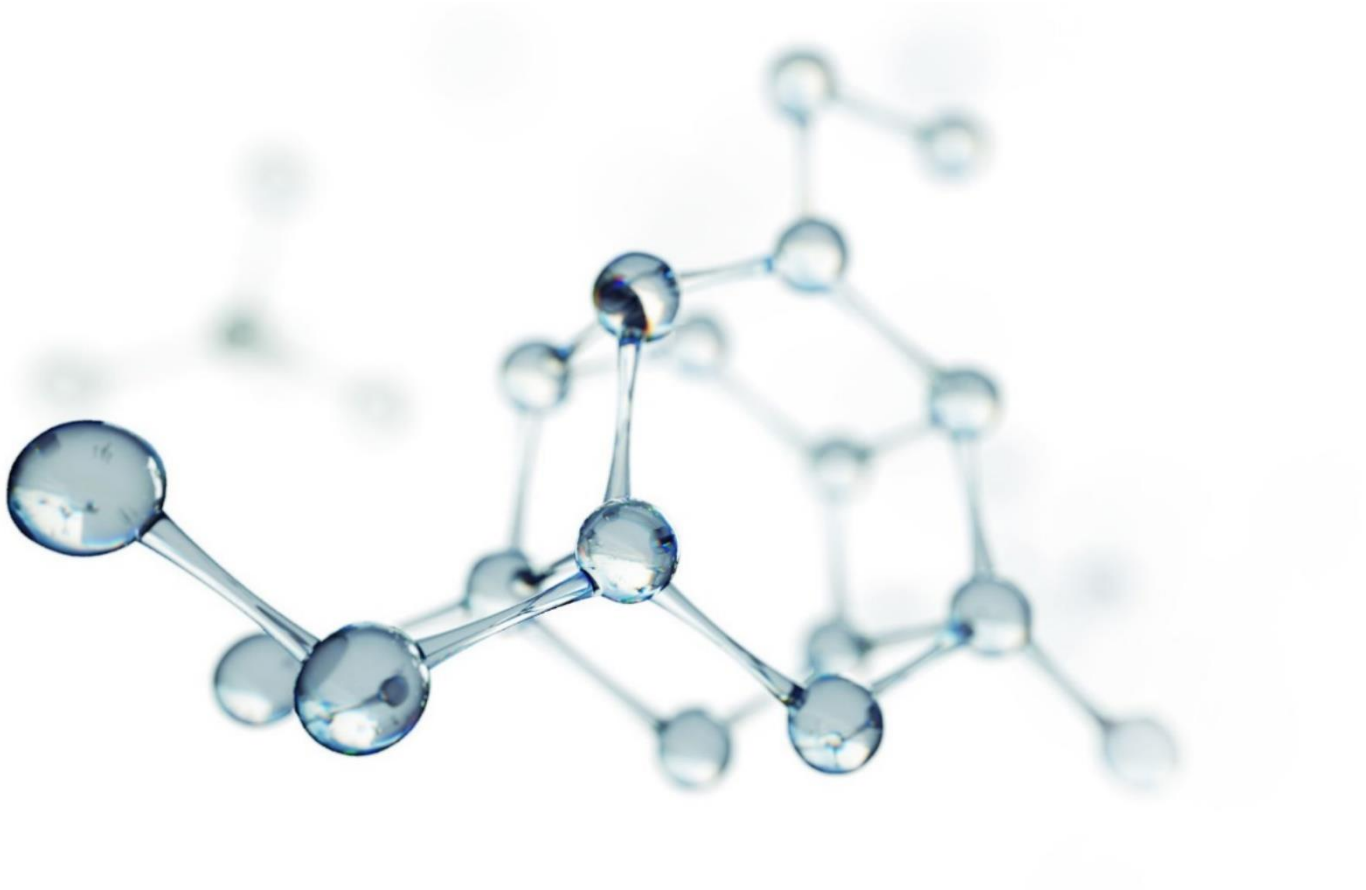
AGENCJA
BADAŃ
MEDYCZNYCH

MEDICAL RESEARCH AGENCY AGENDA FOR 2025



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1. Introduction

1.1. Letter from the President of the Medical Research Agency

The Medical Research Agency celebrates its fifth anniversary. 2024 was a challenging year for Poland's newest science funding institution. A critical evaluation of the Agency's activities, together with audits by the Supreme Audit Office (NIK) and the National Revenue Administration (KAS), provided important insights that formed the basis for a 'new start' for the Agency. The Agency's activities for 2025 include a number of quality enhancing changes in the areas of tendering and project evaluation, as well as in the methodology for initiating and conducting its own research.

The unmet need for funding in non-commercial biomedical research and innovative commercial research was a significant barrier to scientific advancement in Poland. The MRA effectively and comprehensively fulfils its mission in this area. The wide thematic range of projects supported, with a success rate of 33%, has attracted considerable interest among researchers. More than 9,000 patients are covered by the 315 supported projects implemented by 436 healthcare providers, universities and/or companies, with a planned group size of more than 41,000 people. This tangible contribution to advancing medical knowledge and improving treatment quality is a direct outcome of the Agency's activities. With a current project funding budget exceeding PLN 4.3 billion, the need to strengthen evaluation and control mechanisms has become paramount. Analytical systems have been implemented within the Agency to support these processes by identifying risks at all project stages. In 2025, the results of clinical trials initiated during the Agency's first years of operation will be published. We expect that these will be thoroughly analysed and that the findings will help to improve the Polish healthcare system.

2025 will also mark a breakthrough in the mechanisms for assessing proposals. The planned two open calls for researcher-initiated projects, without thematic restrictions, will make use of application evaluation mechanisms involving expert panels to objectively review projects from different areas. With the support of the National Science Centre, we aim to expand our pool of international reviewers to fund the best projects with the potential to impact healthcare systems in Poland and around the world.

International collaboration is another priority for the Agency in 2025. Under the European initiatives EU4Health and Horizon Europe, the Agency plans to support efforts in areas such as personalised oncology therapies and research on oncogenic viruses. We aim to assist Clinical Trials Support Centres in attracting international sponsors, positioning Poland as a key location for major commercial research and a coordination hub for research initiatives in Central and Eastern Europe.

The third pillar of the Agency's activities is education, aimed at developing the personnel necessary to initiate and conduct clinical trials. These initiatives, often conducted in

collaboration with the pharmaceutical industry, ensure that knowledge and skills in clinical trial planning, biotechnology, pharmacokinetics, and regulation meet current and future market demands.

The newly established National Bioethics Centre at the MRA will focus on developing standards and guidelines for clinical trials and research experiments, and will be involved in legislative processes to ensure that the welfare and safety of patients is always at the forefront.

The fourth pillar of the Agency's mission is the support of the biomedical industry. In 2025, this will primarily involve the implementation of projects funded through the recovery and resilience plan (RRP) and activities conducted via the Warsaw Health Innovation Hub. The Agency's efforts in this area for 2025 will focus on evaluating commercial projects, identifying barriers and needs, and shaping future calls for proposals so that results can be implemented into clinical practice swiftly and effectively.

In 2024, the Agency launched two in-house research studies on endometriosis diagnosis and on nicotine addiction. Two additional nationwide projects and a series of system analyses, based on clinical, epidemiological, and statistical data collected by scientific and institutional bodies, are planned for 2025.

With its commitment to refining operational standards, providing a market-driven offer, and a wide range of quality-focused clinical trial efforts, the Medical Research Agency plays a crucial role in Poland's scientific framework, boosting the prominence of biomedical research conducted by Polish researchers. Strategic priorities for the Agency in 2025 include: expanding international cooperation, influencing the structuring of medical data flows, and shaping bioethical standards.

Prof. Wojciech Fendler, MD, PhD
– President of the Medical Research Agency

2. Current organisation of the Medical Research Agency

The Medical Research Agency (hereinafter 'the Agency') is a state legal entity established by the Act of 21 February 2019 on the Medical Research Agency (as last amended on 29 September 2023, Dz. U. [*Journal of Laws*] of 2023, item 2064), hereinafter: 'the Act'. The Agency's strategic directions for the coming years have been defined in the Clinical Research Development Plan 2020-2025, adopted by Resolution No 90 of the Council of Ministers on 20 September 2019 (Official Gazette, item 1024). This plan establishes a framework for the Agency's actions to expand the presence of clinical research within the healthcare system. Following the example of the most advanced healthcare systems, the Agency also aims to support the growth of domestic biotechnology by enhancing the involvement of research entities with implementation capabilities in clinical trials.

2.1. Statutory bodies of the Medical Research Agency

Pursuant to the Medical Research Agency Act, the Agency's bodies are as follows:

- President of the Medical Research Agency
- Council of the Medical Research Agency

2.1.1. President of the Medical Research Agency

The President of the Medical Research Agency is Prof. Wojciech Fendler, MD, PhD.

The Deputy President for Research Funding is Mr Ireneusz Staroń.

2.1.2. The Council of the Medical Research Agency

The Council of the Agency operates based on the Act and the Regulations of the Medical Research Agency Council. The Council's term of office is six years. Its competences include issuing opinions on promising directions of research activities and on division of financial resources. The Council also reviews the Agency's annual activity plan and its amendments, which, according to Article 14.1 of the Act, outline the scope of calls for proposals and own research and development projects for a given calendar year.

- Chairman of the Council: prof. Piotr Rutkowski, MD, PhD – Head of the Clinic of Soft Tissue and Bone Sarcomas and Melanomas; Maria Sklodowska-Curie Institute.
- Deputy chairman of the Council professor Jerzy Sienko, MD, PhD – Department of General and Transplant Surgery with Subdivision of Oncological Surgery, SPWSZ.

Members:

- Prof. Waldemar Priebe – Professor of Medicinal Chemistry; Department of Experimental Therapeutics; Division of Cancer Medicine; The University of Texas MD Anderson Cancer Centre

- Prof. George Wilding – Former Vice President and Deputy Chief Academic Officer/Vice Provost; Clinical and Interdisciplinary Research; The University of Texas MD Anderson Cancer Centre and Professor/Director Emeritus; University of Wisconsin Carbone Cancer Centre
- Prof. Christopher JL Murray – The Chair and Professor of Global Health at the University of Washington; Director of the Institute for Health Metrics and Evaluation (IMHE)
- Col. Krzysztof Różanowski, PhD – Director of the Department of Investment Evaluation
- PhD Michael J. Pencina – Vice Dean for Data Science and Information Technology; Professor of Biostatistics and Bioinformatics; Duke University School of Medicine
- Prof. Tadeusz Faustyn Krzemiński MD, PhD – Head of the Department of Pharmacology, Clinical Pharmacology, and Clinical Toxicology, Andrzej Frycz Modrzewski Krakow University
- Prof. Jerzy Chudek, MD, PhD – Head of the Department and Clinic of Internal Medicine and Oncological Chemotherapy, Medical University of Silesia
- Bernard Waśko, MD PhD – Director of the National Institute of Public Health
- Prof. Alojzy Z. Nowak, MD, PhD – Rector of the University of Warsaw
- Prof. Tomasz Byrski, MD, PhD – Department of Oncology and Chemotherapy, PUM in Szczecin
- Father Arkadiusz Nowak, PhD – President of the Institute of Patients' Rights and Health Education
- Prof. Mansur Rahnama-Hezavah, MD PhD – Head of the Department of Oral Surgery at the Medical University of Lublin, national consultant in dental surgery, President of the Polish Society of Dental and Maxillofacial Surgery, Secretary of the Presidium of the Council for Scientific Excellence for the second term
- Prof. Rafał Dziadziuszko, MD, PhD – University Clinical Centre in Gdansk, Medical University of Gdansk
- Prof. Krzysztof Warzocha, MD, PhD – Institute of Medical Expertise in Łódź
- Zbigniew Teter, MD PhD – Department of Military Health Services
- Tomasz Jerzy Stefaniak, MD, PhD – University Clinical Centre in Gdansk, Medical University of Gdansk
- Prof. Andrzej Matyja, MD, PhD – University Hospital in Krakow
- Mirosław Jarosz, MD, PhD – WSEI Academy of Lublin

2.2. Structure of the Medical Research Agency

The Agency comprises the following main units:

- Agency Office led by Director Anna Tyniec
- Department of Non-Commercial Project Management led by Director Krzysztof Górski

- Finance and Accounting Department led by Director Urszula Myszka
- Department of Innovation and Biotechnology Development led by Director Karolina Maria Nowak, PhD in Pharmaceutical Sciences, MBA
- Department of Science and Evaluation led by Director Zuzanna Nowak-Zyczyńska, PhD
- Clinical Research Development Centre led by Director Elżbieta Bylina, PhD
- National Centre for Bioethics led by Monika Trawińska

The position of Chief Accountant is held by Jolanta Patalan.

2.3. The Medical Research Agency in numbers

- 27 calls for proposals currently underway
- 312 signed funding agreements for projects
- Total value of signed funding agreements – over PLN 4,326 million
- 277 projects currently in progress
- Typical project duration – 5 years
- 4 open calls for proposals
- 2 calls for proposals in preparation

3. Planned statutory activities of the Medical Research Agency

3.1. Summary of statutory activities

The statutory activities of the Agency (Article 2 of the Act) include:

1. Funding scientific research and development in the fields of medical and health sciences, as well as interdisciplinary projects selected through calls for proposals, with a particular focus on clinical, observational, and epidemiological studies, as well as experimental research;
2. Issuing opinions and expert reports in medical and health sciences for public administration bodies or other entities based on concluded agreements;
3. Initiating and developing international cooperation in medical and health sciences under programmes referred to in Article 15(1)(1);
4. Initiating and carrying out its own research and development work;
5. Supporting the activities of the Supreme Bioethics Committee, as specified in Chapter 4 of the Act of 9 March 2023 on clinical trials of medicinal products for human use (Dz. U. [*Journal of Laws*], item 605);
6. Initiating and developing educational and training activities.

