Kristin Brooks
Contract Pharma

CROs & Next-Gen Drug Development

R&D trends drive outsourcing in today's market

Photo courtesy of PPD Laboratories

The role of contract research organizations (CROs) in helping pharma and biopharma firms address today's complex drug development challenges, has grown considerably these past few years. Sponsors increasingly engage CROs to provide data-driven insights and navigate the changing drug development landscape for the next generation of medicines. The global CRO market value is expected to exceed $32 billion in 2017[1] and reach $45 billion by 2022, according to a report by Grand View Research, with growth attributed to greater R&D spend, M&A activity, as well as government contracts with CROs.

For pharma and biopharma firms, developing a product and gaining regulatory approval used to be the end goal. Now, there is the further challenge of procuring reimbursement and market access, adding cost and complexity to the drug development process. Once strictly retained for clinical trials and lab services, sponsors now also seek data and analytics for trial insights and design, drug development planning, medical affairs and regulatory consulting from CROs. Additionally, demand for safety and pharmacovigilance, clinical trial feasibility, protocol optimization, and real-world evidence, are on the rise.

Contract Pharma spoke with the industry's top CROs to explore the pharma/biopharma R&D trends impacting services, new ways sponsors are collaborating with CROs, industry challenges, and the greatest motivators for outsourcing in today's market.

MARKET DRIVERS

The pharma/biopharma industry faces numerous hurdles getting their products to market, among them is the growth in payer exclusion lists, challenging the industry to provide more evidence-based assessments of the value of their products. According to

analysis by the Tufts Center for the Study of Drug Development, rising drug prices in the U.S. will lead payers to increase the number of drugs ineligible for reimbursement, requiring drug developers to provide more concrete evidence of clinical superiority and cost-effectiveness of their products.

Additionally, advances in immuno-oncology R&D are boosting funding from investors and cultivating alliances. A new analysis by Tufts CSDD shows investments in new immuno-oncology drugs, along with dramatic improvements in complete response rates in trials for new therapies, are helping to increase the number of alliances between pharma and biopharma companies and university and cancer centers. According to Tufts, more than 130 biopharma and 20 pharma companies are currently developing immuno-oncology therapies.

Another main driver is information technology (IT), which has fostered tremendous advances in clinical trials. The need to make data-driven decisions and elevate the quality of trials leveraging technology, is greater than ever. This is evidenced by the Quintiles/IMS merger in October of last year, creating a global IT-enabled healthcare service provider with global scale and a suite of clinical and commercial offerings, in a transaction valued at more than $17.6 billion.

GOVERNMENT/NON-PROFIT COLLABORATIONS

CROs are not just service providers as evidenced by recent collaborations with non-profit health and government agencies. CROs not only work to enhance the drug development process, but contribute to the development of new drug products and advancing healthcare and outcomes.

For example, ICON was recently awarded a project by the U.S. FDA to validate Patient Reported Outcomes (PRO) instruments that will measure clinical endpoints in antibacterial drug trials. Separately, ICON recently acquired Clinical Research Management, Inc., which extends its presence in the market for government sponsored research and expands capabilities in vaccines and infectious disease.

Additionally, PPD was awarded a National Institutes of Health Contract for HIV research support that includes monitoring trials, prevention trials and vaccines work. This is PPD's fifth renewal of its long-standing NIH contract, which will extend until 2024.

Also, INC Research was selected to manage The Leukemia & Lymphoma Society's first-ever Master Trial to advance new targeted therapies for Acute Myeloid Leukemia.

R&D TRENDS

The conduct of clinical trials and how data is obtained and analyzed is changing. John Hubbard, chief executive officer, Bioclinica and ACRO chairman, said, "A key trend in pharma/biopharma R&D is how to leverage technology in new ways to advance the drug development process. There is an increased focus on virtual trials and utilizing novel technology and data collection tools to access data in more 'real-world' settings. This focus coincides with more evidence-based research and changing clinical trial designs to incorporate input from patient communities. This will require a fundamental change in the way safety and efficacy of new drugs are assessed. With this model, we may be collecting different data than the conventional approach, but we're finding real-world data is more relevant to outcomes."

In an effort to advance products more efficiently, sponsors aren't just engaging CROs early in the development process, they're taking a more holistic R&D approach. "More recently, CROs have been developing and implementing new methods in response to biopharma's efforts to re-evaluate traditional models and core competencies, and consider new operational, organizational and partnership-based approaches," said David Johnston, executive vice president, Global Clinical Development, PPD. "For example, biopharma is providing CROs with increased visibility into R&D pipelines to improve the accuracy of workflow planning and forecasting, and to proactively mitigate risks. These partnerships require a robust and effective governance structure to achieve value creation and ensure appropriate oversight of quality, costs and deliverables."

