Insight Brief

What Does It Take?: Achieving A Smooth Transition From Clinical Development To Commercialization For Mid-Sized Pharmaceuticals

Examining insights from these clinical trial sponsors regarding the need for clinical innovation and strategic service partnerships to ensure treatment access for patients

Executive summary

For clinical trial sponsors, the goal will always be to ensure patients have access to viable treatments to improve health outcomes. This makes the need for a smooth transition from drug development to commercialization critical. However, as the broader global healthcare ecosystem rapidly evolves, the drug development industry must adapt to increasing and changing regional regulatory requirements, research expanding across countries and patient populations, considerations for integrating a host of advanced technologies into clinical trials, and more. In a competitive marketplace, where does this leave mid-sized pharmaceutical companies, and what will it take for this type of clinical trial sponsor to achieve their business goals and ensure they have a hand in filling the gaps in unmet patient needs?

Insights gathered from functional leaders of several mid-sized pharmaceuticals explain what these companies need to ensure a smooth transition from clinical development to commercialization, including effective strategy components and how they must address challenges that impact them in ways that large, global pharmaceuticals may not experience.

Drug developers are constantly adapting to a complex and dynamic environment shaped by geopolitical conflicts, social uncertainties, technological advances and other issues. For industry stakeholders, this compounds the need for innovation in research and development efforts.

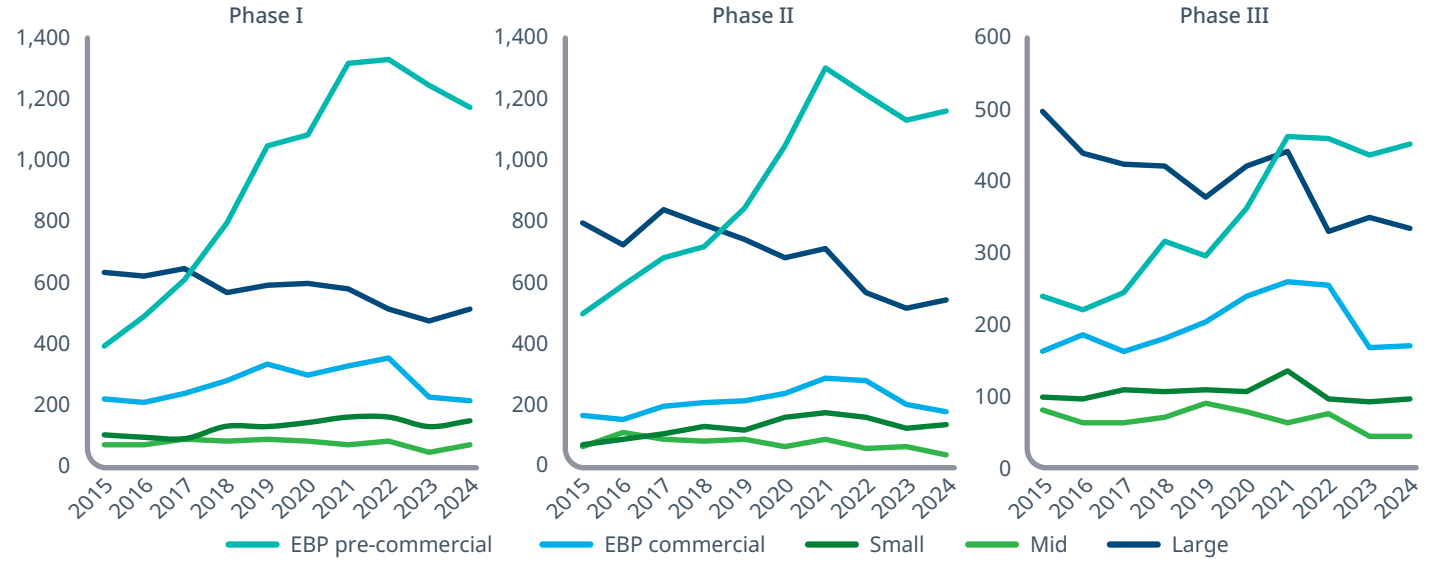
Clinical innovation is often a core focus for drug developers because it raises questions about how much treatment may benefit patients. However, clinical research is one critical piece of a larger puzzle that drug developers must address to successfully contribute to treatments on the market. As most know, by the time the general public sees a new drug, the pharmaceutical company has been at work for a decade or more on an extensive process that starts with clinical development, contends with regulatory compliance and requires commercial activities and much more.

