Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of orphan mitochondrial and neuromuscular diseases.

In September 2015, our leading product Raxone® (idebenone) received European Marketing Authorization in the treatment of patients with LHON (Leber's Hereditary Optic Neuropathy). Raxone® is not only the first and only medicine approved for this condition, but it is also the first medicine approved for any mitochondrial disorder.
The company currently develops Raxone® in other areas of high unmet medical needs, like the treatment of Duchenne Muscular Dystrophy (DMD) and Primary Progressive Multiple Sclerosis (PPMS). In addition, Santhera's pipeline includes omigapil, an investigational drug with anti-apoptotic properties, a compound in development to address unmet medical needs for patients with Congenital Muscular Dystrophy (CMD).

For more information, please visit the company's website www.santhera.com

We are currently looking to hire a:

## Clinical Trial Manager

to be based at our Headquarters in Liestal, close to Basel.

**Scope of Work**

The role currently reports to Head of Clinical Operations and works closely with Clinical Trial Leader, clinical development functions, medical affairs and CROs.
The overall scope of the role is to support Clinical Trial Leader in execution, oversight and report of clinical trials, from vendor selection and site feasibility through study close out.
The role contributes to the cross-functional Study Management Team (SMT) to support timely delivery of all trial outputs within budget and with high quality standards, in adherence to internal SOPs, GCP and applicable regulatory guidelines.

**The responsibilities for this role include the following:**

- Contribute to the development & review of study documentation such as the study protocol, Informed Consent Form (ICF), study-specific guidelines, regulatory documents, monitoring, data management and statistical analysis plans and clinical study report, in accordance with internal SOPs and GCP requirements
- Contribute to the development of regulatory documents, support the approval of submission packages to Health Authorities and ECs/IRBs and support the Regulatory Department in answering to Health Authority, IRB/IEC and/or DSMB questions/requirements
- Supports identification and selection of ESPs, including establishment of scope of work and budget negotiation; ensure that related contracts comply with internal SOPs and legal requirements
- Contribute to the development of specifications for Interactive Response Technology (IRT), Electronic Data Capture (EDC), and any study-related systems. Review ESP specifications in collaboration with SMT and ensure appropriate quality control of deliverables
- Perform User Acceptance Testing (UAT) and provide feedback to CTL prior to validating study re-related systems
- Attend or chair regular TC meetings with specific ESP and provide feedback to the CTL
- Manages ESP's oversight activities including monitoring and conduct co-monitoring visits to ensure data quality. Perform & document necessary quality checks. Perform ongoing ESP management, performance management and issue resolution
- Check ESP invoices and ensure appropriate tracking and reconciliation
- Act as SMT member, attends cross functional SMT meetings and deputizes CTL as needed.
- Review feasibility results and provide feed-back to the CTL

- Review forecasting of IMP and study supplies
- Contribute to the planning & organization of Investigator meeting and CRA training(s), review related material and perform presentation(s) as appropriate.
- Assist with the set up and maintenance of TMF (Trial Master File) for studies to ensure proper study documentation is maintained and archived in the TMF
- Resolve issues in a proactive and timely fashion and escalate unresolved issues and identified risks to the Clinical Trial Leader and Head of Clinical Operations as appropriate
- Supports database lock activities oversight, to ensure timely data availability and coordinate study close out with ESPs as needed
- Contribute to the development and follow-up of CAPA
- Adhere to personal development plan and maintain training records to ensure appropriate level of competence in compliance with this job description including GCP and applicable regulatory guidelines

**Required background and experience:**

- Master degree or equivalent university education/degree in life science or healthcare
- Minimum of 4 years relevant experience in clinical development and clinical trial management, field monitoring experience is highly desired
- Experience in managing international complex studies (e.g., large studies, specific patient populations, management of several external service providers)
- Experience in selecting and managing external service providers
- Thorough understanding of the drug development process
- Advanced knowledge of International Conference on Harmonization (ICH)/Good Clinical Practice (GCP) guidelines and other relevant clinical trial regulations
- Solid experience in project management (including risk management and contingency planning)
- Experience in executing a wide range of clinical trial activities across PhI to Ph IV studies (from initiation to clinical study report)
- Good understanding of clinical trial budget
- Fluency in English, both written and oral (additional languages would be a plus)

**Required competencies and skills:**

- Excellent communication, interpersonal and networking skills
- Self-motivation, strong leadership skills
- Pro-active and problem-solving attitude, very good prioritization skills
- Able to work independently, as well as in global cross-functional (matrix) and multicultural teams
- Excellent planning and organizing skills
- Personal resilience, perseverance, energy and drive
- Team player, collaborative attitude
- Ability and willingness to travel internationally

If you are interested to apply for this role, please send your CV and motivation letter by email to:
career@santhera.com

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