EXECUTIVE INSIGHTS

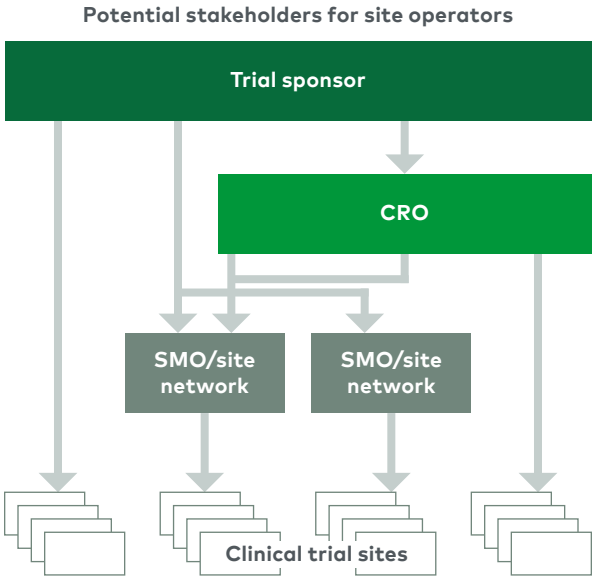
Exploring the Risks and Opportunities within Clinical Site Management Organizations

Site management organizations (SMOs) are organizations that own multiple commercial clinical trial sites and offer dedicated site management services and a single touchpoint for sponsors (see Figure 1). SMOs provide high-value clinical services to customers, including patient recruitment, institutional review board documentation, trial site selection, trial site contracting and data reporting.

In recent years, SMOs have received increasing consideration from sponsors as partners for trial execution. Underlying this trend is the idea that in an increasingly expensive and complex trial environment with more complicated therapies and niche patient populations, SMOs are able to reduce costs, effectively recruit and retain patients, and standardize operations to ensure timelines and data readout dates are met. In other words, the centralized functions that SMOs provide across their trial sites have become more attractive to sponsors, fundamentally enhancing the SMO value proposition.

In this *Executive Insights*, L.E.K. Consulting shares perspectives on key trends shaping the SMO value proposition, what strategic levers can maximize the value proposition, and what risks and opportunities the rise of SMOs will generate for organizations across the clinical services ecosystem.

Figure 1
Site operations stakeholders



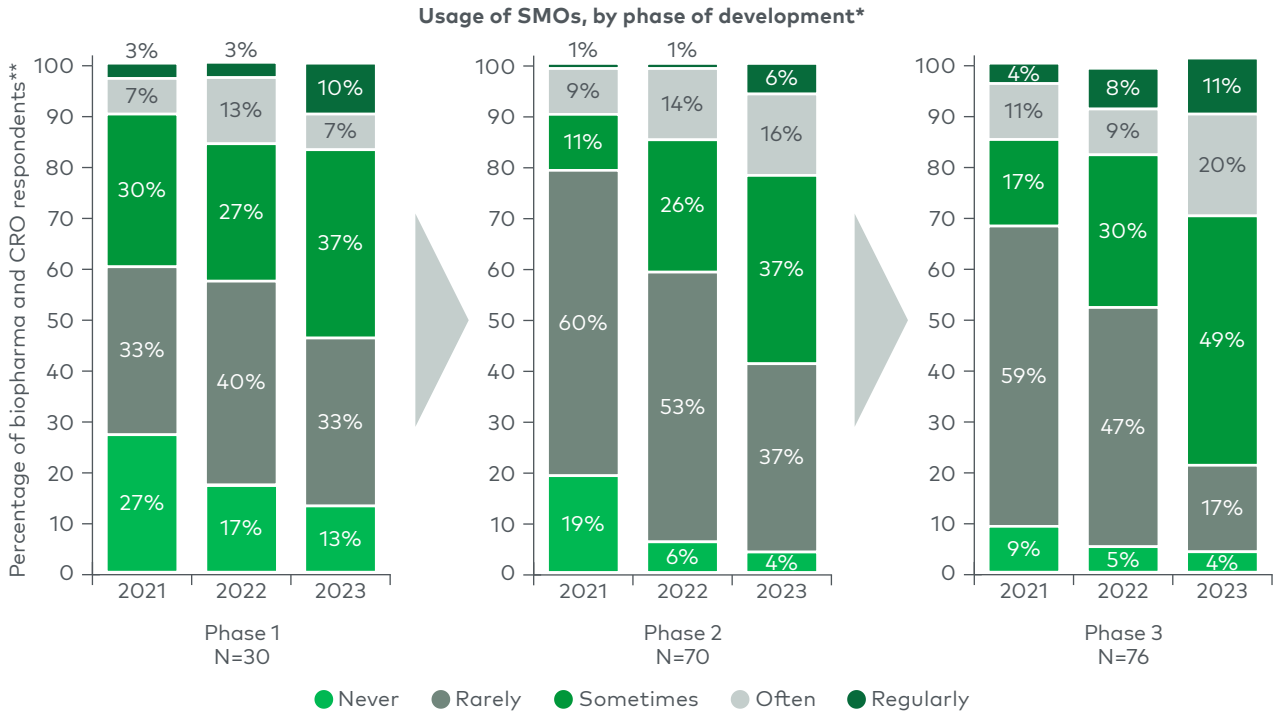
Note: CRO=contract research organization; SMO=site management organization
Source: L.E.K. interviews, research and analysis

