Smarter, faster, better: How AI is reshaping neuroscience clinical trials

A KEY QUESTION

How can neuroscience clinical trial sponsors use AI to reduce complexity, accelerate timelines and lower costs in a high-risk, delay-prone research environment?

KEYWORDS Neuroscience, Technology Integration, Artificial Intelligence (AI) In Research, CNS Case Scenarios, Clinical Trial Efficiencies

How neuroscience sponsors can use AI to cut complexity, compress timelines and control costs

Why smarter, faster, better matters now

Neuroscience clinical trials play a pivotal role in addressing complex neurological conditions that profoundly affect human health and quality of life. Characterized by high complexity protocols, these diseases create inherent challenges for clinical trials, including subjective endpoints, difficulty in measuring disease progression, disease heterogeneity and high patient screening failure rates.

Such challenges often translate to delays. According to GlobalData's Clinical Trials database, 38% of the 610 neurodegenerative disease trials started between January 2023 and August 2025 recorded a delay in their start or end date—13% higher than the industry average of 25% across the same period.[1]

For patients awaiting new therapies, delays can mean deteriorating health due to the absence of effective treatments. For sponsors, prolonged trials incur extra costs, such as additional patient recruitment efforts, extended site management and increased operational expenses. The high-risk nature of neuroscience research, linked to the high failure rates of clinical trials in this area, creates a challenging environment for pharma, and especially biotech's, to navigate.

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AI as a strategic tool

Artificial intelligence (AI) could be a powerful lever to reduce these costly delays, bringing unprecedented precision, efficiency and insights to a complex research domain.

Clare Campbell-Cooper is Global Head of Digital Health and Innovation at Fortrea, a contract research organization (CRO) that collaborates with biotech and large pharma to drive healthcare innovation. Campbell-Cooper describes AI as having the potential to be transformative, emphasizing AI's capabilities to identify risks, analyze predictions and track trends via real-time monitoring.

She says: "With technological advancements using AI, subjective data can be strengthened with objective data collected and reported in near-real time, which is critical in neurological research where protocol requirements and assessments are often complex and variable."

Deployed responsibly, AI is a strategic, and at times practical, tool which can enhance clinical trial processes. In this whitepaper, we explore how such tools are now beginning to support neuroscience sponsors in navigating this complex and high-risk field with intelligence—smarter, faster and better.

- **Smarter:** AI enables leaner operations, letting scientists focus on science. It could also help neurologists identify complex disease progression patterns, select biomarkers and target patients more effectively
- **Faster:** AI has the potential to significantly accelerate neuroscience trials through faster patient screening and real-time monitoring, helping sponsors avoid delays with proactive decision-making
- **Better:** AI improves data integrity, reduces errors, and lowers the risk of protocol amendments. AI-driven improvements also reduce costs, helping sponsors do more with less

Using this smarter, faster, better framework, this whitepaper draws on real-world examples that illustrate how AI is transforming neuroscience clinical trials, from streamlining protocol design and regulatory documentation to enhancing patient recruitment in pain studies and improving assessment accuracy in Parkinson's disease. We reveal how pharma can harness AI to overcome bottlenecks and reduce costs while bringing therapies to patients faster.

1. Smarter: Driving operational efficiency with AI

AI can help design leaner, more targeted protocols

Joanie Brown, Head of Operations, Rapid Development AI/ML Studio at Fortrea, says that AI tools have great potential in sifting through documents and generating subsequent reviews, synthesis and related forms. For instance, AI tools can be leveraged to conduct full and rapid literature reviews, as they are capable of scanning, selecting, analyzing and synthesizing external data sources in around an hour,[2] compared to previously spending weeks on the process.

Moreover, once a protocol has been designed, AI tools can suggest modifications and improvements upfront, anticipating potential challenges in advance based on historical trial outcomes. Following that, AI platforms can generate all associated documents, like consent forms and regulatory paperwork, reducing manual work and ensuring consistency.

"AI excels because it's too much data for one individual or team to process," Brown says. "The aim is to focus people on the right action that needs to be taken when AI has done the synthesis. For me, this is the most exciting possibility in AI's application in clinical trials."

Using AI to identify previously overlooked trial candidates

Neuroscience trials often face recruitment challenges due to complex eligibility criteria, limited patient pools and oversaturated sites, but AI can help identify niche patient populations and match them to capable sites. AI is already using electronic medical records (EMRs) to transform patient identification,[3] with vendors now able to analyze data and accurately identify suitable patients based on protocol inclusion/exclusion criteria.

