Can We Make Monitoring Better? THAT'S THE $5 BILLION QUESTION.

Incredibly, only 6 percent of new pharmaceutical products ever recoup their development costs. Any other industry would simply cease production of such an unprofitable venture. But we don't have that luxury. We need to change the way we do things and reduce resource-sapping redundancies. And that's exactly what strategic data monitoring sets out to do.

In 2011, the FDA published draft guidance in support of risk-based monitoring. Subsequently the EMA released a reflection paper. Together, these documents help clarify regulators' expectations for clinical monitoring. With this support and guidance, the opportunity for change is evident. It's time for our industry to implement innovative approaches to trial data collection and monitoring.

Open Up to Open Collaboration

How many times have you heard people say we need to develop new products not only more quickly, but more cost effectively, too? It's frustrating, because if it were that simple, we'd do it. However, several issues are hampering our efforts. For example, increases in trial complexity and post-approval commitments have drained many companies' resources even further. But there is hope.

In September 2012, ten leading pharmaceutical companies formed TransCelerate BioPharma — a non-profit organization focused on simplifying and accelerating the delivery of drugs to patients. For some, the founding of this group marks a new era in drug development. An era built on open collaboration to drive clinical development transformation. To date, TransCelerate has identified 10 initiatives to drive industry change, but their number one priority is to develop a standardized approach to risk-based monitoring.

There's that $5 Billion

The way in which we monitor has been overengineered. In fact, some estimate cutting down on unnecessary data collection, without compromising patient data or quality, could save our industry up to $5 billion annually. So data selection and management are prime targets for cost reduction. However, any cuts must preserve patient safety and data quality, while satisfying regulatory requirements. Enter strategic data monitoring.

Contributed by

AMY KISSAM, *Executive Director, Integrated Clinical Processes, INC Research*

Strategic data monitoring is a holistic approach to developing an optimized operational strategy. By performing an upfront protocol evaluation, we can:

- Assess the dimensions of trial risk (e.g., patient safety, operational delivery, data integrity and scientific)
- Promote clinical/data/project management plan synergy
- Identify the right monitoring methodologies (including frequency and intensity)
- Identify potential waste or areas where we may streamline data collection

This strategic approach utilizes a protocol-specific mix of monitoring strategies:

- **Targeted source data verification (SDV):** Focuses on data that is critical to subject safety and the study objectives, allowing for a reduction in source data verification activity.
- **Triggered monitoring:** The initiation of monitoring activities is based on an event such as a quality indicator or data volume. This may trigger an on-site SDV monitoring visit or an off-site contact with the site to mitigate potential risks.
- **Integrated monitoring:** Combines the use of on-site monitors and central monitors for improved efficiencies and subject safety, data integrity and regulatory compliance.

The result is a strategy that addresses medical, scientific, regulatory and operational risks in order to focus on critical data and risk mitigation. For example, the right strategy can ensure site visits are focused on high-value tasks and conducted as needed rather than solely based on calendar frequency.

Times are Changing

Traditional monitoring arose from the 1988 FDA guidance, which stated that sponsors needed to provide "adequate" monitoring. However "adequate" was never defined and a "better safe than sorry approach" became the norm. As a result, we often employed over-engineered monitoring strategies focused on on-site review — a resource-intensive approach that doesn't offer oversight commensurate to risk.

In contrast, risk-based monitoring capitalize on cutting-edge data-handling platforms to yield real-time trial data access and oversight remotely. With this in mind, you'd expect this approach to be used wherever possible. But this isn't the case. However, growing regulatory support is bolstering confidence in the approach. This begs the question: If we already know how to make monitoring better, isn't it time we did? PV

A:

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