Life Sciences in Russia: Priorities in 2014-2020

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ABSTRACT **Life sciences are a priority in scientific development in Russia. The scientific interests of Russian research teams working in this area cover a range from the design of devices to sophisticated molecular biological experiments. The concept of implementation of the Life Sciences was developed based on proposals for research topics and projects submitted to the Ministry of Education and Science of the Russian Federation in 2013–2014. The concept defines four major directions of developments: (1) personal genomics and post-genomic technologies; (2) integrating devices and materials with the body; (3) memory and brain plasticity; and (4) bioactive substances.**

KEYWORDS **big data, biomaterials, implantable devices, sciences, neurosciences, postgenome technologies.**

ABBREVIATIONS **Programme – Federal Programme for Research and Developments in of Russian; Proposal – proposal for research topics and projects under the Federal Programme for Research and Developments in of Russian; Call – competitive offer for conducting applied research under the Federal Programme for Research and Developments in of Russian.**

In accordance with the Order of the President of the Russian Federation, applied research has been financed from the Federal Programme for Research and Developments in of Russia (hereinafter the Programme). The Programme supports projects focused on achieving clear characteristics of the developed products, meeting a specific consumer of these products, and a business partner ready to co-finance the development and sell the product in the future [1].

The Expert Group for the Life Sciences (hereinafter the Expert Group), in collaboration with the Russian Ministry of Education and Science, Directorate of Scientific and Technical Programmes, and Technological Platforms "Medicine of the Future" and "BioTech2030," has established promising research directions for the Russian Federation. The directions were unified into The Concept of Life Sciences in 2014–2020 (hereinafter Concept).

The Concept was developed based on an analysis of proposals for research topics and projects collected by the Russian Ministry of Education and Science (hereinafter Proposals) with alignment with modern research trends. The Expert Group identified effective research teams capable of conducting advanced research and obtaining results in cooperation with a business partner. These research teams should have a significant history of publications as proof of experience and groundwork and be competent to prepare a design and technical documentation in accordance with the requirements of The Unified System of Technological Documentation. Otherwise, the project results will be unsuitable for further practical use, which means ineffective spending of budget funds.

This article presents the basic directions of Life Sciences and summarizes examples encountered in the work of the Expert Group.

MECHANISMS USED BY THE EXPERT GROUP TO ANALYZE PROPOSALS

The Expert Group is composed of researchers and engineers. Representatives of technology platforms, the business community, universities, and state customers of the Programme were included in the Expert Group as well. Members of the group were chosen based on bibliometric indicators but also on their willingness to make quick decisions and remain permanently involved in the group's activity, all of which was dictated by the large number of proposals (over 50 per month) submitted for consideration. For example, the processing time by a scientist with a h-index above 40 exceeds the Programme's allotted time. The following ten-

dency was observed: the higher the expert's h-index, the lower the expert's activity is during the analytical assessment of proposals that are outside the scope of his narrow competence. Within the sphere of the expert's competence, the only result of the expert activity in the vast majority of criticism of potential competitors.

One of the main activities of the Expert Group is selection and preparation of topics for competitive calls to conduct applied research and experimental developments (hereinafter Call). Preparation of a Call is carried out on the basis of consideration of the Proposals registered in the information system of the Programme (http://tematika.fcpir.ru). When submitting a Proposal, the initiator should provide basic information about the project, which includes substantiation of the project implementation and the need for funding from the federal budget; a list of publications reflecting the scientific level of the expected results and characterizing the technological background conducted by the team in the field of research.

During the preparation of the Call, members of the Expert Group need to assess the possible risks associated with the subsequent implementation/non-fulfillment of work at the expense of federal budget funds. Therefore, a crowdsourcing mechanism was used. The Proposals that were deemed to be the most promising were posted on the web site of the Expert Group (http://rgls.wikivote.ru/), which is used as a tool to discuss expert opinions. There, the Proposals were accompanied by a brief description of the planned activities, publications supporting scientific and technological experience, and draft of the project statement.

The validity and feasibility of the topic was proved by publications in journals with an impact factor of at least 0.8 for the last 5 years. Proposals that were not supported by related publications of Russian teams were excluded, since this situation indicated a lack of competencies in the Russian Federation required for implementation of the project. Also, we excluded Proposals whose project statement did not contain numerical indicators of achieved results, or lacked a comparison with experimental (published article or patent) and/or industry analogues (or the absence of analogues was indicated).

