JOB SPECIFICATION – CLINICAL STUDY MANAGER

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Title:	Clinical Study Manager
Reports to:	Clinical Program Director

Position Summary:

The clinical study manager works on all aspects of clinical development planning, clinical study planning and execution within ABK Biomedical's medical device development programs, timelines, and budget. This includes preparation of study related materials, relationship management between study sites and vendors (CROs, etc), supervision of study related activities, identification of project risks and contingency planning.

Key Responsibilities:

The Clinical Study Manager (CSM) is focused on designing, planning, implementing, and managing the conduct of clinical trials. The goal of the CSM is to ensure compliance with the protocol, clinical objectives, and applicable SOPs and regulations.

Responsibilities:

- Manages all study-related activities to meet defined study timelines while ensuring compliance with GCP/ICH guidelines and the relevant SOPs.
- Lead Study Management Team(s), including cross-functional team(s), CRO(s), and third-party vendors as applicable.
- Oversight of clinical studies including activities of site monitors, clinical vendors, review and approval of site visit reports, and participation during site visits, as necessary.
- Maintain and review budgets, timelines, and forecasts preparation for clinical studies.
- Provide operational and strategic input into study documents such as synopsis, protocol, ICF, CRFs, CRF Completion Guidelines, Study Execution Plans, Clinical Data Review Plan, Clinical Database edit specifications, Clinical Study Report (CSR) development, etc.
- Identify and communicate risks to study timelines and propose mitigation strategies.
- Track study progress reporting progress of studies to internal stakeholders, including patient screening, enrollment, data collection, adverse events documentation, and reporting.
- Develop and approve study-specific documents, tools, presentations, and processes.
- Routinely reviewing data / CRFs to ensure data integrity, accuracy, and protocol compliance
- Assist with the management of medical device distribution, receipt, and use.
- Maintain focus on strategic objectives while accomplishing operational goals.

Experience Required:

Required Qualifications:

- Bachelor's degree in science or health-related field.
- A minimum of five years of direct clinical research experience in a sponsor and/or CRO role.

- Experience managing CROs, vendors, and/or clinical trial consultants.
- Experience developing RFPs and vendor selection processes.
- Experience with protocol, ICF, CRF, CSR development and review.
- Computer skills include proficiency with Microsoft Office suite of software, electronic TMF systems, IXRS and EDC systems.
- Organizational skills, flexibility, and ability to multi-task.
- Strong verbal and written communication skills.
- Willingness to travel up to 30%, mainly North America based travel.
- Excellent working knowledge of FDA & ICH GCP regulations and guidelines.
- Demonstrated ability to develop and implement SOPs and Study Plans.

Desired Qualifications:

- Experience in clinical medical device / pharmaceutical industry highly preferred.
- Highly motivated and self-starter; able to organize and perform complex tasks with minimal supervision.
- Experience working on cross-functional teams.
- Previous experience in oncology studies.

Electronic signatures are used to certify that this document has been reviewed, accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.