Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company committed to developing and commercializing innovative medicines to meet the needs of patients living with rare and other diseases with high unmet medical needs.

At Santhera, our people are the driving force behind our success. Our collective loyalty, courage, and resilience set us apart and help us thrive through change as a collaborative team. We create a purposeful workplace where your contribution matters, growth is fostered, and together we make a real impact for those living with rare diseases and for each other.

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)

Who You Are

You are an experienced, hands-on biostatistician with a strong background in Phase IV studies, real-world evidence (RWE), market access, and scientific publications. You have successfully supported evidence generation across the product lifecycle and understand the role of data in informing clinical practice, market access, and patient outcomes. Your experience may embrace clinical development activities (phase 1 to 3) as well, although this may not be the primary focus of this role.

You bring experience working within small to mid-sized pharmaceutical or biotechnology companies, where you have combined strategic thinking with hands-on statistical analysis and programming, while collaborating closely with cross-functional teams to deliver high-quality evidence and insights.

Please note that this is an Associate Director-level position.

Scope of Work

The Senior Biostatistician provides statistical leadership across one or more products lifecycle, supporting clinical development, regulatory submissions, safety surveillance, medical affairs activities, and market access activities.

The Senior Biostatistician works closely with Data Management and serves as a key scientific partner to Clinical Development, Clinical Operations, Regulatory Affairs, Drug Safety and Pharmacovigilance, Medical Affairs and Market Access and external partners to ensure robust evidence generation supporting regulatory and commercial objectives.

The role combines strategic statistical and collaborative leadership, with hands-on responsibilities. It is responsible for the statistical design, analysis, interpretation, and reporting of clinical trials and observational studies, while performing the statistical programming required for study analyses and reporting. The role requires strong technical expertise, scientific rigor, strategic thinking, and the ability to communicate complex statistical concepts to multidisciplinary teams.

Key Responsibilities, but are not limited to:

Scientific & Technical Excellence

- Lead statistical activities for Phase I-IV.
- Contribute to clinical development plans and integrated evidence-generation plans.
- Provide statistical input into study design, endpoint selection, estimand strategies, multiplicity control, sample size determination, and analysis methodologies.
- Provides input into study protocols, develops Statistical Analysis Plans (SAPs) and statistical sections of relevant clinical and regulatory documents, and publications.
- Perform and oversee statistical analyses ensuring scientific validity, reproducibility, and regulatory compliance.
- Apply state-of-the-art statistical methodologies.
- Independently perform statistical programming required for study data analyses.
- Develop and validate analysis datasets, tables, listings, and figures (TLFs), as needed.
- Conduct exploratory, sensitivity, and ad hoc analyses to support clinical and strategic decision-making.
- Ensure traceability, quality, and reproducibility of statistical outputs.

Regulatory Strategy & Submission Support

- Provide statistical support for registration-enabling clinical studies.
- Support preparation of:
    - Clinical Study Reports (CSRs)
    - Integrated Summaries of Efficacy (ISE)
    - Integrated Summaries of Safety (ISS)
    - Regulatory briefing documents
- Provide statistical expertise for regulatory strategy discussions.
- Support preparation for interactions with health authorities including FDA, EMA, MHRA, PMDA, NMPA, and other agencies.
- Maintain awareness of evolving regulatory guidance, industry standards, and statistical methodologies.

Safety Analytics & Pharmacovigilance Support

- Provide statistical support for aggregate safety evaluations and benefit-risk assessments.
- Support preparation of:
    - Development Safety Update Reports (DSURs)
    - Periodic Safety Update Reports (PSURs/PBRERs)
    - Annual safety reports
- Collaborate with Drug Safety and Pharmacovigilance and Clinical development on:
    - Signal detection activities
    - Safety trend analyses
    - Integrated safety assessments
- Provide statistical expertise for Risk Management Plans and post-authorization safety commitments.

Real-World Evidence & Market Access

- Support design and analysis of observational studies, patient registries, and real-world evidence programs.
- Participate in planning and actively support analysis of external control arms and synthetic comparator cohorts.
- Generate evidence supporting medical affairs and market access objectives.
- Provide statistical expertise for:
    - Comparative effectiveness studies
    - Healthcare resource utilization analyses
    - Outcomes research
    - Payer evidence generation
    - Health Technology Assessment (HTA) submissions

- Support development of value dossiers and reimbursement evidence packages.

Scientific Communication & Publications

- Provide statistical leadership for manuscripts, abstracts, posters, scientific presentations
- Review scientific publications and communications for statistical accuracy and methodological rigor.
- Collaborate with investigators, academic experts, and key opinion leaders.

Required Qualifications & Experience

- MSc or PhD in Statistics, Mathematics, Epidemiology, or related discipline.
- Minimum 8 years of relevant experience in biostatistics within the pharmaceutical, biotechnology, medical device, or CRO industry.
- Strong experience supporting Phase I-IV clinical development programs.
- Demonstrated experience supporting regulatory submissions and interactions with health authorities.
- Experience preparing integrated efficacy and safety analyses.
- Experience supporting observational studies, registries, and real-world evidence programs.
- Experience supporting market access, HEOR, HTA, or payer evidence-generation activities is highly desirable.
- Strong knowledge of ICH E6(R3), ICH E9, relevant regional regulatory requirements.
- Solid understanding of CDISC standards including SDTM and ADaM.
- Advanced proficiency in SAS programming, including development of analysis datasets and TLFs.
- Experience independently generating and validating statistical outputs.
- Experience with R programming and modern statistical computing environments is highly desirable.
- Experience working in rare disease and/or orphan drug development is advantageous.

Required Competencies & Skills

- Strong strategic thinking with the ability to align statistical approaches with clinical, regulatory, and commercial objectives.
- Excellent communication and presentation skills, including the ability to explain complex statistical concepts to non-statistical audiences.
- Strong scientific and analytical problem-solving capabilities.
- Strong hands-on statistical programming and data analysis skills.
- Ability to independently execute analyses while effectively collaborating in cross-functional teams.
- Strong collaboration and influencing skills.
- Detail-oriented, quality-focused, and solution-oriented mindset.
- Ability to manage multiple priorities in a dynamic environment.
- Commitment to scientific excellence and continuous learning.
- Fluency in English; additional languages are considered an asset.

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.