The Expert Group analyzed the Proposals received under the arrangements 1.2 and 1.3 of the Programme[1] and rejected about 20% of them because of a lack of references to applicants' publications confirming the scientific potential in the area of the proposed research topic. PubMed search was used to reveal any experience of the initiators in the field of life sciences.

Other Proposals were rejected because of a lack of the information necessary for an objective peer review. Despite compliance with the formal requirements for preparation, consistent presentation, and seemingly outstanding ideas, their relation to experimental work and feasibility of the project implementation raised doubts. We may assume that these Proposals were prepared by persons not related to practical research. The amount of requested funds in many Proposals, including those satisfying the basic requirements, often exceeded the actual capabilities of the Programme. In this regard, the Proposal selection principles were developed and included in the main document (Concept) underlying the Expert Group's activity.

According to these principles, promising topics were brought up for discussion by the Expert Group, and their initiators made a report to substantiate the key positions of the stated topic. The main decision criteria were as follows: 1) compliance with modern international scientific trends, 2) result that has potential impact on the economy, 3) availability of an industrial partner interested in the result, 4) availability of Russian research teams working in the particular field, and 5) support of a specific technology platform[2].

Proposals were voted on by experts of the group and were numerically scored. Seventy-two per cent of the Proposals picked up for discussion received a positive score. In this case, generalization of the initial topic formulation and objective were performed at the stage of preparing the Call. This was done due to the requirement of the Russian Ministry of Education and Science for competition of several research teams. In other words, the Expert Group generated Call so that they could fit a rather broad interpretation of the requirements necessary to achieve the result. This approach enabled the participation of many teams in competitions held by the Russian Ministry of Education and Science and, thereby, expanded the possible range of participants from the scientific community to select the most competitive contractors. It's worth noting that the selection of contractors was carried out without participation of the Expert Group.

Generally, 341 Proposals under the 1.2 arrangement (research) and 214 Proposals under the 1.3 ar-

[1] *The arrangement 1.2 means conducting applied research for the development of industries. The arrangement 1.3 means conducting applied research and developments aimed at creating products and technologies.*

[2] *The technology platform is a communication tool aimed at intensifying efforts to develop advanced commercial technologies, new products (services), attracting additional resources for research and development through the participation of all stakeholders (government, business, science and education), as well as improving the legal framework in the field of scientific and technological development and innovation (source: www.hse.ru).*

