EXECUTIVE INSIGHTS

L.E.K. Consulting's Look at Key Trends in Pharma Services for 2023

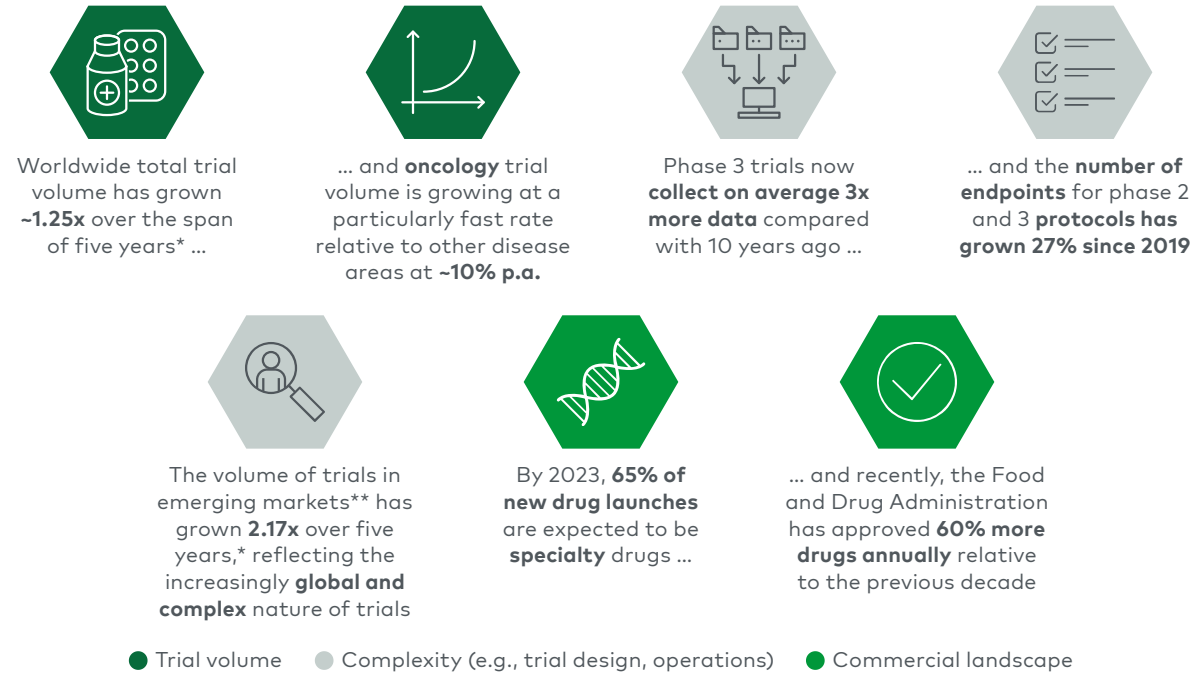
Introduction

Biopharma organizations face an increasingly complex landscape as new technologies, platforms and patient expectations necessitate innovation throughout the ecosystem, from R&D through commercialization and manufacturing. Trial volume has increased across the industry, with particularly strong growth in certain therapeutic areas and modalities like oncology and specialty drugs. Yet operational hurdles stemming from the growing complexity of trials, such as the volume of data and the number of endpoints and geographies, will require pharmaceutical companies to enhance their capabilities across the trial workflow in areas like data collection, regulatory operations and patient recruitment.

The broader biopharma landscape has evolved from high-volume blockbusters to diffuse low-volume, high-value drugs like rare disease and specialty drugs. This shift has altered both the size and structure of trials and the challenges that occur across a product's life cycle, from early R&D through commercialization and manufacturing support, requiring pharmaceutical services companies to evolve in tandem (see Figure 1).

As stakeholders respond to this shifting dynamic, forward-thinking pharmaceutical services organizations have strategic opportunities to drive differentiation and serve as critical partners to biopharma over the coming years, even in a mixed macroenvironment.

Figure 1
Looking ahead at global trial volume



*"Five years" denotes 2016-2021
**"Emerging markets" refers to Africa, Asia, Western Asia/Middle East
Source: L.E.K. research and analysis; Tufts Center for the Study of Drug Development; Trialtrove; Truveris; Congressional Budget Office

In recent years, pharmaceutical services have evolved from a nascent high-growth market to an established active market with sustained and significant growth year over year. Several macro trends have impacted pharmaceutical services in the past and are expected to continue, including advanced modalities and increased trial complexity.

