Chapter 4

Clinical trial execution: Reimagine each step to drive productivity gains

Executive summary:

The stakes are high in any clinical trial, with drug developers working to demonstrate the safety and efficacy of their novel investigational therapies, and healthcare professionals and patients anxiously awaiting the arrival of tomorrow's life-changing and life-saving medications. Throughout every clinical trial, there are many opportunities to streamline workflows using the best mix of high-tech and high-touch interventions. The goal is to drive efficiency and improve overall productivity in ways that can tangibly improve timelines, budgets and the satisfaction of trial participants and investigators. To deliver bottom-line productivity improvements, drug developers should be willing to work closely with their selected contract research organization (CRO) to create a holistic, agile trial execution framework and be willing to pivot as additional data-driven insights are created over time. Such insights help inform decision-making and fine-tune specific efforts throughout the trial.

Author:

Kenneth Park, Vice President, Consulting, R&D Strategy and Innovation, Fortrea, Inc.

Acknowledgment:

The authors want to thank their Fortrea colleagues Georgina Strickland, Teri Athreya, Melissa Harris, Gordon Cummins and John Kennett for their assistance during the production of this article.

Fortrea

Introduction

Clinical trials require a series of tasks, ranging from patient recruitment and onboarding to data collection and analysis, site management, preparation for regulatory filings and more. As these many tasks are conducted at multiple sites across the globe, inefficiencies can often creep in, undermining productivity objectives.

Productivity in clinical trials is a reflection of how much time, cost and effort it takes to bring a medication to market, and how valuable a therapeutic intervention will be throughout its commercial lifecycle. Stakeholders often use the concept of effectiveness and efficiency as proxies for assessing productivity. These are related but not synonymous:

- **Effectiveness** refers to the extent to which the drug development process can achieve its intended outcomes (to produce approved therapies that address unmet clinical need in patients)
- **Efficiency** refers to how well the resources (such as time, budget, personnel, technology and materials) are utilized to achieve the target outcomes of the drug-delivery process

Irrespective of how it is assessed, productivity is essentially a measure of the risk-adjusted net present value (NPV) of a particular pharma/life sciences asset.

While the primary objective of any clinical trial is to demonstrate the safety and clinical efficacy of the investigational therapy and explore the most appropriate dosing strategies, trials also seek to measure their success according to several common performance benchmarks. All of these are measures of the trial's productivity. These include speed (which impacts timelines), cost (which impacts budgets) and quality (which impacts the patient and investigator experience).*

Look for opportunities to streamline and optimize trial execution

Different tasks associated with any given trial are always part of a complex, interconnected trial ecosystem. However, when individual tasks are operated in a silo, it can lead to costly and avoidable productivity lapses that have tangible bottom-line consequences for all stakeholders.

For instance, inefficiencies throughout the trial ecosystem can create time delays, cost overruns and quality issues for the drug sponsor. And inefficiencies throughout the trial can create frustration and added burden for two other key stakeholder groups, trial investigators and patients, as well.

Even though increasing attention has been paid to the critical productivity benchmarks of time, cost and quality across the drug-development landscape, industry-wide data shows that trial costs and timelines have been consistently trending upward over the past decades.[1] While some rising costs can be attributed to ongoing trial complexity (as the sophistication of many investigational biologics and precision therapies continues to grow) and the impact of inflation, strong productivity headwinds further underscore the need for drug sponsors and their CRO collaborators to be more rigorous in how they explore options to intervene and make improvements. The shared goal is to confirm the clinical findings as quickly as possible and to meet or exceed budget and timeline expectations at every opportunity.

* For more details, see Chapter 1 of this Fortrea multi-part series on improving efficiency in clinical trials: **modern-clinical-trials-mix-of-co-iinovation.pdf**

This article is the fourth chapter in a multi-part series on how to drive productivity in clinical trials.* It discusses the challenges that today's drug sponsors face and provides specific recommendations for how drug sponsors and their CROs can identify productivity gaps that impede trial execution and then use targeted initiatives to shorten timelines in all phases of the trial, reduce overall labor and operating expenses, reduce the white space between trial phases and improve the overall experience for trial investigators and for patients and their caregivers.

