Zavod Republike Slovenije
za transfuzijsko medicino
Slovenian Institute for Transfusion Medicine

SLOVENIAN INSTITUTE FOR TRANSFUSION MEDICINE

ZAVOD REPUBLIKE SLOVENIJE ZA TRANSFUZIJSKO MEDICINO

SELF-EVALUATION REPORT

SAMOEVALVACIJSKO POROČILO

according to Article 31 of the Act on Scientific Research and Innovation Activities (ZZrID)

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Ljubljana, May 2026

DATA OF THE STABLE FINANCING RECIPIENT

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Content

1. INTRODUCTION- PRESENTATION OF THE RESEARCH ORGANIZATION

Slovenian Institute for Transfusion Medicine (Zavod Republike Slovenije za transfuzijsko medicino; ZTM) operates as the central national institution in the field of transfusion medicine, based in Ljubljana, with a network of six blood transfusion centers across Slovenia. Approximately 350 professionals are employed at ZTM, whose fundamental mission is to ensure a safe and high-quality supply of blood and to implement the national program for blood-derived medicines for patients. The institute's activities encompass four key areas: blood donation, diagnostic services, therapeutic services, and blood-derived medicines. ZTM conducts extensive blood donation activities, receiving more than 60,000 blood donors annually and organizing around 250 field blood donation campaigns, which provide about 70% of all blood collected in Slovenia. Special attention is given to the health and safety of blood donors and preventive activities, such as epidemiological monitoring, monitoring of new pathogenic agents, and conducting regular health check-ups. As the National Laboratory for Tissue Compatibility, ZTM supports the transplantation of hematopoietic stem cells and organ and tissue transplants. The institute also manages the register of unrelated hematopoietic stem cell donors Slovenia-Donor, which is part of the international WMDA network. Key activities of ZTM include modern molecular-biological diagnostic methods and the implementation of the national program for targeted protection with IgG anti-D in D-negative pregnant women. The therapeutic services significantly support transplantation activities and treatment with advanced medicines. The institute collaborates in the development of advanced therapies in the fields of hematology, oncology, cardiology, orthopedics, and dermatology, and collects and stores hematopoietic stem cells for therapeutic purposes. Annually, it performs more than 4,000 therapeutic blood collections. ZTM also coordinates and professionally implements the national program for the preparation of blood-derived medicines obtained from Slovenian plasma. In doing so, it ensures reliable national supply of strategically important therapeutic products and high standards of quality, safety, and traceability of all procedures related to their preparation and use. With professional support to healthcare institutions, it contributes to the safe and effective clinical use of blood-derived medicines.

A significant part of ZTM's operations is research activity with a long-standing tradition. The institute is registered as a research organization in the ARIS database under code 0311, with 50 registered researchers involved in research work. From 2020 to 2025, ZTM published 421 professional and scientific contributions, including 94 original scientific articles. It actively collaborates with domestic and international research and academic institutions, including the Faculty of Medicine at the University of Ljubljana, the Biotechnical Faculty at the University of Ljubljana, the Faculty of Pharmacy at the University of Ljubljana, the Faculty of Chemistry and Chemical Technology at the University of Ljubljana, the Jožef Stefan Institute, the National Institute of Chemistry, the University Medical Centre Ljubljana, the Institute of Oncology Ljubljana, and the University of Primorska. Research activity significantly contributes to the development of new diagnostic methods, improving blood quality control, and enhancing the safety of transfusion and transplantation treatments. Since 2020, ZTM has participated in 13 ARIS research projects and in 3 ARIS research and infrastructure programmes. The strategic goals of the institute are focused on strengthening research excellence, developing innovative solutions, and effectively transferring knowledge into clinical practice, while

striving to increase national and international research funding and actively engaging in research partnerships.

Special attention is given to the development of personnel and the creation of a supportive research environment. ZTM supports the professional and career development of researchers, encourages the publication of high-quality scientific works, and their active participation in domestic and international professional meetings. The institute's experts also serve as reviewers and members of editorial boards for professional and scientific journals both domestically and abroad. As part of the promotion of science and knowledge transfer, ZTM organizes numerous professional and scientific events, including symposia and congresses of the Slovenian Immunological Society, professional meetings in the field of transfusion medicine, and the ZTM Research Day.

A significant part of ZTM's mission also includes educational and mentoring work. The institute pays special attention to mentoring students, training young researchers, and participating in postgraduate education. The research group consists of four full professors, and ZTM conducts lectures in the field of transfusion medicine and diagnostic methods, as well as providing clinical practice for students from eight faculties. Each year, more than 1,000 individuals participate in educational programs. ZTM is authorized to conduct specialization in transfusion medicine and specific parts of specializations in the fields of surgery, hematology, gynecology and obstetrics, pediatrics, traumatology, and other medical disciplines. In addition, it offers internships for healthcare professionals, a residency for doctors, a postgraduate school of transfusion medicine, and a transfusion school for healthcare workers and collaborators.

ZTM closely collaborates with various faculties of the University of Ljubljana and other higher education institutions in implementing undergraduate and postgraduate study programs. It cooperates with the Faculty of Pharmacy of the University of Ljubljana in laboratory biomedicine programs, the Biotechnical Faculty of the University of Ljubljana offers a course in Therapeutic Biotechnology, and the Faculty of Medicine of the University of Ljubljana collaborates on the course Blood and the doctoral program in Biomedicine. Additionally, it participates in nursing programs and training for master's degrees in pharmacy within specializations in clinical pharmacy and drug testing.

2. PRESENTATION OF THE SELF-EVALUATION APPROACH

With the implementation of the Act on Scientific Research and Innovation Activities (ZZrID) on January 1, 2022, the model for financing scientific research activities has changed, based on three pillars: institutional, programmatic, and developmental. The institutional pillar includes funds for management (ISF-U) and research infrastructure (ISF-I), while the programmatic pillar finances research programs and training for young researchers. In September 2022, ZTM adopted the Regulation on Stable Financing of Scientific Research Activities, which defines the manner of implementing and monitoring research activities within the new financing system.

Self-evaluation for the contractual period 2022–2027 is conducted to systematically monitor the quality, effectiveness, and developmental orientation of research activities at ZTM and to track the achievement of stable financing goals. The funds from stable financing at ZTM are used in accordance with the ZTM Strategy and directed towards the development of research excellence, strengthening

research infrastructure, and transferring knowledge into practice. The self-evaluation process encompasses key areas of research activity, with effectiveness assessed based on scientific publications, personnel development, mentoring, training of young researchers, knowledge transfer, and involvement in national and international research projects and professional meetings. Based on this, the goals of stable financing, corresponding measures, and performance indicators are established.

The long-term goals of ZTM's research activities are focused on acquiring new knowledge and its application in healthcare practice, particularly in the development of laboratory tests and services, preparation of cells for treatment, and further research and educational work. Stable financing also significantly contributes to the training of scientific personnel, development of research competencies, and promotion of scientific careers. The acquired knowledge serves as a foundation for the development of research infrastructure and more effective connections with other research groups and professional fields.The effectiveness of ZTM's research activities is also monitored through the number of completed bachelor's, master's, and doctoral theses, scientific publications, active participation in conferences, knowledge transfer into practice, and achieving concrete developmental results, such as the introduction of new services, diagnostic methods, or products. At the end of the five-year contractual period, the research achievements will be comprehensively presented in a joint evaluation report.

The self-evaluation of research activities is carried out by an internal working group composed of full professors from ZTM, the medical director, and researchers from ZTM. The process is coordinated and led by the Service for Research and Development Activities of ZTM. Monitoring the achievement of scientific research activity goals occurs annually through annual reports collected and stored by the Research and Development Office (RD Office). Data for preparing reports are gathered from internal records, bibliographic databases, project documentation, and other reports, utilizing both quantitative indicators and descriptive analyses of results. Self-evaluation of scientific research work at ZTM is designed as a critical and continuous process of assessing scientific excellence and the societal impact of research activities. Its purpose is to identify strengths, limitations, and development opportunities, and based on this, to formulate measures for improving the quality and effectiveness of research work. Self-evaluation is understood as a tool for strategic guidance and continuous improvement of scientific research activities.

3. SELF-EVALUATION OF RESEARCH ACTIVITIES

3.1. Scientific excellence

The National Institute of Chemistry has implemented the national research programme P4-0176 Synthetic Biology and Immunology in collaboration with ZTM since 2004. Since 2022, the programme has been funded through stable financing of scientific research activities at both institutions. Within the programme, ZTM developed original monoclonal antibodies against several biological targets linked to disease development using hybridoma technology. These antibodies are unique tools for research, diagnostics, and therapy.

Through international collaboration, the programme contributed to advances in understanding neurodegenerative diseases. Results published in Acta Neuropathologica (Song, F., et al., 2024, open access) were the first to demonstrate the natural proteolytic cleavage (“shedding”) of the prion

protein by the metalloprotease ADAM10 in humans. In healthy individuals, the cleaved protein is evenly distributed in the extracellular matrix, whereas in neurodegenerative diseases it becomes part of amyloid aggregates. The research followed good laboratory practice and ethical standards, ensuring reliable and reproducible results. ZTM contributed key monoclonal antibodies, expertise, and co-authorship with shared first and last authorship. The significance of the discovery was further confirmed by an invitation to prepare a perspective article in Neural Regeneration Research (Song, F., et al., 2026, open access).

Within P4-0176, two biomedical platforms were developed. The first enables preparation of human antibodies from single B cells isolated from peripheral blood of immunized donors, while the second focuses on monoclonal antibodies against membrane proteins. Because published methods for preparing fully human monoclonal antibodies lacked reproducibility, we established our own platform using a hepatitis B virus model, enabling reproducible preparation of recombinant human monoclonal antibodies from single peripheral blood cells of vaccinated donors. Results were published in the Journal of Immunological Methods (Omejec, S., et al., 2024). Using a BCMA protein model, we also developed and validated methods for selecting antibodies that bind live cells. Partial results were published in the Journal of Immunological Methods (Kern, P., et al., 2026). Both platforms support development of new diagnostic and therapeutic approaches, including cancer immunotherapy tools such as CAR-T cells.

As part of the development pillar of stable funding, we upgraded the pilot biobank of blood samples from healthy donors established within the Interreg ITA-SLO Cross-Border Platform for Effective Biobank Management (C3B) project. Permission was obtained from the National Medical Ethics Committee of the Republic of Slovenia to establish a national biobank containing samples from 10,000 healthy donors. The biobank represents important infrastructure for high-quality and reproducible research and contributes to the strategic goals of ZTM.

