EXECUTIVE INSIGHTS

L.E.K. Consulting's Clinical and eClinical Pharma Services Outlook

Executive summary

As the volume and complexity of clinical trials continue to rise, biopharmaceutical sponsors and contract research organizations (CROs) are increasingly turning to outsourced clinical and eClinical services to streamline execution, enhance patient data collection and accelerate timelines. L.E.K. Consulting's proprietary survey of industry stakeholders reveals several clear shifts shaping the next 12 months:

- **Outsourcing momentum continues to build:** Over 55% of respondents expect to increase spend on outsourced services across all trial types and therapeutic areas. Rising trial complexity, global expansion and growing regulatory demands are fueling this trend.
- **Endpoint management is evolving:** Patient-centric endpoints, novel biomarker validation and digital health technologies are pushing endpoint collection beyond traditional measures. Clinical outcome assessments (COAs)/patient-reported outcomes (PROs), imaging and actigraphy are poised for strong growth across multiple therapeutic areas.
- **Recruitment investments are tilting toward identification and enrollment:** As patient recruitment challenges intensify, sponsors are prioritizing digital solutions that enhance outreach and reduce site burden. Patient identification and enrollment are drawing more budget attention than are retention efforts.
- **Centralized support models remain dominant — but site-based models are gaining ground:** While centralized models are valued for scale and consistency, nearly half of respondents are increasing site-based support to better reach niche populations and improve local execution.

Together, these findings point to a market that increasingly values evidence-based decision-making and solutions that integrate operational execution with strategic impact — underscoring the growing importance of thoughtful vendor partnerships and adaptable clinical infrastructure.

Introduction to clinical and eClinical pharma services

The life sciences ecosystem is facilitating an expanding pipeline of novel assets in development and an increasing number of clinical trials to support them. The costs and timelines to bring new molecular entities through approval are rising rapidly. Several factors contribute to this trend:

- **Increasing complexity of trials:** The demand for deeper and more diverse sets of endpoints, accelerated by the advent of advanced modalities (e.g., gene and cell therapy), has increased trial complexity.
- **Ongoing globalization of trials:** There is a growing need for trials to access more sites to generate representative data, including global considerations, adding clinical and operational complexity.
- **More stringent regulatory and payer demands:** There is mounting pressure from global regulators and payers to collect more patient-oriented, validated endpoint data.

Biopharmaceutical companies outsource clinical and eClinical services to CROs and dedicated solution providers to access specialized expertise, alleviate logistic burdens, expedite timelines and/or improve quality of data. Outsourced services support every aspect of the clinical trial process — from site selection through endpoint collection to regulatory submission. CROs and solution providers continue to expand their breadth to act as one-stop shops for customers and/or increase their depth in more niche offerings by specializing.

Our team of experts examined key aspects of the clinical trial value chain, inquiring about the key areas of growth and underlying drivers that fuel the outsourcing and innovation seen in clinical and eClinical pharmaceutical services.

Overview on survey composition

For the Clinical and eClinical Pharmaceutical Services Survey 2024, we recruited 139 biopharmaceutical and CRO respondents with involvement in outsourcing clinical and eClinical services. These respondents primarily worked on Phase 2 and Phase 3 clinical-stage assets with experience across a variety of therapeutic areas (see Figures 1a and 1b).

The survey explored key emerging trends in clinical trials and how they are catalyzing growth and changing decision-making dynamics in the outsourced pharmaceutical services market over the next 12 months.

Figure 1a

Survey respondent demographics (biopharmaceuticals)

N=139		Biopharmaceuticals
Total N		**76**
Geography	U.S./Canada	93%
	EU4 + UK	7%
Functional area	Clinical operations	41%
	Clinical development	59%
Company size	Fewer than 100 employees (e.g., emerging)	13%
	101 to 500 employees (e.g., small)	21%
	501 to 4,999 employees (e.g., midsize)	26%
	5,000 or more employees (e.g., large/top 25)	39%
Title	Manager	5%
	Associate director	11%
	Director/executive director	55%
	Vice president/senior vice president	21%
	C-suite	8%
Years of clinical trial experience	3-5 years	4%
	6-10 years	22%
	More than 10 years	74%

Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

Figure 1b

Survey respondent demographics (CROs)

N=139		CROs
Total N		**63**
Geography	U.S./Canada	77%
	EU4 + UK	23%
Functional area	Clinical operations	25%
	Clinical development	41%
	R&D	19%
	Project/data management or business development	15%
Company size	Fewer than 100 employees (e.g., emerging)	14%
	101 to 500 employees (e.g., small)	38%
	501 to 4,999 employees (e.g., midsize)	29%
	5,000 or more employees (e.g., large/top 25)	19%
Title	Manager	5%
	Associate director	3%
	Director/executive director	24%
	Vice president/senior vice president	14%
	C-suite	30%
Years of clinical trial experience	3-5 years	6%
	6-10 years	54%
	More than 10 years	40%

