Programme

to support medical applied research

in 2015 to 2022

Contents

1. Programme name

Programme to support medical applied research in 2015 to 2022 (hereinafter the "Programme").

2. Legal framework of the Programme

The Programme will be implemented pursuant to:

- Act No 130/2002, on the support of research and development from public funds, and on the amendment of some related Acts (the Act on the Support of Research and Development), as amended (hereinafter "Act No 130/2002");
- Commission Regulation (EC) No 651/2014 of 17 June 2014, declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the EU, Official Journal of the European Union L 187 of 26 June 2014, page 1 (hereinafter the "Commission Regulation");
- Framework for state aid for research and development and innovation - Official Journal of the European Union of 27 June 2014, (2014/C 198/01) (hereinafter the "Framework");
- and other related regulations.

The Programme is, pursuant to Article 108(3) of the Treaty on the Functioning of the European Union, exempted from the reporting obligation as it complies with the conditions of the Commission. The Programme will be implemented in accordance with the National priorities of oriented research, experimental development and innovations, which were approved through Resolution of the Government of the Czech Republic No 552 on 19 July 2012, and in accordance with the document Implementation of the National priorities of oriented research, experimental development and innovations, approved through Resolution of the Government of the Czech Republic No 569, on 31 July 2013. The Programme is also in accordance with the "National strategy on rare diseases for 2010 to 2020", approved through Resolution of the Government of the Czech Republic of 14 June 2010 No 466, and also with the "National action plan for rare diseases for 2012 to 2014", approved through Resolution of the Government of the Czech Republic of 29 August 2012 No 633. The Programme also takes into account Health 2020, a WHO strategy document, the Concept for the hygiene service and primary prevention in public health protection.

3. Provider

The Provider of this aid is the Ministry of Health, registered office Palackého náměstí 4, Prague 2.

4. Programme identification code

For the purposes of documentation in the Research and Development Information System the Programme was allocated the code "**NV"**.

5. Programme duration

The duration of the Programme has been set at 2015 to 2022, meaning 8 years.

The duration of a project will be at least 3 years, and at most 5 years, and in the case of individual public tenders in research, experimental development and innovation, their length will be determined in such a way that the available state budget expenditures are optimally used. Projects implemented within the framework of the Programme will have to be completed by 31 December 2022 at the latest. Five-year projects will focus on addressing very difficult and complex issues and will have to demonstrate that they fulfil demanding criteria for the achievement of excellent research, set in the Project Assessment System. More details will be provided in the documentation for the tenders.

The Timeframe, tied to the Commission Regulation, was set to 2022, with the provision that no new projects will be started in 2021 and 2022, but multi-year projects commenced before 2020 will be completed.

6. Deadline for the announcement of Programme tenders

The first tender in research and development (hereinafter a "Tender") will be announced in 2014 and the provision of aid commenced in 2015. Subsequently, annual announcement of Tenders is planned for 2015, 2016, 2017, 2018 and 2019, with public aid provision commencing in 2016, 2017, 2018, 2019 and 2020, with the proviso that projects with a maximum duration of 4 years can be registered for a Tender announced in 2018, and projects with a maximum duration of 3 years can be registered for a Tender announced in 2019 so that these projects will be completed by 31 December 2022 at the latest. The Tenders will be implemented taking into account the financial possibilities and needs relating to the fulfilment of the Programme objectives.

7. Total Programme expenditure

The total expenditure for the duration of the Programme in 2015 to 2022 is envisaged to be CZK 7 223 000 000, of which CZK 6 500 000 000 will be from the state budget for research and development, while the financing of the Programme will be performed pursuant to the possibilities of the state budget. The average intensity of Programme aid is, in view of the envisaged involvement by research organisations and companies in the implementation of Programme projects, proposed at 90%.

The total expenditure on the Programme is, for the duration of the Programme, planned in accordance with the envisaged gradual announcement of the Tenders and in relation to the expected average duration of the projects.

Table No 1: Total expenditure on the Programme and expenditure from the state budget (in CZK millions)

year	2015	2016	2017 [1]	2018 [2]	2019	2020	2021	2022	total
Total expenditure	500	944	1000	1000	1167	1167	889	667	7 223
State budget expenditure	350	850	900	900	1050	1050	800	600	6500
Non-public sources	39	94	100	100	117	117	89	67	723

8. Form, intensity and amount of aid

Aid will be provided to legal entities or natural persons in the form of a subsidy for recognised costs; and in the form of an increase in the expenditure of state or ministry branches.

The intensity of aid, set as a percentage of the recognised costs of a project, will be calculated for each Programme project as well as for each beneficiary and other participants separately pursuant to the Commission Regulation. For projects in which only research organisations are participating, the highest permitted intensity of aid per project can be up to 100% of total recognised costs in accordance with Act No 130/2002 and the Commission Regulation. For projects in which companies are participating, the highest permitted intensity of aid for applied research[3] and individual categories of beneficiaries and other participants will be indicated in the tender documentation for each Tender according to the current European Union regulations.

The maximum permitted amount of aid for a project (without a reporting obligation and more thorough assessment by the EC), stipulated pursuant to Article 4(1) i) of the Commission Regulation, will not be exceeded. The amount of aid will be assessed for each project individually. The requested amount of aid must be justified and appropriate to the objectives, the duration of the project, and the envisaged results of the project.

9. Aid beneficiaries

An applicant, respectively beneficiary of aid from the Programme for a project pursuant to Act No 130/2002, the Commission Regulation and the Framework, as well as other project participants, may be:

[1] The difference between the expenditure program and planned expenditure of the state budget will cover the claims of unused expenses from previous years.

[2] The difference between the expenditure program and planned expenditure of the state budget will cover the claims of unused expenses from previous years.

[3] In accordance with Article I. (1.3) point 15 e) of the Framework, applied research means industrial research, experimental development, or combinations thereof.

1. Organizations for research and dissemination of knowledge (hereinafter "Research Organisations" – legal entities that comply with the definition of a research organisation pursuant to the Commission Regulation[4] and that will implement the project independently or in cooperation with other participants, and demonstrate their ability to co-finance the project from non-public resources.

2. Companies – both legal entities and natural persons that, pursuant to Annex 1 of the Commission Regulation, carry out an economic activity and that will implement the project independently or in cooperation with other participants, and demonstrate their ability to co-finance the project from non-public resources. The aid beneficiary, in accordance with Art. 1 (4) a) of the Commission Regulation, cannot be a company which was issued recovery orders.

The Commission Regulation and the Framework, the Provider will perform the assessment as to whether or not an applicant or other participant complies with the definition of a research organisation pursuant to Act No 130/2002, for each applicant or other participant individually during the assessment of the project proposal, during the implementation of the project, and after its completion. The control over compliance with the definition of a research organisation will be performed on the basis of the submission of the documents stipulated in the tender documentation for a Tender.

10. Qualification of aid applicants

Aid for a project in this Programme can only be received by those applicants who comply with the qualification conditions pursuant to Section 18 of Act No 130/2002. If more than one applicant registers together to implement a single project, the obligation to demonstrate qualification will apply to all such applicants. An applicant will demonstrate its qualification pursuant to Act No 130/2002 in the method stipulated by the Provider in the tender documentation.

Compliance with qualification conditions will be assessed by the commission for receiving project proposals before the assessment of the project proposals. Failure to comply with any of the qualification conditions is reason for not placing a project proposal into a Tender.

[4] In accordance with Article 2 (83) of the Commission, "organization for research and dissemination of knowledge" is an entity (e.g. a university or research institute, agency for the transfer of technology, innovation intermediary, a physical or virtual cooperating entity focusing on research) regardless of its legal status (under public or private law) or way of financing, whose main objective is to carry out independent basic research, industrial research or experimental development or publicly disseminate the results of these activities in the form of teaching, publication or transfer of knowledge. If this entity also performs an economic activity, it is necessary to keep separate accounts regarding the financing, costs and revenues associated with these activities. Companies that can exert a decisive influence upon such an entity, such as shareholders or members, must have priority access to the results which have been reached.

