Outsourcing M&A on the Rise

▶ Pharmaceutical outsourcing remains big business, as companies cut internal costs and with the rise of smaller specialist companies focused on rare diseases and genomics-based therapies.

The move to outsource is growing, with reports that companies are turning to partners more now than they did five years ago. This has led to a steep rise in the number of people employed at CROs – from about 30,000 15 years ago to around 100,000 today.

At the same time, outsourcing organizations are following pharma companies down the path of mergers and acquisitions. For example, Syneos Health was the result of a merger between INC Research and inVentiv Health, and in August 2018, the company acquired Kinapse to expand its ability to provide end-to-end solutions to life-sciences companies. Other big mergers have included Quintiles and IMS Health as well as the acquisition of DrugDev by Quintiles, PPD's acquisition of Acurian, and LabCorp's purchase of Covance. Capital investors have also been acquiring CROs, for example, Pamplona Capital bought Parexel and Amulet Capital Partners acquired SynteractHCR.

The Impact of M&A

According to a 2017 report from Industry Standard Research, the top nine CROs control 60% of the market, a figure that is likely to have risen with more M&A activity.

For pharmaceutical companies there may be concern about fewer choices, but for large pharma companies working with just a small number of big, consolidated CROs opens the door to preferred provider agreements.

Larger CROs are also more likely to have global presence, which means sponsors don't have to search for support from different vendors as they enter new markets. These big companies also are more likely to have the latest technologies and to invest in solutions to manage site identification, selection, and start up.

Often the M&A activity is designed to expand the types of services CROs offer to pharma companies. For example, in 2017, Parexel bought specialty CRO Anolinx to gain the data science expertise it needed to provide clients with support in informatics and epidemiology. These are increasingly important services for pharma companies, so having a partner with those skills does add value.

Many such CROs are looking to provide a "one-stop-shop" to pharmaceutical clients, which is ironic as they often have multiple external partners.

While the M&A trend may be worrisome for smaller companies that can't afford to work with large CROs or that don't believe they will get the support they need, industry experts note that there are still many small, niche CROs in the industry and that this is unlikely to change any time soon.

There are other concerns that these large M&As raise. For example, smaller companies that serve CROs — such as patient recruitment organizations — find themselves with less work as companies merge. In addition, disruption is inevitable during a merger so clinical trials being carried out by a company that is in the process of being acquired will likely be affected. One impact might be due to labs closing, forcing data to be transferred to a different site.

> Across its various functions a market authorization holder may work with 350+ external partner contacts, unsurprisingly many in the industry wish to shrink this number. Manufacturers are seeking strategic partnerships so they can maintain a global reach with the technologies they require but via a smaller base of contacts.
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> Source: PharmaIQ

Why Companies Outsource

The good news is that for larger pharma companies at least, the CRO M&A activity isn't expected to detract from one of the major objectives of outsourcing: to cut costs. In fact, companies may save money and resources by not having to set up agreements with multiple partners.

Given the high costs of bringing a drug to market together with the huge risks involved, pharmaceutical companies have looked to service providers to help them tackle many aspects of their R&D and manufacturing. In fact, for some products, half or nearly half of development is now outsourced. This includes 51% for vaccines, 46% for blood factors, and 44% for hormones.

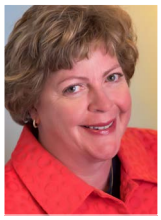
Often, the start-up costs involved in producing and manufacturing a product are too high for small companies to absorb, so outsourcing makes sense. Biopharmaceutical analysis can also be costly and for smaller companies it often doesn't make sense to acquire the equipment needed to carry out analysis of compounds.

Because CROs are carrying out studies on behalf of many clients, they perhaps have more reason to invest in technology, with a Tufts Center for the Study of Drug Development report finding CROs invest 10% more than sponsor companies.

Efficiency goes hand-in-glove with cost savings, and there is evidence that CROs may be more efficient at site selection, feasibility assessment, and study activation. The Tufts report found CROs report completing site-related activities between six and 11 weeks faster than sponsors and have a shorter cycle time of site identification, selection, and study start up.

