

# WHY PHARMACISTS SHOULD CONSIDER CLINICAL DATA MANAGEMENT AS A CAREER

*Vanessa Woodhead, clinical data associate at Amgen Ltd, describes the role of clinical data management in the approval of drugs for marketing and says that pharmacists might like to consider the specialty as a career to use their analytical skills and clinical knowledge*

In order to gain approval to market a drug, a company must conduct extensive clinical trials in both healthy volunteers and patients to prove the safety as well as the efficacy of the drug. These trials must be conducted under a strict set of guidelines (Good Clinical Practice) designed to protect the safety of the volunteers and patients participating, and the integrity of the data. The role of clinical data management in this process is to collate the data from these clinical trials and ensure they are of acceptable quality for reporting to the regulatory authorities. A company's clinical trials database is considered to be one of its most valuable assets.

Clinical data management is a key component of the multidisciplinary team involved in setting up, running and reporting clinical trials. A data manager defines how these data are collected, tracks the data, and checks their completeness, accuracy and consistency.

Pharmacists might consider a career in clinical data management in order to make use of their analytical skills and clinical knowledge in a setting other than a hospital. Pharmacists may develop an interest in the wider drug development process or, for example, coding of concomitant medications, and wish to move into a clinical data management role to explore these interests. Payment scales may be similar for staff within clinical data management as for scales for pharmacists, but additional benefits can be more competitive in pharmaceutical companies.

## WHAT IS CLINICAL DATA MANAGEMENT?

Data management is involved in all aspects of processing clinical trial data, working with a range of computer applications and database systems to support collection, cleaning and management of subject or patient data. Typically this includes:

- Input into the design of protocols, which define what data are to be collected and at what times
- Design and approval of case report forms, on which subjects' data are collected
- Database design for the study, ensuring it meets requirements for data entry and reporting

Data managers are responsible for the completeness and consistency of the data and ensuring they are of a high quality, and

this may involve writing programmes to assist the process. The role can be diverse and can include conducting training sessions with clinical research associates (CRAs) or study site personnel to help improve the timeliness and quality of the data collected. Data managers produce summaries and listings of safety and efficacy data and may contribute to the production of tables for the clinical study report. They are closely involved in the development and testing of new processes and systems for the management of clinical trials.

A data manager is a core member of the clinical project team and interacts closely with other team members such as clinicians, CRAs, statisticians, medical writers and specialists in regulatory affairs and quality assurance to achieve project goals. The data manager is a key contact point for other groups on project database issues and is often involved in communicating globally with project team members.

The data management role is wide, varied and constantly evolving. It may involve some travel for global teams or developing new technologies for data collection. There is the opportunity to be involved in a broad range of activities, or specialise in an area of particular interest, such as database design, laboratory data or programming for data management.

## DYNAMIC ENVIRONMENT

Recently there has been a growing trend of company mergers within the pharmaceutical industry. These mergers and acquisitions can provide opportunities and benefits for both partners. However, as companies grow, they may have operations all over the world — each site often operating via its own systems and procedures, which also brings benefits to employees.

**Globalisation in data management** Companies are now striving towards the use of standard database systems and structures, standard data collection forms, data entry and analysis procedures. This requires global definitions of roles, responsibilities and

objectives, the production of global standard operating procedures, and the ability to work with people from different countries and cultures. This globalisation of standards should improve communication and increase efficiency.

**Technological advances affecting data management** All clinical data management groups are under pressure to develop faster ways of producing clean databases, thus enabling speedier trial results, faster registration and therefore quicker sales of new drugs.

Some specific data types are now routinely supplied in electronic form, eg, laboratory data, but other types of data are increasingly becoming available directly from analytical machines.

Most companies have experimented with various forms of remote data entry where computerisation of the data is performed at the collection site. However, no methodology has yet emerged as universally acceptable. Fax technology and optical character recognition have been piloted but neither has been without its drawbacks. As worldwide accessibility becomes a reality and everyday use of the internet commonplace, this provides the most potential for computerising data at source. Validation checks can be run at the time of entry, ensuring that clean data are collected.

