Infinant Health Inc
2535 Capitol Oaks Dr., Ste 130
Sacramento, CA 95833

Clinical Operations Director

- Full-time, Remote
- Salary range $160K-$225K + Bonus
- Infinant Health (www.infinanthealth.com)

About the job:

Infinant Health was born out of UC Davis and is a small, privately held company committed to changing the trajectory of human health one baby at a time by supporting the development of healthy immune systems through gut microbiome science. The FDA has granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to Infinant Health's investigational drug candidate, INF108, for the prevention of necrotizing enterocolitis in preterm infants.

We are looking for a Clinical Operations Director to work on our Phase 1/2 clinical trial followed by our Phase 3 clinical trial with preterm infants in the NICU.

Read more about our company past published research at https://www.infinanthealth.com/publications.

Resumes or questions can be sent to: mkennedy@infinanthealth.com with "COD" in the subject line.

Clinical Operations Director Role:

CRO (Contract Research Organization) Oversight & Study Governance

- Serve as sponsor operational lead for trials executed by CRO(s)
- Lead study governance structure (e.g., weekly/monthly operational calls, joint steering committees)
- Ensure CRO execution aligns with protocol, timelines, and sponsor priorities
- Review and challenge CRO deliverables (timelines, monitoring reports, enrollment forecasts, etc.)
- Hold CRO accountable to key metrics (enrollment, SDV quality, query aging, protocol deviations)

Clinical Study Start-Up & Planning (Sponsor-Side)

- Oversee CRO-led site selection and activation strategy
- Review and approve key study startup documents (monitoring plans, risk plans, study manuals)
- Ensure operational feasibility of protocols in collaboration with Clinical/Medical teams
- Support regulatory submission readiness (IND amendments, study updates)
- Align study timelines with clinical, regulatory, and drug availability constraints

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Clinical Study Execution Oversight

- Monitor trial execution across multiple sites (US based)
- Track enrollment velocity and implement mitigation strategies for underperformance
- Oversee site performance issues escalated by CRO
- Ongoing review of data quality/data cleaning executed by CRO
- Ensure protocol deviations are identified, assessed, and managed appropriately
- Ensure regulatory documents and filings are updated as needed with IRBs (institutional research boards) and regulatory agencies
- Support drafting and reviewing clinical study report

Risk Management & Quality Oversight

- Implement and maintain Risk-Based Quality Management (RBQM) approach with CRO
- Ensure audit readiness of Trial Master File (TMF)
- Oversee inspection readiness activities and support audits (FDA, EMA if applicable)
- Drive CAPA (corrective and preventative actions) development and resolution for operational issues

Budget & Timeline Accountability

- Own sponsor-level study budgets and oversee CRO budget execution
- Review CRO invoices, pass-through costs, and change orders
- Manage CRO change orders and keep Finance team informed of changes in budget or timeline

Phase 3 Preparations

- Assist in protocol design, study document development
- Create Phase 3 CRO request for proposals, lead CRO selection for Phase 3 study
- Support execution of natural history study to support Phase 3 endpoint definition – Coordinate meetings and study execution

Key Experience:

- ***Must have:***
  - Early clinical phase development leadership (Phase 1, 2)
  - Experience with a Phase 3 clinical trial
  - Experience in start-up/resource constrained environment (prioritization, lean operation, cross functional work without hierarchy)
  - Experience as sponsor side CRO oversight
  - Clinical study start-up experience (site selection, contracting, IRBs, feasibility, activation and management), TMF, audit and CAPA review experience.
  - Minimum 5 years of experience.
- ***Nice to have:***
  - Pediatric hospitalized patient populations
  - Rare disease experience
  - Natural history study experience
  - Full study project management/execution history
- ***Delightful to have***: NICU experience

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Base Salary Range

- $160,000 - $225,000 + Bonus

Application Process

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Infinant Health is an equal opportunity employer and does not discriminate on the basis of race, color, religion, sex, national origin, age, disability, veteran status, sexual orientation, gender identity, or any other characteristic protected by applicable law.