Complexity remains a key driver for R&D outsourcing. According to Mark Goldberg, president and chief operating officer, PAREXEL, "We continue to see an industry focus on specialty indications such as oncology, autoimmune diseases, and rare diseases, which tend to require more complicated trials. We've seen trial complexity increase significantly in terms of the amount of data collected per patient, the numbers of studies and tests performed, and the numbers of endpoints included."

With respect to the development of immuno-oncology therapies and precision medicines, Chris Smyth, executive vice president, oncology division, Novella Clinical, said, "These new treatments are incredibly exciting; however, their development can present challenges in clinical research. Developers face a landscape that is increasingly complex. For example, it's becoming more challenging to design a protocol for a specific indication, particularly one that includes an investigational drug in combination with a checkpoint inhibitor, due to the pace of new approvals and rapidly shifting standards of care. We counsel our customers to remain flexible given the unknowns, allowing for multiple combination therapies or being open to protocol amendments based on shifts in the industry. It's important to track upcoming approvals, monitor competitive intelligence and leverage feedback from active investigators, and then plan accordingly."

Another trend is the vast amount of innovation emanating from small and mid-sized biopharma companies. Mr. Goldberg said, "It's estimated that 60 to 80% of the intellectual property in the industry resides within these smaller companies. These businesses are often funded to take products further down the development pipeline before they look to monetize their investments. Our biopharm unit caters to these small and mid-sized companies by providing them with the right level of support and services to conduct complex and global programs."

Peter Benton, president and chief operating officer, Worldwide Clinical Trials, added, "With small to mid-sized pharma and biopharma companies driving the majority of innovation, we're seeing that, generally, speed and innovation are inversely related to the size of the company; not by design or desire, but by the shear reality of organizational size and complexity. Often, these small to mid-sized biopharma companies want to continue their capacity for innovation by partnering with a CRO."

Finally, the age-old standard of saving time and money persists. Patrick Jordan, enterprise head, next generation clinical


Photo courtesy of PPD Laboratories


Photo courtesy of Worldwide Clinical Trials

development, QuintilesIMS, added, "As the cost and complexity of developing new therapies continue to soar, biopharma companies have sought to amend their cost structures by partnering with CROs who have the scale, technology, and expertise to drive efficiency into the drug development process. Today, we are seeing that sponsors are increasingly looking for more from these engagements by aligning strategically to bring CROs into the full lifecycle of a study. The best outcomes can start at the beginning in early design, when data and analytics can both challenge and validate trial assumptions. When you consider that as many as 45% of protocol amendments could have been avoided with better insights, the notion of a strategic alliance that allows you to glean insights from experienced CROs, strengthen protocols, and potentially save substantial cost, makes a lot of sense."

IT SOLUTIONS

Intelligent data capture software is pervasive in the industry. Data analysis in clinical trials is critical to the drug development process and payer reimbursement strategies, as well as overcoming trial management and data visibility issues. "The next generation of clinical development is characterized by an increased market demand for data and analytics to improve the performance and predictability of clinical research, and ultimately mitigate the challenges that have persistently plagued our industry," said Mr. Jordan of QuintilesIMS.

Increasingly, these IT solutions impact outsourcing decisions. Dr. Steve Cutler, chief executive officer of ICON said, "Where organizations decide to outsource to CROs, IT solutions have a key influence on the selection of the service provider. Typically, sponsors are looking to CROs to deliver process automation, sophisticated analytics and informatics at an efficient and cost effective price point using best in class IT solutions. Successful CROs must be able to leverage IT solutions to be able to differentiate and deliver added value. It is critical that CROs are also able to streamline their IT solutions and reduce the number of systems involved to deliver a standardized environment on a unified, centralized platform."

According to Mr. Goldberg of PAREXEL, "Up until now, technology had primarily helped the industry automate or semi-automate existing, manual processes. We are now at a transition point where technology plays a more valuable role in enabling innovations in trials designs. From an operational standpoint, analytics supports clinical trial conduct by identifying outliers and highlighting trends. Another example is the use of wearable sensors to monitor new and more easily collected endpoint assessments."

Technology also plays an increasingly important role post-approval in terms of real-world evidence for payers. Mr. Goldberg added, "Payers want assurance that the value of a product demonstrated in a well-controlled clinical trial plays out in the real world. It's often the case that we encounter new information regarding safety and efficacy in the real world, and it's increasingly possible to leverage various data assets to look for signals in this environment. This technology-use case is much more innovative than we have seen in the past and is quickly becoming a reality."

Getting the most from technology requires a thorough evaluation process and limiting customization where possible. According to Dr. Hubbard of Bioclinica, "We're seeing a big shift from homegrown systems in favor of either enterprise systems or moderately customized solutions. Companies are really trying to go with best in class solutions that have minimal customization. Many companies have realized that they've over-engineered their technology solutions, adding costs and complexity. To be successful with any technology, one must first find out how the technology fits in with the organization, connectivity, workflows, and even culture. This requires an extensive assessment, but changing technology can be a big investment and a company needs to see tangible savings to justify the effort required to make the change."

