Career Pathways in Research: Pharmaceutical Industry

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This article on the pharmaceutical industry within this series on career pathways is to highlight to nurses careers that are open to them in associated industries. Demonstrating to nurses that their nursing qualification along with their knowledge, skills and expertise can enable them develop a career within another sphere of employment.

Introduction

Within the UK the pharmaceutical industry reinvests 15% of its sales income back into pharmaceutical research and development (R&D) (anon, 2000). This investment was $2.7 billion, which in 1998 increased by more than 5%. Indeed during the year 2000 this investment was predicted to rise by 14%. However, the UK government civil funding of R&D has little changed over recent years at 1.7% of the gross domestic production (GDP) (Dawson et al., 1998). Thus highlighting the value the pharmaceutical industry place on R&D and the production of world leading medicines within the UK. It has to be considered that despite rhetoric of altruism by the pharmaceutical industry the major driving force for R&D is the competitive advantage and profit margins. Nevertheless, it could be argued as stated by Gilmartin (1999) that, “Pharmaceutical innovation holds the greatest promise for providing long-term, sustainable solutions to our current and future health care challenges worldwide”.

Research conducted by the pharmaceutical industry originally emanates from development of potentially therapeutic material within the laboratory environment. However, this research employment pathway describes the career progression of those organising clinical therapeutic trials, which are the systematic study of medicinal products in human subjects. There are usually four phases in the research process:

- **Phase I** – The first human studies are usually conducted on healthy volunteers, except in certain cases such as the administration of cytotoxic drugs that can only be given to patients.
- **Phase II** – The first randomised controlled trials for new drugs, which are frequently placebo controlled to be able to determine that they have a therapeutic effect.
- **Phase III** – These studies are to confirm therapeutic effect and dose range compared to established treatments.
- **Phase IV** - These are formal post-marketing surveillance studies, conducted to monitor if a high incidence of toxicity occurs with a new compound to enable the withdrawal of the drug at an early stage.

The conduct of this type of research is dictated by the International Conference of Harmonisation (ICH) Tripartite agreement between the USA, Europe and Japan. This agreement is being implemented within Europe by the development of European Directives which are then legislated as law within the UK (International Conference of Technical Requirements, 1996). All the research should be conducted to a minimum standard of good clinical practice (GCP) which was the inspiration of the American Food and Drug Administration (FDA) for a code of conduct for clinical therapeutic trials. There are also strict European guidelines the principle of which is to protect the human subject. In the UK the source of guidelines for good clinical research practice (GCRP) is the Association of the British Pharmaceutical Industry (ABPI).

There are two different types of companies that conduct clinical therapeutic trials, the pharmaceutical companies and Contract Research Organisations (CROs). The CROs are contracted to undertake specific projects or programmes of research by the pharmaceutical companies, which makes these
companies very aware of resource and time management. Within a pharmaceutical company it is possible to follow a compound from the laboratory through to the market product. Whereas within a CRO, due to the very nature of obtaining contracts, the research may be very diverse in nature.

Career development

Many who work in the pharmaceutical industry go through a traditional route - with a science degree or nursing qualification they start as a trainee clinical research associate. This trainee period lasts for approximately 12 weeks before becoming a clinical research associate with appropriate remuneration. The main role of the trainee and clinical research associate is the monitoring of clinical therapeutic trials at the investigator site, which may be anywhere in the world (Table 1). Consequently, these positions entail a great deal of travelling and detailed checking of data with investigators especially where English is not the first language.

As with all senior positions the senior research associate and project manager is involved in strategic planning and management and in the pharmaceutical industry this is often at an international level.

Competencies

As with all roles there should be a minimum standard against which people should be judged. Each company has its own basic competency requirement, which is normally tied into a traditional appraisal scheme. The competencies list the job skills and the transferable skills, which can allow individuals to move up a set ladder or to, choose a change in direction without loss of position. Different jobs can add to the skill base. In pharmaceutical companies there is often a very narrow therapeutic avenue explored and the individual gains a thorough insight into design and conduct of studies in a particular therapeutic area. In CROs the individual works on several therapeutic areas and becomes skilled in the mechanics of conducting clinical trials in any therapeutic area rather than being an expert in one particular therapeutic field.

