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Development of Biomedical Startups and Innovations in Medicine

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Abstract **Background:** Venture capital investment in the biomedical sector has grown steadily over the past five years, exceeding USD 28 billion in 2024. Despite this growth, early-stage biomedical startups remain financially vulnerable, highlighting the need for systematic analysis of development trends and constraints, particularly in innovative diagnostic and therapeutic technologies. **Methods:** This study is based on a systematic literature review conducted in accordance with PRISMA 2020 guidelines, supplemented by content analysis and the methods of analysis, synthesis, comparison and systematization. **Results:** The findings demonstrate a significant increase in biomedical startup activity, including a rise in IPOs from 11 in 2023 to 18 in 2024 and 113 exits recorded in 2025. More than 62% of venture capital funding is directed toward artificial intelligence–based projects. Implemented innovations show substantial clinical and economic benefits, including a 45–70% reduction in hospitalizations and measurable cost savings. However, financial instability, workforce shortages and ethical risks remain key barriers. **Conclusion:** Biomedical startups demonstrate strong growth potential, but targeted investment strategies and regulatory support are required to ensure sustainable development and maximize clinical and economic impact.

Key Words Surgery, Ultrasound in Surgery, Rehabilitation, Physical Therapy, Biomedical Startups, Medical Innovations, Learning Intelligence

INTRODUCTION

Today, the development of biomedical startups is one of the key factors in the transformation of the healthcare system, based on the integration of innovative technologies, entrepreneurial models and scientific achievements. Unlike classical pharmaceutical and medical corporations, startups are characterized by high flexibility and the ability to respond quickly to market demands, create new tools for diagnosis, therapy and prevention [1, 2]. The creation of new tools for diagnosis, therapy, prevention and surgical practice, in particular using ultrasound technologies, is a pressing issue. It is these structures that ensure more efficient use of basic research results, reducing the time gap from scientific discovery to clinical implementation [3].

However, despite the growing role of startups in the biomedical sector, a number of systemic issues remain unresolved. Regulatory barriers significantly slow down the entry of innovative products into the market, which leads to a high proportion of projects that stop at the prototype or clinical trial stage [4]. In addition, the financial vulnerability of startups leads to their dependence on other investments and the fragility of business models, especially in times of global economic instability [5]. There is a shortage of personnel who combine biomedical knowledge with entrepreneurial competencies, which reduces the competitiveness of new companies [6]. An additional challenge involves the limited integration of rehabilitation technologies and physical therapy innovations within biomedical startups, despite their potential to improve patient recovery and long-term outcomes. Finally, the ethical and social aspects of innovation remain insufficiently regulated and the use of artificial intelligence technologies in the field of medicine is accompanied by discussions about the transparency of algorithms, personal data protection and access to new solutions [7, 8].

Thus, the formation of an effective strategy for the development of biomedical startups requires a systematic analysis of both the opportunities and risks of their operation.

This determines the relevance of the study aimed at summarizing modern scientific approaches and identifying prospects for integrating innovations into medical practice.

However, despite extensive research, there is still a lack of integrated analyses that simultaneously consider financial, technological, regulatory and ethical aspects of biomedical startup development. This gap limits the formation of comprehensive strategies for sustainable innovation in healthcare.

LITERATURE REVIEW

Biomedical startups are one of the key factors in the effective modernization of the healthcare system and economic growth of the country in the context of rapid technological change [9]. In the context of globalization, medical research and innovation require integration between biotechnology, information technology and clinical practice. Ukraine, which has highly qualified technical and medical personnel, has the potential to create competitive solutions with global scale. Recent studies also highlight the growing role of ultrasound in surgery as a minimally invasive and cost-effective tool, complementing both diagnostic and therapeutic innovations.

In the scientific community, biomedical startups are seen as a catalyst for change in the healthcare system due to their flexible organizational models and rapid integration of knowledge into practice [1, 10]. For SaMD companies, a business model framework that combines regulatory compliance, evidence and digital distribution channels is relevant [3]. The concept of "coopetition" (a combination of competition and cooperation) in digital health demonstrates the link between research/operational capability and growth [6]. At the same time, clinical organizations and digital startups often experience a "clash of cultures" that requires managed alignment of values and processes [11] and digital maturity strategies [12].

