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Развитие исследований и разработок в сфере технологий искусственного интеллекта для здравоохранения в Российской Федерации: итоги 2021 года

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АННОТАЦИЯ

Применение технологий искусственного интеллекта в российском здравоохранении является одним из приоритетных направлений реализации национальной стратегии развития искусственного интеллекта в нашей стране. Внедрение цифровых решений в медицинских организациях на основе искусственного интеллекта должно способствовать повышению уровня жизни населения и качества медицинской помощи, включая профилактические обследования, диагностику, основанную на анализе изображений, прогнозирование возникновения и развития заболеваний, подбор оптимальных дозировок лекарственных препаратов, сокращение угроз пандемий, автоматизацию и повышение точности хирургических вмешательств и т.д.

Идёт развитие нормативного и технического регулирования в сфере применения искусственного интеллекта в здравоохранении. Создан отечественный рынок соответствующих решений, некоторые из них получили регистрационные удостоверения Росздравнадзора как медицинские изделия. Различными научными коллективами выполняются исследовательские работы. Вместе с этим мы пока существенно отстаём от стран-лидеров в сфере искусственного интеллекта, таких как США и Китай. Инвестиции в продукты искусственного интеллекта для здравоохранения существенно снизились по итогам 2021 г. Основные причины отставания, как минимум с точки зрения рыночных показателей, находятся в низком спросе и ограниченных возможностях государственных медицинских организаций финансировать проекты искусственного интеллекта, а также в сфере доверия к безопасности и эффективности таких решений.

Ключевые слова: цифровое здравоохранение; искусственный интеллект; машинное обучение; большие данные; системы поддержки принятия решений; программное обеспечение; медицинские изделия.

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Evolution of research and development in the field of artificial intelligence technologies for healthcare in the Russian Federation: results of 2021

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ABSTRACT

The use of artificial intelligence technologies in Russian healthcare is a priority area for implementing a national strategy for the development of artificial intelligence in the country. The introduction of digital solutions based on artificial intelligence in healthcare facilities should improve the standard of living of the population and the quality of medical care, including areas of preventive examinations, diagnostics based on image analysis, prediction of disease development, selection of optimal drug dosages, reducing the threat of pandemics, and automating and increasing the accuracy of surgical interventions.

Policy management and technical regulation are under development in the field of artificial intelligence in healthcare. The domestic market for relevant solutions has been created, and some products have been certified as medical devices from Roszdravnadzor (Federal Service for Surveillance in Healthcare). Various teams of scientists are conducting research. However, Russia is still behind the leading countries in the field of artificial intelligence, such as the United States and China. Investments in healthcare products based on artificial intelligence decreased significantly in 2021. The major reasons for the lag, at least in terms of market indicators, are low demand and the inability of state medical organizations to fund artificial intelligence projects. There are also other issues related to trust in the safety and effectiveness of such solutions.

Keywords: digital health; artificial intelligence; machine learning; big data; decision support systems; software; medical devices.

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俄罗斯联邦保健事业人工智能技术领域的研发发展：2021年结果

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简评

人工智能技术在俄罗斯保健事业的应用是我国人工智能发展国家战略的优先领域之一。在医疗机构中引入基于人工智能的数字解决方案应有助于提高生活水平和医疗救护质量，包括预防性检查、基于图像分析的诊断、预测疾病的发生和发展、选择最佳的药物剂量、减少流行病的威胁、自动化和提高手术干预的准确性等。

人工智能在医疗保健中的应用领域的规范和技术规定正在发展。相关解决方案的国内市场已经建立，其中一些已获得　俄罗斯联邦卫生监督局的医疗器械注册证书。各个科学团队开展研究工作。与此同时，我们在人工智能领域仍显着落后于美国、中国等领先国家。2021年对医疗保健人工智能产品的投资显着下降。至少从市场指标来看，滞后的主要原因在于公共卫生组织资助人工智能项目的需求和能力较低，以及对此类解决方案的安全性和有效性的信任。

关键词：数字健康；　人工智能；机器学习；　大数据；决策支持系统；　软件；医疗产品。

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BACKGROUND

Currently, one of the most promising areas for the digital transformation of the healthcare system is the use of various IT solutions based on artificial intelligence (AI) technologies. The growing interest in AI is driven by several trends, including the increase in hardware computing power, the development of cloud computing, the rapid accumulation of large amounts of digital data, and the development of machine learning algorithms. These prerequisites have created conditions for increased expectations for the improvement of the efficiency of healthcare through the introduction of various AI products, including improvements in practical medicine and healthcare organization, with the ultimate goal of improving the quality of medical care and increasing the efficiency of healthcare resource management [1].

The main areas of research and development in the field of software based on AI technologies include the diagnostics and prediction of the development of diseases and their complications, the selection of personalized therapy, the work of personal medical assistants for monitoring and assessing the condition of patients in real time, and the development of new drugs and support for their clinical trials. A separate, albeit still underdeveloped, area is the creation of robotic, truly autonomous devices for the healthcare sector.

AI-based software can potentially improve the efficiency of doctors, nurses, and healthcare organizations, reducing the time of documentary support of the medical care process, providing patient routing and the necessary communication of all participants in the process. COVID-19 pandemic has significantly increased interest in the use of AI products. Simultaneously, the widespread introduction of AI systems in practical healthcare will require additional research and development, including for independent clinical testing and cost-effectiveness assessment, according to recent publications [2, 3].

According to analytical data, the size of the global AI market for healthcare amounted to $8.19 billion in 2021, $10.11 billion in 2022 at a compound annual growth rate (CAGR) of 23.46%, and $49.10 billion in 2026 at a CAGR of 48.44% [1].

Since 2017, there has been an increase in investment in AI for healthcare (Fig. 1). According to CB Insights[2], in 2021, the volume of total investments in companies offering various products based on AI technologies amounted to $12.2 billion (505 transactions). For comparison, this figure was $6.627 billion in 2020 (397 transactions), $4.129 billion in 2019 (367 transactions), and “only” $2.7 billion in 2018 (264 transactions)[3].

MAIN PRINCIPLES FOR THE DEVELOPMENT OF AI MARKET FOR HEALTHCARE IN THE RUSSIAN FEDERATION

The basis of statutory regulation of the AI market in the Russian Federation is determined by the Decree of the President of the Russian Federation No. 490[4], which approved the National Strategy for the Development of Artificial Intelligence for the period up to 2030.

The growth of population welfare and quality of life, maintenance of public order and national security, achievement of sustainable competitiveness of the Russian economy, including leading positions in the world in the field of AI, are the aims of the development of AI in the Russian Federation.

