REDUCE TURNAROUND TIME, MAXIMIZE SUCCESS

End-to-end anatomic pathology and histology solutions and the power of biomarkers combine to reduce turnaround time for global oncology clinical trials

Drug development challenges exist on multiple fronts: finding enough patients to recruit for global clinical trials; operating under greater regulatory and commercial pressures; delivering against more stringent expectations from healthcare providers and patients. How do successful companies navigate through this barrage of demands to achieve a quality submission?

One factor remains constant: testing, which drives drug development. Sponsors will always need high-quality specimens to provide all the clinical data necessary for a new drug application. Therefore, you must preserve specimen integrity through all stages. You should also strive to minimize the variations that would inevitably occur when testing at different locations so that you can provide consistent data and results globally.

In response to these requirements, the trend toward centralized testing has gathered pace. For example, oncology trials are now frequently being concentrated in a single, central laboratory, rather than carried out in local labs. Therapeutic and clinical specialists perform tests, analyses and diagnoses, supported by advanced technology and global logistics. Collaborating with partners as necessary, a central laboratory can offer you a broader range of solutions, from integrated anatomic pathology and histology (APH) services to the discovery and exploitation of biomarkers for more targeted treatments, making the global submission more efficient and productive.

Integrated APH services in a central lab: safety, consistency, precision, more targeted therapies

With five central laboratories—in Indianapolis, Geneva, Singapore, Shanghai and Tokyo—and significant experience in running global trials, Covance uses the same SOPs, processes and data analysis tools in all labs, to deliver greater consistency and integrated solutions that support you throughout your clinical trials.

The primary benefit of a central lab is to eliminate as much variability as possible within the testing environment. It is counter-productive to have different labs choosing different types of specimens to test on and coming up with different results, at various stages. You need ‘combinable data.’
The end product is that a result from a central laboratory is similar, regardless of the global location where it originated and the lab location where it is tested.

Standardizing the entire collection and specimen management process is critical: using a uniform collection kit specific to each trial and containing details of all articles necessary for collection and return of the sample, ensures that irreplaceable tissue biopsies arrive at the lab intact; allocating and tracking patient tissue blocks through each phase. All this makes the investigator’s and site’s jobs much easier. Following Covance’s optimized collection procedures, sites can handle samples with confidence, start enrolling patients for trials faster, reduce redraws and generate reliable data.

Covance central labs give you access to APH skills rarely available in a local lab. Selecting the right piece of tissue to test is critical to a successful oncology trial. Tools routinely used in our central labs help personnel identify optimal target samples. Documents, personalized to each study, provide further direction to investigators for identifying blocks containing the target specimen or not, thus improving study yields.

Despite these advances, sending samples across the world is not always practical. However, with digital imaging, we can now perform “target enrichment” in the lab. This proves particularly valuable in oncology trials where a biopsy of a sample may contain 100% of the target lesion, whereas a blood sample represents only a small portion of the body. Anatomic pathology specimens are unique, because unlike blood or urine samples that can be redone, biopsies cannot easily be re-collected.

High-resolution imaging and a network of web-based systems enable pathologists to evaluate samples from anywhere in the world. More specifically, the technology allows the lab to create an image of a stained slide, send it to a pathologist who can then identify and mark the target tissue and send it back to the lab for cutting. A scraping of this tissue is finally sent to the Covance genomics department for gene mutation testing. We can also return images to sponsors for their own evaluation. By helping you select the right target tissue, digital images can contribute to greater precision and reduced variation in your testing results.

When choosing Covance central labs for your oncology trials, you are tapping into this broad experience, complemented by global specialty testing expertise through our alliance with NeoGenomics Inc., a leading provider of oncology-focused testing services. Our integrated, end-to-end APH services are designed to help you reduce your turnaround time and data variability, resulting in faster, more consistent and more precise data package submissions.

Harnessing the power of biomarkers for accurate predictions

As drug development moves toward more personalized medicine, it is critical that you understand how a particular compound is going to affect a patient. Biomarker tests are extremely valuable in predicting adverse, positive or non-existent response to a treatment and can involve a variety of testing types, from tissue/cell-based markers to genomic-based markers. They therefore offer huge potential for more effective drug development.

