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WORLD ECONOMIC FORUM

Intelligent Clinical Trials: Using Generative AI to Fast-Track Therapeutic Innovations

WHITE PAPER

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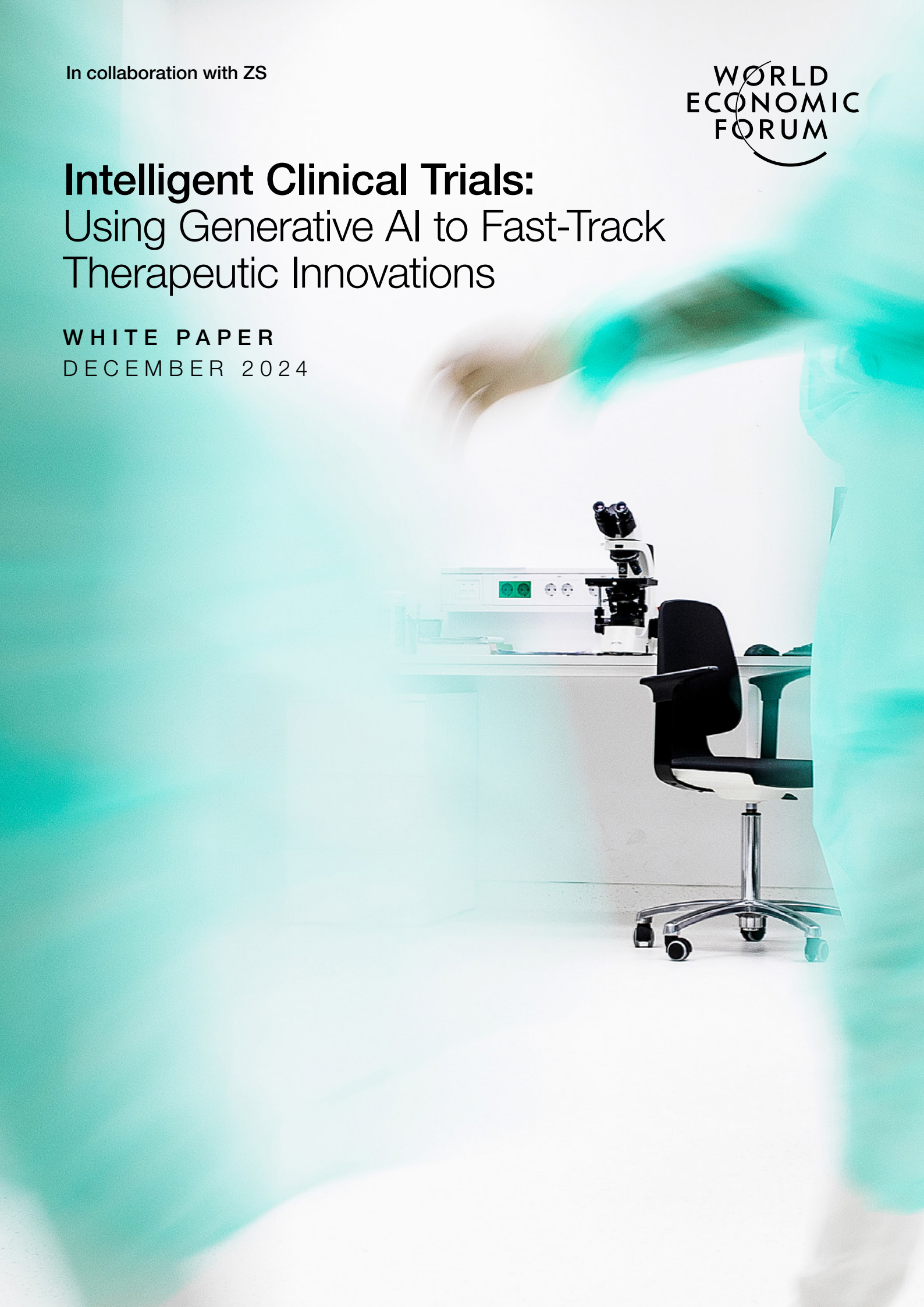

Images: Getty Images

Contents

Foreword

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Artificial intelligence (AI) promises to have a transformative impact on healthcare – improving patient outcomes and supporting the broader healthcare system and industry by reducing costs and overcoming geographic and logistical barriers as it brings care where it is needed most.

