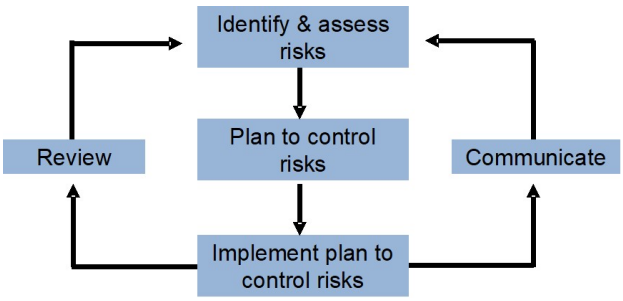
Learning and Development for the Future

PEER REVIEWED

As financial pressures continue to bear down on the clinical research sector, it is vital that both sponsor companies and the CROs that conduct their studies continue to invest in the development and capabilities of their staff. Only through retaining competent staff will the clinical research sector be able to meet the forthcoming challenges which include increased trial complexity, the rising use of 'big data', and the advent of artificial intelligence in both the diagnosis and treatment of disease. Competent staff are also essential for the continuing protection of patients and integrity of data.

Organisations must use their resources effectively and efficiently in developing their staff. Tools to train and develop staff must be used in a targeted way so that the outcomes support the business needs of the organisation. It is undeniable that learning and development costs money and time and takes people away from their frontline jobs. It is very important that money spent on these activities produces results in the shape of satisfactory performance and supports the drive for constant improvement. Learning and development interventions can be targeted using a combination of two approaches; one applies risk analysis as its basis and the other uses a competency-based methodology.

The concept of risk management is now well established in the clinical research sector. A risk-based approach to monitoring was described in the FDA's Guidance for Industry (Guidance for Industry, Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring, August 2013), in response to the FDA's opinion that not all studies are equal in terms of complexity and risk to patients. The aim was to focus sponsors' monitoring efforts into those areas that will pose the greatest risk to patient safety and data integrity. Many sponsors and CROs now use a risk-based approach to monitoring. In Europe, the European Medicines Agency (EMA) had a similar standpoint. Their view was that the practices of the day were not proportionate or well adapted. The EMA's position was presented in their Reflection Paper on risk-based quality management in clinical trials (September 2013). In this document the EMA outlined a risk management process summarised by the illustration below.



It is a dynamic system which involves identifying risks, planning and implementing control measures, then reviewing, communicating, and reassessing risk. Applying such a methodology to the design and delivery of training would seem to present a logical extension to the use of this model.

The concept behind a risk-based approach to learning and development is that it is targeted at high-risk areas and therefore has the maximum impact for each learning intervention by preventing non-compliance. This ultimately supports the protection of patients and data integrity. Using a dynamic approach and regularly reassessing risks helps keep staff capabilities contemporary and relevant, particularly with respect to the use of new technologies and methodologies. The first step in a risk-based framework is to conduct a risk analysis. A risk can be defined as a threat and those risks which have both a high impact and a high probability of occurring are the ones which should be targeted as a priority. Risk tends to be associated with high complexity (for example complex studies or processes), and novelty (such as a new disease area, emerging or relatively untried technology, new organisational structures). Risks can also include known undesirable outcomes from past experience such as problems encountered with certain types of study or results based on historical trend analysis of data. Risks can be grouped in clusters such as those pertaining to patient safety, data integrity, regulatory compliance and may also include operational metrics such as quality standards and project overruns in terms of cost and time.

The second stage is to identify the possible root causes of risks. There are various tools and techniques available for root cause analysis such as the cause-and-effect diagram (for example Ishikawa), the interrelationship diagram, and the current reality tree. The cause and effect diagram is helpful when identifying possible causes for a specific problem, particularly when a team's thinking has become stagnated and an impasse has been reached. An interrelationship diagram shows graphically the cause-and-effect relationships that exist among a group of potential threats. It is best used when helping to identify the potential causal relationships that might lie behind a recurring issue (i.e. a threat that keeps manifesting itself) despite previous attempts to resolve it. A current reality tree depicts the current situation in a series of dependent logical cause-and-effect relationships. It starts with the symptoms, i.e. the apparent threats (sometimes known as undesirable effects) and drills down to one or a few core root causes. Current reality trees are best used when there are number of threats which may have common or similar root causes which may result in system-wide problems.

The third stage is to decide what part learning and development can play in dealing with these fundamental problem areas. The ultimate goal is to prevent the risks occurring. Depending on the nature of the threat and its root cause(s), various learning interventions can be used. These may include case study analysis (perhaps of the actual threat itself), coaching, focus groups, problem-solving techniques and training courses either face-to-face or by webinar. Lastly the effectiveness of the learning intervention needs to be assessed. The ultimate goal is to prevent the threat occurring so any measure of effectiveness should involve an assessment of whether the threat has occurred, or if it has, to what extent. If the threat has manifested itself despite the implementation of the learning intervention (and any other preventive measures), a back-up plan should be deployed to contain the threat.