Note: CROs=contract research organizations
Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

Spend on outsourced clinical and eClinical services is expected to increase

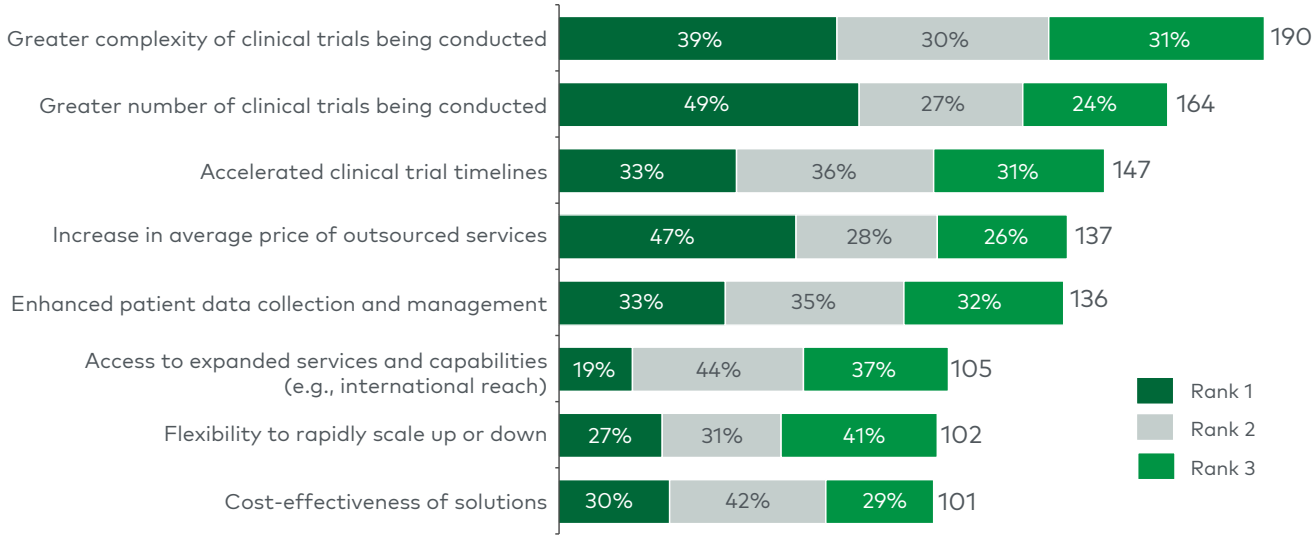
More than 55% of respondents anticipate increasing their spend on outsourced clinical and eClinical services across surveyed areas in the next 12 months, regardless of therapeutic area or trial type. Outside of rising prices (see Figure 2 for details), this growth is primarily driven by the increasing complexity and number of trials as well as the desire for accelerated trial timelines and enhanced patient data collection and management. These trends highlight mounting pressure on stakeholders to execute trials more efficiently. CROs and solution providers are well positioned to meet this need — enhancing speed, quality and operational impact.

Respondents' views generally assume clinical trial starts will continue a measured recovery through 2025, with additional tailwinds derived from increasing cost and complexity of trials. At a market level, there is a relentless moderate increase in outsourcing rates to manage this complexity and needed specialization.

Figure 2

Drivers of increased anticipated spend in outsourced clinical/eClinical services

Percentage of respondents expecting an increase in spend ranking in top three (N=129)*



*Survey question: Which of the following reasons drives the anticipated increase in spend for outsourced services? Please select up to three reasons in order of importance, where 1 is the "most important"
Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

One specific area that is expected to evolve and support a growth in outsourced spend is the role of the trial site. The role of sites in decision-making for vendor selection of outsourced services continues to evolve over time relative to a historically centralized process. Approximately 63% of respondents already engage sites for decisions on site-related outsourced services. In addition, 25% also expect the sites' involvement to increase in the next 12 months:

1. The greatest increases are expected in patient engagement, patient retention and patient identification, which are more nascent, emerging offerings; stakeholders may be increasingly interested in gathering insight or providing solutions tailored to specific site or trial needs.
2. The lowest increases were observed in more mature, established services such as randomization and trial supply management, electronic data capture, and ongoing services (e.g., participant payment services), which may require relatively little site-specific or trial-specific input.

