U NOVARTIS

Monitoring Services Oversight Manager

Job ID REQ-10018275

8月 20, 2024

United Kingdom

摘要

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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部门 Development

Business Unit Innovative Medicines

地点 United Kingdom

站点 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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