Study Start-Up Director

Job ID
REQ-10038674

2月 24, 2025

USA

摘要

In this vital role, the Study Start-Up (SSU) Director plans and executes global SSU activities to ensure timely trial document and task completion to enable country HA (Health Authority) submission and site activation to meet ambitious recruitment plans. The Study Start-Up Director works collaboratively with other key CTT members and leads the SSU delivery sub-team of the CTT, 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. In addition, the SSU Director may take on additional line management responsibilities leading a community of practice for 8-10 SSU Leads, supporting associate development, training, culture building, resourcing and performance management tasks or other key initiatives.
Don ' t miss out on the chance to join this growing and influential team at Novartis!

About the Role

Position Location: The ideal location for this role is the East Hanover, NJ site, but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to East Hanover, NJ site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

Your Key Responsibilities:

SSU Community Leadership:

- Contributes to SSU culture building and ways of working by leading a community of 8-10 SSU Leads that share lessons learned and leading practices
- Fosters associate development, training, and performance management
- Contributes across the SSU function to promote continuous learning and improving mindset

Early Planning and Team Leadership:

- Aligns the SSU plan and strategy accordingly as reflected in SSU systems, milestones, and dashboards with Study Leader/Clinical Trial Team (CTT).
- Configures and ensures proper trial-specific set-up of SSU systems (e.g., Expected Document Lists, eTMF, milestones, tasks, personnel, vendors, languages/translations, confirmed and back-up countries, CTMS, enrollment plan, vendor management tool, site contracting and budgeting tool, ICF template tool, etc.)
- Prepares 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)

Leads Global SSU Activation:

- Manages critical path to ensure timely collection of trial level document readiness (including vendor and IMP) into eTMF as necessary for country health authority submission and site activation
- Supports the Vendor Project Manager (VPM) as needed to ensure timely global vendor activation and HA submission documents
- Ensures Protocol and ICF (Informed Consent Form) global trial template is ready for country usage as necessary including translations

Essential Requirements:

- A bachelor's degree in scientific or health discipline required and with clinical trial experience and/or project management, is preferable
- Minimum 7 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Minimum 3 years of people management experience in some aspect of conducting clinical trials 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
- Demonstrated effective influencing and negotiation skills at all levels.
- Data and Digital expertise. Experience working with electronic databases, clinical and/or project management planning and reporting and analytics systems
- Proven record of accomplishment in process improvement

- Data and timeline driven, Willingness and ability to champion the use of new technology

Preferred Qualifications:

- An advanced degree in scientific or health discipline

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: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion / EEO: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $204,600 to $379,400/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 factors.

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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:

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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.

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Development

Business Unit
Innovative Medicines

地点
USA

状态
New Jersey

站点
East Hanover

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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