Job Description

Job Title:	Clinical Trial Assistant		
Department:	Clinical Operations	**Job Type:**	☒ Full-time ☐ Part-time ☐ Temporary ☐ Permanent
Prepared By/Date:	Kristen Yen 12.13.22		
Approved By/Date:	Kristen Yen 12.13.22		

SUMMARY OF JOB (brief description):

- Responsible for providing support to clinical trial teams in vendor oversight, site management and other trial related activities, including trial start-up, interim monitoring as well as closeout activities. Monitors progress of clinical trials at the site level and works to ensure that clinical standard operating procedures (SOPs), protocols, and documentation are followed as per the International Conference on Harmonization Good Clinical Practice (ICH GCP) / Code of Federal Regulations (CFR). Has the responsibility to verify that the rights and well-being of human subjects are protected and that the reported trial data are accurate, complete, and verifiable from source documents.

RESPONSIBILITIES:

- Provide high quality assistance supporting clinical trials according to applicable regulatory requirements and SOPs within budget and timelines
- Communicate effectively with colleagues and vendors
- Prepare, ship and manage inventory of study related supplies.
- Assist in preparing materials for investigator and team meetings, study manuals etc.
- Perform various job functions including but not limited to the following: tracking study specific documents, i.e. regulatory documents, enrollment and site activation, sample tracking, TMF maintenance, etc.
- Contribute to the development of study specific tools
- Coordinate and arrange meetings
- Other duties and assignments as requested for the overall performance of the function and Company.

QUALIFICATIONS:

- BS/BA in a relevant scientific discipline is preferred
- Minimum 0-2 years related experience, preferably in the pharmaceutical industry or equivalent
- Knowledge of applicable regulatory guidelines (i.e. ICH and GCP) is strongly preferred
- Possess a general understanding of clinical trial and drug development process, strong attention to detail, and meticulous follow-through
- Proficiency using Microsoft Outlook, Word, PowerPoint, and Excel
- Ability to prioritize multiple tasks, plan proactively, and accomplish goals using well-defined instructions and procedures in a fast-paced environment
- Exceptional oral, written, and interpersonal skills

Please submit resume to hr@soleno.life.