

JOB DESCRIPTION	
JOB TITLE	Clinical Research Manager
REPORTING RELATIONSHIP	Sr. Director, Global Clinical Research Operations
DATE AVAILABLE	ASAP
LOCATION	Corporate Office, Lexington, MA
RESPONSIBILITIES	<p>This person will be a key contributor to the company's clinical development and primarily responsible for the hands-on management and monitoring of early and late-stage clinical studies in ultra-rare disease indications. This person will work closely with the Senior Medical Director, Chief Medical Officer and Commercial Operations Management in assisting with protocol feasibility analysis, country assessment(s), site identification, patient recruitment and ultimately, leads the planning to ensure successful execution and completion of the clinical trial(s). Must be an expert in the field that can drive activities internally and externally to ensure successful execution and reduced cycle times for clinical trial activities.</p> <ul style="list-style-type: none"> <li>• Assist in protocol feasibility analysis, country assessment, site identification, and patient recruitment planning.</li> <li>• Identification and management of Clinical Research Organization(s) and other vendors as needed.</li> <li>• Identify investigators and provide assistance to facilitate timely selection of investigators and sites</li> <li>• Develop recruitment plans</li> <li>• Manage all logistical and operational activities for the clinical trials</li> <li>• Implement monitoring plans</li> <li>• Design CRF completion guidelines</li> <li>• Assist in the preparation of the draft protocol, draft CRFs, and template informed consent</li> <li>• Create study documents such as Operations Manuals, Laboratory Manuals, and Pharmacy Manuals</li> <li>• Collect and review essential documents for study start-up</li> <li>• Maintain internal trial master file to ensure inspection readiness</li> <li>• Ensure that the site personnel have a good understanding of the protocol, the investigational product and the requirements of the study and that they can fulfill their obligations to conduct the study accurately and to deadlines.</li> <li>• Perform site visits to ensure that the site personnel are conducting the study in accordance with the protocol, GCP and ICH requirements. Ensure that any issues arising from the visit are documented in a visit report and addressed with the site in a timely manner. Any concerns or ongoing issues to be escalated to the Chief Medical Officer and Program Manager.</li> <li>• Interact with investigators to obtain necessary documentation and information before, during and after the study. Ensure accurate inventory of central, investigator site and core files on an ongoing basis to ensure that the files are complete and can be used as a source of reference.</li> <li>• Maintain project tracking system on an ongoing basis to ensure that progress regarding the sites can be tracked.</li> <li>• Prepare and manage detailed project plan in MS Project.</li> <li>• Provide regular status updates of project progress to Head of Program Management and Chief Medical Officer.</li> <li>• Assist with the preparation and presentation at investigator meetings as required to ensure that the clinical and investigational site staff team is well informed about the study and related procedures.</li> </ul>

	<ul style="list-style-type: none"> <li>• Establish and ensure consistent use of clinical project planning processes.</li> </ul>
<p><b>REQUIREMENTS QUALIFICATIONS</b></p>	<ul style="list-style-type: none"> <li>• Educated to degree level (biological science, pharmacy or other health related discipline preferred) or equivalent nursing qualification/experience.</li> <li>• Minimum 5-7 years of industry experience within clinical research/operations and 3 – 5 years monitoring experience.</li> <li>• Experience managing global clinical trials in rare diseases with orphan drug designation.</li> <li>• Excellent interpersonal, verbal and written communication skills (including presentation skills).</li> <li>• Able to take initiative and work independently with sense of urgency in completing assigned tasks.</li> <li>• Flexibility towards work assignments, new learning and travel (overnight, weekend and international travel may be required). Flexibility to accommodate travel up to 30%.</li> <li>• Ability to manage multiple and varied tasks and prioritize workload with attention to detail.</li> <li>• Team player with outstanding negotiation skills and organizational skills.</li> <li>• Computer Proficiency: MS Office suite and working knowledge of MS Project required.</li> <li>• Preparation and maintenance of a clinical study budget.</li> <li>• MS, MBA or MPH and Regulatory Affairs experience a plus.</li> </ul>
<p><b>NOTES</b></p>	<p>Synageva BioPharma is a publicly held biopharmaceutical company with headquarters, research and development facilities in Lexington, MA, and research and production facilities in Athens, GA. Synageva was formed to concentrate on novel orphan treatments for rare diseases. Our lead program, SBC-102, an enzyme replacement therapy for LAL Deficiency, is in clinical development and has been granted orphan designation by the FDA. LAL Deficiency is a rare, serious and devastating disease that leads to significant morbidity and mortality. Synageva has four additional orphan products in development. To ensure that these therapeutic candidates reach patients in need, Synageva has recruited a team with a proven record of discovery, development and commercial experience within rare diseases.</p> <p>Our work is based on creating value for patients and their healthcare providers, our shareholders and our employees. Our success brings new treatments to patients and providers. We are building a sustainable business and value for our shareholders because good medicine is good business. Our culture attracts and retains principle-minded individuals of integrity, drive, energy and passion.</p>