Against the backdrop of today's increasingly competitive pharmaceutical landscape, the ability to cut costs and reduce the trial timeline can provide strategic advantage against competitor products that are also racing to gain regulatory approval and enter the market more quickly. This not only initiates cash flow sooner, but in some cases, may also result in first-to-market advantages and the opportunity to garner larger market share within the therapeutic space.

Similarly, the ability to reduce overall expenses associated with each phase of the trial helps to improve the therapy's overall return-on-investment (ROI) profile. Meanwhile, productivity-related improvements that deliver tangible budget and timeline improvements can also position the investigational therapy to be a more valuable asset when it comes to licensing or acquisition opportunities.

Improving trial execution to improve productivity delivers results

As discussed earlier in this series, many innovative technologies are already making inroads to help automate, streamline and improve specific aspects of trial execution. These include (but are not limited to):

- Generative AI and other machine learning (ML) techniques
- Robotic Process Automation to automate repetitive tasks (such as data entry, query resolution, trial master management), thereby enhancing operational efficiency and reducing human error
- Natural Language Processing to extract insights from unstructured data, such as medical records, to support patient eligibility screening
- Tokenization and Patient Right of Access to enrich trial data with real-world insights
- Broader use of approved mobile devices and other wearable devices to streamline data monitoring and simplify the gathering of patient-reported outcomes
- Telehealth to ease patient burden and support adherence objectives while reducing time and travel requirements
- Specialized services such as customized site supports, home nursing visits and more
- Advanced capabilities in data analytics and modeling to enable greater data-driven decision support and trend analysis

When used appropriately, these advanced tools and techniques can help drug sponsors and their CRO collaborators conduct their clinical trials in more productive and efficient ways. For example, optimizing overall trial design helps stakeholders to improve protocol development and predict trial outcomes better.[2] Similarly, such efforts help to inform site selection so that sponsors and their CRO collaborators can more easily identify top enrolling sites and thus forecast recruitment success better. Meanwhile, the use of automated data-cleaning processes can help reduce manual effort and can improve overall data quality. Additionally, using generative AI to speed up document creation (such as clinical study reports and informed consent forms) can help to create overall efficiencies, which translate to time and money savings.

* All chapters in Fortrea's productivity series can be found at **www.fortrea.com/insights**

While increased use of automation can and should play a big role reducing the manual labor and administrative burden associated with many trial activities, it is also important to remember that all clinical trials are still inherently people-centric operations (with patients and trial investigators being the most critical stakeholders). As such, efforts to streamline and optimize trial execution will always require a thoughtful mix of "high-touch and high-tech" interventions. Efforts to identify specific productivity lapses at each step of the trial will help the drug sponsor and its CRO collaborator to then prioritize opportunities for improvement using the most appropriate, targeted initiatives.

Please review Chapter 2 in this multi-part series to learn more about how AI, ML and other forms of automation can drive productivity in clinical trials.

Table 1 provides a framework of how Fortrea assesses opportunities drug sponsors should consider improving trial execution in ways that can deliver bottom-line productivity results.

Table 1.

	Opportunity to improve productivity factors			
Clinical trial operations	**Asset revenue**	**Likelihood of asset success**	**Cost**	**Time to launch**
Trial design	High	High	High	High
Site selection	Low	Low	High	High
Site management	Low	Low	High	High
Patient recruitment	Low	Low	High	High
Data collection	Low	Low	Medium	Medium
Biostatistics and programming	Low	Low	Low	Medium
Quality control	Low	Medium	Medium	Medium
Safety and med monitoring	Low	Medium	Medium	Medium
Regulatory filing	Low	Low	Medium	Medium
Cross-operational coordination	Low	Low	High	High

As noted, closing productivity gaps can provide direct benefits for drug developers. But such improvements can deliver tangible results for two other critical stakeholder groups, as well. Consider the following:

Trial investigators and site coordinators. The ability to streamline, automate and improve processes and workflows throughout the trial can help to reduce frustration and burnout among trial investigators and site coordinators. This allows healthcare providers (HCPs) involved in the trials to focus more on patient care and less on administrative tasks and logistical burdens.

