Clinical Data Manager based in Stockholm

Oncopeptides is a global biotech company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The Company has recently been granted accelerated approval by the U.S. FDA for PEPAXTO (melphalan flufenamide, also known as melflufen), in relapsed or refractory multiple myeloma. PEPAXTO is the first drug originated from the Company´s proprietary PDC-platform and is evaluated in a comprehensive clinical study program, including the ongoing phase 3 OCEAN study. PEPAXTO is the first anticancer peptide-drug conjugate for patients with relapsed or refractory multiple myeloma. The product uses innovative technology that links a peptide carrier to a cytotoxic agent, resulting in a lipophilic compound. Due to its lipophilicity, it is distributed into cells. PEPAXTO is designed to leverage aminopeptidases, which are overexpressed in multiple myeloma cells and cause the release of the cytotoxic agents.

Oncopeptides´ global Headquarters is in Stockholm, Sweden and the U.S. Headquarters is situated in Boston, Mass. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. Today the company consists of 250+ co-workers in Europe and USA. More information is available on www.oncopeptides.com

We are looking for a clinical data manager to join our growing biometrics team, currently consisting of 14 people. The position is a full-time employment, and you will report to our Head of Biometrics. The role is in Stockholm, but remote work is also possible.

As a clinical data manager, you will be responsible for oversight of data management activities performed by our clinical study vendors. The work involves frequent interaction with other functions such as external and internal statisticians, programmers, data managers, clinical operations, and scientific experts. The role is for you who wants to work in a fast growing and dynamic company that is dedicated to make a big difference to patient lives.

Job description

- Actively drive, co-ordinate and follow-up on data management plans and activities to ensure high quality data in line expected timelines.
- Oversight of DM activities performed by vendors to ensure compliance with the agreed scope of work, study protocols, regulatory requirements, and standard operating procedures.
- Provide data management expertise to clinical study teams.
- Participate in reviewing data from clinical studies to ensure robust, complete, and accurate data, and contribute to and review data related reports.
- Identify and manage data driven risks, in close collaboration with statisticians and clinical operations, in assigned Oncopeptides clinical studies.
- Participate in the development and implementation of process improvements and standard operating procedures.

Required Background, Skills, and Knowledge

- At least 5 years' experience from data management work in clinical research in pharmaceutical industry. The following experience is also preferrable:
    - Management and vendor oversight of data management activities in clinical studies.
    - Oversight of vendor SOPs and ensure that they are compliant with company SOPs.
    - Familiar with CDISC data standards and FDA, EMA and ICH guidelines and regulations.
    - Experience from various phases in clinical development (oncology experience is advantageous).
- Experience with DM systems such as Medidata Rave, Oracle InForm or JReview.
- Experience with SAS, R, Python or similar is not a requirement but advantageous.
- Excellent problem-solving skills.
- Comfortable with working towards projects with set timelines, both independently and in a team.
- Positive and solution-oriented personality.
- Good cooperation and communication skills.

Required/Preferred Education

We are looking for a person with a university degree in relevant discipline.

Application

Please send your CV and cover letter to career@oncopeptides.com and write Clinical Data Manager in the subject line. We handle screening and selection continuously and therefore encourage you to apply as soon as possible. Start-date will be in August 2021 or according to agreement. All enquiries are treated confidentially and will be handled in accordance with GDPR.

For further information regarding the role please contact Hanan Zubair, Head of Biometrics, at hanan.zubair@oncopeptides.com. If you have questions regarding the recruitment process, please contact Johanna Tysell, HR Coordinator, at hr@oncopeptides.com.