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 Leader

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

Scope of Work

The role reports to Head of Clinical Operations and works closely with CRO, clinical development functions and medical affairs. This is a highly visible role in the organization and will manage key internal and external stakeholders.
The overall scope of the role is to plan, execute, maintain oversight and report on clinical trials, from planning, vendor selection (if applicable) and site feasibility, through study close out. Lead and provide direction to the cross-functional Study Management Team (SMT) to ensure all trial outputs from protocol development to final clinical study report (including archiving of the Trial Master File) are delivered on time, within budget, and with high quality, in adherence to internal SOPs, GCP and applicable regulatory guidelines.

The responsibilities for this role include the following:

- Provide clinical operations related input to the Clinical Development Plan
- Ensure that the design of clinical studies under area of responsibility is in line with the objectives defined in the Clinical Development Plan or other relevant plan such as Risk Management Plan
- Develop or coordinate development and approval of study documentation such as the study protocol, 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
- Define and drive study timelines and milestones
- Define the needs for External Service Providers (ESPs), identify and select ESPs, including negotiation of scope of work and budget and ensure that related contracts comply with internal SOPs and GCP requirements
- Form and lead a cross functional SMT including representatives of appropriate internal or external functions such as Technical Development, Regulatory Affairs, Clinical Science and any expertise required to implement and oversee the study according to GCP, the Protocol and the requirements of the Management Team
- Coordinate the development of specifications for ESPs in collaboration with SMT and ensure appropriate quality control of deliverables
- Contribute to the development of regulatory documents, responses to Health Authority, EC/IRB and DSMB questions

- Oversee study approval processes for Health Authority, EC/IRB approvals for all study document as required
- Oversee forecasting of IMP and study supplies
- Review and approve feasibility (within SMT as appropriate)
- Plan, organize and lead Investigator meeting and CRA training & review related material
- Perform ongoing ESP management, performance management and issue resolution
- Oversee monitoring activities and conduct co-monitoring visits to ensure data quality
- Ensure adequate trial resources in personnel and material are available cross-functionally (internally and at ESP) and escalate issues to respective Function Head if needed
- Ensure study team members are timely informed, trained and updated on their role and responsibilities through-out the duration of the study
- Provide study specific direction to study team members and ensure that they are regularly updated on the study progress, challenges and risks through-out the duration of the study
- Address enrolment and retention issues, identify and implement actions to keep study on track
- Ensure proper study documentation is maintained and archived in the TMF
- Chair SMT meetings and ensure timely follow up of agreed upon actions
- Resolve issues in a proactive and timely fashion and escalate unresolved issues and identified risks to Head of Clinical Operations and Head of Development as appropriate
- Provide regular study status updates including critical issues to SMT, Development Management and Senior Management as needed
- Create, manage and ensure tracking of study budget including revisions and perform final reconciliation at trial close out
- Check and approve ESP invoices and ensure appropriate tracking and reconciliation
- Implement best practices and lessons learned and share outcome with the teams
- Oversee database lock activities to ensure timely data availability and coordinate study close out with ESPs as needed
- Coordinate pre-audit and CAPA resolution activities ensuring satisfactory outcome
- Adhere to personal development plan and maintain training records to ensure appropriate level of competence in compliance with this job description including GCP etc

Required background and experience:

- Master degree or equivalent university education/degree in life science or healthcare
- Minimum of 6 years relevant experience in clinical development and clinical trial management, field monitoring experience is desired
- Demonstrated expertise in global clinical research & development and project management (including risk management and contingency planning)
- Demonstrated project management experience and leadership skills (e.g., leading project teams) working in global cross-functional (matrix) and multicultural teams
- Experience in managing complex studies (e.g., large studies, difficult patient populations, involvement of many external service providers)
- Experience in executing a wide range of clinical trial activities (from initiation to clinical study report)
- Experience selecting and managing external service providers
- Very good understanding of clinical trial budget
- 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
- Ability and willingness to travel internationally
- Fluency in English, both written and oral (additional languages would be a plus)

Required competencies and skills:

- Excellent communication, interpersonal and networking skills
- Pro-active and problem-solving attitude, very strong prioritization skills
- Self-motivation, able to work independently as well as on cross-functional teams
- Excellent planning and organizing skills
- Personal resilience, perseverance, energy and drive
- Team player, collaborative attitude