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Talent Challenges in Oncology Clinical Monitoring

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The development of new therapies and treatment regimens for treating cancer is vital. However, oncology clinical trials can be complex and lengthy because of the highly variable biology of the disease and the increasing demands of the regulatory bodies. Supporting new drug development requires recruiting and retaining the best possible qualified research professionals for oncology-focused clinical trial teams.

Though the five year survival rate for cancer has increased to 68% in 2010 from 50% in the 1970s, cancer is still the second leading cause of death in the US [1]. To meet these needs, drug development in oncology is extremely active – according to PhRMA (Pharmaceutical Research and Manufacturers of America), there were 981 different therapeutics in development for cancer in 2012 [2] (see Figure 1).

In drug development within each distinct therapeutic area, phase I trials involve healthy volunteers. However, because cancer drugs are often more likely to have toxic side effects, phase I and phase II trials in oncology will generally recruit patients with advanced, untreatable, or heavily pretreated disease, who are often physically frail and on a number of concomitant medications. These patients may also be willing to accept higher levels of risk or of toxicity, especially if they have only weeks or months to live, as either they wish to take any opportunity for treatment or they feel that they can contribute to overall knowledge about the disease. The trials can be long and have multiple treatment arms, according to the stage of disease, level of pretreatment, cancer type and subtype, and other factors.

Oncology clinical trials need to be more intensively monitored than many other studies, because of the severity of the disease (particularly in early stage trials) and the complexity and potential toxicity of the treatment or the use of newer approaches such as biologics and personalized (precision) medicine.

These issues, along with the increasing demands of regulatory authorities and other factors, mean that clinical trial costs are rising. In the aftermath of the global financial downturn, study sponsors (the pharmaceutical companies developing the drugs) are looking to reduce the financial risks of development and to optimize their cash flow. One way to do this is to move the variable costs of clinical trials to CROs (clinical research organizations), either on a fee-for-service basis or under a collaborative (hybrid) model. In this way, the CRO takes on part or all of the financial risk. The combination of this and the rising volume of clinical trials is driving an increased need for qualified research professionals in CROs, including in the area of oncology clinical monitoring.

Finding the Right People

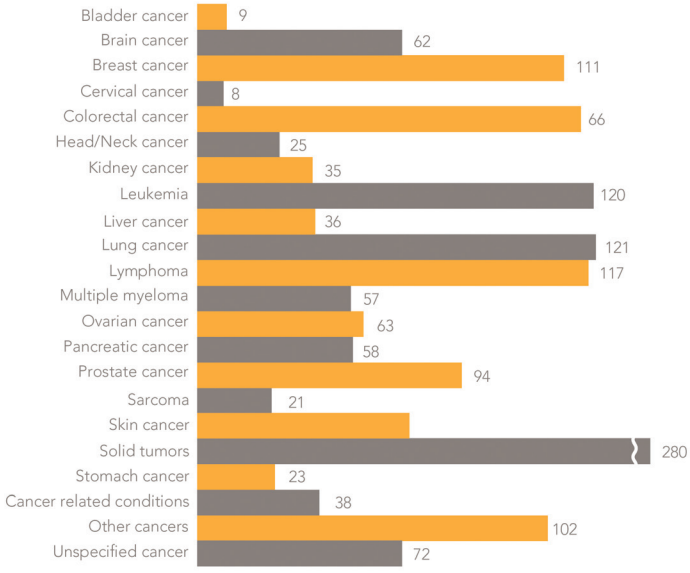
The role of an oncology clinical monitor (also known as a clinical research associate or CRA) is to support the implementation of oncology clinical trials, from data collection and administrative reports to ensuring the gathering of good quality data [3]. The role of a CRA is an attractive one; in 2013 CNNMoney and PayScale ranked it as #9 in its top 100 "Best Jobs in America," with 36.4% job growth and median annual salary of $95,100, rising to a high of $127,000 [4].