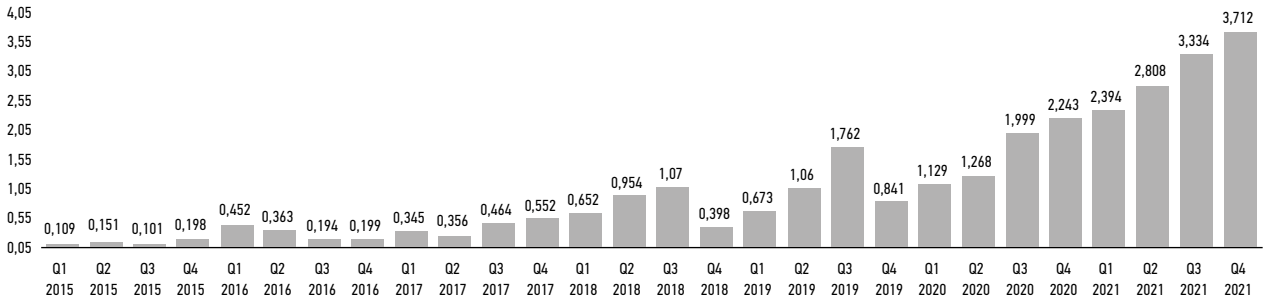

Fig. 1. The dynamics of venture investment in artificial intelligence systems for medicine and healthcare, according to CB Insights, billion US dollars.

[1] Companies in the artificial intelligence in healthcare market are introducing AI-powered surgical robots to improve precision as per the business research company’s artificial intelligence in healthcare global market report 2022 [Internet]. Access mode: https://www.globenewswire.com/news-release/2022/03/30/2413072/0/en/Companies-In-The-Artificial-Intelligence-In-Healthcare-Market-Are-Introducing-AI-Powered-Surgical-Robots-To-Improve-Precision-As-Per-The-Business-Research-Company-s-Artificial-Inte.html. Reference date: 15/03/2022.

[2] A US private company with a business analytics platform and a global database that provides market information on private companies and investor activity.

[3] State of AI 2021 Report [Internet]. Access mode: https://www.cbinsights.com/research/report/ai-trends-2021/. Reference date: 03/15/2022.

[4] Decree of the President of the Russian Federation of October 10, 2019 No. 490 “On the development of artificial intelligence in the Russian Federation” (together with the “National Strategy for the Development of Artificial Intelligence for the period up to 2030”). Access mode: http://www.consultant.ru/document/cons_doc_LAW_335184/. Reference date: 03/15/2022.

Healthcare in the strategy is defined as one of the priority sectors for the implementation of AI, which should contribute to the achievement of the strategic goals and objectives of the national Healthcare Project, including the reduction of morbidity and mortality, increase in life expectancy, and so forth[5].

The implementation of digital solutions in healthcare organizations based on AI technologies should contribute to the improvement of the standard of living of the population and the quality of medical care, including preventive examinations, diagnostics based on image analysis, predicting the onset and development of diseases, the selection of optimal dosages of drugs, the reduction of the threat of pandemics, and the automation and improvement of the accuracy of surgical interventions.

The main directions for the development of AI are the stimulation of demand and the introduction of Russian products, ensuring the safe use of AI, improving the regulatory and technical regulation and development of high-quality data sets. For this purpose, at the level of federal and regional executive authorities, a number of tasks should be solved:

1) long-term support for research and development;

2) promoting the implementation of software based on AI technologies in public health authorities and healthcare organizations;

3) development of education in the field of AI, including raising the level of awareness of the population about the possibilities of AI technologies;

4) development of normative and technical regulation;

5) export support and promotion of Russian AI products on international markets;

6) creating incentives to attract investment in the development of science, research and development of AI products;

7) formation of integrated security in the creation and use of AI products.

According to the national strategy for the development of AI, the priorities are the following:

1) production of high-quality labeled data sets and providing controlled access to them for scientific organizations and developers and

2) stimulating the creation and development of a competitive market for software products based on AI technologies in the healthcare sector, including the creation of conditions for paying for the use of such products at all levels of medical care.

The fulfillment of these tasks will guarantee an increase in the quantity and quality of scientific research and publications, a significant increase of the volume of investments, an increase in the competition rate between developers and, as a result, an improvement of the quality of software solutions based on AI technologies for healthcare, and an increase of the volume and the efficiency of their application.

The main indicators characterizing the success of the implementation of the AI strategy in the healthcare sector are the increase in the following:

1) the number of companies developing AI products for medicine and healthcare;

2) the number of results of intellectual activity (patents, publications in Russian and international scientific peer-reviewed journals, etc.);

3) the number of products that have passed the state registration, including as software medical devices;

4) the number of government bodies and organizations in the healthcare sector using AI-based products to improve the efficiency of their activities;

5) the number and citation index in the world's leading publications of scientific articles by Russian scientists on AI in healthcare;

6) the number of available data sets labeled and verified by qualified medical professionals.

Development of statutory regulation

The basic principles and objectives of the statutory regulation of AI include the creation of mechanisms for simplified implementation of software created using AI technologies, the establishment of legal liability when using such software, the development of insurance institutions, the improvement of the data circulation regime, the creation of a national system of technical regulation and conformity assessment, and the development of a set of measures to stimulate the development of technologies. These are defined by the Decree of the Government of the Russian Federation No. 2129-r[6].

From the perspective of the implementation of AI, the healthcare industry is a special case, as for it, the issues of safety, efficiency, and trust in the application of AI solutions in real clinical practice are key aspects.

Statutory regulation of the development, launch on the market, and the use of AI products in the healthcare sector are developing in two key areas:

1) ensuring the safety, quality, and efficiency of AI products as software medical devices;

2) ensuring measures for data protection and confidentiality, including cyber security and the circulation of anonymized medical data for the purposes of machine learning.

[5] Decree of the President of the Russian Federation of 05/07/2018 No. 204 "On the national goals and strategic objectives of the development of the Russian Federation for the period up to 2024." Access mode: http://publication.pravo.gov.ru/Document/View/0001201805070038. Reference date: 03/15/2022.

[6] Decree of the Government of the Russian Federation of 08/19/2020 No. 2129-r "On approval of the Concept for the development of regulation of relations in the field of artificial intelligence technologies and robotics for the period up to 2024". Access mode: https://www.garant.ru/products/ipo/prime/doc/74460628/. Reference date: 03/15/2022.

