

Joining the Dark Side, from CRA to QA

I doubt that many people would argue that the role of the Clinical Research Associate (CRA) is vital to the success of any clinical trial. This is not only because this job provides a direct link between the sponsor and investigator but also because the CRA is the last guardian of quality, ensuring that the site staff are well informed, provided with the necessary study materials and able to resolve site level issues or decide when further action is required.

Quality is the cornerstone of the Pharmaceutical industry. When a news article reports on the latest wonder drug that has been found to cause unexpected side effects, we should feel safe in the knowledge that everything was done by the book. As unfortunate as these situations are, we should be able to remind ourselves that they could not have been foreseen. However, with such time pressures on everyone involved in the clinical trials process, I am not always convinced that this is the case.

Unfortunately with the increasing need to conduct trials in a shorter space of time, to collect and process data to ensure that marketing authorisation is granted as quickly as possible, the quality aspect of the CRA role is not always prioritised appropriately. Every CRA is required to monitor a larger number of subjects, sites and studies and although a good CRA has a plentiful supply of time management and negotiation skills, under excessive pressure they cannot continue to ensure high quality and timely data. It is often the quality aspect that loses in this battle, owing to companies often rating the success of an individual trial on its timelines (which can be easily calculated), rather than on levels of quality, which are much less tangible.

Such pressures were among the reasons for me choosing Quality Assurance (QA) as a career. As a former member of a team of CRAs I can tell you (and I'm sure that you won't be very surprised) that we were never particularly polite about clinical trial auditors. The reasons for this are two-fold. Firstly, being the CRA of a study site that is to be audited is a nerve-wracking experience. Though the CRA may be very good at their job, it is inevitable that things will go wrong, and although the CRA will have tried to resolve the issues, the time constraints imposed upon them will leave no doubt that the auditor will find something to report. Secondly, although an audit should be a learning experience for everyone involved, to help improve the quality of the trials that are being run, too often a blame culture develops and the CRA can feel like the subject of a witch-hunt.

After experiencing an audit myself, I began to realise that many of the skills required to be a CRA are the same as the skills of a good auditor. The ability to understand the reality of the clinical trials process, to negotiate with people and to be able to prioritise tasks due to the limited amount of time available at site, are all essential skills for an auditor. In addition, having been on the receiving end of the audit process, there will be a certain level of empathy for the auditees, which can be no end of help when trying to explain the importance of an audit observation.

However, the biggest draw for me in QA was the understanding that you are there to help people. I would like to think, now that I am an auditor myself, that the view of auditor's as the "Policemen" of clinical trials, has changed and that the role can be recognised as one of an "educator". Just like everyone involved in clinical research,

the auditor wants to ensure a high level of quality is achieved. They are lucky enough for this to be their main focus, being independent of the actual trial, which means that the ever-present trial timelines put them under less pressure. A CRA must have a sound knowledge of clinical trial guidance and regulations. This same knowledge is also vital for an auditor but in addition there must be an understanding of why such regulations exist and what they were designed to achieve. This will help an auditor to establish the seriousness of a problem and advise on how it could be resolved or prevented in future.

The QA function is involved in the entire trials process, not just in the auditing of trial sites. There is beginning to be an understanding that by introducing quality at an early stage, with study design and protocol writing, many of the audit findings at the trial site could be reduced or even eliminated. My job as an auditor involves me developing SOPs, reviewing study documentation such as protocols, informed consent forms and CRFs, as well as performing audits at both CROs and investigative sites.

The job is varied and I can be in Poland one week auditing a trial site, and in Germany the next reviewing a CRO's SOPs on behalf of a sponsor. The travelling is something that most CRAs are used to, the fact that most of my travel is international makes the whole process much more interesting.

There is still an aspect of project management involved, with large programmes of audits to be organised and ensuring that adequate resource and expertise is available. In addition some projects are over very quickly and it is satisfying to have the experience of organising, conducting, reporting on and closing a single project, which is something that you may never have had the opportunity to do as a CRA working on long term phase III studies.

The role involves meeting many people, and you need to be able to establish a productive relationship very quickly in order to achieve your goals. As mentioned previously, people are not often looking forward to being audited and minds will have to be put at ease within the first few minutes if the audit is to be a useful learning experience. Get the balance right and you will find people are usually very open and honest and make your job easier.

It is also a fantastic opportunity to learn about the industry. I am expected to be able to audit in almost any country in the world, and to audit any aspect of the trial process, which means staying abreast of new developments in regulations from Good Manufacturing Practice to Pharmacovigilance. The scope for development is huge and I personally feel that a job in QA can prepare you for many other roles within the industry.

Although most CRAs do not become auditors, the move from CRA to QA seemed as natural to me as, for example, moving into project management. When I changed roles from a CRA to become an auditor, one comment on my leaving card said, "So you've joined the Dark Side!" but I would prefer to think that I have become a Jedi Knight rather than Darth Vader.