The responsibilities of the Agency under the activities specified in Article 15 include:

1. Creating and managing programmes for funding projects, including interdisciplinary projects;
2. Disseminating information on planned or announced calls for proposals;
3. Evaluating proposals and signing agreements with beneficiaries;
4. Supervising and monitoring project implementation, including interdisciplinary projects;
5. Carrying out its own research and development work;
6. Funding non-commercial clinical trials and experimental research projects;
7. Providing administrative support to the Supreme Bioethics Committee, as specified in Chapter 4 of the Act of 9 March 2023 on clinical trials of medicinal products for human use;
8. Undertaking educational and training activities in the area of innovation in healthcare, with a particular focus on scientific research and development in the fields of medical and health sciences;

as well as:

9. Funding projects, including interdisciplinary projects, aligned with the programme and selected through a call for proposals;
10. Organising and funding ad hoc scientific research or development work in the field of medical and health sciences, with a particular focus on clinical, observational, and epidemiological studies, as well as experimental research, including interdisciplinary projects;
11. Disseminating the outcomes of completed tasks;
12. Supporting businesses in conducting and expanding innovative activities in the field of medical and health sciences, as well as interdisciplinary projects.

The Agency is also obliged to carry out the activities set out in Article 23 of the Act: systematic evaluation of the projects funded and the scientific research and development work carried out on their basis, as well as other tasks of the Agency, including the financial benefits of the research and analysis carried out for the State budget and the health care system.

3.2. Analysis of funding needs for scientific research and development

Investments in biomedical and health research have consistently shown an upward trend, growing from USD 240 billion in 2009 to approximately USD 300 billion in 2023, with government organisations remaining the primary source of biomedical research funding.[1] Proper development of the sector requires effective models for funding projects.[2] An appropriate funding model should consider the incidence rate of a given disease, mortality, clinical need for new therapies, effectiveness and costs of existing therapies, and funds from other financing bodies. The balance between the identification of social and clinical needs, appropriate allocation, provision of infrastructure and preparation of staff for project implementation (including appropriate levels of training) appears to be crucial. Excessive funding without developing infrastructure and improving the skills of research teams can lead to poor quality clinical research. The Agency undertook a comprehensive analysis, taking into account the multifaceted nature of funding.

3.2.1. Expert assessment

3.2.1.1. Assessment of the need for scientific research support among scientific societies

As part of the preparations for developing the Agency's 2025 Agenda, public consultations were organised regarding calls for proposals and own research. Representatives of scientific societies and patient organisations active in specific areas of the healthcare system participated in these consultations.

These consultations provided a better understanding of priority research areas and identified key challenges, such as:

- The need for supporting interdisciplinary research, research on rare diseases and research on populations at high risk of exclusion (e.g. paediatric, geriatric, chronically ill populations);
- The need for continued support for non-commercial clinical trials, including those sponsored by patient organisations, and opportunities to expand international research;
- The need for extensive integration of non-clinical research results from patient sample analyses (e.g., genetic) to improve diagnostics and personalise treatment;
- The need for epidemiological research conducted in the Polish population, including long-term studies of small cohorts;

[1] Gomes CM, Marchini G, de Bessa J Júnior, et al. The landscape of biomedical research funding in Brazil: a current overview. *Int Braz J Urol*. 2024;50(2):209-222. doi:10.1590/S1677-5538.IBJU.2024.9905

[2] Sampat BN, Buterbaugh K, Perl M. New evidence on the allocation of NIH funds across diseases. Milbank Q. 2013;91(1):163-185. doi:10.1111/milq.12005

- The need for system-level analyses, including those related to prescription practices for selected indications or specific patient groups;
- The need for combating 'fake news' and providing patients with reliable information;
- The need for developing soft skills among medical personnel and researchers as a tool for improving project performance indicators;
- The need for funding medical assistants to support physician-researchers and patients.

Additionally, representatives of patient organisations suggested implementing a researcher evaluation as a potential mechanism to increase the success rate of subsequent studies, and highlighted ongoing issues with understanding study documentation.

The scientific societies confirmed their willingness to implement basket and umbrella studies, in which the Agency would act as the sponsor.

Based on the gathered information, the Agency has planned two open calls: one for non-commercial clinical trials and one for research experiments, as well as own research aimed at raising awareness among Poles about clinical trials and enhancing general knowledge about evidence-based medicine.

3.2.1.2. Assessment of R&D needs according to members of the Medical Research Agency Council

The Council members of the Agency were able to provide their feedback on the issues related to the proposed 2025 Agenda for calls for proposals and own research through an online CAWI survey. According to the Council members, continuing the annual open calls for non-commercial clinical trials and research experiments is a good strategy. In calls for non-commercial clinical trials, studies that incorporate Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) should be prioritised. Surveyed Council members also confirmed that integrating beneficiaries conducting similar studies into research teams to develop a modern research protocol (e.g., basket studies) would be a beneficial initiative. Additionally, the introduction of a digital component and/or reliance on real-time collected digital data (RWD) in clinical trial protocols could improve the quality of Agency-funded research. The majority of respondents also felt that the Agency should conduct its own non-commercial umbrella clinical trial, which would be conceptualised and co-organised by a national scientific association.

In 2025, the Agency will promote collaboration among research centres, the use of modern research techniques in clinical trials and experimental research, as well as the introduction into clinical trial protocols of indicators relating to the perceptions and experiences of patients participating in trials.

3.2.2. Assessment of health needs:

3.2.2.1. Analysis of Health Needs Maps

For the purposes of the MRA's Agenda, an analysis was conducted based on data from the Health Needs Map - Long-Term Care for 2022–2026[3], focusing on epidemiological projections, risk factors, and long-term care, with particular emphasis on challenges anticipated for 2025. The document highlights the growing demand for care services in Poland, primarily driven by the ageing population and the need to address the healthcare requirements of elderly and dependent individuals.

Based on the published results, a key data was analysed to identify areas that will be prioritised in open calls announced by the Agency in 2025:

- Cardiovascular diseases
- Nervous system diseases
- Chronic respiratory diseases
- Musculoskeletal diseases
- Skin diseases and subcutaneous tissue diseases
- Diabetes and kidney diseases
- Mental disorders
- Cancer

3.2.2.2. Analysis of medical needs based on literature data

The global clinical trials market is expected to grow at a compound annual growth rate (CAGR) of 6.49% from 2024 to 2030. Market growth was particularly notable in 2020 due to the COVID-19 pandemic, which impacted both virtual and traditional clinical trials. Rapid technological evolution, digitalisation of biomedical research, an increasing incidence of chronic diseases, globalisation of clinical trials, and the growing role of personalised medicine are expected to positively influence market growth. The increasing adoption of decentralised solutions and telemedicine in clinical trials is enhancing recruitment, which positively impacts the market's overall growth potential.[4] According to ClinicalTrials.gov data, as of 17 May 2023, a total of 452,604 clinical trials were registered, with 64,838 actively recruiting participants worldwide.[5] There has been increased investment in R&D

[3] Obwieszczenie Ministra Zdrowia z dnia 27 sierpnia 2021 r. w sprawie mapy potrzeb zdrowotnych. Dz. Urz. Min Zdrowia, 30 sierpnia 2021 r. poz. 69.

[4] Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II, Phase III, Phase IV), By Study Design, By Indication, Indication By Study Design, By Sponsors, By Service Type, By Region and Segment Forecasts, 2024 – 2030. Clinical Trials Market Size, Share And Growth Report, 2030 (grandviewresearch.com)

[5] Clinical Trials Market - By Phase (I, II, III, IV), Study Design (Interventional, Observational, Expanded Access), Service Type (Outsourcing, In-house), Therapeutic Area (Oncology, Dermatology, Neurology, Cardiology) – Global Forecast (2024 – 2032) Clinical Trials Market Size & Share Report, 2024 – 2032 (gminsights.com)

programmes, a shift towards outsourcing to reduce time and costs of clinical trials, and an increase in the number of patents expiring on widely used medicines. Phase III trials dominated the market, accounting for 53.3% of total revenue in 2023.[6] According to the World Health Organisation's (WHO) International Clinical Trials Registry Platform (ICTRP), of the 271,906 clinical trials at a known development stage in February 2023, 35% were in Phase II. By May 2023, Phase II trials accounted for 74,432 clinical studies, representing 36% of all registrations. This significant representation of Phase II trials highlights their crucial role in evaluating the efficacy and safety of new treatments before moving on to large-scale Phase III trials and final regulatory approval.[7] Depending on the source, autoimmune/inflammatory diseases accounted for the largest share of the clinical trials market revenue in 2023 (Clinicaltrails.gov lists more than 8,900 interventional trials for autoimmune/inflammatory diseases)[8] or oncology. According to WHO ICTRP, the number of registered oncology clinical trials grew steadily, from around 19,211 in 2013 to 26,396 in 2022. This growth trend is attributed to significant breakthroughs in immunotherapy, precision medicine, gene therapy, and combination therapies, which have strengthened the position of oncology.[9] It also highlights the increasing role of non-clinical research, including experimental models to better understand tumourigenesis or the response of the tumour microenvironment.[10] Data extracted from biological samples of patients enrolled in clinical trials can provide information on optimal combinations of therapies.[11] Clinical trials are expected to become more complex in the future, generating a significant amount of diverse data.[12] As the amount of data increases, algorithms to assess safety and efficacy, and algorithms to reduce costs (e.g. excluding centres based on their predicted cost-effectiveness) are likely to become more important. By 2050, AI-assisted simulations are projected to play a key role in clinical trials. Wearable devices are also expected to have a significant impact on the quality of life and medication adherence, thereby influencing therapeutic outcomes. For example, instead of manually checking blood glucose levels and

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[6] Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II, Phase III, Phase IV), By Study Design, By Indication, Indication By Study Design, By Sponsors, By Service Type, By Region and Segment Forecasts, 2024 – 2030. Clinical Trials Market Size, Share And Growth Report, 2030 (grandviewresearch.com)

[7] Clinical Trials Market - By Phase (I, II, III, IV), Study Design (Interventional, Observational, Expanded Access), Service Type (Outsourcing, In-house), Therapeutic Area (Oncology, Dermatology, Neurology, Cardiology) – Global Forecast (2024 – 2032) Clinical Trials Market Size & Share Report, 2024 – 2032 (gminsights.com)

[8] Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II, Phase III, Phase IV), By Study Design, By Indication, Indication By Study Design, By Sponsors, By Service Type, By Region and Segment Forecasts, 2024 – 2030. Clinical Trials Market Size, Share And Growth Report, 2030 (grandviewresearch.com)

[9] Clinical Trials Market - By Phase (I, II, III, IV), Study Design (Interventional, Observational, Expanded Access), Service Type (Outsourcing, In-house), Therapeutic Area (Oncology, Dermatology, Neurology, Cardiology) – Global Forecast (2024 – 2032) Clinical Trials Market Size & Share Report, 2024 – 2032 (gminsights.com)

[10] Non Clinical Trials Market Size, Share, Industry, Forecast and Outlook (2023-2030) Non-Clinical Trials Market Analysis, Size, Share and Report 2023-2030 (datamintelligence.com)

[11] Spreafico A, Hansen AR, Abdul Razak AR, Bedard PL, Siu LL. The Future of Clinical Trial Design in Oncology. *Cancer Discov*. 2021;11(4):822-837. doi:10.1158/2159-8290.CD-20-1301

[12] Gibney E. How many yottabytes in a quettabyte? Extreme numbers get new names. Prolific generation of data drove the need for prefixes that denote 1027 and 1030. *Nature.* 2022 November 18; doi: 10.1038/d41586-022-03747-9.

administering insulin as needed, a patient could rely on an electromedical device—not only for monitoring but also for administering correct (and variable) doses based on specific patient needs. This approach would alleviate the patient's mental burden.[13] New technologies will not only make it easier to recruit participants, but also to identify patients. As wearable devices become more widespread, they could be combined with genetic testing to provide earlier and more definite diagnoses for a wide range of diseases.[14] Additionally, a broader dataset could lead to a better understanding of the pathophysiological processes responsible for disease development and progression.[15]

Based on the analysis, the Agency outlined the directions for clinical trials development for 2025:

- Strengthening translational medicine through the implementation of the TransMED call for proposals (announced in 2024);
- Supporting laboratory research (including patient sample studies) to better understand disease pathophysiology, progression, and treatment responses;
- Analysing the use of data from biological samples and wearable devices for personalisation of treatment;
- Supporting 'smart' clinical trials based on data and algorithms;
- Using innovative medical technologies in research, including artificial intelligence and digital tools, to optimise recruitment and research processes (including cost optimisation);
- Promoting research in the areas of chronic, autoimmune/inflammatory, and oncological diseases.

3.2.3. Analysis of research funding in Europe

Research funding in Europe is provided by several key agencies that support the development of innovation, clinical trials, medical devices, and other aspects of medicine. These agencies offer various funding programmes, enabling scientists and research institutes to carry out projects that are crucial for public health and medical advancement. Table 1 provides a detailed overview of the key national and international research agencies in Europe, which plan to launch strategically significant medical and research projects starting in Q3 2024. The table includes information on the main funding programmes offered by these

[13] Hardman TC, Aitchison R, Scaife R, Edwards J, Slater G. The future of clinical trials and drug development: 2050. *Drugs Context*. 2023;12:2023-2-2. Published 2023 Jun 8. doi:10.7573/dic.2023-2-2

[14] Wetsman N. Theranos promised a blood testing revolution – Here's what's really possible. *Innovation is possible, even if it's not magic.* https://www.theverge.com/22834348/theranos-blood-testing-innovation-drop-holmes.

[15] Hardman TC, Aitchison R, Scaife R, Edwards J, Slater G. The future of clinical trials and drug development: 2050. *Drugs Context*. 2023;12:2023-2-2. Published 2023 Jun 8. doi:10.7573/dic.2023-2-2

agencies, the types of projects that will be implemented, and the planned start dates for the initiatives.

