

White Paper

The AI Reform of Clinical Trials: Biopharma Benefits

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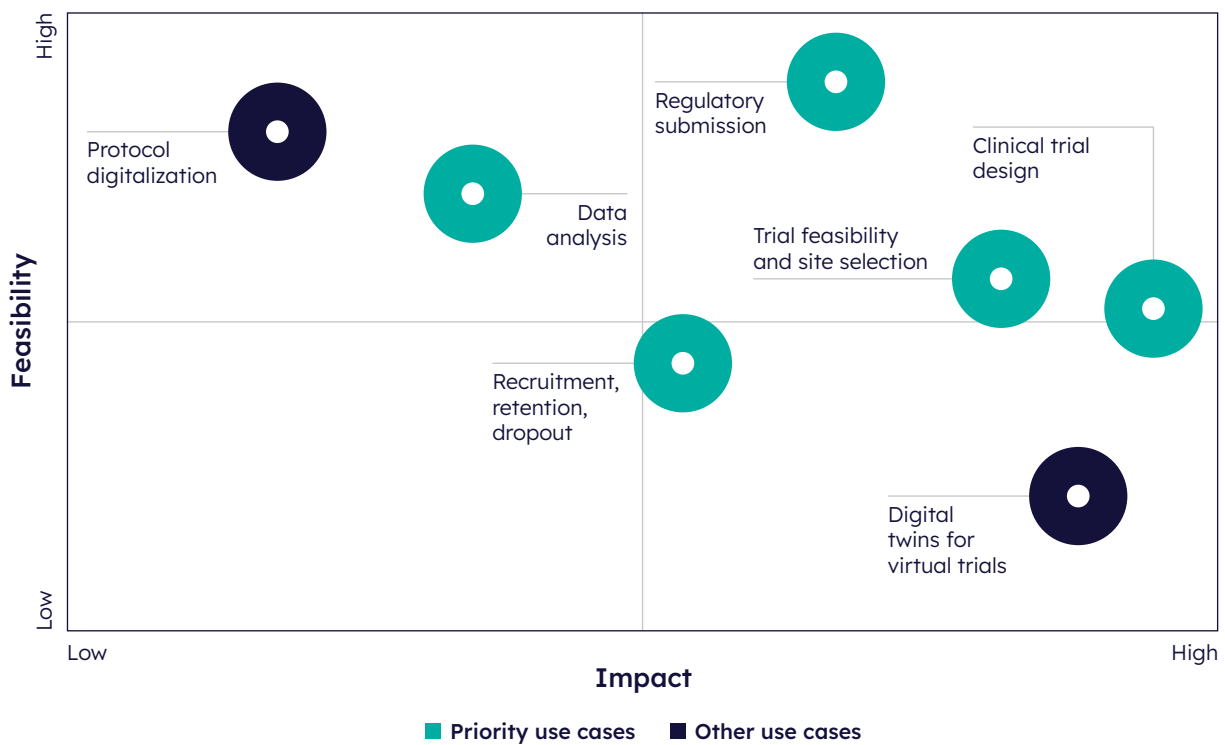
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Introduction

Artificial Intelligence (AI) is reshaping clinical trials across the entire drug development pipeline, from planning through to execution and monitoring. Multiple AI use cases have

been identified across all clinical development functions (Fig. 1) and their impact is significant. An 80% success rate can be achieved in Phase I, compared to the industry average of ~50%.¹

Figure 1: A use-case prioritization framework for AI in clinical development



Note: List is not exhaustive.

Source: World Economic Forum (WEF)

More generally, according to recent industry analyses, the AI market is projected to grow from \$4.35 billion in 2025 to about \$25.73 billion by 2030 for the pharmaceutical sector, driven by innovations in clinical trials, precision medicine, and commercial operations. Within that, GenAI is set to expand at a 43.12% CAGR through 2030.² For clinical trials, market valuations reflect this traction: the global AI in clinical trials sector is projected to grow from \$2.6 billion in 2025 to \$22.4 billion by 2034.³

AI can process both structured and unstructured multimodal data — text, tables, figures/images and videos — making it a powerful enabler for drug development. At a foundational level, this capability allows experts to shift from manual data handling and processing to higher-value activities, such as validating, curating, and enriching trial data, often integrating insights among internal and external validated sources.⁴