Nowadays, the key for medical devices is the implementation of established quality management processes [13], expanding approaches to risk identification at the development stage [4]. At the level of evidence, the NICE Evidence Standards Framework serves as a guide for digital technologies and sets the bar for clinical relevance and safety [5]. Recommendations of expert guidelines on the quality of virtual care structure the requirements for continuous quality monitoring and patient-centred services [14]. At the integration stage, tools are needed to justify the viability of technologies and prioritize them [15].

The ever-increasing need for personalized medicine, effective diagnostics and remote services is creating a demand for digital and biotechnology solutions. Researchers Khalid *et al.* [7], Mohsin Khan *et al.* [8] note that the speed of healthcare digitalization increases costs and accelerates the introduction of new diagnostic methods.

The high quality of biomedical and technical education, the presence of research institutions and their active participation in international projects create the basis for the development of prototypes and validated data. For example, Singh [16] notes that multimodal approaches with the fusion of images, texts and structured data expand diagnostic capabilities but require careful validation.

Recent healthcare challenges associated with the Covid-19 pandemic, the global burden of chronic respiratory diseases and related risk factors, are increasing the demand for innovations that improve prevention, early detection and management [17]. A broader view of digital technologies emphasizes the duality of opportunities and challenges, emphasizing the need for clear regulation and evidence [18]. Recent works also highlight the role of rehabilitation and physical therapy technologies as essential components of digital health ecosystems, ensuring continuity between diagnostics, treatment and post-treatment recovery.

Studies in the context of reforms show that institutional changes are a prerequisite for the introduction of innovative services [19, 20]. The gradual harmonization of regulations in the field of medical devices, electronic medical data and telemedicine facilitates faster market entry, provided that international quality and safety standards are met.

Thus, despite significant scientific and practical progress, the literature review revealed significant gaps. There are no single classification of biomedical startups and no unified criteria for evaluating their performance, which makes it difficult to compare results globally. There is a lack of research that systematically integrates financial, regulatory, technological and ethical factors, mostly limited to the analysis of individual components. The socio-ethical aspects of AI in medicine, including the transparency of algorithms, data privacy and fair access to innovations, remain insufficiently studied. The hypothesis of current research is that a comprehensive consideration of these factors can increase the sustainability of biomedical startups and accelerate their integration into the healthcare system. Thus, the relevance of this paper is determined by the need to systematize current approaches and form a holistic vision of biomedical startups that combines scientific evidence, financial stability, regulatory predictability and ethical responsibility.

The purpose of the study is to conduct a systematic analysis of current trends in the development of biomedical startups and innovations in medicine.

The objectives of this study are:

- To analyse current trends in the development of biomedical startups;
- To identify key technological and financial drivers;
- To assess the clinical and economic effectiveness of innovations;
- To determine major barriers and future prospects for integration into healthcare systems

METHODS

The research methodology for this article is based on theoretical analysis and systematization of scientific literature on the development and integration of the latest technologies and biomedical startups into the medical industry. A systematic literature review was conducted in accordance with the PRISMA 2020 methodology (Preferred Reporting Items

for Systematic Reviews and Meta-Analyses) [21]. To achieve this goal, the authors used the method of analysis and synthesis, comparative analysis and data systematization.

The literature search was conducted using the following databases: Scopus, PubMed, Web of Science and Google Scholar. The main search keywords included “biomedical startups”, “digital health”, “artificial intelligence in medicine” and “medical innovations”.

Analysis and synthesis were used to study and summarize research data on modern innovative diagnostic and treatment technologies. This made it possible to identify key trends, problems and effective areas.

Comparative and contrastive analysis was used to identify common and different directions and approaches to the development of scientific areas of diagnostic medicine in Ukraine and the world, as well as to compare the existing needs and challenges of biomedical startups.

Systematization was used to structure the data obtained, which made it possible to identify modern scientific approaches to the development of biomedical startups, summarize empirical research data over the past 5 years and identify the main trends, barriers and prospects for integrating innovations into medical practice.

