Associate Director/ Director, Clinical Scientist

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, but Checkmate is open to a wide range of levels based on years of experience, educational accomplishments, & oncology therapeutic experience.

The Clinical Scientist will be responsible for all day-to-day aspects of clinical development programs in support of the implementation and execution of our medical strategy. He or she will work in cross-functional teams to assure the highest standards of clinical drug development and GCP.

- Responsible for review of clinical trial data
- Responsible for external data collection and review of competitive intelligence
- Responsible for medical aspects of regulatory or communications documents

Other responsibilities include, but not limited to:

- Works closely with Head of Clinical Development or Medical Directors (as the function grows), research, exploratory biology, external experts, and investigators to accumulate scientific and medical knowledge necessary to support clinical development plans and study designs and protocols
- Assists Medical Director(s) in creation of proposed concept sheets for clinical studies and may write protocols or work with medical writing to write protocols through incorporation of input from both internal and external experts
- Drives the clinical contribution to annual safety and IB updates while liaising with Clinical, Translational Medicine, Safety, Regulatory, and Medical & Communication Experts
- Drives and integrates clinical contribution to answer regulatory queries and other submissions related to studies
- Works closely with clinical operations, data management and biostatistics to monitor real time study data to ensure the integrity of the study and the study data and interacts with investigators and internal and external experts to resolve any study issues as they arise
- Involved in high level data cleaning activities requiring clinical judgment
- Involved in analysis of complex data for regulatory submissions, publications and design of studies and programs
- Acts as clinical/scientific expert on the products and studies in the therapy area

- Attends scientific meetings to remain abreast of new developments within relevant areas, inform the organization of relevant changes in the clinical development landscape, and to interact with investigators, and advisors
- Works with investigative sites to answer protocol related questions, resolve study conduct and design issues
- May present data, protocol designs and other information at advisory boards, investigator meetings, site initiations, and other internal and external settings
- Support of Strategic or Clinical Advisory Boards
- Supervision of external consultants if applicable
- Internal resource for all Company functions requiring clinical input
- Primary point of contact for clinical trial staff at study sites
- Together with Clinical Operations, prepare Investigator Alert letters and SAE reports as required
- Medical Affairs activities as needed

Qualifications:

- Master's degree or PhD in Life Sciences (or Bachelor's degree plus equivalent experience); Pharm D, or other equivalent clinical qualifications with experience in a major pharmaceutical and/or biotech company.
- Strong interpersonal, organization, planning and communication (oral and written) skills.
- Extensive knowledge of clinical development, FDA and international global clinical trial regulations and ICH GCP guidelines
- Ideally, experience in both early and late phase development and regulatory submissions
- Medical knowledge and experience in clinical development/ operations (Oncology preferred)
- Minimum of 10 years in the biopharmaceutical industry with experience reviewing clinical data.
- Ability to perform literature searches, to utilize library services and to conduct basic data analyses using Excel and other tools
- Basic understanding of biostatistics to allow effective interaction with biostatistics expert
- Ability to drive decision-making within a multi-disciplinary, multi-regional matrix team
- Diplomacy and positive influencing abilities
- Experience building data presentations
- Team player and an entrepreneurial and hands-on attitude and highly self-motivated.
- Proficiency in Microsoft Word, Excel and PowerPoint
- Strong preference for candidates to be in Boston area

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

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