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Photo courtesy of PPD clinical research business, Thermo Fisher Scientific

CRO Industry Report

R&D trends, challenges in today's market, and growth drivers and opportunities.

Today's drug development landscape demands contract research organizations (CROs) provide flexible models that leverage the latest technologies to support sponsor needs. From overcoming data and trial design complexities to working faster and smarter, CROs must adapt to cater to ever-changing drug development needs providing therapeutic expertise and sophisticated capabilities to help advance drugs to market.

According to *MarketsandMarkets*, the global CRO market is estimated to be $82 billion in 2024 and poised to reach $129.8 billion by 2029, growing at a CAGR of 9.6% from 2024 – 2029.[1] This is inclusive of early phase research, clinical research, consulting, and data management, across various therapeutic areas. Growth is attributed to the number of drug products in development, along with high in-house costs for discovery and development of therapeutics and medical devices, driving outsourcing.

Contract Pharma gains insight from some of the industry's top players in the CRO space on current R&D and outsourcing trends, challenges in today's market, as well as growth drivers and opportunities coming down the pike.

R&D TRENDS

Among the pharma and biopharma R&D trends impacting CROs and services is the use of artificial intelligence (AI) to address data analysis and create efficiencies, development needs around emerging biopharma therapeutic candidates, as well as efforts to bring new therapeutics to market faster in the face of upcoming patent expirations.

"In the CRO industry we're witnessing truly transformative trends that are reshaping the way we approach drug development," says Peyton Howell, CEO, Parexel. "The integration of AI and machine learning (ML) is already beginning to streamline data analysis and enhance efficiency across the drug development lifecycle. With precision medicine enabling treatments to be customized for individual patients, it complicates study designs and necessitates the analysis of extensive datasets. Coupled with a heightened emphasis on patient-led drug development, these trends underscore the necessity for CROs to adapt and innovate to remain at the forefront of a rapidly evolving sector."

Additionally, matching complex scientific innovation with

highly efficient and timely clinical trial design and execution is at a high, according to Cyndi Verst, president, design and delivery innovation, research and development solutions, IQVIA. "The industry is gaining a stronger understanding of both investigator and patient burdens to clinical trial participation while also adjusting to the impact of broader macroeconomic influences," she says. "Drug developers are re-evaluating clinical research priorities amidst dynamic regulatory and legislative landscape shifts, recognizing the value in staying nimble in R&D approaches to continue meeting investigator and patient needs worldwide."

Here sponsors are relying on CROs to match their scientific innovation with equally advanced clinical trial approaches that are fine-tuned as programs and funding evolves. Verst adds, "Coming together earlier in the design phase, sponsors can leverage CRO expertise and tech-enabled tools (e.g., digitalization, AI/ML, etc.) to guide key decisions in trial protocol design and feasibility."

Additionally, the emerging biopharma development landscape (EBPs) is a primary contributor of innovative therapies. Verst notes that in 2023, EBPs contributed to more than half (56%) of all new drugs.[2] "Given the potential of breakthroughs coming from EBPs, end-to-end strategic and operational guidance from an experienced and consultative CRO partner can be critical to EBPs that may have gaps in in-house resources, to ensure they move forward in developing their limited but highly valuable assets," says Verst.

Another key driver for sponsors is the looming patent cliff expected around 2029 and the need to expedite development timelines, according to Graham Clark, CEO of Phastar. "Sponsors are setting ambitious targets to bring new therapeutics to market, demanding faster turnaround times within the R&D process," he says. "This necessitates a significant shift in how CROs provide services in the industry, as they work to conduct complex trials in a highly regulated market, essentially at breakneck speed."

GROWTH AREAS IN OUTSOURCING

Several areas contributing to outsourcing to CROs include an increase in demand for specific services through functional service models, smaller biopharma companies needing to adopt cost-effective development methods, as well as access to therapeutic expertise, namely oncology and obesity drug development.

Sponsor/CRO partnership models for services requiring scale and/or specific skills is driving an increase in demand for functional service models. "A significant trend we're seeing impact CROs is the shift to greater use of functional service provider (FSP) solutions," says Les Enterline, global head, functional service partnership solutions, PPD clinical research business, Thermo Fisher Scientific. "This trend is materializing both through an increase in stand-alone FSP engagements as well as through more hybrid FSP/FSO (full-service outsourcing) engagements where FSP solutions are added to existing FSO arrangements."

