Clinical trials: Using AI to drive productivity in clinical development

Executive Summary:

The strategic use of tools and solutions that are enabled by artificial intelligence (AI) and machine learning (ML) provides a valuable opportunity to improve productivity by streamlining and improving many clinical trial processes (ranging from up-front protocol development and trial design to patient recruitment, site selection, trial execution and data management) and delivers tangible bottom-line results for drug developers. Deployed at scale, today's state-of-the art technology interventions provide benefits to all constituents in the clinical trial ecosystem. Using these state-of-the-art tools, trial sponsors and contract research organization (CRO) partners are able to close information gaps, trim timelines and budgets, increase quality and improve both clinical and commercial outcomes. Similarly, trial investigators are able to develop deeper insights, reduce mundane, time-consuming tasks and focus on what matters most—patient care and creating the most streamlined trial experience for patients, their caregivers and trial investigators. Although the use of AI/ML is not a universal panacea, its appropriate application will transform clinical development.

Author:

Alaric Jackson, Chief Technology and Data Officer, Fortrea, Inc.

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Introduction

Ongoing innovation in—and growing use of—artificial intelligence (AI) and machine learning (ML) capabilities continue to make headlines across the drug-development landscape from bench to bedside. Early activity has focused on using AI/ML-related initiatives to improve the drug-discovery process. Meanwhile, parallel opportunities to use various AI/ML-related approaches to improve outcomes and drive the overall productivity of randomized clinical trials represent the next exciting frontier.

As discussed in this series of articles all stakeholders in the clinical trial ecosystem —ranging from drug developers and their contract research organization (CRO) partners to trial investigators, patients and their caregivers—stand to benefit. The industry is becoming more imaginative in how it can put these powerful capabilities to work and reap tangible rewards, but plenty of opportunities remain and early movers will be able to shape the best practices driving productivity in this space.

When drug sponsors are willing to embrace this innovative technology paradigm—and explore various options to deploy strategic AI/ML solutions to address specific problems—they can create opportunities to increase efficiency and effectiveness at each step in the clinical trial process. This helps improve the productivity of many complex, cumbersome processes and creates direct, bottom-line impact for drug sponsors and trial investigators, as well as a less burdensome and more satisfying experience for patients.

Specific AI/ML-related initiatives should be investigated when developing a comprehensive strategy to improve efficiency, effectiveness* and productivity during clinical trials. To improve both clinical and commercial outcomes during each phase of the trial process, pharma/life sciences companies and their CRO partners must create a comprehensive strategy—one that integrates the most appropriate data, technology options, human knowledge, innovative solutions and best practices. When this is done successfully, drug developers and trial investigators are better equipped to focus on advancing the underlying science and improving patient care—rather than being bogged down in time-consuming tasks that can easily be automated and improved using innovative technologies.

* Note: Many people use the terms effectiveness and efficiency interchangeably with productivity, yet the concepts are not synonymous. *Effectiveness* is a measure of how well the drug-development process is able to achieve its intended outcomes (which is to produce approved therapies that address unmet clinical need for patients and physicians); *Efficiency* is a measure of how well resources such as time, budget, personnel and more are utilized to achieve the target outcomes of the drug-development process.

What's in your AI/ML toolkit?

Clinical trials are often looked at as a set of vertical tasks and duties (such as protocol development, trial design, patient recruitment, site selection, site management, data collection, regulatory compliance and more). But the truth is, all these interconnected processes are part of an integrated trial ecosystem.

Advanced AI/ML capabilities make use of large data sets to generate greater insights compared to traditional statistics and conventional analytics. As such, specific AI/ML initiatives can be used to make each step more productive through (for instance) automation, enhanced data-driven insights, and more to help to optimize the overall performance of this interconnected ecosystem. Embracing an integrated "systems thinking" approach will help to drive greater results.

For the purpose of simplicity in this paper, the terms AI and ML are used collectively to represent the entire range of AI-enabled methodologies that are available today and those that will continue to emerge over time. All AI/ML modalities share a common trait: They all harness mathematical modeling and advanced analytics to create timely, actionable insights and provide data-driven decision support that can help users to resolve uncertainty.

