Geneva, August 18th, 2020

Clinical Trial Manager

The Company

STALICLA is a near clinical Company developing a first in class precision medicine platform to accelerate drug development for patients with Neurodevelopmental Disorders (NDDs). Founded on a comprehensive understanding of the impact of NDDs on patients, their specificities and their unmet needs, STALICLA's approach starts with patients with the goal to match the right patient with the right drug. First focus of development has been Autism Spectrum Disorder (ASD). Today, patients diagnosed with NDDs account for 5-7% of births worldwide. The condition remains a high unmet medical need.

In its Geneva and Barcelona units, STALICLA has assembled a world class team of experienced drug developers and computational biologists. The company is recognized as a disruptive key player in the NDD space, using its innovative and proprietary DEPIv3 innovative systems biology AI platform.

DEPIv3 integrates multi-layered analyses of domain specific large-scale genetic, molecular, pharmacological and clinical data to generate new insights and define patient subgroups with identified personalized treatments. It is the first time that such technologies have been utilized within the field of neurodevelopment with the potential to change the direction of the specialty.

In less than 4 years, the STALICLA platform has already proven successful in expediting and de-risking drug development for a first subgroup of patients with Autism Spectrum Disorder and identifying two additional subgroups.

STALICLA's first therapeutic package - STP1 - addresses this first distinct subgroup of ASD patients estimated to 1.5 - 2M people in the EU and North America. Clinical entry for STP1 is planned in 2020.

To support its platform and pipeline development, STALICLA has developed a network of top tier research and clinical partners in the US.

STALICLA is currently scaling up DEPIv3 to advance new pipelines for additional groups of patients with NDDs.

The Role

STALICLA is currently expanding its pipeline of drug development programs and clinical activities in the US, with ongoing observational trials and interventional trial studies starting in 2020.

STALICLA, is therefore, expanding its Team and opening a 'Clinical Trial Manager' position to reinforce its Clinical Development Team and ensure the efficient and smooth execution of these studies. The right candidate for this role will be fully accountable for all project management and operational aspects of clinical studies. S/he will work closely with the Chief Medical Officer.

Primary Location: Geneva, Switzerland

Schedule: Full time

Key Responsibilities/Expertise

The candidate will be an experienced Biotech/Pharma industry professional, with a demonstrable track record in clinical trial management, ideally in the CNS therapy areas, and in preparation of regulatory dossier to enable First-In-Human studies (including IND). Experience in paediatric indications is a plus.

Clinical trial overall:

- Develop and manage comprehensive study timelines and metrics (incl. budget development, timelines, milestones definition)
- Develop and manage study budget with financial goals
- Prepare and present project debriefings, as required, plan, execute and lead or participate in study specific meetings

Vendor Management:

- Identify and assist in selection of external vendors as required and in the development of vendor specifications
- Track & manage study contracts to provide timely and accurate forecast
- Ensure adequate study-specific training to clinical research staff
- Lead and coordinate study-related vendors and serve as primary point of contact for contracted CROs, study staff and contract labs
- Identify potential risks and resolve issues with CROs while establishing vendor management plans and reviewing quality metrics

Clinical site selection and management:

- Participate in site selection
- Develop relationship with PI and site staff
- Participate in the preparation of contracts
- Prepare or participate in review site documents, including site specific informed consent form, study tools/worksheets
- Participate in site monitoring visits as appropriate

Using your extended expertise in operational and knowledge of CNS, ideally neurodevelopmental disorders, optimize trial design and execution through:

- Design clinical trials protocols with Clinical team and consistent with clinical development plan
- Prepare, or provide input on, study related documentation including CRFs, ICF template, monitoring templates, protocol worksheets, procedural manuals
- Prepare and/or review study related documents, including monitoring plan, patient diary, clinical site procedures manual, pharmacy/laboratory manuals, CRF completion guidelines
- Provide input and support documentation for AEs safety monitoring while collaborating with Clinical Team for regulatory authorities report submissions
- Coordinate with CMC, clinical supply study drug manufacture, packaging, labeling, and distribution
- Track enrollment status of subjects and document dropout information such as dropout causes and subject contact efforts
- Review proposed study protocols to evaluate factors such as sample collection processes, data management plans
- Communicating with laboratories or investigators regarding laboratory findings
- Ensure trial execution as per international GCP guidelines, local regulations and SOPs
- Participate in planning of QA activities, coordinate and ensure resolution of audit findings
- Ensure audit-ready clinical trial documentation including study-related files
- Lead cross-functional study Team (internal and external) including CROs, vendors, Clinical sites, Regulatory Affairs

Requirements

Basic Qualifications/Requirements:

- Confirmed experience in Pharma/CRO industry with at least 6 years' background in Clinical Project Management, including prior experience managing contracted resources/CRO
- In depth know-how and strong experience in site monitoring and clinical data review
- Excellent knowledge of clinical trial design and development
- Good understanding/previous experience in regulatory affairs, documentation to FDA (incl. IND)
- In depth knowledge of ICH-GCP, local legislation and procedures
- Experience in management of study budget and contracts
- Experience in risk assessment, development of mitigation plans and continuous review and adjust plans as required
- Good negotiation and communication skills
- Fluent in English (verbal and written communication)
- Highly motivated by clinical research in Neurodevelopmental Disorders – Results oriented
- High performer with capacity to work independently
- Able and willing to travel as the role requires
- Passionate and enthusiastic about the company vision and the patient needs

Preferred Qualifications/Capacity:

- Clinical research or pharmaceutical experience in CNS disorder, with in depth understanding of early to late-phase clinical development programs
- Training in Psychology or Neuropsychology with working knowledge of neurodevelopmental disorder patients' population preferred
- Experience in pediatric programs is a plus

In addition, the candidate is expected to have:

- A high comfort level working in a high paced start-up environment, where a pragmatic, resourceful, well organized and effective approach is required with limited resources
- A passionate, energetic and enthusiastic personality that will ensure commitment to the company and its vision
- The ability to work in a multidisciplinary and international environment
- Strong adaptation capacity to novel frameworks and work environments

Female and minority candidates are encouraged to apply.

Please submit application to: hr@stalicla.com