

# BIOTECH INNOVATION: A NEW COVANCE CENTRAL LABORATORY SOLUTION FOR TODAY'S COMPLEX CLINICAL TRIAL TESTING



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With more than 4,000 biotech firms having active molecules in their pipelines and an increasing share of new drug approvals, it is clear that biotechs are driving innovation throughout the entire drug development continuum. “For the first time in 2018, more than half of the novel new drug approvals by the FDA were from biotech companies,” notes Erin Bennett, executive director of business development for central laboratory services at Covance. “Biotech funding is at an all-time high and it doesn’t appear to be slowing down. Because of that, biotechs are increasingly bringing drugs to market themselves rather than relying on acquisitions or out-licensing.”

Many of these novel therapies are rooted in precision medicine. Especially given the complexity of these therapies, biotechs expect a more collaborative and personalized development approach. This means working with a central lab that has a dedicated support team structured specifically with the needs of biotech ventures in mind.

“We’ve tailored our clinical trial testing solution to ensure biotech clients have a dedicated, experienced team that understands the intricacies of designing, maintaining, supervising, and managing trials that are increasingly complex,” says Mark Slette, director of global project management for central laboratory services at Covance.

Going beyond safety and efficacy testing, the biotech focus on complex indications within oncology and rare diseases means requirements often include biomarkers, genomic studies, and other esoteric analysis.

To navigate such complexity, Bennett says, “Biotechs are looking to collaborate with a lab that can bring them more insight, expand their scientific expertise, and help them manage multiple vendors because they may not have all of these capabilities or bandwidth in house.”

“They are also expecting that their clinical trial testing partner will help put all the pieces together,” Slette elaborates. That means managing samples in multiple labs as well as performing the testing. “A lab should have the assays, logistics, or network to manage this effectively. We’re able to bring these essentials into focus in a holistic way for our biotech clients.”

Sample tracking is one example. “As studies become more complex with multiple assays, biotechs have formed relationships with niche labs, biomarker labs, and academic labs,” Bennett says. “And since most of the data used in submission comes from laboratories, being able to track results consistently, regardless of where the test was conducted, is key to a timely and accurate submission.”

Slette, as a leader in global project management, knows what this takes. “Engaging immediately with the setup team in complex trial designs drives quality and efficiency,” he says, “and we have a vast global network — in North America, Europe, China, Japan, and Singapore — and industry-leading logistics capabilities to maintain the quality alongside delivery timelines.”

"All of our labs follow the same procedures, and use the same equipment, reagents, and software to reduce lab-to-lab variability. This ensures that consistency around the globe, reducing the risk of unnecessary delays and assuring globally combinable data," Bennett emphasizes.

## Tailored For Biotech

While delivering high quality results and meticulous project management to each of its clients is standard, the team also understands that biotech needs can sometimes differ from those of their large pharma counterparts. Covance biotech solutions are designed to meet those unique requirements. For example, Bennett says, "The interactions and engagement points can be different, so we flexibly adapt our approach to address the way biotechs prefer to work."

"Our project management teams understand the complexity of novel study design and are positioned to be agile, proactive, and responsive. They also have experience working with biotechs," Slette says. "They're focused on customizing solutions from beginning to end — from identifying biomarkers and companion diagnostics and performing esoteric testing to sample tracking and external lab management. Our teams approach projects in a consultative, collaborative fashion, which ultimately improves efficiency and quality," Slette continues.

## A Collaborative Approach

Throughout their program, clients get continuity. "A client engages early and often with a single point of contact to ensure the smooth management of every patient kit, sample and the resulting data," Slette says. "This single point of engagement can then tap into broader resourcing to make sure the right scientists, managers, and executives are involved on each aspect of the project," he explains. It also ensures that biotech clients can get comprehensive answers from one point of interaction if that's what they prefer. "Of course, we have some clients who prefer a governance model based upon scientist-to-scientist and executive-to-executive communication, and we can facilitate those connections, as well."

The solutions available through Covance are developed from a deep understanding of the specific requirements of biotechs and their preferred collaboration style — built from insights generated through working with more than 1,000 biotechs each year. Those engagements, along with scientific, operational, and logistics expertise — managing more than 5,600 trials in the past five years and supporting more than 70 percent of all FDA-approved drugs in 2018 — enable the Covance team to help biotechs deliver innovation with confidence.

Further, Covance biotech clients are able to streamline their clinical trial program by tapping into [the hub](#) of innovative solutions — clinical trial services, actionable data and analytics, and regulatory and commercial consulting — designed distinctly for nimble biotech firms.

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