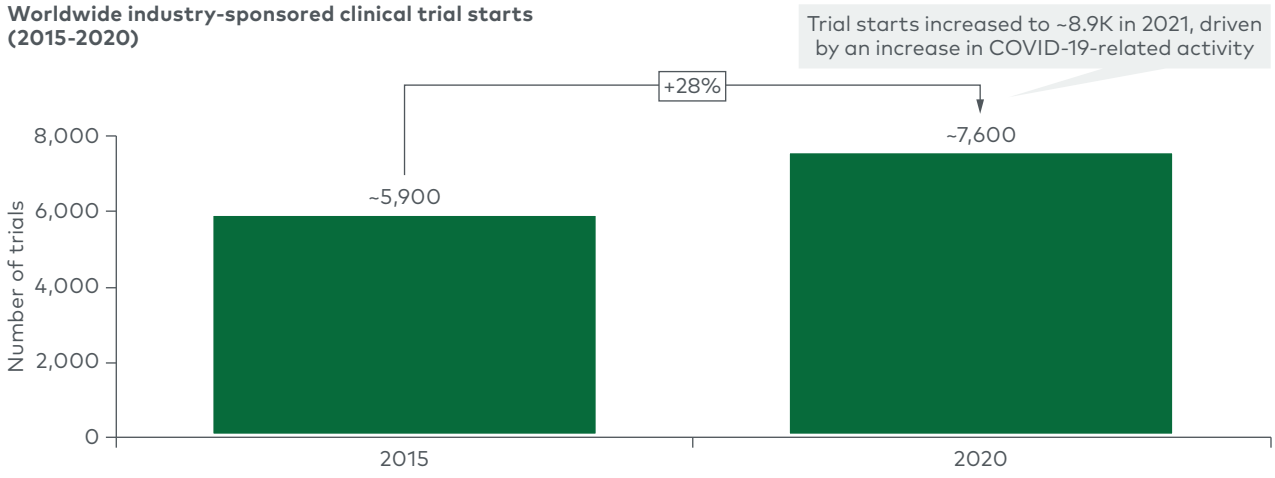
EXECUTIVE INSIGHTS

Building Clinical Trial Leadership in Biopharma

The biopharma industry has undergone tremendous growth over the past decade as technological improvements, new modalities and a supportive fundraising environment drove industrywide expansion. This dynamic has fostered a growing clinical pipeline and trial ecosystem to support it. This growth is particularly notable in highly competitive therapeutic areas such as oncology, where both volume and a diffuse range of trials per asset create a complex trial environment. This increase in volume and activity across the clinical pipeline has created a more competitive, crowded environment than ever before (see Figure 1). However, within that increasingly dense development landscape, it is well known that stakeholders — sponsors, trial sites and patients — face a myriad of frustrations.

Figure 1

The total number of industry-sponsored clinical trials per year has seen consistent growth, reaching ~7,600 in 2020



Growth in trial volume has been even sharper in certain therapeutic areas, including **oncology** (+40% over the same time horizon) and **cardiovascular** (+28%)

Source: Citeline (TrialTrove)

The status quo for trial execution is focused on getting patients into investigational therapy at a sufficient rate to meet endpoints; this method fails to account for an integrated, holistic approach to clinical trial execution that meets the needs of all stakeholders and fails to account for opportunities for leadership in meeting the diverse needs of patients, sites and principal investigators. Thoughtfully developing an integrated clinical trial approach enables sponsors to differentiate and develop solutions that work to strengthen and reinforce stakeholder relationships rather than fray them.

The industry sponsors that L.E.K. Consulting works with regularly cite issues with site identification, activation and operations as critical pain points in their process. These lead to significant cost and timing delays, potentially impacting fundraising cadence and/or commercialization timing. For example:

- Eighty percent of all sponsors are not satisfied with existing trial startup processes, with more than half of sponsors citing budget negotiation and approval as key sources of delays[1]
- This frustration continues during trial execution, where more than 80% of trials globally fail to enroll on time[2] and more than 10% of sites regularly fail to enroll a single participant[3] (see Figure 2)

Figure 2
Pain points across the clinical trial life cycle have material impacts on sponsors

Source: Tufts Center for the Study of Drug Development (CSDD)

Clinical trials are foundational to a successful biopharma organization

The aforementioned issues create delays for biopharma organizations in generating important data readouts and news flow that support critical fundraising and, eventually, commercialization of assets. Clinical trial execution is the ultimate governor to growth for biopharma sponsors and represents a significant cost driver of any organization. As the landscape becomes increasingly competitive, it underscores the criticality of becoming

