Study Start Up Senior Lead (Assoc Dir)

Job ID
REQ-10038073
fév 14, 2025
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

The Study Start-Up 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 Health Authorities and Ethics Committee submissions and site activation to meet ambitious recruitment plans. This key and influential role works collaboratively with other key team members and leads the Study Start-Up 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:

Early Planning and Team Leadership:

• Responsible for all Study Start-Up (SSU) activities for medium to highly complex high priority studies.

• Undertake decisions for all study start-up activities.

• 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).

• Configure and ensure 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.)

Lead 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 • Guides the Vendor Program Manager (VPM) as needed to ensure timely global vendor activation and HA submission documents

• Ensure Protocol and ICF (Informed Consent Form) global trial template is ready for country usage as necessary including translations

• Drive transparency of timelines of global SSU deliverables with SSU Managers to ensure country alignment and efficiency

• Direct the Study Grants Expert for investigator grant plan/fair market value assessment initiation and finalization of country site budget and contract template readiness in conjunction with protocol timelines • Global accountability of timelines, accuracy, and quality of global TMF (Trial Master File) documents in study start-up to ensure TMF inspection readiness • Ensure proactive oversight and risk management for SSU team activities to achieve start-up timelines and quality execution, proposing and implementing corrective actions where appropriate, according to Novartis standards and local and international regulations • Collaborates with GCS (Global Clinical Supply) to ensure coordination and readiness of global clinical supply

Accountable for country SSU:

• Coach 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.

Essential Requirements:

• Bachelor’s degree in scientific or health discipline

• Fluent English, spoken and written

• 6 years' experience in project management, in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials

• 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

• Proven ability to effectively engage and lead associates from varying backgrounds and functions within dispersed and highly matrixed organizations

• Comprehensive experience in leading multidisciplinary teams in a complex matrix environment

• Demonstrated leadership driving high performing teams involving complex stakeholder management

• Excellent communication, influencing and negotiating skills

• Good knowledge of Good Clinical Practice, clinical trial set-up design and global drug development process

Desirable Qualifications:

Advanced degree in scientific or health discipline

Clinical trial and/or project management experience

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Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Basel (City), Suisse
Alternative Location 2
Dublin (NOCC), Irlande
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
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