Patients and their caregivers. Efforts to optimize trial execution, especially by incorporating patient-focused considerations as early as possible during protocol design,* can help to anticipate and then reduce specific burdens patients may face. These may include significant time or travel demands, substantial out-of-pocket expenses, clinical complexity, medication-adherence challenges and decreased quality of life. When such burdens are excessive, patient recruitment and retention suffer. Heightened patient-dropout rates extend patient recruitment and onboarding efforts, creating additional costs and delays. It also increases the risk of protocol deviations or amendments later.

Challenge the status quo

When clinical trial sponsors work in close collaboration with their CRO, the team can create an organized process for identifying opportunities to increase productivity across the entire trial ecosystem. An experienced CRO can bring the right mix of proven best practices and fresh ideas that can help drug developers to rectify specific issues that drag down productivity.

Specifically, the right CRO, particularly one that has breadth and depth of experience across therapeutic spaces and geographic regions, can streamline and improve trial execution in these ways:

- By implementing processes and workflows that have already been validated in prior engagements (bringing perspective that the more-focused or less-experienced drug developer may not have)
- By exploring novel opportunities that break existing paradigms
- By sharing deep domain proficiency related to the therapeutic space, the geographic region, the intricacies of the prevailing regulatory framework and more
- By deploying the most appropriate mix of state-of-the-art technology options
- By building agile, integrated teams with staffing and proficiency that can scale up and scale down, as needed over time, at each site involved in a given trial

Wherever possible, data-driven insights should be developed to both inform decision-making and create feedback loops that can help stakeholders to finetune the specific initiatives and interventions over time.

Table 2 reviews the types of questions drug sponsors should be asking to identify both productivity challenges throughout their trial processes and opportunities for improvement.

* **Note:** A deeper discussion of options that are available to drive productivity during protocol design can be found in **Chapter 3** of this multi-part series.

Table 2.

Don't be afraid to ask the tough questions

To build an efficient and successful trial execution strategy, all stakeholders must dig deep to identify problems and potential solutions and recognize which metrics will be most relevant to track ongoing progress. Asking these types of questions can help drug sponsors to get the ball rolling:

Protocol design[7]	• Is the protocol written in a way that explicitly aims to minimize the burden on patients and investigators, in terms of streamlining activities and reducing the number of tasks and types of burdens that could deter or frustrate both stakeholder groups? • Do the trial endpoints adequately capture the patient perspective?
Site selection	• Do we have a proven process for stratifying which countries and which specific trial sites are most likely to produce the best results for the therapy/disease state in question? Have we evaluated regulatory timeframes and requirements for local participation, standard of care, competitor trial landscape, patient and site availability, etc? • Are there better ways of doing this that we have not yet considered? • Do we fully understand the outcomes that specific sites have historically achieved, as well as the factors that contributed to both favorable and unfavorable trial performance at competing sites? • Are we evaluating each site based on a full range of factors (rather than just going back to the same sites repeatedly)?
Site training	• Are we evaluating differences in potential outcomes between lower- and higher-performing sites not just from past outcomes data, but by considering the site's processes, workflows, training and behaviors, as well? • Have we considered working with organizations such as the Society for Clinical Research Sites (SCRS) to facilitate the sharing of best practices between sites, systemize practical training programs (for instance, to help sites maintain good operational hygiene, maximize patient outreach and recruitment, improve quality of site operations and revenue opportunities)?
Initial patient recruitment	• To optimize recruitment efforts, are we taking advantage of all available tools and technologies? (These include strategic analysis of real-world data (RWD) and the application of artificial intelligence (AI) and machine learning (ML) methodologies to obtain data-driven insights, which facilitate the identification of relevant patients and physicians in a timely and accurate manner.) • Are we dedicating resources to explore community outreach, collaboration, and social media opportunities—especially in specialized or narrow therapeutic areas where patient word-of-mouth is a vital element of enrollment? (Drug sponsors that do this well reap the benefits when it comes to more robust trial recruitment.)