According to the IQVIA Institute's Global Trends in R&D 2025 report, mid-sized drug developers contributed less to overall clinical trial starts compared to large and emerging biopharma companies across all development stages in 2024. This trend runs across most therapeutic areas, where mid-sized companies had less of a footprint. Specifically, these company segments with revenues between $500 million and $10 billion in annual sales represent 10% of trial starts, down from 12% in 2022 and 13% in 2015.

The question "why?" is an important one to explore to learn how this segment of R&D stakeholders can advance their drug development goals.

Given the long, costly and complex process, we sought the perspectives of key decision-makers within mid-sized companies about the current and future state of clinical R&D and what strategic drivers are helping create a smoother transition from clinical development to commercialization stages and what roadblocks are hindering their success.

Pre-commercial EBP trials starts have gradually overtaken those of large companies over the last 10 years



Source: Citeline Trialtrove, Jan 2025; IQVIA Institute, Jan 2025.

Leaders in clinical operations, procurement, outsourcing, payer and access marketing, etc., shared key insights regarding end-to-end market access considerations and what this segment of drug developers may look for in a clinical research organization partner.

Transitioning from Phase II to Phase III studies: noteworthy challenges

For mid-sized pharmaceuticals, it can be difficult to successfully transition from Phase II to III studies. According to leaders we contacted, there are several dominating challenges to account for early in trial planning.

SCALING UP

Typically, mid-sized pharmaceutical companies lack the resources and capabilities of large and established pharmaceuticals. Scaling up from a smaller Phase II study to a much larger Phase III study is one of these leaders' biggest areas of concern.

Part of the challenge in the transition to Phase III is the need to work in multiple regions and countries, each of which can have its own nuances and challenges, including regulatory considerations and varying patient and site support needs. For example, as trials go global, drug developers need to assess potential patient participation from remote areas or without internet access as well as variables in cold chain processes and how they may impact adequate treatment access in low-to-middle-income countries.

Leaders said in-house knowledge and capabilities required for larger studies can be difficult to cover on their own. They must ask themselves such questions as:

- How well are we going to really understand the nuances of treatment and patient care in these regions?
- Do we have the expertise and understanding to effectively develop a protocol that will appropriately capture the care needs across all the regions and countries involved?

FINANCIAL CHALLENGES

It is also obvious in a "do more with less" R&D environment that these pharmaceutical segments may have budgetary restrictions, which can present major challenges when going into Phase III studies. Leaders said that, unlike large, global pharmaceuticals, there is always a concern that if even one larger study fails, the financial consequences can cause the entire company to shut its doors.

As one leader noted, “The financial challenges are different when you go from having 100 patients enrolled in a Phase II study, and then you go to 300, 400 or 500 patients in the Phase III study.” For many companies, it can be a “make it or break it” time in their journey.

SITE STAFFING ISSUES

While a drug developer aims to minimize patient burdens, it is equally important to consider the potential added burdens on clinical trial sites. These may arise from technology integrations, process modifications, and the necessary resources and training to effectively implement the trial strategies as intended.

Since the global impact of the COVID-19 pandemic on R&D, stakeholders recognize that many sites have had persistent staffing issues at an institutional level. This can extend timelines and adversely impact on patient experience during Phase III studies.

GEOPOLITICAL UNCERTAINTY

Aiming to conduct and maintain clinical research in multiple markets, including in some experiencing volatile geopolitical situations, can be difficult. For example, clinical trials currently underway in Ukraine or Israel require close oversight and monitoring as companies work to scale operations and services to meet challenging conditions.

