CROs, convergence, and commercial opportunities

How industry convergence is creating win/win opportunities for contract research and life sciences organizations

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With the Contract Research Organization (CRO) sector experiencing modest growth in recent years, many are starting to explore whether ongoing convergence in the U.S. healthcare industry may be creating opportunities for *higher* revenue growth. Our research suggests that significant untapped advantages may result from expanding the existing strategic relationships between CROs and their life sciences clients, and, thereby, creating new value streams.

Steady, but tentative growth for CROs

The good news for CRO organizations is that the dark days seem to be over. Compared to the lackluster growth from 2010 to 2014, the next five years appear ready to deliver steady, albeit modest, growth. Life sciences product pipelines have regained their strength, approvals by the FDA have rebounded, and strong new products are set to launch in key therapeutic areas. As a result, topline growth for the CRO sector is expected to hover between six to seven percent over the next five years (see figure 1).[i] Of course this growth is not uniform globally. As the cost of conducting clinical trials in emerging countries is 40 to 60 percent less than that of developed countries, the CRO market in emerging countries is growing by double digits. This is mainly being driven by China, which grew in market size from RMB 8.5 billion (approximately US$1.4 billion) in 2007 to RMB 42.5 billion (or US$6.5 billion) in 2014 at a compound annual growth rate (CAGR) of nearly 26 percent.[ii] While the United States and Europe are still predominant in the global CRO market, they are experiencing slower growth, leading to an estimated global industry CAGR of about seven percent.

Yet with the sector highly fragmented, even this small measure of growth may be unevenly distributed. The reality is that the top 10 CROs currently represent more than half of the market (see figure 2),[iii] with the remainder divided among an estimated 700 to 1,000 small and mid-sized companies operating around the world. We anticipate that the top 10 will enjoy above-average growth, as will a handful of the more innovative niche players, particularly in emerging areas such as pharmaceutical analytics and market access. The vast majority of the others, however, will likely suffer lower-than-average growth rates and possibly risk becoming acquisition targets.

Fig. 1 **Estimated growth returns**

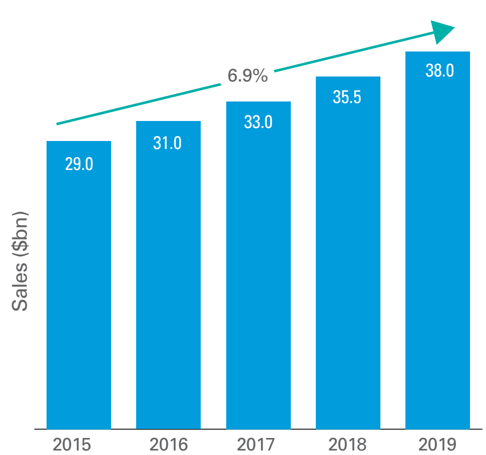
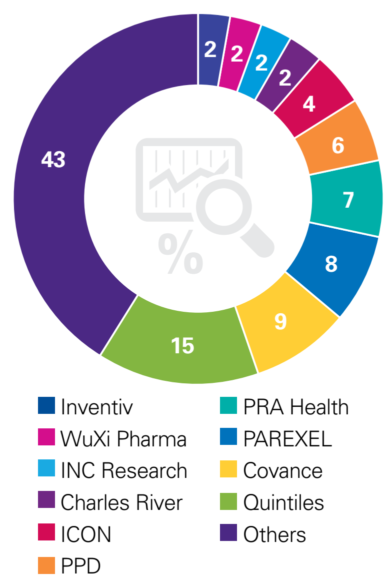


Fig.2 **Highly fragmented markets**



i) Contract Research Organization Industry Overview; Harris, Williams & Co; April 2014

ii) China Contract Research Organization Industry Report, 2015–2018; Research in China; The Vertical Portal for China Business Intelligence; July 2015.

iii) Analyst reports, KPMG Research and Analysis

Convergence: Disruption or opportunity?

