

Vital Therapies is hiring! www.vitaltherapies.com

We are an exciting life science company located in the Carmel Mountain Ranch area of San Diego. Vital Therapies is a pioneer in the treatment of acute liver failure. We are expanding our national team and are currently hiring **a Clinical Research Associate** for our phase 3 clinical trial. This position will be based out of our San Diego office, and will travel to clinical sites approximately 50-80% of the time, depending on patient enrollment and stage of trial. Our ideal candidate will be a former RN with significant in-patient study experience. Our CRA will be a site manager for 6-8 clinical sites, and be responsible for all activities at those sites, including study start up, ongoing monitoring, and study close out activities.

Qualified candidates please submit **a resume and salary history** to <areers@vitaltherapies.com

Essential Duties and Responsibilities:

- Act as the main line of communication between the sponsor and the investigator
- Conduct pre-study visits to evaluate investigational sites (onsite or by phone), study initiation, interim monitoring and close-out visits as required.
- Verify that all research staff, facilities and investigational products have appropriate qualifications and resources and these remain adequate throughout the study life.
- Verify that the investigator and the site's staff follow the approved protocol and all GCP procedures and applicable regulatory requirements with respect to study conduct and investigational product accountability.
- Verifying that source data/documents, essential documents and other trial records are accurate, complete, and maintained up through site study closeout in order to assure that site and sponsor study documentation is "inspectionready".
- Assure that subject safety information, concomitant medications, and inter current illnesses are reported in accordance with the protocol on the CRFs and associated issues are addressed in a timely manner.
- Provide training/mentoring and general support for various aspects of site study needs as they arise through interactions with study staff from start-up, through activation, recruitment, maintenance and closeout.
- Assist as needed in maintaining site study supplies, plus study and site tracking tools and attending periodic department meetings as available for assuring appropriate study, site and subject management, as well as maintain personal training level associated with SOPs and systems (i.e. EDC, etc) related to study conduct.
- Communicate deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and site staff, and that such deviations, as appropriate, are escalated through the Sponsor organization and as applicable the IRB up to full resolution.



Minimum Education and/or Experience:

- BS or BA degree in scientific or health care field is preferred, with RN, LVN or other allied health and/or Masters level credentials helpful
- And/or at least 3-5 years of relevant experience in the clinical trials setting, but prefer 5+ years.
- Understanding of FDA regulations, GCP and/ SOPs in the clinical operations context plus experience with site/subject compliance issues.
- Will be required to travel on occasion, and, at times, frequently.

Vital Therapies offers competitive salary and benefits. Please send your salary requirements and CV to <u>careers@vitaltherapies.com</u>. We are an Equal Opportunity Employer.