

Job Description Head of Clinical Operations

The company

TargED Biopharmaceuticals (TargED) is a Netherlands-headquartered biotechnology company that develops first-in-class biological drugs to improve treatment of thrombosis. TargED stands for Targeted Enzyme Delivery and the company's unique biological drugs use small antibodies ("VhH") to deliver enzymes to sites of thrombosis, enabling 'targeted' thrombolysis.

TargED's lead compound is TGD001, which provides effective thrombolysis for various forms of thrombosis. It is currently preclinically validated in two thrombotic indications for thrombotic thrombocytopenic purpura (aTTP – an orphan indication) and Acute Ischemic Stroke (AIS). The objective is to accelerate thrombolysis in all forms of thrombosis, irrespective of the thrombus composition. In 2022, TargED raised €45M of funding from an internal syndicate of VC investors and a loan from the Dutch government. TargED has a worldwide, exclusive license on the IP, covering TGD001 and variant fusion proteins.

TargED has a strong founding leadership team consisting of:

- CEO & co-founder Kristof Vercruyse, with 20 years' worth of drug development experience, and 13 years in the TTP field;
- CSO & co-founder Steven De Maat, PhD, with 10 years of experience as a technical expert in protein engineering, and the inventor of TGD001;
- COO & co-founder Marc Van Moorsel, PhD, with 5 years experience in translational business development in nanomedicines;
- CDO Gerben van 't Klooster, PhD, with 30 years of experience in drug development and senior roles in Galapagos and Tibotec;
- CMO Josi Holz, MD, with 25 years of experience in pharmaceutical drug development and managerial positions at Ablynx, Gilead Sciences, and LEO Pharma.

TargED's objectives over the coming years is to grow as a company and achieve the following milestones:

- Deliver a full CMC (non GMP and GMP) and toxicology program in 2024 enabling phase I study in Healthy Volunteers in 2025, including preliminary PoC in patients
- For Acquired Thrombotic Thrombocytopenic Purpura (aTTP), deliver the successful completion of a pivotal study in 2026
- Deliver the successful completion of a Phase II PoC study for AIS by the end of 2026

Search

TargED is a small, virtual company (approx. 10FTE over 15 persons), comprising a core of full-time employees and a number of highly experienced consultants and advisors. The plan is to stay

both virtual and lean, however, with funding secured and TGD001 rapidly progressing through preclinical development and towards the clinic, there is a requirement to strengthen the team with the appointment of a **Head of Clinical Operations** for 0.8-1.0 FTE. The starting date is to be discussed.

The role and responsibilities

As Head of Clinical Operations , you will be primarily responsible for:

- Leading and managing the Clinical Operations across all regions from First in Human to Pivotal studies
- Actively providing guidance and reviewing the scope of work against objectives, timelines, quality and other clinical management activities for studies
- Ensuring that project budgets meet company and financial targets
- Assessing the budget, risks, scope of projects, and contracts with third party vendors undertaken
- Improving business processes
- Ensuring compliance with company SOP's, processes, and ICH-GCP Guidelines
- Overseeing the management of external vendors to ensure that they are performing in accordance with contract specifications
- Using your expertise to build, coach, mentor, and advise the clinical operations team
- Ensuring the team is compliant with training requirements
- Ensuring SOPs and other quality documents are complete and up to date

What do we expect from you?

TargED expects its Head of Clinical Operations to:

- Have a PhD / Master's degree or other relevant disciplines and knowledge of Clinical Operations;
- Have at least 5 years' experience in project/program management experience
- Have strong knowledge of early clinical development (phase I/II) and clinical trial requirements from First in Human to Phase III studies
- Have proven knowledge of bringing a medicinal product from Proof of concept in animals towards the first human clinical study.
- Have Knowledge of Indications (e.g. Stroke, MI, etc ...). Knowledge of Orphan drug development is a plus.
- Have leadership skills combined with strong organizational management skills.
- Have strong planning, strategizing, management, monitoring, scheduling, and communication skills
- Have excellent written and verbal communication skills to clearly and concisely present information
- Have strong interpersonal skills in a fast-paced, deadline oriented, and changing environment

- Have the excellent ability to handle multiple tasks and many administrative details
- Exercise sound judgement and make decisions independently.
- Have excellent knowledge of MS Office 365
- Speak Dutch and English fluently
- Be operational in the Netherlands
- Be available in the Utrecht office for at least 2 days per week (including at least Tuesday and Wednesday)

What can you expect from us?

Working with TargED Biopharmaceuticals encompasses an attractive salary, as well as a competitive rewards package of fringe benefits (bonus, equity), but - above all - working in an informal yet professional and international start-up environment with a team of colleagues that are both enthusiastic and driven to reach their goals (work hard, play hard). You will be encouraged to work independently and to take initiative in an inspirational work environment full of development opportunities.

The office (Utrecht) is easily accessible by public transport and has a parking should you come to the office by your own vehicle.

For more information please contact:

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Chief Operating Officer

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