Clinical Project Manager
Job description

12 April 2021
Per Fischer

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 so far, 53 pregnant women. The vaccine has proven safe, highly immunogenic and giving rise to functionally active antibodies (read more at www.minervax.com). In addition to several ongoing Phase I and Phase II clinical trials, MinervaX is engaged in the development of correlates of protection, which can be used as surrogate markers of efficacy in future Phase III trials. The correlates of protection are based on measuring natural immunity to GBS in pregnant women and correlating it to risk of invasive neonatal GBS disease, in order to develop predicted thresholds of protection. MinervaX is engaged in several CoP studies around the world, either through academic collaboration or via a local CRO. MinervaX is looking for a Project Manager to lead this effort.

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

Clinical Project Manager

About the position

As first priority, the clinical project manager will lead, define, manage and develop the correlate of protection pilot study. Among this, will give input to the scientific rationale, practical conduct, as well as lead the way for MinervaX to reach a decision as regards the design of the phase III study with the MinervaX GBS vaccine in collaboration with the remaining MinervaX team and the CEO. Moreover, the clinical project manager will contribute to the other clinical studies ongoing at MinervaX both with clinical, scientific and regulatory expertise.

Drawing on previous experience the clinical project manager will for example:

- Lead the protocol outline and development of the correlate of protection pilot study by giving scientific, clinical and medical advice and clinical operations support to the CRO and the maternity hospitals
- Project managing tasks related to other clinical studies at MinervaX e.g. development of documents for the clinical trial applications to ECs and CAs, Pre-IND submission, risk management (assessment, mitigation, planning and review), trial vendor and monitoring oversight, questions from ECs and CAs, financial agreement negotiation and management (sites and CROs), RBM monitoring (define, review of plans and oversight), oversight of DM and statistics CROs, set-up and oversight of DSMB, laboratory (safety and immunogenicity) oversight, participant diary (decide on set-up, review)
- Manage stakeholders at all levels, including clear communication on deliverables

Qualifications:

- You have a MSc (natural science) with at least 5 years' experience. Preferably with experience in immunology and vaccines.

- 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 creating consensus across professionals and geographical borders and good at establishing mutually profitable working relationships

Reference

Project Manager will have reference to the Head of Clinical Development

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 CEO Per Fischer at PBF@minervax.com or +45 20252038.