

Study Start-Up Lead

Job ID
REQ-10038093
Feb 01, 2025
USA

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

Internal Job Title: Study Start-Up Lead (Level 4/GJFA 5)

Position Location: The ideal location for this role is the East Hanover, NJ site, but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to East Hanover, NJ site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

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.

Roles and 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.

Leads 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
- Directs 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
- Provide 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
- Ensures proper hand-off of activities applicable to the Study Leader and other roles as necessary
- Ensures the use and date completeness/accuracy of applicable technology platforms during SSU

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
- 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.
- Supports 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
- Ensures global and country budget (TCF (Trial Commitment Forms)) processes and approvals support SSU activities and timelines

Minimum Requirements:

- A degree in scientific or health discipline, with a preference for an advanced degree with clinical trial and/or project management experience
- Minimum 2 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Minimum 1 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.
- Excellent English 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, Willingness and ability to champion the use of new technology

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$114,100 to \$211,900/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

Development

Business Unit

Innovative Medicines

Location

USA

State

New Jersey

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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