



CROs, Service Providers, and Sponsors:

An Evolving Relationship

Sharing information on how to best approach these complex business relationships is important for the industry.

Managing the Relationship

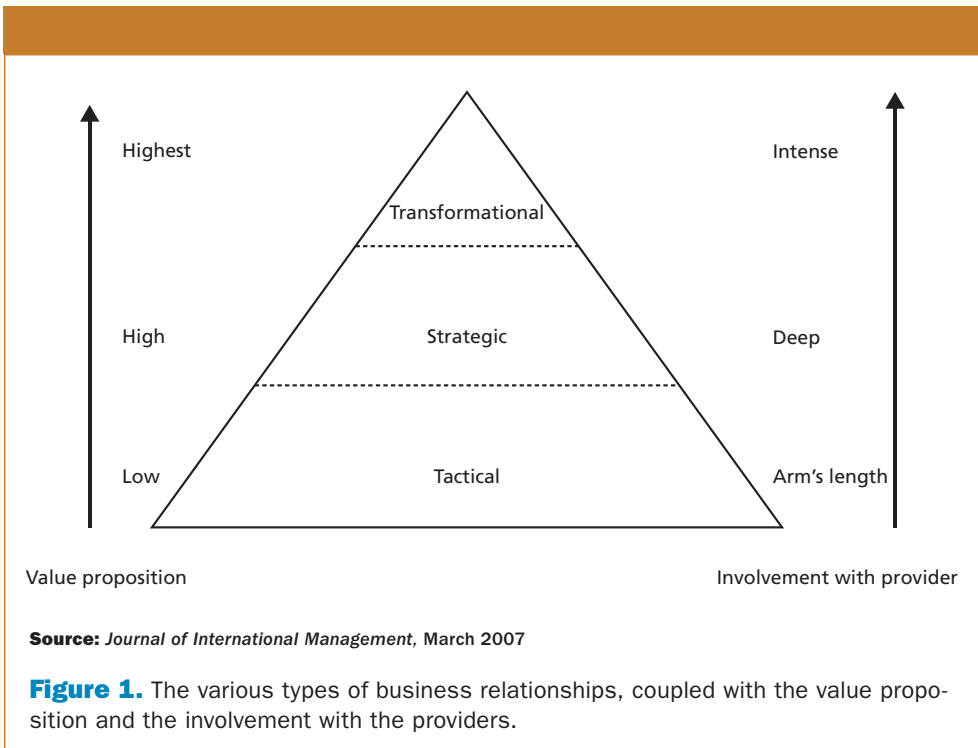
Applied Clinical Trials' Editors

Partnerships in clinical trials are nothing new. CROs began dotting the drug development landscape over 30 years ago. Managing the pharmaceutical sponsor, CRO, and service provider relationship became the focus of IIRs conference of a similar name 22 years ago—and for good reason. The sharing of information of how to best approach these both simple and complex business relationships is important for the industry.

Figure 1 shows the various types of business relationships, coupled with the value

proposition and the involvement with the providers. Of course, the lower-end transactional relationship—tactical—doesn't require the same degree of communication, governance, or detail as the higher-end, more transformational relationship of an alliance. However, all relationships are made that much more complex because of regulatory requirements. Specifically, that pharmaceutical sponsors ultimately are the ones responsible for the conduct of the trial.

As quoted from the first archived reference in the sidebar, “a recent study conducted by CenterWatch found that for leading CRO



companies, the majority of their revenue comes from strategic, integrated relationships. Among the top 10 largest CROs, 71% of their reported revenue comes from functional service and integrated alliances, and 29% from transactional relationships. In contrast, the majority (60%) of revenue for niche and mid-size CROs comes from transactional service relationships. Smaller pharmaceutical and biotechnology companies continue to primarily use transactional relationship outsourcing—often under preferred arrangements—to augment capacity for a specific project-related task.”