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At a more advanced level, AI can extract valuable insights from historical data to guide operations and help to forecast future trends via ML-driven predictive analytics. This complements traditional descriptive and diagnostic analytics, which focus solely on interpreting past events, on which traditional inferences are anchored. Thus, AI enhances and accelerates expert decision-making through

not only predictive but also prescriptive analytics instead, offering recommendations and optimal next steps — such as protocol writing and optimization, cohort identification, investigator and site selection, patient recruitment and retention strategies, etc. — to maximize added value, while minimizing time and costs to deliver it.⁵

Generative AI taking machine learning to the next level

ML is best suited for enabling predictive analytics consistently, based on high-quality, representative, and timely training data, such as forecasting trial timelines and outcomes, identifying biomarkers, or optimizing treatment plans, including drugs and dosages. It can be either trained on structured, labeled datasets, or work on unlabeled datasets to identify and showcase certain groupings in the data, such as similar diseases or adverse events. Common applications include maximizing patient recruitment and retention in clinical trials, as well as optimizing the protein structure for drug design.⁶

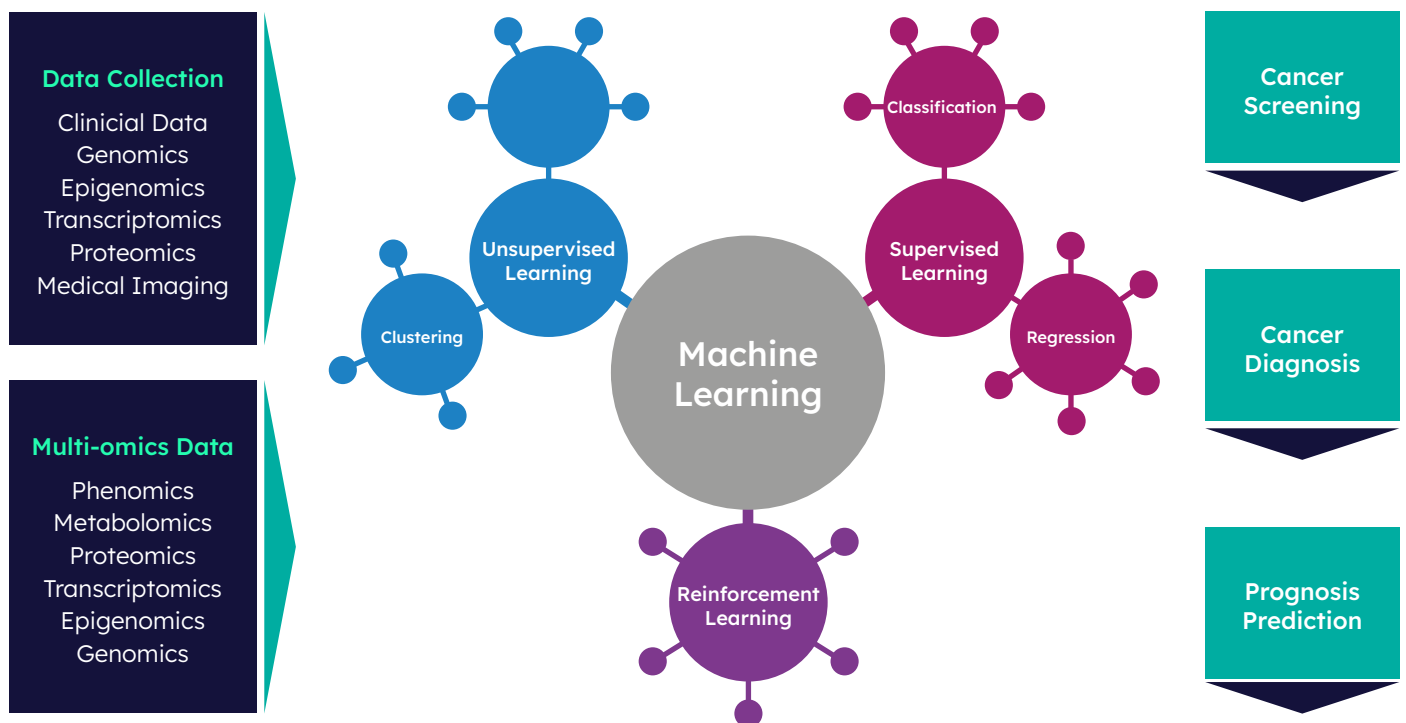
GenAI is a branch of ML that enables and powers creative and generative tasks, such as designing new molecules, drafting or summarizing clinical and regulatory documents in trials, or simulating patient responses. It thrives on large, unstructured datasets, whether text and/or images and/or videos, hence the term “multimodal,” and can either summarize existing content or even generate novel outputs beyond merely existing data. In life sciences, GenAI is already used for accelerating drug discovery, protocol writing, and regulatory documentation as well as personalizing patient engagement during trial execution.⁷

AI for next-gen pharma and operational excellence

AI continues to accelerate drug discovery and development by supporting and enhancing the analysis of vast and diverse datasets, including comprehensive drug databases, biochemical

data, clinical trial data, multi-OMICS data, real-world data (RWD), and electronic health records (EHR) (Fig. 2).

