NOVARTIS

Study Start-up Lead

Job ID
REQ-10048363

Apr 21, 2025

Ireland

Summary

Onsite - Dublin, Ireland or London, England
2 openings

In this influential role, the Study Start-Up (SSU) Lead will use their relevant experience to plan and execute 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. In addition, this key role 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.

If you love Study Start-up, don ’ t miss out on this fantastic opportunity!

About the Role

Key Responsibilities:

Early Planning and Team Leadership:

- Contributes 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.)

- 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)

- Implements global aspects of protocol and OEP amendments, activates and oversees country implementation of amendments as determined per trial and in conjunction with Study Leader.

Lead Global SSU Activation:

- Ensures timely collection 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

- Supports the Vendor Program 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

- Drives transparency of timelines of global SSU deliverables with SSU Managers to ensure country alignment and efficiency

- 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:

- Enables country Study Start-up Managers to drive timely start-up activities from country allocation to "Ready to Enroll" within assigned trial

Essential Requirements:

- Bachelor's degree in scientific or health discipline required
- 2 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- 1 year of experience contributing to and proven success 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; ability to champion the use of new technology

Preferred Qualifications:

- Advanced degree with clinical trial experience and/or project management

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部門
Development

部門
Innovative Medicines

国
Ireland

勤務地
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
London (The Westworks), United Kingdom

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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