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A Review On: Artificial Intelligence in Preclinical and Clinical Trials

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Abstract: Artificial Intelligence (AI) is rapidly transforming pharmaceutical research and drug development. The traditional process of discovering and developing new medicines is time-consuming, expensive and associated with a high rate of failure. AI, including machine learning, deep learning, natural language processing and generative AI, can analyses large and complex datasets and assist researchers in making predictions and decisions. In preclinical research, AI can support target identification, drug discovery, molecular screening, toxicity prediction, pharmacokinetic and pharmacodynamics modelling, and analysis of animal and laboratory data. In clinical trials, AI can assist with protocol design, patient recruitment, eligibility screening, clinical data management, monitoring, endpoint assessment, adverse-event detection and prediction of trial outcomes. The U.S. Food and Drug Administration (FDA) reports increasing use of AI across nonclinical, clinical, post-marketing and manufacturing stages of drug development. Despite these benefits, challenges such as data quality, algorithmic bias, lack of transparency, privacy, cybersecurity, regulatory uncertainty and the need for human oversight remain important. Therefore, appropriate validation, monitoring and risk-based regulatory approaches are necessary for the safe and effective use of AI in pharmaceutical development.

Keywords: *Artificial Intelligence, Machine Learning, Preclinical Trials, Clinical Trials, Drug Development, Drug Discovery, Pharmacovigilance, Toxicity Prediction, Patient Recruitment. Generative AI.*

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I. INTRODUCTION

Drug development is a complex process involving discovery, preclinical evaluation, clinical trials, regulatory review and post-marketing surveillance. Conventional drug-development approaches require substantial time, financial resources and experimental work. Machine learning and other AI technologies are increasingly being used to complement conventional methods and improve decision-making throughout the drug-development process.

The U.S. Food and Drug Administration (FDA) reports increasing use of AI components in drug applications across nonclinical, clinical, manufacturing and post-marketing activities.

AI can process large volumes of biological, chemical and clinical information more rapidly than conventional manual approaches. Current applications range from drug discovery and toxicology to clinical-trial design and post-market safety surveillance.

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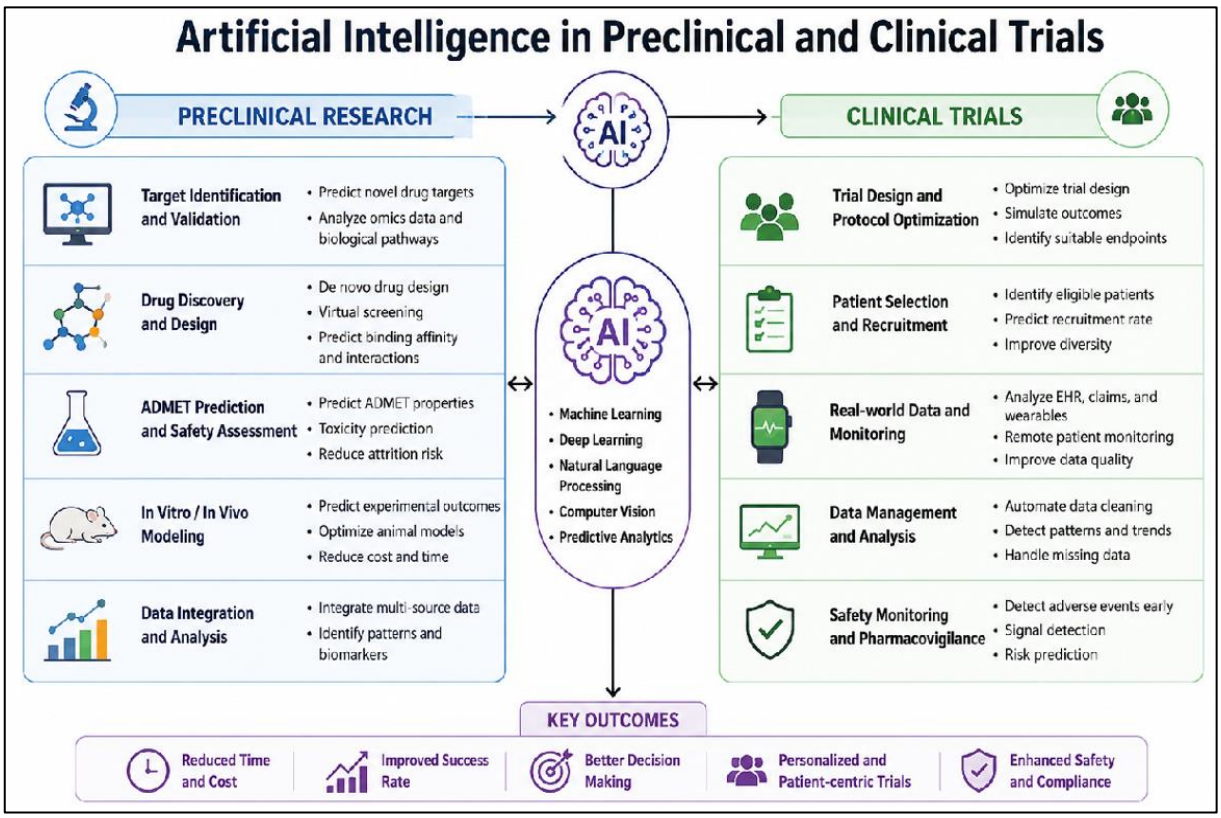

