Approved by The Order No V-228 of the Chairman of the Research Council of Lithuania of 3 June 2026

IMPACT-DRIVEN PROGRAMME "PERSONALISED MEDICINE FOR LONGER LIFE EXPECTANCY AND BETTER QUALITY OF LIFE"

CHAPTER I
GENERAL PROVISIONS

1. The impact-driven programme "Personalised Medicine for Longer Life Expectancy and Better Quality of Life" (hereinafter referred to as the Programme) is intended to create a sustainable ecosystem of scientific and practical competences in personalised medicine in Lithuania by developing interdisciplinary, large-scale, and high-level international research and experimental development (R&D) activities that strengthen the country's personalised medicine infrastructures and resources, increase the accessibility of personalised medicine innovations, improve quality of life and extend life expectancy, enhance the competences of specialists in healthcare, life sciences, and other fields, and increase patient involvement and public awareness.

2. Personalised medicine is an individualised model of disease control based on knowledge of an individual's genotype and phenotype, as well as the molecular profile of the disease, which has led to significant breakthroughs in the early diagnosis and treatment of complex diseases such as cancer, diabetes mellitus, cardiovascular diseases, neurodegenerative diseases, rare diseases, and others, as well as in the development of effective measures for disease prevention and healthy lifestyles. The development of personalised medicine has been enabled by advances in DNA and RNA sequencing, gene editing and cell therapy technologies, the digitisation and reuse of health data, and the collection of clinical data and samples in biobanks. In Europe, the personalised medicine ecosystem is growing rapidly, delivering significant benefits to society through a reduced burden of disease, improved quality of life, and longer life expectancy.

2.1. Personalised medicine is based on the following key principles:

1) precise (precision) disease diagnostics and personalised treatment, while giving priority to disease prevention;

2) team-based health decision-making grounded in multidisciplinary competences, with the active participation of the patient;

3) sustainable and growing data and biological resource infrastructure that promotes scientific innovation, as well as the smooth translation of scientific innovations into practice;

4) inter-institutional, interdisciplinary, intersectoral and international cooperation in the development and application of personalised medicine innovations.

2.2. ''The feasibility study on the development of personalised medicine in Lithuania'' carried out by STRATA showed that Lithuania has already established the necessary preconditions (infrastructure, competences, and legal framework) for a significant breakthrough in the field of personalised medicine; however, targeted investment is needed in research and innovation in this

field, in strengthening the competences of specialists in healthcare, life sciences and other areas, and in public education.

3. The Programme directly contributes to:

3.1. the implementation of the State Future Vision "Lithuania 2050" and the progress strategy "Lithuania's Progress Strategy "Lithuania 2030", which highlights the need to develop personalized medicine in Lithuania, as well as the implementation of the Programme of the Eighteenth Government of the Republic of Lithuania and its implementation plan, which emphasises the application of personalised medicine technologies at all stages of personal healthcare services;

3.2. The implementation of the European Union (EU) Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU), the Council Conclusions on personalised medicine for patients (2015/C 421/03), the EU Regulation on the European Health Data Space (EHDS; 2025/327), the Artificial Intelligence Act (2020/1828), Europe's Beating Cancer Plan, and the EU Mission "Cancer";

3.3. Preparations for the implementation of the European Commission's Life Sciences Strategy and the Biotech Act, by developing the EU life sciences and health infrastructure and creating an ecosystem for research and innovation in cancer, rare and low-prevalence diseases (European Commission political guidelines 2024–2029).

4. The Programme aims to:

4.1. promote top-level research and experimental development in personalised medicine by ensuring inter-institutional, interdisciplinary, intersectoral and international cooperation, as well as the efficient use of existing infrastructure and resources;

4.2. accelerate the practical application of personalised medicine innovations by creating a sustainable, innovation-oriented national personalised medicine ecosystem bringing together research and higher education institutions (hereinafter – RHEIs), university hospitals and other healthcare institutions, the private sector, support and charitable foundations, and non-governmental organisations representing patients' interests (hereinafter – Patient Organisations);

4.3. based on the principles of open and transparent science, create new and activate existing large-scale research and health data sets, as well as biobank resources, for the rapid development of personalised medicine innovations;

4.4. create favourable conditions for the development of innovative preclinical and clinical personalised medicine research, based on good laboratory and clinical practice and initiated by academic groups or researchers, with clear potential to improve quality of life and life expectancy;

4.5. promote talent attraction and the formation of scientific groups of the highest international level in the field of personalised medicine, while improving the commercialisation and practical application of scientific innovations;

4.6. create the preconditions for the effective application of personalised medicine innovations in disease prevention, diagnosis and treatment, as well as for the development of the foundations of a healthy lifestyle in society;

4.7. ensure the dissemination of information on scientific achievements and innovations in personalised medicine, the education of specialists and the public, the provision of science-based information for the preparation of strategic personalised medicine documents, and close intersectoral cooperation.

