CLINICAL RESEARCH ASSOCIATE (CRA) I

ABOUT US:

Cytrellis, a venture-backed medical technology company, is developing a new, proprietary category of micro-coring devices designed to remove sagging skin associated with aging, without surgery or scarring. The devices have the potential to provide aesthetic practitioners with an unprecedented ability to improve age related changes in skin and restore youthful beauty. Cytrellis is dedicated to working with leading physicians to develop unique product solutions which emphasize safety, clinical results and improved quality of life.

SUMMARY:

The Clinical Research Associate I (CRA I) will be responsible for supporting clinical activities for domestic clinical trials. The individual will perform clinical Site start-up, management and monitoring activities for assigned studies. The CRA I will ensure Site readiness by performing Site Qualification Visits (SQV) and Site Initiation Visits (SIV) to ensure compliance with protocol requirements, FDA regulations and Good Clinical Practices (GCP). In addition, the CRA I will perform administrative tasks including IRB submissions and amendments, data QC and support clinical team members with study activities as needed.

The CRA I may be required to perform all, or a combination of, the following essential responsibilities as determined by necessity. This position will report to the Clinical Research and Operations Manager. This role is located in the Company's Woburn, MA office.

Essential Responsibilities and Authorities:

- Manage Site feasibility and start-up activities for new protocols
- Perform clinical investigator identification and qualification visits
- Conduct study initiation visits and routine monitoring visits to assure compliance with protocol requirements, FDA regulations and GCP
- Perform Site management activities including development/enrollment plans, device training, treatment coverage, protocol compliance, answer Site related protocol questions in a timely manner, and track subject enrollment and study progress
- Prepare and submit Sponsor and Site IRB Submissions and Amendments
- Ensure the timely, accurate and complete collection and submission of study data
- Ensure adverse event reporting and follow-up is accurate and timely
- Identify, address, and resolve issues and problems as they might occur
- Perform QC of data entry and data tables and listings, as needed
- Ensure product accountability and reconciliation occurs at Sites

- Manage TMF activities and ensures required documents are on file throughout the course of the study
- Review Site and vendor invoices
- Ability to travel approximately 25% as needed

Experience & Training:

- Bachelor's Degree in Health or Science Field preferred
- Minimum of 2-3 years' relevant clinical research experience, including at least 1 year as a field monitor
- Experience in Class II aesthetic medical devices is strongly preferred, but not required
- Excellent interpersonal skills, organizational skills, attention to detail, and problem-solving skills
- Excellent oral and written communication skills
- Team player with ability to work independently
- Ability to multi-task and work effectively in a fast-paced environment
- Computer literacy, proficiency in MS Office, Excel, PowerPoint, etc.
- Intermediate knowledge of GCPs and regulations relating to clinical research

Interested candidates should send their resume to careers@cytrellis.com for consideration. Local candidates only please.