ISO 9001:2015 AND UPDATED GUIDELINE FOR GOOD CLINICAL PRACTICE: CONSIDERATIONS FOR SYNERGIC APPLICATION

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Recent decades brings a lot of changes into clinical trial enterprise caused by growing of research market, study complexity, costs and emerging of advanced technologies. From the other hand, the evolution of quality management framework guided by increasing of quality and efficiency demands creates a new environment for performing clinical trials. In 2015 the new version of ISO 9001 standard was introduced. This standard provides a range of new concepts for building strong quality management system. Next year ICH GCP Guideline was also updated providing changes and new requirements for assuring quality of clinical trials. Thus the issue of proper implementation of ISO 9001:2015 while ensuring strict compliance with ICH GCP (R2) raises a serious challenge to investigational sites as well as clinical trials sponsors.

The core of ISO 9001:2015 is risk-based thinking which has not been a new idea for clinical trials investigators. But, in contrary to eventual and systematic measures, risk-proportionate approach finds appropriate reflection in ICH GCP (R2) which also recommends sponsors to introduce risk-based quality management in order to assure reliability of trial results and human subject's protection while effectively using available resources and efforts. However, more practical measures should be taken in order to implement risk-proportionate approach: identification of critical processes and data, risk identification, risk evaluation, risk control (mitigation), risk communication, risk review and risk reporting.

The revised ISO 9001:2015 places more emphasis on process approach that requires investigational sites to define more clearly the inputs and outputs of clinical trials processes as well as their parameters, necessary resources and infrastructure for its appropriate performing.

Other new changes introduced by revised ISO 9001 are evaluation of the context of an organization, more orientation on stakeholders and defining their preferences and demands regarding the clinical trials. These aspects are also reflected in ICH GCP (R2) which underlies the importance of two-way dialogue between sites, sponsors and CRO, better communication and collaboration as well as patient engagement. Such an approach helps to take into account the needs and expectations of all parties involved in a trial. The vivid example of orientation on interested parties is an idea of patient engagement which has become recently a highly discussed topic and a range of practical and theoretical approaches were developed and proposed by the clinical trials community and commercial companies. Patient engagement is an important pre-requisite for planning and performing studies considering patients' perspectives which permits to make trials more efficient and more compliant with the needs of patient.

Leadership is one of the most important concepts introduced by ISO 9001:2015 which requires responsibilities of top management with regards to quality management. In comparison, ICH GCP (R2) emphasizes the 'leadership' of both the principal investigator and the sponsor. For instance, it increases the responsibility of the investigator for supervising performance of clinical trial functions being delegated to other persons. Accordingly, sponsors' responsibility was also enforced by obligation to oversight actively quality of clinical trials processes including those outsourced to CROs that implies sponsors qualification/requalification audit of the CRO.

It is worth to mention that revised ISO 9001 standard and ICH GCP (R2) contain changes that are concordant and targeted on efficient achieving quality goals in the modern context. Thus, investigators as well as sponsors should consider these two documents simultaneously within the whole integrated system which will allow enhancing clinical trial performance at the fundamental level.