Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company focused on medical science and the development and commercialization of innovative pharmaceutical products for the treatment of rare neuromuscular diseases with high unmet medical need. For further information, please visit the Company's website www.santhera.com

Come and join our team to contribute to providing treatment options for patients with rare diseases that have a severe impact on the lives of affected children and adults. You can make a difference as:

# Head Biostatistics

Location: Pratteln, Switzerland (Hybrid)

## Scope of Work

As Head of Biostatistics you will lead the Biostatistics team, provide the Statistical and Data expertise to the Program Team and ensure adequate implementation of statistical methodology to the Santhera's drug development program, including clinical development, global registration of the product, market access, medical marketing and life-cycle management. This role currently reports to the Head of Development.

## Key Responsibilities

- Ensures that appropriate statistical methodology is used in the assigned Santhera's development program.
- Provides line management to the Biostatistics team such as statisticians, statistical programmers and data management.
- Acts as Program Statistician in the Global Program Team.
- Define appropriate outsourcing strategy for biostats activities and ensure appropriate oversight.
- Reviews/approves study-level essential documents (e.g. clinical study protocols, statistical analysis plans, clinical study reports) and project-level documents (e.g. clinical development plans, target product profiles).
- Provides input to the regulatory strategy for global regulatory submissions.
- Participates in global meetings & interactions with regulatory authorities as an expert statistician role.
- Provides input/reviews relevant sections of global regulatory submissions, e.g. documents in Module 2 of the dossiers.
- Develops processes and standard operating procedures related to statistical programming and statistics.
- Works in a matrix function with the development and commercial teams.

## Required Qualifications & Experience

- M.Sc. degree or higher in statistics or life sciences.
- At least 10 years' professional experience as clinical data analyst/statistician in a pharmaceutical company or CRO.
- Minimum 5 years of people management experience.
- Experience in designing global pivotal programs.
- Experience in global regulatory interactions.
- Experience in supporting market access, medical marketing and life-cycle management of products.

## Required Competencies & Skills

- Expertise in designing clinical studies, authoring statistical sections of clinical trial protocols, authoring statistical analysis plans, reviewing and providing statistical feedback and interpretation for clinical study reports, authoring and reviewing regulatory documents, e.g. briefing books.
- Thorough understanding of statistical methods typically used in clinical development and ability to implement novel methodologies.
- Outstanding level of written and spoken English.
- Good communication skills.

For this position, the relevant working/residency permit or Swiss/EU-Citizenship is required.

If you are interested in a multicultural, challenging, and innovative working environment and your profile matches our requirements, we are looking forward to receiving your online application in English via LinkedIn or Email, at career@santhera.com

**Strictly no agencies:** Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.