

# Project Application Form

## Under the Recovery and Resilience Facility

### 1. Project name

**Establishment of a national register (database) for prevention and monitoring of oncological diseases**

### 2. Description of the project (objectives, main activities)

#### Primary objective:

Establishment of a national register (database) for prevention and monitoring of oncological diseases, analysis and prevention of risk factors and inclusion of Bulgaria in a pan-European cancer control centre.

#### Specific objectives:

- Establishment of a national register (database) with data on oncological patients and for conducted prophylactic examinations and screening tests;
- Integration of the national register to the NHIS;
- Conducting staff trainings.

Oncological diseases are the second leading cause of death in Bulgaria, as they are part of the socially significant diseases in the country, which is why the fight against them and the strive to reduce them are a top priority of the state and the Ministry of Health. According to the National Statistical Institute, in 2019 the total number of deaths in Bulgaria was a little over 108 thousand people, as according to the International Classification of Diseases - tenth revision, with the largest share of death are "IX Diseases of the circulatory system" - over 70,000 died, followed by "II. Malignant neoplasms" - over 17,000 dead. These data show that cancer deaths account for 16% of the total number of deaths in the country, as the next group of diseases leading to death in 2018 and 2019 - "X. Diseases of the respiratory system" - remains far behind with just under 5,000 dead. In order to fight the disease, in addition to modernizing the infrastructure and medical equipment, it is necessary to invest funds in additional activities related to better understanding of the disease, support for patients and their families, conducting information campaigns, including the promotion of risk factors and timely prevention, as well as the creation of a database on the current state of the population in the country in terms of cancer.

The establishment of a national register (database) of oncological diseases will allow monitoring the health status of all citizens with regard to oncological diseases and will greatly assist the health authorities in the country to prepare and implement the right policies for early detection of the disease, and provision of quality treatment and care for the sick and their families.

The purpose of the investment is the establishment of a national register (database) for oncological diseases, which will be integrated into the National Health Information System, facilitating the occurrence of a two-way exchange of information. The established register will include data from the patient file of all citizens of the country related to oncological diseases, in terms of conducted preventive examinations, results obtained from them, participation in screening programs. When diagnosing cancer, the information will include the treatment performed, the result, the medications used, etc. In addition, the register will analyze statistical information regarding age, gender, family history of cancer and more.

In addition to the direct benefits of having up-to-date and accurate information on the oncological status of the population in the country, the establishment of the national register will help for more accurate and precise forecasting and distribution of funds allocated by the state for prophylactic examinations, purchase of medication and others, for the diagnosis and treatment of cancer.

In accordance with the development of modern information technologies and artificial intelligence, the next step in the development of the National Register will be the introduction of "Machine learning", with the help of which it will be possible to make analyzes and forecasts regarding the risk of developing an oncological disease by a specific individual, including assessment of the possibilities for the best treatment and the chances for a favorable outcome from it, etc.

In view of the country's membership in the European Union and the identification of the fight against cancer as a top priority for all Member States, the establishment and development of the National Register will allow in a next stage its connection to similar databases of other countries and the exchange of information, the expansion of research and studies of solutions to combat cancer.

Last but not least, the development of the National Register is in line with the European Commission's Cancer Action

Program, according to which the lives of 3 million people with cancer must be saved in the EU member states by the end of 2030, by accelerating the development and implementation of cancer prevention and control programs and making these programs more accessible.

#### **Primary activities:**

#### **Activity 1: Establishment of National Register for Oncological Diseases**

##### **Sub-activity 1.1. Selection of contractors for the development of National Register for Oncological Diseases and for the provision of material and technical base**

In accordance with the requirements of the current legislation, for the selection of a contractor to develop, integrate and put into service the National Register for Oncological Diseases, public procurement will be organized under the Public Procurement Act. For this purpose, a working group will be established in the Ministry of Health, which will include experts with the necessary professional competence and experience, which will develop detailed technical specifications, requirements for participants, eligibility criteria, etc. The main requirement for the documentation, in addition to completeness and accuracy, will be to ensure maximum competition between stakeholders. In order to provide the necessary material and technical base, two more procedures will be organized and conducted under the Public Procurement Act - for selection of a contractor who will deliver the necessary hardware and for selection of a contractor to repair and furnish the premises in which the National Register for Oncological Diseases will be located. In this regard, separate working groups will be established, including experts from the Ministry of Health, with the necessary experience and professional competence, who will prepare the complete documentation for conducting the above-mentioned public procurements. The documentation will contain objective, clear and completely open to stakeholders parameters and requirements, in order to ensure competition and equal opportunities for participants.

