Job Opening

MaaT Pharma is a clinical-stage biotechnology company and industry leader in microbiome therapies in oncology, leveraging our whole ecosystem restoration approach to develop biotherapies to treat serious diseases.

We are implementing an innovative new medical approach focused on the gut microbiota as a source of drug candidates, leveraging our drug development expertise, our gutPrint® computational biology platform and our biomanufacturing capabilities. Our pipeline consists of several drug candidates, the first of which is now in Phase 3 clinical testing.

We are driven by our pioneering spirit, and we are the first microbiome-derived drug development company listed in continental Europe; we listed on EURONEXT Paris on November 8, 2021. We have a humanistic approach to our entrepreneurial adventure. Every recruitment is an opportunity to consolidate our rich and diverse human capital, which will soon reach 50 people.

Currently based in Lyon (69007), we are looking for:

Senior Clinical Trial Project Lead (M/F)

Position able to people with disabilities

Job description

By joining MaaT Pharma, you will have the opportunity to participate in the development and production of solutions at the cutting edge of pharmaceutical innovation. Your main role will be to manage and monitor clinical trial projects under the responsibility of the Director of Clinical Operations.

Main responsibilities

- Ensure that the clinical trial(s) of MaaT Pharma run smoothly and according to budget and plan;
- Under the supervision of the Head of Clinical Operations, collect, summarize and report study information for the creation, review and maintenance of study trackers, including presentation of the trackers during team meetings;
- Collaborate with the Clinical Development team to elaborate protocol, to review clinical data, to answer to regulatory authorities, to review CSR;
- Perform submission to competent authorities and Ethic committee if applicable;
- Collaborate with the Clinical Supplies Platform to validate IMP needs, specifications, packaging, shipment (including resupply) and reconciliation processes.;
- Help ensure proper and timely IMP availability at all study centres. Provide forecast of IMP to supply chain Department;
- Involvement in the preparation of study-related materials, like newsletters and forms to support inclusion.
- Ensure the availability and distribution of study-supporting material;
- Organise and lead study-specific meetings as needed, including participation in regular meetings with vendors;
- Ensure consistent, efficient and effective communication with vendors and sites;
- Participate in the selection of new vendors and the development/follow-up of associated budgets;
- Ensure that MaaT Pharma carefully selects and effectively manages its CROs;
- Preparation and oversight of study audits/inspections, both internal and external. Provide oversight and preparation for regulatory authorities' meetings and inspections;
- Ensure that the clinical operations department runs according to GCP.

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Qualifications and experience

- Possess a bachelor's degree in Life Sciences;
- +5 years of minimum experience in the pharmaceutical industry or clinical research organisation. Preferably in the oncology/haematology area. This should include negotiating study contracts, budget management, study tracking, documentation of follow-up activities, and related administrative duties;
- Ability to take leadership roles and to be a team player in meetings and for projects;
- Fluent English and French both oral and written;
- Experience in managing multi-site, multi-country clinical studies from an operations perspective;
- Ability to anticipate and escalate issues, propose appropriate action plans, monitor KPIs, CAPAs, etc;
- Ability to manage study tracker tools;
- Ability to lead cross-functional projects with good project management skills and knowledge to coordinate multiple interfaces, both internally and externally;
- Ability to foster team spirit and motivation across different departments;
- Strong understanding of regulatory and safety aspects associated with clinical trials, clinical trial master files, and general clinical study documentation;
- Good working knowledge of GCP, ICH, and EMA regulations – of FDA regulations would be a plus;
- Solid document writing skills for all documentation related to competent authorities;
- External vendor management and business communication skills; leadership potential;
- Excellent organisational skills, including attention to detail and multi-tasking abilities;
- Strong change adaptability, managing resources in an efficient and outcome-oriented manner.

You have good interpersonal skills, you are a good communicator (able to explain solutions in simple terms), dynamic and you have a good ability to adapt in complex project contexts.
Dynamism, ability to listen, proactivity, rigor and a very good team spirit and synthesis are all qualities we are looking for in this great opportunity.

Working at MaaT Pharma is

A friendly and stimulating work environment with challenges, within a passionate team… and also the opportunity to develop your skills and grow.

If you are motivated to join a curious team of human size and evolving in an entrepreneurial and innovative environment, then join us by applying for this offer!

If you are interested in this job at MaaT Pharma and you meet the criteria above, please send an email with your resume and your motivation to: **careers@maat-pharma.com.**