



REPORT

Biotechnology as an engine of innovation Polish-American cooperation

VII EDITION OF THE CONFERENCE
“THE BEST WAY TO PREDICT THE FUTURE
IS TO CREATE IT”

Warszawa-Washington, October 2022

THE KULSKI FOUNDATION

FOR POLISH-AMERICAN RELATIONS



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1. THE CONFERENCE BIOTECHNOLOGY AS AN ENGINE OF INNOVATION – POLISH–AMERICAN COOPERATION CONTEXT

1.1 INTRODUCTION

The crises we have faced in recent years, such as the COVID-19 pandemic and war in Ukraine, have demonstrated to us the value of dynamic scientific development in strategic sectors for countries. One of the keys and simultaneously rapidly growing fields is the biotechnology sector. Many countries underpin this sphere, systemically support companies, and engage in the evolution of innovative solutions. The USA is undoubtedly a leader in the global development of biotechnology. Among other factors, they create space for the advancement of projects in the private sector through appropriate legal solutions encouraging the commercialization of innovations. The experience of American experts will be immensely valuable to Poland, which intends to become a leader in Central and Eastern Europe in the field of biotechnology. Thus, it is an ideal time to talk in an international setting about transnational measures to foster the development of science and the opportunities it offers in biotechnology.

Poland's relations with the United States have been significantly strengthened over the past few years. The close cooperation between the two countries was expressed in the "Declaration on the Polish-American strategic partnership", signed in September 2020 at the White House by President Andrzej Duda and President Donald Trump. The text of the declaration stresses that the bilateral relations between Poland and the US are based on respect for and commitment to common democratic values and principles, including freedom, human rights, and the independence of institutions. The Declaration also emphasizes strong ties and common interests of countries in the areas of security and defense, energy, trade and investment, and research and innovation. It is important to work towards ensuring that the objectives of the Declaration are achieved through concrete actions. Over the last few years, the dynamics of meetings at the highest level has been very high. Relations between the two countries should be assessed based on their specific results in terms of political, economic, scientific and defense cooperation.

In 2019 (June 12 and September 23), the Presidents of Poland and the USA signed two joint declarations on the deepening of defense cooperation. An important event influencing the quality of Poland's relations with the US was Poland's inclusion in the Visa Waiver Program on November 11, 2019.

Poland remains one of the most active donor countries of aid for Ukraine, both in terms of aid for residents and the supply of military equipment, the value of which is estimated at USD 1.7 billion. Ukraine has been on the list of priority partners for Polish development cooperation since 2005. Polish aid for this country remains consistently high. Poland is very active within The Ukraine Defense Contact Group, which was established by the USA in March 2022 at the U.S. Air Force Base in Ramstein.

According to the data of the US Department of Commerce, US exports of goods to Poland in 2019 amounted to USD 5.96 billion, which is an increase of 11.4% compared to 2018. In turn, imports from Poland increased by 4.3%, from USD 8.04 billion to USD 8.38 billion. As a result, the total trade in goods between the USA and Poland reached USD 14.34 billion and was 7.1% higher than in the previous year. The negative balance of the United States in trade in goods with Poland amounted to USD 2.42 billion and was USD 270 million lower than in the previous year. Since the dynamics of mutual trade in goods was higher than in the case of some other countries, Poland moved from 40 to 37 in the ranking of the most important trading partners of the United States. The United States is Poland's ninth most important trading partner, including the fourth among non-EU countries (after China, Russia, and Great Britain). The US share in Poland's trade in goods in 2019 was 3.06%. Exports to the USA ranks 8th among the most important directions for the supply of Polish goods abroad and in 2019 it had a 2.87% share in all Polish exports. In turn, imports from the United States accounted for 3.24% of the total supply of goods to Poland during this period, which also placed this country on the 8th place among the most important import destinations.

With regard to economic cooperation, one should first of all mention intensive efforts to engage the United States in the Three Seas Initiative, involving 12 countries of Central and Eastern Europe working together to develop transport, energy and digital infrastructure in the region. Another important initiative should be added to the cooperation within the Three Seas project – the Partnership for Transatlantic Energy Cooperation (P-TEC). The main topics of the talks were cooperation in nuclear energy, natural gas, cybersecurity, and clean coal technologies. Energy cooperation in the field of supplies of American LNG gas is particularly important, making Poland independent from cooperation with one supplier that has been dominant so far. In addition, it is worth mentioning the supplies of American LNG to Ukraine in cooperation with Poland. In line with Poland's interests, the United States has become actively involved in preventing the implementation of the Nord Stream 2 (NS2) project through specific measures. Polish-American cooperation is also developing in the use of nuclear energy for civil purposes. In October 2020, a Polish-American agreement on cooperation in the field of civil nuclear energy was concluded. On November 2, 2022, the Council of Ministers adopted a resolution on the construction of large-scale nuclear power plants in Poland. It states that the first nuclear power plant in Poland will be built based on the American technology of AP1000 reactors. The choice of American technology will not only strengthen Poland's energy security but will also be a significant development impulse for our economy. Poland joined the allies of the United States in building a fifth-generation wireless telecommunications network, as one of the main

instruments to strengthen future international economic contacts in the conditions of the growing role of the digital economy.

Currently, the scientific cooperation is based on the Polish-American agreement on scientific and technological cooperation, signed on April 23, 2018, in Washington, which will be valid for a period of ten years. The benefits of regulating cooperation in the form of an international agreement include, inter alia, the possibility of developing contacts between scientists at different stages of their careers. In addition, participation in conferences and joint research are of key importance for building a broad partnership between Poland and the USA. The agreement enables closer cooperation between Polish and American government agencies responsible for the distribution of research funds. The platform for such activities will be regular meetings of the joint committee, the so-called Joint Committee Meetings. On July 13, 2018, in Washington, an agreement was signed between the Ministry of Health and the Ministry of Science and Higher Education and the U.S. Department of Health and Human Services to cooperate in health and medical science. The agreement was concluded for a period of five years and defines Polish-American cooperation in the field of biomedical sciences and health. It is worth mentioning the Polish-American Science Award, which aims to strengthen the rank of cooperation between scientists from Poland and the USA. The prize is awarded jointly by the Foundation for Polish Science and the American Association for the Advancement of Science, which recognize researchers from the USA and Poland for outstanding achievements in the framework of Polish-American scientific cooperation. The award is given to pairs of scientists, one conducting research in Poland and the other in the United States. The awards were granted in 2014, 2016 and 2018. In addition, it is worth noting that in 2017, the National Committee on Foreign Medical Education and Accreditation (NCFMEA), which is part of the U.S. Department of Education, extended the American accreditation of Polish medical universities until September 2020.

The amount spent on health care compared to the size of the overall economy varies over time owing to differences in both the growth of health spending and overall economic growth. In 2019, prior to the COVID-19 pandemic, OECD countries spent, on average, around 8.8% of their GDP on health care – a figure more or less unchanged since 2013. The United States spent by far the most on health care, equivalent to 16.8% of its GDP – well above Poland at 7.2% of its GDP. In 2019, average per capita health spending in OECD countries (when adjusted for differences in purchasing power) was estimated to be more than USD 4 000, while in the United States it reached the equivalent of almost USD 11 000 for every US citizen – compared to Poland, which spend USD 2 289 for every citizen (5 times less). But still price levels in the health care sector are in favor of Poland – price level index for OECD = 100, for USA=127 and for Poland = 34. In OECD countries, health and social care systems employ more workers now than at any other time in history. In 2019, one in every ten jobs (10%) was in health or social care. In USA employment in health and social work as a share of total employment amounted to 13,6% in 2019, but in Poland only 6%. The number of doctors in OECD countries increased more rapidly than population size, so that, on average, the number of doctors rose from 2.7

per 1 000 population in 2000 to 3.6 in 2019. In USA number of practicing doctors per 1 000 population amounted to 2,6/1 000 in 2019 and was very similar to Poland – 2,4 per 1 000 population. But, in terms of number of practicing nurses, USA is ahead of Poland, having 12 nurses per 1 000 population vs. 5,1 in Poland.

The above data clearly shows that the United States is and will be a key partner of Poland, and the recent years have greatly strengthened cooperation between the two countries in all key areas.

1.2 FORMAT OF THE CONFERENCE

The conference consisted of:

1. Two roundtables:
2. Workshop
3. Bilateral meetings and discussions,

The scientific summary of the conference will be a report published after the conference and a complex scientific monograph on Polish-American cooperation in the field of health care, education, development, and technology in the first quarter of 2023.

1.3 HONORARY PATRONAGES

- Minister of Health; Minister of Education and Science; Ministry of Development and Technology.

2. ROUNDTABLE I: POLISH-AMERICAN COOPERATION IN PUBLIC-PRIVATE PARTNERSHIP IN THE FIELD OF BIOTECHNOLOGY

ROUNDTABLE I: Polish-American cooperation in public-private partnership in the field of biotechnology

Examples – participants' own experience regarding the Polish-American cooperation in the implementation of biotechnology projects within the public-private partnership format. Good practices and US experience that might be adapted to Polish local conditions and can contribute to the development of the Polish biotechnology sector. Polish-American scientific cooperation – proven and reliable cooperation platforms, as well as new opportunities for effective project and research development. Public-private sector cooperation within the Warsaw Health Innovation Hub (WHIH) – a cooperation platform that unites, among others, US companies and Polish public institutions. COVID-19 pandemic – examples of the rapid response to the crisis both by industry and countries, which led to the development of innovative drugs, as well as COVID-19 vaccines.

2.1 THE BEST WAY TO PREDICT THE FUTURE IS TO CREATE IT, MAŁGORZATA BOGUSZ

Małgorzata Bogusz, President of the Kulski Foundation for Polish-American relations, President of the Institute for Social Policy Development, Member of the European Economic and Social Committee, Poland

Thank you very much. It's an honor to welcome all of you distinguished guests here in Washington, D.C. Ladies, and gentlemen, it's my pleasure to extend my warm welcome to all of you, especially to Catharine Kulski, wife of Bill Julian, the founder of the Kulski Foundation. After three years, we are meeting in Washington again – as the late Professor Julian Kulski would like to. Welcome and thank you for accepting the invitation of so many distinguished guests. I wholeheartedly welcome the Minister of Health of Poland – Mr. Adam Niedzielski. I would like to give a cordial welcome to the Undersecretary of the Polish Ministry of Health Mr. Marcin Martyniak, I also welcome the President of the Medical Research Agency prof. Radosław Sierpiński. Let me, welcome prof. Łukasz Szumowski, Director of the National Institute of Cardiology, Polish Minister of Health 2018–2020. Let me welcome Grzegorz Cessak, Ph.D., President of the Office for Registration of Medicinal Products,

Medical Devices, and Biocidal Products, Poland. I would also like to greet representatives of the Polish and American medical communities and all other participants of today’s roundtable discussions. My hearty welcome to the representatives of partners of today’s conference and all guests.

Ladies and Gentlemen, this is already the seventh edition of this conference. Each of them is guided by the words of President Abraham Lincoln The best way to predict the future is to create it. We launched our series of conferences here in Washington, D.C. back in 2019, exactly in the same hotel, the Willard very historical building. At that time, we celebrated the 100th anniversary of Polish-American relations. No one expected then that shortly after both our countries would need to tackle such great challenges. We have survived the COVID-19 pandemic. Now we are facing war.

Amid these dramatic circumstances of recent years, we should emphasize one key issue! Both the pandemic, as well as the brutal attack unleashed by Russia on Ukraine have further enforced Polish-American cooperation. Our relations are now stronger than ever. They have a positive impact on the development of bilateral cooperation not only from the security perspective but also in a range of many other areas.

The alliance with the United States is one of the key pillars of Poland’s security. We want this close cooperation to concern more than just military domains. It is important to develop cooperation in other fields as well. One of the crucial areas remains biotechnology. The United States has been a world leader in biotechnology for years. By deepening bilateral cooperation in this regard, we are opening up entirely new horizons for Poland and the United States.

Henry Ford once said, “If everyone is moving forward together, then success takes care of itself”. Today, Poland and the United States are moving forward hand in hand. There are countless examples of excellent cooperation between our countries. At today’s conference, we are particularly interested in cooperation in the fields of biotechnology, medicine, and science. For years, we have been proudly observing the solid career growth of Polish scientists in the United States.

They have a truly relevant contribution to the development of medicine and biotechnology. Gaining solid experience in the United States, they successfully use it upon return to Poland or cooperate with Polish centers or institutions. A great example can be Professor Maria Siemionow, today prof. Siemionow will receive a nomination to the Council of the Polish Medical Research Agency.

Esteemed guests. In conclusion, I would like to emphasize that I’m very confident that today’s conference will not only enable us to exchange experiences and good practices in the field of biotechnology but will also become the beginning of new joint projects and initiatives. I firmly believe that today we are taking other steps forward so that Poland becomes a leader in the biotechnology sector in Central and Eastern Europe, while the United States further strengthens its global role in this

area. I would like to thank you. It's an honor that such an eminent group of people has accepted our invitation to take part in today's conference. I am convinced that we have a fruitful discussion today. The conference will consist of two roundtables: "Polish-American cooperation in public-private partnership in the field of biotechnology" and "Biotechnology as a strategic sector in economic and security dimensions", bilateral meetings and discussions.

The scientific summary of the conference will be a report published after the conference and a complex scientific monograph on Polish-American cooperation in the field of health care, education, development and technology in the first quarter of 2023.

2.2 INNOVATION AND INTERNATIONAL COOPERATION ARE A KEY ISSUES TO ADDRESS CHALLENGES IN HEALTHCARE SECTOR, DR ADAM NIEDZIELSKI

Adam Niedzielski, Ph.D., Minister of Health, Poland

Honorable Ambassador. Dear Professors, guests, and all experts that gather here to discuss biotechnology. First, let me say that I am very happy to be here because three years have passed since the last conference. So that time we had to deal with and fight the pandemic. And this is some kind of a symbol that right now we can meet, we can discuss face to face all the issues that throughout all this time we had to discuss via teleconference or other electronic means of communication. So first, let me say that I'm happy that we can gather traditionally. We can talk, we can discuss all these issues. Thank you very much to President Malgorzata Bogusz, that you gather all of us here and we have an opportunity to discuss a very important issue. Why it is relevant, perhaps it is not my sake to explain it in detail, but I will tell you about a few words from the perspective of the Minister of Health. We have some lessons learned from the pandemic. We have some new challenges. I think that innovation and especially biotechnology seems to be a key issue to answer, to address all these challenges. The first point is that we have a huge challenge of an aging society. I mean that within a decade or two because this is not a very long perspective, we will have a society with an average age over 50 even, especially it matters in medical workers in Poland – this seems to be quite a danger. But what does it mean that we have an aging society? First, it means that we will have a rising demand for medical services in the upcoming years and this growth will rise at a huge pace. On the other hand, we have the same problems, the same issues as other European countries. I know that here in the United States, this is also a problem – the lack of medical staff. So, we have two different tendencies – the rising demand for medical services and on the other side very severe limitations as far as we consider medical staff. The only issue, the only hope for the medical system is technology, are innovations, including biotechnology. Innovation and biotechnology are the answer to this dilemma. When we observe in the upcoming years that we have a dramatic increase in medical services and on the other hand, still suffering the lack of medical staff. So, this is one point, and I think that this point is

one of the main reasons to invest in technology. From the Polish perspective, we have already taken this step – we are walking through this path. Why? Because in 2019, just before the pandemic, we established the Medical Research Agency. We have President Sierpiński with us, so he probably, in our discussion, will explain in detail what are the main tasks and are also the resources allocated for that issue. But it means that we want to invest in clinical research, in any research related to the development of innovation.

It is very important to say here that the Agency is also responsible and President Radosław Sierpiński himself is responsible for the introduction of the biomedical program for Poland. We are still working on regulation, but we have a strategy in this field, and I think that it shows that it is a very important issue for us. The second point is important, and I think it should be some point in our discussion. This is one of the lessons learned from the pandemic. It means that only innovation can allow us to break through this kind of disaster. I mean, when we look back and think, about what was the most important issue that allowed us to get out of this problem, these are, of course, vaccination and drugs, but first, vaccination. In two years, we – as an international society, invented vaccinations. It was a joint project of the government side and the private side. And this kind of cooperation enables this very quick pace, to invent, to discover the vaccination and apply it on a large scale, on a scale that was not present, that was not existing before that issue. It is very important that when they think about any pandemic crisis, about any kind of disaster, only innovation and investing, of course, in innovation can allow us to break through this kind of issue. And the third point, I mean, is also very important from a Polish perspective, it was an issue of independent production, I mean, especially in the field of pharmaceuticals and this kind, which is called API.

