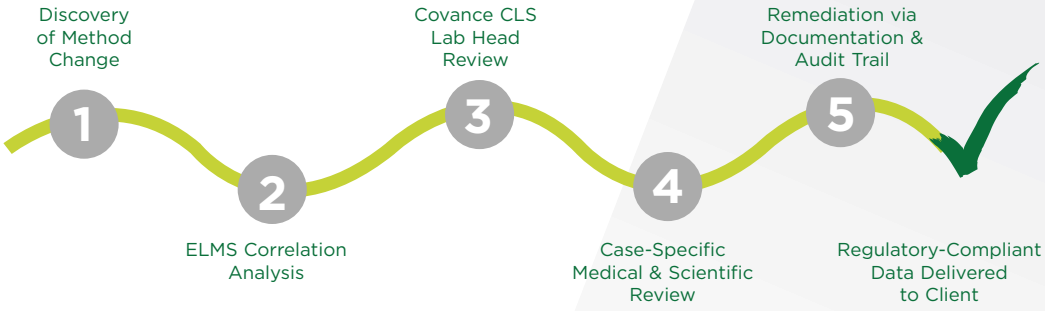
DATA INTEGRITY AND COMPLIANCE THROUGH PROACTIVE, COLLABORATIVE APPROACH

Acetaminophen Assay Change Management

As the percentage of clinical trial testing performed by external labs gradually increased, Covance anticipated sponsors' needs for more rigorous quality management and performance monitoring and, to this end, launched new Expanded Laboratory Management Solutions (ELMS) in September 2013. On one occasion, ELMS detected a change in the reporting range used by an external laboratory performing acetaminophen testing for a series of studies. Covance Central Laboratory Services (CLS) worked closely with the external lab to manage potential quality implications.



Understanding the Challenge

- Change of methodology and instrumentation by the external lab, resulting in change in lower limit therapeutic reporting range from < 10 µg/mL to < 3 µg/mL
- Lack of notification to Covance CLS, potentially compromising client's ongoing study results
- Need to verify external lab's data correlation claims and to assess potential correction factors, to safeguard data consistency
- Potential regulatory risks during audit and at submission

Proactive Expertise and Full Accountability for Client's Success

To mitigate potential doubts later in the study, upon discovering the change in the reporting range, Covance's ELMS immediately requested validation and correlation data from the external lab for expert Covance CLS scientific review.

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ELMS reviewed the data and leveraged CLS's expertise by requesting calculation of the correlation data between assays using their correlation analysis software. This would confirm whether the lab data really correlated with the previous instrumentation and method or whether it required any correction factors. Results indicated that the data correlation was adequate for diagnostic patient testing but did not meet the more stringent requirements of clinical trial testing. To obtain even more insights, a multi-functional team of medical, scientific and quality experts, headed by the CLS director, then investigated potential implications for the study. They concluded that the testing was used in such a way that the change to a more sensitive lower level of detection in therapeutic ranges did not have a material effect on any results nor, consequently, affect overall data quality.

In the end, by proactively identifying, documenting and creating an audit trail for the methodology changes, Covance delivered a regulatory-compliant data package. We also protected the sponsor from the uncertainty that would have arisen if the validity of the correlation data had been questioned during an audit. Between ELMS proactively bringing correlation issues to light and CLS investing approximately 30 hours in specialist reviews, our collaborative approach saved the client's time and internal resources and demonstrated our accountability to the client's data integrity and ultimate study success.

Managing methodology changes can be challenging at the best of times. When dealing with assays, data integrity is at stake. With Covance as your testing partner, you will discover new insights and solutions that transform your results into timely, regulation-compliant data packages.

Learn more about how ELMS can help you reduce your external lab management costs at **www.covance.com/elms**

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 **Asia Pacific** + 800.6568.3000

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