Ongoing recruitment over time to address patient dropout issues	• Are we doing everything possible to address the common causes of patients dropping out? • Are we providing appropriate monitoring and mitigation strategies to allow for earlier interventions (as needed) that can avoid adherence lapses and patient dropout? • Have we developed an effective strategy (and dedicated resources) designed to continuously recruit additional participants on an ongoing basis, to safeguard the statistical requirements of the trial?
Site activation and startup	• Are we critically assessing and streamlining all aspects of the logistics planning, training and overall workflows (accounting for site-specific language requirements and different regulatory frameworks across different regions) to support timely and effective startup for each site in the study? • Are we taking full advantage of Gen AI embedded in dedicated technology offerings to help patients and trial investigators streamline and manage the tasks at hand?
Duration of each trial phase and white space between subsequent trial phases	• Are we working to identify and rectify specific productivity lapses that can lead to timeline delays and budget escalation? • Are we engaged in thoughtful advanced planning and resource allocation that can help to deliver the shortest white space possible between trial phases?
Data collection, biostatistics and programming	• Are we using state-of-the-art technologies to capture and analyze the most relevant quantitative and qualitative data? (Note: We discuss this topic in greater detail in the main body of this paper.) • Are we working to disrupt traditional paradigms and expand upon traditional KPIs to enable richer data-driven insights that can inform decision-making and identify next-best actions?
Technology selection	• Are we verifying that selected technologies for automation, data gathering and analysis are being effectively integrated into the daily workflow for stakeholders? • Are we providing adequate training and change-management support for all stakeholders?
Inspection readiness	• Are systems in place to safeguard that routine inspections will not create issues that can translate into avoidable delays?

The impact of rigorous data collection, biostatistics and programming

Historically, a major impediment to real-time database lock is the sheer volume of data collected, and the rigor needed to deliver confidence in the accuracy of the data. Each time a database is locked, it requires time and resources. Each iteration scales the resource requirements roughly linearly.

However, with rapid ongoing advances in machine learning (ML) and other software tools (which are helping to build capabilities while driving costs down) this linear scaling effect can be significantly reduced, thereby allowing drug developers and their CRO collaborators to carry out database lock and analysis more frequently with positive impact on study timeline and budget.

On its own, this one intervention may be able to reduce clinical timelines by a few weeks, relative to a normal timeline required to lock a database. However, such advances also bring even greater potential to help drug sponsors realize the full potential of the novel adaptive trial design construct.

Using an adaptive trial design (one that is powered by ongoing data analysis that is reviewed on a monthly, weekly or even daily basis as the trial is progressing) gives drug sponsors and CROs another great opportunity to drive productivity.[3] For example, several common trial scenarios discussed below underscore the value of the adaptive trial design as an alternative.

One of the most frustrating outcomes for a clinical trial is to narrowly miss demonstrating the statistical significance of the clinical findings on its primary endpoint because the patient cohort was too small. When this happens, it often requires the drug developer to publish its findings with the hope that there is enough evidence in its secondary endpoints to eventually achieve regulatory approval. In these instances, the drug sponsor may be forced to extend the trial to enroll more patients or conduct the trial again with a larger sample size, thereby increasing both time and expense.

At the opposite end of the spectrum, in some clinical trials, the clinical findings for the investigational therapy may far exceed their target statistical significance. This can be an indication that excessive resources were consumed to conduct the trial. Only in hindsight did the stakeholders realize that the use of more appropriate primary clinical and safety endpoints could have allowed the clinical findings to have been validated with a much smaller patient cohort, which could have significantly lowered clinical trial costs and timelines.