11. Cooperation between companies and research organisations

Effective cooperation on a project between a company and a research organisation is, in accordance with the Commission Regulation, understood to be their joint share in the project proposal, their (joint) contribution to the implementation of the project, and (joint) sharing of the risks and results of the project. Fulfilment of the conditions in Article 6 of the Commission Regulation (meaning the required minimum share of the research organisation in the eligible costs and the right of the research organisation to publish the results of the research project) will enable the Provider to provide the company with a bonus for effective cooperation with a research organisation. The basis for the assessment of whether a project proposal includes effective cooperation between a company and a research organisation will be the draft contract for cooperation between an applicant (beneficiary) and proposed other participants, which indicates the fulfilment of the above indicated conditions of effective cooperation. This assessment will be performed during the assessment of the project proposals.

12. Eligible and recognised costs of the Programme

Aid will be provided for recognised costs of a project defined in accordance with Act No 130/2002 and the Commission Regulation (Article 25(3)). Recognised costs are such eligible costs that the supplier approves, that are justified, demonstrable through the accounting, and whose necessity for the implementation of the project is clear from the project proposal. Recognised costs must be reasonable (must correspond to normal prices at that time and place) and must be invested in accordance with the principles of economy, efficiency and effectiveness.

Eligible costs of a project in the Programme are:

a) staff costs: researchers, technicians and other supporting staff to the extent necessary for the project,
b) costs of instruments and equipment to the extent and for the period that they are utilized for the project. If there are no such instruments and equipment used in the project throughout its lifetime, only depreciation over the duration of the project is considered an eligible cost, calculated on the basis of generally accepted accounting principles,
c) costs for building and land, to the extent and for the period when they are utilized for the project. For buildings, eligible costs are only depreciation over the duration of the project, calculated on the basis of generally accepted accounting principles. In the case of land, costs of commercial transfer or actually incurred capital costs are considered eligible,
d) costs of contractual research, knowledge and patents bought or acquired under license from external sources under normal market conditions, as well as costs of consultancy and equivalent services used exclusively for the project,
e) additional overheads and other operating expenses, including costs of material, supplies and similar products incurred directly as a result of the project.

13. Programme focus

The decisive assumption for a society that is successful in economic, social and human terms is a healthy population. The basic aspect of "health" is a dynamic of changes and processes; this, however, usually displays a significant level of momentum resulting in many discrepancies, the most visible of which are between developments in medical science and the economic possibilities of a country. In the area of medicine it is necessary to focus on the most common and most dangerous areas: chronic non-infectious diseases such as cardio- and cerebrovascular disease, oncology, dementia and other mental diseases, or chronic diseases of the musculoskeletal system, etc. Attention must also be paid to the external influences of the environment, which are going through significant changes. It is important to support the establishment and development of new treatment technologies (genetics, nanotechnology). It is also necessary to monitor new infectious diseases and the ever increasing resistance of new agents. It is therefore also necessary to stress, among other things, the importance of virology. The fight against chronic non-infectious diseases of civilisation, caused in the vast majority by the unhealthy behaviour of a large part of the population, will be a great challenge. The mission of the health service is to adapt to changes in the environment and knowledge, as well as society in such a way that all citizens are guaranteed access to support and protection of their health, so that people are encouraged to maintain a healthy lifestyle and so that the rules of effective disease prevention are thoroughly applied.

14. Accord between the Programme and R&D priorities

The focus of the Programme, its primary objective as well as how it is broken down, is fully in accordance with the R&D Priorities, specifically with Priority No 5: Healthy Population. Priority No 5: Healthy Population is broken down into three areas (1. The incidence and development of diseases; 2. New diagnostic and therapeutic methods; 3. Epidemiology and prevention of the most serious diseases), which are further broken down into 20 subareas and 41 component objectives, similarly to the breakdown of the Programme. The following table outlines the breakdown of the Programme (which is identical to the structure of Priority No 5: Healthy Population). The Programme is also in accordance with the National strategy on rare diseases for 2010 to 2020 and with the National action plan for rare diseases for 2012 to 2014 (1 subarea and 2 component objectives).

Table No 2: Programme accord with R&D Priorities

Area 1. Incidence and development of diseases
Subarea 1.1. Metabolic and endocrine diseases
• Priority component objective 1.1.1. Etiology and pathophysiology of insulin resistance
• Priority component objective 1.1.2. Etiology and pathogenesis of immune mediated endocrine diseases
• Priority component objective 1.1.3. Pathogenesis and treatment of diabetes complications
Subarea 1.2. Diseases of the circulatory system

- Priority component objective 1.2.1. Clarification of etiological factors and pathophysiological phenomena influencing the incidence and course of cardiovascular (CaVD) and cerebrovascular disease (CeVD)
- Priority component objective 1.2.2. The development of timely diagnosis of cardiovascular (CaVD) and cerebrovascular disease (CeVD) and the discovery of treatment modalities and procedures in therapy of cardiovascular and cerebrovascular disease with increased therapeutic effectiveness and increased consideration for the ill

Subarea 1.3. Tumoural disease

- Priority component objective 1.3.1. Tumoural biology in relation to diagnostic and therapeutic objectives
- Priority component objective 1.3.2. Analysis of the host-tumour relationship as a means to create individual diagnosis and treatment

Subarea 1.4. Nervous system and mental disease

- Priority component objective 1.4.1. Mental and neurological disease
- Priority component objective 1.4.2. Diagnosis of diseases of the nervous system
- Priority component objective 1.4.3. Increased effectiveness of treatment procedures for diseases of the nervous system
- Priority component objective 1.4.4. Ensuring quality of life for patients with diseases of the nervous system

Subarea 1.5. Diseases of the musculoskeletal system and inflammatory and immunological diseases

- Priority component objective 1.5.1. Etiology and pathogenesis of degenerative and metabolic diseases of the musculoskeletal system
- Priority component objective 1.5.2. Defining risk factors for the incidence of allergic disease and identification of new objectives for the targeted treatment of such diseases

Subarea 1.6. Infection

- Priority component objective 1.6.1. Etiology and therapy of important infectious diseases

Subarea 1.7. Diseases in childhood and rare diseases

- Priority component objective 1.7.1. Prenatal, perinatal and early childhood diseases
- Priority component objective 1.7.2. Rare diseases

Area 2. New diagnostic and therapeutic methods

Subarea 2.1. In vitro diagnosis

- Priority component objective 2.1.1. Improving knowledge in the area of –omics and high-capacity methods
- Priority component objective 2.1.2. New IVD technology

Subarea 2.2. Low-molecular-weight medicines

- Priority component objective 2.2.1. New low-molecular-weight compounds
- Priority component objective 2.2.2. Identification of new therapeutic objectives, new methods and procedures for biological testing

Subarea 2.3. Biological medicines, including vaccines

- Priority component objective 2.3.1. New vaccines for the prevention and treatment of disease and dependence

Subarea 2.4. Drug delivery systems

- Priority component objective 2.4.1. Development of new carriers for managed release and transport of medicines

- Priority component objective 2.4.2. Systems to overcome biological barriers and chemoresistant diseases

Subarea 2.5. Gene, cell therapy and tissue replacement

- Priority component objective 2.5.1. Sources for cell and tissue therapy
- Priority component objective 2.5.2. Methods for differentiation and genetic modification of cells/tissues
- Priority component objective 2.5.3. Biomaterials

Subarea 2.6. Development of new medical devices and equipment

- Priority component objective 2.6.1. Electric and magnetic mapping and stimulation
- Priority component objective 2.6.2. Endovascular procedures
- Priority component objective 2.6.3. Navigation and robotic systems, neurostimulators. Improving accuracy a control of invasive techniques

Subarea 2.7. Innovative surgical procedures, including transplantation

- Priority component objective 2.7.1. Surgical procedures and transplantation
- Priority component objective 2.7.2. Non-invasive treatment

Area 3. Epidemiology and prevention of the most serious diseases

Subarea 3.1. Metabolic and endocrinal diseases

- Priority component objective 3.1.1. Assessing the influence of preventive measures in the incidence of the most common metabolic disorders