What's driving this increase in FSP partnerships, according to Enterline, is some clients simply need to scale up resources to meet increasing demand and keep projects on schedule. Enterline notes that other drug developers want to maintain closer control of a specific functional area or need access to specific skills and expertise that the client doesn't have internally or their current provider can't meet the scale required to service their growing portfolio. Additionally, some clients want to leverage global resources to create cost efficiencies or implement a follow-the-sun approach for a specific clinical development function like pharmacovigilance case processing, according to Enterline.

Survey data from PPD's most recent FSP Trends Report shows 41% of respondents have increased their use of FSP partnerships compared to two years ago, while only 27% have increased their use of FSO engagements.[3] The report also indicates that almost nine out of 10 respondents (87% of drug developers) are using FSP or hybrid FSP/FSO arrangements for their clinical development outsourcing.

Another contributing factor driving outsourcing is the decline in biopharma funding these past couple of years, which has exacerbated development challenges. Phastar's Graham Clark says, "Smaller biopharma companies have been disproportionately affected by the macro environment that has been challenging funding for new trials. The number of new trials starts, particularly the latter more expensive Phase 2 and 3 trials, has been under pressure." While the growth in outsourcing must be viewed in the context of what has been a relatively tricky macro market, Clark notes, smaller biotech companies need to adopt more cost-effective methods for testing their compounds. This in turn places greater emphasis on designing trials more efficiently, maximizing the chances of success, and ultimately achieving this in the most cost-effective manner. Here outsourcing provides the opportunity to access the services and capabilities needed to help achieve these goals.

Meanwhile, according to IQIVIA's Global Trends in R&D 2024 report, oncology remains the largest therapeutic area of R&D activity, with 2,143 Phase I to III trials started or planned to start in 2023. Of these trials, 25% are focused on novel oncology mechanism, including cell and gene therapies, antibody drug conjugates, and multi-specific antibodies. Cyndi Verst at IQVIA notes that radioligand therapy (RLT) is also generating excitement in the industry because its targeted modality allows for delivery of radioactive agents directly to cancer cells and/or the tumor microenvironment. "RLTs need experienced and skilled site staff who understand nuanced aspects of imaging, treatment calibration and dosimetry, complex investigational product logistic management, etc.," she says. "Also, some countries' oncology regulatory frameworks may be playing catch-up to therapeutic innovations, making thoughtful evaluation of country and regional regulations critical."

There has also been vast growth in obesity drug development. Glucagon-like peptide-1 or GLP-1 agonists are garnering

tremendous attention in the pharmaceutical space, giving rise to extensive R&D of these and other modalities in obesity. Verst says, "Obesity clinical trials were up 68% from 2022 and have nearly doubled compared to five years ago, including 124 drugs in active development. Of these drugs 40% are GIP/GLP glucagon receptor agonists, and 46% of which have oral formulations in development for greater patient convenience. Also, post-marketing evaluations via real-world evidence studies will be of interest to regulators."

ADDRESSING CHALLENGES IN TODAY'S MARKET

In this industry, there is no shortage of challenges sponsors and CROs face. Chief among them, complex protocol procedures and an evolving regulatory landscape, topped by the rapid advancement of technology. According to Cris Nieto, senior vice president of clinical operations, PPD clinical research business, Thermo Fisher Scientific, "The challenges of protocol and regulatory complexities, retaining talent, and keeping up with data and technological advancements requires CROs to be adaptable, innovative, and proactive in their approach to meet the evolving needs of the industry and their clients."

Protocols are becoming more complex in terms of procedures, involving multiple vendor interactions and an increase of the overall data volume to process, according to Nieto. "Investing in technology and digital solutions is crucial to increase efficiency of study procedures, decrease site burden and help to bring research directly to the patient," Nieto says. Meanwhile, the regulatory landscape in clinical research is constantly evolving, with new guidelines and requirements being introduced. CROs must stay updated and ensure compliance with these regulations, which can be a complex and time-consuming process, Nieto adds.

Conducting global trials in an evolving regulatory landscape requires greater agility and the ability to proactively adapt to streamline sponsors marketing goals. Graham Clark of Phastar, says, "The complexity of the data landscape, combined with the various regulatory requirements, be that in the U.S., EU, and APAC etc., and the requirements around privacy, General Data Protection Regulation (GDPR) and the like, creates a significant challenge to manage within the various markets, and is growing exponentially as a challenge in terms of its size and complexity."

