Chapter 7

Unlocking long-term value: Clinical trial productivity considerations for emerging biotechs

Executive Summary:

Clinical trials are more than a scientific milestone for emerging biotech companies, they are also a strategic lever for attracting investment, enabling collaborations and positioning assets for acquisition or commercialization. Under pressure to quickly reach early proof-of-concept, often short-term decisions made can unintentionally limit long-term potential.

Productivity gaps, whether in trial design, operational execution or data strategy, can erode value through delayed timelines and inflated costs, that ultimately weaken the asset's appeal to investors or collaborators. When addressed early, these same gaps provide opportunities to strengthen the clinical and commercial profile of the therapy through enhanced trial performance.

This article, part of a multi-chapter series on driving productivity in clinical trials,[1] explores how biotech companies can work with contract research organizations (CROs) to identify and address productivity gaps at key milestones throughout the clinical development journey. Through targeted operational strategies, sponsors can reduce trial burden, accelerate timelines and create tangible value, without losing sight of financial objectives or shorter-term exit plans.

Authors:

Kenny Smith—Executive Strategic Partnerships Director, Fortrea
Rebecca Beatty—Executive Director, Business Development, Fortrea

Acknowledgment:

The authors of this article wish to thank Fortrea colleagues Jeff Cohen, Alicia Baker, Kathryn Plante and Tyler Knight for their participation during the development of this chapter.

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Balancing short-term goals with long-term productivity

Emerging biotech sponsors often operate in a pre-commercial, pre-revenue environment, where funding cycles and resource limitations shape every decision. The focus of early phase trials is typically on validating a novel mechanism of action, demonstrating target engagement and pharmacodynamic effects or reaching a key milestone to support the next round of funding or a strategic transaction.

Given this context, it is understandable that long-term productivity planning may not be top of mind. However, deferring these considerations can lead to missed opportunities, especially when trial inefficiencies result in delays, evidence gaps or operational missteps that weaken the asset's perceived value.

Early investment in productivity-enhancing strategies—such as smarter protocol design, integrated regulatory and data planning and proactive site engagement—can yield outsized returns. These efforts optimize trial execution and support a stronger narrative for investors, collaborators and potential acquirers.

CROs bring deep subject matter expertise, global infrastructure and strategic insight that can help biotech sponsors navigate this balance. By identifying sponsor-specific productivity levers aligned to financial and strategic goals, CROs can help unlock efficiencies that translate into higher asset valuation and greater optionality—whether the path leads to collaboration, acquisition or commercialization.

Lessons from the field: How early productivity planning pays off

Experienced CRO collaborators provide global reach, regulatory insight, operational knowledge across the development lifecycle and deep therapeutic knowledge that can help biotech sponsors bridge capability gaps and unlock value. More importantly, they offer a broad perspective that can illuminate how early decisions can shape downstream outcomes, from data quality and site performance to investor confidence and negotiation strategy.

Four case examples presented below illustrate how emerging biotech companies have leveraged productivity-focused strategies to improve trial execution and enhance asset value:

- **Accelerate Phase I trials** with a co-located Current Good Manufacturing Practices (cGMP) facility
- **Regulator engagement** to resolve issues early to maintain trial timelines
- **Harness the power of real-world data (RWD)** to optimize clinical trial design and execution
- **Enhance trial value** through patient-centric design and strategic collaborations

Each of these examples underscores a key message: Productivity is not just about operational efficiency; it is a strategic enabler. For biotech sponsors navigating financial constraints and planning for exit, early productivity planning can be the difference between a good outcome and a great one.

Case example 1:
Accelerate Phase I trials with a co-located cGMP manufacturing facility

For biotech sponsors conducting small molecule Phase I trials, speed and cost-efficiency are critical. One high-impact opportunity to drive productivity is to co-locate a current Good Manufacturing Practices (cGMP) pharmacy within the Phase I Clinical Research Unit (CRU). This integrated model streamlines drug preparation and delivery, reduces operational complexity and enhances data quality while supporting regulatory readiness.

Unlike traditional compounding pharmacies, a cGMP pharmacy operates under FDA compliant manufacturing standards, confirming each drug product meets rigorous safety, purity and quality specifications. When this capability is embedded directly within the CRU, sponsors gain immediate access to the investigational therapy at the point of care, thereby minimizing packaging, shipping and external handling delays.

This setup is particularly advantageous for Phase I trials, which typically require small batch production of active pharmaceutical ingredients (API). Onsite cGMP manufacturing enables rapid turnaround of these drug product batches, allowing for real-time dose adjustments and faster study progression for early clinical trials. It also reduces financial exposure by deferring full-scale CMC campaigns until early safety signals and formulation stability have been confirmed.