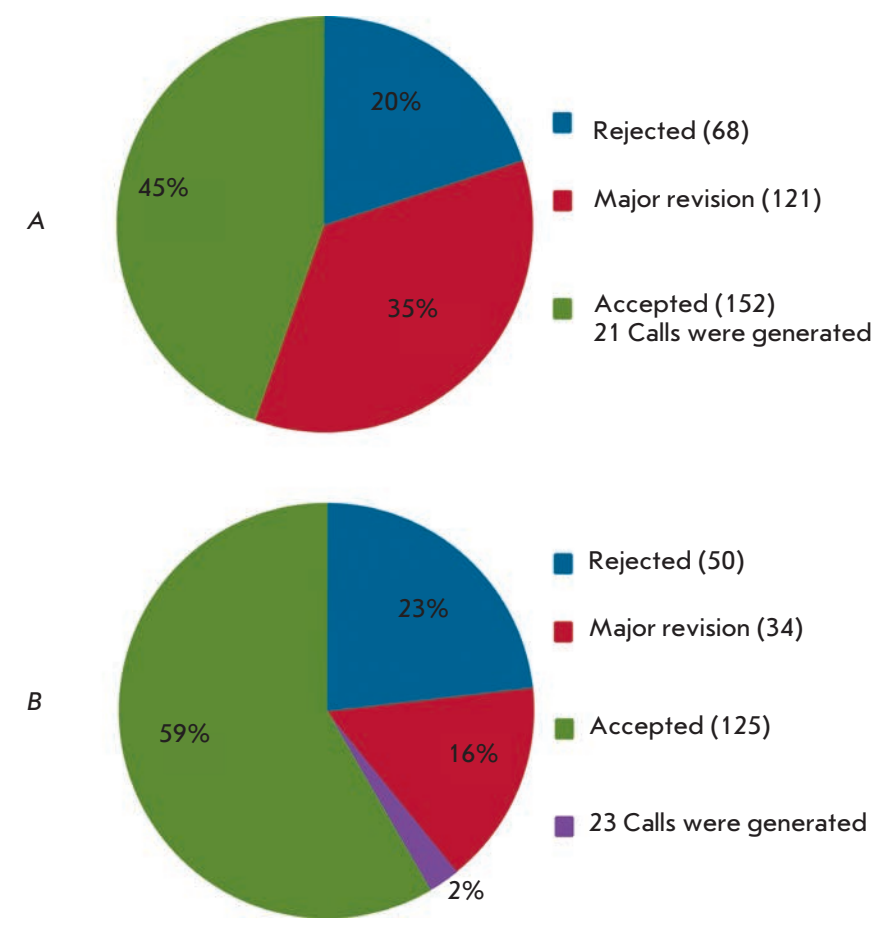

Fig. 1. The distribution of submitted Proposals: (A) research, (B) research and development

rangement (research and developments) were processed in the period from November 2013 to the end of 2014. On the basis of 152 Proposals (45% of the total), 21 research Calls were issued. On the basis of 125 Proposals (59% of the total), 23 research and development Calls were produced. The Proposal distribution is shown in *Fig. 1.*

THE CONCEPT ROLE IN THE SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT

The spectrum of Proposals submitted to the Expert Group was used to formulate the strategic directions (*Fig. 2*). The selected directions were considered topical to the Programme for the following reasons:

1) availability of recent publications on the topics of each area in peer-reviewed journals;

2) availability of Russian strong, dynamic research teams engaged in the appropriate areas, whose expertise is confirmed by publications; and

3) a set of particular products for a real sector of the economy[1] are expected as a result of the implementation of projects in these areas.

The submitted Proposals may be divided into two categories: medical sciences and life sciences. Despite division is artificial, it was necessary because the Expert Group should not implement tasks that are under the cognizance of the Ministry of Health of the Russian Federation. Therefore, the development of medical technology, medical devices, and pharmaceuticals was not included in the Concept. This separation is also due to the specialization of members of the Expert Group. Inclusion of researchers with a high h-index in the Expert Group naturally led to a shift in emphasis towards molecular and cellular biology.

The diagram in *Fig. 2* depicts four sectors corresponding to the strategic directions of the Concept: Genomes, Integrability, Brain, and Bioactive substances. The first strategic direction of the Concept, Genomes, is dedicated to post-genomic technologies. It includes large-scale studies of genomes/transcriptomes/proteomes that offer a selection of strategies for individual diagnosis and/or therapy. The sector is characterized by priority issues, such as the resistance of tumors and infections to treatment, carcinogenesis, immune system disorders, and aging. It is important to emphasize that the prioritization within the sector is not related to the social significance of diseases but indicates models where post-genomic research should demonstrate its effectiveness.

Let us illustrate the logic of the application of the priorities of the Genomes sector with the example of carcinogenesis. A project whose stated aim was to reduce incidence and mortality from cancers or choice of individual chemotherapy would not match the Concept. The quality of implementation of these clinical problems should be monitored by the relevant executive authority, i.e. by the Ministry of Health. On the other hand, a project aimed at decoding tumor genomes and identifying mutations specific to the Russian population is entire-

[1] *A real sector of the economy is a set of industries that produce tangible and intangible goods and services, excepting financial, credit, and exchange operations. This is a footnote*

