AM-Pharma is a clinical-stage biopharmaceutical company developing proprietary recombinant human Alkaline Phosphatase (AP) therapeutics. Its most advanced asset, known as recAP, is a fully human recombinant form of AP. In 2018, the company successfully completed a Phase IIb trial in sepsis-associated acute kidney injury patients (SA-AKI). The focus has since been on funding and preparing to launch the Phase III / registration trial. The company is gearing up to build the organization that will deliver on the next phase of evolution.
The new AM-Pharma organization will involve several new key positions with large pharma / biotech Phase III experience. The focus will be on Operational Excellence and flawless execution of pivotal studies with the objective to deliver a quality market authorization submission package. The bandwidth of the organization will allow for expanding the pipeline and/or accommodating new strategic opportunities.

To support the expansion of AM-Pharma's business, we are currently looking for a

Clinical Data Manager

About the role
The Clinical Data Manager takes care of AM-Pharma data handling processes (storage, access, documentation) from study start-up to database lock and enforces the companies' expectation of Data Management during the study (interim analysis, database lock etc.) in order to produce a clean and analyzable database . He/she will develop a data and query review plan and ad hoc data query tools for clinical studies and will develop internal standards so that the highest level of quality can be maintained. He/she will contribute to detailed discussions about DM solutions proposed by the selected CRO, comment on contract aspects for DM and represent the AM-Pharma DM role in kick-off meetings as well as Investigator Meetings. He/she will represent AM-Pharma in the review and approval of DM documents during the study (DMP, DVP, CRF, EDC etc.), manage the DM work-stream and keep DM oversight and data extracts. He/she will represent DM in clinical project team meetings, review study protocols and discuss data related issues. In addition, he/she will pre-design CRF's and understand all data flows during protocol development. He/she will contribute to oral and written reports to effectively communicate data of clinical trials, respond to queries from clinical monitors, regulatory agencies, and/or investigators related to study design, data analysis and data interpretation. He/she will compile and standardize study data in preparation for study (and project) submission to worldwide regulatory agencies (e.g. NDA, MAA). He/she will maintain data systems to ensure they meet organizational requirements, monitor change control and assist with the validation of the DM systems. He/she will oversee system development and facilitate the review of systems and ensure that information is communicated with the project team.

What we expect
We expect our new Clinical Data Manager to

- Bring a minimum of 15 years of experience in Data Management in a GCP/FDA regulated pharmaceutical company or a Clinical Research Organization and have experience in supporting Phase-III programs, preferably also with complex eCRF design.

- Demonstrate expertise in Data Management planning from Protocol review, CRF development, eCRF setup and validation, Data validation to Clean File.
- Understand Data Management systems, data flows and data integrations. Have experience with CDISC and Standardization of Study data, in preparation of study data for eCTD submissions.
- Have experience in Vendor selection, collaboration, oversight and management for Data Management, and have experience in Sponsor oversight and collaboration with Data Management CRO's, to secure delivery high quality data.
- Bring a general understanding of worldwide regulatory requirements.
- Be experienced in taking on Sponsor responsibility for all Data Management aspects of an outsourced study. He/she is part of project teams and keeps strong interactions with the CRO's biostatical department, AM-Pharma's statistical advisors, Clinical Operations, Clinical Scientists and Regulatory Affairs.
- Have the ability to work successfully in a small organization.
- Be pragmatic, solution-oriented thinker who possesses a "can do" and" whatever it takes" attitude, coupled with excellent organizational and communication skills (verbal, written, listening, conveying messages).

About our company culture

The company culture of AM-Pharma is built on four important competences: Collaboration, Quality orientation, Accountability and Resilience. In our company, we work together in a constructive and team-oriented way. We work on our own objectives, while helping others to achieve theirs and put the common interest of the company above our own individual interest. We set high standards regarding the quality of our materials, processes, documentation and collaborations, and we act accordingly. We are motivated to deliver excellence and we endorse the principle of First-Time-Right. Our leaders and employees make an effort to improve the quality of our work and take initiative for quality improvements regularly. We are fully accountable for the things that are in our power and control while working on the goals of the organization. We have an obligation to report, explain and justify the things we do. We accept responsibility for our performance and we are transparent about the results of our work. Finally, we know how to cope effectively with setbacks and obstacles. We overcome hurdles on our way to reach our common goal. We stay committed to agreed objectives and company culture despite resistance while having the strength to adjust our plans when necessary. We are tolerant to stress and we deal effectively with criticism and resistance building on our own strength.

Remuneration

At market level.

Start date

We expect the candidate to start its employment latest as of Q4 2019.

Location

The future organization will be based in the Netherlands along the A2 corridor between Amsterdam and Den Bosch, preferably located close to a major train station connected directly with Schiphol Amsterdam Airport with maximum travel distance of 1 hour nominally.