



The Role of Artificial Intelligence in Modern Biotechnology: A Comprehensive Review

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Abstract

Artificial Intelligence (AI) is rapidly transforming biotechnology, unlocking unprecedented opportunities for innovation across the life sciences. As the complexity and volume of biological data continue to grow, AI-powered tools are revolutionizing how we understand, design, and manipulate biological systems. This review provides a comprehensive examination of how AI is reshaping core biotechnological domains, from drug discovery, protein structure prediction, and multi-omics integration to synthetic biology, genome editing, bioprocess optimization, and personalized medicine. Advances such as AlphaFold, generative models for molecular design, and digital twins underscore AI's pivotal role in accelerating research, improving precision, and enabling real-time decision-making. The integration of AI with robotics, microfluidics, and lab automation further enhances high-throughput experimentation and reproducibility. In addition to technical advancements, this review addresses ethical, legal, and regulatory challenges, including data bias, algorithmic transparency, and biosecurity concerns. This review also highlights future frontiers such as AI-enabled organoid modeling, foundation models for biology, and sustainable applications in biomanufacturing and environmental biotechnology.

Keywords: Artificial Intelligence, Biological Sciences, Deep Learning, Machine Learning, Digital Transformation

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Introduction

The convergence of artificial intelligence (AI) and biotechnology represents one of the most transformative shifts in life sciences research and development. Over the past decade, AI, particularly machine learning (ML) and deep learning (DL), has emerged as a critical enabler in deciphering complex biological data, streamlining experimental workflows, and accelerating therapeutic discovery.¹ Biotechnology, an interdisciplinary domain rooted in molecular biology, genetics, and biochemistry, has benefited significantly from AI's ability to extract patterns from large-scale datasets that would otherwise be intractable through traditional methods.² AI applications in biotechnology span a wide spectrum, including drug discovery, genomics, protein structure prediction, synthetic biology, and biomanufacturing.² Notably, DeepMind's AlphaFold, released in 2021, revolutionized protein structure prediction by achieving atomic-level accuracy, with AlphaFold 3 further integrating small molecule and nucleic acid interactions as of 2024.³⁻⁵ According to a 2024 report by Grand View Research, the global AI in biotechnology market was valued at USD 3.8 billion in 2023 and is projected to expand at a compound annual growth rate (CAGR) of 29.7% from 2024 to 2030, driven by increasing demand for precision medicine and

data-centric approaches in biomedical research.^{6,7} Additionally, the volume of biological data is another significant catalyst. The total amount of genomics data generated annually is estimated to exceed several exabytes, surpassing data produced by astronomy or social media platforms.⁸ AI models are uniquely suited to integrate multi-omics datasets, comprising genomics, transcriptomics, proteomics, and metabolomics, enabling holistic systems-level understanding of biological functions and disease mechanisms.⁸ Despite these advances, challenges persist, particularly in areas such as data standardization, model interpretability, and ethical governance. As AI technologies continue to evolve, the need for comprehensive evaluations of their roles, limitations, and prospects in biotechnology becomes imperative.

This review aims to provide a comprehensive analysis of the current landscape, emerging trends, and future directions of artificial intelligence (AI) applications in biotechnology. It seeks to summarize recent advancements in AI methodologies and their integration into pivotal domains of biotechnology, such as drug discovery, protein engineering, multi-omics analysis, and bioprocess optimization. In doing so, the review critically evaluates the inherent limitations and ethical challenges associated with the deployment of AI

in biological contexts, including concerns related to algorithmic bias, data privacy, and the lack of standardized regulatory frameworks. Furthermore, it explores emerging opportunities and interdisciplinary trajectories through which AI could further enhance the efficiency, personalization, and sustainability of biotechnological innovations. By adopting a

multidimensional approach, this review aims to elucidate the transformative potential of AI while highlighting the pressing issues that must be addressed to ensure its responsible and equitable integration into life sciences research and practice. A schematic representation of this review is provided in Figure 1.

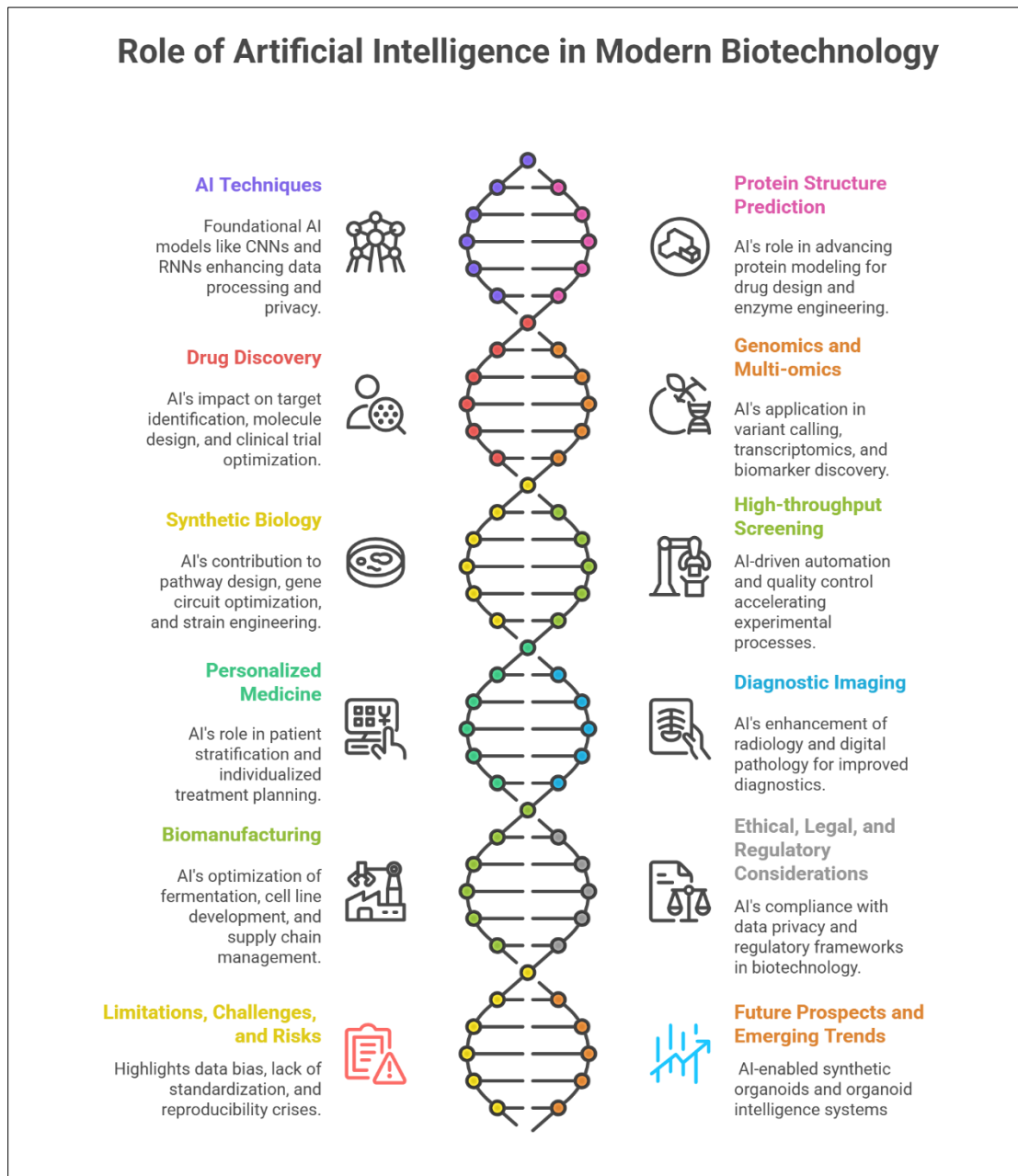


Figure 1. A Schematic Representation of the Role of AI in Modern Biotechnology.

Study Design

This review article was developed using a structured, thematic approach to identify, screen, and synthesize peer-reviewed literature and authoritative sources on the integration of Artificial Intelligence (AI) in biotechnology. The process ensured that only the most relevant, recent, and

scientifically rigorous articles were included.

Literature Search Strategy

A comprehensive search was performed across five major scientific databases, PubMed, Scopus, Web of Science, and Google Scholar. The time window for literature inclusion

spanned from January 2018 to May 2025, covering both foundational developments and the most recent advancements. Search terms were formulated using Boolean operators and keyword combinations such as,

- “Artificial Intelligence” AND “Biotechnology”
- “Machine Learning” AND (“Drug Discovery” OR “Synthetic Biology”)
- “Deep Learning” AND (“Protein Structure Prediction” OR “Omics”)
- “AI in Biomanufacturing” OR “AI in Precision Medicine”
- “AI” AND (“Diagnostics” OR “Robotics” OR “Ethics”)

Filters were applied to limit results to peer-reviewed journal articles, high-quality reviews, and white papers, and only articles published in English were considered.

Screening and Selection Process

From the initial search, 1,152 articles were retrieved. The following selection process was implemented,

- **Title and Abstract Screening:** Articles were screened for relevance to the themes of AI in biotechnology. Irrelevant topics, duplicates, and non-biotech-focused AI studies were excluded. This step resulted in 473 articles retained.
- **Full-Text Review:** Each article was then evaluated for:
 - Relevance to at least one major domain of biotechnology (e.g., drug discovery, genomics, diagnostics, synthetic biology).
 - Inclusion of AI-specific methodologies or applications.
 - Recency (preferably 2018 onward) and methodological soundness.

