Biophytis SA (www.biophytis.com) is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. BIO101 (20-hydroxyecdysone), our lead drug candidate, is a small molecule in development for muscular (sarcopenia, phase 3 ready to go, and Duchenne muscular dystrophy, phase 1-2 to go), respiratory (Covid- 19, phase 2-3 complete) and metabolic (obesity, phase 2 to go) diseases. The company is headquartered in Paris, France, with subsidiaries in Cambridge, Massachusetts, USA, and Brazil. The Company's ordinary shares are listed on Euronext Growth Paris (ALBPS - FR001400OLP5) and its ADSs (American Depositary Shares) are listed on the OTC market (BPTSY - US 09076G401). For further information, visit www.biophytis.com.

To sustain our development, the company is now opening the following position:

Clinical Operations Leader

Organization: Clinical Medical Team Operations, reporting to the Chief Clinical Operations Officer

Team: Clinical Medical Team

Position overview:

The Clinical Operations Leader (COL) represents a key member in Biophytis Clinical Operations Organization. He/She will be leading the clinical project in all its dimensions. The COL takes a key part in the interface between Biophytis, Clinical Research organizations (CRO) and governance bodies to successfully and efficiently conduct clinical trials.

The COL will be accountable for the clinical trial timelines and objectives from start-up activities to finalization of Clinical Study Report. He/She is responsible for the preparation and/or the timelines of numerous clinical study documentation (Clinical development plan; Clinical trial design / synopsis; Monitoring Plan). He/She is also contributor for the governance bodies management of the clinical trial, and responsible for the budget and site contracts negotiation. He/She is responsible for the CRO selection for the targeted clinical study (ies) as well as the country selection. He/She is a member of the core project team and will bring all relevant information and inputs related to the clinical trial for achieving the milestones and success of the project.

The position is located in Ivry sur Seine, France and provides a global coverage. The Clinical Operations Leader reports to the Chief Clinical Operations Officer and works in close links with the Program Director, Regulatory and Medical Director and with the relevant functions in Research and Development and Pharmaceutical Operations functions.

Key Responsibilities:

- Main Leader of the Clinical Operations activities
- Responsible for Clinical Study management, setting and meeting goals, timeline, budget and resource allocations, under the guidance of the Chief Clinical Operations, Chief Medical, Core Team and the Executive Committee
- Contribute to updating Biophytis' internal Standard Operating Procedures (SOPs) to ensure studies are conducted in compliance with Good Clinical Practice.
- Establish strong interactions for responding to questions and issues raised by sites, suppliers, monitors, and consultants as regard clinical operations.
- Strong contribution in Database lock and Data cleaning

- Responsible for CRO selection
- Contribution in clinical trials governance body management (DSMB/DMC; Steering committee).
- Review/providing input to clinical documents (clinical development plans, study protocols)
- Participate in—and, if necessary, oversee—the development of tools required for study monitoring and the maintenance of Trial Master Files; participate in the development of informed consent forms and the design of Case Report Forms, etc….
- Review or co-authoring the following documents (Clinical development plan, Monitoring plan, Drug development plan, the translational plan, the scientific communication plan etc...)
- Contribute to the analysis, summary, and reporting of clinical data of the study.
- Maintain professional expertise regarding clinical documentation and scientific literature.
- Involved in identifying appropriate contacts with all stakeholders for the success of the trial.
- Maintains professional expertise through familiarity with therapeutic area and clinical research literature.

Qualifications:

- A Master or PhD in life-sciences
- Experience of at least 5 years in the pharmaceutical industry – in clinical or drug-product development
  - Experience in project management – of clinical trials and or projects with a budget of ≥ 10ME
  - Experience in late-stage development
- Knowledge in some of the following areas: drug development, clinical development, regulatory affairs, CMC or Knowledge in quality assurance.
- A thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial management, with an up-to-date certification, from the last 3 years.

Skills:

- Strong synthesis & analytical capacity
- Good communication, coordination and organizational skills, mostly for planning
- Ability to influence and negotiate effectively.
- Ability to work well in a dynamic and constantly changing environment, with flexibility and agility.
- Ability to combine a strong scientific knowledge and understanding of medical challenges, with focused and value-adding delivery of tasks and commitments.
- Ability to work with internal and external stakeholders in a multicultural and diverse environment with respect and patience.
- Excellent oral and written English communication skills (Fluency in Spanish will be considered an advantage).
- Knowledge of the French culture will be an advantage.
- Demonstrated awareness of emerging AI technologies and their practical application within a professional environment.

Salary package : according to experience and qualifications

Contact: Write to Marie-Paule Julienne: rh@biophytis.com with motivation letter & resume