Figure 2: Comprehensive, AI-driven framework that integrates multi-OMICS, clinical data, and imaging to train ML-driven models for identifying predictive biomarkers, developing personalized patient models and discovering new therapeutic targets towards precision medicine



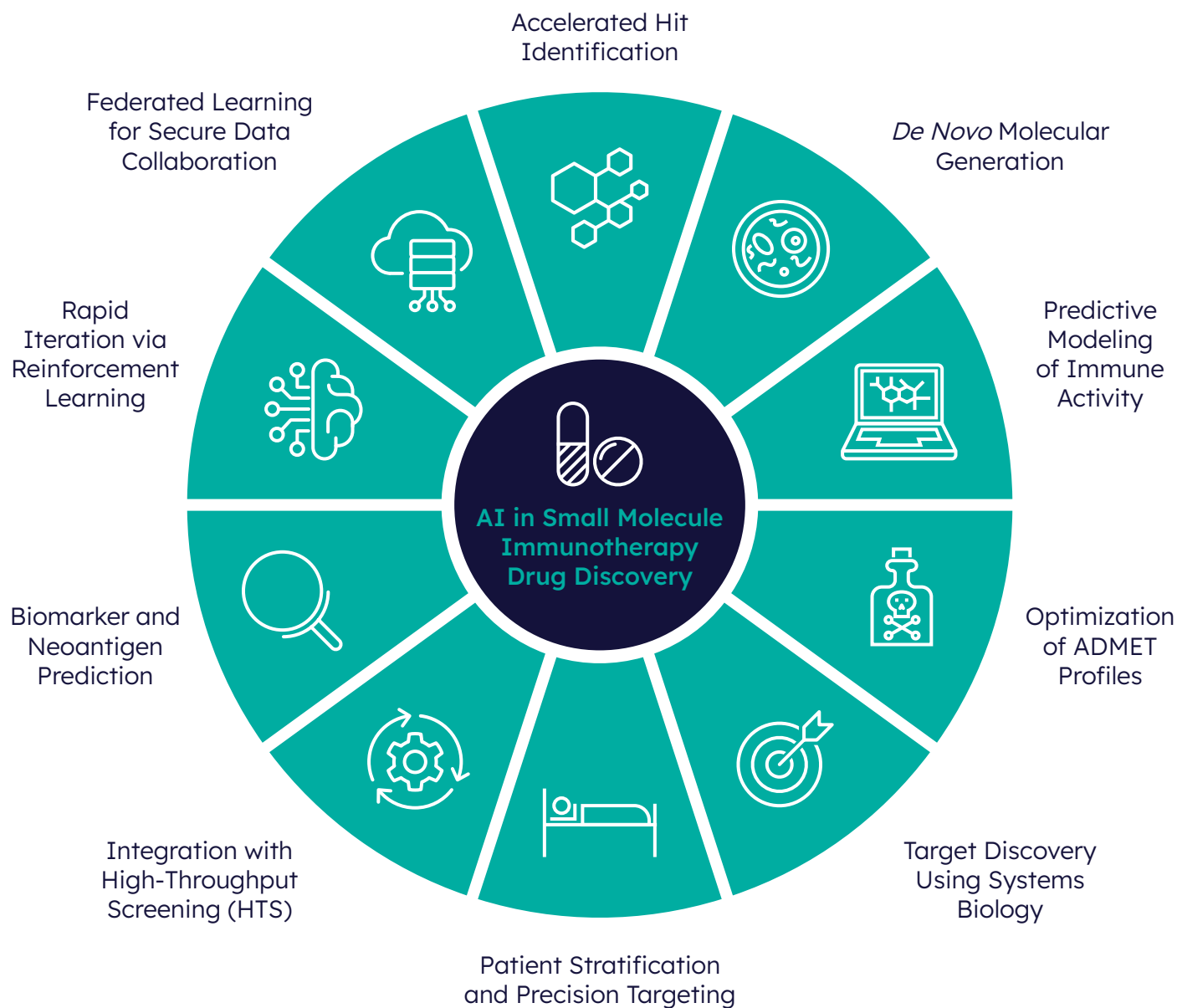
Source: European Journal of Medicinal Chemistry (2024)