Inclusion and Exclusion Criteria

Included

- Studies demonstrating the application of AI (machine learning, deep learning, neural networks, etc.) in a biotechnology-related context.
- Articles presenting case studies, frameworks, or models with real-world or experimental validation.
- High-quality review papers that consolidate state-of-the-art advances in subfields of AI-biotech integration.

Excluded

- Editorials, opinion pieces, and non-peer-reviewed reports.
- Articles unrelated to core biotechnology domains.
- Studies with insufficient technical or methodological detail.

Data Extraction and Synthesis

Relevant data were extracted and categorized under 12 thematic domains:

1. AI fundamentals in biotechnology
2. Protein structure prediction

3. Drug discovery and development
4. Genomics and multi-omics
5. Synthetic biology and metabolic engineering
6. High-throughput screening and automation
7. Personalized and precision medicine
8. Diagnostics and imaging
9. Bioprocess optimization
10. Ethical and regulatory frameworks
11. Limitations and risks
12. Prospects and innovations

Each domain integrates recent case studies, toolkits, industry platforms, and statistical models, with figures and tables used to illustrate technological trends and impacts.

Results

The preliminary examination encompassed 473 scholarly articles, of which, following an initial assessment, 218 articles satisfied the established inclusion criteria and were consequently incorporated into the final review.

AI and Machine Learning (ML) Fundamentals in Biotechnology

Artificial Intelligence (AI), particularly Machine Learning (ML) and Deep Learning (DL), has become central to addressing complex biological questions by enabling predictive modeling, pattern recognition, and data-driven decision-making.⁹ In biotechnology, these computational techniques facilitate the interpretation of large-scale biological datasets, often characterized by high dimensionality, noise, and sparsity.¹⁰ This section delineates the fundamental categories of AI methodologies, such as supervised learning, unsupervised learning, and deep learning architectures, along with their distinct functions in diverse biotech applications.¹¹

Supervised Learning

Supervised learning is the most widely applied ML paradigm in biotechnology, where models are trained on labeled datasets to predict outcomes such as disease states, gene function, or drug response.¹² Common algorithms include Support Vector Machines (SVM), Random Forests (RF), and Gradient Boosting Machines (GBM).¹³ In a recent application, supervised models have been employed to classify cancer subtypes using RNA-seq expression profiles with an accuracy exceeding 90%.¹⁴ Table 1 presents common supervised learning techniques in biotechnology.

Unsupervised Learning and Clustering

Unsupervised learning techniques, such as k-means clustering,¹⁸ hierarchical clustering, and dimensionality reduction methods like PCA, t-SNE, and UMAP,¹⁹ are essential for exploratory analysis in high-throughput biological datasets.²⁰ These methods are widely used in genomics

Table 1. Common Supervised Learning Algorithms in Biotechnology

Algorithm	Application area	Example use case	References
Support Vector Machines (SVMs)	Gene expression classification	Breast cancer subtype prediction	[13,14]
Random Forest (RF)	Feature selection, biomarker ID	Drug response modeling	[13,15]
Gradient Boosting Machines (GBMs)	Disease risk scoring	Cardiovascular risk prediction from genetic data	[13,16]
Neural Networks (MLPs, FNNs)	Omics integration, classification	Protein annotation, phenotype modeling	[17]

and proteomics for tasks such as identifying cell types in single-cell RNA-seq (scRNA-seq) data or uncovering latent disease subgroups.²¹ Hierarchical clustering on single-cell transcriptomic data has been used to identify novel immune cell phenotypes within the tumor microenvironment.²²

Deep Learning Architectures (CNNs, RNNs, Transformers)

Deep learning architectures provide a robust framework for capturing nonlinear and hierarchical representations from complex biological data.²³ Convolutional Neural Networks (CNNs) are predominantly used in image-based analysis, such as histopathological image classification.²⁴ Recurrent Neural Networks (RNNs) and Long Short-Term Memory

(LSTM) models are suitable for sequential biological data like DNA, RNA, or time-series data from biosensors.^{24,25} Recently, transformer-based models, inspired by natural language processing (NLP), have demonstrated superior performance in protein language modeling and genomics.²⁶

AlphaFold 3, based on transformer architecture, predicts protein-ligand interactions and nucleic acid structures with atomic precision.^{27,28} Similarly, DNABERT and ProtTrans are transformer-based models that have been trained on large-scale genomic and proteomic corpora, enabling annotation and function prediction with minimal labeled data.²⁹ Table 2 presents some deep learning architectures and their applications in biotechnology.

Table 2. Some Deep Learning Architectures and Their Biotech Applications

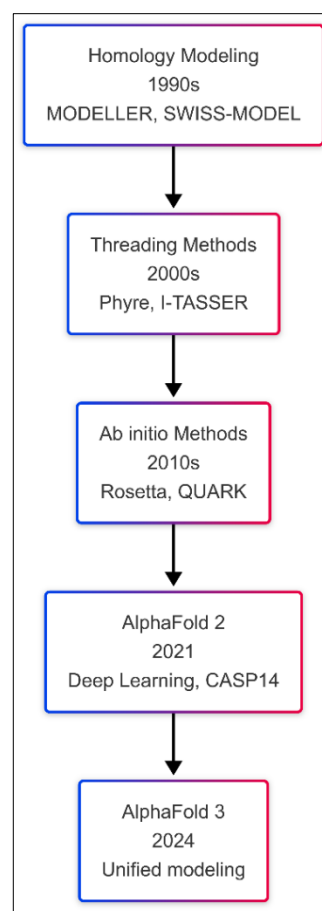
Architecture type	Application domain	Example models	Key contributions	References
CNN	Medical imaging	ResNet, U-Net	Tumor detection, cell segmentation	[30]
RNN/LSTM	Genomic sequence analysis	BioLSTM	Splice site detection, mutation prediction	[31]
Transformer	Protein structure, NLP	AlphaFold, DNABERT	Protein folding, enhancer/promoter analysis	[32]

Data Requirements and Preprocessing in Bio-Data Contexts

The performance of AI models in biotechnology is heavily contingent on the quality and preprocessing of input data. Biological datasets often suffer from issues like batch effects, missing values, and imbalanced classes.³³ Preprocessing techniques include normalization (e.g., TPM for RNA-seq), data augmentation (in imaging), imputation, and feature engineering.³⁴ Moreover, multi-modal integration, such as combining genomics, proteomics, and clinical data, requires sophisticated harmonization techniques to ensure consistency and reduce bias.³⁵ In addition, ethical concerns arise from the use of sensitive patient-derived genomic data.³⁶ Frameworks such as federated learning and differential privacy are gaining traction to mitigate data privacy concerns while enabling collaborative AI development.³⁶

Protein Structure Prediction and Modeling Using AI

The accurate prediction of protein structures has long been considered a grand challenge in computational biology due to the complexity of protein folding mechanisms and their dependence on both primary sequence and environmental context. In recent years, artificial intelligence has drastically transformed this field, particularly through the emergence of deep learning models like AlphaFold, developed by DeepMind.⁴ The release of AlphaFold 2 in 2020 and its successor AlphaFold 3 in 2024 has redefined the standards of accuracy, generalizability, and applicability in protein structure prediction, impacting not only structural biology

**Figure 2.** Timeline of Major Milestones in Protein Structure Prediction Techniques.^{4,28,37-40}

but also drug discovery, enzyme engineering, and synthetic biology.^{5,37}

Evolution of protein structure prediction models

Historically, protein structure prediction relied on homology modeling,³⁸ threading (fold recognition),³⁹ and ab initio (de novo) approaches.⁴⁰ While homology-based methods depend on known templates, their effectiveness was limited by the availability of experimentally resolved homologs.³⁸ Figure 2 illustrates a timeline of significant advances in protein structure prediction techniques.

AlphaFold and its Successors

AlphaFold 2 integrated attention mechanisms and geometric constraints to predict 3D structures from amino acid sequences with high fidelity.³⁷ However, AlphaFold 3,

released in 2024, marked a substantial leap forward by enabling the modeling of protein-ligand, protein-nucleic acid, and protein-protein complexes using a single unified model.⁴¹ Unlike its predecessor, AlphaFold 3 includes explicit modeling of small molecules and cofactors, offering applications beyond static protein structures.⁴¹

AlphaFold 3 was trained using multimodal data, including structural databases, molecular docking datasets, and experimental interaction maps, and utilizes a combination of transformer architectures and 3D equivariant neural networks for spatial reasoning.^{42,43} AlphaFold's database now covers over 200 million protein structures, including predicted models from humans and model organisms, with open access provided through the EMBL-EBI portal.⁴³ Table 3 presents a comparison between AlphaFold 2 and AlphaFold 3 models

Table 3. A Comparison between AlphaFold 2 and AlphaFold 3 Models

Feature	AlphaFold 2	AlphaFold 3	Reference
Release Year	2021	2024	
Input Type	Amino acid sequence + MSA	Sequence + Ligands + Nucleic Acids	
Output	Single-protein 3D structure	Multi-complex 3D interactions	[44]
Accuracy (GDT for CASP targets)	~92.4	~94.5 (for complexes)	
Algorithmic Difference	Attention-based Transformer + Geometric Constraints	Multimodal Transformer + 3D Equivariant Neural Networks	

