Department	Clinical Development
Position	Manager/Sr. Manager – Clinical Trial Coordinator
Reports to	Head Medical Affairs
Location	Whitefield, Bangalore

The Clinical Trial Coordinator will be a leading figure and key point of contact to support the development of novel diagnostic solutions with efficient clinical study designs and evidence generation strategies. The Clinical Trial Coordinator will contribute to the development and implementation of Bioplus' long-term, medical value strategy and pipeline.

KEY RESPONSIBILITIES SHALL INCLUDE:

- Serve as a senior subject matter expert for clinical study design and evidence generation strategies for internal and external stakeholders in the assigned indication area. Has overall responsibility of the ongoing studies.
- Act as an ambassador and senior representative of Clinical Development establishing effective collaborative relationships with key functions for new and existing products, incl. Clinical utility, intended use.
- Expect to be a key contributor to the strategy for pharmaceutical solutions.
- A Clinical Trial Coordinator is strategically responsible for all clinical trial related activities. This includes managing the planning, implementation, and tracking of the clinical monitoring process, administration of clinical trials and maintaining an overview of ongoing clinical trials.
- Play a leadership role in completion and submission of regulatory filings and other regulatory documentation. Writes sections of health authorities meeting packages and develops and reviews clinical documents required for regulatory submissions, ethical submissions, and other regulatory processes.
- Act as a key driver for innovation, early pipeline activities, as well as competitive differentiation and intellectual property strategy. Lead the clinical development plan & scientific strategy.
- Assists the Regulatory team to formulate the Regulatory Strategy Development, including International Regulatory Submissions.
- Policy Making for Product Introduction
- Should be an expert in ICH-GCP guidelines.
- Assuring compliance with sops and local regulations, and CFR, ICH, and GCP guidelines.
- Build and maintain relationships with international opinion leaders, investigators, and key customers, bringing external know-how in-house for the development of new products and innovative study designs.
- Management of CRO's/CRA's.

- Inviting proposal, review, and analysis of proposal.
- Clinical Trial Documentation & creation of important study documents (Protocol writing, Study design, CRF, etc.)
- Participate in protocol development, CRF design and clinical study report writing.
- Conduct feasibility studies: Initiate BA/BE studies, Phase 1,2,3,4 (PMS/RWS/RWE)
- Do statistical analysis of the generated data.
- Article writing & Article publications.
- Medical Monitoring & Surveillance
- Oversee patient recruitment.
- Supervise in-house clinical trial staff & Ensure compliance of staff with the organizations Standard Operating Procedures
- Conduct team meetings and staff training programs
- Creating and overseeing the trial budget.
- Optimize costs and resources to help improve the organizations profitability.
- Collaborating with Project Manager to set targets for clinical monitoring staff and ensuring the recording of trial in compliance with project goals.
- Creating and implementing study-specific clinical monitoring tools and documents.
- Identifying, enlisting, and choosing sites, and coordinating site management activities.
- Coordinating and supervising clinical monitoring team.
- Providing Clinical Research Associates with project-specific training and having regular meetings with them.
- Recording and sharing interactions with clients.
- Arranging and overseeing site visits.
- Gathering and examining trial documents.

QUALIFICATION REQUIREMENTS

- MD Pharmacology
- 3-5 years relevant experience
- Strategic and Innovation mindset for the development of novel medical value products that improve patients' lives.
- Demonstrated track record of influencing people and decisions on complex projects.
- Proven ability to lead with a creative attitude and very high self-awareness.
- Understands agile culture and exhibits an agile mindset.

- Experience in IND/NDA applications is preferred.
- Thorough understanding of the drug development process with extensive knowledge of ICH-GCP
- Extensive knowledge of clinical trial regulations such as those of US FDA, EMEA, DCGI etc
- Influential & assertive communication skills
- Excellent leadership skills
- Good record keeping skills
- Ability to motivate
- Self Confidence
- Ability to think Out-of-the-box
- Problem solving skills
- Ability to navigate within an organization with evolving needs, maintaining objectivity, respect for differences of opinion, fairness, open communication, and consensus building skills. Someone who is comfortable with change and able to foster positive partnerships through effective influencing, negotiation, and conflict management skills.