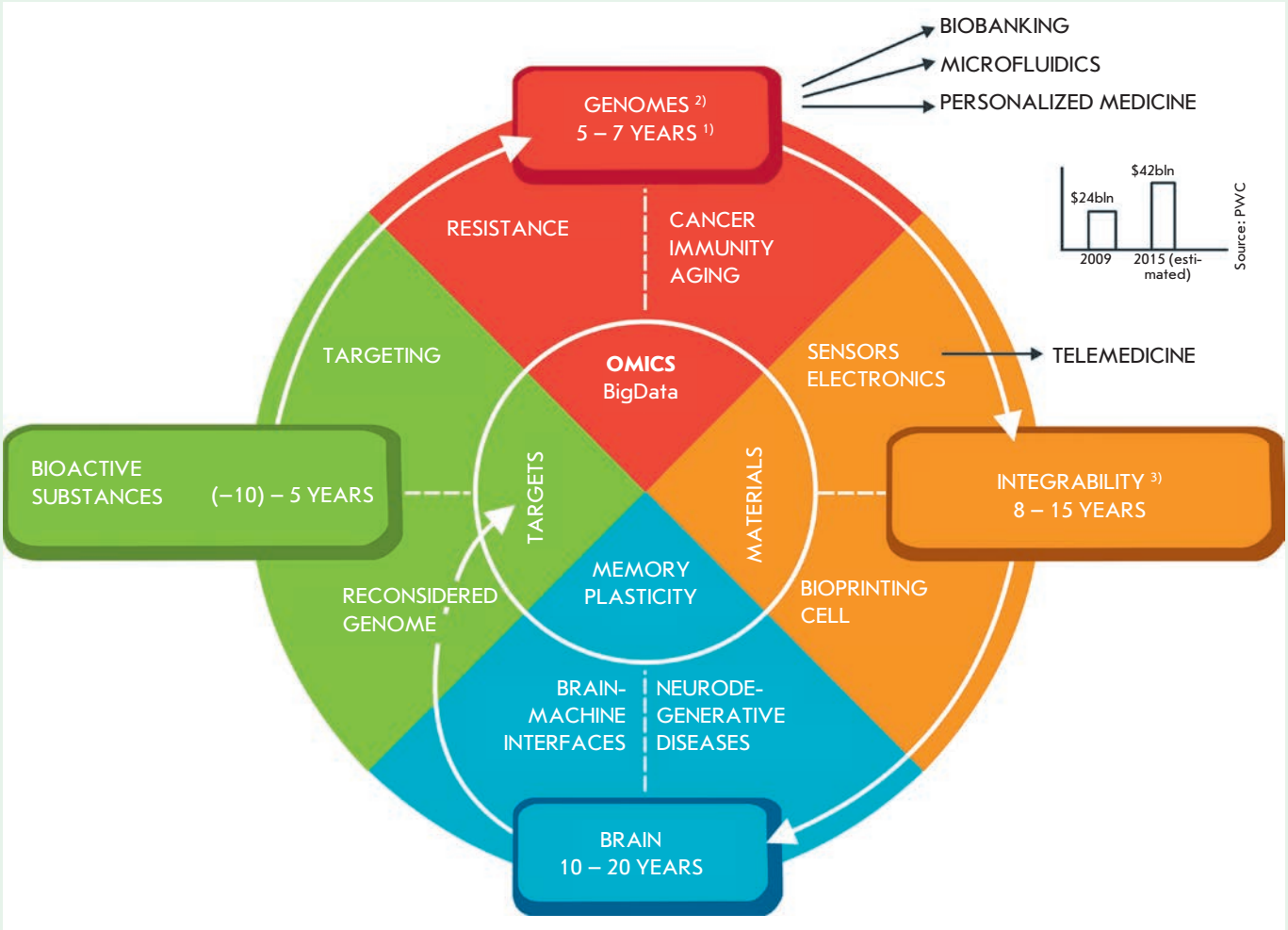

Fig. 2. The Concept of Life Sciences in 2014–2020. (1) Periods of the anticipated economic effect are depicted. (2) Personal genomics and post-genomic technologies. (3) Implantable devices and materials

ly consistent with the Concept. In this case, the result of the project will be a verified database of specific mutations, i.e. a tool for solving the previously mentioned clinical problems of oncological diseas. The quality of the result, in turn, will be evaluated by an industrial partner interested in the transition from applied research to the commercial product. Since a database of oncogenes can be used to solve diverse problems, it will be the case of implementation of the principle of multi-disciplinary development, which is in line with world trends in the development of medical sciences [2].

