ACTIONABLE CONSENT DATA HELPS CLIENT SAVE AN ESTIMATED $100M

No-Go Decision Achieved in 5 Days Before Initiating Phase III Trials

A large pharmaceutical company's clinical development team was tasked with evaluating the impact of a safety finding on their early stage Alzheimer's disease drug development program for a promising compound progressing through Phase II trials. Patients throughout Phase I and Phase II trials had a skin reaction reported as a severe adverse event (SAE) that was considered to be market-limiting for the compound.

The company had partnered with Covance to manage informed consent and specimen tracking for the program. Informed consent was negotiated, codified and linked to all specimens in GlobalCODE®. Specimen collection was tracked in real time. Working with the GlobalCODE platform, the company was able to ensure that there would be broad consent for additional testing of patient specimens as needed.

Understanding the Challenge

- During Phase I and Phase II trials, the client's promising early stage Alzheimer's drug was linked to a severe skin reaction among some participants.
- In order to determine if there was a predictive marker, in particular a specific genetic association with the affected patients, the client needed to perform additional testing outside the original scope on the trial specimens.
- The team would need to execute testing quickly and evaluate data prior to the scheduled Phase III initiation. They needed specimens from all patients with the SAE, consent information in real-time and to locate, ship and analyze specimens within a five-day decision window.
- Speed was critical because the client was only three months out from incurring the expense of a Phase III trial with a compound that would potentially have limited commercial uptake.

Rapid Determination of Genetic Association

Because of the SAE, the team needed to investigate whether there was any specific genetic association among the patients who experienced it that would predict the prevalence of the rash in the target population. The results could indicate that the drug was unsuitable for regulatory approval or would have high commercial risk. In this case, it would not advance to a Phase III trial.

In order to perform this additional genetic testing, the client needed to quickly verify which patients had specimens with corresponding consent for genetic analysis that was now needed. They needed to know where those specimens were and had to initiate analysis for a data result return within 5 business days.

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Ready Access to Critical Consent Information

Fortunately, the company quickly determined they had sufficient specimens with consent to perform the required genomic testing.

The client utilized GlobalCODE® to find this information and decide to proceed with analysis. GlobalCODE® gives clients access to live specimen data and provides management of codified informed consent and material transfer agreements. In GlobalCODE®, qualified specimens with appropriate consent can be instantly identified and used without delay. In this instance, GlobalCODE® enabled the client to quickly access critical information confirming authorization to perform additional testing on specimens.

If the client managed the informed consent documentation in the traditional way, the site approved consent forms and electronic case report form informed consent collector data would need to be pulled manually from the Trial Master File or from the site (if incorrectly filed) and reviewed. These consent forms are often updated at the investigator site level and even throughout the life of the trial. Performing a manual review of this magnitude would have delayed the initiation of the needed genomic testing by weeks or months and postponed the critical decision on whether to proceed with the Phase III trial.

Timely Decision-Making Enables Rapid Pivot and Saves Money

Using GlobalCODE® to quickly determine patient eligibility for additional testing, the client was able to launch the genetic association study. The genetic association study found an association with an HLA marker and the client was able to act on this data within 5 days, instead of months. The client made the decision to discontinue trials on the initial compound and instead pivoted to a back-up compound that did not have the side effect of a rash. This decision saved an estimated $100 million, which would have been spent on a Phase III trial that would have had a low probability of success before it even began.

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CSCLS019-1216

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