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Job Description

Job Title:	**Part-time Senior Global Study Manager (EU + US Clinical Trials)**
Location:	**Remote**
Pay Range:	**Market Rate Pay – depending on experience and skills**

About Oxford Biotherapeutics:
Oxford BioTherapeutics (OBT) is a clinical-stage biotechnology company developing antibody therapeutics for the treatment of cancer. You will play an integral role in the pre-clinical development of novel immuno-oncology therapeutics. Our OGAP® platform is the world's largest, cancer specific, membrane protein library, directly measuring plasma membrane protein expression in patient tumors. OGAP is used to identify novel, highly tumor specific antigens for novel first-in-class ADC, Bispecific T-cell Engager (BITE®) and Chimeric Antigen Receptor (CAR) targets. Our lead asset, OBT076, is an Antibody Drug Conjugate (ADC) in Phase 1b clinical development. Our clinical and pre-clinical pipeline of novel biologics is balanced between internal programs, focused on ADCs and checkpoint regulators, and externally partnered programs with key innovators in oncology such as Boehringer Ingelheim, ImmunoGen and Genmab.

Purpose of the Role
We are seeking an experienced Senior Global Study Manager to work with us on a contract basis for circa 6 months to oversee and develop our clinical trials in both the European Union and the United States. In this role, you will be responsible for managing the entire clinical study process, including planning, execution, and finalization of studies in compliance with regulatory requirements.

Roles and Responsibilities:

- Develop and manage study timelines, budgets, and resource plans for global clinical trials in the EU and US
- Collaborate with cross-functional teams including clinical operations, data management, biostatistics, and medical writing to ensure that studies are executed according to protocol, SOPs, and regulatory requirements
- Oversee study conduct, including site initiation, monitoring, close-out, and management of external vendors
- Participate in the selection and management of Contract Research Organizations (CROs), including contract negotiation and performance evaluation
- Develop and review study protocols, informed consent documents, and other study-related documents

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- Collaborate with the Medical Director to ensure clinical trial data is accurate, complete, and consistent with regulatory requirements and study protocol
- Ensure compliance with Good Clinical Practice (GCP) and other applicable regulatory guidelines
- Develop and implement risk mitigation strategies to ensure the successful completion of clinical trials
- Collaborate with regulatory affairs to prepare and submit study-related documentation to regulatory agencies for approval
- Manage and maintain study budgets, including tracking of costs and forecasting of expenses

Please note the roles and responsibilities for the position include but are not limited to the above.

Knowledge, Experience, and Skills:

- Bachelor's or Master's degree in a scientific or healthcare-related field
- Minimum of 7 years of clinical trial management experience in oncology or biotech/pharmaceutical industries
- Strong knowledge of clinical trial operations, including study design, execution, and monitoring
- Excellent communication, interpersonal, and leadership skills • Experience managing global clinical trials in the EU and US
- Ability to work effectively in a matrixed environment and collaborate with cross-functional teams
- Knowledge of GCP, ICH guidelines, and regulatory requirements for clinical trials in the EU and US
- Ability to effectively manage multiple priorities and projects simultaneously
- Experience with monoclonal antibody clinical trials is a plus

Behaviours

- Team player
- A positive customer centric attitude
- Enthusiastic and resilient
- Organised and proactive
- Takes initiative
- Self-motivated
- A flexibility and adaptable approach
- Readiness to learn new methods

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Equal Opportunities Statement
We are committed to equality of opportunity for all employees and contractors. Applications from individuals are encouraged regardless of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief and marriage and civil partnerships.

If you are passionate about oncology and want to join a dynamic and innovative team, please apply for this exciting opportunity to make a meaningful impact in the lives of patients.
Job link - Part-time Senior Global Study Manager (EU + US Clinical Trials)