

Why clinical trials need pharmacists

Through a wide variety of roles, pharmacists play a crucial part in research into new medicines. Tom Moberly looks at the work involved in clinical trials and at the opportunities available for pharmacists and pharmacy technicians thinking of moving to a career in clinical research

Establishing the safety and efficacy of a new medicine necessarily involves, at some point, giving a novel chemical entity to people.

The new compound, developed in a pharmaceutical company's laboratory, needs to be formulated so that it can be administered to patients. Those providing treatment must be blind to whether the study drug or a placebo is being administered, and they must also know how to unblind treatments should this become necessary. The drug must be packaged and labelled, sometimes in a variety of languages. And those receiving the study drug must be carefully monitored for adverse events or other unexpected outcomes. All these processes involve pharmacists working in various stages of the clinical trial.

This diversity of opportunity means pharmacists can move into a broad range of roles in clinical research, allowing them to work independently using a number of skills.

Pharmacist involvement in clinical research is steadily expanding, says John Gilroy, chairman of the pharmacy special interest group of the Institute of Clinical Research (ICR). "In many roles a pharmacist is needed to ensure good clinical practice is in place, particularly as regulatory requirements increase," he says. "Pharmacists can work in a range of other roles in clinical research — there are pharmacists working in phase I trials units, or as trials co-ordinators, or in the pharmaceutical industry. Pharmacists entering clinical research could start in any one of those areas, develop a role in that area, and then move into other areas, or they could just stay one particular area and more towards an advanced role."

Clinical research roles also involve core skills that pharmacists can learn and take with them if they decide to look at a career overseas, according to Mr Gilroy. "Although the extent to which the EU 2001 clinical trials di-



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rective is implemented varies, in essence the requirements for clinical research are the same across the EU and broadly similar to those in the US, Australia and Canada," he says. "So there are definitely fundamental skills that can be learnt and applied to clinical research work in different countries."

Pharmacists working in clinical research collaborate with a wide variety of other professionals in the course of a trial, including research nurses and people involved in research and development, as well as clinical research associates and project managers from funding agencies and pharmaceutical companies.

Working in clinical research also involves solving a range of problems that arise over the course of a study, Mr Gilroy says. If a pharmacist is working on an investigator-led study, that will entail working out how ideas about the way in which the study could be carried out might work in practice. "It may be that the drug needs to be formulated into opaque capsules and that may have an impact on the stability of the medicine, or that some other aspect of the drug's formulation needs to be worked on," Mr Gilroy says. "And pharmacists will also be involved in decisions about packaging and how blinding will be carried out in the trial."

There are five main areas of clinical research in which pharmacists are principally involved: phase I clinical trials, clinical trials co-ordination, research and development, research ethics committees and clinical supply.

A pharmacist working in a phase I clinical trials unit will be managing all aspects relating to the investigational medicinal product, liaising with researchers to define the needs for a new study, manufacturing subject-specific doses of a wide range of dose forms, and training other members of the clinical team, including investigators and nurses. As clinical trials legislation increases, phase I tri-

als are also likely to provide many opportunities for pharmacy staff to undertake additional training.

The role of an NHS hospital clinical trials co-ordinator requires a pharmacist to review the trial protocol and provide protocol-specific training and written instructions for pharmacy staff explaining how to handle the study drug and how to carry out code breaks. The role will also involve reviewing packaging and storage arrangements and advising patients on the correct use of the drug being studied.

Pharmacists working in research and development ensure that the pharmaceutical aspects of a clinical trial are managed in accordance with legislation and with the NHS's research governance framework. They also help investigators with applications for clinical trial authorisation and advise on pharmacovigilance systems.

Work on research ethics committees is unpaid, but may form part of the wider role of a pharmacist working as a clinical trials co-ordinator or in research and development. Pharmacists are required to provide expert opinion on the pharmaceutical aspects of the study drugs. This involves assessing study design and methodology, choice of study drug and comparator, blinding, formulation and administration issues, as well as considering possible side effects and interactions.

Clinical supply pharmacists manage the manufacture, packaging and distribution of the study drug. Although the basic requirements for the quality of an investigation medicinal product are the same as for any other medicine, because products are still under development, the process is often more complex and clinical requirements tend to change frequently. "A complex logistical exercise is what makes the job so interesting and challenging," an ICR booklet says (see Panel).

Technicians

There are many roles that pharmacy technicians can undertake, even if there would need to be input from a pharmacist at the end of the process, Mr Gilroy says. "There are some parts of clinical research where it would be more likely that a pharmacist would be required, such as working in a phase I unit, but other positions, such as sitting on an ethics committee, could certainly be filled by a pharmacy technician." For instance, although there must be a designated pharmacist who takes ultimate professional responsibility for the pharmacy clinical trials services, the role of a pharmacy clinical trials co-ordinator could be undertaken by a pharmacy technician, rather than a pharmacist.

Finding out more

A booklet aimed at those seeking a career in clinical research as a pharmacist or pharmacy technician has been developed by the ICR. "To be a pharmacy professional in clinical research" can be obtained via the ICR website (www.instituteofclinicalresearch.org) or by telephoning 01628 536960. Anyone wanting to know more about moving to a career in clinical research can also find out at the ICR's annual spring meeting in Birmingham on 8–9 April (further information on the ICR website). The ICR is also planning to have a stand at a number of upcoming meetings, including the UK Clinical Pharmacy Association and the Guild of Healthcare Pharmacists joint conference in Kenilworth, Warwickshire on 9–11 May.