EXECUTIVE INSIGHTS

Findings From L.E.K. Consulting's Inaugural Clinical and eClinical Pharma Services Survey

Research and development (R&D) costs incurred by biopharmaceutical companies to bring new therapies to market are extraordinarily high. The median pivotal trial cost per new molecular entity (NME) approved by the U.S. Food and Drug Administration (FDA) between 2015 and 2017 has been estimated at $48 million, and the median cost per patient per pivotal trial for those NMEs has been estimated at over $40,000, according to a recent analysis.[1] In the midst of this, patients and the sites that recruit and enroll these patients are changing how trials are executed.

Clinical trial sponsors, as noted in L.E.K. Consulting's *Executive Insights* "Looking Ahead in Pharma Services: Key Trends Impacting the Industry,"[2] often fail to reach their recruitment targets. There is also a lack of appropriate racial representation among study participants. On the other hand, while trial sites still play a critical role in the determination of trial outcomes, more activities today are taking place in distributed locations than they did before the onset of the COVID-19 pandemic. Together, these dynamics have led to a greater reliance on clinical trial partnerships for execution.

In its inaugural Clinical and eClinical Pharma Services Survey (see Figure 1), L.E.K. asked biopharmaceutical, contract research organization (CRO) and trial site experts about these and other key emerging trends in clinical trials and how they are impacting the outsourced, clinical and eClinical pharmaceutical services market. This report also makes clear how sites and patients are changing the way trials are executed and how those changes are driving growth in the market.

Figure 1
Clinical and eClinical Pharma Services Survey respondent demographics

		Biopharmaceuticals and CROs
Total N		**108**
Country of employment	U.S.	~58%
	U.K.	~16%
	EU4*	~20%
	Canada	~6%
Company size**	Private	~54%
	Small	~21%
	Mid-size	~19%
	Large	~6%
Title	Senior vice president and above	~11%
	Vice president	~23%
	Director/executive director	~37%
	Associate director	~7%
	Department head	~7%
	Project leader	~1%
	Manager	~14%
Modality^^	Advanced^	~61%
	Biologics	~53%
	Small molecule	~47%

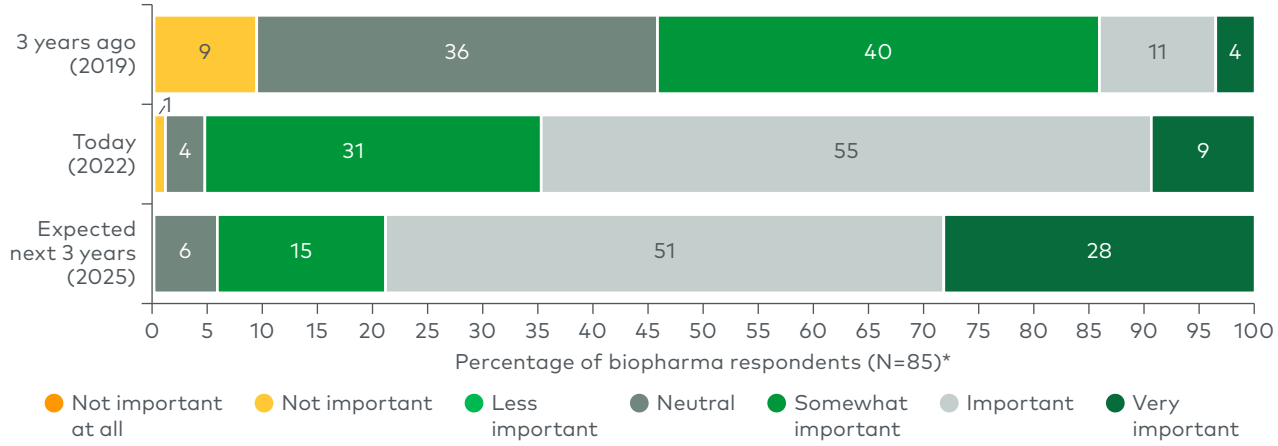
		Trial Sites
Total N		**54**
Country of employment	U.S.	~58%
	U.K.	~16%
	EU4*	~20%
	Canada	~6%
Company size**	Private	~54%
	Small	~21%
	Mid-size	~19%
	Large	~6%
Title	Principal investigator	~11%
	Co-investigator	~23%
	Clinical trial administrator	~37%
	Other***	~7%
Modality^^	Advanced^	~7%
	Biologics	~1%
	Small molecule	~14%

