presage BIOSCIENCES

a new era in cancer drug development realized

Clinical Research Associate

Our Company

Presage Biosciences, Inc. is an innovative oncology company with a novel platform for assessing new drugs and drug combinations in solid tumors. Our proprietary technology platform, CIVO®, enables simultaneous injection and downstream pharmacodynamic analysis of investigational drugs in the tumor microenvironment. We have an active portfolio of Phase 0 clinical research in the United States and Australia.

Presage is a privately held company, headquartered in the vibrant South Lake Union area of Seattle, WA.

The Role

We are looking for a Sr. CRA/CRA to be an integral part of our Clinical Development team. The selected candidate is responsible for ensuring the quality and integrity of Phase 0 clinical trial conduct. They will act as a lead to onboard new sites, drive patient enrollment activities, manage and monitor overall clinical trial workflow, and coordinate final study close-out and reporting activities. The candidate will also interface with third-party vendors to manage study data quality and investigational product distribution. They collaborate with cross-functional teams to align timelines, budgets and resources. This is a unique opportunity within an emerging company to lead, create, and develop high-impact initiatives that directly affect company objectives and growth.

The selected candidate has a versatile mindset, an attention to detail, and the ability to manage and integrate content from multiple workstreams. They show passion for the quality of their work and can independently and efficiently manage through competing priorities. The right candidate thrives in a dynamic environment, is enthusiastic, is organized, and independently takes initiative to seek solutions. A collaborative attitude and positive ethos are leveraged in navigating important external clinical research relationships with sites.

Key Responsibilities

- Support the successful conduct of CIVO Phase 0 clinical studies ensuring compliance with the protocol, regulatory requirements, SOPs, and GCP to protect the rights of human subjects and ensure human subjects are treated equitably
- Assess site qualification potential and conduct pre-study visits on an as-needed basis; continually assess study site and personnel on an ongoing basis
- Support identification and recruitment of study sites and investigators
- Manage study start-up processes and site communication to include clinical trial agreement and budget negotiations with the sites
- Collaborate in drafting and reviewing clinical study documents to include the protocol, protocol amendments, informed consent form, case report forms, and training materials
- Provide protocol-specific training to study personnel and ensure training is properly documented
- Ensure accountability of investigational product and related supplies are performed

- Ensure identification and reporting of safety issues, when applicable, from research site staff to the Sponsor and IRB
- Verify data integrity and provide assistance to the site with internal audits or regulatory inspections
- Conduct routine monitoring visits in accordance with the study-specific monitoring plan and document monitoring activities
- Ensure complete and timely reporting and documentation of monitoring activities
- Support the collection, review, and updating of essential documents in the site regulatory binder and the Sponsor's Trial Master File to ensure accuracy and completeness of study records
- Serve as a central contact of the clinical study team in study-related communications, documentation, and correspondence
- Collaborate cross functionally to identify and implement GCP policy and procedures in compliance with applicable regulations/guidelines for clinical study programs

Qualifications:

- Bachelor's Degree
- Certificate in Clinical Trials or equivalent education
- Clinical Research Certification (ACRP or SoCRA) a plus
- 2+ years prior CRC or CRA experience
- Excellent communication and interpersonal skills (in person and via phone, email, and chat) for both internal and external interactions
- Strong organizational skills
- A collaborative mindset
- Positive, support-focused attitude
- Strong attention to detail and the ability to multi-task and prioritize assignments
- Microsoft Office Suite proficiency; prior experience with EDC and eTMF systems
- Solid analytical and critical thinking skills
- Ability to adapt to changes in a fast-paced environment
- Up to 20% travel (when allowed and safe due to COVID) may be required

Join Us!

If you want to be part of a dynamic team, work on cutting edge science, 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

Presage Biosciences, Inc. is an Equal Opportunity Employer