

SSO Feasibility Manager

Job ID
REQ-10026918
Oct 21, 2024
Japan

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

- 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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Role Requirements

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Division

Development

Business Unit

Innovative Medicines

Location

Japan

Site

Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity

JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular
Shift Work
No

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