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The evolution of pharma services: Adapting to a new era in R&D

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Introduction

Pharmaceutical research and development (R&D) is experiencing significant evolution, driven by diverse and complex factors. Notably, National Institutes of Health (NIH) funding plays a pivotal role, with substantial sums allocated annually to support biomedical research in the US. This funding underlines the importance assigned to innovation in healthcare. However, the global pharmaceutical industry is also influenced by government funding sources outside the US, which are investing heavily in biopharmaceutical innovation and infrastructure (e.g., China). These dynamics have created some peculiar circumstances in pharma R&D.

Pharmaceutical companies are responding to these financial and competitive pressures by strategically cutting R&D budgets. However, rather than diminishing their commitment to innovation, these firms are reallocating resources to prioritize clinical assets that are closer to commercialization. This readjustment is driven by the immediate need to enhance pipelines with assets that promise quicker returns on investment.

The pharmaceutical industry is also internalizing these changes by reducing overall spend on internal staff while simultaneously increasing their reliance on outsourcing. This shift is expected to create more opportunities for contract research organizations (CROs), contract research and development organizations (CDMOs), and other pharma services providers, as pharmaceutical companies seek external expertise and efficiencies.

Preclinical R&D – A shifting paradigm under intense scrutiny

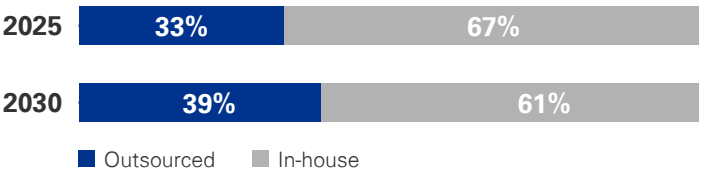
Preclinical R&D has historically been an internal fortress for pharmaceutical companies, deemed too integral to be outsourced. Traditionally, discovery, preclinical toxicology, and other early-stage R&D activities were maintained within company walls, considered a core competency crucial for innovation and proprietary knowledge.

However, this paradigm is steadily shifting.

Growth drivers for outsourced preclinical R&D outfits:

1 **Scrutiny from activist investors on long-term effectiveness of in-house R&D:** The productivity of in-house preclinical R&D has come under scrutiny, particularly by activist investors who demand higher returns and better resource allocation. By engaging outsourced providers on a project-by-project basis, pharmaceutical companies can enhance transparency and control over R&D activities, ensuring cost-efficiency and accountability.

Figure 1. Percent of research spend outsourced to third-party vendors, 2025 and 2030



Source: KPMG R&D Outsourcing Trends Survey, n=150 (January 2025)

2 **Desire to obtain efficiency and expertise without expensive capital outlays:** Outsourced providers often bring specialized skills and innovative methodologies that can accelerate the drug-development process. For example, the KPMG R&D Outsourcing Trends Survey (January 2025) indicated that toxicology studies and PK/PD (pharmacokinetics and pharmacodynamics) studies are increasingly being outsourced. The ability of these external providers to swiftly deliver high-quality services continues to make them attractive partners.

3 **Rapid evolution of technological advances in biosimulation:** The advancements in high-throughput screening, automation, and artificial intelligence (AI) facilitate more efficient and innovative preclinical research. Partnering with research service providers that leverage these technologies allows pharmaceutical companies to access cutting-edge techniques without bearing the full cost of in-house development.

> Activist investors are more active … both because they've seen results and because there is greater acceptance of activist investing as part of a larger portfolio….What you're seeing in pharma, particularly companies that were heavily invested in COVID vaccines, is they may have bloated operations or under-performance."[1]
>
> *Steve Segal, M&A lawyer, Buchalter*

Limiting factors for growth of outsourced preclinical R&D outfits:

1 **Patent cliffs and revenue pressures resulting in prioritization of late-stage assets:** Impending patent cliffs and anticipated revenue losses necessitate a focus on assets closer to market. Pharmaceutical companies are keenly aware of the need to fill revenue gaps left by expiring patents and are therefore prioritizing clinical stage assets and M&A opportunities with a clear, short-term revenue pathway.