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AI-driven analysis remains significantly faster and more cost-effective than traditional manual or statistical methods at identifying potential drug candidates, reducing the time required for drug discovery and maximizing the quality

of novel compounds (Fig. 3), as estimated via pharmacokinetics and pharmacodynamics modeling, and assessed based on the safety profile and efficacy associated with them.⁸

Figure 3: Application of AI for drug discovery of small molecules



Source: npj Drug Discovery (2025)

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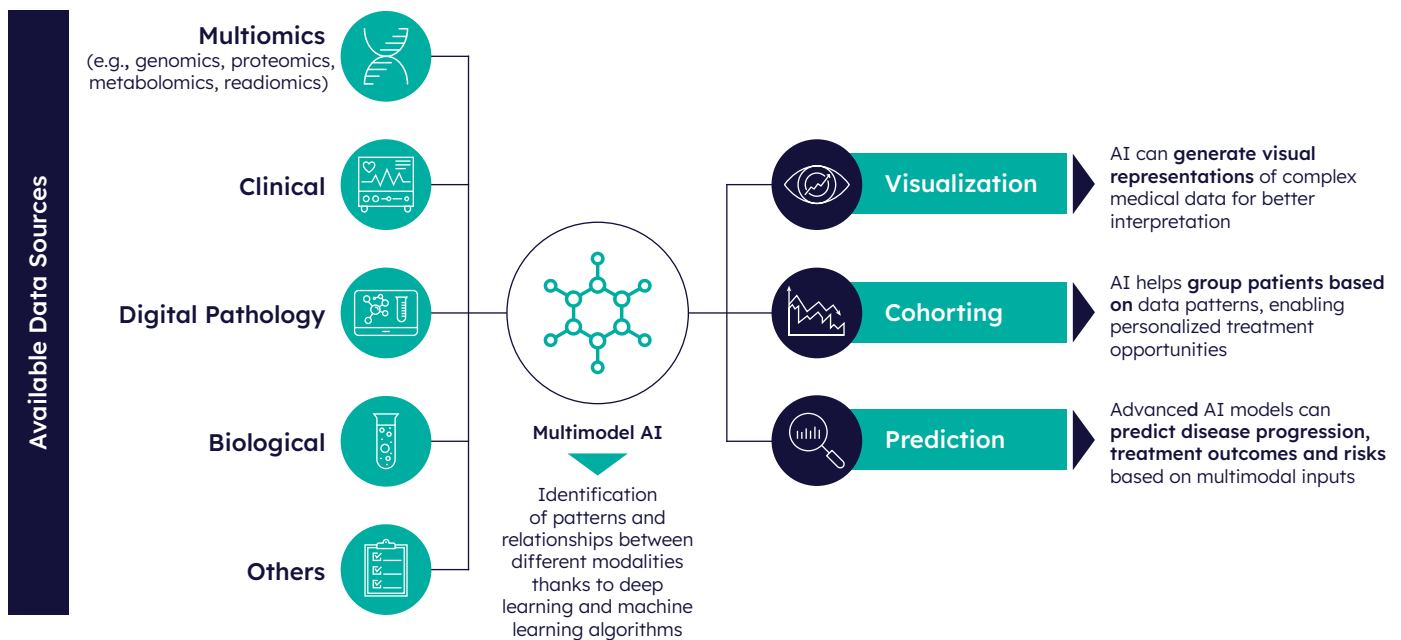
For instance, AI-driven drug discovery platforms have now reduced the time to identify drug candidates from four to five years to as little as six to eight months, particularly when leveraging GenAI models. These models can simulate molecular structures, predict binding affinities, and even generate compounds de novo, expanding the chemical space beyond what traditional methods could explore.^{9,10}

AI also facilitates drug repurposing or repositioning. It can identify existing approved compounds that could be effective for new therapeutic uses and estimate their likelihood of success in treating different diseases, or even compounds that did not pass earlier phases of clinical development in certain indications and repurposing them for diseases where their safety profile and efficacy are predicted to be more favorable. AI-enabled systems now integrate RWD and representation learning to identify and prioritize the most promising

candidates and estimate the safety profile and efficacy of existing drugs for other, similar or even seemingly unrelated diseases, such as type II diabetes mellitus and cognitive impairment.¹¹

AI supports both the creation of personalized therapies and the optimization of treatment pathways via accurate and reliable titration on a subject-specific basis (Fig. 2). It can advise on medication switching and tailor dosage to an individual's specific needs by analyzing multimodal, longitudinal patient data, including multi-OMICS, imaging, lifestyle data, and even data collected from wearable devices and assessed via edge AI, or AI deployed on such devices (Fig. 4). The integration of AI with OMICS technologies and digital twins is now enabling more proactive disease detection for earlier treatment strategies and more accurate and reliable predictions of individual treatment responses over time.¹²