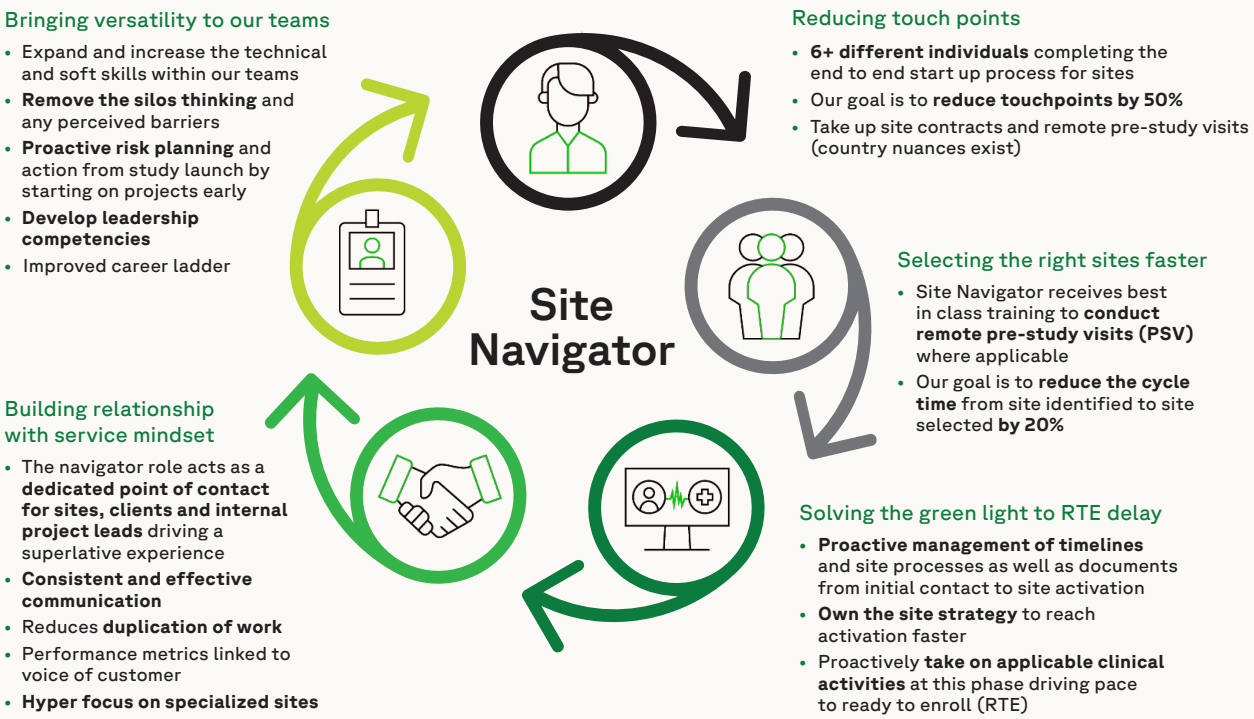
Using an adaptive trial design, a trial may be completed earlier if all data being evaluated periodically over time were able to demonstrate the safety and efficacy of the drug much earlier than expected.

The benefits of including a Site Navigator on the trial team

An issue that can impede productivity in clinical trials is a lack of a single point of contact empowered to oversee integrated site operations. Without proper integration or oversight of handover processes, fragmented workflows can create timeline, budget and quality issues. Efforts to address and overcome this fragmentation and improve cross-operational coordination can help to optimize end-to-end trial execution, which creates value for all stakeholders.

To drive efficiency and close productivity gaps during trial activation, Fortrea has created a dedicated professional role called the Site Navigator. This individual provides a dedicated point of contact for sites and project teams. The Site Navigator helps to simplify and coordinate activities from site selection through activation and beyond, helping to deliver site readiness in ways that can demonstrably reduce avoidable budget and timeliness issues.

Site Navigators are not just domain subject matter specialists. They are also given broad, cross-functional, country-specific training with a focus on driving productivity and quality improvements. With a goal of proactively reducing the number of touchpoints in any trial, the Site Navigator seeks to eliminate blind spots and confirm that parallel aspects of the trial are moving smoothly and are appropriately integrated for optimal results. Results are promising, with an overall reduction of 30 days from outreach to activation on studies where Site Navigators had not previously been used.



Moving the needle: Recommendations for how to improve trial execution

As noted, drug sponsors have many options for improving productivity during trial execution. The suggestions discussed below are just the tip of the iceberg. Working with an experienced CRO can help create the most appropriate mix of opportunities.