So when we had a crisis and still right now during the war in Ukraine, this is also the issue, we did have some kind of elements that are used in the production of drugs. From that point on, the forum of the European Union started a discussion that we should be independent. We shouldn't depend only on the especially in Asia, located production, in India. You know that part of the drugs and elements that were used in production were specially produced in India, and part of them were produced in China, which seems to be an even worse case than India. This is the third argument for that that we should discuss and should treat this discussion not only as an academic topic. This is a very important issue that can be used in our future and that can save us and save a lot of lives in this kind of crisis. So, dear guests, it is a pleasure to be here. It is a pleasure that I will have an opportunity to listen to that discussion. I know that both are on the side of Poland because you see that best of the best are with us, that on your side we can discuss and we can strengthen cooperation, because which is also a very important sector. Poland has the biggest industry in Central Europe as far as we consider pharmaceuticals. In European Union, I think it's the sixth country, so we have a good position to start.

I think that our discussion was much broader than biotechnology itself. The discussion allows me to present some points that can be treated as a take-off from this meeting, of course, for me. But I think

that also for all participators. First of all, this is one keyword that should be mentioned here, and it was mentioned in a presentation in a speech by Professor Sierpiński. I think that when we are talking about how to look at the possibility of cooperation, where we can put our finances, and where we can define projects, we should think about the word resilience. It's the most important word here. It is, of course, repeated many times on the European Forum. Taking this word as some kind of leitmotiv, we can think about the definition of cooperation areas. And when we think about resilience, we should put a few points making the sense of that notion. First, resilience is very much about crisis procedures. I mean that during COVID we had a lot of things to do, which was completely new. We have, for example, set up temporary hospitals which were built in some kind of places not devoted to conducting medical services. Thinking about crisis procedures does not only mean the direct fight with pandemics or other crises. I mean that we should also think in our context about some kind of fast track for innovative projects. This is the sphere for biotechnology, for other innovative technologies that can be applied during the crisis. So not only procedures related to this kind of crisis management, but also the fast track for projects that in the end can allow us to fight more efficiently the pandemic. So I think that this is probably the one point that we should have in our heads when thinking about what the next step in our cooperation is. The second point is, of course, drug production. I mean that everyone is sure right now that starting from the pandemic crisis and then coming to the Ukrainian crisis, we can see that some kind of autonomy of independence from different sources of supplies is necessary. It was seen from the Polish point of view, and it was seen from the European point of view. I think that in other countries it was also the case. The third issue is elasticity. We should work on our system to give them this kind of elasticity that allows us to switch between, for example, more tailored medical services and traditional medical services, because we cannot be in a world where only one kind of these services is supplied. After all, we must have this kind of elasticity switch in case of any other crisis from one to another. The fourth issue is a mass campaign. I mean that we have the case of vaccination, and it was a campaign that didn't happen in the past. But I mean, that this campaign does not only mean to make a vaccination, but it also means only to convince people. So, this is also a very important issue to have a complementary communication plan of information. We live now in a world of fake news. So especially COVID-19 was the case when this level of fake news was huge. All these sources that presented this fake news are when only the Ukrainian conflict started, turned to the issue of Ukrainian making some kind of propaganda for the Russian side. So, I think that this is a very relevant issue, and we cannot omit them. And maybe the last issue is the investment. It is obvious from all this discussion that we should first invest in people and then in technology. A very good example in Poland is the establishment of agents. I think that the establishment of agents for the Polish word for Polish medical authority does not only mean additional sources for funding the projects. The effect of consolidation of all people that have something to present around the Agency was a very nice effect from the point of view of the Minister of Health. Consolidation can be even seen during our meeting today because you can meet the best of the best I mean, the best Polish scientist managers from the medical sector. So overall, the possibilities are broad. There are a lot of areas where we can cooperate. What is very important is that this cooperation is not

at a very early stage. So, we are not in a position where we can put some declaration. We are far from that stage. We have several projects that are executed. In my opinion, this kind of cooperation within projects of commercial nature, but of course, also general clinical research gives a huge possibility. thank you for this discussion.

2.3 POLISH–AMERICAN COOPERATION IS A GUARANTEE OF THE DEVELOPMENT OF BIOTECHNOLOGY, PROF. PRZEMYSŁAW CZARNEK

Prof. Przemysław Czarnek, Minister of Education and Science, Poland

Ladies and Gentlemen, I cordially congratulate you on organizing the conference Biotechnology as an engine of innovation – Polish–American cooperation. Unfortunately, due to my parliamentary duties, I cannot be with you today. I remain convinced, however, that the event will become a far-reaching impulse for developing Polish – American cooperation. The United States is our pivotal ally, not solely as regards security. Therefore, undertakings and initiatives that deepen/aimed at deepening bilateral cooperation are particularly significant. Today's conference is an excellent example of this. Fostering cooperation in science creates exceptionally strong ties. We see this in the example of numerous Polish scientists who carry out outstandingly ambitious projects in the USA. They share their knowledge and experience, contributing to the development of both countries. Poland wants to be a leader in the biotechnology sector in our part of Europe. We are convinced that advancing research in this sector may become one of the driving forces behind Polish innovation. I believe this can be achieved, among others, through cooperation and the adaptation of the world's best practices, especially those originating in the USA. In the upcoming years, Poland may not only take up the position of a regional leader but also begin to implement global projects in biotechnology. I firmly believe that because of the undertaken discussions, the established contacts, as well as the exchange of know-how, we will soon be able to observe the first effects of Polish–American cooperation. My cordial greetings go to all the participants of the conference. I wish you a fruitful discussion.

2.4 MEDICAL RESEARCH AGENCY AS A PLATFORM FOR SCIENTIFIC COOPERATION, PROF. RADOSŁAW SIERPIŃSKI

Prof. Radosław Sierpiński, MD, President of the Medical Research Agency, Prime Minister's Plenipotentiary for the Development of the Biotechnology Sector and Poland's Independence in Blood Derivative Products, Poland

Thank you very much, ladies and gentlemen, Mr. Ambassador. It is a great pleasure to start the discussion and to give you some short remarks about the general role of the Medical Research Agency, as, let's say, an animator of the medical sciences in our country. First of all, I would like to emphasize what Minister said, that we believe that our role as a government, as decision-makers, is to create a friendly ecosystem and to make transparent business in our country. We believe that biotechnology

might be a kind of wheel that will give us the possibility to move forward, to create a smart economy in Poland. First of all, I would like to give you just a short overview of the history and the role of the medical research agency in Poland. As the minister said, we were established three years ago by the decision of the Polish government. Our annual budget is about 100 million US dollars and for the last three years, we have organized at least 150 projects in the field of non-commercial clinical trials. When we started our work in Poland, it was about 6 to 7 non-commercial clinical trials done in our country. Currently, it's about 60 per year, so it is ten times more than when we started. And probably the most important figure for me as the president of the agency is that about 50,000 Poles are getting access to novel therapies through clinical trials, through the non-commercial programs. So that's the possibility for them to gain access to novel therapies. That's the chance for life, for better and longer life by itself.

I would like also to give you an overview of our commercial programs because we started last year, and the first commercial program was dedicated to mRNA technology. Probably also the minister emphasized the keyword for further collaboration. I think around the world will be resilient to build the resilience of the healthcare system and probably the innovations. High technology might be the key to moving forward everywhere. While talking about resilience, the technology, we found out that many countries are facing the same problems in the field of biotech, in the field of clinical trials. It is not that Poland has different scenarios and different scenes for the problems, but the digitalization, the networking of the clinical trials, and the feasibility of the clinical trials are the problem not only for Poland but probably the same globally, including in the USA. So, I believe we have to build a mutual collaboration. We have to build the platforms of the grants in the field of medical sciences, which may give us the possibility to exchange our knowledge. There is a sentence that science is a kind of new diplomacy. I believe it is. So, there are no political boundaries. There are no boundaries by themselves. There are no different countries. We are working together in the field of science, in the medical sciences to find out new drugs, and new devices. And that is the main role of the Medical Research Agency.

We believe that our budget can be dedicated to creating extramural grants to find the best science teams to work together with Poland. That's why last year we decided to create the Marina program. It was dedicated to the Polish top pharma companies. It was about 80 million US dollars and currently, it is the second year of this program. We are crossing our fingers to introduce this technology in our country. It was the same with the CAR-T technology in the first year of the existence of the Medical Research Agency we found out that there is a big problem with the accessibility to the CAR-T technology. It is very expensive in Poland, and hard to access. So, we decided to create the grant to have this technology in Poland, to build it in Poland, to make the consortia with the best universities, with the National Institute of Oncology, to have the technology and it can be at least five times cheaper than in the normal market. I believe we will achieve this goal and it is the third year, so we are in the middle of this grant. Everything is going quite well. The first patients may receive the current technology in Poland next year.

I would like also to give you an overview of the strategy. So, the Minister said how important is biotechnology as a part of the smart economy. With the great support of the Minister and Prime Minister, our government decided to create a strategy for biotech, the strategy for the life science economy, and we decided to fund at least two billion Polish zlotys. It's about 500 billion US dollars for the next ten years to support startups in our country, to support the digitalization of health care, and to build self-sufficiency in the production of drugs in Poland during the COVID, we have faced up with the problem that some drugs were missed. There were, again, boundaries. We found out that some drugs are not accessible in Poland, so we must have the API in our country. We have currently about 30 of them, where there is more than 1000 around the world. So, we are preparing also the program which will give us self-sufficiency in this field. We also believe that Poland must be self-sufficient in the field of plasma vaccination. It is also a problem which was never been solved in our country for many years. The Polish plasma was fractionated around the world, but now we are preparing the Legislation Act in the Ministry of Health, which will give us self-sufficiency in this, and it will also enhance our resilience in the future. Finally, I would like to give you an overview of public-private collaboration. We believe that public-private collaboration is the new beginning in Poland. We can be the leader in the region.

That's why we established the Warsaw Health Innovation Hub. It is the first initiative of such in this region in Europe. There are about 30 international pharma companies included in the hub. We did more than five projects, more than ten are in the pipeline currently, and these are the projects which are made in pure public-private collaboration. We are giving the platform to discuss what are the possibilities, what are the chances, what are the challenges for the health care system. Our friends from the pharma companies are giving the funds or giving the benchmarks internationally, and our great success is that the hub, which was started two years ago with the great support of Prime Minister Mateusz Morawiecki, is currently moving around Europe. We established the same hub in Latvia for a few days. We are going to sign up for the establishment of the hub in Croatia. Then we will move to the Czech Republic and Slovakia. So, it will be a real collaboration. It will be the real benchmark where everything is started in Poland. It is a big issue for the future and you are more than welcome to join such a hub and build the future healthcare in Poland. Thank you for your attention. I hope we will have a fruitful discussion. And I believe that the ecosystem to make the clinical trials to make the international extramural grants is very, very friendly in our country. Thank you very much.

The data, which is the key to moving forward in the digitalization of medicine, and the kind of, let's say, the keyword about education in young people, about the scholarships. And I would like to say that somehow the investment on the one level can give you the fruits on the other level. A few years ago, the Minister of Health established the program for Professor Walczak. He was the boss of professor Szumowski and mine. He passed away and he was also the father of Polish electrophysiology. The Minister of Health decided to create the fund, which is operated by the Polish Academic Exchange Agency. It is in the Ministry of Science and for the last four years, we have created three

editions of such a scholarship program. It is a full board program for about six months where young physicians preparing their Ph.D. thesis in Poland can move to the USA for half a year. It's, as I said, full board, and currently, more than 75 Polish physicians did it. And the fruits, what we can see is that the people from the first edition are now preparing the grants for the Medical Agency for our goals with the collaboration from friends from the USA. So that's a great example of how the investment at the basic level can give you the fruits very high. And we are looking for such a collaboration and we can see that all the friendships, all the mutual collaboration which you start when you are a young physician, what you are doing, and the research can last for many years and can give the good example of very, very high-level science.

We have different MOUs with different countries. Every MOU has some specific template/topic. So we have the templates, and we have frame documents that can be used in every collaboration model with our partners. I mean, the private partners, these are also the MOU is, let's say some kind personalized for each partner. Probably from our perspective and the key point in the field of the let's say the templates of the different documents are not the MOU or the framework for some collaboration, but it would be the trilateral agreement – I mean the agreement with which is done during the clinical trials from the side of the university to the hospital and the sponsor to the private entity. And it is a kind of good question because we have done it today and this was done a few hours ago. We started our work with our private collaborators with the universities to create the standard trilateral agreement, which will be used in Poland in the Polish clinical trial network for the future. So it's a kind of huge step forward.

2.5 DATA SHARING IN HEALTHCARE IS A BASIS FOR DEVELOPMENT, PROF ŁUKASZ SZUMOWSKI

Prof. Łukasz Szumowski, MD, Director of the National Institute of Cardiology, Minister of Health 2018–2020, Poland

Thank you for inviting me to this conference. It's a pleasure to be here again. First, I would like to say that the last time I've been here with my visit was in a different position. I was running the Ministry of Health and I said that we would create a such thing as Medical Research Agency. And I think that we can say that now that Mr. Niedzielski is the Acting Minister of Health, we are doing what we have promised. That agency is working and funding the collaboration between researchers all around the world. I am very happy that we could create the agency and make it work as efficiently as now it is working under minister Niedzielski. I think that the main topic that we will have to deal with shortly is to internationalize grants and funding from the agency. As far as I am aware, President Sierpinski is working on the topic. But the issue with that is the data sharing – Legal issues. I think we will have to face how to share the data that we have between different countries and different organizations. Today's currency is data, and I think that in Poland we have huge potential for data mining because we are a centralized country, we have a National Health Fund that is centralized. We have now

an international national e-prescription. That means that every drug that is prescribed in Poland is in a database in our national database of electronic prescriptions as well as the e – sick leave document. What does it mean? It means that if we combine these huge databases that are centralized in Poland, we have the ICD code of the health status of the patient, and we have all the drugs that are prescribed. We know whether the patient was buying the drug from the pharmacy or not. Then we have the sick leaves, and which is the national document on whether there are sick leaves or not, whether there are hospitalizations or not, whether the patient is leaving/living or not. That means that we have all the data to do large database mining in terms of new drugs and new procedures. So I hope that we would work out a way to research these databases. With a safety issue in the back of our heads, because these are very delicate data that we have in these databases. I think is crucial to share these databases in terms of outcomes, in terms of efficiency, in terms of pharmaco-economy And I think Poland has the potential to show that we can do real research in terms of national databases with 30 over 30 million of the population that we have in a centralized, well-run database by the Ministry of Health. I think that our potential lies in that field of data, and I hope that we could collaborate on that issue in the future with the safety and legal issues solved.

We are talking about cooperation. We should ask ourselves, what America can do for Poland, and what Poland can do and can offer for America. And starting from that, it must be a win-win situation. What can we do? What is a partnership? Partnerships can be investments or capital investments. Can we offer something? Yes, we can. We have a Medical Research Agency. You have a minister of health that is supporting the medical research Agency with all his strength. And we can offer that our clinical trials, our clinical research, and the implementation of new drugs are well funded now in Poland, which is a change and was not there before. Cooperation and investment and public partnership with the private sector could be also something else. We were talking about data mining and big data sharing. And again, I just read that the Texas prosecutor, Ken Paxton, is suing Google for gathering illegally our biometric data, which is kind of scary. So, we must be very careful with that. But on the other hand, if we have centralized data in Poland and these data are covering the whole nation, we can offer something that is, I think, exceptional. That means that we can look for specific populations of patients that are targets for new drugs, new molecules, and so on. On the other hand, we have a new network of clinical study centers that are just being built to the same standard as the GCP standard in Poland by the Agency with the support of the Ministry of Health. We can say that we have a network of clinical study centers that are supporting clinical trials with GCP. We have nationwide databases to look for the specific patient populations and to look whether interventions with new drugs and new technologies are working. So, I think this is what we can offer as Poland in that partnership. But on the other hand, as well-structured infrastructure, and databases that, as I'm aware are not available in other nations, such as electronic prescriptions. And that knowledge, whether the drug is prescribed, whether it's bought in the pharmacy. This is something that we don't have in other countries. I don't know if in any state we have the database of all the prescriptions that are written and whether the patient is buying the drug in the pharmacy. I think that we can collaborate on that

matter. Still thinking about Google and Eye of Sauron. Be careful. But I am aware that the Minister of Health and President Sierpinski initiative lately is initiating such database mining in Poland in terms of cardiology. I hope that with this pilot study we can work out some methods and legal tools that could cover the safety issue, the legal issue, and the collaboration with other entities, such as also private sector and industry.

