



From Algorithms to Startups: A Systematic Literature Review of Artificial Intelligence's Role in Shaping Healthcare Entrepreneurship

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ABSTRACT

The convergence of artificial intelligence (AI) and healthcare is creating new opportunities for entrepreneurship, innovation, and value creation. However, existing research remains fragmented across healthcare, technology, entrepreneurship, and related disciplines, limiting a consolidated understanding of how AI shapes healthcare entrepreneurship. This study conducts a systematic literature review (SLR) to examine the role of AI in healthcare entrepreneurship, the challenges associated with its adoption, and its broader impacts on the sector. Following PRISMA 2020 guidelines, 484 records were retrieved from the Web of Science and Scopus databases, of which 19 peer-reviewed journal articles published between 2020 and 2025 met the inclusion criteria. The findings show that AI supports innovation in diagnostics, personalised care, operational efficiency, predictive analytics, and venture scalability, while enabling startups to develop new value propositions and healthcare delivery models. However, adoption remains constrained by regulatory uncertainty, data governance, ethical concerns, institutional resistance, and limited technical literacy. The review develops a conceptual framework linking AI capabilities across three entrepreneurial stages: ideation, venture development, and implementation. The findings highlight that sustainable AI-driven healthcare entrepreneurship requires alignment between technological innovation, clinical needs, regulatory requirements, and stakeholder trust. Future research should empirically validate the proposed framework through longitudinal and cross-cultural studies, examine AI entrepreneurship in diverse healthcare settings, and investigate the effectiveness of education and accelerator programmes in strengthening entrepreneurial capabilities and responsible AI adoption.

Keywords: Artificial Intelligence, Digital Health, Healthcare Entrepreneurship, Systematic Literature Review

INTRODUCTION

The convergence of artificial intelligence (AI) and healthcare entrepreneurship represents one of the most significant paradigm shifts in modern healthcare innovation. AI has emerged as a transformative force capable of enhancing efficiency, diagnostic accuracy and access to care (Topol, 2019). At the same time, entrepreneurship has been increasingly recognised as the vehicle through which technological innovations are translated into scalable solutions that address unmet medical and operational needs (Giones & Brem, 2017). Together, these two forces are reshaping how healthcare value is created, delivered and financed. AI-enabled ventures no longer simply automate existing workflows; they unlock novel value propositions for entrepreneurs seeking to disrupt traditional models of care. For instance, AI allows startups to build virtual health assistants, automate triage, and design predictive care pathways tailored to individual patient risk profiles (Phillips, 2021).

The topic carries particular significance from a health systems perspective, where AI-enabled entrepreneurship promises improved clinical outcomes, reduced operating costs and an enhanced patient experience (Gennatas & Chen, 2021). From an academic standpoint, the intersection of AI and entrepreneurship in healthcare offers an opportunity to synthesise insights from disciplines that typically operate in silos, including computer science, biomedical engineering, innovation studies and public health. Each of these fields has generated a substantial



but scattered body of knowledge: computer science and biomedical engineering have advanced the technical capability of AI systems, while innovation and entrepreneurship studies have examined how such capability is commercialised and scaled. What remains underexplored is how these two streams interact, that is, how the technical affordances of AI are actually mobilised by entrepreneurs to build viable healthcare ventures, and what barriers stand in their way. A systematic review is therefore necessary to consolidate the current state of knowledge, identify the dominant themes and theoretical framings used across this literature, and propose a coherent agenda for future research.

Interest in this area has grown rapidly alongside the proliferation of digital health startups, the expansion of machine learning applications in clinical settings, and heightened investor attention to health technology ventures. Yet the pace of practice has outstripped the pace of theory: while individual studies document specific AI applications, financial outcomes, or regulatory obstacles, few attempts have been made to integrate these fragments into a single account of how AI shapes the entrepreneurial process in healthcare from opportunity recognition to scaling. This review responds to that gap by systematically synthesising the empirical and conceptual literature published since 2020, a period marked by rapid advances in generative and predictive AI as well as intensified entrepreneurial activity in digital health following the COVID-19 pandemic.

Research gap and contribution.

Although existing studies have examined AI applications in healthcare, digital health innovation, and technology entrepreneurship (Kais et al., 2021; Zahlan et al., 2023), the literature remains fragmented in explaining how AI capabilities translate into entrepreneurial activity across the healthcare venture lifecycle. Existing studies frequently focus on individual applications such as diagnosis, monitoring, cost prediction, fraud detection, or patient engagement, while less attention has been given to integrating these applications into a coherent entrepreneurship-oriented framework. This review addresses this gap by synthesising the literature according to three interconnected entrepreneurial stages: ideation and diagnostics, venture development and operational scaling, and market implementation and impact. In addition, the review identifies the regulatory, ethical, data-related, and capability conditions that shape whether AI capabilities can be converted into entrepreneurial value. By bringing these dimensions together, the study provides an integrated framework for understanding AI-enabled healthcare entrepreneurship and identifies priorities for future empirical research.

Research Objectives

The general objective of this systematic literature review is to explore and synthesise existing research on how artificial intelligence influences healthcare entrepreneurship. Specifically, the review aims to (i) develop a deeper understanding of the role of AI innovation in healthcare entrepreneurship, (ii) identify the challenges entrepreneurs face in adopting and deploying AI, and (iii) examine the impact of AI-driven innovation on healthcare entrepreneurship. In addressing these objectives, the review also seeks to organise the fragmented literature into a conceptual framework that can guide future empirical work and inform practice.

LITERATURE REVIEW

Artificial intelligence, broadly defined as computational systems capable of performing tasks that ordinarily require human intelligence such as pattern recognition, prediction and natural language understanding, has moved from a research curiosity to a central pillar of contemporary healthcare delivery (Topol, 2019). Gennatas and Chen (2021) trace this trajectory from early rule-based clinical decision systems to present-day machine learning and deep learning models capable of diagnostic reasoning, and argue that AI is increasingly positioned as a core infrastructure of medicine rather than a peripheral tool. This technological maturation has coincided with, and arguably enabled, a wave of entrepreneurial activity in digital health, as founders seek to embed AI capabilities into new ventures that can be scaled across health systems.