These evolving dynamics within the outsourced pharma services market underscore an opportunity for CROs and solution providers to increase their support of clinical trials by delivering streamlined, efficient clinical trials.

The following sections of this *Executive Insights* examine in detail specific areas within the clinical/eClinical ecosystem.

Spending on outsourced endpoint management services is expected to rise

Endpoint management services focus on collecting and aggregating patient data for evaluation of clinical trial endpoints. More than 50% of respondents expect spending to increase, driven by the growing emphasis on patient-centric endpoints or regulatory validation requirements. However, this also heightens logistic and technical challenges for patients, trial sites and sponsors. These challenges will support a continued evolution toward leveraging outsourced support, a trend that respondents see expanding in the following areas of interest (see Figure 3):

1. **eCOA/ePRO** As patient-centric endpoints gain prominence, trials are increasingly expanding their focus beyond traditional efficacy measures to capture real-world outcomes and quality-of-life indicators.

2. **Imaging:** Stringent Food and Drug Administration validation requirements and evolving biomarker frameworks are catalyzing greater investment in high-resolution imaging and analytics, particularly in oncology and central nervous system trials.
3. **Actigraphy:** Momentum is building behind actigraphy as a scalable digital endpoint, especially as wearable technologies become more standardized and regulatory bodies provide greater clarity.

Figure 3

Therapeutic areas or disease states driving greatest anticipated growth, by endpoint

Endpoint type (in order of maturity)	Top three drivers of growth (in order of importance)	Rating of importance (on a scale of 1-7)
eCOA/ePRO (N=35)*	• Increasing utilization of digital eCOA/ePRO options over traditional paper COA/PRO	6.0
	• Increasing focus on TAs where quality of life is key to track besides efficacy (e.g., oncology)	5.8
	• Increasing focus on TAs that depend on COA/eCOA as primary endpoint (e.g., CNS/neuro)	5.6
Imaging (N=35)*	• Rising quality of imaging technology/equipment (e.g., higher resolution, 3D, new radiotracers)	6.3
	• Ongoing clinical/regulatory validation of imaging endpoints in indications where it has not yet been adopted	6.2
	• Increasing utilization of digital imaging options compared to traditional paper imaging	6.2
Actigraphy (N=25)*	• Ongoing clinical/regulatory validation of actigraphy endpoints in indications where it has not yet been adopted	6.1
	• Increasing utilization of digital actigraphy options compared to traditional movement endpoints	6.1
	• Rising quality of actigraphy technology/equipment (e.g., better hardware or software to capture movement data)	6.0

*Survey questions: Which of the following therapeutic areas or disease states do you anticipate will see the largest increase in utilization of X endpoints in the next 12 months (2025)? Please select up to three therapeutic areas, with the first selected being most likely. How important do you consider the following factors in driving increasing adoption of X as an endpoint over the next 12 months (2025)? Please rank all drivers on importance, with 1 as "not at all important" and 7 as "very important"
Note: eCOA=electronic clinical outcome assessment; ePRO=electronic patient-reported outcome; TAs=therapeutic areas; CNS=central nervous system
Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

This evolving landscape for endpoint management services presents an opportunity for CROs and solution providers to leverage their expertise and specialized services on behalf of sites. They can invest in enabling technologies (e.g., movement trackers) that allow for and streamline the collection and validation of patient data.

Willingness to spend on patient recruitment solutions will likely continue to grow, with a strong focus on patient identification and an emerging emphasis on enrollment services as the market evolves

Unmet needs in patient recruitment are ramping up as trials become more intricate, sites compete for the same set of eligible patients across pipeline candidates and site capacity remains relatively stagnant. According to our 2023 analysis, Clinical Trial Challenges: Patient Recruitment and Diversity,[1] only 5%-15% of patients are aware of clinical trials and approximately 25% of volunteers screened are eligible to participate. Additionally, around 50% of clinical trial sites fail to achieve enrollment targets, with roughly 20% failing to enroll a single patient. This results in a system reliant on high volume to account for substantial "leakage" throughout the process — by some accounts, only one to five out of 100 prospective patients will **enroll** in, let alone complete, a trial.[2] This is further complicated by a broad lack of access to clinical trials, with only a small percentage of patients and physicians involved in clinical trials today.

When given budget constraints to spend on solutions for patient recruitment, respondents report more willingness to spend on solutions for patient identification (42%) and enrollment (36%) over patient retention (22%) in the next 12 months. This is driven by both the relative nascency of patient retention services and a perception that patient identification and enrollment solutions provide greater immediate return on investment.

