



# Challenge

## Critical FDA milestones at risk due to slow vendors and rigid processes

Prior to contracting with Boca Bio, a global diagnostics company was in preparation for the market launch of 12 new blood tests for viral infections, including HIV, HBV, HCV, and HAV. The clinical program had been in process for 15 years and was launched in the United States in 2019. Each program consisted of multiple sequential phases, beginning with patient enrollment and concluding with the completion of comprehensive laboratory testing in advance of market entry. Having begun a review of resources in anticipation of the launch, a Clinical Affairs Senior Manager recognized that the high-lift process would require extensive vendor support. An external partnership would be essential during the sample collection and clinical validation phases.

The sponsor's clinical team required vendor services in several crucial areas, including:

- Sourcing and purchasing disease samples that were not readily available or in short supply
- Identifying and collecting samples from patients with signs or risk factors of the studied infections
- Conducting reliable laboratory testing to generate clinical trial data
- Storing and managing samples within required safety parameters

Infrastructure presented itself as a particular challenge. The team would require laboratories to be fully compliant with all federal regulations, including those related to sample storage and chain of custody. In early attempts to source vendors, the Senior Manager and their team faced several challenges.

- **Slow contracting:** Prolonged vendor negotiations delayed target start dates, eliminating essential schedule buffers. The Global Diagnostics Leader waited four to six months for new site preparation, with some vendor contracts taking the same amount of time to complete.
- **Poor communication:** Confirmed vendors often failed to respond to messages, forcing the internal team to wait up to 10 days for replies.
- **Focus on process, not results:** When circumstances required earlier deadlines, vendors were inflexible and adhered rigidly to the initial timelines. These issues added months to the project's lifespan.
- **Regulatory risk:** Crucially, when the FDA requested additional data post-submission, vendors were unable to meet deadlines, a failure that placed years of development work at risk.

# SOLUTION

## A PARTNER WITH THE EXPERTISE, SPEED, AND FLEXIBILITY THE PROGRAM REQUIRED

To prevent further risks to project goals, the global diagnostics leader developed stringent criteria for new partners. Clinical sites needed to be in locations with sufficient patient populations, given the infectious diseases being studied. In addition, laboratories required the necessary testing equipment or the capability to coordinate across facilities.

The sponsor required partners with the capacity to run assays efficiently and to adapt quickly to changing FDA requirements. The team made the decision to exclusively consider partners with knowledge of the therapies and infections under study.

## A PARTNER WITH THE EXPERTISE, SPEED, AND FLEXIBILITY THE PROGRAM REQUIRED

The global diagnostics company chose to partner with Boca Bio, which aligned with all required criteria. Boca Bio delivered value from day one by delivering rare infectious disease specimens from its biorepository. The availability of these otherwise elusive samples allowed the global diagnostics leader to move forward with research and testing.

Boca Bio continued to deliver value with support across the clinical development process, from prospectively collecting essential patient samples to delivering reliable laboratory data to assuming long-term storage and management of collected samples. Further, Boca Bio provided hands-on management to launch clinical trial sites and ensure smooth operations, maximizing trial success.

These accomplishments resulted in Boca Bio becoming the global diagnostics leader's preferred partner. The clinical affairs manager says, "Boca is our first thought when we need vendor support."



## TIMELY SAMPLE PROCUREMENT AND TESTING

Timeliness was a critical requirement for the diagnostics company, which operated under firm FDA deadlines. Requests for additional data proved to be particularly challenging to fulfill, as the non-negotiable deadlines required assays to move quickly toward completion.

"If we have to do additional work during a submission, those milestones don't move. If we miss them, we might be forced to withdraw — and that's catastrophic," the Clinical Affairs Senior Manager emphasized.

When the FDA requested additional testing, a competing vendor estimated that the process would take 12 weeks. Boca Bio completed the entire process, from receipt of samples to data delivery, in one week. This expeditious turnaround allowed the company to meet FDA-established deadlines and stay on track toward approval.

As the partnership proceeded, Boca Bio continued to exceed sample procurement and testing timeline expectations, delivering results weeks earlier than external vendors and the manufacturer's internal team.

## RAPID SITE ACTIVATION UNDER STRICT DEADLINES

In the majority of cases, the launch of a new clinical site requires a four- to six-month process. The vendor contracting process can be equally prolonged, sometimes doubling the time frame for site launch. These extended timeframes can jeopardize project completion goals and FDA commitments.

Any delays would require costly backup plans and force the company to onboard additional vendors. Having already committed to meeting the FDA's milestones, the company needed a vendor that could deliver. The partner would be required to expedite results without compromising quality or regulatory compliance.