Entrepreneurship theory offers a complementary lens through which to understand this phenomenon. Giones and Brem (2017) conceptualise digital technology entrepreneurship as the process by which entrepreneurs recognise and exploit opportunities created by emerging digital technologies, translating technical capability into viable business models. Applied to healthcare, this perspective suggests that the value of AI is not intrinsic to the technology itself but is realised through the entrepreneurial process of identifying unmet clinical or operational



needs, designing a product or service around AI capability, and navigating the institutional structures of the healthcare sector to bring that offering to market. This framing is consistent with the broader literature's emphasis on AI-enabled entrepreneurship as a vehicle for improving health outcomes, reducing costs and enhancing patient experience (Gennatas & Chen, 2021).

Healthcare entrepreneurship refers to entrepreneurial activities involving the identification, development, commercialisation, implementation, or scaling of products, services, platforms, or business models intended to create value, which may include profit generation, improved patient outcomes, or increased efficiency in healthcare delivery (Glover et al., 2024). AI-enabled healthcare ventures are defined as entrepreneurial ventures in which artificial intelligence constitutes a substantive technological capability supporting the development, delivery, operation, or scaling of healthcare-related products or services (Grüning et al., 2023). Studies were considered relevant when AI was connected to an entrepreneurial outcome such as innovation, value creation, business model development, venture growth, market implementation, or healthcare service transformation.

A recurring theme in the literature is that AI's entrepreneurial value spans the full lifecycle of a healthcare venture rather than a single point of application. During the ideation and diagnostic stage, entrepreneurs exploit AI's pattern-recognition capabilities to build tools for early disease detection and predictive care, using machine learning to identify high-risk patients ahead of clinical deterioration (Phillips, 2021). During venture growth, AI supports operational functions such as workflow automation, fraud detection and financial forecasting, which reduce overhead and support the scalability that early-stage ventures require to survive (Wang et al., 2025; Zou et al., 2023). This lifecycle perspective, though rarely made explicit in individual studies, provides a useful organising principle for synthesising a literature that otherwise spans clinical, operational and financial applications of AI.

At the same time, the literature signals that AI-enabled entrepreneurship does not unfold in a frictionless environment. Healthcare is a highly regulated, safety-critical sector in which new technologies must satisfy clinical validation and procurement requirements that differ substantially from those in other digital industries (Olaye & Seixas, 2023). This regulatory and institutional context is frequently cited as a distinguishing feature of healthcare entrepreneurship relative to digital entrepreneurship more broadly, and helps to explain why barriers such as data governance, ethical oversight and institutional resistance recur across otherwise disparate studies (Young, 2022; Vandersluis & Savulescu, 2024). Because AI systems depend on the quality and availability of data, and because healthcare data are subject to stringent privacy and ethical requirements, entrepreneurs in this sector face a distinctive combination of technical and institutional uncertainty that is less pronounced in other application domains.

Taken together, the literature suggests three interrelated lines of inquiry that this review draws upon to structure its synthesis: the substantive roles that AI plays across the entrepreneurial process, the challenges that condition or constrain the realisation of AI's entrepreneurial potential, and the broader impacts of AI-enabled ventures on the healthcare sector. These three lines correspond to the research objectives of the present review and are examined systematically in the sections that follow.

METHODOLOGY

Research Design

This study adopts a systematic literature review (SLR) design to consolidate and synthesise existing knowledge on the role of artificial intelligence in healthcare entrepreneurship. An SLR approach was chosen because it enables a transparent, replicable and rigorous identification of knowledge and methodological gaps in a scattered body of literature (Kitchenham, 2004). Searches were conducted separately in Web of Science and Scopus between 4th and 13th July 2025 by using database-specific search syntax. These two databases were selected due to their track record as globally recognised bibliographic sources (Zhu & Liu, 2020) and met the key criteria for systematic reviews such as broad disciplinary coverage, advanced search functionality including Boolean operators, and transparent, repeatable search processes that safeguard study integrity (Gusenbauer & Haddaway, 2020). The search strategy combined three conceptual blocks: AI-related terms, healthcare-related terms, and entrepreneurship-related terms. The complete search strings, including field restrictions and Boolean operators, are reported in Table 1 to facilitate replication.



PRISMA Guidelines

The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, chosen for their transparency, consistency and methodological rigour. The PRISMA flow chart presented in Figure 1 is adapted and modified from the original template of Page et al. (2021) and summarises the four stages described below.

Identification. The identification stage applied literature search techniques including Boolean operators, phrase searching and field-specific searching to retrieve relevant records. This process returned 484 publications in total, comprising 357 records from Web of Science and 127 records from Scopus. The search strings used across both databases are summarised in Table 1.

Table 1: Database search strings

Database	Search String
Web of Science	ALL FIELDS = ("artificial intelligence" OR "machine learning" OR "deep learning" OR "natural language processing") AND ("healthcare" OR "digital health" OR "health sector") AND ("entrepreneurship" OR "startup" OR "healthcare entrepreneurship" OR "entrepreneurial ventures")
Scopus	TITLE, ABSTRACT, KEYWORD = ("artificial intelligence" OR "machine learning" OR "deep learning" OR "natural language processing") AND ("healthcare" OR "digital health" OR "health sector") AND ("entrepreneurship" OR "startup" OR "healthcare entrepreneurship" OR "entrepreneurial ventures")

Screening. Records identified from the two databases (357 from Web of Science and 127 from Scopus, totalling 484) were merged and screened using Microsoft Excel to detect duplicates. Thirteen duplicate records were removed, leaving 471 unique articles for further screening. The remaining records were then screened against a set of selection criteria covering year of publication, type of publication, document language and open access status; only journal articles published between 2020 and 2025 in the English language were retained. This step excluded 290 records that did not meet the criteria, leaving 181 articles for the next screening stage. The full inclusion and exclusion criteria are presented in Table 2.

