

RISKY BUSINESS

As clinical trials have become more and more complex, so has trial monitoring – but a risk-based monitoring approach can make it more efficient

Whereas traditional methods often involve 100 percent source data verification and frequently monitoring every trial site, risk-based monitoring (RBM) uses a combination of risk assessment and software to scan data and identify areas of particular risk in trials, allowing the monitoring to be focused only on these areas and resulting in time and cost savings.

In addition, the FDA notes that there is a “growing consensus” that RBM is more likely “to ensure subject protection and overall study quality” as more effort can be expended on the areas of most need.

Adam Baumgart, business lead for risk-based monitoring at Covance, agrees: “RBM is really about improved patient safety, data integrity and regulatory compliance for running clinical trials.”

The main components of any RBM approach, he says, are the technology, the process, the people and the organisational design. “You can’t just implement a system without having thought through what the true needs are, how the processes have to fulfil those needs, and then how people will execute their jobs.”

On the technology side of things, Baumgart says that implementing a risk assessment and categorisation tool (RACT) and centralised monitoring capabilities are essential for initially identifying where risks lie.

“From a process perspective, you really need something that looks at both the study planning phase and then the study execution and maintenance phase, and not just something that assesses risks once the study is live and you’re recruiting patients.”

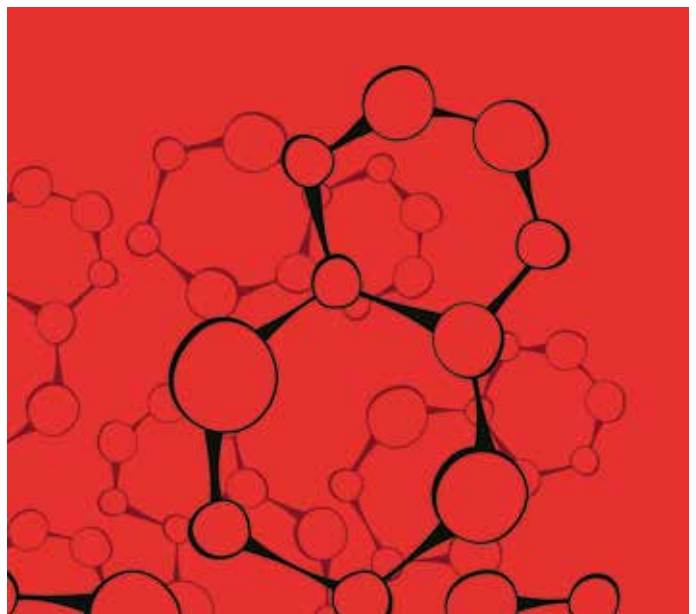
And when it comes to people and organisational design, “you have to expand and transform the roles performed in traditional trials and take them into the new world of RBM”.

“That could mean specialised roles – we’re developing roles to look at risk analysis, but also central monitoring. We’ve also seen a need for data scientists, because you’re consuming so much more data.

“And the role doesn’t often fit with the old paradigms of the way that we’ve worked. So what we’re doing is trying to pilot those roles with people from traditional backgrounds who show a critical thinking and an analytical thinking skill set.”

All of this can help avoid common mistakes in clinical trials and getting a drug through to the market.

“[The industry] still misses key data points or critical safety issues despite the fact that we’ve historically done so much checking,” says Baumgart. “If we’re able to observe that more effectively using big data, visualisations and statistical algorithms, we should get cleaner data with better integrity for submission to the regulators.”



This also feeds into how RBM can improve patient safety.

“Patient safety is really about trying to make sure we’re not missing anything and observing patterns. Are we missing any signal, or any patterns in adverse events, that might indicate something about the safety profile of the drug we’re investigating on behalf of the client?”

“If we’ve got access to the data then we can analyse the patterns. You can then begin to see gaps in the data, and when you begin to see sites that aren’t reporting as many adverse events as other sites within the study, or against the disease norm, then you begin to proactively identify and address any missing information.”

Baumgart says that he has seen improvements in both study budgets and the number of quality results in trials that use RBM – a sign that the days of traditional trial monitoring could be numbered. ○