TRACKING AND MONITORING CHALLENGES

Alongside monitoring geopolitical changes in various countries and at specific trial sites, mid-sized pharmaceuticals also find it hard to track and monitor the status of multiple clinical trial programs running in parallel. With multiple programs at different stages of development, determining how to prioritize strategies, responsibilities and action items can be daunting. This is especially true when these companies may not have the full scope of expertise or resources in-house to stay on top of every program, from preclinical through clinical and into commercialization.

In many cases, leaders may find it challenging to make sure team members across functions and programs understand how their work is connected to the bigger goal.

ORGANIZATIONAL CAPACITY

For many of these companies, leadership wears several different hats because teams are smaller and resources are tight. At times, those working as program managers, on study teams and in other roles may also help navigate market access questions and strategies. However, their experience in commercialization can be limited or focused heavily on a specific therapeutic space.

Often, if a product reaches Phase III development, an entirely new team is brought in for the commercialization strategy. How the development team’s efforts and experience are weaved into the commercialization plans can be critical.

Ensuring smooth transition from clinical to commercialization: tailored resolution

Leaders of mid-size pharmaceuticals cited the following ways to address their nuanced needs for commercialization.

VALUE OF EARLY COLLABORATION — CLINICAL AND COMMERCIAL

According to mid-sized pharmaceutical leadership involved in effective commercialization strategies, information gained early in the clinical development process or even during preclinical activities is often used to guide development direction and where market opportunities may lie. These companies are considering challenges to market access years in advance. They find common ground in recognizing the value of having commercial team experts involved and engaged from the start of the clinical development process.

- Identify unmet patient needs.
- Understand how many patients may benefit from the new treatment.
- Examine similar therapies already on the market and provide key insights.
- Determine potential distribution channels to maximize access upon approval.

- Develop a pricing strategy and begin discussions with the payer community.

"As we're planning and moving through [the process], commercial is intimately involved. As we make decisions, they will rescope the commercial plan. There's a real interplay from very early on in the program"

— Director of Clinical Development for a mid-size neurology-focused company

Some company leaders pointed out key functional experts who help connect clinical efforts to commercial strategies, including:

- Medical liaisons. This role can focus on education and creating awareness among healthcare providers and other stakeholders prior to market approval, helping with sales-specific efforts in the long-term.
- Clinical development medical affairs experts. This role can focus on several products within a company's development pipeline to provide connected insights from an early clinical development aspect to scientific discoveries, late-stage development considerations and marketing approaches.

NAVIGATING REGULATORY COMPLEXITIES: BREAKTHROUGH DESIGNATION

For pharmaceutical companies of any size, effectively navigating the regulatory landscape — in the U.S. and globally — is a necessity. Specifically for mid-sized pharmaceuticals, those who have secured a breakthrough therapy designation by the U.S. Food and Drug Administration say it is a tremendous benefit to create additional opportunities to engage the agency and provide more background context and insights to shorten regulatory feedback cycles.

As discussed further below, these leaders emphasized the value of leaning on a CRO partner experienced in navigating discussions and maximizing interactions with regulators secured via breakthrough designations and other means.

"Something like breakthrough therapy designations, the team really needs to take advantage of those touch points with the regulators… When looking at other regions… we learned heaviliy on our CRO partner to help us understand the regulations and our options"

— Associate Director of Clinical Operations for a biotech venture capital company

FINE-TUNING SITE SELECTION

There was strong agreement among leaders of these company segments that an essential component to successfully transitioning from Phase II to Phase III development is enhanced site selection techniques to reach target patient populations and ensure these centers are equipped and experienced enough to efficiently participate.

Drug developers are seeing the value in data-driven methodologies that rely on applied analytics and artificial intelligence/machine learning to better gauge which sites will optimize clinical trials. A clinical development leader for a mid-sized biopharmaceutical company noted how repeatedly refined and analyzed data insights helped improve site selection for a global study in China. As a result, 25% of all participants enrolled were in China.