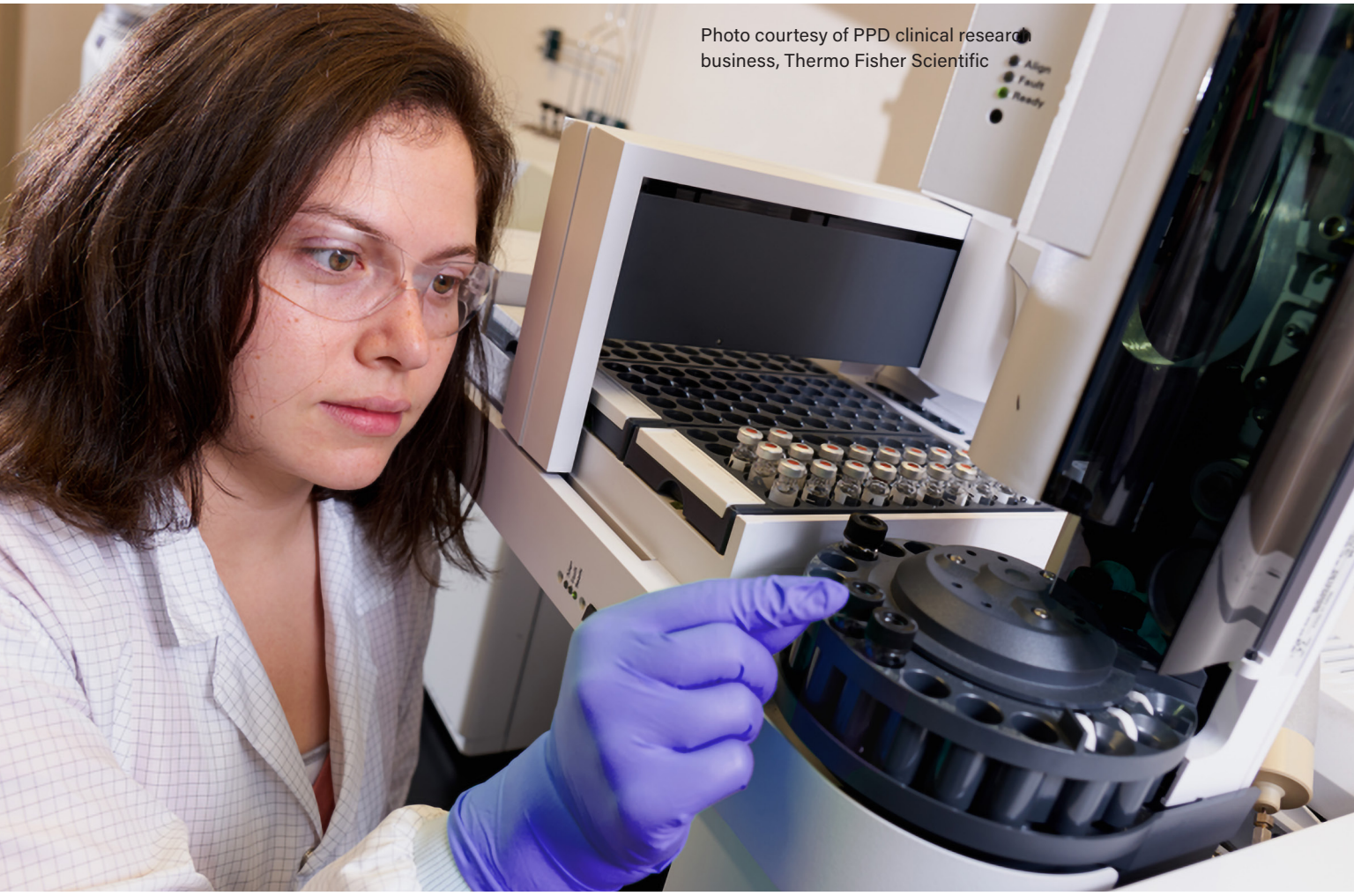

Photo courtesy of PPD clinical research business, Thermo Fisher Scientific

Historically sponsors would take a relatively chronological approach to getting new drugs approved globally, Clark notes. "They would have a home location, say the U.S., where they would get approval, and then pivot across to the UK or the EU," he says. "Now we're seeing that the global trial is being run concurrently and at greater speed. Analyzing results, understanding the differences, interpreting the varying results across different populations, and getting approvals across those different areas, for example, is where the time frame for the R&D funnel is being massively compressed."