Jobs that can develop your expertise and knowledge

It is clearly sensible for the individual to have worked in both the CRO and the Pharmaceutical environment in order to acquire all the necessary skills to proceed along their chosen pathway. It is also sensible to take note of transferable skills in order for individuals to change from one pathway to another without necessitating a regression of a level.

Benefits of the Job

- Plan your own schedule
- Can work frequently work from home but depends on the company
- Job usually includes International travel for training, attendance at conferences and if monitoring International studies site visits
- Get good pay for work done and all expenses paid
● Improves your knowledge of languages or should do

**Drawbacks of the Job**

● Frequently away from home
● Can be boring checking other peoples work
● May be put in a position of establishing that fraud has occurred
● Travelling to study sites Nationally and Internationally
● Get to know all European and International airport departure lounges
● Due to the time zone changes this is not a 9-5 job due to the travel and frequently the need to take part in International teleconferencing

**Links to other Careers**

Clinical Research Nurses CRNs after conducting numerous CTTs for investigators or as investigators frequently seek employment within the pharmaceutical industry due to career prospects and financial reward. Indeed there are many other employment arenas within the pharmaceutical industry in which nurses with research expertise may consider working such as a medical writer or auditor. These are usually very well paid and many people undertaking these roles choose to work in a freelance capacity and as such, an experienced auditor, can earn as much as £500 a day.

**Medical writer**- This role can be writing up specific research reports, manuscript, patients information or other documentation required by pharmaceutical or related companies. However, there are now new opportunities to develop medical communications programmes in conjunction with business departments to develop strategic marketing. One of the benefits for this job is the ability to work from home.

**Auditor**- This role is to check that the clinical therapeutic trial has been conducted to the standard required by GCP and that all the documentation from the initiation visit to completion is above reproach.

**Qualifications**

Frequently people who work within clinical research are qualified as scientists and worked within the laboratories within the companies and then decided to change roles. They may have worked as scientists within the academic environment prior to moving into the pharmaceutical industry hence many have already got a PhD in their scientific area of expertise. Similarly, nurses moving into the pharmaceutical industry have their own speciality expertise. However, there are courses in clinical research for personnel from the pharmaceutical industry
Pay scales

Pay scales can differ according to whether the clinical research associate is employed by a Pharmaceutical Company or a Clinical Research Organisation. The salary figures do not vary greatly but the benefits awarded may be much better in the Pharmaceutical company. These are not precise figures as these will differ between companies but normal pay parameters that are meant as guidance. There are some pharmaceutical companies that have higher scales than others and there are some small Biotec companies that are prepared to pay high salaries for the right people with the required expertise. However, it has to be noted that jobs usually have agreements for cars, portable computing facilities and occasionally stock options.

Table 1. Guidance for pay scales in the pharmaceutical industry

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Salary</th>
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</thead>
<tbody>
<tr>
<td>Trainee clinical research associate</td>
<td>£17000 plus</td>
</tr>
<tr>
<td>Clinical research associate</td>
<td>£18-25,000</td>
</tr>
<tr>
<td>Senior clinical research associate</td>
<td>£25-35,000</td>
</tr>
<tr>
<td>Project manager/Clinical research officer</td>
<td>£30-45,000</td>
</tr>
</tbody>
</table>

Curriculum Vitae

All job advertisements request the submission of a detailed curriculum vitae (CV). This does not mean the precise documentation of all your activities at work and at play from secondary school onwards. It is actually a document that illustrates concisely your achievements and abilities, in order, to demonstrate your appropriateness for employment for the job advertised. It has to be remembered that those wishing to employ new team members have normally decided what is essential and desirable characteristics required, so in reading your CV they need to feel that you have considered these necessary requirements.

Places jobs advertised

- Clinical Research Focus (CRF) published by the Institute of Clinical Research.
- Daily Telegraph on a Thursday
- New scientist
Acknowledgements

We would like to every body who attending meetings and gave us feedback on the career pathways especially, Abigail Masterson, Abi Masterson Consulting Ltd, Roswyn Hakesley-Brown, President of the RCN Ann McMahon, R&D Co-ordinating Centre Director.

