



Executive Interview

How does a preclinical CRO assess the business?

By **Steve Snyder**
Contributing Editor

FOR OVER A YEAR NOW, I HAVE BEEN sharing my opinions with you about preclinical outsourcing. Among the topics I have discussed: the importance of the sponsor-CRO business relationship, how sponsors can evaluate CROs, and why the coordination of resources is so critical in a preclinical research environment. As regular readers are aware, I believe this is one of the more complex and least understood areas of drug development. It is enjoyable to share experiences from my 28 years in this industry, although I must admit that having to meet my editor's deadlines often rekindles memories of writing book reports as a youth.

As a consultant, I am frequently asked for an opinion regarding the state of the preclinical outsourcing industry. Investment analysts want to know about industry capacity and if there will be a glut as CROs race to bring new capacity on-line. CROs want to know if the demand for preclinical outsourcing will soften as it did in 2003. Sponsors want to know which CRO offers the best chance for a successful outsourcing experience. I respond to these questions based on a compilation of observations from my own consulting projects and from feedback from industry veterans. Having spent most of the past year sharing my experiences and my opinions, it finally occurred to me that perhaps I should seek another perspective.

Wendel Barr is a Corporate Senior Vice President and the President of Early Development, North America for Covance. Covance provides preclinical and clinical development and commercial service offerings to pharmaceutical and biotechnology companies. Mr. Barr joined the company in 2000 and graciously agreed to be interviewed for this article. Through telephone and E-mail communications, Wendel shared his views on preclinical (a.k.a. nonclinical) outsourcing.

Steve Snyder: *From your perspective, do you see the demand for preclinical outsourcing increasing, decreasing, or remaining the same? Is Covance seeing any volatility in the demand?*

Wendel Barr: Overall, we see a trend toward a greater demand for preclinical outsourcing.

There is an emerging paradigm — called “learn and confirm” — that is being driven by a substantial number of new molecules that have been flowing from discovery since the beginning of this decade, attributed to a well-funded biotech

industry and advances in combinatorial chemistry, high throughput screening, genomics, and other new sciences.

Over the last five years, the number of compounds entering preclinical development has grown at a compound annual growth rate of 15%.

This new paradigm has driven the industry to more fully characterize and kill poor new drug candidates as early as possible before entering the expensive Phase III stage. Drug candidates are more rigorously screened before and during preclinical safety testing. Candidates that make it out of preclinical now face more rigorous studies in Phase I and IIa in order to prove the concept. Once the concept is proven, the drugs enter into Phase III studies to confirm what was learned in the earlier stages.

This new model supports the forecast for increases in both the number and complexity of preclinical studies.

SS: *CRO demand has been traditionally cyclic in nature. What trends do you watch that you believe are indicative of market demand?*

WB: A significant number of large pharma companies are moving away from the traditional transactional model of outsourcing and developing a more strategic approach to outsourcing their development work. For example, at least one large pharmaceutical company has targeted an increase in outsourcing from 10% to 30%. This is a major shift in development strategy. As this happens at more companies — and we believe it will — demand for preclinical services will become less cyclical and more predictable.

SS: *Covance has been particularly successful in signing dedicated space agreements. Can you describe the way these agreements work for Covance and the sponsor and the benefits of these relationships for clients?*

WB: Pharmaceutical companies are under continual pressure to improve their development productivity. This pressure, in turn, is leading these companies to make strategic decisions about where they will invest their money. Some companies will decide to find an alternative to adding new preclinical facilities or replace aging facilities, and invest their funds in other ways. For those companies, securing long-term access to preclinical resources is critical to their success.

We recently signed the largest agreement in our company's history, worth a minimum of \$187 million, to provide services to a major pharma company through 2013. Earlier this year, we signed an agreement with another large pharma company to provide dedicated support for preclinical development. We are talking with several other large companies as well.

Steve Snyder is a consultant with more than 25 years of experience in preclinical toxicology as an outsourcing customer and provider. He can be contacted at info@outsourcesupport.com.

The sponsor obtains guaranteed long-term capacity and infrastructure to run a broad array of preclinical studies, enabling the future development of its pipeline without logistical constraints. Due to the increased project visibility from the strategic relationship, Covance is able to maximize capacity and resources as well as provide higher levels of quality, speed, and efficiency.

SS: *Because the preclinical outsourcing demand is so great, anecdotal accounts of sponsors "double-booking" study start dates at CROs have been reported. Has Covance encountered this practice?*

WB: No.

SS: *Many of the CROs are adding capacity to meet the preclinical outsourcing demand. Can you describe what capacity Covance has added and what factors do you consider when determining when and where to add capacity?*

WB: We have added capacity in our facilities in several locations worldwide. As the market leader in many preclinical services, we look at a number of demand factors, including overall industry outsourcing growth rates, before we decide to add capacity.

Our success developing and executing strategic partnerships with several of our large pharma clients is another factor we consider when we decide to add capacity.

SS: *With so many CROs adding new capacity, are you ever concerned that your business or the industry as a whole will be impacted by an overabundance of capacity?*

WB: While many companies are adding capacity, there is also a significant increase in the outsourcing rates of the medium to large pharma companies. Additionally, small biotech companies are becoming an increasingly important source of potential new drugs. These companies often have little to no internal capabilities for developing these drugs so they must rely on outsourcing.

Both of these trends are contributing to strong growth in demand for preclinical outsourcing, so we are not concerned about an overabundance of capacity in the industry.

