Sally Thirkettle

Elective at a contract research organisation

Summary

I carried out my elective placement at a contract research organisation (CRO), which carries out research on behalf of sponsors on a project by project basis. The majority of the work carried out at this organisation is Phase I, first in human, clinical trials. These aim to determine the safety of the compound of interest, once initial dosing studies have been carried out in animal studies. The majority of Phase I clinical trials are carried out using healthy volunteers.

The learning outcomes of my elective placement were to gain a greater understanding of drug development and how clinical trials operate, to compare an NHS laboratory to a contract research lab and to gain some insight into the workings of a private research organisation. The organisation is involved in all aspects of the study, from devising a research plan and protocol, to submitting the study to the Research and Ethics Committee, ensuring appropriate research governance procedures are followed, to recruiting volunteers, through to administering the drug under investigation, monitoring of the volunteers (both clinically and in the laboratory), and pharmacodynamic and pharmacokinetic analysis of the drug of interest. I was able to spend time on the clinical wards, in volunteer recruitment with nurses and medics, in the quality assurance department and in the laboratories. During this placement I was able to observe Good Clinical Practice, Good Manufacturing Practice and compliance with MHRA requirements first hand, and gain a greater understanding of the operations of the clinical trials process and commercial research.