A comprehensive assessment of clinical studies on Artificial Intelligence-enabled interventions: uncovering trends and potential implications

Gogna S[1], Madathil S[2], Sharma S[1]
[1]Parexel, Chandigarh, India; [2]Parexel, Bangalore, India

View all Parexel's posters at ISPOR 2025

SA1

Background

- Artificial intelligence (AI) and machine learning (ML) are revolutionizing healthcare industry by enhancing drug discovery, diagnostics, prevention and disease management.[1]
- AI-enabled interventions are transforming disease management through personalized treatment approaches and early detection capabilities. ML algorithms are being used for detecting early-stage cancers and retinal diseases with precision, before they become symptomatic. AI-powered clinical decision support systems integrate patient-specific data to recommend personalized treatment protocols that significantly improve outcomes.[2,3] Also, with the help of remote monitoring applications, physiological changes that predict disease exacerbations before patients experience symptoms can be analysed, thereby enabling proactive interventions that reduce hospitalizations[4,5].
- Our research was focused to identify the trends in AI/ML use in clinical trials and to gain insight into the upcoming applications of AI/ML in healthcare.

Methods

- A comprehensive search was performed at the ClinicalTrials.gov site[6] on May 20, 2025 from database inception to identify all published trials using AI-related terms.
- The key words used for searching were 'artificial intelligence' and 'machine learning'
- A total of 507 trials were retrieved and screened to find the relevant trials. The included trials were categorized based on region, disease areas, primary endpoint, status of trial, year for conducting the trial and the type of trial.
- Our analysis also examined patterns in clinical trial distribution across global regions and identified emerging therapeutic areas receiving increased research attention.

Results

- A total of 507 records were identified from ClinicalTrials.gov site. Of these, after screening, 272 trials which utilized any AI/ML-enabled techniques were included in this study.
- Most studies were identified from the Asia-Pacific (36%), followed by North America (25.3%) and Europe (23.5%; **Figure 1**).
- Of 272 trials, 225 (82.7%) were randomised controlled trials (RCTs) and the remaining 47 (17.3%) were nRCTs (patients were recruited via non-randomised process, no observational studies). Most of the included trials were parallel group (76.8%), followed by single arm trial (14.3%) and others (8.9%).

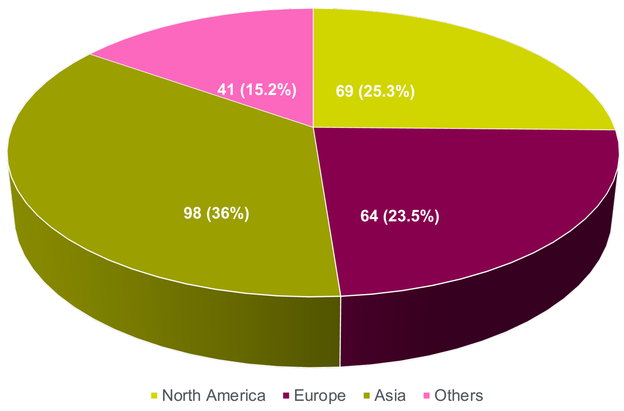

Figure 1: Geographic distribution of included trials

- It was also observed that 91.5% of all identified trials were conducted by academic/government institutions and the remaining 8.4% were company sponsored. Among ongoing trials (n=146), 95.9% were conducted by academic/government institutions as compared to 86% of completed trials indicating higher focus on AI-related interventions in recent years.
- The most common applications of the AI-enabled interventions were treatment (25%), diagnosis (24.6%) and screening (11.3%). The other applications were reported to be prevention, supportive care and health service research and others. (**Figure 2**).