$236B Estimated patent cliff between 2025 and 2030

200 Number of brands exposed

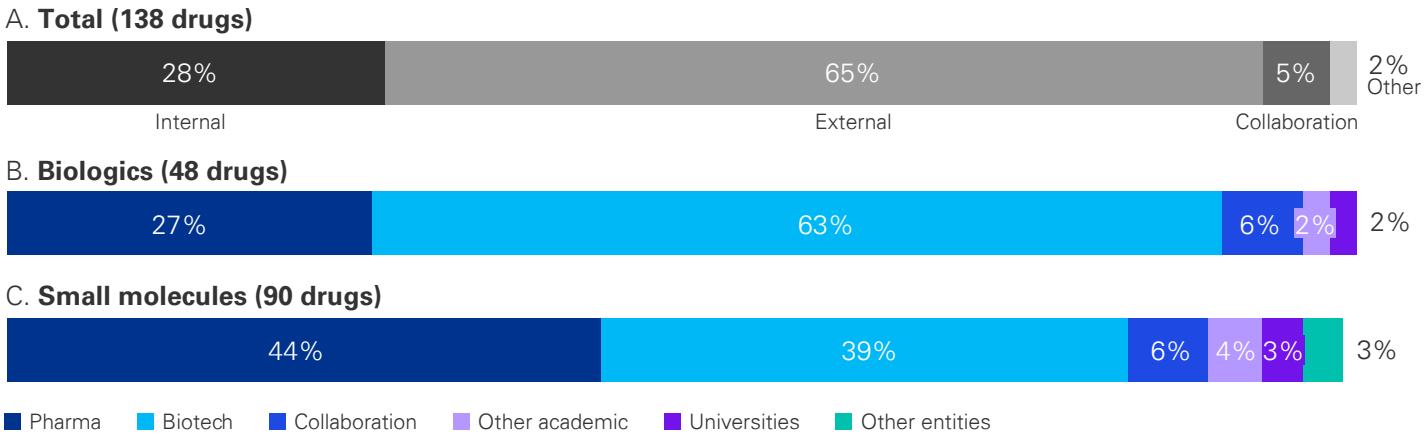
~70 Number of blockbusters* exposed

Source: KPMG analysis; Medpath; company annual reports
*Blockbuster refers to drugs with peak sales >$1B/year.

[1] "With activist investment rising, Pfizer's battle with Starboard reflects the industry's post-pandemic tumble," PharmaVoice, October 22, 2024

2 **Low percentage of internally discovered drugs reducing top-line preclinical R&D spending:** The fact remains that the percentage of drugs discovered within pharmaceutical companies' four walls is historically low. Most drugs in current pipelines have been licensed from smaller biotechs or academic institutions. This trend means that pharmaceutical companies are inherently more reliant on external innovation sources, reinforcing the emphasis on clinical stage assets and M&A for immediate revenue potentials.

Figure 2. Origins of FDA-approved new drugs filed by the top 20 biopharma companies between 2015-2021



Notes: Overall, 65% of the new drugs originated from external sources. The majority of biologics (63%) originated in biotech companies, while the largest group of small-molecule drugs (44%) originated in pharma companies. Other acacdemic institutions include non-profit research organizations and governmental research institutes.

Source: "Investigating the origins of recent pharmaceutical innovation," nature.com, July 5, 2023

3 **Regulatory changes and next-generation models to replace animal testing:** The FDA's recent announcement that drugs tested in humans outside the US do not require additional animal testing before initiating US studies is a significant development.[2] This regulatory change leverages global clinical data, making international collaboration more attractive and minimizing the preclinical burden for US-based clinical development. Consequently, the prioritization of clinical-stage assets over preclinical investments is expected to continue, because now the burden of evidence for clinical drugs outside the US will not require additional pre-clinical interrogation.

[2] Source: "FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs," fda.gov, April 10, 2025

Clinical R&D–Maintaining momentum post-COVID-19

Clinical R&D gained unprecedented attention and investment during the COVID-19 pandemic, as the race to develop vaccines and treatments took center stage. While the initial boom catalyzed by the urgency of the pandemic has tapered, clinical R&D remains a vibrant and critical area in the pharmaceutical landscape.

Growth drivers for outsourced clinical R&D outfits:

1 **Prioritization of top-line clinical spend and outsourcing:** As noted previously, even as overall R&D growth is expected to be stable or grow in the low-single digits, pharmaceutical companies are allocating more of their R&D budget to clinical development, favoring assets closer to market. This prioritization is coupled with a strategic outsourcing model to streamline operations and focus internal resources on core competencies.

