Training New Clinical Research Professionals to Work on the Front Line

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- Trials & Training

In spite of economic turmoil, flat or decreasing R&D budgets, and public distrust in the pharmaceutical industry, the reasons why clinical trials with new therapeutics must be done remain unchanged, if not stronger. The shift of study placement from traditional sites in North America and Western Europe to emerging regions in the East and South, the overwhelming size of megatrials needed to demonstrate smaller but statistically significant differences in complex outcomes, and the general risk aversion of regulators, all point to one single direction: we need more patients participating in clinical trials, and more professionals taking care of them and of the data generated. At the same time, the clinical development process is so expensive and unproductive, that nobody has a doubt that changes are badly needed. Reduction in cost and development times is a mantra repeated universally, preferably without loss in data quality, or jeopardy to the participants.

In economic terms, if one needs to produce a better product or service, faster and with lesser costs, the orthodox recipe is to look for better raw materials, nimbler production processes, performed by more skilled workers, without any waste, and with strict budget controls. It is easy to discern that we have not yet achieved many, if not all, those goals. This paper will concentrate specifically on the aspects related to the training of new and more skilled professionals, and how this could contribute to the economy of the clinical research enterprise. Most of the information included here is not based on scientifically gathered data and published in peer-reviewed journals, it is mainly the result of many years of direct contact with people working in the front line in different emerging regions, and hundreds of interviews made with young professionals willing to find a place for them in the clinical research industry.

CHARACTERISTICS OF NEW CLINICAL RESEARCH PROFESSIONALS

The first question is where do they come from? What is the trajectory new clinical research professionals (CRP), defined as specialized workers who spend most of their time doing tasks related to the conduction of clinical trials, such as assisting participating volunteers, generating, controlling or managing clinical information generated by a study protocol. Figure 1 describes, in a graphic way, the source and flow of CRPs in the marketplace.

Professionals graduating from college and universities are often inclined to work in research sites. Most of the new CRPs entry positions at sites are related to data capture and management, research administration, and simple patient-related tasks (like

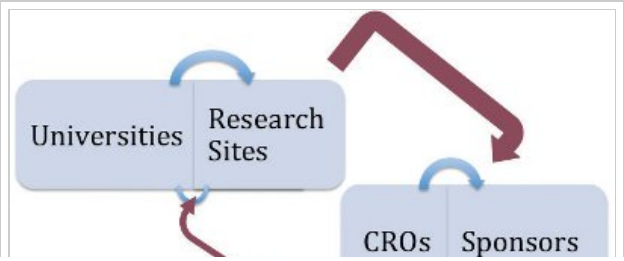

Figure 1. Where do Clinical Research Professionals come from?

measurement of vital signs, pill counting, etc.), with little or no exposure to sponsor/CRO personnel. CRPs from universities and research sites are the main source of labor recruited by sponsors and CROs, once they are trained at sites. At this other side of the work bench, they usually start doing in-house work, like collecting study dossier documents, archiving, system updating, database cleaning, etc., with little or no interaction with the sites. The main flow of people is from universities to sites to sponsors and CROs. These companies interchange people constantly; CROs currently concentrate the largest workforce, since most sponsors tend to outsource the clinical operations functions. The flow of people back to the sites and universities is very limited.

A health science degree is the most common background of CRPs, but there is a wide variation in titles according to geography. For example, in the USA and Canada, nurses are more prevalent, followed by pharmacists and others. In Latin America, pharmacists are much more common, followed by nurses, biologists, and others like, psychologists, biochemists, etc. Specific countries have specific concentrations of other professionals, like veterinarians in Chile, medical doctors in Peru and certain countries of Eastern Europe and Asia. Medical doctors tend to appear more frequently only in countries where the average wage of a young clinician is low enough, and comparable to the salary offered by pharma and CROs to a knowledgeable but inexperienced worker.

Interestingly, regardless of the graduation course, new CRPs get little or no information there about GCP, or about the daily routine of the clinical research enterprise. So, the next important question is why do young professionals choose clinical research? The first and most frequent answer is because they are strongly driven by science, they like to study and learn countinuously. Higher payments, above the average for their age, title or experience, is also a potent motivator. In emerging regions, where this is a new career, and the labor demand is higher, clinical research is a constantly expanding field, with an appeal for professionals coming from different graduate schools, which do not find a clear entrance in other traditional careers. International exposure and travel opportunities are also important attracting factors (which some will later regret). Some common statements in job interviews are: "I want do to something good in my work", “I want to help people" , and other idealistic ideas. It is noteworthy that newly entrants do not seem to be affected by the negative image that the pharmaceutical industry has with the general public, much on the contrary. Some also express that they like to work with people, and others that they like dealing with data. They are always very energetic and proud of their choice. Before they are mired by company bureaucracy and idiossyncracies, interns and other types of newbies frequently show an innovative spirit and come up with creative solutions to daily problems.

