EXECUTIVE INSIGHTS

Looking Ahead in Pharma Services: Key Trends Impacting the Industry

The cost and complexity of biopharmaceutical research and development (R&D) is increasing at a rapid pace. As of 2020, Pharmaceutical Research and Manufacturers of America (PhRMA) member companies were investing approximately 21% of their total sales in R&D, compared to approximately 16% in 2000.[1,2] And not only do companies commercializing products now need to embark on multichannel sales and marketing campaigns in order to gain access to their target markets, but they are also faced with increasingly extensive post-launch marketing regulatory requirements. Simultaneously, new trends in digitalization, clinical trial deployment, globalization and integration are impacting the way companies execute R&D and go to market. Together, these forces are causing the pharma services ecosystem to evolve and mature and, as a result, are changing the way companies win in the space.

This report discusses four key trends that are impacting the clinical and commercial pharma services markets:[3]

1. Greater distribution and patient-centricity of clinical trials
2. Maturation of data aggregation capabilities
3. Increased need for global coordination of local requirements
4. Growing tension between integration and specialization

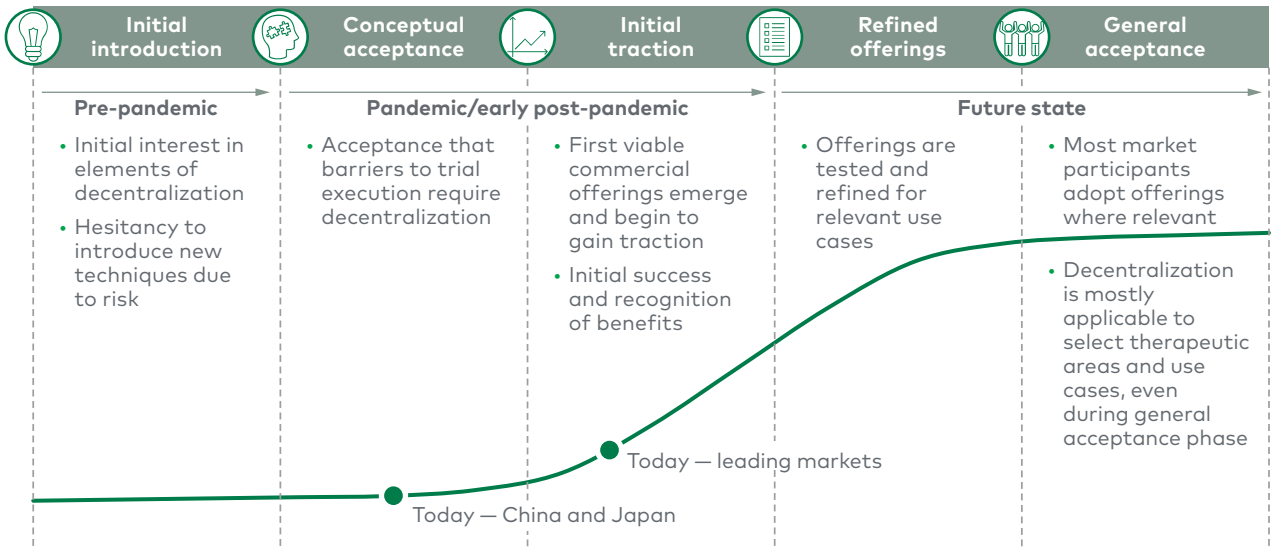
Drawing on its deep expertise and analytical experience, L.E.K. Consulting breaks down those four trends and lays out what they will mean for pharma services players going forward.

1. Greater distribution and patient-centricity of clinical trials

Clinical trials are evolving to include greater decentralization — of both locations and activities — across clinical trial workflows, impacting sponsors, sites, and study participants. Interest in elements of decentralization has existed for several years, but the underlying risk-aversion within biopharma has created hesitancy around introducing new techniques. The COVID-19 pandemic, however, provided a catalyst for companies to rethink the risk-reward equation for elements of trial decentralization and has helped increase openness and accelerate adoption.

Most trials and functions will continue to require some form of centralized, site-based services (this will be particularly driven by endpoint and protocol design). However, industry participants now generally understand that a spectrum of decentralization is possible and will gain more traction with appropriate use cases. For now, GlobalData projects that approximately 1,300 clinical trials with a virtual or decentralized component[4] will begin in 2022, up 28% from 2021 and 93% from 2020.[5] With those trials, decentralization is moving into the next phase of maturity: initial traction in specific offerings (see Figure 1).

