Study Start-up Team Lead

Job ID
REQ-10034092
Ene 17, 2025
Italia

Resumen

The Study Start-up Team Lead (SSU Team Lead) is accountable for the governance and oversight of a country study start-up managers team.
We are seeking a dynamic and experienced SSO Study Start-Up Team Lead to join our passionate team. This pivotal position reports directly into the Study Start Up (SSU) Country Head and is responsible to lead, mentor and provide governance to the Study Start-Up Managers (SSUM) team, crucial to the success of our clinical trials. In fact, SSUMs lead the local Study Start-Up teams for assigned trials and they hold significant responsibilities within our organization, spanning from trial and budget planning to ensuring timely completion of trial start-up activities up to the site ready to screen stage.
As SSO Study Start Up Team Lead, you will therefore play a critical role in guaranteeing that all trial start-up timelines and results are met according to our country commitments. You will be key in shaping the country SSU strategy and prioritization in close collaboration with the SSU Country Head and SSU leadership team, to deliver operational excellence in compliance with Novartis processes, ICH/GCP and regulatory requirements. You will be also a member of the Italian SSO extended Leadership Team.

About the Role

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 Study & Site Operations SSU 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 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)
- Monitoring and optimization of processes within the respective area of responsibility

Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, SSO Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial 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 clinical data standards, financial standards, applicable laws, ICH/GCP, ethics committees, Health Authority and SOP requirements as well as the necessary training plans
- Implements innovative and efficient processes which are in line with Novartis strategy

People and resource management

- Leadership, development and coaching of SSU managers
- Resource management and reporting of SSU Managers

Key Performance Indicators

Supervises the strategic and operational planning/management from the perspective of clinical trial execution. Oversight of the budget and the allocation of resources within the assigned trial. Enables operational excellence through process improvement and knowledge sharing among trials within the program/franchise. Empowers an enhanced organization to navigate a matrix environment and quickly adapt to business needs.

Background:

• A degree in scientific or Health discipline required

• Fluent in both written and spoken English.

• Deep knowledge of the clinical trial regulation, international standards (GCP), health authorities (FDA/EMA), EU-CTR requirements and country environment.

• Minimum of 5 years of experience in clinical research and/or project management with demonstrated team management and leadership skills.

• At least 4 years of personnel management experience.

• Understanding of all aspects of clinical drug development with a particular emphasis on start-up

Skills:

Project Management: Proficiency in managing multiple projects simultaneously; skilled in developing and implementing start-up plans and timelines.

Problem Solving and Decision Making: Strong analytical and problem-solving skills, capability to make informed decisions efficiently under pressure.

Regulatory Knowledge: In-depth understanding of ICH/GCP guidelines and regulatory requirements. Familiarity with Novartis processes (or other relevant industry frameworks).

Collaboration and Teamwork: Ability to work collaboratively with cross-functional teams and country leadership, Strong interpersonal skills to build and maintain effective working relationships.

Leadership Skills: Strong ability to lead, mentor, and develop a high-performing team, proven experience in

managing and motivating employees to achieve set objectives.

Commitment to Diversity and 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

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