Inclusion Criteria

Sources with data on financial (venture capital investments, IPO, M&A), technological (AI, telemedicine, nanomedicine, etc.), regulatory or organizational aspects of startup development; studies that provide indicators of clinical and/or economic efficiency of innovative programs; scientific articles that contain a visual methodology for data collection.

Exclusion Criteria

Articles, press releases, PR materials and other publications without scientific verification; papers without quantitative or qualitative indicators necessary for analysis; data published before 2020.

A total of 42 studies were included in the final analysis after applying the inclusion and exclusion criteria.

Limitations

Regulatory environments and financial mechanisms for supporting startups vary considerably between countries, which limits the generalizability of the data. Most sources contained generalized indicators (investment amounts, number of IPOs, economic impact), which did not allow for analysis at the primary data level.

A thematic analysis approach was used to identify key trends, barriers and outcomes across the included studies.

As this study is based on previously published data, no ethical approval or informed consent was required.

RESULTS

The main trends in biomedical startup development are summarized in Table 1. Key technological areas are presented in Table 2, while examples of clinical and economic effectiveness are shown in Table 3.

Analysis of recent years shows a steady increase in funding for biomedical startups. According to Bahadori *et al.* [5],

Table 1: Empirical indicators of biomedical startups development (2020-2025)

Indicator (units)	2020	2021	2022	2023	2024	2025*
Volume of venture capital investments in biomed/MedTech ($ billion)	n/a	n/a	n/a	21.6	28.0	28.0[a]
Average investment round size (mln $)	n/a	n/a	n/a	35.2	50.0	50.0[b]
Number of IPOs of biomedical/MedTech startups (pcs.)	n/a	n/a	n/a	11	18	n/a
Estimated number of biomedical startups in the world (pcs.)	n/a	n/a	n/a	~5200	>5800	>5800[c]
Multiplicity of growth of quality assurance costs after market entry (times relative to the R&D stage)	~3×	~3×	~3×	~3×	~3×	~3×[d]
Frequent barriers according to the results of reviews (qualitative assessment)	regulatory, financial	+ human resources	+ ethical/ AI	confirmed	confirmed	confirmed[e]

Source: The latest available estimates/intervals from the included review (without annual breakdown), [a,b]: Aggregated values from review/analytical papers for 2024-2025; 2025 is presented as a stabilization of the 2024 level, [c]: Global number of startups in 2024 >5800; for 2025, the designation ">5800" is retained, [d]: Post-commercialization costs are ≈ three times higher than during the development phase (ISO 13485, post-market), [e]: "confirmed" means consensus in the included systematic/narrative reviews on barriers

Table 2: Main technological areas of biomedical startups (2020-2025)

Technology area	Examples of application	Potential for medicine	Main barriers (2020-2025)	Sources
Multimodal AI	Integration of images, texts and clinical data	Personalized diagnostics, more accurate prognoses	High cost of validation, difficulty of reproducibility	Singh, 2025; Escudero Sanchez *et al.*, 2023
AI in NGS (Next-Generation Sequencing)	Algorithms for interpretation of omics data	Precision medicine, rapid mutation detection	"Black box of algorithms, low transparency	Athanasopoulou *et al.*, 2025
AIoT / IoMT	Real-time patient monitoring via sensor networks	Chronic disease management, home services	Data security risks, cyber threats	Belbase *et al.*, 2024
Telehealth	Remote monitoring, consultations	Access scaling, hybrid service models	Integration with local healthcare systems	Chakraborty *et al.*, 2023
Nanomedicine	Targeted drug delivery, nanosensors	New therapies, oncology, gene therapy	Strict regulatory restrictions, high R&D costs	Nature Nanotechnology, 2022

