ReNeuron
pioneering stem cell therapeutics

Role Profile

Job Title	Senior Clinical Research Associate	**Reports to:**	Clinical Operations Manager
Date	July 2015	**Location**	Guildford/Home-based

Role Purpose

Operational CRO management and site monitoring responsibility for early Phase clinical studies in accordance with Company SOP's, ICH GCP and applicable local and national regulations and guidelines.

Responsibilities

- Assist in the operational site management of assigned clinical trials
- On-site monitoring: site initiation, monitoring, close out visits Source Data Verification, drug accountability, data querying and resolution, regulatory binder review, essential document collection, report writing etc.
- Review, draft and update clinical Protocol/amendments, IBs, PIS-ICFs and other study documents.
- Regulatory and Ethics submissions.
- Development and maintenance of SOPs in conjunction with QA
- Management/oversight of external service providers e.g. CROs, data management, PV etc.
- Financial input for clinical study budgets.
- Prepare monthly progress reports
- Set-up and/or maintain study trackers using excel and other software and reporting tools
- Ensure Trial Master File maintenance

Additional information (e.g. Part-time, remote working etc.)

- Life science/ Nursing Degree or equivalent.
- At least 2 years independent monitoring experience either working in CRO or Pharmaceutical Company
- Desired therapy area experience, cardiovascular / stroke
- Good understanding of the clinical trial process
- Excellent written and oral communication
- Full clean driving license
- Current UK valid permit to work in the UK.
- Willingness to travel both nationally and internationally.
- Office based is Guildford, but some flexibility for remote working available