Today, there is an even split of total R&D budget allocated to research versus development (50 percent to each) (Figure 3). By 2030, a slight shift towards development will need to address upcoming patent cliffs as assets closer to revenue generation will need to be prioritized.

Overall, outsourcing spend will continue to increase (Figure 4) within development, rising from 48 percent in 2025 to 52 percent in 2030. Outsourcing development spend is set to outpace research spend as pharma tries to manage variability and expertise in trials.

Figure 3. Percent of R&D budget allocated to research versus development activities, 2025 and 2030

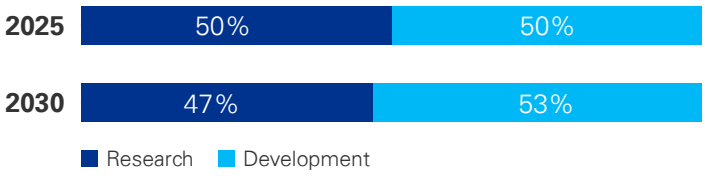
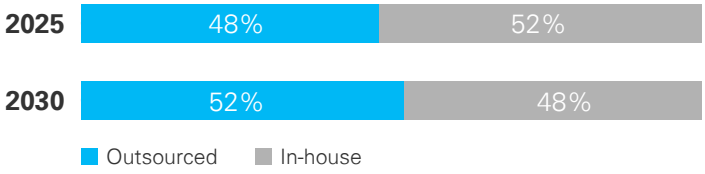


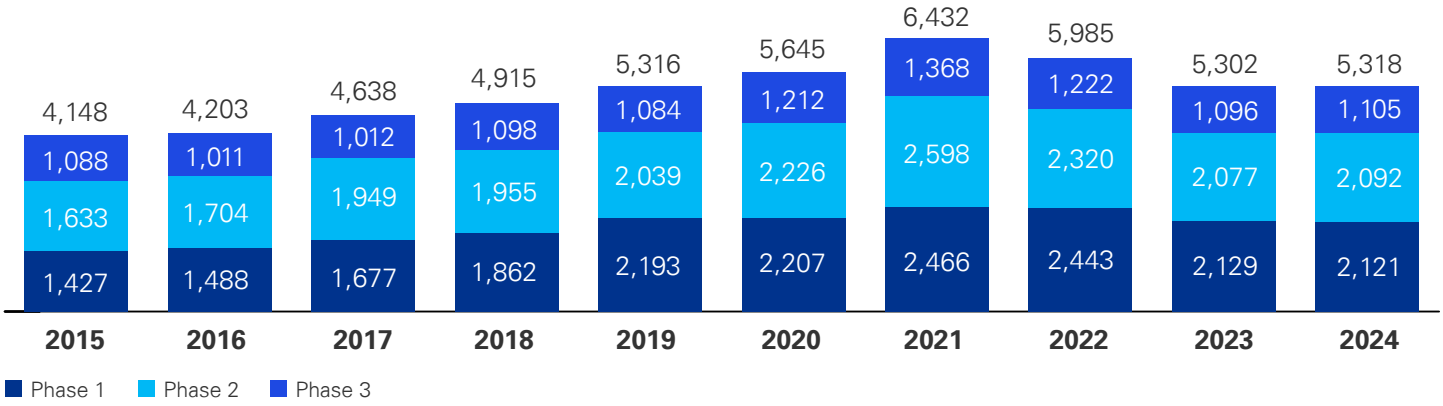
Figure 4. Percent of development spend outsourced to third-party vendors, 2025 and 2030



Source for Figure 3 and Figure 4: KPMG R&D Outsourcing Trends Survey, n=150 (January 2025)

2 **Phase 2 and Phase 3 trials emphasis:** Clinical trials, particularly in Phase 2 and Phase 3, are crucial for demonstrating efficacy and safety on a larger scale. Phase 2 and 3 is typically where the value inflection for assets is realized, leading towards increased focus from pharma relative to preclinical and phase 1 studies.