Site selection. Deciding which countries or regions and which specific trial sites should be included is a critical aspect of optimizing trial execution. Typically, drug sponsors lean into sites where they have had good experience in the past, in terms of the availability of willing investigators or a high likelihood of enrolling sufficient patients who meet the required clinical and demographic profiles.

However, reflexively prioritizing sites just because of past success increases the risk of potential saturation issues at the site. Such facilities may be overextended regarding trial volume or the availability of appropriate, treatment-naïve patients.

Working closely with a CRO that has demonstrated global reach across many therapeutic areas can help to create a more effective and less risky site-selection strategy. This can help to shorten the timeline required, allowing patients to be enrolled and activated more quickly and potentially reducing the overall duration of the trial, while also reducing overall risk.

Patient enrollment and ongoing recruitment. Traditional quantitative metrics are essential when building the patient-recruitment strategy for any given trial. These familiar metrics include the number of patients screened, the number and percentage of patients enrolled, the number and percentage who failed, the amount of time from enrollment to activation and more.[4]

However, traditional quantitative metrics alone rarely tell the entire story, and overreliance on them may miss opportunities to identify other potential trial candidates.

In recent years, the industry has begun to embrace the use of certain qualitative metrics to build a more complete profile of patients who may be appropriate for a given trial.

Broader use of real-world data (RWD) provides an excellent way to identify relevant quantitative and qualitative metrics that could help streamline and improve patient enrollment, including:

1. **Social determinants of health (SDOH) data:** Includes socioeconomic status, geographic location and access to healthcare

   By way of example, two patients from different towns with diverse backgrounds may respond differently to the same therapy (with up to 50% variation), given the impact of SDOH data on their ability to seek healthcare, remain adherent to therapy and more

2. **Sexual orientation and gender identity (SOGI) data:** Increasingly relevant for inclusive trial design

   By way of example, a transgender man with a uterus may still need pregnancy testing during a trial despite self-reported abstinence; this raises ethical and safety concerns

3. **HIV status inclusion:** Historically, HIV+ people have generally been excluded from trials outside of those specifically aimed at treating HIV infection and associated complications, even when HIV replication has been maximally suppressed. In recent years, only a handful of protocols in the U.S. allow HIV-positive patients to participate more broadly in trials

Similarly, there is growing reliance on real-world data (RWD) to improve trial design and execution. The potential uses cases include (but are not limited to):

- Supplementing trial data with broader population insights
- Identifying underserved or underrepresented groups
- Informing protocol design to improve inclusivity

Current limitations on the broader use of RWD include restricted access to certain data types, limited granularity for recruitment-specific insights and the fact that RWD and related real-world evidence (RWE) insights are often useful to identify clinical endpoints, but not necessarily for the initial recruitment strategy.

Assessment of qualitative metrics and contextual data provides timely, invaluable insights that help stakeholders support equity, representation and ethical integrity throughout the clinical trial. Developing ethical frameworks for collecting and standardizing SDOH and SOGI data and using RWD to identify gaps in recruitment and improve trial accessibility can help to improve trial recruitment and execution, delivering improvements to both trial budget and timeline.

Site activation and startup. Poor coordination during site activation and startup creates inefficiencies that undermine long-term productivity goals. Efforts to shorten timelines using improved monitoring strategies, automation and other technology-based solutions and streamlined workflow processes can reduce timeline and budget drag and close productivity gaps.[5]

Keep in mind that strategic technology investments to automate certain aspects of site activation and startup will not be able to achieve their full potential if they are not coupled with comprehensive training and integration efforts.[6] Meanwhile, an added benefit is that increased automation can also help to improve quality by reducing the opportunity for human error.

Two-way dashboards. Combining Gen AI, predictive analytics and a two-way dashboard can provide an effective way to establish greater real-time support between the CRO and individual trial sites. Fortrea has invested to enable and empower sites in ways to improve data quality, reduce protocol deviations and improve operations.

Such an approach can also power Risk-Based Quality Management (RBQM) so that resources can be allocated and deployed in the most effective and efficient ways. The goal is to allocate resources most effectively at sites that have the greatest risk of quality lapses, while still giving sufficient attention to identify and address any quality concerns at lower-risk sites.

