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A Review: Artificial Intelligence in Clinical Trails: Applications, Challenges and Future Perspectives

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Abstract: ***Clinical trials are an essential component of drug development and are conducted to establish the safety, efficacy and quality of new medicines and therapeutic interventions. However, conventional clinical trials are often associated with high cost, prolonged duration, complex protocols, difficulties in patient recruitment, large volumes of data and challenges in monitoring. Artificial Intelligence (AI), including machine learning, deep learning, natural language processing and large language models, has emerged as a promising technology for improving different stages of clinical trials. AI can assist in protocol design, patient identification and recruitment, eligibility screening, trial-site selection, data management, patient retention, safety monitoring and prediction of clinical outcomes. Recent research indicates that AI-based approaches may improve the efficiency of recruitment and clinical-trial risk assessment, although their performance depends strongly on data quality, validation and appropriate implementation. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) are increasingly developing frameworks for responsible use of AI in medicines development. Despite its potential, AI implementation is associated with challenges including algorithmic bias, data privacy, lack of transparency, interoperability, regulatory uncertainty and the need for human oversight. This review discusses the major applications, advantages, limitations, regulatory considerations and future perspectives of AI in clinical trials.***

Keywords: ***Artificial intelligence, clinical trials, machine learning, patient recruitment, clinical research, digital biomarkers, clinical trial monitoring, drug development.***

I. INTRODUCTION

Clinical trials are systematic investigations performed in human participants to evaluate the safety, efficacy and clinical benefits of medicines, vaccines, medical devices or other interventions. They are fundamental to evidence-based medicine and pharmaceutical drug development.

Traditional clinical trials can require substantial financial and human resources. Recruitment of suitable participants, protocol complexity, data collection, patient retention and safety monitoring can contribute significantly to delays and increased costs.

Artificial Intelligence (AI) refers to computational methods capable of performing tasks that normally require human intelligence. Machine learning (ML), deep learning (DL), natural language processing (NLP), computer vision and large language models (LLMs) are important components of modern AI.

Recent research has demonstrated increasing interest in applying AI throughout the clinical-trial lifecycle. A 2025 npj Digital Medicine perspective highlighted applications including AI-based eligibility optimization, adaptive trial design and digital twins.

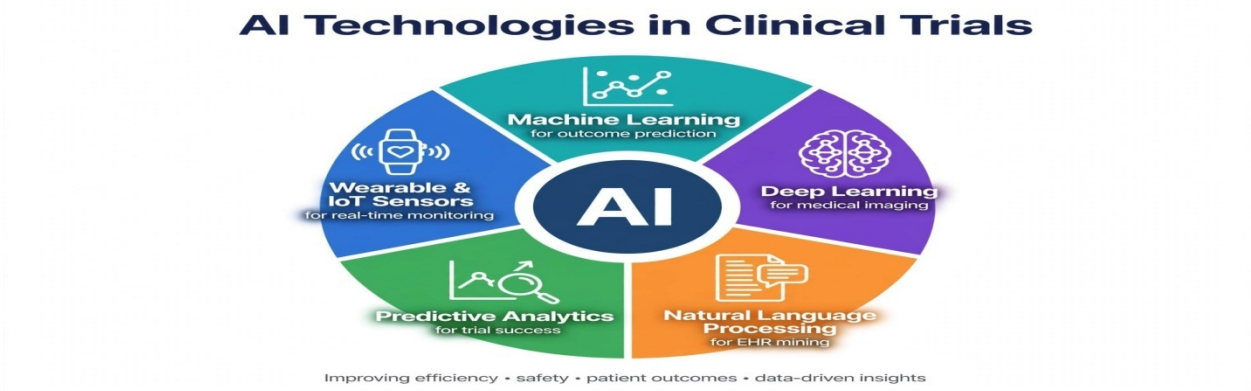


Fig.1 AI Technologies In Clinical Trails

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II. OBJECTIVES OF THE REVIEW

The main objectives are:

1) To describe the role of AI in clinical trials.
2) To discuss AI applications at different stages of clinical research.
3) To evaluate the benefits of AI-based clinical-trial approaches.
4) To identify limitations and implementation challenges.
5) To discuss ethical and regulatory considerations.
6) To describe future opportunities for AI-enabled clinical trials.

