NOVARTIS

Study & Site Operations Country Manager - Saudi Arabia

Job ID
REQ-10029864
Nov. 13, 2024
Saudi-Arabien

Zusammenfassung

Job Purpose:
The SSO Country Manager is accountable for all country clinical operation activities related to the allocation, initiation, conduct (recruitment, quality data collection) and timely completion of Phase I-IV Oncology and Pharma clinical trials. The SSO Country Manager is responsible for implementing the Study & Site archetype and Hub/Cluster/Country strategy, while delivering to Country budget and productivity targets in line with Study & Site and local business objectives. Operationally responsible for building a high performing team culture and including performance management and established monitoring procedures in accordance with GCP, ICH and local regulations. The SSO Country Manager is responsible for monitoring integration within Country CSO and Medical Director to ensure alignment on portfolio strategy, prioritization, and performance to aligned objectives for GDD trial delivery.
The SSO Country Manager can also undertake additional responsibilities as GDD Country Coordinator (if applicable refer to separate GDD Country Coordinator Role Profile).

About the Role

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Accountabilities:
Portfolio execution strategy
• Implements the defined Study & Site Operations and OPC country structure monitoring strategies to deliver country business and trial strategy objectives in close collaboration with the SSO Cluster Head Portfolio, Clinical Research Associate (CRA) Manager and Country CSO and Medical Director
• Aligns Country monitoring objectives to the SSO Country Head (OPC) and country CSO/Medical Director

• Identifies and implements innovative practices and patient engagement strategies in collaboration with Clinical Research Associate (CRA) Manager, Country CSO and Medical Director within the country to advance clinical trial planning, execution, and quality

Allocation, initiation and conduct of trials

• Responsible for the alignment between SSO Feasibility Manager and relevant medical/clinical functions to ensure strategic allocation and execution of global development trials within the Country (Innovative Medicines Phase I-IV trials)
• Drives collaborative engagement model with Cluster Head Portfolio to ensure Country participation in GDD trials is aligned with the overall OPC Country structure portfolio execution strategy
• Ensures Country trial site selection, activation, enrolment, resource allocation, timelines and budget commitments are delivered per established trial objectives

Builds and maintains effective site relationship management to ensure site performance to trial commitments and delivery of quality monitoring

Delivery of quality data and compliance to quality standards
• Actively monitors the KQI's and develops, maintains and follows-up on the yearly process control plan in the Country to ensure adherence to clinical data standards, prevailing legislation, GCP, Ethical Committee and SOP requirements
• Is responsible for Country Monitoring issue identification, escalation and resolution pathways in CPO, partnering with relevant medical/clinical functions, Country QA, GLF's and Dev QA
• Actively manages Country issue identification and resolution in relation to CPO and trial audits, inspections and delivers to CAPA implementation requirements
• Promotes a compliance culture advocating the adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
• Is accountable for Country adherence/compliance to SOPs and roll-out/adoption across the Country Study & Site structure for required training curricula per GDD targets
• Responsible for local Study & Site SOPs creation and lifecycle management as well as implementation of all relevant country rules and regulations
• Drives continuous improvement in Monitoring operations and fosters best practice sharing within the Country
• Primary contact for FSP/BiS vendors to ensure overall quality & performance
• Responsible for escalation and follow-up of non-performance issues to FSP/BiS line managers

Management of people and resources management
• Along with FSP/BiS line manager is responsible for selection of CRAs, Study Start-up CRAs and enabling function associates
• Along with FSP/BiS line manager participates in the allocation of the field-based resources within the country in alignment with Country Head (OPC) (as appropriate)
• Develops performance management processes to proactively manage key performance and quality indicators to ensure achievement of Country/OPC Country performance targets
• Is responsible to implement and adopt global training strategy, tools/systems and processes within the country and ensure country training needs are communicated to Global Training

Budget and productivity

• Manages Country budget and Monitoring headcount allocation to target in close collaboration with Country Head (OPC) (as appropriate)
• Identifies, documents and shares Country productivity initiatives in line with Study & Site productivity goals
• Responsible for the local development vendor identification, contracting, oversight and management

Activities & Interfaces
Interfaces with GMA and Commercial organization within country to ensure aligned portfolio strategies across the business
• Partners with OPC S&O and OPC Portfolio teams to drive resourcing and allocation strategies and track execution to established timelines.

Ideal Background:
Education:
• Bachelor's Degree in life sciences required; Advanced Degree in life sciences or business preferred
Languages:
• Fluent in both written and spoken English
Experience/Professional requirement:
• Minimum 8 years' experience in clinical research - planning/executing and/or monitoring clinical trials with minimum 4 years in a people management role
• Expert understanding of all aspects of clinical drug development with particular emphasis on trial execution and monitoring
• Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
Competencies:
• Leadership, strategic thinking and matrix management skills
• Established track record of leading successful teams
Skills & Knowledge:
• Excellent negotiation and conflict resolution skills
• Excellent organisational, interpersonal skills with extensive networking expected
• Excellent communicator and presenter (oral and written), ability to communicate to Sr. Leaders

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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Abteilung
Development
Business Unit
Innovative Medicines

Ort
Saudi-Arabien
Website
Riyadh
Company / Legal Entity
SA01 (FCRS = SA001) Novartis Saudi Arabia Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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