We emphasize that the Programme is open also for clinical studies: the prescriptive way is provided for this purpose based on an agreement between the Russian Ministry of Education and Science and another interested executive authority (in life sciences, it is primarily the Ministry of Health and Ministry of Agriculture of the Russian Federation). A Call is announced for a specific topic proposed by a federal authority. Many scientific directions were excluded from the Concept due to the presence of a prescriptive way to form such Calls. These include devices for diagnosis and treatment, medical technologies, clinical, preclinical and epidemiological studies, and software and hardware for medicine and health. Also, the Concept did not include analytical instrumentation, biodiversity and bioremediation, monitoring and protection of the environment, and functional foods and GMOs. Studies in these areas are initiated by the relevant authorities, but not by the Expert Group.

The Genomes sector (*Fig. 2*) also illustrates well the principles of practical implementation of the Concept. For example, a biobanking project cannot serve as a topic of the Call, because this is a large-scale infrastructure task. At the same time, any well-designed project to study biological material using genomic and post-genomic technologies will contribute to the standardization of the protocols of the sampling, transportation and storage of materials. Similarly, the need for automation and unification of sample preparation stages will contribute to the development of microfluidic devices. Finally, the results of applied research in the Genomes sector are expected to be used in the field of personalized medicine. According to a prognosis by Price Waterhouse Coopers, the personalized medicine market will be worth 42 billion US dollars by 2016.

For understanding the Concept's structure it is important to account for the trends of modern biotechnology. A biotechnology company has no access to the market of medical services or medical devices, since this sector is occupied by large corporations. It is impossible to compete with corporations like Pfizer, AstraZeneca, Bayer, etc., since the entire federal budget of the Life Sciences is less than 1% of the pharmaceutical industry's expenditure on research and development. However, there is no need for such competition, since growth in the biotechnology sector in the biopharmaceutics and biomedicine areas in the XXI century is achieved through the development and improvement of technologies. Human genome mapping has led to the creation of 310,000 new jobs and created, with the investment of 3.8 billion dollars, a market 10 times larger [3]. In this case, the genome, in terms of medicine, was in demand in rather limited use. Today, genome mapping technologies are more interesting to IT companies than to physicians: for example, Google has launched its Baseline Study project [4].

What is the output of the Programme in the area of Life Sciences? It would be speculation to say that it is people's health or the treatment of patients. It takes decades to implement a real result of clinical application. This matches neither the time nor financial frameworks of the Programme. Any Proposal of this kind is automatically qualified as not matching the format of the Programme and is rejected.

At the same time, Proposals of an exploratory kind also do not match the format of the Programme, which requires an application-oriented deliverable. Things useful for research may be such an intermediate result. In fact, the product is "a set of tubes" and the instruction on how to use this set to conduct scientific research. Actually, a high market growth rate is attributable to such reagent kits but not to "test kits for early cancer detection" or "medications for the cardiovascular system." For example, Luminex company provides dynamic capital growth of 30–40% (this means that if you bought the company shares for 100 thousand rubles in 2014, you could sell them for 130–140 thousand rubles in 2015). Turning to the 2013 Luminex financial statement (http://investor.luminexcorp.com), we see that much of its growth (72%) came from orders for reagent kits, while plate reader sales and the sector of health services accounted for about 10 and 5%, respectively. In the letter case, innovative medical services are provided in the CLIA format (www.cdc.gov/clia/), which is the system of health services registration. Russia has no analogues of such a system.

The narrow window of opportunities available to Russia in the field of genomic and post-genomic technologies is based on the related concepts of "big data" and "omics-science" (*Fig. 2*). The concepts are based on the paradigm of processing someone else's information, rather than on generating original datasets. A fundamentally important contribution to the development of post-genomic data processing was made by Yandex company [5], which provided long-term "buoyancy" of Russian developments in the field of bioinformatics.

The second strategic direction of the Concept is "Integrability" (*Fig. 2*). This sector represents a tendency to implant artificially created stuffs in to the human body. This sector includes cellular technologies, microelectronics, and micro- and nanoelectromechanical systems (MEMS and NEMS, respectively). An example of a development that would have been appropriate in the sector 3–4 years ago is a micro-device converting the heart's motion energy into electrical energy [6]. Currently, the gap in the bio MEMS area is not critical for Russian science, so the Expert Group considers projects from this area within the Concept.

Reprogrammed cells are of interest as a part of projects on tissue engineering, and this process should be performed on bioresorbable matrices formed by bioprinting [7]. Within this task, the Expert Group gave up on stem cells and the development of prostheses for orthopedics and maxillofacial surgery. Similar projects were substantially funded by the 2009–2013 Programme and are currently funded under the federal targeted programme Pharma 2020. Therefore, they were excluded from the Concept.

