JOB DESCRIPTION FOR THE ROLE OF *SENIOR CLINICAL RESEARCH ASSOCIATE*

Position title	Department	Reports to
Senior Clinical Research Associate	Clinical Operations	Line Manager

Position summary
As a member of the Study Team, the Senior Clinical Research Associate (sCRA) is responsible for routine trial site visits to ensure that the rights and well-being of trials subjects are protected; that the reported trial data are accurate, complete and verifiable from source documents; that the conduct of the trial is in accordance with the currently approved protocol/amendment(s), internal or sponsor's Standard Operating Procedures, Good Clinical Practices/International Conference on Harmonisation Guidelines and other regulatory requirements. In addition, the sCRA is responsible for the oversight of less experienced study team members assigned to the same projects.

Principal Accountabilities

- Participates in trial design and execution, provides input into protocol, Case Report Form, Subject Information sheet and Consent Form design, tools and templates preparation
- Oversees monitoring activities of junior CRAs by providing training on assigned studies, by reviewing monitoring visit reports and follow up letter, by supervising field activities, etc.
- Assists with trial or site feasibility process
- Coordinates or supports the clinical trial submissions to ethics committees and other relevant bodies/boards
- Ensures timely and accurate communication in accordance with communication plans
- Participates in coordination of clinical trials meetings (e.g. investigator meetings, Study Team meetings, CRA meetings, Contract Research Organisation meetings) by liaising with the Clinical Trial Assistant
- Sets-up, tracks and maintains audit-ready clinical trial documentation and study status in Clinical Trial Management System:
  - Manages and tracks regulatory, ethics committee documentation, pre-requisites documents and other clinical trials documents on paper as well as electronically
  - Creates and maintains Trial Master File and Investigator Site File
- Conducts site initiation visits, periodic monitoring visits and closure visits to ensure adherence to the trial protocol, trial timelines, Good Clinical

Practices/International Conference on Harmonisation and internal or sponsor's SOPs. Performs the following tasks during these visits:

- Trains the site staff according to above mentioned requirements
- Performs CRF data entries checks, source data verification, queries resolution
- Ensures that necessary trial supplies are available on site (Case Report Forms, lab kits, etc.)
- Updates ISF
- Visits the site pharmacy, performs drug accountability
- Arranges return of any trial material or trial medication no longer needed
- Provides corresponding reports within the pre-defined trial timelines
- Sends follow-up letters to sites after each visit

- Follows-up all trial-related issues at investigational sites and escalates if necessary to the Clinical Project Manager

- Assists in activities related to audits and regulatory inspections

- Finalises and transfers Trial Master File at end of study to sponsor or arranges internal archiving

Knowledge and skills
Bachelor's degree in biological sciences or equivalent A minimum of 4 years independent monitoring experience Detailed knowledge of drug development, ICH/GCP Guidelines and knowledge of regulatory requirements Ability to lead a team of CRAs Good organisational skills Strong interpersonal skills and teamwork Good computer skills: MS office, Internet