PRECISION-DRIVEN REVIEWS DELIVER FDA-COMPLIANT RESULTS AND SAVE TIME

Change Management for Proprietary Assays

Occasionally, Covance Central Laboratory Services (CLS) calls upon external labs for help with either rarely performed or proprietary assays. In this case, we had to send a proprietary hepatitis marker assay, used in screening trial patients, to the only referral lab in the US that can currently handle it. The lab informed us that there was a change in methodology. In order to ensure data consistency in ongoing client trials, Covance Expanded Laboratory Management Solutions (ELMS) requested validation and correlation data from the external lab.

Understanding the Challenge

- Covance medical and scientific directors identified inconsistencies in data provided by the external lab
- Further investigations revealed that, unbeknownst to Covance, an intermediate method had been used briefly, showing poor correlation with the previous one
- Although acceptable for routine testing, this method would not stand up to more stringent clinical testing requirements and would potentially invalidate the entire clinical trial
- As the assay was to be used in screening trial patients, any error in data could potentially jeopardize patients' safety

Responsiveness and Proactive Audits Lead to Precision Solutions

With experience of over 550 assays, we knew that any questionable result could have led to incorrect screening decisions. To check this out, leveraging the insights gained from the initial review into the validation and correlation reports, we proactively reviewed all data from patients screened using the intermediate assay. As this assay had only been performed for a short period of time, only one sponsor's data required corrective action. We quickly notified the sponsor of the situation and kept them informed while we were implementing remedial actions.

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The first step was to create a rigorous documentation trail, relating patients to samples and results. After thorough review, we were able to confirm that no patient had been put at risk during the brief period when this assay was performed. Because the audit trail clearly identified which assay had been used to screen each patient, and we also documented all method changes, we succeeded in restoring the integrity of the data package: with a new reliable, high-precision assay, enrollment could now proceed safely.

In the end, by relentlessly reviewing and documenting trails and changes, Covance saved the client approximately 50 hours and delivered a high-quality, regulatory-compliant data package that would pass any audit and lead to a smoother, faster submission.

Proprietary assays can prove complex to manage, especially when methodology changes. Working with Covance, you will be backed by experience and focus on delivering precision and reliable assays, no matter which lab performs the assay.

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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