Source: Created by the author

Table 3: Examples of innovations and their effectiveness

Startup/initiative	Innovation	Effect (compared to control)	Source
Cera Care	Digital Care Plan (DCP)	↓30-day hospitalization: -45 %.	Windle *et al.*, 2023
Cera AI tool	AI prediction of falls (97 % accuracy)	↓ hospitalizations of 65+ by up to 70%; NHS savings of £1 million/day	Digital Health report 2024-25 (NHS England, 2025)
Participatient (NL)	Mobile application + patient participation	↓CAUTI: -3 % or = 0.54	Bentvelsen *et al.*, 2024
Health Call (UK)	App for home care	↓ED: -11%, hospitalizations -25%, duration -11%, savings £57-£113/month	Garner *et al.*, 2024

Source: Created by the author [40-43]

Table 4: Quantitative indicators of clinical and economic efficiency of digital medical technologies and startups (2024-2025)

Source	Indicator	Figures / Data
Accuracy vs. cost-effectiveness in a diabetic retinopathy model (Wang *et al.*, 2024)	Cost-saving scenario	US$ 5.54 million in savings; conditions: sensitivity ≈ 88.2%, specificity ≈ 90.3%
Economic outcomes of AI-based diabetic retinopathy screening (meta-analysis)	Incremental Net Benefit (INB)	INB ~ 615.77 (95% CI: 558.27-673.27) in high-income countries; ~ 1739.97 (95% CI: 423.13-3056.82) in middle- and lower-income countries
Optimizing Diabetic Retinopathy Screening at Primary Health Centres, India (Purohit *et al.*, 2025)	Best model (tele-supported screening)	ICER = ₹57,408 (~US$730) per QALY; 17.3-38.5% reduction in VTDR and blindness depending on state/diabetic group
Systematic review ... Nature Digital Medicine	DR screening: cost reduction and ICER	Reduction of screening cost per person by 14-19.5%; ICER ~ US$1,107.63 per QALY in selected studies; significant clinical benefits in different countries/contexts
Hospital at Home evaluation (UK NHS)	Reduced costs due to alternative to hospitalization	Cost at home ~ £118.49/day vs. £569/day in hospital; £1.33 million saved over 12 months; average length of stay reduced by ~2.8 days

Source: Created by the author [44,45]. Notes: QALY is a quality-adjusted life year; a combined indicator that takes into account the duration and quality of life; ICER is an incremental cost/incremental benefit ratio; it is used to assess the cost-effectiveness of a new technology; INB is an incremental net benefit; an economic indicator that takes into account the cost and effect of an intervention compared to the standard; DR is diabetic retinopathy; a retinal damage associated with diabetes; VTDR is diabetic retinopathy.

in 2024, venture capital investments in the biotechnology sector exceeded $28 billion and the average amount of spending reached $50 million. A study by Liu *et al.* [6] confirms that startups that combine partnership and competition demonstrate more sustainable growth and better financial results. At the same time, there is an increase in entry into the medical market [9].

To empirically verify the trends, the authors summarize the available quantitative indicators for 2020-2025 from the included sources; in the absence of an annual breakdown, the latest validated values are presented with relevant notes (Table 1).

AI technologies and related solutions play a special role in the current startup dynamics. The integration of multimodal data processing (images, texts, clinical data) creates prospects for more accurate diagnosis, but is accompanied by high validation costs [16]. In the field of genomics, AI is used to interpret next-generation sequencing (further - NGS), although barriers to algorithm transparency remain [22]. The concept of artificial intelligence (further - AI) of things (further - AIoT) allows for continuous monitoring of patients through sensor networks with real-time analytics, which opens up new opportunities for the management of chronic diseases [23].

Modern AI technologies play an important role and have a significant impact on various sectors, including healthcare, technology and science. AI has the potential to improve the quality of patient care and treatment outcomes by minimizing the risk of human error in diagnosis and treatment planning. Over the past decade, automated identification of craniofacial landmarks and analytical measurements have attracted considerable interest [24-26].

The data presented in the table shows that the technological development of biomedical startups in 2020-2025 is centred around the integration of artificial intelligence, multimodal data processing, telemedicine platforms and nanomedicine (Table 2).