Table 1. Planned medical and research projects in Europe starting in Q3 2024

Agency	State	Main programmes	2024/2025 projects	Starting date	Sources
Agence Nationale de la Recherche (ANR)	France	**PRCI (Collaborative Research Projects - International)**: Support for international cooperation projects. **PRCE (Collaborative Research Projects - Enterprises)**: Support for projects carried out with companies.	- Research into new genetic therapies. - Artificial intelligence projects in medical diagnostics.	July 2024	ANR
Deutsche Forschungsgemeinschaft (DFG)	Germany	**Collaborative Research Centres (CRC)**: Support for long-term research projects implemented by groups of researchers. **Priority Programmes (SPP)**: Focus on promoting new research themes with high innovation potential.	- Sustainable medicine projects - Research into neurodegenerative diseases.	August 2024	DFG
National Institute for Health Research (NIHR)	United Kingdom	**Health Technology Assessment (HTA)**: Support for research to assess the effectiveness, costs and benefits of new medical technologies. **Research for Patient Benefit (RfPB)**: Funding for research projects with a direct impact on patient care.	- Research into the effectiveness of new medical technologies. - Youth mental health programmes.	September 2024	NIHR
Instituto de Salud Carlos III (ISCIII)	Spain	**Strategic Action in Health (AES)**: Programme to support health research of high national priority. **CIBER (Biomedical Research Networking Centres)**: Research networks focusing on different areas of medicine.	- Cardiovascular disease projects. - Cancer immunotherapy research.	July 2024	ISCIII
Fonds National de la Recherche (FNR)	Luxembourg	**CORE**: Major funding programme for basic and applied research. **INTER**: Support for international research projects.	- Research into biotechnology. - Personalised medicine projects.	August 2024	FNR

Agency	State	Main programmes	2024/2025 projects	Starting date	Sources
Netherlands Organisation for Health Research and Development (ZonMw)	Netherlands	**Vici**: Programme to support experienced researchers. **Off Road**: A programme to support innovative, high-risk research projects.	- Innovative high-risk projects. - Research on population ageing and public health.	September 2024	ZonMw
European Research Council (ERC)	EU	**ERC Starting Grants**: Support for early career researchers. **Consolidator Grants**: Support for mid-career researchers. **Advanced Grants**: Support for experienced researchers. **Synergy Grants**: Support for groups of researchers carrying out joint projects.	- Neuroscience and mental health research. - Cancer and gene therapy projects.	July 2024	ERC
Innovative Health Initiative (IHI)	EU	**Research projects in innovative medical therapies and technologies:** Promotes public-private collaboration in the development of new medicines and medical technologies.	- Research into medical technologies. - Projects on public-private collaboration in the development of new medicines.	August 2024	IHI
European Health and Digital Executive Agency (HaDEA)	EU	**Horizon Europe**: Funding research and innovation **EU4Health**: Support for health projects. **Digital Europe Programme**: Support for health system digitalisation.	- Initiatives for health system digitalisation. - Clinical trials for rare diseases.	September 2024	HaDEA
European and Developing Countries Clinical Trials Partnership (EDCTP)	EU and sub-Saharan Africa	**Research into malaria, tuberculosis, HIV/AIDS and other infectious diseases:** Support for clinical trials for infectious diseases in resource-limited regions.	- Clinical trials of new therapies for HIV. - Malaria control projects in resource-limited regions.	July 2024	EDCTP
European Clinical Research Infrastructure Network (ECRIN)	EU	**Multinational clinical trials:** Support for international clinical trials in the form of logistical and financial support to research consortia.	- International research into new cancer treatments.	August 2024	ECRIN

Agency	State	Main programmes	2024/2025 projects	Starting date	Sources
			- Chronic disease management projects in different European countries.		

In 2024 and 2025, European research agencies in will focus on key areas of medicine (Figure 2), with an emphasis on innovation and personalised treatment. New gene therapies and personalised medicine will be dominant themes, highlighting the growing importance of tailoring therapies to individual patient needs. Sustainable medicine and chronic disease research is also a priority, responding to the challenges of an ageing population. Investment in innovative medical technologies, including artificial intelligence, has the potential to transform diagnostics and healthcare. Mental health, particularly among young people, is becoming an increasingly important area of research in response to growing needs. Research on infectious diseases, such as malaria and HIV, remains essential for global public health. The digitalisation of healthcare systems is gaining significance, indicating a move towards modernisation and improved healthcare efficiency. Overall, European research agencies are focusing on innovative, sustainable solutions that have the potential to have a significant impact on the future of medicine. These priorities reflect efforts to improve the quality of life for patients and to manage healthcare resources more efficiently.

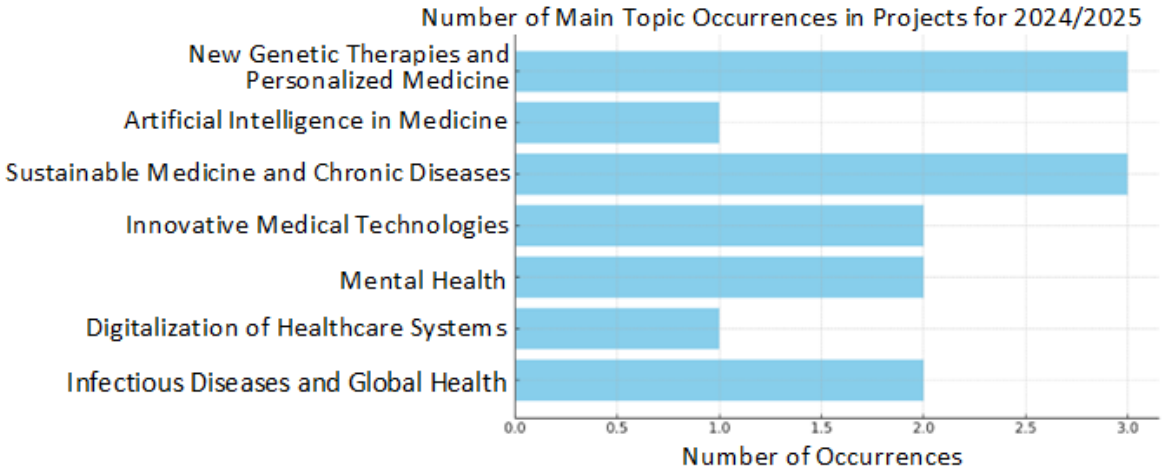

Figure 2: Planned medical and research projects in Europe starting in Q3 2024

Tasks defined in the calls for proposals announced by the Agency in 2025, as well as those undertaken by the Agency, will include:

- Actions aimed at developing digital health systems;
- Actions supporting the development of personalised medicine;
- Actions to analyse health issues in areas such as global health and dementias.

3.3. Funding plans for statutory activities

3.3.1. Calls for proposals

3.3.1.1. Open call for non-commercial clinical trials

Objective

Launching a call for clinical trials aimed at identifying and evaluating medicinal products in new therapeutic indications. Key tasks within this call include:

- Developing new standards of treatment, diagnostics, or rehabilitation within ongoing non-commercial clinical trials and expanding knowledge on the most clinically optimal therapies for a wide range of conditions, with particular focus on:
  - Cardiovascular diseases,
  - Nervous system diseases,
  - Autoimmune diseases,
  - Chronic respiratory diseases,
  - Musculoskeletal diseases,
  - Skin and subcutaneous tissue diseases,
  - Cancer.
- Increasing the number of non-commercial clinical trials in populations particularly at risk of exclusion, including the pediatric population.

Problem Description

The primary purpose of funding non-commercial clinical trials is to improve public health by developing new methods of treatment, diagnostics, and disease prevention that may not have direct commercial potential. These studies often focus on areas that may be overlooked by pharmaceutical companies, such as rare diseases, therapies targeting specific populations, optimisation of existing therapies, or assessing the long-term effectiveness and safety of available drugs. Non-commercial trials can also address issues like reducing treatment costs, improving patients' quality of life, or understanding disease progression mechanisms, potentially leading to more personalised and cost-effective therapies.

Outcomes

- Identifying the most clinically effective medicinal products used for specific diseases at the same stage of treatment or diagnosis;
- Providing high-quality scientific evidence to optimise clinical practice guidelines for the use of medicinal products;
- Increasing patient access to the most clinically effective medicinal products;

- Improving patient care by gaining knowledge of new/most effective therapeutic options for a given disease at a particular stage of treatment.

Implementation Timeline	Q2 2025
Indicative Funding Sources	PLN 200,000,000.00
Monitoring Indicators	➲ Number of validated innovative therapeutic methods developed within non-commercial clinical trials; ➲ Number of patients included in non-commercial clinical trials; ➲ Number of publications identifying the most clinically effective therapeutic procedures used for a specific disease to optimise clinical practice guidelines; ➲ Number of clinical trials launched in Poland in compliance with regulatory requirements; ➲ Number of biobanked biological material samples.

3.3.1.2. Open call for research experiments

Objective

Launching a call for conducting research experiments focused on evaluating medical procedures, including diagnostic and therapeutic procedures. Key tasks within this call include:

- Developing new medical procedures and patient pathways within the framework of research experiments, as well as expanding knowledge on the most clinically optimal diagnostic procedures for a wide range of conditions, with particular focus on:
  - Cardiovascular diseases,
  - Nervous system diseases,
  - Autoimmune diseases,
  - Chronic respiratory diseases,
  - Musculoskeletal diseases,
  - Skin and subcutaneous tissue diseases,
  - Cancer.
- Conducting research experiments according to the best standards.

Problem Description

Head-to-head studies play a crucial role in directly comparing the effectiveness and safety of two or more treatment methods. Their goal is to provide reliable and objective data on which medical procedure is more effective or has fewer adverse effects, aiding physicians and medical decision-makers in making informed therapeutic choices. Identifying the most effective medical procedures among those available on the market will optimise therapeutic management and serve as an essential tool for public payers in making reimbursement decisions. Due to limited financial resources, public payers often need to choose between alternative medical technologies.

Areas requiring support:

- Procedures,
- Personalised medicine.

Outcomes

- Identifying the most clinically effective medicinal procedures used for specific diseases at the same stage of treatment or diagnosis;
- Providing high-quality scientific evidence to optimise clinical practice guidelines for the use of medical procedures and change clinical practices;
- Increasing patient access to the most clinically effective medical procedures (diagnostic and therapeutic);

- Improving patient care by gaining knowledge of new/most effective therapeutic procedures used for a given disease at a specific stage of treatment or diagnosis, and developing an efficient patient pathway;
- Standardising procedures and documentation submitted during the registration process for research experiments and enhancing the quality of patient monitoring during the experiments.

Implementation Timeline	Q3 2025
Indicative Funding Sources	PLN 75,000,000.00
Monitoring Indicators	➲ Number of validated innovative therapeutic (treatment) or diagnostic methods developed within the framework of research experiments; ➲ Number of patients involved in research experiments; ➲ Number of publications identifying the most clinically effective medical procedures used for a specific disease at the same stage of diagnosis or treatment, with the aim of optimising clinical practice guidelines; ➲ Number of research experiments initiated in Poland in compliance with regulatory requirements; ➲ Number of biobanked biological material samples.

3.3.2. MRA's own projects

3.3.2.1. ***Own project: Comparative study evaluating the use of the non-invasive EndoRNA test in diagnosing endometriosis versus laparoscopy – ENDO*** *– continuation*

Objective

To evaluate the clinical utility of the EndoRNA test compared to laparoscopy in detecting endometriosis.

This involves assessing the specificity and sensitivity of the EndoRNA test and demonstrating its applicability for patients with ambiguous imaging results or with no abnormalities in imaging despite clinical symptoms suggestive of endometriosis, as well as for patients receiving hormonal treatment due to suspected endometriosis.

2025 objective

Enroll 450 women in the study, conduct the non-invasive EndoRNA test, and compare the test results with laparoscopy outcomes.

Problem Description

Endometriosis is one of the most common gynecological conditions among women. According to the World Health Organisation, endometriosis may affect around 10% of women of reproductive age globally. Data from the Endometriosis Foundation in Poland indicates that up to 3 million women in Poland may be affected by endometriosis. The disease is diagnosed in approximately 40% of women treated for infertility and over 60% of women with chronic pelvic pain. Endometriosis is a chronic condition that poses a significant health problem and greatly impacts the quality of life of affected women. Additionally, even small lesions of endometriosis can often lead to infertility. At the same time, due to the heterogeneous clinical picture, the uncharacteristic symptoms and the similarity or coexistence with other diseases, the diagnosis of endometriosis is often delayed until the first clinical signs appear. The average time from the first symptoms to diagnosis is approximately 6-8 years in all developed countries.

To date, confirmation of the disease has been possible through imaging studies such as transvaginal ultrasound or magnetic resonance imaging. However, both methods lack sufficient sensitivity. The gold standard for diagnosing endometriosis, allowing not only confirmation of the diagnosis but also the collection of material for histopathological examination, is laparoscopy. However, it is an invasive procedure and is associated with complications in patients.

In 2022, the European Society of Human Reproduction and Embryology published new guidelines for the diagnosis and treatment of endometriosis,

proposing a shift away from laparoscopy as the gold standard towards imaging studies and the use of biomarkers as an auxiliary diagnostic tool. Since not all forms of endometriosis can be confirmed by imaging studies, research has been ongoing for many years to identify markers in blood serum, endometrium, and peritoneal fluid that would allow for early and non-invasive diagnosis of endometriosis. Based on a mandate from the Ministry of Health, the Agency is conducting a research experiment to assess the clinical utility of a non-invasive test based on the presence of a biomarker. The results of this study may help to develop a diagnostic algorithm and reduce the need for laparoscopy. In addition, a comparative analysis of the utility of the test in relation to the current diagnostic standard could also serve as scientific evidence for the inclusion of this method in the catalogue of guaranteed health services.

Outcomes	➲ Verification of the utility of biomarker measurement (*FUT4* gene mRNA expression level) in patients with diagnosed endometriosis; ➲ Development and publication of a report describing the analysis and its findings; ➲ Preparation of a scientific publication.
Implementation Timeline	By 30 April 2026
Indicative Funding Sources	National Health Fund (NFZ) allocation: PLN 7,939,000
Monitoring Indicators	➲ Number of agreements signed with centres ➲ Number of patients enrolled.

