Study statistician located 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 study statistician to join our 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 located in Stockholm, but remote work is also possible.

As a study statistician you will be responsible for providing statistical input in the design, analysis, reporting and interpretation of assigned Oncopeptides clinical studies. This includes working closely with cross-functional study teams such as clinical data managers, clinical operations managers/directors, study physicians, safety physicians and regulatory affairs managers. The role is for you who want to work in a fast growing and dynamic company that is dedicated to make a big difference for the patient.

Job description

- Write/review statistical aspects in clinical study protocols.
- Write/review Statistical Analysis Plans (SAPs).
- Analyze data from Oncopeptides clinical studies.
- Participate in interpretation and reporting of data.
- Oversight of statistical activities performed by vendors to ensure compliance with the agreed scope of work, study protocols, timelines, regulatory requirements, and standard operating procedures.
- Analytical oversight of processes for risk-based/centralized monitoring in assigned clinical studies, in close collaboration with clinical operations and data management.
- Participate in the development and implementation of process improvements and standard operating procedures.
- Involvement in preparations of data deliveries to health authorities in close collaboration with regulatory affairs and other functions as needed.
- Contribute to review and development of analysis-ready datasets, tables, listings and figures.

Required Background, Skills, and Knowledge

- At least 5 years' experience from biostatistical work in clinical research in pharmaceutical industry. The following experience is also preferrable:
  - Development of statistical strategies in clinical protocols, SAP and related documentation.
  - Selection, management, and oversight of vendors for statistical activities in assigned clinical studies.
  - Interpretation of results and review of clinical study reports and scientific communications.
  - Experience from statistical programming in SAS and/or R.
  - Experience from various phases in clinical development and preferably oncology endpoints
  - Familiar with FDA, EMA and ICH guidelines and regulations and CDISC data standards
- Excellent problem-solving skills.
- Positive and solution-oriented personality.
- Good cooperation and communication skills.

Required/Preferred Education

We are looking for a person with a university degree in statistics or mathematical statistics.

Application

Please send your CV and cover letter to career@oncopeptides.com and write *Study Statistician* in the subject line. We handle screening and selection continuously and therefore encourage you to apply as soon as possible. Start-date will be 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.