LEVERAGE IT INFRASTRUCTURE

As a company grows additional layers of expertise/roles, remote capabilities and overall complexities, its ability to be nimble and make business decisions quickly can decline.

Leaders within mid-size pharmaceuticals who aim to expand pipeline growth say they rely on a comprehensive IT infrastructure that enhances virtual collaboration across functions, therapeutic focuses and locations. As they grow, these companies are committed to furthering innovation through collaboration in-house and with service partners, sites, and ultimately, patients.

"When companies become larger, they add more people, become more decentralized, develop more layers and become more complex organizations, which slows down decision making and speed. An important way to navigate amid this increased complexity is to leverage and IT infrastructure that supports collaboration"

— Head of U.S. Clinical Operations for a mid-size global pharmaceutical company

AI-DRIVEN INNOVATION

Whether transforming asset evaluations, clinical development, trial program management, prior authorization, provider outreach or other parts of development and commercialization, mid-size pharmaceuticals recognize how AI and other tech-enabled solutions show unique value from end-to-end. Specific ways AI-driven solutions benefit these companies include:

SEEING PATIENTS AS PARTNERS FOR MARKET ACCESS STRATEGIES

- "Some of the AI stuff will help in the writing of protocols and certainly from a data perspective in being able to assimilate and map out scenarios." – *U.S. Head of Clinical Operations*
- "From a true operational perspective, the technology will help with remote visits . . . and decentralized trials, which benefits patients and hopefully allows us to enroll studies quicker, with less burden on patients." – *Senior Director of Clinical Operations*
- "I would love to see some AI application around streamlining the CRO study plans … and how some AI application can make sure those plans are more consistent." – *Associate Director of Clinical Operations*
- "I've seen AI in the context of helping streamline back-office invoice processing … It's about doing things more efficiently." – *Associate Director of Clinical Procurement and Outsourcing*

When shifting toward developing drugs with patients, rather than for patients, and aiming to move forward toward market availability, every key stakeholder needs to be engaged, including patient advocacy groups. Leaders from these company segments emphasize the importance of a holistic comprehensive strategy that involves maintaining open discussions with patient advocacy groups from pre-clinical through post-marketing evaluation.

Ongoing patient engagement via advocacy groups and others can help ensure patient access across multiple segments and various markets by understanding and addressing logistical, operational, cultural and educational barriers. Including patient perspective early in clinical development helps ensure trial design and strategies beyond will consider their needs. Keeping nuances, such as how likely patients are to travel to receive care and where patients are typically diagnosed, can help vital clinical research to move forward.

"In my experience, engaging regional patient advocacy groups has been invaluable, as it provides key insights into the patient journey within specific markets"

— Associate Director of Medical Communications for mid-size biotech company

CREATING A ROBUST CRO PARTNERSHIP: CUSTOMIZED SUPPORT

For a strong sponsor-CRO relationship, there are several elements to help maximize the collaboration and foster success from clinical through commercialization for mid-size pharmaceuticals. The key factor is for CROs to meet the drug developer where they are with the right solutions, services and knowledge to operationalize trials with efficiency from the start and transition further into the development process.

CROS AS SERVICE "PARTNERS"

Unlike large pharmaceutical companies, which may work with CROs on a tactical level to execute clinical trials across many therapeutic portfolios, mid-size pharmaceuticals may need a CRO service partner for strategic guidance, end-to-end services and solutions, and deep and varied expertise within an exclusive and/or growing pipeline to help them meet their ambitious goals with efficiency.

LISTENING WITH INTENTION TO THE COMPANY'S NEEDS IS KEY.

Mid-size pharmaceuticals may be experiencing change during pipeline expansion and overall company growth. Leaders of these companies say they prefer a CRO partner who knows where their resource gaps are and how to prioritize where they most need support based on extensive experience working in similar capacities for other drug developers of similar size, focus and situation.

