Clinical Document Management: Technology Release Manager

Job ID
REQ-10014888
Jul 10, 2024
Switzerland

Summary

-Contributes, with appropriate oversight, to all relevant aspects of global clinical trial(s) activities to deliver study outcomes within schedule, budget, quality/compliance and performance standards. May lead specific aspects of global clinical trial(s). Core member of the Clinical Trial Team, Contributes to operational excellence through process improvement and knowledge sharing and/or provide inputs to clinical development process. -Applicable to Clinical Scientific Expert IIThe Clinical Scientific Expert II (CSE II) provides clinical and scientific support through all phases of a clinical study under the guidance of the (A)CD(M)D in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CSE II is a core member of the Clinical Trial Team (CTT). In addition, the CSE II supports/leads program level documents or activities as assigned.

About the Role

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Effective planning and delivery of releases of Novartis enterprise-wide clinical electronic document management systems (eDMS), partnering with technical vendors, internal IT and business stakeholders.

Drives implementation of CDGM initiatives, projects and process improvement activities to enhance the planning and execution of releases of enterprise clinical eDMS at Novartis.

o Act as CDGM point of contact for specific releases of eDMS, partnering with CDGM, IT (internal and external) and business stakeholders to plan and deliver releases to clinical eDMS, in line with Novartis technology roadmap, compliance and operational requirements.
o Partner with CDGM and business stakeholders to understand business requirements, identify functionality gaps in eDMS and contribute to the planning of future releases through prioritisation of backlog items.
o Contribute to activities to ensure efficient processes & integrations of systems with eDMS based on strong understanding of Novartis enterprise systems landscape and in line with compliance and business priorities.
Serves as Subject Matter Expert for training materials, formal and informal processes and tracking tools for eDMS release management activities in collaboration with CDM Process team and other key stakeholders
o Plan and contribute to agile working methodologies being applied during development cycles to prepare for releases and during post release hypercare period.
o Owner or Contributor of activities related to release related Incident Management, Change Management and

ongoing operations of the eDMS.
o Support forecasting of internal resource allocations and vendor provided activities as part of eDMS release management.
o Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
o Provides support for inspections/audits, contributes to root cause analysis identification and creation/delivery of CAPAs.

Role Requirements :

Bachelor’s degree or equivalent and relevant industry experience
• Minimum of 6 years working in Pharmaceuticals, Lifesciences and Clinical Research with specific experience in managing releases of clinical document management, TMF and/or records & information management.
• Minimum 1 year of Veeva related hands on and provable experience in leading and planning of releases for Veeva and Internal business.
• Prior experience in Electronic Document Management systems, specifically in Clinical and Regulatory highly desired.
• Business relevant technical and working experience of eDMS systems like Veeva Clinical vault, RIM, Documentum D2LS or similar
• Knowledge of industrywide Electronic and Clinical Document Management systems and features
• Working knowledge of incident management and hyper care principles post releases
• Deep knowledge of Agile way of working with cross functional teams for releases
• 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.
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

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https://talentnetwork.novartis.com/network

Division
Development
Business Unit
Innovative Medicines
Location
Switzerland
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area

Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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