2.6 PUBLIC–PRIVATE PARTNERSHIP IS A SOLID FOUNDATION FOR DEVELOPMENT IN CARDIOLOGY, PROF. PIOTR PONIKOWSKI

Prof. Piotr Ponikowski, MD, Rector of the Medical University of Wrocław, Poland

Thank you very much indeed for the invitation. I am privileged. That's a great pleasure and honor to be here. So, once again, thank you very much. Again, we are debating, and we have been asked to focus on the word cooperation between Poland and the US and discuss the public–private partnership. Let me just give you a few comments and remarks based on my position. First of all, I'm very glad that we mentioned that in Poland we are developing very broad projects. I see this private–public partnership based not only on the partnership, but I see this as a triangle of public, private, and academia. I truly believe that academic involvement would give a strong added value. And only in this triangle, as Professor Szumowski already alluded to, we can go for innovative projects, and we can develop great collaborative projects, not necessarily only with the US. I truly believe that that's the direction. It brings me back to the concept already mentioned by the Minister that the Medical Research Agency started with clinical trials. This is a great idea indeed, I did virtually all my life as a tri-
alist for many years in cardiology, which I do not regret to be honest. But now it's a step forward to do something else. What I truly believe is that this biotechnology concept, professor Sierpiński briefly summarized, is something we need to discuss and keep our fingers crossed. To support this would be the next step. And we discussed this as a real partnership between public and private resources, having academia, not in terms of control, but in terms of an added value for all experts, which truly belong not necessarily to academia, but they are meant to be at the universities. I must tell you that quite recently I flicked through the most recent rankings of all the universities in the world. And as you know very well, always in the top 50 half, if not more, are American universities. We always wanted to know why what we are doing wrong, that we could never achieve this kind of a level. Obviously, many different issues, one of which, in my humble opinion, is what we will be discussing for young entrepreneurs who should be shown and supported in their early life or their career with all the resources to develop startup ideas, to go for the patents, to go for all these crazy ideas, many of which would fail. We do not have such a climate at our universities. Regrettably, I must say. We are rather focused on a very old–fashioned traditional way. We desperately need to change it, to move a real step forward to encourage these young people. Yes, at the early age of your university career, think broadly, think big, and develop even risky business and we are going to support you. I think that ABM is going to help us in this area. And I think this is the only way to go for this innovative biotechnological

project. So once again, thank you very much and I am very much looking forward to the next steps of this meeting to see some very concrete projects and a summary of this meeting. Once again, thank you very much.

2.7 POLISH–AMERICAN COOPERATION IN PEDIATRIC RESEARCH IT HAS A LONG HISTORY AND A BRIGHT FUTURE, DR MAREK MIGDAŁ

Marek Migdał, Ph.D., MD, Director of the Children's Memorial Health Institute in Warsaw, Poland

Thank you very much. I'm proud to be here and to represent the pediatrics. Our hospital is the biggest, and at least in my opinion, the most modern pediatric hospital in the country. We are also the Research institute dedicated exclusively to pediatrics. I would like to give you some practical examples of how we cooperate with partners from the United States in the field of clinical trials in children. Four years ago, the biggest project in Europe dedicated to the development of the pediatric research infrastructure on the clinical trials only pediatric population was established. Thanks to the IMA stands for the Innovation Medicines Initiative 50% of the budget 1 billion of euros at that time was funded by the European Commission, whereas 50% was funded or given to the project by the pharma industry. Now we get an infrastructure called C4C Connect for Children. There are 35 academic centers plus ten pharma industry, some of them from the United States, like Johnson, Eli Lilly, and others. We have built a real infrastructure with the standards that are fully accepted by the pharma industry to run clinical trials in Europe, and we are very proud that Coordinating Center for Poland is in our hospital. So it is a very good example of this academic–industry cooperation to improve, first of all, the standards and also to get a kind of trust between both sides.

What is also important when talking about drug development, we must get the three parties, the academia, industry, and regulators. In Europe, we get since 2006 the pediatric regulation like the best pediatric act for children in the United States. And we have real cooperation with the European Medicines Agency. I am honored to represent Poland on the pediatric committee of this agency, and we are doing a lot to improve the situation, we are open to a partnership with the United States. We have a kind of working contact with the FDA and we get a pediatric cluster to discuss issues with the FDA, the pediatric committee, and the Health Canada in other parts of the globe. As we know, what is important in pediatrics, is that the number of the patients is extremely limited, especially if you are talking about the rare diseases. I would like to finish my talk by saying that our healthcare system in some medical or clinical problems is still centralized. Our hospital is a national center, for example, for liver transplantation or kidney transplantation. We do the same numbers as colleagues from the States or in Europe. He's just the King's College, London. We get a real deep experience.

So for all new developers and please remember the talking about the future and biotechnology. We are not thinking and discussing the problems of the new drugs, but also, please remember that what

is extremely important, especially for children, is the medical devices, which are still an open space for future research. So once again, I am very glad to be here and to sit close to Dr. Gallo from the Children's National Hospital in Washington. This is an example of how we cooperate daily. In I met first-time Professor Kurt Newman, CEO of the Children's National Hospital. It was a meeting of the CHEFs (Children's Hospital Executive Forum). I was invited to this meeting to talk about the situation in Ukraine, and how we support Ukrainian patients, especially children, and pediatric patients. It was in May and we started to talk. When a couple of weeks ago the Polish Minister of Health and the Polish Medical Research Agency asked us if we are going to Washington, and whether we have any contact in Washington. I said, of course, this is the best choice. Tomorrow we are going there to see what the real examples are, the best examples of the private-public and cooperation you are going to see this amazing Research and Innovation campus. Thank you.

2.8 UNITED STATES OF AMERICA AND POLAND TOGETHER EDUCATE NEW STAFF IN MEDICINE, PROF. MARIA SIEMIONOW

Prof. Maria Siemionow, MD, Director of Microsurgery Research at the University of Illinois Chicago, USA

Thanks for the invitation. It is a great pleasure to be in this great audience. I have the privilege to train many Polish young adepts in medicine. They are coming to my laboratory and clinical practice for the past many years. I train about 60 Polish scientists, surgeons, also medical students right now in Chicago in my lab there. Three young women from Poland, one person from biotechnologies, one resident of orthopedics, and they are one resident of surgery. So they are learning from my experience and interest in therapeutics. But cellular therapies for the future, which was mentioned here by both Minister Niedzielski, as well as Professor Sierpiński. I think from this perspective, one lesson they are getting when they are coming to the US, to the lab is that there is a whole different system that even biotechnologies, who are having a great experience in biotechnology, that there is a lack of link quite often to the medical applications. So they can perform many assays and have a lot of experience. However, they don't link it to application in clinical practice. In this aspect, I believe thinking about the future of biotechnology in Poland, it will be very important to have a new generation of clinical trial coordinators who will be trained differently than coordinators for, I would say, conventional research and clinical trials which are run with such a success in Poland. So that will be number one. I think that will be very important that we will be able to these new technologies, and find clinical coordinators who know the rules, and who know what the requirements by regulators for advanced therapy are, and medicinal products. And that's what goes with an ABM's interest to develop new technologies.

As Professor Sierpiński already said we will have CAR-T in Poland very soon. So we have one example of advanced therapy, medicinal products. But the future is in developing more products like that. We need more coordinators, well-versed in applications, and clinical applications. I was looking at

the list of advanced therapy medicinal products, which are either cellular therapies or gene therapies, or a combination of both. In Poland, on one hand, we can say how many are approved by the regulators – URPL in Poland and Europe, in the European Union, there are not many. So what I would propose with all interested and the agency, ABM, and interest of all in the future, it will be to have Poland as a leader in advanced therapy, and medicinal products. And we have a great chance because, as I said, there are not many countries in Europe that will have approved already advanced therapy medicinal products. So that will be number one. And then thinking about what Minister Niedzielski said, the society is aging. We want a better life. The advanced therapy medicinal products of different types of therapeutics, cell-based therapies will be great because this is for arthritis, for inability, for many patients after cancer, they have sarcopenia, they are already healthy, but they are having problems with communication, with moving and so on. So I think Poland has a great chance and can be a champion and have a fast track in the new generation of therapeutics, which will be cell-based therapies as it is actually under the Agenda of the Medical Research Agency, which is represented at today's conference. Thank you.

2.9 POLAND AND USA PERFORM RESEARCH AND OPTIMIZATION OF CARE IN ONCOLOGY, PROF PIOTR RUTKOWSKI

Prof. Piotr Rutkowski, MD, President of the Polish Oncology Society, Poland

It's also my great privilege to be here and thank you for your invitation. I represent the field of oncology. Poland is a leading country in clinical trials in oncology in our part of Europe, but not only because we are in the ten largest countries in Europe, in the world performing clinical trials in oncology. So this means how what is the real potential of our country. And it is now better and better organized because quality is the first point, but also due to collaboration with Medical Research Agency, we have established a very good structure for performing clinical trials. Our institute, because I also represent the National Research Institute of Oncology, was the first to establish an early-phase clinical trial unit. Currently, due to the funding from ABM, we have several early-phase clinical trial units in Poland. What is exceptional and it means that we can start biotechnology development from the beginning, not only be included in the late phase, which is less important for real drug development. So of course, for Poland – US collaboration in biotechnology, we had several phases. We started with a real bilateral collaboration with some help for Alliance for Innovation and some help from biotech companies. Now it's much more mature. So even coming back to these clinical trials, which is the first part, of course, now we are performing the trials, which are examples of very good collaboration because we have the funding from the Medical Research Agency, but the drugs and coming from us and even we can perform the trials in parallel between Poland and US in our institute. We have two examples of it, like, for example, the collaboration with Agenus, which is one of the US companies, and another molecule linked to MD Anderson Cancer Center. So we are performing both such trials originally developed in Poland, but in collaboration with the drugs from the US. Moreover, with the

strong translational part which is performed in Poland. So we can do it, this is the first point. Second, it's I would like to echo what has been said by Minister Niedzielski and Professor Szumowski about the data analysis. This is a very important point because we have our national oncological strategy and now we are establishing a national oncology network of comprehensive cancer centers. And this is much easier to analyze the big data in our field. Of course, we have also collaborated on the smaller field, like, for example, in NCCN for some skin cancer projects and gynecological projects. But I think that it is a very good field for future collaboration, including some genetic data because another step for next year is a huge project for molecular testing, diagnostic, and predictive markers in oncology. So we also established the Warsaw School of Epidemiology of Prevention with the help of speakers and knowledge from NCI. I think that we are doing a lot but now it's time for another step. And thank you again for the invitation to this conference. Thank you.

2.10 COLLABORATION BETWEEN ACADEMIA, BIOTECH, AND PHARMA IS A KEY, DR PAWEŁ KALIŃSKI

Paweł Kaliński, Ph.D., MD, Roswell Park Comprehensive Cancer Center, USA

Thanks for the opportunity to share my experience from Roswell. A senior vice president for science. My role is to promote collaborations between laboratory and clinical scientists at Roswell. As far as our partners occur in the region, in the United States, and internationally. This involves collaborations between different academic partners academia, biotech, and pharma. One of the areas that we are trying to focus on is a local collaboration between Roswell Park, Ontario Institute for Cancer Research in Canada to cover not only our interests in making the lives of patients with cancer easier and moving forward research but also to mobilize Polonia in that corridor. In addition to lots of biotech, and lots of pharma, there are half a million Polish Americans and Canadian Americans and several thousand people who work in this field. We want to tap into these resources to make sure that we can mobilize old countries and new countries, including Polish, American, Ukrainian Americans, Hungarian, Slovak, Czech, Croatian, Serbs, and others. As one of the examples of this interaction, since 2019, we organized Marie Skłodowska Curie symposia, which are focused on collaborations between initially Poland and the United States. Last edition between Poland, Canada, Ukraine, and all of the Visegrad and three CIS initiative countries in these four areas. Mostly it is cooperation in the area of education, cancer education and training, clinical research or basic research, but also improvement of the quality of life of patients. It is well known that we do need to collaborate in such areas that require hundreds of thousands and millions of US dollars to advance to help our patients lead better lives, but also for several hundred dollars, several tens of thousand dollars we can completely use expanded experience in improving cancer care patients experience from the United States into something that is largely neglected in Europe, not only in Poland but also in Western Europe as well. This is the second area.

One of the areas which are very close to what we want to do is to figure out how can we collaborate better between American Polonia and Polish clinical and laboratory entities. One of the great examples

that I think Poland can use is the National US–Israeli Binational Science Foundation. I'll be very curious to talk to Ambassador Magierowski to talk about it. When each side pays their expenses is the same project. So first, scientists from one country moves to the United States for one or a couple of years. But then the other side is providing matching funds to continue the same project in the parent country. This allows us to continue this project expand the science started in the US in other places and allows to run it in a much less expensive manner. It's generally known that putting one patient on a clinical trial in the United States averages about 70,000 USD. It's highly possible to do it at a fraction of the cost in Central and Eastern Europe, including Poland. The last thing that I do believe is worth mentioning is just a lack of information. At this moment many of the organizations which are represented here are trying to promote these collaborations. There is not any one single database that would let people know around the world what are available projects, what entities want to work, that are seeking collaborations, what are new drugs and new, for example, cellular therapies have been developed in the US or Poland that we are looking for partners in further development and clinical testing.

So one of the issues that were brought up by several speakers was this need for a win-win. We need to make sure that everyone who participates in it benefits differently but to a similar extent. One of the most difficult parts of every project is to start in case of biomedical interactions. There is a whole set of legal documents, documents, and arrangements that need to be in place. It is legal how to make sure that we assure patient safety and privacy issues. There is a question of intellectual property protection and development. There is the issue of budgetary arrangements. One of the things that we met trying to interact not only with Polish partners but with other partners, for example, within the Translational Regional Consortium of Cancer Centers, which involves 12 cancers from the United States and Canada, is every time we start talking, we need to get through these separate documents from the beginning. So, what we are trying to do in that forum is to try to agree on a few templates of legal documents, IP documents, and budgetary documents to make sure that we can promote these interactions with others faster. So, a question occurred to Professor Sierpiński and Minister Niedzielski and everyone here. Are there other considerations from the Polish side and partners to make available any of the documents which have been approved by the Polish and American sides, talking about a regulatory, for example, how to translate American R&D into approval for clinical trials in Poland, how to develop a budget that is commensurate with the needs of Polish and American partners, how to protect IP, having this kind of set of documents may be separate for industry or industry or industry-academia collaborations in other than for strictly academic collaborations? I think that would dramatically accelerate our chance to develop similar agreements in the future with other partners. Are we thinking about it?

2.11 OUR GOAL IS TO BRING TOGETHER PROFESSIONAL HEALTH PROVIDERS AND BIOMEDICAL SCIENTISTS WITH THE PURPOSE OF SHARING MUTUAL PROFESSIONAL, CULTURAL, AND SOCIAL INTERESTS, DR ANNA KORZAN

Anna Korzan, MD, President of the Polish-American Health Association (PAHA), USA

Polish American Health Association (PAHA) is a Washington DC based, non-profit charitable organization dedicated to bringing together professional health providers and biomedical scientists with the purpose of sharing mutual professional, cultural, and social interests [<http://pahausa.org/>]. PAHA organized scientific programs, workshops and symposia for its members and general public, promoted joint programs with Poland, provided support to medical schools, universities and biomedical research institutions in Poland since 1992. One of the goals of PAHA is to bring together professional health care providers and biomedical scientists with the purpose of sharing mutual professional, cultural, and social interests. The Board has decided that the agendas of our meetings must be related to medicine and health issues; that they may include practical aspects, basic sciences, and health care organization and delivery; and that the selection of subjects for presentation at the meetings, and the level of presentation must correspond with the needs, interests, and the educational level of our current and prospective membership. Many of the lectures were by world-renowned medical scientists and several of whom were visitors from Poland. The Polish American Health Association is interested in establishing relations with sister organizations in the United States and abroad.