Table 2: Inclusion and exclusion criteria

Criteria	Inclusion Criteria	Exclusion Criteria
Type of publication	Empirical articles, open access journal	SLR articles, review articles, conference proceedings, book series, book chapters
Language	English	Non-English
Year of publication	2020 to 2025	2019 and earlier
Index	Indexed in Scopus and Web of Science	Not indexed in Scopus or Web of Science
Country	Worldwide	None

Eligibility. The eligibility assessment examined the title, abstract, findings and discussion of each of the 181 remaining articles to confirm alignment with the scope of the review (Page et al., 2021). During this stage, studies were excluded when AI was discussed only as a clinical or technical application without an identifiable entrepreneurial, innovation, business, or value-creation dimension. The final set of eligible studies was then subjected to quality assessment and thematic coding. This process excluded a further 162 articles judged not



directly relevant to the review topic, leaving 19 articles that satisfied all inclusion criteria and were retained for the final synthesis.

Quality Assessment. The quality of the 19 included articles was appraised using a checklist adapted from Kitchenham's (2004) guidelines, comprising 15 items covering research objectives, the context of AI's role in healthcare entrepreneurship, methodological rigour, results, and future recommendations. Each item was scored 1 (yes), 0.5 (partially) or 0 (no), yielding a maximum possible score of 15; articles were then classified as Excellent (13.5 to 15), Good (9.5 to 13), Average (5 to 9) or Failed (0 to 4.5). Each included article was independently assessed against the 15 quality criteria. A score of 1 indicated that the criterion was fully satisfied, 0.5 indicated partial satisfaction, and 0 indicated that the criterion was not satisfied or insufficiently reported. The scores were summed across the 15 criteria to obtain an overall quality score for each study. The resulting scores were used descriptively to assess the methodological strength of the evidence base rather than to exclude studies solely on the basis of numerical performance. The quality assessment (QA) questions used in this study were:

QA1: Does the study clearly state the main objective or research problem in the context of healthcare entrepreneurship and Artificial Intelligence (AI)?

QA2: Does the study clearly explain the context of AI application in the field of healthcare entrepreneurship?

QA3: Does the study identify the key challenges or barriers in implementing AI within healthcare entrepreneurship?

QA4: Does the study describe the types of AI impacts being investigated (e.g., impact on innovation, operational efficiency, clinical outcomes, or business growth)?

QA5: Does the study clearly specify the data sources (e.g., journal articles, industry reports, medical databases, etc.)?

QA6: Does the study mention the data collection methods used (e.g., systematic literature review, narrative review, database exploration)?

QA7: Does the study apply appropriate tools or analytical approaches (e.g., thematic analysis, bibliometric analysis, or conceptual frameworks) to analyse the data?

QA8: Is the quantity and quality of data sufficient to support the study's findings?

QA9: Does the study implement steps to reduce bias in the selection and analysis of studies (e.g., PRISMA guidelines, strict inclusion/exclusion criteria)?

QA10: Does the study use an appropriate framework or approach to assess the impact of AI on entrepreneurship components?

QA11: Are the findings presented clearly and logically (e.g., through models, thematic categories, matrices, or visualisations)?

QA12: Does the study compare its findings with previous studies or existing literature?

QA13: Does the study state and justify the analytical method or research approach used?

QA14: Does the study acknowledge any limitations or weaknesses?

QA15: Does the study provide recommendations or implications for future research in the field of AI and healthcare entrepreneurship?

