NOVARTIS

SSO Study Start-Up Manager

Job ID
REQ-10076764
май 07, 2026
Великобритания

Сводка

The SSO Study Start-Up Manager is accountable for study planning, SSU 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. 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. In satellite countries acts as primary back-up and deputy of the country manager.

About the Role

Key responsibilities but not limited to:

- Support country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Country Head Portfolio / SSO Cluster Head Portfolio.
- Collaborate 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 milestone) in assigned projects.
- Ensure close collaboration with local IRBs/IECs and Health Authorities as applicable.
- Ensure that study start-up activities are conducted and completed on time, including preparation and review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for Health Authorities submissions, as required.
- Prepare and finalises local submission package for submission to IRB/IEC, CTA Hub (Europe: according to new EU-CTR) as well as Health Authorities as applicable (including subsequent amendments, IBs, DSURs, CSRs).
- Coordinate timely response to deficiency letters in close collaboration with local and global stakeholders.
- Coordinate reportable events and notifications to IRB/IEC and Health Authorities, e.g. substantial and non-substantial amendments, IB updates, ICF updates as applicable, including preparation, update, and review of submission documents.
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness.

Essential criteria:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable
- Strong experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials
- 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

Desirable criteria:

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

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
Development
Место
Великобритания
Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Job ID
REQ-10076764

SSO Study Start-Up Manager

Apply to Job

Job ID
REQ-10076764

SSO Study Start-Up Manager

Apply to Job

Source URL: *https://www.novartis.ru/careers/career-search/job/details/req-10076764-sso-study-start-manager*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/SSO-Study-Start-Up-Manager_REQ-10076764-1
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/London-The-Westworks/SSO-Study-Start-Up-Manager_REQ-10076764-1