Crucially, AI represents a promising solution to the significant challenges of patient identification in rare neurological diseases, offering hope for more comprehensive and precise research approaches.

Leone Atkinson, MD PhD, Executive Medical Director, who previously led Fortrea's Rare Disease, Advanced Therapies and Pediatrics Team and is now Therapeutic Strategic Leader for Neuroscience at Fortrea, highlights the potential for AI to support rare disease research by uncovering patients who might have been previously overlooked. Dr. Atkinson says that AI has the potential to analyze large patient data sets or medical records and "find those needles in a haystack."

"Awareness, together with lack of data for most rare diseases," she says, "makes appropriate diagnosis and subsequent identification particularly difficult." Her vision is to use AI to create new pathways to support more timely diagnosis and patient identification, especially in neurological conditions where diagnosis can be complex and is often markedly delayed.

Rare neurological conditions such as different types of muscular dystrophies and neurodevelopmental disorders are potential areas where AI could make significant breakthroughs by uncovering patient populations that might otherwise remain hidden, including those who may have been overlooked or misdiagnosed.

Predictive analytics can choose high-performing sites faster and more accurately

AI can play a pivotal role in enhancing site selection decision-making processes, utilizing a variety of data sources to identify high-performing trial sites based on critical factors such as patient availability, investigator experience and historical enrollment rates. AI tools are also adept at conducting geospatial

analysis, which involve mapping patient populations and aligning them with site capabilities, ensuring that trials can reach a diverse range of participants and improving the representativeness of the findings.

For example, Fortrea is leveraging its own extensive historical trial data to develop an advanced "intelligence engine" that will transform its site selection methods through predictive analytics, creating a more dynamic, data-driven approach. The core strategy involves using machine learning models to analyze complex factors that influence site performance, going far beyond simple demographic matching. Drawing on years of experience in both healthcare, clinical and technology settings, the company's modeling team focuses on understanding nuanced patterns in patient enrollment and site productivity.

Importantly, predictive models can anticipate challenges before they emerge, allowing clinical teams to make faster, more informed decisions about site selection and resource allocation.[4] This approach enables sponsors to pivot quickly, suggesting replacement sites or reallocating resources with unprecedented speed and accuracy.

Case scenario:

Parkinson's trials requiring complex, multi-modal endpoint assessment across motor and non-motor symptoms

Challenge:

- Traditional Parkinson's assessments such as UPDRS and MDS-UPDRS are episodic, subjective and miss fluctuations in symptoms throughout the day
- Combining motor assessments with cognitive testing and imaging biomarkers creates logistical complexity, high costs and patient burden that can impact recruitment and retention

Current solutions (and where they fall short):

- Standardized rating scales, centralized imaging analysis, periodic clinic visits for motor assessment and paper-based cognitive testing
- Most trials rely on snapshot assessments that may not capture true disease progression or treatment effects

Innovation opportunities:

- **More data, better decisions:** With wearable sensors now providing continuous motor monitoring,[5] machine learning algorithms can detect subtle changes in gait, tremor and cognitive function that predict disease progression months before traditional scales. Automated imaging analysis is also becoming possible, with AI-powered analytics being used to quantify brain atrophy and structural changes from MRI scans,[6] providing objective biomarkers that correlate with clinical progression
- **Empowering Parkinson's patients:** Wearables also allow patients to understand more about their disease and take ownership. As the older generation becomes increasingly digitally enabled, it's time to start challenging current perceptions and making sure trials aren't excluding patient populations who can benefit from these technologies

Implications for sponsors:

- Sponsors gain access to sensitive, continuous biomarkers that can detect treatment effects earlier and with smaller patient populations. This enables shorter proof-of-concept studies, more precise dose selection and the ability to identify optimal patient subgroups for pivotal trials
- With a wealth of vendors and wearables now being discussed for Parkinson's, identifying and finding the right technologies can be difficult. Fortrea can support you with deeply understanding these vendors' capabilities, expectations and regulatory matches

2. Faster: Compressing timelines without compromising quality

AI models that predict trial risks and delays before they happen

The identification and mitigation of risks through AI models could be a game-changer for accelerating trial delivery in neuroscience. By collecting both structured and unstructured data from diverse sources, including trial registries, digital health records and databases from CROs and sponsors, machine learning models can be trained on historical trial outcomes, enabling better prediction of enrollment rates, as well as the risks of screening failures and participant dropouts.

AI can model different trial designs, geographies and timelines to evaluate feasibility under various conditions and predict the probability of success. AI models have the potential to offer improved accuracy in enrollment predictions compared to traditional methods. They could also facilitate early identification of feasibility risks, which allows for proactive strategies such as adding backup sites.