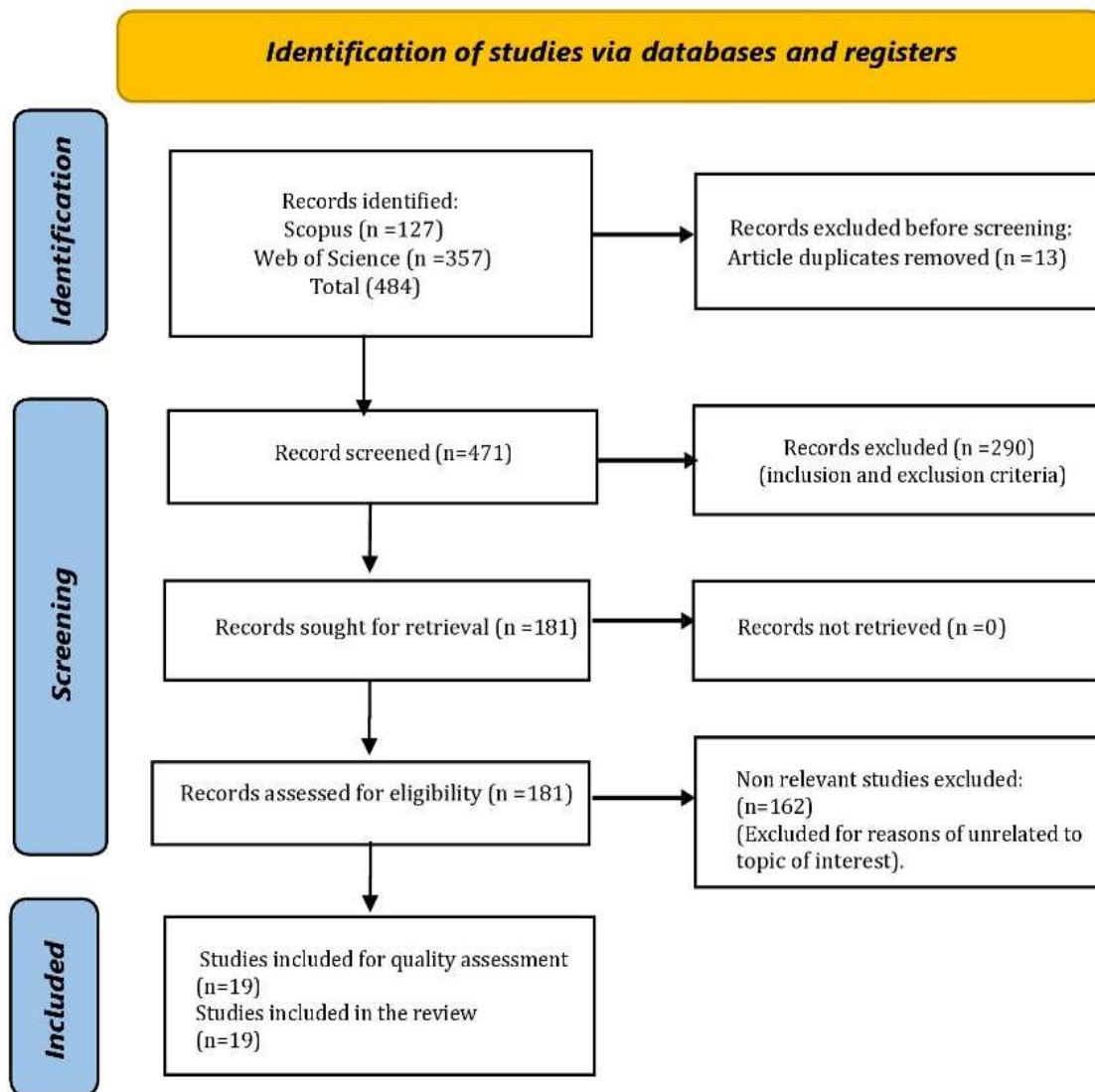


Figure 1: Study selection process

Data Extraction and Analysis

Data were extracted according to the reviews' objectives and organised into a structured table to facilitate systematic comparison across studies. A thematic analysis approach following Braun and Clarke (2006) was used to identify relationships and patterns across the extracted data. This technique was selected for its flexibility and descriptive orientation, which allowed the themes to be organised inductively while remaining anchored to the review's stated objectives.

Data Coding and Thematic Synthesis

The extracted studies were coded using a structured thematic coding framework developed from the review objectives and refined during the analysis. Each article was examined for information relating to (i) the type and role of AI technology, (ii) healthcare application, (iii) entrepreneurial activity or venture stage, (iv) value creation or innovation outcome, (v) adoption barriers, and (vi) contextual conditions. Initial codes were compared across the 19 studies and grouped into conceptually related categories. These categories were subsequently consolidated into three overarching themes: the role of AI in healthcare entrepreneurship, challenges of AI adoption, and the impact of AI-driven innovation. Within these themes, recurring subthemes relating to innovation, business models, operational efficiency, regulation, data governance, ethics, digital competencies, scalability, and value creation were identified.



RESULTS

Quality of the included studies

The quality assessment results showed that the average article score was 10.03 with the majority of articles (63.2%) falling into the Good and Excellent category. The assessment indicates that the included studies were of sufficient methodological quality for inclusion in the final synthesis. The articles stood out in several key aspects including a clear statement of the study objectives, the use of appropriate tools for data collection and analysis, and the presentation of detailed study results. In addition, the discussion of the study findings and implications was also comprehensively explained. This assessment ensured that all selected articles were suitable for the final analysis in this systematic literature review. On this basis, all 19 articles were retained because they met the predefined eligibility criteria, while the quality assessment was used to characterise the strength and methodological limitations of the evidence base in the final analysis. The results of the article quality assessment are presented in Table 3.

Table 3: Article's quality assessment (Kitchenham, 2004)

No.	Author (Year)	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Score
1	Joerin et al., (2020)	0.5	0.5	0.5	1	0.5	0	0.5	0.5	0	0	1	1	0.5	0.5	1	8
2	Olaye & Seixas (2023)	1	1	1	1	0.5	1	1	0.5	0.5	1	1	1	1	1	1	13.5
3	Chen et al. (2024)	0.5	0.5	0.5	1	1	0.5	0.5	1	0	0	1	1	0.5	0.5	0.5	9
4	Mavrogiorgou et al. (2022)	0.5	0.5	0.5	1	1	1	1	1	0.5	0	1	1	1	0.5	0.5	11
5	Kulkov et al. (2023b)	0	0	0	0	1	0.5	1	0.5	0	0	1	1	0.5	0.5	0.5	6.5
6	Roppelt et al. (2025)	1	0.5	0.5	1	1	1	1	1	0.5	0.5	1	1	1	1	1	13
7	Zou et al. (2023)	1	0.5	0.5	1	1	1	1	1	0	0	1	0.5	1	0.5	1	11
8	Wang et al. (2025)	0.5	0	0	0.5	1	0.5	1	1	0	0	1	0.5	1	1	0.5	8.5
9	Achuthan et al. (2025)	0.5	0	0	0.5	1	1	1	1	0.5	0.5	1	1	1	1	1	10.5
10	Vandersluis & Savulescu (2024)	0.5	0.5	1	1	0.5	0	0.5	0.5	0	0	1	0.5	0.5	0.5	0.5	7.5
11	Kumar et al. (2023)	0	0	0	0.5	1	1	1	1	0.5	0.5	1	1	1	0.5	0.5	9.5
12	Jovy-Klein et al. (2024)	0.5	0.5	1	0.5	1	1	1	1	0.5	0	1	1	1	1	1	12
13	Korzynski et al. (2023)	0	0	0	0.5	1	1	1	1	0.5	0	1	1	1	1	0.5	9.5
14	Fritzsche et al. (2021)	1	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0	0.5	1	0.5	0.5	0.5	1	8.5
15	Liu et al. (2024)	0.5	0	1	1	1	0	0.5	0.5	0	0.5	1	1	0.5	1	1	9.5
16	Irina Dijmărescu (2021)	1	0.5	0.5	0.5	0.5	0.5	0	0.5	0	0	1	0.5	0	0	0.5	6
17	Young (2022)	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	14
18	Kulkov et al. (2023a)	1	1	0.5	1	1	0.5	1	1	0	0.5	1	1	1	0.5	0.5	11.5
19	Hayder et al. (2024)	1	1	0.5	1	1	0.5	1	0.5	0	1	1	0.5	1	0.5	1	11.5
	AVERAGE = 10.03																

