NOVARTIS

SSO Study Start-Up Manager

Job ID
REQ-10077303
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Сводка

Job description summary
#LI-Hybrid
Job Posting Title: SSO Study Start-Up Manager
Location: Prague, Czech Republic

The SSO Study Start-Up (SSU) Manager is accountable for study planning, SSU activities and activation deliverables of assigned projects in compliance with Novartis processes, Good Clinical Practice/International Council for Harmonization (GCP/ICH) and regulatory requirements in a standalone country, OPC (operating country) or satellite country. Leads all SSU activities of assigned projects in close collaboration with SSO Feasibility Manager and SSO Site Partnership Manager as well as the global study team.

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.

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
Research
Место
Чехия
Сайт
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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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.

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