<http://www.algomedix.com/contactus.html>

AlgoMedix – outside of Everett. Pain/Inflammation novel drug development. V.small, no employment section of website.

BioClinica looks like a global CRA that’s supposed to have offices in Portland but I’m not sure if it does. Here is a sample job posting for a Clinical Research Associate that looks like some of what I’m interested in doing:

nhouse Clinical Research Associate (CRA)

**Tracking Code**

1226-050

**Job Description**

Bioclinica, Inc. is looking for intelligent, creative and dedicated professionals to join our growing team. We are a company that values technical excellence, teamwork and a commitment to success. We employ cutting edge technology to provide our customers with industry leading solutions and are currently seeking to fill the position of In-house Clinical Research Associate (CRA) to work out of our Princeton, NJ office.

The Clinical Research Associate (CRA) I is an entry level professional position in clinical research and works closely with Project Managers (PM) and project team. The CRA requires training and mentoring from the Director and/or CRA mentor and may conduct onsite co-monitoring/training prior to serving as a primary CRA. As a key member to the project team, the CRA ensures that study documents are tracked, filed and study materials prepared and distributed. The CRA also monitors Investigative sites to ensure protocol and regulatory compliance.

**Primary Responsibilities**

Supporting Clinical Trial Assistant (CTA), Project Manager (PM) and Project Director (PD) in the management of investigational sites in compliance with the study protocol, ICH/GCP and applicable regulations by

* Answering field site and CRA protocol questions
* Tracking information on FAQ logs and escalate issues and trends to PM
* Performing routine phone calls to sites to ensure compliance with protocol and answer questions
* Monitoring sites in conjunction with CRA mentor and instruction from Director, Project Management
* Ensuring that sites comply with GCP/ICH regulations and applicable SOPs
* Conducting Site Initiation Visits in accordance with the study specific Clinical Monitoring and Site Management Plan, including advising and training

Performs project analysis and management by

* Assisting sponsor with protocol development, case report form design, informed consent form content, investigator agreement and monitoring plan development
* Assisting site personnel with the development of recruitment strategies and enrollment plans
* Reviewing site files and records, investigational product accountability records, case report forms and source documents for accuracy, completeness, consistency and compliance
* Identifying deficiencies and discrepancies, providing additional training and initiate corrective action as required
* Documenting and maintaining all site contacts utilizing the Site Contact Form
* Advising and training study site personnel on sponsor and regulatory requirements for study conduct, adequate screening and enrollment of study subjects, data management expectations and adherence to study specific timelines
* Preparing timely and accurate monitoring reports, confirmation letters and follow-up letters for all site visits as per the study specific Clinical Monitoring and Site Management Plan and applicable BioClinica SOPs
* Ensuring compliance to Data Management procedures for monitoring and perform timely resolutions of CRF queries resulting in smooth database lock

Assists with study start-up, maintenance and close-out by

* Collecting, tracking & reviewing required Regulatory Documents for accuracy
* Interacting with investigative sites, BioClinica & Sponsor personnel to resolve discrepancies
* Assist with Investigator Meeting Planning and prepare materials for meeting
* Assist with Investigator Grant Payments
* Attending applicable meetings
* Conducting Interim Monitoring Visits per the schedule defined in the study specific Clinical Monitoring and Site Management Plan to ensure compliance with the study protocol, GCP/ICH regulations, BioClinica/Sponsor SOPs and overall clinical objectives.
* Interacting directly with multiple study vendors to order and distribute clinical supplies
* Conducting Close-out Visits per the study specific Clinical Monitoring and Site Management Plan including final investigational product reconciliation and disposition, site study file reconciliation, data query resolution and resolution of outstanding action items

Performs Investigator Evaluation and Recruitment by

* Utilizing BioClinica tools to evaluate potential Investigators for new studies
* Utilizing CTMS or other approved format for managing Investigator recruitment
* Performing feasibility studies

Performs Quality Control (QC) review of the files according to applicable SOPs

* Cross-referencing documents between folders and/or files for accuracy & consistency
* Completing QC review of the regulatory files and Clinical Trial Management System (CTMS)
* Assisting with the preparation of required regulatory submissions to Central Institutional Review Board (IRB) and other regulatory authorities (Ethics Committees and Competent Authorities)
* Acting as intermediary between the investigative sites, the Central IRB, other regulatory agencies & the Sponsor

Performs study-related administrative tasks by

* Preparing and submitting monthly calendars, time and expenses, both project related and on-project related, within the required timeframes.
* Reviewing CRFs for Safety Trigger and send to Sponsor for review
* Maintaining contact lists, sending mailings, distributing newsletters, etc.)
* Serving as back up for Patient Outreach Center Specialist for performing patient interviews and inbound/outbound calls.
* Filing for Trial Master File (TMF)
* Preparing expense reports, managing time, and scheduling subsequent visits in accordance with sponsor expectations and within the study budget

**Secondary Responsibilities**

Maintains Quality Service and Departmental Standards by

* Reading, understanding and adhering to organizational Standard Operating Procedures (“SOP”)
* Assisting in establishing and enforcing departmental standards

Contributes to team effort by

* Working with internal staff to resolve issues
* Exploring new opportunities to add value to organization and departmental processes
* Helping others to achieve results
* Performing other duties as assigned

Maintains Technical and Industry Knowledge by

* Attending and participating in applicable company-sponsored training

**Working conditions:**

Travel: 0-50%

Lifting: 0-10lbs

Other: Computer work for long periods of time

**Required Skills**

**Qualifications:**

Education:

* Bachelor’s Degree in the life sciences or health care background (RPh, RN, etc.) or equivalent work experience including some work in a related field required

Additional skill set:

* In depth knowledge of the clinical drug development process, GCPs, ICH Guidelines, FDA regulations and all applicable regulatory requirements.
* Excellent communication (written and oral), interpersonal and organizational skills.
* Strong attention to detail.
* Strong knowledge of Microsoft Office® applications
* Self-motivated and flexible.
* Ability to plan and prioritize site visits, travel, etc.
* Ability to work independently as well as in a team environment.
* Ability to work in a matrix management environment

**Required Experience**

Experience:

* 2 years previous experience in the clinical research or general research preferred
* Familiarity with scientific and/or regulatory guidelines & SOPs is preferred

**Job Location**

Princeton, New Jersey, United States

**Position Type**

Full-Time/Regular

Cromos Pharma, office in Portland, CRO for eastern Europe (??!)