Reducing enrollment time

The use of adaptive digital questionnaires represents a significant innovation in the screening process for conditions like multiple sclerosis (MS). These AI-powered tools adjust the flow of questions based on individual patient responses. For instance, if a MS patient indicates they do not experience certain symptoms, the questionnaire can skip irrelevant questions, thereby making the screening process

quicker and less burdensome for patients. This not only helps in quickly identifying eligible participants but also improves patient engagement and satisfaction.

Richard Gambie, a senior delivery director for neuroscience studies at Fortrea comments: "In the current era, the need for medical data review in near real-time can be a game changer for accelerating early-stage clinical research for neurological conditions like MS. Yet the burden on participants to complete long validated questionnaires can be cumbersome and time-consuming. I would always advise clients to approach digital questionnaires regardless of a study population's age range, as improvements in screen design and AI use enhance usability, alongside informative recruitment material, will gain greater compliance and deliver clearer outcomes."

Studies have shown that AI-assisted screening can dramatically speed up enrollment in clinical trials. Considering enrollment periods for Phase III neurodegenerative disease trials have taken an average of 24.8 months since January 2015, according to GlobalData's Clinical Trials Database Enrollment Module, there is substantial room for improvement here.[7]

Case scenario:

Chronic pain trials with unpredictable and high placebo response rates

Challenge:

- Placebo response in clinical trials can reach 50% and exceed 70% of the overall analgesic effect in some pain clinical trials,[8] masking true treatment effects and leading to failed studies
- Preferential placebo response (when patients show a higher response than normal to placebo but not the active treatment) can be particularly harmful
- Traditional patient-reported outcome measures are subjective and influenced by psychological factors or life events, site effects and patient expectations that are difficult to predict or control
- Pain tolerance differs between every patient
- Subjective questionnaire data lacks routine error control and traditional monitoring cannot tackle deeper measurement errors that contribute to placebo response

Current solutions (and where they fall short):

- Protocol design elements such as placebo run-in periods and efforts to recruit "non-placebo responders" are costly, wasteful and have not been shown to be effective in general
- Standardized pain scales (e.g., VAS, NRS) and centralized pain assessment training and verification processes have been implemented, but many trials still struggle with site-to-site variability in placebo response rates
- Central statistical monitoring (CSM) supports the detection of data quality issues which contribute to inflated placebo responses
- Greater incorporation of electronic formats would facilitate better review, with potential to combine with wearables, real-time platforms and other tools
- Ultimately, more precision is needed. By reducing noise from poor reporters and placebo responders, assay sensitivity can be improved
- Data should be collected in real-time (i.e., ecological momentary assessment or EMA), since recall introduces bias

Innovation opportunities:

- **Faster data:** Pertinent and timely data collection using EMA ensures more accurate data collection and tracking of pain. Meanwhile, AI could be used to better identify trends in large data sets, potentially enabling faster decision-making
- **Blinded monitoring:** AI can provide real-time data monitoring in a blinded fashion, helping to appropriately encourage patient compliance and adherence to protocol-defined data collection

Implications for sponsors:

- Sponsors can improve trial success rates through better patient stratification, reduced screen failure rates and more efficient and adaptive trial designs. This leads to smaller, more predictive studies that deliver cleaner efficacy signals and faster regulatory pathways
- With AI-powered analysis, the risks of unblinding and jeopardizing data integrity are minimized, with algorithms providing blinded analytical output to facilitate human decision-making and judgement

Adaptive trial management powered by machine learning

Real-time monitoring is a transformative approach to clinical trial management powered by machine learning and AI. Fortrea's Xcellerate® suite of data-enabled technology solutions[9] provides dynamic insights designed to help clinical studies succeed and represents the cutting edge of this technology, moving from traditional"descriptive" data analysis to "predictive and prescriptive" approaches. The AI-powered system continuously monitors trial data in real-time, providing immediate insights that would take humans months to recognize.

Key capabilities include identifying potential risks, tracking trends, detecting inconsistent site performance and flagging potential patient recruitment issues. The system aims to provide actionable intelligence, not only telling researchers what is happening but what actions they should take in response.

While still in its early-stage development, the more data that is entered, the more accurate the model becomes, creating a dynamic system that continuously improves its predictive capabilities. The goal is to enhance data integrity, reduce query resolution time and accelerate processes.