Figure 1
The decentralized clinical trials market's stages of maturity



Source: L.E.K. research and analysis

Clinical trial decentralization has the potential to generate significant benefits, namely reduced costs, increased efficiency and improved patient experience. It also could facilitate faster and more diverse recruitment, which is among the most significant unmet needs in clinical trial operations. Indeed, as of 2019, around 85% of clinical trials fail to reach recruitment targets while 80% are delayed due to difficulties with recruitment.[6] And analysis

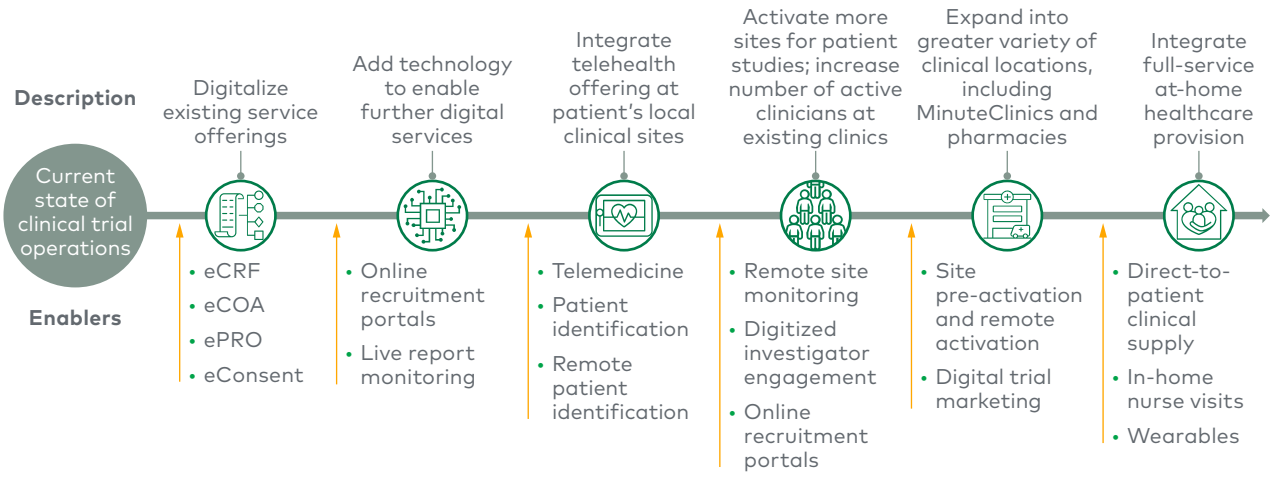
by the U.S. Food and Drug Administration (FDA) of global participation in clinical trials between 2015 and 2019 revealed that 76% of participants were white while just 11% were Asian and only 7% were Black.[7,8]

The European Medicines Agency[9] and the FDA[10] published guidance around certain elements of decentralization in order to promote safety during the pandemic. Such guidance may be a precedent for the continued use of decentralization going forward. China's National Medical Products Administration (NMPA) included guidance for utilizing digital technology to remotely manage clinical trials during the pandemic;[11] Japan's Ministry of Health, Labour and Welfare (MHLW) is also discussing decentralization of trials.

In terms of location, the meaning of "trial site" is evolving as more activities take place in physicians' offices as well as in pharmacies, homes, mobile clinics and retail sites. Some of the activities at this wider set of locations range from recruitment to enrollment and all the way to the capture of endpoint data. For example, in February 2022, CVS partnered with Medable to use the latter's decentralized clinical trial platform to enroll patients and conduct trials at its CVS MinuteClinics.[12]

The next wave of innovation in the space will be more targeted and specific, with emerging point solutions across domains that help distribute the function and location of trial activity. They include underlying technologies for patient engagement and data collection, data management and storage, and supply shipment. Among the companies offering solutions for decentralized clinical trials are Thread; Science 37; ConcertAI, for real-world evidence; and Cloudbyz. Some types of point solutions that will enable increased decentralization are shown in Figure 2 below.

Figure 2
Enablers for clinical trials decentralized by site and function



Note: eCRF=electronic case report form, eCOA=electronic clinical outcome assessment, ePRO=electronic patient-reported outcome
Source: L.E.K. research, interviews and analysis

Ultimately, clinical trial sponsors are trying to optimize their R&D investments, and so are concerned about risk as well as failure due to high costs and long timelines. Some of the leading drivers of operational risk within trials, such as recruitment and data quality and consistency, could be exacerbated in decentralized trials. To build credibility, distributed functions need to actively mitigate these risks and provide sponsors with the confidence that they will not be an issue. As more decentralized trials are completed, the industry should see additional proof points on data quality and uniformity, the validation of digital health technology for remote assessment, participant retention, data management, safety monitoring, the identification of trial conduct issues, and documentation and record-keeping.[13]

Decentralization is still in its early stages, but there is a growing belief that it will be a main feature in relevant future clinical trials. Stakeholders involved in clinical trials — including sites, sponsors, and service or technology providers — will need to understand how decentralization may impact them and be forward-thinking in preparing for this evolution in the market.