SMO utilization has been increasing, driven by key trends that have amplified the SMO value proposition

According to data from L.E.K.'s inaugural Clinical and eClinical Pharma Services Survey,[1] biopharma and contract research organization (CRO) sponsors have increased their utilization of SMOs since 2021, especially in later-stage trials. Thirty-one percent of respondents indicated that they expect to utilize SMOs "often" or "regularly" for phase 3 trials in 2023, compared with only 15% in 2021, with a similar twofold increase expected in phase 2 trials (see Figure 2).

One significant trend emerges from this data: The utility of an SMO increases significantly as trials become more complex. Only 17% of respondents expect to use SMOs "often" or "regularly" for phase 1 trials in 2023, compared with the 20% figure for phase 2 and the 31% figure for phase 3. Later-stage clinical trials, with higher patient counts necessitating more sites as well as more complex data collection and reporting for both safety and efficacy endpoints, amplify the SMO value proposition.

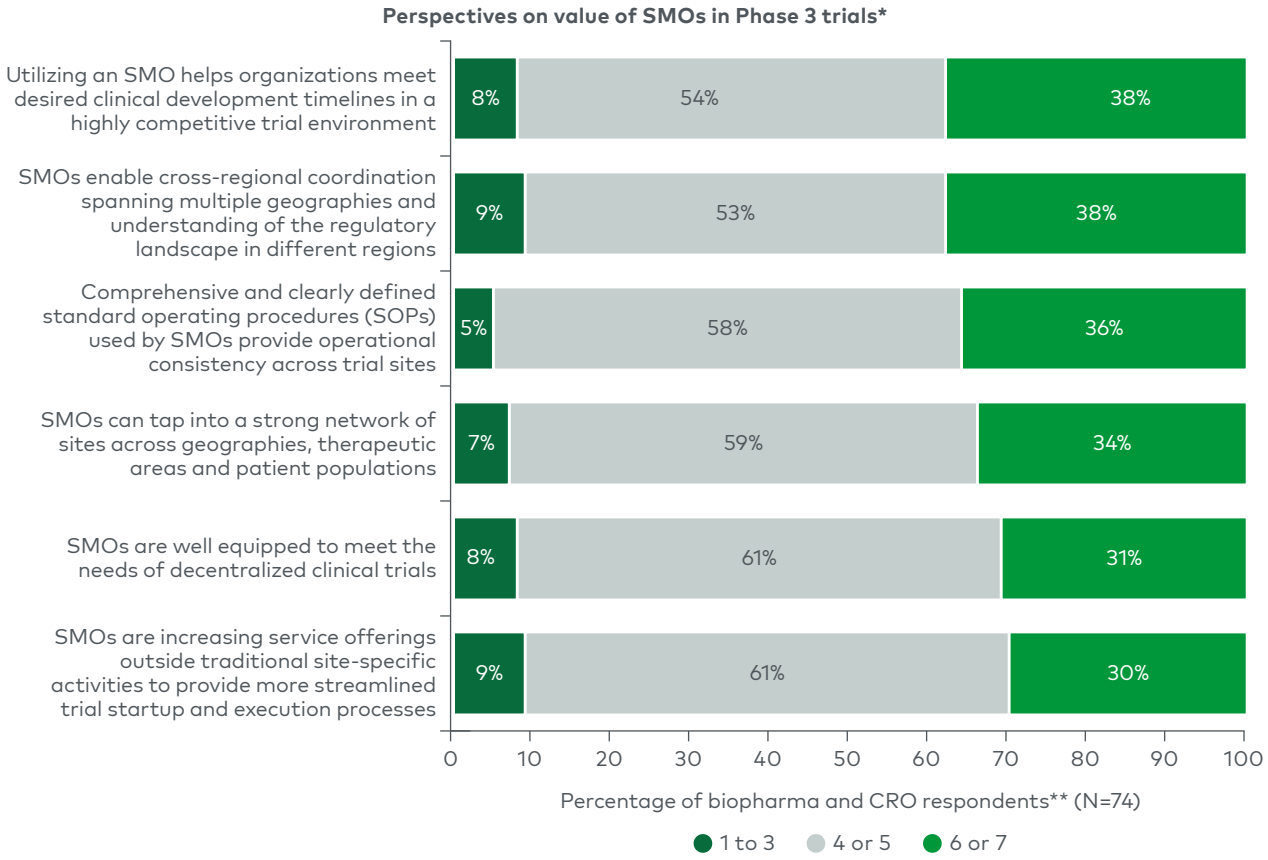
Figure 2
SMO utilization across development phases