Fig 1 Artificial Intelligence (AI) in Preclinical and Clinical Trial.

➢ *Definition: Artificial Intelligence (AI) in Preclinical and Clinical Trial*

AI helps make drug development faster, safer, more accurate, and cost-effective from the laboratory stage to clinical testing.

➢ *Objectives of Review:*

The main objectives of this review are:

- To describe the role of AI in preclinical drug development.
- To discuss AI applications in clinical trials.
- To identify the advantages of AI-assisted drug development.
- To discuss limitations, ethical issues and regulatory challenges.
- To describe future perspectives of AI in pharmaceutical research.

➢ *Types of Artificial Intelligence (AI) Used in Drug Development:*

- *Important AI Technologies Include:*

✓ Machine Learning-Learns patterns from existing data and makes predictions.
✓ Deep Learning-Uses multilayer neural networks for complex datasets.
✓ Natural Language Processing-Analyses scientific literature, clinical documents and other text.
✓ Generative Artificial Intelligence-Generates or proposes new molecular structures and other data.
✓ Predictive Analytics-Predicts outcomes such as toxicity, treatment response and trial performance.
✓ Computer Vision-Analyses medical images and digital pathology data.

➢ *Artificial Intelligence (AI) in Preclinical Trials:*

Preclinical studies are performed before a new drug is tested in humans. They generally include laboratory experiments, pharmacological studies, pharmacokinetic studies and toxicity testing.

- *AI can Improve Several Aspects of Preclinical Research*

✓ Target Identification
✓ Drug Discovery
✓ Virtual Screening
✓ Drug–Target Interaction Prediction
✓ Toxicity Prediction
✓ Pharmacokinetic and Pharmacodynamics Prediction
✓ Digital Pathology
✓ Reduction of Animal Studies

➢ *Artificial Intelligence (AI) in Clinical Trials:*

- Clinical Trial Design
- Patient Recruitment
- Patient Stratification
- Dose Selection and Optimization
- Monitoring of Clinical Trials
- Adverse Drug Reaction Detection
- Clinical Data Analysis

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II. REPRESENTATION IN ARTIFICIAL INTELLIGENCE (AI) IN PRECLINICAL AND CLINICAL TRIALS

The diagram illustrates how AI is used throughout the drug development process, from identifying potential drug targets to post-market monitoring. AI technologies such as machine learning, deep learning, natural language processing, robotics, and big data analytics help researchers discover new drug candidates, optimize their properties, predict toxicity, improve clinical trials, and support regulatory approval. Overall, AI can make drug development faster, smarter, more efficient, and cost-effective, while also helping improve drug safety and effectiveness.