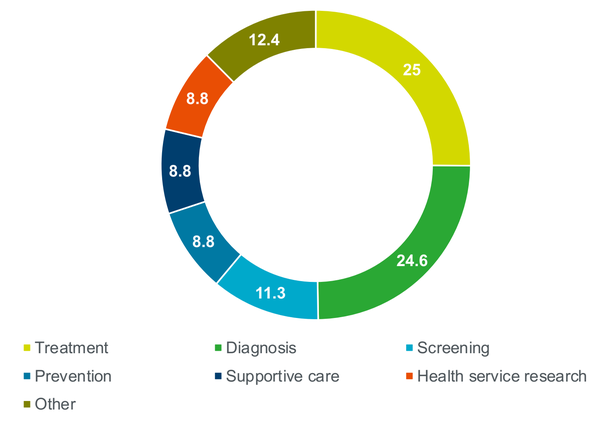

Figure 2: End-usage scenarios of included trials (data in percentages)

- Most of the trials were conducted in the field of cancer, followed by cardiovascular diseases, mental and neurological disorders, and diabetes. (**Figure 3**).

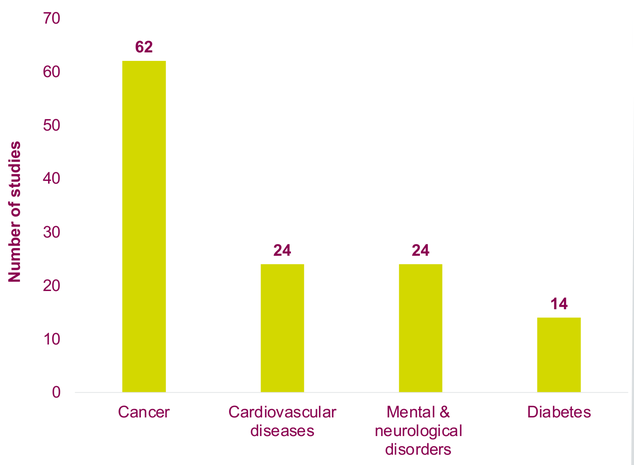

Figure 3: Disease categorization of trials (Top 4 diseases)

- The utilization of AI/ML in clinical trials has increased over time. A 6.6-fold increase was observed in AI/ML related interventions during the time period 2021-2025 as compared with 2015-2020.

- The study found that there was an increase in the number of trials from 2012 to 2024 and majority of trials being conducted during 2021-2024 period. In **Figure 4**, it can be observed that higher number of trials started in recent years as compared to the earlier years.

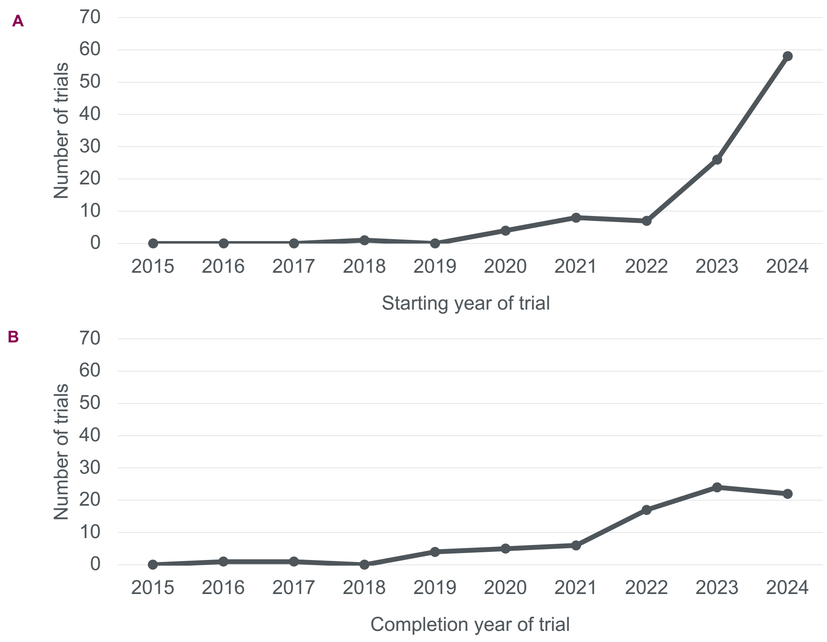

Figure 4: Trends in the utilization of AI/ML in clinical trial in the last 10 years: A. Ongoing trials B. Completed trials

- To understand the evolving trends in the use of AI in trials, we analysed information from completed trials versus ongoing trials (**Table 1**). In general, there has been a greater adoption of the use of AI across all diseases.
- The majority of ongoing trials utilizing AI, were being conducted in cancer, cardiovascular diseases, mental disorder, metabolic disorders and neurological disorders.

