NOVARTIS

SSO Feasibility Manager

Job ID
REQ-10026918
Ott 21, 2024
Giappone

Sommario

Accountable for the oversight and coordination of program and study level (re-)feasibility assessments in the country, in collaboration with program and/or trial feasibility teams, in compliance with Novartis processes, GCP, ICH and regulatory requirements. This position is key to establish good communication and professional relationships with clinical investigators and company stakeholders on country/cluster/hub/global level Closely collaborates with Study & Site Operations and relevant medical/clinical functions to ensure successful allocation, realistic country targets, recruitment according to planned timelines, early identification of risks and opportunities as well as potential delays and mitigation plan.

About the Role

Major Accountabilities

- Single point of contact for communication between Clinical Operations Program Managers / Clinical Operations Program Head, country/extended country group Study & Site teams and local relevant medical/clinical functions for all requests for program/study feasibility
- Coordinates the feasibility activities on country by ensuring:
  o Site identification and selection, trial feasibility evaluation
  o Collates/validates the list of potential sites by utilizing internal and external data (e.g. historical data, individual knowledge within local Study & Site Team and relevant medical/clinical functions, internal and external databases)
  o Manages the study specific feasibility questionnaire and sends to all participating sites together with any supporting documentation, if applicable
  o Follows up with sites to ensure questionnaires are answered and any additional feedback is obtained
  o Assess the clinical feasibility of implementing a clinical trial protocol based on regional/local medical practice using physician interviews, local databases (RWE, payer data, patient association feed-back, etc.) and analysis of the competitive environment
  o Enters feedback into global database if applicable (e.g. CLIP).
- Collects, analyses, and interprets data to provide comprehensive proposals and timelines for country allocation of clinical programs and assigned trials
- Responsible for early identification for potential risks and opportunities as well as potential synergies and back-up strategies within the country
- Closely collaborates with the Study & Site team to ensure fast clinical trial start up, recruitment according to planned timelines, early identification of potential delays and robust recruitment mitigation plan. Co-own start-up phase and the recruitment plan for development
  clinical trials with the Study & Site Operations

Key Performance Indicators

- Timely submission of feasibility data
- Performance against study commitments at the country level, including delivery of studies per defined number of patients and quality
- Delivery of study milestones esp. in startup phase in adherence to prevailing legislation, GCP, Ethical Committee and SOP requirements

Work Experience

- Scientific degree and advanced degree with clinical trial experience and/or project management, is preferable
- Minimum 5 years' experience clinical development experience in pharmaceutical industry
- Capable of leading in a matrix environment, without direct reports and working cross-border
- Ability to manage a study from the medical/clinical perspective, and a demonstrated capability to problem solve and mediate complex-clinical / medical / operational issues
- Agility to move fast across different therapeutic areas and indications

Skills

- Strong project management capabilities
- Ability to assess the feasibility of implementing the protocol based on regional medical practice and sound understanding of the overall clinical development plan
- Demonstrated negotiation and conflict resolution skills both internal and external
- Communicates effectively in a local/global matrixed environment

Language

- Fluent in both written and spoken English

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REQ-10026918

SSO Feasibility Manager

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