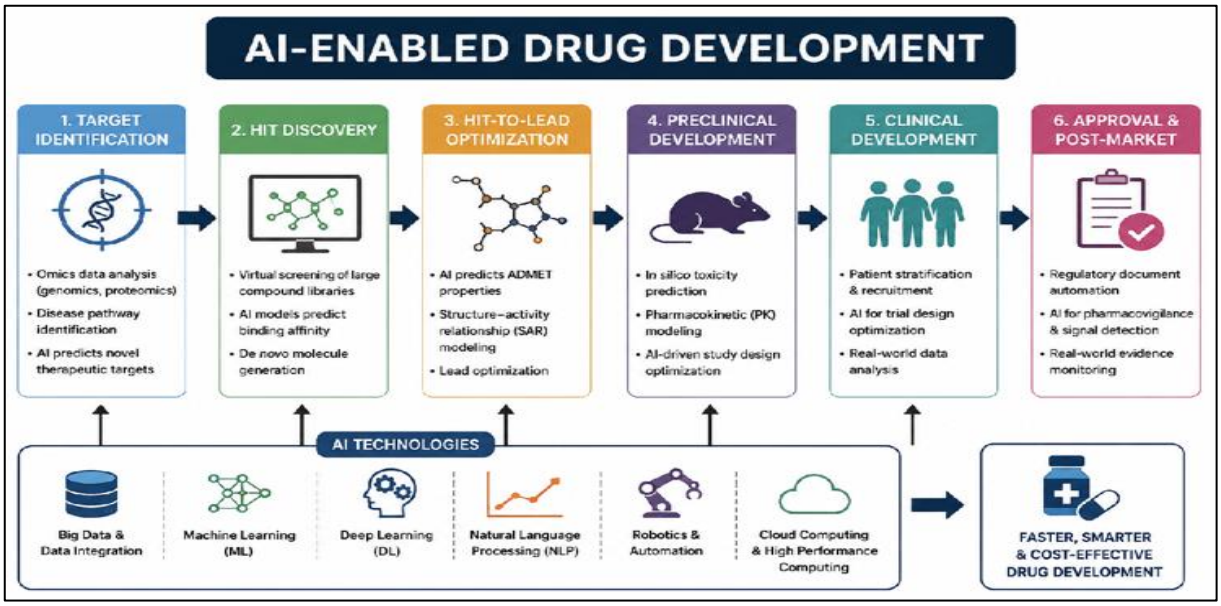

Fig 2 AI Enabled Drug Discovery

➢ *AI Application in Preclinical Research:*

The diagram shows the applications of AI in preclinical research, where AI supports drug development before human clinical trials. It helps in identifying and validating drug targets, discovering and designing new drugs, predicting ADME/Tox properties, performing in silico modeling and simulations, optimizing experimental design, and analyzing imaging and biological data. AI also helps discover biomarkers and translate research findings into clinical applications. Overall, AI makes preclinical research faster, more accurate, efficient, and cost-effective, while reducing the risk of late-stage failures.