Note: Protocol design also plays a significant role in helping to drive more productive trial execution. We discuss this in greater detail in Chapter 3 of this multi-part series.

Optimizing the CRO's role

Not surprisingly, there is no one-size-fits-all playbook when it comes to creating and implementing the perfect strategic framework to optimize trial execution. Rather, the needs of any trial will vary from company to company, from site to site and from country to country.

Factors ranging from budget and bandwidth to mindset and strategic objectives will influence how big a role the CRO will play in any given trial. The best CROs are sensitive to the needs of individual drug sponsors and their asset(s), and will work to build clinical trial teams, technology platforms and workflow processes that meet them where they are. In an ideal scenario, the CRO's spheres of influence and control will be highest when the drug sponsor engages that strategic collaboration as early as possible in the process.

Engaging the CRO early also allows both parties to take full advantage of the CRO's broad experience, geographic reach and best practices, and to influence many aspects of trial execution with productivity in mind.[7]

When the CRO is brought onboard later in the process, after critical aspects of the trial have already been locked down, its ability to influence the trial design, study protocol, country and site selection, vendor selection, patient enrollment, site activation, regulatory preparedness, data strategy and overall trial execution in ways that can optimize timelines, budget and quality may be limited. When this happens, the CRO's role often relates more to operationalizing the trial rather than making strategic decisions upfront that can meaningfully improve the overall trial design and execution. To read more about how to optimize your working relationship with your CRO, please see Chapter 6 in this multi-part series.

Today, engaging a CRO to support clinical trials can run the gamut from:

- **The Full-Service Offering (FSO) model.** A fully outsourced solution, whereby the CRO is responsible for complete end-to-end trial execution (with full autonomy and accountability), with minimal resources or involvement from the drug sponsor; to
- **The Functional Service Provider (FSP) model.** A tailored outsourcing solution, whereby the CRO provides the most appropriate mix of specific capabilities during the trial, to augment other aspects of the trial that are conducted by the drug sponsor
- **Hybrid offerings.** A mix of the FSO and FSP models that allow stakeholders to tailor the individual program elements that are needed to meet the specific needs of sponsors and their trials

As an alternative to a full turnkey outsourcing arrangement, the flexible FSP model is a desirable choice for those drug sponsors that prefer to retain a greater amount of control and autonomy over some aspects of the trial. Specifically using the FSP model, the CRO can provide the right resource at the right time, on a flexible, as-needed basis that can evolve over time.

For instance, with the FSP arrangement, the CRO can provide targeted knowledge and skilled personnel related to clinical operations (start-up, monitoring, centralized services), project management, data management, biostatistics, statistical programming and analysis, medical writing, safety and more, as required to complement the sponsor's capabilities. A CRO with an established global footprint can draw upon its existing personnel and technology infrastructure and cross-functional engagements, as well as its established standard operating procedures and economies of scale, to help drug sponsors quickly scale up or down their trial footprint in any region quickly and cost-effectively.

Retain control of your development program

Service delivery models

FTE

- Staff Augmentation or embedded line management
- Performance at the individual level
- Full FTEs
- Fast implementation, more customer control
- Does place more burden on customer

Centralized Delivery

- Task delivery centralized to a delivery hub
- Leverage 24-hour workflow, high standardization
- Limited to services appropriate to centralization
- Examples include eTMF, trip report review, safety processing

Unitized

- Delivery of a task/work product as a unit, not by FTE
- FSP option when Full FTEs not needed
- Examples include: Unblinded monitoring, long term follow up monitoring, study start up (ICF, package review/approval)

Cross-Functional

- Single or multi-function
- Customer or Fortrea SOPs and/or systems
- Examples: Training as Service, Therapeutic Area or Country in a Box, Mobile Clinical Services, Regulatory Submissions, Data Management, Feasibility Clinical Intelligence

End-to-End Full Service

- Comprehensive delivery of all services for a clinical study
- Fortrea ownership and accountability
- Fortrea systems and SOPs

Importantly, close collaboration with an experienced CRO also helps to support appropriate training (during both onboarding and over time). This is especially important to provide essential scaffolding for less experienced or resource-constrained drug sponsors, helping them to navigate country-specific regulatory frameworks and language requirements quickly and efficiently in all regions of the world.