If the software created based on AI technologies is intended by the manufacturer for medical and diagnostic purposes (provision of medical care), it refers to medical products. The legal foundation for this is Federal Law No. 4-FZ[7], by which the Russian Federation ratified the "Agreements on uniform principles and rules for the circulation of medical products (medical devices and equipment) within the Eurasian Economic Union." According to the document, the development of a common coordinated policy for the circulation of medical devices should be based on the rules and recommendations of a voluntary group of regulators in the field of medical devices from around the world (International Medical Device Regulators Forum, IMDRF), which has collaborated to develop and harmonize the guidelines [4]. The IMDRF has created the AI Medical Devices Working Group, which aims to achieve a consistent approach to the management of this type of medical devices. Its activities cover the standardization and development of unified regulatory and technical approaches for medical devices based on machine learning.

Since the autumn of 2019, a special working group has been operating under Roszdravnadzor, which is considering proposals to change the current regulatory legal acts of the Russian Federation and create new documents to regulate the development and launch of AI-based software in the market, based on recommendations and regulatory documents IMDRF.

In accordance with Federal Law No. 323-FZ[8], the circulation of medical devices, including software medical products, is permitted only subject to prior state registration in the manner prescribed by law.

Until 2022, the registration of software based on AI technologies in Russia was performed according to national rules. For this purpose, Roszdravnadzor, in cooperation with the Ministry of Health of the Russian Federation, made all the necessary amendments to the current statutory instruments governing the circulation of medical products, considering the characteristics of AI. In particular, new versions of the following documents have been released:

1) Decree of the Government of the Russian Federation of December 27, 2012 No. 1416 "On approval of the rules for state registration of medical products"[9], as amended and supplemented by Decree of the Government of the Russian Federation of November 24, 2020 No. 1906 "On Amendments to the rules for state registration of medical products"[10];

2) Order of the Ministry of Health of the Russian Federation dated January 19, 2017 No. 11n "On approval of the requirements for the content of technical and operational documentation of the manufacturer of a medical device"[11];

3) Order of the Ministry of Health of the Russian Federation dated August 30, 2021 No. 885n "On approval of the Procedure for assessing the conformity of medical devices in the form of technical tests, toxicological studies, clinical trials for state registration of medical devices"[12];

4) Order of the Ministry of Health of the Russian Federation of 06/06/2012 No. 4n "On approval of the nomenclature classification of medical devices"[13], as amended and supplemented by Order of the Ministry of Health of the Russian Federation of 07/07/2020 No. 686n "On amendments to Annexes No. 1 and No. 2" to the Order of the Ministry of Health of the Russian Federation dated 06/06/2012 No. 4n "On approval of the nomenclature classification of medical devices"[14].

Starting from January 1, 2026, registration of medical devices will be performed only in accordance with the rules of the Eurasian Economic Union. For this purpose, the necessary changes have been made to the laws and regulations of the Eurasian Economic Commission (EEC ЕЭК), in particular, to the recommendations of the EEC Board dated November 12, 2018 No. 25[15], which provide for a separate section No. 7 "Software."

Development of technical regulation

National strategies or other documents that establish national aims, objectives, and plans for the development of AI have been adopted in Russia, as well as the leading countries of the world in terms of the implementation of AI (USA, China, Canada, South Korea, and EU countries), [5]. These documents consolidate the fundamental principles and approaches to the regulation of AI technologies. Based

[7] Federal Law No. 4-FZ dated 01/31/2016 "On ratification of the Agreement on uniform principles and rules for the circulation of medical products (medical devices and medical equipment) within the Eurasian Economic Union". Access mode: https://ipbd.ru/doc/0001201601310008/. Reference date: 03/15/2022.

[8] Federal Law No. 323-FZ dated 11/21/ 2011 "On the basics of protecting the health of citizens in the Russian Federation" (last revision). Access mode: http://www.consultant.ru/document/cons_doc_LAW_121895/. Reference date: 03/15/2022.

[9] Access mode: https://base.garant.ru/70291692/. Reference date: 15/03/2022.

[10] Access mode: http://www.consultant.ru/document/cons_doc_LAW_368970/92d969e26a4326c5d02fa79b8f9cf4994ee5633b/. Reference date: 15/03/2022.

[11] Access mode: https://base.garant.ru/71626748/. Reference date: 15/03/20222.

[12] Access mode: https://docs.cntd.ru/document/608935477. Reference date: 03/15/2022.

[13] Access mode: https://docs.cntd.ru/document/902353334. Reference date: 15/03/2022.

[14] Access mode: http://publication.pravo.gov.ru/Document/View/0001202008100015. Reference date: 15/03/2022.

[15] Board of the Eurasian Economic Commission. Recommendation No. 25 dated November 12, 2018 "On Criteria for classifying products as medical devices within the Eurasian Economic Union (as amended on June 29, 2021)". Access mode: https://docs.cntd.ru/document/551663485. Reference date: 03/15/2022.

on national strategies, statutory instruments and technical standards are being established.

Since 2019, Russia has launched its own process of development and approval of national technical standards in the field of AI for medicine and healthcare. The major aims of this work are the promotion of social and economic development of Russia, integration into the world economy and international standardization systems, as well as improvement of the quality of solutions and services and an increase in their competitiveness.

In July 2019, by the order of the Federal Agency for Technical Regulation and Metrology (Rosstandart) No. 1732[16], a technical committee for standardization "Artificial Intelligence" (TC 164) was established, which deals with AI issues and improving the efficiency of standardization work in this area [6]. A separate special subcommittee 01 "Artificial Intelligence in Healthcare" (SC 01) was established within the TC 164, which develops national and international standards and aims to coordinate work on the unification and standardization of requirements for the development, testing, and operation of AI systems in healthcare, as well as to establish certification requirements for medical devices using AI technologies (Order of Rosstandart dated December 31, 2019 No. 3471[17]). SC 01 operates at the Moscow Scientific and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow City Health Department. The subcommittee consists of 24 specialized organizations and independent external experts. Members of SC 01, in accordance with the performance plan of TC 164, are constantly working on the creation of national standards. In 2021, the first six documents from the series "Artificial intelligence systems in clinical medicine" were developed, including "Clinical trials," "Program and methods of technical tests," "Change management in artificial intelligence systems with adaptive algorithms," "Evaluation and control of operational parameters," "Requirements for the structure and procedure for using a data set for training and testing the algorithms," and "General requirements for operation" (Table 1) [7].

The issued standards have no analogs around the world. According to the long-term work plan until 2025, TK 164 should coordinate the development of about 50 standards in the field of AI in healthcare. In addition, a number of individual methodological recommendations have been issued, which can also be used as technical regulation tools (Table 2).

