NOVARTIS

CSR Appendices Oversight Manager

Job ID
REQ-10027368
Nov 13, 2024
United Kingdom

About the Role

Major accountabilities:

- Responsible for efficient and appropriate management, coordination and oversight of CSR appendices for assigned studies to meet electronic publishing requirements, Health Authority guidelines, Good Clinical Practices and Novartis SOPs.
- Support implementation of the submission document readiness management strategy for clinical documents and clinical documents templates.
- Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
- Develop and maintain submission readiness processes, contribute to or drive initiatives to improve and innovate business and technical aspects of submission readiness activities, in collaboration with other CDGM groups, business and IT Functions.
- Collaborate with cross-functional stakeholders (e.g., Regulatory Writing & Submissions, Regulatory Affairs, Trial Management, etc.) on the planning, preparation, and delivery of high-quality documents within timelines, including expedited support for urgent requests to meet regulatory deadlines.
- Identify and communicate processing risks/trends/patterns related to CSR appendices and works with key stakeholders to define and implement appropriate remediations.
- Serves as Subject Matter Expert on CSR appendices training materials, formal and informal processes, and tracking tools for CSR appendices oversight activities in collaboration with CDM Process team and other key stakeholders.
- Provides Audit/Inspection support, contributes to root cause analysis identification and creation/delivery of CAPAs.

Minimum Requirements:

- Bachelor’s degree in life-sciences/healthcare/pharmacy/information management and relevant industry experience.
- English fluency (written, oral) required.
- Thorough knowledge of clinical document management processes
- Advanced knowledge of clinical documentation practice guidelines & principles (Good Documentation Practice, Data integrity, ICH eCTD and FDA Portable Document formatting specifications (PDF) guidance)
- Experience of authoring, compilation and formatting of CSR appendices according to ICH E3
- 3-5 years in clinical development/clinical operations or similar business area
- 2-3 years working experience with document management systems and excellent understanding of system structures and generic document management functionality

- Good understanding of technical processes and PC environment including Microsoft suite of products
- Advanced ability to work independently
- Experience with project work or project management in a global, cross- functional multicultural and international matrix organization
- Excellent communication, organization and tracking skills

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Ireland
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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