

Study & Site Operations (SSO) Study Start-Up Team Leader

Job ID
REQ-10050472
May 29, 2025
Czech Republic

Summary

We are looking to hire a multi-layered Study Start-Up (SSU) person who will balance leading a team of up to 7 people, with being accountable for the governance and oversight of study start up for the Czech Republic. At the same time, you will retain oversight through collaboration with other Team Leads for SSU in Switzerland, Slovakia and Austria and with external managers working for 3rd party suppliers to Novartis. You'll also help support new initiatives, and the overall study start up country strategy and prioritization, to deliver operational excellence of the Global Drug Development (GDD) portfolio in compliance with Novartis processes, ICH/GCP and regulatory requirements.

About the Role

Study Start-Up Strategy

- Support Study & Site Operations Country Leadership Team to identify innovative practices to optimize country operations and operational excellence, especially in terms of study start-up activities to increase performance, productivity, and business impact
- Drive expertise in EU CTR and ensure close collaboration with local IRBs/IECs and Health Authorities, as applicable

Allocation, initiation and conduct of trials

- Collaborate with Head Portfolio, SSO Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial Lead) to ensure SSU timelines and deliverables are met according to country commitments

People and resource management

- Ensure associates have the required level of skills to successfully set-up and execute studies with high quality and according to business objectives

Archive

- Ensure adherence to global procedures and standards as well as availability of and adherence to local processes and standards for filing TMF documents.

Essential Requirements

- A degree in scientific or health discipline required

- Fluent in both written and spoken Czech and English
- Minimum 5 years' experience in clinical operations and planning
- Proven leadership capabilities and experience (with or without direct line management responsibilities).
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- 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

Desirable Requirements

- Proven successful leadership of teams (with or without direct reports), preferably with experience in working with international teams
- Strong interpersonal, negotiation and conflict resolution skills; strong capability working and communicating effectively in a local/global matrixed environment

Why Novartis?

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Division

Development

Business Unit

Innovative Medicines

Location

Czech Republic

Site

Prague

Company / Legal Entity

CZ02 (FCRS = CZ002) Novartis s.r.o

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Accessibility and accommodation

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