The self-evaluation highlights key strengths of the programme P4-0176, including originality of research tools, successful international collaboration, methodological advances through two research platforms, implementation of open science principles, and establishment of the biobank as strategic research infrastructure.

At the same time, the self-evaluation identifies important limitations. Limited research capacity (2.47 FTE) restricts the scope of research activities and reduces the ability to conduct several complex research directions simultaneously. Dependence on international partners increases organizational complexity and the influence of external factors on implementation. Additional systemic challenges include insufficient regulation of biobanking in Slovenia and unresolved regulation of scientific research within healthcare. To address these limitations, the following measures are proposed:

- Continued strengthening of international collaborations, particularly in neurodegeneration and oncology.
- Expansion and rejuvenation of research staff, especially early-career researchers.
- Advocacy for national biobanking legislation to ensure sustainable operation of the biobank.
- Transfer of research results into practice, including development of diagnostic tools and novel therapies.

3.2. Societal impact

The social impact of the research and development activities of ZTM stems from its unique role in the Slovenian healthcare system. As a national institution in the field of transfusion medicine, ZTM ensures safe, high-quality, and effective supply of blood, cells, tissues, blood-derived medicines, and advanced therapy medicines. The ZTM Strategy 2023–2030 links this role to national self-sufficiency, the development of therapeutic and diagnostic activities, and the values of safety, quality, professionalism, collaboration, responsibility, and transparency.

The social impact of ZTM is therefore not limited to scientific publications but primarily focuses on the transfer of research knowledge into healthcare practice, diagnostic procedures, clinical support, the development of cellular therapies, and the shaping of the professional and regulatory environment in the fields of transfusion, transplantation, and advanced therapeutic medicine. This approach aligns with the definition of social impact within the framework of the institutional self-evaluation ARIS, which emphasizes the demonstrable contribution of research to improvements in healthcare, society, technology, and practice.

Strategic positioning of social impact

Social impact is positioned among the key development directions of the ZTM strategy. Among the strategic goals, influential scientific research achievements that can be transferred to practice and education, an excellent quality and safety system for donors, recipients, and employees, and the development of modern transfusion medicine with complex diagnostics, cell and tissue supply, and the production of drugs for advanced treatments are particularly highlighted.

Initiatives for establishing a unified national transfusion service, developing a plasma collection program with plasmapheresis, optimizing diagnostic activities, developing therapeutic activities with drugs for advanced treatment, international networking, and collaboration in shaping health policy are also important.

The main areas of social impact

The most important area of social impact for ZTM is the contribution to the safety and quality of blood supply, blood components, cells, tissues, and blood-derived medicines. Research and development activities directly support the safety of donors and recipients, laboratory diagnostics, risk management for infection transmission, optimization of apheresis procedures, and support for complex clinical treatments.

Annual reports indicate that internal projects during the period 2022–2025 were focused on issues with direct applicability to transfusion and clinical practice. Among the more significant projects were the determination of ferritin in blood donors, pathogenic inactivation of plasma, next-generation sequencing for transplant diagnostics, determination of biological markers for GvHD, development of sterility tests for umbilical cord tissue, monitoring HBV and HEV in blood donors, development of laboratory procedures for extracellular vesicles, optimization of apheresis procedures, and the introduction of advanced HLA typing and erythrocyte sequencing methods.

The second important area of impact is support for transplant medicine, perinatology, immunohematology, and clinical diagnostics. Projects in the fields of HLA, anti-HLA, and anti-HPA-1a antibodies, RhD, and monitoring patients after organ transplantation directly contribute to more individualized and safer treatment of patients, pregnant women, and newborns.

The third area represents the development of cell therapies, tissue preparations, biobanking, and drugs for advanced treatment. ZTM has participated in projects in the fields of MSC, extracellular

vesicles, CAR-T therapy, cancer cell immunotherapy, and the development of advanced cellular medicines. Internal projects further supported the preparation of MSC for clinical research, the development of tumor vaccines, and the production of tumor-infiltrating lymphocytes. This area has significant social importance as it enables the development of public health-relevant advanced therapies in Slovenia and reduces dependence on expensive commercial solutions.

The fourth area of impact is the strengthening of research, development, and educational culture in the field of transfusion and transplant medicine. ZTM conducts mentorship for young researchers, doctoral students, and undergraduate and master's theses, and maintains stable scientific production with original and review articles and extensive conference activities.

Knowledge transfer mechanisms

ZTM implements knowledge transfer to the social and clinical environment through development projects, the introduction of new methods, optimization of procedures, clinical studies, and collaboration with hospitals and research partners. An important mechanism is internal research and development projects that transform needs from routine practice into structured development questions. Projects are often designed at the intersection of laboratory diagnostics, clinical needs, quality, and safety. For the application of internal projects, ZTM has a standardized form that includes elements of planning for social or clinical impact. The applicant must define the connection of the project to the ZTM Strategy, the possibility of translation into medical practice, the impact on the education of personnel, and the professional relevance of the project. It is also important to define the expected use of the results in everyday practice.

In the period from 2022 to 2024, ZTM established several elements of systematic management of research and development activities, including regulations, a committee for monitoring research programs, SOPs for implementing internal projects, and performance indicators for projects. Important mechanisms of social impact also include quality and accreditation systems, such as ISO 9001, JACIE, EFI, and ISO 15189, which ensure traceability, validation of methods, and quality control in the transfer of research results into practice.

Assessment of performance and far-reaching impact

ZTM assesses that the social impact of research and development activities is particularly high at the national level, as the results are directly linked to the tasks of public health infrastructure. The impact is reflected in supporting safe blood supply, transplantation and perinatal programs, development of diagnostic methods, introduction of modern technologies, and development of cellular therapies.
The far-reaching impact is especially important in strategic self-sufficiency, development of advanced therapies, and laboratory and data infrastructure, including biobanking, HLA, and molecular diagnostics. In this way, ZTM strengthens Slovenia's professional autonomy in strategically important areas of the health system.

Critical self-reflection

Despite numerous examples of the direct applicability of ZTM's research and development work, it finds that the social impact has not always been systematically recorded in the form required by institutional evaluation. A large part of the impact is documented in SOPs, validation reports, laboratory introductions, and routine quality indicators, but less so as a distinctly defined case of social impact with a clear research basis and evidence of knowledge transfer.

The existing system does include planning for the usability of projects, but it should more consistently monitor whether the anticipated translation is actually realized after the project is

completed. There needs to be a clearer distinction between the expected impact at the time of project application and the achieved impact after completion, as well as between scientific excellence, professional activity, and actual social impact. Publications, lectures, and mentorships alone are not sufficient evidence of social impact if they are not linked to demonstrable changes in practice or benefits for users.

Planned measures to strengthen social impact

In the future, ZTM will strengthen systematic planning, monitoring, and documentation of the social impact of research and development activities. When applying for internal projects, the anticipated social or clinical impact will be further defined, and in final reporting, it will be monitored whether the project led to the introduction of a method, optimization of a process, support for clinical decision-making, regulatory documentation, or other demonstrable knowledge transfer.

A clearer record of social impact will be established, linking research projects, introduced methods, validation reports, clinical applications, and external evidence from users. Special emphasis will be placed on collecting evidence from clinical partners and incorporating results into guidelines, regulatory documents, and other external sources.

At a strategic level, the ZTM will continue to build its social impact in areas where it has the greatest national responsibility and development potential: blood safety and self-sufficiency, plasmapheresis programs, modern diagnostics, biobanking, cellular therapies, and advanced treatment drugs. Thus, the research and development activities will be even more closely linked to ZTM's goal of remaining a national, public, efficient, and technologically advanced institution of transfusion medicine.

4. QUALITY OF THE INSTITUTIONAL RESEARCH ENVIRONMENT

4.1. Strategic management

ZTM represents the central national institution in the field of blood supply, providing diagnostic and therapeutic services, and developing innovative approaches in transfusion medicine. Through research work, the development of new diagnostic and therapeutic procedures, and advanced information solutions, we significantly contribute to improving the safety of transfusion treatment, supporting transplantation activities, and comprehensively monitoring the health of blood donors and patients. In our work, we develop our own methods and professional approaches tailored to the specific needs of the Slovenian healthcare system. The operation of ZTM has a distinct national significance, which is also defined by legislation. We prepare and formulate professional guidelines in the field of transfusion medicine for the entire Slovenia, manage national registers, operate as a reference laboratory, and perform diagnostic procedures and therapeutic services that are exclusively provided by ZTM in Slovenia. A significant part of our activities also includes international cooperation in the fields of transfusion medicine, cellular therapies, and advanced forms of treatment, while simultaneously strengthening the strategic independence of the country in the supply of blood, tissues, and cells. Research and development activities are closely linked to the transfer of scientific knowledge into the education of students, employees, and other professional stakeholders.

In addition to professional, research, and development activities, ZTM is also an important educational center. We conduct undergraduate, postgraduate, and specialist education, internships for nurses, health technicians, and laboratory medicine engineers, as well as professional training for

healthcare workers and collaborators. This ensures a systematic transfer of knowledge, the development of new generations of professionals, and a close connection between clinical practice, research, and education.

Due to its professional, research, development, and educational activities, as well as its strategic importance for the healthcare system of the Republic of Slovenia, ZTM represents an indispensable part of the Slovenian healthcare and research infrastructure. The effects of research work are evaluated through the achievement of practical goals and broader social impact. This includes the development of new services or products of ZTM, successfully completed doctoral theses, publications in scientific journals, active participation in conferences, and their organization or co-organization. Important indicators also include the transfer of knowledge into practice, involvement in national and international associations, collaboration with domestic and foreign research groups, and the organization of professional events.

During the period of stable financing from 2022 to 2027, ZTM participates in the implementation of the research programme P4-0176 "Synthetic Biology and Immunology." The ISF and PSF funds are intended for the implementation of the research programme and the achievement of research and development goals outlined in the ZTM strategy. The goal of the P4-0176 programme "Synthetic Biology and Immunology" is to develop the tools necessary for designing original chimeric antigen receptors for cancer immunotherapy and to continue research from the previous programme period. The programme P4-0176 is based on obtaining antigen-specific antibodies using classical immunization and selection approaches with hybridoma technology. In the future, we plan to upgrade these approaches by introducing innovative methods that will enable more effective acquisition and selection of the most suitable antibody candidates for the development of potential advanced therapeutic drugs. To achieve these goals, we will use a combination of modern immunization and selection approaches. We build on past successes, where we developed original monoclonal antibodies used in both diagnostics and fundamental research.Our achievements include the establishment of the production of diagnostic reagents and patented antibodies that have contributed to understanding the mechanism of action of the enzyme ADAM-10 and open new possibilities for the diagnosis and treatment of neurodegenerative diseases. The target values of the programme have a broader context, as original antibodies against selected targets can be used in the preparation of effective immunotherapy with chimeric antigen receptors. The aim of the work is to obtain antigen-specific antibodies against the selected target using various immunization approaches and innovative selection methods with hybridoma technology. The goals can be achieved by using several different approaches to immunizing laboratory animals, developing screening tests for selecting clones against the desired targets, developing an effective platform for antibody selection, and defining collections of hybridomas prepared within the programme P4-0176.