Each of these areas has significant potential to improve diagnostic accuracy, personalize treatment and expand access to healthcare. At the same time, empirical evidence confirms the existence of systemic barriers, ranging from the high cost of technology validation and the opacity of algorithms to regulatory restrictions and data security risks. This underscores the need for comprehensive strategies that simultaneously take into account technological innovation, financial support and ethical responsibility, which is why the study is still relevant. Particularly promising are biomedical startups that integrate artificial intelligence into rehabilitation and physical therapy, using sensors and telehealth platforms to support patient monitoring and functional recovery.

For example, physicians typically use their experience to manually or semi-automatically identify landmarks in lateral skull radiographs or computed tomography (further - CT) images, either incrementally on two-dimensional (2D) planes or using three-dimensional (3D) models for a holistic view [27, 28].

With the development of medical imaging technologies and the use of large datasets, AI helps to detect signs that cannot be seen by the human eye [29]. This approach facilitates early detection of disease, reduces treatment costs and prevents complications [30, 31]. In addition, ultrasound-based solutions in surgery are increasingly supported by AI algorithms, enabling automated detection of anatomical structures and enhancing surgical precision.

The integration of AI into medical diagnostics opens up prospects for the interpretation of omics data, with simultaneous challenges of reproducibility and transparency [22]. The AIoT concept combines sensor networks with AI analytics to improve continuous monitoring and personalization of care [23]. In parallel, telemedicine platforms and remote supervision models accelerated by the COVID-19 pandemic have laid the groundwork for sustainable hybrid services [32, 33].

Experienced entrepreneurial scientists demonstrate the ability to align technology and the market, allowing them to deeply understand what their product can bring to the market and who their target customers are. Karl Hansen, CEO and co-founder of AbCellera, developed his microfluidic technology at the very beginning of his academic career, specifically focusing on antibody research. For Basilard BioTech, the market need was continuous gene delivery, especially relevant for CAR-T cell technology; Cytosurge aimed to develop a technology for precise delivery or sampling of femtoliter volumes to/from cells for drug delivery and biopsy; and Aligned Bio's targeted biomarker detection and DNA sequencing. High-quality publications in each case provided the credibility needed for fundraising and early patenting, which is fundamental to guaranteeing intellectual property protection [26].

Sustainable AI adoption in medicine depends on privacy, controllability and fairness of algorithms. Reviews emphasize the range of privacy techniques and their application limitations [7], as well as approaches to data obfuscation in AI risk management [34]. The issues of trust, responsibility and explainability appear as central elements of "reliable/trustworthy AI" – trustworthy AI in the clinic [8, 35, 36]. At the intersection of healthcare and social media, the emphasis is shifting to FATE principles (fairness, accountability, transparency, ethics) and methods of reducing systemic biases [37].

The use of AI in medicine is accompanied by significant ethical risks. Authors Mohsin Khan *et al.* [8], Goktas and Grzybowski, [35] emphasize the need to build "trusted AI" systems focused on security and transparency. The analysis of AI practices in healthcare shows a significant difference between potential capabilities and actual clinical effectiveness, which is confirmed by the results of recent analytical studies [36]. The issues of privacy and personal data protection in digital health startups remain unresolved – even when using differential privacy or federated learning, there is a risk of reducing the accuracy of models [7, 34]. Research on indigenous elderly communities shows that cultural sensitivity and customization of interfaces are critical to truly reaching target groups [38].

A systematic analysis has shown that in the early stages, the key success factors are business model transparency, a validated product and investor confidence [3]. Telehealth startups have proven to be globally scalable, especially after the COVID-19 pandemic [33]. Successful examples of digital health services also show a significant effect on patients, from reduced hospitalizations to increased access to healthcare services.

Studies show that companies are forced to spend several times more resources on maintaining a quality system after a product enters the market than during its development [13]. An expanded risk management framework provides greater predictability in medical device development [4]. At the same time, early Health Technology Assessment (HTA) demonstrates the value of selecting commercially viable areas, allowing investors and regulators to make informed decisions [15].

Studies of process maturity in the context of reforms show that the level of organizational culture and patient-centeredness affects the ability of companies to scale innovations [19, 39].