*Survey question: Across all trials conducted/managed by your organization, in what percentage of trials does your organization contract with a site management organization (SMO)?
**Excludes one-two respondents who selected "I don't know" per phase, reflected in Ns shown
Note: CRO=contract research organization; Percentages may not add to 100 due to rounding
Source: L.E.K. Clinical and eClinical Pharma Services Survey 2022

When investigating the value proposition of SMOs, L.E.K. found that sponsors value SMO partnerships in addressing several key hurdles in late-stage trials. The greatest value in phase 3 trials included helping sponsors meet desired clinical timelines, enabling cross-regional coordination, ensuring operational consistency across trial sites and accessing alternative trial site locations for decentralized trials (see Figure 3).

Figure 3
Value of SMOs in phase 3 trials



*Survey question: To what extent do you agree or disagree with the following statements when considering the value of SMOs in Phase 3 trials? Please rate each statement on a scale of 1 to 7, where 1 means "strongly disagree" and 7 means "strongly agree"
**Data includes only respondents who have used SMOs in 2021 or 2022 for at least one phase of trials or expect to use SMOs in 2023 for at least one phase of trials
Note: SMO=site management organization; CRO=contract research organization; Percentages may not add to 100 due to rounding
Source: L.E.K. Clinical and eClinical Pharma Services Survey 2022

These value propositions are on trend for three key developments we have seen in the clinical trials space.

1. Increasing complexity of clinical trials

As more advanced-modality assets, such as cell and gene therapies, have entered the clinic and disease focus has shifted to rare disease and oncology indications, trial designs have become increasingly complex. The growing use of biomarkers for patient stratification and eligibility as well as safety and efficacy endpoints, in addition to more complex operational and technical requirements for therapy administration, has created additional hurdles to efficient trial execution.

SMO sites are typically fully dedicated to running trials, unlike academic medical centers (AMCs), community hospitals or physician offices that have other patient care priorities. This enables SMOs to dedicate more focused resources and attention to execution of complex trial designs. Furthermore, many SMOs have specific therapeutic area expertise and employ principal investigators who have a track record of executing trials in emerging-modality therapeutics and experience with biomarker data collection and reporting. This focus and expertise, in addition to sponsors' ability to negotiate a single contract and have a single point of contact across an SMO's network, reduce the burden of trial complexity on CRO and biopharma clients.

2. Increasing difficulty with patient recruitment and retention

The rise of personalized medicine has led to a reduction in eligible patients for trials. The shift in pipeline focus toward orphan diseases as well as assets that have additional gating criteria to patient eligibility (e.g., specific tumor markers for targeted therapies in oncology) has created hurdles for patient recruitment, emphasizing the need for recruiting niche populations and including genetically diverse patients.

SMOs have broader recruitment reach than independent sites and can develop best-in-class recruiting capabilities, enabling them to mitigate patient recruitment and retention hurdles. SMOs are also able to build out more robust decentralized trial functions through partnerships and "hub and spoke" models to reduce geographic barriers to patient access.

