ANTABIO Developing tomorrow's antibacterials	**Clinical Project Manager**
	April 2024

Antabio is a Labège, France-based biopharmaceutical company dedicated to the discovery of first-in-class small molecule compounds to treat severe infections caused by antibiotic-resistant bacterial pathogens. The company has a particular focus on life-threatening respiratory infections, including carbapenem-resistant nosocomial pneumonia and chronic pulmonary diseases. Antabio's lead program, **MEM-ANT3310**, is being developed for the treatment of hospital-acquired infections such as nosocomial pneumonia caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB) and carbapenem-resistant Enterobacterales (CRE).

Antabio is seeking a **Clinical Project Manager** to join our clinical R&D team and co-ordinate ongoing and future clinical trials.

The candidate must have excellent communication and management skills and be able to interact with a multidisciplinary team across different time zones.

Flexible with regards to work/home location (in France), with regular onsite (Toulouse) meetings required.

Start Date: Summer 2024, permanent contract.

Responsibilities

- Responsible for participating in the development and authoring of clinical study protocols, informed consents, clinical study reports, investigator brochures, and regulatory submission documents
- Participate in CROs and third-party vendors selection, including budget negotiation, follow-up and reconciliation
- Lead, at the operational and scientific levels, clinical trials: set-up, organize the planning and the execution and delivery, coordinate the different involved parties (internal and external), validate the project plans, ensure common understanding of activities, identify risks and manage them for quality outcomes
- Assist with establishing and tracking clinical timelines and appropriate performance metrics.
- Oversee performance of CROs and third-party vendors to assess the quality and to ensure compliance with study protocol and in accordance with scope of work and corporate timelines; identify areas of concern and escalate to CMO or CRO as appropriate
- Oversee monitoring activities, including co-monitoring visit and may participate in clinical sites audit
- Review monitoring reports for accuracy, completeness and conformance with SOPs
- Assurance of regulatory compliance of investigational sites with company SOPs, EMA/FDA and ICH guidelines
- Coordinate Investigator meetings and CRA trainings, maintain frequent contact with and work effectively with investigators and clinical sites team
- Develop and administer study budgets

- Negotiate and manage the contracts, budgets and payments for third-party vendors, including CROs. Work closely with Head of Program Management to accurately track spending and monitor cash flow forecast for clinical plan delivery
- Track items related to budget and contract completion status
- Review of research ethics committee/regulatory documentation
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures
- Perform clinical data review of data listings and summary tables and participate in Safety Review Committee meetings
- Assist in the preparation of Clinical Study Reports and annual safety reports
- Contribute to SOP writing or updates

Qualifications

- Master's degree (or equivalent) with in depth experience of Phase 1/Phase 2 clinical development
- ≥ **5-8** years relevant experience in the pharmaceutical and/or biotech industry and/or CRO

Previous experience

- Experience in the set-up, conduct, and operational oversight of clinical studies conducted by CROs
- Experience with first in human studies for NCEs/NBEs and/or phase 2 preferred
- Experience in Infectious diseases would be beneficial

Personal skills

- Fluent oral and written English mandatory
- Able to work in a global company environment
- Detail oriented, organized, and able to work effectively in a team environment
- Confident, capable and proactive communicator
- Excellent time management skills and rigorous attention to detail
- Enthusiastic, motivated and creative
- Experience with MS Project, or similar, would be an advantage
- Discretion and an understanding of confidentiality issues