*Includes Germany, France, Spain and Italy
**Small: <$5B market capitalization, Mid-size: $5B-$40B market capitalization and Large: >$40B market capitalization
***Includes Data coordinator: 19%, Research coordinator: 9%, Regulatory specialist: 2% and Regulatory coordinator: 2%
^Includes gene therapy, gene editing and cell therapy
^^Respondents could select multiple modalities
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Survey 2022

The site-sponsor relationship is becoming critically important

While the relationship between the sponsor and the site is often overlooked in clinical trial settings, such relationships are critical to a trial's success, as sites are at the center of patient recruitment and enrollment, data collection, and regulatory compliance. With that in mind, the percentage of biopharma survey respondents who believe it is very important to be seen as a "sponsor of choice" at sites soared to ~65% in 2022 from just ~14% in 2019, and a staggering ~79% of them anticipate it will continue to be very important over the next three years (see Figure 2).

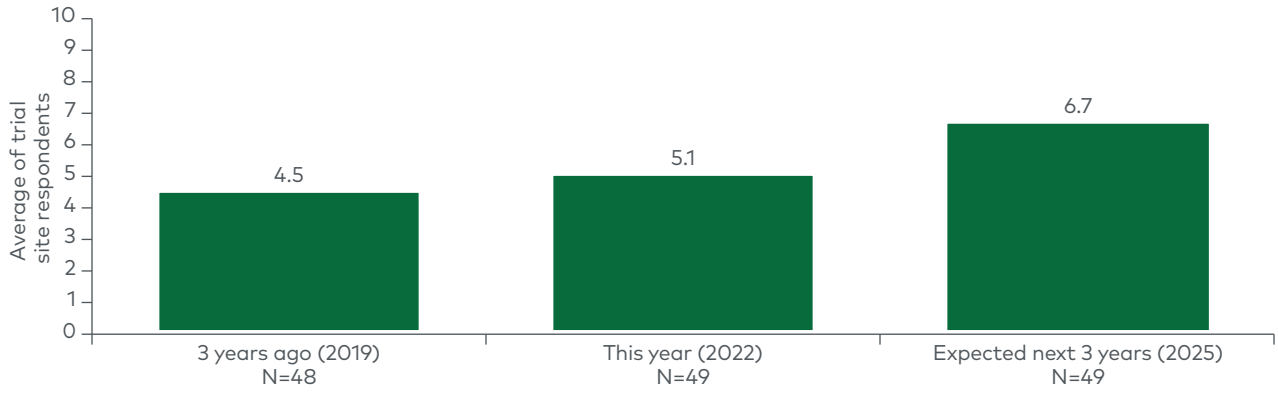
Figure 2
Importance of being seen as 'sponsor of choice' at trial sites



*Survey question: How important is being seen as a "sponsor of choice" for a trial site to your organization? How does that compare to 3 years ago and how do you expect it to compare 3 years from now? Please rate the importance on a scale of 1 to 7, where "1" means "not important at all" and 7 means "very important."
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

The desire to be seen as a sponsor of choice is largely fueled by the intensifying competition for a finite number of sites, of which there is a shortage. Indeed, with a growing pipeline of assets, the gap between the number of trials and the number of sites available is bound to widen in the future unless the industry makes significant strides in its site and patient recruitment efforts. As per the trial site survey respondents, the number of distinct industry sponsors running trials at sites is expected to increase from five per site today to about seven by 2025 (see Figure 3), making it important for individual sponsors to stand out as a sponsor of choice with whom sites can partner.