REVIEW OF RUSSIAN SOLUTIONS IN THE SPHERE OF AI FOR HEALTHCARE

The Russian AI market for healthcare is currently moving from the stage of formation to the stage of rapid growth, in accordance with the concept of the S-shaped curve of development. This transition velocity depends not only on the developers of AI technologies but also on the speed of updating regulatory legal acts and creating mechanisms for financing medical services provided using AI-based software.

P.A. Komar et al. [8] developed a rating of Russian AI startups offering various products for medicine and healthcare,

Table 1. List of current national standards of the Russian Federation in the field of artificial intelligence for medicine

No.	Title and details of the standard
1	National standard of the Russian Federation GOST R 59921.1-2022 "Artificial intelligence systems in clinical medicine. Part 1. Clinical trials."
2	National standard of the Russian Federation GOST R 59921.2-2021 "Artificial intelligence systems in clinical medicine. Part 2. Program and methods of technical tests."
3	National standard of the Russian Federation GOST R 59921.3-2021 "Artificial intelligence systems in clinical medicine. Part 3. Change management in artificial intelligence systems with continuous learning."
4	National standard of the Russian Federation GOST R 59921.4-2021 "Artificial intelligence systems in clinical medicine. Part 4. Evaluation and control of operational parameters."
5	National standard of the Russian Federation GOST R 59921.5-2022 "Artificial intelligence systems in clinical medicine. Part 5. Requirements for the structure and procedure for using a data set for training and testing the algorithms."
6	National standard of the Russian Federation GOST R 59921.6-2021 "Artificial intelligence systems in clinical medicine. Part 6. General requirements for operation."

[16] Order of the Ministry of Industry and Trade of the Russian Federation, the Federal Agency for Technical Regulation and Metrology dated July 25, 2019 No. 1732 "On the establishment of a technical committee for standardization "Artificial Intelligence"". Access mode: https://docs.cntd.ru/document/560916332. Reference date: 03/15/2022.

[17] Order of the Ministry of Industry and Trade of the Russian Federation, the Federal Agency for Technical Regulation and Metrology dated December 31, 2019 No. 3471 "On Amendments to the Order of the Federal Agency for Technical Regulation and Metrology dated July 25, 2019 No. 1732 "On establishment of a technical committee for standardization "Artificial Intelligence"". Access mode: https://docs.cntd.ru/document/564243465. Reference date: 03/15/2022.

Table 2. List of guidelines on the topic of artificial intelligence systems for healthcare

No.	Name and details of the document
1	Regulations for the preparation of data sets with a description of approaches to the formation of a representative sample of data. Part 1: guidelines/comp. S.P. Morozov, A.V. Vladimirsky, A.E. Andreichenko, et al., series "Best practices of radiological and instrumental diagnostics," issue 103, *GBUZ NPKTs DiT DZM*, Moscow (2021).
2	Clinical trials of software based on intelligent technologies (radiology). K-49 S.P. Morozov, A.V. Vladzimirsky, V.G. Klyashtorny, et al., "Clinical trials of software based on intelligent technologies (radiation diagnostics)," series "Best practices of radiological and instrumental diagnostics," issue 57, Moscow (2019).
3	Methodological Recommendations on the Procedure for Conducting an Examination of the Quality, Efficiency, and Safety of Medical Devices (in terms of software) for State Registration within the National System, *FGBU VNIIIMT Roszdravnadzor*, Moscow (2021).

based on a multi-factor assessment methodology, including market prospects, investor interest metrics, intellectual property data, and so forth. This rating indicates that there are more than 30 different companies in the Russian market of AI solutions for healthcare. More than 60% of them work in the medical image analysis sector, including products, such as Third Opinion, Botkin.Ai, and Celsus. For comparison, there are about 2,800 companies in the world, working in the field of AI for medicine and healthcare; thus, the share of the Russian segment in the global market in terms of the number of companies is about 1.25%.

Simultaneously, the mechanical calculation of the number of companies should be treated critically. In a global perspective, the influx of investments frequently results in an explosive growth of business activity, namely, the emergence of numerous startups focused only on a temporary existence "on the wave of hype" due to the support of investors, and not on the creation of real products. It is strategically more acceptable to monitor the dynamics of product entry into the market, their registration as medical products, the scope of application, and revenue through the implementation of their own innovations (rather than through investments). Thus, the process of transition from quantity to quality can be identified.

At the end of 2021, 7 (20%) out of 35 companies received 11 registration certificates from Roszdravnadzor for their products as medical devices, using the one-step registration procedure provided for by Government Decree No. 1906[18]. The Webiomed predictive analytics platform was the first product created using AI technologies and received a registration certificate, which passed the corresponding state registration in the spring of 2020. Then, in November and December 2020, two more products in the field of medical image analysis using AI also received registration certificates; these were the platform for analysis and processing of medical images Botkin.Ai and service platform for radiation diagnostics Care Mentor AI, respectively (Table 3).

SCIENTIFIC RESEARCH IN THE FIELD OF AI IN HEALTHCARE

A bright but almost forgotten episode in the development of AI technologies in Russia can be considered the book "Inscription of a new method of research using machines that compare ideas", published in 1832 by a veteran of the Napoleonic wars and an official of the Ministry of Internal Affairs, Semyon Nikolayevich Korsakov (1787–1853). In this work, the author proposed a multi-criteria search method using weight coefficients, punched cards, the first method to process big data (the forerunner of modern AI algorithms), and designs of five "idea comparison machines", which was based on the principles of mechanistic materialism [9].

The interdisciplinary seminar "Automation and Thinking", held in 1954 under the guidance of Academician A.A. Lyapunov, marked the official beginning of developments and research in the field of AI in Russia [10]. At the end of the 1980s, the level of theoretical research in the USSR in the field of AI at least corresponded to world trends, but developments in the field of automated analysis of medical data (especially the works of Y.I. Neimark and A.P. Matusova in the field of mathematical processing electrocardiosignals) were obviously ahead of them. In 1974, a scientific council on the problem of AI was created in the Committee for System Analysis under the Presidium of the USSR Academy of Sciences, which supported work in the fields of natural language processing, knowledge and data representation, intelligent behavior of robots, and so forth. However, since the 1980s, there has been a gradual lag in the applied technologies of AI and machine learning, caused by the deterioration of the social and economic situations and the subsequent collapse of the USSR. However, in the field of healthcare, one more factor of stagnation of AI development in the period of the 1980–1990s should be considered, when a considerable number of "expert systems" (actually automated medical decision support systems) were proposed for cardiology, surgery, endocrinology, neurosurgery, and so

[18] Decree of the Government of the Russian Federation of November 24, 2020 No. 1906 "On amendments to the Rules for the State Registration of Medical Devices". Access mode: http://publication.pravo.gov.ru/Document/View/0001202011270010. Reference date: 03/15/2022.