Within the realm of clinical trial management, the most commonly used tools in the AI/ML toolkit include (but are not limited to):

- Machine learning (ML) techniques
- Natural language processing (NLP)
- Generative AI functionality
- Robotic process automation (RPA)
- Large language models (LLM)
- Real value logic systems
- Game theory
- Probabilistic logic

It is important to remember that the bold use of the AI/ML toolkit should be viewed as a means to an end—not an end in itself. Thoughtful selection and integration of the most appropriate AI/ML methodology for the task at hand is essential.

The goal is to ensure that state-of-the-art technologies will be integrated smoothly into the workflow. AI/ML options should not simply be added on as the latest "bright shiny thing"—only to be abandoned over time without making a demonstrable impact on productivity.

Similarly, to realize the broadest possible impact, a top-down commitment from executive leadership is required. Similarly, to encourage widespread acceptance and adoption of the new technology paradigm on a day-to-day basis, appropriate change-management strategies should be used.

Next, we will explore how a bold embrace of the full AI/ML toolkit can be a key enabler—and a key differentiator—for clinical trial sponsors and their CRO partners in each of these high-stakes endeavors.

Putting the AI/ML toolbox to work

Increasingly, technology advances based on the various AI/ML modalities discussed here are being put to work to automate, streamline and improve specific processes and operations. Thus increasing the overall productivity of the multi-faceted clinical trial process. This is helping trial sponsors and their CRO partners to extract value in many ways, simultaneously helping to improve the experience and satisfaction of both trial investigators and enrolled patients.

Specifically, the strategic use of AI/ML capabilities can help to drive productivity and create tangible, bottom-line impact in the following ways:

1. **Increase speed:**
   - Shorten trial timelines
   - Streamline and automate data collection and management
   - Accelerate analysis of site performance, overall trial performance and trial results
2. **Reduce costs:**
   - Reduce overall trial expenditures
3. **Improve quality:**
   - Improve trial design and study protocols
   - Improve site selection and site management
   - Improve patient enrollment
   - Improve patient satisfaction and retention
   - Improve engagement with diverse patient populations and achieving Diversity Action Plan (DAP) goals
   - Increase engagement with investigator sites through more valuable interactions
   - Fortify compliance monitoring
   - Narrow the performance gap between top- and bottom-performing trial sites
   - Enable insight generation, pattern recognition and outlier detection
   - Enable data-driven decision support for study teams to ensure better outcomes and patient safety
   - Improve risk detection and mitigation

When the use of AI/ML tools and solutions helps to both automate and streamline many processes throughout every step of the trial, stakeholders are able to increase productivity by reducing toil and wasted effort. Similarly, streamlined efficiency can potentially reduce labor requirements, improving satisfaction among both trial investigators and enrolled patients.

At the same time, today's powerful AI/ML options can provide actionable insights and data-driven decision support that help guide all stakeholders. The ability to make more timely decisions and harmonize precision workflows at each phase of the trial leads to potentially better outcomes. Such improvements deliver real bottom-line results for drug sponsors and improved clinical outcomes for patients and their physicians.

As acceptance of today's rapidly-advancing AI/ML toolkit continues to grow, this new technology paradigm is no longer a novelty but an essential part of any modern clinical trial. Specific opportunities for doing this at each phase in the trial process will be explored—and recent case study results will be presented—in subsequent chapters in this multi-part productivity series.

What's in it for the drug sponsor and the CRO?

By harnessing the unprecedented data analytics, modeling, simulation and computing capabilities that are available using today's AI/ML solutions, CROs that have the appropriate experience and expertise are able to bring more value to the table in three distinct (yet interrelated) ways:

1.

By creating fearless, forward-looking opportunities to deploy AI/ML tools to optimize **internal operations** as a strategic imperative—that is, working to optimize internal efficiency, effectiveness and productivity, and enabling a more nimble and agile CRO partner for drug sponsors to entrust with clinical trial development and management, and

2.