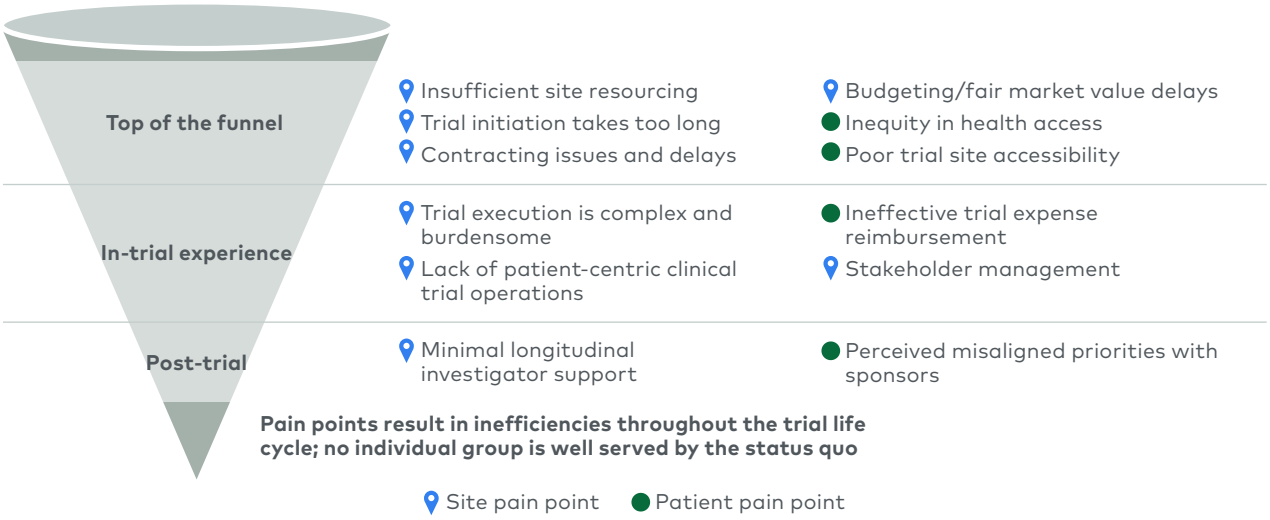
both more focused and more effective in trial and site engagement/planning strategy. An integrated clinical trial strategy enables sponsors to achieve both of these objectives while benefiting patients, physicians and shareholders.

Clinical trial status quo does not optimize successful trial execution

Sponsors need to be cognizant of the pain points for sites and patients created by the current clinical research status quo (see Figure 3). These can generally be thought of as occurring in one of three places during the life cycle of a trial:

1. At the "top of the funnel" (i.e., impacting the total universe of potential sites or patients a sponsor could work with)
2. During the "in-trial experience" (i.e., once a site or patient is in the sponsor's ecosystem)
3. During the "post-trial" portion (i.e., after/as operations are wrapping and final payments, protocols or support are given)

Figure 3
Sponsors are negatively impacted by pain points throughout the trial life cycle, leading to a smaller site/patient ecosystem and poorer retention



Source: L.E.K. research and analysis

The above visual lays out a range of specific pain points for each of these three layers; while the severity and solution to each may range by sponsor, trial protocol and therapeutic area, L.E.K. has consistently encountered these as the core challenges. This range of pain points across the life cycle of a trial creates inefficiencies, from timing delays to poor patient retention, ultimately resulting in no individual stakeholder group being well served by the status quo. Another factor heightening tensions is the fact that these difficulties are often self-reinforcing and further stress dynamics between stakeholders.

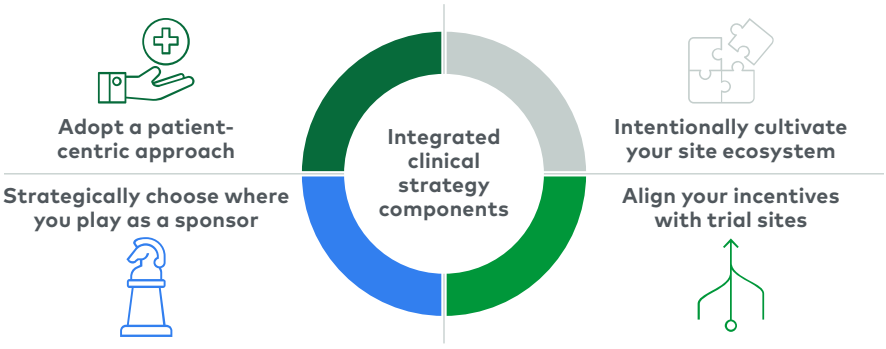
One example of this self-reinforcing tension is when sponsors see slow enrollment or failure to enroll at a site and they may push for more from the site. The site is typically operating in a negative cash flow situation, given the nature of reimbursements and delays in payments, stressing an already resource-constrained operation. Ultimately, this leaves less bandwidth for the sites to drive patient care and can leave potential or current trial participants feeling unappreciated and lacking in information. While the metrics for any one sponsor vary, many difficulties are universal (e.g., trial sites failing to be paid on time or lengthy travel times for patients) and pose significant cost risks for sponsors.

The current trial status quo is no longer fit for purpose as trials seek more targeted, narrow patient populations in more diffuse and diverse areas of the U.S. and internationally. Addressing this requires an integrated clinical trial strategy.

