NOVARTIS

Study Start-Up Clinical Research Associate

Job ID
REQ-10053385
Jun 17, 2025
France

Summary

Surveille les données des patients et l'information liée aux études liées aux sites d'études cliniques et à la participation aux essais cliniques. S'assure que l'enquêteur adhère aux protocoles de recherche, aux exigences réglementaires et aux bonnes pratiques cliniques et donne son avis sur le plan de validation des données. Fournit une surveillance rapide et précise des données sur les patients et de l'information liée à l'étude à partir de documents sources, de dossiers de recherche et de visites sur place, le cas échéant. Surveiller, au besoin, les sites d'étude et la sélection des installations de vérification.

About the Role

Key responsibilities:

- Collaborates with SSO Study Start-Up Team (Manager, Team Lead, and global study team) to meet Study Start-Up timelines and deliverables per country commitments.
- Manages start-up activities at assigned sites from country allocation to Green Light, including site selection visits and eligibility verification.
- Acts as main contact for trial sites during site selection, start-up, and submission preparation for IRB/IEC and Health Authority approvals.
- Prepares, collects, and finalizes country and site-specific documents (e.g., ICFs, CVs, GCP certificates) and supports the reduction of site-specific IRB/IEC deficiencies.
- Supports vendor setup and negotiates financial contracts and investigator payments in coordination with the SSU Manager.
- Updates internal systems and ensures inspection readiness by maintaining timelines, accuracy, and quality of country and site TMF documents.
- Ensures adherence to ICH/GCP, regulatory requirements, and Novartis financial standards while implementing efficient and innovative processes.
- Prepares for audits and inspections and ensures sites are ready for "Green Light," submitting approvals to the SSU Manager for review and final authorization.

Essential requirements:

- A degree in scientific or health discipline, preferably with clinical operations experience (or, for United States: 4-year degree plus relevant, related healthcare experience)
- Minimum 3 years' experience in clinical operations in a monitoring / site management role
- Advanced understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable
- Strong site management capabilities with demonstrated negotiating and problem-solving skills

- Advanced 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
- Strong interpersonal, negotiation and conflict resolution skills
- Ability to travel, e.g., for site selections, if applicable

You'll receive:

- Attractive salary range
- An annual bonus
- A focus on your career development
- Access to our Quality of Life at work program
- Flexible working
- Advanced social coverage for you and your loved ones
- 27 days of paid leave & 14 days of RTT per year
- Various employee recognition programs

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

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

Division
Development
Business Unit
Universal Hierarchy Node
Location
France
Site
Field Non-Sales (France)
Company / Legal Entity
FR12 (FCRS = FR012) Novartis Pharma S.A.S.
Functional Area
Research & Development
Job Type
Full time
Employment Type
CDI
Shift Work
No

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