Each procedure will last for up to 12 months, as follows:

- preparation of documentation - 3 months;
- deadline for submission of bids - 1 month;
- conducting public procurement - 8 months, including a deadline for possible appeal.

As a result of the implementation of sub-activity 1.1. three public procurements will be organized and conducted, as well as contracts will be concluded with the selected contractors.

##### **Sub-activity 1.2. Conducting business process analysis**

In order to correctly, completely, accurately and legally determine the level of information that will be collected, analyzed and evaluated, the implementation of sub-activity 1.2. is critical for the overall successful implementation of the project and the achievement of the set with objectives. For its implementation, the selected in sub-activity 1.1. contractor will conduct an analysis of business processes, which will include analysis of all available sources of information in the country, tracking the patient's path and stages of prophylactic examinations or screening campaigns, through evaluation of their results, diagnosis and treatment of proven diseases. An analysis of the current national and European legal framework will also be carried out, and if necessary, the contractor should prepare specific proposals for changes in the national legislation and regulations. The analysis will also include a detailed structure of the National Register for Oncological Diseases, all subjects that will be included in it, the levels of access of individual participants, etc. Sub-activity 1.2. will be fulfilled with the acceptance of the completed document by the Assignor or his representative.

##### **Sub-activity 1.3. Development of National Register for Oncological Diseases**

Sub-activity 1.3. will start running after completion of sub-activity 1.2. Based on the prepared framework of the National Register for Oncological Diseases, the Contractor will start the actual implementation of the activity. For its successful implementation, close communication will be established with the Assignor and a team of experts appointed by him. The Contractor will be obliged to provide information on the progress of the implementation, as well as data from the iterations. Prior to the acceptance of the finished product, the Contractor will provide a demo version to be checked and tested by the Assignor. The Contractor will also be obliged to load the register with all the information available to the Assignor, which is relevant to the subject of work of the register. After successful completion of all tests by the Contractor, a "no remarks" handover protocol will be signed, which will complete sub-activity 1.3.

##### **Sub-activity 1.4. Putting the National Register for Oncological Diseases into service and integrating it with NHIS**

Within sub-activity 1.4. the Contractor will install the developed register on the server and / or cloud space provided by the Assignor, will train the experts appointed by the Assignor to work with the register, will provide them with the appropriate access levels, and will integrate the developed Register with NHIS. For the successful implementation of sub-activity 1.4. and the completion of the integration, the Assignor will provide the necessary level of access to the NHIS, as well as will provide the necessary coordination between the Contractor and the entity that provides the technical support for the NHIS. The implementation of sub-activity 1.4. will start after acceptance of the completion of sub-activity 1.3.

##### **Sub-activity 1.5. Delivery and installation of hardware for the needs of the National Register for Oncological Diseases**

With the completion of sub-activity 1.5. the necessary hardware for the functioning of the national cancer registry will be provided. The implementation will start after the end of sub-activity 1.1. and selection of a contractor for delivery of the provided hardware. The selected contractor will deliver, install, test and put into service the delivered equipment, and will provide the necessary assistance in the installation and fine-tuning of the settings of the National Register for Oncological Diseases. Work on sub-activity 1.5. will start after the necessary construction and installation works on the premises where the National Register for Oncological diseases will be located are completed. To accept the completion of sub-activity 1.5. a bilateral acceptance-transfer protocol will be signed between the selected supplier and representatives of the Assignor.

**Sub-activity 1.6. Construction and installation work and purchase of equipment for the needs of the National Register for Oncological Diseases**

In order to ensure the necessary material and technical conditions for the functioning of the National Register for Oncological Diseases, premises owned by the state or the property of a medical institution with over 50% state participation in the capital will be determined. In order to create the necessary conditions for work and functioning of the National Register for Oncological Diseases, the premises and their equipment, including the furniture will be repaired. The implementation and completion of construction and installation work will ensure compliance of the premises with the requirements for the operation of the hardware purchased during the implementation of sub-activity 1.5. Sub-activity 1.6. will commence after completion of sub-activity 1.1.