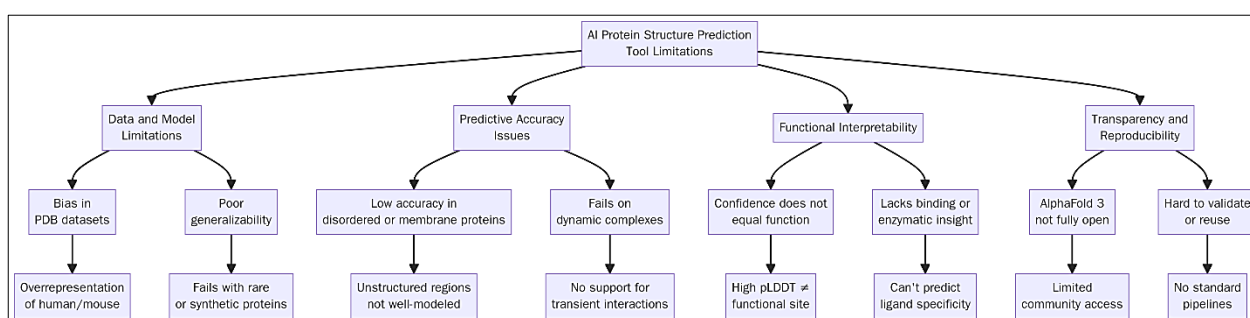
Applications of AI in Drug Design and Enzyme Engineering

AlphaFold and related tools have profoundly impacted structure-based drug discovery, protein engineering, and enzyme design. Pharmaceutical companies and biotech

startups are integrating these models into early-stage virtual screening and binding site prediction workflows. Table 4 presents some applications of AlphaFold and related tools/techniques in biology and biotechnology.

Table 4. Some Applications of AlphaFold and Related Tools/Techniques in Biotechnology

Application Area	Description	Tool/Framework used	Reference
Drug Target Discovery	Binding site prediction & docking	AlphaFold + AutoDock	
Enzyme Engineering	Rational mutation based on structural insights	AlphaFold + RosettaFold	[45–48]
Vaccine Design	Epitope mapping & immune complex modeling	AlphaFold-Multimer	
Functional Annotation	Predicting structure for uncharacterized proteins	AlphaFold Database	



Limitations and Data Transparency Concerns Regarding Protein Structure Prediction Models

Despite these advancements, limitations remain. AlphaFold models are trained on experimentally solved structures and therefore inherit biases from the PDB, which overrepresents stable and well-studied proteins.⁴⁹ Their predictions can be less reliable for intrinsically disordered regions, membrane

proteins, or transient complexes.^{50,51} Furthermore, AlphaFold's confidence scores, while informative, do not directly indicate binding affinity or functional activity.⁵² Figure 3 illustrates the principal limitations of existing protein structure prediction tools and techniques.

Data transparency has also been a concern. While AlphaFold 2's source code and structural database were

made publicly available, AlphaFold 3 remains partially closed, limiting reproducibility and hindering broader validation efforts in the scientific community.⁵³ This restricts its integration into fully open-source bioinformatics pipelines.

AI in Drug Discovery and Development

The integration of Artificial Intelligence (AI) into drug discovery and development has revolutionized the pharmaceutical landscape, enabling faster, cost-effective, and more targeted therapeutic design.⁵⁴ Traditional drug discovery pipelines, often spanning 10-15 years with costs exceeding USD 2.5 billion per drug,⁵⁵ are now being compressed through AI-driven approaches.⁵⁴ From target identification to clinical trial optimization, AI technologies such as machine learning, deep learning, and generative chemistry have transformed nearly every stage of the drug

development continuum.⁵⁶

Target Identification and Validation Using AI

Identifying biologically relevant, druggable targets remains a bottleneck in early-stage drug discovery. AI models trained on multi-omics data (e.g., genomics, transcriptomics, proteomics) and literature mining facilitate systematic target prioritization.⁵⁷ Platforms like PandaOmics, developed by Insilico Medicine, are pioneering platforms that utilize natural language processing (NLP), deep feature selection, and biological network analysis to prioritize drug targets.⁵⁸ Recently, PandaOmics identified 28 novel disease targets validated *in silico* and *in vitro* within months.⁵⁹ Additionally, Insilico Medicine's AI predicted fibrosis-related protein targets later validated in preclinical models, substantially reducing the hypothesis-generation phase.⁶⁰ Table 5 delineates various AI techniques employed in target identification.

Table 5. Various AI Techniques are Employed in Target Identification

Technique	Role	Example platform	References
NLP on biomedical literature	Discovering target-disease links	PandaOmics	[61]
Network-based machine learning	Mapping protein interaction networks	BenevolentAI	[62]
Omics integration with AI	Multi-dimensional target scoring	Healx	[63]

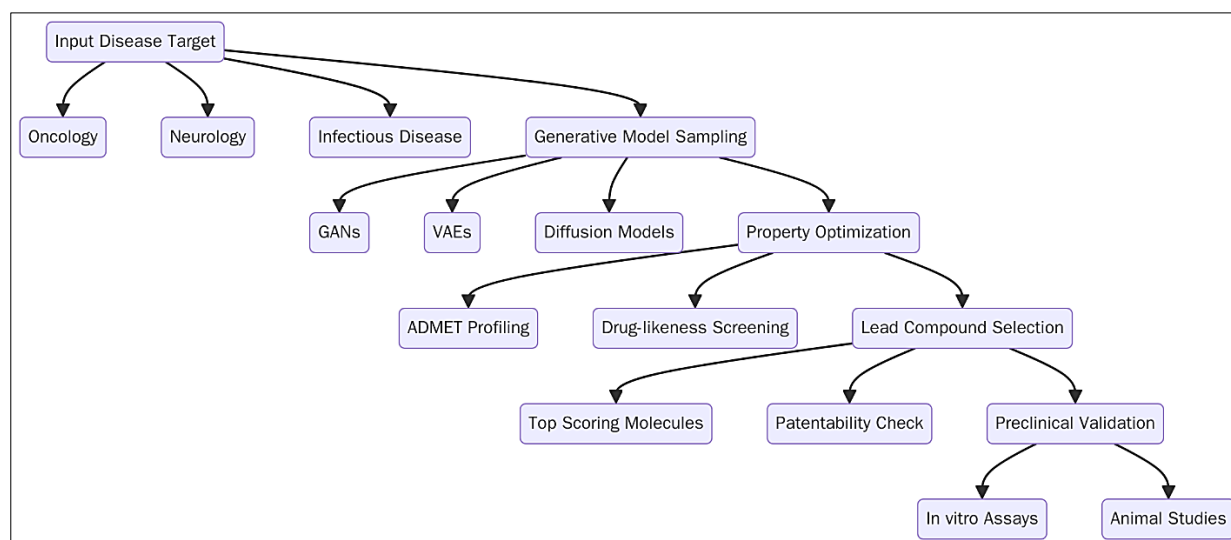


Figure 4. Workflow of AI-Driven Molecule Design.

AI-Driven Generative Models for Molecule Design

AI-driven generative models, particularly variational autoencoders (VAEs), generative adversarial networks (GANs), and reinforcement learning (RL) frameworks, are reshaping molecular design.⁶⁴ These models can generate novel chemical structures with desirable pharmacokinetic and pharmacodynamic properties.⁶⁴

Platforms like Chemistry42 and IBM RXN leverage SMILES-based encoding to navigate chemical space efficiently, suggesting molecules optimized for binding affinity, selectivity, and ADMET (absorption, distribution, metabolism, excretion,

and toxicity) profiles.^{65,66} The Chemistry42 platform has successfully proposed a novel fibrosis drug candidate, INSO18, which moved from computational design to Phase 1 trials within 18 months.⁶⁵ Recent advances also include 3D-structure-based generative models such as DiffDock and GeoDiff, which enable spatially aware ligand design.⁶⁷ Figure 4 illustrates the workflow of AI-Driven Molecule Design, encompassing the input illness target through preclinical validation.

Preclinical and Clinical Trial Optimization Using AI

AI models also significantly contribute to preclinical and

clinical trial phases by optimizing study design, patient recruitment, and biomarker-driven stratification. Predictive modeling tools can simulate pharmacokinetic responses, forecast toxicity risks, and prioritize candidates for in vivo testing, thus streamlining the go/no-go decisions in early development.⁶⁸ In clinical trials, AI algorithms analyze real-world patient data, electronic health records (EHRs), and

genomic profiles to identify suitable participants and predict clinical outcomes.⁶⁹ AI-assisted trials demonstrated a 20-30% faster recruitment time and a 15% increase in trial success rates compared to conventional designs.⁷⁰ Figure 5 illustrates the influence of AI on clinical trial success rates from 2020 to 2024, and Table 6 delineates diverse applications of AI in preclinical and clinical optimization.