3.3.2.2. ***Own project: Analysis of the prevalence and factors associated with the use of selected addictive substances in the polish population – NIKO*** *– continuation*

Objective To determine the prevalence of nicotine product use across various demographic groups in Poland by:

- ➲ Determining the frequency of nicotine product use among users,
- ➲ Identifying the age of nicotine initiation and the history of nicotine product use;

- Assessing the quantity and types of nicotine products used (investigating dual use and polyuse) and factors influencing the switch from one nicotine product to another;
- Identifying motivations for starting to use tobacco/nicotine products, particularly new products;
- Evaluating circumstances and factors influencing the initiation of nicotine products, in particular new products;
- Identifying the determinants and circumstances that lead people to quit using nicotine products;
- Determining the circumstances and reasons why some people who quit using nicotine products resume usage;
- Identifying differences in attitudes, behaviours, and self-assessed health related to nicotine product use among various social groups in the Polish population.

2025 objectives

To launch a quantitative study on a sample of 9,000 individuals, analyse the data, and prepare a report containing both quantitative and qualitative findings along with their interpretation.

Problem Description

According to the Announcement of the Minister of Health of 27 August 2021, regarding the health needs map for 2022-2026,[16] tobacco has been the leading risk factor causing the highest loss of healthy life years in Poland since 1990. Every third Pole smokes traditional cigarettes daily.[17] The peak year for tobacco smoking in Poland was 1982, with over 60% of men and more than 30% of women smoking daily, marking the highest smoking prevalence in the country's history and one of the highest in Europe, as well as in Central and Eastern Europe.[18]

Heated tobacco use is increasingly common among smokers. Data from 2019 show that 1.4% of adult Poles were current e-cigarette users.[19]

[16] Announcement of the Minister of Health of 27 August 2021 regarding the health needs map. (Official Gazette of the Ministry of Health, 2021, item 69).
[17] Jankowski M, Ostrowska A, Sierpiński R, et al. The Prevalence of Tobacco, Heated Tobacco, and E-Cigarette Use in Poland: A 2022 Web-Based Cross-Sectional Survey.
Int J Environ Res Public Health. 2022;19(8):4904.
[18] Pinkas J. (ed.). Współczesne wyzwania zdrowia publicznego. Wybrane zagadnienia. (Contemporary Challenges of Public Health. Selected Issues.) PZWL 2021. ISBN 978-83-200-6513-8.
[19] Pinkas J, Kaleta D, Zgliczyński WS, et al. The Prevalence of Tobacco and E-Cigarette Use in Poland: A 2019 Nationwide Cross-Sectional Survey. Int J Environ Res Public
Health. 2019;16(23):4820.

Epidemiological studies conducted in 2019[20] among high school students aged 15 to 19 in Poland indicated that the percentage of individuals who had used only e-cigarettes in the past 30 days increased from 2% in 2010-2011 to 8% in 2013-2014, and reached 11% in 2015-2016. The most common reasons teenagers turn to e-cigarettes include the absence of the unpleasant odour associated with smoking tobacco, flavour experiences (such as inhaling aerosols with sweet flavours), and the lower cost of e-cigarettes compared to traditional cigarettes. The dynamic epidemiological situation suggests a halt in the decline in traditional tobacco product (cigarette) consumption in Poland and an increase in the use of new tobacco or nicotine products (e-cigarettes, heated tobacco, nicotine pouches, etc.). Currently, no studies are being conducted to comprehensively assess these phenomena from a public health risk perspective, hindering evidence-based decision-making. Due to insufficient regulations, Poland is a rapidly penetrated market for new tobacco industry products, particularly among adolescents and young adults. Making health policy decisions based on solid knowledge and critical data analysis is crucial to the effectiveness of public health actions.

Outcomes	➲ Assessment of the Polish population's exposure to addictive substances, ➲ Mapping of health policies in EU countries to identify areas for improvement in Poland, ➲ Preparation of recommendations for national health policy, considering global trends, ➲ Development of a publication/report presenting the analysis results.
Implementation Timeline	By 31 March 2026
Indicative Funding Sources	National Health Fund (NFZ) allocation: PLN 2,147,608.88
Monitoring Indicators	➲ Qualitative research report ➲ Primary quantitative research report

[20] Smith DM, Gawron M, Balwicki L, Sobczak A, Matynia M, Goniewicz ML. Exclusive versus dual use of tobacco and electronic cigarettes among adolescents in Poland,
2010-2016. Addict Behav. 2019;90:341-348.

3.3.2.3. ***Own research and educational project: 'Awareness, knowledge, and attitudes toward clinical trials in Poland'***

Objective

To assess the level of knowledge and attitudes of the public towards clinical trials.

To evaluate the impact of educational initiatives on the perception of clinical trials and attitude shifts within selected groups.

Problem Description

Clinical trials play a crucial role in developing new and effective treatment methods and improving patient quality of life, as they are responsible for generating some of the highest levels of scientific evidence used in medical practice.[21] Unfortunately, many trials are unable to address their research questions because they fail to meet recruitment indicators.[22] The increasing complexity of study protocols negatively impacts not only the costs and duration of drug development but also potential volunteers' interest in participating in trials.[23] Clinical trials should be perceived as a public good, and society should understand its role in disease prevention, diagnosis, and treatment.[24] Currently, public knowledge about clinical trials is low, and media coverage of clinical trials is often negative.[25] Low interest in clinical trials is influenced by factors grouped into three primary domains: trial accessibility, awareness of trials, and trial acceptance.[26] Improving recruitment and retention rates for clinical trial participants depends heavily on public and patient engagement in clinical research.[27] The lack of diversity among trial participants (including age, gender, ethnicity, and comorbidities) prevents a proper assessment of the generalisability of results for practical implementation.[28] One of the main factors limiting potential participants'

[21] Leiter A, Diefenbach MA, Doucette J, Oh WK, Galsky MD. Clinical trial awareness: Changes over time and sociodemographic disparities. *Clin Trials*. 2015;12(3):215-223. doi:10.1177/1740774515571917

[22] Massett HA, Dilts DM, Bailey R, et al. Raising Public Awareness of Clinical Trials: Development of Messages for a National Health Communication Campaign. *J Health Commun*. 2017;22(5):373-385. doi:10.1080/10810730.2017.1290715

[23] Getz KA, Campo RA. Trial watch: trends in clinical trial design complexity. *Nat Rev Drug Discov*. 2017;16(5):307. doi: 10.1038/nrd.2017.65

[24] The Need for Awareness of Clinical Research | National Institutes of Health (NIH)

[25] Mackenzie IS, Wei L, Rutherford D, et al. Promoting public awareness of randomised clinical trials using the media: the 'Get Randomised' campaign. *Br J Clin Pharmacol*. 2010;69(2):128-135. doi:10.1111/j.1365-2125.2009.03561.x

[26] Denicoff AM, McCaskill-Stevens W, Grubbs SS, et al. The national cancer institute-american society of clinical oncology cancer trial accrual symposium: summary and recommendations. *Journal of oncology practice / American Society of Clinical Oncology.* 2013;9:267–276

[27] Anderson A, Borfitz D, Getz K. Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials. *JAMA Netw Open*. 2018;1(6):e182969. Published 2018 Oct 5. doi:10.1001/jamanetworkopen.2018.2969

[28] Bodicoat DH, Routen AC, Willis A, et al. Promoting inclusion in clinical trials-a rapid review of the literature and recommendations for action. *Trials*. 2021;22(1):880. Published 2021 Dec 4. doi:10.1186/s13063-021-05849-7

involvement in research is a lack of trust in trials, doctors, researchers, medicines, and the pharmaceutical industry.[29] This situation may stem from previous negative experiences with the healthcare system or personal beliefs or fears.[30] A large number of studies indicate that a lack of understanding of various aspects of clinical trials, such as recruitment or data collection, serves as a limiting factor in interest in participating in the process.[31] Psychological resistance to participation in trials is often population-specific. For example, older people may believe they are 'too old' to participate.[32] Privacy concerns, immigration status, religious beliefs, fears of being seen as a 'guinea pig,' and lack of social acceptance (including family or friends) are also significant barriers.[33] Regular assessment of clinical trial awareness and targeted educational programmes addressing specific barriers are essential.[34] The issue of public awareness and recruitment has been recognised for many years. In Scotland, a media campaign titled 'Get Randomised' was launched in 2008 to boost public engagement in clinical trials, leading to an approximate 40% absolute increase in awareness of clinical trials compared to the period before the campaign.[35] Examples of globally piloted and implemented initiatives include: meetings held by the U.S. Food and Drug Administration and the European Medicines Agency with patients and their families to understand direct treatment experiences for selected diseases; collaboration between pharmaceutical and biotechnology companies and patient advocacy groups, as well as patient communities on social media; the use of patient advisory panels to gather feedback on protocol designs; the implementation of telemedicine and home care networks to enhance the convenience of participation; and the creation of plain-language summaries of clinical trial results aimed at

[29] Fischer SM, Kline DM, Min SJ, Okuyama S, Fink RM. Apoyo con Cariño: strategies to promote recruiting, enrolling, and retaining Latinos in a cancer clinical trial. *J Natl Compr Canc Netw.* 2017;**15**(11):1392–1399. doi: 10.6004/jnccn.2017.7005.

[30] Cunningham-Erves J, Barajas C, Mayo-Gamble TL, McAfee CR, Hull PC, Sanderson M, et al. Formative research to design a culturally-appropriate cancer clinical trial education program to increase participation of African American and Latino communities. *BMC Public Health.* 2020;**20**(1):840. doi: 10.1186/s12889-020-08939-4.

[31] Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, Jamerson B, McCullough C, Pierre C, Polis AB, Puckrein G, Regnante JM. Increasing diversity in clinical trials: overcoming critical barriers. *Curr Probl Cardiol.* 2019;**44**(5):148–172. doi: 10.1016/j.cpcardiol.2018.11.002.

[32] Bloch F, Charasz N. Attitudes of older adults to their participation in clinical trials: a pilot study. *Drugs Aging.* 2014;**31**(5):373–377. doi: 10.1007/s40266-014-0168-2.

[33] Bodicoat DH, Routen AC, Willis A, et al. Promoting inclusion in clinical trials-a rapid review of the literature and recommendations for action. *Trials*. 2021;22(1):880. Published 2021 Dec 4. doi:10.1186/s13063-021-05849-7

[34] Yadav S, Todd A, Patel K, et al. Public knowledge and information sources for clinical trials among adults in the USA: evidence from a Health Information National Trends Survey in 2020. *Clin Med (Lond)*. 2022;22(5):416-422. doi:10.7861/clinmed.2022-0107

[35] Mackenzie IS, Wei L, Rutherford D, et al. Promoting public awareness of randomised clinical trials using the media: the 'Get Randomised' campaign. *Br J Clin Pharmacol*. 2010;69(2):128-135. doi:10.1111/j.1365-2125.2009.03561.x

participants who took part in the trial.[36] Ongoing assessment of public and patient attitudes, perceptions, and experiences regarding clinical trials helps create strategies and tactics for patient engagement that can ultimately accelerate the pace at which investigational drugs reach the market and help mitigate the rising costs of drug development.[37]

Outcomes	➲ Analysis of public's knowledge and attitudes toward clinical trials in Poland ➲ Educational materials aimed at spreading information about the role of clinical trials ➲ Materials promoting the quality of information based on evidence-based medical knowledge
Implementation Timeline	January 2025 – December 2027
Indicative Funding Sources	Targeted grant of PLN 3,000,000.00
Monitoring Indicators	➲ Report on public opinion and knowledge regarding clinical trials ➲ Number of evidence-based reports and educational materials on clinical trials and diagnostic-therapeutic standards ➲ Number of informational and educational activities conducted by the Agency as part of its own research

3.3.2.4. Impact of widespread use of continuous glucose monitoring devices on diabetes treatment effectiveness

Objective	To evaluate the impact of using reimbursed continuous glucose monitoring (CGM) systems compared to classic glucose monitoring among adults with diabetes on metabolic control of the disease and risk of complications.
Problem Description	The introduction of reimbursement for CGM systems for adult patients with type 1, type 3, and other forms of diabetes requiring at least three insulin injections per day has significantly increased the use of this tool among the Polish population. Reimbursement enabled patients who previously lacked

[36] Sacristán JA, Aguarón A, Avendaño-Solá C, et al.. Patient involvement in clinical research: why, when, and how. *Patient Prefer Adherence*. 2016;10:631-640. doi: 10.2147/PPA.S104259

[37] Anderson A, Borfitz D, Getz K. Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials. *JAMA Netw Open*. 2018;1(6):e182969. Published 2018 Oct 5. doi:10.1001/jamanetworkopen.2018.2969

access to CGM due to financial or technological barriers to incorporate it into their daily disease management. Studies in limited groups indicate significant improvement in metabolic control; however, large-scale studies have mainly been based on anonymised aggregated patient data, making it challenging to identify groups that benefit most and those for whom CGM does not yield the expected results. At the same time, the reimbursement criterion for assessing CGM usage duration is difficult to enforce based on the available technological solutions and is impossible on an epidemiological scale.

This scientific and administrative issue could be addressed through an in-house project aimed at:

- a cross-sectional evaluation of the use of reimbursed CGM in Poland based on system data,
- a cohort study assessing the impact of CGM implementation on the incidence of acute and chronic diabetes complications and metabolic control of the disease,
- evaluating the effectiveness of an IT tool for converting and archiving CGM data and integrating it with patients' electronic medical records.

The project will include a representative sample of diabetic patients treated in diabetes centres in at least five voivodeships.

During the project, programming work will be undertaken to adapt the application for integration with the electronic patient records in the IKP (Internet Patient Account) or personal electronic health records. Integrating the analytical tool will allow for epidemiological-scale testing of CGM usage frequency at a central level and cross-referencing this information with medical service data, sick leave records, and hospitalisations collected at the NFZ (National Health Fund) or ZUS (Social Insurance Institution) level.

Outcomes	A report will be produced to assess whether incorporating CGM monitoring into standard diabetes treatment improves metabolic control, how quickly this improvement occurs, and to what extent it impacts the risk of complications. The results will help identify patient groups for whom CGM inclusion in therapy yields the greatest improvement in metabolic control and reduction in complication risk.
Implementation Timeline	June 2025 – May 2028
Indicative Funding Sources	National Health Fund (NFZ) allocation: PLN 3,000,000.00

Monitoring Indicators	➲ Number of patients included in the analysis ➲ Implementation of the application for integrating CGM results with electronic patient records ➲ Summary report of analysis results

3.3.3. Systemic analyses

3.3.3.1. Analysis of dementia diseases

Objective To enhance medical knowledge about the Polish population with dementia diseases, particularly Alzheimer's disease; establish a reward system for research and development work in this area; and conduct independent research based on the results of systemic analysis.

