(Senior) Clinical Research Associate

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 laborintensive 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 seeking an enthusiastic (Senior) Clinical Research Associate to join our team. The position will be based in the Netherlands and will report into the Clinical Project Lead. 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 Research Associate will proactively coordinate the necessary activities required to initiate and manage an international multi-center phase I/II clinical trial. Key responsibilities are:

- Support development of clinical operations plans and processes
- Development of task-related plans and SOPs
  - Support management of vendors
  - Support with identification of clinical sites
  - Preparation of packages for CTA and IRB submissions
  - Preparation of site budget, negotiations of site budget
  - Organization, preparation, performance, follow-up of site qualification, initiation and monitoring visits
  - Identification, communication, resolution of site-related matters, issue escalation

Qualifications

- Bachelor or Master degree in medical or scientific field
- At least 5 years of clinical research experience including site monitoring experience and earlyphase clinical trial experience in hemato-oncology and/or cell therapy
- Experience in study start-up and EC submissions
- Excellent working knowledge of ICH-GCP and clinical trial processes and operations
- Good planning and organizing skills
- Excellent written and oral communication skills, fluency in English
- Result-driven and can-do mindset in a fast-paced env, 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.

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