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UniversitätsKlinikum Heidelberg Voßstraße 2, Geb. 4040 69115 Heidelberg, Germany

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Clinical Project Manager (m/f/d)

The European Vaccine Initiative (EVI) is a non-profit organisation that is dedicated to accelerating the development of vaccines for diseases of poverty and emerging infectious diseases. We work with academic partners, pharmaceutical companies, public health institutes, The WHO, The European Commission and many other like-minded organisations across the world to discover and develop safe, effective, and affordable vaccines.

EVI has an exciting full-time opportunity for a motivated individual to join the organisation as a

Clinical Project Manager

You will join an enthusiastic non-profit organisation that includes a diverse, international team of scientists, vaccinologists, experts in clinical trials and regulatory matters, project managers, and office support staff.

As clinical project manager, you will work with internal colleagues and external partners on vaccine development and the evaluation of new or improved vaccines for global health at all stages of development, but particularly in early clinical phases. The successful candidate is expected to support the progress of international collaborative clinical trial projects and to ensure that the clinical trials are conducted, recorded, and reported in accordance with protocols, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirement(s).

Responsibilities:

- To lead the coordination and execution of clinical trial projects
- To ensure absolute adherence to Good Clinical Practice (GCP) in accordance with ICH-GCP standards, Declaration of Helsinki, regulatory requirements, and study procedures
- To develop/update SOPs in accordance with ICH-GCP standards, Declaration of Helsinki and regulatory requirements
- To develop, review, and edit clinical trial-related documentation, including but not limited to: protocols, CRFs, Informed Consent Forms, study-specific SOPs, monitoring plans/ reports and clinical study reports
- To complete and compile all necessary research, documentation, and information in order to gain appropriate regulatory and ethical committee approval, where required
- To assist in scientific advice requests to regulatory agencies
- To interact with and manage vendors and stakeholders, as required
- To assist in project management and reporting activities
- To facilitate effective implementation of project activities, in particular the delivery of projects within agreed upon timelines and budgets



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- To report and present to core teams and upper management
- To highlight and present any difficult issues that need the attention of upper management
- To maintain good working relations with key stakeholders

Qualifications/Essential Skills/Competencies:

- MD, PhD, or Masters in a relevant scientific discipline
- Minimum 3 years' experience in investigational clinical research in a pharma company, product development partnership, academic clinic, CRO, or regulatory agency
- Monitoring expertise in ICH-GCP-compliant clinical trials
- Proven track record of training and adherence to ICH-GCP
- Knowledge of the EU regulatory requirements for investigational clinical trials
- Ability to contribute to the development of clinical trial-related documents and materials
- Clear understanding of the development process for new medicinal products
- Excellent presentation skills, written and oral, and keen attention to detail
- Ability to work independently (and remotely), yet still as part of a team
- Willingness and ability to travel
- Fluent in written and spoken English (German not required)

Desired Skills/Competencies:

- Experience in clinical research quality management
- Experience in clinical trials in low- and middle-income countries, particularly Africa
- Experience in working in a non-profit organization with a global health mission
- Proven ability to be able to plan and manage clinical trials
- Ability to work within deadlines and budgets
- Ability to work in multicultural environments and maintain effective working relations with people of different nationalities and cultural backgrounds

Conditions of Appointment:

- Contract period will start as soon as mutually agreeable
- Our headquarters are situated in Heidelberg (Germany) and our staff is always welcome to use our office but can work remotely from home, following the onboarding.
- The position is initially limited to two years, with the possibility for permanent offer

Please visit our website (www.euvaccine.eu) to learn more about us and what we do.

Applications should contain a **CV and a Motivation Letter.** In the motivation letter, please explain why you are applying to EVI and why you think you are qualified for the position. Kindly include any relevant certificates in the email. Applications must be submitted in **English!**

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Applications must be received no later than **01 July, 2025 Please send your application by email to:** <u>sten.larsen@euvaccine.eu</u>

Insert "Clinical Project Manager Application" in the subject line.

We reserve the right to close the application process earlier in case a suitable candidate is identified - so please, forward your application as soon as possible.

Thank you for your kind interest thus far!