

Monitoring Services Oversight Manager

Job ID
REQ-10018275
Aug 20, 2024
United Kingdom

Summary

Primary contact for FSP and other monitoring services (vendors) to assure adequate quality of the services & performance in Novartis sponsored clinical trials. Oversees vendor monitoring performance targets per defined quality performance indicators, including site recruitment commitments, timely data entry and issue resolution KPIs. Aligns with FSP and other vendor's managers on CRA and other vendor resource related allocation to trials and studies. Requires strong communication skills and ability to influence internal and external stakeholders in order to maximize quality and efficiency of external service providers.

About the Role

Key Responsibilities:

- Develop country resource needs/expectations strategy and align with vendor line management (CRAs and other vendor resources). Establishes governance model
- 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
- Escalates non-compliance, performance issues, competency gaps and/or needs to vendors
- Oversees country trial site activation, enrolment, data flow and timeline commitments are delivered per established trial objectives
- Oversees monitoring quality, timely data entry and issue resolution including oversight of CRA oversight visit performance
- Supports Clinical Development Audit and FSP vendors for site audits and inspection
- In collaboration with SSO Clinical Project Manager (CPM), supports recruitment strategies and site performance by ensuring high quality and compliance of monitoring activities
- Ensure country FSP strategy is aligned with global and hub plans

Essential Requirements:

- Minimum 7 years' experience in clinical research - planning/executing and/or monitoring clinical trials
- Experience and evidence of team leadership capabilities
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and trial execution
- Demonstrated negotiation and conflict resolution skills
- Fast change adaptability to best partner & influencing with FSP vendor on fast changing landscape
- Trust and rapport building is a very important skill needed
- Good communication skills, ability to influence others & Relationship management
- Excellent communicator and presenter (oral and written)
- Good analytical thinking

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Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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