Polish American Health Association (PAHA) and The National Cancer Institute Center for Cancer Research (NCI-CCR) of the United States of America are organizing collaborative training program for early career Polish scientists called the CCR-PAHA Fellow Program. Trainees supported under this program would be appointed as Supplemental Fellows in the National Institutes of Health (NIH) Intramural Research Program. The CCR-PAHA Fellow Program should build long term collaborations in the biomedical and biochemical sciences between the NCI and Polish research institutes, medical schools, universities, and research communities. Program will promote and ensure the selection of the best Polish trainees to receive outstanding scientific mentorship at NIH. It should provide a unique opportunity for potential collaboration in future research. To be eligible for the CCR-PAHA Fellowship Program, the potential award recipient must be a Polish citizen or of Polish descent (a Polish citizen or Polish American of Polish descent defined as within the last three generations. Candidate should be formally accepted by a CCR Principal Investigator into a lab, in chemical sciences related to medical research or chemical biology including but not limited to the areas of drug discovery (design, synthesis, bioorganic, medicinal chemistry) and development (biochemistry, pharmacology, toxicology); and appointed as a CCR Fellow, Intern, Guest Researcher, or Special Volunteer by the NCI. This appointed position can be at the post-doc, graduate student, or post-doctoral level. Not more than 5 years has passed after receiving the doctorate; the Nominating Committee will give

the first priority for approval to the young graduate and post-graduate students; however a limited amount of funding is available to award to more experienced scientists under special circumstances.

The second important project, which I believe can be helpful and I've been actively looking for candidates, is the The Krystyna Lesiak Endowment Fund for the Professional Development of Graduate and Post-Graduate Students of Polish Heritage. It's a fund that gives grants to young scientists either in graduate or post-graduate education, also of Polish origin. This endowment will fund awards supporting graduate and post-graduate student research presentations at national or international scientific meetings. Depending on the financial request and available endowment funds, the award will cover fully or partially the payment of registration fees, travel and accommodation costs, and other expenses related to presenting scientific findings relating to the above Statement of Purpose. The foregoing objectives constitute the rightful activities for which the Krystyna Lesiak Fund has been created. We have people coming from Nencki Institute. We had some candidates from the Polish Academy of Science. During COVID time no one was able to come in, but currently, I would like to advertise that because it's a huge opportunity for Ph.D. students to come for a conference and we can sponsor that. I would like to also mention that I think we should investigate the intellectual potential of the retired scientists who are part of our organization. They have a lot of experience and are less busy than us being professionally involved and they can offer a lot of help. So I am open to discussion and collaboration. Again, I'm looking for candidates for Krystyna Lesiak Endowment Fund and also trying to open the possibility of cooperation with NCI.

2.12 BEST EXPERIENCE SHARING BETWEEN POLAND AND USA WILL OPTIMIZE HEALTH CARE, DR MARCIN CZARNIECKI

Marcin Czarniecki, MD, Assistant Professor, Advanced Radiology, University of Maryland Medical System, USA

Thank you for the invitation. I just want to make a few remarks regarding maybe some of the as a clinical somebody that practices clinically here in the US, but also worked in Poland before. You know, regarding what minister Niedzielski said about the lack of doctors and there is the same problem here in the US. You know, it's estimated that from 30 000 to 100 000 doctors will be missing by 2033 in the US as well. Luckily in the US, we have the benefit of about a quarter of our doctors being immigrants, including myself. One of the positive aspects of the war in Ukraine, I know that there are now new arrangements for physicians from Ukraine to have a practice in Poland. There are many differences when it comes to the two systems. You know, the fee-for-service approach in the US doesn't allow, you know, it's more specialists driven and it causes problems for the primary care provider, which is very different from the, I guess, Polish system. But I mean our great Polish solutions that are something that the US can look forward to. I know the bariatric surgery program now that that is very outcomes, the outcomes-based approach in Poland, that that's something that the US can learn

from as well. I'm in a private practice that is affiliated with a university, so I think that kind of joint venture is worth looking at. So, when it comes to private primary care in Poland, you can tell. Those are it is public–private partnerships already because those are all private entities having a contract with the central healthcare system. When it comes to hospitals, though, I know there are good examples of this that this happening. I know there's a Canadian company that opened a hospital in Żywiec, which is a great example of this. It's still missing so infrastructure investment from the West and in the hospital, infrastructure is something that as a public–private – partnership would be very interesting. I think the most important, most interesting for me is education and what we can do in that field. So, we've been collaborating with Lazarski University in Poland, which is a great example of a private institution, which has shown the ability to collaborate with public institutions to build a new healthcare education system. So right now they're collaborating with public entities that are within Warsaw and through that, they're able to do something that perhaps the older universities weren't able to do before. And that's something to look forward to. So right now I know that Lazarski university is ranked amongst the students the first is where they want to go because they're interested as this is something that wasn't available in some of the older universities.

The public universities are coming to the private ones for help. And I know that. So the governments the university in Gdansk, as well as Śląsk (Silesia) – they're collaborating with some of the private universities to build an executive MBA for healthcare. And this is something that I feel like the US can help with in Poland is how to manage the hospitals and the healthcare system in general. So I'm looking forward to collaborating in that field. What/s more research. I mean, you, Professor Poniowski, I know you mentioned that there is so much to do in this field, and I agree. And I think there must have to be so much investment in infrastructure to do this in a meaningful way. And there are great examples of this already actually, with Warsaw Polytechnic University and Polytechnic and Central Laboratory CEZAMAT in Warsaw, which is a material science incubator. I'm looking forward to seeing something similar in Poland. Maybe there is already I'm not sure. Professor Szumowski, you mentioned data sharing. I agree. During my time at NIH, you know, companies were knocking on our doors, wanting our data, and there was a problem with regulation. And once that's solved, that's something that Poland could help in. So I look forward to collaborating with anybody. Thanks.

2.13 WE NEED TO BUILD AND DEVELOP PEDIATRIC RESEARCH NETWORKS, DR VITTORIO GALLO

Vittorio Gallo, Ph.D., MD, Interim Chief Academic Officer, Children's National Hospital Interim Director, Children's National Research Institute, USA

Thank you so much. So, first, it's exciting to be here. It's exciting to be part of this incubator of ideas. And thank you, Professor Migdał, my pediatric partner. So when I think about Children's Hospital and when I think about what we're doing, we have a very broad mission and it's a very complex mission. We are doing many things. Not only we are taking care clinically of our children and our families. We

are also involved in training, education, advocacy, international collaborations, and cooperation in pediatric networks. And finally, we are a pediatric academic center, so we have a focus on research and innovation. We are ranked number five of all children's hospitals in the United States, and some of that derives from excellence in research. So when I think about the future, I've always I always think about how we support this mission, but how we support this mission thinking about pediatrics and pediatric care, pediatric research would be in five or ten years from now. We have to develop a very complex vision that not only thinks about what we're doing now but also where we want to be in five and ten years from now.

We need to keep in mind that children are not small adults. So when we think about devices, when we think about therapeutic interventions, when we think about drugs, we need to think about pediatrics, not as taking from the adult world and transferring to downscaling to the size of children. So to face these challenges, we have developed a new research and innovation campus. We have thought for many years about how to integrate our mission into a vision where we create a very unique ecosystem, where there is a partnership between us as a pediatric academic center, the private sector with Johnson and Johnson's labs, with J Labs as an accelerator, an incubator of ideas to transfer research findings into therapeutics, and then a partnership with a government and a partnership with other academic institutions. So we have a partnership with BARDA. We have a partnership with Virginia Tech because these agencies are complementary and what we're doing. So this campus, we've just completed the first phase of this campus, and I'm looking forward to the visit of the Polish delegation tomorrow. But this is a very unique ecosystem where we think that we will be able to face and respond to the challenges that pediatrics and pediatric care will present in the next five or ten years, and also will give us a unique opportunity to collaborate both nationally and internationally. We are not only part of many pediatric networks, pediatric research networks. There's been a conversation about data, big data, data analytics, and data sharing. So we are part of all these networks, including PEDSnet, but we want to open this campus as a new site where this vision is. There are many innovation campuses in the United States, so many most of the academic institutions are developing innovation campuses, but our campus is the only pediatric, the only one that is focused on pediatrics. So we want this campus to be an open site for international collaborations. And I think there are a lot of opportunities to look at this site as a new hub for pediatric collaborations nationally and internationally. So thank you so much for inviting me. It's exciting to hear all these ideas and I'm taking a lot of notes. So thanks again.

2.14 TO ADDRESS THE UNMET MEDICAL NEEDS THAT EXIST TODAY AND TO ACHIEVE THE IMPACTFUL HEALTH OUTCOMES THAT ARE NEEDED, WE AS A GLOBAL PUBLIC HEALTH COMMUNITY NEED TO WORK IN COOPERATION, HERLYS GIANELLI

Herlys Gianelli, Associate Vice–President, Global Vaccines Public Policy & Partnerships at Merck & Co., Inc., USA

Thank you for the organizers to have me here today. Before addressing the question, I want to take the opportunity to express my compliments to you personally, Minister Niedzielski, and to your colleagues around the table for your extraordinary efforts in adapting your health care system in support of the Ukrainian refugees in Poland. I have been following this work with a great sense of admiration. Now, going back to the question. Biopharmaceutical innovation is one of the driving forces behind the great progress that we have seen with life expectancy and other important health and social development outcomes in recent decades. Just looking at immunizations alone, one of modern sciences and biotech's greatest success stories, there are now around 30 vaccine-preventable diseases, with millions of deaths averted every year. We must have been at the forefront of research to advance the prevention and treatment of diseases that threaten communities around the world. However, to address the unmet medical needs that exist today and to achieve the impactful health outcomes that are needed, we as a global public health community need to work in cooperation. A good example that I would like to highlight is the ongoing efforts in support of the Global Cervical Cancer Elimination Agenda, a strategy that was adopted by the World Health Assembly in 2020, calling on all stakeholders to unite behind this common goal. To achieve this elimination, goal all countries must attain specific HPV vaccination, as well as cervical cancer screening and treatment outcomes by 2030. When it comes to HPV vaccination, one of the most impactful tools that are part of this strategy as well as individual country public policies, it is important for stakeholders, like all of you sitting around this table today, to work in close partnership. And we applaud the efforts of the Polish government in acting with urgency to introduce HPV immunization as part of your national immunization program and in alignment with the country's national oncology strategy, as well as by doing so joining other EU countries in achieving the outcomes outlined as part of Europe Beating Cancer plan. At MSD, we have had the great privilege to work with many governments and organizations around the world to support the introduction and implementation of HPV national programs, and we look forward to collaborating with Minister Niedzielski and his staff, as well as many of the other stakeholders that are here today as part of our common mission to eliminate cervical cancer as a public health problem in Poland, as well as other efforts where the value of biopharmaceutical innovation can bring better health outcomes to the people of Poland. Thank you.

2.15 PUBLIC-PRIVATE PARTNERSHIP BETWEEN PHARMA, ACADEMIA AND GOVERNMENTS CREATE A SOLID FUNDAMENTS FOR DEVELOPMENT, DMITRI GITAS

Dimitri Gitas, Managing Director, MSD Poland

I think the current state of partnerships has been better than they've ever been. From a clinical research perspective, MSD runs around 140 clinical trials on an annual basis in Poland. And so through these clinical trials, we treat around 3000 patients and we partner with 400 different research institutions. On an annual basis, we invest around 150 million zloty in these clinical trials. And so that's one level of partnership where I think is strong. I think to answer your question in terms of what is required to further enhance partnerships, I think it goes to trust optimal sharing and optimal dialogue. When I look at the platform that has been discussed earlier today, the Warsaw Health Innovation Hub, I think that's a huge advance in public-private partnerships that will, at the end of the day, result in a more resilient healthcare system. So I'd like to identify maybe two specific examples where we can partner together to optimize patient outcomes. We heard earlier about HPV and national immunization programs. Right now, we're a little bit behind in Poland and introducing a national immunization program or one of the last countries to do so in Europe. However, there's an opportunity to learn a lot from some of the other countries that have either had success or maybe some challenges in implementing these programs. And this is where together between the government and industry, we can share some of those experiences so we can introduce the right type of education, leveraging data as well, and leveraging the learnings from COVID so we can maximize the vaccination rates and at the end of the day, prevent as many cancers as possible. The other area is that I think there's an opportunity for partnership as well as lung cancer. Lung cancer represents one of the biggest burdens in the healthcare system today. Cancer accounts for around 20% of the mortality in Poland, and the biggest contributor is lung cancer. Today there is a good drug program put in place with innovative treatments. However, only around 55-60% of stage four diagnosed patients are getting these innovative treatments. The ESMO guidelines state that around 80% of patients that are diagnosed with stage four should be getting these innovative treatments. So if we leverage data that exists today to map out hospital by hospital, what is the patient pathway so we can better understand where there are gaps then we can go in with focused strategies to address those gaps to have a more effective and efficient system of care. So those are two examples where we can partner together between industry or our government stakeholders, but also with scientific leaders and patient organizations so we can optimize patient outcomes.

2.16 ENVIRONMENT FOR RESEARCH AND DEVELOPMENT SHOULD BE CREATED BY GOVERNMENTS, MICHAEL SOLDAN

Michael Soldan, CEO of Polpharma Biologics Group

Thank you for the invitation. It's a real pleasure to be here. And I've carefully listened to all that you said and I'm trying to address now the remaining points which I need, which I think need to be mentioned here. So first, I think I am very happy that we are now the first Polish biotech company who has manufacture biologics in Poland and where the patients in the US are now treated. So that means we are FDA approved facility, and I can tell you it's a long way to come there. For this long way, you need three main things. environment, the right attractiveness, the right experts, and support. The environment is important so that something can grow. So that means we can only be successful in Poland if we have the right people, and they feel at home there. They have seen knowledge from everywhere in the world. That means sending people from Poland to the US, bringing the US people in. Do that right at the beginning when the students exchange. And then also what I believe is missing is what you mentioned, Professor Gallo, these centers for the universities where you have then also the industry included, where you can support young startup companies. So these examples help, of course, to get the right experts and right innovation into a country and then also as a kind of starter to bring startup companies and also in Poland to grow. This is, I think, very important. On top of that, experts should be thrilled when they want to work in Poland in a biotech company. And this is only possible when we have biotech companies who are selling the product in the world where people can learn a lot. We need to have the support and I mentioned it already, it's the right environment for these people. There are a lot of different possibilities for how you can foster that, how you can support that. I think this is nothing that we need to discuss now. But I think there are very good examples, especially also in the US of that and we can learn a lot from that. And one additional topic when it comes to the future of biotechnology. I think everybody is now seeing the example of COVID-19 and how fast you need to manufacture products for that. You need to have manufacturing capacity in Europe, in Poland. So, this is something that you cannot do like this. This is something that grows over the years and needs a lot of dedication and an investment into that to support that in the future is extremely important. So, with that, I leave it, but I'm happy to discuss even more throughout the break so whenever we have a chance to do so.

Polpharma Biologics is the trusted developer & manufacturer of biosimilars. We are an international company, with integrated operations in the European Union, passionate about broadening access to biological medicines. We care about global sustainability, speed to market, scientific standards – in compliance with the highest quality requirements. We care that our partners and our people enjoy working with us.

At Polpharma Biologics we are focused on developing the next generation of biosimilars to improve patient access and reduce health care costs. The development of biosimilars is a long and complex

process to ensure that they are as safe and effective as the originator biologic. Below you find detailed information on what biosimilars are, how they are made and information on how they reduce health care costs.

