



Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need.

Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group.

For further information, please visit the company's website [www.santhera.com](http://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

### **Clinical Operations Team & Trial Leader**

at our Headquarters in Pratteln, Switzerland (close to Basel) on a full-time basis.

#### **Scope of Work**

The Clinical Operations Team & Trial Leader provides operational guidance and oversight across clinical trials and leads assigned Clinical Operations team members. Acting as a Clinical Trial Leader, she/he plans clinical trials in accordance with company strategy and ensures it's compliant and timely execution to final study report within budget. She/he leads the cross-functional Study Management Team (SMT) aligning efforts to common goals.

The role reports to the Head Clinical Operations acting as the deputy and works in close collaboration with multiple functions, technical development & operations, regulatory affairs, clinical science, biostatistics and drug safety.

#### **The core responsibilities are:**

- Provide line management and inspirational leadership to assigned Clinical Operations team members
- Provide operational guidance and oversight across clinical trials including clinical operations related input to clinical development plans
- Act as a Clinical Trial Leader executing clinical trials from planning to final study report
- Development and approval of study documentation, management of study approval process
- Identification and selection of external service providers ensuring GCP compliant contracts
- Coordinate and oversee pre-audit and CAPA resolution activities relevant for Clinical Operations

#### **Required background and experience:**

- University or equivalent education/degree in life science or healthcare
- 6+ years of experience in clinical development and clinical trial management; field monitoring experience is desired
- Thorough understanding of the drug development process
- Advanced knowledge of ICH-GCP guidelines and other relevant clinical trial regulations

- Experience in external service providers management incl. selection
- Profound project management experience and leadership skills
- High financial acumen to manage clinical trial budgets
- Fluency in English (any other language is a plus)

#### **Required Competencies**

- Strong leadership skills acting comfortably in a matrix organization.
- Strong verbal and written communication and presentation skills
- Ability to work independently to manage multiple projects in a fast-paced environment with a sense of urgency
- Strong problem solving and analytical skills with a high attention to details
- Well organized and structured work style ensuring accurate work results
- Ability to identify opportunities / major issues and to communicate impact, excellent project management skills
- Reliable team-player

If you are attracted by this exciting opportunity and the prospects of joining a motivated international team operating on a global level, please send your CV and motivation letter mentioning the position “**Clinical Operations Team & Trial Leader**” as the subject by email to: [career@santhera.com](mailto:career@santhera.com)

#### **Strictly no agencies**

Recruitment agencies are kindly invited to refrain from sending to Santhera unsolicited CVs.