Subarea 3.2. Circulatory system diseases

- Priority component objective 3.2.1. Population studies: data on diseases
- Priority component objective 3.2.2. Population intervention, assessing the influence of preventive measures

Subarea 3.3. Tumoural diseases

- Priority component objective 3.3.1. Screening and prevention of tumour incidence
- Priority component objective 3.3.2. Identification of risk factors and individuals in populations

Subarea 3.4. Neural and mental diseases

- Priority component objective 3.4.1. Population study: data on diseases
- Priority component objective 3.4.2. Population intervention, assessing the influence of preventive measures

Subarea 3.5. Diseases of the musculoskeletal system and inflammatory and immunological disease

- Priority component objective 3.5.1. Epidemiology of degenerative and metabolic diseases of the musculoskeletal system

Subarea 3.6. Dependency

- Priority component objective 3.6.1. Connections
- Priority component objective 3.6.2. Impact on society

Subarea 3.7. Infections

- Priority component objective 3.7.1. Epidemiology of infectious diseases
- Priority component objective 3.7.2. Domestic and imported foodstuffs as a source of infection

15. Programme objectives

The principle and primary objective of the Programme is to ensure an internationally comparable level of medical research and the use of its results to improve the health of the Czech population and to secure the current needs of the health service in the Czech Republic.

The Programme has three primary areas: Incidence and development of diseases; New diagnostic and therapeutic methods; and Epidemiology and prevention of the most serious diseases, which are further broken down into 21 subareas and 43 component objectives. The specific objectives characterise the individual subareas. The thematic definition of the Programme is fully in accordance with and is based on the National priorities of oriented research, experimental development and innovation (hereinafter the "R&D Priorities"), respectively on Priority 5: Healthy Population and also on the National strategy on rare diseases for 2010 to 2020 and the National action plan for rare disease for 2012 to 2014".

The projects proposed into this Programme must be placed into one or more of the following subareas and must ensure the fulfilment of one or more of the component objectives of the Programme.

Area 1. Incidence and development of diseases

Subarea 1.1: Metabolic and endocrinal disease

Key objective 1.1:

The etiology and pathogenesis of the primary metabolic and endocrine disorders in today's population will be clarified, and this will enable their prevention, moderation of their course and, in particular, a reduction of their consequences, which are reflected in almost all medical areas and contribute towards overall mortality. This will result in not only an extension of the length, but also an improvement in the quality of the active life of a large group of the population, with corresponding social and economic impacts.

Component objective 1.1.1: Etiology and pathophysiology of insulin resistance and Metabolic syndrome

Clarification of the pathogenesis of the mutual relationships between congenital, developmental and environmental factors contributing towards obesity, insulin resistance syndrome, and intermediary metabolism disorders leading to diabetes mellitus type 2 and connected diseases.

Component objective 1.1.2: Etiology and pathogenesis of immune mediated endocrine diseases

The identification of causal factors and the mechanism for the incidence of autoimmune mediated disorders of glands with internal secretions, in particular diabetes mellitus type 1, thyreopathy, adrenal gland disease, hypophysis, but also other glands with internal secretion and polyglandular autoimmune syndromes. The identification of etiological and pathogenetic factors contributing to the incidence of other diseases of glands with internal secretion, their complications, and associated diseases. In this area it is also necessary to support the study of the etiopathogenesis of hereditary disorders of the metabolism and, on the basis of these findings, develop new diagnostic and treatment procedures.

Component objective 1.1.3: Pathogenesis and treatment of the complications of diabetes
The identification of the mechanisms of the development of chronic complications of diabetes such as diabetic nephropathy, retinopathy, polyneuropathy, diabetic leg syndrome and diabetic macroangiopathy and the introduction of new procedures in their prevention and therapy. It is also necessary to support the creation of registers of patients with all the above described diseases, which will enable the use of such acquired data for science and research.

Subarea 1.2: Circulatory system diseases

Key objective 1.2:
The impressive progress in the prognosis, diagnosis and therapy of ischemic heart disease, the risk factors and other CaVD would be unthinkable without close cooperation between theoretical and clinical cardiologists, heart surgeons, angiologists, and vascular surgeons. This cooperation has a long tradition in this country and is the driving force behind scientific progress. The aim of the research activities will be to contribute towards the clarification of etiological factors and molecular and cellular pathogenetic mechanisms that contribute towards the incidence of ischemic heart disease and the risk factors, heart attacks, heart rhythm disorders, structural and inflammatory diseases of the heart, congenital heart defects, and diseases of the arterial and venous system, with special focus on improving their prevention, timely diagnosis, and highly individualised treatment. New etiological factors and new pathophysiological mechanisms influencing the incidence and progression of cardiovascular disease will be identified, in particular: ischemic heart disease, heart failure, heart rhythm disorders, hypertension, structural heart disease, peripheral vascular disease of the lower extremities, aortic aneurysm, chronic venous insufficiency, inflammatory heart disease, as well as other diseases of the arterial and venous system; with a clear impact on improving their prevention, timely diagnosis, and highly individualised treatment.

The etiopathogenetic mechanisms that cause CMP will be established, and the possibilities for influencing them – and this in particular from the area of "non-traditional" risk factors. The mechanisms will also be established that lead to the incidence of neurological disability for patients with stroke, spontaneous haemorrhage on the brain and spontaneous subarachnoid haemorrhage, and the possibilities for influencing these will be clarified. The reasons for the success and failure of therapeutic procedures for patients with CMP will be clarified. The regeneration mechanisms that are a reaction to disability of the nervous system, including brain plasticity mechanisms and the regeneration of brain tissue within the framework of neurorehabilitation, will be understood.

Component objective 1.2.1: Clarification of etiological factors and pathophysiological phenomena influencing the incidence and course of cardiovascular (CaVD) and cerebrovascular disease (CeVD)

Preferred will be multi-field biomedicinal research providing qualitatively new findings about the causes and mechanisms influencing the development and course of CaVD and CeVD, with clearly defined clinical benefits for improving their prevention, diagnosis or treatment.

Component objective 1.2.2: Development of timely diagnosis of cardiovascular (CaVD)

and cerebrovascular disease (CeVD) and finding treatment modalities and procedures in therapy for cardiovascular and cerebrovascular disease with increased therapeutic effectiveness and increased care for the ill

Preferred is multi-field research and development of new technologies, methods, medicines, and diagnostic and treatment procedures with clearly defined clinical benefits for timely diagnosis and/or highly effective targeted treatment of CaVD and CeVD, respecting the uniqueness of each patient. This area also includes research leading to the identification and verification of regeneration, rehabilitation, re-socialisation and educational procedures for patients with cardiovascular and cerebrovascular disease to shorten the convalescence and inability to work of patients, and improve their social involvement.

Subarea 1.3: Tumoural disease

Key objective 1.3

Preferred is multi-field research providing qualitatively new findings about the causes and mechanisms influencing the development and course of tumoural disease, with clearly defined clinical benefits for subsequent improvements in their prevention, diagnosis and treatment. New diagnostic procedures will be developed for the timely identification of tumoural disease with the use of newly identified tumoural biomarkers that can be used for quick and cheap screening of the whole population and individualisation of treatment. Therapeutic approaches based on a description of the biology of the individual tumour with a minimisation of side effects will be developed.

Component objective 1.3.1: Tumoural biology in relation to diagnostic and therapeutic objectives

Study of the biological mechanisms leading to tumoural disease. Identification of new therapeutic objectives and biomarkers that will enable improved diagnosis and treatment of tumoural disease. Special attention will be paid to linking diagnosis with targeted treatment and the introduction of new therapeutic approaches based on combined treatment, epigenetics, sophisticated drug-delivery systems, and treatment of resistant tumoural disease.

Component objective 1.3.2: Analysis of the host/tumour relationship as the means to individualise diagnosis and treatment

Study of the relationship between the tumour and its host will contribute towards the development of diagnostic and therapeutic methods enabling the monitoring and therapeutic use of the interactions between normal and tumorous cells, understanding the importance of the tumoural stroma, inflammatory and immune responses for the incidence and development of tumours.