Many leading healthcare and life sciences organizations across the ecosystem have been working more collaboratively for some time now. This trend is picking up pace, driven in part by the recognition that healthcare is transitioning to an outcomes-based system that rewards organizations based on the effectiveness of a therapy or medical intervention rather than the consumption of it. Consequently, a high degree of consolidation, or *convergence*, is being observed through a number of vertical and horizontal integrations among different healthcare ecosystem participants. These are aimed at increasing and redefining companies' product and service offerings. Successful industry players are already seeking to expand into new areas to reposition themselves as leaders in the new environment. As life sciences manufacturers seek to do *more with less* in this resource-constrained environment, CROs can be positioned as strategic partners to help them reduce operating costs and focus on advancing innovation.

Additionally, we have seen a flurry of mergers, acquisitions and consolidations in the CRO sector over the past few years, mostly comprising larger CROs targeting small- to medium-sized companies,[iv] as shown in figure 3 below.

Fig. 3 **Consolidation picks up pace in the CRO sector**

2013

Dec 31, 2013
PRA International acquires Lifetree Clinical Research to build early phase CNS platform – undisclosed transaction cost

2014

Mar 13, 2014
Charles River acquires Galapagos" Argenta and BioFocus to strengthen its offerings earlier in the drug development process – **$186 million**

March 31, 2014
ICON acquires Aptiv Solutions to enhance their clinical trial decision making and expand into Japan and medical device market – **$144 million**

May 12, 2014
Quintiles acquires Encore Health Resources to add EHR expertise and gain access to large U.S. provider network – undisclosed transaction cost

July 1, 2014
PAREXEL acquires Atlas Medical Services to expand capabilities into Middle East markets – undisclosed transaction cost

October 3, 2014
PAREXEL acquires ClinIntel, which is a provider of clinical randomization and trial supply management (RTSM) services, based in Crawley, U.K.

Nov 21, 2014
LabCorp acquires Covance to improve clinical trials by leveraging LabCorp health database – **$5.6 billion**

2015

Jan 9, 2015
WuXi acquires NextCode, a bioinformatics company – **$65 million**

Feb 2, 2015
ICON PLC acquires Medimedia, a strategic consulting and medical communications company – **$120 million**

May 20, 2015
Quintiles acquires Clio Science to enhance their footprint in Japan

July 7, 2015
Charles River acquires Celsis to enhance their quality control microbial testing – **$212 million**

July 31, 2015
PRA Health acquires Value Health Solutions, a clinical software company

The rationale for these deals tends to align with one of three (often interrelated) objectives:

1. **Diversifying the service offering:** With the risk of commoditization rising in the pre-clinical and clinical research segment, CROs are looking to diversify their service portfolios in order to offer the latest technological advancements to their clients. Analytics and predictive modeling have proven to be the most desirable new services, whether developed internally or by acquisition.

2. **Expanding the client base:** While most of the major players currently enjoy strong demand and stable books of business from the larger life sciences organizations, they often struggle to attract small- to medium-sized pharmaceutical companies with significant R&D budgets and fragmented operations. To expand into this important client base, some larger CROs are now acquiring smaller competitor firms, who tend to relate better to this market segment.

