NOVARTIS

Study Start-Up Lead

Job ID
REQ-10054676
Jun 13, 2025
Ireland

Summary

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:

- Integrates SSU insights into the trial Operational Execution Plan (OEP), ensuring alignment with milestones and dashboards alongside the Study Leader/CTT.
- Oversees trial-specific setup of SSU systems, including tasks, personnel, vendors, translations, site contracting tools, and templates (e.g., ICF, enrollment plans). Prepares SSU planning and leads the SSU Team from kick-off through completion for global site enrollment, adhering to timelines and trial requirements.
- Ensures timely collection of global trial-level documents for submission and eTMF entry, supporting health authority and Ethics Committee approvals.
- Collaborates with Vendor Program Manager and GCS to ensure vendor activation, site readiness, and clinical supply alignment for site initiation.
- Provides proactive oversight, managing risks to ensure quality SSU execution and adherence to timelines/regulations, implementing corrective actions if required.
- Ensures the proper use of technology platforms, completeness of data, and alignment of global budgets/processes to support SSU activities and timelines. Enables and oversees country Study Start-up Managers to ensure local submission package readiness, IRB/IEC approvals, and timely delivery of SSU deliverables.

Essential requirements:

- Degree in scientific or health discipline required; advanced degree with clinical trial and/or project management experience preferred.
- Fluent English, spoken and written.
- Minimum 2 years overseeing and/or monitoring clinical trials, plus 1 year contributing to their planning, execution, and reporting. Proven ability to engage and lead diverse teams in a global, matrixed environment.

- Excellent influencing, communication, and negotiation abilities at all organizational levels.
- Strong understanding of Good Clinical Practice, clinical trial design, and global drug development processes.
- Experience with electronic systems, clinical/project management analytics, and willingness to embrace new technologies.
- Data-driven mindset and dedication to meeting deadlines effectively.

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Division
Development
Business Unit
Innovative Medicines
Location
Ireland
Site
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
London (The Westworks), United Kingdom
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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