We have included several strategic and long-term goals and a development goal in the strategy for stable financing.

Training of young researchers

In the field of training young researchers, we are successfully achieving the set goals. Currently, two young researchers are in the final stages of their doctoral studies and are expected to obtain their PhD titles this year, thereby reaching the target value planned for 2027. The results achieved confirm

the successful implementation of the mentoring process and the effectiveness of the supportive research environment, so we assess that the set goal will be achieved on time and in full.

Active participation in national and international scientific and professional meetings

In the area of active participation in national and international scientific and professional meetings, we are successfully exceeding the set goals. We have participated in numerous congresses, where we presented the results of our research work in the form of invited lectures, presentations, contributions, and posters. Based on the current number of participations and presentations, we have already surpassed the target value, which confirms our high engagement in the international scientific community.

Table 1: Number of active participations since 2022

	Scientific meetings	Professional meetings
National level	47	55
International level	31	0

Of these, active participations that were carried out within the program are found in Appendix 1.

Organization and co-organization of scientific and professional meetings

As part of the goal of organizing and co-organizing national and international scientific meetings, conferences, and symposiums, we have already exceeded the target value of three organized events. So far, we have held the 8th Symposium of the Slovenian Immunological Society (2023), the 8th Slovenian Pneumology, Allergology and Immunology Congress (2024), a research day at ZTM (2024), 9th Symposium of the Slovenian Immunological Society (2025) and participated in the organization of the international event MESIA 2026 (Congress of Middle European Societies of Immunology and Allergology). The results indicate successful and continuous implementation of the goal and good integration into the national and international professional environment. By the end of 2027, we will maintain the goal through continued collaboration in organizing scientific meetings and strengthening international relations.

Increasing the visibility and accessibility of scientific publications

As part of the goal to increase the recognition and accessibility of scientific publications, we published 48 research articles with an impact factor during the period of stable funding at ZTM, of which 7 articles were prepared under the programme P4-0176 (4 original research articles, 2 review articles, 1 other scientific article (perspective); available in Appendix No. 1). By the end of 2027, we plan to further increase the number of scientific publications, particularly in high-impact journals and open access, and to strengthen the share of publications that directly arise from program activities.

Strengthening the scientific research activity workforce

As part of the goal of strengthening the human resources in R&D activities, we have employed 3 junior staff members in the field of research and development and one person for administrative work in the RD Office, within the framework of stable financing. These employments have contributed to more effective implementation of research activities, support for research projects, and strengthening organizational support for research work.

Knowledge transfer through pedagogical processes in higher education institutions

The head of the research programme at ZTM, Prof. Dr. Vladka Čurin Šerbec, is the course leader of two elective courses within the postgraduate study of Biomedicine at the Faculty of Medicine, University of Ljubljana: Biological Drugs Based on Monoclonal Antibodies and Monoclonal Antibodies: Their Preparation and Application in Research, Diagnostics, and Therapy. She is also a member of the National Medical Ethics Committee of the Republic of Slovenia, which evaluates the ethical aspects of research, and serves as the president of the Slovenian Immunological Society, which brings together medical professionals, researchers, and university teachers and teaching assistants in the field of basic and clinical immunology.

International cooperation

As part of the goal of international cooperation, we have successfully strengthened our involvement in key European professional and regulatory associations and groups. We have established new international connections with researchers from Germany, Italy, the United Kingdom, Austria, Croatia, Hungary, the Czech Republic, and Slovakia (8), which contributes to greater recognition and collaboration of the institute and the programme group in the international arena. At the level of involvement in professional associations, we are actively engaged in the EBA expert group for Advanced Therapy Medicinal Products and in the expert group for Innovation and New Blood Products. This has strengthened our presence in important European professional structures. The objective is being successfully implemented, and further activities will be directed towards expanding the network of partnerships and deepening collaboration in existing international expert groups by 2027.

Development goal

Within the framework of RSF, we continue with activities to establish a national biobank of blood samples from healthy donors, for which we have obtained the consent of the National Medical Ethics Committee of the Republic of Slovenia. With this, we have upgraded the Interreg C3B project, which we successfully implemented in collaboration with Italian partners as part of a European cross-border cooperation project and for which we have been awarded twice: in the field of management and in the field of health.

Within the framework of ISF, we provide infrastructural support for scientific research activities in the form of personnel and equipment. From ISF funds, we will ensure personnel who will offer technical, administrative, and professional support in the implementation of scientific research activities at ZTM. We will also draw on ISF funds for the depreciation of equipment, regular maintenance and qualification of scientific research equipment, replacement of outdated equipment, purchase of new equipment, and software tools.

4.2. HR policy, rejuvenation of the research community, PhD training

The personnel policy at ZTM is closely linked to the scope of research activities, organizational structure, and available human resources. Research work under stable funding (2.47 FTE) is carried out within a relatively small but highly specialized interdisciplinary programme group, which allows for the direct involvement of researchers in all phases of the research process, while also representing a limitation in terms of long-term personnel stability and the scalability of research activities.

During the period 2022–2027, we trained four young researchers as part of our research activities. Two young female researchers were trained under the research programme P4-0176, while two young male researchers were trained under the research programme P3-0371, which was not extended in 2022. One researcher (P4-0176) successfully completed her doctoral studies in 2024 and has since been employed in the industry. Two young researchers (P3-0371) completed their training and found employment outside of ZTM. The later have not yet completed their doctoral studies. One young female researcher (P4-0176) was employed for further research work on the national research programme after completing her training. She is currently in the final phase of her doctoral studies. Due to the limited funding period, we decided to include researchers at the beginning of their research careers (2 individuals) in the programme group instead of young researchers. These researchers are employed for a fixed term, for the duration of the national research programme. This staffing dynamic indicates that the rejuvenation of the research community is taking place, but it is heavily dependent on current financial availability.

Training of young researchers takes place through active involvement in research work, where they participate in experimental work, data analysis, preparation of scientific publications, and presentation of results. This helps them develop competencies for independent research work. Their involvement in research is evident from co-authorship of scientific publications, contributions to professional and scientific events, and participation in research projects. This also contributes to their professional growth and increases their visibility in the scientific community. Additionally, it is evident that the career development system for young researchers has not yet been fully formalized in terms of long-term employment after training, which limits the predictability of career paths and affects the ability to retain the most promising talents.

Technical support is included in the programme group as technical assistance for research work. This integration allows for direct collaboration in the execution of experimental procedures, maintenance of laboratory equipment, and support for routine and specialized laboratory tasks. Such a model contributes to greater efficiency, but at the same time means that the extent of technical support is directly dependent on the stability of the programme group and the available personnel and financial resources.

In the field of human resource management, personnel procedures are carried out in accordance with internal regulations. Due to the small scope of scientific research and innovation activities at ZTM, career development systems for researchers are not developed. Elements that follow modern European guidelines (ERA, CoARA) are gradually being introduced, particularly in the direction of broader evaluation of research work that goes beyond mere bibliometric indicators and includes mentoring, knowledge transfer, collaboration, and other forms of scientific contribution. This needs to be implemented in the internal regulations governing scientific research activities.

Self-evaluation shows that the key advantages of the personnel policy at ZTM are the direct involvement of researchers and technical collaborators in the research process, a high level of professionalism, and the effectiveness of integrating young researchers into scientific work. Limitations mainly relate to the small size of the programme group and limited opportunities for long-term employment after training, which reflects in difficulties with the continuity of research work and knowledge transfer.

Based on the findings of the self-evaluation, we plan the following measures:

- systematic planning of personnel development with a greater emphasis on planning career paths for researchers and long-term employment of successful young researchers,
- strengthening mentoring and structured knowledge transfer within the research group,
- gradual introduction of modern approaches to evaluating research work in accordance with the principles of open science and European guidelines (ERA, CoARA),
- increasing the involvement of researchers in the international environment to enhance their scientific visibility and career development.

These measures aim to strengthen long-term personnel stability, improve the predictability of career paths, and ensure the sustainable development of the research community within ZTM.

4.3. Research infrastructure and equipment

ZTM has advanced research infrastructure and modern laboratory equipment that enable high-quality educational, professional, and research activities. The research infrastructure consists of several specialized laboratories, including a modern laboratory for working with cell cultures and a laboratory for working with genetically modified organisms (GMOs), which meets all safety, technical, and regulatory requirements for work in safety class II. An important part of the infrastructure also includes a laboratory for molecular techniques, where we conduct analyses of nucleic acids and proteins, and a flow cytometry laboratory equipped with the latest technology for precise analyses of cell populations, cellular particles, and cell sorting.

ZTM actively collaborates with numerous research, educational, and other institutions both domestically and internationally, promoting interdisciplinary connections and knowledge exchange among various professional fields. Such an environment fosters the development of new ideas, innovative approaches, and advanced research solutions, significantly contributing to the production of high-quality scientific publications in domestic and international journals.

The ZTM infrastructure programme significantly supports research work within the national research programme and domestic and international research and development projects. The resources from the infrastructure programme and the development pillar enable the employment of highly qualified professional staff, ensuring quality support in planning and conducting research. The programme also supports the educational process, which includes undergraduate, postgraduate, and specialist education at ZTM. Laboratory equipment and trained personnel facilitate the execution of specialist, doctoral, and master's theses, making it easier for students to access modern research methods, laboratory equipment, and professional mentorship. Direct involvement in work with advanced research infrastructure allows students to gain practical experience, develop research competencies, and be better prepared for further academic or professional advancement. Therefore, the infrastructure programme represents not only technical support for research work but also an important connecting and developmental pillar of scientific research activities.

4.4. Collaboration, knowledge transfer, and diversity of funding sources

The research and development activities of ZTM are deeply embedded in the Slovenian health, academic, and research landscape. As a national institution for transfusion medicine, ZTM supports national self-sufficiency in blood, cellular therapies, tissues, blood-derived medicines, and advanced treatments. The institute's strategy emphasizes the development of advanced therapeutic and diagnostic activities, strengthening research work, transferring scientific knowledge into clinical practice, and actively participating in shaping the healthcare system and profession.

