Position Title: **Clinical Data Manager**

Reports to: **Associate Director Bioinformatics (or higher)**

Department: **Clinical Operations**

Created: **5Apr2021**

Email CV: **hr@traconharma.com**

General Summary:

The Clinical Data Manager is responsible for all data management tasks for multiple clinical studies from set up in electronic data management system (EDC) to database lock. Other responsibilities include:

Principal Duties and Responsibilities:

- Review data and generate queries according to the data validation specification (DVS)
- Maintain documentation relating to clinical data management including maintaining the data management portion of the Trial Master File
- Write and maintain DVS
- Interface with and train site personnel (globally), monitors (globally) and clinical operations staff to provide support related to data management, including but not limited to the following:
  - EDC issue resolution,
  - acquisition of outstanding data,
  - assisting in visit reconciliation for site payment,
  - and site closure
- Develop trainings for online delivery
- Assist in streamlining clinical data management procedures to create effective practices
- Set up studies in EDC system
- Write edit checks in in EDC software
- Write data listings and simple reports in SQL or R or other languages (on the job training provided), participate in peer code review, validate code, and maintain code repositories
- Contribute to development of reports and plans (ie: clinical study reports/statistical analysis plans)
- Coordinate with pharmacovigilance to review and generate queries related to serious adverse events
- Correspond with and oversee data management vendors
- Coordinate medical coding
- Manage data from external vendors in compliance with 21 CFR Part 11
- Perform tasks according to company standard operating procedures (SOPs)

Qualifications:

Education

- Bachelor's degree or equivalent experience

Experience/Skills

- Minimum of three years of direct clinical data management experience in the biotechnology or pharmaceutical industry
- Working knowledge of Good Clinical Practices and ICH guidelines related to CDM

- Exceptional organizational skills, highly adaptive in the face of changing priorities and practices
- Effective written communication skills

Position Requirements:

- May require limited travel for training purposes

NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.