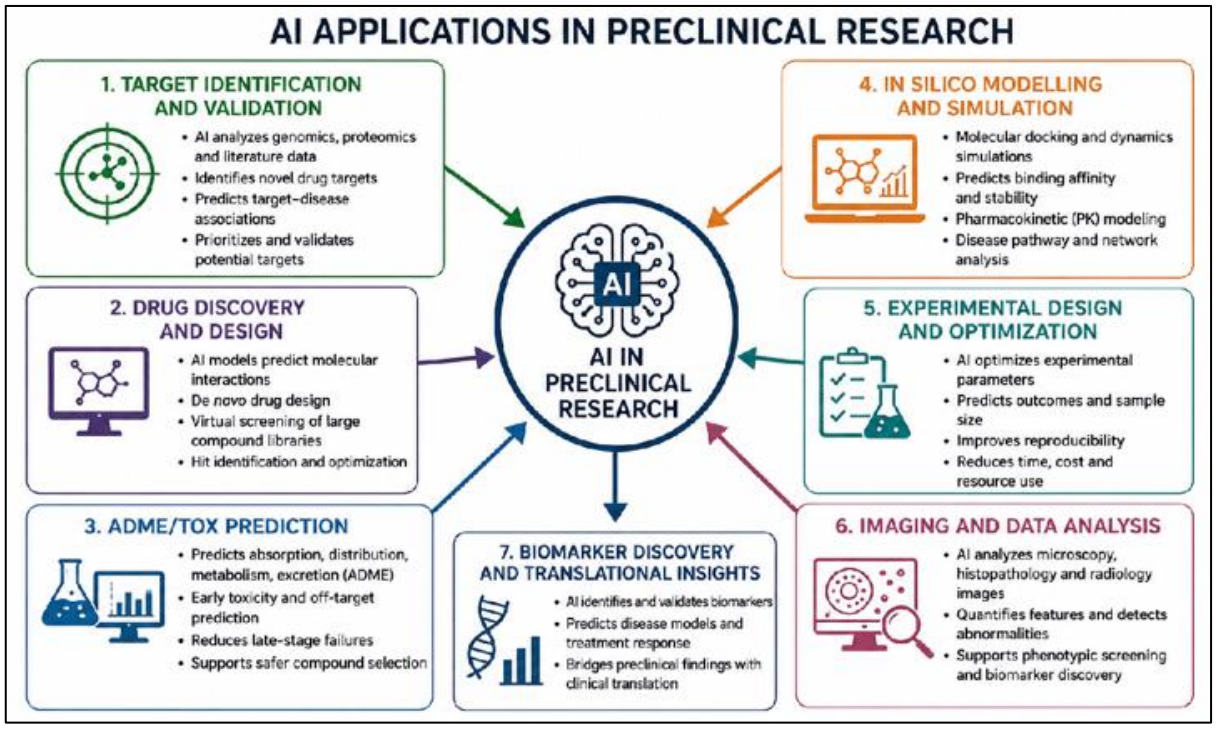

Fig 3 AI Application in Preclinical Research.

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➢ *AI Application in Clinical Research:*

The diagram explains the role of AI in preclinical research, where AI helps improve the early stages of drug development. It supports target identification, drug discovery and design, ADME/Tox prediction, in-silico modeling, experimental design, imaging and data analysis, and biomarker discovery. By analyzing large amounts of biological and experimental data, AI helps researchers make faster and more accurate decisions, reduce costs, improve reproducibility, and identify promising drug candidates before clinical trials.

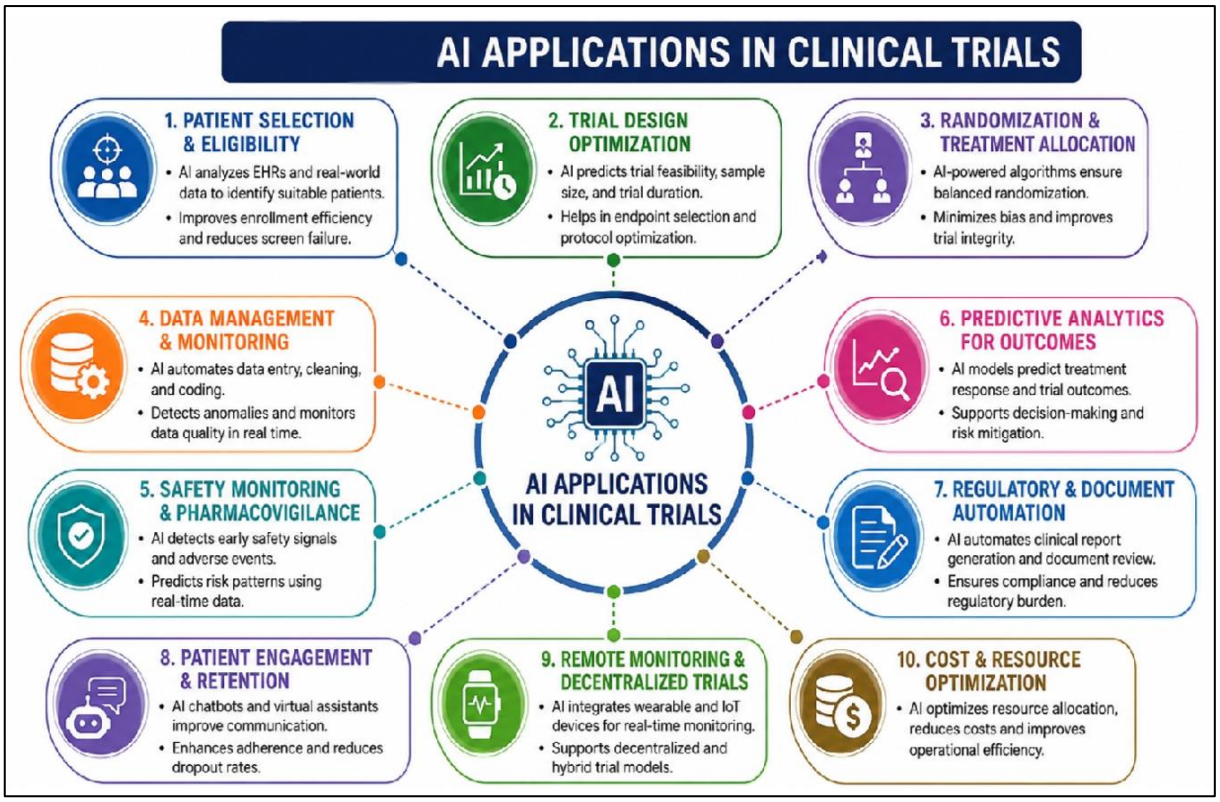

Fig 4 AI Application in Clinical Research.

