ANTABIO Developing tomorrow's antibacterials	**Clinical Pharmacologist** Full/Part-time
	June 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 Pharmacologist** to join our clinical R&D team and to design, evaluate and report future clinical trials. Flexible with regards to work/home location (in France), with regular onsite (Toulouse) meetings required.

Start Date: As soon as possible, permanent contract.

Requirements

- Clinical pharmacologist (MD, PharmD, PhD) with in-depth experience of clinical pharmacology principles
- ≥ 5 years' experience in the pharmaceutical and/or biotech industry
- Experience in the design, analysis, and reporting of clinical pharmacology studies, including experience with FIH studies for NCEs
- Understanding the unique aspects of conducting such studies in healthy volunteers and patient groups/special populations.
- Proven history of positive interactions with Phase 1 units, CROs, and competent authority, ethics committees as the representative of the sponsor
- Experience with regulatory submissions, including CTA and IMPD
- Experience in applying regulatory guidances (FDA and EMA, GCP) to the design and interpretation of Phase 1 trials
- Infectious diseases experience would be beneficial
- Fluent oral and written English mandatory
- Able to work in globally distributed company environment
- Flexible with regards to work/home location in France, with travel to Antabio (Toulouse) on an occasional basis, as required

Responsibilities

- Responsible for scientific quality of clinical pharmacology studies: design, implementation, analysis, interpretation, reporting and regulatory submission
- Key contributor (author/and or reviewer, as required) to high quality clinical pharmacology plans and content for global regulatory documents including protocols, investigator's brochures, briefing documents, IND applications/annual reports, responses to regulatory queries, CSRs, safety monitoring plans, data management plans, data review, summary Documents in NDAs/MAAs

- Perform and oversee the conduct of Phase 1 studies in collaboration with Clinical Operations
- Collaborate with other scientists, including from CROs (*e.g.*, PK/PD, statistics, ADME, modeling and simulations) and contribute to writing of IB, IMPD and other IMP-related documents.
- Support preparation of high-level plan for late-phase studies
- Effectively collaborate as a member of cross-functional project teams
- Provide high quality review and interpretation of study results so the data can be incorporated into the strategy for the overall development program
- Participate in CRO identification and selection, in conjunction with the clinical operations group.
- Assist in planning process and participate in study start-up meetings and other activities to provide the appropriate training and information to investigators and site personnel.
- Serve as resource to clinical trial managers, clinical research monitors, investigators and ethical review boards to address any questions or clarify issues arising during the conduct of study.
- Monitor patient safety during the conduct of studies and conduct the appropriate tracking and follow-up of adverse events.
- Provide appropriate oversight and partnership with Third Party Organizations in collaboration with Clinical Operations to ensure successful study execution.