Using the FSP model, drug sponsors can also benefit from the use of the CRO's centralized delivery system, which can streamline trial execution by centralizing the delivery of specific trial processes at multiple sites from a centralized hub. Such centralized hubs are operated at geographic locations that can provide strategic advantages related to cost, labor pool, scientific or technology knowledge and more.

Closing thoughts

The biggest challenge in improving trial execution is that, too often, the trial is already under way by the time the drug sponsor realizes that issues are starting to arise. When drug developers can work with their CRO to critically assess all aspects of their trial execution framework as early as possible in the process, they are in a better position to identify opportunities to close productivity lapses and demonstrably reduce timeline and budget overruns. At the end of the day, investment in improving the trial execution process can prove to be money well spent.

Ken Park, MD

VP, R&D Strategy and Innovation, Consulting, Fortrea

Ken Park, MD has spent the last 20 years in healthcare, focused on building and delivering innovative businesses and solutions to the life sciences industry. He advises clients on their R&D strategy and leads Fortrea's productivity initiatives.

As an Associate Principal at McKinsey & Co., he pioneered the establishment of Real World Evidence in the Life Sciences industry and co-led the firm's application of big data in healthcare. While the VP of Payer and Provider Solutions at Elevance, he managed the internal operations of Carelon, a subsidiary of Elevance and launched CalINDEX, a privately funded Health Information Exchange in California. For six years, Dr. Park built new business lines across data, R&D services and genomics as VP of Offering Development at IQVIA. At Clarify Health Solutions, he served as SVP and GM of their Life Sciences business where he established a product suite across the clinical trial and commercial spaces. Most recently, he was co-founder and CEO of Veda Life Sciences, a next-generation integrated research organization.

Dr. Park has an AB cum laude in psychology from Harvard College and an MD from the University of Southern California, Keck School of Medicine.

References

1. Respite from rising trial costs is a distant dream in 2025, *Clinical Trials Arena*, January 13, 2025. Retrieved from https://www.clinicaltrialsarena.com/analyst-comment/respite-rising-trial-costs-distant-dream-2025/
2. Shukla, R., & Bahl, A. (2025). Transforming clinical trials with AI-driven protocol optimization and next-gen statistical programming. *Syneos Health.* Retrieved from https://www.lexjansen.com/phuse-us/2025/et/PAP_ET15.pdf. [lexjansen.com]
3. Kaizer, A. M., et al. (2023). Recent innovations in adaptive trial designs: A review of design opportunities in translational research. *Journal of Clinical and Translational Science,* 7:e125. Retrieved from https://www.cambridge.org/core/services/aop-cambridge-core/content/view/S205986612300537X[arxiv.org]
4. *OneStudyTeam.* (2025). Key Clinical Trial Metrics to Evaluate Patient Recruitment Campaigns. Retrieved from https://blog.onestudyteam.com/clinical-trial-metrics-to-evaluate-patient-recruitment-campaigns
5. Hershaw, G., Kotchie, N., & Jones, J. (2025). The Future is Now: Four Ways AI and Other Tech Advances are Enhancing Clinical Trials. *Applied Clinical Trials Online.* Retrieved from https://www.appliedclinicaltrialsonline.com/view/future-now-four-ways-ai-tech-advances-enhancing-clinical-trials
6. Hussain, Z., et al. (2025). How process automation and employee training jointly drive workflow efficiency. *International Journal of Productivity and Performance Management*. Retrieved from https://www.emerald.com/ijppm/article/doi/10.1108/IJPPM-07-2025-0651/1316117/How-process-automation-and-employee-training
7. *Tufts Center for the Study of Drug Development.* (2024). Impact of Early CRO Engagement on Clinical Trial Efficiency. Retrieved from https://csdd.tufts.edu/publications/impact-reports

LEARN MORE at fortrea.com

Fortrea