

Bioeconomy and its role in the context of digitalization

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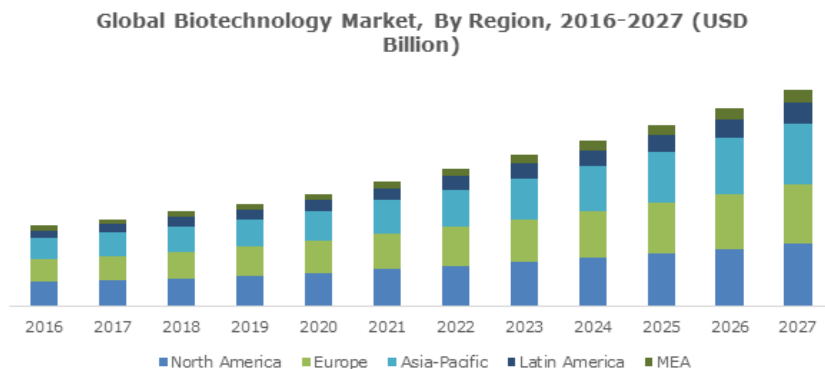
Abstract. A country's progress in innovative development through the bioeconomy is contingent on the extent of research, development, and production within the biotechnology sector. Biotechnology research aimed at producing biologically active compounds has yielded successful applications, including the development of enzymes, vaccines, vitamins, hormones, and antibiotics. Additionally, active research is underway in creating and manufacturing pesticides, enhancing plants' resistance to diseases, developing new plant and animal varieties, innovating food and animal feed, crafting new strains of beneficial microorganisms, and using biotechnologies for environmental conservation. The adoption of biotechnologies has the potential to reduce production costs in both industry and agriculture, enhance the availability of medicines, improve the quality of medical diagnostics and treatment, and contribute to environmental preservation.

1 Introduction

Numerous international and domestic scientific conferences, publications, reports, and reviews created by leading consulting firms, stock analysts, and various government and non-profit organizations are dedicated to the exploration of biotechnology trends, their global significance, and the assessment of their impact on national economies. Biotechnology is anticipated to emerge as the most rapidly growing sector of the global economy in the 21st century. According to prominent experts, biotechnology is projected to contribute 2.7% of the GDP in developed countries by 2030. In developing nations, the impact of biotechnology will be even more substantial. With the utilization of biotechnological advancements, it is expected that, by 2030, 80% of medical products, 35% of chemical industry products, and 50% of agricultural output will be realized. By 2050, the global bioenergy market is set to generate \$150 billion, with 30% of the world's total energy demand originating from renewable sources. Leading the way in the development of biotechnology are countries like the United States, Germany, the United Kingdom, China, and Japan. Presently, Russia's presence in the global biotechnology market is estimated at just one-tenth of one percent [1]. Overall, a structured framework for the advancement of biotechnologies has been established, with a focus on specific application areas, as mentioned earlier in this study. The most significant scientific and practical results,

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consequently drawing substantial interest from investors, are found within "red" biotechnology, encompassing biomedicine and biopharmacology. According to the Institute for Investment Policy Analysis, "red" biotechnology holds more than 70% of the global biotechnology market, with biopharmaceuticals accounting for 61% of that market. It is predicted that the global biotechnology market will reach \$600 billion by 2020, and by 2025, as projected by Global Market Insights, it will expand by over one and a half times compared to 2018, reaching \$742 billion. Such growth is expected to facilitate the introduction of a new wave of pharmaceutical biologics into the market. The forecasted growth rates for various sectors within the global biotechnology market are illustrated in Figure 1. The graph reveals that biopharmaceutical companies are experiencing significantly faster growth compared to other segments of the biotechnology industry.



Source: www.gminsights.com

Fig. 1. Biotechnology Market Size

The investment appeal of biopharmaceutical companies can be assessed by examining the trends of the IBB index, which comprises the stocks of biotechnology firms traded on NASDAQ. This index includes shares from some of the major biopharmaceutical companies, including Amgen, Biogen, Gilead Sciences, Celgene, Illumina, Regeneron Pharmaceuticals [2], Vertex Pharmaceuticals, Alexion Pharmaceuticals, BioMarin Pharmaceuticals, and Mylan. In Figure 2, you can see a five-year chart depicting the fluctuations in the IBB index.

