



Mentoring the Monitor

Nicola Murgatroyd at Phlexglobal outlines the benefits of developing the clinical research associate in your organisation

We are told that the clinical research industry is struggling with a profound lack of trained, experienced clinical research associates (CRAs), yet there are ever more opportunities for adequately skilled and experienced individuals to monitor clinical studies. This may be due to attrition driven by the desire to progress from the CRA role into a study manager position and, in some cases, the need for improvements in flexible working and childcare allowances, to assist in facilitating CRAs with young families to continue their career. Whatever the reasons, we often see the CRA lifespan limited to a few years. Furthermore, if we look at the challenges for a clinical project associate (CPA) or a clinical trials administrator (CTA) wanting to move into the role of a CRA but needing the required experience before stepping up, then we can see how the CRA talent pool may be diminishing. However, as stipulated in ICH guidelines for Good Clinical Practice, “the sponsor should ensure that the trials are adequately monitored” (1). The guidelines also state that the purpose of monitoring is to verify that “the rights and well-being of human subjects are protected; the reported trial data are accurate, complete and verifiable from source documents” (2).

THE PATH TO BECOMING A CRA

While there is a clear requirement for skilled CRAs to properly monitor clinical studies, becoming a CRA is all about gaining the right on-the-job training at the right time. While a CRA ideally has a science background or qualification, giving them basic knowledge of the way in which drugs work and how the body

works, they also need the practical experience only gained in monitoring real clinical studies. Theoretical knowledge plays a key part in developing the ability to report on adverse events and understand laboratory or examination results, as the CRA is expected to be proactive in reporting anything that is not expected. However, the difficulty that aspiring CRAs face is getting the relevant training and experience to be able to identify when something is missing or not as it should be. This is particularly difficult when pharmaceutical companies are unwilling (or perhaps unable) to devote the time and money to providing the necessary background experience.

In the current economic environment, there is less and less investment in training CRAs who are unlikely to remain with the original sponsor company. Many pharmaceutical companies are using a functional outsourcing model to run studies, taking advantage of the possibility to buy in the necessary skills and experience on a study by study basis. This then places the challenge of providing the necessary experience with the CROs. Since they have the responsibility for “overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedure, Good Clinical Practice and the applicable regulatory requirements”, ensuring CRAs are adequately trained and experienced is critical (3).

Historically, the role of the CRA involved many administrative tasks such as ordering and tracking. The advent of the CTA meant that many of these tasks were delegated, leaving the CRA to concentrate on overseeing the scientific and ethical integrity for the initiation, progress and conduct of a clinical trial. The CRA may be involved in several studies from the very start (pre-study

design) to close-out and archiving; and these studies could be across different phases or therapeutic areas, and even cross international boundaries. The range and importance of the role played by the CRA in the successful conduct of a clinical study should not be understated.

INVOLVEMENT ACROSS THE BOARD

The CRA should be involved at every stage – from study protocol design and source data verification, to archiving study documentation and producing final reports. Most importantly, they monitor drug accountability: what's gone out, what comes back, if there is a gap or surplus, and why. They need to verify what has been taken, and refer to the study protocol for the guidelines on how to dispose of any surplus drug. As the primary point of contact between the sponsor (commercial pharmaceutical company) and the study site, the CRA is the communication link as the study progresses. While their scientific outlook is important, much of what they do revolves around interpersonal skills, focusing in particular on site and team motivation.

The key to successful monitoring, at any level, is to determine the intensity and focus of the monitoring activity to be undertaken at the start of the clinical study, ideally including the specific methods to be used as part of the trial design. With experience in monitoring a range of studies, the CRA develops the ability to interpret the specific nature of a study, understand variables such as complexity, phase and treatment period, and adapt the nature and focus of the monitoring activity. How the CRA acquires these skills is likely to depend on the people he or she works alongside – and in particular the mentor. By assigning a mentor to junior and trainee CRAs, the nuances of the role can be passed on.

The need to adhere to regulations, guidelines, procedures and policies governing the conduct and process of a clinical study applies as much to non-commercial as to commercially run clinical trials. Indeed, the recent changes to the EU Directive – bringing the trials run by NHS trusts in the UK and other non-commercial bodies under closer scrutiny – are proving to be a challenge for those involved. With skills, knowledge and experience gained in the commercial environment, the CRA is ideally placed to support NHS trusts in meeting the challenge of making sure all NHS-run clinical studies follow the appropriate processes. The CRA is there to ensure that those running clinical studies are following the processes and managing the study in

accordance with regulations, so that, in the event of an MHRA inspection, they are in a good position to pass.

TRUST-BASED MONITOR

In the non-commercial domain, the term CRA is not used – although some innovative centres are adopting the title – and, in general, the person is simply referred to as a monitor. This is due not only to the infancy of the role to the NHS and the requirement for the job title to indicate what they are actually doing, but also because the industry more often refers to CRAs as monitors, probably as a result of the move to more field-based monitors rather than office-based CRAs. Specialist CROs are now providing monitors on relatively short-term contracts to troubleshoot and bring the non-commercial sites up to speed. Using a combination of very experienced monitors and trainees with some on-the-ground experience, this model is starting to work well. We can predict, budget and resources allowing, that the trust-based monitor will become commonplace.

However, there is still a conflict of duties and roles in the NHS environment when it comes to defining clearly, for example, the responsibilities of the research nurse from the new monitor, and even from the auditor (or the person assigned to conduct the 'audit'). There is much knowledge to be passed around and those specialist CROs, along with alliance partners from industry and the health service, are building solid training curricula to identify training needs and deliver competency-based training days.

The same keenly observed and evolving training curricula, based on competencies, need to be brought back to the pharmaceutical companies and CROs that want to develop and keep their aspiring CRAs. Collaborations are underway, with some of the specialist CROs providing longer-term training plans for their CRAs, based on competencies achieved, alongside more robust support from the in-sourcing pharmaceutical companies. We would expect to see that the development of the CRA is no longer a 'rush-job' and the concept of the CRA or monitor as a profession may well return. With further use of the mentor to guide and coach aspiring CRAs, we can expect the training curricula to include coaching and mentoring sessions too.

MULTI-FACETED COLLABORATION

For those aspiring to be a CRA, often using the CTA position as a career step, with a natural enthusiasm for the responsibility, involvement and variety of monitoring activities, they may become incredibly frustrated if they cannot get the necessary experience. We want to be able to source talent effectively, give efficient training, and then provide adequate and agreed career pathways. A multi-faceted collaboration between industry and healthcare organisations is needed, with a focus on competence gained over time and no more quick fixes. We truly believe though that we can confidently meet the needs of the patient student with ambitions to be a CRA.

References

1. ICH GCP 5.18.3, <http://www.fda.gov/cder/guidance/959fnl.pdf>
2. ICH GCP 5.18.1, <http://www.fda.gov/cder/guidance/959fnl.pdf>
3. ICH GCP 1.38, <http://www.fda.gov/cder/guidance/959fnl.pdf>

About the author



Nicola Murgatroyd is Chief Executive Officer of Phlexglobal Ltd. Nicola founded Phlexglobal Ltd in 1998 and has built the company to its current position as the industry's leading support service organisation for the clinical research industry. Nicola has 20 years' experience in the pharmaceutical industry, and also previously had a business career, holding directorships of successful companies in the engineering and retail sectors. Nicola has been instrumental in pioneering the role of the CTA and was a founder member of the Institute of Clinical Research's (ICR) CTA subcommittee.

Email: info@phlexglobal.com