Table 3. List of registration certificates issued by Roszdravnadzor for software-based medical devices created using artificial intelligence technologies, as of December 2021

No.	Date of issue	Data on the registration certificate, product, and manufacturer
1	03.04.2020	Software "System for supporting medical decision-making WEBIOMED according to TU 62.01.29-001-12860736-2019," RU No. RZN 2020/9958, developed by K-Sky, website: https://webiomed.ai/
2	03.11.2020	Botkin.AI application software for visualization and image processing of the DICOM standard according to TU 58.29.32-001-45146066-2020, RU No. RZN 2020/12028, developed by Intellogic, website: https://botkin.ai/
3	11.12.2020	Software "Neural network system Care Mentor AI" according to TU 62.01.29-001-28263422-2019, versions: Webshow, API. RU No. RZN 2020/11137, developed by CareMentorAI, website: https://carementor.ru/
4	27.05.2021	Software "Care Mentor AI neural network system for diagnosing a new coronavirus infection COVID-19 according to computed tomography" according to TU 58.29.32-002-28263422-2020, versions: Webshow, API. RU No. RZN 2021/14406, developed by CareMentorAI, website: https://carementor.ru/
5	27.05.2021	CELS® software according to TU 58.29.32-001-28139219-2019, RU No. RZN 2021/14449, developed by Medical Screening Systems, website: https://celsus.ai
6	01.06.2021	Software module for analysis of fluorograms and radiographs of the human chest according to TU 58.29.32-001-21494354-2020, RU No. RZN 2021/14506, developed by PTM, website: https://thirdopinion.ai/
7	27.07.2021	Software "Care Mentor AI neural network system for the analysis of X-ray projection mammography" according to TU 58.29.32-003-28263422-2021, versions: Webshow, API. RU No. RZN 2021/14869, developed by CareMentorAI, website: https://carementor.ru/
8	12.10.2021	Software "Neural network system Care Mentor AI for determining longitudinal platypodia according to lateral radiography of the foot under load" according to TU 58.29.32-004-28263422-2021, versions: Webshow, API. РУ № РЗН 2021/15554, RU No. RZN 2021/15554, developed by CareMentorAI, website: https://carementor.ru/.
9	22.06.2021	Software complex for automatic processing of radiological images "RADLogics Platform" according to TU 58.29.32-320-17493389-2020, RU No. RZN 2021/14627, developed by Radlogics Rus, website: https://www.radlogics.com/
10	24.09.2021	Software module for the analysis of human computed tomography studies according to TU 58.29.32-002-21494354-2021, RU No. RZN 2021/14651, developed by PTM, website: https://thirdopinion.ai/
11	27.11.2021	Gamma Multivoks software package for registration, visualization, processing, archiving and transfer of medical images and data according to TU 62.01.29-001-16428326-2018, RU No. RZN 2021/13277, website: https://www.gammamed.ru/

forth. However, they did not have a significant effect. These innovations were based on structured "decision trees" (they could be very extensive, but predictable and completely static); there was no actual training and development of algorithms during operation. For physicians, such software was of no practical importance, and interest in the automated analysis of medical data had declined sharply.

AI owes its revival in the early 2000s to a new mathematical apparatus (including artificial neural networks), a rapid increase in computing power, and large-scale accumulation of biomedical data in digital form.

According to the "National strategy for the development of artificial intelligence for the period up to 2030"[19], one of the priorities for the development of AI in Russia is the development of scientific research and development in this sector, including in healthcare. Fig. 2 illustrates the dynamics of the number of scientific publications by Russian authors in international scientific journals and authoritative scientific conferences indexed in the Scopus scientific information database, which subjects correspond to the application of AI technologies in medicine and healthcare. The steady growth since 2016 is clearly visible. In 2021, the number of publications found in the query given in the caption amounted to 227 articles and reviews. An analysis of publications showed that more than 60% of the work was performed jointly with international colleagues. This fact, which testifies to the expansion of international scientific cooperation between Russian researchers and doctors in this rapidly developing field, can only be acclaimed.

It should be noted, nonetheless, that the number of published world-class research results in the field of medical AI remains relatively small compared with the leading countries in this field. Thus, a similar query in Scopus shows that in 2021, 1,926 articles were published by Chinese researchers, 1,661 articles were published by authors from the UK, and 4,087 articles were published by

[19] Decree of the President of the Russian Federation of October 10, 2019 No. 490 "On the development of artificial intelligence in the Russian Federation" (together with the "National strategy for the development of artificial intelligence for the period up to 2030"). Access mode: http://www.consultant.ru/document/cons_doc_LAW_335184/. Reference date: 03/15/2022.

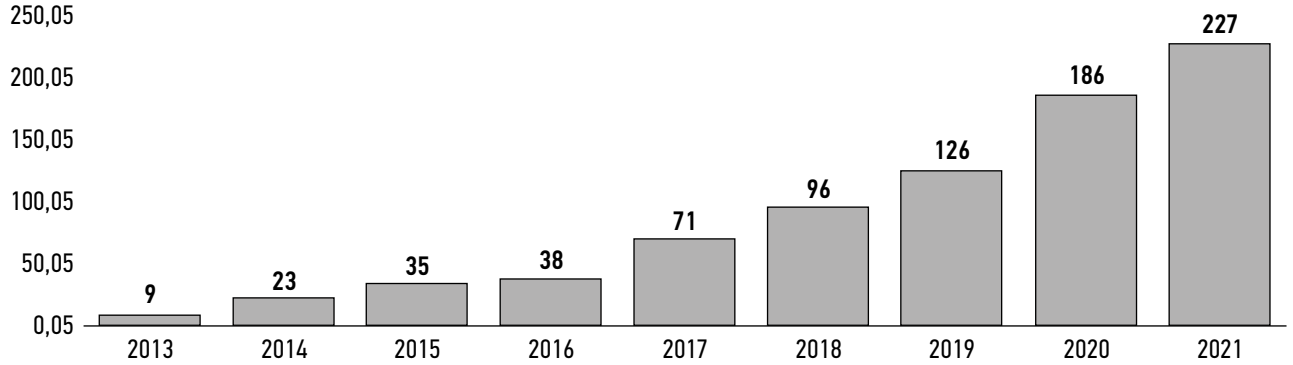

Fig. 2. The number of indexed publications in the Scopus scientific information database, published by Russian authors at the interface of medicine and artificial intelligence over the past 10 years.

