

JOB DESCRIPTION	
JOB TITLE	Senior Clinical Research Associate
REPORTING RELATIONSHIP	Sr. Director, Global Clinical Research Operations
DATE AVAILABLE	ASAP
LOCATION	Corporate Office, Lexington, MA
RESPONSIBILITIES	<p>This role 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 Clinical Operations, Program Management, Senior Medical Director, the Chief Medical Officer and Commercial Operations Management in assisting with protocol feasibility analysis, country assessment(s), site identification, patient recruitment, study monitoring and study management.</p> <ul style="list-style-type: none"> • Collaborates with Study Management Team to drive successful execution of global clinical studies in rare diseases. • Assist in protocol feasibility analysis, country assessment, site identification, and patient recruitment and planning. • Collaborates with Study Management Team to drive patient recruitment. • Independently performs monitoring visits, including site qualification, study site initiation, routine monitoring and study site closure visits. • Establishes and maintains regular contact with investigators, vendors and study sites to ensure GCP/ICH/protocol compliance, and assessment of accrual rates. • Ensures site compliance with study protocols. GCP/ICH, applicable regulations prior, during and following visits. Works with site personnel and study team to prevent, address and resolve issues. • Assists in study start-up activities including site selection and review of regulatory documents and ensures site is qualified for the study. • Documents monitoring activities in monitoring reports and follow-up letters. • Communicates serious issues to the team in a timely manner. • Communicate project-specific information to/from trial sites and documents communication with study site/ team and escalates issues to team in a timely manner. • Collaborate with Clinical Operations Team and CRO to collect data from sites within established timelines. • Performs on site visits and source data verification of CRFs, DCFs, as stipulated. • Ensure the reporting of high quality data and timely query resolution. • Reviews adverse event reports and ensures the site is reporting the events appropriately and in a timely manner. • Provide full support to CRO and investigative sites to facilitate study conduct. • Maintain ICH-GCP documentation for trial sites as stipulated. • Presents at and participates in Investigator Meetings, other study trainings and meetings as required. • Act as mentor and co-monitor with less senior CRAs to ensure high quality as required. • Take active role in project team activities including monitoring report review and tracking. • Collaborate with Director of Clinical Operations and Head of Program

	<p>Management (and other departments as required) to report study status.</p>
<p>REQUIREMENTS QUALIFICATIONS</p>	<ul style="list-style-type: none"> • At least 3-5 years previous CRA experience in the biotechnology and/or pharmaceutical industry. • Experience monitoring global clinical trials in rare diseases and orphan drug indications is a plus. • Willing to travel up to 60-70%. • Must have an excellent understanding of ICH GCP and monitoring practices with a track record for ensuring quality data and performing superb site management. • Must be organized and able to produce high quality work independently or as part of a team be able to multi-task and work in a high volume, deadline controlled environment. • Must have excellent writing, verbal communication, interpersonal and diplomacy skills. • Must have professional demeanor and appearance. • Must have high degree of accuracy and attention to detail.
<p>NOTES</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>