Covance’s specialized biomarker unit, Translational Biomarker Solutions, focuses on translational assets that inform clinical and discovery programs. Complementing our central labs, the unit functions as an extension to your biopharmaceutical technology transfer team. If you want to experiment with an assay
for an ongoing trial, our scientists can customize and validate it for you and then transfer it to the central lab where our genetics and APH specialists will prepare the specimens you require.

When focusing on target lesions—in oncology or personalized medicine—we can support your safety testing, together with endpoint assays. We can also provide our own in-house biomarker expertise and ultimately combine all the data obtained to facilitate your reviews.

**Companion diagnostics: effective strategies to bridge the gap between clinical study and drug development**

The predictive benefits of biomarker tests are well-established, especially in oncology, given the challenge in recruiting patients for global trials. However, as with any other therapy, before these tests can be recognized and used in conjunction with a safe therapy, as proper “companion diagnostics” they must also go through clinical validation and regulatory approval.

The last 10 years have seen an increase in the development and successful commercialization of these companion diagnostics, particularly in oncology. Regrettably, in the past, their introduction often came as an after-thought, either late in the development process or sometimes even after the drug reached the market. More recently, the industry has started to recognize that these tools should be developed much earlier on, well before the compound’s pivotal trials.

**Your route to market with the right partner**

As a player in this market, you need to devise a strategy to make your biomarker tests deliver results for you and for your target patients. It is helpful to start by categorizing patients based on biomarker expressions. Stratification is now welcomed as a critical tool in clearly identifying patient groups for targeted therapies. So, if a patient group exhibits a biomarker indicating diverse responses to a therapy, you have a powerful tool in your hands. Furthermore, this assay can later be re-used to exclude non-responders. Therefore, including biomarker tests early on can influence the design of the entire clinical trial and determine the future success of a compound. This represents a huge opportunity. In fact, targeted drugs have gained such momentum as to be given the term “niche busters.”

The criteria and regulations involved in commercializing companion diagnostics are similar to those for drugs. However, as most pharmaceutical companies do not have internal diagnostic expertise, finding a partner with a track record of delivering companion diagnostic development projects can help them avoid costly mistakes. To help clients capitalize on these opportunities, Covance has established partnerships with top diagnostic providers. Working with sponsors and their commercialization partners to make informed decisions on both assays and drugs, we operate a three-way partnership model known as companion diagnostic co-development. With the global coverage of our central labs and specialized Translational Biomarkers Solutions group, we can enroll patients globally, develop and validate biomarkers, while our collaborative approach gives you an insight into real clinical diagnostic work and assists you through regulatory approvals.

“There’s a trend toward the death of the blockbuster, so people are moving toward the niche buster.”

*Christopher Milne*
We recently entered into this type of partnership with a client and their diagnostic partner to support a global clinical trial to evaluate a novel companion diagnostic. Once the completed lab assay reached the clinic, following our feedback, the client managed to reduce variability between sites through standardized procedures and training, and thus obtained consistent global study data.

As the appetite for personalized medicine increases, companion diagnostic development is expanding from its initial oncology focus. With companies keen to deliver ever more targeted compounds, development is starting in other therapeutic areas, such as inflammation or neuroscience. Many drug developers even claim that companion diagnostics may eventually accompany half of their future compounds. The inclusion of companion diagnostic strategies in clinical trials is clearly an emerging revolution in drug development.

While these exciting developments in the biomarker arena are relatively recent, centralized labs have been in existence for some time. Their benefits have long been recognized and Covance is now taking them further. By offering uniform processes, streamlined specimen management, precision technologies and data analysis, as well as integrated APH solutions, we can ensure consistency, increase safety, minimize variability and produce combinable results in global clinical trials. Personalized medicine, with companion diagnostics at its heart, can only benefit from standardized, globally supported testing methodologies. At Covance, we are proud and excited to assist our partners in joining the revolution toward better targeted treatments.