


JOB DESCRIPTION	
JOB TITLE	Clinical Project Specialist
REPORTING RELATIONSHIP	Director, Clinical Research Operations
DATE AVAILABLE	ASAP
LOCATION	Corporate Office, Lexington, MA
RESPONSIBILITIES	<p>The Clinical Project Specialist will be responsible for providing administrative and operational support to the clinical operations group. Specifically, this role will assist with the planning and coordinating of Synageva's clinical research studies.</p> <ul style="list-style-type: none"> <li>• Supports the Clinical Operations study team to drive successful execution of global clinical studies in rare diseases.</li> <li>• Coordinates with the manufacturing team and drug distribution vendor to manage distribution of clinical trial material</li> <li>• Assists in securing necessary supplies for clinical trials and processes site requests for shipping supplies, as needed.</li> <li>• Coordinates logistics for patient relocation.</li> <li>• Coordinates outreach activities (maintain activity spreadsheet, identify/update web sources, format educational tools, etc.)</li> <li>• Set up, track, and maintain audit-ready clinical trial documentation.</li> <li>• Collect, review and track all necessary site-specific clinical regulatory documents throughout the course of each study.</li> <li>• Review documents and submit them to appropriate departments such as Regulatory Affairs or Clinical Operations</li> <li>• Generate, finalize, and distribute study team agendas and meeting minutes</li> <li>• Support planning and logistics for meetings including investigator meetings, study team meetings, and meetings with CROs and other vendors</li> <li>• Create and assemble study manuals, binders, tools and presentations</li> <li>• Ad hoc assignments and special projects on request</li> </ul>
REQUIREMENTS QUALIFICATIONS	<ul style="list-style-type: none"> <li>• BA or BS degree, science or nursing degree preferred</li> <li>• 3+ years of experience supporting clinical research operations</li> <li>• Strong organizational and project management skills</li> <li>• Must have high degree of accuracy and attention to detail</li> <li>• Excellent writing, verbal communication, interpersonal and diplomacy skills</li> <li>• Ability to handle and prioritize multiple assignments in a fast-paced environment</li> <li>• Some knowledge of GCP and FDA regulatory requirements is a plus</li> <li>• Proficient in Word, Excel, PowerPoint and Microsoft Project</li> <li>• Must have professional demeanor and appearance</li> </ul>
NOTES	<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>



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.