Subarea 1.4: Neural and mental diseases

Key objective 1.4:

The primary objective is basic and applied research leading to clarification of the etiology and pathogenesis of serious disease of the nervous system within a scope that will lead to the earliest possible correct diagnosis and commencement of causal treatment. The final result

will be the cure or minimisation of problems, and an improvement in the functional capacity as well as the quality of life of ill people. This will reduce the mental, social and economic burden for the families of the ill people, and also for society. The key objective also includes timely identification of the risk to individuals and preclinical states in such a way as to ensure the most effective prediction and timely prevention of nervous and psychological diseases.

Component objective 1.4.1: Mental and neurological diseases

The clarification of genetic, epigenetic and environmental factors contributing towards the incidence and development of psychological and neurological disease is an essential prerequisite for improving prevention, developing new treatment procedures, and improving comprehensive care for patients with a wide range of diseases, including vascular stroke, epilepsy, dementia, schizophrenia, depression, bipolar disorders, anxiety disorders, autism, hyperkinetic disorders, eating disorders, multiple sclerosis, extrapyramidal and cerebellar disease, neuromuscular and neuropathic disability and other disorders of the nervous system that manifest themselves through psychological or neurological disease.

Component objective 1.4.2: Diagnosis of diseases of the nervous system

Expansion and innovation in existing diagnosis including molecular genetics (e.g., whole-exome sequencing), electrophysiological techniques of all modalities, and structural and functional neuroimaging methods and technologies leading to clarification of the physiological, developmental and individual diagnosis of specific changes in the brain connectome for patients with autism, epilepsy, schizophrenia and other disorders related to key areas of the brain. The diagnosis includes the search for biological markers of individual diseases as well as new experimental and clinical neuropsychological tests.

Component objective 1.4.3: Increased effectiveness of treatment procedures for diseases of the nervous system

Finding new treatment modalities and improving the accuracy and innovation of existing treatment procedures on the basis of genotype or endophenotype, including pharmacogenetic analyses with the purpose of minimising side effects. One criteria for effectiveness will be not only the cure or moderation of clinical problems, but also the maximum possible quality of life, including a dignified psychosocial level of the patient and their family.

Component objective 1.4.4: Ensuring quality of life for patients with diseases of the nervous system

In the context of the preceding objective the primary priority of neuroscientific research must be ensuring the maximum possible quality of life for individuals suffering from diseases of the nervous system, and this through not only timely diagnosis and therapy but also the related continuous neurorehabilitation, psychotherapeutic and psychosocial care, psychoeducation and modern community social care including stationary and respite services.

The objective is not only to increase functional capacity and quality of life while limiting reversion (the frequency and duration of hospitalisation) and to strengthen the resilience of the patient, but also economically significant savings connected with shortening the inability to work as well as the convalescence of ill people.

Subarea 1.5: Diseases of the musculoskeletal system and inflammatory and immunological diseases

Key objective 1.5:

The etiopathogenesis will be established with stipulation of the corresponding treatment of inflammatory, in particular the main systemic, rheumatic, degenerative, metabolic and immune diseases. The etiology and pathogenesis of diseases of the musculoskeletal system will be clarified, which will significantly contribute towards improving the quality of life of the older population.

Component objective 1.5.1: Etiology and pathogenesis of degenerative and metabolic diseases of the musculoskeletal system

The study of the molecular biology of bone, cartilage and muscle cells. The study of genetic polymorphisms and epigenetic factors related to the incidence of autoimmune disease. The monitoring of environmental factors related to the incidence of these diseases. Further development of imaging methods of the microstructure of bone enabling improved assessment of bone quality. The development of imaging methods to assess the progression of osteoarthritis. The understanding of other factors that encourage the healing of fractures. The development of methods of tissue engineering with the objective of preparing artificial cartilage and bone. The study of the metabolism of chondrocytes and extracellular matrixes, especially an understanding of the misbalance between degradation and reparation processes that enable the synthesis of targeted preparations.

Component objective 1.5.2: Defining risk factors for the incidence of allergic diseases and identification of new objectives for the targeted treatment of such diseases

The genetic polymorphisms and epigenetic regulation of molecules involved in allergic reactions, and also external factors for the incidence of such diseases will be studied. Attention will be paid to the interaction between the immune system and microorganisms and environmental factors, and also the regulatory mechanism of allergic inflammation.

Subarea 1.6: Infection

Key objective 1.6:

Clarification of the etiology, epidemiology and pathogenesis of diseases in relation to new, reappearing, opportunistic as well as overlooked infections, enabling the individualisation of treatment and improvement in the quality of life for patients and the population as a whole. The development of new diagnostic methods for the timely detection of infection as well as new treatment procedures for important infectious diseases. The characteristics of the molecular mechanisms of resistance to antimicrobial substances, including analysis of molecular-epidemiological markers for the spread of resistance. The development of new antimicrobial substances and the identification of alternative objectives for rational chemotherapy.

Component objective 1.6.1: Etiology and therapy of important infectious diseases

The clarification of molecular-genetic mechanisms responsible for changes in virulence and resistance of the agents of infectious disease. Establishing the pathogenic potential of microorganisms related to the incidence and development of infectious, metabolic (including endocrine), tumoural, cardiovascular and neurodegenerative disease and mechanisms/factors responsible for the activation of latent or opportunistic infection. The definition of the basic molecular-epidemiological markers for the spread of multi-resistant bacteria, yeasts, moulds and viruses in the human population with the objective of retarding their incidence and spread and retaining the effectiveness of anti-infectives. The development of new diagnostic methods for the timely identification of infectious disease and the search for new markers for infectious disease as potential diagnostic and therapeutic objectives. The development of new substances with antimicrobial effects and their basic characteristics.

Subarea 1.7: Diseases in childhood and rare diseases

Key objective 1.7:

The primary objective of the basic research in this area is to deepen the knowledge about etiopathogenesis of serious rare diseases (in particular with monogenic heredity) and developmental disease in prenatal age, perinatal complications and of chronic disease in childhood with the use of comprehensive approaches. The findings from the basic research will be incorporated into clinical practice, while applied research will focus on the development of new diagnostic methods and algorithms and on the development of new treatment and preventive procedures, including prenatal and pre-implantation diagnosis.

Component objective 1.7.1: Prenatal, perinatal and early childhood diseases

Study of the impact of genetically conditioned factors and the negative influences of the external environment on the etiopathogenesis and pathophysiology of serious disease in childhood. The development of non-invasive diagnostic methods of chronic disease in childhood. The preparation of preventive procedures and treatment methods in care for an ill child with the objective of improving the quality of life of chronically ill children.

Component objective 1.7.2: Rare disease

The number of known rare diseases is not final and with the gradual development of new generations of modern technologies for sequencing it is possible to describe new genetically conditioned clinical units. However, the work does not end with the discovery of the mutations and genes of new diseases, and for the clarification of pathogenetic mechanisms it is necessary to use a series of additional procedures from the areas of genomics, metabolomics, proteomics, molecular and cellular biology and, in many cases, it is also necessary to make use of animal models. For as-yet incurable genetically conditioned rare diseases the development of pre-implantation and prenatal diagnosis is important, providing effective primary and/or secondary prevention of these diseases in affected families. The priorities in this area are therefore research focused on the clarification of etiology for diseases whose causes are still not known and the study of molecular, biochemical and cellular mechanisms of etiologically defined rare diseases (as an essential prerequisite for related research into new diagnostic and treatment procedures). Another priority is support for

research into their nosological classification (meaning phenotype ontology), epidemiology, the development of methods for the timely prevention of these diseases, and research into the cost-effectiveness of diagnostic and treatment procedures in the area of rare diseases.

Area 2. New diagnostic and therapeutic methods

Subarea 2.1: In vitro diagnosis

Key objective 2.1:

Pathogenetic mechanisms for selected genetic variants found during whole-genome sequencing and their association with various human diseases will be clarified. New in vitro diagnostic methods reacting to these results and also to newly discovered threats or to newly discovered biomarkers will be created. In silico approaches and systemic biology approaches for the use of large volumes of data generated through massively parallel methods will be developed. There will be integration of diagnosis with the actual treatment through systemic and translational medicine approaches.