What is coming to the fore now with the increase in strategic, integrated relationships is the need for optimizing the relationships for improved efficiency and costs in clinical trials. More and more, technology is taking a front seat to achieve these goals, but technology integration between sites/sponsors/CROs and/or service providers adds its own set of challenges to the partnerships paradigm.

Another challenge is in the very real need for less oversight—sometimes misconstrued as micromanagement—by pharma of its providers. This is tackled in the April issue of *Applied Clinical Trials*’ Clinical Insights column.

And even more challenges present themselves with multinational trial or global trial management. Partnering in other countries is a must in the clinical trial industry, but cultural and societal nuances, in addition to region-specific regulatory requirements, need to be properly navigated.

The next few pages detail how certain CROs and service providers view their role in the ever-changing relationship with the sponsor. Some provide food for thought, others an overview of accomplishments in new alliances, and others specific case studies on how goals were achieved among these partnerships.

If you are heading to the Partnerships in Clinical Trials conference this year, you can expect to hear more discussion and updates in tracks on operational excellence; optimization of current outsourcing models; enhancing new partnering paradigms; innovative technology; and medical device optimization.

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FROM THE APPLIED CLINICAL TRIALS’ ARCHIVE

Will CROs Drive Faster Solutions Adoption?

<http://bit.ly/Xx1ugi>

Navigating Beyond the Plateau

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Pharma Chooses CRO Based on Needs

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Outsourcing Landscape

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Sponsor-driven, CRO/recruitment provider collaborations propel cost-efficient study completion.

Collaboration Planning

Helen West

As outsourcing to CROs and specialty providers continues to grow, and more sponsors move to strategic partner models with select providers engaged at program and enterprise levels, expectations for collaboration among study partners are rising. Sponsors are recognizing that there are opportunities for CROs and recruitment providers to be stronger allies for on-time, cost-efficient study completion through more intentional collaboration.

Some aspects to achieving a high-performing CRO-recruitment provider collaboration are particular to this combination of stakeholders. On-time study completion is central to both groups' performance measures. However, perceived and real overlap of their respective recruitment responsibilities can create counterproductive tensions and barriers to success. Sponsors can steer their study partners away from these roadblocks by driving the development of clear collaboration planning, based on an understanding of the dynamics between these provider types and how to best position them for shared success. The considerations offered here are from the recruitment provider's perspective with the intent of shining gentle light on some sensitive areas that are not often openly discussed.

The collaboration, or co-performance, plan starts with the sponsor's sourcing management. Primary factors in the dynamics between a CRO and recruitment provider are the sequencing of selection and whether the recruitment provider is engaged independently by the sponsor, along with the CRO, or solely by the CRO. When both the CRO and recruitment provider are selected by the sponsor, the recruitment provider is often

engaged after the CRO partner is onboard. This allows the sponsor to consider the need for engaging a recruitment provider in the context of the CRO's recruitment expertise and capabilities. It also gives the CRO an opportunity to contribute their insights to the recruitment provider selection. This is especially appealing to sponsors when they are approaching a new therapeutic area or indication, or have limited experience working with recruitment providers.

Depending on the sponsor's familiarity working with independent patient recruitment providers, they may not consider that patient recruitment providers are often in competitive bidding with CRO patient recruitment teams. CRO recruitment teams range from small teams of strategists who manage preferred partners, to large groups that execute programs using a combination of in-house and external services. Many CROs have struggled to determine whether recruitment specialty services should be part of their capabilities, or are better strategically partnered. Not all trials need recruitment support, yet significant resources are needed to maintain strong talent, full capabilities, and keep up with emerging tactics. Sustaining an investment in capabilities that are needed for a subset of trials presents a business challenge. There is a contingency of CROs that have approached and abandoned, some several times, the development of internal recruitment service teams. Others have opted to form strategic partnerships with recruitment providers, which benefit from established working practices and team familiarity.