Characteristics of Included Studies

The 19 articles retained for synthesis were published between 2020 and 2025, with the yearly distribution set out in Figure 2. Publication activity was concentrated in the more recent years of the review window, with six articles published in 2023 (Kumar et al., 2023; Kulkov et al., 2023a; Korzynski et al., 2023; Kulkov et al., 2023b; Zou et al., 2023; Olaye & Seixas, 2023) and five in 2024 (Vandersluis & Savulescu, 2024; Jovy-Klein et al., 2024; Chen et al., 2024; Liu et al., 2024; Hayder et al., 2024), together accounting for more than half of the included sample, while a further three articles (Roppelt et al., 2025; Wang et al., 2025; Achuthan et al., 2025) from 2025 indicate continued growth of the field at the time the search was conducted. The included studies were also published across a disciplinary mix of outlets spanning health informatics and biomedical engineering journals, entrepreneurship and business management journals, and journals in bioethics and health services research, a spread that empirically reflects the interdisciplinary fragmentation identified as the motivation for this review.

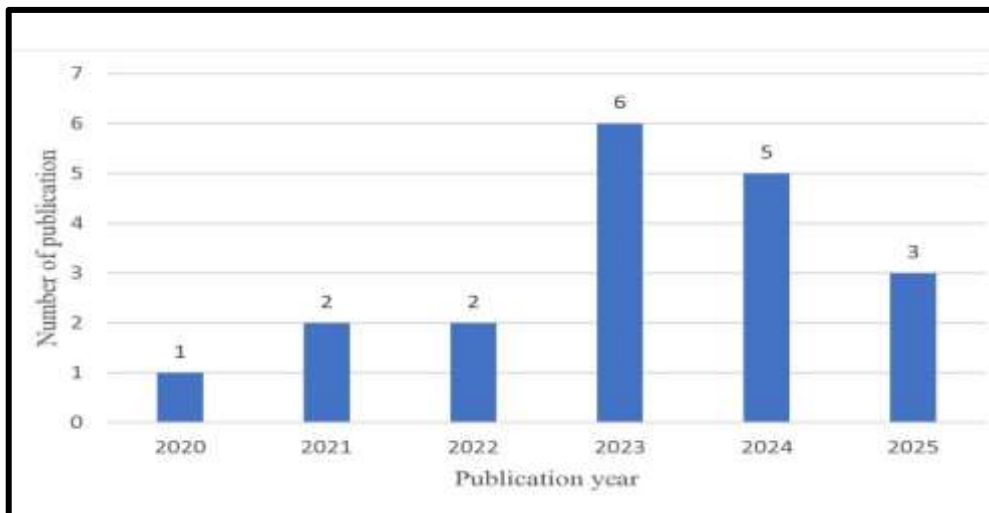


Figure 2: Publication year of included studies

Characteristics of the studies based on continent (Figure 3) found that nine of the 19 selected articles came from the Europe continent (Mavrogiorgou et al., 2022; Kulkov et al., 2023a; Roppelt et al., 2025; Vandersluis & Savulescu, 2024; Jovy-Klein et al., 2024; Korzynski et al., 2023; Fritzsche et al., 2021; Irina Dijmărescu, 2021; Kulkov et al., 2023b). seven articles came from Asia (Chen et al., 2024; Zou et al., 2023; Wang et al., 2025; Achuthan et al., 2025; Kumar et al., 2023; Liu et al., 2024; Hayder et al., 2024) and 3 articles came from North America (Olaye & Seixas, 2023; Young, 2022; Joerin et al., 2020).

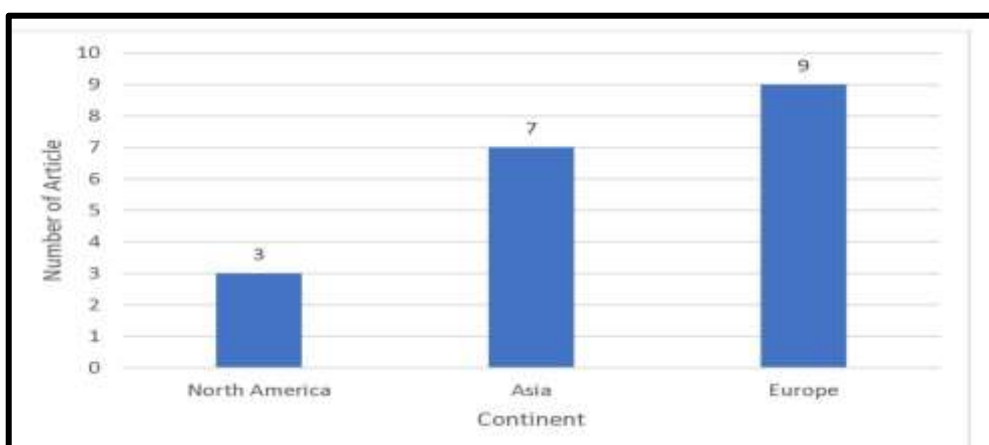


Figure 3: Distribution of studies by continent

Role of AI in Healthcare Entrepreneurship

Artificial intelligence emerges from the reviewed literature as a transformative force in healthcare entrepreneurship, enabling startups to innovate across clinical, operational and financial domains. AI plays a



pivotal role in enhancing diagnostics and risk prediction: startups use machine learning algorithms to identify high-risk patients and anticipate disease progression, creating opportunities for personalised care and targeted intervention (Mavrogiorgou et al., 2022). Such capabilities improve patient outcomes while simultaneously generating business value by aligning services with preventive models of care.

Operationally, AI facilitates workflow automation, fraud prevention and administrative efficiency, all of which reduce overhead and enhance the scalability that is critical to startup survival and growth (Wang et al., 2025; Roppelt et al., 2025). AI's synergy with complementary technologies such as blockchain and cloud computing further boosts innovation capacity, helping entrepreneurs build comprehensive, intelligent systems (Kulkov et al., 2023a). Predictive analytics allow health startups to optimise decision-making and identify high-risk patients, aligning clinical impact with entrepreneurial viability (Mavrogiorgou et al., 2022), while AI-driven cost prediction tools improve financial forecasting and resource allocation, enabling startups to deliver sustainable, value-based services (Zou et al., 2023). AI-based fraud detection in insurance claims similarly contributes to operational transparency and risk management, both of which are critical to entrepreneurial trust and integrity (Wang et al., 2025).