So why else do companies outsource? Specialist knowledge is a key priority for many companies when it comes to outsourcing. Sponsor companies often turn to vendor part-

EXECUTIVE VIEWPOINTS



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MEGA MERGERS

For pharma companies, mega-mergers can often lead to greater efficiencies and a reduction in overall costs by identifying and eliminating redundancies between the merging companies. Outsourced service partners with experience in managing integrations and aligning resources can play a critical role. An integration period can be a good time for pharma companies to evaluate which of their trusted service providers can help reduce costs in lower volume areas or their non-core services, which in turn may increase the new company margins.

THE FUTURE OF OUTSOURCING

For the CRO industry, the future is built around big data and their ability to leverage data on behalf of pharma companies to make decisions that reduce costs, improve profitability and to help get medicines and devices to market faster. As more therapies come to market, drug developers will be required to provide more concrete evidence of clinical superiority and cost-effectiveness of their products to regulators, payers and prescribers, which will lead CROs to become increasingly focused on delivering new sources of data. To meet the growing market demand, I believe we will continue to see more M&A deals between CROs and data/technology companies.

ners for scientific and regulatory expertise that they don't have in-house, from managing regulatory submissions to advising on guidances by the regulatory authorities. Increasingly, CROs offer more complex services such as data analytics, another priority for sponsors.

Pharmaceutical companies also look for access to specialty equipment with partners, particularly with regard to contract manufacturing.

It's likely that CROs and other outsourcing businesses will continue to look for ways to expand their reach and services, perhaps through partnerships or through M&A. Sponsor companies should monitor these trends to assess what will work best for them now and into the future. PV

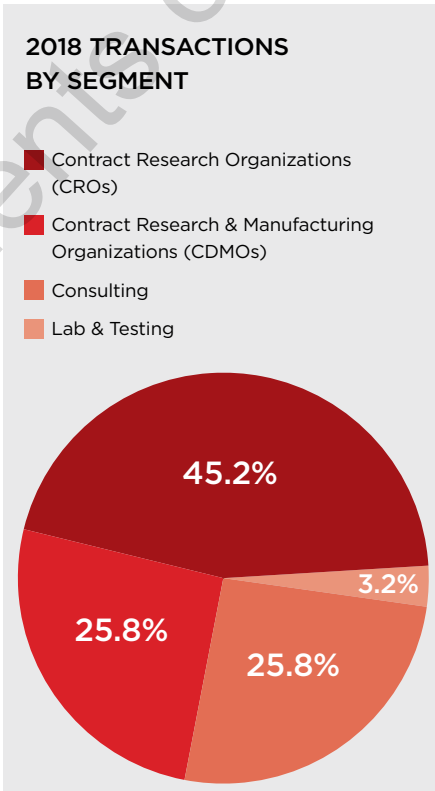
In drug discovery alone, outsourcing is expected to become a $43.7 billion business by 2026, rising from $19.2 billion in 2016.

Source: Biopharma Trend

M&A: Outsourcing

Contract research organizations (CROs) remain the most targeted segment in the pharmaceutical outsourcing industry, accounting for 45.2% of deals to-date in 2018 compared with 38.3% in all of 2017. Buyers have sought to cut clinical trial times and reduce spending through these strategic acquisitions.

2018 TRANSACTIONS BY SEGMENT



BUYER PREFERENCES

- Scalable business models with proven results: Businesses that have displayed strong growth characteristics with the ability to capitalize on significant future growth opportunities have been highly valued by buyers.
- Reputation for delivering superior solutions to life sciences sector: Acquirers have sought outsourced providers with proven capabilities, instruments, and technical staff to deliver high quality and responsive outsourced services.
- Tenured management team: Strategic suitors, and in particular private equity groups, have targeted businesses with strong management experience and depth.
- Rigorous quality assurance protocols: A sterling audit record with the FDA and clients has been viewed as a critical attribute for success in the life-sciences outsourcing sector and has attracted buyer attention.
- Recurring revenue and visibility: Businesses that have developed recurring revenue streams and long-term visibility are highly sought after in the space.