As in the sector of Genomes, in the sector of Integrability is marked by the basic technology – materials, where Russia can compete. Demand for this area depends on whether

researchers developing new materials can switch to a new format where a clinical problem, which is solved through creation of a high-technology device, applies the requirements to the properties of new materials. But not vice versa, when medical challenges are adjusted to the possibilities of creating new materials. This approach is relevant not only in materials science. The Concept means that advances in chemistry and physics are not what should define life sciences, but on the contrary, life sciences should specify the problem for nanotechnology, laser physics, high energy physics, as well as for electronics and circuit engineering. For professionals who are not biologists (e.g., materials scientists), this approach is a paradigm shift. In fact, they cannot be project leaders in life sciences but should limit themselves to the role of subcontractors.

The third strategic direction of the Concept, "Brain," was formed under the influence of the largest projects of our time: the American Connectome project [8] and the European Brain project [9]. The horizon of implementation of this key area is 20–30 years, i.e. the main experts living in this country will reach retirement age by the time of project implementation.

Investment into this research area in America, Europe, and Japan exceeds Russian expenses by more than 2 orders of magnitude. In the Russian Federation, there is experience of investment into the field of drug treatment of neurodegenerative diseases that is limited to two products: Dimebon (withdrawn from clinical trials by Pfizer [10]) and Semax, which was not interesting to major pharmaceutical companies, although the first publication dates back to 2000 [11].

The terms of memory and plasticity were taken as the basis of the strategic Brain direction in the described Concept. Investigation of the brain's properties will allow us to, if not close then, at least not widen the gap with more advanced countries. The direction became part of the priority research problems set forth by the Russian Ministry of Education and Science [12]. Brain sector Calls are oriented toward the development of tools to study and manage the living brain activity. Currently, there is a Russian research group that has learned and implemented optogenetic techniques in freely moving animals [13]. The next step is the development of tools for simultaneous transmitting and recording of a signal upon studying the mechanisms of memory and other cognitive processes. The brain responses recorded for different activities of a freely moving organism will form a large data array requiring supercomputers with a new architecture [14]. Today's markets in the field of eye-brain-computer neurointerfaces for game consoles and managing "a smart home" have already been formed [15, 16]. Brain activity reading will also be crucial for assessing the quality of presenting audio and video advertising (neuromarketing), training and coordinating co-working teams, and accelerated foreign language training [16].

The fourth strategic direction of the Concept is "Bioactive substances." In Russia, there are a number of professional companies committed to the biotechnology market and with the necessary capabilities. These include Biocad, R-Pharm, Generium, Microgen, and PharmEco, and others. Within the Programme, biotechnology companies can be involved only in inventions that are based on the molecular mechanisms of interactions of proteins, antibodies and peptides with living cell. Nontargeted drug delivery, creation of liposomal forms, development of long-acting biopolymer-based systems, gene therapy, investigation of small molecules, and screening of combinatorial libraries are areas of high patent activity, which means that developments in these areas should either be implemented under the federal targeted programme Pharma 2020 or be excluded from the priorities of scientific and technological development.

DEMAND FOR APPLICATION-ORIENTED RESULTS IN THE FIELD OF LIFE SCIENCES

The field of Life Sciences is a multisided area that can be characterized as "an infinitely small point" between the public tasks of the scientific institutions of the Federal Agency for Scientific Organizations and Ministry of Health and Ministry of Agriculture of the Russian Federation, as well as between the federal targeted programme Pharma 2020 supervised by the Russian Ministry of Industry and the programme Basic Research for Medicine of the Russian Academy of Sciences and grants of the Russian Foundation for Basic Research in the areas of medicine and biology. This "small point"can be transformed to the field of development of the scientific and technological potential when teams confirming their qualification by publications. In biomedical sciences, publication of well-cited papers in high impact factor journals is a basic skill [17].

The Proposals analyzed by the Expert Group reflect, to some extent, the current state of the Russian scientific community: the presence of great academic ideas but a lack of skills in structuring, planning, and achieving the desired result. It should be stressed that the Expert Group treats publications not as the assessment of the scientific viability of the project idea but as proof that the project's initiator is able not only to begin research, but also to bring it to conclusion.