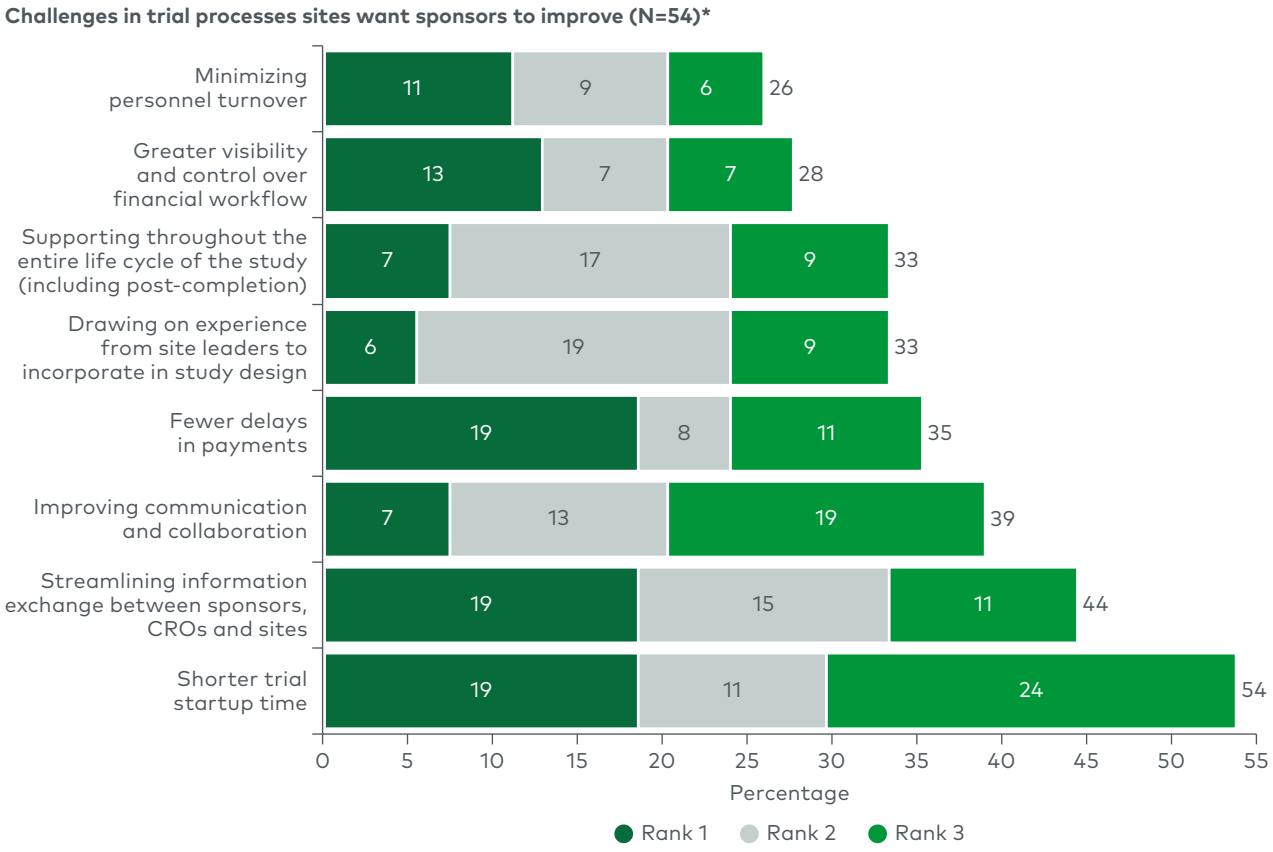
Figure 3
Number of distinct industry sponsors at trial sites over time*



*Survey question: What is the number of industry sponsors your site is partnering with for clinical trials today? How does that compare to 3 years ago and how do you expect it to compare 3 years from now? Please consider a single industry sponsor running multiple trials at your site as 1. For example, if two different industry sponsors are running 5 different trials each, please enter "2."
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

So, what does it take to become a sponsor of choice? Trial site experts cite shortening trial startup times, streamlining the exchange of information between different stakeholders, improving communication and collaboration, and ensuring payments are made on time as processes they most want sponsors to improve (see Figure 4). Additionally, sponsors should proactively try to improve the processes that cause the most frequent delays in trials: negotiating budgets, enrolling study participants and retaining participants.

