

DESCRIPTION OF MINERVAX

Company

MinervaX is a Danish Company engaged in clinical development (now in phase II) of a Group B Streptococcal vaccine targeting pregnant women for the prevention of life-threatening infections in newborns. So far, the vaccine has been dosed to 300 healthy adult women, and over 150 pregnant women. The vaccine has proven to be well tolerated, highly immunogenic and giving rise to functionally active antibodies (read more at www.minervax.com). In addition to pregnant women, the vaccine is also being explored for use in older adults, where GBS cause significant disease such as sepsis, pneumonia, cellulitis and soft tissue infections. Furthermore, MinervaX is engaged in the development of correlates of protection, which can be used as surrogate markers of efficacy in future Phase III trials.

Minervax offers you an exciting and challenging position in a rapidly growing international oriented company. You will work with highly skilled and experienced colleagues forming a great and successful team.

JOB DESCRIPTION

Title

Senior Clinical Trial Manager (CTM)

About the position

For this position we are looking for an experienced CTM with project management mindset and a good understanding of the drug development process as well as GCP and other relevant guidelines. It is important that you have experience with all aspects of clinical trial conduct, as you will be responsible for setting-up and managing a phase I trial from start to end. You will be part of the clinical operations team at MinervaX that currently consist of 3 dedicated and experienced people. The working environment is flexible, with an informal atmosphere, where we strive to have fun while reaching for our goals.

MinervaX is a small company which means that you will have a unique opportunity to be a contributor to the success of a well-regarded, well financed and well positioned late-stage biotech company.

At a personal level, you must be comfortable operating independently and effectively in a small, dynamic, collaborative, and innovative environment, being able to juggle both strategic tasks and being able to “roll up the sleeves” and to get into the detail, as required. You must possess the energy, passion, and ambition to make a difference in an exciting biotech organization.

Main tasks and responsibilities

- Effective management of assigned clinical trial(s) by carrying out all the functions of a Clinical Trial Manager (CTM) as defined in MinervaX Standard Operating Procedures, ensuring the conduct of high-quality clinical trials according to ICH-GCP Guidelines, all relevant SOPs and other regulations, guidelines and laws, as applicable.
- Oversee all aspects of the start-up, conduct, close-out and reporting of assigned clinical trial(s), including but not limited to providing input towards production, maintenance, review and approval of clinical trial documents and trial related tasks, as applicable.

- Project management of assigned Clinical trial(s) in collaboration with selected CRO(s) by driving timelines and deliverables to ensure execution and delivery of assigned clinical trial(s) within time, cost, and quality.
- Documented oversight of outsourced clinical activities.

Educational background and experience:

- You have a BSc or MSc level within the medical, biological, pharmaceutical science or equivalent
- You have at least 7 years' experience as a clinical trial/ project manager.
- You have solid experience with good clinical practice (GCP), clinical studies and clinical IT systems (EDC etc.)
- You are good at English (speaking and writing)
- You like to navigate within unknown areas, and to be in a position with cross-functional responsibilities
- You take responsibility and are self-motivated
- You are good at communication and creating consensus across professionals and geographical borders and good at establishing mutually profitable working relationships

Reference

CTM will report to the VP Clinical Operations

Place of Work

Copenhagen, Denmark

Languages

Proficient in English on a professional level, both written and spoken.

GENERAL INFORMATION

For more details about the job, please contact VP Clinical Operations Karina Nymark at kan@minervax.com or at +45 30 16 79 06