NOVARTIS

Study Start Up Manager

Job ID
REQ-10076762
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Италия

Сводка

The Study Start-Up Manager (SSUM) reports to the Study Start-Up Team Lead and Study Start-Up Country Head and is accountable for end-to-end study planning, study start-up activities, and site activation deliverables for assigned projects in Italy.

The role ensures that study start-up activities are delivered on time, with quality and compliance, in line with Novartis processes, ICH/GCP, and applicable regulatory requirements, from country allocation through to Green Light (Ready to Initiate Site).

About the Role

Global Clinical Operations (GCO) is the powerhouse behind Novartis clinical trials, redesigned to accelerate study start-up, enhance trial delivery, and ensure patients gain timely access to potentially life-changing treatments. Every day, we act as the vital link between science and medicine. Imagine the impact you could have as a Study Start-Up Manager in the Study & Site Operations (SSO) team in Italy.

Key Responsibilities:

- Lead all Study Start-Up (SSU) activities for assigned studies, in close collaboration with internal study team and global study teams.
- Contribute to the country SSU strategy, working closely with the SSU Team Lead, SSU Country Head, and Country Portfolio team
- Partner with global and country stakeholders to ensure SSU timelines, milestones, and deliverables are met according to country commitments.
- Be accountable for timely site activation, from country allocation through Green Light / Ready to Initiate Site milestones.
- Oversee and ensure completion of study start-up activities.
- Coordinate timely and effective responses to ethics committee and Health Authority deficiency letters, working closely with local and global partners.
- Ensure timelines, accuracy, and quality of country documentation, maintaining inspection readiness throughout the start-up phase.
- Ensure full compliance with Novartis SOPs, financial standards, prevailing legislation, ICH/GCP, and regulatory requirements.

Essential requirements:

- Previous experience in clinical operations, preferably in a role involving study start-up activities, project oversight and/or clinical trial monitoring
- Proven ability to lead in a matrix environment
- Understanding of the clinical drug development process, with focus on: Study start-up.
- Experience working with Ethics Committees/IRBs, Health Authorities, and country-level regulatory processes

Desirable requirements:

- Strong problem-solving skills, with the ability to navigate and resolve complex operational and regulatory issues
- Excellent collaboration and stakeholder-management skills in cross-functional and global environments
- Strong understanding of international clinical research standards (ICH/GCP)
- Knowledge of Health Authorities (e.g. EMA/FDA) and local/national regulatory requirements
- High attention to quality, timelines, and inspection readiness mindset

Education:

- Degree in a scientific or healthcare discipline
- Experience in clinical operations and/or project management is strongly preferred

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

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Дивизион
Development
Business Unit
Development
Место
Италия
Сайт
Milano
Company / Legal Entity
IT08 (FCRS = IT008) Novartis Farma S.p.A.
Functional Area
Research & Development
Job Type
Full time
Employment Type

Regular
Shift Work
No

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Study Start Up Manager

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