Senior Clinical Trial Manager

About Versantis

Versantis is a clinical-stage biotech company focused on the development of orphan drugs in liver diseases and pediatric inborn errors of metabolism. Venture capital-backed, Versantis recently closed a CHF 16m Series B financing round to advance clinical development of novel therapeutics for liver diseases. Founded by leading scientists from ETH Zurich and industry experts, Versantis is pursuing innovative therapies for the acute care of serious liver conditions based on its proprietary liposomes-based technology. Versantis has successfully raised private and public capital and was rewarded with prestigious scientific and entrepreneurial prizes (MassChallenge winner, Best Swiss Biotech Startup, Top100 Award, VentureKick, Pfizer Research Award).

INFORMATION

Website: www.versantis.ch
Sector: Pharmaceuticals - Biotech
Size/stage: <10 FTE / Clinical Ph1b
Sector: liver diseases, orphan drugs
Locations: Zurich, Switzerland
Role: Senior Clinical Trial Manager, global
Commitment: 100%

EXPERIENCE REQUIREMENTS

Required
5+ y experience in clinical operations
Hands-on management of clinical trials
Experience dealing with health authorities
CRO management
Desired
Design clinical development strategies
Preparation of regulatory submissions

Versantis' lead candidate, VS-01, uses a disruptive approach to treat decompensated cirrhosis (Versantis' most advanced program), as well as rare pediatric hyperammonemic crisis caused by genetic disorders. VS-01 is about to complete a Ph1b first-in-human trial. It was granted two orphan drug designations in acute liver failure by the EMA and in Acute-on-Chronic Liver Failure by the FDA, which should streamline its clinical development pathway. In parallel, Versantis' R&D programs continue to grow via close collaborations with Top Research Institutions.

The Position – Key Responsibilities

We are looking for a full-time Senior Clinical Trial Manager with experience in the overall conduct of clinical trials from start to closure, including aspects related to budgeting, data review, reporting, project management, regulatory filings, and compliance to applicable regulations/guidelines.

Clinical Operations

- Select and manage CROs and Sites, perform visits and training as required.
- Act as a primary point of contact for CROs and other External Service Providers (ESPs) for all clinical activities.
- Conduct and manage clinical trials from start up to close out: monitoring visits, recruitment and enrolment of patients, covering informed consent, eligibility and compliance with the protocol, study drug accountability, protocol deviations…
- Support CRA with queries generation and resolution, track and follow-up on serious adverse events, review eCRF, and maintain Study Files.
- Support ESPs with all queries related to sample lists, shipments.
- Ensure continuous update of Trial Master File in view of audits/inspections.
- Forecast drug supply needs in collaboration with Head of CMC.
- Participate in the development of the clinical study protocols and other study related documents in collaboration with other functions (*e.g.*, Is, Investigator Brochures, clinical study reports, publications and internal /external presentations).

Project Management

- Design, manage and track clinical trial timelines, risk and quality plans (single and multi-centered) and clinical trial budget.
- Communicate timely and accurately on operational clinical trial activities for internal reporting.
- Organize study-related meetings and training sessions.
- Organize scientific/medical reviews and evaluation of clinical trial data (e.g., IDSMB, Medical Advisory Boards), including the development of meeting agenda and minutes.

Regulatory

- Develop regulatory documents and responses to Health Authorities/Ethics in collaboration with other functions (*e.g.*, CTA, IND, DSUR, Briefing Documents for advice meetings).
- Ensure quality, on-time delivery of all documents to meet submission targets to Health Authorities and Ethics.
- Communicate with regulatory authorities (*e.g.*, document preparation, coordination of meeting rehearsals and minutes…) and with Ethics Committees as required.

QA

- Review all QC/QA relevant issues and support internal and external audits.
- Support development of internal clinical-related SOPs as required.

Qualifications and Experience

- MS or higher degree in Life Sciences with at least 5 years of experience in clinical trial operations (in a service provider or pharma/biotech company).
- Validated expertise and knowledge in international clinical trial planning and execution.
- In depth knowledge of ICH-GCP guidelines and GLP regulations.
- Proficiency in common MS Office packages.
- Fluent in both written and spoken English. German is an asset.

Person specification

- Hands-on experience in managing all operational aspects of clinical trials and developing all study-related documents on-time, within budget and of high quality.
- Proven active involvement in the management of clinical Site and third-party vendors (CROs).
- Proactively identifies deficiencies and new risks in trial conduct, suggests corrective / preventive actions and escalate internally, as required.
- Formulates critical decisions, suggests alternatives, and obtains internal approval.
- Work closely with the senior executive team in a collaborative and welcoming environment.
- Solution-driven personality with strong initiative and drive. Organized, rigorous and self-starter who can anticipate the company's needs.
- Able to define its own workflow & execute it independently, while handling multiple priorities.

Why should you apply?

- You will actively contribute to the development of new potential life-saving medicines.
- Your work will give you a sense of ownership as you directly contribute to Versantis' success.
- You will grow in your role and embrace more responsibilities as the company grows.
- Dynamic and flexible work environment with little bureaucracy – ideal for innovation to thrive!

Contact

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