UDK 330.332
JEL Classification: D81, G1, I18, O32
DOI: 10.15587/2706-5448.2026.352711

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DETERMINING THE INVESTMENT ATTRACTIVENESS OF THE BIOHACKING AND BIOINNOVATION MARKET BASED ON MARKET TRENDS IN THE PHARMACEUTICAL BUSINESS

The object of the study was the process of venture investment in biohacking as a component of the pharmaceutical business, which embodies the development of the specified market. Since research requires significant capital investments, it is worth studying in detail and carefully the issues of financial investments and obtaining income from the specified processes. This work proposes a comprehensive economic analysis of the biohacking industry as a modern investment tool. The consistency of the high growth forecast with the main statistical risks inherent in biotechnology enterprises was described and analyzed. The basis for the hypothesis was the methodology for analyzing the development of the biohacking investment market. The analysis is based on the success rates of clinical trials and the development of FDA medical products from phase I to approval. The results are based on an assessment of the capital market of biotechnology companies in the world after IPOs since 2020. The results confirmed the hypothesis of rapid market growth with a compound annual rate of 19.09% from 2025 to 2034 (forecast). However, there is a rather low overall clinical success rate, about 9.06% between phase I and final drug approval, considering the highest percentage of research outflow between phases II and III (only 31% success). The best value was obtained for rare diseases (about 25.0%), the worst for oncology research (5.1%). The results indicate that most of the investments (about 56%) end in loss. As a result, it was determined that biohacking is currently a high-risk and at the same time highly productive direction, which has a radically different nature of investment. That is why investment should be based on careful, substantiated, reliable data analysis and assessment of the clinical portfolio, considering diversified risks.

Keywords: *biohacking, investment analysis, clinical trials, biotechnology IPOs, risk management, longevity economy.*

Received: 16.12.2025
Received in revised form: 03.02.2026
Accepted: 15.02.2026
Published: 28.02.2026

How to cite
Andriushchenko, A., Liezina, A., Kolybo, D., Gurina, G., Havrysh, K., Mazur, N., Kushnir, O., Kyryliuk, O. (2026). Determining the investment attractiveness of the biohacking and bioinnovation market based on market trends in the pharmaceutical business. Technology Audit and Production Reserves, 1 (4 (87)), 21–33. https://doi.org/10.15587/2706-5448.2026.352711

1. Introduction

In the global market, biohacking currently occupies a very significant and important position. Cash flows in this direction play a huge role in the formation of GDP of countries that are most developing the direction of life extension, the formation of healthy lifestyle habits and longevity [1]. According to the latest data, the leader is the United States of America, within which the market as of 2024 is estimated at 24.81 billion USD. These indicators are representative in view of the development perspective, which strengthens the dominant position and, according to economists, biohacking will provide a turnover of over 69 billion USD by 2030. First of all, it is worth relying on the components of the scientific direction of biohacking and its scientific and historical basis [2]. Currently, it includes a wide range of scientific achievements and developments. By its nature, it is based on the use of clinically justified means that generally improve human life and improve its quality of life. Currently, these include pharmaceuticals, various means and devices that monitor health, form good habits, help maintain a healthy lifestyle and form a general idea of longevity.

If to turn to the conversion in monetary terms, the size of the entire biohacking market in the world is currently recorded at 24.81 billion USD. But if to take into account the rapid growth rates in terms of added value, then by 2030 it is possible to get an approximate market size of 69.09 billion USD. According to the results of the analysis, it is possible to conclude that the average annual growth rate for the main indicators of investment, revenue and profit (Compound Annual Growth Rate – CAGR) will be 18.95%. The potential distribution by region of development of the biohacking market is not stable. The global community has different development vectors – from scale to innovation. Thus, the analysis can be concluded that the US market is characterized by scaling up existing research and developing a product range policy, South America is characterized by entering the markets and introducing generics (unpatented analogues of drugs that contain similar pharmaceutical composition and medicinal properties), the EU is characterized by developing marketing and promoting wearable devices, the Asia-Pacific market is developing due to the absorption of small startups by large industry giants. In recent years, it has become a habit and a commonplace that powerful businessmen direct their fortunes to prolong life and longevity through global innovations [3].

ISSN-L 2664-9969; E-ISSN 2706-5448

In recent decades, the Silicon Valley of the USA has become the center of such actions, and its prominent representatives direct their financial flows to the pursuit of improving life, improving lifestyles and introducing healthy habits [4]. The facts of the use of psychedelics, genomes of various formats of influence, and CRISPR therapy are already known [5]. All these experimental actions are aimed at one goal – to increase the number of years of life and improve its quality regardless of age. Some of the indicated directions are currently only experiments, and as is known, do not always have a positive effect (following the example of Steve Jobs). But at the same time, they required and require large financial investments, which indicate the field of investment attractiveness for investors.

In recent years, the development of biohacking has not lost momentum, so now its supporters define themselves as a separate type of scientists (which is important to note – interdisciplinary in nature) who are engaged in the development of science and call themselves transhumanists [6]. Their main efforts are aimed at various aspects - from extending life by changing the genome [7], to changing cognitive thinking abilities at the expense of at least a meditative space [8]. That is, it is worth generalizing and considering that the new direction of biohacking is forming a renewed generation of scientists who seek to qualitatively improve the standard of living of the population through the synergistic effect of work [9]. And from the point of view of economic aspects, it is worth noting that the development of what we currently have is, first of all, a struggle for life and improving its quality by investing a large amount of investment. According to the theory formed by transhumanists, the main emphasis of their work is directed at any achievements in the scientific world that can practically improve the duration and quality of life [10]. This is once again confirmed by the multidisciplinary nature of their work and its impact on all areas of human cognition. In addition, it is worth noting that biohacking, in the usual sense for most people, has a place in already established things [11]. That is, the function of neurotransmitters, which is inherent in the human body as its main function of life, has been introduced by biotechnologists to a new level of perception through the use of gadgets and devices [12].

The usual intake of vitamins and probiotics also fully relates to the concept of transhumanists. In general, all of the above, on the one hand, only partially describes the development and spread of biohacking as a scientific direction, but on the other hand, it fully reflects the scale of its spread and the conceptual level of penetration [13]. The results obtained by scientists are carefully analyzed in laboratories for the content of gene changes, which produces the development and compliance with the protocol for further biological implementation [14]. After all, the reformatting of neurobiological processes is much longer in terms of implementation time than the parallel changes in the economic component that accompany them. That is, the investment contribution is an important and significant step, but more instantaneous, while research in biohacking will always be accompanied by longer time intervals.

A vivid example is the use of biohacking as a way to prolong life expectancy. In its personal experience, there is a large list of the use of laser drugs, tracking the rhythm of life, carefully scheduled intake of biologically active substances and vitamin supplements. That is, instead of expecting a quick result and capitalizing on its own funds, the investor became the main leader and example for biohackers [15].

The next key figure is the co-owner of PayPal. His idea was to support young and active scientists who did not have funding, but talked about longevity, creating their own startups [16]. Of course, it is worth noting that biohacking in general is characterized by a large investment capacity, because this kind of research must be carefully financed. This is what the business representative focused on, basing his motives on any methods that would help it eliminate aging for as long as possible. The most interesting idea that the billionaire used on itself was a blood transfusion from a young person to an older person, which received a lot of criticism among the scientific community. This practice is based on the initial stages of clinical trials, that is, there is currently no reliable evidence base for this rejuvenation method. But in parallel with rather controversial practices, it also uses already familiar methods – improving sleep quality, coordinating the rhythm of life, scientifically based individual training schedule and forming one's own biological rhythm of life, which are based on the already determined positive results of research.

