NOVARTIS

Study Start-Up Manager (Remote)

Job ID
REQ-10040451

2月 19, 2025

USA

摘要

Multiple Listings

The Study Start-Up (SSU) Manager is accountable for study planning, SSU activities and activation deliverables of assigned projects in compliance with Novartis processes, GCP/ICH and regulatory requirements in a standalone country. Leads all SSU activities of assigned projects in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team.

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require 10% travel

#LI-Remote

About the Role

Your Key Responsibilities:

- Supports country SSU strategy in close collaboration with relevant stakeholder to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until Green Light (ready to initiate site millstone) in assigned projects
- Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/IEC submission packages, review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for Health Authorities submissions, as required
- Coordinates reportable events and notifications to IRB/IEC and Health Authorities as applicable
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- Implements innovative and efficient processes which are in line with Novartis strategy
- Supports study feasibility in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team.
- Leads site selection in collaboration with Portfolio Team Lead and Clinical Project Manager if already assigned
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and local and international regulations
- Leads/chairs local SSU team meetings in assigned studies, participates in global study team meetings, as required
- Leads the development of country site initiation and patient enrolment plans together with SSU CRA, CPM and SSU Lead

Role Requirements:

- BS/BA Degree. Degree in scientific or healthcare discipline preferred
- Minimum 5+ years ' experience in clinical operations. A role that oversees (project management) and/or monitoring clinical trials experience preferred
- Capable of leading in a matrix environment, without direct reports
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Strong project management capabilities with demonstrated ability to problem solve and mediate complex issues
- 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
- Strong interpersonal, negotiation and conflict resolution skills
- Communicates effectively in a local/global matrixed environment

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $114,100 and $211,900/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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 factor

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential

functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Innovative Medicines

地点
USA

状态
Remote, US

站点
Remote Position (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Job ID
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