Senior Director, Clinical Operations

Background: Checkmate Pharmaceuticals is a clinical stage company that is leveraging its expertise in the field of CpG oligonucleotides to discover and develop immunotherapies designed to increase the efficacy of existing immunotherapies and to provide new treatment options for patients and their healthcare providers. Checkmate's lead product candidate, CMP-001, is an investigational cancer immunotherapeutic that has been shown to reverse resistance to PD-1 therapy in some patients. Checkmate is a privately held company headquartered in Cambridge, MA. Additional information regarding Checkmate is available at www.checkmatepharma.com.

Location: Cambridge, MA

Essential Functions:

- Provides leadership for the operational strategy and overall execution and development of assigned clinical program(s) which includes budget, timelines, quality, resource management and provides operational strategies to achieve clinical program goals
- Develop and coordinate operational plans for a clinical study or multiple clinical studies within a development program
- Manage clinical budget planning/forecasting
- Select and manage CROs, contract laboratories and other vendors, leading cross-functional teams ensure work quality, timeliness, and adherence to budget and study agreements; serves as primary contact and resource for CRO and vendor personnel in overarching functions as well as Checkmate team members
- Evaluate CRO and vendor performance and support improvement initiatives
- Ensure adherence to regulatory requirements (ICH, FDA, EMA, etc.) and GCP guidelines through establishment and reporting of clinical performance indicators KPIs/KQIs, and through innovative and agile methodology to improve processes
- Lead or provide oversight of the writing/reviewing/approving clinical project deliverables such as protocols, IP labeling, manuals, study plans and related materials
- Manage and/or provide oversight of the identification and evaluation of investigators and sites and actively manage and assess subject enrollment against established targets
- Lead oversight of clinical trial operations and all aspects of site management in accordance with ICH/GCP standards and SOP's
- Collaborate cross-functionally to oversee the clinical operations aspects of work processes involving medical writing, legal, finance, quality assurance, pharmacovigilance, biometrics, program management, regulatory, pharmaceutical sciences, IT, medical affairs, translational science and clinical science

- Provide oversight to Institutional Review Board/ Ethics Committee (IRB/EC) approvals, as appropriate
- In coordination with vendors, provide regular study updates and review correspondence and trial status to leadership
- Ability to anticipate potential operational, risk or study issues and to prepare contingency plans with minimal oversight
- Lead and manage clinical operations team, including effective performance reviews, feedback and development of staff
- Maintains knowledge of therapeutic areas knowledge current medical practice and pharmaceutical regulations in order to ensure best practice across all activities
- Escalates issues and provides relevant, recommendations to management for resolution
- Leads and/or participates in initiatives for process, technology or other continuous improvement to achieve cost-reduction, time-savings, efficiency, quality or other business objectives
- Build collaborative relationships with key internal stakeholders to facilitate the planning and execution of clinical trials, operational strategy, risk management and mitigation

Qualifications:

- BA or BS, PharmD / Master's degree preferred
- 12+ years of experience in clinical research in the pharmaceutical industry, including 9+ years clinical study/program management; clinical monitoring experience preferred
- Experience in setup, execution, and operational management of domestic and international Phase 1, 2, and 3 clinical trials; oncology experience preferred
- Proficiency in managing and developing clinical operations personnel and CROs
- Excellent written and verbal communication skills, strong problem-solving ability, and attention to detail and quality
- Must be proficient in MS Office Suite, various CTMS, IVRS and EDC platforms as well as willingness to learn as needed
- Ability to prioritize tasks and resources, meet deadlines, and be flexible to changing priorities and innovations of a small start-up environment
- Track record of leadership and project management success at the director level required
- Thorough and expert knowledge of global regulatory and compliance requirements for clinical research including ICH GCP
- Previous line management or direct management of team members
- Ability/willingness to travel as required

Candidates must be authorized to work in the U.S.
This is a full-time position and is eligible for company benefits.
Checkmate is an EEO employer

Send resumes to: careers@checkmatepharma.com