ZTM's collaboration occurs through national and international research projects, internal development projects, clinical studies, scientific publications, mentorships, and partnerships with universities, research institutes, clinical institutions, companies, and professional networks. The research activity is distinctly translational, as it arises from clinical and diagnostic needs and is directed towards developing practical solutions for transfusion, transplantation, regenerative, oncology, perinatal, and laboratory medicine.

National research and academic collaboration
ZTM has developed a network of collaborations with research organizations and higher education institutions. Continuous collaboration with the University of Ljubljana is particularly important, especially with the Faculty of Pharmacy (UL FFA), the Faculty of Medicine (UL MF), and the Biotechnical Faculty. The collaboration includes joint research projects, co-authorship of scientific publications, mentorship of doctoral, master's, and bachelor's theses, and the transfer of research content between the academic and clinical-diagnostic environments.

With UL FFA, ZTM has collaborated on projects in the fields of immunology, immunotherapy, mesenchymal stromal cells (MSC), Toll-like receptors, cystatin F, NK cells, and platelet-mediated immune response. Among the significant projects are studies on the immunoproteasome in platelet-mediated immune response, immunomodulatory MSC in the treatment of COVID-19, and the development of low-molecular-weight modulators of Toll-like receptor 7 (project J1-4417). Collaboration with UL MF and UKC Ljubljana is particularly important in the areas of clinical translation, transplantation medicine, regenerative medicine, perinatology, HLA/immunogenetics, and clinical studies. Projects include the Slovenian genomic project, research on MSC and extracellular vesicles for corneal tissue regeneration, transplantation diagnostics, and monitoring patients after transplants.

Collaboration with the Institute of Oncology Ljubljana is also significant, particularly in the fields of oncology, immunotherapy, and advanced treatments. The research work includes projects on cellular immunotherapy, tumor vaccines, treatment of post-radiation xerostomia, and the development of post-neoadjuvant therapy for triple-negative breast cancer with autologous cellular immunotherapy.

ZTM collaborates with the Chemical Institute, the National Institute of Biology (NIB), and the "Jožef Stefan" Institute (IJS). The research programme P4-0176 Synthetic Biology and Immunology is conducted in collaboration with the Chemical Institute. ZTM collaborates with NIB on CAR-T immunotherapy research and with IJS on research related to cystatin F and the glioblastoma microenvironment.

Collaboration in scientific publications

An important indicator of ZTM's collaborative engagement is also scientific publications and co-authorships. The ZTM bibliography for the period 2021–2026 contains 88 bibliographic units, including 66 original scientific articles and 22 review articles. The publications include collaborations with universities, clinical institutions, research institutes, and international partners. Co-authorships reflect collaboration with UL FFA, UL MF, UKC Ljubljana, the Oncology Institute of Ljubljana, the Chemical Institute, NIB, IJS, and other domestic and foreign institutions. Research topics include MSC and osteoarthritis, corneal regeneration, dendritic cells, cystatin F and NK cell cytotoxicity, TLR7/8 modulators, extracellular vesicles, COVID-19 convalescent plasma, transplantation medicine, immunohematology, and neurodegenerative diseases. Publications where ZTM researchers serve as leading, first, or corresponding authors, or as key translational partners, hold special value. This confirms that ZTM contributes specific expertise and infrastructural knowledge in the fields of transfusion medicine, cellular therapies, diagnostics, immunology, and the translation of research into clinical practice.

Collaboration with the clinical environment and knowledge transfer

Knowledge transfer into medical practice primarily occurs through collaboration with UKC Ljubljana, the Oncology Institute of Ljubljana, other hospitals, and transplantation programs. Collaborations are related to the development and optimization of methods such as HLA typing, monitoring anti-HLA antibodies, determining anti-HPA-1a, perinatal immunohematological diagnostics, testing for heparin-induced thrombocytopenia (HIT), monitoring infections in blood donors, diagnostics post-transplantation, optimization of apheresis procedures, and the development of cellular therapeutic products.

Internal development projects play an important role, enabling the conversion of clinical and laboratory challenges into development tasks. In 2025, notable projects included automated determination of antibody titers in sensitized pregnant women, the introduction of Oxford Nanopore sequencing for HLA typing of deceased organ donors, expansion of testing to monitor immunological status after heart transplantation, development of production of tumor-infiltrating lymphocytes, and the introduction of sequencing of erythrocyte blood group systems.

Knowledge transfer also occurs through internal professional-research presentations and the ZTM Research Day, where results of internal projects and the development of new methods are presented.

International cooperation

During the self-evaluation period, ZTM participated in several international projects and professional networks. Among the more significant are the INTERREG SLO-ITA C3B project "Cross-border Management of Biobanks" and the IMMUNOCLUSTER-2 project, focused on the introduction of a clinical study with the advanced cellular medicine aHyC.

International engagement is also evident from publications with international co-authors, participation in European professional networks, and contributions to international standards. Particularly important are the areas of extracellular vesicles, immunology, cellular therapies, transfusion safety, and advanced therapy medicinal products. ZTM's international collaboration

provides access to modern knowledge and methodologies while simultaneously enhancing the institute's visibility in the European research space.

Collaboration with companies and users outside the academic environment
Although most research collaboration is tied to public research and health institutions, ZTM also collaborates with companies and other users, primarily in the fields of advanced cellular therapies, biotechnology, diagnostic methods, and translational projects. An example of such collaboration is the inclusion of the company Celica d.o.o. in the IMMUNOCLUSTER-2 project.

The forms for the application of internal projects already include requirements regarding the usability of results and the potential for transfer to medical practice, indicating an established administrative framework for collaboration with external users.

Diversity of funding sources
The research and development activities of ZTM are financed through a combination of stable funding, ARIS programmes and projects, international projects, and internal development resources. ZTM participates in the research programme P4-0176 and in several national research projects, where it acts as a partner or translational organization.

The project structure for the period 2022–2025 includes national research programmes, several ARIS projects, international projects, and numerous internal development projects. In 2024, there were 12 active internal projects, and in 2025, there will be 15.

The bibliographic output from COBISS for the period 2021–2026 shows that the largest share of funds outside ARIS comes from international projects, while funds from the economy and other sources are present to a lesser extent. This means that research activities remain primarily dependent on public national and international funding sources.

Critical self-reflection
ZTM assesses that the collaborative engagement of research and development activities is good, especially considering the size of the research FTE and the specific nature of the institute. A key advantage is strong collaborations with leading clinical and academic partners and the actual transfer of results into practice through joint projects, publications, mentorships, and the implementation of methods. At the same time, ZTM identifies the need for more systematic recording and evaluation of collaborations. Currently, data is scattered among project reports, bibliographies, mentorships, and internal records, so it would be sensible to establish a unified record of collaborations, publications, projects, and the effects of knowledge transfer.

In the area of funding, the relatively limited dispersion of sources remains a challenge, particularly the small share of funds from the economy and long-term international consortia. Nevertheless, this represents a developmental opportunity for further internationalization and connection with the applied environment.

Planned measures
In the upcoming period, ZTM will strengthen the strategic management of collaborations and funding sources. The establishment of a clearer record of national and international partnerships is planned,

which will connect projects, publications, mentorships, clinical studies, and results of knowledge transfer. In scientific publications, ZTM will systematically monitor the affiliation structure, the share of publications with external and international partners, and the role of ZTM researchers in publications. In the area of knowledge transfer, the focus will be on monitoring the actual effects of internal projects, such as implemented methods, validations, SOPs, clinical protocols, and educational outcomes.

In the field of financing, ZTM will continue to apply for national and international calls and encourage earlier alignment of project ideas among researchers, the medical director, and the RD Office. In the long term, special emphasis will be placed on involvement in larger international consortia and projects in the areas of advanced therapies, biobanking, digitalization of transfusion medicine, transplant diagnostics, and the safety of blood components.

4.5. Internal system for ensuring the quality of research

The quality assurance system for scientific research work at ZTM is based on institutional infrastructure, which includes the RD Office, internal regulations for conducting scientific research activities, and the election to research titles, as well as a broader quality management system according to the ISO 9001 standard. The established system provides formal and organizational support for research work and ensures the standardization of processes, traceability, and administrative oversight.

An important advantage of the organization is that scientific research activities are conducted in an environment where the culture of quality has long been embedded in the operation of the institute. The ISO 9001 system contributes to the organization of procedures, documentation of processes, and accountability in the execution of activities. The new regulation governing the conduct of scientific research activities and the election to research titles (Regulation on the Implementation of Scientific Research and Development Activities, on the Conditions and Procedures for Election to Research Titles at the Slovenian Institute for Transfusion Medicine, adopted on March 11, 2026) represents a step towards updating the formal framework and adapting to the current needs of the organization, but certain articles still need to be aligned with the stakeholders of the activities.

Self-evaluation shows that the internal quality assurance system for scientific research work remains in a developmental phase and that there are significant structural deficiencies. For more than a year, the organization has not had a valid commission for conducting scientific research activities, which has reduced formal professional monitoring of research work. The newly adapted regulation does specify procedures for conducting activities, but it does not foresee a specific professional or scientific body for systematic monitoring of quality, developmental directions, and strategic issues of research work.

Oversight of activities under the new regulation is primarily carried out by the expert council and the medical director. This arrangement provides a formal governance structure, but it also has limitations. The Professional Board includes representatives of professional fields; however, researchers and principal holders of scientific research activities are not systematically represented. Consequently, researchers at Career Levels I and II, as well as heads of research activities, do not have sufficient direct representation in shaping development directions, criteria, and decisions affecting research activities. Final decisions are made by the medical director, which ensures a

certain degree of operational efficiency but at the same time reduces the level of collegial professional assessment and autonomy in research work.

Researchers perceive the need to establish a scientific council or a comparable advisory body that would provide independent research expertise to the medical director and the professional council, contribute to strategic development, and strengthen the involvement of the research community in self-evaluation and decision-making processes. Currently, there is insufficient institutional support for such a solution. According to researchers, the new regulation further increases administrative oversight in certain segments, which limits research autonomy and may have long-term effects on the development of research culture and the motivation of researchers.

Analysis shows that the greatest advantage of the existing system is formal organization, administrative traceability, and integration into the broader quality system of the institute, while key weaknesses are related to limited participation of researchers in governance of research activities, the absence of a specialized expert body for the quality assurance of scientific research work, and centralization of decision-making.