Need for an integrated approach

Each sponsor's situation is unique — from the volume, type, modalities and design of the trial portfolio to the therapeutic area(s) they play in to the stage of development — and therefore, the specific point solutions to build their strategy and enhance execution must be unique. An integrated clinical trial strategy requires balancing all these factors across four key areas (see Figure 4).

Figure 4
Developing an integrated clinical strategy requires accounting for a sponsor's specific situation across four components



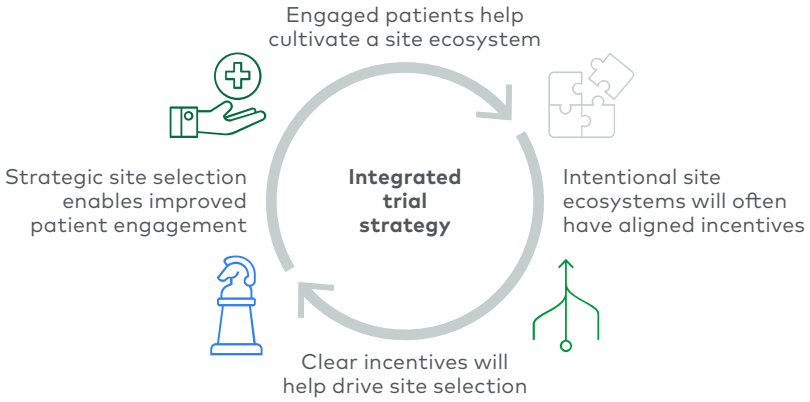
Source: L.E.K. research and analysis

1. **Put patients first —** Sponsors need to own and prioritize ensuring potential, current and past patients are supported and engaged as the critical participants they are as trials evolve
2. **Intentionally cultivate your site ecosystem —** Sponsors need to identify the correct sites to target, onboard and cultivate longitudinal relationships at both traditional and emerging site types to meet portfolio needs while also developing relationships with new sites and investigators

3. **Align incentives —** Sponsors need to work to ensure that sites receive the proper operational, reimbursement and logistical support to serve as the face of the trial to patients and conduct trials in a sustainable, positive way that meets the needs of their business
4. **Choose wisely —** Sponsors need to proactively position themselves as the leader on trials and avoid information disintermediation by sites and/or third parties

Each component of an integrated strategy must be addressed in a unique way based on a sponsor's positioning, asset profile and pipeline (see Figure 5). It is critically important to understand where a sponsor's unique "leakage points" are in this process — for example, losing patients to competing clinical trials versus enrollment barriers versus retention — and address them in an integrated fashion. One critical leakage point sponsors face is the gap between patient interest and access; in fact, 70% of potential patients are located more than two hours away from a trial site, which creates a material barrier to both recruitment and retention.[4] After accounting for each of the four components of an integrated trial strategy, targeted solutions can come in a mix of ways. Broadly, they can be categorized into three types: (1) those requiring additional or reallocated internal bandwidth, (2) those leveraging third-party services sold to sites and/or sponsors, and (3) those that require a sponsor to engage directly with other stakeholders.

Figure 5
The four components of an integrated trial strategy create a positive feedback loop that supports greater trial sponsor differentiation



Source: L.E.K. research and analysis

Custom-fitting each of the four components to your specific organizational and portfolio requirements creates a self-reinforcing trial dynamic where the whole is greater than the sum of the parts. It ensures sponsors are able to execute timely and cost-effective trials, with a site ecosystem that is equipped and incentivized appropriately, all leading toward better patient care, engagement and treatment — while building the sponsor's disease leadership position.

Approaches that treat any of these components in isolation will fail to account for how pain points flow across stakeholders and serve to restrict sponsors' efficiency and growth.

Conclusion

The clinical trial landscape has seen massive growth in assets and trials as well as staggering competition for limited patient pools — and this trend will only continue as pipeline volume and trial complexity continue to increase. An integrated clinical trial strategy that accounts for a sponsor's unique therapeutic/disease area dynamics, stage of development and competitive set is crucial to maximizing the clinical development and trial opportunity, which both drives organizational success and meaningfully improves patients' lives.

You can read more of L.E.K.'s perspectives on the clinical trial ecosystem and how sponsors should think about its evolution in our inaugural Clinical and eClinical Pharma Services Survey.[5]

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

Endnotes

[1]Tufts CSDD

[2]Perspectives in Clinical Research: Recruitment and retention of participants in clinical studies (Desai)

[3]Tufts CSDD

[4]Sanofi (via Fierce)

[5]L.E.K. Consulting's Inaugural Clinical and eClinical Pharma Services Survey, Sept. 2022

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Jonathan Kfoury is a Managing Director in L.E.K. Consulting's Chicago office and oversees the firm's U.S. Large Biopharma practice within a broader focus on healthcare and life sciences. He is active within the firm's Sustainability Centre of Excellence. Jonathan has worked in the infectious disease space throughout most of his career and has published and spoken extensively across the industry on the global AMR (antimicrobial resistance) crisis, including key initiatives to move it forward.

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