POLISH BIOTECH: LANDSCAPE & OPPORTUNITIES

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PORT
Polski Ośrodek
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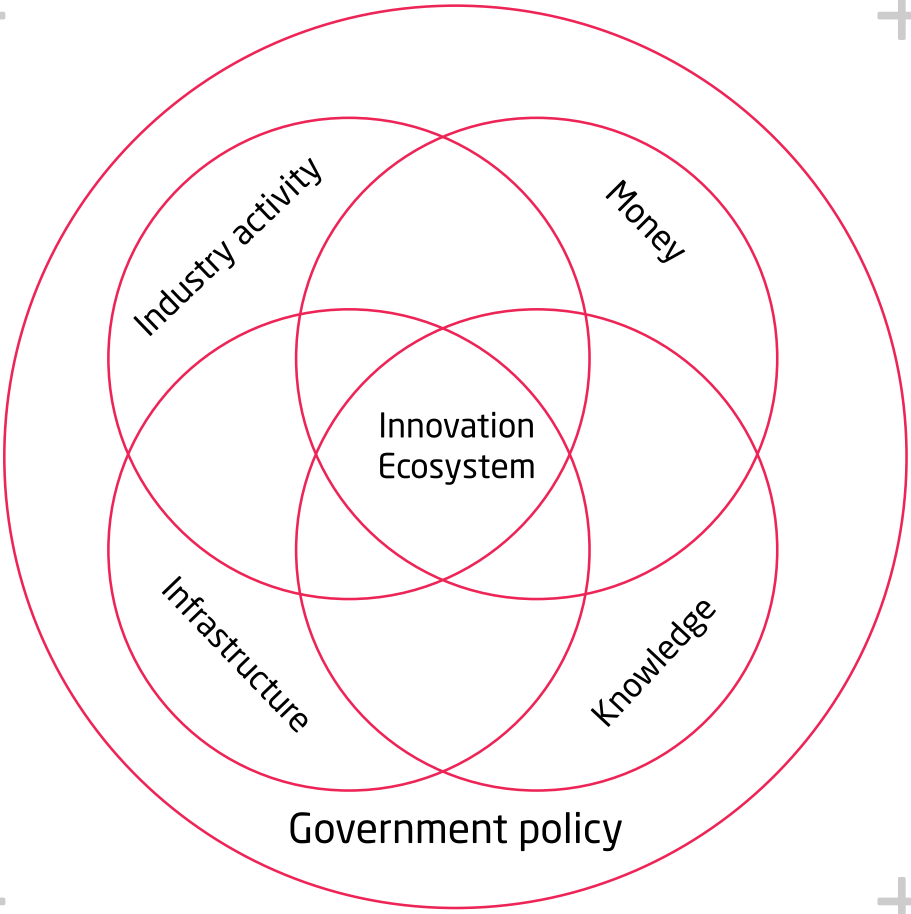


Figure 1. The main pillars of the biotechnology innovation ecosystem in Poland

We looked at the four main pillars of the biotechnology innovation ecosystem in Poland: scientific and commercial knowledge and know-how, the current industry's activity, money and infrastructure availability. We also looked at selected international organisations working between science and business and dedicated to catalysing knowledge generation and translation. Based on that, we are providing recommendations for government policy around the Virtual Research Institute (Polish: WIB) and other key opportunities to advance Polish biotech to its next development stage.

Table 1. Assessment of the Polish biotechnology innovation ecosystem

PILLAR	ASSESSMENT
Knowledge (science & commercial)	30%
Industrial activity (R&D; production)	30%
Money	20%
Infrastructure	20%

Biotechnology and its medical arm in particular is a relatively young industry in Poland. It is clear from our analysis and based on the opinions of key experts that this sector of the Polish economy is on an upwards trajectory. A number of critical challenges remain but there are also unique opportunities which we discuss in this report. If the former can be correctly addressed Poland stands a chance of building a robust biotechnology sector.

Polish scientists in the area of life sciences do not yet produce as many high impact publications as their Western European colleagues, however there is an upwards trend and importantly Polish research groups are actively involved in multinational projects on the cutting-edge of the life sciences in such disciplines as genomics, epigenetics or molecular and structural biology of RNA. Also, importantly, Polish bioinformatics is an area of excellence. Given Poland's strength in mathematical sciences, biophysics and informatics we believe this represents a major opportunity for Poland to establish itself as a player in the newly developing space between life sciences and data science, namely artificial intelligence applied to new therapeutic targets and drug discovery. Another area of strength for Polish science, based on our analysis and an analysis done by the Polish Scientific Policy Committee, is neuroscience. This again presents an important opportunity as neurotechnology and the diseases of the Central Nervous System (CNS) as well as mental health represent one of the largest areas of insufficiently met medical needs and is increasingly becoming a priority for governments and is attracting interest and investment from a number of the global pharmaceutical players.