Postponing selection of the recruitment provider until the CRO is identified can have unintended consequences. CROs sometimes

interpret a sponsor's request to engage a recruitment provider as a criticism or an indication that the sponsor lacks confidence in the CRO's capabilities. This can create a conflict of interest in their recommendations for recruitment provider selection. For example, one of the core strengths of a recruitment provider is crafting study value proposition messaging to patients, influencers, and referral sources. Even if the CRO does not have recruitment services and would need to outsource a patient outreach program, they may have materials development capabilities, and view the involvement of a recruitment provider as a lost revenue opportunity. Their recommendation may be based on which group they believe will defer to their boundaries and not challenge their primary position with the sponsor. The result can be that the recruitment provider that has the strongest capabilities is not selected; timing the recruitment provider selection after the CRO puts recruitment program start-up activities initiating closer to FPI. Ideally, recruitment providers have three months to launch a program to maximize efficiencies and avoid rush charges in pass through expenses. If the CRO is involved in recruitment provider selection, sponsors should recognize that the recruitment provider may be sensitive to the CRO having access to their budget and other competitive intelligence.

During program execution, CROs and recruitment providers intersect most heavily in the areas of IRB/EC approvals, materials fulfillment, and site support. Obviously the goal is to leverage the strengths of both groups and operate cohesively to achieve greater combined performance. The dynamic nature of patient recruitment management makes it more similar to how CROs operate than other specialty services. Central and core lab services, EDC, PRO and IWR systems, and drug supply support are designed to operate along a well-defined path. Adjustments are made to accommodate program specification changes, such as protocol amendments and shifts in study countries. In contrast, patient recruitment programs morph in flight with multiple variables being continually adjusted in response to changing conditions. Strong performance requires ongoing

strategic planning, quick response, and nimble management, which are best achieved when recruitment providers have direct communication with sponsors and first-degree access to program data and information. A classic example of a communication cascade delay that derails recruitment performance is notification that an ethics approval has been secured to deploy outreach tactics for an individual site. If the CRO holds responsibility for all IRB/EC submissions, responding to reviewer questions takes longer and the process is delayed. While securing ethics approvals for outreach has a high urgency for the recruitment provider, it understandably ranks lower in priority for CROs who place higher priority on key study initiation performance indicators such as completing site identification and contracting tasks on schedule. With a myriad of moving parts and intersection points with multiple study partners for sometimes hundreds of sites, notification of an IRB approval for outreach can easily be delayed a week or more. The impact of seemingly small losses in outreach time on recruitment program effectiveness and cost efficiency is widely underestimated, and needs to be carefully considered when performance-based risk share agreements are involved.

Sponsors can empower their CRO and recruitment provider partners to achieve superior co-performance by crafting up-front collaboration plans that establish primary responsibility and relative roles for: recruitment strategy decisions; country and site allocation of recruitment tactics; IRB/EC submissions and tracking; materials and messaging development; provision of materials to sites; and recruitment-focused site communications and support. Ideally the plans should also address operational aspects, specifically information sharing practices, communication flow, and escalation pathways.

Thoughtfully designed, comprehensive CRO-recruitment provider collaboration plans empower study partners to fully leverage their combined capabilities and deliver superior outcomes for sponsors.

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How partnering can speed companion diagnostic development.

Personalized Medicine

When FDA approved Pfizer's Xalkori for non-small cell lung cancer in August 2011, it cemented a remarkable two months for companion diagnostics. A month earlier FDA posted draft guidance on companion diagnostics and then, over nine days in August, approved two cancer drugs and their accompanying tests.

Such simultaneous approval of drug and companion diagnostic is the very approach laid out in the guidance. Yet achieving this synchronicity is a major challenge, particularly because few, if any, companies are equipped to handle development of a drug and diagnostic on their own. In the case of Xalkori, it took close collaboration between Pfizer, Abbott, and LabCorp. Pfizer and Abbott, which created the companion diagnostic, jointly met with FDA starting in July 2009. Just over two years later, the drug and companion diagnostic were approved.