3. Increasing cost of clinical trials

In recent years, recruitment delays, bureaucracy at AMCs and trial miscues, in addition to greater complexity of trial design, have resulted in sustained increases in clinical trial costs.[2]

The SMO model enables economies of scale by distributing back-office costs across multiple trial sites. Furthermore, SMOs tend to invest in capabilities to ensure operational efficiency throughout their network of sites that streamline site management in comparison to sponsor-driven cross-site coordination.

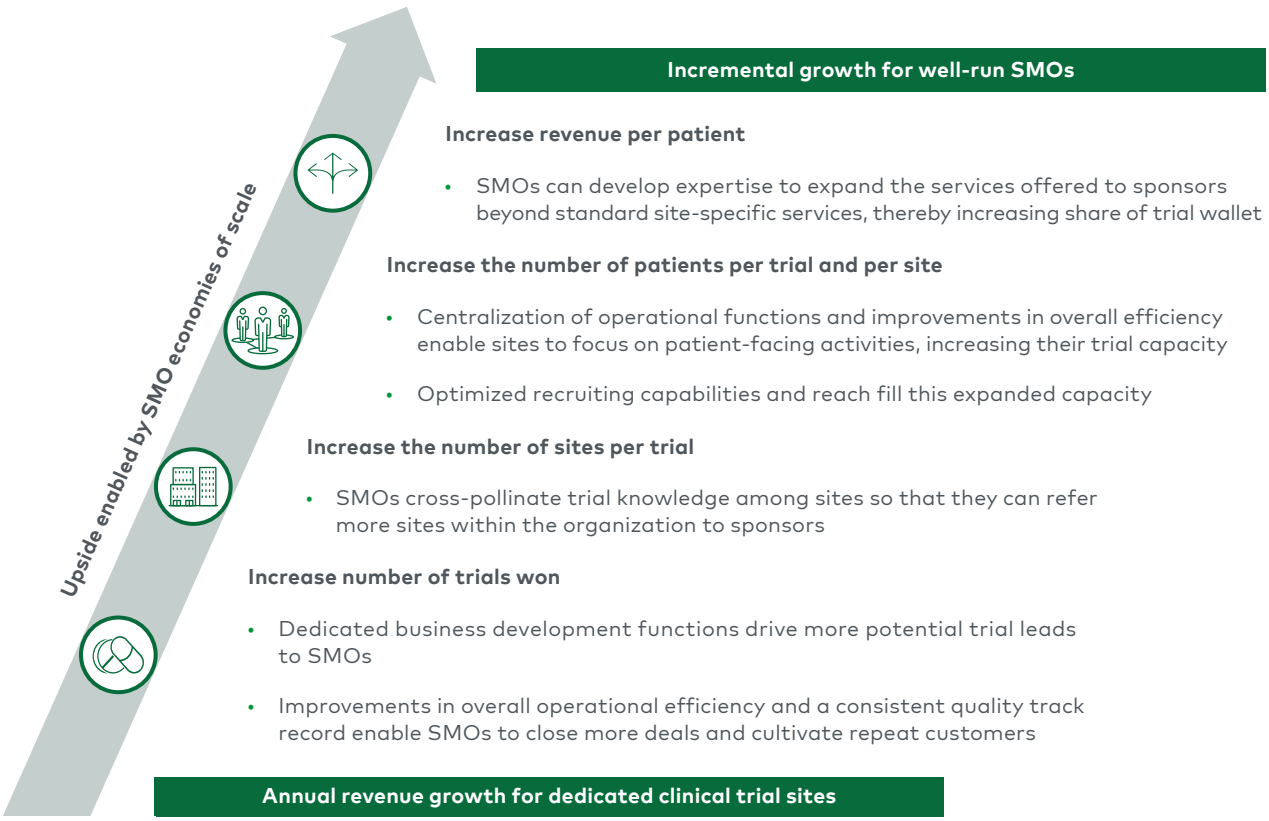
Implications for investors and operators in the SMO space

The trends mentioned in the previous section are expected to continue in the coming years, potentially driving further consolidation of clinical trial sites under SMO umbrellas. However, the rise of SMOs will not be homogenous, and increasing investment in the clinical trial space will result in increased competition among SMOs and their private equity backers. Industry experts indicate that EBITDA multiples for clinical trial sites have risen in recent years,[3] and

some SMOs have seen mixed results with expansion, sometimes closing sites shortly after startup or acquisition, as Headlands Research did in Houston and in Lake Charles, Louisiana.[4] Winning in this competitive environment requires investors and operators to focus on high-value aspects of strategic execution.

