F-STAR JOB DESCRIPTION

POSITION:	**Senior Clinical Trial Manager**
ABOUT F-STAR:	At F-star, we are dedicated to developing next generation immunotherapies to transform the lives of patients with cancer. We develop mAb², a novel class of disruptive bispecific antibody-based therapies that have the potential to overcome tumor resistance and restore anti-cancer immunity and responsiveness. We are committed to delivering life-changing treatments for the estimated 80% of patients with cancer who currently fail to have a durable response to immunotherapies. Our wholly owned pipeline shows focused and potent immune activation, with a promising safety profile to date. F-stars research team is based in Cambridge UK with an expanding footprint in the US from our Hub in Cambridge, Massachusetts to support our clinical stage requirements.
LOCATION:	UK or US
REPORTING TO:	VP, Regulatory Affairs and Clinical Operations

JOB PURPOSE:

We have an exciting opportunity for a Clinical Trial Manager to join our Clinical Operations team. We're looking for an individual who has great experience at running and managing an outsourced clinical development and operations function. You will have significant experience (preferably a minimum of 6+ years) in the healthcare or clinical trial industry monitoring and managing clinical trials, or equivalent combination of education and experience. You will also have experience running oncology clinical trials from the setting of sponsor, and/or CRO is essential. You'll enjoy working in a hands on role to drive the planning and execution of our clinical trials, whilst playing a key role in establishing a world-class clinical operations function to support F-stars exciting and ambitious programs.

KEY RESPONSIBILITIES:

Your key responsibilities will be to deliver all aspects of a clinical protocol, working closely with key manufacturing and supply, medical and research functions and third-party providers. You'll oversee study timelines, clinical trial budgets, coordinate development of study plans, CRF's and other study reports as well as reviewing and approving monitoring reports as appropriate. It will also include:

- Manage clinical studies from concept through Clinical Study Report completion in good clinical practice and to relevant national and international requirements.
- Manage study execution, including management and oversight of CROs, vendors and consultants that are involved with the clinical trial and program.
- Develop and track study timelines, milestones, budget, and quality metrics.
- Organize, lead and manage the clinical project team to ensure adherence to overall project timelines and budget and provide ongoing financial reporting and projections to the finance group.
- Ensure good clinical practice and regulatory compliance is maintained at all times.
- Assist in preparation and review of study-related documents.
- Participate in CRO and other vendor selection, budget negotiation and management, including monitoring of associated budgets and contracts.
- Ensure the Trial Master File (eTMF) is set up and maintained appropriately throughout the trials, including periodic reviews.
- Participate and respond to Quality Assurance and/or regulatory authority inspection audits
- Oversee and participate in review of clinical trial data and clinical trial files. Provides clinical review of annual reports, IB updates.
- Maintain departmental policies and SOP's to assure compliance with GCP and cooperate policies is met.

- Keeps management informed by escalating issues requiring intervention to the study and project teams.
- Maintain professional expertise through familiarity with therapeutic area and clinical research literature

PERSON SPECIFICATION:

- Entrepreneurial, self-driven mindset with the ability to bring creative solutions to challenges.
- Flexible and innovative, and able to deal effectively with ambiguity.
- Strong personal values and the highest level of integrity and ethics.
- Possesses maturity and good judgment; swift action taker; decisive and makes informed decisions.
- Hands-on, pragmatic, highly committed and leads by example.
- Strong listening, communication and interpersonal skills.
- Ability to multitask, prioritize and time manage.
- Possesses vision, global awareness and sensitivity, and works effectively across cultures.
- Work off own initiative or as a team.

ESSENTIAL SKILLS AND EXPERIENCE:

- Significant experience (preferably a minimum of 6+ years) in the healthcare or clinical trial industry monitoring and managing clinical trials; or equivalent combination of education and experience in managing early phase oncology trials
- Bachelor's degree ideally in science or medicine.
- An understanding of clinical development principles, theories and concepts and knowledge of the pharmaceutical industry practices and stands, including good clinical practice.
- Familiarity with the lifecycle of a clinical trial from protocol development and feasibility through to stay close-out and reporting.
- Ability to manage complex and global clinical trials
- Ability to balance multiple priorities cross studies and programs
- Excellent understanding of EU, UK, FDA and other regulatory requirements that may impact global clinical studies.
- Thorough knowledge and application of GCP and ICH guidelines, current EU, UK, FDA and other regulatory requirements for clinical trial management.

OTHER SKILLS:

- Communicate in medical and scientific terms with vendors, consultants and peers.
- Ability to write reports, business correspondence and procedure manuals.
- Present information to managers and sites and be able to respond to questions.
- Experience with interfacing and managing multiple stakeholders, vendors and contractors.
- Collaborate effectively with the study team, cross-functional team members and external partners.

What F-star can offer you	We get things done, we keep things simple and we're driven by the science. We're ambitious so we work hard to create an environment where we can take smart risks. We want to be innovative so encourage debate and collaboration to challenge the usual way of doing things. We love our celebrations, socialising and perks, which make F-star a fun and diverse place to work. And most of all, everyone has the opportunity to make a difference.