Trial Vendor Senior Manager (TVSM)

Job ID
REQ-10030968

12月 03, 2024

United Kingdom

摘要

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare.

We are currently looking for a Trial Vendor Senior Manager to join our team in London.

This is a hybrid position with 12 days a month from our White City offices.

The main purpose of this position is to be accountable for all vendor related operational trial deliverables, according to timelines, budget, operational procedures, quality/compliance and performance standards. To collaborate with the VSM for the VSM ' s category specific responsibilities and be responsible for all activities for which no VSM is assigned with, and for all of the service deliveries after Study Start-up when the VSM is no longer assigned to the study.

As a Core member of the Clinical Trial Team (CTT) you will independently managing all vendor-related aspects of global clinical trial(s) to deliver study outcomes within schedule, budget, quality/compliance and performance standards, you will be accountable for vendor service delivery at study level and collaborate closely with the Vendor Start-up Manager (VSM) for selected services

(central labs, electronic clinical outcomes assessment/electronic patient reported outcomes (eCOA/ePRO), interactive response technology (IRT), cardiac and respiratory diagnostics, patient recruitment and retention (PR&R), and imaging reading) during study start-up and leverage your technical and study start-up (SSU) expertise to ensure a timely study start-up. You will proactively manage vendor-related risks and potential issues and implement global vendor strategy.

#LI-Hybrid

About the Role

Key responsibilities:

- Close interaction and collaboration with study team lead and study team members during study lifetime
- Review of vendor related protocol sections during protocol development
- Collaborate with Vendor startup manager to the development of Study Specification Worksheet (SSW) to facilitate bid process. If no VSM is assigned to the category, drive the SSW completion.
- Manages interface with vendors in cooperation with vendor partner functions
- Quote/proposal review in collaboration with procurement, support contract negotiations, if required
- Contributes to the development of vendor contract amendments · Accountable for vendor cost control, budget review, invoice reconciliation and PO close-out
- Vendor service excellence at study level, ensures vendors meet quality and service level standards in their service delivery for the trial
- Covers all vendor activities after study start-up and all categories not covered by VSMs during start-up
- Initiates/co-ordinates vendor kick-off meeting for categories not covered by VSMs
- Attends vendor kick-off meeting for VSM supported categories
- Optimizing a frontloaded and timely study-start-up process, manages vendor-related activities for DB go live
- Performs user-acceptance testing (UAT) for eCOA and IRT
- Drives and monitors central vendor-related activities for site activation, compiles Final Protocol Package (FPP) required documents centrally, monitors site activation progress and addresses related issues and risk
- Creates and maintains vendor-related risk maps with contingency plan for documentation in FIRST
- Manages system and portal user access for vendor, sponsor and site staff, maintain access logs
- Uses Unified Vendor Portal (UVP) to manage vendor
- Uses Clinical Insights to manage vendors and to achieve site readiness timelines
- Plans and tracks supply delivery to sites and return of equipment from sites
- Interacts and collaborates with Data Ops, reviews vendor-related cycle times (e.g. DTS finalization, data transfers, DBL)
- Acts as escalation point for vendor-related query management
- Follow-up with countries and hubs for their vendor-related risks and issues
- Document issues identified with vendor oversight/performance in FIRST tool and implements

and monitors corrective action

Essential requirements:

- Bachelor degree or equivalent degree is required, with advanced degree preferred.
- Fluent English (oral and written)
- 3+ years working experience and excellent knowledge of the clinical operation processes and vendor management
- Excellent knowledge of GxP and ICH regulations
- Very good knowledge of clinical trial design and mapping to supplier requirements
- Thorough and technical understanding of Novartis specifications for supplier provided services
- User Acceptance testing for eCOA and IRT
- Site collaboration and site activation
- Vendor management; outsourcing, contracting, sourcing, of clinical services
- Results-driven: demonstrated ability of completing projects on time
- Ability to work in cross-functional teams and a matrixed environment
- Strong influencing and negotiation skills
- Good written and oral communications skills
- Very good problem-solving skills
- Demonstrated willingness to make decisions and to take responsibility for such
- Excellent interpersonal skills (team player)
- Proven networking skills and ability to share knowledge and experience amongst colleagues.

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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.

Alternative Location 1
Dublin (Country President Office (CPO)), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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