



PredictImmune Ltd
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Clinical Trial Manager OR Project Manager (Clinical Studies) – Consultant Role

PredictImmune Ltd, Cambridge, UK

This position will oversee our US-based clinical IBD (inflammatory bowel disease) study with oversight of the day-to-day operations. This is an observational study recruiting 100 newly diagnosed IBD patients from centres across the US and is being jointly funded by PredictImmune and the Crohn's and Colitis Foundation. Sites will be enrolled from across the US, with recruitment starting in Q1 2019.

You will work closely with internal team members assisting with the identification and enrolment of suitable clinical sites, as well as working directly with clinical study sites to ensure that all activities and deliverables are completed on-time, with high quality, and within budget. Additionally, you will perform oversight monitoring visits throughout the US, conduct monitoring visit report reviews, ensure site compliance with study protocols, and assist with protocol and study plan development/periodic review. This position reports to the VP of Research Operations.

Responsibilities

- Supervise the development/review of study plans
- Overall success of enrolment for Study
- Oversee the preparation, review and approval of study tools and documents (e.g. Protocol, Study Manuals, IRB approvals and associated documents)
- Implement and supervise site and investigator selection process
- Manage and ensure enrolment occurs effectively and to the study plan
- Oversee study deliverables, clinical trial budgets, and timelines to meet objectives
- Monitor US site performance in relation to study timelines
- Set clear expectations and monitor the deliverables to mitigate risk and fast track the data cleaning and end of study activities
- Provide regular study status updates to senior management while escalating higher level issues with proposed solutions when necessary
- Assist with the planning and preparation of investigator meetings; provide presentations at investigator meetings as required to ensure that the clinical teams are well informed about the study and related procedures
- Be a key interface with Crohn's & Colitis Foundation
- Work with the Medical Liaison and Marketing team on critical activities

Qualifications

- Minimum of a Bachelor's degree in a scientific discipline or health related field (Comparable Nursing experience acceptable)
- Minimum of 3-5 years of clinical research experience, preferably in industry (Pharma/CRO/Biotech) or within the healthcare sector
- Working knowledge of HIPAA and regulatory regulations and guidelines

- Demonstrated extensive experience managing complex protocols
- Excellent oral, written, and medical communication skills required as well as presentation skills
- Ability to establish and maintain effective working relationships with co-workers, assigned staff, and senior management
- Expert knowledge of planning and managing clinical program budgets
- Understanding of inflammatory bowel disease area desirable
- Integrity, strong work ethic, and willingness to put in the time and effort to complete critical tasks on time without compromising quality
- Must be available to travel ~10 - 20% of the time

**For additional information and submitting your resume, please contact:
info@predictimmune.com.**