2.17 INTERNATIONAL COOPERATION IS DEVELOPING MEDICINE IN POLAND AND USA, STANISŁAW PISARSKI

Stanisław Pisarski, President of Factor Consulting, Poland

I'd like to raise just one topic related to medical needs and how international cooperation needs to be organized so that both sides benefit from it. We analyze needs and then help develop solutions and implement them. As I listen to this discussion, I heard many speakers mentioning various public needs related to cancer, neurological diseases, contagious diseases, and immunology, diseases. Various speakers have mentioned that you deal with gene therapy, cellular therapy, and biotechnology. Mostly I heard about RNA-based gene technology and transmitter technology attacks, super personalized technologies, and targeted technologies. But I'd like to point out, I'd like to emphasize that Poland has opened up for international cooperation in this area, particularly in implementing or complying with international standards. The government has invested massive amounts of funds in health services and therapeutics, and the results of this have been visible during the pandemic. Of course, all research must be conducted within a certain legal regime or legal regulations and ethical considerations. Yet we should keep the research going. We are aware that there are always risks, but those risks should not prohibit us from continuing the research. We want to be a partner in formulating solutions internationally, but we also want to benefit from them. For these research projects to bring fruit to be useful, there needs to be a large enough scale. And that is why Poland needs to participate in international projects to make them happen. Also, as we look into the future, we shouldn't forget about the past. And I just would like to outline several stages or chapters that we've gone through, including the participation of several individuals around this table. It is Dr. Szumowski's vision, thanks to which many study trips or study tours were undertaken over the years. Thanks to the study tours people from Poland's health sector, but also public administration and legal community related to medicine have been able to travel abroad and see clinical research projects and other projects and other considerations abroad. Thanks to that visionary effort, the Medical Research Agency was formed in Poland and Professor Sierpiński became the head of it. We've all benefited from its existence. The emphasis on best research practices was transferred to Poland and benefited Poland. We're talking about ABM in Poland whose budget is equal to all the budgets of all the private medical research companies in Poland combined. Summarising, I'd like to also express my appreciation for Minister Niedzielski, who continues this mission and other transformational efforts, thanks to which a new agency was formed, and other projects are reaching fruition, including commercialization.

2.18 FOCUSING ON DEVELOPING NEW SOLUTIONS IN BIOTECHNOLOGY IS THE FIRST WAY TO HAVE A GOOD HEALTHCARE SECTOR, MARCIN MARTYNIAK

Marcin Martyniak, Undersecretary of the Ministry of Health, Poland

Thank you. First of all, I would like to say that it was a pleasure to be there. So thank you for the invitation to this conference. So, what we know, we know that focusing on developing new solutions in biotechnology is the first way to have a very good healthcare sector, especially when we cooperate with our partners and make our relationships stable. Investing in sources of innovation in healthcare is the straight way to developing an economy. I would like to say a few words about a special finance mechanism, which is working for three years. I'm speaking about the medical fund. The medical fund is a special mechanism which is an extra supporting tool for the Polish health sector in the first phase. Three weeks ago, we were celebrating officially the first transfer of over three billion Polish zlotys into the pediatric subsector for building, rebuilding, and adapting pediatric hospitals. This phase is also a big opportunity to cooperate in biotechnology. As Mr. Sierpiński said and Professor Szymanski earlier, that database, which is very closely connected to this medical fund can be the best way to build a modern well-working structure, which can be in the future the main source of well-working partnerships between Poland and the USA. Thank you very much.

3. A CEREMONY OF HANDING OVER A NOMINATION OF PROF. MARIA SIEMIONOW TO THE COUNCIL OF THE MEDICAL RESEARCH AGENCY

Prof. Maria Siemionow received nomination to the Council for the Medical Research Agency Board. The Council is one of the bodies of the Medical Research Agency and its term lasts 6 years. It is composed of 16 members, appointed, and dismissed by the Minister of Health. Its competences include issuing opinions on promising directions of research activities and on division of financial resources. The Council also delivers opinions on the annual activity plan of the ABM, which is a document that specifies the scope for competitions and own projects run by the ABM in a given calendar year.

Minister Adam Niedzielski: *Let me say a few words. In Poland, we are usually very proud when someone from Poland has such international success when it is well-recognized in the international environment. But to be honest, we also regret it a little bit because it means that the person doesn't work for Poland directly. So we have a idea together with Professor Sierpinski, that we will make Professor Siemionow work much more for Poland. So, dear Professor, to be very serious, I am, of course, very impressed with your achievements in your international position, and it is a privilege that I can nominate you to the Council for the Medical Research Agency board. So this is a pleasure and I hope you will still be working for Poland. So, thank you very much.*

Prof. Maria Siemionow: *Minister Niedzielski, Professor Sierpiński, thank you so much. This is a great moment for me, allowing me to come back to Poland officially and work for both the Agency, as well as the whole generation of young scientists, and researchers who are still coming to my laboratory. So I'm taking part in working and supporting a new generation of Polish biotechnologies. That's a great honor. I hope I will be able to show that I deserve it. Thank you.*

4. A CEREMONY OF HANDING OVER A NOMINATION OF PROF. MARIA SIEMIONOW TO THE COUNCIL OF THE MEDICAL RESEARCH AGENCY

ROUNDTABLE II: Biotechnology as a strategic sector in economic and security dimensions

The impact of the economy's innovation on its competitiveness, including the biotechnology sector as one of the most innovative areas. Providing innovative treatments and making them available as a factor of economic development. Shifting effective treatment into higher labour force participation of sick people, as well as reduction of the phenomenon of presenteeism, i.e. sickness presence – a positive impact on human resources in the economy and GDP. Reduced state expenditure on social benefits via decreasing the number of people using sick leave and permanent work incapacity. Less expenditure for the healthcare system related to long-term treatment and hospitalization of people, who do not have access to innovative treatment. The impact of a strong biotechnology sector and international cooperation on national security. An innovative biotechnology sector as an element of state sovereignty and economic independence. The development of international cooperation – both at the state level, as well as at the level of research centers and companies – as a factor in enhancing state drug security by securing supply chains and domestic production. The example of the COVID-19 pandemic – disrupted supply chains and limited/reduced drug production. The Government Plan for the Development of the Biomedical Sector in Poland in 2022–2031 as a strategic government programme in biotechnology. The role of the Plan in building Poland's position as a biotechnology leader in the region, as well as various opportunities for Polish-US cooperation in this field.

4.1 INTRODUCTION TO THE PANEL, DR JAKUB GIERCZYŃSKI

Jakub Gierczyński, MD, PhD, MBA. Expert and lecturer at the Institute of Healthcare Management, Center of VBHC and MBA Healthcare of the Lazarski University, Business School of the Warsaw University of Technology, and the Medical Reason of State. Member of the Team of Experts at the Patients' Rights Ombudsman.

Biotechnology is a strategic sector in economic and security dimensions. Please note that we will be talking about the impact of economic innovation on this competitiveness, including the biotechnology

sector, as one of the most innovative areas, providing innovative treatments and making them available as a factor of economic development. The impact of the strong biotechnology sector and international cooperation on national security and the development of international cooperation both at the state level as well, as the level of research centers and companies as a factor of enhancing state drug security by securing supply, supply chains, and domestic production. We were talking during the first-round table about the differences and similarities between USA and Poland, and I would like to remind you that the population of the United States of America is 330 million people in Poland, 38 million people, which is approximately 9% of the population of states.

The GDP of the USA is 23 trillion dollars. Polish GDP in 2021 was \$591 billion, and the GDP for health-care spending in states is 17%. In Poland, 6.5%, which means that this is about \$11,000 PCP per person yearly in the United States for health care in Poland, \$2.3 thousand. But what is the similar element? Doctors for 1000 citizens 2.6 in the USA, 2.4 in Poland, which means that this is a very similar statistic – a relatively low number of doctors, but nurses, 12 per 1000 citizens in Poland, only 5. The data from OECD is also interesting: investments in R&D in the US pharma R&D was \$75 billion in 2019, which is 0.36% of GDP. Whole Europe’s investment in R&D was 24 billion compared to 75 billion in the US. Government R&D was 44 billion USD, which is 0.2. Gross domestic product – in the whole of Europe was 16 billion. please maybe you will comment Professor Moniuszko also those data from the perspective of science and development in Poland in Europe compared to us. The medical and social workers, as a percentage of the total employment in the USA is 14%. In Poland, only 6%. This means that the sectors and economy you are talking about also transforms the people’s life working for those sectors. And this creates GDP.

4.2 SCIENTIFIC COOPERATION IS CRUCIAL FOR NEW MEDICINES DEVELOPMENT, DR GRZEGORZ CESSAK

Grzegorz Cessak, Ph.D., President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products, Poland

Thank you so much for the privilege to be the first one to talk on this panel. Thanks for the invitation to this conference. It’s a huge honor. A pleasure to speak to you today. I would like to very briefly at the beginning of my speech and describe the authorization of medicinal products. It’s very important to understand our role in all changes in biotechnology. Of course, from the regulatory perspective, I have a view that the strengthening of the biotechnology sector will be possible through the appropriate scientific advice and an increasing number of clinical trials conducted thanks to new legislation in the European Union, supported by the medical, medical funds and which consequently will enable an in a number of the authorization of medicinal product and early access to medicine like compassionate use. But very briefly, we have three possibilities for the authorization of medicinal products in Europe and Poland as well. The most innovative medicine, including those derived from

the biotechnology method, are authorized by centralized procedure via the European Medicines Agency. Its scientific committees play a crucial role in the assessment of the dossier. It's worth noticing that Polish experts like me and Director Marek Migdał, are members of the scientific committees and by the input to support biotechnology or originated medicine and of course, before the authorization, it's important from this kind of strengthening of the biotechnologies scientific advice when planning the development of the medicine, especially manufacturing using biotechnology methods scientific advice is very important. It's also important to understand that not all the studies might be approved, especially for fast-track authorization.

Therefore, scientific advice is so valuable to support the development the proper drug research and study conduct and also eliminate not effective efforts. The best example from the near past is that it's COVID-19. The main goal of scientific advice in the COVID-19 crisis was to capture the best possible treatments for this disease. We had over 100 proposals, and only a few of them had a chance to to be authorized. And coming next, coming to Greek clinical trials that our agency's competent authority and the important role to provide scientific advice concerning efficacy and safety. I would like to say that clinical trials are the key element to developing innovative medicine. We need to focus on the scrambling process currently in Poland and in. European Union as well. We are in the process of legislative changes. This regulation aims to harmonize legal requirements related to clinical trials in the EU and serve for facilitating clinical trial approval. We mentioned earlier that IT systems and databases are crucial. It is an important change in clinical trials in Europe establishment a clinical trial information system that enables effective communication between regulatory authorities and sponsors. It's a key element, especially for this kind of biological procedure. These IT tools are dedicated to clinical trial application submission in the EU and they give optimal functionality and workplace. In the European Union, there is a need of developing optimal conditions for enterprises, and academic researchers. Besides the legal support, some initiatives might be a forum for further support, the development of innovative medicine, and non-drug innovation.

We have a special program – Accelerating Clinical Trials in the EU created by the European Commission, the European Medicines Agency, and the Heads of the Medicines Agency as well. I would like to mention here one important aspect of biological medicinal products in June 2022, the European Medicines Agency and National Competence, authorities in Europe issued a joint statement confirming that biosimilar medicine approved in the European Union is interchangeable with the reference medicine or with an equivalent biosimilar. This gives us wider access to important therapeutic options and popularization of the use of biosimilar drugs, pharmaco-economic significance, and development of the biotechnology industry producing biosimilar drug. I would like to add some Polish accent to the discussion – we have the Polish biotechnology drug, for example, combined human insulin, insulin produced by Polish Bioton, biosimilar Nathalizumab developed by Polpharma Biologics and this application for marketing authorization was submitted to the European Medicines Agency. We should talk about the vaccine against COVID-19 that American Novavax has a manufacturer in

Poland – the company Mabion, to produce from the active substance. I think that the authorization process is a little bit different, in fact, not similar to that in the US. But if you have any questions about our procedure in Europe and authorization mechanisms, feel free to ask.

4.3 THIS IS NO PROGRESS IN THE DEVELOPMENT OF BIOTECHNOLOGY WITHOUT COLLABORATION BETWEEN UNIVERSITIES, PUBLIC INSTITUTIONS AND INDUSTRY, PROF. MARCIN MONIUSZKO

Prof. Marcin Moniuszko, MD, Vice-Rector for Science and Development at the Medical University of Białystok, Poland

First of all, thank you very much for having me here. It's a great pleasure and a privilege. Of course, the conclusion is very simple. We need more money and that's what we are trying also to make up in Poland. And this is why we have the president of the Medical Research Agency as the honorary guest of this session. He's responsible for the money. So, this is the question that will come to you. Representing one of the public universities that are also running in the center of artificial intelligence in medicine. And from my perspective, from the perspective of public universities, what I really can say and it's obvious that there is no progress in the development of biotechnology without industry, without collaboration between universities, institutions, public institutions, and industry. No question about it. However, the problem sometimes is that in the majority of cases of this kind of collaboration, we are seeing the positions of partners are not equal, which is normal because the big pharma as many and usually public institutions, hospitals, and universities, unfortunately, they serve as just some kind of service provider either with the patients, data patients themselves or the physician's work. I'm not saying it's something very bad because there is this investment coming to these institutions. However, it doesn't make it doesn't turn these public institutions more innovative than they used to be before starting to launch this kind of program. That's normal. And I think that's one of the reasons the Medical Research Agency is working so hard is trying to encourage this sector of biotechnology to start some new and even riskier projects to try to come up with some new ideas. I think it's really important. So it's just to at least try to make up this unequal imbalance in terms of the relationship between the public institutions and big pharma that is coming from around the world. So I think that's also for security, which has been discussed today quite widely. This is very important to stay independent in terms of the base at least in some sectors of biotechnology on their sources. That's the national security issue. I think it's we are going in the right direction. The other thing is that maybe let me just make one experiment. Let's try to let's say let's look at the word biotechnology in a wider way because we look at biotechnology only as some kind of term that is defining the development of new innovative products. And this is true, but biotechnology is also about using the already existing products in a more personalized way, which is on one side, something that is good for patients. On the other side, it doesn't necessarily be good for big Pharma because with all due respect, of course, I know that everybody is saying that personalized medicine is the right way to go.

However, of course, if you look at somebody who is producing let's say, cancer drugs. Of course, the most interesting to distract be used for as many patients as possible and personalized medicine. Sometimes it's not the very right way from the commercial point of view. However, it can be very good for patients. So biotechnology is also about using already existing drugs in a more personalized way. So to reach this kind of development, because I find it important especially from the perspective of such a big country, a relatively big country in Europe as Poland, is to use the resources, financial resources associated with them, reimbursing this kind of novel drugs in a more personalized way. So we would have to build the databases that would let us know who is the best candidate for innovative products. So not just based only on the already existing data, but maybe try to to make a one step of actually had to take a look more closely at those patients that could benefit from innovative products most efficiently in terms of clinical outcome and with at least side effects as possible.

How can we achieve it? We can achieve it by building our own, of course, databases and data. It's a new currency, as everybody is saying here. And that's something natural. We should focus and this kind of solution that will allow us to take closer at the patients that are already receiving the drugs that are reimbursed by the Polish state to take a look at which patients can be the best candidates for the clinical benefit coming from this kind of product. And how can we do it? We should not only look at clinical data, but we should try also to combine this with some more comprehensive analysis. Like, for example, what's especially in cancer is very important genomic analysis to make sure that we can also find the most selected and the most beneficial group of patients that could benefit the best from the current therapies. And this is something that, of course, is very expensive if we would like to do it on a larger scale, however, it can be done in institutions that can already have experience in doing this kind of stuff. Just to make sure that maybe with the use of some new diagnostic tools, like, for example, genomic analysis, we can maybe find. But again, it's not like a developing new biotechnology product, but we can develop a product that is a diagnostic product, which I think is sometimes even more important than just I mean, equally not maybe more important, equally important as finding a new drug. So to find a test, to find the algorithm. To find something that will help us to find the best patients for the already existing therapies. And that's also innovation in my opinion. However, it's difficult to combine this kind of data, and integrating the genomic data of clinical data is something that changes. And we are not used to this as a medical community because it takes actual experts from completely different worlds. Physicians and clinical workers are coming from another world as being for medicines or genomic specialists that are running this kind of status. It takes a lot of effort. This is the reason that we've created the Center for Artificial Intelligence. When we are running this kind of product we are looking closely at the patients with malignancies and some other civilization diseases like diabetes, for example, to take a look at this pharmacy – genomic issues that will help us to identify the best candidates for the already existing innovative therapies.