Since 2023, the World Economic Forum and ZS have collaborated to publish two reports on the impact of AI on global health and healthcare: Scaling Smart Solutions with AI in Health: Unlocking Impact on High-Potential Use Cases (June 2023) looked at the potential of AI to overcome the global shortage of healthcare workers, widening health disparities and unsustainable healthcare spending; Patient-First Health with Generative AI: Reshaping the Care Experience (January 2024) examined generative AI's potential to empower patients and alleviate health system burdens.

This white paper looks at the perennial challenge of efficiently shepherding experimental drugs through clinical trials. While testing new drugs in humans to evaluate their safety and efficacy has always been a complex and arduous process, the growing sophistication of trials has led to lengthening timelines, mounting costs and increasing failure rates. The result is drugs that take longer to get to patients and cost more when they do.

Generative AI (Gen AI) offers the opportunity to reverse this trend by helping clinical development teams design smarter trials and bring new efficiencies throughout the clinical trial life cycle. Drawing on interviews with leaders spanning the life sciences, tech, government and non-governmental organizations (NGOs), this paper not only examines Gen AI's promise to revolutionize clinical development and erode the barriers that stand in the way, but also considers how stakeholders throughout healthcare can mobilize to overcome these barriers.

Executive summary

Generative AI promises to help bring therapeutic innovation to patients more quickly – and to reduce the costs.

Stakeholders throughout the life sciences field and beyond have struggled for decades to bring new therapies to patients faster and at lower cost. Inefficiencies in clinical development are the primary obstacle, and despite sustained focus and investment from the healthcare industry, the problem has only intensified.

- **Up to 12 years in development:** It takes eight years on average for non-oncology treatments to move through clinical development – and nearly 12 for oncology treatments.[1]

- **$2.5 billion in costs:** Meanwhile, the average cost of bringing a new treatment to market exceeds $2.5 billion,[2] and clinical trials account for roughly 40%[3] of the total research budget for US pharmaceutical companies.

- **90% failure rate:** Despite the implementation of multiple strategies to overcome the possible reasons for development failure, the success rate of clinical drug development remains at 10–15%.[4] Even so, roughly 75% of clinical development drugs[5] do not address the needs of historically underserved groups, denying these patients access to experimental treatments and producing therapies with differential efficacy.

Gen AI is already being used to revolutionize drug discovery. While this is vital work, clinical development bottlenecks are the bigger impediment to therapeutic innovation.

In interviews, clinical development leaders throughout the pharmaceutical industry, tech sector, NGOs and more stated their belief that Gen AI will also revolutionize clinical development. It will do this by enabling new forms of trials, such as decentralized clinical trials (DCTs), and improving existing forms through integrating new data streams, including from real-world evidence (RWE). While DCTs have shown promise in expanding trial participation, reducing patient burden and improving trial efficiency, their complexity has so far hindered widespread adoption.

With smart investments and an enabling environment, Gen AI can help development teams optimize trial design, improve trial feasibility and site selection, overhaul clinical operations, automate data analysis and speed up and error-proof regulatory submissions. Beyond transforming traditional trials, Gen AI also opens the door to entirely new approaches to clinical research built on real-time RWE, adaptive designs and continuous learning.

A ZS analysis found that a typical top-10 pharma company would realize cost savings of more than $1 billion over five years just from implementing AI-driven trial design and decentralized trial execution. The cost and time savings will be even higher when companies infuse AI across the entire clinical development process.

There are obstacles to making this a reality, however: a fragmented data ecosystem; insufficient data standards and infrastructure; a lack of system-wide incentives for data sharing; industry inertia; a murky regulatory environment; and skill gaps. This white paper calls on policy-makers, life sciences professionals and others to unite around the cause of using the power of Gen AI to improve clinical development.