Note. Database query: (TITLE-ABS-KEY (medicine OR healthcare) AND ("artificial intelligence" OR "machine learning") AND AFFILCOUNTRY (Russia OR "Russian Federation")).

authors from the USA. This indicates a backlog that needs to be overcome at a rapid rate of development in the field of research and development on medical AI systems in the Russian Federation. Undoubtedly, additional targeted funding for researchers from medical scientific centers and clinical institutions is required in addition to investments in development.

It is indicative that most of the works of Russian authors in 2021 were funded by state science support bodies, namely, the Russian Foundation for Basic Research (38 articles), the Ministry of Education and Science of the Russian Federation (20 articles), and the Russian Science Foundation (13 articles). Russian universities are mentioned among the funding organizations, although there are practically no published results of research funded by private Russian investors or businesses. This confirms the low interest of businesses in investing in research and development in the field of AI in medicine in Russia over the past few years, as well as the prevailing state funding for research in this sector (notably in 2021, mainly the results of research conducted in previous years were published, given the long-time preparation, review, and publication of the article in leading journals).

The aims and content of Russian research in the field of medical AI largely follow global trends. A large number of works in 2021 were focused on pilot projects to study the possibilities of AI in various aspects of care for patients diagnosed with a new coronavirus infection COVID-19. At the 38th International Conference on Machine Learning (ICML, 2021), the Sberbank AI Lab presented two AI services, namely, a model for identifying pneumonia foci on X-ray images with further prioritization of patients for treatment and a model for assessing the risk of severe disease in patients hospitalized with pneumonia, including that caused by COVID-19[20]. The model for detecting pneumonia foci on X-ray images has achieved an accuracy of 97.8% due to continuous learning and improving parameters.

The National Research Tomsk Polytechnic University, conducted development in the field of using AI for diagnostics of pneumonia, including those associated with COVID-19, in collaboration with the Research Institute of Complex Problems of Cardiovascular Diseases and EPAM Systems (St. Petersburg) as well as a number of American colleagues from various companies and universities [11]. The authors revealed that the standard deep learning approaches used in most lung disease diagnostic work do not activate around patterns indicative of COVID-19 or pneumonia. A neural network training based on indirect observation was proposed, which provided accuracy comparable with the accuracy of specialized networks created for diagnostics of COVID-19 and pneumonia. The authors demonstrated that the pre-trained convolutional network VGG-16 [12], retrained using controlled attention, and demonstrated the most accurate classification at the levels of 88% and 84% on the validation and test subsets, respectively.

A system for detecting COVID-19 using AI based on X-ray images was also developed at Innopolis University (Kazan), within the Institute of Artificial Intelligence. The data set for AI training included 28,000 lung images of healthy people and patients with various types of pneumonia as well as 94 X-ray images of the chest organs infected with coronavirus. The result of the study was a neural network that diagnosed coronavirus from X-ray images with an accuracy of up to 80%; this is how the neural network learned to identify common signs of pathologies caused by COVID-19.

In addition, we note that the Botkin.Ai platform is actively working in the field of solutions for radiation diagnostics. The solution provides automated selection, depersonalization, and processing of medical images using AI, and it is easily integrated with medical information systems. Since 2017, the company has been working with leading pharmaceutical companies, private clinics, and public health facilities (more than 30 successful projects in Russian regions, CIS countries,

[20] SberPress [Internet]. At ICML, Sber presented its innovations based on artificial intelligence in medicine. Access mode: https://press.sber.ru/publications/na-icml-sber-predstavil-svoi-razrabotki-na-osnove-iskusstvennogo-intellekta-v-meditsine. Reference date: 03/15/2022.

Latin America, and the Middle East). At the moment, the company's main solutions are related to the automated analysis of the results of mammography, computed tomography of the chest organs, and brain.

Naturally, the work of Russian researchers in the field of AI systems for medicine is not limited to the problems of COVID-19. The Helmholtz National Medical Research Center for Eye Diseases of the Russian Ministry of Health (Moscow) is studying the use of AI methods for diagnosing diabetic retinopathy using fundus images [13].

The use of machine learning in solving prognostic problems, including in terms of prevention of cardiovascular diseases, is being studied in the Far East under the guidance of K.I. Shahgeldyan [14].

Research and development in the field of predicting chronic non-communicable diseases, as well as research on data from real clinical practice, based on AI technologies, are conducted within the development of the Webiomed platform [15]. The platform is designed for automatic analysis of anonymized medical data to predict the possible development of diseases and their complications at the personal and population level. The analysis of more than 2,700 various signs is supported, which are extracted from medical protocols and other documents using NLP technologies by the system of electronic medical records of the patient. For 40 different diseases, automated analysis is possible. This includes 18 predictive and diagnostic machine learning models; some of which have an accuracy of over 80%. The Webiomed platform is so far the only solution in the Russian Federation for analyzing data from electronic medical records.

N.I. Pirogov National Medical and Surgical Center of the Ministry of Health of Russia (Moscow), in cooperation with the Center for Neurotechnologies and Artificial Intelligence of the Immanuel Kant Baltic Federal University (Kaliningrad) and the Laboratory of Neuroscience and Cognitive Technologies of the Innopolis University (Kazan), handles the issues of constructing systems of explainable AI in medicine in relation to diagnosing the diseases of the central nervous system. In particular, in 2021, a system for labeling epileptic electroencephalography data based on unsupervised learning was developed, based on the representation of epileptic discharges using the theory of sentinel events [16]. The created medical decision support system, developed by the Immersmed company, a Skolkovo resident, is currently undergoing clinical testing at the Pirogov Center [17]. The team also proposed AI-based methods for diagnosing age-related neurodegenerative changes based on functional motor and cognitive tests [18].

The use of machine learning methods for the analysis of bioelectrical signals is in demand in the implementation of brain–computer interface technologies for the rehabilitation of patients after traumatic brain injuries and strokes [19]. Training through the mental representation of movement in the circuit of the brain–computer interface, which enables to control the result of each attempt to imagine a movement, is one of the approaches of rehabilitation after a stroke.

The Moscow Experiment on the Application of Computer Vision Technologies in Radiation Diagnostics, launched in 2020 with the support of the Government of Moscow, is the largest research project in Russia in the field of AI in healthcare. It is in the form of a multicenter prospective study of the feasibility of using AI technologies in real clinical practice (www.mosmed.ai). The study involved 18 development companies; 53 AI services are integrated into the Unified Radiological Information Service of the Unified Medical Information and Analytical System for analyzing the results of radiographs, computed tomography, and mammography. Over 2 years, automated analysis of over 5.6 million X-ray studies was performed, and the results of which are available to more than 10,000 doctors of 150 healthcare organizations. A comprehensive scientific analysis of user engagement, technological quality, and diagnostic accuracy of AI algorithms, as well as their impact on the efficiency of doctors and healthcare organizations is being performed. It has previously been proven that the duration of descriptions of the results of some types of radiological examinations is reduced due to preliminary automated analysis. The expediency of using AI services in radiation diagnostics to increase the productivity of radiologists has been unambiguously established. As part of the experiment, constant work is being conducted with participating companies, including in the format of seminars and meetings with doctors, to develop the AI market. A library of data sets is being created to fulfill the provisions of the National Strategy for the Development of AI in the Russian Federation [20]. The materials of the experiment served as the basis for the first national standards mentioned above and for methods of clinical trials conducted in the process of registration of AI-based software as a medical product.

