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:

Senior Biostatistician

Location: Pratteln, Switzerland (Hybrid)

Overview

As a Senior Biostatistician, you will play a critical role in supporting clinical development and real-world evidence (RWE) initiatives. You will be responsible for the statistical design, analysis, and interpretation of clinical trials and observational studies, ensuring scientific rigor, regulatory compliance, and high-quality deliverables.

This role is hands-on and highly collaborative, working closely with colleagues across clinical science, clinical operations, data management, statistical programming, regulatory, and medical affairs, as well as with external vendors and CROs. This position reports to the Head of Clinical Operations and offers an excellent opportunity to contribute to the advancement of innovative therapies within a dynamic and multicultural environment.

Key Responsibilities

Scientific & Technical Excellence

- Contribute to the design and statistical methodology of clinical trials and RWE studies.
- Develop and review Statistical Analysis Plans (SAPs), study protocols, and clinical/regulatory documents.
- Perform and oversee statistical analyses, ensuring accuracy, reproducibility, and regulatory compliance.
- Apply statistical methods (e.g., mixed models for longitudinal data, time-to-event analyses, methods for matching with external datasets) with a focus on rare disease development.
- Ensure statistical integrity in studies with small sample sizes.
- Proficiently use SAS for programming and analysis.

Operational Support

- Collaborate with internal cross-functional teams (clinical science, clinical operations, regulatory, medical affairs, data management, programming).
- Interact with CROs and external partners to ensure quality and consistency of outsourced statistical activities.
- Provide statistical input during study start-up, conduct, and reporting phases.

Regulatory & Compliance

- Contribute to statistical content for regulatory filings, including IND, NDA/BLA submissions, briefing packages, safety reports, and responses to health authority questions.
- Support preparation for regulatory interactions (FDA, EMA, and other agencies).
- Stay current on evolving methodologies, regulatory requirements, and statistical best practices.

Required Qualifications & Experience

- MSc or PhD in Statistics, Biostatistics, or a related field.
- Minimum 8 years of experience in clinical biostatistics within the pharmaceutical/biotech industry or CROs.
- Strong background in clinical trial design, and advanced statistical modelling.
- Experience in contributing to regulatory submissions and interactions with health authorities.
- Experience with real-world evidence analyses and strategies.
- Experience in applying statistical methods in post-approval stage.
- Solid knowledge of ICH guidelines, and CDISC standards (SDTM, ADaM).
- Proficiency in SAS.
- Previous leadership or mentoring experience advantageous.

Required Competencies & Skills

- Excellent communication skills, with the ability to present complex statistical concepts to non-statistical audiences.
- Detail-oriented, solution-focused, and adaptable in a dynamic environment.
- Strong collaboration skills, with experience working in cross-functional teams.
- Fluency in English (other languages are an advantage).

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

Note for Agencies: Recruitment agencies are kindly invited to refrain from sending unsolicited CVs to Santhera.