The key to successfully capitalizing on the core SMO value proposition lies in economies of scale. As an SMO expands to acquire or open additional sites and enter into partnerships with AMCs and hospitals, careful consideration must be given to the synergies and capabilities that a new site can bring to the table. Trade-offs exist between adding a novel capability or specialty and adding a site that has similarities to existing sites in order to expand patient access and expertise in a given therapeutic area. The strategy for adding new sites must seek to maximize value along key growth vectors; these include increasing the number of trials won, increasing the number of sites serving a trial, increasing the number of patients per site and growing revenue per patient by capturing additional share of the trial wallet (see Figure 4).

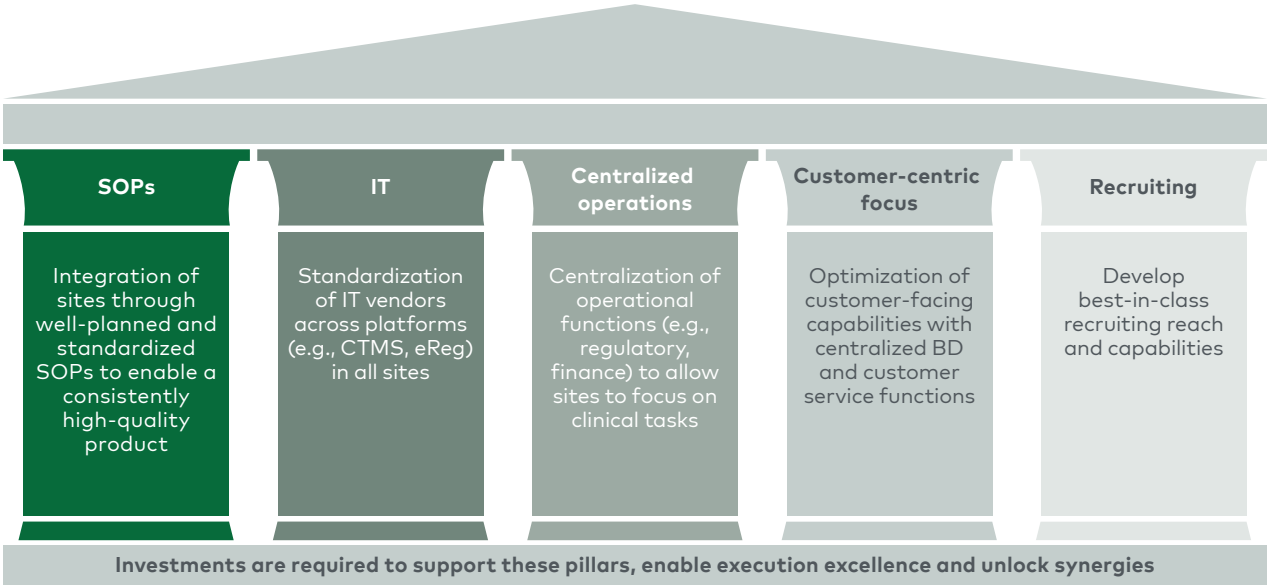
Figure 4
Growth enablers for SMOs



Note: SMO=site management organization
Source: L.E.K. interviews, research and analysis

Beyond scale, operational excellence needs to be pursued across several key metrics. Figure 3 suggests that sponsors place the highest value on the ability of SMOs to streamline processes and ensure effective execution in order to meet desired timelines. In the context of the current macroeconomic environment, meeting clinical timelines becomes increasingly important for smaller biopharma sponsors that face greater challenges in raising capital as public and private financing markets have tightened. Additionally, generating robust data by ensuring consistent implementation of standard operating procedures across trial sites is deemed highly valuable. In order to deliver on these promises and effectively communicate them to customers, SMOs should invest in five key pillars of execution excellence (see Figure 5).