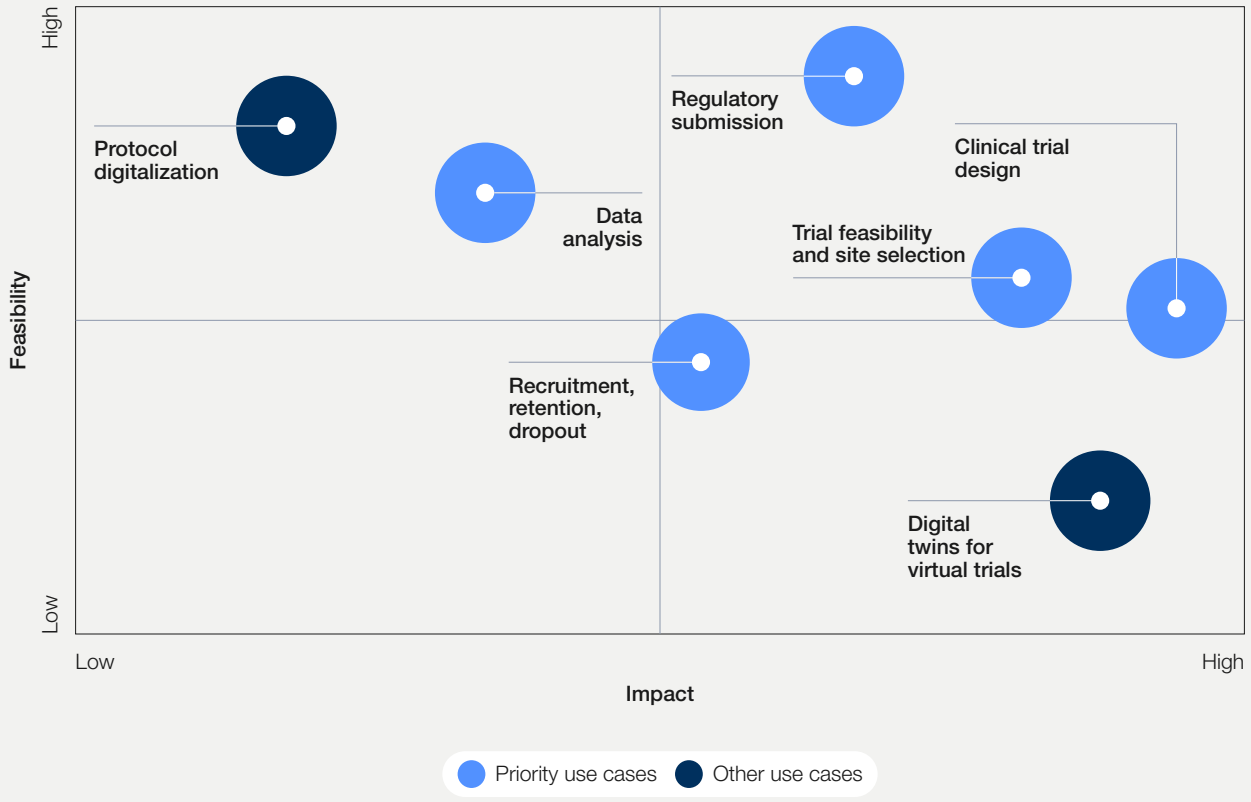
1 How Gen AI will transform clinical development

Five clinical development processes are ripe for transformation thanks to Gen AI.

Advancing experimental therapies through clinical trials is an arduous process. Clinical development leaders interviewed by the World Economic Forum and ZS identified seven core development processes as ripe for transformation.

They singled out five as being the most feasible today and as offering the highest potential impact on development cost, duration and probability of success (Figure 1).

FIGURE 1 | **A use-case prioritization framework for Gen AI in clinical development**



Note: List is not exhaustive.

Source: ZS analysis

Interviewees placed the five development processes into three prioritization groups:

- **The Holy Grail – clinical trial design:** Optimizing clinical trial design using Gen AI can cut clinical development time and costs significantly. Measuring return on investment (ROI), however, will be challenging, given the impracticality of running comparator trials – with one based on traditional methods and another designed using predictive AI. Feasibility is further challenged by the fact that trial design is the most complex and interconnected use case, necessitating intricate decision-making processes.

- **The low-hanging fruit – regulatory submission:** Writing regulatory submissions has traditionally been a manual process, lasting weeks to months and requiring hundreds to thousands of hours throughout the clinical development cycle.[6] Automating this process can save a significant amount of time and money. Accuracy will be paramount, so the model will need to be tuned correctly.

- **Evolution, not revolution – patient recruitment, retention and dropout prevention; data analysis; and clinical operations:** Predictive AI has already brought heightened efficiency to trial feasibility, site selection, clinical operations and data analysis. Gen AI will amplify traditional algorithms, marking a step forward in sophistication rather than a disruptive revolution.

