SSO Study Start Up Manager

Job ID
REQ-10048230
Απρ 11, 2025
United Kingdom

Περίληψη

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

Major Accountabilities:

- 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 commitment
- 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)
- Coordinates timely response to deficiency letters in close collaboration with local and global stakeholders
- Coordinates reportable events and notifications to IRB/IEC and Health Authorities as applicable
- Accountable for timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness
- Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
- Implements innovative and efficient processes which are in line with Novartis strategy
- Supports study feasibility in close collaboration with Feasibility Manager and Site Partnership Manager as well as the global study team.
- 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

- Ensures sites are prepared for “Green Light” and ensures all documentation is in place for initial and subsequent drug release. Responsible for review and sign off of the site “Green Light”
- Oversees local SSU team activities in assigned studies to achieve start-up timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and local and international regulations
- 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

Education & Qualifications:

- A degree in scientific or health discipline required and advanced degree with clinical trial experience and/or project management, is preferable

Experience:

- Experience in clinical operations in a role that oversees (project management) and/or with monitoring clinical trials

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Τομέας
Development
Business Unit
Universal Hierarchy Node
Τοποθεσία
United Kingdom
Τοποθεσία
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
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