



*a new era in cancer drug development realized*

## **Associate Director / Director, Clinical Operations**

### **Our Company**

Presage Biosciences, Inc. is an innovative oncology company with an entirely novel platform for assessing new drugs and combinations to treat solid tumors. Our proprietary technology platform, CIVO®, simultaneously analyzes multiple cancer drug candidates and drug combinations within a single living tumor.

Presage is a growing, privately held company led by an experienced management team and is headquartered in the vibrant South Lake Union area of Seattle, WA.

### **Key Responsibilities**

- Direct the planning, implementation, and execution of all drug and device clinical trial programs at Presage Biosciences, Inc.
- Oversee Clinical Operations activities including project planning, project timelines, resource management, strategic site selection, site relationship management, and recruitment strategies
- Ensure compliance with good clinical practices, good manufacturing practices, and global regulatory guidelines, as applicable
- Align study start-up, enrollment, study conduct, and close-out activities with project goals and timelines
- Oversee and manage the selection, negotiation, and oversight of all outsourced service providers and consultants to facilitate achievement of clinical program objectives
- Prepare, track, and monitor study budgets, resource demand (both internal and external/outsourced) and study timelines for all clinical projects
- Oversee the clinical operations team and act as a cross functional liaison to ensure study plan aligns with business development strategies
- Participate and assist in preparation of protocols and regulatory submissions
- Oversee the development of study manuals, case report forms and provide oversight of Trial Master File (TMF)
- Contribute expertise in all operational activities pertaining to the execution of clinical trials
- Recommend and implement innovative processes to improve and impact clinical trial management and deliverables and Inspection Readiness
- Lead development of standard operation procedures (SOPs), policies, charters, and plans in close collaboration with regulatory and quality team.
- Ensure senior management team are routinely informed and aware of clinical trial progress and challenges.
- Other duties as requested

### **Qualifications**

- A Bachelor's/Master's degree in a scientific discipline is required
- 8+ years' experience in clinical research in positions of increasing responsibility
- Experience leading Clinical Operations within an organization and having direct oversight and management of employees

- Previous oncology, surgical or drug/device combination trial experience
- Experience supervising, mentoring, and training clinical operations personnel at all levels
- Direct experience managing CROs and with vendor/site contract negotiation
- Thorough knowledge of the drug development, device development, and clinical research processes as well as FDA/ICH GCP regulations and guidelines
- Excellent project management, negotiation, and organizational skills; expertise in leading cross-functional meetings and initiatives
- Demonstrated track record of collaboration and leadership skills
- Must be able to work productively in a fast-paced environment with high levels of interruption
- Ability to anticipate and solve problems in a detailed, comprehensive manner
- Excellent written and verbal communication skills

### **Work Environment**

In-office with the possibility of working remotely for a portion of that time, with prior approval. Travel may be required up to 20% in support of clinical study activities.

### **Join Us!**

If you enjoy a stimulating office environment, are based in the Seattle area, and most importantly, have a passion for improving the lives of patients with cancer, come join us!

To apply for this position, please send your CV with cover letter to:

Presage Biosciences, Inc.  
Attn: Human Resources  
530 Fairview Ave N, Suite 1000  
Seattle, WA 98109  
E-mail: [hr@presagebio.com](mailto:hr@presagebio.com)

Presage Biosciences, Inc. is an Equal Opportunity Employer.