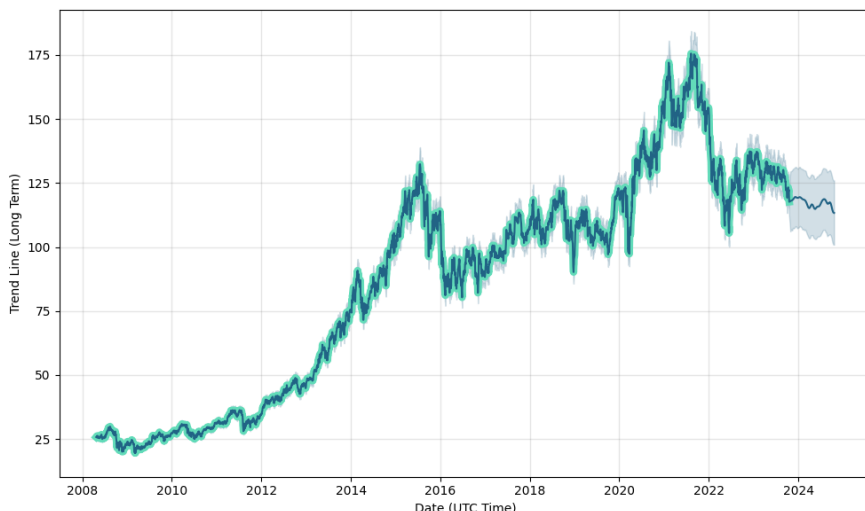


Fig. 2. IBB index chart for 5 years

The graph illustrates the substantial volatility in stock returns that is characteristic of pharmaceutical and biotech companies, indicating the significant risks associated with this industry. The most prosperous period for this sector occurred between 2016 and 2023 when there was a substantial surge in the stocks of biotech companies, resulting in a remarkable 250% increase in the index. Stock returns reached their peak in 2022, followed by a sharp decline in index returns until 2014 [3]. The decline in stock returns can be attributed to various events, notably the U.S. government's efforts to tighten regulations on pharmaceutical companies. However, the market's positive response to the successful completion of clinical trials for new drugs by major biotechnology companies at the end of 2022 led to an upward adjustment in the dynamics of the IBB index. In 2018, companies in this sector experienced an average stock price growth of nearly 20%, which is approximately four times higher than the average growth seen in the technology sector. The beginning of 2019 provided a good indication of the factors contributing to the investment attractiveness of biotechnology shares. During this period, the market capitalization of world-leading companies, such as Celgene Corp and Seattle Genetics, Inc., increased by 33%, reaching \$63 billion and \$12.14 billion, respectively.

2 Research Methodology

Changes in the regulatory environment, particularly those related to the introduction of new drugs to the market, have the potential to reduce the investment attractiveness of biotechnology companies' shares [4]. Industry consolidation has also had a significant impact. Notably, Celgene emerged as the most valuable and fastest-growing company in the sector, largely due to a positive investor response to its merger with Bristol-Myers Squibb (BMY), which created new opportunities for drug development and expansion.

To understand the role of clinical trials in the process of developing and bringing new medicines to consumers, it's essential to delve into the existing requirements for conducting these trials. Prior to putting a new substance into practical use, several stages must be completed. Preclinical studies, which last from 3 to 6 years according to the European Patient Academy EAPUT, are the first step. The outcome of this stage includes identifying the most promising treatment option, evaluating safety, and establishing a scientific foundation for advancing to clinical research. The selection of a treatment option is based on computer modeling, laboratory testing, and animal trials [5].

Following successful preclinical studies and the registration of intellectual property rights, the new substance progresses to clinical trials, a complex process that typically lasts at least 6-7 years. Clinical trials are generally divided into four phases:

1. Phase one assesses tolerability, safety, and therapeutic effects in healthy individuals.
2. Phase two investigates the effects of the drug on patients with a specific disease.
3. Phase three, the most extensive and expensive phase, involves testing the medication on large groups of patients with the condition being treated. The goal is to identify all aspects of treatment, potential risks, and contraindications. Approval or denial of drug registration is based on the results of this phase. Extending this phase can be costly, at an average of about \$670,000 per additional month.
4. Phase four clinical trials only begin once the drug is approved and may last from two to five years. This phase aims to clarify the drug's distinctions from others in its category and demonstrate its effectiveness for overall healthcare.