CHAPTER II
OBJECTIVE, TASKS AND IMPLEMENTATION MEASURES OF THE PROGRAMME

5. The objective of the Programme is to develop interdisciplinary, large-scale, and high-level international R&D activities that help achieve a major breakthrough in the field of personalised medicine in Lithuania, and to create and implement innovations in practice that improve the accessibility of personalised medicine tools, as well as the quality and length of life of society.

6. The tasks of the Programme are:

6.1. to carry out comprehensive research into the causes and mechanisms of diseases for the personalisation of disease prevention and diagnostics, as well as for the development of healthy lifestyle foundations based on the principles of personalised medicine;

6.2. to develop and implement innovative personalised disease treatment and monitoring technologies and measures that improve treatment effectiveness and patients' quality of life.

7. In implementing the first task of the Programme, R&D activities will be carried out in the following and related thematic areas:

7.1. comprehensive studies (genomics, proteomics, metabolomics, pharmacogenomics, radiogenomics, metagenomics, etc.) for elucidating the causes of diseases and mechanisms of pathogenesis;

7.2. multidisciplinary studies of interactions between external and internal risk factors (environmental, behavioural, genetic, epigenetic, biochemical, immunological, etc.);

7.3. comprehensive studies (genomics, proteomics, metabolomics, pharmacogenomics, radiogenomics, metagenomics, etc.) for disease prevention, precision diagnostics and monitoring;

7.4. next-generation personalised medicine biomarkers or biomarker panels, new diagnostic methods and technologies for identifying inherited and/or somatic genomic changes;

7.5. new personalised medicine methods, technologies, devices and (or) equipment: advanced therapy medicinal products, gene-editing technologies, ultra-fast laboratory diagnostic methodologies, artificial intelligence interpretation technologies, etc.;

7.6. non-invasive precision diagnostics: liquid biopsy, digital biopsy, digital pathology, radiogenomics, digital twins, smart devices, etc.;

7.7. new artificial intelligence methods for personalised medicine solutions integrating various types of data, including synthetic data, while ensuring the explainability of decisions.

8. In implementing the second task of the Programme, R&D activities will be carried out in the following and related thematic areas:

8.1. advanced therapy methods, technologies and/or measures for personalised disease treatment: gene therapy, cell therapy, therapy using live biopharmaceutical products and their metabolites, immunotherapy, gene editing, theranostics, etc.;

8.2. collection, preparation and scientific research and/or application of real-world clinical big data sets (genomic, pharmacogenomic, imaging, clinical, etc.) to improve treatment effectiveness and safety and to control adverse effects;

8.3. development and testing of simulation platforms enabling the modelling of different research scenarios based on the physiological, biological and clinical data of participants;

8.4. development and application of new adaptive clinical trial designs and/or models to increase treatment effectiveness and safety;

8.5. preclinical and/or clinical validation and integration into practice of personalised medicine innovations (technologies, devices, medicines, biomarkers, etc.);

8.6. early-phase (I–II) clinical trials of advanced therapy medicinal products, products, measures, and other personalised medicine clinical trials initiated by academic groups or researchers.

9. If, in implementing the first or second task of the Programme, the R&D activities include an early-phase (I–II) clinical trial of a medicinal product initiated by academic groups or researchers, the application shall take into account Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC. The clinical trial shall be implemented in accordance with the Law on Ethics of Biomedical Research of the Republic of Lithuania and other legal acts regulating the conduct of clinical trials.

10. The thematic areas of the Programme's R&D activities specified in paragraphs 7–8 of the Programme are preliminary and may be adjusted as needed when calls for proposals are announced for the implementation of the Programme's tasks.

11. The Programme is funded from:

11.1. appropriations from the State budget of the Republic of Lithuania allocated to the Research Council of Lithuania (RCL) and/or other funding sources managed by the RCL;

11.2. appropriations from the State budget of the Republic of Lithuania allocated to ministries of the Republic of Lithuania and/or other state institutions, and/or other funding sources managed by those ministries or other state institutions.

12. In implementing the Programme, funding may be provided for:

12.1. R&D activities in the field of personalised medicine;

12.2. acquisition of personalised medicine resources (biobank sample collections, health data packages, etc.);

12.3. big data analytics and bioinformatics services, as well as the development and licensing of software and analytical tools;

12.4. traineeships of project implementers in foreign scientific, healthcare or business institutions;

12.5. traineeships of foreign researchers in the institutions of project implementers related to the implementation of the Programme's activities;

12.6. costs of conducting preclinical and clinical trials;

12.7. patenting and publication of research results, as well as other dissemination costs related to activities and results;

12.8. other R&D activities related to the implementation of the Programme.