Problem Description Dementia diseases, including Alzheimer's disease (AD), are among the most significant health challenges facing modern society. The Alzheimer's Association report (2023) highlighted the negative impact of a lack of early diagnosis on effectively slowing disease progression, which, in turn, results in a lower quality of life for patients.

Systemic analyses and health policy changes are crucial for the effective management of dementia diseases. Early diagnosis, standardised treatment, and investments in research and education can significantly improve the quality of life for patients and their families and reduce the burden on healthcare systems.

According to an analysis by the Ministry of Health on the Polish population affected by Alzheimer's disease,[2] multimorbidity is a prominent issue within this patient group. Among individuals diagnosed with Alzheimer's, additional conditions most frequently identified include essential (primary) hypertension, atherosclerosis, degenerative spine changes, acute infections of the upper respiratory tract with multiple or unspecified locations, and polyarticular osteoarthritis.

Although the number of people with Alzheimer's disease is rapidly increasing, there is no single, effective treatment algorithm for this neurodegenerative disease.[3] Numerous studies have shown that the clinical efficacy of combination therapy is higher than monotherapy. Additionally, the early use of combination therapies can reduce the occurrence and severity of neurobehavioral symptoms, such as aggression or agitation, and may delay the need for patients to be transferred to care homes.[4] Several combination therapy regimens exist, which, combined with the phenomenon of multimorbidity in this

patient group, significantly impact the risk of adverse effects related to polypharmacy.

So far, the actual costs of the therapy, taking polypharmacy into account, and the impact of such extensive treatment on the health outcomes of patients with Alzheimer's disease have not been estimated.

Regular evidence-based updates to Alzheimer's disease guidelines are essential to integrate rapidly advancing technological and medical achievements and introduce new approaches to managing early disease stages into clinical practice. To pave the way for early AD prognosis, targeted treatment, and the inclusion of modern techniques, such as biomarkers in precision medicine, an analysis of the Polish population with dementia diseases is necessary. An analysis of this patient group, taking into account the phenomena of multimorbidity and polypharmacy, will primarily enable an assessment of the need for medical procedures and various medical specialists.

Outcomes	Report on the assessment of the impact of polypharmacy and multimorbidity factors on therapies used in Alzheimer's disease, health outcomes, and costs for patients affected by Alzheimer's disease.
Implementation Timeline	by June 2025
Indicative Funding Sources	Institutional grant: PLN 200,000.00
Monitoring Indicators	➲ Detailed analysis report of the population diagnosed with dementia disorders, with a particular focus on Alzheimer's disease, including an assessment of polypharmacy in the context of multimorbidity and the impact of these factors on treatment costs and the demand for hospital and long-term care.

3.3.3.2. Assessment of multimorbidity, polypharmacy, demand for medical procedures, and treatment accessibility in patients with rare diseases

Objective To determine the scale of rare diseases and the demand for specific medical procedures and medicinal products, as well as to assess medical security, understood as meeting the demand for medical procedures and medicinal products.

Problem Description Approximately 30 million people in the European Union live with a rare disease.[38] The considerable heterogeneity of rare diseases impacts not only the time required for diagnosis, the need for a multidisciplinary medical team, and the provision of specialised procedures, but also affects the drug development process.[39] The classification of rare diseases also heavily depends on diagnostic effectiveness,[40] as many individuals with rare disorders often remain undiagnosed. The diagnostic process depends on the availability of diagnostic tools, local resources (human and/or economic), and the level of knowledge about the specific disease.[41] Patients with rare disorders face numerous unmet medical and social needs, and effective treatments are still lacking for 90% of rare diseases. Advanced analytics enable the identification of disease occurrence patterns, prediction of disease progression, assessment of patient responses to treatment, establishment of optimal care guidelines, and generation of research hypotheses based on narrowly defined patient populations under study.[42] Population-level analyses and non-commercial research focused on the diagnosis and treatment of rare disease patients are valuable sources of information, as many pharmaceutical companies find rare disease research too financially risky.[43]

A comprehensive analysis of the scale and complexity of this phenomenon within the Polish population has not yet been conducted.

[38] Fehr A, Prütz F. Rare diseases: a challenge for medicine and public health. J Health Monit. 2023 Dec 13;8(4):3-6. doi: 10.25646/11826. PMID: 38235014; PMCID: PMC10790412.
[39] Fehr A, Prütz F. Rare diseases: a challenge for medicine and public health. J Health Monit. 2023 Dec 13;8(4):3-6. doi: 10.25646/11826. PMID: 38235014; PMCID: PMC10790412.
[40] Li D, Tian L, Hakonarson H. Increasing diagnostic yield by RNA-Sequencing in rare disease-bypass hurdles of interpreting intronic or splice-altering variants. Ann Transl Med 2018;6:126. 10.21037/atm.2018.01.14
[41] Danese E, Lippi G. Rare diseases: the paradox of an emerging challenge. Ann Transl Med. 2018 Sep;6(17):329. doi: 10.21037/atm.2018.09.04. PMID: 30306068; PMCID: PMC6174191.
[42] Groft SC, Posada M, Taruscio D. Progress, challenges and global approaches to rare diseases. Acta Paediatr. 2021 Oct;110(10):2711-2716. doi: 10.1111/apa.15974. Epub 2021 Jun 19. PMID: 34105798.
[43] Lippi G, Plebani M. Biomarker research and leading causes of death worldwide: a rather feeble relationship. Clin Chem Lab Med 2013;51:1691-3. 10.1515/cclm-2013-0210

Outcomes	➲ Assessment of the prevalence of specific rare diseases ➲ Evaluation of the demand for particular medical procedures and medicinal products, along with an assessment of medical security, understood as meeting the demand for medical procedures and medicinal products Identification of additional factors affecting the treatment process (including comorbidities) ➲ Evaluation of medical security, understood as meeting the demand for medical procedures and medicinal products ➲ Assessment of the need to stimulate specific research and development areas ➲ Preparation of a report containing a comprehensive analysis of rare disease issues within the Polish population, serving as a substantive basis for the criteria of the call for non-commercial clinical trials in the area of rare diseases
Implementation Timeline	By December 2025
Indicative Funding Sources	Institutional grant: PLN 300,000.00
Monitoring Indicators	➲ Number of patients included in the analysis ➲ Report detailing the results of the analysis

3.4. New initiatives at the Medical Research Agency

3.4.1. Establishment of the Digital Medicine Hub

According to the regulations of call for proposals no. ABM/2023/2, 'Creation and development of Regional Digital Medicine Centres,'[44] the Digital Medicine Hub, established as part of the Agency's activities, will serve as a data hub and analytical centre for the Regional Digital Medicine Centres (RCMC) affiliated with the Network of Digital Medicine Centres under the overarching authority of the Agency. Data collected by RCMCs will be used for real-time analysis, support for clinical trials and hospital care in digital solutions, and retrospective analysis. The types of collected data will include, among others, health-related data (e.g., diagnoses), omics data obtained from biobanked samples, omics data from the

[44] REGULATIONS OF CALL FOR PROPOSALS NO. ABM/2023/2 'CREATION AND DEVELOPMENT OF REGIONAL DIGITAL MEDICINE CENTRES'

Agency's previous research projects, as well as data from clinical trials (including imaging data and data on performed procedures).

Data will be collected in accordance with existing quality standards, ensuring their suitability for analysis while maintaining security in data sharing and storage. RCMCs will be responsible for medical data management, including descriptive, pharmaceutical, and imaging data and test results sourced from Hospital Information Systems (HIS), Electronic Case Report Forms (eCRF), and other sources. The call for proposals documentation also recommends collecting data from omics studies (metabolomic, proteomic, transcriptomic results).

RCMCs will also transmit data upon request from the Digital Medicine Hub for big data analysis related to Polish population genome analysis, aligning with the EU health digital transformation programme under Regulation (EU) 2021/522 of the European Parliament and the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027. The assumptions regarding the Network of Digital Medicine Centres are also aligned with the European Health Data Space (EHDS)[45] and, therefore, with the European Health Union strategy[46] and the European strategy for data.[47]

The Agency's focus as a central data repository aims to improve preventive, diagnostic, and therapeutic processes by enabling the collection and analysis of clinical trial data, data from the National Health Fund (NFZ), and genetic data of the Polish population. Deriving insights into relationships between genetic profiles, disease risk, and treatment response will enable comprehensive analyses and lead to actions to optimise patient diagnostic-therapeutic pathways within the healthcare system, contributing to the development of an efficient patient pathway.

As part of establishing the Digital Medicine Hub, the following infrastructure is planned for acquisition:

- High-availability analytical system compliant with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016. The infrastructure will be based on a clustered or cloud system, offering scalability and expandability. It will utilise multiprocessor and array technologies for sequential data analysis, enabling the storage and processing of large data volumes (up to 3 PB).
- Servers equipped with specialised processors to support efficient and precise data analysis and quality control for genomic data.
- Network infrastructure appropriate for the volume of data processed.
- Backup system.

[45] European Health Data Space - European Commission (europa.eu)
[46] European Health Union - European Commission (europa.eu)
[47] A European strategy for data | Shaping Europe's digital future (europa.eu)

- Archiving system/data warehouse for archival data.

The Digital Medicine Hub will be adapted to perform a range of tasks. One of the first activities planned for the Digital Medicine Hub will be analyses aimed at identifying new therapeutic and diagnostic targets within the population of patients with rare diseases.

Objective	To strengthen translational medicine for rare diseases. To create a national environment for the rapid identification of diagnostic/therapeutic targets based on advanced multiomic analyses of patient samples, addressing the unmet medical needs of patients with rare diseases.
Problem Description	Approximately 80% of rare diseases have a genetic basis, and nearly 70% of them manifest in childhood, with an average wait time for an accurate diagnosis of 4.8 years.[48] Genomic research is transforming the landscape of rare disease diagnostics in terms of cost, time required for diagnosis, and diagnostic accuracy.[49] Whole-genome and exome sequencing have increased the likelihood of identifying pathogenic variants compared to single-gene analyses; however, integrated multiomic analysis can further enhance diagnostic efficiency. Additionally, multiomic analysis can help elucidate the genotypic and phenotypic heterogeneity that may affect both disease presentation and treatment response.[50] Currently, despite advancements in diagnostics, around 95% of rare diseases lack approved treatments.[51] Studies have shown that integrating multiomic approaches with ultra-rapid whole-genome sequencing improves diagnostics for critically ill infants and children suffering from rare diseases and can be successfully implemented on a national scale.[52] Omics technology holds significant potential to address current needs for improved diagnostics, greater understanding of the pathophysiological processes behind the development and progression of rare diseases, and support in identifying therapeutic targets.[53] However, multiomic analyses must be standardised,

[48] The Lancet Global Health. The landscape for rare diseases in 2024. *Lancet Glob Health*. 2024;12(3):e341. doi:10.1016/S2214-109X(24)00056-1

[49] Lunke S, Bouffler SE, Patel CV, et al. Integrated multi-omics for rapid rare disease diagnosis on a national scale. *Nat Med*. 2023;29(7):1681-1691. doi:10.1038/s41591-023-02401-9

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	and the sample size sufficient to identify new diagnostic and therapeutic targets. As part of the call for proposals 'Creation and development of Regional Digital Medicine Centres,'[54] the establishment of the Digital Medicine Hub is planned, which could be adapted for centralised multiomic analyses. Additionally, as part of the independent study, a comprehensive, open scientific environment is planned, with the potential to enhance understanding of rare diseases and provide the scientific evidence needed for developing new treatment methods.
Outcomes	Creation of the dedicated OmiRare360 platform within the Agency's Digital Medicine Hub for holistic multiomic analyses focused on rare diseases, intended to be accessible to researchers, including the Network of Digital Medicine Centres (and powered by data from the Digital Medicine Hub), in line with the EU open science policy, to expand the scope of multiomic research on rare diseases. Obtaining a multiomic profile of patients to accelerate biomarker research for therapeutic purposes. Possibility of performing omic analyses in the context of applied treatments to better tailor therapies.
Implementation Timeline	January 2025 – December 2028
Indicative Funding Sources	Reserve fund PLN 15,000,000.00
Monitoring Indicators	➲ Creation of the dedicated OmiRare360 platform within the Agency's Digital Medicine Hub for holistic multiomic analyses dedicated to rare diseases, ➲ Number of individuals diagnosed with a rare disease who underwent multiomic analyses ➲ Number of multiomic analyses conducted ➲ Number of competition areas prioritised based on the results of the analyses ➲ Number of research results made available

[54] Creation and development of Regional Digital Medicine Centres – 2023 – Medical Research Agency (abm.gov.pl)

3.4.2. Activities related to the 1+MG Initiative

Incorporating genomic medicine into the healthcare system involves significant challenges, such as creating or standardising technical infrastructure for the collection, analysis, and interpretation of genomic data; establishing informational foundations to build public trust and engagement; and developing policies that ensure equal data access. Therefore, there is a need for managing a complex, interconnected ecosystem, and developing processes necessary to ensure effective diagnostics, treatment, and prevention based on genomics.[55] The action plan for the use of genomics in healthcare initially focuses on determining the maturity level according to the B1MG Maturity Level Model. (MLM)[56] As part of the 1+MG Initiative, a National Node and a National Mirror Group (NMG) must be established by 2027, along with the development of a consistent National Genomic Plan. These efforts will be supported by B1MG Working Group no. 1 (WG1) on National Coordination, responsible for preparing guidelines for the NMG (standardised guidelines across the EU). National Mirror Groups (NMGs) are key instruments for the implementation of the guidelines and recommendations developed at the EU level—namely through the 1+MG Initiative—and adapting them to national realities. It is expected that NMGs will be established in all countries by 2027,[57] and will work on implementing the guidelines developed by the 1+MG Initiative. Another objective to be achieved by 2027 is to have genomic data ready and compliant with guidelines developed by one of the Initiative's working groups. Poland has taken steps in this area—the Agency announced a competition for Regional Digital Medicine Centres to develop methods for data sharing, including genomic data, in line with European guidelines.

