NOVARTIS

Senior Study Start Up Lead

Job ID
REQ-10003476
Apr 26, 2024
USA

Summary

About the role:
The Study Start-Up (SSU) Lead plans and drives global SSU activities 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 Lead works collaboratively with other key Clinical Trial Team (CTT) members and leads the SSU Team (CTT sub-team) 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.
Key Responsibilities:
• Contributes 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
• Configures and ensures proper trial-specific set-up of SSU systems (e.g., Expected Document Lists, electronic Trial Master File (eTMF), milestones, tasks, personnel, vendors, languages/translations, confirmed and back-up countries, CTMS (Clinical Trial Management System), enrolment plan, vendor management tool, site contracting and budgeting tool, ICF (Informed Consent Form) template tool, etc.)
• Ensures timely collection 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
• Ensures Protocol and ICF global trial template is ready for country usage as necessary including translations
• Global accountability of timelines, accuracy, and quality of global TMF (Trial Master File) documents in study start-up to ensure TMF inspection readiness
• Provide 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
• Collaborates with GCS (Global Clinical Supply) to ensure coordination and readiness of global clinical supply
• Enables country Study Start-up Managers to drive timely start-up activities from country allocation to “Ready to Enrol” within assigned trial

About the Role

• A degree in scientific or health discipline required and an advanced degree with clinical trial experience and/or project management

• Fluent English, oral and written

• Experience 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, implementing, 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.

• Excellent communication, influencing and negotiating skills

• Good knowledge of Good Clinical Practice, clinical trial set-up design and global drug development process

• Data and Digital expertise. Experience working with electronic databases, clinical and/or project management planning and reporting and analytics systems

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

You'll receive
You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $158,400-237,600/year; *however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.* The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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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Site
East Hanover
Company / Legal Entity
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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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EEO Statement :

Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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