In general, as a result of the processing of existing scientific research, it is possible to form a statement that currently the coverage of venture investment mechanisms in the pharmaceutical business is a widespread phenomenon. But the correlation between the number of investments in the field of biohacking and pharmaceutical research that has a positive result, and as a consequence the determination of the number of successful investment processes and potential profits for investors, is not sufficiently studied. As a result, the formation of a spectrum of risks inherent in biomedical technologies in the process of forming venture portfolios is currently ignored. Accordingly, within the framework of this research, *the object* is defined as venture investments in biohacking as a component of the pharmaceutical business of the future. *The aim of research* is to prove the investment attractiveness of biohacking based on market trends and clinical trials, taking into account risk and uncertainty factors. To achieve this aim, the following objectives have been formulated.

1. To analyze the general trend of the development of the biohacking market in the world.

2. To determine the investment attractiveness of IPOs among the open information of pharmaceutical companies.

3. To investigate the statistical basis of positive clinical trials and their percentage ratio among the total number of studies.

4. To identify the correlation between key factors of riskology and the development of venture investments in biohacking.

5. To form generalizations and recommendations on the feasibility of investing in the pharmaceutical industry in terms of balancing risks and threats within the development of the biohacking market.

2. Materials and Methods

From a financial perspective, it is worth paying attention to the cash flows of the biohacking market in the world. In the overall picture of world leadership, it is worth noting the countries of the Middle East, Latin America and the Asia-Pacific region. As a result of the analysis of the biohacking market and the turnover of funds at the macro level, a positive development trend was established (Fig. 1). The average annual growth rate for this direction is about 18.95% per year.

In terms of analyzing the biohacking market share in different countries of the world, it is worth noting that it is developing rapidly and occupies leading positions. For example, an analysis of the countries already mentioned was carried out. Thus, in the North American market, biohacking occupies 36.73% according to the results of financial revenues in 2024. But among the leading countries, it is again worth noting the USA, for this country the issue of prolonging life and development against the background of this pharmaceutical business is becoming quite relevant. That is, 79% of the mentioned North American market is occupied by the United States of America. Latin America is characterized by the development not of biotechnology, but of the development of generics and their analogues. Let's attribute this to lower costs and the ability to make worthy copies of already known pharmaceuticals against the background of the development of territorially close countries.

European countries are characterized by the development of devices that help track human development and its physiological characteristics. That is, the related direction of digital transformation is fundamental for the development of biohacking, because it helps to track physiological changes in their carriers in real time and accumulate information for further analysis and clinical trials.

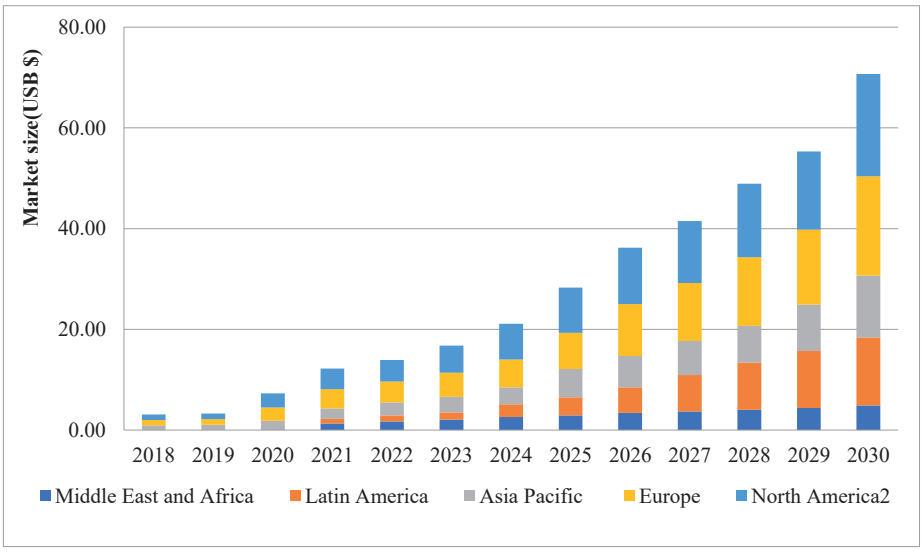

Fig. 1. Indicators of the global biohacking market by region for 2018–2030 (calculated by the authors based on data from [17])

The next components of biohacking are clinical trials, drug use and testing at the stage of drug approval, in this direction the countries of the Middle East and Africa are the leaders. It is in these countries that the change in activity is most often tracked and currently there is a tendency towards the highest demand among free testing at the stage of trials. In general, it is possible to explain this by the low-income level of the population and the ability to receive free treatment for serious (often incurable) diseases. In this case, such countries account for 32.15% in 2024 of the entire biohacking market in the world.

And the last component remains the segment of income from pharmaceutical serial production of drugs, diagnostics and development of biotechnology companies, which falls on the market of the Asia-Pacific region. It is for the countries of the East that the percentage of the biohacking market of over 32% is due, in our opinion, to the development of global pharmaceutical giants and corporations.

In the context of the previously presented research on the relevance of biohacking as a direction of scientific knowledge, it is worth noting that it is worth focusing on the financial component of supporting developments, which in turn affects the development of business structures [18]. After all, in particular, potential profit-making investors have a unique opportunity to receive valuable information and develop the human capital of enterprises [19]. Currently, it is information flows, along with money, that can be considered a significant liquid management factor. That is, the interest of investors is built on obtaining primary sources of research in order to use them for their own needs. Recently, these include devices that are constantly on the human body and are aimed at tracking all its physiological changes: from sleep patterns to the level of stress that a person experiences throughout the day. The most effective of the latter is Dexa (Dual-Energy X-ray Absorptiometry, medical densitometers for measuring the density of human bone tissue. For example, GE Lumar iDXA – full body scan, USA; DMS STRATOS DR - advanced body fracture scanning functions, France), this is a device that is constantly on a person and, by reading information, analyzes it, makes predictions about the condition and sends notifications to a smartphone with recommendations for improving the general condition of the wearer [20]. That is, the device not only scans all human conditions in the latent movement mode, but also accumulates the results obtained throughout the entire time of use, which makes it a general database about the wearer. From a biohacking perspective, such devices are important and unique, but it is also worth paying attention to ethical norms and information leakage, which requires additional funding to ensure the cybersecurity of server storage.

Against the background of the use of biohacking developments by investors, the world practice of introducing devices in their companies on an ongoing basis is already known. In this way, they stimulate and improve the work of their employees, increase labor productivity and form the general concept of companies regarding a healthy lifestyle [21]. Such examples include healthy lifestyle programs, specially equipped meditation rooms, created organic workplaces with chairs with built-in magnetic stimulation and radiation [22]. Recently, wearing corporate devices in the form of a ring or bracelet to track one's own labor productivity has become quite popular. It is currently known that such devices help employees track their activity, which allows them to adjust flexible work schedules [23]. Global companies are forming the habit of working for pleasure and taking advantage of the privileges of testing recently developed but not yet patented devices in real life. These also include glasses that read the intensity of a person's visual sensors and form recommendations for breaks [24]. Thus, it is economically justified for the owner to invest in biohacking developments, apply them in their own companies and thus stimulate the general culture of longevity in the region [25]. Currently, smart owners of holdings are more interested in stimulating and growing employees than in constant staff turnover, primarily in connection with tracking the financial flows of the enterprise.