In the first contractual period of stable funding, ZTM is still in the process of developing a more comprehensive self-evaluation system, which is also in line with the broader institutional development guidelines. Based on the findings of the self-evaluation, we identify the following developmental priorities:

- establishing a more inclusive internal self-evaluation system that will systematically involve researchers,
- the establishment of a scientific council or a similar research advisory body,
- greater representation of scientific research performers in formulation of strategic decisions,
- further upgrading of internal regulations towards a better balance between organizational oversight and research autonomy,
- development of clearer internal quality indicators for scientific research work, aligned with the principles of open science, research integrity, and modern ERA policies,
- establishment of an ethics infrastructure.

For the long-term strengthening of scientific excellence, it will be crucial for the internal quality system to evolve from a predominantly administrative framework into an inclusive mechanism that actively supports research culture, strategic development, and high-quality scientific research work.

4.6. Open science principles

ZTM understands the principles of open science as an important part of modern and responsible scientific research work, particularly in terms of open access to research publications, transparency of research results, responsible handling of research data, reproducibility of methods, communication of science, and quality assessment of research work. In self-evaluation of this area, ZTM relies on the provisions of ZZrID, the Regulation on the Implementation of Scientific Research Work in accordance with the principles of open science, and the Action Plan for Open Science, which ARIS explicitly cites as the starting points for this chapter.

Current state and existing practices

ZTM already has some elements of open science present in research practice, but these are not yet connected into a comprehensive institutional system or an independent open science strategy. The most evident and already established element is the publication of research results in scientific journals, a significant portion of which is available in open access. The ZTM bibliography for the period 2021–2026 includes numerous publications marked "Open Access," including in the fields of immunology, advanced therapies, cellular therapies, extracellular vesicles, regenerative medicine, and transfusion medicine. Examples of open access publications include research on the modulation of cystatin F and the cytotoxicity of NK cells in glioblastoma models, reviews on aging of the bone marrow niche, works on extracellular vesicles and corneal regeneration, publications on dendritic cells, and other articles recorded in COBISS/SICRIS with DOI, bibliographic data, and links to publications. In this way, ZTM contributes to the accessibility of research results for the broader research and professional community.

The second important element of open science is the traceability of research results through public bibliographic systems, primarily SICRIS and COBISS. Annual reports on RR activities systematically list the number of publications, conference contributions, professional articles, monographs, and mentorships, using SICRIS as a source. In 2022, for example, 7 original scientific articles and 4 review scientific articles were recorded; in 2023, there were 6 original and 2 review scientific articles; in 2024, 10 original and 5 review scientific articles; and in 2025, 9 original, 4 review, and 6 other scientific articles.

ZTM has also established some procedural elements that indirectly support the transparency of research work. In 2022, regulations on the election to research titles, regulations on stable financing of scientific research activities, a contractual framework for stable financing, a commission for monitoring, evaluating, and supervising research programmes, and SOPs for applying for and implementing internal research and development projects were prepared. These mechanisms are not specific acts of open science, but they create a foundation for more transparent planning, monitoring, and evaluation of research work.

Open access to publications and research results

ZTM encourages researchers to publish in internationally visible scientific journals, often utilizing open access publications or journals that allow public access to articles. This is particularly important in fields where research has direct translational value for transfusion medicine, transplant medicine, regenerative medicine, diagnostics, immunotherapy, and advanced treatments.

In the bibliography of ZTM, many articles are marked as open access, indicating that open access already exists in research practice. However, ZTM currently lacks a unified internal system for monitoring the share of open access publications by year, types of publications, sources of funding, or projects. Therefore, it will be sensible to establish a simple annual monitoring of the share of publications in open access, publications with publicly accessible protocols, publications with accessible data, or publications where research data or additional materials are available under conditions compliant with legislation and ethical restrictions of biomedical research.

A special advantage of ZTM is that part of the research is conducted in the form of clinical studies or translational research, where protocols are often published in open access. This approach increases

the transparency of the research design, allows for a better understanding of the methodology, and reduces the risk of selective reporting of results. This aligns with the principles of open methodology and early exchange of information about research, which ARIS cites as important practices of open science.

Handling of research data and FAIR principles

The biggest developmental challenge for ZTM in the field of open science is the systematic handling of research data according to FAIR principles, meaning that data should be findable, accessible, interoperable, and reusable, as far as legislation, ethical rules, personal data protection, patient rights, and the nature of biomedical data allow.

ZTM operates in areas where research data often include sensitive health, biological, genetic, immunological, diagnostic, or clinical data. Therefore, data openness cannot mean unlimited public access to raw data. In research in the fields of blood donation, transplant medicine, HLA/immunogenetics, cellular therapies, infection diagnostics, perinatology, and clinical studies, open science must be balanced with GDPR, personal data protection, informed consents, ethical approvals, regulatory requirements, biosafety, and the protection of confidential health data.

Therefore, the most suitable model for ZTM is controlled openness: public access to publications, methodological descriptions, protocols, aggregated results, metadata, and, where possible, anonymized or pseudonymized datasets; while limited or controlled access applies to sensitive individual data. In the future, it will be necessary to more systematically determine which types of research data can be open access, which can be accessed upon justified request, which can only be shared within approved research collaborations, and which are not suitable for open sharing due to legal, ethical, or security reasons.

Currently, ZTM does not have a unified institutional system for preparing data management plans for all research projects. Data management plans are primarily prepared where required by funders, project consortia, clinical protocols, or ethical/regulatory requirements. This is an acceptable starting point for the first contractual period, but it is not sufficient as a long-term institutional arrangement. ARIS specifically mentions the preparation of data management plans as one of the key elements of open science in its proposal.

Staffing and Organizational Support

ZTM currently does not have a specifically designated institutional function for open science, such as a data advisor, data librarian, or open science coordinator. Support for researchers primarily occurs through the RD Office, project leaders, mentors, research activity monitoring committees, quality systems, and collaboration with external academic partners. This arrangement is understandable given the size of the research FTE, but it means that open science has not yet been systematically and staff-wise clearly positioned as an independent field.

In the next period, it will be sensible to designate at least a responsible person or contact point for open science, who would oversee the basic coordination of this area: monitoring open access publications, informing researchers about funder requirements, guiding the preparation of NRRP, connecting with repositories, monitoring best practices, and integrating open science into internal research processes. It is not necessary for ZTM to establish a new independent service due to its size;

a functional placement within the existing research and development and quality support is more sensible.

Communicating Science, Education, and Knowledge Sharing

ZTM communicates the results of its research and development work through scientific and professional publications, conference contributions, professional meetings, mentorships, internal project presentations, and employee training. Annual reports demonstrate extensive conference, professional, and mentorship activities, including doctoral, master's, and bachelor's theses.

In 2024, the annual reports of internal projects for 2023 were presented in the form of lectures, which represents a good practice of internal knowledge exchange. Such presentations contribute to the open exchange of information within the organization, reduce the isolation of individual project groups, and enable the results of internal projects to connect more quickly with other departments, routine procedures, or new research initiatives.

In communicating science externally, ZTM already participates in professional meetings, publishes professional articles, and collaborates in the education of professional profiles in healthcare. However, it should be emphasized that communicating science in itself does not equate to social impact if it is not linked to demonstrable application or change in practice. This distinction is also important in open science: popularization and professional communication are beneficial, but they must be part of a broader system of transparency, accessibility, quality, and responsible knowledge transfer.

Open Evaluation of Research Work

ZTM currently relies on a combination of bibliographic data, project results, professional achievements, mentorships, and contributions to the development of activities in evaluating research work. In the context of open science, it is important that evaluation does not solely rely on the place of publication, journal impact factor, or quantitative indicators. ARIS emphasizes in its guidelines that self-evaluation of scientific results should focus on assessing essential substantive achievements, while bibliometrics should be used limitedly, responsibly, and always supplemented with narrative explanation. In this regard, the recipient can also rely on the recommendations of ERA and CoARA.

This is particularly relevant for ZTM, where a significant part of the research and development work is not directed solely towards highly cited publications, but also towards the introduction of methods, improvement of procedures, clinical support, validations, quality, safety, regulatory compliance, and education. Therefore, in the future, it will be sensible to more clearly recognize contributions to open science in internal evaluation processes: open access publications, published protocols, well-documented methods, data sets or metadata, collaboration on open standards, transparent research documentation, and knowledge transfer into practice.

Critical self-reflection

ZTM assesses that some elements of open science are already present, particularly open access publishing, public bibliographic traceability, publishing protocols, conference and professional communication, and internal presentations of results from internal projects. However, the field of open science is not yet comprehensively institutionally regulated. ZTM currently lacks specific

regulations, an action plan, or a strategy for open science, does not have a specifically appointed responsible person for this area, and does not have a unified system for monitoring open access publications, data practices, NRRP, or open methodological materials.

A key limitation is also the nature of ZTM's research work. A large part of the research involves sensitive biomedical data, human-derived samples, clinical data, transplant data, blood donor data, or diagnostic results. Therefore, the implementation of open science at ZTM must be particularly carefully aligned with ethics, personal data protection, legislation, informed consents, biobanking rules, regulatory requirements, and quality systems.

The second limitation is staffing. Given the small research FTE and the nature of ZTM as a public health institution, it is unrealistic to expect extensive independent infrastructure for open science. A more realistic and effective approach is the gradual integration of open science principles into existing processes: internal project applications, final reports, project documentation, publication strategy, mentoring, quality systems, and support for researchers.

Planned measures

ZTM will regulate the field of open science gradually and proportionately to the size and nature of its research activities in the upcoming period. The first measure will be the preparation of short internal guidelines for open science, which will define the basic principles of open access, handling of research data, preparation of NRRP, use of repositories, sharing of methodological materials, and limitations regarding sensitive biomedical data.

The second measure will be the appointment of a responsible person or contact point for open science within the existing research and development or quality support. The task of this person will not be to establish a new administrative layer, but to provide practical support to researchers regarding funder requirements, publishing in open access, preparing NRRP, and documenting data practices.

The third measure will be the enhancement of application and final report forms for internal projects. When applying for a project, a short section on the anticipated accessibility of results, methods, protocols, or aggregated data can be added, and in the final report, a section on which publications, data, methodological materials, or professional results were publicly accessible or why open sharing was not possible. This approach would be consistent with the existing project logic of ZTM, which already requires the definition of professional and scientific relevance, translation into medical practice, and impact on training personnel.

