Head of Clinical Operations (m/f/d)

The Head of Clinical Operations will be accountable for the implementation, management and reporting of assigned clinical trials. He / she will also be responsible for design input to ensure trial design results in maximizing design to ensure optimization of "deliverability". In this role, he / she will lead the execution of the clinical studies in conformance with Good Clinical Practices (GCP) and in accordance with the International Conference of Harmonization (ICH) guidelines. The executive will be a key member of the clinical team working closely with the management team, with a reporting relationship to the CMO. Moreover, he / she will lead the clinical operations and be held accountable for all aspects of assigned study execution including (where applicable): CRO selection, study plan design, execution, study start-up, CRO and vendor management and performance, study budget and timelines. He / she is responsible for managing the full scope of the protocol and for the execution of all aspects of the clinical operational plan.

Responsibilities:

- Ensure successful completion of clinical studies that are on time and within budget
- Accountable for ensuring all needed aspects of clinical operations are identified (drug, resources, contracts, budgets, etc) and planned in timely manner
- Generate contingency plans where necessary, proactively identify potential issues / risks and mitigate keeping manager informed
- Select and manage CROs and monitor performance of all CROs and vendors to ensure successful completion of program with respect to timelines and budget
- Manage the budget, contract requirements, and performance metrics to ensure that trials/development program plans are on target together with CMO / COO
- Work with DM to develop data capture tools that reflect the requirements of the protocol
- Review clinical data and metrics to identify trends
- Develop mitigation plans as necessary
- Review and approve clinical supply and dispensing design and drug labels
- Liaise with CRO on Investigational Review Boards (IRBs) and Ethics Committees (ECs) requirements and questions
- Review and contribute to key study documents including protocols, case report forms (CRFs) and Informed Consent templates
- Meet regularly with Clinical Team and Management Team to ensure alignment in goals and contingency activities
- Staff clinical operations through outsourcing to reflect a set of capabilities and experience levels appropriate to the clinical plan

Qualifications:

- At least 7 years of experience working in industry and or with a CRO is required as manager of clinical studies
- Ability to work collaboratively with others both internally and externally
- Neuropsychiatric experience preferred or 10+ years of multi-therapeutic clinical operations experience

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