Such global giants as Google and Apple have been constantly introducing the use of their own developed devices for wearing and tracking biometric parameters for their employees for over 10 years [26]. A bonus for employees is a loyalty system and free use of a subscription for data analysis [27]. It is worth noting that from an economic point of view, all biohacking developments have their own stages of capital infusion: from initial investments to supporting the software product based on the results of development. That is, obtaining the final profit and delisting occurs precisely from the constant use of the product and its so-called subscription fee or subscription for use [28].

In general, the biohacking direction covers a very wide range of areas and tools. It cannot be said that these are only devices for tracking life. It is worth considering the new scientific direction more broadly and comprehensively. Therefore, related industries are included in it. For example, pharmaceutical development plays a significant role in view of achievements in drug development, genetic engineering creates new and updated modifications of compounds at the cellular level and their interaction, the paramedical direction initiates the use of devices to make life easier for people with disabilities, which is especially relevant for our country in terms of the increase in the number of victims in recent years,

ISSN-L 2664-9969; E-ISSN 2706-5448

electronics and electrical engineering – helps to implement and implement devices that are the result of biohacking work. All developments in various areas have usually recently been built not in large companies, but characterize the development of startups. Accordingly, their size and the amount of investment from an economic point of view create a general aggregate competition for the giants of these industries, due to rapid development and flexibility to market changes.

Accordingly, it is worth considering in detail the aspect of investing in biohacking, when a person who invests in the development of future longevity from the first stages of testing can use the achievements on itself and receive profits in the future [29]. But from the point of view of capital injections, it is worth carefully analyzing the markets and thoroughly studying the technical and economic documentation of the proposed developments. It is caution that plays a huge role in investing in the development of biohacking. Because on the one hand, the analysis of the dynamics of the development of biohacking showed rapid growth and fairly high CAGR indicators, but on the other hand, not all the funds that were invested can have financial income in the future. Therefore, it is worth considering the ethical aspects of supporting the development of biotechnology in general [30].

In this regard, it is worth noting that, for example, the development and market entry of some biologically active additives, vitamins and dietary supplements is justified from the point of view of popularization and the latest trends in improving life. But at the same time, not all of them have undergone full clinical trials and are confirmed by certified conclusions [31, 32]. Many of them are in the so-called "gray zone", that is, the preliminary market entry is due to the created need to already receive profits for investors who once invested a sufficient amount of money, but currently do not have income. When using such funds, there may be various consequences, which complicates the overall reputational component for enterprises. Also, the disadvantages of these actions include financial costs associated with risks and legal issues. That is, the regulatory framework that exists in the markets of the relevant industries is not yet fully ready for the release of the latest inventions and developments in biohacking [33].

A striking example of a recent entry into the general market is a drug containing peptides such as GLP-1 mimetics, or a commonly known weight loss drug [7]. These drugs are not medicines, but are classified as supplements with active ingredients, currently known as Ozempic and Wegovy with the active ingredient semaglutide. At the time of the release, the Danish company Novo Nordisk received income that became the lion's share in the formation of the country's GDP as a whole. That is, as of 2023, the country has repaid investors' investments by more than 1000% [34]. From an economic point of view, this was a breakthrough and an incentive for new achievements in the development of biohacking. But such cases are currently rare. And it is also worth paying attention to the long-term result from the use of these drugs. Although clinical trials were successful and the results demonstrated efficacy, the Food and Drug Administration (FDA, USFDA, USA) has raised concerns about the long-term effects of semaglutide [35]. That is, the process of investing in the fairly widespread biohacking trend of maintaining health through weight loss is quite questionable, since not all the consequences of using the developed drugs on a regular basis have been fully understood.

Therefore, for a reasonable investment in the development of biohacking, it is worth studying in detail the previous achievements, which, as already indicated earlier, have an interdisciplinary nature. First of all, it is worth paying attention to the reliability of scientific research and its validity, that is, the technology itself may have development prospects, but not have a technically correct calculation of the nature of the action and financial income from them. Also, an important factor is the determination of the objectivity and subjectivity of the obtained research results, i.e. clinical trials. Therefore, it is worth paying attention to the progress of research and determining the result in the presence of the use of the latest management tools, business analysis and economic components. In this case, if the company has a bright marketing strategy, but does not reasonably use the data, it is easy to prove the opposite result by using tools from related scientific areas and protect yourself from such an investment direction [36]. The second aspect is the comparison of the expected, declared results and the real ones that can be obtained as a result of research in biohacking. In this case, the initial concept requires careful analysis, which requires investment injections, and for this it is necessary to have an interdisciplinary list of specialists for analysis. Accordingly, conduct a thorough comprehensive check and protect yourself from excessive investment in unjustified initiatives. The next component is the desire of investors to receive too quick a result and dividends. As already indicated earlier, the analysis revealed that although biohacking is developing rapidly, clinical research and scientific developments by their nature cannot have quick results. This contradicts, first of all, the nature of the construction of any experiment, both from a biological point of view and from the point of view of neuromediation forecasting [37]. In this case, the calculation of the financial equivalent of future profit will also be subject to many restrictions and risks, which forms a complex calculation system with most of the unknowns in a set of events. In this case, from a mathematical point of view, solving an equation where there are more unknowns than established indicators, which at the same time have a tendency to change, is almost impossible even with the use of large language models. In this case, it can be partially summarized that the indicated components should serve as indicators that stand at the intersection of the desire to invest and quickly hold funds and invest profitably in order to receive real profit after a certain time. For the latter actions, it is necessary to choose trusted companies that do not shy away from providing all their accounting data and openly demonstrate a policy of supporting ethical values.

That is, the above-mentioned aspects of development and progressive dynamics of biohacking allow to talk about investment attractiveness for business leaders. In this case, it is worth emphasizing the careful analysis of any clinical studies, assessment of risks (explicit and hidden) from a financial point of view and monitoring of regulatory aspects that change rapidly depending on the research [38, 39]. Currently, anyone who invests in the development of any direction of biohacking can either get a jackpot or lose all investments, which makes this scientific breakthrough a risky but quite liquid direction from an investment point of view [40].

3. Results and Discussion

3.1. Current development of the biohacking market in the world

To determine the essence of biohacking, let's first turn to its definition. It is not found a clear, generally accepted definition of "biohacking" in the scientific literature, since this is a fairly new direction. Each author interprets it in its own way, so let's turn to the literal translation from English. "Biohacking" ("bio" – related to biology, life; "hacking" – breaking) means breaking biological systems, that is, breaking a living being. The term "biohacking" itself is associated with the hacker culture that emerged in the 1960s in the United States. As noted in the explanatory dictionary, a "hacker" (from the English hacker, from to hack – to chop, to shred) is a computer hacker; a person who fixes errors in software in some quick and unconventional way [41]. At the same time, [42] emphasizes that biohackers borrow from ordinary hackers a radical demand for open, free access to scientific data and information in the field of biology. The study [43] indicates that biohackers were called genetic engineers who were engaged in science outside the laboratories and conducted their own experiments, today a "biohacker" is an independent amateur scientist in the field of molecular biology. The term "biohacking" was first used in 1988 in the United States, so it is worth referring to foreign sources [43].