In addition to general trends, practical cases of innovation implementation demonstrate a positive impact on clinical outcomes and the healthcare system. Table 3 shows examples of successful innovations/startups and their proven effectiveness.

For example, Cera Care demonstrated a 45% ($p < 0.001$) reduction in 30-day hospitalization rates after implementing the Digital Care Plan (DCP) [40]. The use of an AI model for predicting falls with 97% accuracy reduced hospitalizations in patients aged over 65 by 52-70%, while saving the NHS about £1 million per day [41].

In the Netherlands, the Participatient mobile app, designed to prevent urinary tract infections, demonstrated a 3% reduction in CAUTI rates (OR = 0.54; $p < 0.001$) [42]. The UK Health Call platform, implemented in long-term care facilities, reduced emergency visits by 11%, hospitalizations by 25% and length of stay by 11%, resulting in savings of up to £113 per resident per month [43].

According to the data for the first half of 2025, the global exit activity of the digital health sector amounted to 113 cases, including 6 IPOs and 107 M&As. AI-oriented companies received 62% of all venture funding, with an average round of $34.4 million, which is 83% more than their non-AI competitors. The projected digital health market is estimated to reach $396 billion in the US and over $400 billion globally by 2025. AI also significantly improves the efficiency of clinical trials: the success rate has increased by 20-30%, the duration has been reduced by 50%, which saves up to $26 billion per year. The example of Cera Care demonstrates a real output: revenue increased from £3.6 million to £300 million in 2019-2024, while hospitalizations decreased by 52%, falls by 17% and infections by 15% [40].

The results presented in Table 4 quantitatively confirm that innovative biomedical technologies combine clinical effectiveness with a pronounced economic effect.

Thus, the introduction of digital care platforms can significantly reduce hospitalizations and healthcare costs and AI screening models provide both direct savings and QALY gains while maintaining high accuracy parameters. The presented data show that the effectiveness of startups can be assessed in three complementary dimensions – clinical, economic and social – which enhances their integration into modern medical practice.

DISCUSSION

The results confirm that biomedical startups are an important driver of the transformation of the medical industry, ensuring the rapid commercialization of scientific advances and the introduction of new technologies into healthcare practice. However, recent empirical evidence indicates that there are both opportunities and significant barriers to their sustainable development.

Financial dynamics show an increase in venture capital investments, but their concentration in a narrow range of technologies, primarily in the field of artificial intelligence, creates an imbalance in the innovation environment [6]. Such concentration leads to a high risk of an "investment bubble" when inflated expectations are not confirmed by real results of clinical effectiveness [36]. Similar trends can be observed in companies with strong positions in AI and digital medicine have higher chances of entering the market, while startups in classical biotechnology often face a lack of investor support [9]. At the same time, surgical ultrasound serves as a vivid example of how biomedical startups can integrate AI with traditional imaging methods, expanding opportunities for intraoperative monitoring and postoperative recovery.

It should be noted that regulatory challenges remain one of the key factors limiting the rapid implementation of innovations. Studies emphasize that constant changes in certification, quality and cybersecurity requirements put disproportionate pressure on small companies [4]. This leads to significant compliance costs, which for startups often become critical and impede scaling. Compared to large corporations that have stable legal departments and access to resources, young companies demonstrate significantly lower resilience to regulatory changes [5].

AI plays a key role in technological innovation, but the effectiveness of its integration into biomedicine remains limited. Despite significant progress in the creation of molecules and diagnostic algorithms, no drug developed exclusively with the help of AI has yet been approved for clinical use [16]. According to analysts of digital maturity, it is institutional support and public investment in digital transformation that act as a catalyst for the successful integration of innovations [8].

The human resources aspect also remains critical for the development of startups. The lack of specialists able to combine biomedical expertise with entrepreneurial skills reduces the efficiency of innovation commercialization [19]. International comparisons show that countries with a developed system of interdisciplinary education and innovation clusters demonstrate twice the survival rate of startups. Another promising area involves startups focusing on digital rehabilitation and AI-assisted physical therapy, which have demonstrated measurable improvements in recovery speed, patient motivation and adherence to treatment plans. Thus, the development of educational programs focused on combining biomedicine, management and digital technologies is one of the strategic directions for creating a sustainable innovation ecosystem.

