Raising Clinical Trial Standards through Competency-Based Training

PEER REVIEWED

The Clinical Trial Directive – 2001/20/EC – has been in place for about a decade. In that time the number of drug trials conducted in the EU has fallen by about 25%.[1] Opinion has been divided about the benefits of the directives and various stakeholders in the clinical research community have expressed concerns about the rise in bureaucracy, the increase in costs of running trials and the continuing lack of uniformity in the EU. The call has been for more streamlining, which includes taking a proportionate risk-based approach to the conduct of trials with more public openness about each trial and the results they produce.

The European Commission has responded by introducing legislation, the EU Clinical Trial Regulation 536/201. This regulation will replace Directive 2001/20/EC, which will be repealed. The regulation was approved by the European Parliament in April last year and has now been published in the *Official Journal of the European Union*, with an implementation date planned for 28th May 2016. The Regulation sets out the requirements for a single clinical trial approval portal and the content of clinical trial applications to be standardised.[2] It also deals with making information about trials more transparent and the results more accessible to the lay person. This will be achieved through an EU portal which will allow the EU database on clinical trials to be publicly accessible, with the data presented in an easily searchable format.

A Welcome Regulation

The Regulation will ensure that the rules for conducting clinical trials are identical throughout the EU. It also allows the EU Commission to conduct controls in member states and other countries to make sure the rules are being properly supervised and enforced. One of the problems of directives is that they allow national authorities to draw up their own legislation, which has resulted in varying degrees of interpretation of the directives and has not achieved the harmonisation initially hoped for, particularly with respect to competent authority approvals.

The EU Regulation has been brought in to remedy some of the difficulties caused by the current situation, one of which requires submission of separate applications for each of the countries involved in a trial. This has caused delays in the start of clinical trials and a disproportionate administrative burden, despite the use of the Voluntary Harmonisation Procedure which took a more centralised approach to Competent Authority approvals. The new Regulation provides specific timelines for the different steps in the authorisation process and confirms the concept of tacit authorisation to ensure that timelines are adhered to. Furthermore, it provides a mechanism to extend the clinical trial to one or more additional member states, without requiring the reassessment of the application by all member states involved in the initial authorisation.[3] It will also clarify when modifications to an already approved trial should be subject to a new authorisation procedure.

In summary, the main features of the new Regulation include:

- A single approval portal
- Standardised content of clinical trial applications
- Greater transparency about clinical trials
- Information about subject protection and informed consent, including some details about specific groups of patients such as pregnant women
- More stringent requirements for reporting trial progress
- Safety reporting is to be via one EU database, using a standard form
- Reporting of serious breaches of the protocol or the Regulation
- Reporting of urgent safety measures taken to avoid hazards to study subjects
- Archiving of essential documents for 25 years

One area which the new Regulation neglects is in ensuring the competence of people working in clinical research. Under the heading "Suitability of individuals involved in conducting the clinical trial" (Article 49) the Regulation restates the directive it was designed to repeal (2001/20/EC) when it reaffirms that "… individuals involved in conducting a clinical trial shall be suitably qualified by education, training and experience to perform their tasks."

Clinical research is becoming ever more complex and demanding and it is unfortunate that the Regulation has not been used as an opportunity to define more precisely how these demands are going to be met by the skills and abilities of the individuals working in the sector.

The Increased Need for Industry Competence

Most people working in the clinical research industry are highly qualified, with many of them having degrees in medicine or biological sciences, or a nursing qualification. However, none of these qualifications is related specifically to conducting clinical trials competently. Nowhere in the Regulation is there a mention of competence in terms of the ability of individuals to conduct clinical trials. Having internationally recognised and accredited professionals whose competence has been independently assessed would give both the industry and the general public further reassurance that those in clinical research are competent to fulfil their roles.

Unfortunately, neither education, training nor experience

can guarantee competence. Clinical research staff need to have the skills and abilities that reflect the contemporary setting in which they work to ensure that out-of-date and substandard practice is eliminated.

Training and Competence

As the clinical research environment grows increasingly pressured and complex, there is a need for consistent standards in training. Currently there is no requirement for the type of training that should be conducted, who delivers it and, most important, the learning outcomes that each training intervention should accomplish. Having a competence-centred approach based on defined learning outcomes would enable organisations to 'recognise' each other's training programmes and avoid unnecessary repetitive training.

An initiative to recognise training courses has been developed by an organisation called TransCelerate. This body is a collaboration between biopharmaceutical companies to design and facilitate the implementation of solutions to drive efficiency and effectiveness in the development of new medicines.[4] Founded in 2012, the organisation has eleven initiatives at the time of writing this.

One of the TransCelerate initiatives (initiative 2) is centred on minimum criteria for GCP training content that will enable member companies to mutually recognise one another's training, including the use of a common "TransCelerate GCP Training Certificate". The focus is on the content of the training rather than the learning outcomes. While this is a welcome step, the initiative does not go far enough, focusing only on inputs rather than the all-important outputs – the learning outcomes.