Component objective 2.1.1: Improving knowledge in the area of -omics and high-capacity methods

High-throughput screening (HTS) methods produce huge quantities of data and information that it will be necessary to understand and whose clinical usability must be systematically verified. One of the objectives will be to clarify the molecular and cellular pathogenetic mechanisms for selected genetic variants found during whole-genome sequencing, and to verify their association with various human diseases. For effective analysis of the data from HTS technology, in silico approaches and systemic biology approaches will be developed to use the large volume of data generated by the HTS methods. The identification of new diagnostic, prognostic and predictive biomarkers through "-omics" technologies, the integration of the data acquired with their links to clinical characteristics in health and illness.

Component objective 2.1.2: New IVD technologies

New technologies or parts of them will be developed, enabling fast, sensitive, specific, minimally invasive or non-invasive diagnosis and monitoring of the course of an illness. These new technologies will work either with material taken from the patient: blood or other bodily fluids, tissues (tissue sections, e.g., of tumours) or with the patient as a whole in the form of whole-body functional imaging methods (MRI, PET-CT); research in this area will concentrate on the preparation of new imaging enhancers and specific radiopharmaceuticals, which will enable imaging of the pathological events over time (e.g., angiogenesis, specific localised metabolic events, the imaging of receptors) for a specific patient. Some of these substances will also have a therapeutic character (e.g., antibodies with PET radiopharmaceuticals).

Subarea 2.2: Low-molecular-weight medicines

Key objective 2.2:

New biologically active low-molecular-weight substances with therapeutic potential verified in "proof-of-concept" studies will be prepared. More effective procedures in the monitoring of the biological activity of medicines with the use of a comprehensive approach to assessing desirable, undesirable and toxic effects of new low-molecular-weight compounds (improving biological tests, introducing new testing methods, prediction of biological activity, toxicity and side effects in silico) will lead to the timely elimination of inactive or toxic molecules. The identification of new basic structures (leading structures) and their modification, or the modification of clinically verified medicines will improve their pharmacotherapeutic usability.

Component objective 2.2.1: New low-molecular-weight compounds

The preparation of new low-molecular-weight compounds and structural motifs with relevant pharmacological effects. New molecules will be synthesised and discovered through studies of the relationship between structure and activity, combinatorial chemistry, high-capacity screening or isolation in natural, in particular plant, sources. In many areas (e.g., in the area of high-throughput screening (HTS)) the Czech Republic has international-standard infrastructure.

Component objective 2.2.2: Identification of new therapeutic objectives, new methods and procedures for biological testing

New therapeutic objectives will be generated on the basis of the results of basic research, while new procedures and methods in assessing effectiveness and toxicity in vitro to increase the probability of the clinical usability of small molecules will be discovered. Selected candidate compounds, new methods and procedures will subsequently be validated at the level of preclinical assessment in vivo.

Subarea 2.3: Biological medicines including vaccines

Key objective 2.3:

There will be a wider use of biological therapy and immunotherapy, to which knowledge of the exact mechanism of the effect and the specific objective will in particular contribute, reductions in manufacturing costs, and new findings connected with in vivo monitoring of the course of the biological response to the treatment. New biological medicines will be introduced, with for example improved stability and the possibility of non-invasive application, together with new vaccines with improved effectiveness as well as safety profiles.

Component objective 2.3.1: New vaccines for the prevention and treatment of diseases and dependence

New targets will be developed for vaccination (e.g., for the treatment and prevention of serious societal threats), new vaccination approaches (DNA vaccines, reverse vaccinology – the development of vaccine sequences of the whole genome of infectious agents, anti-tumour, desensitization etc.)

Subarea 2.4: Drug delivery systems

Key objective 2.4:

New transport systems for medicines as well as their combination will be created and used, potentially also genes enabling therapy of target tissues or cells, the managed release of active substances and the penetration of medicines in therapeutically important concentrations into hard-to-access organs (skin, CNS), tissue, cellular, and/or subcellular structures.

Component objective 2.4.1: Development of new carriers for managed release and transport of medicines

New carriers of medicines on the principle of macromolecular structures and/or nanoparticles will enable the managed release of medicines throughout the whole organism, or the targeted transport and managed release of biologically active molecules (medicines, genes) in specific tissue, cellular, or subcellular structures. Research will lead to the development of more effective, safer (less toxic) medicines with more suitable pharmacokinetic and pharmacodynamics characteristics, and potentially also enabling personalised therapy.

Component objective 2.4.2: Systems for overcoming biological barriers and chemo-resistant diseases

The study of the principle of biological, chemical and physical barriers in an organism, leading to the development of new methods to overcome them and the development of new types of medicines, formulations and drug-delivery systems overcoming skin, hematoencephalic, testicular, or ocular biological barriers, as well as overcoming drug-resistant phenotypes, etc. The results of this component objective will have direct use, for example in the treatment of patients with neurological, inflammatory, infectious, oncological, reproductive, or eye diseases, and last but not least in the treatment of diseases resistant to existing therapy.

Subarea 2.5: Gene, cell therapy and tissue replacement

Key objective 2.5:

The introduction of new safety procedures based on the use of autologous or modified autologous, allogeneic or xenogeneic cells and biomaterials and on the methodology of gene therapy for the treatment of diseases where existing treatment procedures fail and/or are too expensive.

Component objective 2.5.1: Sources for cell and tissue therapy

The preparation and characterisation of cells and cell lines that can be differentiated into the required phenotypes. This could mean allogeneic or xenogeneic sources, the development of lines with defined characteristics, including not only the possibility of the required differentiation, but also a high degree of safety (e.g., autologous stem cells of fat tissue, continuous and bone marrow, immortal lines from cells from foetal and embryonic tissue, iPSC, tissue grafts, transgenic animals etc.). Lines from genetically modified tumoural cells

and from activated cells of the immune system for the needs of immunotherapy of malignant tumours.

Component objective 2.5.2: Methods for differentiation and genetic modification of cells/tissues

Methods to differentiate target cells or tissue, potentially related genetic modification. Differentiation can include both the use of low-molecular-weight, and/or high-molecular-weight substances, and also genetic modification.

The induction of stem or precursor cells into cells with the required phenotype and degree of safety.

The use of activated dendritic cells for the immunotherapy of tumours.

Genetic modification of tumoural cells and cells of the immune system in vivo and ex vivo. Isolation and characterisation of lines suitable for immunotherapy of tumours

New procedures for gene therapy of human diseases, including the verification of new, safer and more effective vectors for gene transfer.

Component objective 2.5.3: Biomaterials

Defined structures with specific functions, e.g., as part of tissue replacement (scaffolds, biohybrid equipment etc.). The development of these materials includes polymer carriers, hydrogels, nanofiber structures, nanoparticles, allogeneic materials and decellularised extracellular matrix from allogeneic as well as xenogeneic sources.

Subarea 2.6: Development of new medical devices and equipment

Key objective 2.6:

New hardware and software technologies and methods will be developed for the timely diagnosis, effective and standardised treatment of cardiovascular, neurological, oncological and other diseases. Imaging methods based on the use of nanotechnology will also contribute to the timely diagnosis of such diseases. Nanotechnology will also find medical use without doubt.

Component objective 2.6.1: Electric and magnetic mapping and stimulation

Preferred is multi-field research and the development of new hardware and software technology for electric or magnetic mapping activities of individual cells, tissue and organs, and/or their stimulation with clearly defined clinical objectives in the area of improving the diagnosis and/or treatment of disease. The research projects will include development to at least the stage of fully functional prototypes.

Component objective 2.6.2: Endovascular procedures

Preferred is multi-field research and development of new technology enabling the creation of new endovascular diagnostic and treatment procedures with clearly defined clinical objectives in the area of improving the diagnosis and/or treatment of diseases. The research projects will include development to at least the stage of fully functional prototypes or biological models, and the introduction of new verified techniques and technology in the endovascular area.