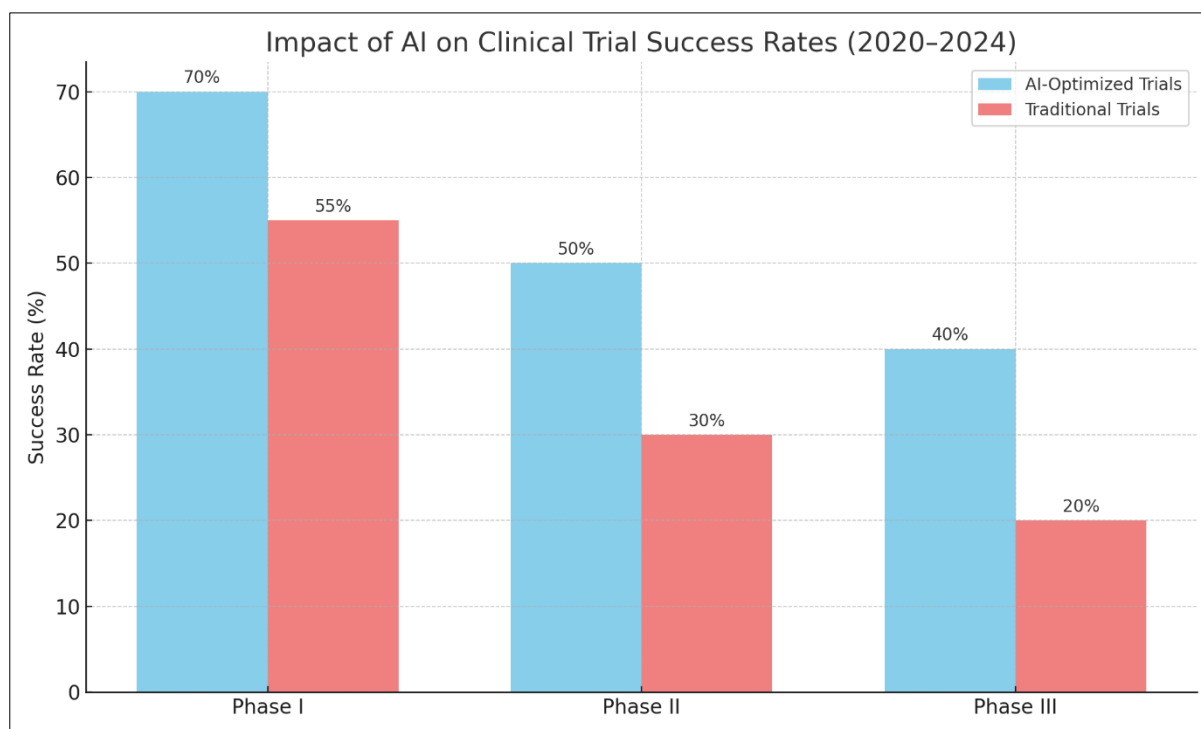


Figure 5. Impact of AI on Clinical Trial Success Rates (2020-2024) (A bar graph showing success rates of AI-optimized vs traditional trials across different phases).⁷¹

Table 6. Various Applications of AI in Preclinical and Clinical Optimization

Stage	AI application	Benefits	Reference
Preclinical	Toxicity prediction	Early filtering of unsafe compounds	[72]
Phase I-III Trials	Patient stratification	Higher trial success rates	
Post-Market	Pharmacovigilance AI	Adverse event monitoring	

Commercial Platforms and Case Studies that Use AI for Drug Discovery/Development

Several case studies highlight the tangible impacts of AI on drug development, such as

Exscientia: Developed DSP-1181 (a molecule targeting OCD) using AI in collaboration with Sumitomo Dainippon Pharma; the molecule entered clinical trials in less than 12 months, a record time.⁷³⁻⁷⁵

Insilico Medicine: Used its end-to-end AI platform to develop a novel anti-fibrotic drug (INS018_055), which successfully advanced to Phase I clinical trials in 2023.⁷⁶

Atomwise: Employed convolutional neural networks to predict small molecule binding and initiated over 250 drug discovery programs across oncology, neurology, and infectious diseases.⁷⁷ Some of the leading AI platforms for

drug discovery are delineated in Table 7.

AI in Genomics and Multi-Omics Integration

The integration of artificial intelligence (AI) into genomics and multi-omics has significantly enhanced our ability to detect genetic variants, profile gene expression, and discover biomarkers.⁷⁹ These advancements are pivotal in understanding complex biological systems and in the development of personalized medicine.

Variant Detection and Interpretation Using AI

Accurate detection of genetic variants is fundamental in genomics.⁸⁰ Traditional variant calling methods often struggle with the complexity of genomic data, especially with the advent of long-read sequencing technologies.⁸¹ AI-

based variant callers, such as DeepVariant⁸² and Clairvoyante,⁸³ have demonstrated superior performance in identifying single-nucleotide variants (SNVs) and insertions/deletions (indels) across various sequencing platforms.⁸⁴

Moreover, ensemble learning approaches can improve

the identification of genetic variants associated with quantitative traits, addressing challenges like genotype multicollinearity and stringent p-value thresholds.⁸⁵ A comparison of AI-based variant callers is delineated in Table 8.

Table 7. Some Leading AI Platforms in Drug Discovery

Company/Platform	Specialization	Notable achievements	References
Insilico Medicine	Target ID + Molecule Design	Fibrosis and oncology candidates	[76]
Exscientia	Automated molecule design	First AI-designed molecule in clinical trials	[73–75]
Atomwise	Structure-based virtual screening	Leads for Ebola and MS	[77]
BenevolentAI	Knowledge graph-based target ID	Novel targets for amyotrophic lateral sclerosis (ALS)	[78]

Table 8. A Comparison of AI-Based Variant Callers

Tool	Sequencing platform	Variant types detected	Notable features	Reference
DeepVariant	Illumina, PacBio	SNVs, indels	High accuracy, deep learning-based	
Clairvoyante	Oxford Nanopore	SNVs, indels	Real-time variant calling	[86]
Ensemble Models	Various	SNVs, indels	Improved detection of quantitative traits	

AI in Single-Cell and Spatial Transcriptomics

Single-cell RNA sequencing (scRNA-seq) and spatial transcriptomics have revolutionized our understanding of cellular heterogeneity and tissue architecture.⁸⁷ However, the high dimensionality and sparsity of the data present analytical challenges.⁸⁸ Deep learning models, such as autoencoders and graph neural networks, have been employed to denoise data, impute missing values, and

integrate multimodal datasets.^{89–91}

Tools like STALocator utilize domain-adaptive networks and supervised autoencoders to accurately localize single-cell data onto tissue sections, facilitating the reconstruction of spatial relationships between cell populations.⁹² Figure 6 depicts a flowchart that illustrates the integration of scRNA-seq and spatial transcriptomics data through AI models for cell type identification and spatial mapping.

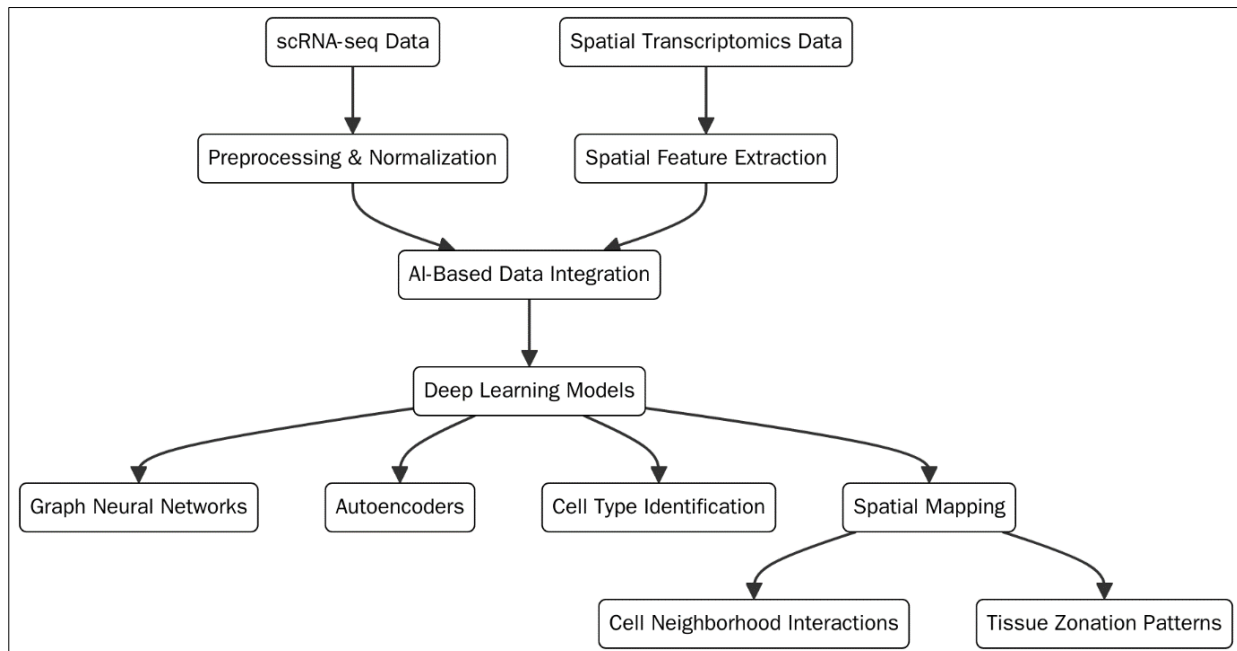


Figure 6. Workflow of AI-Enhanced Single-Cell and Spatial Transcriptomics Analysis (A flowchart illustrating the integration of scRNA-seq and spatial transcriptomics data through AI models for cell type identification and spatial mapping).

AI in Proteomics and Metabolomics Integration

Proteomics and metabolomics provide insights into the functional state of cells and organisms.⁹³ AI algorithms have been instrumental in analyzing mass spectrometry data, enabling the identification of proteins and metabolites

with greater accuracy and speed.⁹⁴ DeepMass, a software program that offers a reliable way to identify and annotate metabolites in intricate biological systems, employs deep learning to predict peptide fragmentation patterns, enhancing protein identification.⁹⁵ Integrating proteomics with genomics

and transcriptomics through AI has facilitated the discovery of novel drug targets and the understanding of complex

disease mechanisms.⁹⁶ Applications of AI tools and methods in proteomics and metabolomics are delineated in Table 9.