In foreign scientific literature there is no exact definition of the term, and the concept of "Do-It-Yourself" is used as a synonym [44]. According to [45], the "Do-It-Yourself" (DIY) movement is associated with the spread of ideas of synthetic biology. As the author notes, a new aspect of synthetic biology claims to be a new type of science based on the use of available drugs and DIY scientific practice. Based on genomic recombinant DNA technologies, synthetic biology uses engineering principles and computer technology to inspire research by a younger generation of scientists, both inside and outside universities [46].

In [47], the diversity of disciplines and the renewal of traditional scientific knowledge in biology are demonstrated. An interesting element is the elements of "hacking" and open source software. He emphasizes that he does not use the term "hacker" because amateur scientists who turn to open science tools and methods do not consider themselves hackers. In this regard, the author refers readers to cases of "DIY Biology" that have "clear links" to hacking. The author also emphasizes the difference between "biology hacking" and "DNA hacking", noting that the former concerns the alteration of technoscientific institutions, not genes and cells. Biohacking goes beyond the laboratory, testifying to the opening of biology to public participation and new forms of mass entrepreneurship [48]. Thus, a biohacker is a scientist who researches, experiments in the field of biology and makes his results open for review. One of the founders and initiators of the biohacker movement is physicist Robert Carlson. He made a great contribution to the spread of biohacking around the world [49]. He organized the first home laboratory to popularize science, where he recommended the use of "biolifehacks" in everyday life (for example, to study the genome for changes; to evaluate the composition of products, etc.).

Modern research is aimed at identifying the risks of using biohacking technologies and their impact on various aspects of human health [49]. Thus, scientists are investigating the implementation of biohacking methods from the perspective of informatization of society and man [50]. These works emphasize the idea of an ambiguous opinion regarding the use of biohacking technologies in medicine and genetics [51]. The biohacking industry is characterized by a bright feature, such as innovation and novelty. The main characteristic is the combination of rather complex, incompatible and interdisciplinary features, which together form a synergistic effect, which is the main component of this scientific direction [52]. For this purpose, artificial intelligence tools, bisensory diagnostics, neurostimulators and genetic engineering are currently constantly used and used [53]. That is, leading companies no longer rely on traditional tools (experiment, research, testing), but are forming a new era of continuous implementation of prototypes of means and devices with safety for life and health support in humans [54]. For example, bioelectronic implants are widely used in dentistry, which are used to improve tracking of engraftment in the bone tissue of the carrier. In the future, they remain on a permanent basis, and their programmed mechanisms provide signals to the doctor and the patient about the need for intervention if necessary. Such devices in practice act as a basic and standardized opportunity for the patient to change the doctor without restrictions, and all the results obtained during the study period remain initially with the client and can only be transferred to the doctor for further scientific and clinical research with its consent. It is also worth noting the constant parallel improvement of the regulatory and legal aspects of such actions, which ensures ethical considerations. Accordingly, the above forms an overall picture of ethical control, prudence, and reliability, which both protects the patient and provides motivation for interest in scientific achievements.

3.2. Justification of the investment attractiveness of IPOs and the biohacking market

The biohacking market in the USA as of 2024 was analyzed. According to estimates, it amounted to 9.22 billion USD. Also, using the method of mathematical extrapolation, the potential development for the next 10 years was calculated, which ultimately showed significant profits and achieved indicators of almost 53 billion USD (Fig. 2).

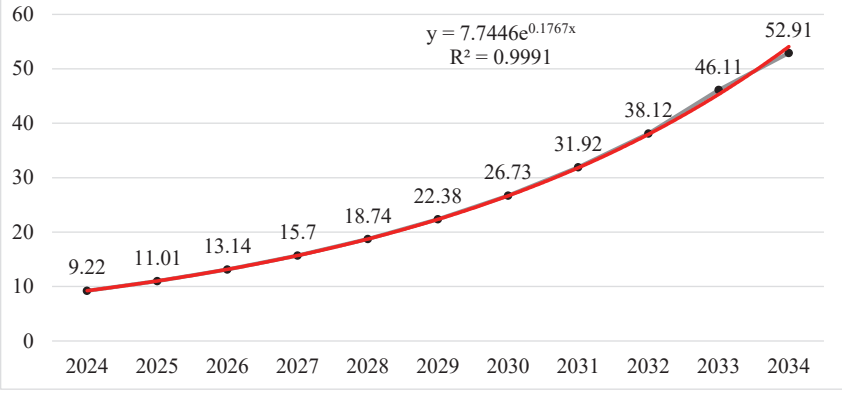

Fig. 2. The size of the biohacking market in the USA from 2024 to 2034 (billion USD) (calculated by the authors based on data from [17])

An important factor in the analysis and, accordingly, the formation of a justification for investment attractiveness was given to the study of the effectiveness of clinical trials. As a result of calculations of aggregated statistical data of clinical trials [55–57], it was determined that the average level of success of biotechnology developments currently has positive dynamics, especially in the aspect of integrating biohacking into pharmaceutical research. The calculated data on the percentage of positive trials were obtained, which have the following distribution:

– *Phase I – safety* – success is observed in 68–72% of trials;

– *Phase II – effectiveness* – 32–45%, but there are the greatest risks for investors;

– *Phase III – confirmation* – 58–64% positive results from all submitted research protocols.

From the perspective of investment attractiveness, it is Phase II and III that have the highest percentage of return on investment due to the segmentation of medical research and increased personalization, which is part of biohacking and an important indicator for the growth of IPOs.

Collaboration in the field of biohacking is growing due to partnerships between biotechnology companies, academic institutions, healthcare providers and open source biohacking communities [58].

Companies form alliances to accelerate research, improve product development and expand market reach. Crowdsourcing innovation platforms and co-development initiatives promote cross-industry synergies, which contribute to rapid technological progress [59]. In addition, collaboration between biohacking startups and established pharmaceutical companies promotes the commercialization of biohacking solutions, especially in the areas of personalized medicine and neurotechnology. However, intellectual property issues and regulatory barriers sometimes limit the scope of such partnerships [60].

Global practice is a prime example of such collaboration. For example, in October 2023, Muse was approved for use in Health Savings Accounts (HSA) and Flexible Spending Accounts (FSA), allowing customers to improve their health and save on taxes. Again, emphasizing the interdisciplinary nature, with support from Truemed, they were able to simplify the process of connecting and paying for the tariff through the developed savings accounts. New service packages can be used for the updated meditation devices [61].

ISSN-L 2664-9969; E-ISSN 2706-5448

In November 2022, CardieX Limited acquired Blumio, Inc., a Silicon Valley company specializing in advanced algorithms and technologies for cardiovascular sensors. This acquisition underscores CardieX's ongoing commitment to investing in cardiovascular health monitoring technologies. Blumio's innovations have the potential to significantly improve the clinical effectiveness of CardieX's cardiovascular health monitoring solutions.

In February 2022, Sengine Precision Medicine Inc. and Oncodesign entered into a research agreement to develop a new personalized cancer treatment. The goal of the partnership is to evaluate the potential of transforming the established Nanocyclix inhibitor series into potentially clinically effective drugs. Accordingly, this practice of transitioning from experimental developments to conducting reliable clinical trials of drugs creates a basis for a statistical basis for raising capital through IPOs, as it thereby reduces the share of speculative investments. At the same time, it is always worth remembering the ethical aspects of interaction, copyrights for developments and the percentage of developments from invested investments. Thus, the report [62, 63] forecasts revenue growth at the global, regional and country levels, and also provides an analysis of the latest industry trends in each of the subsegments from 2018 to 2030. For this research, Grand View Research segmented the biohacking market report by product, application, end use, and region (Fig. 3).