Figure 4
Key trial processes sponsors must improve to be seen as a 'sponsor of choice'



*Survey question: Which of the following challenges in clinical trial processes would you like sponsors to improve to ensure an optimal site experience and being seen as a "sponsor of choice" at your site?
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

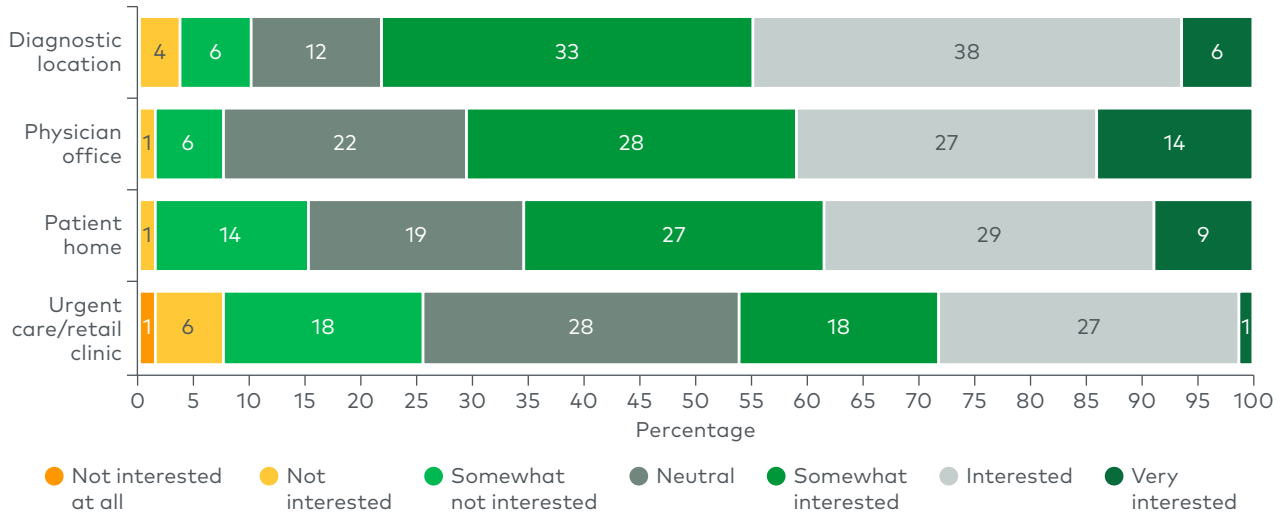
Mitigating these site-based challenges may seem simple, but there is no one-size-fits-all approach. In order to identify key drivers of startup delays, sponsors must account for how these challenges uniquely impact them. They must also develop robust site training materials, establish clear guidelines for startup activities and provide careful coordination among the various stakeholders involved at each step. Only then will they be able to optimize trial execution and, ultimately, reduce the costs and prolonged timelines associated with delays.

Use of distributed functions in trials is increasing

The COVID-19 pandemic has helped solidify some of the benefits and increased acceptance of decentralized clinical trials (DCTs), and as a result, many biopharmaceutical companies now see the execution of key trial functions at distributed locations as increasingly feasible. The expected benefits include expanded access to more potential participants, reduced time and cost for patients to participate in trials, improved rates of patient compliance, and ultimately, greater patient retention.

Of the biopharma and CRO respondents surveyed who are involved in conducting phase 3 activities, ~77% are interested in using diagnostic locations, ~70% are interested in physician offices, ~65% are interested in patient homes and ~46% are interested in urgent care/retail clinic locations (see Figure 5). Furthermore, more than a quarter of respondents are already adopting some of these alternative trial locations in at least some phase 3 trials, and an additional half are expected to adopt them within the next three years.

Figure 5
Level of interest in alternative trial locations for phase 3 trial activities (N=78)*



*Survey question: What is your organization's level of interest in each of the following alternative trial locations for phase 3 trial activities? Please rate the importance on a scale of 1 to 7, where 1 means "not interested at all" and 7 means "very interested." Additional language (if CRO respondent): Please answer questions in this section thinking holistically about your biopharmaceutical clients and their interest in elements of decentralized clinical trials (DCTs).
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

As technology advances, sponsors will begin progressively adopting distributed locations and activities in trials. Doing so will require them to identify more sites, onboard different types of sites and optimize trial location to each trial's activities to preserve the quality of the data being generated, all while ensuring patient compliance and engagement. Third-party service and solutions providers, on the other hand, will need to understand how geography, disease

area, indication and target population will inform the most appropriate use of distributed locations and be ready to offer point solutions that adequately address sponsors' needs.

