NOVARTIS

Study Start-Up Lead

Job ID
REQ-10026534
Oct 22, 2024
China

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.

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

Essential Requirements:

- Advanced degree or combination Bachelor’s Degree with equivalent experience
- Fluent English, oral and written
- 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

Desirable Requirements:

- Strong financial and business economics background
- Strong process and system understanding
- Independent, dynamic, structured and committed way of working

Communicates effectively in a local/global matrixed environment

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

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Accessibility and Accommodation:

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to

diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
China
Site
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
China
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID

REQ-10026534

Study Start-Up Lead

Apply to Job

Source URL: *https://jobapi.novartis.com/req-10026534-study-start-lead*

List of links present in page

1. https://jobapi.novartis.com/req-10026534-study-start-lead
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
4. mailto:diversityandincl.china@novartis.com
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/about/strategy/people-and-culture
7. https://talentnetwork.novartis.com/network
8. https://www.novartis.com/careers/benefits-rewards
9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Shanghai-Shanghai/Study-Start-Up-Lead_REQ-10026534-1
10. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Shanghai-Shanghai/Study-Start-Up-Lead_REQ-10026534-1