

END-TO-END DRUG & DIAGNOSTIC DEVELOPMENT SUPPORT FOR A NEW IMMUNO-ONCOLOGY AGENT: A CASE STUDY

Immuno-oncology drug development is inherently complex and requires special considerations across the entire spectrum, from preclinical to commercial support for the approved product. In this example, a prominent pharmaceutical company was developing an innovative new programmed death receptor-1 (PD-1)-blocking antibody indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC). This company selected Covance / LabCorp for support at multiple junctures—from manufacturing to biomarker evaluation to market access—to enable a faster and more effective launch.

Key Highlights of This Case Study:

- ▶ Speed to market was crucial—rival companies were pursuing the same or similar indications with therapies having a similar mechanism of action, creating deadline pressure without compromising trial success.
- ▶ The molecule required the co-development of a diagnostic laboratory assay, which requires a distinct set of capabilities and CRO / diagnostic company collaboration.

The Common Denominator

Multiple functions touch the drug development path. At Covance, our relationship with LabCorp gives us a unique capability to perform end-to-end services to support trials, starting as early as nonclinical work. In this case, our diverse early development services group—including BioPharm CMC—was engaged to assist in the manufacture and qualification of drug lots that went out to trial use.

Moving from Early Development to Central Laboratory services, Covance provided biomarker evaluation to enroll patients in pivotal clinical trials, enabling patient stratification and selection for trial participation which were critical to the therapies' approval. In addition work was done with an *in vitro* diagnostic company in the co-development of the diagnostic laboratory assay, so that it could be available at the same time as the therapy. This was facilitated through the extensive experience LabCorp has in supporting such test development and then commercially launching the test to coincide with the drug's launch.

The immunotherapeutic launched with great success for patients, but still encountered some market access challenges. Its proposed buy-and-bill model—along with high product costs—required careful understanding and communication about payer policy and coding. Covance Market Access was selected to provide post-launch commercial support—specifically a robust reimbursement strategy to: 1) fend off a rival's encroachment with a similar oncology product; 2) handle access-related issues unique to each oncology provider to facilitate more efficient reimbursement and build stronger provider relationships; and 3) improve overall market access in an increasingly competitive space.

Covance's reimbursement team educated healthcare providers on the client's access services so that they could easily obtain billing and coding support, co-pay assistance and handle underpaid or denied claims. By providing crucial insights, maintaining provider relationships and quickly responding to case-specific concerns, Covance was recognized as an integral part of the client's oncology field team that helped strengthen market presence.

Lastly, for post-approval, Covance CMC in Harrogate (UK) was retained for release and stability testing to verify quality of the manufactured product for its intended audience.

Value to the Client

Most of the FDA-approved diagnostics used to guide therapy decisions are primarily for oncology indications. In addition, most oncology drug development initiatives are biomarker-driven. With so many of these new therapeutics earning a Breakthrough Designation and/or fast-track approval, there can be a significant benefit to having a single partner efficiently support multiple steps in the drug development and diagnostic co-development process. This consolidation of service outsourcing could result in a higher probability of success and accelerated speed to market.

In immuno-oncology, a variety of biomarkers and corresponding assays are being considered to help assess the efficacy of a therapeutic approach, and these include a variety of proteomic and genomic approaches that require specific expertise. As this vibrant area of research continues to expand the options for oncology treatments, Covance's combination of highly specialized expertise and comprehensive end-to-end drug development enables sponsors to better inform patient decision-making and advance the field of personalized medicine.

**Covance and LabCorp
have supported more than
75% of all FDA-approved
diagnostic assays included
in drug labels, involving
both companion and
complementary designations.**

Learn more about our drug development solutions at www.covance.com

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

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