Pfizer accelerated development by running relatively small Phase III trials on patient populations identified by the companion diagnostic. LabCorp provided validation and global testing to support Abbott's regulatory submission for the assay and then, when it was approved, immediately made the service commercially available at multiple sites. LabCorp played a similar role in the approval and roll out of Roche's Zelboraf, the other targeted drug and companion diagnostic approved in August 2011. In both cases, collaboration between LabCorp and the pharmaceutical company throughout companion diagnostic development ensured everything was in place to quickly ramp up testing volumes post-approval.

Pfizer, Abbott, and LabCorp will discuss these projects, and the role of alliances in bringing drugs and companion diagnostics to market, in a joint presentation at the upcoming Partnerships

in Clinical Trials conference. The approvals of August 2011 put each firm at the forefront of the personalized medicine sector. Genentech started back in 1998 when Herceptin was approved. Since 1998, targeted drugs and companion diagnostics have struggled to live up to the hope and hype, but partnerships across the different industry sectors are changing that with expectation that more companion diagnostics will be approved. Now, by working with external partners, the stage is set for pharma to finally fulfill the promise of companion diagnostics and personalized medicines.

Faster, less risky companion diagnostic development

In the past, the route to approval for a companion diagnostic was for an in vitro diagnostics (IVD) company to submit data in a premarket approval application to FDA. Under this model, a third-party laboratory, such as LabCorp, often generates data and then becomes one of several sites offering the test. It is a model that works very well for some companies, notably Pfizer and Roche in the August 2011 approvals, and one LabCorp continues to support through its testing labs. The use of laboratory-based assays has provided another route for approval and commercialization.

FDA opened the door to the alternative model by re-thinking its oversight of laboratory developed tests (LDT). Historically FDA took a hands-off approach to LDTs, but signaled a change in 2010 when it called a public meeting. The shift was prompted by the growing complexity of LDTs and their emerging role in personalized medicines. FDA was so overwhelmed by demand to attend the meeting that it had to relocate to a bigger site.

This approach develops and validates assays on established IVDs. FDA investigational device exemption is sought for clinical trials in which the

Learn More

Partnerships in Clinical Trials, Featured Presentation

Tuesday, April 23, 1:30 p.m.

Track E: Medical Device Trial Optimization

Partnering for Personalized Medicine: Spotlight on Companion Diagnostics

- Shane Weber, PhD, Director Diagnostics, Clinical Research and Precision Medicine, **Pfizer**
- Christopher J. Jowett, Global Commercial Head, Companion Diagnostics, **Abbott Molecular**
- Alan Wookey, Executive Director of Companion Diagnostics, **LabCorp Clinical Trials**

test is used as an inclusion criteria. All this can be done in a centralized approach, with one service provider handling test development, regulatory submissions, and eventual commercial launch. Alternatively, if volumes or prescribing preferences call for a decentralized model, IVD partners can come on board for kit development when needed.

For pharma companies, and particularly small biotechs, the model offers several advantages. By running the tests in one or more labs, the upfront financial and time costs of kit manufacture may be reduced. Taking this approach also standardizes operating practices by restricting use of the assay to a network of laboratories run by one company. Piggybacking on the existing standards of a central lab network helps assays, especially those that are expecting low volumes, achieve a greater assurance of quality because you are using the same reagents, procedures, and laboratory equipment to ensure consistency of assay results.

Many of these advantages mean FDA-approved LDTs are particularly well suited to orphan indications, or occasions when time or money are constrained. Yet any drug developer, both big and small, can benefit from the shortened development timelines. Experience at LabCorp shows time is saved by the elimination of various development steps, such as verification of packaging lot sizes or manufacturing processes. Reducing the need for large scale kit production lowers up front investment, while running the tests in labs gives greater control. In conversations with FDA and EMA, LabCorp has heard both regulators welcome the running of patient selection assays in controlled environments.