Upon selecting a CRO partner that aligns with the company's needs and goals, several leaders said that the hope is to continue the collaboration for future program needs, which will change, and to strengthen the working relationship for long-term success.

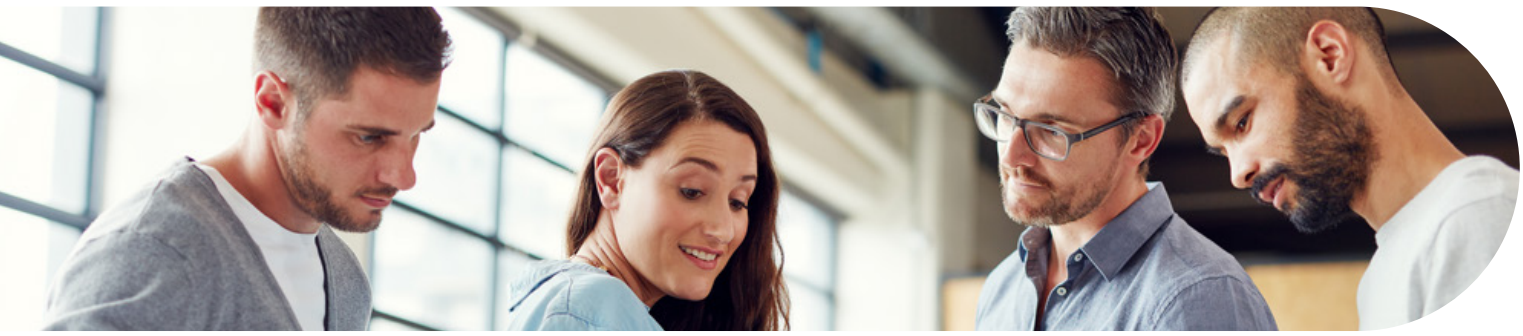
PREFERENCE FOR LARGER CROS

Generally, leaders of these company segments said they prefer to partner with large CROs to reach their development goals because they see greater value in their work together, including:

- Consultative, guided engagement with proactive relationship management that prioritizes quality and consistency.
- Strong relationship management.
- Depth of experience and varied areas of expertise (e.g., rare disease).
- Capability to scale globally.
- Level of site quality.
- Ability to effectively navigate regulatory changes in various regions.

"For smaller and mid-sized companies, CROs can offer experience and capabilities that you just don't have at your company. You're not as large and maybe don't have as much experience. That's a great way to get experience and to capture the breadth of experience CRO's have across the industry"

— Head of U.S. Clinical Operations for a mid-size global pharmaceutical company



"The larger CRO's tend to have good relationship management strategies and to appreciate the importance of keeping in touch above and beyond the day-to-day operation of the project, addressing quality concerns and consistency across protocols"

— Associate Director of Clinical Procurement and Outsourcing for a mid-size pharmaceutical company

Enhancing treatment access: nuanced but necessary steps for mid-sized companies

To develop and get treatments for patients, drug developers must shift from producing clinical trial outcomes to commercialization. However, crossing that finish line is no easy feat, with varying barriers to address at every step of the journey, such as keeping patients engaged in trials, protecting patient data, staying compliant with evolving and expanding regulations, securing reimbursement, etc. Also, on average, it can take up to 12 years for a drug to receive FDA approval and bringing a new drug to market costs $983 million.

For these reasons, mid-size pharmaceuticals can find it difficult to stay competitive in a rapidly changing market.

As we continue to actively listen to these companies, we can pinpoint helpful trends in the holistic process toward commercialization and what needs more attention. This includes considering commercial team perspectives in early trial strategy discussions; purposeful integration of advanced technologies, including healthcare-grade AI, to create efficiencies to overcome longstanding issues; and forging a stronger service partnership with CROs that understand nuances in development and work together to meet companies' goals.

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04.2025.RDS-BCS2025-1022