➢ *Advantages of Artificial Intelligence (AI) in Preclinical And Clinical Trials:*

- *Major Potential Advantages Include:*

✓ Faster analysis of large datasets.
✓ Improved selection of drug candidates.
✓ Reduction in unnecessary laboratory experiments.
✓ Better prediction of toxicity and drug properties.
✓ Improved patient recruitment.
✓ Support for personalized clinical trials.
✓ Earlier identification of safety signals.
✓ More efficient clinical-trial data analysis.
✓ Potential reduction in development time and cost.

➢ *Limitations and Challenges:*

- Data Quality
- Algorithmic Bias
- Lack of Explainability
- Privacy and Security
- Regulatory Uncertainty
- Human Oversight
- Validation

➢ *Ethical Considerations:*

- *Important Ethical Considerations Include:*

✓ Protection of patient privacy.
✓ Informed consent.
✓ Transparency of AI systems.
✓ Prevention of discrimination.
✓ Human oversight.
✓ Accountability for AI-assisted decisions.
✓ Secure handling of clinical data.
✓ Appropriate validation before clinical use.

AI should therefore be implemented with strong scientific, ethical and regulatory oversight.

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Fig 5 Ethical Consideration

III. REGULATORY CONSIDERATIONS

Regulatory agencies are developing approaches to ensure that AI can be used without compromising the safety, efficacy, and quality of medicines.

Good Clinical Practice is also evolving to accommodate technological innovation. The final ICH E6(R3) Good Clinical Practice guidance, announced by FDA in September 2025, includes flexible and risk-based approaches to clinical-trial design, conduct, and technology while maintaining participant protection and reliable results.

In January 2025, FDA issued draft guidance concerning AI used to support regulatory decision-making for drugs and biological products. The guidance proposes a risk-based credibility assessment framework for evaluating an AI model in its particular context of use. Therefore, future AI-based clinical research should combine technological innovation with regulatory compliance, scientific validation, and patient protection.

