Job Description – Clinical Trial Associate

Reports To – Clinical Project Manager

Job Responsibilities

The Clinical Trial Associate will support projects and studies within the Clinical Affairs department. Study-related tasks will be conducted in accordance with the protocol, Standard Operating Procedures (SOPs), ICH-GCP, and all applicable regulatory requirements.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required to perform this job effectively.

- Supports study execution (both internally and externally) is in accordance with the study protocol, Instructions for Use, FDA regulations, Good Clinical Practices (GCP), and Standard Operating Procedures (SOPs), as applicable
- Completes all delegated tasks associated with clinical study execution
- Supports activities to meet project milestones
- Identifies and/or escalates issues that have a significant impact to the study execution
- Supports site management activities for training (e.g., study/site initiation, continuing enrollment, and closeout).
- Supports study conduct and maintains essential documents (e.g., correspondence with sites and review/retention of essential documents)
- Supports internal data review, including resolution of queries and review of data outliers
- Maintains all relevant documentation and communications as part of study files
- Supports the activities of clinical operations or project specific documents (for example: SOPs and work instructions)

Projects and Other Duties:

- Other duties as requested by the manager

Position Qualifications

- Ability to problem solve
- Ability to understand relevant clinical data
- Ability to convey accurate, concise communication
- Strong organization skills and attention to detail
- Broad knowledge and understanding of the design and critical review of clinical studies
- Knowledge of Trial Master Files and essential documents
- Ability to work effectively in teams
- Excellent verbal and written communication skills required
- Advanced skills with Microsoft Office Suite

Minimum Education:

- Bachelor's degree preferred

Minimum Experience:

- Minimum two (2) years' experience in clinical research within the Medical Device, Pharmaceutical, or Biotech industry
- Knowledge of clinical research compliance including GCP, ICH-E6, ISO-14155, Code of Federal Regulations
- Experience with navigating an electronic data capture (EDC) system

Work Environment & Physical Demands of the Job:

- The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to remain in a stationary position at least 50% of the time; operate computers and other office equipment; and communicate and exchange information. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.
- The job requires travel by air, train, and car travel, sometimes for long distances and extended periods of time.

Additional Important Information:

- Axonics may make reasonable accommodations to enable individuals with disabilities to perform the functions of this job, unless doing so would result in an undue hardship on Axonics.
- This job description is subject to change and management reserves the right to assign or remove duties and responsibilities of this job at any time.