

Courtney Clinical Consulting Overview

Senior Clinical Operations Consulting

Holly Courtney, MPH - Senior Clinical Operations Consultant | Fractional Head of Clinical Operations

Senior / Head of Clinical Operations level expertise • 18+ years in global clinical research • Pre-IND through global pivotal Phase 3 • CNS, neurology, psychology, metabolic, autoimmune, gastroenterology, microbiome, nephrology

About Me

I am a senior clinical operations leader with more than 18 years of experience guiding clinical programs from pre-IND through global, pivotal Phase 3. I work with biotech and pharmaceutical companies to build effective operational strategies, accelerate timelines, and lead cross-functional teams through complex development milestones.

My background includes operational strategy, study rescue, vendor governance, global study start-up, site engagement, and inspection readiness. I've held leadership roles at Sage Therapeutics, Clexio Biosciences, Synlogic Therapeutics, Summit Therapeutics, and Massachusetts General Hospital, building on earlier hands-on experience as a study coordinator. After working with investigators at Massachusetts General Hospital supporting development of fecal microbiota transplantation approaches, I joined Seres Therapeutics. There, I supported the Phase 2 trial and served as the lead Clinical Trial Manager for the Phase 3 program for SER-109, later approved and marketed as VOWST®, a first-in-class orally administered microbiome therapeutic. In subsequent roles, I have led clinical operations across multiple programs and therapeutic areas, building and mentoring teams while overseeing the end-to-end execution of complex clinical development programs spanning live biotherapeutic products, biologics, and small molecules.

Through Courtney Clinical Consulting, I work with biotech and pharmaceutical companies to deliver high-impact clinical operations leadership and hands-on execution, adapting the scope and structure to meet each organization's needs. I support programs across a wide range of therapeutic areas and development stages.

Core Consulting Services

Interim & Fractional Leadership

- Functional leadership for early-stage through global late-stage programs
- Team structure, mentoring, and operational alignment
- Cross-functional alignment and change management

Clinical Finance & Program Oversight

- Budget development & forecasting
- Vendor financial governance and change order management

Study Start Up & Feasibility

- Protocol & ICF development & operational feasibility
- IND/CTA readiness support
- Country selection & strategy
- Site identification and qualification

Vendor Oversight & Governance

- CRO and vendor oversight frameworks and governance models
- eCOA/ePRO implementation
- rater training oversight

Site Management & Engagement

- Site training & management
- CRA visit preparedness and support
- Site performance review
- Site visit strategy

Study Acceleration & Rescue

- Enrollment curve analysis
- Enrollment rescue strategy and execution

Inspection Readiness & Quality

- Audit preparation, TMF quality
- Database lock planning and execution oversight
- Data quality and cleaning strategy
- SOP and operational process development

Dashboard design & Analytics

- Dashboard design and visualization
- KPI development
- Milestone tracking

Risk Management

- Risk identification, assessment, and mitigation planning

Who I Support

- Seed, Series A/B biotech companies needing fractional leadership
- Sponsors seeking rapid operational lift or study rescue
- Clinical development teams preparing for first-in-human or global expansion
- Companies needing experienced oversight without full-time headcount

Typical Engagement Models

- Fractional or Interim Leadership
- Project-Based
- Short-Term Rescue
- Long-Term

Services are provided in a consultative capacity.

Contact

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