Component objective 2.6.3: Navigation and robotic systems, neurostimulators. Improving accuracy and control of invasive techniques.

Preferred is multi-field research leading to the standardisation of intervention and minimally invasive surgical procedures, to improvement in their safety and effectiveness. Neuromodulation is another developing direction for the treatment of various diseases (arterial hypertension, heart failure, obesity, pain, neurodegenerative disease, epilepsy and psychiatric diseases). This involves the development of technological units using intervention or minimally invasive methods of controlled mapping and navigation systems, imaging techniques and various sensors (measuring contact with tissue, etc.) Neuromodulation is composed of the use of neurostimulators, potentially in the targeted destruction of part of the nervous system. In cardiovascular surgery this mainly involves the expansion and standardisation of robotically assisted intervention in the heart (the actual heart muscle, valves, coronary arteries) as well as arteries, especially the aorta (aneurysm, obliterating disability, the resolution of some complications with endovascular procedures). The research also includes development to the stage of technological units or fully usable prototypes in terms of function.

Subarea 2.7: Innovative surgical procedures, including transplantation

Key objective 2.7:

The objective is the development and use of new surgical procedures which are less invasive, and hence place a smaller burden on the patients' organisms. New methods will be more effective, will enable improved healing, a reduction in potential complications, and will provide quality long-term prognosis for the ill person. On the other hand this will enable more extensive interventions for findings that cannot yet be treated surgically. In the area of transplantation there will be the cultivation of tissue, the creation of artificial organs and facilitation of the acceptance of transplants by the patient. Increasing the treatment possibilities will enable a transfer to the minimisation of the essential hospitalisation time, or will offer the possibility of out-patient treatment with a shorter total treatment time.

Component objective 2.7.1: Surgical procedures and transplantation

New, gentler surgical procedures with sophisticated navigational techniques will be developed. The objective is research focused on the development and implementation of new surgical techniques and procedures. The resulting state will be a shift to one-day surgery or a significant shortening of the hospitalisation time with retention of its safety and effectiveness. There will be development of biological replacements for tissue and organs, immunomodulation and protective procedures improving the efficiency, safety and tolerance of surgical and transplantation treatment. The objective of multi-field research will be the transplantation of both tissue and organs sourced from donors as well as grown in vitro, which the body accepts well and whose function replaces that of the organ (tissue).

Component objective 2.7.2: Non-invasive treatment

Focused radiation treatment, non-invasive local and locoregional treatment (e.g., radiosurgery, lithotripsy, treatment using ultrasound including sonothrombolysis). Multi-field

and multimodal research is targeted at non-invasive techniques that are still surgical in character but without penetration of the skin. Precise diagnosis and development of new treatment methods will increase their use in the out-patient mode. New modalities will be developed to the stage of a clinically usable prototype.

Area 3. Epidemiology and prevention of the most serious diseases

Subarea 3.1: Metabolic and endocrinal diseases

Key objective 3.1:

Validated epidemiological data will be available about 1) incidence, trends, health and the economic consequences of the most commonly occurring metabolic disorders and 2) their social, socioeconomic, behavioural, and biological determinants.

The effectiveness of individual interventional preventive and therapeutic procedures will be analysed and simulated in such a way that the results can be used to promote and strengthen the most effective comprehensive society-wide programme even outside the health sector, the acceptance of which would contribute towards halting the growth or even starting a drop in their incidence and a positive impact on the overall health of the population.

Component objective 3.1.1: Assessing the influence of preventive measures on the incidence of the most common metabolic disorders

Clinical as well as community assessment of new pharmacological and non-pharmacological procedures focused on the prevention of obesity, glucose metabolism disorders, hyperlipoproteinemia and hypertension, thyroid function disorders, endocrine conditioned disorders of reproduction and other autoimmune endocrinal diseases.

Subarea 3.2: Circulatory system diseases

Key objective 3.2:

The monitoring of both classic and new (non-traditional) risk factors in cardiovascular and cerebrovascular disease in the Czech population will help to reduce the incidence of these diseases in the Czech Republic. It will contribute towards innovation and improving preventive programmes with the integration of current knowledge and the needs of society in the area of the implementation of the health policy at individual levels.

Component objective 3.2.1: Population studies: data on diseases

The collection and processing of data about the incidence and prevalence of cardiovascular and cerebrovascular diseases and their risk factors.

Component objective 3.2.2: Population intervention, assessing the influence of preventive measures

Verification of intervention procedures leading a) to a reduction in incidence, the societal and economic impact of cardiovascular and cerebrovascular disease, and their risk factors, b) to the education of the population with the objective of timely recognition of symptoms by the patient, which will enable timely diagnosis and treatment.

Subarea 3.3: Tumoural disease

Key objective 3.3:

The epidemiology of tumoural diseases will be understood, the risk factors in individual populations identified, both specific and non-specific methods proposed for their prevention, with precise and specific screening, finally leading to the identification of the risk to individuals, timely diagnosis of tumours, relapse as well as the side effects of treatment, providing a reduction in mortality, morbidity and cost of anti-tumour treatment, taking into account the subjective assessment of the quality of life of the patient. The need for specialised palliative care for patients who have exhausted the possibilities for specific anti-tumour treatment will be understood. The number of quality clinical studies in all the above areas and the availability of results from them will increase.

Component objective 3.3.1: Screening and prevention of tumour incidence

Attention will be paid in particular to the possibilities for the chemoprevention of tumours, for strengthening and improving the accuracy of existing, and the introduction of new, highly sensitive, specific, non-invasive or minimally invasive screening programmes, which will be usable for the timely diagnosis of tumoural disease in the overall population or in risk groups of individuals.

Component objective 3.3.2: Identification of risk factors and individuals in populations

Research will focus on the identification of factors contributing to the incidence and development of tumoural disease, risk factors in the population (in particular genetic, environmental, physical, addictive, nutritional, physical exercise and infection), and will lead to the proposal of specific preventive measures and the further investigation of biological mechanisms.

Subarea 3.4: Neural and mental diseases

Key objective 3.4:

The primary demographic and epidemiologic characteristics of diseases of the nervous system will be mapped, and their links discovered and identified (e.g., age, sex, geographic and environmental, developmental, genetic and comorbidity), and preventive measures and programmes implemented to reduce the prevalence and incidence of diseases of the nervous system including mental disorders, reducing reversion (frequency and duration of hospitalisation) and reducing the socio-economic burden that diseases of the nervous system represent. At the same time research will be performed into the effectiveness and efficiency of provided interventions and services (services research), with the objective of optimising the offer and coordination of such interventions.

Component objective 3.4.1: Population studies: data on diseases

Establishment of registers (mental and nervous diseases, suicide, somatic comorbidity, early and late morbidity for at-risk new-borns etc.) and support for longitudinal studies will form the basis for a database that will enable preventively focused interventions.

Component objective 3.4.2: Population intervention, assessing the influence of preventive measures

Primarily preventive whole-population interventions will in particular be focused on destigmatising individuals who suffer from brain diseases: this stigmatisation represents a stressor potentially worsening the course of the disease, and leads to delays in searches for therapeutic help, while such delays can negatively impact the resulting state of the ill person.

Primarily preventive programmes will further focus on the at-risk population, such as e.g., perinatal at-risk children or individuals with a higher risk of developing psychotic disorders, CMP or dementia. The latest methods will be used, including e.g., telemedicine.

At the same time research will be performed into the effectiveness and efficiency of provided interventions and services (services research), with the objective of optimising the offer and coordination of such interventions.

Subarea 3.5: Diseases of the musculoskeletal system and inflammatory and immunological diseases

Key objective 3.5:

Not only factors of prevalence and incidence, but also other important environmental factors contributing to the etiopathogenesis of these diseases will be known. Of the most important it is necessary to name the relationship between infection and the development of autoimmune disease, and also endocrinal factors, the influence of aging, factors related to environmental pollution, the impacts of smoking and other addictive substances.

