



tknife TRANSFORMING
T-CELL THERAPY

We are a fast-growing, preclinical stage biopharmaceutical company developing tumor-specific T cell receptor (TCR) therapies. Our dynamic, international team sets out with the ambitious goal to revolutionize the TCR landscape using our unique and proprietary transgenic HuTCR mouse platform to produce fully human TCRs for the treatment of cancer. To achieve this ambitious goal, we have successfully completed our Series B financing and could raise 110 million US dollar from international investors in August 2021.

We already made it to a size of over 50 colleagues, and we can't wait to welcome new members to our team. Despite San Francisco, we are located at the BiotechPark Berlin-Buch in the north of Germany's vibrant capital, and our city-office is close to Charité Berlin-Mitte.

For our further company development, we also plan to grow our operations in the US. With T-knife we have demonstrated preclinical proof-of-concept with multiple TCRs. In addition, T-knife has validated the platform for over 90 undisclosed cancer targets and has several drug candidates currently in preclinical development.

To achieve our goals, we are looking for you as our next

Project Assistant in Clinical Research (F/M/X)

In that role you will provide administrative support to the clinical team as well as supporting them with efficient management of clinical trials.

This position will be based in our office in Berlin, Mitte.

Your Responsibilities:

- Responsible for setup, preparation and filing of Clinical Trial documentation including Operating Manual, Investigator Site File, Pharmacy File, Investigator Brochure and Protocol
- Set up and maintain the Trial Master File (TMF) in compliance with ICH GCP and T-knife SOPs. Perform regular TMF checks to monitor TMF completion.
- Prepare the TMF for archiving as required
- Update and oversee clinical trial systems
- Collaborate with external service provider to manage clinical trial supplies and including tracking and shipment of materials
- Update and oversee study tracking systems e.g. investigational product tracking, payment tracking, CRF tracking, patient tracking, etc
- Facilitate the study documents printing process
- Assist clinical team in the production of study reports and updates
- Facilitate project meetings with respect to the preparation and distribution of materials and final meeting minutes, as well as the coordination of participants
- Prepare and support material preparation for external meetings, other trial trainings and meetings as required.
- Support clinical team with other study related activities as needed
- Perform other duties as assigned by management

Your Profile:

- Scientific or medical education (Example: nursing/physician assistant's degree, or bachelor, or higher in Chemistry, Biology, Pharmacy or Medicine)
- First professional experience in clinical research and in the conduct of international clinical studies in a CRO or pharmaceutical environment, or transferable knowledge. Previous monitoring experience is a benefit
- May have significant transferable clinical research and administrative experience
- Good computer skills, including word processing and spreadsheets
- Working knowledge of ICH-GCP guidelines and clinical trial legislation
- Excellent collaboration and communication skills.
- Fully fluent in English, German is an advantage

What We Offer:

- A permanent position in a young, growing, and dynamic company in Berlin
- An inspiring work environment where we shape therapeutic innovations and continuously strive to improve the lives of patients
- The possibility to contribute to the built-out of our innovative and unique HuTCR mouse platform and in the development of novel T cell therapies
- Our company culture develops from a start-up mentality with professional execution, team spirit, motivation, and personal drive
- One of our maxims: **We walk our talk**

Please send us your full application including possible starting dates and your expected compensation using the email subject "Application TKN0031" to career@t-knife.com