Interview subjects identified regulatory submission and clinical trial design as the best places to start. These use cases represent a mixture of a quick pay-off (regulatory submission) and high return on investment (clinical trial design). But to realize AI and Gen AI's full potential for revolutionizing clinical development, pharmaceutical companies must evolve all five phases.

1 The Holy Grail: Clinical trial design

Feasibility
Medium

Impact
High

Time horizon
Long (5+ years)

Barriers
Lack of infrastructure and standards for data sharing and data quality. Lack of incentives for data sharing and ecosystem collaboration. Bias towards "tried-and-true" methods over untested approaches.

Biggest unlock
Collaboration throughout the healthcare ecosystem to align on AI's role in clinical trial protocol design and change behaviours.

Trial design today
Trial protocols outline a study's objectives, design, methodology, inclusion and exclusion criteria, clinical end points, statistical considerations, execution plan and more. They do more than anything else to dictate a trial's success or failure.

Today, the design process is complex, slowed by manual workflows and reliant on historical data and subjectivity. The result: suboptimal trial designs that drive long cycle times, high development costs and increased probability of failure.

Roughly 60% of trial protocols require at least one amendment,[7] nearly half of which are considered "avoidable". Avoidable amendments cost pharmaceutical companies $2 billion per year[8] in direct costs, with amendments adding an average of 260 days to development timelines.[9] These costs are passed on to patients and payers, while patients wait longer for innovative therapies. Meanwhile, clinical research teams spend as much as 30% of their time[10] on conducting trials, with some labour-intensive tasks accounting for 25% of clinical trial budgets.[11]

Trial design enhanced by Gen AI
In the future, teams will use Gen AI to mine unstructured data from prior protocols and previous trial results, real-world data (RWD), regulatory precedence and guidance, patient and site feedback and more. They will use this to develop trial concepts and plans, design key statistical elements, optimize protocols and simulate scenarios to aid design decisions. In time, trial teams will use Gen AI to create digital and surrogate end points, synthetic control arms and in silico trials (which will be conducted through computer simulation only). Gen AI will unlock greater predictive power using unstructured data and will streamline trial design and protocol drafting by automating traditionally manual processes. Doing so will reduce errors, eliminate redundant work, relieve the administrative burden and accelerate trial initiation.

> **On clinical trial design, AI could help by analysing inclusion and exclusion criteria from similar studies, predicting patient profiles and ensuring that the criteria are practical. This could prevent issues where the designed trial doesn't match the available patient population, thus requiring amendments and wasting time.**
>
> Gavin Corcoran, Chief Development Officer, Formation Bio

USE CASE

Insilico Medicine

US-based biotech company Insilico Medicine has developed inClinico,[12] an AI platform designed to predict clinical trial outcomes, and has partnered with multiple pharmaceutical companies to enhance drug development efficiency. inClinico uses multimodal data – including omics, text, trial design parameters and small-molecule properties – to predict the success or failure of phase 2 clinical trials. To validate its model, inClinico predicted the outcomes of phase 2 clinical assets with roughly 80% accuracy. Forecasting clinical trial outcomes with this degree of accuracy can help drug companies prioritize the therapeutic programmes most likely to succeed and optimize investment decisions, thereby reducing the costs associated with failed trials and improving the efficiency of pharmaceutical research and development (R&D).

2 Evolution, not revolution: Trial feasibility and site selection

Feasibility
Medium

Impact
High

Time horizon
Medium (2–4 years)

Barriers
Fragmentation of health data and lack of standardized data and data-sharing practices. Regulatory requirements concerning patient data privacy and security. Frequency of protocol amendments caused by suboptimal protocol design.

Biggest unlock
Collaborative efforts to develop robust data integration standards and enhanced regulatory frameworks. Optimization of the trial design process resulting in fewer protocol amendments.

Trial feasibility and site selection today
The growing complexity of clinical trials has made it increasingly difficult to evaluate trial feasibility. Slower-than-expected patient enrolment is an ever-present challenge, typically taking 1.8 times longer than planned,[13] with enrolment shortfalls affecting roughly 85% of clinical trials. Each day that a trial extends beyond its patient enrolment deadline translates to between $600,000 and $8 million[14] of missed market opportunity.