Keys to a successful partnerships

While LDTs ease development in some cases, many of the challenges for simultaneous drug and companion diagnostic FDA approval remain. Bringing a drug to market is tough. Timing it so a companion diagnostic gets approval at the same time is even trickier, yet this is what FDA wants. To complicate matters, drug and diagnostic developers are two distinct sectors with different business models. As *The New York Times* once memorably said, drug and diagnostic developer alliances are “a dance between a giant and a pixie, locked in an embrace but with a tendency to move in opposite directions.” Companion diagnostic projects are inherently complicated.

Choosing the right companion diagnostic partner can minimize these potential problems. In both the IVD and LDT models, deep experience in test development, regulatory submissions, and commercialization is vital. In the case of FDA-approved LDTs, excellent links to IVD companies are also needed to ease the potential switch to a decentralized model if necessary. Equally, both partners must show a degree of fiscal flexibility. In some cases a fee-for-service model might make most sense. Other times, the two partners might agree to each shoulder some of the development costs.

There are many considerations, lots of which are new to drugmakers. Going forward, successful drug development programs will need partnerships with diagnostic companies, so the pressure is on to make these alliances work. Given that approval of a targeted therapy is tied to the success of its companion diagnostic, the partner selection process is particularly important and can only enhance the chance of success.

Partnership agreements for CROs and eClinical technology providers can be as beneficial as sponsor/CRO partnerships.

Some Things Work Better as Partnerships

Graham Bunn

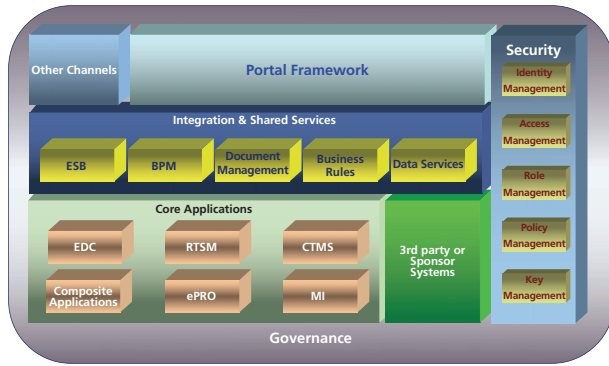
In the perfect world (a flat floor), a three-legged stool is always more stable than one with two or even four legs. In the world of outsourcing however, having more than one outsourcing provider involved in a clinical trial can soon become complicated. There are more contracts to deal with, more inter-relationships between companies and more cracks for responsibilities to fall between, and it becomes more difficult to determine who needs to fix what if things go wrong. This has resulted in a growing trend towards full-service strategic outsourcing with large global CROs who can provide all of the services required for a clinical trial. The outcome is one contract and one outsourcer responsible for delivery. These outsourcing models make sense, except in today's market there is the growing number of technology providers to consider who supply the large range of eClinical solutions required to efficiently run a modern clinical trial. Clinical trials management systems (CTMS), randomization and drug trial supply management, electronic data capture (EDC), medical imaging, electronic patient reported outcomes, and even electronic regulatory information management are but a few of the technology systems frequently used. This often results in a three, four, or more legged stool for the biopharmaceutical company to manage through the outsourcing process with the resultant complexity of contracts, work processes, team management, and technology overload for the users. There are two changes required in the industry to simplify clinical trials outsourcing

for the sponsor who is looking to gain all the efficiencies possible through outsourcing while at the same time continuing to gain the benefits possible through the use of eClinical solutions.

Technology convergence

Just as CROs grew by acquisition and organically to ensure they could provide the wide range of services and geographic presence that sponsors were looking for from their strategic outsourcing partnerships, technology companies now need to grow through the acquisition and internal development of end-to-end eClinical solutions. This evolution has been evident by some of the big players in the industry for some time. The growth in solutions offerings, combined with the industry's move towards cloud based software-as-a-service solutions, has allowed eClinical technology companies to develop more holistic clinical trials technology. The industry has moved away from the need for multiple applications requiring study specific point-to-point custom integrations and towards the convergence of applications and data that simplify the experience for the end users—think of the mobile phone, camera, music player and PC coming together as the smartphone (Figure 1).

