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## Review Article

# Artificial Intelligence (AI) and Digital Healthcare Clinical Research: A Comprehensive Review

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### ABSTRACT

Artificial Intelligence and digital technologies are now making significant inroads into healthcare professions. The present review article highlights the novel role of AI in clinical research. AI-driven software and technologies, Generative AI tools, such as machine learning, deep learning, natural language processing, speech recognition, and large language models are also enabling the healthcare industry. Many clinical trial data are processed by Generative AI, which is common in the clinical research area to organise patient information. Clinical trial documents are the documents that are kept under lock and key to help clinical trials document management. These Electronic Health records are the records of files in which the patient-related information is saved. This technology has become more and more important in the past two decades, but also brought some critical challenges. This technology allowed the physicians to easily facilitate access to patient data, since the datasets were all in one place. It also makes it simple to share the data with other doctors allowed to see it for improved consultation. However, there are some concern challenges to be worried about, as more time and attention is taken up by physicians in putting data than they are seeing patients. And more, it can be hard to integrate the software due to the differences among companies. EHRs are supposed to simplify health care by enabling easy access to patient data, but they're frustratingly difficult to use, and their technical glitches sometimes are holding up patient care. With the increase in AI advancement, there is a risk of cybersecurity, which should have fundamental measures to ensure cybercrimes are diminished. AI in future will work together with doctors to ensure that healthcare improves and gives impactful results.

### INTRODUCTION

This review article examines AI and digital technologies are used in clinical research and healthcare professions.

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Artificial Intelligence has become advanced, where it is reshaping healthcare, revolutionising the clinical practice. It has also facilitated joint contributions in medical research and administrative operations. AI is capitalising on the algorithms and machine learning techniques. AI is forward-looking for betterment in disease diagnosis, providing facilities like personalised treatments, and providing enhancement in patient outcomes. [28,29,35]

Application of AI has increased in hospitals, clinical laboratories, and research department. AI significantly plays a major role in electronic health records (EHR) and life sciences, including neuroscience, and has also contributed to progressive applications in disease diagnosis and treatment. AI is defined as a field of science and engineering focused on intelligent behaviour and computational understanding. It involves AI systems mimic of human intelligence using computer software reducing time and cost. Overall, AI maximize healthcare efficiency by performing the complex task of human with the greater speed with less cost consumption. [28,29,35]

Data outcome from artificial intelligence has to be repeatedly done to reduce errors. The algorithm of artificial intelligence is different from human behaviour. Algorithm is literal, if you set a goal, they can't adjust itself, they can only understand what has been told exactly. Artificial intelligence research began in 1956, contribution of AI in clinical trials were limited. Due to the recent advancement of AI given dynamic hype to application of machine learning in clinical trials. AI in clinical trial helps to analyse medical image and pattern recognition, personalized treatment recommendation using patient data and genetic data. Potential growth in machine learning help in predicting the patient outcomes, optimising the

hospital operation and also service the large dataset analysis in drug discovery. Considering human limitation AI has overcome with handling the complex process and data which are beyond human capability.

AI is widely being used in patient care by robotic surgeries, predictive models for diagnosis and personalized treatment plans. In addition to patient care. During COVID-19, companies such as Apple and Google developed AI based contact tracing systems and blue dot used NLP and machine learning to predict the global spread of the virus. Earlier, in clinical trials the data management is done by maintaining the documentation in paper-based trial master files where the manual filing was used to be done. This was time consuming and causing difficulty in tracking of missing documents. In year 2000s, eTMF was developed and became standardized in 2013 with introduction of the eTMF reference model. Innovation of this AI tools used in clinical trials include Trial pathfinder, Auto Trial, Dquest and Trial gpt, while digital technology has been shown to reduce the control group size by 20-50% in clinical trials.[5,34]

Recent research in AI has been exploring the effective use of generative AI, where AI can facilitate the betterment of clinical documentation. Clinical documentation without AI is time consuming where the maintenance of clinical documentation takes a lot of clinician days and may lead to affecting the patient safety. In order to address this, developments in generative AI technologies such as use of natural language processing and speech recognition and exploring advanced AI, where AI can automatically generate the structurally required clinical notes, such as SOAP (subjective, objective, assessment, plan) and BIRP (Behaviour, intervention, response, plan). Advanced prompting is recently dominating



the market where the study uses the sophisticated prompts in order to guide the AI in generating the appropriate clinical notes. Continuous improvement of AI is an advanced technique where AI system can learn and improve itself over time.[11,36,39]