Biotechnology should start from the actual scratch because even if you would like of thinking of creating or developing new biotechnological products. So they have to base on the existing knowledge

because you know the biotechnology and, and the new innovative products, they are not just coming from the idea of somebody that, you know, this is a nice molecule, this is a nice, I don't know, a receptor that we can because, you know, I've done my Ph.D. thesis based on this receptor. It must be good. It must be important because I was working on this. Yes, it's important that you are working on this. But the important thing is do we have databases? Do we have data showing that another receptor is important because we are so far as Poland is mostly, I hope it's temporary, but that's what's going on right now. We base our knowledge on the databases that were created abroad, like, in clinical studies, the majority of them were carried out, and executed in foreign countries.

Hence, it's important also to take a look at what may be the best targets also in this in our society in terms of different aspects. It's not only about genomics that can be slightly different than in some other parts of the world but also considering some other social issues that might be equally important. So we should start with the right databases and I think that's what we should work on very, very, and efficiently. But also we should take a look at the security. If we are talking about running genomic data, we should be very careful with how we run this data, who is the owner is taking care of the security of this data? We have had the situation so far that the majority of Polish genomic analyses have been sent to China and Korea. Now we, of course, know that the majority of this Chinese, of these Chinese institutions or companies that we're running this analysis at a very low, very competitive price, were just simply supported by different national institutions, not necessarily very friendly. Finally, know that this kind of innovative analysis should be run within the countries that they actually should be interested in. I will stop this and thank you very much for the invitation.

4.4 BIOTECHNOLOGY IS A STRATEGIC SECTOR FOR ECONOMY AND SECURITY, PROF WALDEMAR PRIEBE

Prof. Waldemar Priebe, MD, The University of Texas MD Anderson Cancer Center, USA

From my perspective and personal experience, I just would like maybe to respond that biotechnology, whatever it is, a strategic sector for economy and security is important for the patients, for the average patient in Poland. If we looked around us and you look at ten people, four of them in their life will have cancer that the statistics and, you know, just and this is a cancer is a political such as it should unite everybody to fight the mission at MD Anderson is to, you know, just making a cancer history in Texas, in the United States and around the world. So we are very open to every collaboration possible to improve the treatment in other countries as well. We had such an initiative before COVID to slow down these interactions between MD Anderson and several cancer institutes, which created a sister institution with MD Anderson and try to transfer knowledge and experience, you know, just which was gathered through the years at MD Anderson Cancer Center. We are the number one cancer center in the United States by default in the world. And we employed 21,000 people with a yearly budget, of \$5.5 billion, and are located in a Texas medical center that employs well over 100 000

people with a \$25 billion budget with the two medical schools. Texas Heart Institute, Texas Children's Hospital, Methodist Research Institute with Cornell Medical School Associated, and so on.

I'm trying to say that just that microenvironment or let's say a great-scale microenvironment, creates different opportunities for collaboration. Collaboration is a key word to the success of the in Poland, but also collaboration internally in Poland is still not the best way it should be improved. But also, obviously bringing collaboration with from outside is very important. Very often you could hear the word innovation, but practically innovation doesn't happen out of the blue, you know, just in the United States. Why in Poland, you don't have innovations? Innovations. In the United States happened when we have a scientist, for 20 years is getting 300 and \$500 million a year. That's where the innovations happen. You know, just there is no chance that, as I don't know any scientists in Poland who had that kind of funding for such a long period. So we have to realize that we cannot compete on innovation. Don't tell me just about on a scale of these things and not every scientist who worked down there 20 years on a project received the innovation, which is where commercialization let's face it, it's this is the rare again, events.

So in that case, if we don't have these innovations in Poland in a sufficient amount, but we have certain commercialization potential, let's bring the innovation, create the opportunity to bring innovation through collaborations, through agreements to Poland. It could be an institution with the institution. For me, a very good model. Israel created the United States. It was mentioned here, I think, by several people mentioned about it the by National Science Foundation, for example. And we touched on this thing sometime before in Poland and during the Obama administration, practically, there was some agreement on a table and then was withdrawn that Poland will put \$75 million and the United States and will be common money to fund the common research. That would be something that would create and certainly share just between us, the research institution, or the company, for example. You know, it was said that there is no reason that the Polish company cannot go to the research institution in the United States and license certain discovery patents. And we showed it's possible, you know, just with one of the companies in Poland, we just help with that process. So bottom line, you know, just really, we have to open up. And also, we have to look from the Polish perspective on certain things how the process looks like because I see analyzing data as a certain element of everything you do, an important element, but this will not create necessary immediate treatment or revolutionary new treatment, which is will be a quantum jump in a certain approach or certain tumors. Then, we look at a process from the discovery, there is a process later on of validation, proof of concept, then preclinical development, and translational research. This is something that even the United States called the Valley of Death. Until you go to the clinical stages – Professor Rutkowski mentioned and several other speakers. In Poland, we move clinical studies to a very good level. So they are prepared to work with even Polish biotechnology companies to do clinical studies. But the valley of this still exists not only in the United States, but there are a lot of companies that can help for the money. Obviously, in Poland it's not there is not sufficient help with GMP synthesis,

preclinical toxicology, and so on. So, there is some room for improvement. I put time for myself to tell when I should finish just short.

4.5 BIOTECHNOLOGY SECTOR GENERATE VERY POSITIVE IMPACT ON THE COUNTRY'S ECONOMY, PIOTR TRĄBIŃSKI

Piotr Trąbiński, Executive Director of the International Monetary Fund, Poland

First of all, thank you for the invitation. I'm humbled to be invited to this panel. I have no knowledge about biotechnology, but I do have some knowledge about finances and a little bit about digitization. So thank you so much. And maybe let's step back for a second and have a broader picture of what biotechnology is in terms of economy and in terms of having an impact on a country. So it is a highly efficient and very productive sector. And why is it so? It is mostly because it has a very positive impact on the country's economy, the economy of the country that hosts biotechnology. It also has a positive impact on other countries. And I will explain it a little bit later. Let's look at the numbers. So the dataset that I used is from Europe. It is the EU 28 countries, 2018 just before the pandemic. If we look into the numbers and you mentioned a couple of statistics that are quite familiar to me as well, biotechnology contributes to the GDP on both two levels. First, directly and when we look into the numbers, it's in the amount of a little bit less than €40 billion, which is roughly 0.2% of the European EU 28 GDP. But then indirectly it's 0.4. This is maybe not too much. Many would say it's insignificant. It is significant. These numbers are €40 billion. It's a lot when we see that the countries are struggling by finding €40 billion in their budget to finance certain expenditures. This is a lot. But there is also another positive impact – job creation. When we look from the job market perspective, there is also direct and indirect impact of biotechnology directly. This sector hires 220,000 people in Europe, but indirectly 720,000. Why do we distinguish this? I'm coming back to the introductory point. When we look at the end of this sector, people are hired by biotech directly. This is 220,000. But many companies are working for biotechnology that is down the value chain. They are located in other countries, mostly because the labor cost is cheaper. And this is what makes this sector productive and interesting. We looked at one country that would have, for example, 50,000 workforces directly engaging in biotechnology higher four times more than are located in other countries. Then there is also a positive spillover on trade when you look into the current account balance. Biotechnology has always had a positive impact on this indicator. In terms of the European Union. It's €22.3 billion. This is a significant positive spillover for the current account surplus. And also, that shows one pattern. Biotechnology is a high-end industry. Biotechnology produced the final product, which means it uses components that are lower in the value chain. But it produces very desirable from the economic standpoint, products that then can be exported. And then it is also a driver for growth. It has one additional function. It is highly productive. Apart from this, these are the direct effects of this sector of our economy. There are other spillover effects. First is higher life expectancy which contributes to the overall health of the economy and demographics. There is a question

of higher quality of life. There is a question of innovation, productivity, and also positive environmental effects. And I will stop here. But if needed, I can intervene later.

4.6 INVESTMENTS INTO BIOTECHNOLOGY ARE VERY PROFITABLE FOR PATIENTS AND COUNTRY ECONOMY, MICHAEL SOLDAN

Michael Soldan, CEO of Polpharma Biologics Group

I think we have a long journey behind Polpharma Biologics. We started in Gdansk with the facility and then created also the facility in Warsaw. We are growing. Our perspective for the next years is that we will start building more and more manufacturing units in the Warsaw facility. We will further expand also in Gdansk and there are good reasons for that. Now I'm coming back to what you said with all your numbers. I appreciate that, by the way. Finally, the structure and the ecosystem are very important. So that means you have the right workers, and the right experts to grow. And this is the limitation. If you are more or less alone and you don't have a nice structure around, you. That's the reason why it is important that you need to have I mentioned already, the Light Tower project. And I believe we have one of these projects where you start growing more and more in the biotechnology sector. We are now roughly 1000 people, mainly in Poland, with the two facilities. And then you need to recruit people and good experts from abroad. When they are coming, when they see that we have an FDA-approved facility, and we are manufacturing biosimilars. You mentioned already one is commercialized, the next one is submitted and the next one is coming. So there's an engine coming. Then you can get these experts and then you can start having a kind of nucleus that is growing. People will also go away after some years and then you need to have additional ones. And if they stay in the area, go to other pharma companies, which are very close to it, biotechnology companies, then you can start growing. I'm living in Switzerland and for me, this is the best example of how you should do it. They have started, of course, much earlier. The biggest interest is to get the expert there, to have them living there, and to pay their money. And I'm not talking about taxes to pay their money, their family, or everything in this area. And this creates additional value. And now people are coming. And I think the US is also a very good example of that, especially in some areas in California and also here on the East Coast. And this is something that I believe can also happen in some areas of Poland. When you are investing in the right infrastructure, in the right light tower project, and of course, which of course also supports not only innovation and this is my last sentence innovation is very important, but patient access and having access to medicine, which are more complex of biologics, are even more important also for a lot of people, also in Poland. This is also a very interesting point because we are very often talking about healthcare as costs, but maybe we should change the paradigm and talk about investments because in Switzerland, 30% of the GDP is created by the pharma industry. I think there is a lot of talk about companies going there only for tax reasons and so on. This might be the case, but you go there as a pharma company where you can be sure that you find the right experts and you can develop products with the people you need there. And you mentioned at the

beginning it might be important that you can manufacture in areas where the costs are lower. This might be true, but it does not play such a dominant role in biotechnology. Biotechnology is an area where you need a lot of experts with a lot of knowledge.

4.7 THE INNOVATIVE MEDICINES AND VACCINES HAVE A DIRECT IMPACT ON THE ECONOMY, DIMITRI GITAS

Dimitri Gitas, Managing Director, MSD Poland

The innovative medicines and vaccines have a direct impact on the economy. They keep people healthier, prevent disease and prolong life, and that keeps people more productive, contributing to the economy, contributing tax resources, and at the same time being less dependent on the health-care system as a whole. So there is a direct impact there. Now, when we talk about clinical trials, we talked about the value of clinical trials, but this is also an investment. And so we as a company, as I mentioned earlier, invest on an annual basis 150 million PLN in clinical research. Above and beyond that investment, 3000 patients get treated with free drugs, which otherwise would have been covered by the drug programs. Then these clinical trials also create jobs as well. And so this is how innovative medicines and vaccines contribute directly to the economy. Now, if we look forward to the future, as was also mentioned earlier by Minister Niedzielski, one of the biggest challenges that we have in Poland is an aging population. If you look at projections by 2050, the share of citizens that will be above the age of 65 will double from 17% to 32%. That's four and a half million more citizens above the age of 65 who will be less productive than those below the age of 65, and the same time more dependent on health care resources. When you combine that with an aging healthcare provider community, then that creates a big problem, and it will have a huge impact on the investments that need to be made in the future. It's estimated that investments in long-term care will go from 0.8% GDP to 1.3% GDP, which is a huge increase.

And so strategies need to be put in place today. And I think a lot of the discussions that we're having today are very, very relevant. And so from my perspective and our perspective, what we believe is extremely important is number one, higher investment in healthcare to your earlier point. There's a proverb that states health is wealth. And we need to see healthcare as an investment for the future. Now, there's a commitment to get to 7% of GDP by 2024. I would say we need to continue going further and hit rates close to 10% as a lot of the Western European countries have. The second point is about making innovative medicines and vaccines more rapidly available for patients. And so right there is a study that showed that from 2017 to 2020, it took around 850 days to get medicine to patients in terms of reimbursement from the time of registration by the EMA. In other countries such as Austria, that average time is around 315, so less than half. And so we need to do a better job to get medicines to the people who need them as quickly as possible. We've seen significant progress over the past couple of years and certainly in the area of oncology, and I would say we need to

continue that. And the third area and final area I'll just mention very quickly is delivering more efficient and more flexible systems of care to optimize patient outcomes. It's not enough to just have programs that reimburse medicines and vaccines, we need to get them to the patients who need them as quickly as possible. Thank you.

4.8 EARLY DIAGNOSIS AND EFFECTIVE TREATMENT OF RHEUMATOLOGICAL PATIENTS SECURE THEIR HEALTH STATUS AND PRODUCTIVITY, PROF BRYGIDA KWIATKOWSKA

Prof. Brygida Kwiatkowska, MD, National Consultant in Rheumatology, Poland

Rheumatoid diseases are quite common in the general population. Inflammatory diseases of this type occur among 5 to 10% of younger people. And if we add osteoporosis and other deformations deformation the formative illnesses, we are getting to 40% or more of the general population. Inflammatory rheumatoid diseases are based on other immunology syndromes and cause changes to multiple organs of the body. This complexity causes the necessity for physicians from various fields of medicine to collaborate to treat the disease. That is why we focus on early diagnosis incorporating the possibility or the opportunities for preclinical diagnosis or detection of the disease. At the same time, we are attempting to personalize treatment depending on early signs and which part of which aspects of the disease are dominating. Interdisciplinary cooperation between physicians is the biggest challenge for us, including how to train other doctors from other fields to detect so that they can detect early symptoms of rheumatology-type diseases. And that is why, for that purpose, we are beginning to work on algorithms that would feed into artificial intelligence and leverage our artificial intelligence to detect these illnesses. What's spectacular about the treatment of rheumatoid disease is how we can tailor different medicine to treat different symptoms. At the same time, our field of medicine is facing a challenge that is emanating from the field of oncology, because treatments used by oncology are limiting checks and inhibitors that are necessary to fight off, or they may be consequently rheumatoid diseases may be occurring. So our new approach starting January 1st is to have a pilot program in which patients suffering from inflammation of the joints will be treated comprehensively by different physicians. And once this program starts, its intended result is to come up with a registry or a list of illnesses that can be detected early. Our other track of work is on non-inflammatory diseases, meaning osteoporosis and other deformations. Prevention and early detection of osteoporosis, which is the disease of our times. And we are also focusing on regenerative treatments, which we currently don't have an impact on. So for now, we'll just keep on collaborating with orthopedists. Because so for now, this is how we can work on these illnesses. We are focused on interdisciplinary collaboration, and this is our focus for the next year.

