

SSU Manager

Job ID REQ-10028599

11月 08, 2024

Germany

摘要

The SSO Study Start-Up Manager is accountable for study planning, study start-up 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.

Hybrid working (12 days per month in the office)

#LI Hybrid #LI-HYBRID

About the Role

- 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

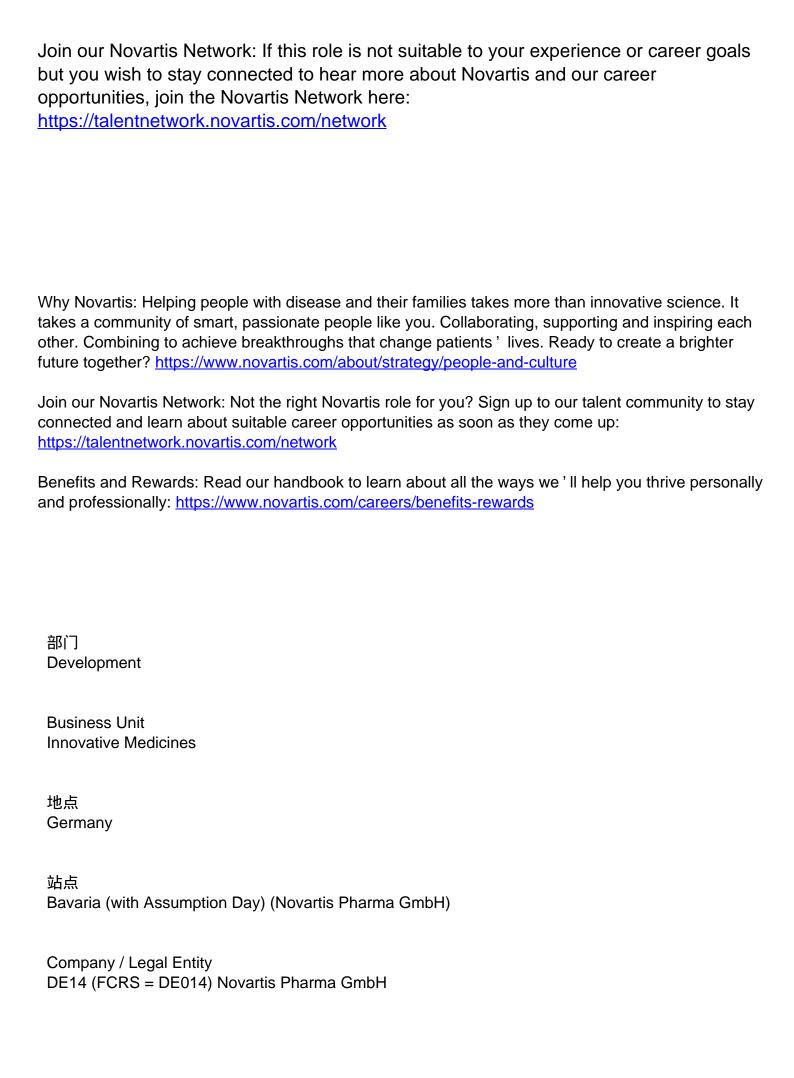
- Leads and global study team to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timely start-up activities from country allocation until Green Light (ready to initiate site millstone) in assigned projects
- Ensures close collaboration with local IRBs/IECs 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)
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- 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
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution
- 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

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You'll receive You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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Accessibility and accommodation: Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.



Alternative Location 1 Nuremberg (Non-Sales Force) (Novartis Pharma GmbH), Germany

Functional Area Research & Development

Job Type Part time

Employment Type Regular (Sales)

Shift Work No

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