Job Title: Sr. Clinical Study Manager / Clinical Program Operations Manager
Location: Fully Remote, US Only
Type: Full Time or Consultancy

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Position Overview

We are seeking a highly motivated **Senior Clinical Study Manager / Clinical Program Operations Manager (Sr. CSM/CPOM)** to join our growing biotech team. This individual will play a pivotal role in the planning, execution, and delivery of clinical trials within our cardiovascular therapy area with a strong emphasis on hypertension. As part of a lean, agile organization, the Sr. CSM/CPOM will have broad responsibilities and direct impact on advancing our pipeline. This full-time role requires a strong clinical operations background, proven experience running global clinical trials, successful CRO and vendor selection and oversight, and the ability to manage multiple responsibilities while ensuring studies are executed in accordance with ICH-GCP, regulatory requirements, and company SOPs. The successful candidate will focus on delivering high-quality data to support the clinical development strategy in this collaborative, agile, and science-driven culture.

Key Responsibilities

Study Planning & Start-Up

- Lead operational planning for cardiovascular/hypertension studies, including project timelines, budgets, scenario planning, risk and mitigation planning.
- Collaborate closely with Medical, Regulatory, and Clinical Development in optimizing protocol design, identifying practical operational considerations for protocol-specific endpoints, and ensuring associated amendments, ICFs, CRFs, monitoring plans and other study-specific plans are aligned.
- Partner closely with Medical to develop criteria to optimize country and site feasibility with emphasis on experienced cardiovascular centers.
- Lead selection, qualification, and contract negotiations with CROs and key vendors (imaging/core labs, central labs, eDiary/ePRO, etc.).
- In collaboration with CRO and internal study team members, prepare key study documents including study manuals, operational plans, sponsor oversight plans, site training materials, monitoring plans, and oversight strategies.

Study Execution & Oversight

- Serve as the primary point-of-contact for CROs, vendors, and cross-functional partners, ensuring a high level of operational oversight.
- Manage vendor deliverables (central and specialty labs, supplies, core lab services, imaging, etc.) according to protocol and contracted services, timelines and budget.
- Partner with Medical to define study measures requiring specific and/or critical monitoring, special training, preparation for data reviews, safety reviews and quality reviews.
- Implement proactive monitoring and issue resolution within the internal and external teams to ensure data reviews, safety reviews, protocol deviation tracking and reviews, risk mitigation planning and review, critical data identification, operational KPIs and quality oversight methods are in place.
- Drive enrollment and retention strategies with the CRO tailored to the protocol-specific population, project timelines, high quality data and cost.
- Communicate all risks, key issues and impacts to project timelines, cost and quality to internal stakeholders.

CRO & Vendor Management

- Manage day-to-day oversight of CRO performance, budgets, KPIs, quality, and deliverables.
- Foster strong relationships with CROs, vendors, committee members, and internal and external stakeholders.
- Oversee vendors (central lab, imaging core labs, device providers, supply/logistics, eClinical systems) and ensure integration across all workflows.

Quality, Compliance & Documentation

- Ensure completeness and inspection readiness of TMF in partnership with CRO and internal team members.
- Monitor adherence to ICH-GCP, protocol, SOPs, and regulatory requirements.
- Prepare for and support internal and external audits, regulatory inspections, and quality reviews including drafting responses, corrective actions, and follow-up documentation.

- Maintain version control and oversight of study documentation in collaboration with team members and document management plans.
- Develop and maintain sponsor oversight plan including quality reviews and thresholds.

Study Close-Out

- Oversee database lock, data review cycles, and cross-functional data QC, particularly for key cardiovascular endpoints.
- Oversee site close-out activities, reconciliation of supplies and budgets, TMF reconciliation and transfer.
- Manage CRO and vendor close-out and end of contract activities including budget reconciliation and resolution of any outstanding items.
- Contribute to clinical study reports, and submission packages.
- Conduct lessons-learned and analyses to support continuous improvement in a scaling biotech environment.

Qualifications & Experience

- Bachelor's degree in life sciences or related field; advanced degree preferred.
- **8+ years of Clinical Operations experience**, including direct management of cardiovascular or hypertension clinical trials.
- Prior **small biotech or early-stage company experience** strongly preferred, with demonstrated ability to operate autonomously in a lean environment.
- Proven experience overseeing global CROs and vendors, including contract and budget management.
- Ability to adapt to shifting priorities and thrive in a culture of agility and innovation.
- Excellent interpersonal, communication, organizational, and vendor management skills.
- Proficiency with modern clinical systems (EDC, CTMS, eTMF, IRT).
- Minimal travel as needed.

Preferred Qualifications

- Experience in Phase II–III cardiovascular or hypertension studies, including endpoint-driven designs.
- Exposure to FDA/EMA submissions and preparation of regulatory documents.
- Strong focus on quality oversight and inspection readiness.
- Background in cardiology, nursing, or clinical research at cardiovascular sites.

To Apply:

Please send your resume and a brief cover letter describing your interest and relevant experience to careers@retensionpharmaceuticals.com
Recruiters and agencies: We appreciate your interest, but we're not seeking external recruitment support for this role.