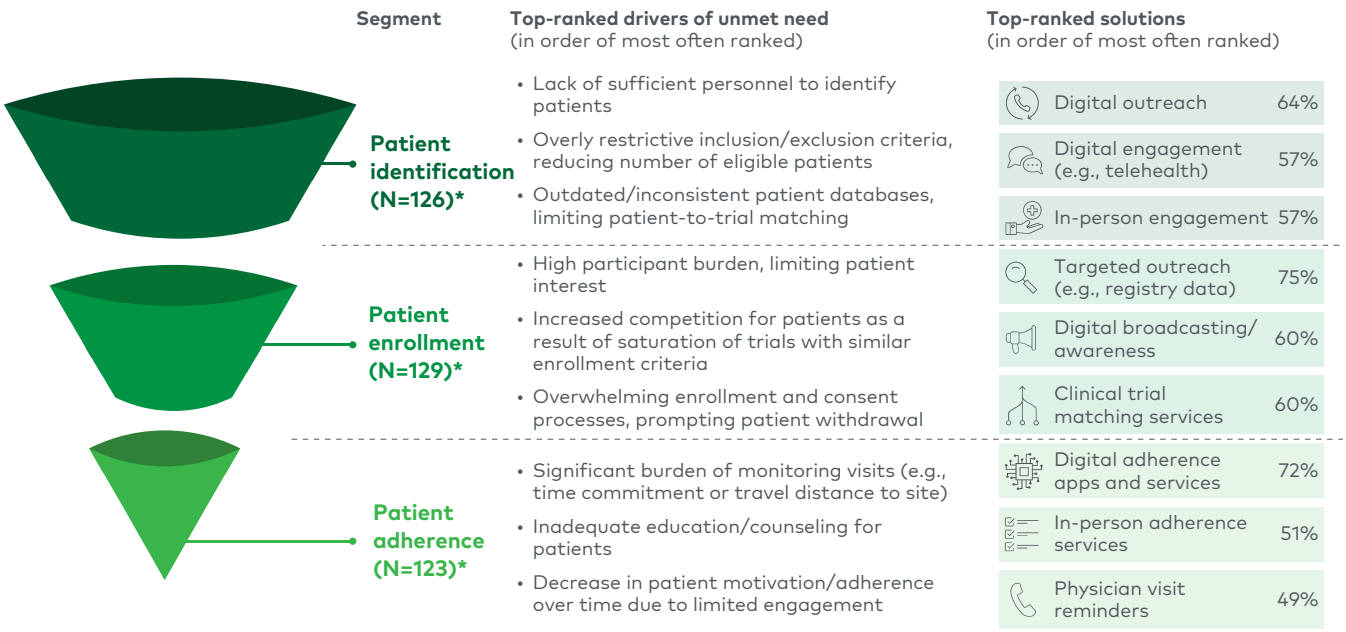
Regardless of the patient engagement segment, respondents are most interested in using digital tools, apps and/or services to address unmet needs (see Figure 4). This speaks to the diminishing bandwidth and increasing competition in clinical trial recruitment, where time and cost-effectiveness are top of mind.

1. **Patient identification:** Top unmet needs include a lack of sufficient personnel for trials and restrictive inclusion/exclusion criteria. This is corroborated by respondents' desire to use targeted outreach tools, clinical trial matching services and digital broadcasting to identify more patients, accelerate trial timelines and improve the quality of data collected.
2. **Patient enrollment:** Respondents cite trials with high participant burden as a key enrollment blocker along with increasing competition and complex enrollment/consent processes driving unmet needs. To ameliorate this, they seek flexible digital and in-person engagement tools that are expected to reduce administrative burden and streamline initial recruitment timelines.
3. **Patient retention:** Burdensome monitoring, inadequate education efforts and waning patient engagement over time are top unmet needs that diminish retention. Digital tools (e.g., reminders, gamification apps) and in-person services offer practical solutions to improve data quality and ease site workload.

Figure 4

Top-ranked unmet needs and solutions in patient recruitment, by segment

Percentage of respondents ranking solution in top three



*Survey questions: Imagine your organization had $100,000 to spend on outsourced solutions to address patient recruitment for a clinical trial. How would you allocate the $100,000 across the three segments of the patient recruitment funnel today (2024) and 12 months (2025) from now? Please enter a percentage. Your best estimate/approximation is fine. Which of the following solutions to improving X do you anticipate being most effective in addressing unmet needs?
Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

As CROs and solution providers look to expand their books of business with patient recruitment, they should focus on developing or acquiring digital outreach or engagement tools that prioritize the time and cost-effectiveness for sites while enriching clinical trial timelines and patient data collection.