Emotional AI applications, exemplified by the Tess chatbot, illustrate how startups can provide scalable, cost-effective mental health support while maintaining ethical and user-trusted practices (Joerin et al., 2020). Similarly, AI-enabled sensors and Internet of Medical Things platforms allow startups to deliver real-time monitoring and early diagnostics, offering commercially viable and technically sophisticated solutions (Chen et al., 2024). From a strategic standpoint, AI empowers entrepreneurs to identify emerging needs, tailor services and develop sustainable business models, and is linked to stronger financial performance through increased market agility, investor appeal and operational resilience (Hayder et al., 2024). Although challenges such as regulatory complexity and data governance persist, ventures that align AI capability with clinical utility and stakeholder needs are better positioned to scale and succeed (Olaye & Seixas, 2023; Young, 2022). Conceptual innovations such as AI concierge systems and smart hospital ecosystems further illustrate AI's potential to transform patient engagement and healthcare delivery (Liu et al., 2024; Jovy-Klein et al., 2024).

Challenges of AI Adoption in Healthcare Entrepreneurship

Entrepreneurs in healthcare face a complex landscape when implementing AI, marked by significant barriers alongside key enablers. One of the most pressing challenges is navigating regulatory requirements, clinical validation and healthcare procurement processes, which often disadvantage startups relative to larger, more established firms (Olaye & Seixas, 2023). AI healthcare ventures must also overcome resistance from institutional stakeholders and align their innovations with existing clinical workflows to secure adoption (Young, 2022; Vandersluis & Savulescu, 2024).

Data-related issues, including data quality, privacy and governance, further complicate implementation. Entrepreneurs struggle to secure access to reliable, ethical and comprehensive datasets necessary for training effective AI models (Mavrogiorgou et al., 2022; Wang et al., 2025), while ethical concerns relating to transparency, user trust and algorithmic bias pose significant risks if not addressed through a structured governance framework (Joerin et al., 2020). More broadly, outdated policies and institutional resistance to change hinder the integration of digital solutions, including AI, into existing healthcare systems (Dijmarescu, 2021), producing a slow-moving environment that obstructs progress despite growing demand for modernisation.

Impact of AI Innovations on Healthcare Entrepreneurship

AI innovation is reshaping the landscape of healthcare entrepreneurship by creating new business opportunities, enhancing clinical services and driving operational efficiency. AI technologies enable startups to deliver intelligent diagnostics, personalised treatment and virtual mental health support that respond to real-world healthcare needs while expanding access to care, particularly in underserved or resource-limited settings (Joerin et al., 2020; Chen et al., 2024). In terms of business strategy, AI enhances entrepreneurs' ability to forecast costs, predict patient needs and streamline services; predictive tools for healthcare cost estimation and insurance fraud detection allow startups to reduce financial risk and increase operational sustainability, which in turn strengthens investor confidence and provider trust (Zou et al., 2023; Wang et al., 2025).



AI further drives value creation by supporting real-time decision-making, patient monitoring and the automation of administrative tasks, improving service delivery efficiency and reducing the burden on human resources while enabling startups to scale quickly without compromising service quality (Roppelt et al., 2025; Mavrogiorgou et al., 2022). Integration of AI with complementary technologies such as the Internet of Things, blockchain and cloud computing further enhances entrepreneurial innovation, offering modular, data-driven systems for diagnostics, treatment planning and patient engagement (Kulkov et al., 2023a), and embedding AI within entrepreneurial innovation ecosystems supports predictive modelling, customer engagement and operational scalability that are particularly relevant to virtual, education-oriented and personalised healthcare platforms (Achuthan et al., 2025).

AI-driven innovation is also associated with improved financial performance, agility and competitiveness among healthcare startups, which tend to attract greater investment and demonstrate stronger scalability and market adaptability (Hayder et al., 2024), while improved transparency in financial performance further strengthens entrepreneurial credibility (Kumar et al., 2023). Educational frameworks and digital competencies, such as prompt engineering, are correspondingly evolving to prepare entrepreneurs for the demands of AI-based innovation (Fritzsche et al., 2021; Korzynski et al., 2023). While regulatory, ethical and structural challenges persist, the overall impact of AI on healthcare entrepreneurship is profound: entrepreneurs who effectively integrate AI into their business models are transforming the sector through smarter, faster and more patient-centred innovation aligned with the goals of modern healthcare systems (Young, 2022; Olaye & Seixas, 2023). Table 4 summarises the role, challenges and impact identified across the 19 reviewed articles, illustrating the range of applications and constraints synthesised above.

Table 4: Summary of the role, challenges and impact of AI in healthcare entrepreneurship

Study	Role	Challenge	Impact
Joerin et al. (2020)	Delivers scalable, ethical AI mental health support	Regulatory, procurement and networking barriers	Transforms healthcare delivery
Olaye & Seixas (2023)	Drives healthcare innovation and AI-startup translation	Regulatory complexity, procurement hurdles, limited networks	Improves healthcare delivery
Chen et al. (2024)	Enables smart monitoring and real-time data analysis	Integration and data-accuracy issues	Commercialises innovative solutions
Mavrogiorgou et al. (2022)	Identifies high-risk patients and optimises decisions	Interpretability, data quality, ethical concerns	Enhances outcomes, efficiency and viability
Kulkov et al. (2023b)	Supports digital transformation in healthcare	Ecosystem complexity, regulatory constraints	Enhances outcomes and commercial viability
Roppelt et al. (2025)	Drives innovation and value creation	Trust, governance and integration issues	Facilitates transformation and strategic growth
Zou et al. (2023)	Improves financial forecasting accuracy	Integration and data-quality challenges	Optimises cost reduction and resource use
Wang et al. (2025)	Detects fraudulent insurance claims	Model robustness and interpretability	Improves efficiency, cost control and integrity
Achuthan et al. (2025)	Enables predictive modelling and customer engagement	Adaptation to healthcare and regulatory settings	Enhances delivery, education and patient experience
Vandersluis & Savulescu (2024)	Enhances cost-efficiency of care	Adoption, regulatory and ethical issues	Enhances value creation
Kumar et al. (2023)	Drives innovation, transparency and transformation	Cross-industry AI-blockchain integration	Enhances value creation
Jovy-Klein et al. (2024)	Enhances smart hospital capabilities	Investment, regulatory and inter-collaboration issues	Creates new value and business opportunities
Korzynski et al. (2023)	Enhances service delivery through prompt engineering	Digital literacy and prompt-engineering skills gaps	Creates innovative business models