Table 9. Applications of AI Tools/Methods in Proteomics and Metabolomics

Application area	AI Tool/Method	Outcome	Reference
Protein Identification	DeepMass	Enhanced accuracy in mass spectrometry data	[94,97–99]
Metabolite Profiling	ML Algorithms	Improved detection of low-abundance metabolites	
Multi-Omics Integration	Network Analysis	Discovery of novel disease biomarkers	

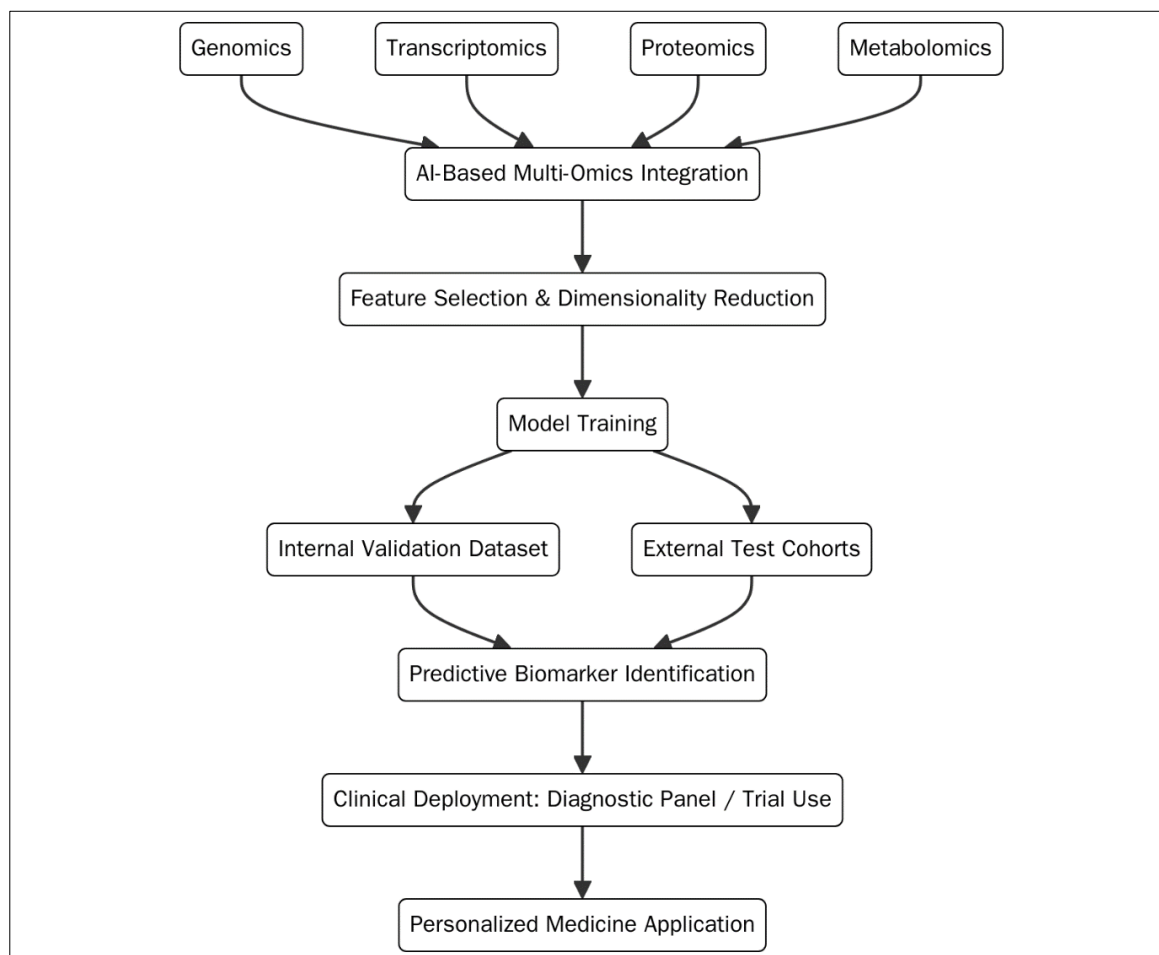


Figure 7. AI-driven Biomarker Discovery to Personalized Medicines (A flowchart illustrating the process from biomarker discovery to personalized medicines driven by artificial intelligence).

Predictive Biomarkers and Personalized Profiles

The identification of predictive biomarkers is crucial for personalized medicine.¹⁰⁰ AI models analyze multi-omics data to uncover biomarkers that can predict disease progression and treatment response.¹⁰¹ Integrating genomics, proteomics, and metabolomics data has led to the identification of biomarkers for autoimmune diseases, aiding in patient stratification and therapy selection.¹⁰²

Moreover, AI-driven analysis of electronic health records (EHRs) and genomic data has improved the matching of patients to clinical trials, enhancing the efficiency of personalized treatment strategies.¹⁰³ Figure 7 illustrates the process from biomarker discovery to personalized medicines driven by artificial intelligence

AI in Synthetic Biology and Metabolic Engineering

The integration of artificial intelligence (AI) and machine learning (ML) into synthetic biology¹⁰⁴ and metabolic engineering¹⁰⁵ has revolutionized the design and optimization of biological systems.¹⁰⁶ These technologies facilitate the rational design of metabolic pathways, gene circuits, and genome editing strategies, thereby accelerating the development of bio-based solutions for various industrial applications.^{104–106}

AI-Guided Pathway Design

AI and ML algorithms have become indispensable tools in metabolic pathway engineering.¹⁰⁷ They enable the prediction and optimization of metabolic fluxes, identification of

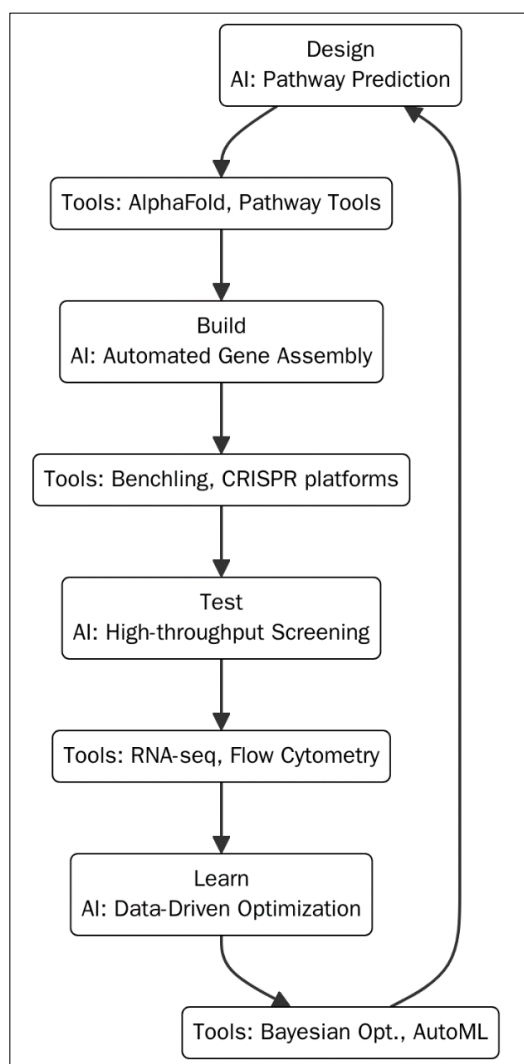


Figure 8. Integration of AI in the Design-Build-Test-Learn (DBTL) Cycle [A schematic diagram illustrating the DBTL cycle with AI integration at each stage: design (pathway prediction), build (automated gene circuit assembly), test (high-throughput screening), and learn (data-driven optimization)].

bottlenecks, and suggestion of genetic modifications to enhance product yields.¹⁰⁸ ML models have been employed to optimize a six-step pathway for n-butanol production, significantly improving yield and reducing by-product formation.¹⁰⁹ Moreover, hybrid approaches combining mechanistic models with ML techniques have been developed to design efficient metabolic pathways.¹¹⁰ These methods leverage large datasets and computational power to predict enzyme activities, metabolite concentrations, and pathway efficiencies, thereby streamlining the design-build-test-learn (DBTL) cycle in metabolic engineering.¹¹¹ A schematic illustration showing how AI is integrated into the Design-Build-Test-Learn (DBTL) cycle is shown in Figure 8.

Gene Circuit Optimization Using AI

The design of synthetic gene circuits has been enhanced by AI-driven approaches that predict the behavior of genetic

components and their interactions.¹¹² ML models can analyze vast datasets to identify optimal promoter sequences, ribosome binding sites, and regulatory elements, facilitating the construction of gene circuits with desired dynamic behaviors.¹¹³

Additionally, AI tools have been utilized to automate the design of genetic circuits, enabling high-throughput screening and optimization.^{114,115} These platforms can predict circuit performance, identify potential failure modes, and suggest modifications to improve robustness and functionality.¹¹⁵

Automated CRISPR Screening Using AI

AI has significantly advanced CRISPR-based genome editing by enhancing target site selection, predicting off-target effects, and optimizing guide RNA design.¹¹⁶ CRISPR-GPT, an AI agent, automates the design of gene-editing strategies by analyzing genomic data to identify optimal editing sites and predict editing outcomes.¹¹⁷

Furthermore, AI-driven platforms have been developed to facilitate large-scale CRISPR screens, enabling the identification of gene functions and interactions at an unprecedented scale.¹¹⁸ These tools accelerate the discovery of genetic elements involved in complex traits and diseases, even cancer,¹¹⁹ thereby informing therapeutic strategies.¹²⁰

AI Applications in Synthetic Biology and Metabolic Engineering

The application of AI in industrial biotechnology has led to the development of efficient microbial cell factories for the production of biofuels, pharmaceuticals, and specialty chemicals.¹²¹ AI models assist in strain optimization by predicting the effects of genetic modifications on metabolic pathways, thereby enhancing product yields and process efficiencies.¹²²

In addition, AI-driven approaches have been employed to design novel enzymes with improved catalytic properties, expanding the repertoire of biocatalysts available for industrial processes.¹²³ These advancements contribute to the development of sustainable and economically viable biomanufacturing platforms. Applications of AI in metabolic engineering and synthetic biology are delineated in Table 10.