Figure 5. Total number of clinical trial starts by phase, 2015-2024

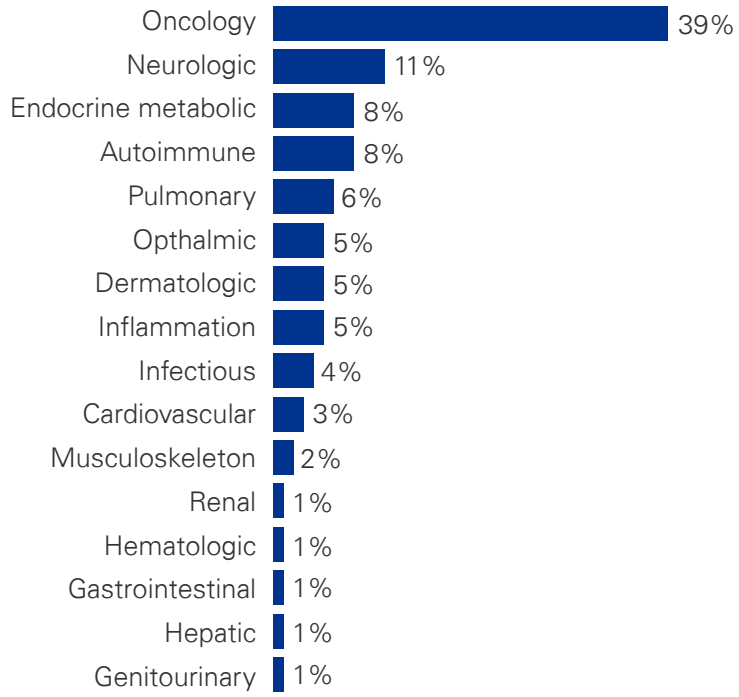


Source: Citeline Trialtrove, January 2025; IQVIA Institute, January 2025

3 **Preference for specific therapeutic area expertise:** Recent data published by Nature indicates that pharmaceutical companies are concentrating their efforts on high-return therapeutic areas such as oncology, urology, CNS (central nervous system) disorders, and cardiovascular/metabolic conditions. These areas represent significant market opportunities due to the high burden of disease and the potential for innovative treatments to transform patient care.

4 **Increasing complexity of trials for execution and data management:** Modern clinical trials are becoming more complex, characterized by extensive data collection, sophisticated inclusion/exclusion criteria, and adaptive trial designs. This complexity demands advanced technological solutions and specialized expertise that CROs can provide. Outsourcing these functions allows pharmaceutical companies to leverage the latest innovations and operational efficiencies.

Figure 6. Global VC funding in biopharma by therapeutic areas YTD 2024



Source: "Biotech financing: darkest before the dawn," nature.com, August 8. 2024

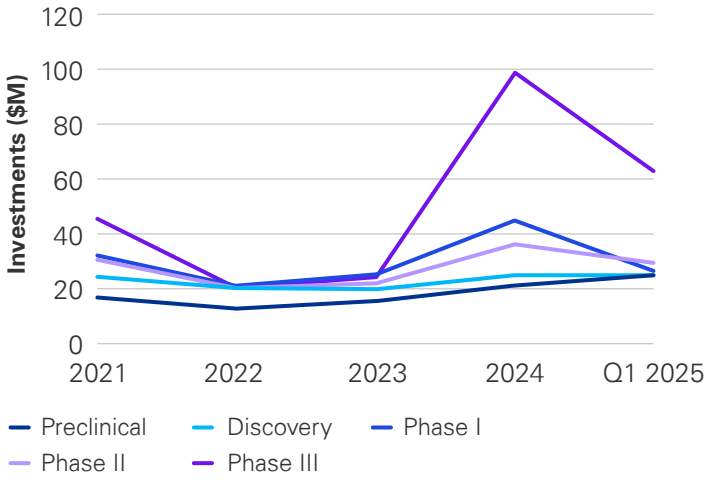
Limiting factors for growth of outsourced clinical R&D outfits:

1 **Emerging biotech decline:** The decrease in new company creation for emerging biotechs—often the source of novel therapeutic candidates—has led to a reduction in the number of large-scale studies initiated by these companies. This is unlikely to reverse until capital markets evolve to support early-stage innovation, through opening of the IPO window and reduced interest rates. This trend has implications for the diversity and volume of clinical trials in the pipeline, placing even more scrutiny on Phase 2 and Phase 3 studies for large and established biopharma.

2 **Shedding low-conviction programs:** To optimize their portfolios, pharmaceutical companies are shedding low-value programs and shelving assets that do not align with strategic priorities. This streamlining process ensures that resources are devoted to high-potential projects. While many of these assets could find homes off balance sheet through other business development and licensing efforts, the overall volume of early-stage clinical studies for new molecular entities is expected to be modest.