Additionally, with the increasing reliance on electronic data capture (EDC) and digital platforms, ensuring data quality and security is of utmost importance. CROs must have robust systems and processes in place to protect patient data and ensure the integrity of clinical trial results, according to Thermo Fisher Scientific's Cris Nieto. "The rapid advancement of technology in the healthcare and pharmaceutical industry presents both opportunities and challenges for CROs," she says "While new technologies such as EDC and remote monitoring can improve efficiency and data quality, CROs need to invest in these technologies and ensure their staff is trained to effectively utilize them. Currently, in most cases, there are still many different solutions being used in silos without a true combined approach."

Additional key challenges that the industry will work to address for some time include a competitive marketplace for similar indications and clinical trial complexities, according to Cyndi Verst at IQVIA. "In total, large pharmaceutical companies spent more than $161 billion on R&D efforts in 2023, indicating an increasingly competitive global marketplace," says Verst. For example, as obesity clinical trials increased 68% from 2022 to 2023, 40% of the 124 drugs in active development were GIP/GLP glucagon receptor agonists, according to IQIVIA's Global Trends in R&D 2024 report. "Companies need to differentiate their assets' scientific aspects to effectively engage investigators and target patient populations within similar indications in saturated areas," Verst says.

To address complexities, getting patient-centered protocols right from the start is key. Verst notes, from 2005 to 2020, the number of required study procedures increased by 139%, and the number of endpoints increased by 214% in Phase III trials. "As such, there is currently an intentional focus on thoughtful planning early in trial design to ensure protocols increase patient engagement, minimize amendments that cause trial delays and inefficiencies and include the right set of endpoints," says Verst.

GROWTH DRIVERS AND OPPORTUNITIES

Having the specialized skills to accommodate innovation in oncology and other complex therapeutics areas, as well as a strong grasp on digital tools and data analyses, are at the forefront of opportunities in the CRO sector.

Graham Clark of Phastar says, "A return to normality in terms of the macro environment and funding for smaller biotechs should effectively feel like growth compared to the last couple of years. Oncology, for example, is experiencing strong growth and is likely to continue this trajectory. This trend should also continue to drive specialization and continue to support the outsourcing of work from sponsors to CROs, particularly in certain therapeutic areas."

A key factor to growth will be access to, and retention of, talent capable of delivering the required capabilities, according to Clark. "This includes not only the standard level of services but also the ability to leverage technology to innovate and become more agile. "It is going to be a double-edged sword for CRO's in the future. They are going to be able to grow by acquiring that talent, but they will find that their growth will be limited if they're unable to retain it. The organizations and leaders that come with a solution to retain that talent will likely gain a larger market share compared to those who lack such solutions or capabilities." Additionally, providing services that are faster and more efficient will drive growth for CROs.

According to Patrick Hughes, co-founder and chief commercial officer, CluePoints, "The CROs who are going to thrive are the ones who do things faster, better, and more economically. This is about more than just cutting costs. It's about utilizing the tools available, embracing AI, and getting drugs to market quicker." The adoption of tools that improve data quality and integrity and have a material impact on trials will be key to driving growth, Hughes notes. "Once data has been collected it needs to be analyzed and critical thinking applied so when the study gets to submission there are no data quality issues," says Hughes.

Helping to address industry challenges, CROs will continue to serve as key players in drug development going forward. Peyton Howell of Parexel adds, "The CRO industry is on the cusp of significant expansion driven by a surge in R&D investment across the pharma and biotech landscapes. This growth reflects the broader industry's push toward innovation to meet evolving needs of patients. With an increasing demand for specialized knowledge in complex therapeutic areas, CROs are becoming indispensable partners in the drug development process. Our sector is well-positioned to not only navigate the challenges of today's healthcare landscape but also to shape the future of medicine."

The backbone of the outsourcing industry is to offer sponsors what they need when they need it, whether it's filling in gaps or partnering across the drug development continuum. Today's drug development complexities continue to drive an increasing reliance on CROs to help improve efficiency and productivity. **CP**

References:

1. *https://www.marketsandmarkets.com/Market-Reports/contract-research-organization-service-market-167410116.html*
2. *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2024-activity-productivity-and-enablers*
3. *https://www.ppd.com/our-solutions/clinical/functional-service-providers/fsp-trends-report/*