By developing and deploying innovative **external processes, systems and user-friendly tools** based on the full AI/ML toolkit that can be integrated seamlessly into the work flow during each step in the trial process—with a goal of streamlining and automating many tasks, enabling greater data-driven insights and increasing productivity in ways that directly improve overall quality and reduce risk while optimizing timelines and budget, patient recruitment and retention, site selection and management, data monitoring and management and clinical outcomes

3.

Providing data-driven insights to a broader set of stakeholders (including drug sponsors, investigator sites and third-party partners) to help them make better decisions and enable continuous productivity gains throughout the entire clinical trial **ecosystem.**

The pharmaceutical/life sciences industry is heavily regulated, so traditionally it has tended to be conservative in its embrace of bold new technology initiatives. However, failure to recognize the vital role of today's advanced AI/ML computing and data-analytics platforms signals a missed opportunity for drug-development business leaders.

While the most appropriate plan to implement AI/ML options will vary on a case-by-case basis, program design should be informed by two components:

- ***Bottom-up drivers***—Relating to specific pain points that a given trial sponsor may be experiencing, and
- ***Top-down drivers***—Relating to industry trends and regulatory guidance that are impacting some or all drug developers

It is worth noting that most clinical trials experience a 'friction zone' where top-down drivers and bottom-up factors collide to drag down the overall productivity of individual processes. AI/ML tools provide effective options for helping to overcome this disconnect, as discussed below.

Creating excellence throughout the clinical trial ecosystem

As noted, the process of bringing various AI/ML capabilities to bear to improve overall trial productivity requires a deep understanding of the complex clinical trial process. Whether you run your trials in-house or partner with a CRO, it is important that you use AI/ML to achieve the following objectives:

- Stay abreast of the dynamic technology and regulatory landscape
- Work closely with drug sponsors to identify gaps and pain points
- Bring a deep bench of experience and expertise related to various AI/ML options

- Deploy specific opportunities where strategic technology solutions and tools can demonstrably improve R&D productivity

Meanwhile, targeted AI/ML-enabled interventions (along with automation and data analytics to create actionable insights) can help trial sponsors in two ways—both of which create overall productivity gains and long-term value.

- Help to automate and streamline repetitive, administrative, machine-friendly tasks, driving efficiency, reducing delays, labor requirements and human error, thereby freeing up finite human capital to focus on more value-added efforts and patient support, and
- Bring next-level modeling, simulation and increased data-analytics capabilities to bear on complex challenges that arise at each step of the clinical trial process

The graphic below reviews specific types of AI/ML modalities that are already being used today to help stakeholders increase productivity at different points throughout the clinical trial ecosystem.

Specific AI/ML interventions that can benefit stakeholders throughout the clinical trial ecosystem

Specialized large language models (LLMs) to improve text comprehension and generation.

Symbolic AI with real-valued logic to enable building logic using real-world scenarios and data.

Advanced data mining and predictive analytics to provide actionable insights and data-driven decision-support at each stage of the trial process.

Mixed reality and augmented intelligence to leverage recent advances in brain science and learning theory, giving all trial participants a deeper, more comprehensive understanding of the protocols and interventions (this can help to reduce deviations and increase patient compliance).

Smartphone-enabled data collection to improve efficiency at the point of care.

Simulations and predictive analytics that identify patterns and trends, inform trial design and protocol development, refine inclusion and exclusion criteria, support clinical and operational decision making, and more.

Digital twin development and external control arms that can help drug investigators to gain clinical insights while reducing the number of actual patients required (thereby streamlining recruitment, patient management and monitoring requirements).

Modeling and simulation to address problems in the existing trial infrastructure and improve operations to create best-in-class user experiences for researchers and patients.

Specific AI/ML tools to efficiently extract safety and efficacy information from published trials and use the insights to inform protocol development and inclusion/exclusion criteria.

Advanced analytics of real-world data (RWD), including laboratory and pathology data and images, electronic health records (EHR), pharmacy records, insurance reimbursement records, to create actionable real-world evidence (RWE) that can fine-tune patient-recruitment and site-selection efforts.

Technology-enabled monitoring and data-collection options that use consumer-grade devices such as properly enabled smart phones and wearable and other mobile monitoring devices right at the point of care.