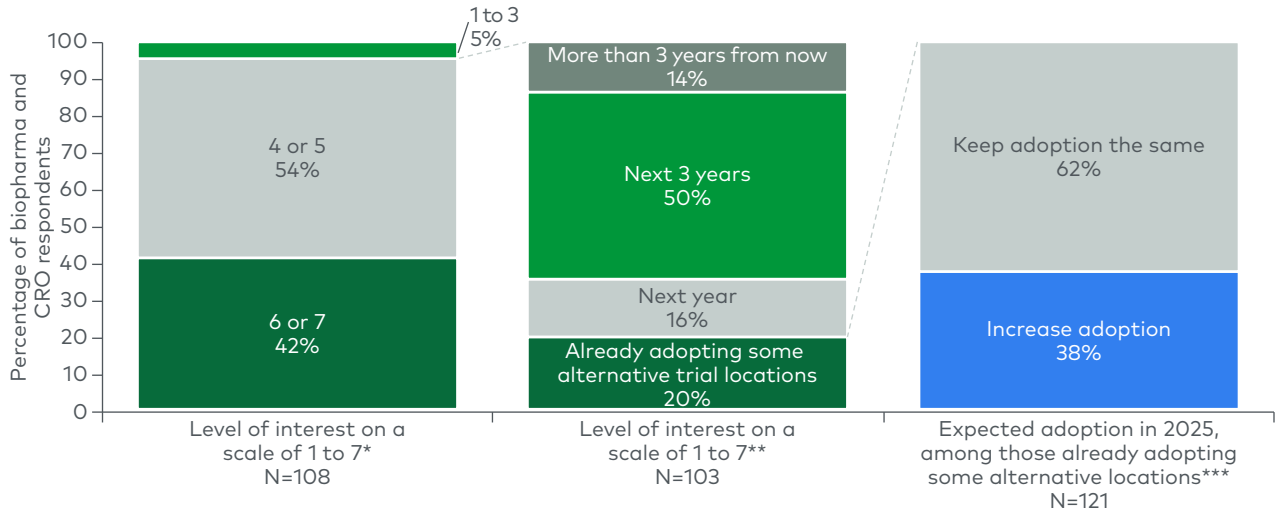
Sponsors are focusing heavily on patient recruitment

Patient recruitment remains one of the most challenging and costly activities of running a clinical trial. According to the FDA, only 3% of U.S. physicians and patients participate in clinical trials leading to new therapies,[3] which has profound consequences for development timelines, including delaying market launches. As of 2019, a whopping 80% of trials were delayed due to recruitment difficulties.[4] Moreover, reaching patients is becoming more challenging as biopharmas increasingly target a variety of complex diseases in their clinical trials and use precision medicine in their drug development, both of which result in smaller, highly specific patient populations.

Biopharma companies are subsequently becoming more receptive to using new methods of recruiting patients, such as virtual and distributed recruitment. Among the biopharma and CRO survey respondents, ~95% are interested in alternative trial locations for patient recruitment. Of those interested, ~66% are likely to adopt such alternative locations for patient recruitment within the next three years while ~20% are already adopting them (see Figure 6). And of those already adopting, more than a third expect their adoption to increase over the next three years while the rest expect their level of adoption to remain the same.

Figure 6

Interest in and expected timeline to adopt alternative trial locations for patient recruitment purposes