3 **Cost containment pressures and buyer leverage:** Given the outsourced provider reliance on large pharmaceutical companies as a contribution to revenue, particularly within the emerging biotech downturn, these companies can exert significant leverage in the marketplace, leading to increased discounting and unfavorable payment scheduled. This dynamic is further complicated by heightened competition among CROs for clinical trial contracts, necessitating competitive bidding and efficient resource management.

Figure 7. Venture financing activity in pharma: Median deal value by highest deal stage, 2021–Q1 2025



Source: "Biopharma venture financing declines 20.2% YoY in Q1 2025 amid persistent investor caution, reveals GlobalData," GlobalData, April 30, 2025

How to win in pharma services

For organizations seeking to navigate and thrive in this evolving landscape, several strategic imperatives are emerging.

Focus on patient enrollment and engagement:

Given the prioritization of Phase 2 and Phase 3 studies in concentrated therapeutic areas, competition for these patients has never been higher. Proprietary relationships with high-performing clinical trial sites, effective use of patient-centric clinical trial technologies, and access to representative and high-quality data sets in particular therapeutic areas are keys to unlocking success.

Therapeutic area expertise:

Success in pharma services increasingly requires deep specialization in key therapeutic areas. Understanding the nuances of patient/physician interactions is crucial, as clinical trial sites are integral to community-based patient enrollment. By focusing on areas with high unmet needs, such as oncology and neurology, service providers can establish themselves as essential partners with the expertise and trust to manage complex trials.

Software applications with obvious, quantifiable ROI:

The ongoing shift from paper-based to digital systems in clinical trials highlights a significant opportunity for technology providers. Despite two decades of transition, the pharma industry's adoption of digital solutions lags behind other sectors. SaaS and data management solutions that demonstrate quantifiable return on investment (ROI) can gain substantial traction. However, these benefits need to be easy to understand and quantify. Key areas include:

- **Cost savings and transparency:** Solutions need to significantly reduce trial costs through efficiency improvements–not just broadly, but through deconstruction of specific, existing processes, and documented success from prior experiences.
- **Patient retention and support:** While software and data continue to be used for identification and recruitment of trial patients, equally important is ensuring research subjects are supported throughout their clinical trial journey. Technology tools can offer significant support here, after the very human decision to enroll in a trial has been made.
- **Improved probability of success:** Tools should improve trial success probabilities, either preclinical or early clinical, through higher-quality data and more representative biosimulation activities.

Enterprise relationships with large pharma:

Pharmaceutical companies prefer working with best-in-class solutions, but they also seek to rationalize the number of vendors. Building strong enterprise relationships that encompass a broad range of services—including CRO, CDMO, real-world data (RWD), and commercial services—is vital. While the industry continues to experience consolidation, maintaining high standards in account management and client services is essential for differentiation and sustained success.

