Job Title: Director of Clinical Operations – Oncology

Location: Remote – US / Europe

Reports To: Head of Development and CMO

Key Responsibilities:

- **Leadership & Oversight:**
    - Provide strategic support and direction to the clinical team or CRO in managing oncology clinical trials from initiation through closeout.
    - Oversee the planning, implementation, and tracking of oncology clinical programs
    - Collaborate with internal and external stakeholders, including investigators, vendors, CROs, and regulatory agencies.
    - Analyse and report on trial data, providing insights and recommendations to optimize study performance.
- **Trial Management:**
    - Lead protocol development, site selection, budgeting, and resource allocation for clinical trials.
    - Ensure trial activities are conducted in accordance with ICH-GCP guidelines, local regulatory requirements, and company SOPs.
    - Manage timelines, budgets, and quality metrics to meet company's goals, addressing risks and challenges proactively.
    - Conduct regular meetings and maintain communication with study teams, vendors, and stakeholders to address challenges and ensure alignment.
    - Contribute to the development, review and finalization of all clinical trial documents and plans including but not limited to the clinical trial protocol, informed consent, investigator's brochure, monitoring plan, risk management plan, data management plan, vendor oversight plan, quality assurance plan, etc.

- **Regulatory & Compliance:**
    - Ensure all clinical trial activities comply with regulatory standards, company policies, and ethical considerations.
    - Support the regulatory activities to prepare for IND filings, regulatory submissions, and inspections.
    - Oversee adherence to data integrity, patient safety, and other compliance requirements.
- **Vendor & Site Management:**
    - Select, negotiate, and manage third-party vendors, including CROs, ensuring high-quality deliverables and adherence to timelines and budgets.
    - Develop strong relationships with clinical sites and investigators to facilitate effective trial execution and patient recruitment.
- **Budgeting & Resource Management:**
    - Manage budgets for oncology clinical trials, ensuring cost-effective use of resources.
    - Identify and resolve financial risks, providing regular updates to senior leadership.

Qualifications:

- Education: Degree in life sciences; oncology specialization preferred.
- Experience: Minimum of 10 years in clinical operations with at least 5 years in oncology.
- **Skills:**
    - In-depth understanding of clinical trial design, implementation, and regulatory requirements.
    - Strong leadership, communication, and interpersonal skills.
    - Proven ability to manage multiple complex projects simultaneously in a fast-paced environment.

- Proficient in clinical trial management systems (CTMS) and project management tools.

Preferred Qualifications:

- Proven track record of successfully leading oncology clinical trials through all phases, particularly phases I.
- Experience with global clinical trials and multi-national regulatory requirements.
- Knowledge of emerging trends and best practices in oncology clinical development.
- Ability to travel as needed to relevant industry conferences, site visits and in person meetings.
- Excellent verbal and written communication skills.
- Proven experience working in a dynamic high-volume environment handling multiple tasks.

What we offer:

- Dynamic and innovative work environment.
- Competitive salary and performance-based incentives.
- Competitive benefits package
- Opportunity to make a significant impact in the field of oncology.

To apply for this opportunity please send your resume via email to careers@ottimopharma.com . Please include the position title in the subject line.

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