Today, evaluating trial feasibility and selecting trial sites is an ad hoc process dependent on limited data. Sites are chosen based on past experiences with trial sites, using metrics such as site capacity and historical enrolment rates. This often overlooks site characteristics with a stronger correlation to suitability, such as local patient demographics, disease prevalence and trial-specific site capabilities. Incomplete site profiles, data siloing and lack of real-time access to data complicate efforts to make data-driven selection decisions, resulting in under-enrolment, costly delays and unreliable feasibility decisions.

Trial feasibility and site selection enhanced with Gen AI
Gen AI can analyse unstructured data, including operational data from past trials alongside real-time RWD, to feed models that predict future outcomes and inform site selection and feasibility planning. By pairing Gen AI with predictive AI, trial planners will be able to accurately predict sites' patient recruitment potential; suggest optimal sites based on up-to-date, multidimensional data; and anticipate recruitment challenges in advance. Gen AI will also enable site planners to simulate scenarios to explore various site configurations and their expected patient recruitment and retention outcomes. In addition, Gen AI can enable decentralized trials, a key industry initiative to make trials more patient-centric, by managing the logistics of using more sites and trial investigators.

> **For trial design, operations and site selection, there is a lot of promise … especially where natural language data can be structured and analysed.**
>
> Andrew Giessel, Executive Director of Artificial Intelligence Engineering, Moderna

USE CASE

Amgen

Amgen, a US-based biotech, has developed an AI-driven tool it calls the Analytical Trial Optimization Module (ATOMIC).[15] It is designed to enhance the efficiency of clinical trial site selection by pairing classical and Gen AI to analyse large structured and unstructured datasets to identify those trial sites most likely to meet participant enrolment goals. By ranking sites based on predicted enrolment rates and other key factors, ATOMIC helps optimize trial design, reduce trial duration and increase the probability of trial success.

3 Evolution, not revolution: Clinical operations, specifically patient recruitment and retention

Feasibility
Medium

Impact
Medium

Time horizon
Medium (2–4 years)

Barriers
Recruitment methods that are slow, inefficient and not designed for trials for which inclusion criteria are narrow and eligible patients are hard to recruit. High site burden leads to inconsistent site performance, low motivation and poor patient experiences.

Biggest unlock
Streamlining the recruitment process by automating recruitment and consent form completion. Alleviating site burden via automation. Increased site performance transparency. Personalizing communications using Gen AI to tailor messaging and predictive AI to identify the ideal channel.

Clinical operations today
Recruitment efforts rely largely on traditional methods such as physician referrals, patient registries and site-driven outreach, all of which are time-consuming and suboptimal for reaching diverse patient populations. Retention strategies involve periodic check-ins, reminders and incentives, but they often fail to engage participants throughout trials.

Although digital end points are helping to address participant burden (e.g. time commitments, disruption to daily life, financial impact), dropouts remain commonplace, driven not only by participant burden but also by poor communication and logistical hurdles that complicate site visits. Participant engagement is reactive and one-size-fits-all, making limited use of predictive tools to identify patients at risk of dropout or tailoring engagement strategies to mitigate risk. Site burden remains a major pain point.

Clinical operations enhanced with generative AI
In the future, clinical trial teams will use Gen AI-driven tools to analyse diverse data sources – such as electronic health records (EHRs), insurance claims and even data from patient advocacy groups – to reach a more diverse participant pool. This unstructured data will be used to feed predictive models that assess the likelihood of participant dropout and suggest tailored next-best actions to improve participant experience – in essence creating personalized "marketing plans" to keep participants engaged and enrolled.

> **Sometimes people cite how only 3% of patients participate in clinical trials. But why? Because their doctors don't want to participate. Administrative overhead is quite high, and the regulated nature of clinical trials can be an order of magnitude more burdensome to sites than care delivery. The more we can simplify what physicians and their teams need to do, the more we can augment the supply and footprint of potential trial sites.**
>
> Henry Wei, Head of Development Innovation, Regeneron

USE CASE

Mass General Brigham

Researchers at Mass General Brigham have demonstrated[16] how Gen AI can be used to significantly accelerate patient screening for clinical trials without sacrificing accuracy. In the COPILOT-HF study, a tailored Gen AI application used EHRs to screen for heart failure patients eligible for a trial. The application identified patients with 100% accuracy, outperforming traditional manual methods in both speed and accuracy. The tool reduced the patient screening cost to just $0.11 per patient. While the potential for streamlining patient identification and recruitment is clear, researchers stress the need for safeguards to prevent bias, protect privacy and ensure accuracy.