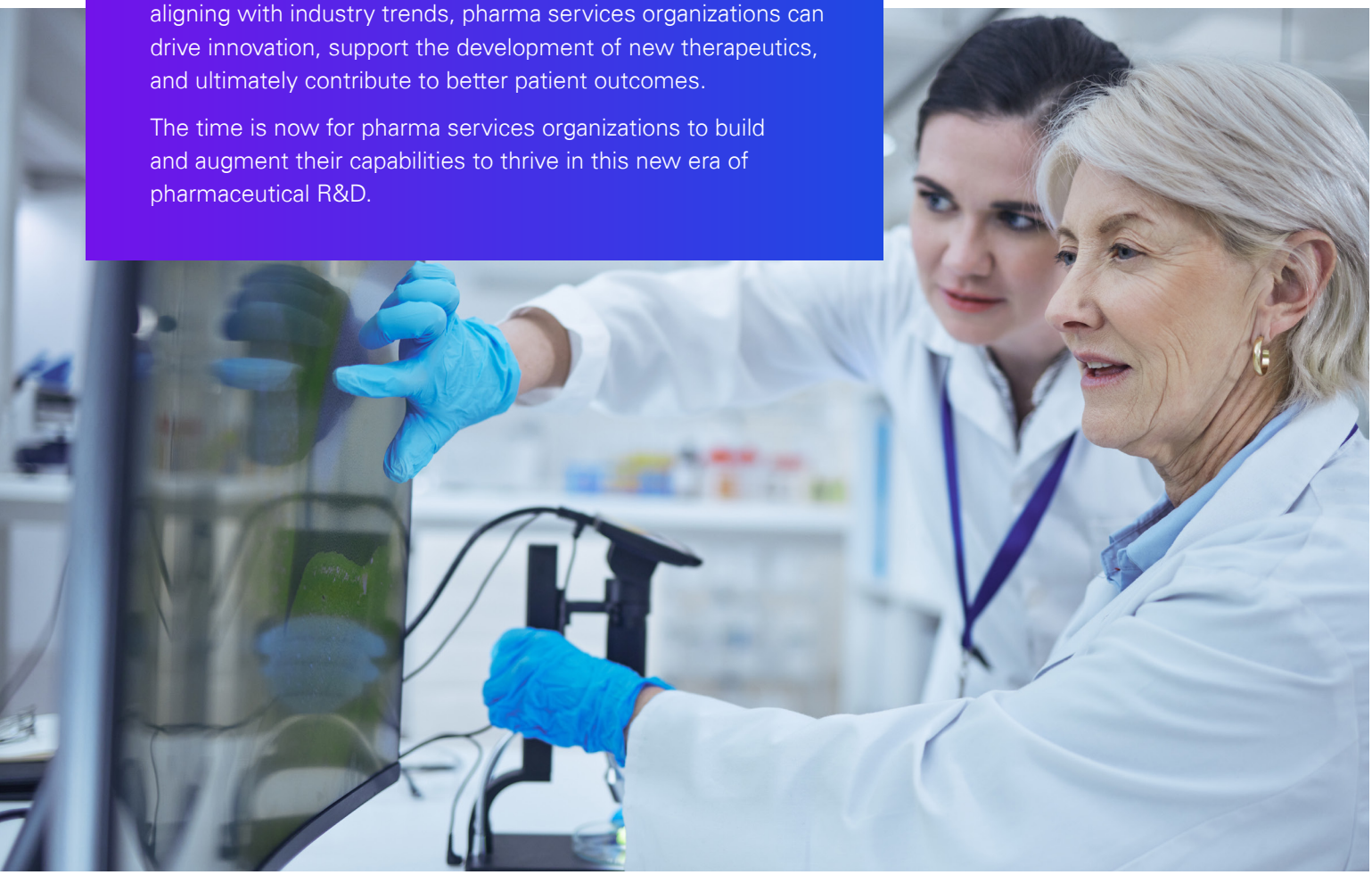
Conclusion

The pharmaceutical services landscape is evolving rapidly, driven by macroeconomic trends, regulatory changes, and technological advancements. These shifts present both challenges and opportunities for research service providers.

Outsourcing has become a key strategy for pharmaceutical companies to manage costs, access specialized expertise, and navigate complex clinical trials. The movement towards clinical assets and the emphasis on outsourcing in both preclinical and clinical R&D highlight the importance of flexibility and strategic partnership.

Service providers that invest in therapeutic area expertise, leverage cutting-edge technology with demonstrable ROI, and build strong, enterprise-level relationships with large pharmaceutical companies will be well-positioned to succeed. By adapting to the evolving needs of pharmaceutical clients and aligning with industry trends, pharma services organizations can drive innovation, support the development of new therapeutics, and ultimately contribute to better patient outcomes.