Advanced analytics of RWD to create generalized behavior profiles that help trial sponsors to understand the patient experience better and identify enrolled patients are most at risk of dropping out (so that additional support resources can be focused on them).

Interactive chatbots that help patients to manage their trial treatment protocols more effectively and find additional resources, as needed.

Automated tools to improve detection of fraud and compliance issues.

Mathematical modeling to propose "next best steps" in multiple domains.

Automated systems to manage trial-related data (including adverse events and side effects) and allow actionable insights to be easily extracted.

Meanwhile, Table 1 shows a diverse array of examples of the types of opportunities that trial sponsors can use, to improve timelines, reduce costs and improve quality through the use of specific AI/ML capabilities and initiatives.

Table 1.

Specific AI/ML interventions that can benefit stakeholders throughout the clinical trial ecosystem

AI/ML-related opportunity	Speed/ Timeline	Cost/ Budget	Quality
Specialized large language models (LLMS) to improve text comprehension and generation	X	X	
Symbolic AI with actual-valued logic to enable building scenarios using real-world data	X	X	
Mixed reality and augmented intelligence to leverage recent advances in brain science and learning theory, giving all trial participants a deeper, more comprehensive understanding of the protocols and interventions (to help reduce deviations and increase patient compliance)			X
Advanced data mining and predictive analytics to provide actionable insights and data-driven decision-support at each stage of the trial process	X	X	X
Digital twin development and external control arms that can help drug investigators to gain clinical insights while reducing the number of actual patients required (thereby streamlining recruitment, patient management and monitoring requirements)	X	X	
Smartphone-enabled data collection to improve efficiency at the point of care		X	X
Simulations and predictive analytics that identify patterns and trends, inform trial design and protocol development, refine inclusion and exclusion criteria, support clinical and operational decision making, and more	X	X	X
Specific AI/ML tools to efficiently extract safety and efficacy information from published trials and use the insights to inform protocol development and inclusion/exclusion criteria	X	X	X

AI/ML-related opportunity	Speed/ Timeline	Cost/ Budget	Quality
Modeling and simulation to address problems in the existing trial infrastructure and improve operations to create best-in-class user experiences for researchers and patients			X
Technology-enabled monitoring and data-collection options that use consumer-grade devices such as properly enabled smart phones and wearable and other mobile monitoring devices right at the point of care	X		X
Advanced analytics of real-world data (RWD), including laboratory and pathology data and images, electronic health records (HER), pharmacy records, and insurance reimbursement records, to create actionable real-world evidence (RWE) that can fine-tune patient-recruitment and site-selection efforts	X	X	
Advanced analytics of RWD to create generalized behavior profiles that help trial sponsors to understand the patient experience better and identify enrolled patients who are most at risk of dropping out (so that additional support resoures and interventions can be focused on them)	X	X	
Interactive chatbots that help patients manage their trial treatment protocols more effectively and find additional resources, as needed		X	X
Automated systems to manage trial-related data (including adverse events and side effects) and allow actionable insights to be easily extracted	X	X	X
Mathematical modeling to propose “next best steps” in multiple domains	X		
Automated tools to improve detection of fraud and compliance issues			X

A bold embrace of the full AI/ML toolkit can be a key enabler—and a key differentiator—for clinical trial sponsors and their CRO partners.

The overarching goal is to map out all the complicated systems and flows that take place when moving promising therapies through the multi-phase clinical trial process. Wherever possible, options to integrate AI/ML-related technologies, systems and apps should favor the use of consumer-grade, location-agnostic devices and systems that can be easily accessed through a single user interface.

Such efforts will help trial sponsors to realize the most streamlined, best-in-class user experiences for both trial investigators, patients, and their caregivers and drive the greatest productivity gains and ROI without exorbitant expenditures. At the end of the day, efforts to use advanced tools and management strategies to streamline all aspects of the clinical trial process also help to create a more engaging and compassionate patient experience, which helps to reduce adherence lapses and improve clinical trial outcomes.

Closing thoughts

The pace of innovation with regard to AI/ML is daunting to some and incredibly energizing to others.