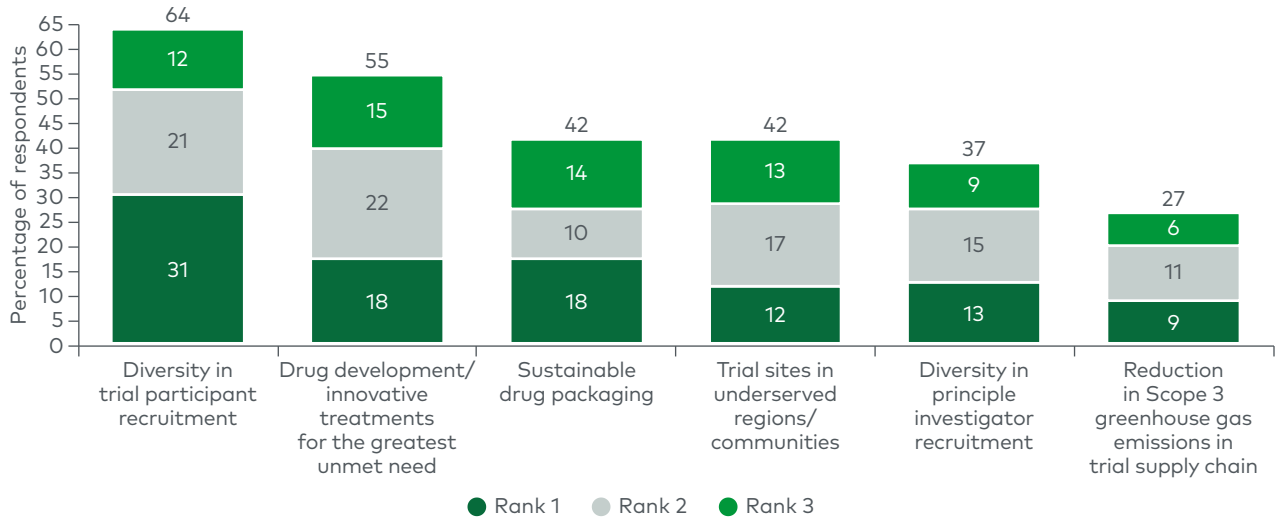
*Survey question: What is your organization's level of interest in any of the alternative trial locations for patient recruitment efforts? Please rate the importance on a scale of 1 to 7, where 1 means "not interested at all" and 7 means "very interested." Additional language (if CRO respondent): Please answer questions in this section thinking holistically about your biopharmaceutical clients and their interest in elements of decentralized clinical trials (DCTs).
**Survey question: When is your organization expected to adopt any of the alternative trial locations for patient recruitment efforts?
***Survey question: Out of the following statements, which best describes your organization's level of interest in using any alternative trial locations for patient recruitment efforts in the next 3 years?
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

Sponsors must apply a holistic lens to patient recruitment to understand the various intricacies involved. An omnichannel approach that incorporates multiple initiatives and complements traditional channels can help overcome the exceedingly complex challenges that can arise. Such initiatives include integrating principal investigator perspectives on how to target patients and where to access them along the patient journey, developing digital tools to capture patients through support groups and self-referrals, and creating comprehensive databases of potential patients for both targeted and regular outreach.

Patient diversity in clinical trials is a key focus

One of the major themes in the industry is the growing importance of environmental, social and governance (ESG) factors in clinical trials. Specifically, some ~64% of biopharma and CRO survey respondents cite diversity in study participants as among their organization's top three ESG initiatives (see Figure 7). The lack of appropriate racial representation has been widely documented; just 8% of global trial participants for novel drugs approved by the FDA's Center for Drug Evaluation and Research in 2020 were Black or African American and only 6% were Asian.[5]

Figure 7
Importance of different ESG initiatives in clinical trials (N=108)*



*Survey question: Which of the following ESG initiatives for clinical trials are the most important to your organization? Additional language (if CRO respondent): Please answer questions in this section thinking holistically about your biopharmaceutical clients and their perspectives on ESG factors.
Note: ESG=Environmental, social and governance; CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey, 2022

Companies are not only looking to broaden access to lifesaving therapies by tapping into a diverse pool of patients, but they are also realizing that widening recruitment efforts through diversity can help mitigate the No. 1 reason trials are halted: failure to reach enrollment targets. Identifying and subsequently removing any barriers that hinder underrepresented

participants from joining their trials and selecting sites that are located near diverse communities are just two of the ways sponsors can improve clinical trial equity.

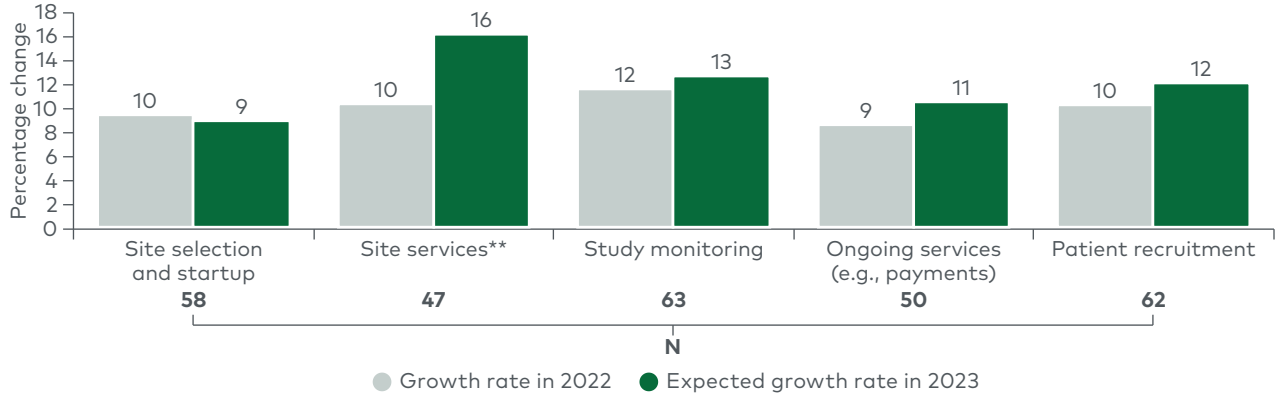
Sponsors are increasingly outsourcing site- and patient-specific clinical and eClinical services