The fourth measure will be the introduction of annual monitoring of basic indicators of open science. These indicators could include the proportion of publications in open access, the number of published protocols, the number of projects with NRRP, the number of publications citing data accessibility, the number of open access professional or educational materials, and the number of cases where data were not openly shared due to legal, ethical, or clinical limitations.

The fifth measure will be the preparation of sectoral guidelines for handling sensitive biomedical data in ZTM research. These guidelines must clearly distinguish between data that can be publicly open, data that can be accessed upon justified request, data that can only be shared within approved

research collaborations, and data that cannot be shared due to legislative, ethical, or security reasons.

In this way, ZTM will develop the field of open science realistically, gradually, and in accordance with the requirements of ZZrID, the Regulation on the Implementation of Scientific Research Work in accordance with the principles of open science, the Action Plan for Open Science, and the specifics of the biomedical and health research environment.

4.7. Principle of equal opportunities

As a public institution, ZTM is bound by public law regulations in the area of ensuring equal opportunities and equal working conditions. The fundamental constitutional basis is provided by Article 14 of the Constitution of the Republic of Slovenia, while the area is further regulated by numerous laws, collective agreements, European legislation, and strategic documents. At the European level, this field is governed by the Gender Equality Strategy for the period 2026–2030, while at the national level it is regulated by the Resolution on the National Programme for Equal Opportunities for Women and Men 2023–2030 (Official Gazette of the Republic of Slovenia, No. 105/23).

Human resources matters, such as education requirements, job classification, promotions, and remuneration, are regulated by law and are based on predefined and transparent criteria that ensure equal opportunities for all employees. Areas not directly regulated by legislation are defined at the institutional level through internal rules, designed to ensure consistent respect for this principle. These include the Anti-Mobbing Anti-Discrimination Policy, the Right to Disconnect Policy, and the Whistleblower Protection Policy under the Whistleblower Protection Act. The Anti-Mobbing Anti-Discrimination Policy also include measures to prevent gender-based violence, including sexual harassment.

In the field of research, ZTM regulates performance criteria, project acquisition criteria, promotion to research positions, and appointments to leadership positions through the Rules on the Implementation of Scientific Research and Development Activities and on the Conditions and Procedures for Election to Research Titles. All these criteria are based on the principle of gender equality.

As part of the preparation of the Gender Equality Plan, an analysis of equal opportunities in recruitment and career advancement was carried out. The findings indicate that the gender structure of employees reflects global trends in the healthcare sector (approximately 80% women and 20% men). ZTM strives to ensure equal opportunities for career development for all employees. An important role in this process is played by the Education Service, which reviews proposals from employees and managers, while final decisions are made by the management of the institute. The analysis also shows a balanced representation of genders in leadership and decision-making positions. Due to the specific nature of the sector and strong competition in the labour market, the pool of available candidates is often limited.

In terms of work-life balance, ZTM promotes an organisational culture that enables employees to achieve an appropriate balance between their professional and private responsibilities. To this end, a Right to Disconnect Policy has been adopted. Certain issues in this area are also addressed by the

Health Promotion Group and the Socially Responsible Employer initiative, which prepare proposals for measures and monitor their implementation.

Within the Gender Equality Plan, ZTM will further strengthen awareness of the importance of gender equality in both education and research, monitor the implementation of legislation, and encourage employees to submit initiatives and proposals for improvements. Particular attention will be given to promoting education, awareness-raising, and research in the field of equal opportunities in science.

Within the Legal Service, ZTM will monitor developments and activities of European Union institutions in this area and, based on these findings, propose measures to improve data collection and analysis, which will support more effective policy-making on equal opportunities in science.

The implementation of the principle of equal opportunities is also monitored by the integrity officer within the framework of reporting to the Commission for the Prevention of Corruption.

4.8. Ethics and integrity

ZTM conducts scientific research activities in the fields of medicine, biology, and public health, where ethics, integrity, human rights protection, and responsible handling of biological samples and data constitute fundamental prerequisites for research work.

Research activities at ZTM is conducted in accordance with Slovenian and European legislation, the principles of the Declaration of Helsinki, the provisions of the Oviedo Convention and its additional protocols, the principles of good scientific practice, and the institution’s internal quality system. All research involving humans, their biological material, or personal data is conducted exclusively with appropriate ethical consent. Before starting research conducted by ZTM researchers or external partners using biological samples obtained at ZTM, a positive opinion from the National Medical Ethics Committee of the Republic of Slovenia must be obtained, ensuring an independent assessment of the ethical appropriateness of the research. This approach contributes to the reliability of research designs, methodologies, and responsible use of biological resources.

In the field of personal data protection, research work follows the provisions of Personal Data Protection Act (ZVOP-2) and General Data Protection Regulation (GDPR). This is particularly important in establishing a biobank of blood samples from healthy donors, where long-term management of sensitive data and biological materials is crucial for maintaining the trust of participating individuals and the credibility of the research infrastructure. Established procedures show a high level of formal compliance, but self-evaluation indicates the need for further systematization of internal protocols for managing research data, tracking consents, and standardized handling when sharing data with external partners.

With regards to publishing, authorship, and open science, the new internal regulation defines the principles of open science, protection of intellectual property, proper use of institutional affiliations, and internal procedures for evaluation of publications, conference contributions, and protecting innovations. A positive aspect of the system is the formal arrangement of responsibilities regarding copyright, disclosure of results, and alignment of research publications with institutional interests. However, researchers point out that the system of prior approval of publications and contributions, in which the final decision is made by the medical director, may limit research autonomy and raise questions of proportionality between institutional oversight, protection of the institution's interests, and freedom of scientific expression. From the perspective of the European Code of Conduct for

Research Integrity, an important challenge remains establishing a more balanced system that, in addition to oversight functions, also strengthens advisory, developmental, and preventive functions in the field of research integrity .

ZTM currently does not have an independent specialized body (e.g., a scientific council or a research integrity committee) that systematically addresses issues of research ethics, conflicts of interest, authorship, whistleblower protection, or potential violations of research integrity. Although a formal framework exists through regulations, the ISO 9001 quality system, and management procedures, self-evaluation indicates an institutional gap primarily in the area of independent expert assessment, preventive education, and internal advisory support for researchers. The current system focuseses on formal compliance and administrative oversight, while placing less emphasis on the development of a culture of research integrity as a shared professional value.

In the area of preventing unethical publications, ZTM encourages publishing in established scientific journals, primarily in open access, and reduces the risk of collaboration with predatory publishers through expert review of contributions. Nevertheless, it would be sensible to further formalize guidelines regarding the selection of trustworthy publishers, managing conflicts of interest, determining authorship according to international standards (e.g., ICMJE), and regular training for researchers and support staff in the field of research integrity.

Self-evaluation shows that ZTM possesses the foundations necessary to ensur ethics and integrity, particularly in the area of ethical review of research involving human participants, compliance with legislation, quality of laboratory work, and formal management of publications and intellectual property. Key weaknesses remain limited institutional independence in assessing research-ethical issues, the absence of an advisory scientific body, and the need for a more development-oriented culture of research integrity.

In the upcoming period, key developmental measures will focus on establishing a more structured internal system of research ethics and integrity, which could include a scientific or ethical advisory body, the preparation of clear guidelines for authorship, conflict of interest, and responsible publishing, regular staff training, and strengthening the balance between protecting institutional interests and research autonomy. Additional formalization of procedures for addressing alleged breaches of research integrity, including the protection of whistleblowers and clear internal review protocols, is also be appropriate. Such an approach would increase compliance with European recommendations, strengthen the organizational culture of trust, and contribute to the scientific excellence and credibility of ZTM.

5. SUMMARY AND SWOT ANALYSIS

ZTM, within the framework of stable funding, successfully implements its strategic, long-term, and developmental goals in the field of research and development activities, thereby supporting and strengthening its role as the central national institution in the fields of transfusion medicine, cellular therapies, tissue compatibility, and biobanking in the Republic of Slovenia. ZTM's research activities are based on the integration of research, clinical practice, and education, as well as the development of new diagnostic, therapeutic, and supportive approaches for the needs of the Slovenian healthcare system.

Self-evaluation shows that ZTM successfully meets or exceeds most of the established stable funding goals for 2022-2027. In the area of training young researchers, one young researcher has completed and one is on the verge of completing their doctoral studies, which already meets the target values for the entire funding period. The results achieved confirm adequate mentoring support and a quality research environment. Significant progress has also been made in the area of national and international scientific activity, where we have exceeded planned goals regarding active participation in scientific and professional meetings, where employees participated with invited lectures, presentations, and posters. Active involvement in the international research space confirms the high professional recognition of the institute and successful connections with international research groups. We have also published a significant number of research articles, including publications in high-impact journals. Positive developments are also evident in the involvement in international professional and regulatory associations and groups.

Activities in the organization of scientific events and professional networking are also being successfully implemented. We have exceeded the planned goals for organizing or co-organizing professional and scientific meetings, further strengthening our role as an important national and international professional center.

Self-evaluation also indicates areas where further improvements are needed. Among the key challenges remain the staffing burdens on research personnel, the need for further strengthening of research infrastructure, and ensuring long-term financial and organizational stability. An additional challenge is the transfer of research achievements into clinical practice, primarily due to complex regulatory requirements in the field of advanced therapies and biomedical research.

In the upcoming period, ZTM will focus on the further development of advanced therapies, strengthening biobanking, increasing research excellence, and developing a supportive and innovative research environment. Special emphasis will be placed on more effective knowledge transfer into clinical practice, long-term staffing stability, and further strengthening of interdisciplinary collaboration.

SWOT analysis

Advantages

- The central national institution with a clearly defined role in the healthcare system.
- Successful achievement or exceeding of most stable funding goals.
- Strong connection between research, clinical, and educational activities.
- High research activity and good international engagement.
- Development of proprietary diagnostic and therapeutic approaches.
- Successful training of young researchers.

Weaknesses

- Limited administrative and organizational capacities relative to the scope of activities.
- Need for further upgrading of research infrastructure.
- Demanding and long-term transfer of research achievements into clinical practice.

Opportunities

- Strengthening international cooperation and involvement in research and professional associations.

- Development of advanced therapies and biobanking in Slovenia.
- Increasing research visibility through publications in high-impact journals.
- Further development of innovative diagnostic methods.
- Connecting academic and clinical environments.

Threats

- Instability of long-term funding for research activities.
- Rapid technological changes and high costs of research equipment.
- Increasing regulatory requirements in the field of advanced therapies and handling of biological samples.
- Increased international competitiveness in acquiring projects and research partnerships.