III. PHASES OF CLINICAL TRIALS

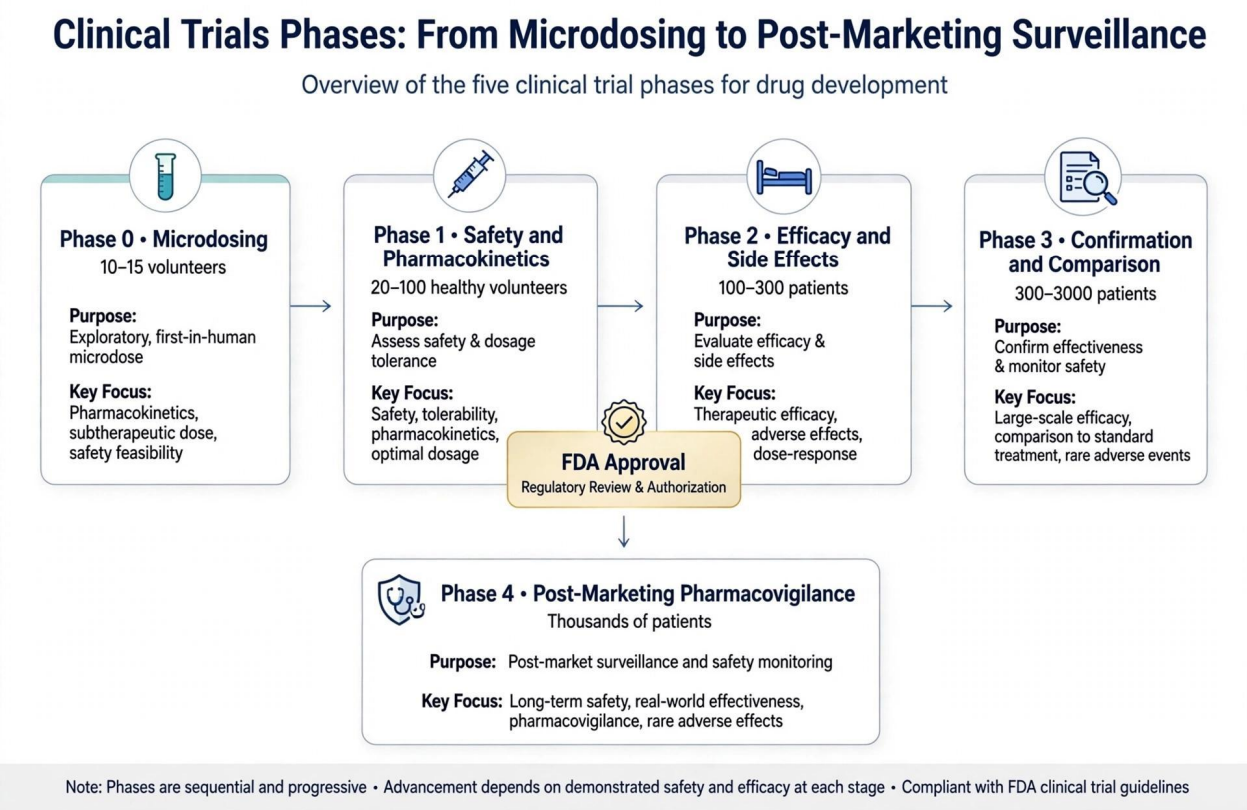


Fig.2 ClinicalTrails Phases

Phase 0 - Microdosing
clinical-trials are small, early-stage studies conducted in a few volunteers (usually 10–15) to understand how a drug behaves in the human body.
Phase I – Safety and Dosage
Usually conducted in a small group of approximately 20–100 participants.
Evaluates the safety and tolerability of a new drug.
Determines the appropriate dose and dose-related adverse effects.
Studies pharmacokinetics (absorption, distribution, metabolism and excretion).
Phase II – Efficacy and Safety
Usually involves approximately 100–300 participants, often patients with the target disease.
Evaluates the preliminary effectiveness of the drug.
Helps determine the appropriate dose.
Continues to monitor short-term adverse effects.

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Phase III – Confirmation of Efficacy
Usually involves several hundred to several thousand participants.
Confirms the drug's efficacy in a larger patient population.
Compares the new drug with a placebo or standard treatment when appropriate.
Collects additional information about adverse effects and benefits.
Phase IV – Post-Marketing Surveillance
Conducted after the drug receives marketing approval.
Monitors long-term safety in real-world use.
Helps detect rare or delayed adverse drug reactions.
Studies long-term outcomes and may identify additional uses.

IV. TYPES OF AI USED IN CLINICAL TRIALS

A. Machine Learning

Machine learning algorithms learn patterns from existing datasets and can be used for patient selection, outcome prediction, risk assessment and trial optimization.

B. Deep Learning

Deep learning uses multilayer neural networks and is particularly useful for complex datasets such as medical images, electronic health records and physiological signals.