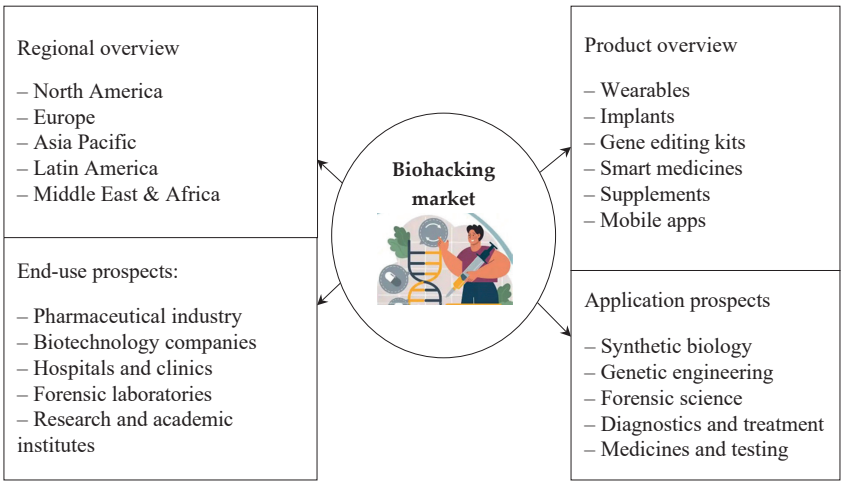

Fig. 3. Biohacking market segmentation report for 21 countries

3.3. Statistical analysis of the correlation between clinical trials and the performance of innovative developments in biohacking

The analysis confirms the data on the widespread use of biohacking. But all of them indicate investments. Therefore, the issues related to obtaining income in the form of dividends from investments are of most interest. There are two main types of players on the market:

– small companies that have recently gone public to raise funds for the development of their promising drug;

– pharmaceutical giants that often absorb startups to further diversify their business and their own innovative developments.

The formers are distinguished by their high-income potential, but at the same time, their risk. If a company is developing only one drug, and unfinished research is its only asset, then in case of failure its value can easily fall by two to three times. In contrast, large companies have a more advantageous position when developing new drugs. After all, even if they receive a negative result and lose on their investments, their shares do not have a strong collapse, because the diversification approach in mastering a wide range of drugs allows them to take risks and make profits [64]. At the same time, it is worth noting that successful development can be a significant driver of price growth, including because pharmaceutical giants can protect themselves from competition. For example, large American companies often pay manufacturers of generics (a cheaper analogue of a patented drug that will perform the same function) to delay market entry. Small players do not have such resources. Thus, drug development can be a source of both risk and profit, especially in biohacking.

For any investment, the main indicator of their payback is their payback period [65]. But there is no clear time frame for the development of a new drug. First, the company must conceptually develop the drug – determine what problem it will solve, what active ingredients will be included in its composition, and how to take it. The drug is then tested on animals to avoid possible toxicity to humans. After that, clinical trials begin, the goal of which is to determine the drug's real effectiveness in combating a predetermined disease [65]. At this stage, companies begin reporting on the progress of their studies to the FDA – the Food and Drug Administration. The first phase of low-dose studies of the drug should confirm that it does not cause harm. Both healthy volunteers and patients suffering from the disease can participate in the test sample. The second and third phases consist of directly establishing the drug's effectiveness. First, it is tested on a sample of several hundred people with the target disease, and then on several thousand. If it is possible to prove that the drug really helps, the company submits an application (New Drug Application) to the FDA and, if approved, brings the drug to the market. Clinical trials and FDA approval can take up to four years, and the entire drug development process can take about ten years. On average, regulators approve a new drug only 9.6% of the time, or one in ten. It is also important for biohacking investors to know how many drugs reach which stage and where most of them are being developed. This is necessary, for example, to avoid overestimating the good news about the transition from phase I to phase II drug testing. As can be seen in Fig. 4, more than half of the drugs in development pass this stage.

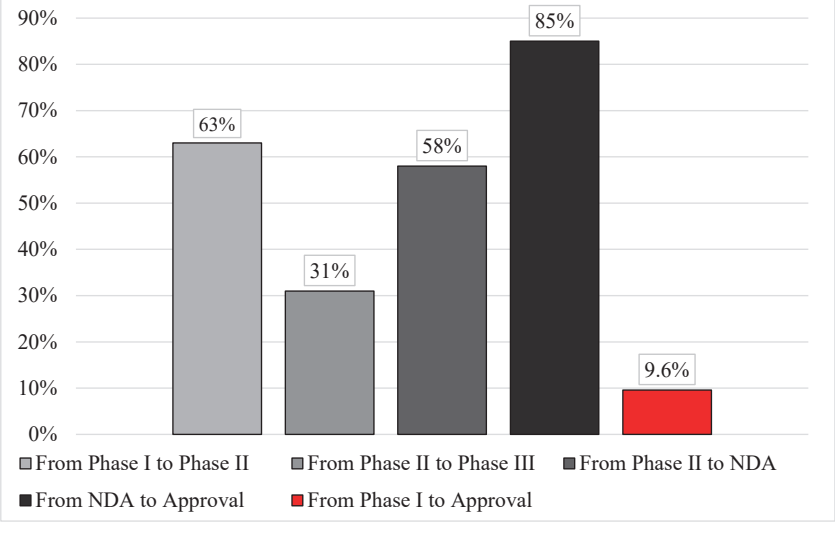

Fig. 4. Probability of successful drug development in biohacking (calculated by the authors based on data from [66–69])

Most drugs do not move from phase II to phase III, that is, they cannot prove their effectiveness in treating the disease. At the same time, if all stages of development are completed and the company submits an application to the FDA, the chances of success are already significant – 85%.

The main goal of the FDA is to provide citizens with treatment for diseases for which there are few or no drugs. Therefore, niche companies developing drugs for the treatment of rare diseases (and this is one of the main goals of biohacking) receive production permits faster and more often – in 25% of cases instead of the average 9.6% (Fig. 5).

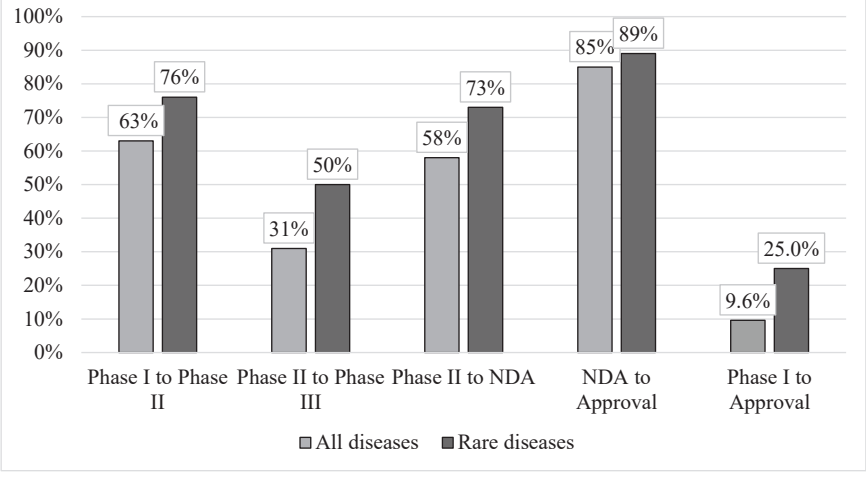

Fig. 5. Probability of successful development depending on the class of disease (calculated by the authors using data [66–69])

3.4. Establishing the influence of risk factors on the processes of investment in biohacking

To determine the correlation between significant risk factors and the development of venture investments, the calculation of the Pearson coefficient was used

$$r_{xy} = \frac{\sum(x_i - \overline{x})(y_i - \overline{y})}{\sqrt{\sum(x_i - \overline{x})^2 \sum(y_i - \overline{y})^2}}, \quad (1)$$

where x_i – the number of successful trials of the II and III phases for the group of biohacking drugs; y_i – the amount of investments attracted during the IPO in the responding pharmaceutical company; $\overline{x}, \overline{y}$ – the arithmetic mean value of the corresponding sample of drugs.

