

SSO Study Start-Up Manager

Job ID
REQ-10032410
Dec 20, 2024
Belgium

Summary

In your role as Study and Site operations (SSO) Study Start-Up Manager you will lead all Study Start-Up (SSU) activities of assigned projects in close collaboration with SSO Feasibility Manager, SSO SSU Team Leads as well as the global study team and are responsible for the coordination of the country start-up team. In Belgium you will act as back-up and deputy of the country manager.

About the Role

Key Responsibilities

- Support country SSU strategy in collaboration with key stakeholder and ensure timely start-up activities from country allocation until Green Light.
- Collaborate with local IRBs/IECs and Health Authorities as necessary and prepare IRB/IEC submission packages and review Informed Consent Forms.
- Coordinate timely responses to deficiency letters and reportable events and ensure quality and compliance of country Trial Master File documents in study start-up.
- Implement innovative and efficient processes in line with Novartis strategy and support study feasibility and lead site selection.
- Oversee local vendor performance and ensure "Green Light" readiness and achieve start-up timelines and quality execution.
- Lead local SSU team meetings and develop site initiation plans and collaborate with the global study team as required.

Essential Requirements:

- Degree in a scientific or health discipline preferred.
- Minimum 5 years of clinical trial operations experience.
- Strong project management and problem-solving skills.
- Understanding of international drug development process and regulations.
- Excellent communication and negotiation skills.
- Ability to work effectively in a matrixed environment.
- Fluent in written and spoken English, local language as needed.

You'll receive:

You'll have countless opportunities to develop, whether it's up, across or outside your comfort zone. We offer you a challenging, international, interdisciplinary and enjoyable work environment. Investment in people is a

priority for Novartis including your well-being. We offer a range of possibilities for personal development and career opportunities within a network of bright and curious minds. We offer you a competitive salary and benefit package.

Why Novartis?

Improving the lives of people living with disease takes more than innovative science. It takes a focus on the needs of people and a community committed to meeting them. It takes a team of people like you. Working together. Learning together. Thriving together. As part of our around 1800 employees in Belgium and Luxembourg, you can be part of an amazing team changing people's lives. Together, we are reimagining medicine. Join us in extending and improving people's lives.

Learn more here and discover some of the stories of who might become one of your future colleagues:
<https://www.novartis.com/be-nl/jobs> & <https://www.novartis.com/be-fr/emploi>

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:
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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

Location

Belgium

Site

Vilvoorde

Company / Legal Entity

BE03 (FCRS = BE003) Novartis Pharma nv-sa

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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