Figure 4: Applications of multimodal AI in life sciences, thus combining multiple data modalities, e.g., medical imaging, multi-OMICS, clinical data, and wearable devices



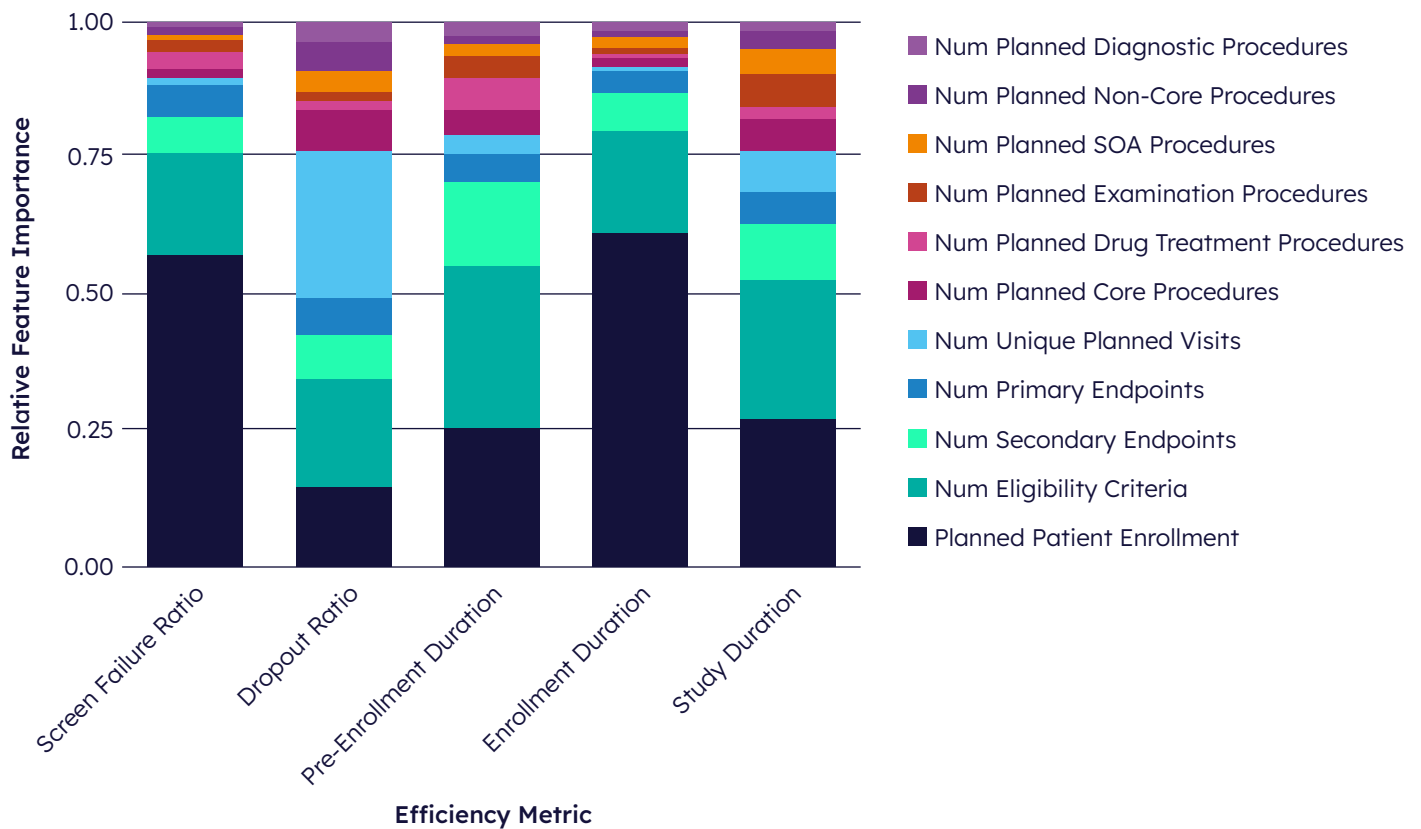
Source: npj Artificial Intelligence (2025)

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AI enhances clinical trial planning and optimizes trial design through tailored protocol development and optimization, investigator and site selection, and real-time monitoring — including the early identification of risks and support for study rescue strategies — to help ensure trials are delivered on time and within budget.¹³

Advanced tools leveraging GenAI and ML can further support this by enabling data-driven protocol optimization (e.g., for integral sections of the protocol such as inclusion/exclusion criteria and endpoints), reducing complexity, and improving feasibility from the onset. These solutions can also provide operational insights that help teams design more efficient and patient-centric trials (Fig. 5).