3. Better: Controlling costs and maximizing ROI

AI tools that model cost scenarios and optimize resource allocation

AI-powered budget forecasting represents an emerging capability that could transform how clinical trials are financially managed, offering more precise, proactive insights into potential costs and resource needs.[10]

AI's ability to quickly analyze complex datasets helps forecast costs more accurately and efficiently by identifying trends and potential risks in real-time. While such capabilities are still in the early stages, this approach utilizes AI to provide more intelligent and proactive financial management for trials. By leveraging the transformation of descriptive data insights to prescriptive data insights, the goal is to move from traditional retrospective cost analysis to a more dynamic, predictive model, potentially preventing budget overruns before they occur.

Joanie Brown explains that the company's approach involves building models that can dynamically adjust resource planning based on real-time trial data. For example, Fortrea created a model that proactively suggested moving forward a clinical research associate (CRA) visit if data shows increasing backlogs, protocol deviations or adverse events.

On-site clinical monitoring typically represents about 30% of the budget for large, global trials,[11] so improving resource allocation can significantly impact overall trial margins. The aim is to move from reactive to proactive resource management, using AI to analyze trends and recommend strategic adjustments that can reduce costs, minimize protocol deviations and ultimately accelerate trial delivery.

Case scenario:

Multiple sclerosis trials struggling with EDSS assessment variability and training burden

Challenge:

- Common primary endpoints in MS trials include relapse rates and disability progression, both measured by the Expanded Disability Status Scale (EDSS)
- EDSS assessments are both subjective and complex, requiring an extensive rater training and certification process which traditionally takes months
- Inter-rater variability can reach 17%,[12] creating noise in endpoint data and requiring larger sample sizes
- **Inter-rater drift:** A single rater's scoring may change over time due to fatigue, evolving interpretation or lack of reinforcement training
- Multinational trials face challenges in ensuring raters interpret and apply scales uniformly across languages and cultures
- Traditional training methods don't provide immediate correction or guidance, delaying improvement

Current solutions (and where they fall short):

- Manual training programs with video-based training modules, followed by centralized rater certification and periodic recalibration sessions. Most trials still rely on in-person assessment with paper-based scoring
- EDSS education and trials are now increasingly being done electronically, enabling quick feedback via programmed edit checks. However, timely education on "why the error occurred" is not yet feasible and is still dependent upon a specialist's manual review

Innovation opportunities:

- **AI in EDDS education:** Interactive simulation training modules could improve and objectively manage expectations, with real-time feedback that explains why an error occurred. This also enables remote and scalable training—important for global, multi-site and multi-national trials
- **Reducing variability:** AI could markedly reduce the subjectivity of rater assessments by identifying out of range scores or scores inconsistent with prior scoring of other areas—similar to current practice, only faster and potentially more accurately. There could also be a future where AI-powered EDSS assessment platforms use computer vision and machine learning to analyze video or audio recordings of patient assessments to detect scoring inconsistencies; however, with much of the neurological exam involving sensory and strength assessments, and patient privacy concerns, this potential application may be a way off
- **Wearables in EDSS:** Incorporating wearables and sensors to enable real-time analysis of gait patterns, motor function and cognitive responses can help augment EDSS interpretation and understanding of clinical meaningfulness. This could also reduce inter-rater variability

Implications for sponsors:

- Sponsors benefit from improved statistical power through enhanced measurement precision
- Improved precision could reduce required sample sizes significantly, cutting assessment costs while improving data quality
- Using AI in EDSS training could accelerate site activation by eliminating lengthy rater training requirements

Reducing protocol amendments

Using AI in protocol design could help researchers avoid costly changes further down the line. Reducing protocol amendments is a critical performance indicator for CROs like Fortrea, and AI offers powerful tools to achieve this goal. By leveraging historical data and advanced predictive analytics, AI can create more robust protocols that anticipate potential challenges before they emerge.

By using machine learning to predict potential limitations, researchers can build more intelligent protocols that are less likely to require costly mid-trial changes, with each protocol amendment costing sponsors an average of $535,000 in a Phase III trial.[13] This not only reduces administrative burden but also minimizes disruptions to trial timelines and patient experiences.

Avoiding underperforming sites, helping sponsors do more with less

According to **Sheri Mersch**, Senior Delivery Director for neuroscience at Fortrea, the effects of underperforming sites can be detrimental in neuroscience trials, which require extensive site-level support from CROs to manage study data integrity on critical endpoint assessments. She notes this is largely due to the complexity involved in collecting subjective questionnaire data from participants, managing digital tools and motion sensors and maintaining consistent rater training and performance.

