



TRIAL FORM SUPPORT

Senior Clinical Research Associate (sCRA)

To be a member of the Study Team when applicable, and be responsible for the initiation, monitoring and termination of tasks during the study process, according to company policies, SOP's and regulatory requirements.

Principal duties relate to:

- Preparing applications to regulatory authorities and ethics committees
- Co-ordinating and being responsible for the completion of study documentation material such as: CRF's, patient diaries, study participation cards, QoL forms etc.
- Preparing study documents such as: Monitoring Manual, Study Operations Manual, Source Data Verification Plan, Laboratory Manual etc
- Preparing and conducting pre-study activities, selection and initiating visits, routine monitoring and closure visits
- Responsible for the site(s) and on-site management during the study process
- Ordering and co-ordinating study supplies
- Preparing study documentation and assisting the Clinical Quality Assurance Manager/regulatory authorities during audits/inspections in-house or at site
- Negotiating contracts with local/central laboratory(ies)/pharmacy etc
- Assisting and supporting the data validation and clean file procedure
- Responsible for the final archiving of all study documentation in-house
- Planning and participating in Investigator's meeting(s)

Desirable qualifications and background:

- Suitable academic education in life sciences or equivalent experience
- At least three years experience of working as a CRA including experience of site initiation, site monitoring and site closure
- Experience of co-ordinating/training CRA's
- Good knowledge of written and spoken English and the native language in question
- Good organisational skills
- Good interpersonal skills
- Ability to maintain effective, professional communication
- Good pedagogical skills
- Service minded
- Ability to prioritise and manage multiple tasks
- Experience of MS Office 2000
- Valid driving license