Beyond operational speed, the model also delivers regulatory-grade data integrity. Master Batch Records (MBRs), Certificates of Analysis and Quality Management System (QMS) documentation are generated in real time, supporting future investigational new drug (IND) amendments and downstream trial phases. The tight integration between manufacturing and clinical operations also strengthens control over chemistry, manufacturing and controls (CMC) specifications—which are critical for long-term asset value.

This approach is especially well-suited for:

- Exploratory IND trials
- First-in-human studies
- Absorption, metabolism and excretion (AME) studies including absolute bioavailability trials (aBA)
- Single and multiple ascending dose (SAD/MAD) trials
- Studies requiring rapid dose adjustments

By embedding cGMP manufacturing within the CRU, biotech sponsors gain a flexible, high-quality and cost-effective delivery model that accelerates timelines and strengthens the foundation for future development.

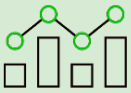
Case example 2:
Collaborate with regulators to resolve issues early and maintain timelines

In a recent client engagement, a biotech company found itself at a standstill midway through development when it realized that the starting point of the product design and manufacturing did not meet regulatory expectations. Subject matter experts (SMEs) from the CRO conducted analysis for a cell and gene therapy (CGT) product, including reviewing non-clinical, CMC and clinical data, as well as a risk assessment. Working together, scenario planning commenced to support a request for both an exemption from a typical nonclinical requirement and a follow-up meeting with the agency.

Through multifaceted analysis (with only minimal additional testing), the company was able to align with the FDA to secure the exemption and resolve a key, potentially time-consuming, development hurdle. Building on that success, the sponsor considered the development of a clinical development plan (CDP), supported by the CRO-led product development team (PDT), to support continuity from strategic development planning to successful operational execution and regulatory success.

Through this effort, the biotech company benefited from access to the CRO's cross-functional SME team and experience in developing a comprehensive plan, creating a roadmap for the product that led to an effective communication strategy with the FDA. Through collaboration and creative problem solving, the joint team achieved seamless transition from one stage of development to the next while adhering to the client's original schedule.

Case example 3:
Harness the power of real-world data (RWD) to optimize clinical trial design and execution



Across the healthcare and drug-development landscape, sponsors, regulators, payers, physicians and others are increasingly leveraging RWD and real-world evidence (RWE) to inform and support their decision-making processes.[2] RWE that is developed by analyzing RWD (from such sources as electronic health records, pharmacy and medical claims databases, laboratory-testing and imaging data and patient registries) provides invaluable insights, such as evidence of unmet need and disease burden across diverse patient sub-populations. Such insights can inform benefit/risk assessments and support market access, especially for products that reach limited patient populations in traditional clinical trials. In parallel, early pressure-testing of the target product profile (TPP) helps ensure that development decisions remain aligned with future payer, market and competitive expectations, strengthening the evidence strategy from the outset.

When it comes to improving trial design methodology, RWD can inform efforts related to trial planning, feasibility and optimization, site selection and patient recruitment. For example, designing trials leveraging RWD on patient phenotype, genotype, healthcare resource utilization (HCRU), laboratory and diagnostic data and social determinants of health (SDOH) can help sponsors to fine tune their inclusion and exclusion criteria. This improves targeting during patient recruitment, reduces time and resources spent on enrollment and ultimately can accelerate patient-enrollment timelines. Leveraging RWD to understand unmet need and disease burden, for example, can also support decision-making by regulators. It is important for drug sponsors to consider ways to leverage RWD in the initial trial design, in anticipation of what regulators will want to see.

Fortrea collaborated with a biotech company to leverage RWD from the PROspective Observational Vascular Injury Trial (PROOVIT) registry to create an external control arm (ECA) to compare against their clinical trial to demonstrate the effectiveness of their product against the gold standard of autologous repair. Fortrea matched patients from the registry to those in the clinical trial by exact artery type using propensity scores derived from key variables such as age, injury severity, ischemia time and fracture status to create an ECA. This approach enabled a robust comparison of clinical endpoints, including amputation, infection, reintervention, pseudoaneurysm, patency and 30-day mortality between Product X and the gold-standard autologous repair.

The results showed that Product X performed similar to the gold standard, helping the biotech company show clinicians and healthcare decision-makers that the product may be used when urgent revascularization is needed, and the gold standard of autologous repair is not available. This innovative use of RWD accelerated evidence generation and strengthened the value proposition for the biotech sponsor.

Additionally, the use of digital tools (such as wearable sensors and virtual assistants) can help drive efficiency through efficient data capture, timely data review and rapid dissemination of results. Drug developers should work with their CRO to explore all opportunities to leverage RWD and generation of RWE to examine aspects of the trial as another way to reduce time and resources both within and between trial phases.