Additionally, staying on top of regulatory and standardization initiatives are important when dealing with IT. "Streamlining the

right technological solution to the right process represents new challenges, especially as the industry moves to implement the new ICH addendum in an already fluctuating regulatory environment, said Michael Gibertini, chief operating officer, INC Research. "We also have multiple other forces, such as TransCelerate, driving industry standardization. Internally, we are faced with the continual challenges of creating patient-centric protocols as we evolve in a more technological environment."

ICH stands for International Council for Harmonization of technical requirements for pharmaceuticals, which brings together regulatory authorities and industry to establish guidelines for drug registration in an increasingly global market.

CHALLENGES IN TODAY'S MARKET

Adaptation to shifting R&D trends, innovation, and being recognized by sponsors as a true partner in drug development, are among the chief priorities for CROs in today's market. According to Dr. Hubbard, "The challenges are really centered on how fast a CRO can evolve in a changing marketplace. If you look at the way the industry is moving and the changes we are seeing, for example industry mergers like IMS-Quintiles and LabCorp-Covance, and some CROs recently purchasing investigator clinical trial sites, it definitely shows an industry in transition and evolution."

Also, the notion of a CRO as strictly a service provider is limiting to advancing the drug development process and creating efficiencies. "CROs will need to overcome the perception in the market that they are simply a resourcing alternative. With the cost of development on the rise, CROs have an opportunity to shed that perception by defining themselves as strategic partners that can collaborate on protocol creation, analytics-driven site identification and targeted patient recruitment. The insights now becoming available can help biopharma companies well beyond where traditional CROs have operated and into market access and product commercialization," said Mr. Jordan of QuintilesIMS.

In the face of all these challenges, the key for CROs is innovation. According to Dr. Johnston of PPD, "As an industry, we must be committed to accelerating the pace of innovation in research and development and harnessing new approaches to our business. For PPD, innovation in technology, operating models and processes are essential components of our strategy for the future. We see innovation primarily focused in three areas: rapid data integration and advanced analytics capabilities; taking advantage of disruptive innovations in order to build a patient-centric approach to clinical trials; and operational excellence and continuous improvement through scientific and therapeutic advancement."

SPONSOR/CRO PARTNERSHIPS

Sponsors are collaborating with CROs in new ways, for example, not just early in the development process, but also on trial design and program management, with productivity as the end goal. According to Tara Gladwell, vice president of operations at Rho, "Small pharma and biopharma companies are engaging with CROs earlier in the process, often well before any clinical studies begin. More are seeking assistance with product development planning rather than just execution of individual studies. Sponsors, especially small companies, are leaning more on CROs for expertise, particularly in early planning and overall program development."

"I think the trend is toward increased collaboration in the trial itself," added Mr. Benton of Worldwide Clinical Trials. "We're seeing more joint site visits, joint training, both the sponsor and CRO, to help investigators and patients throughout the clinical trial process. We're seeing a true, seamless organizational partnership that shows that we have the same goals."

Within this more collaborative role, where CROs are less of a contract service provider and more of a business partner, according to Mr. Benton, sponsors are able to be more creative and open to innovative approaches from the CRO. "We're finding sponsors are more focused on speed and study success, than on rate cards and cost. Sponsors are realizing that having a cost effective clinical trial that takes longer to execute isn't always the best approach," he said.

With greater trust in CROs, sponsors are in a better position to fully utilize expertise with potentially better results. Mr. Jordan of QuintilesIMS said, "CROs are creating deeper, more strategic partnerships with biopharma companies, integrating themselves directly into the design and development process to produce stronger protocols and delivery plans and help avoid costly mistakes. These deeper relationships, combined with the power of data and analytics, are helping us bring important, evidence-based insights to the drug development enterprise that will enable us to bring medicines to market faster."

Still, the most successful partnerships result in streamlining trials and creating efficiencies, regardless of the partnership model. ICON's Dr. Cutler said, "Sponsor-CRO partnerships continue to mature in our industry, such as working together to refine the right ways to drive improved productivity and speed, measure outcomes and enhance governance. We still see great opportunity to work together to be more efficient in delivering trials and programs by eliminating overlapping activities, bringing additional value to both organizations."

Sponsors continue to re-evaluate core competencies while CROs broaden expertise to take on or augment areas once thought to be core for sponsors. According to Dr. Cutler, "Instead of focusing on changing partnership models, we see benefit in committing to a model and making that model increasingly efficient over time."

Driven by growth in R&D spend, drug product complexity, and increasing regulatory and payer demands, the CRO industry's biggest challenge and greatest goal, is addressing this next generation drug development landscape by re-evaluating how trials are conducted and leveraging data in new ways to drive efficiency into drug development processes. **CP**

References

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KRISTIN BROOKS is associate editor of Contract Pharma. She can be reached at kbrooks@rodmanmedia.com.