13. When allocating funding, priority shall be given to projects whose R&D activities:

13.1. use health and other health-related big data sets, biobank resources, open-access databases, artificial intelligence tools and/or other personalised medicine infrastructures and measures, thereby promoting inter-institutional, interdisciplinary, intersectoral and international cooperation;

13.2. create and transfer personalised medicine innovations into practice through the conduct of preclinical and clinical trials, thereby increasing the accessibility of personalised medicine innovations to patients and society and strengthening partnerships among participants in the personalised medicine ecosystem (research and higher education institutions, university hospitals and other healthcare institutions, private sector companies, charitable and support foundations, and Patient Organisations);

13.3. provide for the participation of Patient Organisations in the planning, implementation and dissemination of the results of clinical trials initiated by academic groups or researchers.

14. The main evaluation criteria for project proposals under the Programme are:

14.1. the novelty of the scientific research, the relevance of the problem addressed to the state and/or society, and the prospects for application in creating advanced, transformative personalised medicine innovations;

14.2. the feasibility of the project: the timetable of activities, planned results, suitability of methods and measures, the composition and competences of the implementing team, possible risks in implementing the project and the plan for their management;

14.3. the expected impact of the project results: the potential for practical application of R&D results, the significance of the increase in the technological readiness level of the R&D innovation, the phase and scope of the clinical trial, dissemination of the project results, and the spread of knowledge on personalised medicine;

14.4. the integration of science and practice: enhancement of the competences of project implementers, the number of patients participating in the research, or the use of biobanks and health data resources.

CHAPTER III
EXPECTED RESULTS AND POSSIBILITIES FOR THEIR USE

15. It is expected that during the implementation period of the Programme and upon its completion, the following results will be achieved (specific target indicators are provided in Chapter IV of the Programme):

15.1. the number of personalised medicine innovations created in Lithuania and their application in disease prevention, diagnostics and treatment will increase;

15.2. the number of preclinical and clinical trials initiated by national researchers and based on the principles of personalised medicine will increase;

15.3. the reuse and utilisation of health data, biobanks, and other personalised medicine resources and infrastructures will improve and increase;

15.4. the number of researchers working in the field of personalised medicine science and application will increase, their competence level will rise, and public health literacy will improve;

15.5. a sustainable national personalised medicine ecosystem will take shape; inter-institutional, interdisciplinary, intersectoral and international cooperation in the field of personalised medicine will improve.

CHAPTER IV
MAIN TARGET INDICATORS AND EVALUATION CRITERIA

16. The evaluation criteria for the implementation of the Programme are:

16.1. personalised medicine innovations created, tested and implemented;

16.2. patients involved in the Programme’s R&D activities;

16.3. biobank samples, clinical data sets and open-access resources used;

16.4. inter-institutional, interdisciplinary, intersectoral and international cooperation activities carried out;

16.5. dissemination of the Programme’s activities and results carried out (scientific articles published in journals that fall within the first or second quartile (Q1–Q2) of at least one subject category in the SCIE (Science Citation Index Expanded) collection of the Clarivate Analytics Web

of Science database according to the Journal Impact Factor, presentations at international conferences, science communication tools, and media reports);

16.6. traineeships carried out and participation in professional development events.

17. The main target indicators for the implementation of the Programme, under the conditions specified in paragraph 18 of the Programme, are:

17.1. funded research projects prepared on the basis of inter-institutional, interdisciplinary, intersectoral and/or international cooperation – no fewer than 20 projects;

17.2. implemented personalised medicine innovations: no fewer than 15 documents, consisting of clinical application recommendations and/or updated clinical protocols, prepared and approved in accordance with the internal procedures of a university hospital;

17.3. initiated preclinical and/or clinical trials – no fewer than 5 trials;

17.4. number of patients participating in clinical trials – no fewer than 100 patients;

17.5. official requests submitted to the responsible institutions regarding the reuse of health data sets, open data resources or biobank samples – no fewer than 10 requests;

17.6. high-level international publications (see paragraph 16.5 of the Programme) published or accepted for publication, or patent applications submitted – no fewer than 40 units;

17.7. presentations delivered at international scientific conferences and other scientific events – no fewer than 40 units;

17.8. media reports prepared, dissemination events and training sessions organised – no fewer than 20 units.

CHAPTER V
FINAL PROVISIONS

18. The implementation period of the Programme is 2026–2030. Approximately EUR 20 million is planned to be allocated for the implementation of the Programme.