# Achieve Cost-Efficiencies and Speed Data Delivery

## The benefits of combining bioanalytical and central laboratory services for clinical trials

Several challenges within the pharmaceutical industry are driving change. Sponsors are requiring higher throughput, forcing managers to do more with the same or fewer resources and causing a strain in scientific depth. This pressure on internal resources also increases as the complexities of therapeutic targets and technologies increase.

Therefore, sponsors are seeking faster turnaround times (TATs) from planning to study start, through to reports and transfer. But they are often not aware of the benefits that can be achieved by combining services. This lack of awareness has led to additional costs and operational inefficiencies, essentially negating the savings achieved in other areas.

### The business case for integrating testing services

A recent market research study analyzed the current needs of bioanalytical decision-makers from a wide range of pharmaceutical companies around the world. This study found that 70% of respondents cited *quality, capacity* and *efficiencies* as top factors influencing the selection of a clinical BioA laboratory partner.* Integrating Bioanalytical Services (BioA) with Central Laboratory Services (CLS) outsourcing can reduce development time by leveraging operational efficiency and available capacity. Quality data sources can also be integrated to inform decisions, leading to faster development of plan designs and clinical study protocols.

While increasing efficiency is an important need in clinical testing, combining of services does not yet seem to be a regular practice. Research shows that sponsors are combining clinical BioA with CLS only 14% of the time.

Large pharmaceutical companies are working with multiple BioA laboratories during a calendar year to conduct pharmacokinetic, pharmacodynamic and anti-drug antibody clinical testing. In the following two scenarios, we'll examine the cost of managing multiple BioA providers and the efficiencies of integrating clinical BioA and central laboratory testing.

### Typical solution is to use multiple laboratories

In this example, a large pharmaceutical company (sponsor) contracts with seven BioA laboratories for clinical testing. It conducts 50 clinical studies and processes 60,000 BioA samples per year with their central laboratory service provider. On average, 70% of these samples are distributed among the seven BioA laboratories.

In a typical outsourcing model, the sponsor starts by selecting their laboratory partners—using laboratory identification based on particular requirements outlined in the request for proposal process to determine feasibility, testing capabilities, general testing information and pricing for each clinical protocol. Next, labs are qualified and contracted, inclusive of a quality assurance audit and master services agreement. At this point, the average sponsor will have invested roughly $600,000/year in internal resource utilization to support management of multiple laboratory partners.

Following laboratory selection and contracting, the sponsor also works with each lab on setup and validation, inclusive of

**Labcorp Drug Development market research with 60 BioA decision-makers.*

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test specifications and study setup with the sponsor's project management team. Study execution, which includes activities such as sample transportation to each BioA laboratory, weekly reconciling of data, checks on TAT plus lab data integration, may cost the sponsor more than $1.2 million/year when utilizing multiple laboratories.

Additional required monitoring activities such as evaluating lab performance—including TAT and testing issues through monthly monitoring calls/emails—may cost the sponsor another $240,000/year.

The total cost of evaluation, setup and management of multiple laboratory vendors could be as high as $2 million/year.

## Efficiencies from combining BioA and CLS

Now let's examine where efficiencies can be gained when integrating clinical BioA and CLS testing using a single provider. To start, targeting a single outsourcing partner translates to less duplication of tasks during vendor qualification and contracting. In addition, having a single budget and multi-unit master services agreement that covers legal, business and operational terms, as well as a single invoice aligned with your milestones, also saves management time throughout a project.

Using this outsourcing model during setup and validation can also bring benefits. Following method development, the BioA and CLS teams can jointly discuss the risks of using sample information from the method development to set up the clinical database and kit design. When it is appropriate, the joint team can use the sample information from the method development for the BioA method validation to take place in parallel with the statement of work (SOW) approval and test kit design. This facilitates test kits being ready for production and shipping up to 35% earlier than would otherwise be possible waiting for validation to be complete prior to finalizing clinical database and kit design, ultimately resulting in samples being collected and tested sooner.

Additional streamlining can be seen in improved SOW design between BioA and CLS centralized in the CLS database, reducing systems limitations and future SOW amendments. A single partner for both BioA and CLS can also mean that clinical study protocol amendments can be handled directly through one internal process to expedite communication and implementation of the amendments within BioA. Additional communication efficiencies can be realized from using a single provider for both BioA and CLS, including: planning of shipments, addressing sample discrepancies and performing reconciliation activities.

Finally, a single partner for both BioA and CLS can mean that BioA data can be integrated directly into the CLS database, requiring only one data transfer specification and one set of reconciliation activities that covers both BioA and CLS simultaneously. This saves time and, ultimately, expense during the setup phase and requires fewer personnel hours for data lock.

## The bottom line

The business case for integrating clinical BioA and CLS testing is clear. Sponsors can gain strategic efficiencies in time and money—streamlining contract and budget management, increasing data delivery speed, reducing sample demographic discrepancies and eliminating lab-to-lab transfers. All together, the management cost of using multiple BioA laboratories can total more than $2 million/year. Coupling clinical BioA and CLS with a single provider can decrease the time it takes to ship kits, resulting in faster data lock and milestone achievement.

Beyond savings and efficiencies generated by combining your BioA and CLS, Labcorp Drug Development integrated services can provide competitive advantages through access to scientific expertise across the globe, guidance and insights on regulatory changes, high-quality results from the latest testing platforms and flexible solutions matched to sponsors' unique requirements.

If you face the challenge of trying to save cost in your operation, Labcorp Drug Development can help you reach your goals with game-changing efficiencies. Contact us to learn more about how your team can benefit from integrating your clinical BioA and CLS strategy.

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