The increased in digitalization in the healthcare industry and advancement in new technologies has facilitated the usage of AI in clinical research can pave the way of cybersecurity threats. Due to increased usage of AI in clinical trials in clinical data management, this has given AI wide access to large amount of healthcare data files, which becomes easy target and potential reason to initial the cybercrime. Therefore, it is important to study AI to avoid the risk cyberattack and generate cybersecurity to prevent potential intonement of cybercrime and also the pier the patient safety.[37,38]

AI in healthcare in mainly focusing on five areas likely, health services management, predictive medicine, patient data analytic, diagnostic, clinical decision making. Most of the contribution to the research has been coming from countries like United States, China and the United Kingdom.[26,29,35]

Since AI has been very beneficial to healthcare industry, but there are some challenges to face when it comes to AI major issues such as, adversarial attacks (cybersecurity threats) lack of transparency (black box) limited datasets and privacy concerns. Technologies like natural language processing, computer vision and acoustic AI are widely being used in clinical research practice but also comes with their own risks. To address this problem or challenges Blockchain technology is being explored and practiced to secure the system that safely secures the healthcare data and AI models.[9,37,38]

## AIM AND OBJECTIVES

**Aim:** To evaluate the role and impact of Artificial Intelligence and Digital Health technologies in Clinical Research and healthcare delivery.

### Objectives:

- To study the application of AI in clinical research and healthcare.
- To investigate the role of digital technologies to improve the healthcare systems in provide advance diagnostic facilities.
- To evaluate AI-based tools that can deliver impactful benefits and also to tackle the limitations and overcome them.
- To review the ethical regulations and ensure authorised safety guidelines to tackle cybersecurity risks.
- To understand challenges before introducing AI in healthcare professions.

## METHODOLOGY

This review takes a methodological approach to bring together what we currently know about AI and the digital healthcare application in clinical research. Rather than approaching a snapshot, the goal was to build a broad, and an honest review on where the field stands – one that's challenging enough to be useful but easy enough to be readable.

### Search strategy and Data Sources:

We searched the literature published between 2015 and 2025 among five major databases: Scopus, Web of Science, IEEE Xplore, Google Scholar and PubMed. We searched intentionally across different fields such as biomedical, computer



science, and healthcare informatics, so we could get a wide and diverse range of informatics. We used specific search techniques such as “Boolean Operators- AND, OR, etc, and” “controlled keywords” to find studies related to: (Artificial intelligence, Machine learning, Deep learning, Digital health, Clinical research).

### **Inclusion and Exclusion Criteria:**

- Inclusion criteria:

In these criteria we selected studies which were proper research papers checked by experts (peer-reviewed), or detailed summaries like systematic reviews and “meta-analyses we studied” how AI, machine learning, deep learning are used in clinical research and healthcare. Reviewing the studies which were written in English. Literature survey to understand how AI system is tested in real clinical trials.

- Exclusion criteria:

In these criteria we do not include the studies which were just editorials or not properly reviewed. Articles which were just written theoretical or computer based and have no real-life use in clinical research, are not studied and were not selected for research. Studies which are based only on animals or lab experiments and not on humans, such studies are not considered.

### **Study selection and Quality assessment:**

#### **Study Selection**

- Study is selected by the two independent reviewer, which is checked separately.
- We used the standard form to decide which studies to include.

- According to the result of discussion, we finalise the studies to select.

#### **PRISMA guidelines**

- We followed these guidelines in order to ensure the study selection process is clear (transparent) and easy to repeat (reproducible).

#### **Quality assessment**

- Now, after selection of the good and reliable studies, we check the quality of the studies.
- These are two tools we used in quality assessment (Joanna Briggs Institute method, PROBAST-AI).
- By using these two tools we ensured that overall quality of the studies is assess properly and checked if there is any bias or errors in models.

#### **Data extraction and analysis:**

The researchers collected information in an organised way using a standardized form that included year of publication, study of the design and setting along with the information of all the AI methods which include its algorithm type and the training approach. It also covered diagnosis, prognosis, treatment, and operations which are also called as the clinical uses. We also checked how well the AI works using measures like accuracy and its sensitivity.