The basic talent challenges in oncology clinical monitoring are the same as in any other industry — to recruit the right people for the job and retain them for as long as possible. While the basic skills are similar for CRAs across all therapeutic areas, oncology is a multifaceted disease, and its treatment and clinical trial structure can be complex. This means that individuals wanting to work in this area have to have very specific skills and expertise, not just in oncology overall, but in the specific types and subtypes of cancer being studied in individual clinical trials (see text box).

The role of a CRA is about more than just knowledge and experience. Cancer clinical trials can be high-risk, especially with new approaches to treatment or where regimens are highly toxic. The people who work as oncology clinical monitors in these types of trials have to be prepared to deal with issues such as severe toxicities or deaths and be able to handle the pressure of global media scrutiny.

Finding the right people can be a challenge, but there are a number of solutions and approaches. Referrals and networks

Figure 1: Medicines in Development in Cancer (2012)



*Some medicines are listed in more than one category
Source: PhRMA

are important – the best people are often found through the best people. The oncology community, whether based at charities, hospitals, or research institutions, is full of passionate and talented people who have connections with the disease area, whether it is because of personal experience or a passion for the science. Social media is now a lively and useful way of getting information out or creating networks, including Facebook, Twitter, LinkedIn and other social networks.

Universities often have courses that focus on cancer as an academic or therapeutic area and may hold recruitment fairs or career sessions. Hospitals also employ people who have relevant therapeutic experience and who may have interest in a career transition to a CRO.

Training and Retaining: Keeping Teams Over the Long Term

Entry into careers in oncology clinical monitoring can be difficult. The pharmaceutical industry is not keen on "novices," preferring tried and tested specialists, but these individuals have to gain their training and experience from somewhere.

Characteristics for Oncology Clinical Monitors

Domain Expertise

- CRAs need a science background, with experience and knowledge in cancer (and its subtypes), and should be educated up to MSc or PhD (or equivalent).
- CRA skills must include:
  - o Attention to detail, so that they can identify inconsistencies in data, either intentional or accidental, and handle complex documentation, such as regulatory documents and IRB (institutional review board) submissions
  - o Tenacity and focus, so that they can work through complex data sets and find the essential information
  - o Awareness of the oncology field, to understand why patient safety and working within good clinical practice (GCP) frameworks are so important.

Leadership and Social Skills

- CRAs need to have excellent interpersonal skills, strong verbal and written communication skills (including presentation skills) and good "social IQ."

Business Acumen

- CRAs should be aware of the economics of a fee-for-service business, to ensure that projects remain within budget.
- CRAs need to understand the importance of reaching goals, both for the sponsor and the CRO.

This training and support role typically falls to the CROs, who then have to be able to reassure the pharmaceutical company sponsor that these new entrants to the industry do have the acumen and ability to be productive and useful members of the clinical trial team.

It is important to focus on keeping clinical oncology monitoring teams up-to-date with documentation requirements and current good clinical practice (cGCP) regulations. However, this makes a good clinical research associate very attractive to other CROs in a highly competitive marketplace. Staff turnover is more than just a logistical or economic factor; changes of study personnel mid-trial can have a severe impact on data quality and patient safety because it increases the risk of errors or missed observations.

There are steps that CROs can take to retain good staff. These include a commitment to training and continuing professional education, for example, through the ACRP (Association of Clinical Research Professionals). Staff retention also requires providing interesting work, for instance, the opportunity to travel and to work with different pharmaceutical companies on varied projects. Companies need to ensure that people have the opportunity to grow in the company with a variety of paths to follow, for example, into line management or having a focus on project management or product development. This can be supported by mentoring schemes or the opportunity to shadow someone in another role. Ensuring a competitive reward package is important, but this has to be complemented by interesting work and a positive company culture. In summary, the focus overall has to be on being a good and fair employer, and being a company of choice.

Perhaps most importantly, many clinical professionals remain working on oncology clinical trials because of a passion for the overall mission of advancing therapies to help improve the lives of patients who suffer from many different types of cancer – in short, a desire to find treatments for people who otherwise would not be here. This is coupled with a realization that the only way to have an impact on cancer is if everyone works together, from early detection through new treatments to education and community awareness. People working in this field of clinical drug development truly believe that they can advance in their careers as well as do some good in an area of unmet need.

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