It is common practice in the clinical research sector for individuals to document the training they receive, but what is truly being recorded? What was accomplished in the training session? The piece of paper that says an individual has attended a course is not a meaningful record of the new skills acquired during the session. The answer is to have training sessions with pre-defined learning outcomes which are measurable and competence-based. The term competence is sometimes misunderstood and it can be defined as an **observable** demonstration of knowledge, skills and behaviours. Rather than maintaining just a training file, individuals should be encouraged to keep a competence file which is a record of knowledge, skills and behaviours they have acquired through learning interventions including on-the-job training.

Training programmes can be designed for specific job roles by having competency frameworks for each role. These frameworks can be used as performance standards by setting out the required role-specific competencies.[5] A benefit of using this approach is that it would also cut out redundant and unnecessarily repetitive training – particularly with respect to good clinical practice (GCP), just like the mutual recognition of training courses discussed earlier.

Experience and Competence

There is no doubt that having experience is extremely valuable and certainly increases the chances of an individual being competent. However it is no guarantee and it can be easy to be deceived into thinking that experience equates to competence. Pharma companies and CROs understandably return to known and well-used investigators' sites each time a study is set up, as they are considered experienced researchers having participated in numerous previous studies. The true competence of the investigator and/or the site is unknown. There are no standard methods of assessing competence except for

internal metrics that are not shared between commercial organisations. (These metrics can include patient recruitment targets met, number of screen failures, number of protocol/GCP deviations etc.) The result is that there is over-use of some investigator sites that are substandard in terms of delivery and quality, and under-utilisation of new sites that may lack experience and which are an unknown factor in terms of competence.

The other area where experience currently counts for more than competence is in staff recruitment. From the pharmaceutical companies' perspective, the search is often for people with at least two years' experience. This occurs both for permanent hires and when selecting contract staff from a CRO's team. Staff may appear to have the relevant experience but not necessarily the benefit of **good relevant** experience of the right quality. Bad habits may have been learned and embedded over a number of years. The solution could be to have internationally recognised and accredited professionals whose competence has been independently assessed, which would give both the industry and the general public further reassurance that those in clinical research are competent to fulfil their roles.

In organisations that do not use competence-based assessments, individuals can be promoted or hired based solely on a number of years of experience. Undoubtedly experience is very important in acquiring and perfecting skills, but it is also an opportunity to acquire bad habits, to stagnate and allow competence to become outdated.

Using competency frameworks to manage performance is a far more reliable and objective measure, which allows clarity for both the manager and their reports in highlighting when someone's performance is satisfactory, below par or when that person exceeds expectations. Work-based examples that demonstrate competence can be used by both parties, and this allows a discussion based on objective criteria. Developmental strategies to overcome underperformance can be devised to address any shortcomings. These plans should be reviewed regularly to check progress on how the individual is moving in the right direction to be able to acquire the desired competence.

Conclusions

The new EU Clinical Trial Regulation may need further detail and clarification in some areas in order to be able to implement the new requirements. There may well be some guidance documents already in preparation by the European Commission. Perhaps the solution to the problem of a lack of competence standards in the sector is to have a guidance document which sets out the requirements for training and experience centred on a competence-based approach.

The need for quality, competent and well-trained staff is more important than ever. The danger is that, unless a competence-based approach is used, potentially incompetent people can still be hired, employed or promoted with the resulting risk to the safety and wellbeing of patients and the integrity of clinical trial data. The benefit for clinical research as a whole would be better qualified and more competent people who are able to conduct clinical trials more quickly, efficiently and intelligently.

This represents a great opportunity for the clinical research sector to make a major step forward in developing a talented, flexible and global workforce that is equipped to meet the challenges of conducting top-quality clinical trials internationally.

References

1. Richard Bergström, 2012. European Federation of Pharmaceutical Industries and Associations (Internet) http://www.efpia.eu/mediaroom/63/70/quot-Reform-of-EU-Clinical-Trials-Rules-Europe-can-t-afford-to-fail-33-quot-says-Richard-Bergstroem [Accessed 26/05/2015]
2. Michael Mezher, 2015. EMA Seeks Feedback on Clinical Trial Database (Internet) http://www.raps.org/Regulatory-Focus/News/2015/01/22/21138/EMA-Seeks-Feedback-on-Clinical-Trial-Database/ [Accessed 26/05/2015]
3. NHS European Office, 2014. The new EU Clinical Trials Regulation How NHS research and patients will benefit (Internet)http://www.nhsconfed.org/~/media/Confederation/Files/Publications/Documents/eu-clinical-trials-regulation-2014.pdf [Accessed 26/05/2015]
4. Moe Alsumidaie, 2015. TransCelerate Vs. ACRES: Site Accreditation Initiatives (Internet) http://www.appliedclinicaltrialsonline.com/transcelerate-vs-acres-site-accreditation-initiatives [Accessed 26/05/2015]
5. Peter Schueler, Brendan Buckley, 2014. Re-Engineering Clinical Trials: Best practices for streamlining the development process. Academic Press, London

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