NOVARTIS

Clinical Trial Associate

Job ID
REQ-10061713

9月 12, 2025

India

摘要

Designs and coordinates the overall direction of clinical development projects. Coordinates activities of associates and investigators to ensure compliance with protocol and overall pre-clinical objectives. Maintains a high level of professional expertise through familiarity with clinical literature and participates in project team meetings. May also travel to field sites to supervise and/or coordinate clinical studies. May be responsible for planning clinical trial registration and disclosure postings. May write protocols. -Administers the clinical trial results registration and disclosure process. Ensures compliance due dates and registration timelines are met. Collaborates with clinical trial study teams to compile data required for results disclosures. Maintains a working knowledge of the standard operating procedures for the website registry process. Develops content for internal training materials and job aids.

About the Role

Key Responsibilities

- Supports document collection, preparation, and adaption for submission to IRB/EC and Health Authorities as applicable
- Sets-up systems Supports vendor selection, TPRM process, SIM entries
- IF and TMF management (country and site TMF); set-up and maintenance according to regulatory and Novartis requirements; document oversight and tracking, supports Vendor set-up as applicable
- Checks site "Green Light" completeness and ensures all documentation is in place for initial and subsequent drug release in collaboration with the local Qualified Person(s)
- Supports preparation and translation of ICF into local languages (including vendor management if necessary), Supports preparation of patient facing material
- Responsible for completeness of uploaded trial related documents into CREDI/SUBWAY, including archiving of paper TMFs
- Supports country SSU strategy in close collaboration with SSU Team Lead and SSU Managers to ensure SSU timelines and deliverables are met according to country commitments
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements. Provides logistic support to SSU CRA, CRA, CPM, SSU Manager in all phases of the clinical trial, Implements innovative and efficient processes which are in line with Novartis strategy

Role requirements :

- Commercial or medical training (e.g., vocational qualification, bachelor ' s degree), Medical records administrator or equivalent education, preferably with experience in clinical operations.
- Ideally several years of working experience with 1+ years ´ of experience in clinical operations.
- Understanding of clinical drug development with particular emphasis on trial set-up, and contracting
- Profound knowledge of MS Excel, MS Word, MS PowerPoint, ideally knowledge in SAP.
- Understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards.
- Self-motivated, structured and committed way of working.
- Ability to prioritize and high coordination skills
- Demonstrated collaboration and communication skills.

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.

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.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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