NOVARTIS

Clinical Operations Manager

Job ID
REQ-10074787
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Китай

Сводка

Provide operational and logistical support to clinical trials in Biomedical Research (BR) with focus on increased complexity and/or priority status. Perform defined responsibilities to support the Clinical Trial Team throughout the study lifecycle. May contribute to process improvements, cross-functional collaboration, and knowledge sharing.

About the Role

Key Responsibilities :

- Provides operational and logistical support to clinical trials in Biomedical Research (BR) with focus on increased complexity and/or priority status, in compliance with Novartis processes and Good Clinical Practice (GCP).
- Perform defined activities to support the Clinical Trial Team (CTT) throughout the study lifecycle, via study assignment and/or on-demand support.
- Maintain and share up to date knowledge of ICH-GCP, external regulations, and internal procedures. Continuously enhance expertise through training and practical application of Novartis Standard Operating Procedures (SOPs) and internal policies.
- Contribute to the finalization and management of clinical, regulatory and study-related documents in scope of role such as study protocols, patient-facing documents, etc., by ensuring documents are complete, accurate, and consistent.
- Contribute and/or maintain ownership of the management and finalization of clinical, regulatory, and study-related documents such as study protocols, patient-facing documents, Clinical Study Report (CSR) appendices, etc., by providing support to draft, review, and ensure completeness, accuracy, and consistency of these documents, as needed.
- Support and/or lead interactions and communications with relevant functions including Novartis country organizations to prepare, collect, and/or compile relevant documents, and timely follow-up on pending actions as necessary.
- Support and/or lead external communication such as newsletter development, external meeting organization.
- Contribute to and / or may oversee other study operations support activities (e.g. on-demand operations support, Trial Master File metrics).
- Ensure accuracy and completeness of clinical trial management databases, and trial related systems (e.g. Clinical Trial Management System, Novartis Connect), providing information, timely updates and inputs, and follow up on questions as necessary. Help check for or proactively identify discrepancies and take actions to correct as necessary.
- Identify, contribute and/or lead areas for process or technology improvements regarding activities undertaken within the role.
- Support and/or lead business logistics through the collection or collation of clinical trial supportive systems access and materials in scope of role (e.g. clinical trial application, end of trial, organizing external meetings, following up required signatures).
- Support and/or own onboarding and training others (associates, peers, new starters) by providing on-the-job guidance, training, demo, updates, etc. for assigned mentees or for the community.
- May function as Subject Matter Expert (SME) in the areas of expertise.
- May represent Study Operations in cross-functional and divisional initiatives and workstreams on area(s) of expertise (e.g. process SME).

Essential Requirements:

- A bachelor’s degree or equivalent qualification or work experience, preferably in life sciences or nursing.
- At least 2+ years’ experience in clinical trial/ development
- Adept organizational skills and quality mindset with attention to detail.
- Basic presentation skills and ability to mentor/ train small groups.
- Ability to work in a team as well as independently if required and to manage multiple priorities.
- Knowledge of GCP requirements.
- Office and clinical trial software, IT computer literacy.
- Fluent oral and written English

Desirable Requirements:

- Strong communicator with demonstrated interpersonal skills.
- Ability to successfully interact with a wide range of people, including global teams, different cultures, diverse experience backgrounds, etc.

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.
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Дивизион
Biomedical Research
Business Unit
Research
Место
Китай
Сайт
Shanghai (Shanghai)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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