Study Start Up Senior Lead (Associate Director)

Job ID
REQ-10019651
Nov 13, 2024
Irlanda

Sommario

The Study Start-Up (SSU) Senior Lead independently leads the planning and execution of global SSU activities for multiple medium to complex global studies of high priority 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 Senior Lead works collaboratively with other key CTT members and leads the SSU Team (CTT sub-team / 20+ members across multiple countries) 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.
No direct reports, matrix team leader.

We offering Hybrid Contract (office based) . This means that associates will be expected to work from our London or Dublin offices for 9 – 12 days per month.

About the Role

Major accountabilities:

- Responsible for all Study Start-Up (SSU) activities for medium to highly complex high priority studies.
- Full responsibility to independently deliver 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 (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 (Clinical Trial Management System), enrollment plan, vendor management tool, site contracting and budgeting tool, ICF template tool, etc.)
- Autonomously strategizes 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:

- Responsible for 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
- Global accountability of timelines, accuracy, and quality of global TMF (Trial Master File) documents in study start-up to ensure TMF inspection readiness

Accountable for country SSU:

- Coaches the country Study Start-up Managers to drive timely start-up activities from country allocation to “Ready to Enroll” within assigned medium to complex trials
- Provides oversight and support to country Study Start-up Managers as needed to ensure that study start-up activities are conducted and completed to plan, including set-up and usage of tools/systems, timely delivery of SSU deliverables (e.g. IRB/IEC submission packages, Informed Consent review, local submission package for submission to IRB/IEC, CTA (Clinical Trial Application) Hub (Europe: acc. to new EU-CTR) as well as Health Authorities and adherence to process standards.
- Guides the VPM as needed to ensure global vendor activation and site readiness in collaboration with to meet site activation timelines/plan.
- Ensure global deliverables to enable site initiation readiness is in place for initial drug release

Experience/Professional requirements:

- A degree in scientific or health discipline required and an advanced degree with clinical trial experience and/or project management, is preferable
- Minimum 6 years' experience in project management, in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Minimum 3 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
- Fluent English, spoken and written

Leadership Capabilities

- Proven ability and strong experience in leading multidisciplinary teams in a complex matrix environment (including remote or virtual team environments)
- High learning agility championing new technology platforms
- Strong problem solving, negotiation, deadline driven and conflict resolution skills

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Innovative Medicines
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Sito
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
Hyderabad (Office), India
Alternative Location 2
London (The Westworks), Regno Unito
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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