Fritzsche et al. (2021)	Builds market-ready healthcare solutions	AI adoption and integration barriers	Enables business development and value creation
Liu et al. (2024)	Optimises patient engagement and administration	Ethical concerns, trust and implementation barriers	Supports sustainable business growth
Dijmarescu (2021)	Enhances innovation and healthcare access	Outdated policies, resistance, regulatory constraints	Fosters technology-driven entrepreneurship
Young (2022)	Supports diagnostics, monitoring and treatment	Regulatory, data-privacy and resistance issues	Enables healthcare innovation
Kulkov et al. (2023a)	Enhances performance and adaptability	Complexity of healthcare systems and needs	Accelerates value creation
Hayder et al. (2024)	Optimises operational efficiency	Ethical, legal and talent shortages	Enhances financial sustainability

DISCUSSION

The findings indicate that AI's contribution to healthcare entrepreneurship is best understood as capability-driven rather than purely technology-driven: the same underlying capabilities, namely pattern recognition, prediction and automation, are repurposed by entrepreneurs across clinical, operational and financial functions. This pattern is consistent with Giones and Brem's (2017) conceptualisation of digital technology entrepreneurship as an opportunity-recognition process, and it explains why studies as diverse as diagnostic sensor development (Chen et al., 2024), insurance fraud detection (Wang et al., 2025) and mental health chatbots (Joerin et al., 2020) converge on similar entrepreneurial logics of scalability, cost reduction and value creation, despite addressing very different clinical problems. Rather than treating AI as a single homogenous technology, the review suggests it functions as a general-purpose capability that entrepreneurs adapt to the specific value proposition of their venture.

At the same time, the challenges identified in the review point to a structural tension between the pace of AI innovation and the pace of institutional adaptation in healthcare. Regulatory uncertainty, procurement complexity and clinical validation requirements (Olaye & Seixas, 2023) are not incidental frictions but reflect the safety-critical nature of the sector, which necessarily privileges caution over speed. This helps explain why entrepreneurial success in this domain appears to depend less on the sophistication of the underlying AI model and more on an entrepreneur's ability to navigate institutional stakeholders, secure ethical and reliable data, and build trust with clinicians and patients (Vandersluis & Savulescu, 2024; Young, 2022). Viewed this way, the barriers documented across the reviewed studies are less a temporary obstacle to be engineered away than a permanent feature of the operating environment that entrepreneurial strategy must accommodate.

Equipping current and future healthcare founders with the right skills, education and innovation frameworks is therefore essential to navigating these AI-driven opportunities and challenges, and can meaningfully influence both the commercial success and the ethical integrity of startups in the digital health sector. Curricula that incorporate AI fundamentals, data ethics, user-centred design and problem-based learning help build the technical literacy and entrepreneurial confidence needed to translate AI capability into viable ventures (Fritzsche et al., 2021). Programmes oriented toward innovation design, such as health technology accelerators or entrepreneurship bootcamps, simulate real-world problem-solving and encourage scalable, high-impact solutions, while the emergence of digital competencies such as prompt engineering further strengthens entrepreneurs' capacity to work effectively with generative AI tools in decision-making and creative problem-solving (Korzynski et al., 2023).

These educational gains, however, are unevenly distributed. Access to high-quality AI education and mentorship remains unequal, particularly in low-resource settings or for non-technical founders, and many entrepreneurs struggle to keep pace with rapidly evolving technologies, producing a widening gap between innovation potential and practical application. Over-reliance on short courses or fragmented online learning risks producing superficial familiarity with AI rather than a genuine understanding of its risks, limitations and implementation nuances. Furthermore, education systems have yet to fully adapt to the interdisciplinary demands of healthcare

AI entrepreneurship, which requires the integration of clinical, technological and business knowledge that conventional curricula tend to teach separately. Table 4 consolidates the role, challenges and impact reported across the 19 reviewed studies, and the pattern it reveals, namely that the same set of studies simultaneously documents strong entrepreneurial impact and persistent adoption barriers, reinforces the interpretation that AI's entrepreneurial promise in healthcare is real but conditional on the surrounding regulatory, ethical and educational infrastructure being strengthened in parallel.

This conditional relationship is also consistent with the concentration of included studies in the 2023 to 2025 period noted in the Methodology section. As AI capability has matured and diffused into more clinical and operational functions, the literature has correspondingly shifted from describing isolated technical applications toward examining the organisational, regulatory and ethical conditions under which such applications translate into viable ventures. This trajectory suggests that the field is moving toward the kind of integrated, entrepreneurship-oriented perspective that the conceptual framework proposed in this review seeks to formalise, rather than continuing to treat clinical AI application and entrepreneurial process as separate lines of inquiry.

Theoretical Implications

What distinguishes the present review from existing literature is its integration of AI capability, entrepreneurial stage, and healthcare institutional conditions within a single analytical framework. Rather than treating AI applications as isolated technical innovations, the review positions them within the progression from opportunity recognition and venture development to market implementation and healthcare impact. The synthesis further shows that this progression is conditioned by regulatory, ethical, data governance, and capability-related factors. The resulting framework therefore shifts the discussion from what AI can technically perform toward how AI capabilities are converted into entrepreneurial value within the institutional constraints of healthcare.