C. Natural Language Processing

NLP allows computers to process human language. It can be used to extract information from electronic health records, clinical notes, scientific publications and clinical-trial protocols.

D. Large Language Models

LLMs can assist with information extraction, document analysis, protocol review, communication and other language-based clinical research tasks. However, outputs require appropriate human verification because inaccurate or unsupported responses can occur. EMA specifically highlights the need for critical evaluation and cross-checking of LLM outputs.

E. Computer Vision

Computer vision can analyse medical images and pathology slides. AI-based image analysis is increasingly being explored as an objective method for measuring clinical trial endpoints.

Comparison of traditional vs AI- based clinical trials

Sr.no	Parameters	Traditional Trials	AI-based Trials
1	Trail Design	Manual protocol design; fixed design	Ai-assisted adaptive design; dynamic optimization
2	Participate Recruitment	Manual screening slower,labour intensive	Predictive algorithm for eligibility screening; faster, targeted
3	Data Collection	Paper based or standard eCRF; manual entry	Wearable sensor+ automated data capture; real -time validation
4	Monitoring & oversize	On- site monitoring visits; periodic review	Real-time remote monitoring; AI-driven anomaly detection
5	Cost Estimate	Higher, approx.52-4M for phase 2 trail	Lower; 30-40% cost reduction
6	Timeline	5- 7 year from design to completion	3-5 years; accelerating decision-making
7	Outcome Analysis	Traditional statistical methods; pre-defined endpoint	Machine learning models; predictive & exploratory insights

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V. APPLICATIONS OF AI IN CLINICAL TRIALS

A. Clinical Trial Design

AI can analyse historical clinical-trial data and real-world data to identify factors associated with successful or unsuccessful trials. It can support:

- Selection of appropriate endpoints
- Optimization of inclusion/exclusion criteria
- Sample-size planning
- Identification of suitable study populations
- Trial-site selection
- Prediction of recruitment rates

AI-enabled trial engineering frameworks increasingly integrate AI tools into conventional trial workflows rather than replacing the overall clinical-trial process.

B. Patient Recruitment and Selection

Patient recruitment is one of the major challenges in clinical research.

AI can analyse electronic health records and other clinical data to identify patients who may satisfy trial eligibility criteria.

Potential benefits include:

- Faster identification of eligible participants
- Reduction in manual screening
- Improved matching between patients and trials
- Reduction in recruitment time
- Identification of underrepresented patient groups

A 2024 scoping review identified 51 studies evaluating AI for recruitment and retention and reported potential benefits in efficiency, recruitment, cost savings and accuracy, while also identifying privacy, transparency, discrimination and selection-bias concerns.

A newer 2026 scoping review and meta-analysis included 121 studies and found strong performance for several AI-based patient-screening and eligibility-identification tasks, although performance varied according to the application.

C. Patient Eligibility Screening

AI can automatically compare patient characteristics with inclusion and exclusion criteria.

For example:

Patient medical record → AI algorithm → Eligibility assessment → Investigator verification → Recruitment

This can reduce the workload of research coordinators and improve screening efficiency.

D. Trial-Site Selection

AI can evaluate historical information about clinical-trial sites, including:

- Previous recruitment performance
- Patient population
- Site experience
- Geographic characteristics
- Protocol performance
- Data quality

This information may help sponsors select sites that are more likely to successfully conduct a trial.

E. Patient Retention

Participant dropout can reduce the statistical power and reliability of a clinical trial.

AI may help identify participants at higher risk of discontinuation by analysing:

- Previous visits
- Adherence patterns

- Patient-reported outcomes
- Demographic characteristics
- Communication patterns
- Clinical factors

Early identification can allow researchers to provide appropriate support and improve retention.

F. Clinical Trial Monitoring

AI can assist in monitoring large volumes of trial data and identifying unusual patterns.
Applications include:

- Detection of protocol deviations
- Identification of missing data
- Risk-based monitoring
- Detection of unusual site performance
- Identification of potential safety signals

A 2025 scoping review of AI in clinical-trial risk assessment identified applications in safety, efficacy and operational risk prediction. It also highlighted limitations such as selection bias, limited prospective validation and data-quality problems.

G. Safety Monitoring and Adverse Event Detection

AI can analyse patient records, laboratory data, adverse-event reports and other sources to identify potential safety signals.
AI may help:

- Detect adverse drug reactions
- Identify high-risk patients
- Predict safety outcomes
- Detect abnormal laboratory values
- Support pharmacovigilance activities

However, AI-generated safety signals should be reviewed by qualified healthcare professionals before clinical or regulatory decisions are made.

