The Increasing Role of CROs in the Pharmaceutical Industry

July 11, 2023 by Andrii Buvailo

(Last updated: July 2023)

Pharmaceutical companies are increasingly outsourcing research activities to academic institutions, tech-driven companies, and private contract research organizations (CROs) as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, increasingly sophisticated technologies and an unstable economic environment.

What is a CRO in pharma?

A Contract Research Organization (CRO) in pharma is an entity that offers outsourced services to other organizations in managing various aspects of clinical trials and complex medical testing procedures. As an approach to streamline costs associated with research and development, it has become a pivotal strategy for businesses navigating the evolving terrain of the medical device and pharmaceutical industry. Clinical outsourcing, as this process is referred to, enables the company contracting these services to leverage the expertise of external researchers, thereby conserving resources by circumventing the need for in-house staff or the associated infrastructure. The responsibilities of a CRO encompass a broad spectrum of services, ranging from project management, data management, clinical study management, and research compliance to strategic planning consultation, market research, product commercialization, and medical writing. CROs are increasingly being utilized by a variety of entities including biotechnology, medical device, and pharmaceutical industries, in addition to universities, government organizations, and foundations. They ensure resource allocation, manage logistics, offer support for audits or FDA inspections, and ensure that study monitoring, patient recruitment, and site management are conducted to the highest standards. By mitigating the financial and logistical challenges of research, CROs offer a dynamic solution to organizations in the pursuit of advancements within the medical sphere.

The evolution of Contract Research Organizations (CROs) stems from the mid-20th century. Companies like Huntingdon Life Sciences and Charles River Laboratories came into being during the 1940s and 1950s, addressing the growing demand in the pharmaceutical sector. However, the modern shape of the CRO industry began to crystallize in the late 1970s and early 1980s. This period witnessed the
establishment of leading organizations such as Quintiles (now IQVIA) and Parexel, which diversified the traditionally confined role of preclinical testing to embrace broader areas like clinical trials, data management, and logistics.

The 1990s represented a significant turning point for CROs. Notably, their share of R&D spend leaped from a modest 4% in the early part of the decade to an impressive near-50% by the mid-2000s. This era also marked a flurry of acquisitions and mergers, contributing to the rise of influential players like Covance, which was spun off from Corning Inc in 1997. Despite navigating a series of controversies concerning animal welfare and ethical integrity, the CRO industry has remained resilient and has continued to expand. Today, CROs are pioneering cost-efficient strategies, such as adaptive clinical trials, and facilitating the globalization of clinical research.

Preclinical CRO services are expanding

While traditionally, CRO companies were focused on managing clinical trials, there is an increasing tendency in the pharmaceutical industry to also outsource early drug discovery and preclinical drug development tasks to external organizations.

A preclinical CRO is an independent entity specializing in managing the complexities inherent to the preclinical phase of drug development, employed by pharmaceutical organizations. Preclinical CROs offer their expertise in the multifaceted management of this initial stage of the process, which may include selection of suitable animal models or alternatives, and the execution of toxicity assays. The goal for a pharmaceutical organization in engaging a preclinical CRO is the efficient progression of a potential drug to the market, especially given the expensive nature of the preclinical phase and the specific skill sets it requires, which may not be readily available within the company. Within the competitive field of medical research, where the process of bringing a new drug to market may span approximately a decade, preclinical CROs can facilitate and accelerate this process. Services offered by these organizations span project management, data collection, medical testing, toxicology, regulation compliance, safety reporting, and quality analysis, with some CROs offering specialized expertise in certain fields.

Beyond classical CROs in pharma, big and small, there is a growing wave of technology-first drug discovery companies which offer specialized contract research services to other organizations. Such tech-enabled companies include artificial intelligence (AI)-driven platform companies, able to provide
‘drug candidate as a service,’ or ‘modeling as a service’ offerings. There is also an interesting segment, robotized remote labs for ‘off-the-shelf’ preclinical experimentation, a new category of tech-enabled CRO-like companies in pharma, including Strateous, Emerald Cloud Labs and others.

