Clinical Strategy Lead

Agomab is a young and dynamic biotech company developing medicine for patients with inflammatory and fibrotic diseases, including Crohn's disease. We are headquartered in Gent with offices in Antwerp and Barcelona; and laboratory facilities in Turin and Touro.

We are looking for a highly skilled and motivated **Clinical Strategy Lead** to join our Clinical Team, reporting to the Head of Clinical Strategy and Operations. As a Clinical Strategy Lead, you play a critical role in creation of clinical development plans and the design, analysis and interpretation of clinical trials to support the development and approval of our novel therapeutic products. Furthermore, you drive the strategic planning and execution of clinical development. This position involves solid leadership, strategic thinking, and collaboration with cross-functional teams to ensure the successful development of new therapies while adhering to regulatory and ethical standards.

Who are we?

We are a highly motivated team, valuing ownership, trust, humility and courage in everything we do. We focus on pioneering science and getting results within an environment of continuous self-improvement.

What will you do?

- Lead the development of comprehensive clinical development strategies aligned with the organization's therapeutic focus and business objectives. Drive the identification of target indications, patient populations, trial designs, and endpoints that support the overall product development goals in close collaboration with the Medical Team.
- Drive the development and refinement of the TPP for the investigational product, ensuring that it reflects the evolving understanding of disease, patient needs, competitive landscape, and regulatory considerations. Use the TPP as a guiding document to inform clinical trial designs, endpoints, and overall development plans.
- Act as Clinical representative in Project Teams or participate in/present at R&D Committee meetings as appropriate.
- Provide leadership and direction to cross-functional clinical teams, including clinical operations, regulatory affairs, medical affairs, biostatistics, and data management. Ensure the effective execution of clinical programs, including timelines, budgets, and quality standards.
- Design and optimize clinical trial protocols, including the selection of appropriate endpoints, patient inclusion/exclusion criteria, and statistical considerations. Oversee the implementation of adaptive trial designs when applicable to enhance trial efficiency.
- Collaborate with regulatory affairs to develop and execute regulatory strategies for clinical development programs. Ensure timely and effective interactions with regulatory authorities, including the preparation of regulatory submissions (INDs, NDAs, etc.) and participation in regulatory meetings.

- Oversee the analysis and interpretation of clinical trial data to support decision-making throughout the development process. Collaborate with biostatisticians and data management teams to ensure data quality, integrity, and accurate reporting.
- Identify potential risks and challenges in clinical development programs and develop risk mitigation strategies. Proactively address issues that may impact timelines, patient safety, or the overall success of the program.
- Foster strong relationships with internal and external stakeholders, including investigators, KOLs, CROs, and regulatory agencies. Effectively communicate clinical development plans, progress, and findings to executive leadership, the scientific community, and other relevant parties.

Who are you?

- You have minimum a PhD, MD or master's degree in a scientific field with a focus on life sciences or a related discipline.
- You have ideally 10+ years of experience and prior experience in a similar role within the pharmaceutical or biotechnology industry.
- You are a strategic thinker with a visionary mindset to identify and capitalize on clinical development opportunities
- You have strong knowledge of clinical trial design, execution, and data analysis, along with a solid understanding of relevant regulatory guidelines and GCP.
- You own proficiency in interpreting clinical data, identifying trends, and assessing safety and efficacy outcomes, particularly in relation to biomarker analysis.
- You have solid leadership skills, with the ability to inspire and lead cross-functional teams toward common objectives.
- You have excellent written and verbal communication skills, with the ability to effectively collaborate and present complex scientific information.
- You own strong organizational and project management abilities, with the capability to multitask and prioritize tasks effectively in a dynamic environment.
- You demonstrate problem-solving skills, attention to detail, and a commitment to ensuring data integrity and regulatory compliance.
- You speak and write English fluently. Additional languages are a plus.
- You are most of all a motivated and self-driven person, independently managing your time and projects

What we offer

- The opportunity to develop **pioneering science in a young biotech company**
- Challenging and innovative work environment as part of a driven team
- **Flexibility and responsibility** based in Antwerp with remote working options that can be tailored for you
- Competitive salary and benefits
- An agile and fast paced environment

Interested in having a high-impact contribution in a growing company? **Send your application to HR@agomab.com** to the attention of Paul van der Horst, Chief Business Officer and join the team! Please be aware, Agomab is not working with any recruitment agencies so please reach out directly.