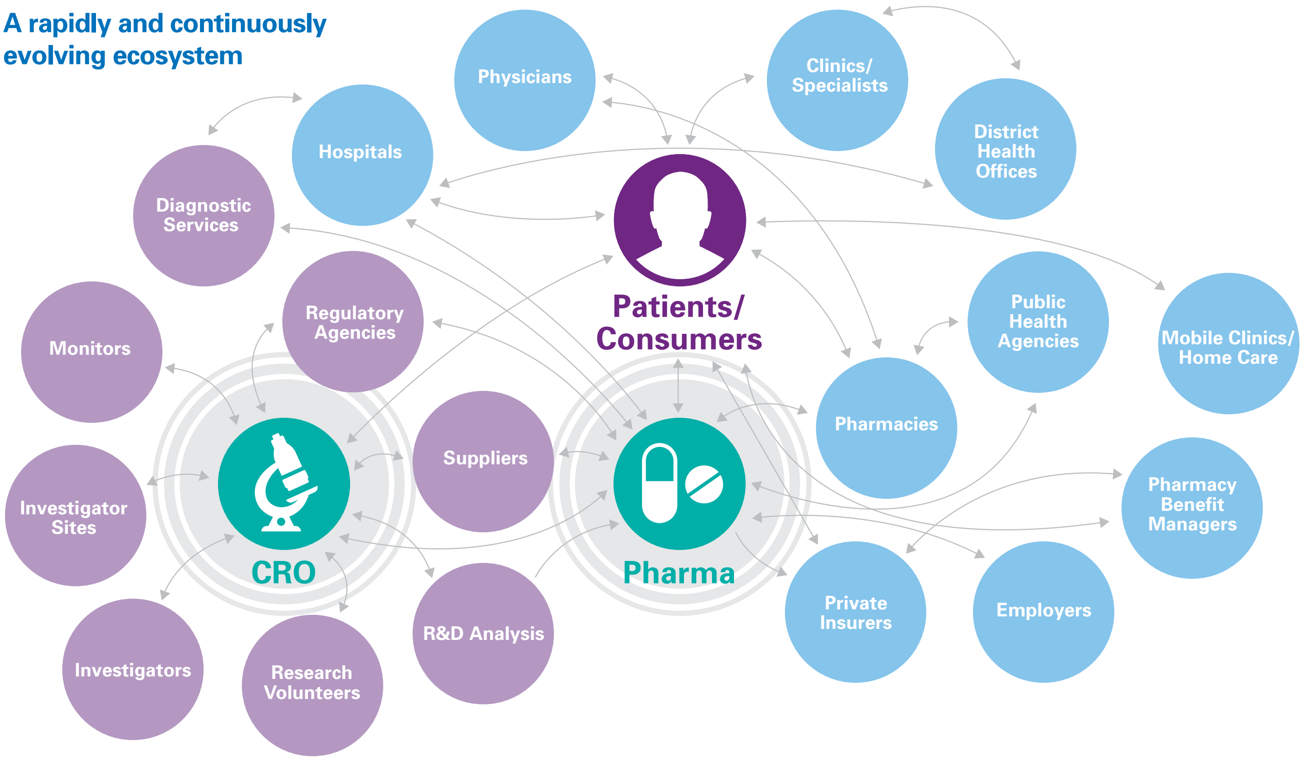
3. **Improving economies of scale:** CROs of all sizes are acquiring peers, competitors and partners, not only to benefit from additional infrastructure and economies of scale, but also to enter into new markets and reach more customers at a lower cost.

iv) KPMG Research and Analysis

Traditional lines are blurring

All of this M&A activity—combined with the forces of convergence—has led to rapid change. As illustrated in figure 4 below, the ecosystem of industry players and business partners is rapidly evolving and, as it does, traditional lines are blurring. This, in turn, is shifting relationships between key players; creating new opportunities for mutual growth, and uncovering avenues where existing capabilities can be leveraged to develop entirely new service areas. As a result, stakeholders across the ecosystem are now starting to reevaluate their roles and value propositions, creating even more opportunities for CROs to drive growth.

Fig. 4 **A rapidly and continuously evolving ecosystem**



An appetite for outsourcing

Opportunities for CROs are not just diversifying, they are also increasing in size. The shift toward convergence has compelled many life sciences organizations to rethink their value propositions and renew their focus on delivering profitable growth in a highly volatile market. As a result, we have seen a growing preference for outsourcing of non-core services (such as clinical research), as well as the creation of strategic partnerships with CROs that can deliver increased productivity, improved quality and reduced costs.