H. AI in Data Management

Clinical trials generate large amounts of structured and unstructured data.
AI can assist with:

- Data cleaning
- Data classification
- Missing-data identification
- Data extraction
- Duplicate detection
- Data integration
- Automated document review

NLP can be particularly useful for extracting information from clinical notes and other unstructured documents.

I. AI and Digital Biomarkers

Digital biomarkers are measurable physiological or behavioural parameters collected using digital technologies such as smartphones, wearable devices and sensors.
AI can analyse:

- Heart rate
- Physical activity
- Sleep
- Movement
- Voice

- Continuous glucose measurements
- Other physiological signals

This may allow researchers to collect information continuously rather than relying only on periodic clinic visits.

J. Digital Twins

A digital twin is a computational representation of an individual or population that can be used to model possible outcomes.
In clinical research, digital twins may potentially support:

- Individualized outcome prediction
- Trial design
- External comparator development
- Simulation of treatment outcomes
- Reduction of unnecessary control-group burden

However, digital twins require high-quality data and rigorous validation before they can be relied upon for important clinical or regulatory decisions.

K. AI for Clinical Endpoint Assessment

AI-based image and data analysis can potentially provide more standardized assessment of certain clinical endpoints.
For example, EMA reported a 2025 qualification opinion for an AI-based tool that assists human pathologists in analysing liver biopsy images for MASH clinical-trial assessment.
This illustrates how AI may support objective and reproducible endpoint measurement while retaining human expert oversight.

VI. ADVANTAGES OF AI IN CLINICAL TRIALS

- Faster patient recruitment.
- Improved patient-trial matching.
- Reduction in manual workload.
- Efficient analysis of large datasets.
- mproved risk prediction.
- Potential reduction in trial delays.
- Improved monitoring.
- Better identification of safety signals.
- Support for personalized clinical research.
- Improved data quality.
- Potential reduction in development costs.

VII. LIMITATIONS AND CHALLENGES

A. Data Quality

AI performance depends heavily on the quality, completeness and representativeness of training data. Poor-quality data can result in unreliable predictions.

B. Algorithmic Bias

If training datasets are not representative of different populations, AI systems may produce biased results.
Lack of Transparency
Some AI models operate as “black boxes,” making it difficult to understand how a particular prediction was generated.

C. Privacy and Data Security

Clinical-trial data may contain sensitive patient information. Strong privacy and cybersecurity measures are therefore required.

D. Interoperability

Clinical data may originate from different hospitals, databases and electronic health-record systems. Differences in formats can make data integration difficult.

E. Regulatory Uncertainty

AI technologies evolve rapidly, while regulatory frameworks may take longer to develop.

F. Limited Prospective Validation

Many AI systems demonstrate good performance in retrospective datasets but have limited evidence from prospective, multicentre clinical settings. Recent reviews have emphasized the need for stronger validation and generalizability.

G. Human Oversight

AI should not independently replace investigators, physicians, statisticians or regulatory experts in high-stakes decisions.

VIII. ETHICAL CONSIDERATIONS

Important ethical issues include:

•Patient privacy
•Informed consent
•Data ownership
•Algorithmic bias
•Transparency
•Accountability
•Explainability
•Equal access to AI-enabled research
•Protection of vulnerable populations

Responsible AI implementation should maintain human oversight and ensure that AI improves rather than compromises patient safety.

IX. REGULATORY CONSIDERATIONS

Regulatory authorities are increasingly addressing AI in medicine development.

The U.S. FDA issued draft guidance in January 2025 describing a risk-based credibility-assessment framework for AI models used to support regulatory decisions concerning drug and biological products.

The EMA's reflection paper on AI in the medicinal-product lifecycle addresses AI and machine learning applications from drug discovery through post-authorisation activities.

In January 2026, FDA and EMA jointly identified ten principles for good AI practice in the medicines lifecycle, covering evidence generation and monitoring across medicine development.

These developments indicate a movement toward risk-based, fit-for-purpose validation and continuous regulatory engagement.

X. FUTURE PERSPECTIVES

The future of AI-enabled clinical trials is likely to involve greater integration of:

•Generative AI
• Large language models
• Digital twins
• Real-world data
• Wearable devices
• Digital biomarkers
• Adaptive clinical trials
• Automated data curation
• AI-supported endpoint assessment
• Predictive analytics
• Multimodal AI

The emerging concept is not to replace conventional clinical trials with AI, but to integrate validated AI tools into appropriate stages of the clinical-trial workflow. Recent literature emphasizes three important principles: fit-for-purpose validation, continuous regulatory engagement and human oversight.

