PHARMICA CONSULTING

Get Better Regulatory

## The Challenge

A global biopharma company had recently received a 483 for not properly overseeing the collection of essential study documents, which was being conducted by their CROs. Although they outsourced 100% of their clinical trials, they lacked the processes for internally monitoring the collection process and ensuring all documents were complete and accurate.

## How Pharmica Helped

Pharmica held a series of workshops to map out the current processes and evaluated the tools the sponsor used to manage clinical trials and interact with their CROs. We helped develop new procedures and policies around collecting and reviewing the essential documents throughout trials, rather than their previous process of trying to reconcile everything at the end of the trial. In addition, we leveraged an existing platform already being used by the CROs and study teams, to build document staging areas with workflows that allowed the sponsor to track, review, and digitally approve documents in real time.

## Lasting Results & Relationships

Pharmica designed and successfully implemented this new solution for our client, enabling them respond to the FDA with their corrective action plan and then implement the plan quickly. The client has since expanded the use of this solution to include other activities and now has increased their awareness of the status of their studies, as well as improved the oversight of their CROs' performance.

As BioPharma moves further into a multi-sourced model, vendor oversight is more critical than ever. Sponsors must continually review and improve their processes in order to adapt to the rapidly changing landscape and evolving regulations. Monitoring compliance is no longer sufficient. Pharmica has been helping sponsors work better with their vendors for years by helping them integrate processes which trust but verify and highlight issues before they become problems.

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