We believe that the continued evolution toward more variable cost bases and the desire to focus on the core business will drive a growing appetite for these partnerships. For a point of comparison, consider the similar evolution the aviation industry undertook in the early 2000s, when purposeful *value chain deconstruction* led to the airlines finding more natural owners for assets and activities once owned or conducted in house (see figure 7 on page 7).

Clearly, this move toward greater use of outsourcing will create new opportunities for CROs. As their life science partners struggle to balance innovation and speed to market with considerations related to safety, compliance, pipeline efficiency, and affordability, CROs are a natural fit to bridge that gap.

Assess the adjacencies

Recognizing potential opportunities, some leading CROs are beginning to explore ways to diversify their revenue streams. And they are expanding their vision beyond the traditional R&D role.

This is perhaps not surprising—R&D represents only 20 percent of the estimated $650 billion of total biopharmaceutical spend each year. We estimate commercial spending (sales, marketing, commercial operations, market access, etc.) to be nearly 25 percent of that amount, or roughly $160 billion.[v] And, for the most part, the vast majority of this work is still conducted in house, at least at larger life sciences organizations.

v) KPMG Research and Analysis

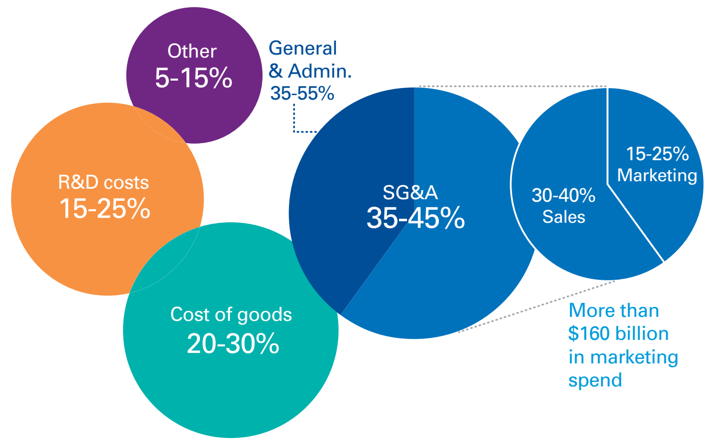
The shift toward convergence has compelled many life sciences organizations to rethink their value propositions and renew their focus on delivering profitable growth in a highly volatile market.

A look across the spectrum of spend categories that fall within the commercial space suggests that there are a number of areas where CROs could leverage or enhance existing capabilities to support their life sciences customers. With the emergence of analytics and data science in healthcare, the life sciences industry is expected to introduce new methodologies of drug discovery as part of their pipeline. The new partnership between Quintiles and IMS Health to leverage real-world data in an attempt to accelerate insights in pre-clinical and clinical R&D demonstrates this. At the same time, CROs can use these capabilities to provide commercial services such as market research, product launch and brand management services.

According to KPMG research, there are several key areas of commercial spending by life sciences companies that could be potential high-revenue areas for CROs.

- **Market planning and development:** Some of the larger CROs have already started offering advisory services to pharmaceutical clients, leveraging their knowledge of drug development, healthcare delivery, and global platforms to enable strategic decision making (products or therapeutic areas, geographies, etc.)
- **Brand management and multi-channel marketing:** CROs could augment their clients' existing HCP and patient engagement strategies by leveraging their wide industry networks, deep understanding of healthcare systems and stakeholders, and regulatory knowledge across markets.
- **Launch planning and execution:** By leveraging existing infrastructure and data assets, CROs can support the planning and launch implementation for specific products or portfolios in different markets at a lower cost than in-house, independently developed strategies.
- **Market research and strategic analytics:** Similar to advisory services, CROs are also offering consulting services around pricing and market research. Their data assets and networks allow them to develop analytics offerings and deliver real-world insights from electronic health records (EHRs). Strategic analytics could also be applied to commercial programs to gauge effectiveness and measure ROI, since CROs already have access to a wealth of information gleaned from following a drug from development through commercialization.

