Reduction of Pre- and Post-Analytical Errors in the Integrated CRO Model

Did you know that in clinical settings, diagnostic testing errors are the most prevalent type of malpractice claim? Advances in automation, sample collection, transport and data reporting, as well as industry-wide standardization of testing protocols, laboratory safety and quality control, have reduced the frequency of these types of errors to less than 10% and have led to a drastic improvement in overall laboratory efficiency and performance. But what about the remaining 90% of errors that occur outside the clinical laboratory?

Types of sample errors

Sample errors can be classified as one of three categories:

- Pre-analytical
- Analytical
- Post-analytical

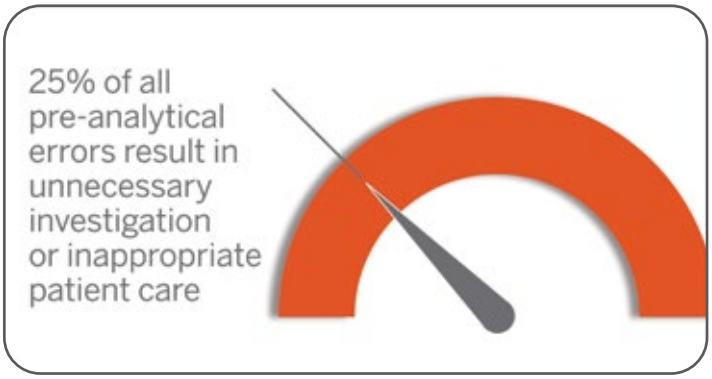
Pre- and post-analytical errors, which occur before and after the laboratory has processed a specimen, account for the remaining 90% of sample errors. These may include ordering the wrong test, improper sample collection, transport issues, unclear protocols, errors in test result reporting, interpretation, follow-up, sample storage, retesting capabilities or data storage.

Although these extra-analytical errors are beyond the jurisdiction of the clinical laboratory, the credibility of central laboratories is at stake. In order to reduce the likelihood of errors, central laboratories that compete in the arena of contract research organizations (CROs) must continue to expand their focus to what happens outside of the lab.

The importance of pre-analytical quality

Pre-analytical quality is imperative to ensuring accurate data throughout the clinical trial process, yet it is the most error-prone and generally least-controllable stage. Though errors may arise at any of the three stages, studies show that the pre-analytical phase accounts for 46-68.2% of errors observed during the total testing process due to the complexity of multi-step processes that occur before the specimen ever reaches the laboratory.

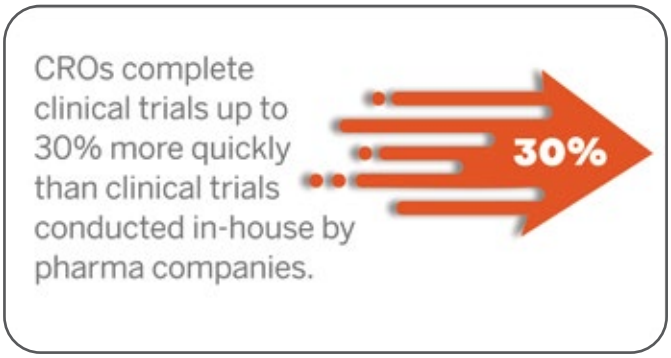
Additionally, studies show that approximately 25% of all pre-analytical errors result in unnecessary investigation or inappropriate patient care, thus resulting in additional financial burden and time delays in clinical trials. Furthermore, the cumulative risk of pre-analytical bias increases in parallel with the complexity of the study – lower for single-center studies and higher in multi-site studies that employ centralized testing. This is due to variability



in sample collection kits, instructions, specimen collection and transportation to and from sites and the testing facility.

Managing extra-analytical errors

Minimizing variability and controlling for extra-analytical errors are crucial factors in any study, particularly those with multiple sites. A 2016 report by ResearchandMarkets showed that CROs complete clinical trials up to 30% more quickly than clinical trials conducted in-house by pharma companies. In many cases, it is faster and more economical to outsource to a high-quality CRO partner than build the infrastructure and expertise in-house. However, with outsourcing comes the introduction of more variables and more opportunities for error.



The solution is an integrated CRO with unparalleled expertise in custom specimen collection kit manufacturing, training of site personnel, logistics and world-renowned central laboratory capabilities, which ultimately minimizes variability between collection and testing. Access to a real-time data platform allows visibility to test results and a central repository of information, which also decreases post-analytical errors. On-site biostorage removes yet another post-analytical variable. Trials conducted by CROs also see an estimated 10% improvement in predicting failure before initiating clinical trials, which could save upward of $100 million in costs associated with drug development.

To reduce the likelihood of pre- and post-analytical errors in clinical trials, consider contracting with one preferred partner with an integrated-model to ensure the most accurate data possible and ultimately, save time and money.

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