The process of selection of the project topics under the Pro-

gramme is based on crowdsourcing combined with expert evaluation of results. Formulation of the described strategic directions of the Concept depended on the number of Proposals received from the scientific community. The expert could not add an idea to the Concept if it did not have three or four Proposals in the information system. Most Proposals that were submitted and then discussed at a meeting of the Expert Group were not relevant due to the impossibility of constructive analysis of the submitted information.

The result of applied research of the Programme should be specific products capable of competing worldvide. This requires efficient interaction of the scientific community with designers and engineers to transit from the searching science format to the applied science format. Involvement of technology platforms with an internal system of topic consideration facilitates the formation of the researcher + engineer + industrial partner = applied result.

Getting an applied result is economically justified if there is an interested business who is capable to use the result. Who is this industrial partner? The Programme is opened to companies that are consumers of the technological result, e.g. Evrogen, Syntol, or DNA Technology. The annual turnover of business partners of Programme projects ranges from tens to hundreds of millions of rubles. So we are not talking about huge company, vertical holdings, or about contribution to the development of entire industries. In life sciences, the market in the next 10–20 years will be a niche market and success in this market will depend on the capacity to master intelligent production technologies.

Prediction of the development of new market niches can be achieved by analyzing global databases, such as the database of the scientific publications Web of Science (WoS) and the Orbit patent database [18]. Keyword search reveals the dynamics of publication and quotation activity, i.e. provides an idea whether interest of the world scientific community in a given topic is growing or declining. The dynamics of patent applications filed and patents issued indicates technological trends. The analysis provides an assessment of the potential for entering the real economy by comparing the number of patents owned by universities and companies.

The problem of automatic foresight adoption is the dependence of the result on the way of formulation of keyword search. The results of an analysis are equally uninformative in the case of both wide and too narrow search patterns. In this case, co-operation with experts who offer variants for correcting of keyword search, as exemplified in *Fig. 3*, turned out to be effective. The initial version of the Lot received 20 out of 100 possible points. After correction of keyword search, the rating amounted to 55 out of 100 points.

According to the results of an analysis of topics proposed by the Expert Group, it can be concluded that drugs, diagnostic tools, and other products for medical and agricultural purposes cannot be the Programme's priority. The Programme, as a part of the Life Sciences area, offers a unique opportunity to develop something essential to the applicant for further self-development. Then, there is a chance that the development will be in demand not only to the applicant but also from other groups working around the world. If practical implementation of the project results is not planned after its completion, that does not qualify to the current Programme requirements.

PERSPECTIVES OF THE CONCEPT

Comparing the Concept with a technological development overview published by the Massachusetts Institute of Technology [19], it is possible to identify coincidence of the strategic directions of the Concept with key trends: modeling the brain, predictive medicine, bioprinting, BigData, digital medicine, and mobile health. This indicates that there are Russian researchers capable of capturing future trends. At the same time, most actively and successfully working in their fields specialists although "catch" breakthrough direction, but do not admit implementation of a breakthrough without personal involvement and control.

In life sciences, the situation of self-setting the problem (appropriate for the Russian Foundation for Basic Research and Russian Scientific Foundation but unacceptable for the target method of Programme implementation) can be solved through the mechanism of multiple "umbrella" Calls offered by the Ministry of Education and Science of the Russian Federation. These Calls are designed for several winners (contractors). The Call topic, for which there is no competition, should be considered inconsistent. For example, if a single application is filed for the Call, then this competition was likely created artificially, without regard for the possibility of further development of the proposed idea. Unfortunately, such examples appeared in 2014 (in particular, competitions aimed at studying single cells (single-cell-omics), creating non-invasive neurostimulators, and deciphering animal genomes).