Figure 5
Pillars of SMO execution excellence



Note: SMO=site management organization; SOP=standard operating procedure; IT=information technology; CTMS=clinical trial management system; eReg=eRegulatory management system; BD=business development
Source: L.E.K. interviews, research and analysis

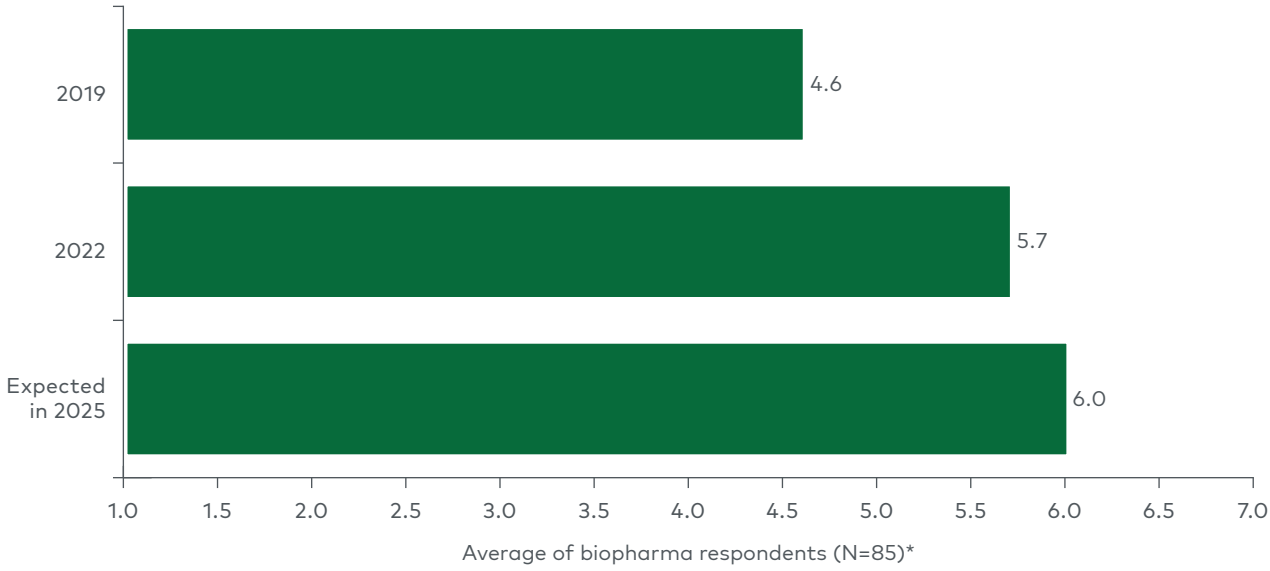
Implications for the clinical trial services ecosystem

The rise of SMOs has wide-ranging implications for organizations across the clinical services ecosystem. Three trends relating to key stakeholder groups are important to consider.

As more sites are acquired by SMOs, the power dynamic in the site-sponsor relationship will change, shifting in favor of the SMO sites. This trend will be compounded by continued growth in demand for clinical sites, outpacing supply. As a result, it will be increasingly important for CRO and biopharma sponsors to position themselves as a "sponsor of choice" for top SMOs

by fostering close working relationships and investing in a collaborative approach to clinical trial execution (see Figure 6). From the SMO perspective, large-scale SMOs that build out robust business development functions and invest in operational efficiency may gain pricing power and increased profitability as a result.

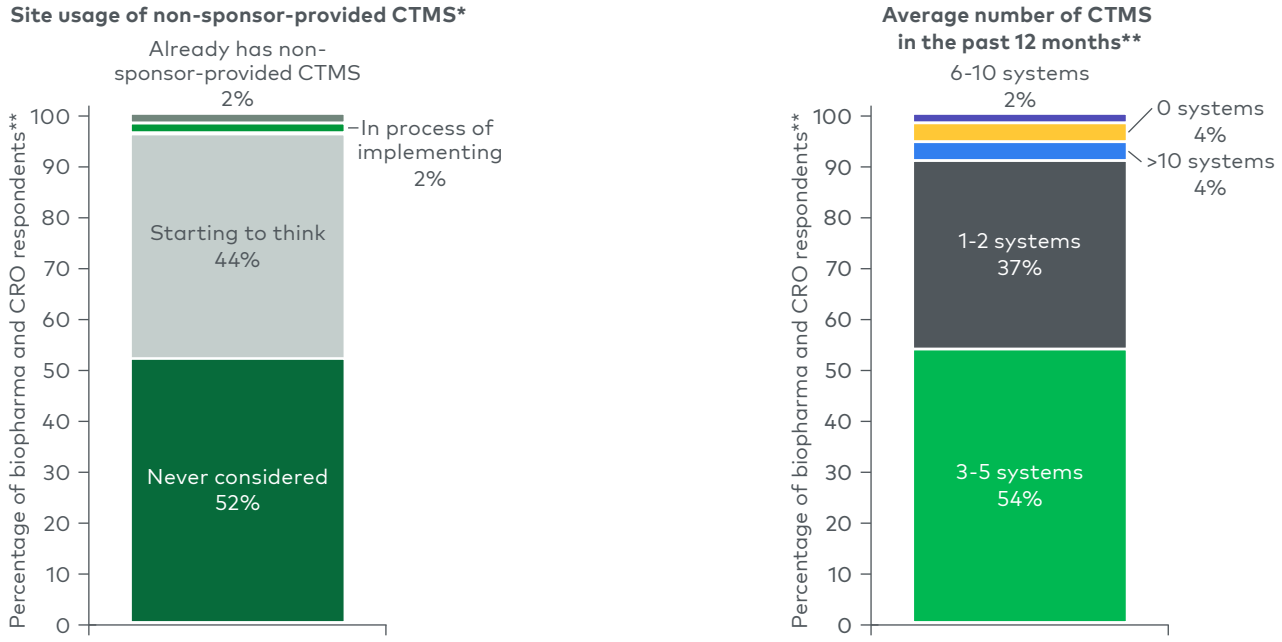
Figure 6
Importance of being seen as a 'sponsor of choice'