The primary challenge for biopharmaceutical companies is to reduce the cost and duration of clinical trials. Determining the optimal amount of spending for each phase is complicated because the development of a new drug can present unforeseen challenges, such as legislative changes, increased testing costs, evolving research programs specific to certain developments, variations in the number of subjects and testing locations, and differences between clinical trials conducted in various countries.

3 Results and Discussions

On average, clinical trials in the first three phases cost approximately \$30 million. Among these phases, the first is the least expensive, accounting for roughly 10% of the total clinical trial costs, while the third phase represents about 70% of the overall expenses. Research at each stage adheres to established standards [6]. Legislative regulations governing clinical trials are typically rooted in international law and the national laws related to healthcare and human rights. International human rights standards for biomedicine are outlined in the 1997 Council of Europe Convention for the Protection of Human Rights and Human Dignity in Connection with the Use of Biology and Medicine.

Contemporary issues in human rights protection concern the regulation of consent to medical procedures, donations, genetic research, and information research that utilizes big data technologies [7]. Russia, in cooperation with the Council of Europe's Committee on Bioethics, plays an organizing role in several of the committee's events and contributes as an expert on specific bioethical matters. Recommendations from the Convention and international and national standards guide the procedure and requirements for conducting clinical trials. In Russia, the Ministry of Health's Order No. 200n, dated April 1, 2016, titled "On the Approval of the Rules of Good Clinical Practice," lays out the stipulations for planning, conducting, monitoring, auditing, documenting clinical trials, as well as safeguarding the rights and health of participants and the confidentiality of their personal data.

The distinct nature of clinical research relationships and the growing complexity of research procedures have led many biopharmaceutical companies to outsource this type of activity to contract research organizations (CROs). The efficiency of clinical trials conducted by CROs stems from the global recruitment of volunteer groups, cost management flexibility, the presence of qualified researchers across different regions of the world, and competent clinical and medical monitoring. These organizations are responsible for organizing document flow and report preparation in accordance with international and national regulations, contributing to their profitability [8]. The global CRO market was valued at \$36 billion in 2017 and is projected to reach \$56 billion by 2023. Many governments incentivize the use of contract research organizations to address social issues and stimulate research in areas requiring the development of new drugs and less-studied

treatments. For instance, China and India provide tax incentives and financial subsidies to CROs for the development of drugs that are crucial to their healthcare systems. The Russian clinical research market comprises both local and international CROs and is estimated at \$1 billion annually. In 2011, Russian participants in the clinical research market established the Association of Clinical Research Organizations, which annually compiles reports summarizing the activities of companies, identifying trends in the clinical research market, pinpointing problem areas, and presenting constructive proposals for enhancing legislative regulations related to contract research organizations.

In 2017 and 2018, the reports from the Association of Clinical Research Organizations highlighted a trend in Russia towards a decrease in the issuance of permits for local clinical trials by Russian organizations [9]. There was little improvement in reducing the time needed to obtain permits for importing drugs, as well as approvals for new centers, additional patients, extensions of studies, etc. This situation raises concerns about the ability of domestic biopharmaceuticals to keep pace with the necessary development. It's worth noting that in Russia, there are approximately 3.5 clinical trials conducted per million people per year, while France has 57, and Poland has 10. Contract research companies are working to increase their efficiency by actively integrating digital technologies and creating internet platforms and applications. These approaches reduce the time required for approval, data collection, and clinical trial analysis.

Additionally, the scope of clinical research has expanded to include digital therapy methods. Digital therapy refers only to applications that have undergone clinical trials, proven their clinical effectiveness, and received state registration. Such applications help patients monitor their condition, receive timely medication reminders, and adjust their treatment regimen if any deviations are detected [10]. They have been widely accepted in the treatment of diabetes, neurological conditions, and mental diseases. Research is ongoing for the use of digital technologies in treating chronic obstructive pulmonary disease and cardiovascular diseases. The use of digital technologies enhances the efficiency and quality of disease diagnosis, the availability of medical services through telemedicine, the range of scientific research, and the introduction of new treatment technologies.

