NOVARTIS

Senior Study Start-up CRA

Job ID
REQ-10080833
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Сингапур
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Сводка

-Monitors patient data & study-related information related to clinical study sites and clinical trial participation.. Ensures the investigator adheres to The Senior Study Start-Up Clinical Research Associate (SSU CRA) is responsible for leading and executing site start-up activities for assigned clinical trials (Phase I–IV), ensuring timely site activation (“Green Light”) in compliance with ICH/GCP, local regulations, and company SOPs.
This role serves as the primary site-facing contact during feasibility, site selection, and start-up, driving proactive site preparation, early issue identification, and risk mitigation to ensure smooth transition to study execution. The senior SSU CRA is expected to act as Subject Matter Expert (SME) for start-up processes, assigned to complex trials, less experienced sites, or partner sites and drives process improvements and supports strategic SSU initiatives.

About the Role

Key Responsibilities

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Collaborates with SSO Study Start-Up Manager, SSO Study Start-Up Team Lead and global study team to ensure Study Start-Up timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until site greenlight at assigned Sites. Conducts site selection visits, verifies site eligibility for a specific study
- Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission. Preparation. Ensures that milestones (KPIs) and time schedule for study start-up are met as planned
- Supports SSU Manager in preparation of country-specific documents, e.g., ICF, patient facing materials, etc. Supports SSO Study Start-Up Manager and assigned sites in vendor set-up activities
- Ensures timelines, accuracy, and quality of country and site 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

Essential Requirements:

- Minimum 3 years of study start-up experience or other relevant experience
- Able to independently manage end-to-end start-up activities from site allocation to Green Light with minimal supervision.
- Consistently delivers site activation milestones (e.g., HA/IRB approvals, SIV readiness) in line with committed timelines.
- Acts as primary contact for sites and effectively manages investigators, site staff, and vendors to drive progress.
  Capable of handling complex studies, new indications, or less experienced sites with proactive issue resolution.
- Proactively identifies risks, site needs, and potential delays and implements mitigation strategies early. Demonstrates strong working knowledge of ICH/GCP, local regulations, and ensures all activities are compliant and inspection ready.
- Ensures accuracy, completeness, and audit-readiness of regulatory documents and TMF throughout start-up.
  Works effectively with SSU Managers, global study teams, and CRAs to ensure seamless handover and
  Contributes as a subject matter resource, supports process improvement, or mentors/trains others where needed

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: Learn about all the ways we’ll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Сингапур
Сайт
Mapletree Business City (MBC)
Company / Legal Entity
SG04 (FCRS = SG004) Novartis Singapore Pte Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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