6. APPENDICES

6.1. Appendix 1 – List of research results

A) List of scientific publications published during the period of stable funding at ZTM, prepared under the programme P4-0176:

1. Kern, P; et al. Optimization of a versatile cell ELISA for detection of antibodies against membrane protein BCMA. J Immunol Methods. 2025;547:114024.
2. Song, F; et al. Cleavage site-directed antibodies reveal the prion protein in humans is shed by ADAM10 at Y226 and associates with misfolded protein deposits in neurodegenerative diseases. Acta Neuropathol. 2024;148(1):2.
3. Omejec, S; et al. Optimizing the method for expressing human monoclonal antibodies from a single peripheral blood cell from vaccinated donors. J Immunol Methods. 2024;534:113747.
4. Šelb, J; et al. Routine KIT p.D816V screening identifies clonal mast cell disease in Hymenoptera allergic patients regularly missed using baseline tryptase levels alone. J Allergy Clin Immunol. 2021;148(2):621-626.e7.
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B) List of scientific contributions at conferences held during the period of stable funding at ZTM under the programme P4-0176:

1. Bertoncelj, P; et al. Immunoprofiling of gamma delta T cells and their potential for the development of cancer immunotherapies, 2026, published in: MESIA 2026: 6th Meeting of Middle European Societies of Immunology and Allergology.
2. Kern, P; et al. Development of a platform for production of antibodies against membrane proteins on a model of BCMA, 2026, published in: MESIA 2026: 6th Meeting of Middle European Societies of Immunology and Allergology.
3. Černilec, M; et al. Prevalence of severe immunoglobulin A deficiency among Slovene blood donors, 2026, published in: MESIA 2026: 6th Meeting of Middle European Societies of Immunology and Allergology.
4. Rupar, U; et al. Development of approaches for isolation, activation and expression of gamma delta T cells, 2026, published in: MESIA 2026: 6th Meeting of Middle European Societies of Immunology and Allergology.
5. Vidic, Z; et al. The impact of cryopreservation on the permeabilization and survival of primary human T cells after electroporation, 2026, published in: IV. Slovenian Congress on Electroporation.
6. Černilec, M; et al. Blood collection for biobanking: experiences from the Slovenian Institute for Transfusion Medicine, 2025, published in: Europe Biobank Week Congress.
7. Kern, P; et al. Development of a cell-based screening platform for selection of antibodies against membrane proteins, 2025, published in: IUIS Vienna 2025.
8. Kern, P., et al. Development of monoclonal antibodies against B-cell maturation antigen as a model for production of antibodies against membrane proteins, 2025, published in: 9th Symposium of the Slovenian Immunological Society.
9. Černilec, M; et al. Monitoring of individuals with IgA deficiency by validated in-house ELISAs detecting IgA and anti-IgA, 2025, published in: IUIS Vienna 2025.

10. Kovač, V; et al. Site-directed antibodies reveal new possibilities in diagnosis and treatment of neurodegenerative diseases, 2025, published in: IUIS Vienna 2025.
11. Kovač, V; et al. Antibody-based insight into prion protein-related neurodegenerative diseases, 2024, published in: 7th Antibody Validation Workshop, 13th EuroMAbNet Meeting.
12. Kern, P; et al. Development of monoclonal antibodies against membrane proteins: challenges and solutions, 2024, published in: 7th Antibody Validation Workshop, 13th EuroMAbNet Meeting.
13. Kern, P; et al. Targeting cell membrane proteins with antibodies, 2024, published in: 8th Slovenian Pneumology, Allergology and Immunology Congress.
14. Čurin-Šerbec, V; Režen, T. Cross-border project for the efficient management of biobanks, C3B, 2022, published in: 17th CFGBC Symposium.
15. Kern, P; Čurin-Šerbec, V. The challenges and limitations of choosing targets for CAR-T cell therapy, 2022, published in: MESIA 2022.
16. Kovač, V; et al. Toward a therapy of neurodegenerative diseases - a lesson learned from prion diseases, 2022, published in: 6th Antibody Validation Workshop, 12th EuroMAbNet Meeting.
17. Čurin-Šerbec, V. Biobanks: an important and critical infrastructure in basic research and clinical studies - an example of a biobank at the national transfusion centre, 2024, published in: 8th Slovenian Pneumology, Allergology and Immunology Congress.
18. Čurin-Šerbec, V; et al. Biobanking in Slovenia, 2023, published in: Biochemistry and molecular genetics in medicine.

6.2. Appendix 2: Form – Impact case study

Report on the case of social impact[1]
Impact name: Research-supported enhancement of safety, quality, and self-sufficiency in the field of transfusion medicine, blood donation, and diagnostic support for healthcare
Research basis: The social impact arises from the research, development, and professional activities of ZTM in the field of transfusion medicine, blood donation, preparation and quality control of blood components, immunohematological diagnostics, infection diagnostics, apheresis procedures, transplant support, and monitoring the safety of donors and recipients. This research basis is directly related to the mission of ZTM, which ensures safe, high-quality, and effective supply of blood, cells, and tissues, blood-derived medicines, and advanced therapy medicines based on national self-sufficiency. During the self-evaluation period, the research and development activities included national and international projects, internal development projects, and research aimed at the implementation, optimization, and verification of laboratory and clinically supportive procedures. Among the research and development topics were, among others, the optimization of apheresis procedures, the development and implementation of new laboratory methods, monitoring pre-analytical factors in extracellular vesicles in blood and blood components, detection of infections in blood donors, determination of biological markers for GvHD, HLA-related research on immune response, development of sterility tests for umbilical cord tissue, and procedures related to the safety and quality of transfusion products.

In 2025, this research foundation continues and expands into areas such as quantitative determination of anti-HPA-1a antibodies in pregnant women, automated determination of antibody titers in sensitized pregnant women, and additional laboratory identification of antibodies in pregnant women, blood donors, and patients, establishment of a list of blood donors with IgA deficiency, introduction of Oxford Nanopore sequencing for HLA typing of potential deceased organ donors, expansion of testing to monitor the immune status of patients after heart transplantation, introduction of sequencing for erythrocyte blood group systems, and improvement of apheresis procedures.

The research foundation is further supported by an organizational culture of quality and ZTM accreditations, including the ISO 9001 quality management system, JACIE accreditation for apheresis and processing of hematopoietic stem cells, EFI for hematopoietic stem cells, and ISO 15189 for the medical laboratory at the Center for Infection Marker Detection.

Impact description:

ZTM has contributed to a safer, higher quality, and professionally justified support for the Slovenian transfusion and broader healthcare activities through its research and development work. The impact is primarily reflected in the transfer of research and development results into processes that are important for the safety of blood donors, the safety of blood and blood component recipients, support for transplantation programs, perinatal diagnostics, immunohematological treatment of patients, management of risks for blood-borne infections, and the quality of laboratory and therapeutic services.

The beneficiaries of the impact are patients, blood donors, pregnant women, recipients of blood components, patients after organ and hematopoietic stem cell transplants, clinical departments, hospitals, the national healthcare system, and the broader professional community. The special value of the impact lies in the fact that ZTM's research work is not separate from routine activities but is directly aimed at improving the procedures used in the public healthcare system.

The impact is reflected on multiple levels. At the level of blood donation and transfusion safety, research and development activities contribute to a better understanding of the factors affecting the quality of blood and blood components, as well as better monitoring of risks in donors and recipients. At the level of laboratory diagnostics, research enables the introduction or optimization of methods that improve the reliability, sensitivity, interpretation, and clinical utility of results. At the level of clinical support, research activities contribute to better treatment of complex patient groups, including transplant patients, pregnant women with alloimmunization, patients with immunological complications, and patients requiring individualized transfusion support.

Particularly important is the impact on national self-sufficiency and the strategic resilience of the healthcare system. ZTM's strategy explicitly defines strategic independence in the supply of blood and blood-derived medicines, as well as the development of advanced therapeutic and diagnostic activities within transfusion medicine. Therefore, ZTM's research and development activities contribute to Slovenia having its own professional, diagnostic, developmental, and organizational support for areas that are crucial for the safe supply of blood, tissues, cells, and related healthcare services.

The social impact is also reflected in the systematic improvement of internal processes. In 2022, internal acts and procedures for research activities were prepared, including regulations for appointments to research titles, regulations on stable financing of scientific research activities, a contractual framework for stable financing, the establishment of a committee for monitoring research programmes and young researchers, and SOP for applying for and implementing internal projects. This organizational foundation has enabled a more systematic direction of research towards the developmental needs of ZTM and the healthcare system.

The impact also has an educational and professional dimension, as ZTM's research activities support mentorship, training of young researchers, professional presentations, development of employee competencies, and dissemination of knowledge in the Slovenian healthcare space. In this way, ZTM strengthens the national professional base in the fields of transfusion, transplantation, and laboratory medicine.

Reinforcement and possible resonance:

The impact can be supported by the following evidence and indicators:

- internal and external documents on the implementation or optimization of diagnostic and laboratory methods;
- minutes from the Expert Council and the Research and Development Committee confirming the selection, monitoring, and completion of internal projects;
- SOPs, validation reports, method implementation reports, quality reports, and documentation from accredited laboratories;
- certificates and accreditations from ZTM, particularly ISO 9001, ISO 15189, JACIE, and EFI;
- evidence of collaboration with clinical partners, including UKC Ljubljana, other hospitals, transplantation programs, and laboratory users;
- professional publications and reports related to hemovigilance, perinatal immunohematology, infection monitoring, blood donation, and the safety of blood components;
- data on the number of implemented or optimized methods, the number of analyzed samples, the number of supported clinical cases, or the number of users of individual diagnostic services;
- external confirmations from clinical partners regarding the usability of new or optimized procedures in clinical practice;
- published research results demonstrating the scientific basis for the development and use of these procedures.

Report on the case of social impact[2]

Impact Name: Development and clinical translation of cell therapies, tissues, biobanks, and drugs for advanced treatment in the Slovenian public health system

Research basis:

The societal impact stems from years of research, development, and translational work by ZTM in the field of cell therapies, cell and tissue supply, biobanking, advanced treatments,

immunotherapy, regenerative medicine, and the preparation of cell products for clinical use. This area aligns with ZTM's strategic direction, which includes the development of advanced therapeutic and diagnostic activities within transfusion medicine and providing modern support for all activities of the institute.

In ZTM's strategy, modern transfusion medicine with complex diagnostics, cell and tissue supply, and the production of drugs for advanced treatment are defined among the strategic goals, as well as influential scientific research achievements that can be transferred to practice and education. Among the strategic initiatives, the development and optimization of therapeutic activities focusing on drugs for advanced treatment, strengthening international collaboration in transfusion medicine, cell therapies, and advanced treatments, and enhancing research and development activities to accelerate the transfer of scientific knowledge into clinical practice and education are specifically mentioned.

