Clinical Trial Associate (CTA)

Job ID
REQ-10015731
Juil 23, 2024
Inde

Résumé

100,000+ That’s how many patients participate in our clinical trials at any given time. GCO is Novartis’ powerhouse of Global Clinical Operations, redesigned to enable faster trial recruitment and enhanced trial delivery resulting in more timely access for patients to potential novel treatments. Every day, we are the link between science and medicine – imagine the impact you could have.

About the Role

Job Purpose:

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.

• 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.

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.

• Fluent in both written and spoken English, local language as needed.

Experience/Professional requirement:

• Ideally several years of working experience with 1+ year of experience in clinical operations
• Understanding of clinical drug development with particular emphasis on trial set-up and contracting
Competencies:

• 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
Skills & Knowledge:
• Strong process and system understanding
• 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

Commitment to Diversity & Inclusion: We are committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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