TITLE: (Senior) Clinical Trial Manager

Background: Checkmate Pharmaceuticals, Inc. 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 publicly held company headquartered in Cambridge, MA. Additional information regarding Checkmate is available at www.checkmatepharma.com.

***** This position is an individual contributor role; Checkmate is open to a range of levels based on years of experience, educational accomplishments, & oncology therapeutic experience.***

Essential Functions:

- Actively provides direction and oversight of clinical trials
- Leads CRO and critical vendor selection process for outsourced activities, including development of scope of services agreements, budgets, plans and detailed timelines, and ensures that performance expectations are met
- Develops and executes operational plans
- Provide technical expertise for the development of clinical documents (protocol, informed consent form, CRF, monitoring plans, regulatory submission documents, clinical study report, investigator brochures, etc.)
- Proactively identifies and resolves operational issues/processes to ensure achievement of study milestones, data quality and data integrity; escalates study-related issues appropriately in a timely manner
- Obtain and relay key study issues, status updates, and other study information to the clinical trial team and management
- Supports the forecast and management of project/program budgets, including long range forecasting of clinical trial costs
- Demonstrated knowledge of international clinical pharmaceutical standards, ICH/GCP guidelines, and regulatory compliance
- Proactively assess potential risks to the study and propose mitigation plans
- May support development of clinical operations quality systems, including standard operating procedures, document management, personnel training, and quality control processes
- May support development of department goals and objectives
- May manage and mentor clinical team members

Qualifications & Required Experience:

- BA or BS, PharmD / Master's degree preferred
- Minimum of 5 years of experience in clinical research in the pharmaceutical industry, including clinical study/project 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
- Strong working knowledge in Good Clinical Practices and ICH Guideline and the application to the conduct of clinical trials
- Demonstrated self-starter and team player with strong interpersonal skills
- Ability/willingness to travel, as required
- Strong preference for local area candidates who can work collaboratively in the corporate office

Position Location: Cambridge, MA

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