Study Start-Up Lead

Job ID
REQ-10058889

9月 16, 2025

Switzerland

摘要

The Study Start-Up (SSU) Lead plans and executes 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 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.

About the Role

Key responsibilities:

- Contributes SSU (Study Start-Up) insights to the Operational Execution Plan (OEP) and

aligns the SSU strategy, systems, milestones, and dashboards with the Study Leader and Clinical Trial Team (CTT).
- Ensures correct trial-specific configuration of SSU systems (e.g., eTMF, CTMS, vendor tools, budget/contract management tools, translations, ICF templates) to support trial operations effectively.
- Prepares and leads the global SSU planning process and the SSU team (as a sub-team of the CTT) from kick-off through the completion of the SSU phase across all countries and sites.
- Oversees global protocol/OEP amendments and document readiness (including vendor and IMP documentation) to ensure timely submission to health authorities and site activations.
- Supports the Vendor Program Manager (VPM) for timely global vendor activation and coordinates investigator grant plans, budget finalization, and contract template readiness in line with protocol timelines.
- Drives transparency for SSU deliverable timelines, ensures TMF document quality for inspection readiness, and manages risks with corrective actions to maintain startup timelines and quality.
- Enables country SSU managers to execute start-up activities efficiently and provides oversight to ensure adherence to processes, timely submissions, and the use of tools/systems for site readiness.
- Works with Global Clinical Supply (GCS) for clinical supply readiness, ensures proper handoff to other roles, and supports final global SSU deliverables for site initiation readiness and initial drug release.

Essential Requirements

- Minimum 2 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Minimum 1 years of 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.
- 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
- Data and timeline driven, Willingness and ability to champion the use of new technology

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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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