First, it extends digital technology entrepreneurship theory (Giones & Brem, 2017) into the specific institutional context of healthcare, showing that opportunity recognition and exploitation in this sector are conditioned by regulatory, clinical and ethical constraints that are less prominent in other digital domains. Existing entrepreneurship frameworks, largely developed with reference to consumer and enterprise technology markets, do not fully account for the safety-critical, highly regulated environment in which healthcare AI ventures operate, and the present review indicates that this context should be treated as a core theoretical variable rather than a peripheral moderating factor.

Second, the review synthesises a fragmented body of empirical evidence into a conceptual framework that maps AI's entrepreneurial role across three interconnected stages, namely ideation and diagnostics, venture development and operational scaling, and market implementation and impact. Prior studies have tended to examine isolated applications of AI, such as diagnostic sensors, fraud detection or cost prediction, in relative

isolation from one another. By organising these applications along a common entrepreneurial lifecycle, the framework offered here provides a more integrated account of how AI capability accumulates and compounds as a healthcare venture matures, and creates a shared vocabulary through which future studies in different sub-fields can be compared and accumulated.

Third, the review clarifies the relationship between AI's technical capability and its entrepreneurial impact by showing that this relationship is mediated by challenges relating to regulation, data governance, ethics and technical literacy. This mediated relationship refines existing accounts that treat AI adoption and entrepreneurial performance as a relatively direct link, and instead positions institutional and educational context as boundary conditions that determine whether AI's technical potential is actually realised as entrepreneurial value. Future theoretical work on technology entrepreneurship in regulated sectors more broadly, such as fintech or agritech, may benefit from testing whether a similar mediated structure applies.

Practical Implications

To strengthen the practical applicability of AI in healthcare entrepreneurship, the findings suggest a staged approach to implementation. Before development, entrepreneurs should identify relevant regulatory requirements, assess clinical needs, and ensure access to appropriate and reliable data. During development, they



should engage clinicians and users, establish appropriate data governance, and validate AI performance within the intended healthcare context. Before scaling, ventures should assess procurement and compliance requirements, strengthen ethical safeguards, and demonstrate both clinical and business value. This staged approach can help entrepreneurs translate AI capabilities into viable healthcare solutions while addressing the regulatory, ethical, technical, and stakeholder-related barriers identified across the reviewed studies. This also provides a practical pathway for aligning technological innovation with healthcare requirements and sustainable venture development.

For entrepreneurs and founders, the review suggests that competitive advantage in healthcare AI ventures depends less on possessing the most advanced algorithm and more on the ability to align AI capability with clinical utility, secure reliable and ethically sourced data, and build trust with clinicians, patients and institutional gatekeepers (Olaye & Seixas, 2023; Young, 2022). Founders should therefore invest early in regulatory literacy and stakeholder engagement alongside technical development, and should treat data governance and ethical safeguards as core product requirements rather than compliance afterthoughts.

For investors, the review indicates that ventures combining strong AI capability with demonstrated regulatory and clinical alignment are more likely to achieve sustainable scalability and financial performance (Hayder et al., 2024). Due diligence processes may therefore benefit from explicitly assessing a venture's regulatory strategy and data governance practices alongside its technical and commercial merits, rather than treating these as secondary considerations.

For educators and accelerator programmes, the uneven distribution of AI literacy identified in this review points to a need for curricula that integrate technical, clinical and business knowledge rather than teaching these domains in isolation (Fritzsche et al., 2021; Korzynski et al., 2023). Embedding structured, project-based exposure to real healthcare data and regulatory processes, rather than relying solely on short technical courses, may help close the gap between innovation potential and practical implementation that this review identifies among non-technical founders and those in low-resource settings.

For policymakers and healthcare institutions, the persistence of regulatory uncertainty and procurement complexity as barriers across the reviewed literature (Olaye & Seixas, 2023; Vandersluis & Savulescu, 2024) suggests a need for clearer, startup-accessible pathways for the clinical validation and procurement of AI-based solutions. Such pathways would not only reduce the disadvantage faced by smaller ventures relative to established firms but could also accelerate the diffusion of beneficial AI innovations across health systems, provided that ethical oversight and data protection standards are maintained in parallel.

LIMITATIONS

This review is subject to limitations common to systematic literature reviews, including reliance on two databases and English-language, journal-indexed sources, which may have excluded relevant grey literature or non-English studies. Although Web of Science and Scopus provide broad multidisciplinary coverage, the exclusive use of these databases may have reduced the retrieval of relevant studies indexed in specialised healthcare, business, or emerging technology databases. Future research should empirically validate AI-driven entrepreneurial models in real-world healthcare settings, using longitudinal studies to assess their long-term sustainability and ethical performance. Subsequent studies should also examine the impact of education and accelerator programmes on entrepreneurial outcomes, and explore cross-cultural differences in AI adoption shaped by local regulatory environments. Greater research attention is needed on risks such as algorithmic bias and ethical dilemmas, particularly in relation to emotional AI and generative technologies within healthcare entrepreneurship.

CONCLUSION

This systematic literature review highlights artificial intelligence (AI) as an important driver of healthcare entrepreneurship, supporting innovation in diagnostics, personalised care, operational efficiency, and venture scalability. Across the 19 reviewed studies, AI enables startups to create new value propositions and improve healthcare delivery, while adoption remains constrained by regulatory uncertainty, data governance, ethical concerns, institutional resistance, and limited technical literacy. The review further develops a conceptual



framework linking AI capabilities across ideation, venture development, and implementation, while emphasising the importance of interdisciplinary skills, ethical practices, and supportive infrastructure. These findings suggest that sustainable AI-driven healthcare entrepreneurship requires alignment between technological innovation, clinical needs, regulatory requirements, and stakeholder trust. Future research should empirically validate the proposed framework through longitudinal and cross-cultural studies, examine AI entrepreneurship in diverse healthcare settings, and investigate the effectiveness of education and accelerator programmes in strengthening entrepreneurial capabilities and responsible AI adoption.

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