4 Evolution, not revolution: Data analysis

Feasibility
High

Impact
Low to medium

Time horizon
Medium (2–4 years)

Barriers
Integrating and cleaning data from multiple sources and in multiple formats, while ensuring data security and privacy. Complex data analysis is not fast enough to inform real-time decision-making. Statistical programming for custom analyses is complex, time-consuming and error-prone.

Biggest unlock
Automated systems for collecting, cleaning and processing sensitive health data. Automated code generation tools that integrate with existing statistical analysis workflows and software.

Data analysis for clinical trials today
Given the increasingly sophisticated methods for collecting trial data, development teams face growing challenges related to data quality and standardization. Data analysis relies on time-intensive processes and analytical methods that, while not entirely manual, still demand substantial time and specialized expertise. Data analysts typically work with fragmented data sources, including EHRs, lab results and patient-reported outcomes, which are often not easily integrated. This necessitates extensive data cleaning, transformation and validation before meaningful analysis can begin. Coding tasks, such as writing scripts for data processing and statistical analysis, are also partly manual, making them time-consuming, costly and prone to human error.

Data analysis for clinical trials enhanced with Gen AI
Gen AI can serve as a co-pilot in data analysis by automating routine tasks, such as writing code and generating tables for submission. Gen AI can also help unlock insights throughout the development life cycle. Co-pilots can integrate data from disparate sources – patient engagement data from chatbots and mobile apps as well as sensor data from wearables – clean it and prepare it for analysis significantly faster than programmers using predictive AI methods, reducing the time between data collection and informed decision-making.

> **In terms of statistical analysis, AI can help optimize clinical trial designs and statistical power – for instance, in randomized clinical trials – by using covariate adjustments and other techniques to reduce noise and improve the design without altering the trial itself.**
>
> Eric Durand, Chief Data Science Officer, Owkin

USE CASE

Eisai and Medidata

Global pharmaceutical company Eisai recently teamed up with Medidata to implement Medidata Clinical Data Studio,[17] an AI-powered platform designed to optimize the management and analysis of clinical trial data. By integrating multiple data sources, both internal and external, Clinical Data Studio breaks down traditional data silos and accelerates data review by up to 80%. This enhanced data control enables Eisai to scale the complexity of its clinical trials while maintaining high data quality and integrity. With streamlined data import and automatic validation capabilities, the platform offers a comprehensive, real-time view of patient data, enabling faster, more accurate decision-making.

This innovative approach helps pharmaceutical companies such as Eisai execute complex clinical trials more efficiently.

5 Low-hanging fruit: Regulatory submission and review

Feasibility
High

Impact
Medium

Time horizon
Short (0–24 months)

Barriers
Reliance on manual processes for data compilation, review and formatting. Submission requirements that differ by regulatory body.

Biggest unlock
Collaboration between regulators and industry to develop frameworks and guidelines supporting the use of Gen AI in regulatory submission.

Regulatory submission today
The increasing complexity of clinical trials produces inefficiency, with the number of procedures per trial growing by 60%[18] over the past decade and the length of trial submission also growing. Many companies still rely on manual processes for regulatory submission, leading to frequent filing errors. Moreover, submission teams often work in silos, leading to inconsistencies and frequent duplication of effort.

Regulatory submission enhanced by Gen AI
In the future, Gen AI will automate many aspects of regulatory submission and review, including generating, organizing and validating submission filings. Gen AI will be used to compile and structure trials data and findings into the required formats and then flag omissions, cross-reference as appropriate and ensure regulatory compliance – reducing the need for costly requests for more information. Gen AI can also feed predictive algorithms to predict the probability of regulatory success.

USE CASE

Moderna

Moderna has launched RegBot, a solution that uses large-language models to streamline interactions with health authorities, reducing the administrative burden on regulatory affairs teams. RegBot features two main components: an automated system for the intake and archiving of health authority enquiries and an advanced chatbot that assists users in navigating internal documents to draft accurate and timely responses, further speeding up regulatory correspondence.

2 Barriers, enablers and recommendations: How to drive a clinical development revolution

Trust, regulation and fragmented data stand in the way of a Gen AI-powered clinical development revolution.

