AMAREX JOB DESCRIPTION

Position Title: Logistics Administrator I	**Department:** Clinical
Reporting Requirements: Reports to the Clinical Department Head or other supervisor as assigned	**Supervisory Responsibilities:** N/A
FLSA Status: Exempt	**Travel Requirements:** < 10%

POSITON SUMMARY:

The Logistics Administrator I serves as the primary point of contact for administrative support to the site and clinical trial team. The Logistics Administrator I is also responsible for coordinating the day to day clinical study activities and maintaining the logistical aspects of clinical trials in compliance with protocol, International Council for Harmonisation guideline for Good Clinical Practice (ICH-GCP), local regulations, applicable Standard Operating Procedures (SOPs) and project-specific requirements.

Key Duties and Responsibilities:

The Logistics Administrator I will be involved in most activities in preparation for study setup, conducting, and completing a Clinical Trial. This includes, but is not limited to:

Primary Trial Master File Duties

- Assume primary responsibility for the setup, development, maintenance, and correspondence of the Trial Master File (TMF) for studies assigned
- Setup and maintenance of electronic filing systems/setup of the Investigator Site File (ISF)
- Track Ethics/Regulatory submissions and approvals for studies
- Prepare, distribute, track, and file essential clinical trial documentation
- Coordinate archiving of study documentation

CRA and Study Team Support

- Assist Clinical Team Leads and Clinical Research Associates (CRAs) with accurately updating and maintaining clinical systems that track site compliance and performance within project timelines
- Point of Contact for CRA assistance with TMF or study-related material support
- Arrange and participate in the organization of Investigator Meetings and Study Team Meetings including taking and distributing minutes and tracking of the final document

Study Management Support

- Assist the Clinical Project Manager and Clinical Team Leads in site selection process
- Assist in initial composition of Operations Manual, Pharmacy Binder, and Investigator Site File (ISF) Binder, etc.
- Manage and maintain study documents and trial supplies, e.g. Patient Information Sheets, Patient Diaries, Lab Kits and Medical equipment for sites

- Ensure that any clinical trial databases/tracking tools are set up and maintained throughout the trial
- Create and maintain study contact lists for team/sites/3rd parties
- Review study mailbox and file emails in appropriate mailbox folders
- Assist in preparation and distribution of Study Newsletters/Study Correspondence to all participating sites on an ongoing basis
- Set up finance systems accurately, process invoices and track payments for the trial for investigator and vendor payments
- Assist with collating, tracking and shipping Case Report Forms (CRFs) and data queries to Data Management
- General study filing

Other possible tasks may include:

- Assist with designing of study logs, source document template, etc.
- Arrange translation of advertisement material and patient documents
- Assist CRAs on monitoring visits
- Reorder clinical drug supplies for sites
- Other duties as assigned

REQUIRED EDUCATION AND EXPERIENCE:

- Bachelor's degree (or equivalent) in scientific discipline
- 1 year of relevant experience in healthcare setting, preferably within the pharmaceutical/biotech industry (or alternatively, an equivalent combination of education, training and experience) is preferred.
- Strong verbal and written communication skills
- Ability to work effectively both independently and in a team environment
- Strong organizational and planning skills
- Excellent interpersonal and professional skills
- Excellent time management skills with the ability to prioritize responsibilities and multitask
- Strong administrative skills
- Excellent documentation and file management skills.
- Self motivated and detail oriented
- Proficient in Microsoft Office and able to learn appropriate software