Job Description: Clinical Operations Director (or Associate Director)
FLSA Status: Exempt
Reports To: Chief Medical Officer
Updated On: 8/22/2016

Primary Objective of the Position

Summary: The Clinical Operations Director (or Associate Director) will support the clinical development programs for the investigational lead drug candidate in company sponsored and investigator-sponsored trials.

Candidate will provide leadership, project management, and program oversight to plan and conduct one or more high quality clinical trials concurrently in accordance with CFR, EMA, and ICH GCP regulations in support of regulatory authority submissions.

Major Responsibilities and Duties
The Clinical Operations Director (or Associate Director) will manage all operational aspects of clinical development projects. Open effective, and proactive communication of the clinical development activities is critical for success in this role. Must have an excellent understanding of the drug/device development process in order to effectively manage internal and external cross-functional teams. Must have strong work ethics and be able to work independently and productively. Must be willing to travel up to 25%.

Responsibilities will include:
- Responsible and accountable for the conduct of clinical trials.
- Oversee, lead, and manage cross-functional team resources and external service providers (including clinical operations, medical monitoring, safety, data management, auditors, and consultants) to conduct trials on time, on budget, in compliance, and of highest quality.
- Coordination/execution of all operational aspects of clinical studies (including identification and management of vendors, availability of clinical supplies at the sites, review and approval of request for investigational test articles).
- Work collaboratively with cross functional internal and external teams including regulatory affairs, medical writing and biostatistics
- Identify, qualify, audit, and manage all external vendors, including CROs. Take initiative to continually monitor each external vendor in performance management, escalate issues where appropriate, and make the appropriate changes in order to ensure trial conduct is completed in compliance and meets company's business objectives.
- Ensure clinical trial team and clinical trial sites are properly trained and in compliance with company and/or CRO SOPs, CFR/EMA regulations, ICH GCP guidance, and study protocol.
- Identify any gaps in company/CRO SOPs and develop internal SOPs as needed.
- Identify, qualify, manage, and maintain relations with clinical trial sites, including collaborating with Principal Investigators and field team on developing robust study

protocols, drive site selection, and patient recruitment programs that deliver enrollment targets. Performs site monitoring with field team, as needed.

- Facilitates all start-up activities including but not limited to investigational site contracts, investigational site, and ethics committee submissions.
- Facilitate confidentiality agreements, negotiate study agreements and budgets with sites and external vendors.
- Responsible for writing, reviewing, and/or approving clinical project deliverables such as scope definition documents, investigational product labeling/kitting, Pharmacy Manuals, informed consent, IRB submissions/approvals, site activations, monitoring plan and tools, CRFs, DMP, edit checks, safety plan, DMC charter, close-out plans, and CSRs.
- Assist with the development of presentations, handouts, and coordination of Investigator Meetings.
- Drive site selection and patient recruitment programs that deliver enrollment targets.
- Responsible for ensuring the trial is "audit ready" at all times.
- Work with appropriate team members to ensure that all TMF-related documentation is current, on-file at respective site, CRO, and sponsor locations throughout trial conduct. Notify and prepare team for regulatory agency audit and address any audit observations appropriately and in a timely manner.
- Performs oversight of trial to ensure that safety concerns and/or adverse events/SAEs are properly tracked and reported.
- Provides regular updates to management team, vendors and contract staff concerning status and progress of the trial.
- Manages each project within agreed upon timelines.
- Proactively monitors and reports trial progress and performance, timelines, and financial metrics on an ongoing basis to management team, including current status of study milestones and forecast budgetary requirements based on scope of work.

Desired Qualifications, Skills, and Experience:

- BS/BA degree required in science/health-related field. A Master's or doctorate degree is preferred.
- The candidate should have a minimum of 10 years of clinical research and/or clinical project management experience in domestic and international clinical trials.
- Excellent working knowledge of ICH GCP guidelines, CFR, EMA, and HIPAA regulations.
- Able to work independently and make appropriate strategic decisions to operationalize and move the clinical trials forward.
- Excellent written and oral communication and presentation skills
- The ability to manage multiple priorities, while maintaining attention to detail is critical.
- Experience operating effectively within a matrixed environment, specifically in a healthcare/pharmaceutical start-up setting.

- Ability to prioritize tasks and resources, meet deadlines, and be flexible to changing priorities.
- Possess strong and influential leadership skills with proven ability to lead internal and external team members at all levels.
- Excellent computer skills (Microsoft Office Suite, Project, Word, Excel, PowerPoint, Outlook, and IXRS/EDC platforms).