Disease area	Ongoing (n=146)		Completed (n=86)	
	n	%	n	%
Cancer	43	29.5	19	22.1
Cardiovascular diseases	17	11.6	8	9.3
Metabolic disorders	9	6.2	3	3.5
Dental disorders	6	4.1	2	2.3
Mental disorder	6	4.1	5	5.8
Neurological diseases	5	3.4	1	1.2
Eye disorders	5	3.4	3	3.5
Bone diseases	3	2.1	4	4.7
Brain diseases	3	2.1	2	2.3
Gastrointestinal diseases*	3	2.1	6	7.0
Respiratory diseases	5	3.4	0	0.0
Kidney diseases	4	2.7	0	0.0
Pain	3	2.1	2	2.3
Suicide	2	1.4	1	1.2
Smoking	2	1.4	1	1.2
Critically ill diseases	2	1.4	0	0.0
Multiple diseases	2	1.4	3	3.5
Infection*	3	2.1	5	5.8
Fractures	2	1.4	0	0.0
Substance abuse	2	1.4	0	0.0
Behavior disorders*	1	0.7	4	4.7
Other	12	8.2	11	12.8

40 trials were either terminated/withdrawn or the status was unknown
*A substantial reduction in the number of trials was observed in these disease areas.

Table 1. Disease distribution of ongoing and completed trials

- In oncology, 47% of trials were focused on timely cancer detection, 16% on enhancing screening, and 8% on personalized radiotherapy. Few examples of AI tools utilized were QuitBot® (for smoking cessation), Digi-Coach® (for reducing physical and psychological distress) and chatbots (for counselling).
- Cardiovascular trials primarily evaluated AI for electrocardiography screening, diagnosis, and personalized treatment, using tools like AI-LVEF® (guided assessment of cardiac function) and AI-SCREENDCM® (screening dilated cardiomyopathy).
- Neuroscience trials explored personalized treatment, prevention, and counseling, using AI/ML tools like SMART-AI® (automated reconstruction of intracranial vessel occlusion) and chatbots.
- Trials on diabetes focused on patient management support. Studies used AI-enabled mobile application for patient coaching, diet management, and personalizing behavioral interventions for self-management. Apart from this, few studies used AI-enabled techniques for screening and diagnosis of diabetes.

Conclusions

- Our analysis reveals a rapid increase in clinical trials evaluating AI-enabled interventions aimed at improving early detection, screening, and personalized treatment strategies.
- The prevalence of mobile apps and chatbots underscores a trend towards accessible, patient-centric AI solutions. As most trials are primarily academically funded, there is significant potential for future AI to be affordable and accessible for patients.
- The study reveals an exciting landscape with multiple AI-enabled interventions potentially entering the market to make healthcare more accessible, affordable and relevant for patients.
- With the increase in the number and applicability of the AI/ML in clinical trials, the reimbursement agencies are also adapting to approve/manage this new technology in the healthcare sector.

REFERENCES
[1] K. Akila, R. Gopinathan, J. Arunkumar, B. Sree Bavai Malar. The Role of Artificial Intelligence in Modern Healthcare: Advances, Challenges, and Future Prospects. European Journal of Cardiovascular Medicine. 2025: 11 (4):615-624.
[2] McKinney SM, Sieniek M, Godbole V, Godwin J, Antropova N, Ashrafian H, et al. International evaluation of an AI system for breast cancer screening. Nature. 2020;577(7788):89-94.
[3] Esteva A, Kuprel B, Novoa RA, Ko J, Swetter SM, Blau HM, et al. Dermatologist-level classification of skin cancer with deep neural networks. Nature. 2017;542(7639):115-8.
[4] Sim I. Mobile devices and health. N Engl J Med. 2019;381(10):956-68.
[5] Dunn J, Runge R, Snyder M. Wearables and the medical revolution. Per Med. 2018;15(5):429-48
[6] ClinicalTrials.gov. https://clinicaltrials.gov/