

Global Clinical Operations- Study Start-Up Manager

Job ID
REQ-10074886
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Китай

Сводка

The SSO Study Start-Up Manager is accountable for study planning, SSU activities and activation deliverables of assigned projects in compliance with Novartis processes, GCP/ICH and regulatory requirements in a standalone country, OPC (operating country) or satellite country. Leads all SSU activities of assigned projects in close collaboration with SSO Feasibility Manager and SSO Site Partnership Manager as well as the global study team. In satellite countries acts as primary back-up and deputy of the country manager.

About the Role

Key responsibilities:

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Country Head Portfolio / SSO Cluster Head Portfolio
- Collaborates with SSO Country / Cluster Head Portfolio, SSO Portfolio Team Leads and global study team to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until Green Light (ready to initiate site milestone) in assigned projects
- Ensures close collaboration with local IRBs/IECs and Health Authorities, as applicable
- Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/IEC submission packages, review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for Health Authorities submissions, as required
- Prepares and finalizes local submission package for submission to IRB/IEC, CTA Hub (Europe: acc. to new EU-CTR) as well as Health Authorities as applicable (including subsequent amendments, IBs, DSURs, CSRs)
- Coordinates timely response to deficiency letters in close collaboration with local and global stakeholders
- Coordinates reportable events and notifications to IRB/IEC and Health Authorities as applicable
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy
- Supports study feasibility in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team.
- Leads site selection in collaboration with Portfolio Team Lead and Clinical Project Manager if already assigned
- In satellite countries oversees local vendor selection and performance as needed. Serves as main contact for quality/compliance issues in SSU phase, escalating as necessary
- Ensures sites are prepared for "Green Light" and ensures all documentation is in place for initial and subsequent drug release. Responsible for review and sign off of the site "Green Light"
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and local and international regulations
- Leads/chairs local SSU team meetings in assigned studies, participates in global study team meetings, as required
- Leads the development of country site initiation and patient enrolment plans together with SSU CRA, CPM and SSU Lead

Essential requirements:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable
- Fluent in both written and spoken English, local language as needed
- Minimum 5 years' experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring

Desirable requirements:

- Strong project management capabilities with demonstrated ability to problem solve and mediate complex issues
- Thorough understanding of the international aspects of drug development process, including strong knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Strong interpersonal, negotiation and conflict resolution skills
- 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>

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Дивизион
Development
Business Unit
Development
Место
Китай
Сайт

Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
Beijing (Beijing), Китай
Alternative Location 2
Guangzhou (Guangdong Province), Китай
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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

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.

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