Figure 5: Key features or inputs assessed via machine learning to predict and optimize trials operationally



Source: The AAPS Journal (2022)

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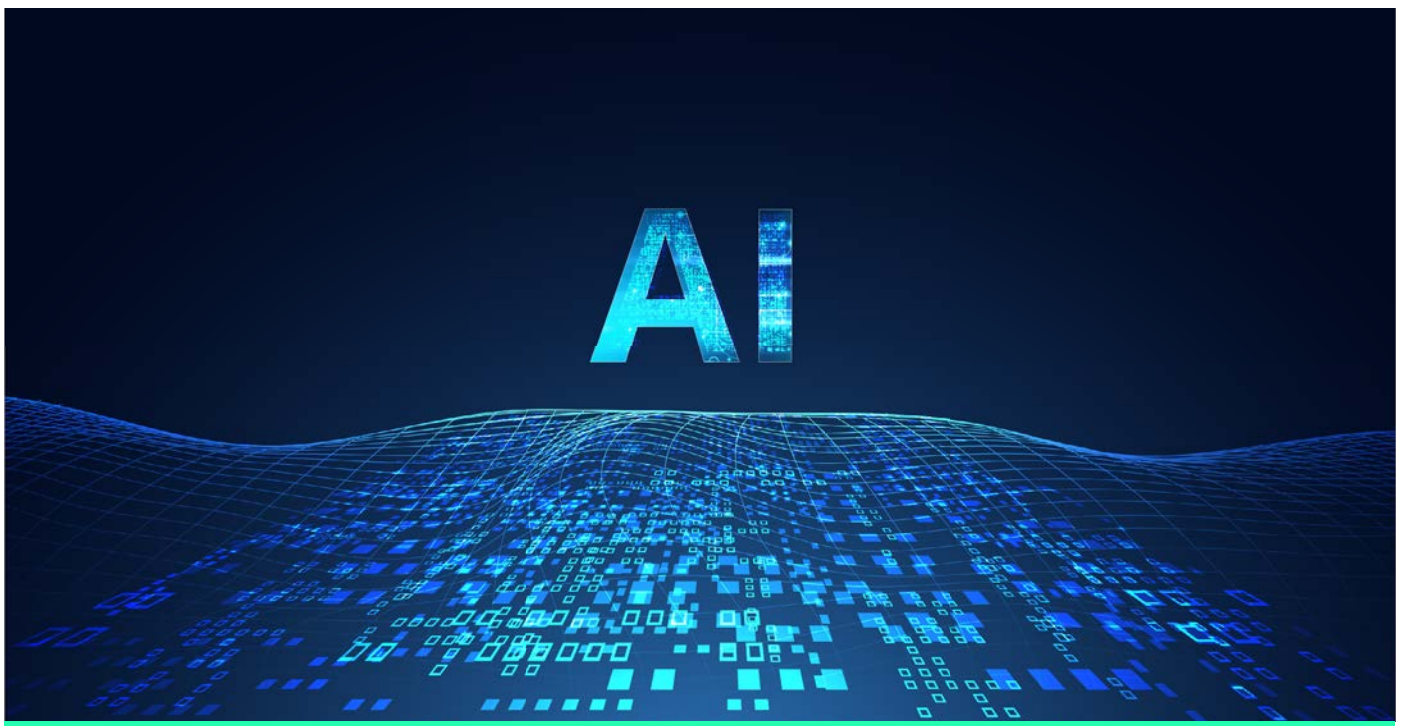
AI-driven platforms are also increasingly used to simulate trial outcomes, predict screen failure rates, dropout risks (Fig. 5), and enhance patient stratification and diversity, including for trials that are diverse by design like Takeda's,¹⁴ ultimately improving both efficiency and success rates. GenAI is also being used to expedite and standardize regulatory documentation and reporting, such as clinical study reports (CSRs) and submission dossiers.¹⁵

To promote diversity in clinical trials, AI-powered systems are used to reduce human bias in trial design and to balance the goal of increasing participant diversity, such as in race, ethnicity, demographics, and socioeconomic factors, with the need to deliver the trial on time and on budget. AI-powered recruitment platforms now enable real-time demographic balancing and adaptive enrollment strategies, helping sponsors, such as Takeda, meet and exceed diversity targets.¹⁶

