Navigating complexities in ADC development with specialized global laboratory support and scientific expertise

A global biopharmaceutical client developing a pipeline of complex antibody-drug conjugates (ADCs) needed a reliable global lab partner. Given the range of cancer applications and the challenges involved in optimizing ADC components and characterizing these multifaceted biopharmaceuticals, the client sought comprehensive lab services and scientific expertise to support their clinical trials through commercialization.

Multifaceted challenges with the client's ADC programs

ADCs are a relatively new domain and continue to evolve across multiple generations. ADCs contain monoclonal antibodies (mAbs) linked to highly cytotoxic payloads via chemical linkers, creating intricate drug structures. The antigen target, mAb properties, linker stability and payload potency must be carefully balanced to create an effective ADC. These challenges pose significant hurdles in exploring the bioanalytical mechanisms of ADCs.

With clinical studies across the globe, the client needed consistent and combinable clinical trial testing data and efficient sample management across sites. Additionally, the complexity of the clinical studies was amplified as the client was pursuing companion diagnostic (CDx) development. They needed an experienced laboratory partner with scientific expertise across central laboratory support, bioanalysis (BioA) and CDx to tackle these challenges and navigate ADC complexity.

KEY TAKEAWAYS

- Holistic solutions including central lab, bioanalytical and companion diagnostic (CDx) services enabled data consistency and combinability
- Scientific experience in CDx development added significant benefit in antibody-drug conjugate (ADC) development
- Reliable, high-quality data built trust and facilitated regulatory approvals
- Successful partnerships led to stable and expanded long-term collaborations

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Delivering global and holistic laboratory solutions

With a global laboratory network and seamless integration of services, Labcorp was able to provide comprehensive and connected solutions tailored to the client's needs. With in-depth experience supporting the client's ADC trials spanning each phase of clinical trials, Labcorp provided holistic services to deliver:

Global central lab support

Safety testing, genomics, anatomic pathology/ histology for target expression, special monitoring, global monitoring and sample management services, among others

Comprehensive BioA support

Dedicated project leadership to implement the detection of small molecule toxins (payload), total antibody (conjugated antibody and unconjugated antibody), conjugated antibody (ADC), anti-drug antibodies (ADAs) and cell-based neutralizing antibodies (NAbs), among others

Companion diagnostic (CDx) services

Experienced pathologists contributed to the speed and accuracy of CDx assay testing; the powerful capabilities of Labcorp's anatomic pathology and histology lab enabled efficient testing support in identifying the targeted patient population and achieving significant increases in the number of patients who can benefit from this ADC

Reliable, high-quality data

Long-term data traceability due to seamless coordination; facilitated regulatory approvals in multiple regions, including the United States, Europe, Japan, China and others

Forging a long-term partnership with the client

By providing holistic support through seamless coordination across the Labcorp enterprise (including central lab, BioA, CDx and other teams), Labcorp was able to support the client in making efficient, science-driven decisions through various stages of their clinical studies. Labcorp enabled the client to achieve their study goals and receive regulatory approvals from the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA), the National Medical Products Administration (NMPA) and other regulatory authorities. Labcorp's unmatched global scale coupled with our laboratory footprint, scientific expertise and reliable data helped build the client's confidence in us as a trusted partner.

Since supporting their first ADC clinical study several years ago, Labcorp has supported the client on their 16 ADC clinical trials, developing a continued partnership with the client. Moreover, given Labcorp's strong capabilities in specialty biomarkers, the client's biomarker team has regarded Labcorp highly as a partner of choice. As their global laboratory services partner, Labcorp continues to facilitate the advancement of the client's ADC pipeline, bringing timely support to this client.

Your proven ADC laboratory partner of choice

In addition to this client, through our partnerships with industry-leading pharma companies, Labcorp has established a strong track record in supporting 13 of the 15 (87%) FDA-approved ADCs in the market. Currently, Labcorp is supporting 16 of the 21 (76%) mid- to late-stage clinical trial ADCs in development for these clients. Working across disciplines while offering central laboratory, BioA, CDx and other services, Labcorp serves as a single partner bringing convenience to clients and providing long-term traceable data across trials at various stages.

Need assistance advancing your ADC drug development program?

Labcorp Biopharma Laboratory Services can help. Please visit our website to submit a contact request or contact your local sales associate for further information.

Visit us at
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