The research basis includes ZTM's participation in the research programme Synthetic Biology and Immunology and in projects in the field of cell therapies and immunotherapy, such as the development of CAR-T approaches, the use of mesenchymal stromal cells and extracellular vesicles for corneal tissue regeneration, immunomodulatory use of MSC, the development of the advanced cell drug aHyC, and advanced post-neoadjuvant therapy for triple-negative breast cancer with autologous cell immunotherapy.

At the same time, ZTM's internal projects have directly supported the translation into clinical and developmental practice: ex vivo preparation of MSC and their use in a clinical study for treating knee osteoarthritis, an academic study on treating xerostomia with allogenic mesenchymal stromal cells, the development and implementation of tests for umbilical cord tissue, the development of functional tests for MSC, the introduction of procedures for analyzing extracellular vesicles, preclinical development of tumor-infiltrating lymphocyte production, and the establishment of criteria for collecting mononuclear cells for tumor vaccine production.

The research basis is also documented in ZTM's publications, including in the field of UC-MSC in osteoarthritis, treatment of radiation-induced xerostomia with allogenic MSC, standardization and heterogeneity of MSC, extracellular vesicles, anti-tumor use of IL-12-transduced MSC, dendritic cells, and cancer immunotherapy, as well as a review of advanced treatment drugs in Slovenian transfusion medicine. ZTM's bibliography for the period 2021–2026 documents a wide range of original and review scientific works, including work in the field of advanced therapies, MSC, EV, immunotherapy, and transfusion medicine.

Impact description:

ZTM has significantly contributed through research, development, and professional work to the development, preparation, and clinical use of cell therapies, tissue products, and drugs for advanced treatment in the Slovenian public health system. The societal impact is reflected in the transfer of knowledge from the research environment to regulated, quality-controlled, and clinically applicable therapeutic activities.

The beneficiaries of this impact are patients with diseases or conditions where standard therapeutic options are limited, clinical partners, research institutions, the public health system,

regulatory authorities, and the broader professional community. The impact is primarily manifested in ZTM providing national professional, technological, and quality infrastructure for the development and preparation of complex biological therapeutic products, which cannot be treated as ordinary laboratory procedures but require a high level of process control, traceability, validation, quality control, and regulatory accountability.

At the clinical-translational level, ZTM has contributed to the development and use of MSC therapies in regenerative medicine, including knee osteoarthritis and radiation-induced xerostomia, as well as the development of new areas such as TIL, tumor-targeted cell therapies, tumor vaccines, cell immunotherapy in cancer, and the use of extracellular vesicles. This strengthens the possibility for patients in Slovenia to access academically developed advanced therapeutic approaches within the public health system.

The impact is not only expressed in individual therapeutic products but also in establishing a complete ecosystem for advanced treatments. This ecosystem includes research design, process development, preparation of the cell product, quality control, clinical collaboration, regulatory documentation, safety monitoring, and knowledge transfer among researchers, laboratories, and clinical departments. In this way, ZTM acts as a connecting link between research partners, clinical institutions, the regulatory environment, and patients.

The special social significance lies in the fact that this is an area where commercial products are often very expensive, accessibility is limited, and development paths require highly specialized knowledge. The research and development activities of ZTM contribute to the national capacity for the responsible, safe, and professionally justified introduction of advanced therapies in Slovenia. This reduces dependence on external providers, strengthens domestic expertise, and creates a foundation for future clinical studies, academic ATMP products, and international collaborations.

The impact also has a regulatory and systemic dimension. The experiences of ZTM in the field of cell therapies and advanced therapy medicinal products contribute to the understanding and development of the national framework for non-routinely prepared medicines for advanced therapy or hospital exemptions. In 2025, the ZTM bibliography also recorded the publication of a European position paper on ATMPs prepared under hospital exemptions, in which representatives of transfusion medicine and ZTM participated.

The long-term potential impact is significant, as the ZTM strategy lists the development of therapeutic services in the field of oncology, the establishment of a single national transfusion service, a new building, and a new information system among its key strategic projects. These projects can further strengthen the conditions for the translation of cell therapies, tissue products, biobanking, and advanced therapy medicinal products into clinical practice.

Reinforcement and possible resonance:

The impact can be supported by the following evidence and indicators:

- Licenses, decisions, certificates, and other regulatory documents that demonstrate ZTM's capability to prepare and release cell products, tissue products, or advanced therapy medicinal products;
- Clinical protocols, approvals from ethics committees, and agreements with clinical

partners for the use of MSC, TIL, tumor vaccines, aHyC, or other cell products;

- Evidence of collaboration with the Institute of Oncology Ljubljana, UKC Ljubljana, the University of Ljubljana, the Institute of Chemistry, the National Institute of Biology, Celica d.o.o., and other partners;
- Documentation of internal ZTM projects that shows the transition from research questions to development processes, validation, clinical use, or preparation for clinical use;
- Published research results in the field of MSC, EV, dendritic cells, cancer immunotherapy, ATMP, and regenerative medicine;
- Evidence of international collaboration, including European professional networks or position papers;
- Data on the number of prepared cell products, the number of patients involved, the number of clinical partners, and the number of therapeutic indications where ZTM has provided developmental or production support;
- Evidence of impact on regulatory understanding, national professional discussions, or the formulation of systemic solutions for advanced therapy medicinal products;
- professional publications, lectures, guidelines or educational activities that demonstrate the transfer of knowledge into the healthcare system.

6.3. Appendix 3: Table – Number of FTE by individual recipients

No. RO	Name of RO	No. FTE (V+R) 2024
101	Institute of Mathematics, Physics and Mechanics	10,77
104	Chemical Institute	57,47
105	National Institute of Biology	21,00
106	Institute "Jožef Stefan"	189,02
176	Center for Applied Mathematics and Theoretical Physics, University of Maribor	2,91
206	Institute for Metal Materials and Technologies	8,38
215	Geological Survey of Slovenia	10,93
302	CANCER INSTITUTE LJUBLJANA	11,06
309	University Rehabilitation Institute of the Republic of Slovenia - Soča	0,37
311	Institute of the Republic of Slovenia for Transfusion Medicine	2,47
312	University Clinical Center Ljubljana	19,96
334	University Clinical Center Maribor	2,74
355	Orthopedic Hospital Valdoltra	0,10
366	Mirovni inštitut	2,39
401	Agricultural Institute of Slovenia	12,09
404	Forestry Institute of Slovenia	5,82
416	Institute of Hop Research and Brewing of Slovenia	1,66
501	Institute of Contemporary History	12,61
502	Institute for Economic Research	4,24
504	Institute of Criminology at the Faculty of Law in Ljubljana	4,10
505	Urban Planning Institute of the Republic of Slovenia	2,45
507	Institute for Ethnic Studies	5,75
510	University of Ljubljana	352,63

552	University of Maribor	75,78
553	Pedagogical Institute	5,94
613	National Museum of Slovenia	3,10
614	Natural History Museum of Slovenia	0,19
618	Scientific Research Center of the Slovenian Academy of Sciences and Arts	101,95
622	Slovenian Ethnographic Museum	0,16
1421	Bistra Ptuj Scientific Research Center	0,58
1500	Institute for Hydraulic Research, Ljubljana	0,68
1502	Institute of Construction of Slovenia	11,16
1510	Koper Scientific Research Center	14,94
1522	Development Center for Toolmaking of Slovenia	0,23
1540	University of Nova Gorica	15,89
1608	Institute of Comparative Law at the Faculty of Law in Ljubljana	2,76
1613	University Clinic for Lung Diseases and Allergy Golnik	1,69
1620	University Psychiatric Clinic Ljubljana	0,37
1636	ICK, Institute for Civilization and Culture Ljubljana	0,56
1988	University of Primorska Universita del Litorale	19,87
2338	Jožef Stefan International Postgraduate School	0,58
2404	INSTITUTE OF NEW REVIEW, Institute for Humanities	2,45
2439	Institute for Development and Strategic Analysis	1,78
2711	International Faculty of Social and Business Studies	0,21
2716	Innovation and Development Institute of the University of Ljubljana	0,34
2721	Study Center for National Reconciliation	1,76
2782	UNIVERZA ALMA MATER EUROPAEA - European Center, Maribor	1,43
2784	Faculty of Information Studies in Novo Mesto	2,79
2885	VIST - Faculty of Applied Sciences	0,28
3018	INSTITUTE OF NUTRITION, Ljubljana	2,38
3030	Center of Excellence for Biosensorics, Instrumentation, and Process Control	0,50
3333	NATIONAL INSTITUTE OF PUBLIC HEALTH	3,13
3334	NATIONAL LABORATORY FOR HEALTH, ENVIRONMENT AND FOOD	1,60
3344	IRRIS Institute for Research, Development and Strategies of Society, Culture and Environment	4,65

6.4. Appendix 4: Translation of Chapter Titles

1. UVOD – PREDSTAVITEV RAZISKOVALNE ORGANIZACIJE
2. PREDSTAVITEV PRISTOPA K SAMOEVALVACIJI
3. SAMOEVALVACIJA ZNANSTVENORAZISKOVALNEGA DELA
    - 3.1. Znanstvena odličnost
    - 3.2. Družbeni vpliv
4. KAKOVOST RAZISKOVALNEGA INSTITUCIONALNEGA OKOLJA
    - 4.1. Strateško upravljanje
    - 4.2. Kadrovska politika, pomlajevanje raziskovalne skupnosti in usposabljanje mladih raziskovalcev
    - 4.3. Raziskovalna infrastruktura in oprema
    - 4.4. Sodelovanje, prenos znanja in raznovrstnost virov financiranja
    - 4.5. Notranji sistem zagotavljanja kakovosti znanstvenoraziskovalnega dela
    - 4.6. Načela odprte znanosti
    - 4.7. Načelo enakih možnosti
    - 4.8. Etika in integriteta
5. POVZETEK SAMOEVALVACIJSKEGA POROČILA IN SWOT ANALIZA
6. PRILOGE
    - 6.1. Priloga 1: Seznam raziskovalnih rezultatov
    - 6.2. Priloga 2: Obrazec – Poročilo o družbenem vplivu
    - 6.3. Priloga 3: Preglednica – Število FTE po posameznih prejemnikih
    - 6.4. Priloga 4: Prevod naslovov poglavij

Document: 6312-2/2026-6

Date: 29.05. 2026

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