It cannot solve every problem, but with the right CRO partner, drug sponsors can and should embrace AI/ML options as confidently as possible, to address many of the pervasive issues that create time, cost and quality issues that hinder overall productivity in clinical trials.

When used in the most effective and strategic way to drive productivity throughout the entire clinical trial ecosystem, augmented intelligence delivers tangible bottom-line results for all stakeholders. Technology-based solutions that were once only in the realm of science fiction now constitute the baseline of what is already possible. Seeing what is already being accomplished using the dynamic capabilities of the AI/ML toolbox is just a sneak preview of what is to come.

CROs and trial sponsors that enthusiastically embrace the possibilities of today's rapidly evolving AI/ML toolkit and work tirelessly to put these powerful capabilities to work at scale will create valuable strategic advantage for themselves—in terms of improving efficiency, effectiveness and overall productivity, and thus delivering stronger clinical and commercial outcomes. To make the most of these opportunities, drug sponsors and their CRO partners must embrace a systems thinking approach. Especially important—all stakeholders must adopt a top-down commitment and work to let go of assumptions, fear and outdated tropes.

To fully embrace these opportunities, drug sponsors should:

- Stay abreast of the dynamic technology and regulatory landscape
- Work closely with a trusted CRO to identify gaps and pain points
- Take advantage of the deep bench of experience, expertise and best practices that are rapidly evolving related to the use of specific AI/ML options to drive clinical trial productivity
- Prioritize all of the options and commit to addressing specific opportunities where the deployment of strategic technology tools and solutions can demonstrably improve R&D productivity and streamline trial operations

A robust, forward-looking embrace of these transformational capabilities can provide strategic differentiation and competitive advantages for companies that are willing to embrace the possibilities. By contrast, those that continue to take a wait-and-see approach are missing a critical opportunity to close productivity gaps and improve their overall performance—and thus create a competitive disadvantage for themselves and their promising therapies.

Incorporating ethical and engineering considerations

An essential aspect of developing and using targeted AI/ML interventions — especially to support various aspects of drug development and patient care — is that all stakeholders consider and prioritize the ethical aspects associated with them. As a CRO, Fortrea prioritizes the protection of patient safety and privacy, as well as safeguarding intellectual property for our partners throughout the drug-development space.

Popular consumer-grade products based on AI/ML have made the public keenly aware of how AI can be misused. The pharma/life sciences industry takes seriously the issue of responsible use of all AI/ML modalities. As a CRO we consider it an ethical and business imperative to follow rigorous industry and dynamic regulatory frameworks to protect patient privacy and respect intellectual property (IP) considerations.

To create productivity improvements that deliver tangible results and drive ROI, drug developers must let go of past constraints and embrace an innovative, multi-faceted AI/ML program. When evaluating potential CRO partners that can help drive this paradigm shift, drug developers should seek one that brings to the table not just a strategic business and clinical mindset but also the engineering ingenuity that is required to solve problems and redesign processes in ways that break from the status quo. The selected CRO partner should have a deep bench of experience in clinical trial management and a proven track record in deploying a range of AI/ML methodologies and a proven record of using strategic levers to drive productivity. This will help improve both clinical and commercial outcomes throughout each phase in the clinical trial process.

Such a partner will be well-positioned to identify parallel opportunities at each phase of the trial and implement state-of-the-art AI/ML options to improve trial design and execution.

The goal is to create new technology-driven productivity opportunities that are not hamstrung by reliance on traditional norms — or fear of the unknown. Examples of such opportunities will be discussed in detail throughout this multi-part series.

Alaric Jackson, Chief Technology and Data Officer, Fortrea, Inc.

Alaric is responsible for developing and implementing Fortrea's enterprise data and technology strategy. Prior to joining Fortrea, Alaric held a number of senior leadership roles at Fern.Ai, GlaxoSmithKline and IQVIA. At GlaxoSmithKline, Jackson led the digital transformation of the Regulatory, Safety, Quality and Medical organizations, overseeing the deployment and adoption of advanced technologies (such as intelligent automation, data fabric and AI/ML).

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