Job Description

Position Title:	**Clinical Affairs Manager**
Report To:	**Senior Director, Clinical Affairs**
Department:	**Clinical**
Location:	**Mountain View**
FLSA:	**Exempt**
Date:	**April 2023**

PURPOSE OF JOB: The Manager of clinical affairs will play an important part in the clinical trial process. The Manager of Clinical Affairs position will perform a wide variety of activities to support the startup and completion of clinical research studies and manage clinical operations personnel.

MAJOR DUTIES AND RESPONSIBILITIES:

- Achieves study objectives by working with team members to set project priorities and milestones and resolve project conflicts.
- Will conduct some site monitoring, along with co-monitoring
- Manage CRO activities.
- Ensures appropriate clinical resources are available for the clinical project.
- Develops and tracks study timelines.
- Ensures GCP and regulatory compliance is maintained.
- Leads the development of study-related documents, including study protocols, informed consent documents, study manuals and plans, trial master files, case report form design, etc.
- Maintains professional expertise through familiarity with the ENT therapeutic area and clinical research literature.
- Manages clinical projects from concept through clinical study report completion.
- Oversees clinical research study conduct.
- Participates in meetings with investigative sites, key opinion leaders and consultants as needed.
- Supports in the analysis, summary, and reporting of clinical data through the course of the study for manuscript acceptance.
- Proactively identifies and resolves issues and participates in process improvement initiatives as required.
- Responds promptly and appropriately to study questions and issues raised by investigative sites, vendors, monitors, and consultants
- Evaluates monitoring reports with significant findings to confirm appropriate conclusions and actions taken.
- Support in reviewing serious adverse events and other pertinent data with the chief medical officer, medical monitor, and other safety team members to identify safety trends and potential risks.
- Performs other duties as assigned.

EDUCATION REQUIREMENTS:

Bachelor's degree in a scientific equivalent or similar discipline

EXPERIENCE REQUIREMENTS:

- 3+ years clinical research experience in an industry setting and a minimum of 1 year management experience.
- Experience in ENT space is highly preferred.

OTHER QUALIFICATIONS:

- Strong Leadership ability
- Excellent communications skills- communicates effectively in both written and interpersonal formats with all levels of the organization. Strong presentation skills required
- Detailed Oriented
- Ability to travel up to 30%.
- Authorization to work in the US for any employer.