*Survey questions: 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 to 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 Survey 2022

Providers of third-party technology solutions for clinical trials, including clinical trial management systems (CTMS), electronic data capture systems, and randomization and trial supply management software, may benefit from SMO expansion and consolidation. Using CTMS software as an example, only 2% of trial sites have a non-sponsor-provided CTMS while approximately 60% of trial sites are coordinating across three or more CTMS (see Figure 7).

Figure 7
CTMS solutions at clinical trial sites



*Survey question: Out of the following statements, which best describes your site's use of clinical trial management software(s) specifically selected and purchased by your site (i.e., non-sponsor-provided)?
**Survey question: Across all clinical trials conducted at your site, what is the average number of sponsor-provided clinical trial management software systems (CTMSs) your site needed to maintain and monitor over the past 12 months?
Note: Percentages may not add to 100 due to rounding
Source: L.E.K. Clinical and eClinical Pharma Services Survey 2022

Large SMOs will have the scale to implement their own software and IT (see pillar 2 in Figure 5) in order to improve operational efficiency, reduce their cost base and ensure integration across sites within a trial. This shift will create opportunities for clinical trial technology providers to grow revenue through SMO-specific technology solutions.

Finally, other third-party service providers, such as patient recruitment organizations, will be affected as large SMOs insource these functions in order to capture additional share of the clinical trial wallet. Initially, these companies may operate as SMO service providers, but as the average scale of the SMO increases, we expect to see both organic insourcing of these functions as well as acquisitions of third-party service providers that complement the SMO core value proposition.

Conclusion

Growing interest in SMO utilization has been driven by sustained trends in clinical trial complexity and cost; the continuation of these trends suggests that the SMO space could see robust growth in the coming years. The ability of scaled SMOs to offer a compelling value proposition to sponsors could result in consolidation of clinical trial sites under SMO

umbrellas and increased partnerships between SMOs, AMCs and hospital trial sites to enable sponsors to recruit and retain niche and genetically diverse patients in a time- and cost-effective manner. The growth of SMOs will have implications across the clinical trial ecosystem, impacting the ways in which SMOs expand their reach, creating a shift in the balance of power between sponsors and trial sites, and creating opportunities and risks for other players in the clinical trial solutions ecosystem.

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

Endnotes

[1]Survey includes respondents employed in U.S., Canada, the U.K. and EU4. See linked report for further details. https://www.lek.com/insights/ei/lek-consultings-inaugural-clinical-and-eclinical-pharma-services-survey

[2]May, M. "Clinical trial costs go under the microscope." March 2019. Nature Medicine. https://www.nature.com/articles/d41591-019-00008-7

[3]Blume, D. "Site Management Organizations Are Trending: Learn How Sites Are Consolidating." Clinical Research. https://www.clinicalresearch.io/blog/industry-trends/site-management-organization-trending/

[4]Pradhan, R. "The business of clinical trials is booming. Private equity has taken notice." Dec. 2022. Fortune. https://fortune.com/2022/12/02/clinical-trials-private-equity-headlands-research/

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