Artificial intelligence plays a crucial role in diagnosing diseases more accurately and efficiently and in selecting treatment methods tailored to individual patient characteristics. This opens up opportunities for developing personalized and preventive medicine, leading to improved cost-effectiveness and treatment quality for severe diseases. The global investment in digital medicine at the end of 2018 exceeded \$14.6 billion, more than ten times the amount invested in 2010. Nevertheless, the pace of development in Russian digital medicine is still considered insufficient compared to countries with a high level of digital medicine, such as the USA and China.

To address this issue, the Russian government has implemented a series of measures aimed at rapidly developing the digital economy and the biotechnology sector in recent years. The national program "Digital Economy of the Russian Federation" outlines specific indicators of achievement from 2018 to 2024 within six federal projects: "Regulatory regulation of the digital environment," "Information infrastructure," "Personnel for the digital economy," "Information security," "Digital Technologies," and "Digital Public Administration." One key objective of the "Information Infrastructure" project is to create a globally competitive environment using domestic developments, connecting all medical institutions and government authorities to the internet by 2024 [11]. The rate of progress in achieving this goal is noteworthy, with plans for connecting paramedics, paramedic-midwife stations, state authorities, municipal governments, and extra-budgetary funds to the network. In 2018, 8.76% of paramedic and paramedic-midwife stations were planned to be connected, while 18.72% of state authorities, municipal governments, and extra-budgetary funds were slated for connectivity.

4 Conclusions

Deputy Prime Minister of the Russian Federation, M. Akimov, who oversees the development and implementation of the "Digital Economy of the Russian Federation" program, emphasized the positive dynamics of the country's digitalization indicators. During a meeting of the Council for Strategic Development and National Projects on May 8, 2019, he highlighted that Russia ranks sixth in the world in terms of the number of cellular subscribers per hundred people and fourth in the world for the affordability of high-speed internet services. The relatively low cost of mobile internet services contributes to a high level of internet resource accessibility, making it more affordable compared to leading countries in mobile communication connectivity like the USA, Japan, and South Korea. The pace of digitalization in the economy has a direct impact on the country's competitiveness, the nature of its innovative development, and the level of research and development in biotechnology. To enhance the role of domestic biomedicine within the context of digitalization, government support measures can be considered. These may include tax incentives for digital medicine developments, creating conditions for expanding applications and platforms for medical diagnosis and treatment, as well as medical examinations of the population. Additionally, supporting Russian contract research organizations and fostering an interdisciplinary educational and scientific environment in the field of biotechnology economics can further contribute to the development and integration of biomedicine in the digital economy.

References

1. R. V. Efremov, *Practice of tax control*, 201 (2017)
2. A. V. Ivanov, *Desk inspections: organization and conduct*, 216 (2018)
3. E. I. Kuzmina, *Tax disputes: judicial protection of taxpayer rights*, 292 (2017)
4. S. S. Khasanova, I. M. Pedaeva, M. S. Sugaipova, In the collection: Science and youth, 443-446 (2022)
5. M. Reynard, V. Panizza, Geomorphosites: definition, assessment, and mapping. *Geomorphol Relief*, 177–180 (2018)
6. EU-Russia Energy Dialogue, Energy Forecasts and Scenarios 2009–2010 Research. Final Report (2021)
7. K. Haegeman, F. Scapolo, A. Ricci, E. Marinelli, A. Sokolov, Quantitative and qualitative approaches in FTA: from combination to integration?, **80**, 386–397 (2021)
8. R. Kh. Ilyasov, Spline modeling and analysis of relationships in the economy with the possible presence of regression switching points, **11(4)**, 165-175 (2018)
9. K. M.-S. Murtazova, Ecological and economic assessment of sectoral agricultural technologies, **3(15)**, 68-71 (2021)
10. A. S. Salamova, Socio-economic factors in the fight poverty and hunger in the modern world: the scientific approach of Amartia Kumar Sen, **17(1)**, 237-245 (2023)
11. A. S. Salamova, Global networked economy as a factor for sustainable development, 03053 (2020)