Associate Director/Director, SAS Programmer

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.

Location: Cambridge, MA

Responsibilities:

- Effectively design/develop SAS programs and programming specifications for producing and validating datasets to support the generation of materials for clinical study reports, publications, conference abstracts/presentations, and/or regulatory agency submissions
- Code complex SAS programs designed to analyze and report complex clinical trial data for electronic review, exchange, transformation, derivation, and submission of data in compliance with CDISC SDTM/ADaM standards as well as regulatory business/validation rules
- Develop and comply with study programming standards and specifications according to regulatory agency guidelines
- Coordinate and oversee CRO preparation, execution, reporting and documentation of statistical programming activities, proactively troubleshooting as needed
- Responsible for accuracy and validity of regulatory submission data and clinical summary report package
- Remain informed of new developments in programming industry standards
- Maintain records for all assigned projects and archiving of trial/project analysis and associated documentation
- Design and implement quality control (QC) programs to ensure the quality and integrity of statistical programs used to generate datasets including CDISC SDTM and ADaM datasets
- Effectively design and code SAS programs with strategic objectives of studies in mind
- Assist with ensuring that programming activities are implemented consistently across clinical studies
- Assist in establishing & maintaining SOPs and work instructions relevant to SAS programming
- Set up standard folder structure and streamline workflow for all SAS programming work
- Develop, test, and document SAS macros for programming efficiency

Qualifications

- MS or PhD in statistics or equivalent with minimum 8+ years of programming experience in pharmaceutical industry

- Experience with SAS® for Windows, including BASE SAS (macros, ODS, SQL), SAS/ACCESS, SAS/STAT, SAS/GRAPH
- Proficient knowledge of FDA, EMA, and ICH regulations and guidelines
- Proven experience as a programming lead, concurrently supporting multiple studies, providing high quality statistical analysis results in a timely manner
- Excellent written and oral communication skills
- Effective at translating technical data so understandable to non-technical teammates
- Knowledge of statistical methods that apply to Phase I-III clinical trials
- Must be proficient in industry standards and clinical trial terminology and methodologies
- Experience in oncology clinical research is preferred
- Experience in R is preferred
- Strong preference for candidates in the Greater Boston area

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