**NY, New Jersey, Massachusetts, East Coast (Remote), March 29th, 2021**

# Clinical Trial Manager

## The Company

STALICLA SA is a Swiss clinical stage biopharmaceutical company leading omics-based precision medicine drug development for patients with neurodevelopmental disorders (NDDs), with a first application in Autism Spectrum Disorder (ASD).

STALICLA is on a unique mission to identify clinically actionable patient subgroups and develop tailored treatments for those most impaired by their symptoms.

Its DEPI technology is the first platform specifically developed to enable precision medicine in complex NDDs. The platform integrates comprehensive metabolomics, whole-genome sequencing, RNA sequencing and its advanced HC match module to pair patient biological signatures with drug candidates. DEPI has reached clinical proof of concept with its first pipeline candidate, STP1, currently in clinical trials in the US.

In 4 years, STALICLA has validated its platform model and proven its potential to significantly accelerate the time to clinic developing STP1 as a first in class precision treatment for a biological subgroup of patients with ASD (this group ASD-Phen1 is estimated to represent 1.5 - 2M people in the EU and North America). STP1 entered clinical trials (Phase 1b), in the US, in December 2020.

## The Role

As a rapidly growing company, STALICLA is currently expanding its team and is opening – for immediate entry – a Clinical Trial Manager position to reinforce its Clinical Development Team. He/She will work closely with the Senior Clinical Project Manager.

## Responsibilities include but are not limited to:

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:

- C2 level or native English mandatory;
- 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;
- Highly motivated by clinical research in Neurodevelopmental Disorders – Results oriented;
- 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;
- Excellent communication both orally and written;
- Respectful of deadlines;
- Proficiency in all of Microsoft Office;
- Hard working, driven to achieve creative and sound results.
- Good negotiation and communication skills;
- High performer with capacity to work autonomously;
- Flexibility to travel.

In addition, the candidates are 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 hands-on approach and a proven ability to work independently and as a team player with excellent communication skills;

- Highly adaptable to novel work environment;
- Ability to work in a multidisciplinary and international environment.

STALICLA promotes diversity, equal opportunity and inclusion. Female, minority and candidates with disabilities are strongly encouraged to apply.

Please submit application to: hr@stalicla.com