As competition for trial sites rises and more decentralized trial sites are being adopted, the reliance of sponsors on site-specific third-party service and solution providers is increasing. Biopharmas and CROs cite double-digit growth in their use of a range of third-party clinical services related to site management — including site selection and startup, site services, and study monitoring — for phase 3 activities in the past year. And as the importance of the site-sponsor relationship continues to grow, sponsors are expecting their use of these services to grow along with it, from ~9% to ~16% in the next year alone (see Figure 8).

Similarly, biopharma and CRO companies are investing substantially more in patient-related services than ever before, to both overcome the mounting complexity in patient recruitment and deliver on diversity targets. Sponsors indicate outsourced patient recruitment to third-party service providers grew ~10% in 2022 over 2021, and they expect it will grow ~12% in 2023 (see Figure 8). Moreover, in therapeutic areas (TAs) with more trial activity, such as oncology (solid tumors), immunology and neurology, outsourced patient recruitment services are expected to increase by some ~14%, ~15% and ~25%, respectively, above the aggregate average across all TAs forecast for 2023.

Figure 8

Growth rate in outsourcing of site- and patient-specific clinical and eClinical services to third-party service and solution providers (excluding outsourcing to CROs) in phase 3*

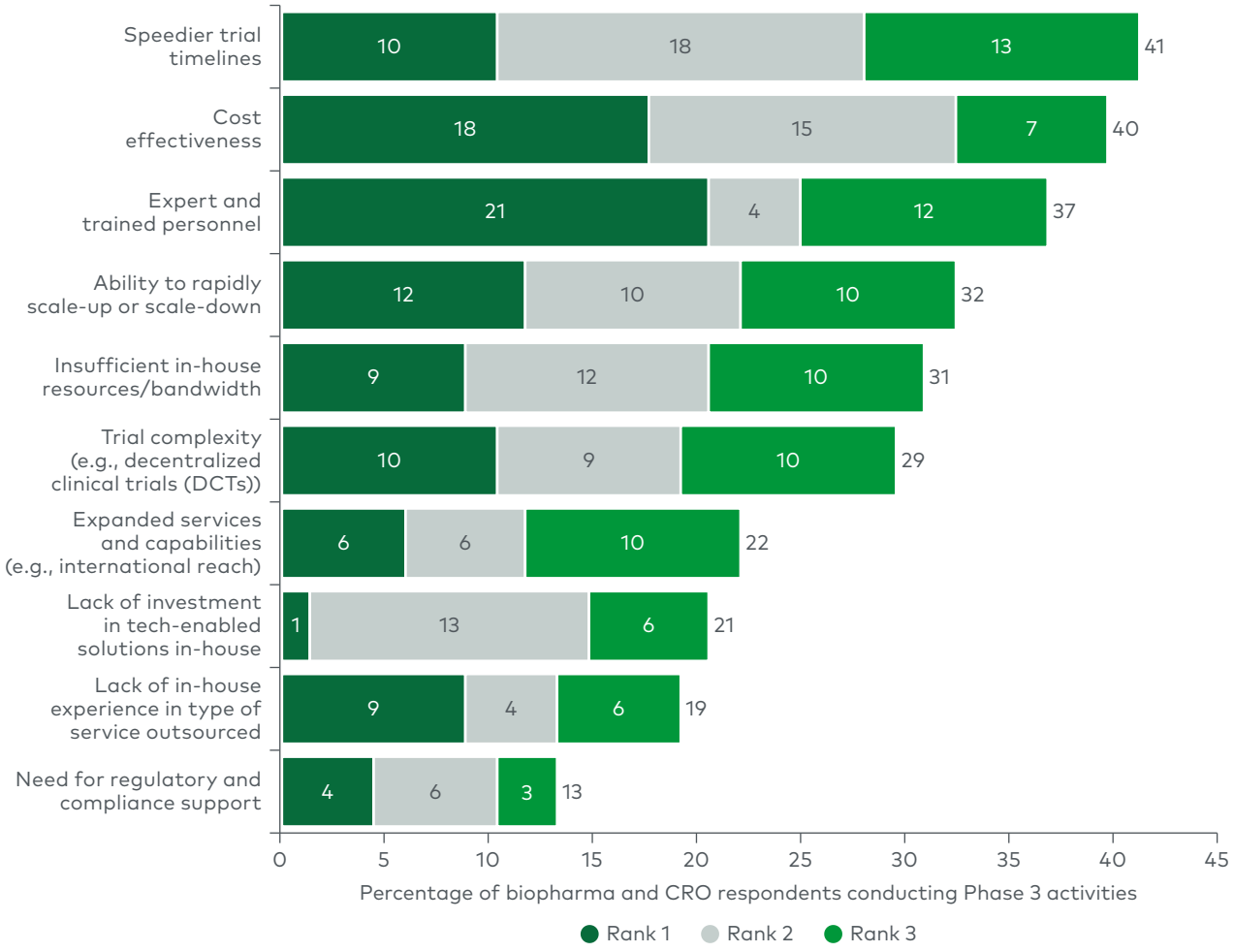


*Survey question (if biopharma respondent): Across all clinical trials conducted by your organization in phase 3, in what percentage of trials are you or your CRO outsourcing each of the following types of clinical and eClinical services to a third-party service or solution provider (as opposed to conducting the service in-house or the CRO conducting the service themselves)?
*Survey question (if CRO respondent): Across all clinical trials managed by your organization in phase 3, in what percentage of trials are each of the following types of services outsourced to subcontractors, i.e., third-party service or solution providers (as opposed to conducting the service in-house)?
**Includes site execution, site optimization, site management and site services
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

A series of unprecedented opportunities