AI in High-Throughput Screening, Automation, and Robotics

The convergence of artificial intelligence (AI), robotics, and automation has revolutionized laboratory workflows, enabling high-throughput screening (HTS) and real-time optimization of bioprocesses.¹²⁴ These advancements have significantly accelerated research and development across various scientific disciplines. Figure 9 shows a schematic diagram illustrating how robotics and artificial intelligence are combined in high-throughput screening.

Table 10. Applications of AI in Synthetic Biology and Metabolic Engineering

Application Area	AI/ML contribution	Reference
Metabolic Pathway Design	Prediction of flux distributions and pathway optimization	[107]
Gene Circuit Engineering	Automated design and performance prediction	[112]
CRISPR Screening	Guide RNA design and off-target prediction	[116]
Industrial Bioprocessing	Strain optimization and enzyme design	[122,123]

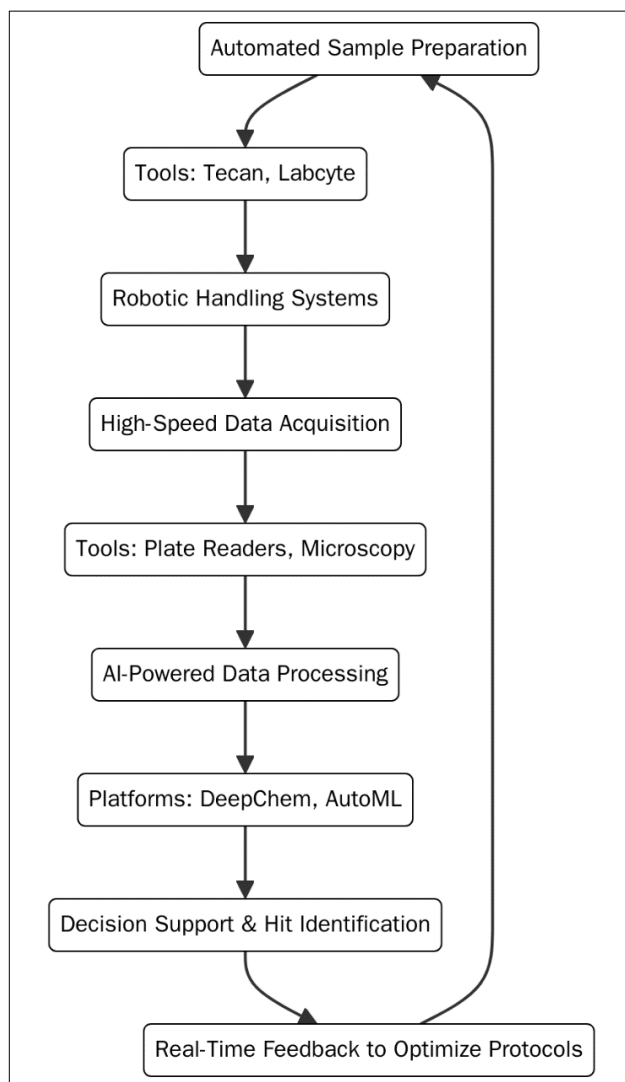


Figure 9. Integration of AI and Robotics in High-Throughput Screening (A schematic diagram illustrating the integration of AI and robotics in HTS workflows, highlighting automated sample preparation, data acquisition, and analysis).

Robot-Assisted Experimentation with AI

Robot-assisted experimentation has become a cornerstone in modern laboratories, facilitating the automation of complex tasks and enhancing reproducibility.¹²⁵ The integration of robotic systems in chemical synthesis platforms has enabled the automation of diverse experiments, reducing human error and increasing throughput.^{126–128}

Moreover, the development of robotic assistants like ORGANA has demonstrated the potential of combining robotics with AI to automate decision-making processes in chemical experimentation.¹²⁹

AI Integration in Lab-on-a-Chip and Microfluidics

Lab-on-a-chip (LOC) technologies and microfluidics have transformed the landscape of biomedical research by miniaturizing and integrating laboratory functions onto a single chip.¹³⁰ These systems allow for precise control and manipulation of small fluid volumes, enabling high-throughput analyses with reduced reagent consumption.¹³¹

The integration of AI/ML with microfluidic systems has further enhanced their capabilities.¹³² AI algorithms can optimize microfluidic designs, control fluid dynamics, and analyze complex datasets generated from LOC experiments.^{133,134}

AI in Quality Control and Process Analytics

AI has significantly improved quality control (QC) and process analytics in laboratory settings. Machine learning algorithms can detect anomalies, predict equipment failures, and ensure consistent product quality.¹³⁵ The convolutional neural networks have been employed to detect defects in microwell-based medical devices, enhancing QC processes.¹³⁶ Applications of robotics and AI in laboratory automation are delineated in Table 11.

AI in Personalized and Precision Medicine

The integration of Artificial Intelligence (AI) into personalized and precision medicine has revolutionized healthcare by enabling tailored diagnostics and therapeutics based on individual patient data.^{137–139} This approach enhances treatment efficacy and minimizes adverse effects, marking a significant shift from traditional one-size-fits-all medical practices.¹⁴⁰

AI-Powered Patient Stratification

AI-driven patient stratification involves categorizing patients into subgroups based on genetic, phenotypic, and clinical data to predict disease risk and treatment response.¹⁴¹ Machine learning models analyze large-scale omics datasets to identify biomarkers and stratify patients effectively.¹⁴²

Sonrai Analytics has developed machine learning algorithms that assist pharmaceutical companies in achieving precise patient stratification, thereby enhancing the delivery of personalized treatments.^{143,144} AI applications for patient stratification are delineated in Table 12.

AI-powered Predictive Modeling for Treatment Response

Predictive modeling utilizes AI to forecast patient responses

Table 11. Applications of AI and Robotics in Laboratory Automation

Application Area	AI/Robotics contribution	Reference
Chemical Synthesis	Automated experimentation and decision-making	[126–129]
Microfluidic Systems	Design optimization and data analysis	[130–132,134]
Quality Control	Defect detection in medical devices	[135]

to specific treatments, enabling clinicians to make informed decisions.¹⁴⁷ These models incorporate diverse data sources, including electronic health records (EHRs), genomic information, and lifestyle factors.¹⁴⁸ A notable example is the development of AI-powered tools that analyze facial features to predict cancer survival outcomes, outperforming traditional clinical assessments.¹⁴⁹ Figure 10 depicts a flowchart illustrating the workflow for AI-driven predictive modeling.

AI-Powered Digital Twins for Patient Physiology

Digital twins are virtual replicas of patients that simulate physiological processes, allowing for personalized treatment planning and disease management.¹⁵⁰ By integrating data from various sources, including wearable devices and medical imaging, digital twins provide a dynamic model of patient health.¹⁵¹ The CURATE.AI platform employs digital twins to personalize chemotherapy dosing, resulting in a 20% reduction in drug usage without compromising efficacy.^{152,153} The impact of digital twins on personalized treatment is presented in Table 13.

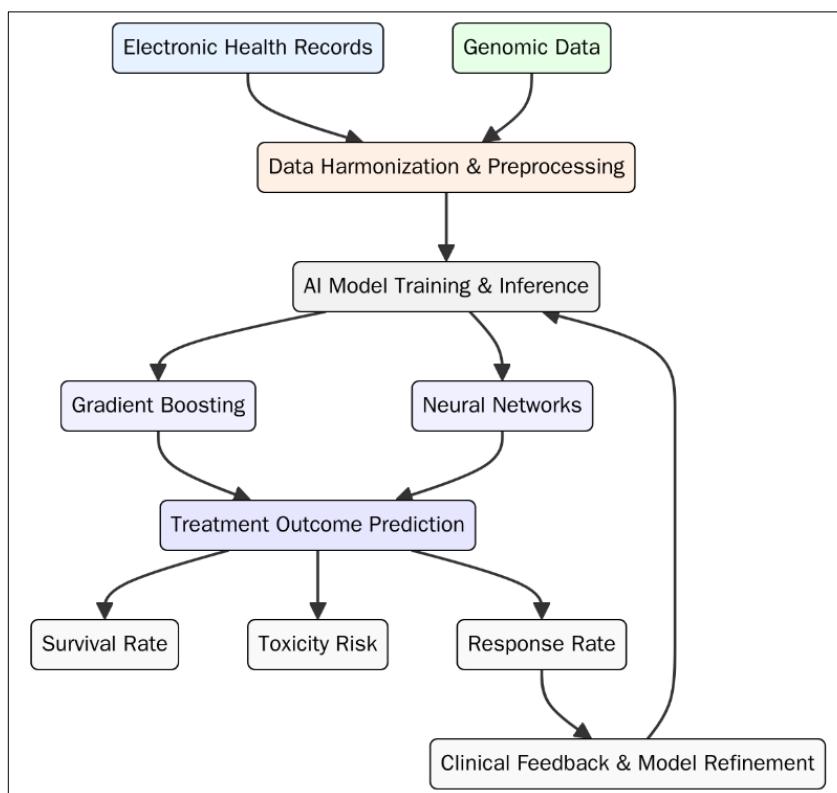


Figure 10. AI-Driven Predictive Modeling Workflow (A flowchart illustrating the integration of EHRs, genomic data, and AI algorithms to predict treatment outcomes).