We are also looking forward for some of the major factors such as; resource constraints and further challenges. There are three criteria in which AI systems in driving major role in diseases diagnosis, medical imaging, model for projecting patient outcomes, and systems that enhances



healthcare process more advance and easier in resource management.

### Addressing Methodological Gaps:

We responsibly evaluated different studies to understand the best findings for the betterment of AI:

- (1) Estimating whether studies cover the rate of interpretability and clinical explainability.
- (2) We evaluate whether this AI system provides unbiased and fair service to all types of patient populations.
- (3) We ensure whether AI is providing a clinical validation status, prospective or external validation.
- (4) To ensure whether new studies or projects of AI models are ready to be used in real hospitals, to check whether AI gives the required results as expected.

### Synthesis and Reporting:

The finding was analysed using thematic synthesis to identify common patterns, similarities, and difference across the studies. The review also identifies the voids in existing research, highlighted best practices and provided recommendations for future studies and clinical use. The current evidences are summarized by structured approach and also pointing out area that need further research and improvement.

### EXPECTED OUTCOMES AND CLINICAL IMPACT.

- The application of Artificial Intelligence and digital health technologies is expected to bring many important benefits to the healthcare industry. Their application has elaborated on

the wide range of improvements in the diagnosis and prediction of diseases, which is one of the best advantages. AI can help doctors detect diseases more accurately and organise more advanced and personalised treatment for patient care. The detection of diseases at the earlier stages can be possible with the help of AI. AI can facilitate the diagnosis at a faster rate in order to prevent medication resistance in patients due to long treatment times. AI gives accuracy in terms of specialised doctors, as well as providing medical imaging and digital pathology.[3,4,28,29,35]

- AI can help in healthcare in analysing the problems and creating solutions for specialised treatments. This helps the doctors to take preventive actions for earlier diagnosis; this helps to avoid future complications and reduces the need for emergency hospital visits.[2,4,5,26]
- AI is helping the healthcare industries to become more efficient in order to make healthcare services more organised. Tools like generative AI and natural language processing can reduce doctor's time on managing documents by 40-50%. As a result, it can help doctors to focus on patients more than paperwork and also reduce the stress and burnout among healthcare workers.[11,36,39]
- AI can help all systems of healthcare to become smoother and more efficient. AI can ensure that everything is better organised, resources like staff, beds and equipment are used. This led to faster management of patient care, especially in busy areas like emergency wards and the surgery department. Overall, it helps the healthcare systems to work more efficiently.[2,5,35]



- AI is expected to make healthcare more personal and tailored to each individual. Doctors can personalise the treatment for each patient and adjust them in real time based on how the patient responds, and also by using the body signals and wearable devices from the data of genes. In order to make care safer and more efficient, doctors may use new ideas like digital twins (virtual models of patients) to test treatments in advance. Likely early use of AI in areas like heart diseases, kidney care and cancer is already showing better results.[6,18,24,25]
  - AI is helping to improve access to healthcare in rural areas and underserved areas. Expert-level care to people who don't have easy access to specialised healthcare, doctors can use tools like mobile diagnostics, telemedicine, and a simple AI system. [23,27,33]
  - However, there are some important challenges that need to be solved, like ensuring the AI systems are properly tested on different types of people to make sure the system works effectively on everyone. Clear rules and guidelines are also needed to ensure safe and reliable use. An AI system should utilise diverse networks in order to establish the benefits of AI in equality. This will improve the sustainability of healthcare in real-world settings.[10,31,33,37]
- collaboration between institutions while protecting patient data privacy. In future, AI will progressively bring a smarter approach toward healthcare professions, by delivering significant results by using many different sources of data. This will improve AI to be more reliable and useful. An AI tool, like explainable AI, will help doctors to understand AI decision-making. This will build doctor's trust in AI-based results, and also be helpful in providing personalised treatment to patients. Advance AI based tools can make doctors' work easier to provide more care towards patients.[9,19,38]
- Due to advancements in AI tools, some new technologies in the market, like quantum computing, could enable AI to function at a faster rate, which will help doctors to provide more accurate treatment facilities in the diagnosis of diseases. Some other AI tool, like multimodal AI, could contribute specialised treatment by combining different types of patient data to predict the disease's intensity level. Patient data like medical records, scans, genetic information, wearable devices, and even glucose level monitoring, by bringing all this information together, AI can better comprehensively report to understand patient condition more precisely. This helps to provide more accurate and personalised treatment. Large language models trained on extensive clinical datasets are expected to evolve.[1,3,20,21]