The following actions will be undertaken by the Agency as part of these endeavours:

- Formal membership of the 1+MG Initiative (Poland has been an observer for several years)
- Formation of a team and assessment of the maturity level of genomics implementation in the healthcare system based on the B1MG Maturity Level Model (MLM).
- Development of a roadmap for 2025–2027,
- Identification of stakeholders
- Development of guidelines for the National Node and national stakeholder groups
- Initiating work on establishing the National Node and the national stakeholder groups.

[55] 202305 B1MG D5.2 - Roadmap and guidance tool for countries (1).pdf
[56] The Beyond 1 Million Genomes (B1MG) Maturity Level Model (MLM) (b1mg-project.eu)
[57] The European 1+ Million Genomes Initiative Roadmap 2023-2027

3.5. Audits of financed projects

As part of the Annual Control Plan (ACP), the Agency will conduct audits of projects funded under the National Recovery Plan (RRP)—covering no less than 10% of projects financed through Agency competition calls in 2024. The ACP will also include audits of non-commercial clinical trials/experiments, projects aimed at establishing Clinical Trials Support Centres, Regional Digital Medicine Centres, and commercial projects that have received Agency funding to date. To streamline the audit process, new procedures will be put in place to expand the range of projects selected for audit. As an initial step, a control questionnaire will be sent to project beneficiaries, and the results will inform decisions on whether to conduct audits, remotely and/or on-site. This will expand the pool of projects subject to preliminary control actions. In addition to the routine audits, the Agency will continue *ad-hoc* audits as per established procedures.

3.6. Evaluation of financed projects, research, and development work

The Agency carries out evaluations of financed projects on a regular basis, conducting:

- ongoing evaluations
- scientific evaluations
- financial evaluations

Ongoing evaluations are conducted during the project's implementation and are aimed at analysing project processes and diagnosing issues encountered by beneficiaries from the time they submit funding applications. Its purpose is to support project implementation and adjust project actions based on ongoing data analysis and outcomes. The ongoing evaluation process is divided into three stages:

I. Preliminary analysis of data related to ongoing projects (based on funding applications and periodic reports)
II. Research phase of the evaluation—qualitative interviews and online surveys with the individuals involved in project implementation
III. Final data analysis and results summary—culminating in an evaluation report

Conducted at the end of or after project completion, scientific evaluation assesses the scientific value of the project and the applicability of its outcomes in the healthcare system. Scientific evaluations are expert-driven, involving panel discussions where experts complete detailed questionnaires assessing the scientific value, applicability, and research approach of the projects. Based on the collected information, summary reports with conclusions and recommendations are drawn up.

The financial evaluation is conducted during the project or after its completion (within the sustainability period) and aims to determine the financial benefits to the state budget from implementing solutions developed in the project within the healthcare system.

In 2025, the Agency will conduct:

1. the ongoing evaluation of projects initiated in 2022 as part of the call for non-commercial clinical trials (13 projects in the implementation phase)
2. II. the ongoing evaluation of projects initiated in 2020 as part of the call for non-commercial clinical trials (29 projects in the implementation phase)
3. scientific evaluation of projects (the final list of evaluated projects will be drawn up in 2025 based on updated information from beneficiaries about project progress and publication of results)
4. financial evaluation of projects (the final list of evaluated projects will be drawn up in 2025 based on updated information from beneficiaries about project progress and publication of results)

3.7. Issuing opinions and expert reports for public administration bodies

As part of its activities (Article 2(2) of the Act), the Agency issues opinions and draws up expert reports in the fields of medical and health sciences for public administration bodies or other entities, based on the executed contracts. This activity is not planned in advance and depends on the nature of the contracts.

3.8. Initiating and developing international cooperation

Building knowledge- and experience-exchange-based relationships is a key element of international scientific collaboration. This includes establishing contacts, initiating joint projects, and accessing unique expertise outside our country. Know-how exchange provides opportunities not only for researchers but also for institutions responsible for advancing specific fields, enabling growth on a transnational level. Additionally, joint projects allow for publishing research results in prestigious scientific journals, which increases the visibility of Polish scientists. International cooperation fosters not only scientific development but also innovation, with a direct impact on economic growth.

As part of its international cooperation efforts, the Agency will undertake the following activities:

- organising Cancer Week 2025 workshops (in collaboration with NIO, ASCO, FDA, EMA)
- building European cooperation with CEE countries, Switzerland, and Denmark in the biomedical area.

3.8.1. Cancer WEEK 2025 workshops co-organised by ASCO, FDA, EMA, and NIO

As part of the planned event, i.e. Cancer Week 2025, workshops will be organised in collaboration with the American Society of Clinical Oncology (ASCO), the U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA). The primary audience will be clinicians from Poland and Central and Eastern European (CEE) countries. These workshops are an innovative initiative aimed at sharing knowledge and experience in the field

of best practices for clinical research and providing access to experienced clinical researchers from various institutions across Europe and the world.

Workshops led by distinguished experts from the FDA, EMA, and ASCO in the field of oncology clinical research are intended for clinicians and clinical researchers at all career stages and representing all oncology specialties. These workshops will also facilitate international collaboration, allowing Polish/European and American researchers and clinicians to exchange knowledge and experience. The innovative concept involves participation of key institutions shaping the healthcare sector in the field of clinical research.

The workshops will provide FDA and ASCO with an opportunity to become acquainted with the Polish biomedical sector and to meet Polish researchers as well as institutions that contribute to the robustness of this sector.

The participation of other CEE countries will give FDA and ASCO an excellent opportunity to understand the healthcare systems in these countries and their clinical needs. This will enable collaboration to include CEE centres in clinical trials for pharmaceutical products and medical devices.

Workshop topics:

- Discussions on differences in regulations, guidelines, and best practices for clinical trials in Europe and the USA;
- Knowledge and experience exchange on ethics and data integrity in clinical research;
- Explanation of FDA expectations regarding commercial clinical trials;
- Description of the role and responsibilities of the clinical investigator;
- Presentation of the FDA's role in research regulation, including a case study analysis;
- Knowledge and experience exchange among researchers, clinical research staff, and experts from FDA, ASCO, MRA, and NIO.

3.8.2. Educational programme: the Polish Clinical Scholars Research Training (P-CSRT)

As part of its statutory tasks, the Agency implements orders for a training programme organised by Harvard Medical School Postgraduate Medical Education for Polish researchers and scientists conducting scientific research, particularly clinical trials or medical experiments. This course is included in the Medical Research Agency's Educational Strategy for 2023–2027, which was positively reviewed by the Agency's Council in Resolution No. 6/2023 of the Council of the Medical Research Agency of 5 May 2023.

The aim of the Polish Clinical Scholars Research Training (P-CSRT) programme, designed and conducted by Harvard Medical School Postgraduate Medical Education for the Agency, is to deliver training in the field of preparing and publishing scientific articles, and research design.

Training 100 Polish researchers and scientists, as part of each edition of the programme, in:

- designing and conducting observational and experimental scientific research,
- analysing, interpreting, and presenting clinical trial data,
- creating high-quality publications.

Through participation in the programme, participants will expand their competencies in clinical research as well as scientific writing and publishing in renowned journals.

In 2025, the second edition of the P-CSRT will be conducted:

- Recruitment commencement: Q4 2024
- Programme start: Q4 2025
- Implementation: 2025–2026
- Number of participants: 100
- as well as the 3rd edition:
- Implementation of the 2nd edition of the P-CSRT:
- Programme start: Q4 2024
- Implementation: 2024–2025
- Number of participants: 100

Expected outcomes:

- Increase in the number and quality of publications by Polish scientists,
- Increase in citations of Polish scientists,
- Enhanced international attractiveness of Poland in the context of clinical research, particularly in terms of clinical trials in Polish centres.
- Expansion of collaboration among Polish scientists

3.8.3. Participation in European initiatives

On 2 August 2024, the Agency received nominations from the Ministry of Health to participate in Joint Actions under the EU Health Programme 2021–2027 (EU4Health Programme) for two areas:

- EU4H-2024-JA-IBA-04 – Direct grants to Member States' authorities: Cancers caused by infections, vaccine-preventable cancers and addressing communicable diseases (HIV/AIDS, Tuberculosis, Hepatitis) (DP/CR-g-24-28) – EUR 20,000,000 EU co-funding
- EU4H-2024-JA-IBA-05 – Direct grants to Member States' authorities: Personalised Cancer Medicine (CR-g-24-41) – EUR 27,900,000 EU co-funding.

For the first area, the Agency will conduct a systemic analysis to assess the impact of viral and bacterial infections combined with other comorbid factors on carcinogenesis. Data will be sourced from infection and alert factor registers, the National Institute of Public Health (PZH) – National Research Institute, and the P1 system (CeZ). Analysis activities will be conducted in stages:

- Stage 1. Determining the scale of cancer types identified following infections caused by specific bacteria and viruses considered potentially carcinogenic (according to literature) and not previously linked to carcinogenic processes.
- Stage 2. Identifying additional factors predisposing individuals to cancer development (including comorbidities).
- Stage 3. Preparing a report with a comprehensive risk analysis for the Polish population, forming the basis for expanding the substantive assumptions of calls for non-commercial clinical trials in oncology.

For the second area, the Agency will conduct own research in collaboration with the National Cancer Institute – National Research Institute, with the primary objective of identifying predictive and diagnostic biomarkers for selected cancer types based on genomic data. As part of the study, there are plans to create a Precision Cancer Analytics (PCA) tool to compile genomic and clinical information (sourced from the National Cancer Registry).

As part of the activities defined by the Health Emergency Preparedness and Response Authority (HERA), the Agency will conduct a systemic health security analysis to:

- Determine the demand for specific procedures during pandemics,
- Assess the current buffer of medical procedures and medicinal products potentially applicable during pandemics,
- Establish the cost of medical security, understood as meeting the demand for medical procedures and medicinal products,
- Assess the need to stimulate specific research and development areas.

The Agency will also support activities of the European Rare Diseases Research Alliance (ERDERA). To improve the health and well-being of individuals living with rare diseases in Europe, the Agency will conduct a systemic analysis of rare diseases diagnosed in Polish patients. It will include an assessment of multimorbidity, polypharmacy, and the demand for medical procedures, with a focus on identifying areas where diagnostics are underfunded. The Agency's activities will aim to:

- Determine the scale of rare diseases and the demand for specific medical procedures and medicinal products,
- Identify additional factors impacting treatment (including comorbidities),
- Evaluate medical security, understood as meeting the demand for medical procedures and medicinal products,
- Assess the need (including in terms of finances) to stimulate specific research and development areas.

All the steps described above will result in a report containing a comprehensive analysis of these issues in the Polish population, which can serve as guidelines for further national actions and support the Rare Diseases Registry's activities.

These activities of the Agency as part of the European initiatives will be implemented upon approval from the Ministry of Health and after funding has been secured.

3.8.4. International cooperation in the implementation of scientific projects within the ECRIN-ERIC network

A priority of the Agency is to support innovative activities in healthcare, with a particular focus on developing non-commercial clinical trials and research experiments.

The ECRIN-ERIC (European Clinical Research Infrastructure Network European Research Infrastructure Consortium) is a leading European network that supports the development, planning, and implementation of international clinical trials. Participation in the ECRIN-ERIC provides access to advanced tools, resources, and expertise necessary for conducting high-quality clinical trials at an international level. Collaboration with the ECRIN-ERIC opens opportunities to connect with other research centres, fostering knowledge transfer and medical innovation. As a participant of the ECRIN-ERIC, the institution gains access to the European research infrastructure, including expert knowledge, technologies, and research platforms. The ECRIN-ERIC supports the comprehensive organisation of clinical trials, from the design phase through implementation to data analysis. Additionally, through the ECRIN-ERIC network, it is possible to use central services such as data management, or services related to regulatory, and ethical issues, which significantly simplifies the conduct of clinical trials.

Participation in the network enhances the international visibility and competitiveness of the research institution. It also provides access to partnerships as part of European research projects, which can bring additional funding and support research development in high-priority areas. By joining the ECRIN-ERIC, the institution becomes part of an elite group of scientific entities that play a key role in shaping the future of clinical research in Europe. Through collaboration with the ECRIN-ERIC, researchers and institution personnel have the opportunity to develop their skills and competencies in the area of international clinical research. Participation in the network enables access to training, workshops, and conferences led by top experts in clinical research. This directly translates into improved quality of research and the professional development of staff. Collaboration with the ECRIN-ERIC ensures that clinical research meets the highest European standards of quality, ethics, and regulation. The network supports researchers in meeting legal requirements and certification processes, which is crucial for achieving internationally significant research results. As a result, the institution can offer its research partners research of the highest quality, which increases its reputation and credibility within the scientific community.

Accordingly, the Agency is strengthening collaboration between centres and the ECRIN-ERIC, promoting the network among researchers, and encouraging centres to join its structure. The Agency also supports the implementation of international clinical trials by engaging in the start-up process, budgeting, contracting, and trial oversight.

Expected outcomes:

- Increased participation of Polish centres, particularly Clinical Research Support Centres (CWBKs), in their ECRIN activities.
- Greater awareness, among the CWBK staff, of opportunities to conduct international non-commercial research.
- Growth in the number of international non-commercial clinical trials conducted in Poland.

3.9. Educational and training activities

3.9.1. Training: "Clinical trials in populations at risk of exclusion"

Clinical trials in populations at risk of exclusion aim to ensure equal access to innovative therapies and medical advancements for individuals excluded due to social (ethnic groups), economic, digital reasons, and so-called special populations, which include patients with impaired excretion, the elderly, pregnant and breastfeeding women, and children. The Agency views the need for research involving excluded groups as essential for creating a more just and equitable healthcare system that caters for the needs of all social groups.

Excluded and special populations are subgroups of patients that require special consideration in clinical trials. Therefore, the planning, design, and implementation of trails involving these groups requires specific knowledge, preparation, and experience.

The training will cover, *inter alia*, information on ethical standards, ways to inform patients and/or caregivers about the study's purpose, procedures, risks, and benefits, and the adaptation of recruitment and data collection methods.

It will address the inclusion and minimisation of potential risks and the provision of necessary facilities and support to reduce feelings of threat and foster patient participation.

