

Principal Scientist, Translational Immunology and Biomarker Development

Company

Visterra is a clinical stage biotechnology company committed to developing innovative biologic therapies (monoclonal antibodies and therapeutic mAbs) for the treatment of kidney diseases, with an immuno-nephrology focus in drug development. Our proprietary technology platform enables the design and engineering of precision antibody or protein-based drug candidates to modulate key disease targets. We are developing a robust pipeline of novel therapies for patients with unmet needs.

Visterra is a wholly owned subsidiary of Otsuka America, Inc., which is a U.S. holding company subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 90 employees, and is located in Waltham, Massachusetts.

Summary

Visterra is currently seeking a talented, highly motivated, and qualified individual for the position of Principal Scientist, Translational Immunology and Biomarker Development. This individual will serve as an integral member of the translational team and play an instrumental role in moving drug candidates from preclinical research to clinical development. This position requires knowledge of immunology, clinical translational research, and analytical and quantitative methodologies, including flow cytometry. This position will report to the Vice President, Translational Medicine, will work closely with the scientific research staff and clinical development teams, and will be responsible for three main areas:

- Biomarker strategy for immunology targets spanning from preclinical to clinical.
- Clinical and preclinical data analysis to support new target identification, and validation of selected targets and mechanisms of action.
- Assisting clinical operations activities related to exploratory data analysis, supported by a familiarity with statistical concepts.

This is a full-time position located at Visterra's facility in Waltham, MA.

Responsibilities

- In a matrix environment, collaborate with Visterra's scientists and clinical researchers to understand prioritized needs within development programs, and provide critical deliverables in a fast-paced timeframe.

- Collaborate with research and clinical colleagues to develop and defend scientifically rigorous translational and exploratory biomarker strategies. Work closely with discovery and preclinical groups to define translational hypotheses including potential pharmacodynamic and predictive biomarkers for novel targets.
- Execute specific components of Visterra's translational biomarker strategy, to support active clinical programs as well as pre-clinical programs approaching IND for FIH studies.
- Oversee flow cytometry assay methodologies. Determine which biomarkers and metrics are critical to measure in early phase trials. Clearly delineate the underlying rationale for such decisions.
- Operationalize other biomarker measurements as needed, including supporting vendor oversight and selection, and bridging research and nonclinical efforts with selected vendor(s) to ensure the data flow provides the information necessary to support program development in a timely manner.
- Support accurate preparation of scientific material for conference presentations and publications, as well as any internal or external scientific communication related to clinical studies or mechanism of action of the study drug.
- Integrate and present published data with non-clinical and clinical data to support the mechanism of action of drug candidates.
- Support authoring and review of protocols, clinical study reports and Investigator Brochures.
- Coordinate and oversee clinical trial interim data analyses and align with key stakeholders. Assist with the operational plan put forth by statistical CRO to ensure smooth interim analysis data flow, documentation & internal communication.
- Support the Clinical Operations team by assisting with SAP and eCRF development, reviewing informed consent forms, advising on minimal blood volumes and appropriate containers (tubes, preservatives), advising on sample processing needed at sites (balanced with site-specific feasibility), providing critical input to trials' lab operations manuals, and assisting with data transfer agreements with CROs.
- Performs other duties as required.

Requirements

- Ph.D. or research-oriented M.D., with focus on immunology or an immunology-related field, and at least 7 years post-doctoral experience.
- Experience with flow cytometry methodologies, and translational applications.
- Knowledge of core biostatistical concepts and ability to communicate with statisticians.
- Ability to synthesize and interpret diverse, multidisciplinary data sets, think critically, synthesize and extract simple principles from complex datasets.
- Clinical trial experience and alliance management skills are preferred.



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- Strong verbal and written communication skills, as well as an ability to communicate effectively across a broad spectrum of audiences, both internal and external.
- The temperament to enjoy and thrive in a multi-tasked and hands-on environment.

Visterra provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

For consideration, please submit a cover letter and resume to careers@visterrainc.com.