Study Start-Up Clinical Research Associate

Job ID
REQ-10053385

6月 17, 2025

France

摘要

Surveille les donn é es des patients et l ' information li é e aux é tudes li é es aux sites d ' é tudes cliniques à la participation aux essais cliniques. S ' assure que l ' enqu ê teur adh è re aux protocoles de recherche, aux exigences r é glementaires et aux bonnes pratiques cliniques et donne son avis sur le plan de validation des donn é es. Fournit une surveillance rapide et pr é cise des donn é es sur les patients et de l ' information li é e à l ' é tude à partir de documents sources, de dossiers de recherche et de visites sur place, le cas é ch é ant. Surveiller, au besoin, les sites d ' é tude et la s é lection des installations de v é rification.

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

部门
Development

Business Unit
Innovative Medicines

地点
France

站点
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

Apply to Job

Job ID
REQ-10053385

Study Start-Up Clinical Research Associate

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10053385-study-start-clinical-research-associate-fr-fr

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/fr-FR/NovartisCareers/job/Field-Non-Sales-France/Study-Start-Up-Clinical-Research-AssociateREQ-10053385-1
5. https://novartis.wd3.myworkdayjobs.com/fr-FR/NovartisCareers/job/Field-Non-Sales-France/Study-Start-Up-Clinical-Research-AssociateREQ-10053385-1