Training related to clinical trials involving excluded populations and other special groups is crucial for conducting research ethically, effectively, and safely. Preparing researchers through appropriate training programmes ensures they have the necessary knowledge, skills, and awareness to meet the challenges associated with research in these particular populations.

Training objectives:

- Supporting researchers in designing clinical trials that include vulnerable populations at risk of exclusion
- Raising researchers' awareness of the relevance of including vulnerable populations in clinical trials

3.9.2. Training: 'Preclinical and Clinical Research on Biological, Biosimilar, and ATMP Products'

Training on new advanced therapy medicinal products (ATMP), including gene and cell therapies is crucial due to the potential of these products to treat patients for whom current methods are insufficient. The ATMPs include a wide range of innovative medicines that can significantly improve treatment outcomes for patients with serious diseases with limited therapeutic options. Despite scientific and research advancements, broad access to these therapies is hindered by regulatory and manufacturing challenges. Training in the field of ATMP regulations, including the full registration pathway, is therefore essential to facilitate the effective implementation of these therapies in Poland.

Additionally, the development of the biosimilar medicine market, supported by the Agency, is equally important for increasing therapy availability and reducing treatment costs. Training in this field can contribute to a better understanding and effective implementation of biotechnology, which is crucial for the development of innovative medical solutions, including targeted, personalized medicines and new pharmaceutical forms.

Education in these areas is essential to meet the growing demand for state-of-the-art and effective therapies that can significantly improve patients' quality of life. In the context of a rapidly growing biomedical sector, such training will help identify, through discussions with speakers and participants, the priority areas that require Agency support.

Training objectives:

- Presentation of the certification pathway for an advanced therapy medicinal product in a non-commercial clinical trial
- Evaluation of product, pre-clinical, clinical data for the ATMPs
- Requirements and documents necessary to start the manufacture of medicinal products containing ATMPs
- Presentation of the development pathway for biological and biosimilar medicines in the context of European legislative requirements

3.9.3. Development of competencies for healthcare professionals in scientific research implementation (European Funds for Social Development 2021–2027 Programme, FERS)

The Agency supports innovative healthcare activities, particularly the development of non-commercial clinical trials and research experiments, also by increasing the involvement of scientific units with implementation capabilities in clinical research.

The objective of training as part of the FERS project is to improve the healthcare system's functioning by enhancing the competencies of healthcare professionals, including organisational, administrative, and management staff. The project will enable upskilling and retraining with an emphasis on entrepreneurship and digital skills, better anticipation of changes and demand for new skills based on labour market needs, facilitating career path changes, and supporting career mobility. The project will be implemented between 2024 and 2027, with three editions of each course type:

- 'Data in healthcare – how to produce quality data in clinical trials?' – training 90 health care professionals involved in the implementation of clinical trials, on data management in clinical trials.
- 'Leader Academy – Planning and Managing Clinical Trial Projects': training for 75 healthcare specialists involved in clinical trial project planning and management.
- 'Biomedical Research – How to Get Started?': training for 75 healthcare specialists involved in clinical trials, on scientific research methodology.
- 'Investigational Product – Manufacturing, Acquisition, and Management at the Centre': training for 90 healthcare specialists involved in clinical research, on managing investigational products in a clinical trial.

3.9.4. Upskilling the staff of the Clinical Trials Support Centre (CWBK) and Research Team Members, and building patient awareness of clinical trials

The field of clinical trials is constantly evolving due to new regulations, guidelines, and recommendations. Providers of services related to clinical trials need to monitor these changes and enhance their competencies regularly.

Given the identified need, the Agency will conduct educational activities to support research team members in improving their skills in managing and coordinating clinical trials, drawing-up and maintaining research documentation, collaborating with patients, and thereby ensuring high-quality services.

Tasks planned for 2025 include:

- Training as part of 'CWBK Academy' series and 'Sharing Knowledge' series
- Informational meetings for Patients

- Informational meetings for medical students

Expected outcomes:

- Reduced time for preparing and increased quality of applications for clinical trial initiation submitted to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,
- Reduced time for processing contracts for commercial clinical trials,
- Increased number of non-commercial trials conducted in Poland,
- Activation of patient organisations to collaborate with CWBKs,
- Improved recruitment for clinical trials conducted in CWBKs,
- Increased engagement of the academic/scientific community in research projects,
- Increased interest among medical graduates in building careers in the field of clinical research.

Indicators:

- Number of training sessions conducted as part of 'CWBK Academy': **4**
- Number of training sessions conducted as part of 'Sharing Knowledge' series: **4**
- Total number of CWBK staff and research team members covered with support: **100**
- Number of informational meetings for Patients: **4**
- Total number of Patients receiving informational support at meetings: **100**
- Number of informational meetings organised at medical universities: **4**
- Total number of students receiving informational support at meetings: **100**

3.10. Support for the activities of the National Bioethics Centre

The National Bioethics Centre is an entity focused on education, analysis, guideline development, and international collaboration on issues related to bioethics, specifically the ethical issues arising from advancements in biomedical sciences.

The main tasks of the National Bioethics Centre in 2025 will include:

- Developing—in cooperation with the Supreme Bioethics Commission for Clinical Research, members of bioethics committees, the scientific community, and social stakeholders—recommendations, guidelines, and standards for ethical review of clinical trials;
- Collaborating with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products on the ethical evaluation of clinical trials;
- Establishing contacts and collaborating with all stakeholders in the clinical trial field: patients, researchers, sponsors, and CROs to promote responsible ethical practices in clinical research;
- Organising training, workshops, and seminars for members of bioethics committees on bioethics and research methodologies involving human subjects or human

biological material, as well as for those providing support to bioethics committees, scientists, students, and others to raise ethical awareness and promote best ethical practices in scientific research;

- Engaging in international cooperation, establishing connections with other bioethics institutions worldwide to exchange experiences and jointly address global bioethical challenges related to scientific research.

3.11. Disseminating the outcomes of completed tasks.

In accordance with its statutory objectives, the Agency undertakes actions to disseminate information about planned calls for proposals and the results of completed projects. Additionally, due to the Agency's dynamic growth, new activities, the high diversity of its audience, and the need to tailor content based on the target group, the Agency's website will be redesigned, and the information posted on the website will be categorised according to user group.

As part of the communication strategy, and in collaboration with the Agency's organizational units and external entities—broadly understood as participants in the clinical research market in Poland—the following ongoing activities will continue, including:

- Increasing awareness of clinical research in Poland and the role of the Medical Research Agency;
- Promoting clinical research and calls organized by the Medical Research Agency;
- Promoting the outcomes of completed research and their impact on the clinical research market in Poland from social, scientific, and economic perspectives.

Efforts to support the Agency's internal communication will continue, including the *ABM Insider* informational newsletter, sent via email to employees and containing short updates on events and progress in planned activities.

3.12. Supporting businesses in conducting and expanding innovative activities

The area of innovation and technological progress is important for societal development and economic prosperity. Innovation results from scientific advancement and research. The Agency supports the development of scientific research in medical and health sciences by providing financial assistance for research aimed at developing new products and technologies in Poland.

The Agency promotes innovative activities, contributing to the development of Polish enterprises. Support provided to entrepreneurs, including those in the pharmaceutical, medical devices, and biotechnology sectors, for research and development work is an investment that can help ensure public health security and increase the innovation of Polish biomedical companies. Under the National Recovery and Resilience Plan (RRP), the Agency

is responsible for conducting competitions for entrepreneurs for projects aimed at creating conditions for the development of pharmaceutical innovations and medical technologies.
In 2025, the Agency will monitor the progress of the projects selected through the competition.

3.12.1. Warsaw Health Innovation Hub

The Warsaw Health Innovation Hub (WHIH) is a collaboration platform involving businesses, members (foundations, associations, etc.), and the public sector in healthcare. WHIH enables knowledge exchange, sharing of experiences, idea flow, and the development of productive relationships through joint projects within a friendly ecosystem created to implement innovative solutions for improving patient health.

WHIH's mission is to establish a cross-sectoral and interdisciplinary platform involving key healthcare system stakeholders to become a leader in innovation in the CEE region in biomedical research and to stimulate regional economic growth in this area.

WHIH activities planned for 2025:

1. Monitoring of WHIH Partner Projects – Project progress will be monitored periodically throughout the year, with results, observations, and summaries presented at both WHIH Council meetings and events organized by WHIH Partners, as well as individual project team meetings.
2. HIH Network – Further expansion and new initiatives.
   The goal of the HIH Network is to create a European platform for thought exchange, collaboration, and projects focused on improving the efficiency of healthcare systems in the CEE region.
   Activities will also include engaging additional countries in the initiative (currently, Croatia and Latvia have signed the MoU) and developing joint activity plans in medicine, pharmacy, and biotechnology, fostering R&D growth, promoting public-private partnerships, jointly seeking European funds to support regional initiatives, and strengthening clinical research development in the CEE region.
3. WHIH Educational Programs

- Pharmacokinetics Course – Targeted at academic staff teaching pharmacokinetics at pharmaceutical faculties of Polish universities. Its primary goal is to expand the academic community's knowledge of the applications of pharmacokinetics in the pharmaceutical industry and clinical research, considering regulatory specifics. The second edition of the course is planned for fall.
- Practical Biotechnology Course – Directed at graduates and students in fields such as medicine, pharmacy, and biotechnology. The course aims to educate, deepen knowledge, and introduce participants to the structure, complexity, and multidimensionality of the biotechnology industry from a practical perspective. The

second edition is planned for fall 2025 and includes one week of online and on-site lectures and sessions.

- Thematic Working Groups – Recurring thematic meetings that support networking among WHIH Partners, Members, universities, entrepreneurs, and public institutions. The purpose of these meetings is to exchange knowledge, experiences, and best practices, fostering collaboration and generating new ideas for healthcare system development in Poland. Meetings will be held quarterly.
- Data in healthcare
- Clinical trials
- Medical devices

4. WHIH Proprietary Programs:

- **WHIH Mentoring Platform – Second Edition –** an advisory and developmental program aimed at supporting scientific projects by enabling academic research teams to access mentorship in business, technology, clinical, and regulatory areas. The second edition will take place between October and November.
- **Career development in the healthcare** – an internship program implemented in collaboration with MSD Polska and with the participation of Deans from Pharmaceutical Faculties of Polish universities. The program aims to support the development of 10 outstanding students in the field of pharmacy.
- **Women in Healthcare** – a one-day event with female leaders in healthcare held once a year in an open panel discussion format. The event targets female students in medical schools and is led by women.
- **Leaders in Healthcare** – recurring meetings for medical students with representatives from the public and private sectors. Meetings will be held four times a year in an open discussion format.

5. Adding new members to WHIH – expanding the collaboration network

- WHIH Partners – enterprises
- WHIH Members – scientific societies and non-governmental organizations/foundations in the fields of science and health

6. Collaboration with scientific societies:
    a. Utilizing the expert database.
    b. Engaging in dialogue with societies to develop potential project themes to be implemented within WHIH. This allows WHIH Partners and Members to work together in consortia on projects that contribute to healthcare system development, addressing sector needs while incorporating current trends and latest scientific findings.
    c. Societies are part of the teams in WHIH Partner and Member Projects.
7. New project proposals – reviewing project outlines, holding meetings with WHIH Partners, and conducting project workshops.

8. “Breakfast with WHIH” – Let’s Talk about Innovation and PPP Collaboration – three meetings are planned aimed at showcasing projects under WHIH and established public-private partnership collaboration models.
    d. Meetings with the media
9. Marketing and promotion of WHIH
    e. WHIH Website – collaboration with the promotion and international cooperation department
    f. Participation in national and international events – e.g., Cancer Week

WHIH for Scientists and Universities:

1. **Participation in WHIH Workshops:**
    - Open workshops for academic staff and students from Polish universities, primarily in medicine, pharmacy, and biotechnology.
    - The workshops aim to initiate innovative projects or develop new solutions for the public and private sectors in the biomedical field.
2. **Mentoring**
    - Led by experts from the public and private sectors in the medical field, this is a versatile program tailored to individual needs.
    - Mentorship meetings focused on commercialization challenges will be held biannually and are open to academic staff and students at Polish universities, primarily in medicine, pharmacy, and biotechnology.
    - Another form of mentoring is the Mentoring Platform, involving the Centre for Technology Transfer (CTT) of Medical Universities and business partners, aiming to select innovative scientific projects in a competitive format that require further consultation for development toward implementation.
3. **Collaboration with Student Governments**
    - Recurring meetings (twice a year) with representatives of Student Governments at Polish universities, primarily in medicine, pharmacy, and biotechnology.
    - These meetings aim to bring together the young scientific community and allow them to directly express their needs and expectations.
    - The meetings are intended to develop joint projects under WHIH (Academia–Businesses–Public Sector).
    - They aim to identify new trends and emerging solutions within the young scientific community.
    - Meetings organized by WHIH between WHIH Partners and Members and the Student Government.
4. **Internships and Practical Training**
    - WHIH facilitates finding private sector partners for these programs.

- Another option is Work Placement, which involves professional internships in enterprises or the public sector.
- Promoting scientific excellence – internships for outstanding students.

4. Other activity

4.1. Polish Clinical Trials Network

The development of the Polish Clinical Trials Network (PSBK) in 2025 is a key element of the strategy to strengthen Poland's position as one of Europe's leading clinical research ecosystems. PSBK, as a comprehensive network of cooperating public research centres, including hospitals, research institutes, and academic institutions, plays an essential role in the discovery and study of new medical technologies. According to data collected in 2023, PSBK members conducted over 1,700 clinical trials (both commercial and non-commercial) and more than 150 research experiments.

In light of increasing health challenges, such as an aging population, the rise in chronic diseases, and global epidemiological threats, the development of PSBK has particular significance. Effective collaboration within PSBK enables the efficient use of resources and the exchange of knowledge and experience between research centres, leading to higher quality and innovation in clinical research. This is essential not only for public health protection but also for increasing Poland's competitiveness in the global market.

