NOVARTIS

SSO Study Start-Up Manager

Job ID
REQ-10077303
May 27, 2026
LOC_CZ

About the Role

Key Responsibilities

- Lead and manage country study start-up activities from country allocation through Country& Site Regulatory Green Lights, ensuring timelines, quality, and deliverables are met.
- Collaborate with country, cluster, portfolio, and global study teams to align on start-up strategy, commitments, and execution plans.
- Prepare, review, and finalize submission packages for EU CTR submission, and other regulatory bodies, including amendments and required study documents, incl. adapting and reviewing Informed Consent Forms.
- Ensure timely completion of substantial modification submissions, including coordination with Regulatory Affairs, CTA Hub, and relevant local stakeholders. Coordinate responses to RFIs in collaboration with local and global teams.
- Maintain inspection-ready Trial Master File documentation by ensuring accuracy, completeness, and timely filing of country start-up documents.
- Ensure compliance with ICH/GCP, SOPs, local regulations, financial standards, and Health Authority/IRB/IEC requirements.
- Lead site selection and support study feasibility activities in collaboration with Feasibility Managers, SSU CRA, Site Partnership Managers, Clinical Project Managers, and study teams.
- Collaborate with Contract and Finance Specialists on contract and budget set-up and review.
- Leads/chairs local SSU team meetings in assigned studies, participates in global study team meetings, as required
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness

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 and Czech
- Minimum 5 years’ experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- Up to 10% travel is required
- 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
- 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

Desirable Requirements

- Strong interpersonal, negotiation and conflict resolution skills; Communicates effectively in a local/global matrixed environment

Benefits & Rewards: Monthly pension contribution matching your individual contribution up to 3% of your gross monthly base salary; Risk Life Insurance (full cost covered by Novartis); 5-week holiday per year; (1 week above the Labour Law

requirement); 4 paid sick days within one calendar year in case of absence due to sickness without a medical sickness report; Cafeteria employee benefit program – choice of benefits from Benefit Plus Cafeteria in the amount of 17,500 CZK per year; Meal vouchers in amount of 105 CZK for each working day (full tax covered by company); MultiSport Card, Company Car, Employee Share Purchase Plan. Find out more about Novartis Business Services: https://www.novartis.cz

Commitment to Diversity and Inclusion / EEO paragraph:

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 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 di.cz@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Role Requirements

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)

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DIV_GD
Business Unit
Research
Location
LOC_CZ
Site
Prague
Company / Legal Entity
CZ02 (FCRS = CZ002) Novartis s.r.o.
Functional Area
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Employment Type
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Shift Work
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