NOVARTIS

Study Start Up Senior Lead

Job ID
REQ-10073545
мар 19, 2026
Ирландия

Сводка

LOCATION: Westworks London or Dublin: Please apply only if either of these locations are accessible to you, as relocation support is not available.

#LI-Hybrid Hybrid (12 days per month on-site if living within 50 miles of our London office)

#LI-Remote Remote UK Only (if living beyond 50 miles of our London office)

About the role:
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

Your Key Responsibilities:

- Responsible for independent delivery of all Study Start-Up (SSU) activities for medium to highly complex high priority global studies.
- Full responsibility to independently deliver SSU insights to the development of the trial Operational Execution Plan (OEP) and aligns the SSU plan and strategy accordingly as reflected in SSU systems, milestones and dashboards with Study Leader /Clinical Trial Team (CTT).
- Autonomously strategizes global SSU planning and leads SSU Team (CTT sub-team) from kick-off through completion of SSU (all countries and 95% sites enrolling or as defined per trial)
- Implements global aspects of protocol and OEP amendments, activates and oversees country implementation of amendments as determined per trial and in conjunction with Study Leader.
- Responsible for global trial level document readiness (including vendor and IMP (INVESTIGATIONAL MEDICINAL PRODUCT) and collection into eTMF as necessary for country health authority and Ethics Committee submission and site activation
- Drives transparency of timelines of global SSU deliverables with SSU Managers to ensure country alignment and efficiency
- Ensure proactive oversight and risk management for SSU team activities to achieve start-up timelines and quality execution, proposing and implementing corrective actions where appropriate, according to Novartis standards and local and international regulations
- Coaches the country Study Start-up Managers to drive timely start-up activities from country allocation to “Ready to Enroll” within assigned medium to complex trials
- Provides oversight and support to country Study Start-up Managers as needed to ensure that study start-up activities are conducted and completed to plan, including set-up and usage of tools/systems, timely delivery of SSU deliverables (e.g. IRB/IEC submission packages, Informed Consent review, local submission package for submission to IRB/IEC, CTA (Clinical Trial Application) Hub (Europe: acc. to new EU-CTR) as well as Health Authorities and adherence to process standards.
- Guides the VPM as needed to ensure global vendor activation and site readiness in collaboration with to meet site activation timelines/plan.
- Key contributor and/or Key SME for initiatives or workstreams. May work as Study Start-Up Director deputy to lead SSU community and may provide mentorship/coaching to team member.

Role Requirements:
Essential Requirements:

- A degree in scientific or health discipline required and an advanced degree with clinical trial experience and/or project management, is preferable
- Fluent English, spoken and written
- Extensive experience in project management, in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization
- Proven ability to effectively engage and lead associates from varying backgrounds and functions within dispersed and highly matrixed organizations
- Comprehensive experience in leading multidisciplinary teams in a complex matrix environment

Why Novartis:
Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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.

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis

Network here: https://talentnetwork.novartis.com/network

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Ирландия
Сайт
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
London (The Westworks), Великобритания
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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List of links present in page

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2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
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