**CRO companies are thriving in pharma industry**

According to a 2021 report by Clearwater International, the global CRO market will potentially rise to a $60.8 billion industry by 2024, exhibiting the current rate of market growth of around 7.9% CAGR. Getting ideas and expertise from external sources is a well-established practice in the pharmaceutical industry with about one-third of all drugs in the pipelines of the top ten pharmaceutical companies initially developed elsewhere, according to a 2014 WSJ article by Jonathan D. Rockoff.

A recent BiopharmaTrend report The CRO Industry in Flux: Navigating Technology, Business Models, and Trends in Pharma R&D Outsourcing reveals evolving roles of CRO in pharma and the ongoing trends in this industry. For instance, the CRO industry is quite dispersed, encompassing over 1000 entities, but only a handful of them offer global full-service capabilities. The bulk of the market is predominantly ruled by a select group of significant players such as Covance, IQVIA, Syneos Health, Parexel, PPD (later acquired by ThermoFisher), PRA Health Sciences, Charles River Labs, Wuxi AppTec, and Medpace. Research conducted by the Tufts University Center for the Study of Drug Development (CSDD) highlights that in 2018, about 57% of the outsourcing spend was enjoyed by the top 10 CROs.

However, the CRO pharma market is witnessing a trend of consolidation, with larger CROs incorporating smaller, specialized providers. Notable mergers and acquisitions in 2021, for example, included ICON’s procurement of PRA and software provider Thermo Fisher’s purchase of the PPD. As major CROs continue to expand, it exerts an intensifying strain on smaller CRO companies to specialize further, leading to a more segmented market. Smaller CROs are discovering a competitive edge in pharma by distinguishing themselves in niche areas, enhancing their marketability and potential for sales growth in these specialized areas, thereby sidestepping direct competition with larger players. These narrowly-focused CROs often concentrate on select therapeutic domains, development phases, or curtailed service portfolios.
The impact of Covid-19 on CRO pharma market

The Covid-19 pandemic has drastically transformed the clinical trial industry, leading trial sponsors and contract research organizations (CROs) to revise their collaborative methods. Traditional reliance on a small set of CROs is waning, with sponsors favoring adaptability and tailored outsourcing models. Pharma companies are considering a diverse mix of specialty and full-service organizations, reducing overall dependence on CROs.

CROs have adjusted their services to address changing sponsor needs, including open data-sharing models and personalized medicine, becoming industry standards. While the popularity of decentralized clinical trials may slightly decrease, the focus on adaptive trial design continues to hold strong.

The pandemic made pharma companies appreciate agile development, given recent increases in patient recruitment delays, drug supply shortages, and adaptive study designs. The need for more trial flexibility is evident, and companies will be quicker to adjust their trial execution strategies to accommodate unforeseen changes.

Data sharing will become more common in the future, with more collaborative models across stakeholders replacing the existing practice of each party controlling separate datasets. This change is due to the increased recognition of the role diverse datasets can play in supporting clinical studies. As a result, CROs are using data to address the growing demand for innovative trial designs and personalized medicine approaches.

The boom in healthcare data may lead to new partnerships between academic research organizations and CROs, with the former providing large datasets and the latter offering operational efficiency.

Despite the significant consolidation in the CRO industry, smaller sponsors still have opportunities to find boutique CROs that can cater to specific needs. The move towards personalized medicine and flexible outsourcing has not limited access to specialty services or smaller CROs.

The term "decentralization" has become a significant buzzword in the clinical trial industry post-Covid-19, with a surge in decentralized clinical trials. However, the role of decentralization will likely be determined by individual patient communities as sponsors move away from a one-size-fits-all approach.

The ideal approach lies in finding the right balance between decentralization and traditional in-person trial strategies that best fit a specific program. This could involve full-service CROs or a collection of specialty...
organizations with more sponsor control. Trials need to be designed to adapt flexibly to new challenges and customize the level of decentralized tools, leading to higher levels of trial customization.

How Decentralized and Hybrid Clinical Trials Change CRO-pharma Collaborations

A study by Tufts CSDD, in collaboration with biopharmaceutical organizations and contract research organizations (CROs), evaluated the impact of decentralized clinical trials (DCTs) and hybrid trials on sponsor-CRO collaborations. The research showed a significant increase in global drug trials with DCT elements from 2020 to 2022, along with higher anticipated usage in the coming years. The primary challenges to DCT implementation included data standards, regulatory inconsistencies, data privacy, and technical validation for health apps and wearables.