Fig. 5 **Average breakdown of estimated total biopharmaceutical spend (2014) 100 percent = $650b+**



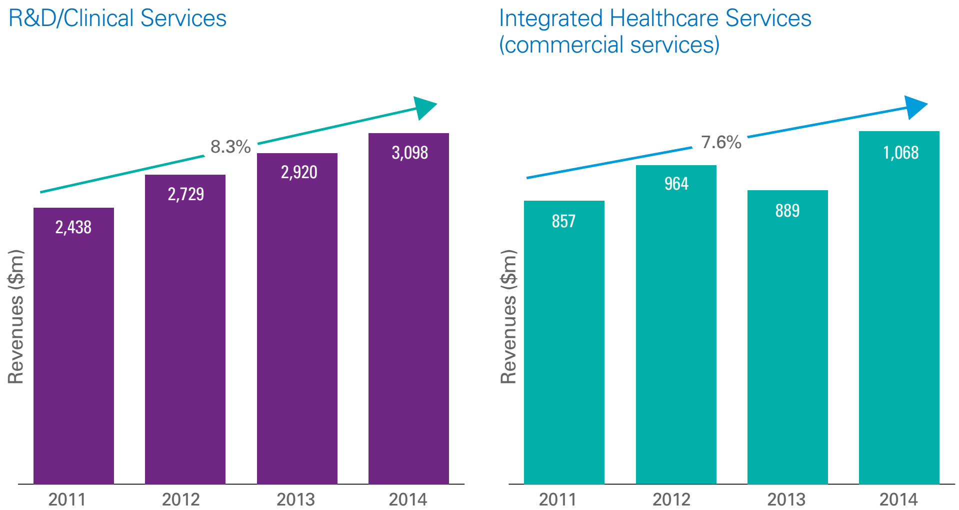
- **Data management:** Large CROs have begun boosting their data science divisions in an attempt to accelerate insights in pre-clinical and clinical R&D, as well as to accelerate EHR consolidation and streamline clinical trial enrollment.
- **Sales force operations:** Utilizing their knowledge of therapeutic areas and access to a wide physician network globally, CROs have also started offering consulting services related to sales force operations, including sales force sizing and design, sales targeting strategies, and effectiveness/ROI measurement.
- **Market access and value-based contracting:** As this topic ramps up in importance globally and the industry adapts to a value-based model, CROs have begun to offer market access strategy services to help pharmaceutical companies target their messages, gain adoption on formularies, and negotiate better pricing and reimbursement. Their knowledge of global payer systems can also help clients better utilize outcomes data and informatics to demonstrate value.

Quintiles, the largest CRO globally, has made sizeable investments in the development of commercial offerings. Their Integrated Healthcare Services group, which primarily addresses the commercial needs of their clients, is growing at a rate of 7.8 percent, which is nearly at par with the 8.3 percent projected CAGR observed in the clinical services group over the past few years. This group also contributes to 25 percent of Quintiles's $4 billion in annual revenues.

The bottom line is that the opportunities that reside within life sciences commercial spend are both massive and diverse.

For CROs and their life sciences clients, the development of these commercially focused, strategic relationships should lead to mutually beneficial outcomes.

Fig. 6 **Quintiles revenue streams**[vi]



CROs will gain access to new and more sustainable revenue streams with better margins, which align well with their current service offerings and capabilities.

For life sciences organizations, the relationships can unlock opportunities for cost reduction, process simplification, and improved strategic and operational focus.

New value opportunities emerge

Getting these new relationships off the ground will take careful consideration and savvy portfolio development. While many CROs already boast some of the skills required to serve these new areas, most will need to develop—or acquire—capabilities and capacity in new markets to grow their businesses and meet clients' evolving demand for services.

