

Vendor Start-Up Manager - eCOA & Translations

Job ID
REQ-10076486
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Великобритания

Сводка

Location: Westworks, London, UK
Full time, Hybrid, #LI-Hybrid

As the study's start-up linchpin subject matter expert for eCOA and Translations, the Vendor Start-Up Manager ensures vendors are fully aligned, validated, and ready to deliver—protecting timelines, quality, and patient experience from protocol finalisation through database go-live.

About the Role

Reporting to the Vendor Alliance Lead, the Vendor Startup Manager (VSM) eCOA & Translations is responsible to provide technical expertise for a given category during study startup to the TVM Trial Vendor Manager and indirectly to the study start-up team.

The VSM enables a flawless and accelerated vendor service delivery at the trial start-up phase and supports implementation of defined category strategies and service standardization. The VSM proactively assesses risk and concludes contingency plans to de-risk study startup. They will also lead initiatives for continuous improvement and optimisation of the Study Start-Up process and will support practice leaders in improvement projects and learning loops.

Key accountabilities and responsibilities

- Reviewing of the vendor and category related specific sections of the protocol, ensure vendor expertise is leveraged when refining specifications aligning to Final Protocol
- Contributing to development of Study Specification Worksheet (SSW) to facilitate bid process and selection of Vendors. Actively contribute to Quote/Proposal reviews, support Contract negotiations and review of final quotes.
- Co-ordinates vendor kick-off meeting and other vendor specific meetings
- Collects HA submission documents from vendor, as requested by countries participating in a study
- Performs robust User Acceptance Testing (UAT) for eCOA
- Ensures changes to protocol or study designs are consistently shared with vendors and incorporated into supplier budgets, timelines, and specifications. Supports protocol amendments and revised vendor contracts alongside Procurement team
- Looks for opportunities to optimise and improve frontloaded and timely study start-up process in support of a timely vendor DB-go-live
- Promotes Vendor service excellence at study level, ensures vendors meet quality and service level standards in their service delivery for the trial. Use of relevant tools such as Unified Vendor Portal to manage service delivery.
- Pro-actively creates and maintains vendor related risk maps with contingency plan for documentation in FIRST tool
- Document issues identified with vendor oversight / performance in FIRST tool and implements and monitors corrective actions. Escalates issue if required to the VAL Vendor Alliance Lead and drives root cause analysis of supplier performance issues and looks for trends
- Supports the implementation of standards, templates, tools, and processes for vendors at SSU for defined categories in collaboration with the VAL

What you will bring to the role:

- Advanced degree in science or business with equivalent experience
- Strong demonstrated experience in the eCOA industry (ideally a period of 5-7+ years working in eCOA) and excellent knowledge of the clinical operation processes and vendor management
- Excellent knowledge of GxP and ICH regulations
- Expert knowledge of clinical trial design and mapping to supplier requirements
- Demonstrated leadership with supplier relationship management and/or expert knowledge of specific service areas
- Strong collaborative mindset and capability to liaise closely with key internal and external stakeholders
- Demonstrated root cause analysis, problem solving, and solution generation skills
- Experience in User Acceptance testing (eCOA)
- Knowledge of key deliverables that impact green light milestones and vendor readiness
- Experience in outsourcing, contracting, sourcing of clinical services with Vendor/CROs (RFP, RFQ, contracting)
- Specific category expertise – specifically eCOA/ePRO

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Место
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Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Remote, Швейцария
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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