MEETING AN AGGRESSIVE TIMELINE IN SUPPORT OF A COMPANION DIAGNOSTIC IN WOMEN'S HEALTH

A Case Study: The First Non-Oncology Companion Diagnostic to Receive CE Marking

A pharmaceutical partner was developing a new treatment for women undergoing in vitro fertilization. Initially, the company had not included a companion diagnostic (CDx) in its clinical strategy, but as the clinical program progressed, it became clear that such a test would be necessary to seek regulatory approval. As the start of the Phase III trial was rapidly approaching, the company needed to fast-track the CDx program and looked to Covance to help meet the accelerated timeline for the pivotal clinical trial needed to support the co-development of the pharmaceutical agent and its accompanying diagnostic.

Understanding the Challenge

- Regulatory approval required the addition of a CDx strategy to personalize the dosing of the therapeutic agent.
- The diagnostic needed to be deployed within the network of central laboratories supporting the clinical trial in a significantly shortened timeframe to meet the first patient visit deadline for the pivotal Phase III trial.

Accelerated Assay Integration into a Late-Stage Trial

Covance Central Laboratory Services (Covance CLS) was engaged by the sponsor based in part on the close partnership between Covance and the diagnostic company developing the assay. As the sponsor had not initially planned to include a CDx strategy within its clinical program, the trial was redesigned and the laboratory infrastructure supporting the trial (patient specific collection kits, clinical database, etc.) was quickly amended allowing on-time commencement of patient screening.

Upon receiving the green light from the pharmaceutical sponsor, Covance CLS assigned a principal investigator for the study, supported by a cross-functional team to complete the clinical laboratory improvement amendments (CLIA) steps required to make the CDx assay clinical trial ready.

The test was initially deployed at one site in Geneva and subsequently expanded to other sites within the Covance global central laboratory network. The sponsor drew upon the extensive global logistics capabilities of Covance – whose dedicated regional personnel oversee the shipment of more than 4.6 million kits per year – to support the expanded global scope.

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Throughout the engagement, the Covance CLS diagnostic development services team hosted regularly scheduled calls with the sponsor and their diagnostic development partner to ensure alignment on key deliverables, providing the assurance of the highest level of study quality.

Value for the Client

With a Phase III trial quickly approaching and an unforeseen regulatory requirement of a CDx, the pharmaceutical company needed a partner that had scientific expertise and experience, specifically with the testing platform on which the assay was to be run, to avoid a delay in the start of the trial. Both the drug trial and the trial of its accompanying diagnostic progressed to a successful conclusion and the CDx assay became the first non-oncology CDx to receive CE marking.

As diagnostic supported precision medicine – in this case providing a personalized dose of the therapeutic agent – continues to expand in indications beyond oncology, Covance offers the specialized biomarker and CDx expertise required to help clients achieve co-development success.

Learn more about our
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