AI continues to accelerate and streamline

processes such as drug discovery, manufacturing, repositioning or repurposing, clinical trial planning, supply chain management, clinical trial execution, monitoring and pharmacovigilance. In 2025, agentic AI systems are being deployed to support the monitoring and estimation of supply chain risks, predict any disruptions, and optimize inventory levels. In pharmacovigilance, AI is used to enable adverse event detection, classification, and streamline reporting, improving both speed and compliance.¹⁷

Traditional ML and cutting-edge GenAI are complementary. ML provides the ability to predict operational trial metrics consistently and reliably, as trained on high-quality data, such as trial timelines, ensuring good practices (GxP) and [Good Machine Learning Practice](#) (GMLP) compliance, while GenAI enables users to summarize and generate insights. Examples include drafting and optimizing protocol design and tailoring the treatment plan to the specific patient population of interest.¹⁸



Benefits outweigh risks if leveraging AI responsibly

The application of AI in clinical trials often involves processing sensitive patient data, including personally identifiable information (PII), which raises important concerns around data privacy and security. To address these, organizations must ensure compliance with relevant regulations, such as [HIPAA](#) in the United States, [General Data Protection Regulation](#) (GDPR) in the European Union (EU), and the [EU AI Act](#), which sets strict requirements for high-risk AI systems including those used in healthcare.¹⁹

It remains best practice to leverage the minimum amount of data required for a business application. The recent International Council for Harmonization (ICH) GCP guideline update, [ICH E6\(R3\)](#), emphasizes that trial protocols should focus on essential data. For instance, when working with RWD, it is best to use age instead of full date of birth, or a partial postal code rather than the complete address, in line with HIPAA compliance guidelines. Furthermore, de-identification and pseudonymization techniques must meet regulatory standards to prevent re-identification risks.²⁰

It is also crucial to apply appropriate encryption to patient-level data — whether stored (“at rest”), transmitted (“in transit”), or actively used (“in use”) — including during model inference via encrypted endpoints. Zero-trust architectures and federated learning are increasingly being adopted to enhance data security without compromising model performance significantly.²¹

Considering recent technological advances, such as GenAI, integrating AI in life sciences requires revisiting existing regulations and standards

to ensure its ethical, responsible application. Guiding principles, such as the [GMLP](#), a joint effort of the US Food and Drug Administration (FDA), Health Canada, and the UK’s Medicines and Healthcare products Regulatory Agency (MHRA), continue to provide a foundation for responsible AI development. These principles were updated in 2025 to reflect the growing complexity of AI-enabled medical devices and the need for transparency, traceability, and human oversight, especially further to recent advancements in GenAI.

While addressing ethical and regulatory issues is key, the evolving nature of these frameworks — and the complexity of achieving full compliance — can pose challenges that may slow the pace of AI adoption in the pharmaceutical industry. The EU AI Act, for instance, classifies some life sciences-related AI applications as “high-risk,” triggering stringent requirements for data governance, algorithmic transparency, and lifecycle monitoring.¹⁹ Nevertheless, if used responsibly, AI-driven devices as FDA-approved Software-as-a-Medical Device (SaMD) have enhanced both the ability to diagnose indications early, such as diabetic retinopathy, as well as to, therefore, apply proactive treatments to manage them more effectively.

From a software development standpoint, supporting GxP compliance involves ensuring the reproducibility of data and models via best practices and industry-grade tools, such as version controls, e.g., using data version control ([DVC](#)). Other tools include comprehensive experiment logging, (e.g., via [MLflow](#) — including parameters, results, and artifacts) and ensuring appropriate documentation of the data, model methodologies, evaluation, and post-deployment monitoring processes to

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promote transparency and explainability for both technical and non-technical stakeholders across the entire software development lifecycle (SDLC).²²

The effectiveness of AI-driven systems is highly dependent on the quality of the training data. This quality can be compromised by various factors, such as outliers, missing or outdated information, unrepresentative samples, biases, and noisy or inaccurate data. As the saying goes, “garbage in, garbage out” — poor-quality input data inevitably leads to subpar outcomes.