Investments in the development of ICT infrastructure, enhancing the competencies of research staff, and promoting Polish research centres internationally are necessary to ensure that Poland can effectively compete with other countries. Importantly, the increase in clinical trials in Poland directly translates to providing patients with access to the latest and most advanced therapies. Additionally, achieving these objectives will foster greater public trust in clinical trials, which is crucial for increasing participant numbers. Meeting these goals requires coordinated efforts across multiple levels. Critical factors include investments in IT infrastructure, as well as in the development of skills and human resources. Strengthening research potential through the development and implementation of guidelines and research standards in line with international norms is essential to ensure the highest quality of conducted research. Promoting PSBK nationally and internationally will help build a strong brand that attracts new commercial sponsors and foreign researchers to Poland.

4.1.1. Expansion of ICT infrastructure, and increased digitalization of the Polish Clinical Trials Network

The dynamic development of technology, expansion of ICT infrastructure, and increased digitalization of the PSBK are essential for optimizing research processes. Investments in IT systems will enable efficient data management, rapid processing, and secure storage. Modern digital solutions will allow for the automation of administrative and research

processes, leading to savings in human and financial resources. Advanced analytical tools will enable precise data analysis, increasing the credibility of research results and accelerating the introduction of innovative therapies to the market.

A key task for 2025 is the development of the electronic Case Report Form (eCRF), which enables efficient management of clinical trial data. The system, launched in Q4 2023, was designed for non-commercial clinical trials funded through calls organized by the Agency. Since its implementation, areas requiring improvement and potential expansion opportunities have been identified through ongoing administration efforts.

Expected outcomes:

- Efficient management of clinical trial data – the implementation and development of the eCRF will centralize and streamline clinical trial data management, significantly speeding up data processing and analysis.
- Increased data security – implementing modern IT systems will provide a higher level of data protection for patient information and research results, minimizing the risk of unauthorized access and data loss.
- Automation of administrative processes – modern digital solutions will allow for the automation of many administrative processes, leading to resource savings and increased operational efficiency.
- Enhanced data accuracy and transparency – the ABM eCRF system will improve the accuracy and transparency of collected data, contributing to higher quality and reliability of clinical trial results.
- Improved quality of project management – expanding the validapp module in the ABM eCRF will enable better monitoring and control of research project progress, allowing for quicker problem identification and resolution and optimizing resource use.

Indicators:

- Number of non-commercial clinical trial projects using the ABM eCRF: **30**

4.1.2. Strengthening the potential and developing the resources of the Polish Clinical Trials Network

Strengthening the potential and developing the resources of the PSBK are essential to ensure the highest quality of clinical research. A key element is the development and implementation of guidelines and standards that align with international norms. Creating guidelines that cover all stages of the research process, from trial design to result analysis, will ensure consistency and reliability in the projects conducted. Quality control at each stage of the research will guarantee high quality and compliance with applicable standards.

In 2025, the network's activities will focus on developing guidelines and instructions that comprehensively regulate all aspects of the research process within the network. A priority will be creating detailed documents covering the process of accounting for clinical trials by the research centres with public payers, such as National Health Fund, and commercial sponsors. Additionally, in 2025, the PSBK will continue its development and expansion efforts to provide even greater reach and efficiency in clinical research. Systematic expansion of the network to include new centres, both those with established expertise and experience in clinical trials and those newly entering the field, is planned. General Assemblies, Working Group meetings, and meetings of the Network Council and the PSBK Business Council will be held continuously.

Expected outcomes:

- Network development and expansion – Adding new public centres, both experienced and new to clinical trials, will increase the reach and effectiveness of conducted studies and enable better utilization of research resources.
- Improved quality of trial management – Systematic organization of General Assemblies, Working Group meetings, and sessions of the Network Council and the PSBK Business Council will enhance coordination and knowledge exchange, resulting in higher quality trials.

Indicators:

- Number of new centres with Observer status in the PSBK: **2**
- Number of new PSBK Partners **5**

4.1.3. Promotion of the Polish Clinical Trials Network both nationally and internationally

Promoting the PSBK both nationally and internationally is crucial for increasing the visibility of Polish clinical trial centres. Active participation in international conferences, publishing trial results in prestigious journals, and collaborating with the media will help build a positive image for the PSBK. Promotion will attract new partners for collaboration, increase interest in Polish achievements in clinical trials, and strengthen Poland's position as a leader in this field.

The goal for 2025 is to increase the PSBK's presence at national and international industry events, with more frequent participation as an exhibitor and the involvement of the PSBK representatives and members in conference panels and events. In 2025, social media activity will be intensified to build public awareness about clinical research and the national infrastructure supporting its development.

Expected outcomes:

- Building a positive image – Active promotion of the PSBK's activities on social media will contribute to building a positive image and reputation for the PSBK.
- Attracting new partners – Effective promotion on national platforms will increase interest in collaboration with the PSBK, potentially leading to new partnerships and collaboration with foundations and patient organizations.

Indicators:

- Number of industry events at which the PSBK participated as an exhibitor: **1**
- Number of industry events at which a PSBK representative participated as a panelist: **2**

4.2. Establishment of a database of clinical trial centres

The creation and implementation of a publicly accessible database containing information on clinical trial centres will facilitate various entities, including clinical trial sponsors, in finding institutions with which they can jointly undertake scientific projects.

Support in locating clinical trial centres has been identified by sponsors as a measure that would simplify the execution of clinical trials in Poland. Although sponsors have their own data resources and internal procedures for selecting centres, a central database could serve as an additional information source for global sponsors experienced in the Polish market, especially for new indications. For smaller sponsors or those who have not previously conducted research in Poland, this would serve as a primary tool for identifying specific institutions. Additionally, the database will act as a promotional platform for new centres offering services in certain indications, including rare diseases. A significant advantage will be the ability to identify the range of services offered, including technical capacity (e.g., freezers, laboratory equipment), infrastructure (e.g., hospital laboratory, pharmacy, genetic engineering lab, biobank), personnel (e.g., number and experience of coordinators, researchers, nurses), procedures in place, diagnostic capabilities, ongoing trials, contracting timelines, and experience in conducting research in specific indications (e.g., rare diseases).

An open, publicly accessible database has been identified by clinical trial sponsors as a preferred tool compared to a single contact point responding to sponsor or other stakeholder inquiries.

In response to market stakeholder expectations, it is advisable to launch a tool facilitating access to information on research centres conducting clinical trials in Poland. To this end, the existing ICT infrastructure (PSBK Communication Platform) can be utilized to expand available information about PSBK centres to include data on:

- Infrastructure, technical, and personnel resources;
- Expected response times to feasibility and contracting inquiries;
- Experience in selected therapeutic areas.

In the second stage, the database can be expanded to include centres outside of the PSBK, including private entities.

Introducing a mechanism to verify and update data regularly is advisable. This could be based on a reporting tool that allows a potential sponsor to send an alert to the Agency regarding outdated information.

Key stages planned for 2025 include:

- Analysis and development of a detailed, standardized scope of data to be collected.
- Development of the visual and technical presentation of data within the Agency's ICT system.
- Data collection, initially from PSBK centres, followed by other public centres, and finally private centres.
- Launch of the database in a test version.
- Stability analysis and error identification.
- Launch of the system in its production version.

Expected outcomes:

- Increased engagement of centres in clinical research activities.
- Growth in the number of centres where sponsors conduct trials in Poland.
- Acceleration of the contracting process.
- Increased efficiency of the trial start-up process.

4.3. Development of a national system for assessing the feasibility of clinical trials

Determining recruitment potential for a specific indication and in a particular area is a challenge for most sponsors. Despite having their own databases and close collaboration with centres for identifying suitable cohorts, a standardized database based on reliable data would facilitate and shorten the decision-making process when choosing a country/region and the number/location of centres. Key functionalities include mapping patients in a given region/centre, assessing the prevalence of comorbidities, and tracking medications and therapies used. From the sponsor's perspective, it was emphasized that data could remain fully anonymous, without the possibility of identifying specific patients. The database would be particularly useful for conducting studies in specific indications, including rare diseases.

Based on available information, it can be assumed that creating a tool to facilitate patient cohort identification would likely improve the process of designing and planning clinical trials in Poland. Access to systematic, extensive data covering a relevant segment of the population (ideally 100%) is crucial. In the case of the Polish healthcare system, the tool could potentially utilize data from RCMCs (local databases) or from the National Health Fund (NFZ) and the e-

Health Centre (central database). Key information identified to ensure the tool's utility includes:

- Patient distribution (regions, centres) in a given indication;
- Age, gender;
- Comorbidities;
- Medications and therapies used.

The second phase would involve expanding the system with additional components and functionality, including enabling direct contact and recruitment of selected patients.

In 2025, the following stages are planned:

- Establishing cooperation with the e-Health Centre to share statistical data.
- Based on an analysis of the obtained data, defining the system requirements.
- Preparing a template for tender documentation.

4.4. Communication and promotional activities

4.4.1. "Pacjent w Badaniach Klinicznych" (Patient in Clinical Trials) Service

"Pacjent w Badaniach Klinicznych" (https://pacjentwbadaniach.abm.gov.pl and https://www.facebook.com/pacjentwbadaniach) is an informational and educational service aimed at patients and their families, intended to provide knowledge about clinical trials, including patient participation, statistics, and legal standards. The information on the website is presented in a way that is accessible to people without a medical background, those not connected to the medical industry, or individuals looking to expand their knowledge in this area. Patients, doctors, and non-governmental organizations working in healthcare can use the service to find detailed information on current standards, procedures, and requirements for conducting clinical trials, tips on participating in clinical trials, patient stories, and answers to frequently asked questions. The purpose of the service is to raise awareness among potential clinical trial participants, improve knowledge about clinical trials, and change negative perceptions associated with potential participation in clinical trials.

Indicators:

- Number of posts on the "Pacjent w Badaniach Klinicznych" Facebook page: **100**
- Increase in followers on the "Pacjent w Badaniach Klinicznych" Facebook page: **100**
- Number of discussion panels/booths organized at national and international events: **2**

5. Organizational plans

5.1. Financial plan for the 2025 fiscal year

DRAFT FINANCIAL PLAN OF THE MEDICAL RESEARCH AGENCY FOR 2025

Item	Details	Draft plan for 2025
		In PLN thousand
1	2	3
I	BALANCE AT THE BEGINNING OF THE YEAR	x
1	Working capital, including:	278.658
1.1	Cash	278.658
1.2	Short-term receivables:	0
2	Long-term receivables:	0
3	Liabilities:	0
II	TOTAL REVENUES	854.947
1	Revenues from operations, including:	519.524
1.1	Revenues from NFZ allocation	519.524
1.1.1	- NFZ allocation	519.524
2	Grants and subsidies from the state budget	279.981
3	Funds from other public sector entities	893
4	Other revenues, including:	54.549
4.1	Interest (e.g., from loans), including:	35.000
4.1.1	Interest from deposits with the Ministry of Finance or treasury securities	35.000
4.2	Funds received from entities outside the public sector	16.962
4.3	Equivalent of depreciation charges	2.587
III	TOTAL COSTS	819.947
1	Operating costs	74.853
1.1	D&A	2.587
1.2	Materials and energy	878
1.3	External services	21.595
1.4	Salaries, including:	35.523
1.4.1	Personnel	24.806
1.4.2	Non-personnel	10.717
1.5	Benefits for individuals	48
1.6	Contributions, including:	7.123
1.6.1	Social insurance	6.151
1.6.2	Labor Fund and Solidarity Fund	837
1.6.3	Bridge Pension Fund	0
1.6.4	Payments to employee capital plans	135
1.7	Taxes and fees, including:	25
1.7.1	Fees to the state budget	12
1.7.2	CIT tax	0
1.8	Other operating costs	7.074
2	Task-related costs, including:	745.094
2.1	- Funds transferred to other entities	739.105
2.2	- Funds transferred to the Clinical Trials Compensation Fund	5.989
IV	GROSS RESULT (Items II to III)	35.000
V	MANDATORY FINANCIAL RESULT CHARGES	0

VI	NET RESULT (Items IV to V)	35.000
VII	GRANTS AND SUBSIDIES FROM THE STATE BUDGET	x
1	Total grants and subsidies, including:	279.981
1.1	- Institutional grant	49.341
1.2	- Specific-purpose grant	0
1.3	- Targeted grant	230.640
1.4	- Targeted grant for projects with EU funds – current	0
1.4.1	Including for co-financing	0
1.5	- Targeted grant for projects with EU funds – capital	0
1.5.1	Including for co-financing	0
1.6	- Subsidies	0
1.7	- For investments and capital expenditures	0
VIII	FUNDS FOR CAPITAL EXPENDITURES (spending on tangible fixed assets and intangible assets)	7.770
1	Funds for capital expenditures, including:	7.770
1.1	Own financial resources – Reserve fund	7.770
IX	FUNDS PROVIDED TO OTHER ENTITIES	1.510.819
X	BALANCE AT THE END OF THE YEAR:	x
1	Working capital, including:	313.658
1.1	Cash	313.658
1.2	Short-term receivables:	0
2	Long-term receivables:	0
3	Liabilities:	0

Supplementing data

Item	Details	Draft plan for 2025
		In PLN thousand
1	2	3
1	Free financial resources placed in management or deposit with the Ministry of Finance	305.888
1.1	- Overnight (O/N) deposits	270.888
1.2	- Term deposits	35.000

5.2. Planned employment

Total planned employment: **145 FTEs**, with the following funding sources:

- Institutional grant – 140 FTEs,
- Clinical trial sponsor fees paid into the account of the Medical Research Agency, managed for the Supreme Bioethics Commission – 5 FTEs.

5.3. Planned investments in technical resources

Planned amount of financial resources for capital expenditures, including: the Own financial resources – Reserve fund amounts to **PLN 7,770 k**, allocated for:

Planned purchase items	Amount planned
➲ IT system of the Medical Research Agency (management)	3,000,000.00
➲ Computer equipment with software and warranty service	70,000.00
➲ Design and implementation services for Multi eCRF ABM software	2,500,000.00
➲ Clinical Trial Management System (CTMS) ABM	1,500,000.00
➲ Information portal for Patients and Researchers – scientific and research projects (with a search engine)	600,000.00
➲ Replacement of network switches in use since 2019 that are no longer under warranty or supported by the manufacturer	100,000.00