4.9 COMPARISON OF ORTHOPEDIC CARE OUTCOMES BETWEEN POLAND AND USA CAN DEVELOP KNOWLEDGE AND SKILLS OF DOCTORS, PROF JAROSŁAW CZUBAK

Prof. Jarosław Czubak, MD, National Consultant in Orthopedics and Traumatology of the Musculo-skeletal System, Poland

Thank you very much. I'm honored to attend this meeting with all those guests and speakers who previously talked about these challenging things concerning an aging group of patients and innovations. I was a little bit depressed to listen to how much money we need for innovation. So it's we cannot afford it as Poland and as a Polish state. There were several talks concerning what we can offer as a society, as a doctor, and as leaders of medicine in Poland. And there were several proposals from Professor Szumowski and also from other colleagues. And I want to say that in the innovations orthopedic sector, we have nothing to talk about the drugs and biotechnology in this meaning it was now talking about that. I think mostly what we can talk this is biomaterials, and this is an enormous improvement in those biomaterials. Quality is the most important in our field. I like numbers and we have now for two years, we have our national arthroplasty register collecting data from all big arthroplasties in Poland based on the data from this register, we can say a lot about our work and the quality of our work and what patients think about our work. So this patient-reported outcome measures. I think this is the way where we can compare our results and cooperate with those groups of surgeons, orthopedic surgeons in the United States, for instance. But we in from my point of view, I think it's difficult to cooperate in the studies because we do have not enough developed industry, the medical industry in producing implants. But I have three examples which show that this is not so bad. For two years we have had two companies in Poland that produce generous implants. And I talk already with President Sierpiński about that, and we need clinical studies, evaluating the long-lasting outcomes of those products. And I think we will create a program for that. And I think this is the simplest thing we can say we can do. The other example is, is maybe a little bit negative. I think that there is a gap between biomaterials, and institutions. There is in Warsaw the Institute of Bio Cybernetics and Bio Biomedical Engineering. We cooperate with them for many years. And they're producing, for instance, maybe 15 scaffolds for cells, culture for the treatment of the cartilage defects, and big joints. And I want to say about the gap, because they, on the one hand, they're producing the scaffolds, but no company would like to put these scaffolds into the market. And, you know, if we got the products and registration of the product, which is our production, there is no company which we would like to sell it. And so this is very it's a little bit frustrating for the younger scientists who are starting to produce, making research. And finally, there is no continuation. And I think that this is the field of improvement based on the knowledge of how to. First made good research and second how to put the results of the research into the market and our patients. And the last what I would like to say is our cooperation with the Institute of Oncology, and I think we try to with Professor Rutkowski, we try to establish the proper location for each of us. I mean, oncologists and orthopedic surgeons and other groups like radiotherapists and chemotherapists as a standard way in the

treatment of metastatic disease. I think this is a big challenge and I represent the biggest orthopedic center in Poland. We just mostly dedicate ourselves to the education of doctors, not for students, but for the doctors. And I think in the near future, I hope maybe we become more scientific and research institutions instead of being only the clinical servant and the didactic center for orthopedic surgeons. Thank you very much. I think that also one remark from your speech is that maybe medical devices should learn from the pharma industry to deliver evidence-based arguments and especially the learning curve from the clinical centers to adopt the new solutions in medical devices which is an extremely attractive topic.

4.10 ACCESS TO GOOD QUALITY HEALTHCARE IS A RIGHT OF EVERY PATIENT IN POLAND AND USA, DR MAGDALENA STARBAN

Magdalena Starban, MD, Member of the Board of Directors at the Polish-American Health Association (PAHA), USA

Good afternoon. I'm a practicing physician. I'm also representing Polish American Health Association. It was previously mentioned by our current acting president, Dr. Anna Korzan, in the morning session. Polish American Health Association has been established about 30 years ago here in Washington and its Association of Physicians researchers. We are also linked to the National Cancer Institute. I would like to mention that we have a Krystyna Lesiak Foundation that is promoting young Polish doctors, physicians, and scientists, and we encourage them to apply for scholarships through our organization to participate in research opportunities here in the United States and also conferences. So, of course, we would like to encourage them to apply through the website and promote this collaboration. This means that the standards which are already implemented in the States and Europe, can be shared among the doctors to improve the also knowledge because sometimes patients are complaining about the knowledge of the doctors and especially about the innovative treatments is very it's very and this is really valuable cooperation. I would like to mention also that it's very important for patients here in the United States and Poland to the accessibility to health care. It is also a kind of very important to talk from a legal standpoint, too. We see here in the United States from a practicing physician perspective that it's becoming a luxury for a lot of patients here to afford medical insurance, for example. And I'm practicing in a Catholic hospital. We have a lot of different programs and charity programs that are supporting these underserved or underprivileged patients as well. So this becomes also one of the problems here in this country in current times. Sometimes we think that when you invest 17% of GDP and \$11,000 per head, you can cover everything. But there are also problems with access to care. One of the most important conclusions of our meeting, that this is not always the level of financing is equal to the level of access for the patients.

4.11 DATA TRANSFERABILITY FOR MEDICAL RESEARCH, DR MAREK MIGDAŁ

Marek Migdał, Ph.D., MD, Director of the Children's Memorial Health Institute in Warsaw, Poland

So I'll try to be a little bit provocative. It's late afternoon, so time for the siesta, not for the discussion. I was thinking that I was invited to this session by mistake. I am not an economist. I spent almost four decades in the field of pediatric intensive care, surrounded by new technologies, new drugs, and everything which we do daily for the treatment of patients. As was already mentioned by some previous speakers, if we are talking about the economic or security dimensions, we should also remember, first of all, the quality of the health system. The systems in the United States and Poland are completely different. We get a public system, but also, we get some problems with the economic analysis. Professor Moniuszko mentioned that if you are using some data for the HTA assessment, and health technology assessment, sometimes the data which were collected in the United States are completely useless in Poland. I remember from my field of clinical practice and when in the nineties there were some results of the use of the natural surfactants Survanta in the States alba vaccine in Europe and colleagues from the States presented the use of the of this natural surfactant prophylactically in the preemies, you can shorten the hospitalization by one day, which was at that time in the States in nineties it was \$4,000 per day in still in Poland you are reimbursed on a much lower level. So this type of analysis is not useful and that should be, as mentioned during the first session by Dr. Marcin Czarniecki, it will be good to get a kind of MBA dedicated to the Pharmaco Economics studies to improve this type of data, because now since four years, I am the CEO of the Children's Hospital Children's Memorial Health Institute in Warsaw. So I am dealing mainly with the financial issues, how to reduce the debt, not to keep the proper neutral balance, because sometimes innovations, a new drug, new, you know, the all of these human monoclonal antibodies, or you know, the for example, in our case, you are the National Center for the Metabolic Disorders. So we use all of these enzyme replacement therapies which are extremely important, and our national health fund still is reimburse our hospital just per procedure without any additional support for the quality of their life. If we treat newborns with RDS later these newborns can work in Poland additional 50 years, increasing the GDP. That's the problem. And such type of analyses should be provided to the institutions which are in charge of the reimbursement for the patients because I fully support and we get the problem with orphan drugs in case of rare diseases that we get, the central system of registration in Europe. The drugs are registered with the help of EMA and later the patients. They have no access because there is no reimbursement. Registration is not enough. So that's something we should also use such opportunities to talk with colleagues from the states about how to solve the problem, and how to calculate the HTA data from this stage to our Polish conditions. So it's I would be glad to get some comments from your side about this issue, and how to use the American experience, especially from the private sector. We are the public sector, and we are paid per procedure, sometimes paid under the price of the real costs of this procedure.

4.12 INTERNATIONAL ADVOCACY AND ENGAGEMENT PROMOTING POLICIES IN PRICING OF DRUGS, HILARY STISS

Hilary Stiss, Director of International Affairs and Program Director of the International Council of Biotechnology Associations at the Biotechnology Innovation Organization (BIO), USA

Thanks for the invitation. I will talk about international advocacy and engagement promoting policies. The pricing of drugs is one of the most critical, I want to say issues, but critical key points that we talk about in terms of providing access. So big teams are working on that and trying to perfect that system. I don't think anyone has been able to get there yet, but something we're looking at. So bio, we represent 1000 biotech companies, mostly American, including MSD and health, agriculture, and industrial space. So we're looking at the larger biotech life sciences field and we are we have small to large companies focusing on how to help all of the different aspects of the sector become stronger because biotech isn't just I don't want to keep saying MSD, but you're sitting right next to me, MSD or Pfizer, but also a lot of small companies, hospitals, Cros and others. And it's not a sector that is national. It's a sector that knows no boundaries. So I mean, we saw this with COVID that not a single country can do this alone. So we need each country to be at its strongest in each of its biotech sector sectors to be at its strongest. And I don't think there's one size that fits all. I mean, I hear everywhere I go, Oh, how do we make Boston here? How do we replicate San Diego here? And I think it's unique to each country.

I think each country needs to lean into where its strengths are. I come from Canada and we're always trying to reach what the US is doing, and I think they're slowly realizing that they'll never quite be there, but they'll try to lean into their strengths. So I think there are a few things that each country well, first, before I say that I know each country since COVID looks at, I think are trying to put out a national biotech sector because it's very clear that biotech is important not just economically, but for national security. And what we've been doing is going around and talking with different countries about what you can do to strengthen that sector policy-wise. You know, we always talk about IP, which everyone gets tired of, but it's just so critical to the sector, making sure that your researchers at the universities discover something that they can then really commercialize. I think that is important and then take that and also find partners around the world that will help them grow that into something that can then reach patients, which is so critical, I think. You know, opening up the world to more clinical trials is important. The first company I ever worked for, Amgen, I know, does a lot of clinical trials in Poland. And so we were working closely with the Polish government then.

But I think we often forget about clinical trials as a way to bring access to patients, and it's such a critical way to do that. Another, I think, is just finding different areas to engage and bring your different aspects of the sector together. So bio hosts one of many different biotech conventions. As I mentioned, there's just it's just such a large sector that requires partnerships. So you have to bring

everyone together to grow that. And so bio has the largest one. It's every year in June. And I know that Poland had a delegation, but we haven't seen any Polish delegates in a while. So it'd be great to bring some of your companies back out, know meet some of the investors, just participate and kind of show the world that Poland is there, it is innovating, has the hospitals the clinical trial sites you know all the different aspects you guys been talking about today that make Poland special in terms of the biotech sector. So I think this can go on. There's a book you can read on this topic, so I will stop there. But I do feel like we have determined that biotech is a critical economic sector and also for national security. So I think that having these opportunities to continue talking about how to strengthen it is just so critical for us.

4.13 ALLIANCE FOR INNOVATION FOR THE UNITED STATES AND POLAND SHOWS HOW BIOTECH EFFECTIVELY BECOMES A FORCE FOR ECONOMIC GROWTH AND SECURITY, GEORGE W. HANDY

George W. Handy, President of the Supervisory Board at the Alliance for Innovation, USA

Well, first, let me thank you for the privilege of being the last speaker and congratulate all the people around me for still being here. That's a privilege and a challenge, and it is indeed a privilege and a challenge because I've been to innumerable numbers of these sessions, and this one, I hope you would agree with me has been particularly significant. I would I'm almost sorry to stop listening and start talking, but I am appreciative of the opportunity to do so. Now I'll come back to your question at the very end. This session excited us at the Alliance for Innovation because we see it as such a challenge for the United States and Poland to determine how biotech effectively becomes a force for economic growth and security under the dynamic situation that we face around our globe today. I'd like to give you two examples that I think illustrate what we see as admirable, significant progress in Poland and between Poland and the United States in developing effective strategies for biotech. A project that's just beginning for us is to provide treatment for Ukrainian soldiers that have lost a limb. Our organization is responsible for the operations of this project, along with the psychosocial dimension. This includes state-of-the-art prostheses provided by a team from Baylor University. Effective physical and mental therapy that's essential to the recovery of amputees. It's being done. It will be done in a Polish hospital in Warsaw, and it will be supported by the application of acupuncture, both for pain management but also for mental therapy.

And I like to ask my friend, Dr. Richard Nemtsov, to hold up his hand. He's an expert within the Department of Defense and specifically the US Air Force in promoting acupuncture on the battlefield and in hospitals. And we hope that we'll be able to have him leading a team in Poland for this amputee project. I mentioned acupuncture with some emphasis because in thinking about biotechnology and a strategy for both economic growth and security, you come to the point that a prosthesis today is about \$100,000. Many of the other technologies that we've been talking about today and some

of the medicines are pretty expensive. An acupuncture needle costs a dollar of \$50 in the hands of a skillful practitioner. It offers the leverage of biotechnology, and biomedical technology, let's say, in just as a profound way as most other advances that we treasure today. This is going to benefit the military sector, but we're going to apply it to refugees as well. Not for amputation, but for the socio-psychological diseases like PTSD that Ukrainian refugees are suffering from today. The second project I'd like to mention is a little different. It is introducing new cancer treatment guidelines for Poland that are adapted from the acclaimed global standards presented by the National Comprehensive Network, a cancer network here in the United States, projects being led by Prof. Rutkowski, along with his colleague Dr. Krzakowski. It's developing guidelines that are going to bring state-of-the-art level treatment that will be updated regularly so Polish patients can count on the best treatment possible, not just today, but next year and the year after. It doesn't only provide top cancer treatment, but it also provides a base for network building that leads to new research and also innovative applications of bioinformatics. We're impressed by these two projects because of the skill capability of the Polish medical community, the partnership with the American medical community, and the support of the Polish government. Encouragement from the Ministry of Health and the Medical Research Agency. And it matches up, in conclusion, with what we see as being the core of what we've been talking about. And that's the ability to pull together knowledge from as broad a range of sources as possible about the latest advances and the latest problems in the area of biomedical technology, and then transform them using the types of teamwork and tools that you all have mentioned during our discussion this afternoon. That allows for a product and an improved service. Certainly, Poland can't do it by itself. But despite those budget numbers, the United States can't either. It's nothing is going on today in the area of medicine that isn't global and dependent upon the goodwill and trust among people like you at this table today.

I don't see a repeat of 1989, but I do see the need for an inspirational force like Solidarity to spur the interests of the free world to say, yes, there are risks in stepping forward. There are risks in challenging Vladimir Putin, but the gains are just simply too important. The other reason for my just automatically saying no is that over the past 30 years I've been privileged to deal with Poland being in and out of Poland and with Poland's neighbors around Central and Eastern Europe. I've watched three things happen. First, the development of the friendship that already existed between Poland and the United States and its application to today's more challenging situation. Secondly, the confidence and cooperation that exists within the Central and Eastern European region, particularly confident that I've seen among the other countries I've dealt with who look to Poland not simply to be a leader, but to be a trusted leader. Lastly, I think that we have an opportunity today to move forward without quite the risks and challenges we did under the old Cold War organization that we confronted on the other side of the old Warsaw Pact. So I'm not only optimistic, I'm convinced. Thank you.

5. CONCLUSIONS, RADOŚLAW SIERPIŃSKI, ABM PRESIDENT AND MAŁGORZATA BOGUSZ, PRESIDENT OF THE KULSKI FOUNDATION, PRESIDENT OF THE INSTITUTE FOR SOCIAL POLICY DEVELOPMENT

Radosław Sierpiński: *Thank you very much for making the conclusions. First of all, I would like to agree that after so many discussions this afternoon, we should have time to rethink the conclusions of this discussion, not to make news. So I will be very, as I was called, the money guy. I would make, let's say, a risky thesis that it is not about money and I believe it can be a kind of conclusion from our discussion. It is about the people and the organization. I believe that for the last few years we make a great increase in Poland, in the field of biotechnology, in the implementation of innovations in the healthcare system. We open our minds, we open our ecosystem for the public-private partnership. So I am pretty sure that we can do a lot of things. And after so many discussions, I cross my fingers and look forward to finding the outcomes of such a collaboration. Thank you very much. We are looking for the next steps in the future.*

Małgorzata Bogusz: *Thank you. I guess for us and for me personally, this kind of event is a very good platform for private-public partnerships. In Poland 20 years ago it would be impossible to sit with such kind of distinguished guests, both from the public and private sectors. So this is extremely important for me personally that we are doing it. Thank you for being here. Thank you for helping us build this platform for cooperation between the United States and Poland. And thank you for your participation, and this fruitful discussion.*

THE SPEAKERS' LIST

(in an alphabetical order)



Małgorzata Bogusz

is the President of the Kulski Foundation since the end of 2018. She is also Co-owner and the Managing Partner of Vision Group. Małgorzata has extensive expertise in public affairs consultancy, political marketing and image creation. For over 15 years, she has been working on projects for pharma and financial clients and also as an independent advisor to the public sector. Małgorzata worked for many years as a journalist, publishing for well-known magazines from Poland and abroad. Many of the domestic and international PR and PA campaigns that she coordinated and implemented received the industry's recognition expressed in nominations and awards including Magellan Awards, SABRE Awards, "TERAZ POLSKA" (POLAND NOW!) Award.



Grzegorz Cessak

is a President of the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products since 2009. Dr. Cessak is a member of the Management Board and the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA), responsible for the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union. Representative of the International Coalition of Medicines Regulatory Authorities – ICMRA, addressing the current medical challenges and the search for strategic solutions to public health on an international scale. In addition, a member of the COVID-19 Medical Council at the Chancellery of the Prime Minister.



