Clinical /Sr. Clinical Trial Associate

Position Code: 23063-18B

Summary Description

Responsible for supporting clinical study teams to manage various aspects of the operational execution and delivery of quality studies including management of the Trial Master File (TMF)and quality processes according to protocols, SOPs, and Gossamer policies and procedures, applicable regulations and principles of GCP.

Key Responsibilities

- Assist the Clinical Operations Manager(s)/Project Team to prepare and maintain eTMF for multiple studies, ensuring tracking of essential study documents and periodic review to assure accuracy and completeness. Inform the Clinical Operations Manager/Project Team on any outstanding document(s).
- Assist in the tracking and oversight of all start-up activities (site and country study submissions, clinical trackers and essential documents status) and oversight of third party vendors.
- Participate in project management meetings and provide an overview of TMF status, clinical study administration, resources, quality, and workload on a regular basis.
- Support the Clinical Operations Manager(s) in preparing meeting minutes/agendas and maintaining study team document repositories.
- Communicate effectively with clinical study administration vendors (Functional Service providers etc.).
- Assist in coordination of Investigator and Vendor payments, tracking of payments and accruals, if applicable.
- Assist in data listing review and clinical study report listing review

Experience & Education

- Bachelor's degree, or equivalent, in a biomedical, life science, or related field of study is preferred. Associates degree with 5 years of clinical operations experience may be considered.
- Experience in managing eTMF platforms in an outsourced environment is required, with a minimum of 2 years of experience strongly preferred.
- Understanding and working knowledge of regulations and standards applied in clinical areas, medical devices, and/or pharmaceutical products is required.
- Good problem-solving skills, a strong sense of urgency, keen attention to detail, ability to work independently and the ability to effectively manage multiple priorities in an environment under time and resource pressures are required.
- Familiarity with GCPs, ICH guidelines, and FDA regulations is preferred. Familiarity with EMA/CHMP regulations and guidelines and other international regulatory requirements is a plus.
- Proficiency with Microsoft Word, Microsoft PowerPoint, Microsoft Outlook, and Adobe Acrobat is required.
- Strong skills with Microsoft Excel and SharePoint are required.
- Travel required < 5%.