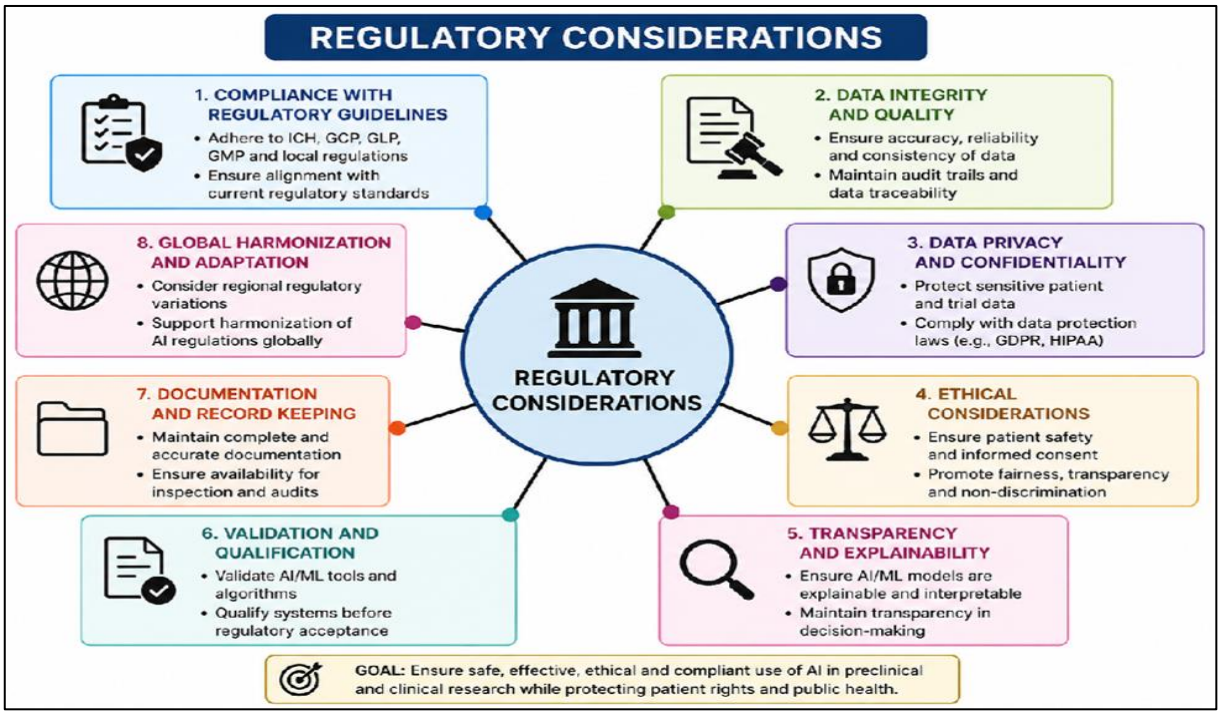

Fig 6 Regulatory Consideration

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➢ *Future Prospective:*

The future of AI in pharmaceutical research is promising. Important areas of development include:

- Generative AI for molecular design.
- AI-assisted personalized medicine.
- Digital biomarkers.
- Virtual patient modelling.
- AI-supported adaptive clinical trials.
- Automated analysis of medical images.
- AI-assisted pharmacovigilance.
- Integration of genomic and clinical data.
- Federated learning for privacy-preserving research.
- Improved AI-based toxicology and preclinical modelling.

➢ *Roles of Pharmacists:*

Pharmacists can contribute to the responsible use of AI in drug development by:

- Understanding AI-based drug-development tools.
- Supporting medication safety and pharmacovigilance.
- Evaluating AI-generated drug information.
- Participating in clinical research.
- Promoting patient safety and ethical use of technology.

IV. CONCLUSIONS

Artificial Intelligence (AI) is becoming an important tool in preclinical and clinical trials. It can help in drug discovery, safety prediction, patient selection, trial design, and data analysis. AI can make drug development faster, more efficient, and more personalized.

However, challenges such as data quality, bias, privacy, validation, and regulatory issues must be addressed. Therefore, AI should work with researchers and healthcare professionals, not replace them. With proper validation and responsible use, AI has great potential to improve future drug development and clinical research.

REFERENCES

[1]. Zhang Y, Mastouri M, Zhang Y. Accelerating drug discovery, development, and clinical trials by artificial intelligence. Med. 2024;5(9):1050–1070.
[2]. Catacutan DB, Alexander J, Arnold A, et al. Machine learning in preclinical drug discovery. Nature Chemical Biology. 2024;20:960–973.
[3]. Artificial intelligence in drug development. Nature Medicine. 2024.
[4]. U.S. Food and Drug Administration. Artificial Intelligence for Drug Development. FDA.
[5]. U.S. Food and Drug Administration Artificial Intelligence Program for Toxicology. FDA.
[6]. Poddar A, Samson M, Innes GK, et al. Leveraging Artificial Intelligence in Drug and Biological Product Development: An FDA and Clinical Trial Transformation Initiative Workshop Report. NEJM AI. 2025.
[7]. Artificial intelligence in clinical trials: A comprehensive review of opportunities, challenges, and future directions. International Journal of Medical Informatics. 2026;206:106141.
[8]. The potential of artificial intelligence in clinical trials. European Journal of Clinical Investigation. 2026.
[9]. U.S. Food and Drug Administration. Artificial Intelligence for Drug Development. FDA. 2026.
[10]. U.S. Food and Drug Administration. Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products: Draft Guidance for Industry and Other Interested Parties. January 2025.
[11]. Aggarwal R, Bhatt DL. The potential of artificial intelligence in clinical trials. European Journal of Clinical Investigation. 2026;56(3):e70182.
[12]. Pontes CB, Netto AV. The use of Artificial Intelligence Algorithms in drug development and clinical trials: A scoping review. International Journal of Medical Informatics. 2025;195:105798.
[13]. Lavecchia A, et al. Artificial intelligence in preclinical research: enhancing digital twins and organ-on-chip to reduce animal testing. Drug Discovery Today. 2025.
[14]. Gupta D, et al. AI in Clinical Trials and Drug Development: Challenges and Potential Advancements. Current Drug Discovery Technologies. 2025.
[15]. Integrating artificial intelligence in drug discovery and early drug development: a transformative approach. 2025.