

## 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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部门

Development

Business Unit

Innovative Medicines

地点

Germany

站点

Bavaria (with Assumption Day) (Novartis Pharma GmbH)

Company / Legal Entity

DE14 (FCRS = DE014) Novartis Pharma GmbH

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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