CatalYm is a young biotech company based in Martinsried, Germany developing innovative immunotherapies to transform cancer patients' lives by effectively engaging their own immune systems to combat this malignant disease. CatalYm has a robust development portfolio, a management team with extensive experience in this field and highly qualified personnel. CatalYm's mission is to rapidly bring its next-generation immuno-oncology products to patients in need. Join us in Martinsried near Munich!

Clinical Trial Manager (f/m/d) - Fulltime

Your responsibilities:

- Responsible for the planning, implementation and management of Catalym's clinical trials in the field of immune-oncology
- Work in the Clinical Development department and report directly to the Head of Clinical Operations (HCO)
- Support assessment of trial feasibility
- Support development of all required trial documents (e.g. Protocol, ICF, CSR)
- Assessment of vendors and support set-up of trial processes (e.g. data management, safety, central laboratory)
- Contribute to the development of trial management plans (e.g. project plan, monitoring plan, data management plan, statistical plan etc.)
- Work with and supervise CRO Team and ensure that all essential documents are in place for submissions to and approval by Health Authorities, Ethics Committees and other relevant instances
- Work with CRO on approval of site initiation and release of Investigational Medicinal Products (IMP) to the sites
- Review site issues and relevant monitoring visit reports to identify quality/compliance issues that require escalation to HCO and/or require follow-up with the CRO Team for resolution with the sites
- Perform co-monitoring visits with the CRO CRA as required
- Perform periodic review of protocol deviations and issues and take appropriate actions with HCO and/or Quality Assurance
- Ensure that all trials are carried out in accordance with all relevant regulations e.g. GCP and applicable SOPs, as well as with the quality, budget and timing guidelines.
- Ensure inspection readiness of assigned trial, participate in internal audits and HA inspections as required

Your requirements:

- Bachelors or Masters degree in life-science preferred
- Ideally 5+ years experience in clinical research and the management of (international) clinical trials in Oncology, ideally in Immune-Oncology
- Experience within clinical trial management/project management required, experience in clinical monitoring is an asset.
- In depth knowledge and understanding of clinical trial processes, regulations and methodology

- Knowledge of ICH guidelines, GCP and any local regulations
- Proven ability to work independently
- Strong organizational and time management skills and ability to effectively manage multiple competing priorities
- Ability to negotiate and communicate with clients in a professional manner
- Good analytical, interpersonal and communication skills
- Proficient computer skills (Goodt knowledge level of MS Excel and MS PowerPoint)
- Limited domestic and international travel required when necessary
- Good English language skills (oral and written)

We offer:

- Creative working in X-functional teams
- Short communication channels
- Open and appreciative corporate culture in a multicultural environment
- Flexible working hours enable time management on your own terms

Contact:

Thank you for your interest! We are looking forward to receiving your pertinent application documents (application letter, CV, references, and certificates) to **recruiting@catalym.com**. Please give us some idea of when you can start and the salary you are looking for.

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