Participants in the experiment's AI services are rated on a monthly basis based on a set of metrics of technological quality and diagnostic accuracy. For each direction of the experiment, three leaders are published in open access, and from among the most permanent participants in such a leaderboard, several innovations described below can be specified.

AI service Third Opinion is one of the first companies that announced itself on the Russian market of intelligent technologies for healthcare. Algorithms are being developed to recognize digitized blood and bone marrow smears, chest radiology, and fundus images. Third Opinion was one of the first companies on the Russian medical technology market to offer a module for continuous AI analysis of video streams from hospitals to prevent bedsores, patient falls, and other hospital accidents. Subsequently, the service was installed in several leading private medical centers in the country. The AI service of the Third Opinion platform for automated analysis of the results of chest radiography is quite consistent among the top three leaders in the corresponding direction of the experiment. In a prospective assessment of diagnostic

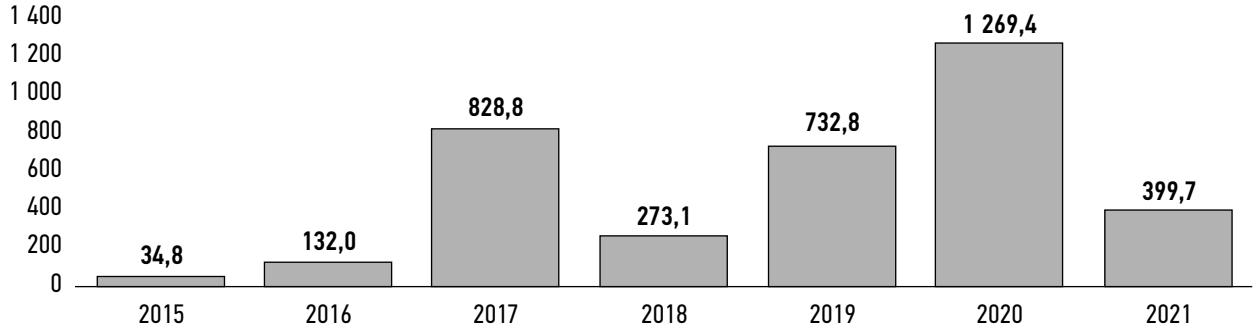

Fig. 3. The dynamics of Russian investments in artificial intelligence systems for medicine and healthcare in 2015–2021 (authors' data), million rubles.

accuracy, the service reaches an area under the characteristic curve of 0.84 (95% CI, 0.83–0.85).

AI service Celsus is a confident participant in the leaderboard of the experiment in the field of mammography. In a prospective assessment of diagnostic accuracy, the service reaches an area under the characteristic curve of 0.74 (95% CI, 0.73–0.74). It is noteworthy that the Celsus platform supports work on four modalities, namely, mammography, fluorography, chest X-ray, and computed tomography of the chest and brain. However, in the experiment, the highest results are associated precisely with the automated analysis of the results of prophylactic radiation examinations of the mammary glands.

IraLabs AI service is characterized by a thorough methodological study of the issues of automated processing of X-ray study results, as well as publication activity. As part of the experiment, the company provides several services at once for opportunistic screening of chronic non-communicable diseases, osteoporosis, as well as assessing the volume of lung lesions in COVID-19. The most stable participation of the company in the leaderboard of the experiment is associated with the recent direction, namely, the accuracy of the algorithm for working with manifestations of a new coronavirus infection on computed tomograms of the chest organs (area under the characteristic curve) is 0.88 (95% CI, 0.87–0.88). In osteoporosis screening, this developer's AI service achieved very quickly a good result of 0.94 (95% CI, 0.88–1.00).

It must be emphasized that the data provided is not a complete or official overview of the leaders of the ranking. This is merely an emphasis on several active market participants developing several directions at the same time. It should be noted once more that 53 AI services participate in the experiment in seven fields, most of which demonstrate quite encouraging results. A detailed analysis will be presented in our subsequent publications.

EVALUATION OF THE SIZE AND DYNAMICS OF THE RUSSIAN MARKET OF AI FOR HEALTHCARE

We analyzed publications posted in the media on investments in Russian companies offering specialized AI products for healthcare, information from the websites of the respective development companies, as well as data received from a number of government institutions, on the volume of government support through grants and other tools. Based on this information, we evaluated the dynamics in AI products for healthcare in Russia (Fig. 3). At the end of 2021, the total Russian investments in AI for healthcare amounted to $5.39 million, or 0.04% of the global level, while in Russia in 2021, the volume of investments decreased by 3.2 times compared with 2020, while it increased by 1.8 times in the world.

The structure of sources of Russian investment in AI products is presented in Fig. 4. According to it, almost 70% of Russian investments in the development of AI products are obtained from public sources of funding, including support institutions, such as the Skolkovo Foundation, the National Technology Initiative, the Innovation Promotion Fund, and so forth. The distribution of investments by market sectors is presented in Fig. 5.

The revenue of the companies on the Russian market is systematically increasing, and the dynamics of growth is presented in Fig. 6. Despite the formal growth of this indicator, it should be noted that the structure of revenue is still quite risky in terms of market maturity, as a considerable share

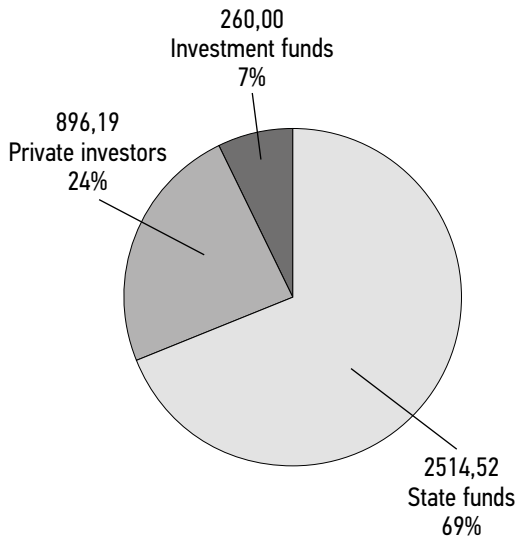

Fig. 4. Sources of Russian investment in artificial intelligence systems for medicine and healthcare (authors' data), million rubles.