Even beyond the commercial services opportunity, we expect to see a wide range of new opportunities emerge for CROs in the future through adjacent and new growth avenues. CROs could, for example, acquire new capabilities in biomarkers and tissue banking and combine this expertise with clinical data to enable personalized medicine. They could acquire (some of) the capabilities needed to manage a fourth-party logistics service offering that provides better visibility across the supply chain with a single point of contact. Given industry convergence, CROs may consider the opportunities that come from partnering—or even acquiring—a healthcare services provider in order to offer a compelling value proposition throughout the healthcare value chain. An example of more broad-based expansion by a CRO is Covance's foray into manufacturing. The company wanted to be able to churn out doses of investigational drugs for ongoing studies—thereby streamlining and enhancing clinical trials, bringing innovative medicines to patients faster, and helping change and improve the way care is provided. Another instance is Parexel's recent announcement to acquire Health Advances, a life sciences strategy consulting firm focused on the commercialization of new medical innovations. This acquisition is intended to boost Parexel's consulting (commercial) business, which currently accounts for about 10 percent of its revenues.[vii]

The value proposition for the pharmaceutical industry

For pharmaceutical organizations, the development of deeper partnerships with CROs that allow them to offer a broader range of services amounts to significant potential value and a renewed opportunity to focus on their core business—drug innovation.

As the forces of convergence continue to shift the life sciences business model, many companies are reassessing what activities they should focus on internally versus what they can outsource. Aside from improved economies of scale, collaborating with CROs can foster "improved" outsourcing of non-core commercial costs and eliminate burdensome operating costs. In making these decisions, life sciences executives will need to answer some tough questions about scale, services, costs, and value. And they will need to look beyond the traditional areas and perceptions of outsourcing to find opportunities to refocus, streamline and enhance their operations.

Ultimately, we expect to see the life sciences sector embark on a phase of *value chain deconstruction* like the airline industry before it. Organizations will strive to identify the natural owners of the functions and operations they choose to outsource so they can truly focus on their core businesses.

vi) Quintiles Translational Holdings SEC 10-K filings

vii) www.fiercecro.com/story/parexel-moves-buy-pharma-consulting-firm/2016-01-21

Will life sciences follow the airlines' model?

As life sciences organizations move toward greater use of outsourcing in their business models, they may be able to learn from the airline industry. Airlines have completely reconstructed their value chains over the past fifteen years and, in so doing, are now enjoying renewed growth.

In the 1990s, the conventional wisdom in the airline industry was that it was critical to own the entire value chain in order to maintain both safety and profitability. A broad range of service areas were managed internally including ticketing, catering, customer service, baggage handling, maintenance and repair, operations, and fueling.