Leaders interviewed by the World Economic Forum and ZS agreed on the biggest obstacles to the transformation of clinical development using Gen AI. Some, such as lack of public trust and data security, are common to any AI implementation; others, such as data fragmentation and the absence of regulations mandating which data must be shared, are more specific to clinical development.

2.1 Data, incentives and regulation

Barriers

The quest to improve clinical development using Gen AI will depend on access to high-quality representative data. Three barriers stand out:

- **Data fragmentation:** Aggregating clinical data from across the healthcare system is of paramount importance, but lack of industry consensus on what data is needed to advance clinical trials exacerbates fragmentation. Healthcare stakeholders have assorted aims, few incentives to share data and even fewer use cases demonstrating the value of greater data sharing.

- **Inconsistent data quality:** Inconsistent collection practices, incomplete datasets and human error feed poor data quality. This impairs AI systems' performance, eroding trust and slowing adoption.

- **Regulatory vacuum:** Regulatory frameworks for AI and data in clinical trials are complex, inconsistent between geographical areas and open to interpretation. This creates ambiguity for stakeholders trying to balance innovation with compliance and patient safety. The European Union's AI Act[19] regulates the use of AI in the European Union, while the United States has a patchwork system,[20] with states crafting their own rules.

Recommendations

Policy-makers and the private sector must join together to create shared infrastructure, standards and incentives to drive greater collection, maintenance and sharing of health data. Three actions are recommended:

1. **Create standards for data collection and sharing:** Regulators and pharmaceutical companies must drive policies that enforce health data standards. Policy-makers should consider mandating that some data, such as failed trial data, be made public after a blackout period. They should also modify regulatory frameworks to allow and encourage more adaptive trials. The USA's Trusted Exchange Framework and Common Agreement (TEFCA)[21] established a national framework for interoperability, but it does not create incentives for companies to share data.

   Pharmaceutical companies, meanwhile, should align on what data they need to optimize clinical trials. The answer will vary from one trial to the next, but patient health data, clinical data and trials data are the "big three". Table 2, which shows the five categories of data that companies will need in order to fuel clinical trials, can be found in the Appendix.

2. **Build data infrastructure:** Governments should establish centralized or federated hubs that aggregate data for improved accessibility and use. For example, the Indian state of Telangana has established itself as a leader in promoting data sharing throughout India's fragmented healthcare system with its Citizen Health Profile initiative to collect biochemical and phenotypic data from 40 million citizens and make it available to healthcare stakeholders. In many cases, public–private partnership will be needed to fund infrastructure and ensure that sharing initiatives maximize the value of data while safeguarding privacy and security. Establishing regulatory sandboxes, where new technologies can be tested in a controlled environment, can encourage innovation while ensuring that new use cases are safe and ethical.

3. **Create incentives for data sharing:** Public–private partnerships must be formed to drive policies that create incentives for networked data sharing and reduce fragmentation by aligning interests throughout healthcare. The UK Biobank – a government initiative underwritten largely by the pharmaceutical industry – is a prime example.[22] Monetization models can create incentives for data sharing – for instance, by monetizing aggregated data that can then be shared among contributors. Quasi-private initiatives, such as Epic's Cosmos[23] – which aggregates data from community health systems and then sells it to pharmaceutical companies for R&D – is another strong example.

Clinical development leaders stressed in interviews that governments need to strike a balance between privacy, safety and innovation. The establishment of the US Food and Drug Association's AI Council,[24] which oversees AI, including its use in regulatory decision-making, is encouraging. The private sector should propose adaptive regulatory frameworks that provide guidance without stifling innovation.

2.2 Innovation culture, trust and workforce considerations

Barriers

Dramatic changes to the clinical development status quo are inherently discomfiting. Inertia, skill deficits and lack of trust must be overcome for humans to fully embrace progress.

– **Overcome inertia:** Although companies have invested in using AI and Gen AI to enable digital end points, adaptive trial designs and synthetic control arms, these efforts have yet to consistently demonstrate their full value. That is starting to change. The Tufts Center for the Study of Drug Development and the Digital Medicine Society (DiMe) united with industry leaders to measure potential ROI from using digital end points in clinical trials.[25] They found that doing so shortened trial phases, allowed for smaller enrolment sizes, increased expected net present value (eNPV) by as much as $40 million per indication and offered returns of between four and six times investment. These results notwithstanding, leaders interviewed by the World Economic Forum and ZS said they were hesitant to fully embrace new trial methods, given the highly regulated nature of life sciences and the high stakes of each individual trial.