Source: Capstone Headwaters

Outsourcing Regulatory Filings with an FTE Model: Five Keys to Consider

As an increasing number of drug and device developers focus their efforts on reducing costs so they can invest more heavily in their core R&D functions, it's no surprise that the outsourcing market for healthcare regulatory affairs is predicted to expand at a rapid pace over the next decade. Some estimates say the market will reach $200 million by the end of 2025.

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While some sponsors choose to outsource regulatory affairs when they are seeking approval for their product, the benefits of regulatory outsourcing can extend far beyond approval. Even when companies have a strong regulatory team in-house, they may find outsourcing can drive cost efficiency and scalability — particularly when the focus is ongoing regulatory maintenance or publishing and chemistry, manufacturing and controls (CMC) activities.

For mid-size and large manufacturers with many products, hiring a full-time staff to manage regulatory filings through the product life cycle can be costly and unwieldy to manage. A Full Time Equivalent (FTE) outsourcing model can help to streamline post-approval regulatory filings, enabling sponsors to maintain compliance and reduce overhead costs without compromising quality or risking deliverables.

If you are considering outsourcing post-approval regulatory work, here are few keys to help you choose wisely:

1. Seek experts with deep experience: The regulatory strategy, including writing key communication and submission documents, is critical in achieving approval and maintaining compliance.

Each therapeutic area and each approval pathway has its own regulatory nuances and special requirements. The last thing a sponsor needs is to lose time, or dollars, funding an outsourcing partner's learning curve. The more in-depth experience your regulatory partners have with your product's therapeutic area — and the specific pathway — the more able those partners will be to hit the ground running.

2. Look for flexibility to integrate with your team: In an ideal FTE outsourcing model, the consultants will have the flexibility to work independently or under the direction of a manager on your team. Additionally, they should be able to operate within your company's established requirements, or bring expertise to help develop those processes and templates if they are not already in place.

Essentially, your outsourced team should have the flexibility to ebb and flow to meet the unique needs of your company — and fill in gaps if any exist.

Some FTE models have a hybrid built in — meaning they can shift from FTE to hourly at times, allowing manufacturers to scale their work up and down quickly.

3. Remember that depth matters: When it comes to the most complex and nuanced components of regulatory affairs, particularly strategy development and regulatory writing, there's no substitute for proven, hands-on experience.

Some potential partners may boast significant experience at the senior-most levels of the organization, then pass your day-to-day project work on to a team with much less experience. That's why it's important to ask potential outsourcing partners to share the average years of experience of the specific team that will be working on your product. An experienced FTE leader, who can anticipate manufacturers' needs and who knows which levers to pull to keep the model at 100% capacity, is also critical to success.

4. Consider your outsourcing partner's employee and customer longevity: Years and depth of experience are critical, but so are team and customer longevity. It can take years to map out and steer successfully through the drug development and commercialization process — and team turnover is a sure-fire way to slow that process down. That's why it's critical to ask potential regulatory affairs partners about their staff turnover rate. It is also helpful to know what percentage of their work comes from customer referrals and repeat business.

The answers to these questions will indicate each potential partner's reliability and whether the staff that works on your product is likely to remain consistent.

5. Request case studies: Anyone can claim to deliver results, but few companies can demonstrate it. Be sure to ask your potential partners to share case studies of how they have helped companies like yours reach regulatory milestones, maintain high quality and achieve cost savings through outsourcing.

Choosing the Right Partner is Key to Success

As sponsors focus on cultivating their own internal R&D talent and expertise, they'll continue to seek out regulatory affairs experts who can help them contain costs while expediting approval pathways and maintaining compliance. However, choosing the right outsourcing partner, from the start, is key to the success of this approach. Sponsors must be thoughtful and strategic in engaging early with partners who have not just the therapeutic and pathway approval experience, but also the depth and breadth of experience needed to remove potential roadblocks and streamline the regulatory process.