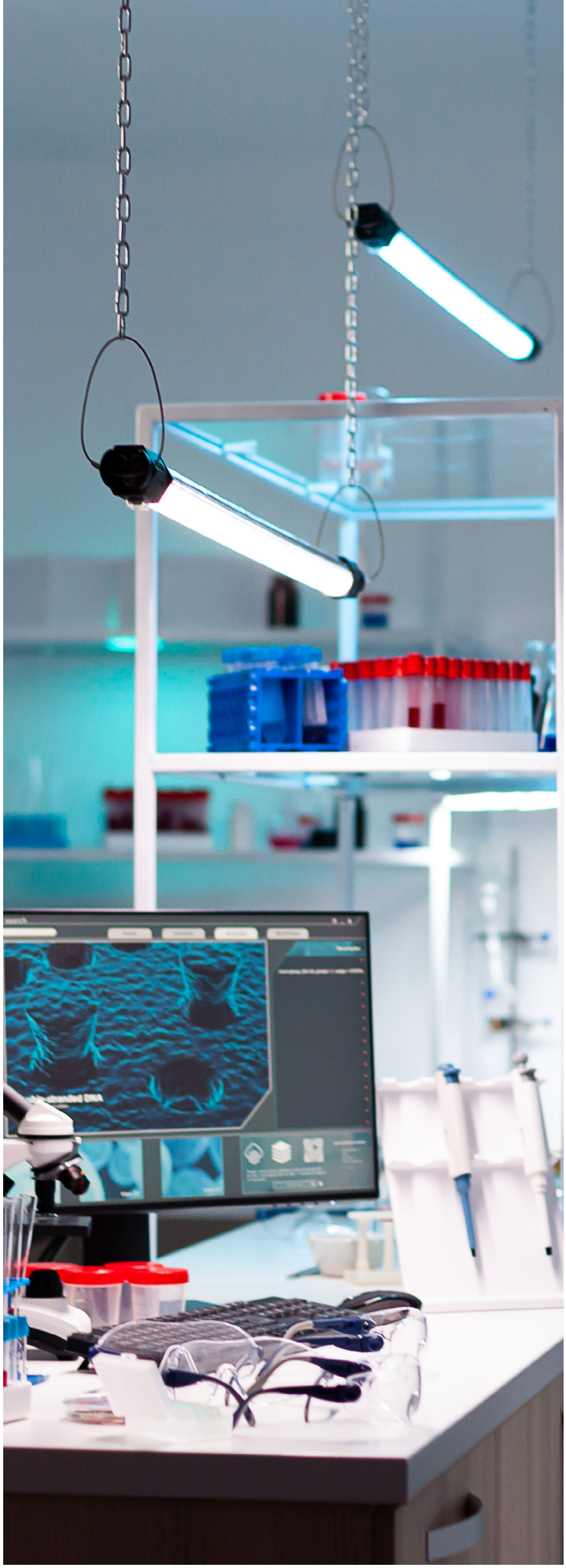
The time is now for pharma services organizations to build and augment their capabilities to thrive in this new era of pharmaceutical R&D.



How KPMG can help

KPMG LLP leverages its deep understanding of the evolving pharmaceutical services landscape to help clients navigate complex environments and achieve strategic goals. With experience in market analysis, R&D optimization, and outsourcing, KPMG supports pharmaceutical companies by validating market opportunities, prioritizing assets with the highest ROI, and streamlining operations. Clients can benefit from our ability to evaluate and build strong relationships with CROs, CDMOs, and technology providers, helping to ensure efficient vendor management and reducing operational risks through robust performance-monitoring frameworks. Additionally, KPMG assists in developing digital transformation strategies, enhancing clinical trial processes, and increasing patient engagement through innovative technologies and SaaS solutions, thereby delivering quantifiable ROI.

Moreover, KPMG offers specialized insights across therapeutic areas, guiding clients in developing operational and growth strategies. Through detailed revenue forecasting and commercial strategy development, KPMG enables clients to make informed acquisition decisions and effectively plan market entry, pricing, and promotional activities. By aligning commercial infrastructure for maximum returns, KPMG empowers clients to adapt to industry shifts, seize opportunities in high unmet need areas, and help drive sustainable growth. Through strategic advisory, technological transformation, and specialization in therapeutic areas, KPMG remains committed to supporting life sciences companies in realizing their full potential and enhancing patient care outcomes.



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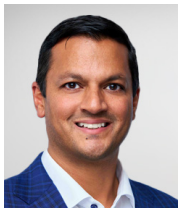

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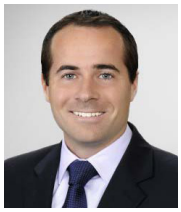

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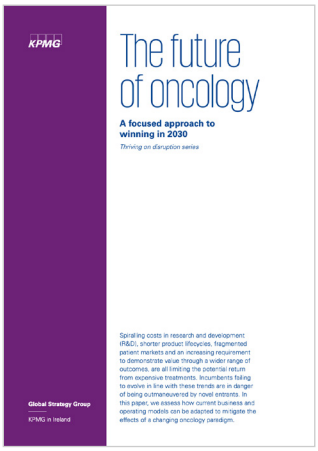

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