In line with prior achievements, Boca Bio completed full site activation, including contract negotiation, Institutional Review Board (IRB) approval, staff training, and site activation, in only 2.5 months, approximately half the estimated time frame of many competing vendors.

"We asked [Boca Bio] to move a mountain last December, and they did. We ran everything in parallel to get the site ready by the first of the year. It was a successful maneuver," explains the Senior Manager of Clinical Affairs.



## ENTREPRENEURIAL SOLUTION-DRIVEN APPROACH

Prior to establishing its relationship with Boca Bio, the global diagnostics company had experienced procedural misalignment with multiple vendors. These process-bound providers followed stringent procedural guidelines with inflexible stepwise stages, regardless of any externally applied urgency or requests to expedite the process.

This operational rigidity led to unacceptable delays and an inadequate pace of response to outreach. Multiple vendors failed to respond to communications for one week or more. Cumulatively, these failures delayed the results of assays by several months.

These delays had potentially catastrophic consequences for the sponsor's infectious disease testing program, which inherently involved rapid turnarounds and presented complex challenges. These challenges required expedient solutions and demanded flexibility as the standard approach.

Default vendor processes proved to be in direct opposition to this requirement by deprioritizing speed in favor of operational predictability. Boca Bio distinguished itself with its notable departure from this approach.

Boca Bio met the sponsor's requirements for a flexible methodology, approaching challenges with a collaborative mindset and a commitment to resourceful thinking and problem-solving.

"The team at Boca is like my team—they don't wait when something needs to be done. Other vendors stick to their process, but that's not how we work."

The solution-oriented approach consistently delivered results and dramatically reduced delays. When a 22-sample daily throughput created a bottleneck in the 2,000-sample project, Boca Bio increased processing rates with the addition of employees scheduled in the evening.

Another such instance occurred when the FDA requested comparator data to facilitate validation. In contrast to competing providers, which had failed in similar situations to adapt procedures to conform to timelines, Boca Bio met the newly added requirement without hesitation. This proactive approach enabled delivery of the comparator results in one week, while competitors had quoted a startlingly long 12 weeks.

"What I appreciate most is Boca's entrepreneurial spirit. We can come to them with any problem, and they'll say, 'Let's figure this out. How can we make it happen faster?'"





# Results

## A SAFETY NET AGAINST TIMELINE SLIPPAGE, SUBMISSION WITHDRAWALS, AND COMPLIANCE GAPS

The sponsor's partnership with Boca Bio has facilitated numerous operational and budgetary improvements since the relationship's inception.

## EXPEDIENT FDA APPROVALS AND MARKET LAUNCH

The sponsor's clinical program requires timely responses to FDA requests for additional data. Each request requires adherence to a strict deadline, with any shortfalls potentially costing the sponsor years of effort and resources.

Our commitment to expedient results consistently prevents these crises and allows submissions to progress toward deadlines. In one instance, our approach reduced the proposed completion time for mission-critical FDA testing from 12 weeks to 1 week. As a result, the global diagnostics leader was able to introduce products to the market months sooner than expected. The expedited launch facilitated additional revenue and strengthened the sponsor's competitive position for its 12-assay infectious disease program.

## ELIMINATION OF SUBMISSION DELAYS AND BACKUP PLAN COSTS

When competing vendors proved consistently unresponsive, the diagnostics company experienced costly cascading delays. These delays required the sponsor to develop backup plans, which placed an additional burden on project budgets.

Boca Bio resolved these issues with an unwavering commitment to results and clear communication with the sponsor team. Our consistency enabled unimpeded progress toward the completion of the multi-phase, 15-year clinical program.

## INCREASED CONFIDENCE WHEN APPROACHING HIGH-STAKES PROJECTS

Consistent operational alignment and speed resulted in Boca Bio becoming the global diagnostic company's default partner. The stability of the relationship and the presence of mutual trust enabled the sponsor to invest fewer hours in identifying and vetting potential vendors. With this partnership in place, the global diagnostics leader possesses the resources and capacity to launch ambitious, expedited FDA projects.



BOCA BIO

# Thank you

At Boca Biologics, we are proud to partner with diagnostics leaders to solve complex clinical and regulatory challenges. This case study highlights our commitment to speed, flexibility, and execution when timelines are tight and stakes are high.

From rapid access to rare infectious disease specimens to accelerated site activation, compliant laboratory testing, and long-term biostorage, our team works as an extension of yours, adapting quickly to evolving FDA requirements and project demands.

We remain focused on one goal: helping our partners move critical programs forward with confidence, efficiency, and reliability, every step of the way.

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