Empowering development and enabling seamless assay transfer

Real-world case studies with
Labcorp Translational Biomarker Solutions

Exploratory and preclinical studies often require rapid development of assays to inform key development decisions. Working in a flexible environment is key to creating novel immunoassays or providing cellular-based analysis, but researchers must also think ahead to proactively plan for a transition to CAP/CLIA or GxP facility for qualification, method validation and implementation to support the requirements of a clinical trial.

These case studies showcase a number of challenging, high-profile projects supported by the Labcorp Translational Biomarker Solutions (Labcorp TBS) team.

In just 12 weeks

the team was able to build a complex custom assay, pull together the various antibodies from different sources and transfer the assay to a regulated environment to support clinical trials.

Case study 1
Creating a biomarker assay for hemophilia A patients

A Labcorp laboratory needed support to develop a complex enzyme-linked immunosorbent assay (ELISA) to measure the B-domain deleted recombinant blood coagulation factor VIII (BDDrFVIII). They wanted to determine if this assay could effectively monitor hemophilia A patients in a clinical trial for a new gene-transfer therapy to ensure the treatment did not pose an increased risk for thrombosis. The laboratory contacted Labcorp TBS to support this complex challenge.

The Labcorp TBS solution

1. **Examined** different antibodies and permutation combinations to develop a prototype ELISA
2. **Handled** challenges to overcome interference from other proteins present in blood samples
3. **Tested** the prototype and ultimately qualified the assay
4. **Aligned** the method validation and transferred the assay to the Labcorp laboratory

The results

Labcorp TBS supported the Labcorp laboratory in:

- Specifically, and reliably, measuring the analyte of interest after transferring to a regulated testing laboratory setting
- Supporting a successful study for the sponsor with the B-domain deleted FVIII antigen assay
- Using the assay to support additional clinical trials for hemophilia

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Demonstrated flexibility

Get the most out of samples in an exploratory environment, helping sponsors build a greater body of research knowledge and inform their future initiatives.

Case study 2
Repurposing an assay to analyze banked biosamples

The Labcorp TBS team helped a leading pharmaceutical company develop a proinflammatory assay that detects 10 biomarkers to support drug discovery and diagnostic development in immune and autoimmune disorders. More recently, as the prevalence of biologics and immuno-oncology treatments increased, the sponsor has used this platform to evaluate adverse events (AEs) in clinical trials at Labcorp Central Laboratory Services, such as the cytokine release syndrome (CRS). This same proinflammatory biomarker assay has also shown value for analyzing banked samples in retrospective studies.

The Labcorp TBS solution

1. **Developed** a proinflammatory assay to measure an exploratory endpoint
2. **Tested** batches in defined intervals to help determine if specific biomarkers were correlated with therapeutic hypothesis and/or AEs
3. **Engaged** with Labcorp Central Laboratory Services to offer a combinable solution to support movement of assay between exploratory and regulated environments

The results

- Compared the results to the same assay running in Labcorp Central Laboratory Services to correlate the clinical trial data and run further analyses
- Enabled the sponsor with flexibility to engage the right assay, in the right environment for the right purpose with a unified Labcorp laboratory solution
- Continued to support additional clinical study protocols in the exploratory environment

Case study 3
Detecting FLT3 mutation to support a lymphoma study

A large pharmaceutical company wanted to monitor drug efficacy and stratify clinical trials based on patient response. They needed an assay to detect FLT3 gene mutations, which are often found in patients with lymphoma or leukemia. At the time, no similar assay existed in the industry and they wanted Labcorp TBS to serve as an extension of their scientific team.

The Labcorp TBS solution

1. **Researched** primary literature to find related academic examples
2. **Built** the FLT3 assay in an exploratory environment and showed its utility
3. **Worked closely** with the sponsor's scientists to meet expectations

The results

- Moved quickly into a regulatory environment after the sponsor recognized the larger value of the assay in clinical trials

Overcame a complex challenge

and aggressive timeline by building an assay from scratch and then quickly scaling it for incorporation in clinical testing.

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