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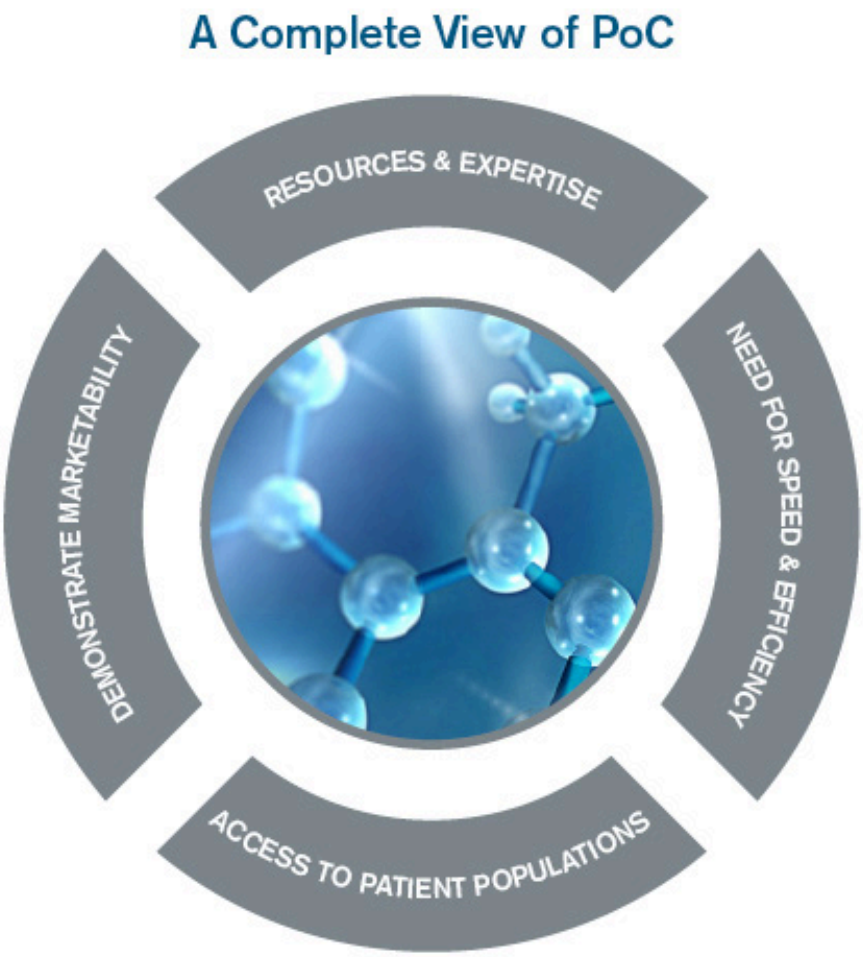
PARTNERING TREND ALLOWS SMART CROs TO PROVIDE GAMUT OF SERVICES TO ANY SIZE COMPANY

Five years ago, contract research organizations were doers; they didn't participate much in the scientific aspects of drug development. Now, some CROs are changing their approach, and acting as drug development partners for pharma companies big and small. Bringing a jumbo company's range of services – preclinical and clinical – to any size client allows cutting-edge CROs to plan and execute each step of drug development, helping clients get to the critical proof of concept milestone in less time than the old-fashioned, hands-off contract research. "If we change things and do something differently we can save you time and money," says Jean-Michel Gries, MBA, PhD, PharmD, General Manager and Vice President, Early Clinical Development, at Covance Inc. "That's a big change in mindset compared to CROs five years ago. Now, we're a scientific partner. A lot of people aren't aware of that."

Of course, you can't claim to be a partner if you can't offer assistance throughout the process. Covance, known globally for its preclinical and central laboratory expertise, offers a comprehensive set of services for the clinical phases of research. Indeed, they've been focusing their translational services on showing pharma and biotech clients how convenient it can be to have preclinical and early clinical services available in one place, making the road to proof of concept much less harrowing – and a lot shorter. A partnering approach by CROs also works well for organizations that don't have the resources of an international pharmaceutical developer. "We work well with smaller clients," Dr. Gries explains. "Our dedicated early clinical development team is nimble, focused and flexible." Smaller companies may need a completely different set of services than big pharma firms, and a competent partner can provide them on the appropriate scale.

‘A SEAMLESS PROCESS FROM PRECLINICAL TO POC’: AN INTERVIEW WITH JEAN-MICHEL GRIES, MBA, PHD, PHARMD



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What is unique about the way Covance works with biotechs?

We understand that there are financial, operational and regulatory hurdles that small and mid-sized biotechs face. Because of their unique situations, we have dedicated resources specifically designed with their needs in mind including customized solutions such as complete PoC to maximize the value of their molecule. As a matter of fact, in 2013, we serviced and delivered value to over 500 small and mid-sized biotechs.

Are preclinical and clinical services available in one place?

Only one place, actually. Covance is the only CRO with both available. We can pretty much create a seamless process to move a molecule from preclinical to proof of concept. No one else in the world can do that.

Gries is General Manager and Vice President, Early Clinical Development, at Covance Inc.

DRUG DEVELOPMENT CRISIS: BARELY ONE IN 10 COMPOUNDS BECOMES A COMMERCIAL PRODUCT

The majority of molecules don't make it into clinical trials, and most of those that do don't make it out. That's drug development legend – and it happens to be true.

In their often-quoted 2004 research paper, Ismail Kola and John Landis noted that the overall clinical success rate is just 11%; in many therapeutic areas, the results are poorer still, with oncology at just 5% and women's health even lower. The area with the greatest success rate: cardiovascular, at 20%. Overall, 60% of drugs make it to Phase II trials, and just over 20% make it to Phase III. Barely 15% make it to registration.

The biggest driver of that failure is compound efficacy, and that's why the pressure is on drug developers – especially small drug developers – to get to proof of concept as quickly and efficiently as possible.

A CASE STUDY: BRINGING BIG CRO RESOURCES TO A SMALL COMPANY SPEEDS DEVELOPMENT

Small drug development companies have great compounds, too. But not every CRO can service their unique needs.

One such enterprise owned a compound that would treat osteoporosis, a disease that causes bones to lose density. The compound increased bone deposition – a good thing. But bone deposition can also cause hypocalcaemia – and that can lead to cardiac arrhythmia. And that, the company knew, meant a thorough safety assessment must guide its clinical program. Covance brought two types of expertise to bear – preclinical safety assessment and clinical operations – and combined them in a translational medicine approach:

- First, we conducted cardiovascular safety pharmacology studies and repeat dose toxicology studies in primates.
- Then, we put our scientists to work using the findings to design a Phase I protocol that addressed the specific clinical challenges.
- Finally, we assisted in developing the early clinical studies with those issues in mind.

Leveraging toxicology results in real time, the client saved two months over a phased approach, and they proceeded with development activity confident that patient safety concerns had been addressed.

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Xcellerate® – Clinical Trial Optimization®

Xcellerate® is a unique approach offered only by Covance that is designed to help improve the selection of high performing investigators and sites, more accurately forecast patient enrollment and more effectively avoid cost delays.

This tool is built upon a foundation of the largest clinical trial knowledgebase in the industry which contains proprietary data of more than 11,000 protocols with 175,000+ unique investigators experienced in conducting clinical trials as well as more than 14 million patient visit information in the past decade worldwide.

The power of this knowledgebase allows Covance to better match study designs and population requirements to the right countries, the right investigators and the right sites to identify and select only those that are likely to perform.

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