Component objective 3.5.1: Epidemiology of degenerative and metabolic diseases of the musculoskeletal system and autoimmune mediated diseases of the gastrointestinal tract

Describe the epidemiologic connections between the incidence of external causes in the development of degenerative disease of the joints and spine, e.g., joint dysplasia, obesity, trauma, inflammation, lifestyle factors and movement burden. Map out the epidemiologically important connections leading to the incidence of various types of metabolic osteopathy, e.g., nutritional factors, the intake of calcium and vitamins, the influence of physical activities, the influence of smoking and other addictive substances, and also the influence of various medicines (e.g., glucocorticoids) and the incidence of idiopathic inflammatory bowel disease and celiac disease.

Subarea 3.6: Dependency

Key objective 3.6:

The objective of the Programme is to reduce the prevalence and incidence of dependency including alcoholism, smoking and gambling, and to reduce their health and socio-economic impacts. One prerequisite for achieving these objectives is mapping the epidemiology, development risks, social burden and predictors of dependency treatment, and the preparation of materials for preventive measures and programmes and for political, legislative and economic decisions.

Component objective 3.6.1: Relationships

Finding the genetic, epigenetic, environmental, public-health, behavioural and social relationships of dependency, including their relationships to other related diseases.

Component objective 3.6.2: Impact on society

Reducing the societal and economic impact of dependency.

Subarea 3.7: Infection

Key objective 3.7:

Preventing to the incidence and spread of agents of infection, including nosocomial as well as newly dangerous etiological agents with zoonotic potential, and improving the quality of their laboratory diagnosis.

Component objective 3.7.1: Epidemiology of infectious diseases

Monitor the morbidity and mortality of infectious diseases and study the factors influencing their incidence. Identify new sources and paths for the spread of infectious disease and develop effective anti-epidemic measures. Develop new diagnostic methods to identify agents and test their characteristics. Develop programmes for surveillance of infectious disease in accordance with European Union requirements. Optimise information systems and registers. Monitor the effectiveness of vaccination programmes and propose their updating according to the epidemiologic situation and the availability of newly developed vaccines. Educate the population.

Component objective 3.7.2: Domestic and imported foodstuffs as sources of infection

Identify the risk factors related to the importing of foodstuffs from various destinations, identify sources of contamination and prepare procedures to protect the citizens of the Czech Republic. Rapid laboratory diagnosis of agents of alimentary infections and tests of their characteristics. Optimise information systems. Educate consumers.

16. Comparison of the current situation abroad

Health and medical research in all countries is supported through a combination of institutional financing and targeted financing. If we take into account the existence of a single institution the Joint Research Centre (JRC), which also focuses in medical research, then this also applies for the EU.

Medical research more and more resembles basic research. This means that with the exception of Austria, a lack of large concrete national programmes for purely applied medical research. Yet research institutions and organisations in all the monitored countries are sufficiently aware of the need to rapidly and effectively use the achieved results of such research. The evidence for this is on the one hand the great attention and support paid to translational research, meaning the interconnection of basic research and clinical research.

Health and medical research in all countries has an unusually wide scope and a very diverse structure of research workplaces (universities, public research organisations, state research institutions). Neurological research, in particular brain research; molecular medicine; genomics, cancer research; and health and medical problems connected with the ageing of the population could to a certain extent be labelled as "moderate" priorities.

In all the monitored countries one can see trans-disciplinary efforts. Fields of science about inanimate nature and technical fields of science are gradually also being drawn into medical research, which for many years had been the standard part of science about animate nature.

In conclusion, it is useful to remember some important specifics of selected countries and the EU. The Netherlands has extensive and generously supported initiatives "Netherlands Genomics Initiative" and "National Initiative Brain & Cognition". The largest and best supported research programme in Austria is GEN-AU (Genome Research in Austria). In Switzerland there are very closely conceived and completely concrete priorities of research (e.g., "SYNAPSY – the Synaptic Bases of Mental Diseases", "Neural Plasticity and Repair"). In the United Kingdom (respectively Great Britain) the standard support for research, in particular basic research, has been expanded through seven field-based research councils (one of which is the Medical Research Council) to aid cross-sectional and trans-disciplinary activities, in which several Research Councils always participate. One outstanding specific of medical research in the USA is that all the websites of medical research institutions have an extensive, comprehensible and regularly updated part with information about the research they perform and its results for the greater public. The European Union emphasises the health and medical issues connected with population ageing. Here there is, however, very low participation by entities from the Czech Republic in medical and health research in framework programmes, in particular in support for basic research provided by the European Research Council (ERC). Participation in health and medical research, however, is no different from participation in other R&D areas.

The state abroad is analysed in detail in the concurrently submitted "Concept for Medical Research to 2022".

17. Comparison of the current situation in the Czech Republic

A detailed analysis of the current situation in research and development in the health system in the Czech Republic is provided in Annex No 3 (Analysis of research and development in the health system in the Czech Republic) "Concept for Medical Research to 2022". In short we can say that the highest share of specific legal forms in terms of the participants in medical research projects are as follows: state contributory organisations of the Ministry of Health and the regions – hospitals etc. (63%), public universities (28.4%) and then public research institutions, in particular institutes of the Academy of Sciences of the Czech Republic (5.2%). The shares of other legal forms are already insignificant.

As a civilised country with a developed and high quality health system, the Czech Republic should continue to devote an adequate intensity of support to the area of medical research in

order to make good use of the years spent building up quality teams and workplaces, whether clinical or in particular research-oriented.

18. Expected results

In connection with the stipulated objectives, only those projects that demonstrably envisage the achievement of at least one primary[5] and one secondary research and development result will be supported. Reaching at least two primary results is also acceptable.

A primary result is considered to be one of the following types of result:

- F - utility model, industrial design
- G - prototype, functional sample
- J_{imp} – reviewed expert article in a magazine with an impact factor[6]
- N – certified methods, medical procedure, specialised maps
- P - patent
- R - software
- Z – pilot plant, proven technology

A secondary result is considered to be one of the following types of result:

- B – expert book
- C – chapter in an expert book
- D – article in a collection
- J – reviewed expert article in non-impact journals

For the purposes of this Programme, primary and secondary R&D results are considered to be new results achieved exclusively within the framework of a project supported in this Programme, and that will be exclusively applied as a result of that project in the R&D information system register of information about results.

For the purposes of this Programme, other R&D results are considered to be new results achieved within the framework of a project supported in this Programme, and that will be completely or partially applied as a result of that project in the R&D information system register of information about results.

[5] Note: Broken down into primary results (posted only in the Programme) and secondary results (also posted in other activities or programmes) proposed because of the future assessment of the Programme – in the case of not enough primary (independent) results, it will be assessed as unsuccessful.

[6] In the assessment of the results emphasis will be placed on the applicability of this type of result in practice.

19. Expected benefits

The fulfilment of the objectives of the Programme should provide in particular the following expected benefits:

1) Ensure the development of clinical research in the Czech Republic as a basic source of new clinical procedures for diagnosis, treatment and prevention in the health system,
2) Develop an internal system for the assessment of the results of research with the purpose of improving their application during the provision of medical services,
3) Improve the concrete benefit of research into health care (in particular diagnosis, therapy and prevention),
4) Expand cooperation with leading workplaces and teams abroad, create conditions for its development,
5) Improve the interconnection and relationships between basic and applied research,
6) Reflect the current health assessment for our population in the priorities of our medical research,
7) Ensure the continuity of our medical research with the development of international science,
8) Support excellence in the area of research,
9) Create conditions supporting a wider involvement of young research workers,
10) Ensure the further expert development of existing leading research medical workplaces,
11) Use the results of research in pre- and post-graduate education of physicians as well as other health workers,
12) Use the results of the research for the presentation of medical facilities and regions.

20. Motivational effect

The Programme will contribute towards increasing, improving the effectiveness and improving the quality of activities in the area of applied research in the area of the health system, and will also increase quality cooperation between industrial concerns (in particular small- and medium-sized enterprises), research organisations and organisations providing services with high added value. The Programme among other things works to change the motivational mechanism of companies and research organisations to increase their efforts in acquiring new knowledge in medical research, its use and introducing it into new products, services and manufacturing processes.

