NOVARTIS

Study Start-Up Senior Lead

Job ID
REQ-10054679
Jun 13, 2025
Ireland

Summary

The Study Start-Up (SSU) Senior Lead independently leads the planning and execution of global SSU activities for multiple medium to complex global studies of high priority to ensure timely trial document and task completion to enable country HA (Health Authorities) and Ethics Committee submissions and site activation to meet ambitious recruitment plans. The Study Start-Up Senior Lead works collaboratively with other key CTT members and leads the SSU Team (CTT sub-team / 20+ members across multiple countries) comprised of the country SSU Management, Vendor Management, Regulatory, Grants and Contracts, Translations, Document Management, Clinical Supplies, and others as needed to accelerate study, country, and site activation.

About the Role

Key responsibilities:

- Responsible for all SSU activities for medium to highly complex high-priority studies, including independent decision-making and strategy development.
- Develops SSU strategies and aligns plans with trial OEP to ensure timely milestones and successful execution across countries and sites.
- Oversees trial-specific setup of SSU systems (e.g., eTMF, CTMS, site contracting tools, vendor management, ICF templates, translations, etc.).
- Ensures readiness of global trial documents, activates protocol amendments, and oversees country implementation for HA and Ethics Committee submissions.
- Guides Vendor Program Manager (VPM) and collaborates with GCS to ensure vendor activation and clinical supply readiness for site activation timelines.
- Leads SSU Teams, coaches country SSU Managers, and ensures effective execution and adherence to process standards across global and country levels.
- Provides oversight, drives risk management, ensures TMF inspection readiness, and maintains compliance with Novartis standards and regulations.
- Drives training, compliance, SOP/WP reviews, and contributes as SME for initiatives, potentially acting as SSU Director deputy and mentoring team members.

Essential requirements:

- Advanced degree preferred or Bachelor’s degree with equivalent experience in scientific or health disciplines.
- Fluent English, oral and written.
- Minimum 6 years in project management roles overseeing and/or monitoring clinical trials.
- At least 3 years of experience contributing to planning, execution, reporting, and publishing clinical trials in global or matrixed environments.

- Proven ability to engage and lead multidisciplinary teams across diverse functions and backgrounds in complex matrix organizations.
- Extensive experience in leading and managing multidisciplinary teams in global, matrixed environments.
- Demonstrated expertise in overseeing the end-to-end clinical trial process, ensuring timelines and standards are met.
- Strong track record of managing complexity and driving collaboration across dispersed organizations.

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
Ireland
Site
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
London (The Westworks), United Kingdom
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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