

## Project Manager

### Permanent position

Horiana is a consulting company dedicated to epidemiology and biostatistics, designing and conducting healthcare real-world Studies. Horiana aims to support its clients – private and public/academic professionals in the healthcare field – at all stages of their projects.

We are currently expanding our team with a full-time permanent position for a Project Manager (M/F). The position is based in Bordeaux (33) or remotely, depending on the profile of the candidate.

#### Job overview

You will be responsible for managing and coordinating clinical or RWE research projects, with a strong focus on protocol development, regulatory submissions, and overall project management. This includes drafting and reviewing clinical or RWE study protocols, preparing and submitting regulatory and ethics documentation, and ensuring compliance with applicable guidelines and regulations. You will oversee project planning, timelines, and resources, and act as a key interface between internal teams and external stakeholders to ensure the successful execution and delivery of clinical studies.

#### Profile

- Education in Healthcare administration or related field ; MSc or ideally a Doctorate degree (PhD, PharmD. MD)
- At least 5y of experience in PM in the healthcare sector, ideally within the CRO/pharma industry
- Strong knowledge of project management principles, methods, and techniques
- Proven experience in writing clinical study protocols (interventional and/or observational, ancillary studies, RWE, post-authorisation).
- Solid track record in regulatory and ethics submissions (Competent Authorities, Ethics Committees / IRB).
- Excellent communication, and organizational skills
- Fluency in English
- Ability to identify priorities and to anticipate potential issues
- Strong team spirit

#### Missions

- Lead and manage clinical research projects from design to completion, ensuring alignment with scientific, regulatory, and operational requirements.
- Draft, review, and maintain clinical or RWE study protocols, including amendments, in collaboration with internal scientific, clinical, and biostatistics teams.
- Prepare, submit, and follow up on regulatory and ethics submissions (Competent Authorities, Ethics Committees / IRB), including responses to questions and requests for additional information.
- Ensure compliance with ICH-GCP, EU Clinical Trial Regulation, GDPR, and applicable local regulations throughout the study lifecycle.
- Develop and manage project plans, timelines, and milestones, ensuring on-time and high-quality delivery of study deliverables.
- Conduct post-project evaluations to assess project performance and identify areas for improvement