



Clinical Research Project Manager

Peptomyc Barcelona, Catalonia, Spain

Peptomyc: a small innovative biotech company, focused in oncology, with a very enthusiastic team is seeking a high quality, ambitious and experienced Clinical Research Project Manager.

Main responsibilities:

- Oversee performance of CROs, third party vendors, to ensure compliance with study protocol and in accordance with scope of work and with corporate timelines
- Develop and administer study budgets
- Review monitoring reports for accuracy, completeness and conformance with SOPs.
- Maintains frequent contact with and work effectively with CRO, investigators and site staff.
- Track items related to CDAs, budget and contract completion status.
- Assurance of regulatory compliance of CRO and investigational sites with company SOPs, EMA/FDA and ICH guidelines.
- Identify areas of concern and escalate to CMO or CRO as appropriate.
- Review and/or submission of research ethics committee/regulatory documentation.
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures.
- Establish and track clinical timelines and appropriate performance metrics.
- Review key study quality metrics (e.g., eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team.
- Manage/oversee investigational product (IP) accountability and reconciliation process.
- Responsible for review or approval of IP release packages.
- Negotiate and manage the contracts, budgets and payments for third party vendors, including CROs. Work closely with the accountant to accurately track spend and monitor cash flow forecast for clinical plan delivery.

Qualifications:

- minimum of 3 years' experience as a Clinical Research Project Manager
- Bachelor's degree or equivalent, in a biomedical, life science or related field of study
- Oncology and early phase development experience
- fluent in Spanish and English

Location:

- Barcelona, office and/or home-based

Please, contact mniewel@peptomyc.com

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