NOVARTIS

Study Start-Up Director

Job ID
REQ-10038103

2月 24, 2025

United Kingdom

摘要

This role can be based at either our London, England, Dublin, Ireland or Basel, Switzerland sites.

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

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

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 & Inclusion: 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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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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部门
Development

Business Unit
Universal Hierarchy Node

地点

United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Basel (City), Switzerland

Alternative Location 2
Dublin (NOCC), Ireland

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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