Feedback

Any comments or feedback that could assist other nurses to develop their career to the RCN R&D Co-ordinating Centre c/o Dave O’Carroll
www.man.ac.uk/rcn/

Sample of job adverts

Clinical Research Associate Region often stated
Megastar pharmaceuticals is a fast growing, innovative and dynamic company with a world wide research programme. This leading edge company is developing life saving treatments for infectious diseases. Due to our great success we need to expand our operations and an opportunity has arisen for a clinical research associate to join our UK and European team. The position will have the responsibility for monitoring phase II and phase III study activity, liaison with investigators, development of protocols, ethics submissions and data collection. The successful candidate will have a science degree or nursing qualification with experience in clinical trials, good clinical practice, ability to organise and take initiative and be willing to travel. In return the company offers an attractive salary and benefits, opportunities for career development and a position in a globally expanding company. Please write and send a detailed CV to:

Senior Clinical Research Associate

£30,000 + Permanent Contract + Benefits + Stock Options Region as stated

Megastar pharmaceuticals is a fast growing, innovative and dynamic company with a world wide research programme. This leading edge company is developing life saving treatments for infectious diseases. This position involves a major contribution to the planning, design and monitoring of clinical trials that are ethical, high quality and within set timescales. This will entail review of protocols and study documentation, involvement in the design of database, validation and verification, evaluation of investigator sites and co-monitoring. Qualified as a life science graduate or nurse, with 3 years experience as a CRA including monitoring Phase II and III trials within the UK and Europe. The candidate must have a sound knowledge of ICH GCP and FDA regulations. A good track record in development of protocols and study documentation, excellent interpersonal and management skills. On offer attractive salary, excellent benefits and relocation assistance. Interested applicants should apply in writing, with a full curriculum vitae, to:
References


Table: Nursing Research Careers: Pharmaceutical Industry Pathway

<table>
<thead>
<tr>
<th>Role</th>
<th>Trainee Clinical Research Associate</th>
<th>Clinical Research Associate</th>
<th>Senior CRA</th>
<th>Project Manager/ Clinical Research Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Typical Role</strong></td>
<td>Perform monitoring visits with mentor to acquire the skills necessary to ensure complete accurate data is retrieved from study sites. Completion of Independent ethics committees applications to gain insight into study protocol and design. Archiving of trial master file data.</td>
<td>Conducting monitoring visits and ensuring data standards are met. Working to predefined standard operating procedures (SOPs) and guidelines. Organising all needs of study site staff in order to conduct a clinical trial acceptable standard. Collate status data.</td>
<td>CRA with the additional responsibility of leading teams. Protocol generation and study specific documentation. Communication and dissemination of information especially within field team structure.</td>
<td>Responsible for strategic planning of the clinical trial process. Production of protocols and project tracking data Resourcing of the clinical trial programme. Financial management of clinical trials.</td>
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<tr>
<td><strong>Experience</strong></td>
<td>First experience in clinical research but with a scientific or nursing background. Works under close supervision of a mentor.</td>
<td>Experience of running concurrent research studies with minimal supervision to the standards required by good clinical practice. Ability to give advice on the organisation and management of the clinical research trial in progress.</td>
<td>Development of research protocols and study documentation.</td>
<td>Negotiating contracts with interested parties; supervision of research teams.</td>
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<tr>
<td><strong>Knowledge</strong></td>
<td>Knowledge of Good Clinical Practice and the pharmaceutical industry.</td>
<td>Knowledge of SOPs, guidelines and regulatory requirements. Knowledge of research design and methods. Knowledge of specific therapeutic areas</td>
<td>Comprehensive knowledge to enable the costing clinical trials appropriately; understanding of the complexity of ethical issues for research staff involved clinical research.</td>
<td>Knowledge of national, ICH GCP and local requirements for the management of global clinical trials; mechanisms for licensing of products.</td>
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<td><strong>Skills</strong></td>
<td>Numerate; computer skills; ability to adhere to pre-determine protocols; ability to liaise with research staff and representatives at all levels. Ability to check and obtain corrections for clinical trial data recorded at site.</td>
<td>Good monitoring skills, organisational skills, IT skills and interpersonal skills.</td>
<td>Ability to develop, assess and direct research protocols; manage resources including finances, equipment and staff members.</td>
<td>Ability to lead, motivate and develop research teams; ability to build research capacity and infrastructure; ability to negotiate with professional colleagues</td>
</tr>
<tr>
<td><strong>Desirable Qualifications</strong></td>
<td>First or higher degree or nursing background.</td>
<td>RGN; First or higher degree with 6-12 months experience Certificate/Diploma in Clinical Research</td>
<td>Diploma in Clinical Research</td>
<td>MSc in Clinical Research</td>
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