The information system of the Programme continues to receive Proposals that are analyzed by experts of the group. The Concept will be changed based on newly received Proposals and the permanently changing picture of the develop-

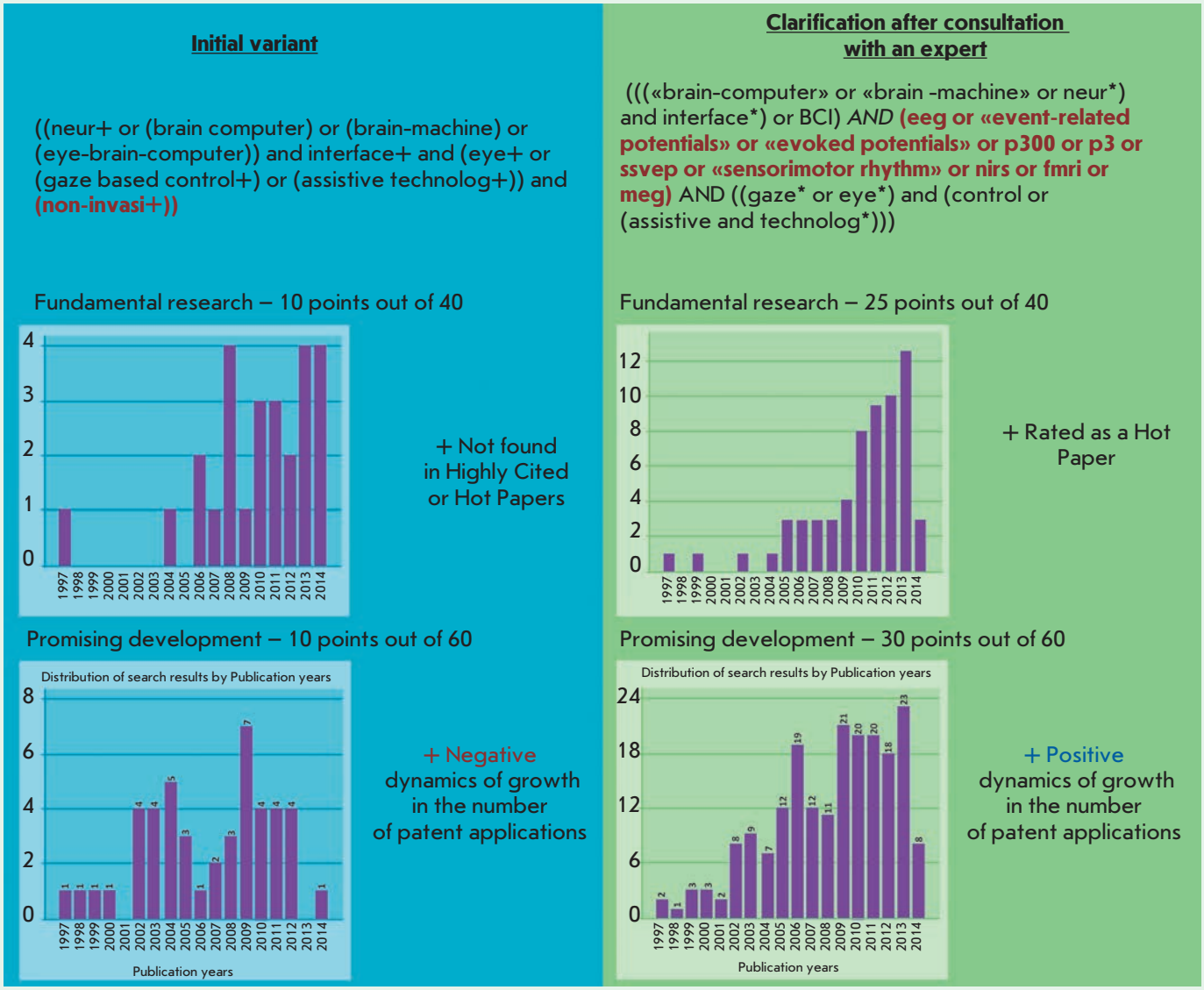

Fig. 3. The effect of keyword search on the results of an analysis of the databases Web of Science (Fundamental research) and Orbit (Promising development)

ment of modern science. On the basis of the analytical capabilities of some scientists to predict far in advance, it is possible to form general topics, since they become landmarks for submitting subsequent Proposals, to support in the framework of these topics not only (or even mainly) leading teams with an established reputation, but also second-tier groups that are ready to enter new areas. Selection among the latter is made based on the quality of Proposal preparation. The training of qualified second-tier professionals requires additional stabilizing efforts in the period of Programme execution, since the conditions of formation of research topics and projects should remain unchanged during the next few years. ●

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