight of evolving tech landscape; builds trusted relationships with internal Compliance and QA functions as well as Health Authorities inspectors
- Set, review and evaluate annual performance objectives for the team in alignment with company goals, establishes priorities and distribution of work, forecasts demand and resource needs and contributes to the CDGM budget cycles
- Recruit, retain, manage and develop associates through coaching and feedback, talent reviews and other available Novartis resources and tools
- Effective vendor management as demonstrated by SLA and KPIs vs budget and resources within 5% of cost overruns
- CDGM systems infrastructure compliant with Regulatory standards, GxP and expectations
- Significant contribution to building CDGM high performing team
- CDGM and travel budget accountability for own resources. Project and External budget accountability for provided services

Essential criteria:

- Advanced degree or combination of Bachelor's degree in information or life-sciences/healthcare and relevant industry experience.
- Significant years experience 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.
- Strong 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. CDISC TMF reference model).
- Demonstrated success in planning and executing cross functional change projects.
- Strong influencing and presentation skills. Ability to communicate effectively at all levels.
- High organisational awareness, including experience working in multi disciplinary teams, across cultures and geographies.
- Good negotiation, problem solving and conflict resolution skills; experience establishing trusted relationships with internal and external stakeholders.
- Good understanding of machine learning, automated workflows and artificial intelligence capabilities applied to records management is strongly desired.

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
Великобритания
Сайт
Home Worker - England/Wales
Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Barcelona Gran Vía, Испания
Alternative Location 2
Dublin (NOCC), Ирландия
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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