When Good Data Goes Bad

Recently, the FDA published an article describing a notification it had issued to a contract research organization (CRO). The notification required certain bioequivalence studies to be repeated based on improper data collection and analysis processes. Bioequivalence studies, often conducted to bring generic drugs to market, establish that the generic drug has the same 'effect' as the original drug. Obviously, these are critical trials, as they also establish the safety profile of the generic compound.

The consequence of this notification has been quite substantial. It has been recommended that a number of generic drugs be removed from the market until accurate data is collected by repeating these trials, incurring significant, additional expense and impacting sales.

According to PulseToday.com, "European Medicines Agency (EMA) advisors said bioequivalence studies carried out on the drugs at Semler Research Centre in Bangalore were 'flawed' and 'cannot be relied on...The EMA advisors concluded 'the studies conducted at Semler cannot be accepted in marketing authorization applications in the European Union' and, therefore, 'no medicines can be approved on the basis of these studies'."

So what went wrong?

Over the last decade organizations have had to become increasingly more stringent on their ability to collect and manage clinical trial data. This has primarily been driven by the 21 CFR Part 11, GCP and GAMP regulations which describe methods and processes that need to be put in place to ensure that only authorized individuals have access to trial data and that adequate controls exist to prevent modification to data

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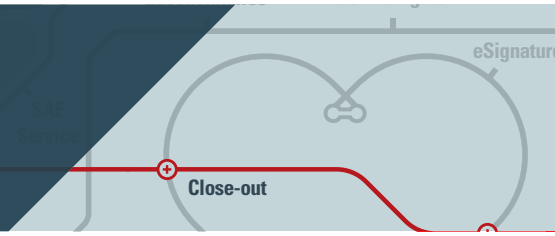
Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.



without appropriate controls. Clearly, at one CRO using spreadsheets to manage laboratory data, this method was insufficient. There was clear evidence to show that by using spreadsheets to store and manage lab data, as well as scope existing data for new errors, the CRO in question had manipulated data to create false results. While spreadsheets may have been acceptable in the past, they are simply no longer viewed as secure and compliant.

Fixing the problem

In this day and age, there is no reason to rely on spreadsheet and off-line data management. Today, good trial data collection and management can leverage advanced technology, built specifically for clinical research. With these data management solutions, pharma companies get a trustworthy, single source of truth for all trial data that they can easily access, in real time, to know immediately when something is going wrong with a trial.

In addition to providing comprehensive security and audit trails to avoid the kind of situation described above, these advanced platforms offer a unified and centralized data management environment where data from any source can be collected, cleaned, and organized for real-time use.

In addition to helping study teams avoid costly delays, this kind of modern data management platform can accelerate study set up, improve data quality, provide better regulatory compliance, and offer more informed decision making, as well as save time and money by automating trial data processes.

How does your clinical trial data collection and management platform measure up?

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generic drugs to be withdrawn in UK over quality concerns

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