

SSO Study Start-Up Team Lead

Job ID
REQ-10034117
Jan 10, 2025
Spain

Summary

~ Supervisa la planificación y gestión estratégica y operativa desde la perspectiva de la ejecución de ensayos clínicos. Supervisión del presupuesto y la asignación de recursos dentro del ensayo asignado. Permite la excelencia operativa a través de la mejora de procesos y el intercambio de conocimientos entre los ensayos dentro del programa/franquicia. Permite una organización empoderada que puede navegar en un entorno matricial y ajustarse rápidamente a las necesidades del negocio.

About the Role

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The SSU Team Lead ensures that processes and goals are met and actively drives innovation and simplification processes while also playing a crucial people management role by mentoring and developing the SSUM team, fostering a culture of excellence and accountability.

Your responsibilities include, but are not limited to:

Study Start-Up Strategy

- Supports 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.
- Supports country SSU strategy in close collaboration with SSU Head and Portfolio Head/Portfolio Team Lead(s)
- Responsible for timely start-up activities from country allocation until site Green Light (ready-to-initiate-sites)
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable

Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial Lead, SSU Lead) 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
- Implements innovative and efficient processes which are in line with Novartis strategy

People and resource management

- Hiring, training, development, and retention of SSU Managers
- Resource management and reporting of SSU Managers
- Ensures associates have the required level of skills to successfully set-up and execute studies with high quality and according to business objectives
- Manages and oversees productivity targets per defined objectives, and serves as an escalation point for Study Start-Up functions
- Interfaces with global trial execution organization through Global SSU managers for all portfolio deliverables.

Experience/Professional requirement:

- Minimum 5 years' experience in clinical operations and planning
- Proven leadership capabilities and experience (with or without direct line management responsibilities).
- 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

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>

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Division

Development

Business Unit

Innovative Medicines

Location

Spain

Site

Barcelona Gran Vía

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Alternative Location 1

Madrid Delegación, Spain

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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