– **Build AI skills:** With AI's advance, there is a growing need for expertise at the crossroads of technology, healthcare and data science. While AI has made inroads in biostatistics for analysis and drug discovery, its integration often sits outside core development teams. AI models can produce varying outputs depending on the specific context, underscoring the importance of teams with expertise in both clinical development and AI. Additionally, AI systems are often deployed within an ensemble of specialized models, requiring teams to coordinate systems and integrate outputs into clinical and operational workflows.

– **Overcome trust barriers**: Operationalizing Gen AI in clinical development depends on trust – from the public, who must consent to their data being used; from research entities, who must believe the benefits of data sharing outweigh the risk of intellectual property leakage; among individual scientists sceptical of AI's value compared with traditional techniques; and among regulators, who must believe that AI's outputs are safe, ethical and reliable.

Recommendations

Trust must be promoted in the ecosystem.

1. **Develop smart AI policies:** Governments must establish guidelines that ensure the safe and effective use of AI, while also promoting workforce upskilling. This could take the form of certifications or training programmes that build confidence in trial teams' skills in using AI in clinical development.

2. **Enforce data transparency:** While there is a push for greater transparency in AI models, companies are hesitant to reveal the data used to train models. Regulators should provide

guidelines and frameworks that balance the need for transparency with the protection of sensitive information. Public–private consortia should prioritize the creation of advanced data security measures to protect sensitive health data. This includes adopting encryption, secure access protocols and regular audits to prevent data breaches and ensure compliance with data protection regulations.

3. **Foster a culture of innovation:** All stakeholders should drive the creation of public–private consortia that create shared objectives and guidelines for AI innovation in R&D throughout the healthcare system – and then create mechanisms for holding participants accountable.

TABLE 1 **Recommendations by stakeholder**

Government

- Create standards for data collection and sharing
- Build centralized or federated data hubs
- Create incentives to drive networked data sharing
- Advocate for transparency in data usage

Regulators

- Drive policies enforcing data standards
- Establish regulatory sandboxes
- Promote adaptive trial designs
- Create AI-specific regulatory frameworks
- Balance innovation and compliance

Public–private consortia

- Establish shared AI innovation goals
- Implement advanced data security protocols
- Spearhead data-sharing initiatives

Clinical development leaders/pharma

- Use Gen AI to improve incomplete or low-quality datasets where possible
- Implement AI-driven adaptive trial designs
- Participate in data-sharing initiatives
- Combat innovation inertia
- Address workforce skills gaps

AI and technology leaders

- Develop AI solutions tailored for clinical settings
- Integrate diverse data sources

Healthcare providers

- Support data-sharing frameworks
- Promote data-driven innovation

3

Without an AI revolution in clinical development, the world's health is at risk

Using generative AI to optimize clinical trials is both a moral and financial imperative.

Global healthcare systems face soaring costs and diminishing returns on their healthcare investments. The health and well-being of billions of people depend on accelerating drug delivery while reducing development costs.

Revolutionizing clinical development requires collaboration among stakeholders who are not accustomed to working together. For governments, this is not only a moral imperative but also a financial one: they cannot afford not to do so. For pharmaceutical companies, too, the stakes are existential. As pipelines grow more complex, blockbusters become rarer and governments take more assertive steps to control drug costs, finding more efficient pathways to secure drug approvals is paramount. And for patients, what is at stake is nothing short of access to the life-saving treatments of tomorrow.

Appendix

TABLE 2 **Data types critical to clinical development transformation**

Patient health data

- **Demographics** Age, gender, ethnicity, etc.
- **Diagnosis** Current medical conditions and diagnoses
- **Treatment outcomes** Prescriptions, over-the-counter drugs and supplements

Clinical data

- **Omics** Genomics, proteomics, etc.
- **Vital signs** Blood pressure, heart rate, temperature, etc.
- **Lab results** Blood tests, urine tests, imaging results, etc.

Administrative data

- **Continuity of care** Scheduled visits, follow-ups, cancellations
- **Billing information** Insurance details, payment records

Research data

- **Clinical trials** Participation details, trial results, subpopulations
- **Evidence generation** Data collected for ongoing research studies

Safety data

- **Safety data** Incident reports and safety assessments

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Endnotes

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