The biggest factor for Covance is the interest we are seeing from large pharma companies in shifting from tactical to strategic outsourcing strategies. This shift has resulted in a number of sponsor companies expressing interest in developing a long-term relationship with us, not just for our toxicology services, but for the full range of preclinical services we can offer. This is a true benefit to both companies, assuring our sponsors have access to the services they need to make fast decisions about their compounds and providing Covance with greater predictability of the demand for our services.

SS: *From your experience, what are the biggest obstacles that a CRO must overcome to get a sponsor company to select outsourcing over in-house development and how does Covance address these concerns?*

WB: Studies in other industries have identified that perceived

loss of control is a significant issue for companies when they choose to outsource services. Developing a close relationship with our clients by understanding and meeting their requirements, providing them with 24/7 access to their data through our online data management tool, StudyTracker[®], and most importantly, establishing and maintaining clear lines of communication are all key elements in reducing sponsor concerns.

SS: *What could sponsor companies do better or differently when working with Covance to optimize their outsourcing experience?*

WB: The responsibility for any relationship is shared by both parties. The foundation for a successful relationship is trust. There are several values that we believe have to be embraced by both sponsor companies and Covance for trust to be established and grow.

These values are:

- Foster teamwork over individual priority
- Remain committed to an open and honest relationship so problems do not escalate
- Treat team members as insiders
- Earn trust through performance — meet your commitments
- Most importantly: communicate, communicate, communicate

SS: *Can you describe how your preclinical program management group functions and how can this group assist sponsors?*

WB: Program Management Services provides our clients with both scientific and logistical support for the preclinical and early clinical phases of molecule development with Covance. This service is particularly helpful to small companies that do not have the internal capabilities to bring their compound to their desired milestone: IND, First In Human or Proof of Concept.

The expansion of our Phase I capabilities through our recent acquisition of the Phase I/IIa business of Radiant allows us to build on our successful Program Management Services with additional early clinical capacity. This will help us accelerate our clients' drug development projects.

Through this integrated offering, we are currently working with more than 50 different clients representing 90 different molecules. Thirty-four of the packages we worked on in 2005 led to an IND or CTA. We have now worked on over 200 such programs.

SS: *Covance offers outsourcing services from preclinical through clinical trials. Why would clients use all of your services versus those who selectively choose specific services?*

WB: The "learn and confirm" model will help fuel the growth in late stage development. For the first time in years, the number of molecules in Phase III is growing and will be of higher quality and greater complexity. Phase III market demand is robust, and our central lab, which we believe touches approximately one-quarter of all Phase III trials conducted in the world, has broad access to this growing market.

Integrated drug development



The success of CROs will be based on their ability to effectively and efficiently integrate service solutions for our biotech and pharmaceutical companies, who are continually looking for ways to move their pipelines forward.

SS: *There is a lot of attention focused on preclinical outsourcing opportunities in China and India. What is your view on this trend and does Covance plan to offer services in these regions? If so, what services and when?*

The largest change by far has been the increasing interest in large pharma companies in discussing how they can secure long-term access to preclinical development resources.

WB: Covance currently offers clinical and central lab services in Asia. We will continue to look at preclinical opportunities in this region. It is too early for us to discuss specifics, but we have activities ongoing to review the landscape in China and India.

SS: *How has preclinical outsourcing changed during the past two years?*

WB: We have seen a greater demand for the services we provide—part of that emerging “Learn and Confirm” model. In addition, large pharma companies are moving toward a more strategic approach to outsourcing their preclinical work. Both of these trends have been very favorable for the CRO industry overall, as well as for Covance.

The largest change by far has been the increasing interest in large pharma companies in discussing how they can secure long-term access to preclinical development resources. Within the past few years, we have worked with several key clients to create a new model for providing preclinical development services.

Our continued progress with the dedicated space model signals changing market dynamics that creates significant strategic opportunities for Covance.

In this article, we have seen that the demand for preclinical outsourcing not only remains strong but appears to be growing. Pharmaceutical and biotechnology companies are bringing more compounds into development and preclinical studies are increasingly more complicated, so that toxicity concerns can be addressed earlier in the drug development timeline.

Outsourcing demand is being driven by a well-funded biotechnology industry and by the pharmaceutical industry that is increasingly using CROs for additional capacity or as a cost effective alternative to internal resources. Based on this perspective, CROs that anticipate and are situated to address customer’s needs will be those that benefit the most from these industry trends. ■

www.contractpharma.com

through dedicated tactical, logistical and scientific support

Covance has symbolized scientific excellence in contract research for more than 50 years. Whether you need help in building your drug development plan or just implementing it, the Program Management Services team at Covance can assist you in managing your program to the desired endpoint.

Facilitate reaching your endpoints:

- CTA/IND enabling package
- First-in-human (Phase I) studies
- Proof-of-concept (Phase IIa) studies

Provides you with:

- Single point of contact
- Real-time issue awareness and proactive resolution
- Staff who understand your goals and critical timelines
- On-time and on-budget execution

For help through the maze of drug development

Program Management Services

COVANCE
THE DEVELOPMENT SERVICES COMPANY

The Americas
+1.888.COVANCE
(268.2623)

Europe/South Africa
+44 (0)1423.500888

Asia
+65.65677333

Australia
+61.2.8879.2000

Visit the Covance Web Site
www.covance.com