"Whether in early Phase Ib/II or larger Phase III trials, complex neurological studies demand strong site-level support from both the CRO and sponsor," she says. "Upholding data integrity of endpoints driven by subjective data capture, digital tools, motion sensors and rater consistency is vital to achieving a successful study outcome. The quality and performance at a site can fail with just the loss of one critical site coordinator, so it is highly important for the CRO to pressure test this at multiple stages during site selection and start-up to make sure the right strategy is in place to deliver on a sponsor's recruitment goals."

By using AI to analyze complex factors beyond traditional site selection metrics, as discussed earlier in this paper, sponsors and CROs can avoid underperforming sites and do more with less, optimizing resources and maximizing the potential of each clinical trial site. As the trial progresses, they can use AI within a sophisticated, data-driven approach to maximizing trial efficiency which might involve tracking nuanced performance indicators like patient enrollment patterns, Principal Investigator (PI) stability and historical recruitment challenges.

When potential performance issues emerge, such as a PI departure or declining enrollment rates, the system can rapidly suggest alternative sites with matching demographic characteristics. By quickly detecting and responding to potential performance issues, sponsors can maintain trial momentum and reduce costly delays.

Navigating complexity: Why many sponsors still hesitate

While Artificial Intelligence is already transforming the future landscape of neuroscience clinical trials, many sponsors are struggling to navigate the complexity.

One key barrier is the intricate ecosystem of existing research tools and data ownership constraints, with researchers often navigating complex sharing restrictions. Additionally, neuroscience trials involve subjective endpoints and complex patient assessments, with sponsors often fearing making missteps in such a sensitive research environment.

Challenges also remain in data access, regulatory compliance and ensuring ethical implementation. While AI shows significant promise, it should be viewed as a complementary tool to human expertise, not a replacement for clinical judgement.

In terms of advice for biotech teams, Fortrea's **Campbell-Cooper** recommends several strategies. Early engagement is crucial, she says, as is an open dialogue regarding appropriate applications. She encourages collaborations with external parties who implement AI effectively and responsibly, noting that successful adoption requires a careful, collaborative approach that prioritizes research quality and patient outcomes. Ultimately, we see that sponsors want to work closely with companies who can strategically collaborate with them to meet their business goals and make individual studies successful. Considered implementation of AI and technology is more widely accepted than pushing technology for its own sake, which is detrimental to all interested parties, she says.

Digital innovation with neuroscience in mind

In the rapidly evolving landscape of neuroscience research, Fortrea is transforming the complexity of AI into actionable clinical insights. As a leading CRO with deep experience in central nervous system (CNS) trials, Fortrea is on a journey to redefine how innovative technologies can accelerate therapeutic development.

With a robust cross-functional team that combines decades of neuroscience clinical research experience and cutting-edge technological understanding, Fortrea has positioned itself as a trusted navigator in the AI-driven clinical research ecosystem. The company's strategy involves carefully curating a broad bank of validated external vendors, ensuring it can leverage the most sophisticated and reliable AI technologies available, while simultaneously building its own tools where appropriate.

With a proven track record in neuroscience research spanning critical areas like protocol design, patient recruitment and site strategy, Fortrea has demonstrated a comprehensive approach to clinical trial optimization. Now, by developing sophisticated 'intelligence engines' that can predict site performance, streamline protocol development and optimize resource allocation, Fortrea is not just adapting to technological change but actively shaping the future of clinical research. This patient-centric philosophy positions Fortrea as a transformative force in translating AI's complex potential into tangible clinical progress which will benefit patients.

Leone Atkinson explains that what makes Fortrea's approach to innovation in CNS trials distinct from other CROs or vendors in the space is its legacy of excellence that spans over 30 years, tracing back to its origins with Covance Inc., one of the pioneering CROs in the industry. "This deep heritage gives us a comprehensive understanding of the drug development lifecycle, from early-stage research and laboratory testing to diagnostics, patient care and market access strategies," she says.

Dr. Atkinson continues: "What truly sets us apart is our ability to combine this extensive experience with the agility of a focused, right-sized organization. We are nimble enough to implement tailored innovations quickly and effectively, adapting to the unique needs of each study. Our teams bring deep therapeutic experience and a proactive mindset, embracing operational challenges and consistently seeking smarter, more efficient ways to advance CNS drug development."

Fortrea's message is clear: Don't wait on the sidelines—sponsors should be proactive in exploring AI's potential. By collaborating with innovative organizations like Fortrea, sponsors can accelerate their neuroscience research, improve patient outcomes and stay at the forefront of medical innovation.

Talk to Fortrea about how we can help you run smarter, faster and more cost-effective neuroscience trials.

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