Willingness to spend on centralized or site-based support has historically favored centralized solutions

Biopharmaceutical companies and CROs have traditionally invested in centralized support, where a single team manages portions of trial processes across multiple sites or studies. However, there is growing interest in site-based support, which provides direct assistance, resources and services to individual trial sites. When asked about budget allocation for the next 12 months, respondents anticipate a similar split between centralized and site-based support (about 54% and 46%, respectively), indicating strong demand for both.

Regardless of preference, centralized services are poised to see continued growth while site-based services gain in adoption. Respondents are focused on solutions that are efficient for

patient recruitment, with a keen eye toward accelerating trial timelines and improving data quality by attracting the right patients. Use of either model or both models of support is driven by the benefits (see Figure 5), which are often synergistic with one another:

1. **Centralized support:** Respondents highlight its scalability and cost-effectiveness by accessing a larger, more diverse patient population efficiently. It suits larger, multisite trials that need consistent messaging across all sites. Centralized support can benefit both broad and rare disease trials targeting general or specific populations (e.g., via social media ads or national registries, respectively).

2. **Site-based support:** Respondents note its potential to accelerate trial timelines and improve matching of targeted/focused outreach to specific patient populations. This is crucial in trials that are seeking highly specialized patients (e.g., 4L+ in oncology) or hard-to-find populations (e.g., undiagnosed rare diseases or specific ethnic subpopulations), and may be more suitable for single-site or smaller-scale trials.

Figure 5

Drivers of increases in anticipated spend in centralized and site-based support

Percentage of respondents ranking in top three (N=51, 28)*

Centralized support	Top 3
Is more easily scalable	51%
Is more cost-effective use of budget	47%
Allows higher-quality data via improved patient matching	43%
Site-based support	**Top 3**
Is more time-effective because of focused outreach to specific patient populations	75%
Accelerates trial timelines by attracting specific patient populations quickly	71%
Allows higher-quality data via improved patient matching	64%

*Survey questions: Imagine your organization had $100,000 to spend on outsourced solutions for either centralized or site-based support for recruitment of a clinical trial today. How would you allocate the $100,000 between centralized and site-based recruitment support today (2024) and in 12 months (2025)? Please enter a percentage. Your best estimate/approximation is fine. Which of the following reasons drives the anticipated increase in allocation for centralized support? Please select up to three reasons in order of importance, where 1 is the "most important"
Source: L.E.K. Clinical and eClinical Pharmaceutical Services Survey 2024

As unmet needs mount in patient recruitment, sponsors should look to leverage both types of support. Both centralized and site-based support aim to improve efficiency of clinical trials and enhance data quality by attracting the right patients for trials. When used together, centralized support can quickly identify and prescreen large patient populations while site-based teams focus on qualified leads, especially in a highly competitive global Phase 3 trial. CROs and solution providers must acknowledge that the two types of services address an overlapping unmet need in patient recruitment in different ways, positioning them as complementary offerings as they develop or expand their offerings of patient recruitment services.

Applications for artificial intelligence/machine learning are expected to increase across many of these use cases. In addition to data access and privacy challenges, respondents cite difficulties in demonstrating algorithm transparency, licensing/implementation costs and an unclear regulatory landscape in limiting use today. The short, medium and long terms are still uncertain and evolving; however, structured analysis, real-time data processing and predictive analytics have exciting potential.

Key questions for the ecosystem persist

Stakeholders across the ecosystem must account for these emerging trends to protect and expand their competitive advantage, including:

- For pharma sponsors, balancing the risk of adopting new technology and processes against the risk of eroding time to market requires a careful, deliberate effort to maximize the value of partners.
- For clinical/eClinical vendors, defining a clear, differentiated value proposition that resonates in the market is increasingly important.
- For CROs, the ability to partner with a leading set of services to adroitly balance internal capabilities with overall offering strength is critical.
- For clinical trial sites, efficiently adopting new technologies and tools to drive site efficiency is key both for operational performance and long-term site resonance and business development.

L.E.K. brings deep domain expertise and evidence-based insights to help sponsors, CROs and solution providers navigate this evolving landscape. To explore bespoke solutions tailored to your organization, please **contact us**.

Endnotes

[1]LEK.com, "Clinical Trial Challenges: Patient Recruitment and Diversity." https://www.lek.com/insights/hea/us/ei/clinical-trial-challenges-patient-recruitment-and-diversity

[2]WCGclinical.com, "Flipping the Funnel: Strategies to Add Value to the Clinical Trial Patient Enrollment Process." https://www.wcgclinical.com/wp-content/uploads/2022/03/flipping-the-funnel.pdf

About the Authors

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