One of the advantages of taking a risk-based approach to learning and development is that it avoids wasting time and money on repetitive and redundant training, particularly if it involves Good

Clinical Practice as a subject area. This is because of a mistaken belief that it is a regulatory requirement to have GCP training annually or that investigator sites must routinely have GCP training as part of the study setup activities. Redundant GCP training is frustrating for the investigator and their site staff and diverts the sponsor's valuable resources from more productive activities. The time could be better spent on targeting learning activities on those high-risk areas which could compromise patient safety, as well as regulatory and protocol compliance. There is no doubt that using a new investigator site is a potential risk for a sponsor. However, a risk assessment in the form of pre-training competence check of the site staff on what they already know about GCP would allow learning activities to be targeted on those areas and individuals where knowledge was weak, so filling the competence gaps.

For study-specific training for both sponsors' staff and investigator site staff, the learning should be focused on those parts of the protocol which have the biggest impact on subject safety and data integrity. Any complex sections of the protocol (e.g. investigational product dose adjustment) or case record form (CRF) should also be the subject of a risk-based approach. In terms of the CRF, analysing trends in data errors can highlight the 'high-risk' data fields and learning activities can be targeted in these specific areas.

The introduction of new regulations often poses a threat of potential non-compliance. A risk-based approach to regulatory training targets those areas of the legislation where the threat of non-compliance is greatest. The same principles apply to SOP training when new procedures are implemented and efforts should be focused on those parts of the process which are complex or significantly different from previous practice.

A risk-based approach to learning and development should be a dynamic system and the results should be analysed and the learning activities refined or refocused as necessary. By using a risk-based approach to learning and development, outcomes can be targeted and designed specifically for managing and preventing risks. This enables the learning interventions to be designed in a logical and constructive way. It also empowers the learners, in that they can see the relevance of the learning activities in preventing risks occurring, improving their performance and increasing their confidence.

Applying a risk-based methodology allows the effects of learning activities to be more readily measured from an organisation's perspective. An end assessment can include whether or not the risk manifested itself, the effect on incidents of non-compliance, reduction in errors and the savings of cost and time.

We have examined the use of a risk-based approach to learning and development. Closely aligned to this philosophy is the concept of using competence as a basis for developing people. Competence can be defined as "the ability of an individual to demonstrate knowledge, skills and behaviours". The word competence is seldom found in regulations governing clinical research. Guidelines and regulations deal broadly with the issue by requiring that "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task". (The Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice E6(R2)), principle 2.8). Education, training and experience are important but this is not the whole picture. Substandard training and narrow, poor quality experience can all have a negative effect on the ability of an individual to perform their job. The key aspect of whether someone can fulfil their role in clinical research is directly related to their competence – i.e. the possession of the required and observable skills, knowledge and behaviours. Unfortunately a search through clinical research regulations and guidelines for the word "competence" produces a scant return. FDA 21 CFR mentions it in the context of IRB membership (56.107) and in the use of foreign data, relating to the competence of investigators (314.106). The ICH GCP Guideline E6 (R2) mentions competence only once, in connection with the documentation of a medical laboratory to perform the required tests.

As covered in the introduction to this article, new innovations in the clinical research environment are putting increasing demands on the requirement that people are competent. A skill set that was valid ten years ago is not necessarily fit for purpose today. Set against this background, there is a shortage of trained new talent coming into the clinical research sector. This seems to be an international problem, particularly in the USA and Europe. A scan of the job vacancies for clinical research positions will reveal that the overwhelming majority require previous experience, commonly at least two years' worth. Many new graduates in biological sciences complain they cannot find work in clinical research because they lack work experience, so that breaking into this sector of the job market proves a frustrating exercise for them. From industry's perspective, the situation is not very satisfactory as organisations are constantly playing catch-up in trying to acquire enough experienced and skilled people to meet their resource demands. Because of the time-pressured environment of clinical research and the shortage of experienced staff, the irony is that there seems to be a reluctance for companies to invest time and money into training new graduates, as the need is for people who can 'hit the ground running' with little or no extra staff development.

The conventional picture of training involves attending a course, either face-to-face, online, or completing an e-learning course using a self-directed approach. Depending on how the training is designed and conducted, these methods can result in a passive experience or irrelevant experience for the so-called learner. A certificate of attendance may be obtained, or completion of a multiple-choice questionnaire may be required in order to obtain a certificate. However, a certificate of attendance of training is verification only that the person physically attended the training course. Without learning through active participation, there is no guarantee that any new skills will have been acquired. The important factor in any training activity is to have very clear goals of what should be learned either in knowledge, skills or behaviours – in other words, competence-based learning outcomes should be used. This enables people to demonstrate their new areas of competence after taking part in a learning activity. The learning intervention should be relevant for the person, their level of competence and their job role which, in turn, should be linked ultimately to their organisation's business goals.

The most important benefit in staff development of using a risk-based approach combined with a learning system based on competence is the positive impact on patient safety and its use as a tool in the protection of the rights and well-being of clinical trial subjects. Focusing on this key aspect helps put the learning activities in context and gives them an underlying theme, making it relevant for the learners, the organisation itself and of course the clinical trial subjects.

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