**Activity 2: „Project management and implementation“**

For the realization of the project the Ministry of Health will put together a team of experts within the Ministry of Health, equipped with the necessary knowledge and skills in the field of information technology, project management and implementation, public procurement and construction. The main task of the team will be to ensure accurate, lawful and timely implementation and completion of activities, achieving the objectives and preventing illegal and / or inexpedient expenses. The necessary communication channels with the selected contractors will be provided and built, periodic working meetings with them will be organized and a necessary audit trail will be created for each action that will be implemented under the project. The management team of the Ministry of Health will provide and implement the necessary measures for information and communication. As a result of all this, a financial and technical dossier of the project will be created and maintained. The implementation of the activity will ensure quality, accurate and secure management, guaranteeing the expedient and lawful spending of European funds.

**3. Beneficiary**

Ministry of Health

**4. Time schedule for project Implementation, including activities, stages<sup>1</sup>**

Total time for project implementation - 36 months.

<sup>1</sup> The time schedule shall be relevant for determining interim targets within the framework of the Recovery and Resilience Plan and is directly related to the disbursement of grant instalments from the Recovery and Resilience Fund.

Activity:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	
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- Initial value - 0 pcs. [2021]
- End value - 115,000 pcs. [2024]

**7. Does the project require the opening of a procedure pursuant to the Public Procurement Act (PPA)?**

Yes.

**7.1. If a procedure under the Public Procurement Act is required, what part of the activities and financial resources will be subject of the public procurement?**

For the implementation of activity 1 it is envisaged to conduct a procedure under the Public Procurement Act (92.50%).

**7.2. If a procedure under the Public Procurement Act is required, what is the indicative schedule for its implementation?**

It is envisaged to conduct 3 public procurements for selection of contractors by conducting an open procedure under the PPA:

1. Development, installation, training and integration of National Register for Oncological Diseases;
2. Purchase of hardware for the needs of the National Register for Oncological Diseases;
3. Execution of construction and installation works for the needs of the National Register for Oncological Diseases.

Each procedure will last up to 12 months as follows:

- preparation of documentation - 3 months;
- deadline for submission of bids - 1 month;
- conducting public procurement - 8 months, including a deadline for possible appeal.

**8. Demarcation and complementarity**

**8.1. If similar projects have been implemented (regardless of their source of funding), describe how this project builds on/complements what has been achieved with previous projects.**

No similar projects have been implemented

**8.2. If similar projects are envisaged to be implemented under the Partnership Agreement programs, the centrally managed facilities of EU or the Just Transition Fund, outline the demarcation with this project.**

No similar projects are envisaged under the Partnership Agreement programs, the EU's centrally managed instruments or the Fair Transition Fund. At the same time, the Ministry of Health is developing a National Health Information System, which will be the backbone of information systems in the health sector. The NHIS will be the basis for the integration with all systems, serving the health and administrative processes, and through it will be provided an opportunity to achieve transparency in the management of financial costs, as well as the activities for organization, control, planning and forecasting in the health care system, an opportunity to assess the quality and safety of medical care. The establishment of the NHIS will ensure the existence of a unified environment for the exchange of medical information, will create a system for electronic medical records, electronic medical prescription, electronic medical practice, will provide centralized maintenance of controlled nomenclatures, classifications and terminology dictionaries, and conditions will be created for financial management and monitoring of healthcare expenditures.

In addition, the Ministry of Health, as a specific beneficiary, is implementing a major investment project BG16RFOP001-4.001-0001 "Support for the Development of Emergency Medical Care System", funded by the Operational Program "Regions in Growth" 2014 - 2020. The main goal of the project is to provide appropriate and efficient health infrastructure, contributing to the improvement of the quality and safety of medical care and to ensuring equal access to quality medical care in emergencies in accordance with the best European practices and requirements. The project provides the necessary investment for the renovation and modernization of this sector of primary health care in the country, and as a result of the implementation of the planned activities will provide equal health care to citizens, including to those in remote and inaccessible areas, and will help create the necessary conditions to increase the efficiency of the hospital sector with anticipated results, such as reducing hospitalizations and hospital stays by building a network of branches with possibilities for up to 24 hours of treatment, monitoring and diagnostics.

Under the Operational Program "Human Resources Development" 2014 - 2020, the Ministry of Health implements the project BG05M9OP001-3.007-0001 "Improving conditions for treatment of emergency", which provides support to employees in the system of emergency medical care for acquiring specific knowledge, skills, and key competencies, as well as the establishment of the National Centre for training and qualification in the system of emergency medical care. Through the center for the first time in the country, a consistent and purposeful policy is being ensured in the field of raising the qualification, knowledge and skills of medical specialists. The second project aimed at the development of human resources in the field of healthcare is project BG05M9OP001-1.015-0001 "Specialization in health". The project enables individuals who have started their training to acquire a specialty to continue and complete their training. Post-graduate doctors, post-graduate dentists, post-graduate nurses and midwives are supported.

