Clinical Project Lead

Leiden, The Netherlands

About CellPoint

Engineering immune T cells from cancer patients using Chimeric Antigen Receptors (CARs) are a great invention from the last decade, eradicating tumors and providing durable remissions. However, first generation CAR-T therapies require shipment of cryopreserved cells to large factories and labor-intensive manual processing, as designed in the '90s. It takes months, while patients cannot wait due to cancer progression. It also takes 300,000 EUR per treatment, limiting wide patient access. At CellPoint, we designed an unconventional CAR-T manufacturing and supply model using 2020 technology to provide affordable and available treatments for cancer patients in need.

About the role

We are looking for an outstanding Clinical Project Lead to help build and manage the clinical operations team and activities. This individual will lead ongoing clinical activities for a first-in-human program and will build out the Clinical Operations group to support our clinical trial activities.
The position will be based in the Netherlands and will report directly to the Chief Medical Officer.
As an experienced professional with a complete understanding of the field of clinical research you will be instrumental in development of our clinical operations system and initiating our lead clinical program with a novel CAR-T therapy in hematology. By doing so, you are contributing directly to the initial treatment of cancer patients, and the generation of data to make these CAR-Ts widely available.
The Clinical Project Lead will oversee clinical trial execution to ensure compliance with regulatory requirements, adequacy of data acquisition and management, and timely completion of clinical studies. Key responsibilities are:

- Development of clinical operations plans and processes
- Implement all logistics associated with execution of clinical studies and provide daily oversight of operations
- Contribute to design and review of clinical trial documents and plans, regulatory submissions, and reports
- Contribute to identification, evaluation and selection of investigators, sites, and vendors
- Serve as the primary point of contact and provide guidance for project specific CROs and vendors
- Expedite problem identification and resolution to ensure timely completion of clinical trials
- Review and provide guidance as needed on monitoring reports from CRAs to ensure applicable regulatory and protocol compliance, issue resolution, and quality management
- Lead strategies for patient recruitment and retention in clinical trials
- Monitor, communicate, and manage budgets for clinical trials

Qualifications

- Bachelor or Master degree in medical or scientific field
- At least 8 years of clinical research experience including trial management and early-phase clinical trial experience in hemato-oncology and/or cell therapy
- Vendor management experience
- Hands-on Pharmacovigilance and/or Data Management experience are an advantage
- Deep knowledge of ICH-GCP and clinical trial processes and operations

- Strong project management and interpersonal skills
- Excellent written and oral communication skills, fluency in English
- Result-driven and can-do mindset in a fast-paced environment, without compromising quality and compliance
- Regular (inter)national travel expected

CellPoint offers

- Competitive salary
- Dynamic environment using cutting edge technologies, aiming to surpass the leaders in the field
- Great culture with strong emphasis on team performance and personal development

Interested?

Get in touch or apply with a CV and short motivation to careers@cellpoint.bio .
Acquisition is not appreciated.

We are a young and fast-growing company. New team members have the opportunity to actively shape their position and contribute to our mission, being part of a very motivated and multidisciplinary team.