Over the last decade applied science in Poland received a substantial amount of investment from the Polish government and through various European Union financed funding schemes. We analysed 248 projects submitted to the National Centre for Research and Development (Pol. NCBiR) by universities, startups and SMEs which received at least 3 Million PLN in grant funding. Our analysis reveals that over one third of the projects was related to drug discovery and the most prominent disease indications targeted are cancer, cardiovascular and CNS disorders. That is in line with global trends and if those projects progress further down the development pathway these could create opportunities for engagement with the pharmaceutical industry. Worth noting, is also a large volume of device-related projects. Despite the high number, commercial feasibility of these projects was mentioned as one of the areas of concern by the industry experts we have interviewed.

In the established startups and SMEs sector of the Polish bio-innovation economy some early signs of return on the R&D investments made can be seen, as first Polish innovative biotechs have developed pharmaceutical assets which are now progressing towards or have already reached the first phase of clinical trials. Notable examples of top Polish biotech companies in that space are Selvita (phase 1 drug targeting hematological cancers and a broad pipeline of other drugs in late preclinical development) and OncoArendi Therapeutics (phase 1 molecule against asthma and an immuno-oncology asset in preclinical development).

Polish companies are also becoming important players in the biosimilars space with Polpharma being a market leader and others, such as Mabion, developing biosimilars-based solutions.

Multinational companies have historically been focused on manufacturing and late stage development in Poland and for the most part that is still the case currently. It is worth noting, however, that several innovation-focused initiatives have been launched recently by some large players. These include Roche which invested in a bioinformatics centre and opened a unit devoted to early stage (first-in-man) clinical trials. Other companies active in the innovation space include AstraZeneca which located one of its global research sites in Warsaw.

Looking at the financing options for early stage innovation in Poland beyond public grants, it is clear that there are several important gaps and imbalances that need to be addressed. Senior investment professionals we have interviewed pointed out that Poland suffers from the lack of “smart money” (i.e. investors with sector specific expertise). Most Polish investors are seed-stage investors predominantly backed by the Bridge Alfa programme of the NCBiR. Our analysis of investment portfolios of 11 of such funds shows that nearly 50% of their investments support medical devices companies and the aptitude for risky investments (for example small molecule drugs) is very limited. What is more, we identified a gap at the early series A funding round with virtually no investors active in that space and only one state-backed investor, the Polish Development Fund, investing at late series A, B stages and no biotech private equity investors.

Poland has benefited from heavy infrastructure investments including R&D facilities and equipment. Despite that, however, our limited survey of leading technology parks and research centres as well as interviews with industry executives revealed that access to professional industry grade laboratories in Poland is very limited as existing facilities are mostly running at full capacity. A large portion of available infrastructure and specialist equipment is located within universities, but mostly not accessible to the industry.

In order to see how other countries support their innovation ecosystems’ growth and development we looked at three unique institutions: the Vlaams Instituut voor Biotechnologie (Belgium), the Milner Therapeutics Institute (United Kingdom) and the BioInnovation Institute (Denmark). All three institutions represent a new model for science development which is seamlessly interlinked with industry and cluster development. All institutions put strong emphasis on next generation interdisciplinary scientific disciplines and all have created an advanced structure for the support of startups creation.

In the context of our landscape research and the analysis of the international catalysts our key recommendations for the development of the Polish biotech ecosystem through the formation of the Virtual Research Institute (Polish: WIB) are that: WIB needs to focus first and foremost on investing in world-class science answering big, fundamental questions within the life sciences as only this approach can lead to the creation of a novel know-how and ultimately to breakthrough innovations. In parallel with that, the WIB needs to develop a robust startup formation support system and create a new type of environment open to startups and large industry players. The WIB could become the platform for the best projects in the life sciences sector showcasing Polish biotech excellence to the industry and investors.

WHERE IS THE POTENTIAL?

I see a realistic opportunity to create a strong and innovative biotechnology sector by focusing on building the capabilities in industrial and research & development areas. We shall start from focusing on biosimilars so today we build the capital and competencies which will become the foundation for tomorrow's innovative Polish research. The establishment of the sustainable and agile biopharmaceutical sector in Poland allows international expansion and real contribution to the growth of the Polish economy."