Table 12. Applications of AI in Patient Stratification

Application area	AI contribution	Reference
Oncology	Biomarker identification for cancer subtypes	[145]
Pharmacogenetics	Predicting drug response based on genetic profiles	[146]

Table 13. Impact of Digital Twins on Personalized Medicine

Clinical application	Outcome improvement	Reference
Chemotherapy Dosing	20% reduction in drug usage	[153]
Cardiac Treatment Planning	Enhanced prediction of treatment outcomes	[154,155]

AI in Diagnostics and Imaging

Artificial Intelligence (AI) is revolutionizing diagnostics

and imaging by enhancing accuracy, efficiency, and accessibility in clinical and research settings.¹⁵⁶ From

radiology to pathology and point-of-care diagnostics, AI-driven tools are transforming traditional workflows and enabling more precise medical decision-making.¹⁵⁷

AI-Enhanced Radiology and Tomography

AI applications in radiology have significantly improved diagnostic accuracy and workflow efficiency.¹⁵⁸ Convolutional Neural Networks (CNNs) and deep learning algorithms are employed to detect anomalies in imaging modalities such as CT, MRI, and PET scans.^{159–161}

The HeartFlow Analysis, an AI-driven 3D heart scan technology, has been implemented in 56 English hospitals,

reducing the need for invasive diagnostic angiograms by one-sixth and cutting secondary heart tests by 12%.¹⁶² This has resulted in nearly £10 million in savings for the NHS.¹⁶³ The effect of AI-enhanced 3D heart scans on NHS diagnosis is seen in Figure 11.

AI-Enhanced Digital Pathology and Whole-Slide Analysis

Digital pathology, augmented by AI, enables the analysis of whole-slide images (WSIs) with high precision.^{166,167} AI models like Prov-GigaPath, developed by Microsoft, have demonstrated high accuracy in tasks such as cancer subtyping and mutation prediction by analyzing over 1.3 billion

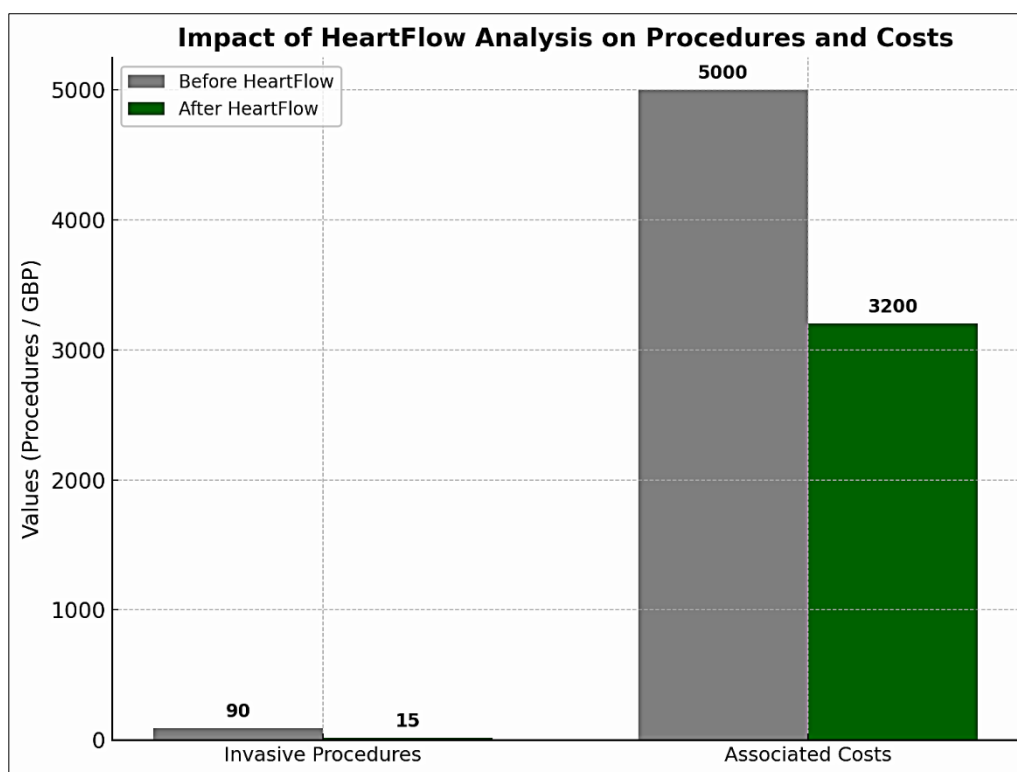


Figure 11. Impact of AI-Enhanced 3d Heart Scan on NHS Diagnostics (A bar graph illustrating the reduction in invasive procedures and associated cost savings due to the implementation of HeartFlow Analysis).^{164,165} The implementation of HeartFlow, an AI-driven 3D heart imaging tool, reduced the number of invasive diagnostic angiograms from 90 to 15 per evaluation cohort and lowered the associated average cost from approximately 5000 to 3200 per patient. These improvements contributed to an estimated 10 million in savings across 56 NHS hospitals in England as of early 2024.

Table 14. Performance Metrics of AI Models in Digital Pathology

AI model	Application	Dataset size	AUC score	References
Prov-GigaPath	Cancer subtyping	1.3 billion image tiles	High accuracy (specific AUC not provided)	[168]
Virchow	Pan-cancer detection	1.5 million WSIs	0.949	[169]

pathology image tiles.¹⁶⁸

Moreover, the Virchow model, a foundation model for computational pathology, achieved an area under the curve (AUC) of 0.949 across 17 different cancer types, showcasing the potential of AI in enhancing diagnostic capabilities in pathology.¹⁶⁹ The performance metrics of AI models in digital pathology are delineated in Table 14.

Point-of-Care Diagnostic Devices Powered by AI

AI integration into point-of-care (POC) diagnostic devices has enhanced real-time decision-making and accessibility.¹⁷⁰ The FDA-approved DermaSensor is a handheld device that uses AI to assist primary care providers in detecting common skin cancers, providing immediate recommendations on

whether to investigate further or monitor the lesion.¹⁷¹

Additionally, AI-powered cough monitoring tools, such as those developed by Hyfe AI, analyze cough patterns to detect health issues, offering a non-invasive and accessible diagnostic method.^{172,173} Figure 12 depicts the workflow of AI-integrated Point-of-care diagnostic devices.

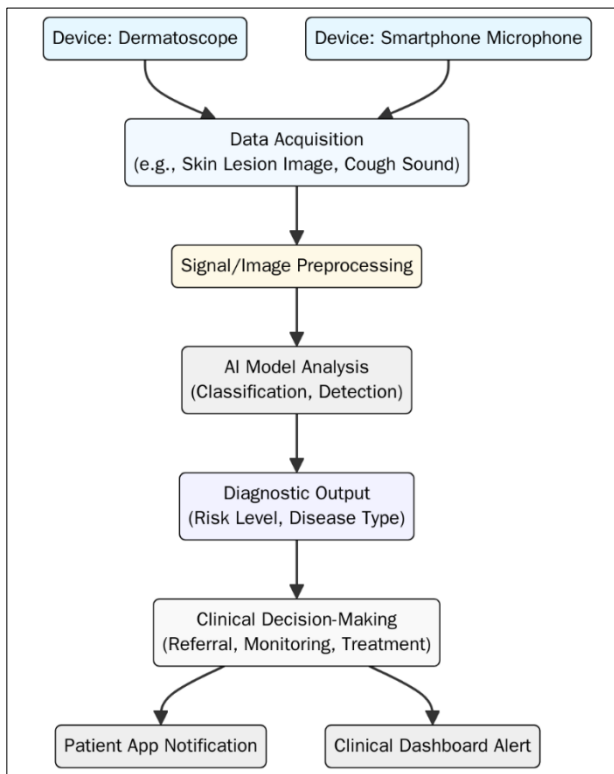


Figure 12. Workflow of AI-integrated Point-of-Care Diagnostic Devices (A flowchart depicting the process from data acquisition (e.g., skin lesion image or cough sound) to AI analysis and clinical decision-making).

AI in Bioprocess Optimization and Biomanufacturing

The integration of Artificial Intelligence (AI) into bioprocessing and biomanufacturing has revolutionized the production of biopharmaceuticals by enhancing efficiency, scalability, and quality control.¹⁷⁴ AI-driven predictive models are now pivotal in optimizing fermentation processes, cell culture conditions, and supply chain logistics, leading to more streamlined and cost-effective manufacturing workflows.¹⁷⁵

AI-Driven Predictive Fermentation

AI has significantly improved fermentation processes by enabling real-time monitoring and predictive control, which enhances yield and reduces variability.¹⁷⁶ Companies like Pow.Bio has developed proprietary AI-driven fermentation software that accelerates process development from months to mere weeks.¹⁷⁷ This technology leverages autonomous control to reduce variability and increase production consistency.¹⁷⁸

Moreover, AI applications in microbial fermentation have been instrumental in transforming industrial biotechnology. AI's applications in diverse fields of food, alcohol, and pharmaceutical industries have led to the development of novel bio-products, reduction of production costs, and improved sustainability.^{179–181} AI-Driven Predictive Control in Fermentation is shown schematically in Figure 13.