The efforts of the Ministry of Health to support pre-hospital care continue in the upcoming new programming period, in which the main priorities for which funding will be sought are aimed at supporting the development of services provided by GPs and group practices (under Operational Program "Development of regions" 2021 - 2027 and to the implementation of measures for the improvement of the promotion and prevention (under the Operational Program "Human Resources Development" 2021 - 2027).

**9. Does the project directly contribute to the implementation of any of the Council's Specific Recommendations addressed to Bulgaria in the framework of the European Semester in the period 2017-2020? Please describe how.**

Regarding the recommendations of the Council addressed to Bulgaria in the framework of the European Semester in the period 2017-2020, the project proposal is aimed at strengthening the sustainability, accessibility, and capacity of the health system in the country. That is why the project proposal is aimed at creating an entirely new National Registry for Oncological diseases, which will provide an opportunity for an entirely new approach to fight with cancer, its early diagnosis and better and more successful treatment. This will be reflected in increasing the possibility of a favourable outcome of treatment, in increasing the survival rate of patients with cancer, as well as will assist institutions in organizing and implementing measures to reduce the risk factors that are a prerequisite for cancer. The implementation of the project will lead to optimization of expenses in the field of oncology at the national level. The successful implementation of the project will contribute to the implementation of the e-health strategy and to the efficiency increase of the health system.

**10. Does the project contribute to the implementation of a reform in a given sector? Please describe how.**

One of the key objectives set in the National Health Strategy 2020 to ensure an effectively functioning health system is the digitalization and integration of systems in the sector through the establishment of a National Health Information System (NHIS) and the development of e-health. The activities envisaged in the project will contribute to the construction and development of e-health in Bulgaria, which will reduce the time for patient care, facilitate access to modern and high-quality health services and optimize the strategic management of the health sector.

The implementation of the project will also contribute to the implementation of Policy 2.8. The National Health Strategy 2020 - "Ensuring the quality and safety of health care" and in terms of efficiency - treatment to be provided in the best way and to lead to the desired results and effectiveness - treatment leads to the desired results with minimal effort, expenses, and losses. According to Priority 4 "Strengthening the capacity of public health national concept" of the national concept "Goals for Health 2020", moving public health to the centre of health improvement requires investing in public health services and considering it as an investment in the long term health and welfare of the population as a whole.

**11. Does the project contribute to the development of any aspect of sustainable economic development? Please describe how.**

The project will contribute to the achievement of PRIORITY 36: "Overcoming regional imbalances and ensuring functional interaction between the different levels of medical care", Objective 124: "Improving access and improving the quality of medical care" - The Government Management Program of the Republic Bulgaria in the period 2017 – 2021.

The National Concept for Health Goals 2020 states that the good health of the population benefits all sectors and the whole society, which makes it a valuable resource. It is a basic prerequisite for economic and social development.

Oncological diseases are the second leading cause of death in Bulgaria, as they are part of the socially significant diseases in the country, which is why the fight against them and the strive to reduce them are a top priority of the state and the Ministry of Health. In addition to investing in the treatment of cancer patients, timely and accurate prevention is key. A significant percentage of newly registered illnesses are due to risks from everyday life, bad habits of people or family burden. All of them could be minimized by conducting a timely analysis of the risk of cancer for each person, according to the environment in which he or she lives and his or her genetic predisposition. This is where the National Register for Oncology Diseases comes in, the establishment of which is the purpose of this project proposal.

By increasing the health status of the population, the time span for temporary work disability of the fit-to-work population will be reduced, because of which the labour productivity and the gross domestic product of the country will increase.

The connection, which is discussed here between the realization of the planned investments and the expected results from them, will guarantee the achievement of sustainable economic development.

**12. Does the project contribute to the implementation of the objectives of the National Development Program BULGARIA 2030? Please describe how.**

The implementation of the planned activities will contribute to the achievement of Priority 12 "Health and Sports", which aims to improve the health characteristics of the population in the country. In this sense, the project activities will contribute to the implementation of Objective 3 "Ensure healthy lives and promote well-being for all at all ages" of the UN Sustainable Development Goals.

**13. Does the project contribute to the implementation of the objectives and priorities set out in the National Integrated Energy and Climate Plan? If yes, please describe how.**

Within Activity 1, activities related to the construction and installation work are set, which will include measures to improve the energy efficiency of the building stock, where the National Registry for Oncology Diseases will be located. This will save energy and reduce harmful emissions into the air.