In accordance with the Commission Regulation, an SME has an automatically demonstrated incentive effect of aid if it begins the project after the agreement on the provision of aid comes into force and if it fulfils the conditions of the tender documentation. If the beneficiary or other party is a large company, it has to meet the incentive effect in accordance with the Commission Regulation in the project design to meet the requirements of Article. 6 (3) of the

Commission, especially to demonstrate that the aid will contribute to a significant increase in the scope of the project or activity, or significantly increase the total amount spent by the beneficiary on the project or activity, or there will be a significant acceleration in the completion of the respective project or activity. The assessment of the motivational effect will be part of the record of the result of the assessment prepared by the expert consultation body of the Provider.

21. General criteria for assessing project proposals

In accordance with the rules stipulated by Act No 130/2002 the Provider will appoint a commission to accept project proposals. The commission for receiving proposals will inspect received project proposals from the perspective of their fulfilment of all the prerequisites stipulated in the tender documentation for the project proposals.

The Provider will decide on the acceptance of a project proposal into a Tender, respectively on its exclusion from a Tender in accordance with Section 21(3) of Act No 130/2002 on the basis of the report prepared by the commission for receiving project proposals, respectively by the expert advisory body. Project proposals excluded from a Tender will not be assessed any further.

22. Project proposal assessment process

The assessment will be performed using a three-level system, which is based on the Project Assessment System:

- The Provider is the decisive body.
- The scientific council is the expert advisory body pursuant to Section 21(4) of Act No 130/2002
- The assessment panels are expert bodies of the Scientific Council pursuant to the Project Assessment System.

The system for the assessment of project proposals has been conceived in such a way as to reduce the space for interested influence and to avoid conflicts of interest at all assessment levels.

Project proposal assessment criteria

The assessment and selection of project proposals will be performed by the advisory bodies of the Provider on the basis of the following criteria:

1. The qualification of the applicant, in particular the applicant's technical and institutional foundation.
2. The capabilities and requirements of the applicant. The expert capabilities of the applicant and the results it has achieved so far will be assessed in particular.

3. The quality of the proposed project:
    a. The project objectives – whether clear objectives of the project have been defined, their newness, difficulty, significance and feasibility;
    b. The proposal for the implementation method – how the applicant intends to achieve the stipulated objectives and results (the clarification of the concept, preparation and the adequacy of the proposed methods);
    c. The results – the relevance of the overview of envisaged results, which will become the basis for the resolution of known or anticipated, current or future problems or opportunities;
    d. Foreign cooperation –the involvement of foreign workplaces in the implementation will be assessed; the mutual use of equipment of cooperating workplaces; the use of complementary approaches and methods;
    e. Accord with National priorities of oriented research, experimental development and innovations, approved by Government Resolution of 17 July 2012 No 552 – it will be assessed whether the proposal contributes to their achievement in the part of the oriented research, for example accord with the National strategy on rare diseases for 2010 to 2020.

The concrete procedure for the assessment of the proposals will be stipulated in the tender documentation for the individual Tenders in the Programme.

23. Interim assessment of implemented projects

The assessment of the course of the implementation of a project will be performed by the Provider annually on the basis of an assessment by expert advisory bodies (assessment panel and Scientific Council), and this on the basis of submitted component reports and results of the control activities of the Provider.

The Provider will assess the procedure for the implementation of a project pursuant to the following primary criteria:

- The working procedures and their accord with the fulfilment of the stipulated objectives;
- The securing of the implementation in terms of expertise and staffing;
- The use of technical and equipment facilities acquired from the project;
- The staffing, organisational and technical approach to building the new team;
- The achievement of the objectives of the solution compared to the plan stipulated in the project proposal, the assumptions for the total time and material completion of the tasks;
- An assessment of the management of the allocated funds to date, eventually the proposed budget for the next period (the drawing down of allocated funds, the efficacy

of their investment and maintenance of their composition, proper justification of any eventual shifts or changes);

- An assessment of the results broken down pursuant to the types defined in part 18 of the Programme.

The expert advisory bodies will prepare a written report about the results of the assessment, which they will submit to the Provider.

If the assumptions for the continuation of project aid are fulfilled and the Provider decides to continue supporting the project, the Provider will provide the beneficiary with financial funds for another year of project implementation.

If the assumptions for the continuation of project aid are not fulfilled, the Provider is entitled to withdraw from the agreement on the provision of aid or to issue a decision on the termination of aid.

During the interim assessment the fulfilment of the obligation to enter information into the R&D information system will also be assessed (pursuant to Section 31 of Act No 130/2002).

24. Assessment of project results (ex post):

The Scientific Council will perform an assessment of a completed project on the basis of an evaluation by the assessment panel, and this on the basis of the final report and result of the control activity relating to the management of funds.

The Provider will assess the final report and the approach taken during the implementation of the project pursuant to the following primary criteria:

- The fulfilment of the primary objective of the Programme;
- The working procedures and their accord with the fulfilment of the stipulated objectives;
- The securing of the implementation in terms of expertise and staffing;
- The use of the technical and equipment facilities acquired using the allocated funds;
- An assessment of the management of the allocated funds to date (the drawing down of allocated funds, the efficacy of their investment and maintenance of their composition);
- An assessment of the results broken down pursuant to the types defined in part 18 of the Programme. When assessing the results of projects emphasis will be placed not only on the publication of the results in respected magazines, but concurrently also on their use in practice.

In their overall assessment of a completed project the Scientific Council and assessment panel will also take into account compliance with the conditions for managing the allocated funds.

The expert advisory bodies will prepare a report about the result of the assessment of a completed project and will submit it to the Provider, which will discuss the proposed assessment and make its decision.

The implementation of a project is assessed in the following manner:

- **fulfilled** – the declared objectives of the project have been achieved. The applied results from the project and publication, and potentially other results are – in terms of number and potential reception or the possibility of use in the resolution of the problems named in the project – excellent or very good and significantly impact the development of the field and this in particular in an international context.
- **not fulfilled –** the published or otherwise applied results of the project (publication, potentially further results) are not – in terms of number and potential reception or the possibility of use in the resolution of the problems named in the project – excellent or very good and will probably not significantly impact the development of the field.

25. Envisaged parameters of the Programme

In relation to the focus of the Programme and from the experience from the previous programme supporting applied research from public funds, an average level of aid per project of CZK 8 100 000 (CZK 8 125 000) is expected, meaning average expenditure per project totalling CZK 9 000 000 (CZK 9 023 000). In view of the total budget of the Programme around 800 supported projects are anticipated, while cooperation in the Programme is expected by around 50 projects (meaning around 5%) implemented through cooperation between research organisations and companies. The Programme anticipates the involvement of around 900 entities in the implementation of supported projects.

26. Criteria for the fulfilment of Programme objectives

The achievement of the primary and other objectives of the Programme will be assessed in accordance with the Methodology for assessing the results of research organisations and assessing the results of completed programmes valid at the time of the assessment of the Programme, and potentially other conditions stipulated by the Provider, and further pursuant to the definitions for entering the results into the R&D information system valid at the time of the assessment of the Programme. The achievement of the objectives of the Programme will be assessed on the basis of a set of indicators intended for the monitoring the course of the fulfilment of the Programme and the assessment of its overall performance and success.

The indicators are placed into three categories according to their character, namely Programme implementation indicators, Programme results indicators and Programme objective achievement indicators.

Table No 3: Programme indicators

Indicator	Number
Programme implementation indicators	
Minimum number of total selected (supported) projects[7]	800
Minimum number of successfully completed projects, total	600
A minimum of 75% of projects will be successfully completed	
Programme results indicators	
Minimum number of primary Programme results	600
Minimum number of secondary Programme results	600
Minimum number of other Programme results	1 200
Minimum number of Programme results	**2 400**
Programme objective achievement indicators	
A minimum of 65% of the other Programme objectives will be achieved	

[7] The minimum number of selected projects depends on the financial funds released for the implementation of projects in the Programme according to the possibilities of the state budget.