2. Maturation of data aggregation capabilities

Legacy data systems for clinical trials and other sources typically do not communicate well with one another, even though they are collecting similar or overlapping data points. As a result, aggregation techniques for integrating such data are often outdated, suboptimal or even nonexistent, and biopharma companies are missing opportunities to generate value from their data. The benefits of data aggregation to pharma companies are twofold. First, it provides better insight into in-house data to drive increased operational efficiency and better decision-making. Second, there is commercial value in the tremendous amounts of clinical, commercial, regulatory and operational data that both pharma companies and providers have amassed. This data could be useful for others in the healthcare value chain if it is aggregated, structured and synthesized. Accordingly, it could be monetized and serve as a new revenue stream. And so, data aggregation technologies in clinical and commercial settings are maturing to enable biopharma companies to realize these benefits.

In the clinical setting, trial sponsors will increasingly demand more tailored, insight-focused data solutions to reduce costs, decrease trial timelines and improve efficiency for use cases ranging from trial design optimization, patient identification and recruitment to site and investigator identification and selection and in-trial decision-making. To that end, service providers are increasingly aggregating real-world data from multiple sources — including electronic health records and claims — and integrating it with medical records in those trials.

Such databases and tools allow for alternative trial designs that incorporate historic or synthetic control arms as well as more efficient recruitment, including constructing

more homogeneous trial arms and identifying hard-to-find patients. They also aid in the identification of sites with high volumes of patients that meet selection criteria. And critically, they facilitate just-in-time in-trial decision-making. In traditional trial operations, data analysis happens after the fact, so when execution fails, trials must be rerun, resulting in high costs. Now, data tools are emerging that analyze and visualize trial data from the cross-trial level to the individual patient level, enabling early decision-making. And a growing ecosystem of companies are gaining traction by providing such clinical data aggregation and/or analysis solutions for one or more of the above use cases, including Saama, eClinical Solutions and Clinerion.

There are also numerous use cases for data aggregation technologies that provide benefits in the commercial setting. These include sales analytics to help with launch planning, sales tracking and targeting, patient care coordination, the demonstration of real-world evidence and value for market access, and health economics outcomes research and product safety. Pharma companies use a range of data sources for these purposes, including claims, patient registries, patient hubs, electronic medical records, third-party transactional records, and inventory and chargeback efforts. Data analytics platforms that integrate these datasets and streamline analysis can help companies execute their launches more efficiently and effectively. These platforms are challenging to build and maintain in-house, so pharma companies are turning to service providers for solutions.

Pharma customers will be more proactive and forward looking with their data strategies and will seek out service providers that are able to support this more sophisticated analysis. Service providers, in order to win target accounts, will need to connect various datasets, apply deep analytical expertise and demonstrate their ability to translate data into insights using a compelling storytelling approach.

3. Increased need for global coordination of local requirements

The life sciences space is becoming increasingly globalized while local requirements continue to become more complex, creating a need for sophisticated coordination. For example, in 2011, the U.S. represented 26% of the worldwide total clinical trials, while in 2021, it represented 18% of the total.[14,15] Sponsors are also running global trials more often in order to increase the efficiency of enabling market access across regions and to recruit patients for increasingly rare indications. This need for coordination is exacerbated by the fact that local regulations vary from country to country and are constantly changing and becoming more complex. Coordinating clinical operations in a compliant manner on a global scale is incredibly difficult to execute.

In the regulatory and commercial setting, biopharma companies require global coordination of numerous functions, including pharmacovigilance, medical communications, regulatory affairs, and finance and distribution, particularly for advanced therapies. The complexity of compliance requirements is increasing, as are the consequences of failing to meet them. It is critical that companies seamlessly adhere to local regulations on a global scale, and they are increasingly turning to service providers to ensure that adherence.

In pharmacovigilance, companies need to aggregate safety signals globally through multiple channels — from email to phone to fax to social media — translate the reporting from local languages, standardize the reporting content and aggregate all of it on a single platform. Responding to product inquiries in a compliant manner involves similar challenges. As a result, local expertise and integrated services are among the most important selection criteria for pharmacovigilance and medical information providers.

This need for global-local agility and fluency is driving innovation in pharma services. It will also inform the next wave of winners in the space. Service providers are already rolling up international firms into consolidated entities to provide the global reach demanded by pharmaceutical companies. Beyond that, they will need to provide truly integrated oversight and visibility while demonstrating that they have boots-on-the-ground presence, knowledge and relationships across markets. Service providers should also build technology solutions to make data codified, centralized, compliant and accessible. These capabilities will increasingly become "table stakes" in the industry.