Additionally, 2023 will present intriguing new opportunities and challenges as the macro situation remains uncertain, point solutions mature and biopharma customers become more sophisticated. The current macroeconomic environment will cause customers to be more conscious of containing costs across the value chain, which offers both opportunity (e.g., for solutions with clear business cases) and challenges (e.g., for nascent, less-proven solutions).

Pharmaceutical services will continue to offer a favorable, high-growth environment with strong opportunities for leading organizations able to offer interoperable, flexible solutions that work to bridge the gap from point solutions to broader workflows. Trends highlighted in these materials are particularly meaningful for management teams and investors as we enter the new year.

Industrywide trends

Rapid growth in the pharmaceutical services industry has increased the complexity of biopharma operations in the manufacturing, research and commercial spaces while driving new best practices, such as requiring ecosystem interoperability. The increased scale of pharmaceutical services companies' solutions has made their value proposition stronger as a partner to drive cost efficiencies and optimize operations for effective R&D, scale-up/manufacturing and ultimately a successful drug launch.

The overall macroenvironment offers significant opportunity for organizations to demonstrate the value of their solutions to biopharma and overcome the inertia of legacy ways of operating, akin to how COVID-19 enabled more rapid adoption of decentralized solutions recently. These dynamics have helped foster rapid growth and a robust M&A landscape. Coming out of this period of growth, experimentation and solutioning, we expect to see five key trends impact the industry, with an overarching focus on internal and ecosystem-wide interoperability (see Figure 2).

Figure 2
Major shifts in pharmaceutical services

Source: L.E.K. research and analysis

Management teams will need to ensure their strategies operate in concert with an industrywide desire for flexible, interoperable solutions. This may take on several forms when put into operation:

- Different customer segments will necessitate unique offerings and processes, so pharmaceutical services companies will need to fulfill those segments' individual needs to differentiate their capabilities. As a result, management teams will proactively address their commercial strategy to ensure they are positioned to serve a broad range of potential customers.
- Forward-thinking management teams will need to ensure that offerings are able to support integration of disparate data, like claims/scripts or economics/genomics, into a cohesive ecosystem that is interoperable internally and with third-party software providers to maintain best-in-breed status.
- Management teams will need to ensure that solutions maintain flexibility across an expanding pool of modalities, such as cell and gene therapy, while remaining alert to evolving global data privacy and ethical requirements (e.g., biospecimen management).
- Leading players must be extremely agile in their response to the changing landscape of customer needs and revise their internal capabilities, regulatory approach and ecosystem interoperability to position themselves for success.

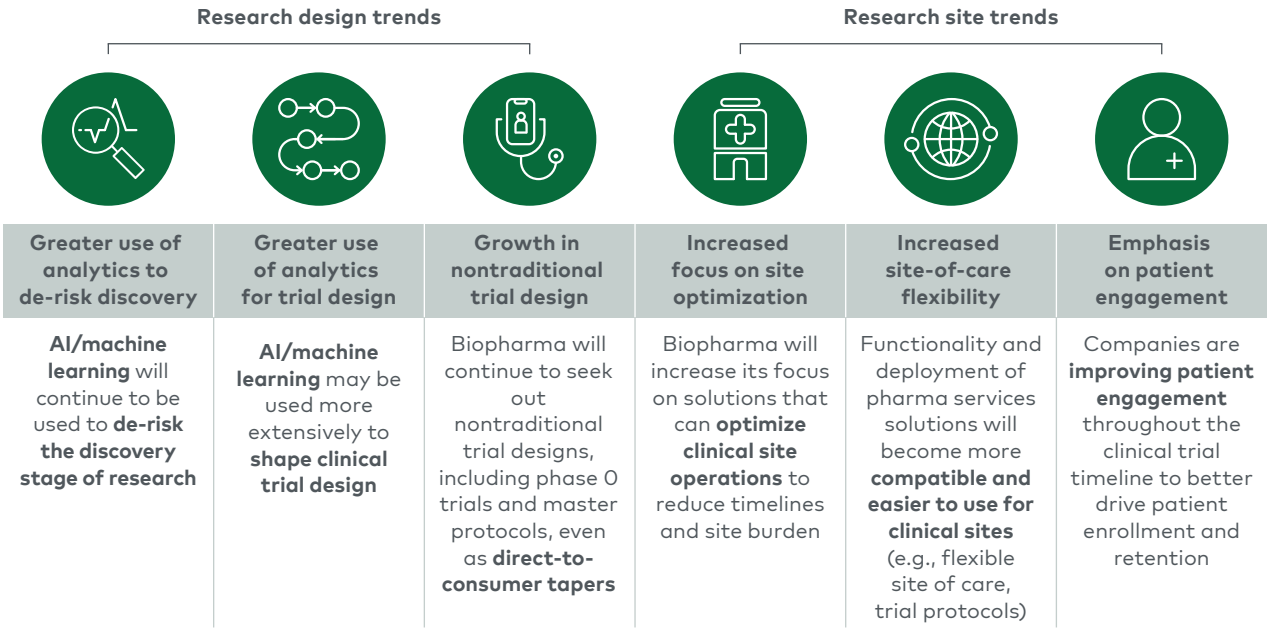
For investors, it will be critical to assess how any additional point solutions can mesh into broader offerings and create further synergies among ecosystems. This will allow investors' potential targets to have a value proposition offering across the unique customer segments. Specific forms this may take include:

- Ensuring that a target's business model can adjust and support the integration of data both internally and with the relevant third-party software providers to have best-in-breed services
- Evaluating their targets' ability to remain agile as the number of advanced modalities increases and simultaneously comply with the evolving regulatory demands

Research trends

Innovations in clinical research are crucial to driving value for biopharma organizations. Two areas helping drive the next wave of research innovation are upfront research design and at the trial site level (see Figure 3). Research design is poised to benefit from a sharper use of analytics, including to de-risk discovery efforts and shape clinical trial design (e.g., artificial intelligence (AI)/machine learning). Taking clinical trial stakeholder feedback into consideration and properly implementing that feedback will maximize the ability to recruit for a diverse set of trial design requirements across site levels. This ultimately feeds into innovations at the site level, where solutions that enable sites to work more efficiently can help drive better patient engagement and outcomes.

Figure 3
The rise of AI in pharma services



Note: AI=artificial intelligence
Source: L.E.K. research and analysis

Management teams can benefit from this broad evolution in research by incorporating analytics and nontraditional trial strategies into their portfolios. Organizations that can proactively solution and drive cost savings for biopharma partners are poised to have success as both macro conditions and overall industry complexity increase their value. For example:

- Forward-thinking management teams have clear policies and procedures for incorporating stakeholder (patient, physician) feedback into clinical design and work to "close the loop" with the patient community. Leveraging solutions to drive better patient engagement creates benefits throughout a trial — from enhancing recruitment, retention and crossover to commercialization — which, for biopharma, helps drive a differentiated "sponsor of choice" status at the individual trial site level.
- Management will need to create a "playbook" for successful trials that enables clinical trials to scale both locally and globally (i.e., at a per-site level and at the site network level) to ensure the ability to drive meaningful data collection while providing comprehensive care.

For investors, research services are a robust area of opportunity. Solutions that help optimize clinical trial sites are particularly attractive, as they can offer a trifecta of supporting biopharma, improving the patient experience and driving returns. Maximizing this opportunity will require several focus areas, including:

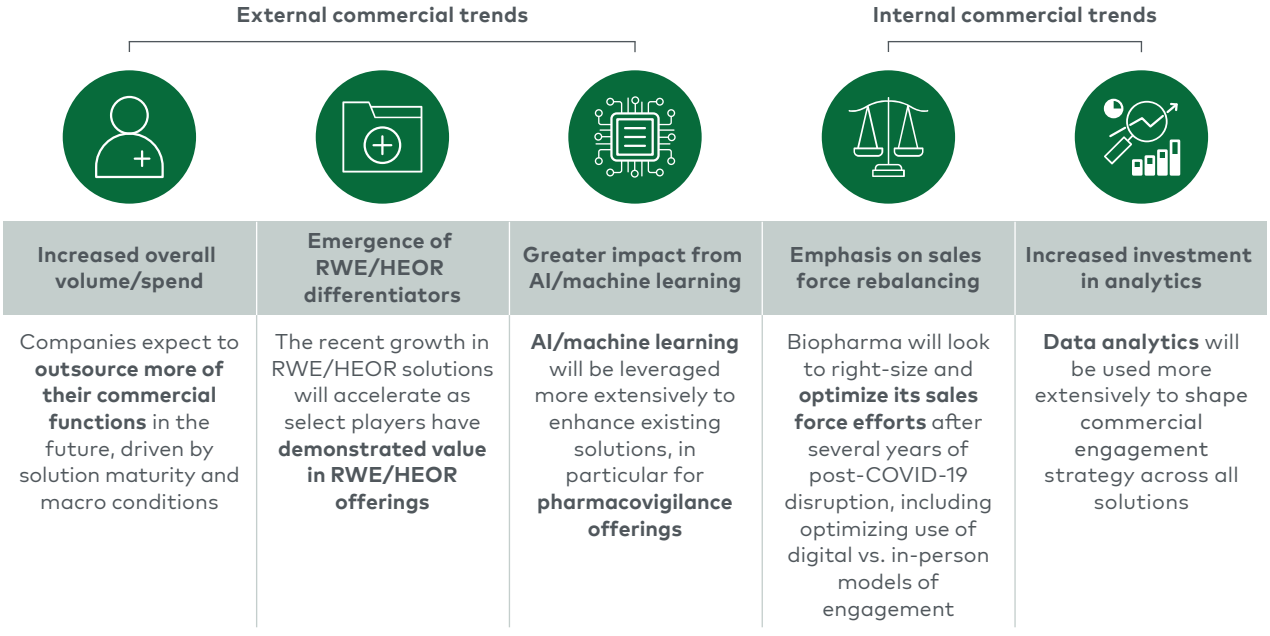
- Ensuring targets have a clear strategy to incorporate stakeholder feedback and properly account for the experience of participating in a clinical trial for each stakeholder by taking key actions, like ensuring that solutions must be additive to each stakeholder and not an additional logistical burden for some
- Evaluating targets' data and analysis capabilities as well as site and patient experience prioritization to assess their levels of differentiation and assess the opportunity to enhance/gain a moat among their competitors