Improving data quality for AI model development should involve several key practices, such as: missing value imputation (i.e., filling in gaps in the dataset using statistical methods or ML techniques, informed by relevant domain expertise to ensure business relevance); data augmentation (i.e., expanding the dataset by generating new samples from existing data, guided by domain experts); and data standardization (i.e., ensuring uniform formatting and structure across datasets to maintain correctness, consistency, and interoperability). AI-driven systems carry the risk of reinforcing existing human biases, particularly when trained on datasets that reflect systemic inequities. To prevent biased predictions, it is essential to identify and mitigate these issues throughout the SDLC.²³ Effective strategies to address bias include collecting a diverse dataset

to ensure fair and representative coverage of different populations, conducting a bias audit as per equity-focused governance frameworks, applying adversarial training techniques to detect and reduce algorithmic and systemic biases, and using data augmentation to improve representativeness of under-represented groups (e.g., due to different socioeconomic and demographic factors).

Moreover, the complexity and limited transparency of certain AI models — particularly large language models (LLMs) — can hinder trust and slow adoption. This challenge is especially pronounced in regulated sectors, such as life sciences, where AI-driven systems must be replicable, reproducible, accurate, reliable, and explainable, given their role in informing and at times influencing decisions that directly impact human health outcomes and safety.

To address this concern, it is paramount to review and validate the evidence used by LLMs. Techniques such as retrieval-augmented generation (RAG) and fine-tuning LLMs on proprietary data are increasingly used to ground outputs in verifiable and expert-curated sources and improve veracity and traceability of the outputs generated. Regulatory bodies now emphasize responsible and explainable AI (XAI) as a requirement for AI systems used in clinical and regulatory contexts.²⁴



Next frontiers of pharma with AI

The next phase of AI adoption in biopharma is redefining clinical trials. In a randomized JAMA study, AI-assisted prescreening achieved an eligibility rate of 20.4% compared to 12.7% for manual screening, and resulted in 35 enrollments vs. 19 with manual methods.²⁵ Companies are accelerating from pilot projects to enterprise-wide agentic AI integrations. In 2025, GenAI, digital twins, edge AI, and quantum AI are no longer experimental; they are pivotal to discover, develop, optimize, and deliver drugs at an unprecedented scale. AI also enables decentralized and hybrid trials.

Edge AI is increasingly being assessed for its potential to support decentralized clinical trials. Wearables and biosensors powered by edge AI (deployed and running locally, on the device) now support real-time analyses and predictions of patient vital signs, enabling holistic, proactive monitoring and early detection of adverse events and reducing the need for in-person visits. This shift is improving trial accessibility and retention, enabling tele-monitoring too, especially for underrepresented populations.²⁶ It is worth noting that TransCelerate's Modernizing Clinical Trial Conduct initiative promotes decentralized methods that include such technological solutions to enhance patient-centric trial models, diagnostics, and care delivery.²⁷

CROs, such as ICON, are also advancing the use of [digital health technologies](#), including [wearables](#) and biosensors, to enable continuous, real-world monitoring of patient health markers in home and on trial sites, such as vital signs, physical activity, sleep, and heart rate. These tools are helping to generate more precise and patient-relevant digital epidemiological fingerprints and endpoints, supporting the broader adoption of decentralized and hybrid trial models.

Moreover, multimodal GenAI is used to integrate imaging, EHRs, genomics, and wearable data

to achieve personalized medicine. This supports more accurate patient risk stratification and personalized treatment plans. Sponsors, such as Bayer, are using AI-driven models to accelerate oncology drug development and rare disease diagnostics.²⁸ For instance, by leveraging GenAI, Bayer developed solutions able to support the completion of about 80% of regulatory documentation, thus expediting delivery and access to treatment.

Digital twins are evolving from early blueprints, with the help of AI for predictive analytics, simulating disease progression, titrating treatment strategies, and predicting treatment responses in various therapeutic areas, such as cardiology, oncology, and metabolic disorders. Digital twin developer Unlearn, which worked with Merck KGaA, Roche and J&J, stated that its technology could simulate placebo results, reducing control arm sizes by about 33%, which in turn can reduce enrollment time by four to five months.²⁹

Additionally, quantum AI is beginning to reshape and modernize pharma R&D further. Hybrid quantum-classical models are being piloted to accelerate hit-to-lead optimization, toxicology prediction, and protein folding simulations. IBM and Cleveland Clinic, for instance, are leveraging quantum computing and AI for accelerating and enhancing drug discovery and disease modeling at an unprecedented speed. In fact, they demonstrated that a hybrid quantum neural network improved response prediction by 15% when compared to traditional methods.³⁰ Meanwhile, quantum-safe encryption is being explored to protect sensitive patient data in RWD and EHR systems.³¹

Indeed, scaling AI in regulated settings requires strong data and AI governance. Platforms such as IBM watsonx.governance provide lifecycle controls helping sponsors and CROs evaluate, train, deploy, and consume AI responsibly across the clinical trial lifecycle.³²

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