

Example Clinical Research Skills

- Manage the delivery of clinical study protocols, clinical study reports, study agreements, applications and other study documentation such as newsletters and study presentations
- Lead overall activities and optimize the performance of the study team
- Monitor study progress such as patient recruitment and protocol compliance
- Study data listings and tables review, including scientific content and data validation
- Track and manage studies to agreed timeline, budget and resource, highlighting significant variances to the EML and study team
- Train internal and external study personnel in study specific procedures
- Develop detailed study outlines and ensure medical and scientific input in study reports
- Forecast timelines, budget, materials and resource for a defined component of the CDP
- Interpret data arising from studies and assess potential consequences for development program
- Communicate findings to sub-team, clinical development team and pharmacokineticist
- Assist in non-project work and the development of clinical R&D procedures
- Provide scientific input to the development of contingencies, where the emerging data require changes to the program and individual studies
- Implement the amended program of work in accordance with a revised Clinical Development Plan Provision of scientific input into program design
- Recommend choice of study placement and participate in negotiations with liaison

Monitoring responsibilities include: conducting pre-study, initiation, routine (as needed to ensure protocol compliance), and close-out visits; training study coordinators/investigators on protocol including study procedures, CRF completion, enrollment, and informed consent; working with staff at study sites to resolve data discrepancies; obtaining/reviewing/processing of regulatory and administrative documents from investigative sites; maintaining investigational product accountability; monitoring IRB requirements; and reporting findings from visits. Travel is approximately 50 – 60% to investigative sites and meetings. Travel to international sites may be required.