For the purpose of practical testing, data from 21 countries of the world [70] were used with the division of market segmentation into pharmaceutical companies and their affiliation to biohacking. When calculating the data on the average value of shares of companies during mergers and acquisitions (taking into account the increase in the value of shares, for example, from 15 USD to 60 USD) and the ratio of positive decisions on drug development (with a minimum value of 5% for oncological diseases to a maximum value of 25% for hematology), the result was obtained at the level of r = 0.78. The obtained result confirms the strong correlation between investments in companies and the positive results of drug trials. That is, the investment attractiveness of the biohacking market is estimated to be 78% and directly depends on successful clinical trials of drugs. It is possible to think that when investing in young biotechnology companies, it is worth investing in drug developers for rare diseases, for example, hematological (because every fourth drug is approved). But the risk actually remains no less high, because most often there is no cure for a disease for a reason – it is very difficult to make it. Therefore, biohacking is now, on the one hand, a very popular and relevant direction, and on the other hand, risky for investment. For example, at the moment, every year there is a disappointing trend in cancer. And drugs aimed at treating oncological diseases are approved only in 5% of cases. The fact is that they do not pass the third stage and show a low percentage of effectiveness in a large sample of patients (20% less than other classes of drugs) (Fig. 6).

The frequent failure of trials is due to the fact that cancer progresses very individually. Therefore, it is difficult to develop a universal remedy for mass consumption and production. In this regard, investors should think carefully before investing in a small company that is developing a cancer drug as a biohacking tool. IPOs are usually conducted by small companies that need funds to complete research and start production. The shares of such companies are attractive with high growth potential and are suitable for aggressive investors. But even they should remember that after going public, the company can develop the drug for many years and not earn anything. And this is not the only risk.

Statistics show that since 2000, 30% of biotechnology companies (especially those working in the field of biohacking) have been delisted from the stock exchange after IPO. This happened either due to bankruptcy or because the young company was bought by a large pharmaceutical corporation. In the second case, investors could earn, for example, if the company was bought at a premium to its market valuation. This happened, for example, with Audentes Therapeutics. The development of this enterprise demonstrates this practice. In December 2016, the enterprise was bought (absorbed) by a large Japanese pharmaceutical company with a stock price calculation that exceeded the original by 4 times (the stock growth was from 15 to 60 USD). To take into account current investment movements and calculate the investment attractiveness of biohacking, the authors proposed a modification of the Cantor-Lipman model.

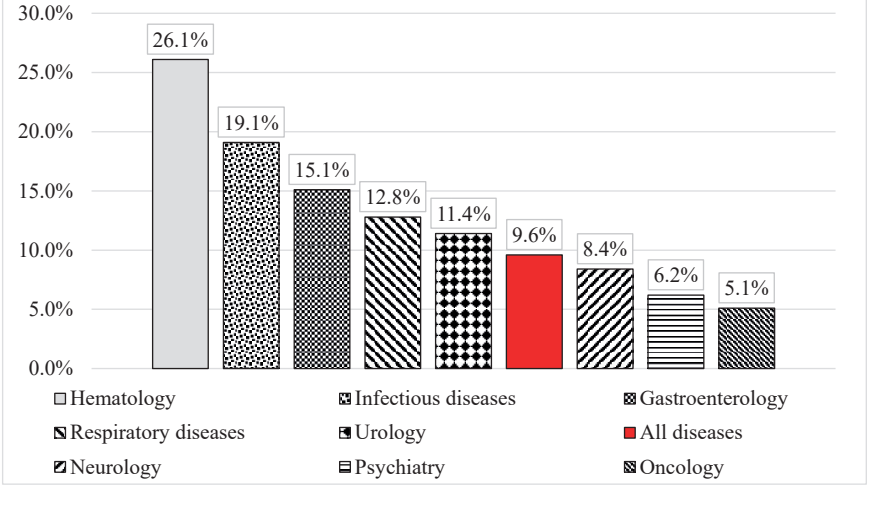

Fig. 6. Probability of successful drug development by disease type (calculated by the authors based on data from [66–69])

ISSN-L 2664-9969; E-ISSN 2706-5448

The mathematical expression of the proposal is to use one's own funds for investment, taking into account "prudent" investment and the use of a thrifty strategy. To do this, it is proposed to calculate the investor's state by the vector $\vec{s}(t) \in R^{r+1}$, i-th component of which is equal to the cash balances at time $(t + 1)$ provided that no new projects and investments have been started since time t. If to denote $u(t)$ as the intensity of project implementation at time t, then the dynamics of the financial condition can be described as follows

$$\vec{s}(t+1) = A(\vec{s}(t)) + u(t)\vec{b}, \quad (2)$$

where

$$\vec{b} = \{b_0, b_1, \ldots, b_r\},\ b_i = \sum_{j=0}^{i} a_j,\ A_{(r+1)\times(r+1)} = \begin{pmatrix} 010\ldots0 \\ 001\ldots0 \\ \ldots\ldots\ldots\ldots \\ 000\ldots1 \\ 000\ldots1 \end{pmatrix}. \quad (3)$$

Investment activity is carried out on the basis of self-financing (no possibility of borrowing funds). Formally, this means that the investor's cash balances must be non-negative at any time: $s_i(t) \geq 0$, $i = 0, \ldots, r$.

It is assumed that the investment environment is non-stationary – there is a risk of a crisis in the biohacking market. The investor does not know the exact moment of the crisis, but can subjectively assess the probability of the disappearance of demand for investments at any time. The model assumes that the investor's assessment is constant and equal to Δ.

Denote the Bellman function as $V(\vec{s})$ that will estimate the best investment result under the described conditions and the initial financial state $\vec{s}$; by $(\vec{s})_r$ the component of the vector $\vec{s}$; with the number r, assuming that the numbering starts from zero. Then let's write the Bellman equation as follows

$$V(\vec{s}) = \max_{\{u|u\geq 0, \vec{s}+u\vec{b}\geq 0\}} \left[\Delta(\vec{s}+u\vec{b})_r + (1-\Delta) V\left(A(\vec{s}+u\vec{b})\right) \right]. \quad (4)$$

The right-hand side of this equation contains the mathematical expectation of the investor's capital for all possible outcomes. If the investor reaches a point where it is unable to initiate new investments (start a new project), then in this equation at the r time point the final calculation of all financial flows by projects takes place, then its capital will be calculated as follows: $(\vec{s}+u\vec{b})$. If the crisis does not occur, the investor finds itself in a state $A(\vec{s}+u\vec{b})$ and makes a new investment decision using the function $\vec{V}(.)$. Then let's write the Bellman equation in such a way that it will be called the optimal investment strategy

$$u(\vec{s}) = arg \max_{\{u|u\geq 0, \vec{s}+u\vec{b}\geq 0\}} \left[\Delta(\vec{s}+u\vec{b})_r + (1-\Delta) V\left(A(\vec{s}+u\vec{b})\right) \right]. \quad (5)$$

In this case, the uniqueness of the Bellman solution cannot be guaranteed. In particular, an example of non-uniqueness of the solution for the simplest project of investing in biohacking, for which $\vec{a} = (-1; 1+q)$, $q > 0$.