4. Growing tension between integration and specialization

All this change — in trial deployment, data aggregation and global coordination — has important implications for how service providers position themselves in the market. Service providers will feel the increased tension of scaling/aggregating services and developing/demonstrating therapeutic and scientific expertise in particular areas. This tension will further stratify the competitive landscape into scaled multiservice providers and niche specialists, a natural outcome of providers solving for distinct customer needs.

Multiservice providers can drive productivity via mitigated development and process risk, time savings, reduced complexity, cost savings, better results, stronger evidence, and improved compliance. To that end, contract research organizations (CROs) and other clinical and nonclinical service providers have made acquisitions to fill gaps in their portfolios by service line (e.g., safety testing, clinical enrollment and recruitment, clinical data management, project management, regulatory support, clinical study design, and biometrics/biostatistics) and/or

therapeutic modality. Increasing their breadth of offerings can allow them to provide a more complete service suite to customers and, in the process, be more competitive.

WCG Clinical, a clinical services company, is an example of a multiservice provider that has created scale effectively. It has made over 30 acquisitions in its history, 15 of them in the past five years,[16,17] to improve its clinical services offerings and provide its clients with a more comprehensive suite of services to address clinical trial pain points. Another example is Charles River Laboratories, which has invested more than $4 billion in over 25 acquisitions since 2012, $1.7 billion of which were made since the start of 2020.[18] Most of these acquisitions have allowed the company to expand its nonclinical portfolio of research and discovery services, safety assessments, and clinical and commercial manufacturing.[19] They have also allowed Charles River to bolster its expertise in certain modalities such as cell and gene therapy.

The contract development and manufacturing organization/contract manufacturing organization industry is not as concentrated as the CRO industry, but similar consolidation is expected as companies seek to expand geographically,[20] bolster their capabilities in high-margin end markets[21] and invest to provide a wider array of services.

As more pharma services companies offer broader portfolios, there is an opportunity for niche players to offer better, more-specialized services than the aggregators. Companies focused on gene and cell therapies and personalized medicine, for example, need highly specialized offerings that reflect specific expertise. Niche specialists, some of which focus on specific therapeutic areas, are also more responsive to the needs of smaller biopharma companies.

In the central nervous system (CNS) space, Evolution Research Group, a clinical research site company, has focused capabilities within CNS studies, including psychiatry, neurology, pain and other areas. Clinical Ink is an electronic clinical outcomes assessment provider that has built a strong track record in lupus, which includes developing a data capture platform to streamline lupus trials.[22]

Going forward, integration and niche specialization will continue to be cyclical. And as the next generation of best-in-class niche specialists emerge, they will become compelling acquisition targets for multiservice providers. The providers should be thoughtful in how they expand their services, as customers will ultimately continue to choose those that are best of breed. They will need to understand where they have a "right to win" based on their starting capabilities and assets. They will also need to ensure areas of expansion have their customers in mind, avoid acquiring suboptimal service providers and provide superior coordination to deliver on the value of a "one-stop shop" value proposition.

The next wave of consolidation will likely involve structuring and scaling around unique expertise. This could include, for example, building a best-in-class, end-to-end platform for a specific therapeutic area (TA) rather than expanding agnostic of TA, modality or specialization. Indeed, to deliver winning value propositions to their clients, integrated service providers will need to be extremely thoughtful about their service offerings.

Conclusion

New market dynamics and emerging trends are forcing biopharma companies to navigate difficult challenges and, by extension, rethink their strategies. They are facing greater complexity and nuance across their businesses, including more complicated data and regulatory requirements, therapeutic modalities, and clinical trial deployment and manufacturing needs. All this is changing the dynamics of the pharma services industry — and at the same time, opening up multiple avenues where those providers can play and win. L.E.K.'s deep knowledge of the pharma services industry allows us to help pharma services companies develop differentiated, winning strategies that capitalize on key trends in this evolving market.

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

Endnotes

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[2]Definition of sales from PhRMA: "Product sales calculated as billed, free on board plant or warehouse less cash discounts, Medicaid rebates, returns, and allowances. These include all marketing expenses except transportation costs. Also included is the sales value of products bought and resold without further processing or repackaging, as well as the dollar value of products made from the firm's own materials for other manufacturers' resale. Excluded are all royalty payments, interest, and other income." See 2021 PhRMA Annual Membership Survey for definition of R&D Expenditure.

[3]Advancements are also occurring in the bioprocessing industry, but these will be discussed in a subsequent "Looking Ahead" *Executive Insights*.

[4]Includes all trials with "mentions of [at least one of] more than 35 specific decentralisation and/or virtualisation elements in clinical registry protocols of trials involving a drug intervention."

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[15]Includes trials listed in the World Health Organization International Clinical Trials Registry Platform. Includes both interventional and observational trials.

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