The Medical Research Agency is five years old!

Before the establishment of the Medical Research Agency, the number of registered non-commercial clinical trials in our country remained at a maximum of a dozen projects. Today, 5 years after the establishment of the ABM, we can speak of a significant change that has taken place in the clinical research market, with a particular focus on non-commercial projects.

We are currently witnessing a threefold increase in the number of non-commercial clinical trials being conducted in our country. To a significant extent, this change has taken place thanks to the funding from the Medical Research Agency of nearly 280 projects with a total value of more than PLN 3.5 billion. Thanks to the studies launched, more than 900 units across the country have provided access to clinical trials for more than 60,000 patients. The development of the clinical research market has consequently resulted in the need to establish specialised units conducting clinical trials. Over the past three years, 23 Clinical Trials Support Centres have been established across the country, expanded by 18 Digital Medicine Centres, providing new jobs, better equipment in hospitals and, most importantly, access to clinical trials across Poland. Private sector-business collaboration has also changed.

- Transparent public-private cooperation in healthcare requires commitment and understanding on both sides, as well as shared responsibility for the initiatives taken to meet the medical needs of Polish patients. Cooperation with business is an essential element of building a strong biomedical ecosystem in which each stakeholder plays a key role and is co-responsible for the created environment - emphasises dr n. pharm. Karolina Maria Nowak MBA - Director of the Biotechnology Innovation and Development Department

An adequate supply of qualified specialists is one of the main conditions for the development of any sector, including clinical research. Supporting the closing of competency gaps in this area is also provided by the Medical Research Agency's competition for the development and implementation of a proprietary postgraduate programme in biomedical sciences, through which 13 proprietary projects will be launched to support the effectiveness of medical personnel training across the country.

Early 2023. The Medical Research Agency has also signed a letter of intent to collaborate with Harvard Medical School Postgraduate Medical Education (HMS PGME). The agreement made it possible to launch the first edition of The Polish Clinical Scholars Research Training programme, designed and implemented by Harvard Medical School Postgraduate Medical Education for the Medical Research Agency. As a result, over the next 5 years, 500 Polish scholars using the experience of Harvard Medical School Postgraduate Medical Education will train under the guidance of top specialists.

- At the Medical Research Agency, we not only help structure the management of clinical trials, but also ensure high quality through systematic pro-quality and educational activities , building the trust of patients and partners. Innovative training is the way forward. Our educational programmes not only introduce you to the world of clinical research, but also inspire you to create new quality standards,

contributing to the improvement of the entire medical sector. For us, quality is the foundation of progress. At the Medical Research Agency, we believe that education and quality activities are integral to our mission, enabling the creation of innovative medical solutions that drive progress and improve the quality of healthcare," stresses Agnieszka Ryniec, Director of the Clinical Research Development Centre at Medical Research Agency.

The dynamically developing biotechnology market requires up-to-date legislation, which is why one of the extremely important activities carried out by the Medical Research Agency was the development of a draft law on clinical trials of medicinal products for human use, prepared by a drafting team appointed by the Minister of Health. The new regulation made it possible to align Polish regulations on clinical trials with the EU regulation, applicable from 31 January 2022, but most importantly, it made it possible to put the domestic biotechnology market in order, making it safer and more accessible.

Extremely important for the implementation of clinical trials is the patient's informed choice of treatment pathway. Therefore, the provision of reliable knowledge and information on clinical trials becomes crucial. The Agency, responding to this need in cooperation with partners, runs the information service 'Patient in clinical trials', which was created to provide knowledge about trials to patients and their families. On the portal, patients can find numerous information materials, brochures and folders on a variety of topics covering clinical trials. To facilitate access to ongoing research, the Medical Research Agency has also launched a dedicated research search engine where patients can find projects dedicated to different health areas.

Clinical trials, from the early phase of searching for a substance demonstrating potential therapeutic activity to marketing, take an average of 10-15 years. The Medical Research Agency has narrowed the possible duration of trials to a maximum of six years. This means that the first complete (final) results of clinical trials funded by the Agency can be expected in late 2026/early 2027, where the first final reports from funded trials will be submitted to the Agency. Independently, we can already speak of real effects from ABM-funded projects.

The study entitled Treatment of children aged 6-18 years with chronic hepatitis C with a pangenotypic drug with direct antiviral activity (sofosbuvir/velpatasvir) treated 50 children (all patients included in the study) with chronic hepatitis C using SOF/VEL therapy.

As part of the Childhood All in Poland project for the treatment of paediatric lymphoblastic leukaemia, which is the most common cancer, all children in Poland (555 so far) with newly diagnosed ALL were included in the study. In this way, all children in our country diagnosed with the disease can have access to innovative therapy.

In a study involving the implementation of a hitherto unavailable personalised treatment for children with the rare disease histiocytic cell proliferations, carried out by the Mother and Child Institute, targeted treatment was included in the worst prognosis group of patients. This allowed a clinical response to be achieved in 100% of patients (resolution of clinical symptoms). This means that all patients responded to the treatment. Previously, this type of treatment was only available to individual patients in Poland.

- I am convinced that the Medical Research Agency has firmly established itself in the research field of

the biomedical sector in our country. We are already seeing an increase in the number of non-commercial clinical trials by several hundred per cent! There are clinical research support centres in public centres, not dissimilar to the best global models. We also try to maintain a dialogue with the research sector of the pharmaceutical industry, believing that Poland can be a leading clinical research market in the world. We know how important the patient is, which is why we have directed a number of our activities towards this group. We do not forget about education, cooperating, among others, with the best medical school in the world, Harvard Medical School. The vision of the ABM was a bold and daring undertaking, but one that was necessary for the research area in Poland to catch up with Western European countries. Every beginning is difficult, so we are open to necessary changes, including, for example, the development of international projects and raising the scientific quality of projects. We believe that together we can change healthcare, as we know that without clinical research and experimentation, there is no progress in medicine," concludes Rafał Staszewski, MD, PhD - Deputy President for Research Funding at the Medical Research Agency

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