



PBI Standard Operating Procedure

Personnel Job Description Form

Reference # QMS-FR-003
v. 1

Department: Clinical
Job Title: Clinical Scientist
Reports To: Director, Research Partnerships

Type of Position: Scientist, Medical Communications **Hours:** 9 am – 5pm, variable

Full Time Exempt Temporary
 Part Time NonExempt Contractor

Summary of Job Description:

The Clinical Scientist is responsible for providing scientific support to the Clinical Project Team, leading medical communications, conducting data analyses, and providing scientific input on Presage’s preclinical and clinical programs.

Duties and Responsibilities:

- Participate in the identification and recruitment of study sites and investigators for clinical sites.
- In tandem with the study CRA, support communications with the clinical sites.
- Develop subject-matter expertise in relevant disease areas.
- Deliver high quality presentations of scientific data to health care professionals in multiple settings, including advisory boards, investigator meetings, and other appropriate venues to enhance understanding and awareness of the CIVO platform and the Presage’s Phase 0 clinical trial product.
- Review and interpret CIVO biomarker data and contribute to data summaries for partners and publications.
- Contribute to the development of quantitative image-based assays of cellular responses within the tumor microenvironment and generate initial data and analyses of these assays.
- Support the qualification of internally developed immunohistochemical assays in collaboration with Presage’s Histology team and external pathologists.
- Participate in the design, development, and review of clinical trial protocols, amendments, informed consent forms, study guides, plans, case report forms, and any other clinical research related documents (including plans, policies, procedures, work instructions, forms, logs, etc.) and study reports.
- Participate as needed in the preparation of the clinical contribution to INDs, IBs/IFUs, regulatory briefing documents, and other relevant documentation for submission to the FDA and other regulatory authorities.
- Manage safety communication and recording, reviewing, and reporting of safety events in concert with the study’s medical monitor.

Qualifications:

- Graduate level education, Ph.D. preferred with at least 3 years of experience in biotech industry. Oncology experience required.
- Must be able to create and foster productive professional relationships and engage in scientific dialogue with KOLs and other external collaborators.
- Experience compiling and delivering written and oral scientific presentations.



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- Ability to develop subject-matter expertise in relevant disease areas.
- Must be able to work well independently and in groups.
- Excellent interpersonal, written and verbal communication skills.
- Must be comfortable working in a fast-paced, competitive environment with ambiguity and complexity.
- Must be able to handle multiple, unrelated tasks simultaneously.
- Must possess strong attention to detail with excellent analytical, critical thinking and organizational skills.
- A positive attitude and willingness to learn new things.
- Experience with image analysis and biostatistics a plus.
- Experience with histology, immunohistochemistry, and microscopy a plus.

Work Environment:

In-office with the possibility of working remotely for a portion of that time, with prior approval. Travel may be required.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is occasionally required to stand; walk; sit; use hands to handle or feel objects, tools or controls; reach with hands and arms; climb stairs; balance; stoop, kneel, crouch or crawl. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by the job include close vision, distance vision, peripheral vision, depth perception, color vision, and the ability to adjust focus.