Convergence of technology brings the optimal product suites the industry is looking for to deliver clinical trials from a one-stop-shop, avoiding the technology chaos of multiple applications and study specific custom integrations by simplifying the workflow and



Source: Perceptive Informatics

Figure 1. Convergence brings a holistic approach to running eClinical trials.

allowing consolidated views of information for effective decision making throughout the lifecycle of clinical trials or programs. Outsourcing technology convergence allows CROs to achieve significant efficiencies to their processes based on these advantages and hence offer these to their sponsors to gain competitive advantage.

Devolved technology responsibility

CROs have long argued that if they are not allowed to select the best technologies to run a clinical trial, then it is difficult, if not impossible for them to offer significant process and technology advantages. Traditionally the industry (especially large pharma) has specified the individual applications that a CRO will use for a study. The CRO then has to work with one CTMS system, a different EDC provider, and yet another laboratory service; this piecemeal process is repeated from study to study resulting in many study specific custom integrations, disjointed processes, and painful technology experiences for all of the end users due to the resulting technology chaos. The industry needs to realize that only by devolving technology selection responsibility to the CROs, can significant gains in usability, process (time/cost), and outsourcing management be obtained with significant reductions in wasted non re-usable application integrations. Once CROs are left to choose the

technologies, they also become fully responsible for the delivery from their selected vendor or vendors. The sponsor signs just one contract with the CRO, and there is no need to control multiple technology vendors and end up with situations of avoidance of responsibility.

This change in approach by sponsors has changed the way technology vendors work with their CRO customers. Some large technology vendors have developed a CRO partner program to better serve this segment of the industry, and in the process provided benefits to both the CRO as well as the sponsor. Vendors

have implemented strictly controlled, high quality training and testing programs along with user testing (certification), company accreditation and associated branding to recognize high quality CRO partners who are familiar with their technology. This not only enables the CRO to differentiate themselves in the marketplace, but also allows sponsors to feel confident that their strategic CRO partner is correctly qualified and supported throughout the contract duration. The relationship accurately mirrors the strategic partnerships that sponsors and CROs are now establishing. The vendor knows that this partnership is important, for the long term, and that the CRO is relying on their delivery to ensure on-time, on-budget delivery to the sponsor. The CRO knows they can rely on the vendors attention at all times, have simplified contracting via an overarching master services agreement, and can focus on one technology provider to optimize service delivery. Clearly some things work better as partnerships and the industry is learning that this is just as true for CROs and eClinical technology providers as it is for sponsors and CROs, and the sponsors benefit from both types of these strategic partnerships.

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How Covance has achieved successful outsourcing relationships with pharmaceutical sponsors.

Groundbreaking Strategic Partnerships

Covance is one of the world's largest and most comprehensive drug development services companies with annual revenues of \$2.2 billion and operations in more than 30 countries. On behalf of its clients, Covance generates more safety and efficacy data for the evaluation of new prescription drugs than any other entity.

With more than 10 years as a Six Sigma company, Covance works diligently to improve cost, quality, and value for clients. More than 400 employees have achieved Green Belt, Black Belt, or Master Black Belt status. Last year, Covance employees worked on 300 process improvement projects to help decrease development cycle time among other goals, capturing millions of dollars in savings.

Covance and Lilly worked together to establish key performance indicators to gauge the quality and efficiency of the contracted work.

Committed to strategic relationships

Among contract research organizations (CROs), Covance is uniquely positioned with a breadth of

The company, which employs 12,000 people worldwide, helped develop 32 of the 39 drugs approved by the US Food and Drug Administration last year.