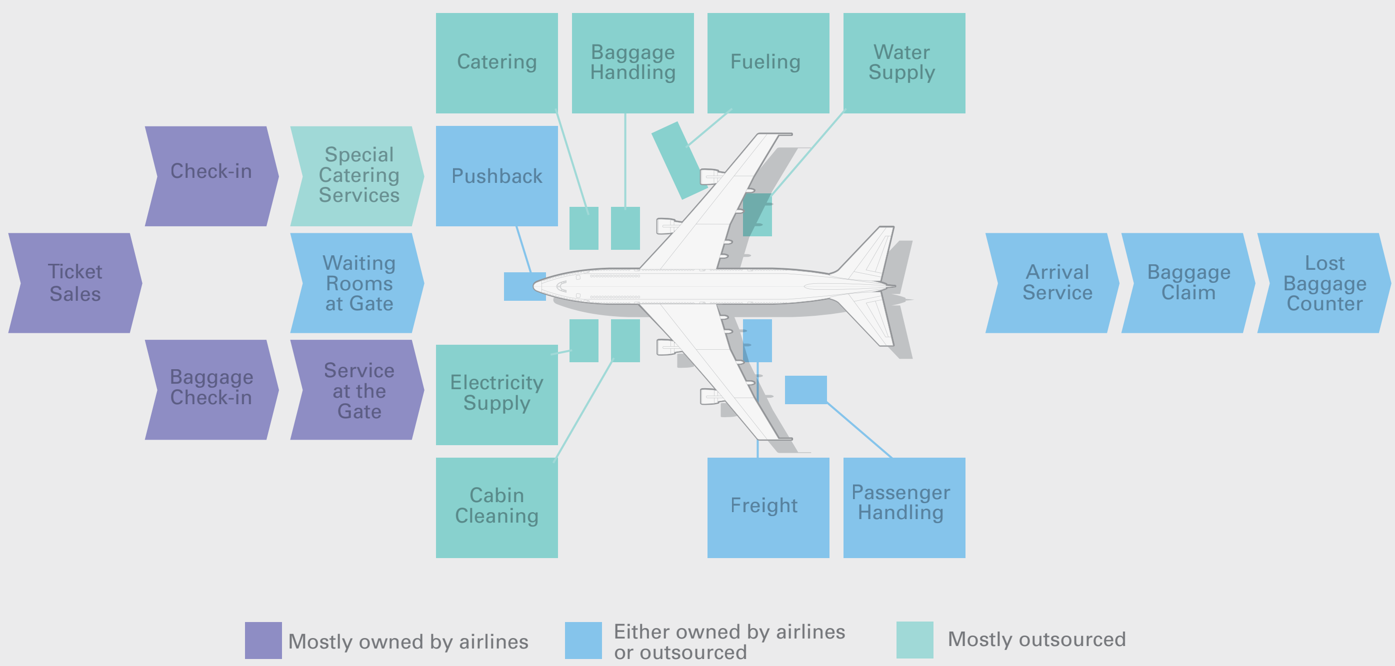
As profitability sagged during the global financial crisis, the airlines recognized that they needed to make dramatic changes to their cost structures if they hoped to emerge from the crisis. Very quickly, they identified operational areas that could be streamlined and contracted out to service providers with the expectation that this would deliver better economies of scale, enable them to focus on core competencies and foster growth without incremental capital costs.

Today, many of the most successful airlines own only business-critical assets. Everything else—from the maintenance and repair of aircraft through to internal sales and promotions—has been outsourced to third-party service providers.

Freed from the distractions of non-core activities, management has been able to focus on innovation and achieving the next strategic advantage. Their outsourcing arrangements have also allowed them to gain access to technology specialists that help them make the most of new innovations and models.

The lessons for life sciences organizations are clear—finding the natural owner of non-core activities, move decisively, and put everything on the table. Nobody wins the race with half measures.

Fig. 7 **A comparative illustration**



How KPMG can help

KPMG LLP (KPMG) has broad and deep experience helping life sciences companies and CROs address their business imperatives and growth agendas. With knowledge in strategy, risk and compliance, and organizational transformation, KPMG brings the capabilities, industry knowledge, and breadth of experience needed to help life sciences companies define and achieve robust growth.

About KPMG

KPMG's Healthcare and Life Sciences professionals have broad and deep experience helping both biopharmaceutical companies and CROs address complex business issues including profitable growth, implications of industry convergence on the business model, and outsourcing. We work with companies to develop approaches and road maps to address their unique needs in the evolving healthcare ecosystem—from manufacturing and supply chain to cost reduction to business model transformation and new value stream identification.

KPMG Strategy takes an enterprise-wide view to business transformation by assisting clients from strategy through to execution. Traditional strategy consulting services primarily focus on business model issues without giving adequate consideration to implications for the operating model and the complex journey companies must undergo to change and realize value. KPMG's proprietary strategy methodology connects business model design (strategy) and operating model implementation (execution). Further, KPMG offers clients a wide range of implementation services through our deal advisory, management consulting and risk consulting capabilities. Together, they establish a platform to support transformation with deep industry experience and strong and differentiated proprietary methodologies and tools. The end result is a customer engagement where strategy, business model and operations are all in sync.

Learn more at kpmg.com/us/strategy

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