

Study Start Up Senior Lead (Associate Director)

Job ID
REQ-10019651
Nov 13, 2024
Ireland

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

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

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Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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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

India

Alternative Location 2

United Kingdom

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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