Other technological advances that have affected data management include the use of video- and internet-conferencing facilities. These provide data management employees with the possibility of effectively working from home, perhaps even part-time, allowing a great deal of flexibility.

The role of a clinical data manager is, therefore, likely to include an increasing demand for both technical and training skills, in addition to computing and biological expertise.

## SKILLS REQUIRED

For those interested in taking up a career in clinical data management, a degree in life sciences, computing, statistics or mathematics or a formal nursing qualification is desirable but not essential. A suitable person will be a team player with good interpersonal skills, an excellent communicator and negotiator, a problem solver with an eye for detail, able to work under pressure and to multitask, and highly motivated with a proactive attitude.

*This article is produced by the public relations subcommittee of the Association for Clinical data Management, with support from other ACDM members. For more information on careers, pharmacists can e-mail [cdm\\_careers@acdm.org.uk](mailto:cdm_careers@acdm.org.uk)*

**Career development** Intensive short courses are available for professionals working in clinical data management to develop their skills. Courses organised by the Association for Clinical Data Management include:

- Introductory, intermediate and advanced clinical data management
- Computer system validation in clinical research
- Postgraduate qualifications in clinical data management

Qualifications that include vocational and competence-based qualifications are currently under development jointly by the Association for the British Pharmaceutical Industry and the Association of Clinical Data Management.

The postgraduate course is a joint venture between the ACDM and Kingston University, where the course is operated within the university-wide postgraduate credit framework. The postgraduate qualification programme aims to provide a formal education leading to an academic and professional qualification for clinical data management personnel. These qualifications include the following awards:

- Postgraduate certificate in clinical data management
- Postgraduate diploma in clinical data management
- MSc in clinical data management

Alternatively, modules from the course can be taken singly as short courses for training on specific topics. The programme provides a stimulating and enjoyable opportunity to develop both as individuals and professionals. Students develop skills that include critical thinking, communication

## ASSOCIATION FOR CLINICAL DATA MANAGEMENT

The Association for Clinical Data Management (ACDM) is an organisation that promotes the professional identity and awareness of clinical data management both in the pharmaceutical and related industries such as regulatory authorities and academia. It is a forum for people from these backgrounds to exchange ideas and make a network of contacts and aims to establish an industry-wide standard. The ACDM brings together diverse groups from many disciplines to enable both the exchange and comparison of perspectives in this exciting field. The ACDM is an independent, non-profit making organisation with an international perspective.

The vision of the ACDM is to lead the profession of clinical data management in the development and appreciation of its essential activities, promoting the development of members and enabling their participation in drug development. This is accomplished by providing key opportunities for the membership to develop standards within the profession and to enhance their skills and knowledge.

The association can be contacted at PO Box 129, Macclesfield, Cheshire SK11 8FG (tel 01625 511818, web [www.acdm.org.uk](http://www.acdm.org.uk))

## USEFUL WEBSITES

Association of the British Pharmaceutical Industry	<a href="http://www.abpi.org.uk">www.abpi.org.uk</a>
Drug Information Association	<a href="http://www.diahome.org">www.diahome.org</a>
European Agency for the Evaluation of Medicinal Products	<a href="http://www.emea.eu.int">www.emea.eu.int</a>
Food and Drug Agency	<a href="http://www.fda.gov">www.fda.gov</a>
Healthcare/pharmaceutical information	<a href="http://www.pharmafile.com">www.pharmafile.com</a>
Medicines Control Agency	<a href="http://www.mca.gov.uk">www.mca.gov.uk</a>
Pharmaceutical employment	<a href="http://www.pharmiweb.com">www.pharmiweb.com</a>

and team working while broadening knowledge in data management. The result is well-rounded clinical data managers who are more efficient, effective and competent in clinical data management. In addition, the programme provides an excellent opportunity for networking with others from different industry backgrounds.

The qualifications thus provide a standard of professional education, facilitate the

recruitment of experienced staff, and enhance career opportunities within clinical data management.

There are also workshops and conferences organised by the Association for Clinical Data Management and other related organisations, in addition to the opportunity to develop extra skills in programming, report writing and project management and line management.