Commercial trends

Commercial services will see evolutions driven by the holistic incorporation of data to drive sharper targeting (e.g., decile, digital vs. in person) paired with strong data/evidence packages (e.g., real-world evidence (RWE) and health economic and outcomes research (HEOR)).

Commercial solutions that can efficiently process, manage and operationalize data will be at the forefront of the industry (see Figure 4). The increased use of commercial services will have subsequent effects on internal operations, such as optimizing digital vs. in-person touchpoints, as sales forces are rebalanced and analytics continue to drive more precise targeting. We also expect to see the use of RWE and HEOR grow into a true strategic differentiator for select players.

Figure 4
Growth among data and analytics



Note: RWE=real-world evidence; HEOR=health economic and outcomes research; AI=artificial intelligence
Source: L.E.K. research and analysis

Management teams will need to ensure their internal strategies are poised to benefit both from broad secular tailwinds and focused excellence in analytics and targeting efforts. Specific areas of focus for forward-thinking management teams over the next several years will include:

- Evaluating commercial services' abilities to improve their existing offerings and distribution to execute a targeted (by customer type) sales strategy.
- Identifying how to operationalize and monetize the wealth of data collected as part of ongoing operations. This requires a clear data management and monetization plan that is supportive of the organization's strategic objectives; for example, incorporating RWE across the workflow to highlight a solution's differentiation in the market.
- In aggregate, many organizations have developed a collection of point solutions, and they now need to take the next step to drive value that is greater than the sum of the parts.

For investors, we expect to see continued interest in acquiring and integrating data-forward solutions into point solutions and portfolio offerings. Several areas of renewed focus will include the following:

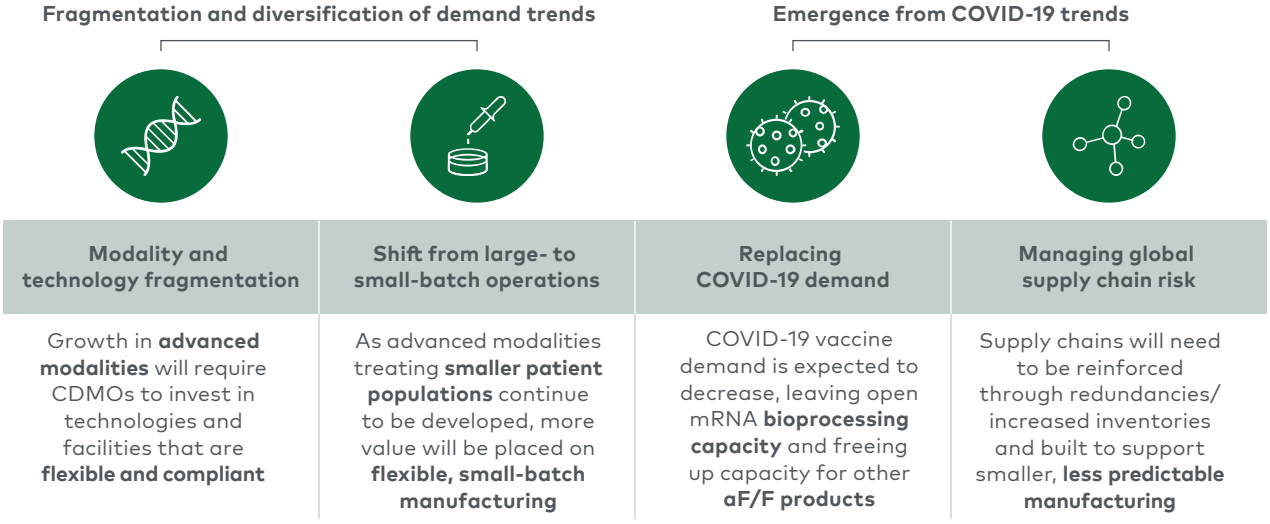
- The accumulation, management and analysis of data will become increasingly important with scale and will be essential for investors to evaluate to understand the level of investment(s) required to drive differentiation
- Leading management teams will not only execute on driving more value from the data but will advertise their ability to do so as a best-in-breed partner