Jarosław Czubak

is a Professor of Orthopedic Surgery. The National Consultant in Orthopedics and Traumatology of the Musculoskeletal System in Poland, the Head of the Department of Orthopedics, Pediatric Orthopedics and Traumatology in Gruca Teaching Hospital in Otwock, Warsaw, the Director of Gruca Teaching Hospital in Otwock, Warsaw, the President of European Pediatric Orthopedic Society (EPOS) 2018–2019. A member of the Editorial Committee of the Journal of Pediatric Orthopedics B and of the "Journal of Children's Orthopedics". The Head of Orthopedic Examining Board for specialty exams in orthopedics and musculoskeletal trauma in Poland. A member of the International Hip Society. The past President of International Society for Musculoskeletal Ultrasound (ISMUS). A promotor of Polish achievements in international orthopedics.

**Marcin Czarniecki**

is a radiologist with Advanced Radiology, a hybrid practice affiliated with the University of Maryland. His interests include telemedicine and e-health, with a focus on cross-border collaboration. He is the author of numerous articles and book chapters in prostate cancer diagnostics, imaging informatics, as well as an open-source textbook in radiology. Previously, he held positions at Georgetown University and the National Institutes of Health. Before moving to the United States, he lived in Poland, Turkey, Malta and the United Kingdom.

**Vittorio Gallo**

is Interim Chief Academic Officer at Children's National Hospital and interim director of the Children's National Research Institute. As an internationally renowned neuroscientist, Dr. Gallo previously served as Director of the Children's National Center for Neuroscience Research for a decade. He is the Wolf-Pack Chair in Neuroscience within Children's National Research Institute. In his role, Dr. Gallo oversees the development and implementation of the Children's National Research Institute strategic plan, including building out the nearly 12-acre property once occupied by Walter Reed National Military Medical Center to serve as a regional innovation hub. Additionally, Dr. Gallo will focus on establishing and enhancing collaborations between research and clinical programs. These cross-collaborative projects are imperative as Children's National continues to define new mechanisms that underlie pediatric diseases.

**Herlys Gianelli**

serves as Associate Vice President, Global Vaccines Public Policy & Partnerships at Merck. In this role, she leads public policy and advocacy efforts to expand access to Merck vaccines globally and guides policy strategy development for the vaccines policy organization. Prior to this role, Herlys was Executive Director, Public Policy, Communications and Population Health for Latin America, where she led policy, communications, and patient engagement operations at the regional level on behalf of the company. Herlys joined Merck in 2014 from Sanofi after serving on various roles as part of both the public affairs and the commercial division. Herlys holds a Master's in Policy Management (MPM) from Georgetown University, a Master's in Business Administration (MBA) from the University of Miami and a Bachelor of Arts (BA) in International Relations from Florida International University.



Jakub Gierczyński

is a doctor of medical sciences and MBA graduate. An expert in the field of health economics, disease management, decision analysis, medical audit, risk management (Burton Certificate), EBM, HTA and VBHC. Co-founder of the Polish Pharmacoeconomic Society, member of the Polish Society of Public Health, HTAi, ISPOR, the Polish Coalition of Personalized Medicine and The International Foundation for Integrated Care – IFIC. Author of many publications, studies and reports. Expert and lecturer at the Institute of Healthcare Management, Center of VBHC and MBA Healthcare of the Lazarski University, Business School of the Warsaw University of Technology and the Medical Reason of State. Member of the Team of Experts at the Patients' Rights Ombudsman. He is the founder of the company Health and Disease Management Institute and the European Health Network.



Dimitri Gitas

is the Managing Director of MSD Polska, who has been leading this organization for the past 2 years and working in 4 different countries (Canada, the United States, Greece, and Poland). Throughout his career, Dimitri has been developing partnerships with stakeholders, including policymakers, patient organizations & scientific leaders. He has led multi-stakeholder initiatives in various therapeutic areas such as HCV (treatment of PWID), HIV (removing stigma), and Antibiotics (implementation of national AMS & infection control strategies). Dimitri is passionate about working with Healthcare Professionals to bring innovative medicines and services to patients who need them. He has worked in the pharmaceutical industry for over 19 years and has held a wide range of positions, spanning from clinical research to commercial management.



Henry Homans

serves as Vice President for the American-Central European Business Association, the American-Czech Business Council, the U.S.-Poland Business Council, the U.S.-Hungary Business Council, the American-Lithuanian Business Council, and the American-Romanian Business Council. Prior to his arrival at ACEBA, Henry gained experience on Capitol Hill working for Senator Tim Kaine (D-VA) and the House Democratic Caucus. He also completed a Harvard Business School Extension program focused on business analytics and financial accounting. Henry holds a bachelor's degree in History from Denison University where he was a member of the 2016 Division III National Champion Swimming and Diving Program.

**Paweł Kaliński**

is Senior Vice President for Team Science, Chair of the Department of Immunology and Chief of the Division of Translational Immuno-Oncology at Roswell Park Comprehensive Cancer Center in Buffalo, NY. Dr. Kalinski received his MD in 1991 from the Medical University of Warsaw, Poland, and Ph.D. in Immunology in 1998 from the University of Amsterdam in the Netherlands. Before joining Roswell Park in 2017, Dr. Kaliński was a tenured Professor of Surgery and the Founding Director of the Immuno Transplantation Center of the University of Pittsburgh Cancer Institute, a cell therapy center focusing on non-genetically-manipulated cells.

**Anna Korzan**

is board certified in internal medicine. Dr. Korzan has been practicing medicine in Washington D.C. area for over 20 years. She has worked in many different clinical settings including academic medicine. She has held an Assistant Professor position at Georgetown University. Dr. Anna Korzan is the President of the Polish American Health Association established by Polish scientists and physicians in 1991. PAHA has sponsored many charitable projects in Poland and now provides grants to promising young scientists in the biomedical field.

**Brygida Kwiatkowska**

is a National Consultant in the field of Rheumatology, who advises the government on the creation of health care programs, including the National Health Program. Moreover, she is also a Head of the Early Arthritis Clinic, as well as a President of the Polish Society of Inflammatory and Autoimmune Diseases. Her main tasks and lines of activity include diagnosis of early arthritis and treatment of rheumatoid arthritis, Sjögren's syndrome, and spondyloarthritis. Prof. Kwiatkowska gives lectures for students of the Medical University of Warsaw and doctors specializing in rheumatology and internal diseases as part of courses organized by the Medical Centre for Postgraduate Education. In 2012, she obtained a postdoctoral degree in medical sciences from the Scientific Council of the Institute of Rheumatology in Warsaw, on the basis of a habilitation thesis entitled "The occurrence of depressive symptoms in relation to the course and clinical picture of rheumatoid arthritis".

**Marcin Martyniak**

is an Undersecretary of State at the Ministry of Health. So far has been Head of the Political Cabinet of the Minister of Health and representative of the Prime Minister on the Medical Fund Council. Is in charge of departments in the investment and analytical areas. He has also gained professional experience in the private sector. He co-founded and managed innovative business ventures, where he was responsible, among others, for the implementation of their development strategy and financing. He worked in the central expert team at the Chancellery of the Prime Minister, being responsible for, inter alia, analyses and consulting in the economic, investment and health areas.

**Marek Migdał**

is the Director of the Children's Memorial Health Institute, one of Europe's largest pediatric hospitals. Its transplantation centre is one of the largest in the world and has conducted many pioneering surgeries dating back to 1990 when the first liver transplant in Poland was conducted. Furthermore, Director Migdał is Deputy Chair of the Ethics Section of ESPNIC (European Society of Paediatric and Neonatal Intensive Care). He also serves as the Polish Co-ordinator of the C4C EU project, as well as the Coordinator of the Polish Pediatric Clinical Trials Network (POLPEDNET). Moreover, Director Migdał is an author of more than 200 publications concerning pediatric and neonatal intensive care, pediatric pulmonology, and clinical trials in a pediatric population.

**Marcin Moniuszko**

is a Vice-Rector for Science and Development of the Medical University of Białystok (UMB). Full Professor and Head of the Department of Allergology and Internal Medicine, as well as the Department of Regenerative Medicine and Immune Regulation. Chairman of the Council of the Medical Research Agency and the Vice-President of the Polish Society of Allergology. Co-author of the establishment of Poland's first Centre for Artificial Intelligence in Medicine at the UMB. Coordinator of numerous scientific projects (NCN, NCBiR), including the project quantifying the risk factors of the severe course of COVID-19.



Adam Niedzielski

is the Minister of Health of the Republic of Poland. He is an expert in public management who authored publications and books on public administration, public finance and management control. He studied economics and quantitative methods, and information systems at the Warsaw School of Economics. Mr. Niedzielski started his professional career in the Ministry of Finance. Afterwards, he worked at the Supreme Chamber of Control, the Ministry of Justice and the Social Insurance Fund. As of November 23, 2016, he served as Director General of the Ministry of Finance. Mr. Niedzielski combined work for public administration with research work at the Institute for Market Research (1998–2004) and the Higher School of Trade and International Finance (1999–2007). Since 2018, he has been a Vice-Executive Director of the National Health Fund responsible for operational matters. Subsequently, in 2019, he was appointed by the Minister of Health as the executive director of the Fund.



Stanisław Pisarski

is the Senior and Managing Partner of Factor Consulting, and at the same time serves as the Corporate Strategy Advisor in all key projects requiring advanced strategic process. Believer in enterprise agility, systemic solutions and real-time decision-making, his office is mostly wherever he travels, still maintaining situational awareness and offering operational support to both his team and Factor Consulting clients. Served at all organizational levels in a great number of projects and enterprises, settling finally for the role of a lead consultant for chairmen of the board and other senior corporate officers. His versatile experience and deep understanding of business processes make him an indispensable component of all strategic development sessions and reorganization or crisis management committees. Over the years of his service to business organizations and institutions, Stanislaw has made his mark in a number of industries and an even larger number of companies.



Piotr Ponikowski

is the Rector of the Medical University and the Director of the Institute for Heart Diseases at the University Hospital, Wrocław, Poland. He served as the President of Polish Cardiac Society and the President of Heart Failure Association of the European Society of Cardiology (ESC). He has been involved in the development of several guidelines on the management of cardiovascular diseases as a member of the ESC Committee for Practice Guidelines. Chairman of the 2016 ESC Heart Failure Guidelines. Co-author of more than 900 peer-reviewed papers with a total number of citations above 150000, H-index=142; selected among Highly Cited Researchers by Thomson Reuters 2016–21.



Waldemar Priebe

is a Professor of Medicinal Chemistry in the Department of Experimental Therapeutics at The University of Texas M. D. Anderson Cancer Center. Prof. Priebe's research is focused on the chemistry and biology of cancer and the rational design and preclinical development of new treatments for cancer and more recently infectious diseases. He has published more than 200 peer-reviewed journal articles and his work has led to over 60 patents and to numerous licenses by pharmaceutical companies. Prof. Priebe is the founder/founding scientist of 7 biotechnological companies. Four companies after successful IPOs were listed on NASDAQ. He served on the scientific advisory board of several pharmaceutical companies. Prof. Priebe is actively involved in facilitating and increasing scientific, cultural, and business exchanges between Poland and the United States and is currently involved in several active collaborations with Polish researchers at several different scientific institutions in Poland. Over 40 researchers from Poland were trained and worked in his laboratory.



Piotr Rutkowski

is Professor of Surgical Oncology at the Maria Skłodowska-Curie National Research Institute of Oncology in Warsaw, Poland. Dr Rutkowski is the current Head of the Department of Soft Tissue/ Bone Sarcoma and Melanoma, the Deputy Director of the Institute for National Oncological Strategy and Clinical Trials at the Maria Skłodowska-Curie National Research Institute of Oncology. He has participated in several investigator-driven trials in melanoma and sarcoma. He is also the Coordinator of the Polish Clinical GIST Registry and Member of the Polish Sarcoma Group, and a reviewer for several international scientific journals, as well as a member of the Editorial Board of Annals of Surgical Oncology and the European Journal of Surgical Oncology. Dr Rutkowski has authored or co-authored over 140 scientific papers in Polish and international journals (with an impact factor of above 4000, index-H: 62, citation index >14000), and is co-author of national and international recommendations for sarcoma and melanoma. He is working very closely with national patient advocacy groups for GIST/sarcoma and melanoma and is Chairman of the Melanoma Academy in Poland. Chair of Task Group of Ministry of Health, Poland, for National Oncological Strategy.



Maria Siemionow

is a world-renowned scientist and microsurgeon, Director of Microsurgery Research, University of Illinois Chicago, USA. Dr. Siemionow is leading the way in developing new technologies for minimal immunosuppression in transplantation, enhancement of nerve regeneration and application of chimeric cell therapies in regenerative medicine. In 2008, she led the team of surgeons that performed the first near-total face transplant in the US. Dr. Siemionow is a member of the American Society of Plastic Surgeons, American Association for Hand Surgery, and American Society of Transplantation. She is past President of the American Society for Reconstructive Transplantation.



Radosław Sierpiński

is the Minister of Health of the Republic of Poland. He is an expert in public health, a doctor and a manager specialized in medical sector management, clinical trials, HTA and management of science. A member of the Board of the National Centre for Research and Development, representing the Minister of Health, and of various teams of experts working for the Minister of Health and the Minister of Science and Higher Education. President of the Social Council of the Silesian Centre for Heart Diseases in Zabrze and Vice-President of the Social Council of the Mazowieckie Voivodeship Branch of the National Health Fund (Narodowy Fundusz Zdrowia – NFZ). A member of an expert group in the area of clinical research of the European Commission. A Polish representative in the group Mission Cancer of the European Commission.



Hilary Stiss

as a Director for International Affairs at the Biotechnology Innovation Organization (BIO), Hilary is responsible for managing the industry association's program of international advocacy and outreach for multilateral organizations. Hilary also manages the association's engagement in Europe, the Middle East, North Africa, Turkey and South Africa regions. In this position, she engages with foreign officials in these regions to promote policies that support a strong biotechnology industry as well as to resolve policy issues relevant to the industry. Hilary also acts as Program Director for the International Council on Biotechnology Associations (ICBA).



Łukasz Szumowski

is the Rector of the Medical University and the Director of the Institute of Cardiology. He is a Polish cardiologist who served as Minister of Health from 2018 to 2020. Currently, Prof. Szumowski serves as a Director of the National Institute of Cardiology – National Research Institute and has been appointed to the Network Committee of ECRIN (European Clinical Research Infrastructure Network). He is also the Head of the Arrhythmia Center focusing on electrophysiology, ablations and implantations. From November 2016, Prof. Szumowski had been the Under Secretary of State at the Ministry of Science and Higher Education. He graduated in medical studies from the Medical University of Warsaw. Afterwards, he started working at the Institute of Cardiology in Warsaw–Anin. He was awarded the title of professor by the President of Poland in 2016.

**Piotr Trąbniński**

is an international finance professional with 15 years of experience in financial markets, monetary policy, digital transformation, digital money, and digital economy. In 2017 he joined the International Monetary Fund where he held the position of Advisor to the Executive Director. Between November 2018 and October 2020 he served as an Alternate Executive Director for the Polish-Swiss Constituency at the IMF. He took over the role of Executive Director in that Office in November 2020. He holds a Master of Arts in Law from the University of Warsaw, Executive Master of Arts obtained at the IWP in Washington D.C. and a Master of Engineering in computer science and cybersecurity from George Washington University. He is an author of publications and articles that are focusing on digital technology, digital money and cybersecurity.

**George W. Handy**

was a Colonel in the United States Army and a senior executive with United Technologies Corporation before becoming engaged in 1992 in support of the post-Cold War transition in Russia and Central and Eastern Europe (CEE). His primary focus has been on work in the CEE region, and continues today. Poland has been the cornerstone for the cooperation that Mr. Handy has organized involving the United States, the CEE region and the European Union. Mr. Handy has directed the completion of over 200 practical projects in economic growth and security in Poland and in other countries across the CEE region. His most recent work with the Alliance for Innovation began in 2017 and focuses on health care and the application of data management and associated technologies. Mr. Handy has also provided consulting services for projects in Central and South America and Asia.



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