The study also revealed that pricing models, DCT implementation strategies, and vendor management greatly influence sponsor-CRO partnerships. Based on global industry surveys, remote monitoring, electronic patient-reported outcomes (ePRO), and eConsent were the most commonly used DCT technologies, although barriers like country-specific challenges, diverse site capabilities, and data collection issues persisted.

Despite these challenges, the majority of biopharmaceutical respondents viewed CROs favorably, acknowledging their proactive role in DCT adoption and noting a positive influence on sponsor-CRO relationships. Although DCTs were perceived as more expensive than traditional trials, the general expectation was that outsourcing of these trials and use of CROs and vendors that implement such solutions will increase in the future. Future research should focus on detailing relationship models resulting from the implementation of hybrid and DCTs.

RELATED: Contract Research Organizations Tap Into AI To Increase Value Proposition
Bioanalytical R&D Outsourcing Grows as Drugs Become More Complex

Bioanalytical outsourcing is poised for considerable expansion as contemporary therapeutics grow in complexity, making partnerships with proficient Contract Research Organizations (CROs) vital. The development of large molecules, which now spearhead drug innovation, often involves intricate processes with over a thousand steps, necessitating diverse assays to understand their efficacy and safety. Among the new modalities, Cell and Gene Therapies (CGTs) and mRNA methods are seeing higher demand from CROs, along with an increase in requests for biosimilar studies. The global pharmaceutical analytical testing outsourcing market, largely driven by the high testing requirements of bio-based drugs, is expected to hit $14.6 billion by 2030, growing at a CAGR of 8.4%.

CRO companies as strategic partners to pharma sponsors

Research from the University of Cambridge suggests a significant change in how pharmaceutical firms interact with contract research organizations, with a clear shift towards strategic alliances over one-time transactions. The data shows that while a quarter of outsourced projects still use a transactional approach, the remaining 75% are split between preferred providers and strategic partnerships, highlighting a preference for long-term collaborations.

These strategic relationships offer advantages such as faster drug development timelines, which translates into substantial cost savings considering a single day’s delay in clinical trials can result in a financial burden ranging from $600,000 to $8 million. Additionally, these partnerships enable more efficient long-term resource planning and can potentially enhance supply chain operations.

Nevertheless, the research does not completely rule out the relevance of transactional dealings, recognizing their value in projects that require less strategic planning and communication.
Thinking Strategically: Pros and Cons of Pharma R&D Outsourcing

The whole pharma R&D outsourcing concept revolves around the idea that it is more efficient to contract out standard and routine R&D activities such as chemical synthesis, toxicology, drug metabolism, formulations etc, while maintaining more creative and judgmental processes ("know-how generating processes") in-house. Not only standard and routine tasks, but also well-understood science, robust and repetitive, is believed to be suitable for outsourcing models of cooperation. Another meaningful use case -- outsourcing expertise in advanced technologies, such as artificial intelligence, which can not be quickly built up internally (however, in this latter case an option of aquirng a suitable technology vendor might be a strong alternative to outsourcing operations).

As outlined above, pharma R&D outsourcing has several decent advantages, which drive the current industry trend up. Flexibility of the externalized R&D is probably among the key pros here, as it basically allows to transform certain R&D research tasks into a preferable variable cost, as opposed to fixed costs of internally maintained R&D resources.

Buying-in molecules at later stages of development to mitigate risks is another lucrative benefit of preclinical R&D outsourcing.

However, rather strong disadvantages are also existent and it is important to realize them during strategic decision making. Those include:

- Significant increases in management overhead costs due to search and monitoring activities. A study by the Center for European Economic Research shows that the added complexity of managing an outsourcing process can easily overshadow the cost reduction of R&D work itself.

- A loss of cumulative knowledge base within pharma organizations due to dissolution of the teams and the weakening of internal R&D capability, thereby weakening their "learning-by-doing" process.

In any case, one of the critical aspects to consider during any R&D outsourcing initiative is choosing the right partner with a decent track-record of success, measurable performance indicators, suitable business model, and state-of-the-art technological and innovative capacity.