## THE FUTURE SCOPES AND EMERGING DIRECTIONS

The future of AI and digital healthcare in clinical research is set for significant growth across multiple areas. New technologies and shifts will fundamentally transform healthcare. Federal learning and privacy-preserving AI are likely to become an essential tool, enabling the

In the future, doctors and AI will work together in order to keep improving the healthcare systems effectively. Instead of replacing humans, AI will contribute its respective role in advancement of healthcare industries. Doctors will sue their experience, judgment, and patient understanding. At the same time, AI will become more specialised for different diseases like heart problems, cancer, kidney, and brain disorders. These focused



systems, will generate more accurate data than general one by appropriate training. AI can also improve the treatment by using real patient data and continuous learning, which can provide personalised medicine for each patient. [7,18,24,28]

The future of healthcare is moving towards what is called as “Healthcare 5.0,” where humans and technologies work together in a connected system in a smart way. Tool such as AI, IoT, cloud computing and blockchain will help make the healthcare system more effective and personalised, increasing the focus on preventing diseases and improving treatment strategies and also improving overall health.[8,38]

AI, in healthcare must be accessible in all areas from smart cities to rural areas, where AI tools like connected devices and body sensors can be used to provide better care. Enrolment of regulatory rules to ensure the safety of AI and fairness across different countries. Guideline which are made should be easy to understand and clear without changing the innovation guidelines. Easy-to-understand guidelines should be provided in order to make it easy for healthcare workers to grasp the new technologies. Doctors and AI can collectively work together to ensure the effective and meaningful use to AI in healthcare.[23,27,31,33]

AI must be designed in equal ways so that all healthcare industries can facilitate the use of AI in healthcare. AI must be trained using the data from different people like different ages, genders, regions and situations, so that it can provide reasonable outcomes while testing patients. Each country should work together to develop advanced or new technologies, which should be shared among all countries. These help countries decide whether the healthcare has a positive or negative impact on AI technologies. Which can be more helpful to every country. For accurate, safe and

reliable information, hospitals should have updated information on patients’ data for AI systems.[10,25,31,37]

## **ROLE OF DIGITAL HEALTH TOOLS IN PATIENT CARE AND MONITORING:**

Health of the patient is allowed to be monitored continuously by digital health tools, even outside hospitals and clinics. Devices such as smartwatches, fitness bands, mobile health apps and remote monitoring systems can keep the track of important health details such as heart rate, blood pressure, temperature, and oxygen levels. This causes occasional doctor visits rather than regular checkups. These tools are especially helpful in managing long term conditions. There are some examples of digital health tools like wearable devices which can track the body conditions such as detections of heart problems, help manage blood pressure, and monitor heart failure. People with diabetes can keep the track on their conditions by tracking blood sugar levels and daily habits. In neurological conditions these devices can identify early changes in symptoms, which further help doctors to provide more personalised treatment.[2,5,26,28]

Digital health tools are not only used for monitoring but also for treatment support. AI-based systems can detect the earlier signs and symptoms in conditions like heart failure, helping to avoid hospital visits. Mobile apps and wearable devices are also been used in rehabilitation, offering results similar to in person therapy. This provides convenient and cost-effective treatment facilities for patient. Platforms such as telemedicine allow the patient to consult doctors remotely, this gives advantage to the people of rural areas. The use of AI with digital health tools is making them even more powerful. This gives the advantage in predicting the health risk and analyse the greater amounts of data, to provide



more personalised advice, and also help in monitoring mental health by tracking behaviour and mood.[2,5,23,24]

In future, these AI-based healthcare technologies are expected to become more advanced and better system integration, and strong data protection will be important. Also, ensuring that these AI-based tools fit smoothly into everyday healthcare systems.[19,33,37]

### **BENEFITS AND LIMITATIONS OF AI IN HEALTHCARE:**

The use of Artificial Intelligence in healthcare brings both significant opportunities and important challenges. On one hand. It can provide greater improvement and efficient care, but on the other hand, it can also have some critical barriers that need to be carefully managed. To amplify the use of AI in healthcare, it's important to understand both the benefits and limitations of AI in healthcare systems.[26,29,35]

