Feasibility Manager

Job ID
REQ-10025938

12月 03, 2024

Mexico

摘要

Accountable for the oversight and coordination of program and study level (re-)feasibility assessments in the country or extended country group (OPCs & satellite countries), 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 rest of 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 Manager/Clinical

Operations Program Head, country/extended country group Study & Site Operations teams and local relevant medical/clinical functions for all requests for program/study feasibility
- Coordinates the feasibility activities on country/extended country group level 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 Operations 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 / extended country group 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/extended country group
- Closely collaborates with the Study & Site Operations 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 organization

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

Work Experience

- 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
- Demonstrates a knowledge of how to adequately review and read a protocol to understand specifics of study design and answer questions regarding the trial
- Applies a detailed understanding of the drug in question to provide medical context as it relates to disease processes, populations, and standards of care
- Ability to assess the feasibility of implementing the protocol based on regional medical practice and

sound understanding of the overall clinical development plan
Skills & Knowledge:
- Demonstrated negotiation and conflict resolution skills both internal and external (site relationships)
- Communicates effectively in a local/global matrixed environment

Language
Fluent in both written and spoken English

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部门
Development

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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