



A new dawn for treatment of mental health conditions

Associate Director, Clinical Operations

The Company:

Newleos Therapeutics is a clinical stage neuroscience company co-founded by Longwood Fund and seasoned leaders in CNS drug development. Newleos' clinical-stage pipeline was in-licensed from Roche and includes multiple oral small molecules targeting novel mechanisms across a broad range of indications, including generalized anxiety, social anxiety, substance use disorders, and cognitive impairment.

Position Overview:

Clinical operations team leader position responsible for operational leadership, planning, management, oversight, and execution of clinical programs in support of the clinical portfolio.

This position is based in Back Bay, reports to the Sr. Vice President, Clinical and Technical Operations, and supports a weekly hybrid work schedule with 3 days (Mon, Tues, Wed) in office and 2 days (Thurs & Fri) remote.

Responsibilities:

- Responsible for planning, oversight and execution of assigned clinical projects: responsible for timelines, budget, and key deliverables as well as contributing to overall clinical strategy.
- Participates on Clinical Team as operational representative and partners closely with Clinical Development, Biometrics, Regulatory Affairs, and Clinical Pharmacology in support of clinical strategy and development plan and in medical/operational execution of clinical projects.
- Provides leadership to Clinical Sub-team/study team and participates in cross-functional team meetings.
- Responsible for project budget/resource planning, re-forecasting, milestone, payment and variance tracking with Head of Clinical Operations, Project Management, and Finance.
- Develops, maintains, analyses, and reports on operational performance metrics for assigned clinical programs.
- Provides input and oversight in development of clinical plans, protocols, SAPs, consent form development, and other program/study related documents.

- Manages relationships and establishes strong partnerships with CROs, vendors, clinical investigators and other external partners.
- Works with Head of Clinical Operations in the selection of CROs and vendors, and participates in contract and budget negotiations.
- Responsible for oversight of all clinical start-up activities including feasibility, country selection/recommendation, budget & timeline planning, supply chain, and regulatory preparation in conjunction with relevant departments and CRO study start-up team.
- Provides oversight for project-related data integration/technology activities including IVRS, ePRO, central lab, etc along with the data management department.
- Provides supervisory leadership and support to CTMs/CTAs direct report(s) including mentoring, training, performance evaluation, and career development.

Qualifications:

- **Education**
 - Science background BS or healthcare degree, Master's/PhD preferred
- **Experience**
 - 7+ years of clinical trial execution experience in a pharmaceutical/biotech or CRO setting or equivalent
 - International trial execution experience and CTA submission experience required
 - Deep knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials
- **Skills:**
 - Strong leadership skills and ability to work within cross-functional teams
 - Excellent interpersonal, organizational, and multi-tasking skills

Newleos Therapeutics is proud to be an Equal Opportunity Employer. Our goal is to have a diverse workforce. We do not discriminate on the basis of race, age, color, religion, national origin, gender, sexual orientation, gender identity or expression, veteran status or disability or any other status protected under federal, state or local law. All employment is decided on the basis of qualifications, merit and business need.