The Role of the CRO in Risk-Based Monitoring

The clinical trial industry is marching towards maturing. However, its advancement confronts stakeholders across the clinical research field with a myriad of challenges. Among the difficulties which stand between sponsors as well as project managers and the completely smooth run of studies are **the increasing costs, additional expenses and the constant insisting of regulators to apply more effective monitoring approaches** that will guarantee improved Good Clinical Practices (GCPs). One such technique turns out to be risk-based monitoring (RBM). Still, in order to put fundamental RBM stipulations and propositions into practice, sponsors can work cooperatively with contract research organization (CRO) partners.

In recent years, the risk-based monitoring paradigm has been perceived as **more efficient than the focused on-site monitoring practice in terms of ensuring bigger safety of patients and enhanced integrity of data**. Behind the power and extreme usefulness of RBM lies the ability of this type of monitoring processes to demonstrate tactical alertness and to identify risks as early as possible. Comparing it to a traditional and previously established monitoring, the risk-based monitoring exhibits more prospective advantages. Some of them include **the benefit of costs being cut down, the opportunity to change, fit, rearrange and balance the act of supervision according to expected and unexpected alterations that occur in risk levels.**

However, the realization of the full capacity of RBM demands **developing a plan in advance, implementing methodological expertise, using proper tools and performing adaptability**. Apart from these core aspects, there are other requirements which shape and trigger a successful risk-based monitoring. These requirements are of utmost importance and they include communication and collaboration between parties as well.

It is essential for sponsors and their CRO partners to begin preparing a plan for RBM at the very start because only this way they **will be enabled to divide and set all of the responsibilities and activities to teams and individuals**. In this sense, sponsors may find the TransCelerate methodology very useful as it offers insights of how to collaborate with the CRO parties in a way that will produce the ultimate level of productiveness and intended results.

But what exactly is **the role of CRO in risk-based monitoring**? Contract research organizations involved in RBM are vital as their presence is poised to deliver what sponsors expect and want. They work to ease and smooth the risk-assessment process by **collecting, reviewing and analyzing data which helps them underscore features and particularities within the protocol design that are hazardous and might affect the levels of risk**. In addition to this, CROs serve to identify and confirm that others who are part in the research carry the process through by utilizing quality standards and common assumptions. The direct contact of a CRO team with sponsors **assures that sites have the right tools, experience, training and feedback needed for the operative implementation of RMB**. Finally, partnering with a CRO team should provide cross-functional expertise accompanied by adaptable technological tools to adjust to potential changes that happen during the course of the study.

As an evolving paradigm, the risk-based monitoring is **essentially based on strategies and technologically-focused, risk-based operations**. By choosing to embrace this type of monitoring, Pharmaceutical and Clinical companies and other establishments are promised to show improved patient safety and much better quality of data. Clearly being a path to follow in the present day and in the future, RBM represents **a risk-based approach that amalgamates centralized and on-site monitoring modes**. Still though, the realization of RBM principles strongly relies on the collaborative work between sponsors and CRO cooperators.

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