PROTECT AND EXPEDITE YOUR CLINICAL TRIALS

Overcoming operational challenges

As a player in an increasingly regulated and competitive industry, your company faces serious operational challenges in bringing treatments to market. Delays in clinical trials – from initial patient enrollment to sample collection and analysis – could have a significant impact on your chances for commercial success. Speed matters; you cannot jeopardize the integrity of your samples, essential to delivering reliable, consistent test results. It is therefore critical that you find a partner who can anticipate and meet your operational needs and provide solutions to speed up your trials and deliver quality results you can act on.

Timely kit production empowers speedy enrollment

It is a well-known fact that missed patient enrollment milestones are one of the leading causes of clinical trial overruns, delaying the approval of potentially life-saving treatments and possibly costing you over $600,000 per day in lost revenues. You cannot start testing until the right test kits are ready on site. Making sure you have the right kits ready is the first step toward keeping your clinical trial on track.

You need a clinical testing partner that understands your site's priorities. With your needs in mind, and building on over 25 years of clinical trial experience, Covance has developed a series of unique automated processes to support you throughout your trial. It all starts with a central automated kit production facility, where we can produce over 20,000 customized sample collection kits per day. With a 97.9% on-time startup kit supply, your study site can meet enrollment milestones and become productive quickly, avoiding costly delays. Since investigators prefer our kits, they are more likely to recruit patients for your trial.

Sample stability solutions maximize data output and save money

We can ensure your kits are produced and delivered on time, but what happens to sample shipments? Time is of the essence. Your unique, time-specific and irreplaceable samples must arrive intact at the lab to be tested while still stable. If one single shipment is delayed, you stand to lose up to $25,000 just to replace those patients in the study. Every sample counts at this stage and you cannot be let down by slow operations.

Covance's central laboratory pre-analytical solutions feature automated box opening, requisition scanning and ambient sample sorting, all designed to speed your samples from receipt to testing. Combined with automated logistics, these solutions account for 99.1% of samples received within stability, giving you the opportunity to maximize your data output while minimizing your trial costs. In order to drive down your costs even further, our couriers use recyclable shipment containers which also help preserve our environment.

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Automated hematology labs deliver consistent results, faster

Now your samples are safe and ready to test, but the race does not stop here. You want combinable results quickly because the longer your blood sample sits in the lab, the less reliable your data output will be.

Covance's central lab facilities – strategically located to optimize specimen delivery – utilize unique automation capabilities for tube handling, data entry and cell morphology testing. These processes guarantee faster and less variable hematology results and can account for reductions of up to three hours in result turnaround time. As we generate 98.5% reportable results – the highest reported figure in the industry – working together we can help you get a higher return from fewer patients with more significant data, and potentially save up to $2 million per Phase III trial.

Superior logistics are essential. When safety matters, you cannot afford to waste time

The kits for your clinical trial need to arrive to the labs quickly. Your samples are always precious. They must remain stable for testing, but even more so when it comes to testing for safety. Even a few minutes count, and a few hours can make a significant difference to your DILI results. So, from the moment your kits reach us in the lab, you need to be sure that coordinated processes are in place to mitigate any potential errors. All the links in the chain – personnel, systems, suppliers – must execute flawlessly to meet your speed and stability requirements.

We know that you start work early. Dedicated shipment tracking processes and strong relationships with couriers enable us to deliver 99.9% courier performance and ensure that your kits reach the central labs early in the morning.

We understand that you are anxious to see your results. Once we have produced them, *you* can view them within 15 minutes from release in LabLink+ anywhere in the world, any time of day. By taking advantage of this feature, you can be informed of any safety risk the same day, and faster DILI answers will enhance your trial outcomes.

When you choose Covance, you are supported by a global team managing a unique mix of integrated automation and logistics solutions that speed up your clinical trial, safeguard your samples' integrity and inform your decisions with consistent, high quality results.

Contingency planning: how a proactive plan and courier partnerships can help your trial weather the storm

The success of your trial depends on data quality, but how can you be confident that your samples will remain stable when essential outside infrastructures are put at risk by extreme weather conditions? What can be done when roads and airports are closed and even referral labs have to shut down, leaving your samples stranded in transit? How can trials continue to operate when power outages bring all transportation and testing services to a halt?

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In October 2012, Superstorm Sandy struck the East Coast of the United States and Covance's logistics experts and systems were put to the test, facing fierce challenges. Inbound sample shipments – from investigator sites to Covance's Indianapolis lab – could be delayed. Samples in transit from our central labs to referral labs would require special management, while those already at their destination would need to be kept stable if the referral labs were to close. The team's task was to salvage potentially more than 1,100 clinical trial protocols from more than 160 sponsors in the affected areas.

As soon as the storm path was predicted, the Covance logistics team began to proactively monitor it and activate contingency plans. Thanks to the strong protocol-level training they had received from Covance's Investigator Support teams, investigator sites felt confident enough to re-schedule visits, while maintaining protocol compliance and maximum sample stability. Working closely with international and domestic courier networks, we monitored their operations in relation to specific site locations to maximize sample deliveries within stability. Once investigator sites themselves were forced to shut down, the focus automatically changed to samples in transit. By constantly liaising with couriers, we were able to divert shipments to different airports and even ensure uninterrupted dry ice supply for those samples that were stuck at airports.

Throughout the crisis, the risks to clients' clinical trials were minimized. Patient safety was never compromised, since >99.2% of shipments from the affected area were delivered to the lab within stability. The figure reached 100% for sample management shipments, allowing for the delivery of the high data consistency critical to our sponsors' success.

Through a mix of proactive planning and risk management, relentless operational performance, robust global infrastructure and courier relationships, Covance safeguarded shipments worth over $7M to our clients during the Superstorm Sandy crisis.

Fortunately, hurricanes of such severity as Sandy do not strike every year. When you choose a partner for your unique clinical trial, you need to know that, however smoothly your operations may run on a daily basis, they can still perform under stress. You strive to make your trials more productive and cost-effective. You know that every minute counts – in financial and life-saving terms – and therefore you must be able to rely on consistent global results quickly.

With Covance as your clinical testing partner, you will discover how unique automation capabilities, high-performance logistics and dedicated team efforts can not only speed up repetitive lab processes, but also lead to more consistent and faster results that enhance your trial outcomes. Together, we can capitalize on the operational excellence we have built to let you focus on drug development and bring your medicines to market sooner.

Learn more about our drug development solutions at **www.covance.com**

Covance Inc., headquartered in Princeton, NJ, is the drug development business of Laboratory Corporation of America® Holdings (LabCorp®). Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

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