Third-party service and solution providers have several opportunities to expand their current offerings to meet the evolving needs of the market. However, providing the bar-raising point solutions in which sponsors are looking to invest will only become more difficult. Providers' current value proposition — clinical development timeline speed, cost-effectiveness and expertise — will soon become table stakes for any player in the market. Sponsors will instead be looking for "nice to have" capabilities, such as the ability to rapidly scale up or down, and availability of point solutions that address the risks associated with increasing trial complexity (see Figure 9).

Figure 9
Reasons for outsourcing clinical and eClinical services to third-party service or solution providers (excluding outsourcing to CROs) (N=68)*



*Survey question (if biopharma respondent): Which of the following potential reasons is the most impactful in the decision to outsource clinical and eClinical services to third-party service or solution providers (excluding CROs)? Please think holistically of all the types of services you are familiar with.
*Survey question (if CRO respondent): Which of the following potential reasons is the most impactful in the decision to subcontract clinical and eClinical services to third-party service or solution providers? Please think holistically of all types of services you are familiar with.
Note: CRO=Contract research organization
Source: L.E.K. Clinical and eClinical Pharma Services Market Survey 2022

As sponsors continue to look for ways to enhance the trial experience for stakeholders, the service and solution providers that can ameliorate specific pain points related to patients and sites will further differentiate themselves and clearly demonstrate their value in this highly fragmented market.

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

Endnotes

[1]Moore, Thomas J. et al. "Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015-2017: a cross-sectional study."

[2]"Looking Ahead in Pharma Services: Key Trends Impacting the Industry," April 14, 2022.

[3]American Medical Association, "Trial-In-A-Box" to help more practices take part in clinical trials." https://www.ama-assn.org/practice-management/digital/trial-box-help-more-practices-take-part-clinical-trials

[4]Paraxel published on Biopharma Dive. "Decentralized clinical trials: Are we ready to make the leap?" https://www.biopharmadive.com/spons/decentralized-clinical-trials-are-we-ready-to-make-the-leap/546591/

[5]U.S. Food and Drug Administration, "2020 Drug Trials Snapshots Summary Report." https://www.fda.gov/media/145718/download

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