#### **Benefits of AI in healthcare:**

- AI helps doctors in diagnosing diseases more effectively and accurately, in areas such as x-rays, scans, eye care, and pathology. AI performs better and even better than experts for the specific tasks.[3,4,9,30]
- AI can reduce time consumption and also reduce clinicians workload by providing helpful benefits in organising clinical documents digitally, such as electronic trail master files.[11,36,39]
- It can increase efficiency in hospitals by predicting health risks, advising treatment methods, and providing faster decision-making.[2,5,35]

- It improves access to healthcare in rural areas and provides expert-level care through telemedicine technology.[23,27,33]
- AI can be helpful in the treatment of chronic diseases by continuous monitoring and prediction of signs and symptoms at earlier stages.[4,5,24]

#### **Critical limitation of AI in healthcare:**

- The performance of AI can drop with a larger population and it also doesn't work equally good for everyone.[24,25,35]
- AI works on the data entered from specific regions or groups in the systems, which leads to less accurate results.[10,31,37]
- AI can not effectively tackle the challenges of a language barrier, for example, people who do not speak the dominant language.[23,31]
- AI is vulnerable to the risk of cybercrime, as the confidential data of the patient can be at risk of hacking or misuse.[37,38]
- Implementing AI in the healthcare system can be difficult due to a lack of clarity and consistency.[8,10,31]

### **ETHICAL, REGULATORY, AND CYBERSECURITY ASPECTS OF AI IN THE HEALTHCARE SYSTEM:**

To ensure the safe use of AI in healthcare, it's important to enforce the storage policies and cybersecurity rules. Many different laws have been created to protect patient confidential information and to guide the usage of technology, but many of the laws were developed before AI became the main focus, so laws don't fully cover all AI-related challenges.



## HIPAA

- To provide clear guidelines for healthcare and to protect the patient data.
- AI-specific risks like re-identification of anonymised data are not fully addressed.

## HITECH Act

- To encourage the use of electronic health records (EHR).
- To strengthen the enforcement of data protection rules.
- Not specifically designed for AI systems.

## 21<sup>st</sup> Century Cures Act

- To promote data sharing and reduce information blocking.
- Help support innovation in healthcare.
- Lacks clear guidelines for AI interoperability.

## GDRP

- Provides strong data protection and privacy rights.
- Includes rules for automated decision-making.
- Can be complex and may slow down AI development.

## EU AI Act

- Focuses specifically on regulating AI systems.
- Aims to improve transparency and safety.
- Introduces stricter rules for AI use in healthcare.

## CONCLUSION

Development in Artificial Intelligence and digital technologies is bringing considerable changes to modern healthcare. Artificial Intelligence has made a potential contribution to the modern healthcare systems. There have been improvements in how care is delivered, how research is done, and how patient outcomes are achieved across different populations. This review highlights how AI is contributing in various aspects of healthcare, such as; medical imaging, clinical documentation, patient monitoring, predicting diseases, and improving overall healthcare systems. AI technologies are helping in earlier detection of diseases, ensuring the possibility of personalised treatment, and making healthcare services more efficient, technologies, such as; machine learning, deep learning, natural language processing, wearable devices, and digital health platforms are successfully contributing to the system. AI can reduce the workload on clinicians by 40-50%, due to electronic documentation technique.

There are many challenges related to AI in healthcare, as there's gap between what AI can do and how well AI is being used in real life. There are limited evidence showing long-term impact on patient outcomes, and also many AI systems have not been properly tested on diverse population. Adaptability AI in many healthcare systems is still lagging the fluency, where large number of hospitals do not have well trained experts to handle the AI system effectively. AI systems may perform unequally in aspect such as; especially for underrepresented population, which can lead to unequal care. In addition, many healthcare systems may find it difficult to provide care confidently using AI, because of unclear and changing regulation. Adaptability of AI in clinical practice also get effected due new developing rules which

are sometimes complex and confusing to understand, which eventually slow down the adaptability.

Even though AI is contributing benefits to the healthcare systems, but still facing challenges in trust and ethical terms; people are facing trust issues in fully relying on it. For example, nursing students believe AI is helpful, but their level of trust in it remains low. Doctors are concerned about decision-making, where they can't confidently rely on AI given results, and who is responsible if something goes wrong.

AI should work alongside doctors and not replace them. AI need to be adjusted and developed in order to offer beneficial applications to healthcare. AI will help doctors in statistics, analysis, and judgment of data, and doctors will work according to their knowledge, experience, and understanding of the patient. This is important because human ethics and emotions cannot be replaced by machines.

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