In this case, investors should choose a "cautious" investment strategy

$$\phi(\vec{s}) = agr \max_{\{u|u\geq 0, \vec{s}+u\vec{b}\geq 0\}} \left[(\vec{s}+u\vec{b})_r \right].$$

This is a strategy in which the investor makes decisions based only on the income that it can get in the event of a crisis (which is a very likely event for the biohacking industry). However, according to the analysis of statistical data using the proposed methodology since 2000, when going public, the investor of a biotech IPO made a profit only in 47% of cases, and in the remaining 53% remained at a loss. And if the company did not go public, the ratio of profitable and unprofitable IPOs is even worse: the investor made money only in 44% of cases, and in 56% suffered losses (Fig. 7).

Thus, most investments in biohacking startups turn into losses for the investor. Fig. 8 below shows that investors most often lose 60–100% of their invested funds. This happened in 32% of cases, that is, every third startup lost more than from the IPO. Delisting leaves IPO investors with a loss of 50% of the value from the IPO moment.

At the same time, in almost 20 years, only 57 startups (4% of all those that went public) brought 1000% of income. Only 22% of companies doubled their investments (+100%). But it should also be noted that the forecast of the biohacking market contradicts the entire life cycle of the market, from the innovator stage to the laggard stage. The main attention is paid to the pace of development in different regions, taking into account the level of financing. In addition, the developing biohacking market has established key criteria for selecting and justifying price sensitivity, which help companies analyze and develop a dynamic analysis of market growth.

In order to refer to the author's position on the application of the modified Cantor-Lipman model and the Bellman equation, the indicators of risks and potential profitability of investments in biohacking were calculated (Fig. 9).

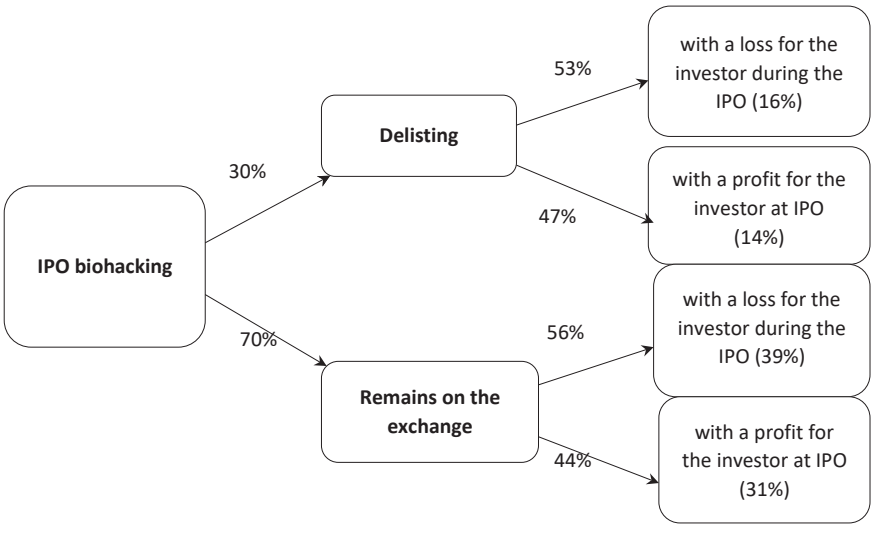

Fig. 7. Profit from investments in biohacking

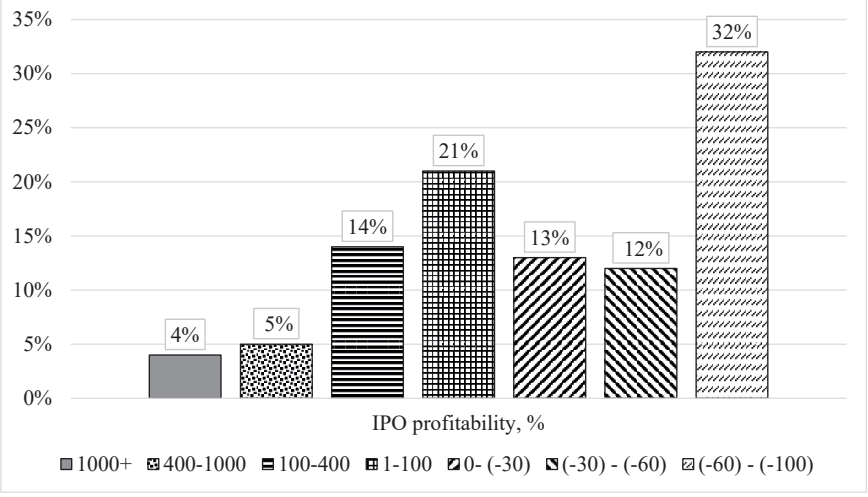

Fig. 8. Distribution of income (calculated by the authors according to [67])

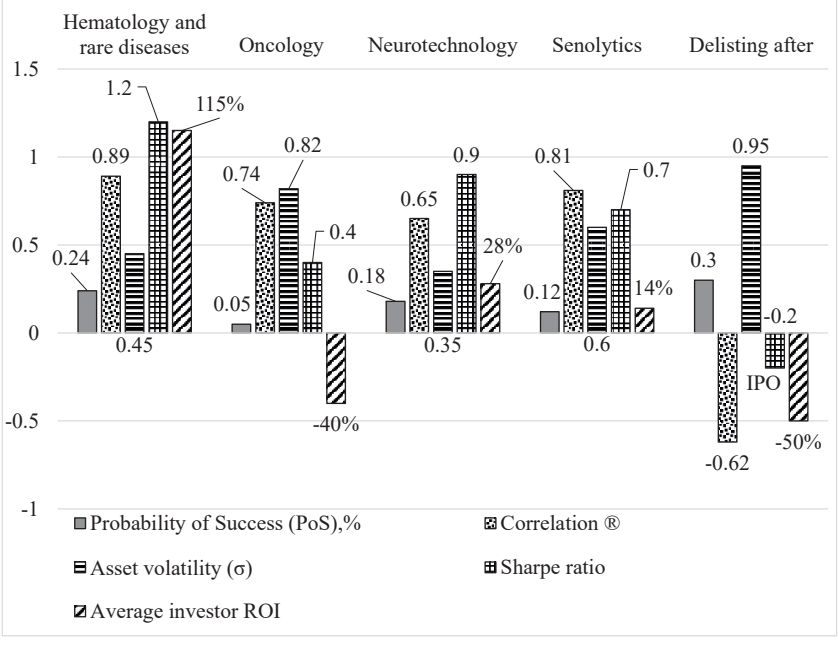

Fig. 9. Statistical indicators of risk and return on investment by biohacking segments (2018–2025) (calculated by the authors based on data from [71])

The use of an improved methodological basis in this research serves not only as a formalization of the definition of risks and venture investments, but also to form the optimal direction of possible exit from investment projects in an unstable environment. As a result of the data obtained (Fig. 7–9), the testing of the proposed approach showed that under conditions of crisis phenomena (in this case, the indicators for the investor will exceed 0.5), the optimal strategy for it will be described by equation (4) and means the mandatory liquidation of investments, because in case of maintaining positions, the investor can lose up to 53% of its investments.

