Clinical Trial Assistant
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. MinervaX is looking for an experience Clinical Trial Assistant

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 Trial Assistant (CTA)

About the position
The CTA is an essential position within both the Clinical Operations, Quality Assurance and Regulatory Affairs area. The CTA will be responsible for supporting projects carrying out a broad variety of tasks in collaboration with relevant Minervax team members depending on the tasks:

- Essential member of the trial management team supporting the Minervax team working with clinical trials, regulatory or quality assurance tasks
- Responsible for oversight of the Trial Master Files to ensure correct filing of clinical trial documentation, preparation of different trial documents and general support both in house and to CROs
- Part of the job will include updating of information, indexing and Quality Control of trial documents, data tracking, monitoring and trending of data.
- Provide assistance in preparation, conduct and documentation of internal meetings: practical arrangements, presentations, minutes
- Assist with periodic review of study files for accuracy and completeness
- Receives and reviews all regulatory documents from sites for accuracy and compliance
- Assist in Sop writing, maintenance and reviews
- Archiving all relevant submission and approval documents

Qualifications:

- A Bachelor's degree is required (science-related discipline preferred), relevant experience may be substituted for degree, when appropriate
- Clinical trial experience within a pharmaceutical, biotechnology, CRO and/or healthcare setting preferred

- Demonstrated understanding of medical terminology and International Conference on Harmonisation (ICH)-GCP principles and the application of those principles to trial planning and conduct of clinical trials
- Demonstrated computer skills (MS Office, MS Project, MS PowerPoint)
- Working knowledge of electronic trial master files and clinical trial portals preferred
- Excellent communications skills (verbal, written, presentation) in English
- Demonstrated collaborative and stakeholder management skills
- Strong attention to detail and planning/organizing skills required

Reference
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.