

Job Description

Division:	R&D
Title:	Director of Clinical Operations
Location:	New York, USA (or Remote USA)
Direct Supervisor:	VP, Clinical Operations
Position Summary:	
<p>OnCusp Therapeutics is seeking an experienced and proactive Director of Clinical Operations to lead the execution of oncology programs from early clinical development through proof of concept and registrational intent trials. This position will be instrumental in driving operational strategy, managing study budgets, negotiating and reviewing budgets and contracts, and ensuring high-quality trial execution in compliance with regulatory standards globally. This leader will serve as the operational point person across internal stakeholders and external vendors, managing CROs, overseeing timelines and resourcing, and ensuring that all deliverables are achieved on time, on budget, and with excellence. This is an ideal opportunity for a hands-on clinical operations leader who thrives in a fast-paced, innovative, and growth-oriented biotech environment.</p>	
Responsibilities:	
<ul style="list-style-type: none"> • Lead the end-to-end operational management of assigned clinical trials, ensuring timely initiation, enrollment, execution, and close-out. • Act as the primary clinical operations lead on cross-functional study teams. • Support clinical development strategy by providing input on study design, site selection, and operational feasibility. • Own and manage clinical trial budgets, including initial budget development, forecasting, accruals, and variance analysis. • Lead contract and budget negotiations with CROs, vendors, and clinical sites. • Review and approve vendor contracts, scopes of work, change orders, and payment terms in partnership with Finance. • Monitor financial performance to ensure alignment with overall program goals and OnCusp's operational strategy. • Manage CROs and third-party vendors to ensure quality execution and compliance with timelines and deliverables. • Define and track key performance indicators (KPIs) to assess vendor performance. • Provide proactive oversight and issue resolution across vendor relationships. • Support and mentor clinical operations team members and contribute to building a high-performing Clinical Operations function. • Contribute to the development, implementation, and refinement of Clinical Operations SOPs and best practices. 	

- Support inspection readiness and quality compliance through risk-based monitoring and internal audit support.
- Partner with Clinical Development, Clinical Science, Regulatory, Translational, and Project Management to align operational execution with strategic goals.
- Contribute to the development of key study documents (protocols, informed consents, monitoring plans, trial master files, etc.).
- Ensure timely and quality data delivery and collaborate on clinical data review and database lock processes.
- Maintain strong relationships with clinical sites and investigators to ensure proactive engagement and recruitment support.
- Participate in clinical site feasibility, selection, and activation activities.
- Support communications with KOLs, regulatory authorities, and external partners as needed.

Qualifications:

- Bachelor's degree in a life sciences field required; advanced degree (MS, MPH, PharmD, or equivalent) preferred.
- 10+ years of experience in clinical operations, with at least 5 years in oncology trials and global program execution.
- Demonstrated experience in clinical trial budgeting, financial tracking, and contract negotiations.
- Strong knowledge of ICH GCP, FDA, and EMA regulations.
- Operates with urgency, ownership, and accountability.
- Comfortable in a lean, high-growth biotech setting where strategic thinking is balanced with hands-on execution.
- Flexible and adaptive; able to pivot and problem-solve in real-time.
- Proven ability to manage and lead in a cross-functional, matrixed environment.
- Hands-on experience with allphasees (FIH/Phase I-IV) clinical trials preferred.
- Excellent organizational, interpersonal, and communication skills.
- Ability to travel domestically and internationally as needed.