3.5. Determining the advantages and disadvantages of venture capital investment processes in the pharmaceutical industry

Accordingly, it is possible to summarize that the research conducted has quite applied and practical significance. It is interdisciplinary in nature and combines an overview of a wide range of scientific developments. First of all, this work will be useful to such a group of stakeholders as venture investors who are interested in analyzing the biohacking and bioinnovation market with the aim of successful investment. For them, it is important to determine the degree of risk, which can be justified by predicting the probability of success of developments and determining the optimal investment directions, which was clarified in this research. The next group of stakeholders who will benefit from this research work are pharmaceutical companies and/or bioinnovation startups that seek to shape their development strategy in the best way possible in order to attract a wide range of investments. In this case, it is useful for them to form their own "frugal" development strategy and form an investment marketing attraction package based on previous research results, experience in launching pharmaceutical products on the market, and forecasting profits based on the results of clinical trials. It is also worth noting such a stakeholder as the state, advisory committees, think tanks, or authorities. For them, the development of business entities is an important factor. And in terms of the object of research, attracting additional investments (both state and international) will always strengthen the country's position in the relevant markets and generally increase the level of GDP. In the future, this has a positive impact on the creation of new jobs, improving the standard of living of workers by increasing wages and establishing new synergistic effects.

ISSN-L 2664-9969; E-ISSN 2706-5448

3.6. Research limitations and directions for its further development

The research limitations are as follows. These include, first of all, the time intervals and fluidity of the data that were presented. Due to the fact that a large number of trials and clinical trials in biohacking are currently underway, it is not possible to cover everything. Accordingly, the information and analysis provided in this work may lag behind some aspects of relevance. That is, work is currently ongoing on the analysis of trials and IPOs related to market conditions, and long-term forecasts can be leveled and adjusted taking into account risks and changes. It is also worth considering that in general, the biohacking market is currently just beginning its journey and is at the initial stages of development, it is characterized by sharp changes, which can also affect investment attractiveness. The next aspect is the ethical, legal and regulatory basis. Due to the fact that the research was aimed at general issues of the development of the biohacking market and the process of investing in it (especially regarding the development of the pharmaceutical industry based on drug research), it was not possible to allocate the ethical component into a separate block of issues. It is worth emphasizing that the data that were analyzed also include issues of compliance with the ethical policy of the country/region/enterprise that published them. But in general practice, for further research, it is worth indicating in more detail the components of ethics, legislation and regulation of research results and the process of their use. This can strengthen the position of scientific research and justification, and the detailing of industry indicators will direct the results obtained to a narrower specificity, which will form an in-depth vision of the results. In this aspect, it is also worth noting that the proposed modified model of modeling investment risks should be deepened in further research through the use of machine programming and building predictive models. In this case, the protection of personal data during clinical trials requires detailed study, which forms the implementation of security tools on a permanent basis and thus takes into account ethical norms. And from the point of view of investment processes, it is advisable to consider long-term processes of investing venture capital and further calculation of the investment attractiveness of biohacking startups.

4. Conclusions

1. As a result of the research a positive dynamics of the biohacking market development on the global stage was established. This generalization was objectively formulated on the basis of an analysis of statistical data on the performance of enterprises in the pharmaceutical, bioengineering, bioinnovation and biotechnology industries, indicating that the leader is currently the United States. Reliable forecasts are formed based on the extrapolation method, according to which by 2030 the total amount of income may amount to about 69.09 billion USD. And the results obtained are confirmed by comparing them with data from previous periods. That is, the annual increase is projected at 18.95% according to CAGP. The results obtained allow to consolidate the generalization regarding the investment attractiveness, innovative growth and economic potential of the biohacking market in the world.

2. The work found that the investment attractiveness of IPOs of biotechnology companies is currently mostly negative. The resulting losses from the investment process are inherent in 56% of pharmaceutical companies listed on the stock exchanges. After the delisting process, 53% of companies also have losses, and a third of enterprises have a decrease in capital from 60 to 100% as a result of the negative trend of the conducted research. But in this trend, there are also individual cases that confirm the positive potential for the investment attractiveness of investors. Thus, there are enterprises (out of the total number of about 6%) that increase their capital by 1000%.

3. Based on the generalization and processing of data on medical drug trials, a relationship was established between the influencing factors and venture investments in biohacking. The analysis made it possible to establish the dependence of the success of investment portfolios on the type of diseases and clinical trials preceding them. As a result, it is possible to conclude that for rare diseases the number of positive clinical trials is significantly higher, which increases their investment attractiveness. For this type of medical products, about 25% of studies from phase I to approval have positive decisions, while in general practice for other (more common diseases) only 9.6% of studies have such an indicator, and in the case of oncological drugs the lowest indicator is less than 5%. That is, the obtained result can be interpreted as the feasibility of investing in highly specialized and niche studies due to the presented results of Sharpe ratio calculations.

4. Statistical data on clinical trials of medical products regarding their implementation at different stages were studied: from phase I to IPO. Economic results were calculated using the Pearson correlation coefficient ($r = 0.78$ at $p = 0.5$), which indicates the reliability and strong relationship between successful clinical trials and the market capitalization of companies. It was established that about 63% of drugs remain until phase II of trials, and even less until the next phase – 31%. The obtained statistical data are the basis for generalizations regarding the determination of risks at each stage of testing. That is, the results of the generalization are not encouraging, but there is also a positive trend in the final approvals from the NDA for the serial production of medicines. The percentage of approvals among the submitted applications is almost 85%, which is a high acceptance rate. Such indicators indicate a high gap in risks at different stages. Accordingly, it is possible to form a generalization that the further the drug progresses in the development stages, the lower the degree of risk is subject to the investments that were made in it.

5. In general, investing in biohacking is a highly risky process that requires a thorough study of the justification. And the methodological bases presented in the research and the results obtained regarding the objectivity of the connection between the development of the scientific basis and the financial components allow to transform the subjective expectations of investors into clearly defined mathematical results. In this case, in order to make investment decisions, it is worth studying in detail the previous clinical trials, technological equipment, maturity and scale of the enterprise that is in charge of it, as well as modeling potential investment risks. Currently, due to the fact that biohacking is a new direction in the development of scientific thought, there is a fairly high probability of losing investments in the early stages of research. However, the data obtained on the payback indicators of the cost of enterprises in the event of successful implementation of research into serial production prove their significance for further development and obtaining excess profits. Therefore, it is recommended for further scientific research to improve the proposed mathematical tools for modeling the investment package and to simulate the implementation of venture investments in several projects simultaneously.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results presented in this paper.

Financing

The research was performed without financial support.

Data availability

Data will be made available on reasonable request.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies in creating the submitted paper.

Authors' contributions

Anhelina Andriushchenko: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Anastasiia Liezina***: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Denis Kolybo***: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Ganna Gurina***: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Kostiantyn Havrysh:*** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Nataliya Mazur:*** Conceptualization, Methodology, Software, Validation, Formal Analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Oksana Kushnir:*** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition; ***Oksana Kyryliuk***: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Visualization, Supervision, Project administration, Funding acquisition.

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