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Refocusing on Risk Mitigation in Starting Clinical Trials

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While risk management efforts in drug development have focused mostly on post-marketing drug safety, the clinical trials process has its own mix of potential risks waiting to derail a company's multimillion dollar development programs. These risks include patient enrollment issues, site staffing shortages, drug supply logistical problems, and regulatory delays. Risk-based challenges are escalating as clinical trials become more global and complex, and as market pressures keep rising for new therapies at an ever-increasing pace.

Both the FDA and EMA state that risk-based methodologies should begin at the start of a trial.

Site selection, traditionally manually intensive, is a critical step in getting clinical trials off to a good start, yet poorly performing sites have long been a tough challenge for the industry. Half of investigative sites under-enroll, 11% of sites fail to enroll a single patient and a mere 13% exceed their enrollment target. In addition, phase II-IV study timelines often have to be extended to almost twice their original length to achieve enrollment goals.

Site selection and feasibility tools can help by combining internal and external data sources so a complete target site profile can be created, mitigating risk factors for recruitment and retention by finding the optimum alignment of top-performing sites with substantial patient databases, and quickly assessing which sites have performed best in similar studies. This data-driven approach to site selection also facilitates communications and fosters a foundation of trust and commitment.

There are numerous steps involved in starting clinical trials, and without risk management planning, each has potential for causing delays, and ultimately, jeopardizing the study. To mitigate this situation, technology providing risk management capabilities is a critical improvement over traditional manual processes. This level of process improvement can help keep studies on track and within budget and speed new therapies to market.

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