XI. CONCLUSION

Artificial Intelligence is becoming an important technology in modern clinical research. It can support clinical-trial design, patient recruitment, eligibility screening, site selection, patient retention, data management, safety monitoring and endpoint assessment. The technology has the potential to make clinical trials more efficient, data-driven and patient-centred.

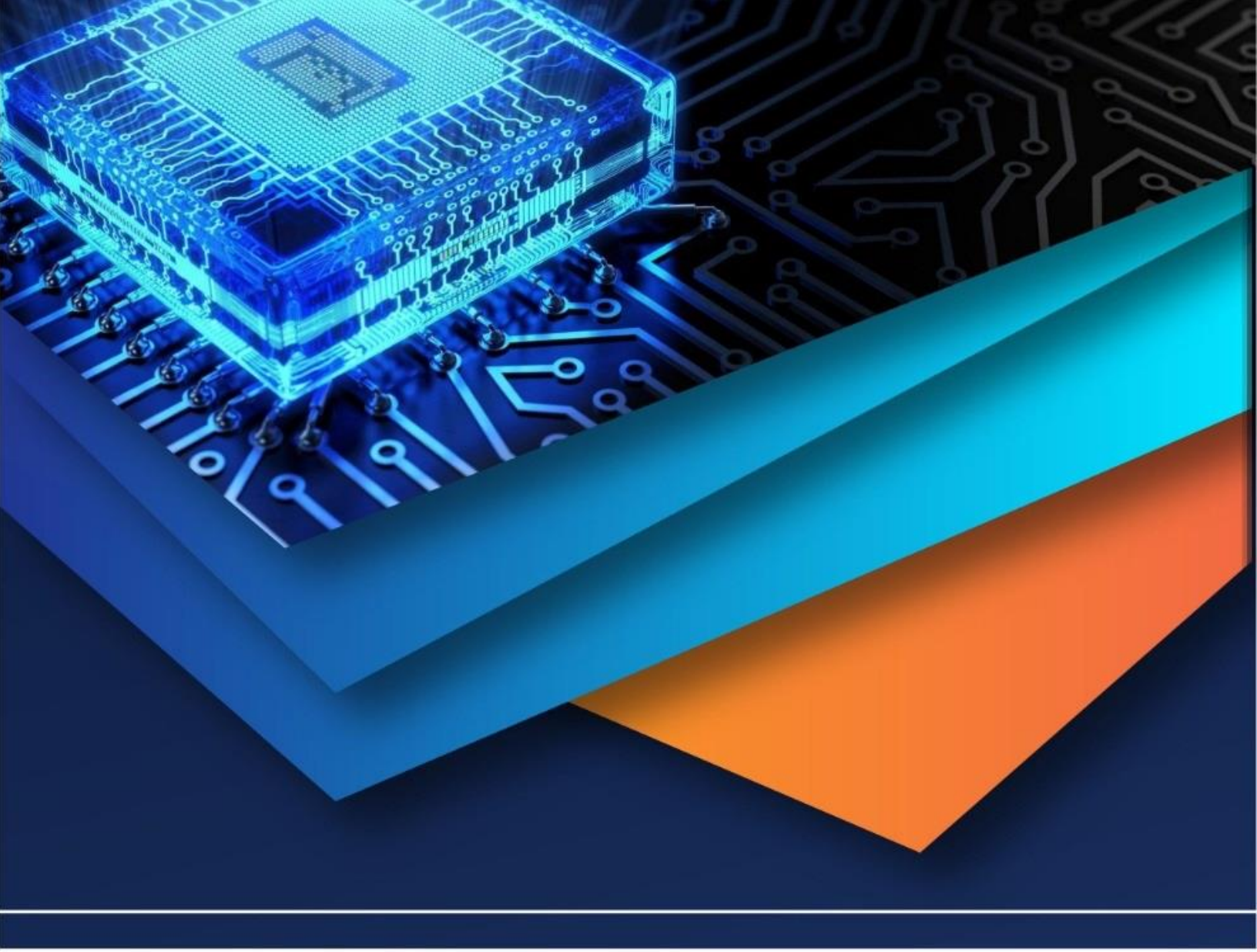
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However, successful implementation requires high-quality data, robust validation, transparency, privacy protection, appropriate regulatory oversight and continuous human supervision. AI should therefore be considered a supportive technology rather than a replacement for clinical investigators and scientific judgment.

With responsible implementation and appropriate validation, AI may significantly contribute to the future development of safer, faster and more efficient medicines.

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