Global Clinical Operations Lead (m/f/d)

ATAI is a Berlin, New York and Amsterdam based biotech company builder with the ultimate vision to cure mental health disorders. We focus on developing solutions for people that suffer from a real unmet medical need; starting with the 320 million people who suffer from depression. We are particularly interested to revive and leverage the existing research on compounds with prior evidence for efficacy and safety in humans, such as psilocybin and ketamine, to initiate a paradigm shift. We currently have two platform companies that are active in the mental health area: COMPASS Pathways and Perception Neuroscience. In addition, we are passionate to back recent advancement in data sciences to enable people to live healthier and happier lives. To deliver on our vision we follow a decentralized platform approach that provides the required technology, human and financial resources to our autonomous teams that develop incubated or acquired compounds. This approach enables us to bring therapeutics to patients in a more innovative, efficient and effective way.

Opportunity:

- Work hands-on as part of execution teams to ensure a fast jump-start of drug development process
- Be a major contributor to the success of a well-positioned, well-financed, early stage biotech company
- Become part of creating a radical new and impactful paradigm shift in drug development and patient care
- An open, results-driven and meritocratic start-up culture

Responsibilities:

- Accountable for implementation, management and reporting of assigned clinical trials at subsidiary ventures
- Work closely with leadership team of subsidiary ventures and report to CMO of ATAI
- Lead execution of clinical studies in conformance with GCP and ICH guidelines
- Generate contingency plans where necessary, proactively identify and mitigate potential risks
- Select and manage performance of CROs and other vendors to ensure successful completion of program
- Manage the budget, contract requirements, and performance metrics to ensure that trials are on target
- Work with data management to develop data capture tools that reflect the requirements of the protocol
- Review clinical data and metrics to identify trends
- Review and approve clinical supply and dispensing design and drug labels
- Liaise with CRO on Investigational Review Boards and Ethics Committees requirements
- Contribute to key study documents including protocols, case report forms and informed consent templates

Qualification:

- Advanced degree in Life Sciences or Pharmacy
- 5-10 years of experience working in industry and or with a CRO as manager of (early stage) clinical studies
- Neuropsychiatric experience preferred or 10+ years of multi-therapeutic clinical operations experience
- Strong understanding of relevant laws and policies guiding the biopharmaceutical industry, including FDA and EMA regulations, European Directive, and ICH/GCP guidelines
- Demonstrated alignment with the company's values and culture
- Strong negotiation skills
- Closely networked to CRO professionals and industry clinical operations peers
- Ability to travel approximately 20% of the time
- Comfortable in fast-paced small company environment with minimal direction and limited structures

Join us to improve the lives of millions suffering from a real unmet medical need - Apply today via careers@atai.life!

Please note that we can only accept applications from people that have a valid EU or US work permit.

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