



Clinical Research Associate II

Bionovo, Inc. (NASDAQ: BNVI – www.bionovo.com), a publicly traded biopharmaceutical company located in Emeryville, California, is currently seeking a qualified, highly motivated individual for the position of Clinical Research Associate II reporting directly to the Director of Clinical Development.

The company is currently focused on one program in late stage clinical development, targeting large, unmet medical needs. Bionovo is preparing to launch a Phase 3 trial of Menerba for menopausal hot flashes in October 2011. In addition, a number of Phase 1 trials of Menerba are in various stages to further look at the drug's safety and tolerability. The company's second compound, Bezielle, is ready to enter Phase 2 testing for the treatment of metastatic breast cancer.

The successful candidate will have the skills necessary to thrive in a small company environment, as he/she assists Clinical Research staff in the conduct of clinical trial activities in accordance with Standard Operating Procedures and all applicable regulations governing the conduct of clinical trials. Particularly important skills include intelligence, logical thinking, ability to prioritize, "can-do" attitude, the ability to adapt quickly to changing business conditions, and strong interpersonal and team building skills.

Overall responsibilities for managing the full scope of clinical operations (protocol development to final report, regulatory filing and/or publications) and coordinating cross functional efforts in the administration and progress of a clinical trial(s) in order to achieve study objectives and corporate goals.

ESSENTIAL FUNCTIONS

Essential functions include but are not limited to the following:

- Assist in managing defined aspects of clinical studies at Bionovo to ensure studies are completed on time, within budget and in compliance with SOPs, FDA regulations and ICH/GCP guidelines
- Collect, review for accuracy, and submit essential documents for filing in Trial Master File
- Perform the activities associated with the implementation and monitoring of clinical trials
- Oversee drug accountability at investigator sites and assist with the projection and management of both clinical and non-clinical supplies
- Assist in the preparation of clinical study reports, annual reports, IND updates, etc.
- Prepare and update study drug forecasts
- Work with Medical Monitor and Director of Clinical Development to select investigative sites, train investigators and investigative site staff, preparation of materials for investigator meetings, clinical supplies
- Maintain study timelines. Identify and communicate study issues that will impact budget, resources and timelines.
- Review and critique CRFs for accuracy and completeness. Oversee data discrepancy management and assists with mapping as needed
- Provide training to internal and external customers as needed
- Ensure that supportive study documents are completed (e.g., IVRS, specific scripts, non-clinical supply materials)
- Contribute to wider organizational goals and/or activities as assigned.
- Travel up to 40%

Desired Background and Experience:

BS/BA in Life Science or related discipline; or equivalent experience

2-5 years industry experience in drug development;

Phase 3 experience preferred

Interested parties, please send cover letter, CV and references to jobs@bionovo.com