Case example 4:
Enhance trial value through patient-centric design and strategic CRO collaboration

A U.S.-based biotech company developing a novel intra-tumoral immunotherapy was preparing for its Phase I trial. With limited internal resources and a complex delivery mechanism involving physical transfection, the sponsor recognized the need for deeper operational and scientific support for trial success and long-term asset value.

Rather than managing multiple vendors, the biotech chose to collaborate with a single CRO (Fortrea) for end-to-end guidance across protocol design, site engagement and trial execution. This decision unlocked several key productivity benefits:

- **Improved patient-centricity and site alignment**
  Fortrea engaged experienced clinical trial sites early to understand the practical implications of the physical transfection method. Recognizing the need for specialized training, the CRO developed a "train-the-trainer" model at regional hubs, ensuring investigators were certified and confident in the technique. This reduced the clinical site burden and improved the patients' experience
- **Data-driven recruitment strategy**
  Leveraging central lab data, historical benchmarks and insights from country heads and academic institutions, Fortrea built a tailored recruitment model aligned with the therapy's unique profile. This proactive approach helped the sponsor meet enrollment targets efficiently, despite the niche indication
- **Protocol optimization and risk mitigation**
  A holistic review of the protocol identified potential regulatory and ethical risks. Fortrea recommended modifications to the cohort design to support robust safety data collection, strengthening the trial's credibility and regulatory readiness
- **Greater transparency and strategic clarity**
  Throughout the engagement, Fortrea helped the sponsor clarify key assumptions, align stakeholder expectations and anticipate payer considerations, paving the groundwork for future commercialization or collaboration

By collaborating early with a CRO, the biotech sponsor was able to design a more efficient, patient-focused trial that not only met Phase I objectives but also positioned the asset for long-term success.

Closing thoughts: Turning early investments into long-term value

For emerging biotech companies, early phase trials represent more than just the opportunity to demonstrate a scientific milestone. Rather, they provide a strategic opportunity early in the development of a new therapy to shape the future of the asset.

The four case examples presented above illustrate how targeted productivity initiatives early in the process can deliver meaningful short- and long-term value. These examples demonstrate how practical, high-return strategies allow biotech developers to create efficiencies early in the process that deliver value in two ways—by overcoming time and financial constraints throughout the trial, and in doing so, positioning the investigational therapy for greater clinical success and commercial opportunities.

Despite prevailing budget constraints or lack of in-house subject matter specialists, biotech companies should focus instead on how to make necessary commitments (even if a few tradeoffs are required) so they are able to convert short-term expenditures into longer-term value creation. When thoughtfully applied, these productivity strategies reduce waste, avoid costly delays and improve trial performance in ways that directly influence investor confidence, regulatory readiness and commercial potential.

Working closely with an experienced CRO enables biotech sponsors to build a tailored blueprint that aligns with their financial realities while maximizing asset value. Even modest early investments, whether in smarter trial design, data strategy or operational execution, can yield exponential returns in valuation, collaboration opportunities and long-term success. The path forward is not just about running a trial; it is about leveraging foresight and broad knowledge to run the right trial, in the right way, and in doing so, to unlock the full potential of innovation and create value.

References

1. All chapters in Fortrea's productivity series can be found at www.fortrea.com/insights
2. the-power-of-real-world-data-in-clinical-development.pdf

Authors

Kenny Smith—Executive Strategic Partnerships Director, Fortrea

Kenny Smith is a seasoned life sciences leader with over 25 years of experience spanning clinical operations, study start-up and strategic collaborations. His career includes roles such as Clinical Research Associate, Study Start-Up Specialist, Operational Delivery Director and Executive Director of Enterprise Partnerships. Kenny has successfully built and managed major BioPharma collaborations, yet his true passion lies in biotech—advancing innovative assets through development and regulatory approval. In his current role at Fortrea, Kenny provides executive-level engagement and strategic guidance to help biotech clients accelerate development and achieve success.

Rebecca Beatty—Executive Director, Business Development, Biotech Sales GCD, Fortrea

Rebecca Beatty leads the Biotech Commercial team at Fortrea, bringing 20 years of experience in clinical research across both the site network and Contract Research Organization (CRO) sectors. Throughout her career, she has demonstrated a consistent commitment to excellence and a passion for advancing medical innovation.

Prior to joining Fortrea, Rebecca led the commercial team at a specialized integrated site network, where she played a key role in establishing and expanding strategic collaborations with pharmaceutical and biotech companies. Her focus included therapeutic areas such as Gastroenterology, Oncology, Urology, Dermatology and Internal Medicine.

Rebecca's deep knowledge across both sites and CRO domains uniquely positions her to collaborate effectively with Biotech companies and startups on building robust site and patient engagement strategies that drive clinical trial success.

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