NOVARTIS

Clinical Trial Associate

Job ID
REQ-10012616
Juil 31, 2024
Chine

Résumé

About the role: The Clinical Trial Associate (CTA) supports SSO Study Start-Up Manager and SSO Clinical Project Manager in assigned studies during set-up and whole study lifecycle in compliance with Novartis processes, GCP/ICH and regulatory requirements.

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

Essential Requirements:

- Commercial or medical training (e.g., vocational qualification, bachelor’s degree), Medical records administrator or equivalent education, preferably with experience in clinical operations
- Fluent in both written and spoken English, local language as needed
- 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
- Strong process and system understanding

Desirable Requirements:

- 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

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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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