TRAINING OF NEW CLINICAL RESEARCH PROFESSIONALS

Where and what are the major sources for initial training of a CRP? As mentioned before, traditional university courses of all natures do not adequately prepare their graduates for working in clinical research. In mature markets of North America and Europe, there are many clinical research administration courses, providing graduate certificate, or a masters degree. In emerging regions there are very few of such courses, if any. Short-term initiatives, with duration of less than 100 hours are more common. American institutions offer curriculi very focused on the domestic regulations and practices, many of which do not apply internationally. The courses are usually expensive and not customized, and there are no universally accepted quality rating of courses by sponsors. There are efforts to create standards in the area, like the Consortium of Academic Programs in Clinical Research in the USA (http://www.coapcr. org/), and PharmaTrain in Europe (http://www. pharmatrain.eu/).

Congresses and symposia are another source of training and knowledge. Organizers of such meetings are very good at luring young professionals to their events, but they provide essentially niche knowledge, and are not indicated for initial training. However, they are very helpful for networking, and may help in engaging new CRPs in contact with more experienced and influential professionals.

Employers of all natures – research sites, sponsors and CROs – have conformed themselves to provide training for nearly all entrant professionals. Online courses, on-the-job training, and mentoring from more experienced personnel are universally provided, and represent the most

important and effective way of knowledge transfer in clinical research so far. It is important to note that employers value practical experience much more than formal, school-based training. This should be eye-opening for institutions who continue to cater on classroom activities, rather than action-oriented human interaction.

In-company training is very expensive, because it consumes valuable time from experienced professionals, and makes employers pay full salaries for training workers. A new and inexperienced CRP is not ready for autonomous work before 3 months of intensive training, and most CRAs undergo probational periods of 6 months to one year before they may work in the field without close supervision.

Two other factors contribute to longer costly training time. Regulatory inspectors have been keener in reviewing training records of CRPs, and often challenge sponsors when they believe that workers are not up to the tasks delegated to them. This has urged sponsors to pay more attention to the documentation of training, rather than actual evaluation of readiness for the tasks. Training is offered mostly through online programs, which do not add much to the actual capacity of CRPs, but are easy to document. The second, and most critical factor, is the high turnover rates observed among site coordinators, as reported by Neuer [1], and among CRAs [2]. It may reach over 40% of new professionals. In the same direction, Glass [3] reported that about 50% of clinical investigators included in the 1572 database from the FDA performed only one clinical trial in 3 years. Even if those investigators conducted a new clinical study after years of the previous one, retraining would be mandatory.

Knowledge about the root causes for high turnover among CRPs is incomplete, and is a mounting need, given the cost consequences. Interviews with professionals leaving their first job frequently mention the following reasons: "I did not feel valued", "professional ascension was too slow", "wanted to see more action". Behind those statements, one may feel that young professionals had their initial enthusiasm curbed by their employers.

One of the reasons why companies have a higher burden in training new CRPs is the lack of a standard set of competencies for their jobs, which would allow a clear definition of levels of readiness for in-training professionals. As a result, most CRPs are tested in new tasks in a trial-anderror fashion. At the same time, as cost controls get tighter, more and more is expected from CRPs in the field.From the standpoint of investigators, quality of the monitors sent by the sponsors and CROs is considered too variable. Investigators tend to put much emphasis on the soft skills of monitors, valuing relationship, teamwork, communication, sometimes more than their technical skills. They also complain quite frequently that CRAs do not have enough understanding of the therapeutic area of their studies, and they do not understand the routines of a research site, and "when they get good, they are promoted and go".

RECOMMENDATIONS

So, what can be done to provide more effective training, and decrease associated costs?

1. Hire well

In spite of a high demand and urgent need to replace vacant positions, or respond to last minute requests, recruiters must hire new CRPs more carefully. The hiring organization must have a defined set of competencies, and evaluate candidates based on it, not on previous experience (e.g., two years as a CRA or a CRC does not mean much per se). It is not uncommon that professionals with performance problems have more experience in their resumés, because they have changed companies more frequently. Hire passionate people.

2. Correct hiring mistakes fast

Define a set of goals and performance milestones that new CRPs should achieve in their first year on the job. Evaluate performance frequently and objectively, and discuss it with the employee in a constructive way. If they do not feel satisfied, or cannot perform according to department standards, he or she should be let go fast, without major fixing efforts.

3. Talent retention

The money and effort spent fixing poor performance should actually be spent in talent retention. Top performers should be retained as far as possible, because they make all the difference. A top

performed CRA or CRC is precious, he or she will help in sales, marketing, business development and company image, all in one.

4. Train mentors how to mentor

Mentoring is probably the most effective way of training, that is , if you have a good mentor. Many experienced professionals are put in a mentoring situation without being trained or, worse, against their will.

5. Maximize field work of new CRPs

There is a tendency to allow new CRPs to go to the field only after they complete the induction training, which is usually done online, and may take up to 100 hours. That is a motivation killer. Mix online learning with field activities, expose trainees to real-life situations, work on their soft skills, build on their enthusiasm, and motivate. It is understandable that companies need to cut their travel budget, and do not want to show their people in training. A high turnover rate is much worse for the business, and will result in a larger training budget. Adults learn more effectively by doing, not by reading.

6. Measure and celebrate progress

CRPs will get a lot of beating in their career paths. Ruthless managers, unrealistic timelines, conflicted situations, are all motivation busters, and sometimes career killers. The training period does not need to be a trailer for those situations, so make interim evaluations, acknowledge progress and celebrate it frequently. Perhaps the new CRP will understand that this is the way to go throughout their professional life, and when they have to train their successors.

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COMMENTS