Manufacturing trends

Manufacturing partners will continue to see increasing fragmentation and diversification in demand coming from their customers as advanced modalities grow and batch sizes shrink.

These advanced modalities, such as rare disease therapy, and corresponding technologies often have lower and/or irregular demand, requiring a new lens through which to view attractive investment and expansion opportunities. This is occurring while the industry emerges from COVID-19 and must adjust for demand shifts and a renewed focus on supply chain risks and vulnerabilities (see Figure 5). Capacity constraints will persist across the industry; however, these trends will impact which portions of the market (inputs, equipment, end products) are subject to the most constraints.

Figure 5
Increased innovation across the ecosystem



Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

These trends will have broad implications for leading management teams as they assess their internal operations and internal/external growth drivers. Specific areas of focus will include:

- Carefully assessing which inputs, technologies/equipment types and end-product demand are best suited to drive growth. As advanced modalities and technologies have inconsistent manufacturing processes, identifying growth vectors that enable a more "product agnostic" approach will be critical to avoiding binary risk.
- As the manufacturing world has been affected by COVID-19 vaccine capacity and the pandemic's effect on exposing the supply chain, forward-thinking manufacturer players will proactively grow capacity in demanded areas while improvising their supply chain management to avoid future disruptions and differentiate to win biopharma business.

For investors, this broad assessment of capacity, operations and growth drivers across manufacturing offers ample opportunity. For example:

- Investors must evaluate targets' ability to invest in the proper inputs (e.g., product agnostic) proactively and effectively to offer best-in-breed solutions for biopharma
- Valuable targets for investors will be well positioned to capitalize on demand for small-batch manufacturing and to drive product-agnostic growth

Management teams and investors must plan and strategize thoughtfully to achieve considerable growth for pharmaceutical services in 2023

Across the entirety of pharmaceutical services, industry tailwinds are poised to support continued strong growth. However, there are broader macro trends that need to be acknowledged and considered in stakeholders' broader strategic goals in order to achieve success. Strategies will need to evolve, including sharper go-to-market approaches and strategic planning that involves innovations like adding features and monetizing data. Leading pharmaceutical services organizations and investors have an unparalleled opportunity to enhance patients' lives through faster, more targeted and better therapeutics.

For more information, please contact lifesciences@lek.com.

About the Authors

Matt Wheeler
Matt Wheeler is a Managing Director and Partner in L.E.K. Consulting's Boston office and a leader in the Pharma Services practice within Life Sciences. Matt joined L.E.K. in 2010 and advises clients on a range of topics, including corporate and business-unit growth strategy, platform and portfolio development, new market prioritization and entry, and strategic mergers and acquisitions. Within the pharmaceutical services space, he has particular expertise and deep experience across clinical services, eClinical tools and commercial services.

Ian Tzeng
Ian Tzeng is a Managing Director and Partner in L.E.K. Consulting's Boston office and leads the firm's Pharma Services practice within Life Sciences. Ian joined the company in 1998 and has extensive experience in growth strategy, regulated markets, innovation, pricing, and mergers and acquisitions. His expertise includes developing strategy for clients in the following areas: pharmaceuticals, vaccines, medical devices, CROs, CDMOs, supply chain operations and distribution, as well as commercial medical and market access services.

Kevin Giffels
Kevin Giffels is an Engagement Manager in L.E.K. Consulting's Boston office and a member of the Pharma Services practice within Life Sciences, where he works with pharmaceutical services and biopharma clients. Kevin joined L.E.K. in 2016 and has experience in portfolio prioritization, strategic mergers and acquisitions, and growth strategy.

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