Study Start-up Team Lead

Job ID
REQ-10022545
Set 17, 2024
Brasile

Sommario

The SSO Study Start-Up Team Leadis accountable for the governance and oversight of a study start-up team in Study & Site Operations Novartis Brazil.
This position is responsible to support the country Study Start-Up strategy and prioritization in close collaboration with Country Head to deliver operational excellence of the Global Drug Development portfolio in compliance with Novartis processes, ICH/GCP and regulatory requirements.
Oversees the strategic and operational planning / management from a clinical trial execution perspective. Oversight of budget and resource allocation within assigned trial. Enables operational excellence through process improvement and knowledge sharing across trials within program/franchise. Enables an empowered organization that can navigate in a matrix environment and adjust quickly to business needs.

About the Role

Major accountabilities:

Study Start-Up Strategy

- Supports Study & Site Operations Country Leadership Team to identify innovative practices to optimize country operations and operational excellence, especially in terms of study start-up activities to increase performance, productivity, and business impact
- Seeks and evaluates external knowledge and best practices to enhance overall operational excellence of country trial operations
- Supports country Study Start-Up strategy in close collaboration with SSU (Study Start-Up)/OPC (Operational Country) Head and Portfolio Head/Portfolio Team Lead(s)
- Responsible for timely start-up activities from country allocation until site Green Light (ready-to-initiate-sites)
- Ensures close collaboration with local Ethical Comiteesand Health Authorities, as applicable

Allocation, initiation and conduct of trials

- Collaborates with Head Portfolio, SSO Portfolio Team Leads and global study team (Clinical Operations Program Head, Trial Lead) to ensure SSU timelines and deliverables are met according to country commitments
- Accountable for timelines, accuracy, and quality of Trial Master File documents, including study start-up and ongoing Trial Master File maintenance to ensure Trial Master File 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

People and resource management

- Hiring, training, development, and retention of Study Start-Up associates
- Resource management and reporting of Study Start-Up associates
- Ensures associates have the required level of skills to successfully set-up and execute studies with high quality and according to business objectives
- Manages and oversees productivity targets per defined objectives, and serves as an escalation point for Study Start-Up functions

Key performance indicators:

- Timely, efficient and quality execution of trials and trial related activities within assigned clinical program(s) within budget, and in compliance with quality standards.
- Appropriate funding and resourcing for assigned clinical program(s).
- Adherence to Novartis policy and guidelines and external regulations.

Minimum Requirements:
Work Experience:

- Minimum 5 years' experience in clinical operations and planning.
- Proven leadership capabilities and experience (with or without direct line management responsibilities).
- Understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring.
- 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.
- Complete graduation.

Languages :

- Fluency in Portuguese and in English.

You'll receive:

Competitive salary, annual bonus, pension scheme, life insurance, 30 days annual leave, year-end recess, hybrid work model (home office 2x a week), flexible working arrangements, birthday day-off, maternity and paternity leave, subsidized dining facilities, health and dental insurance, employee recognition scheme, free parking lot (Santo Amaro and Cambe), Gympass, Space Energized for Life, gym (Santo Amaro) and virtual self-development tools.

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