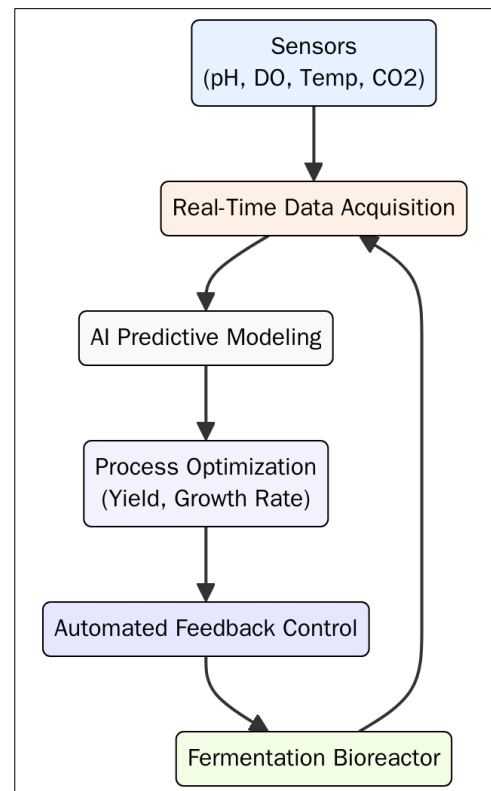


Figure 13. AI-Driven Predictive Control in Fermentation (A schematic diagram illustrating the integration of AI algorithms with fermentation bioreactors, showcasing real-time data acquisition, predictive modeling, and process optimization).

AI in Cell Line Development and Biomanufacturing Scale-up

AI has revolutionized cell line development by enabling the analysis of genomic data to predict the effects of genetic modifications, leading to the engineering of strains with improved productivity and desired characteristics.¹⁸² This accelerates the development of microbial strains and cell lines, resulting in higher yields and enhanced product quality.¹⁸³

Furthermore, companies like Stämm are utilizing AI to build cell-predictive pipelines leveraging multi-omics biological data using generative models.¹⁸⁴ This approach simplifies cell line development and enhances the selection of the most productive clones, facilitating efficient scale-up in bioprocessors.¹⁸⁵ Table 15 delineates the application of AI in cell line development and biomanufacturing scale-up.

Table 15. Applications of AI in Cell Line Development and Biomanufacturing Scale-up

Application area	AI contribution	Reference
Microbial Strain Engineering	Predictive modeling of genetic modifications	[183]
Clone Selection	Multi-omics data integration for optimal clone identification	[185]

AI-Based Modeling in Supply Chain and Logistics

AI enhances supply chain operations in biomanufacturing by improving forecasting accuracy and inventory management. By using AI to optimize processes from the start, manufacturers can bring new therapies to market faster, benefiting patients who rely on timely treatment options.^{186,187}

Additionally, AI can standardize and synchronize data across supply chain platforms, reducing errors and delays. This unified view of inventory, production, and logistics improves tracking and enables real-time accuracy in enterprise applications.¹⁸⁶

Ethical, Legal, and Regulatory Challenges in AI-Driven Biotechnology

The rapid integration of Artificial Intelligence (AI) in biotechnology has ushered in transformative advancements. However, it concurrently raises significant ethical, legal, and regulatory challenges that must be addressed to ensure responsible innovation.

AI systems in biotechnology often process sensitive personal data, including genomic information, necessitating stringent data privacy and security measures.^{188,189} The World Health Organization (WHO) emphasizes the importance of robust legal and regulatory frameworks to safeguard privacy, security, and data integrity in AI applications within healthcare.¹⁹⁰ Moreover, the increasing

role of Chief Privacy Officers (CPOs) highlights the need for dedicated oversight in managing AI-related data risks.¹⁹¹ The International Association of Privacy Professionals revealed that over 80% of privacy teams now handle aspects of AI and data governance, underscoring the expanding responsibilities of CPOs in ensuring compliance with evolving data protection regulations.¹⁹²

Additionally, transparency and explainability are critical for building trust in AI systems.¹⁹³ The European Union's AI Act mandates transparency requirements for high-risk AI systems, ensuring that users are informed about AI interactions and that systems are explainable to stakeholders.^{194,195} In the context of biotechnology, explainability enables researchers and clinicians to understand AI-driven decisions, facilitating better integration into clinical workflows and ensuring accountability,¹⁹⁶ with legal compliance, cultural norms, and user needs all impacted by the essential quality standards of explainability and transparency.¹⁹⁷

Furthermore, the regulatory landscape for AI in biotechnology is still evolving, with agencies like the U.S. Food and Drug Administration (FDA) actively developing guidelines.¹⁹⁸ The FDA has issued guidance on the use of AI to support regulatory decision-making in drug and biological product development, emphasizing the need for transparency, reliability, and compliance with existing regulatory standards.¹⁹⁹ Table 16 delineates the key ethical, legal, and regulatory considerations in AI-driven biotechnology.

Table 16. Key Ethical, Legal, and Regulatory Considerations in AI-driven Biotechnology

Consideration	Description	References
Data Privacy and Security	Protection of sensitive personal data, including genomic information	[200,201]
Algorithmic Transparency	Ensuring AI systems are understandable and decisions are explainable	
Regulatory Frameworks and Compliance	Development of guidelines and legal frameworks to govern AI applications in biotechnology	

Current Limitations and Emerging Risks in AI-driven Biotechnology

While Artificial Intelligence (AI) has significantly advanced biotechnology, it also presents several limitations and challenges that must be addressed to ensure safe and effective applications.

AI models in biotechnology often suffer from data bias due to the underrepresentation of certain populations in training datasets.^{202,203} This can lead to disparities in healthcare outcomes, as algorithms may not perform equally across diverse demographic groups.²⁰² AI systems trained predominantly on data from North America, Europe, and China may not generalize well to populations in South Asia, South America, or Africa, potentially exacerbating

health inequalities.²⁰⁴ Moreover, the lack of standardized data collection and reporting practices hampers the development of robust AI models.²⁰⁵ Variability in data quality and formats across institutions can lead to inconsistencies in model performance and hinder collaborative research efforts.²⁰⁶

Ensuring the robustness and reproducibility of AI models is a significant challenge in biotechnology. In AI research, there is a "reproducibility crisis" when models don't consistently yield findings across datasets or experimental settings.²⁰⁷ Factors contributing to this issue include overfitting, lack of transparency in model development, and insufficient validation of diverse datasets.²⁰⁸

The dual-use nature of AI in biotechnology raises significant biosecurity concerns. Advanced AI models can potentially be misused to design harmful biological agents or toxins, posing risks of bioterrorism or accidental release.^{209,210} The democratization of AI tools increases accessibility, which, while beneficial for research, also heightens the risk of misuse.²¹¹

Future Prospects and Directions

The convergence of artificial intelligence (AI) and biotechnology is catalyzing transformative advancements, heralding a new era of innovation. Emerging areas such as foundation models for biology, AI-enabled lab-on-a-chip devices, and digital twins of biological systems are poised to revolutionize research and clinical applications.

Foundation models (FMs), large-scale AI systems trained on extensive datasets, have demonstrated remarkable capabilities in understanding and generating biological sequences. Protein language models (pLMs), a subset of FMs, are trained on vast protein sequence data to predict structures, functions, and interactions.²¹² Additionally, the integration of AI with synthetic biology is enabling the design and analysis of synthetic cells and organoids, three-dimensional, lab-grown structures that mimic organ functions.^{213,214} AI models can forecast organoid development and functionality, enhancing disease modeling and personalized medicine, along with combining organoids with AI to create biohybrid systems capable of processing information, opening avenues for novel computing paradigms.²¹⁵ Furthermore, the fusion of AI with Internet of Things (IoT) devices and edge computing is transforming data acquisition and analysis in biotechnology.²¹⁶ Miniaturized platforms that integrate microfluidics and AI to perform complex analyses on small samples, enabling rapid diagnostics and high-throughput screening, along with deploying AI algorithms on local devices to process data in real time, reducing latency and preserving data privacy.^{217,218}

Conclusion

The integration of artificial intelligence (AI) into biotechnology marks a paradigm shift in life sciences, enabling faster, more precise, and data-driven solutions across a wide spectrum of applications. From protein structure prediction and drug discovery to multi-omics analysis, synthetic biology, and precision medicine, AI technologies are revolutionizing both fundamental research and industrial practices. Tools like AlphaFold, CRISPR-GPT, and AI-enhanced lab automation exemplify the transformative potential of AI in accelerating discovery, optimizing biological systems, and personalizing healthcare. Furthermore, AI is playing a critical role in advancing high-throughput screening, metabolic engineering, and bioprocessing, contributing to the development of sustainable

and scalable bio-based innovations. However, despite these advancements, challenges remain, particularly regarding data quality, model reproducibility, ethical considerations, and regulatory oversight. The risks of algorithmic bias, biosecurity threats, and the need for transparent, explainable AI systems underscore the importance of responsible innovation. As AI technologies continue to evolve, fostering interdisciplinary collaboration, robust governance frameworks, and equitable access will be essential to harness their full potential.

Authors' Contributions

The author carried out all tasks related to the research and preparation of this manuscript.

Conflict of Interest Disclosures

The author declares no conflicts of interest.

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