Restrictions in the field of intellectual property, increased competition from China and the instability of the global financial market reduce the competitiveness of European and American startups. In this context, the strategy of creating cross-border partnerships aimed at pooling resources, minimizing risks and increasing commercialization efficiency becomes relevant [46, 47].

Thus, the results of the study indicate that the development of biomedical startups has a dual nature: on the one hand, it is a source of innovation and a driver of medical modernization and on the other hand, it is accompanied by numerous challenges that require a comprehensive solution. Further research should be aimed at developing models to support startups in the early stages of their formation, improving government regulation mechanisms and stimulating cross-sectoral partnerships. This will help turn biomedical startups into a sustainable element of the healthcare innovation ecosystem.

Practical Recommendations

Standardization of startup evaluation criteria. It is equally important to create evaluation frameworks for rehabilitation and physical therapy technologies, ensuring their clinical effectiveness and cost-efficiency. It is necessary to develop unified methods for assessing the effectiveness and safety of biomedical innovations, which will help build trust on the part of the clinical community and investors, supporting the integration of diagnostic innovations, including ultrasound in surgery, into clinical workflows.

Optimization of regulatory procedures. It is recommended to introduce mechanisms for early assessment of health technologies (HTA) and harmonize national regulations with international standards, which will reduce the time to market.

Stable financing models. It is advisable to develop hybrid approaches to financing (venture capital + government grants + corporate investments) that minimize the risk of bankruptcy and support innovation at the early stages.

Support for international clusters. It is recommended to strengthen cross-border cooperation and innovation clusters, which will facilitate knowledge sharing, minimize risks and scale successful solutions in a global context.

CONCLUSIONS

Biomedical startups are a key driver of innovation in medicine, but their development is determined by the balance between the growth of investment and technological solutions and existing regulatory, financial, human resources and ethical barriers. Their applications extend beyond diagnostics and treatment to include rehabilitation and physical therapy, providing comprehensive patient-centred solutions.

The literature analysis revealed five key trends:

- Growth of venture capital investments, concentration of funding on AI projects, formation of international

partnerships, strengthening of the role of interdisciplinary educational programs and regulatory, financial, human resources and ethical barriers;

- An analysis of recent publications and reports has shown a steady increase in venture capital investments in biomedical startups, which in 2024 exceeded USD 28 billion with an average investment round of USD 50 million;
- the study found a concentration of funding on artificial intelligence projects, which accounted for more than 62% of venture capital in 2024-2025, in particular, multimodal algorithms for analysing clinical data and genomics;
- A trend towards the formation of international partnerships and innovation clusters has been identified: 113 exits (6 IPOs and 107 M&As) were registered in the first half of 2025 alone, confirming the globalization of the digital health market;
- A comparative analysis has shown the growing role of interdisciplinary educational programs that integrate biomedical and entrepreneurial competencies and ensure twice the survival rate of startups in countries with a developed training system;
- The systematic review confirmed the existence of barriers to development, among which the most significant are complex regulatory requirements, financial instability in the early stages, a shortage of interdisciplinary specialists and growing ethical risks associated with the transparency and safety of AI solutions

The findings of this study can support the development of evidence-based policies, improve investment strategies and guide the implementation of innovative technologies in modern healthcare systems.

Prospects for Further Research

The practical significance of the study lies in identifying strategic directions for improving regulatory mechanisms, forming stable financing models, developing interdisciplinary educational programs and implementing ethical standards. This creates the basis for developing effective policies to support biomedical startups and integrate innovations into medical practice.

Limitations

This study has several limitations. First, the narrative nature of the review limits the ability to perform quantitative synthesis. Second, the included studies are heterogeneous in terms of methodology and outcomes. Third, potential publication bias may affect the interpretation of results. These limitations should be considered when applying the findings.

Ethical Statement

The study was reviewed and registered by the Institutional Ethics Committee of Dr. Volokhova Medical Centre. Protocol No.: 21/26 dated January 6, 2026).

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