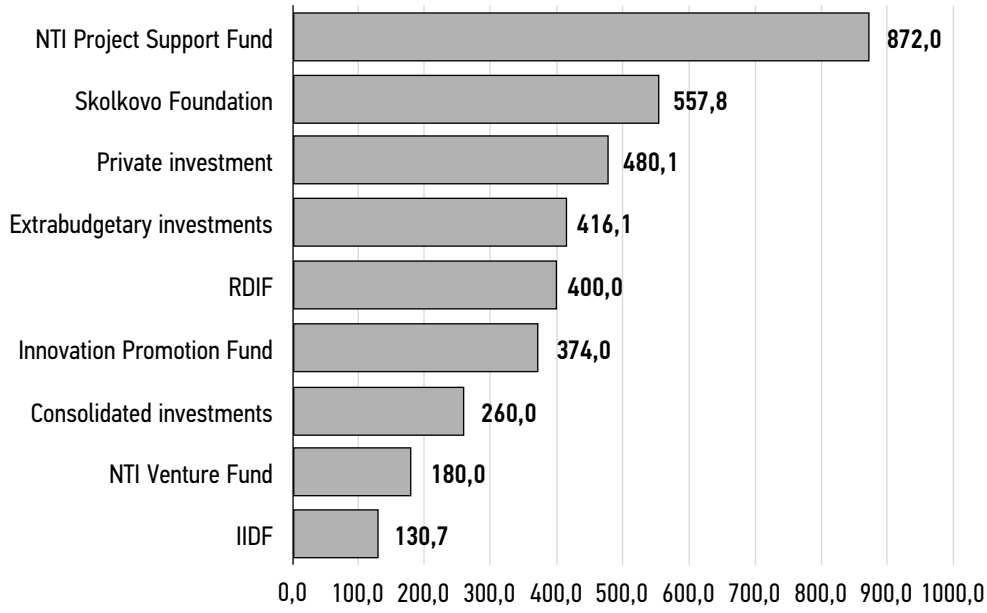

Fig. 5. Directions for investing in artificial intelligence systems for medicine and healthcare (authors' data), million rubles.
Note. NTI, National Technology Initiative Foundation; RDIF, Russian Direct Investment Fund; IIDF, Internet Initiatives Development Fund.

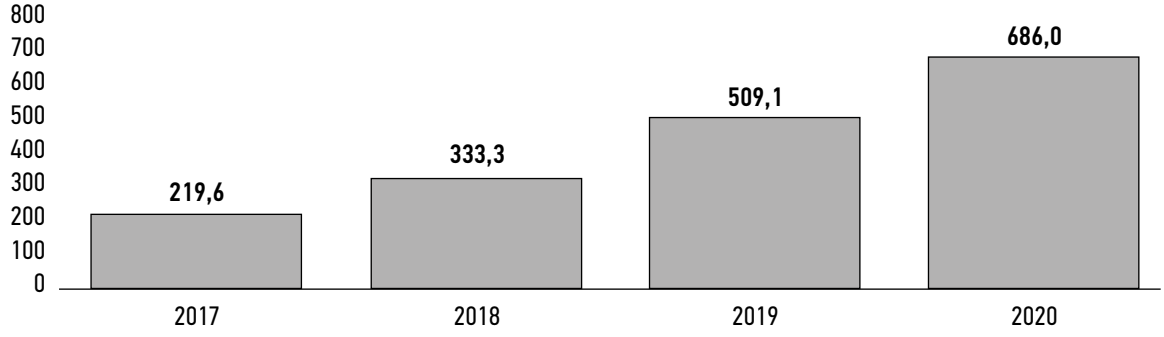

Fig. 6. Revenue dynamics of Russian developers of artificial intelligence systems for medicine and healthcare in 2017–2020 (authors' data), million rubles.

of the revenues of Russian companies was received through participation in the Moscow experiment, as well as other grant support tools, including from industry development institutions. This situation indicates that, so far, Russian companies have not been able to reveal scalable and market-based tools to promote their products, which can be due to the specifics of state regulation of healthcare markets in general.

We estimated the size of the AI market for healthcare in 2021 of about 700 million rubles, or 0.11% of the global indicator, based on the data revealed on the revenue of Russian AI startups.

We estimated the total capitalization of Russian development companies at $200 million, while the same indicator for the whole world is $49 billion based on the average market multiplier and revenue. As a result, our share in this indicator is 0.4%.

In total, at the end of 2021, more than 20 constituent entities of the Russian Federation launched various projects for the implementation of AI products, including those implemented in the form of pilot projects or scientific and practical experiments. The COVID-19 pandemic has become a key driver of growing interest in AI in Russia.

CONCLUSION

The data presented demonstrate clearly that Russia needs to make additional systematic efforts to develop research, development, and implementation of products based on AI technologies for healthcare. This field is one of the largest and most vital segments of the digital economy, and the lag here can be extremely critical.

One of the problems of low results, at least from the perspective of the market, is the lack of scalable sales and mass implementations in practical healthcare among Russian companies.

We suggest three key reasons for this phenomenon. The first is the lack of targeted state funding for the implementation of AI systems in healthcare organizations and health authorities in terms of innovative AI products and services. The current federal programs and national projects, including the project to create a single digital circuit in the healthcare sector, do not have at disposal any measures or funds for the introduction of AI. There are no medical services that could be provided using AI technologies, which creates a barrier to the growth of purchases of relevant products, at least in public healthcare sector. Second, the value of the proposed solutions is not sufficiently expressed. Many companies are focused on improving their products, improving the accuracy of machine learning algorithms, but not paying enough attention to scientific research and providing convincing evidence of the effectiveness and value of their solutions for healthcare in Russia. Moreover, the third reason is distrust of products. Few of the Russian developers pay due attention to properly organized clinical trials and testing of their products. Currently, 11 registration certificates of Roszdravnadzor have been issued for AI systems to seven development companies. However, in medicine, the issues of trust in new technologies are essential, as here, first, when deciding on the use of something new, the "Nonmaleficence" principle is borne in mind.

It seems that solving problems with sources of payment for the implementation and use of AI products in practical healthcare, conducting additional scientific research on trust in the quality of AI products, and strengthening their value for consumers are the main strategic tasks that must be solved in the Russian Federation for ensuring the growth of research, development, and real application of AI technologies in the healthcare organizations of Russia.

ADDITIONAL INFORMATION

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