

Study Start-up Manager M/W

Job ID
REQ-10035803
fév 18, 2025
France

Résumé

~ Superviser la planification et la gestion stratégiques et opérationnelles du point de vue de l'exécution des essais cliniques. Supervision du budget et de l'allocation des ressources dans le cadre de l'essai assigné. Permet l'excellence opérationnelle grâce à l'amélioration des processus et au partage des connaissances entre les essais au sein du programme/de la franchise. Permet à une organisation autonome de naviguer dans un environnement matriciel et de s'adapter rapidement aux besoins de l'entreprise.

About the Role

Responsibilities:

Your responsibilities include, but are not limited to:

Study Start-Up Strategy

- Supports Study & Site Operations Country Leadership Team to identify innovative practices to optimize country operations and operational excellence, especially in terms of study start-up activities to increase performance, productivity, and business impact
- Seeks and evaluates external knowledge and best practices to enhance overall operational excellence of country trial operations
- Supports country SSU strategy in close collaboration with SSU/OPC Head and Portfolio Head/Portfolio Team Lead(s)

Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, SSO Portfolio Team Leads and global study team to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timelines, accuracy, and quality of TMF documents, including study start-up and ongoing TMF maintenance to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements

People and resource management

- Hiring, training, development, and retention of Study Start-Up associates
- Resource management and reporting of Study Start-Up associates

- Ensures associates have the required level of skills to successfully set-up and execute studies with high quality and according to business objectives

What you'll bring to the role:

- Minimum 5 years' experience in clinical operations and planning
- Proven leadership capabilities and experience
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Thorough 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

Desirable requirements:

A degree in scientific or health discipline required

Fluent in both written and spoken English and French

You'll receive:

- Salary range : 70 240€ -105 360€
- 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 embraces diversity, equal opportunity and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration, and empowers our people to unleash their full potential.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn 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>

Division

Development

Business Unit

Innovative Medicines

Emplacement

France

Site

Paris Headquarter (Novartis Pharma S.A.S.)

Company / Legal Entity

FR12 (FCRS = FR012) Novartis Pharma S.A.S.

Functional Area

Recherche & Développement

Job Type

Full time

Employment Type

CDI

Shift Work

No

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