Covance is driven by a strong commitment to people, process, and clients. Covance people are dedicated to the company's vision of bringing miracles of medicine to market sooner with a process excellence mindset that helps its clients reach major drug development milestones faster and more cost-effectively. Covance doctors, nurses, pathologists, scientists, and clinical researchers work side by side with its clients' medical and scientific leaders, providing experienced, ready-to-go teams that help clients bring their new medicines from laboratory bench to bedside. Strong teamwork and innovative thinking exhibited by Covance employees are hallmarks of exceptional client service.

services that spans from pre-clinical to post-approval, a significant geographic footprint, and industry-leading experience in structuring and managing large strategic relationships. The company's groundbreaking 2008 strategic alliance with Eli Lilly—a 10-year, \$1.6 billion service agreement and transfer of the company's Greenfield, IN, research facility—has grown organically to include six new service lines: nutritional analysis, sample storage, biotech services, biomarkers, specialty toxicology, and market access services. The site, once an internal cost center for Lilly, is now a thriving CRO facility that employs 500 people, most of whom are former Lilly employees, and serves more than 100 clients.

To help drive mutual success, the two companies worked together to establish key performance indicators (KPIs) to gauge the quality and efficiency of the contracted work

and a joint, multi-tiered governance structure to oversee KPIs, project implementation, and critical milestones.

Two years into the original agreement, the Covance-Lilly partnership expanded to include an additional three-year biotechnology services agreement in which Lilly transferred bioproduct analytical testing to a \$15 million biotech facility Covance built on the Greenfield campus.

The Covance-Lilly agreement has helped change the perception of CROs from a tactical provider of drug development services to a true partner. It is considered an industry-leading example of how CROs and biopharmaceutical companies can partner for mutual success.

In 2011, Covance once again led the industry by establishing a strategic relationship with Sanofi that was unparalleled in size and scope. The 10-year, \$2.2 billion alliance, which included the transfer of Sanofi sites in Alnwick, England, and Porcheville, France, as well as revenue commitments for a broader range of services, is the largest-ever research and development outsourcing agreement. One of the more significant benefits of both the Lilly and Sanofi agreements is the economic impact on the community. In both cases, jobs were preserved and, in the case of Lilly's former Greenfield site, new jobs were created, and an industry that fosters scientific innovation continues to thrive.

Last year, Covance and Bayer HealthCare established a long-term strategic relationship in the area of clinical drug development including R&D services related to Phase II-IV clinical studies and central laboratory services. Through this relationship, Bayer plans to leverage Covance's broad range of experience and services to attain best in class operational delivery, efficiency, and quality.

As pharmaceutical companies work to reduce their cost structures and make fixed costs more variable, analysts predict that the trend toward research and development outsourcing will continue to grow.

Outsourcing partnerships are financially beneficial and build a competitive advantage for both parties, and Covance's capabilities combined with an experienced management team and passion for patients make it an ideal partner for building collaborative relationships, both large and small.

The agreement has helped change the perception of CROs from a tactical provider of drug development services to a true partner.

Investing in the future

Covance's central laboratory services has been involved in one-third of all clinical trials and, as a result, has collected more than 20 years' worth of data. This data, combined with Covance's extensive clinical knowledge has been a key differentiator for the company. In 2011, the company launched Xcellerate®, an informatics tool that leverages the company's vast clinical trial expertise and data sources to expedite clinical trials.

By providing cutting edge site and investigator selection tools, clinical trial scenario planning, forecasting, and resource management, Xcellerate enhances the company's ability to increase the predictability of clinical trial performance, and helps to ensure more cost-effective and timely clinical trials.

In addition to Xcellerate, Covance has made significant investments in other information technology assets, which will help it to build world-class informatics capabilities. These technological advances will replace many manual labor-intensive processes with highly efficient reporting tools, providing clients with faster access to information and advanced visibility into critical operational data, allowing them to make more informed decisions at critical junctures along the drug development continuum.

It is clear that technological innovation will change the way drugs are developed, and Covance is committed to help drive this innovation.

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