Markus Sieger, CEO, Polpharma

There are a number of trends favouring the development of the biotechnology industry in Poland. The activities of the public sector stimulating innovation give hope for the creation of appropriate conditions for the emergence and development of new ideas and solutions. The extensive experience of Polish doctors in conducting clinical trials, which is reflected in the high percentage of Polish patients included in multi-center international clinical trials, creates excellent conditions to confirm in clinical conditions the effectiveness and safety of therapeutic solutions implemented. In addition, global pharmaceutical companies are increasingly interested in partnership with external entities in the conduct and implementation of research and development activities. Because of that a project developed in Poland can potentially become an element of a therapeutic solution used in the treatment of patients around the world. Finally, it should be noted that new solutions in the medical sciences are not only the development of a new molecules. In the conditions of increasing pressure on the use of usually limited funds allocated to health care, bioinformatic solutions are of great importance. The potential for their development in Poland is associated with the undisputed high position of Polish IT specialists in the world."

Michał Kurzelewski, Medical Director, Pfizer

The main competitive advantage of the Polish biotechnology industry is the large number of well educated, open and diligent young Polish scientists. We can create a strong branch of the economy by using the talents of those who have been studying in the country and those who work or study abroad by ensuring that they continue their careers in Poland. I see the greatest chance for the development of the sector in carrying out research and development work for international pharmaceutical concerns in the field of integrated projects, chemistry, biology or bioinformatics, because in these areas a large number of productive and high-paid jobs can be created relatively quickly. We should also invest in our own original medicines based on basic research conducted at Polish universities and research institutes as well as biotechnology companies. This requires more patience and capital, but it is the most forward-looking, especially in the context of global competition with Asian companies. The condition for the development of the industry is a steady increase in the level of life science education, especially doctoral studies, and a definite improvement in the level of basic and applied research, so that biotechnology companies are able to acquire know-how and licenses."

Paweł Przewięźlikowski, CEO & Co-founder, Selvita

The biotechnology industry can be a huge opportunity for Poland in many aspects. Its development could make the dreams of Polish scientists possible, constitute an important element of our economy and, above all, give Polish patients a chance for faster access to innovative treatment. If we want to enter the path of rapid development of this sector, we must take courageous decisions, establish cooperation with countries and companies that have significant know-how in this area and create an environment promoting such cooperation. I believe that it is in the form of a partnership that we have the best chance of reaching breakthroughs and making them available to the benefit of patients."

Wiktor Janicki, General Manager, Roche

INTRODUCTION

Biotechnology is a broad global industry encompassing a wide range of activities, including agriculture, industrial processing of food and beverages and healthcare. For the purpose of this report we are focusing solely on biomedical research and innovation in Poland, that is, this fragment of the biotechnology industry which is directly related to the development of innovative therapeutics; diagnostics, medical devices and related technologies.

The biomedical sector is a key strategic area of focus for most governments around the world and that is also the case in Poland. The Polish government includes "biotechnology" as one of key sectors of the economy in its Responsible Development Strategy and GovTech initiative. In order to create a vibrant biotechnology industry in Poland several key elements are necessary. These include high quality globally competitive science, an effective mechanism for translating scientific discoveries into innovative products or services, an adequate financing ecosystem and finally, industrial capacity to clinically test and scale up production and sales of new solutions.

In industry 4.0 all of the above elements and especially the worlds of academia and early stage industrial research and development become increasingly intertwined. A strong and burgeoning academic base stands to provide companies with the skilled workers they require to undertake research and contributes to the knowledge exchange process through the creation of spin-off and startup companies which are frequently the vehicle for innovative new products and concepts to reach the market. The clustering of nascent life science companies, academic researchers and clinical output is sometimes referred to as the "triple helix" and increases collaboration and the exchange of ideas and research(1).

Beyond increased connectivity other key factors driving the growth of the bio-pharma industry are the increasingly ageing global population and the demand for improved longevity and quality of life.

OTHER KEY GLOBAL TRENDS SHAPING THE LIFE SCIENCE SECTOR INCLUDE(2,3)

- The emergence of personalised medicine and stratified medicine which are being enabled by the recent advances in machine learning and artificial intelligence.
- The growing trend by big pharma businesses towards partnering, outsourcing and corporate venturing, which has been driven by the steady decrease in the number of new approved drugs over the last 15 years.
- Increasing moves towards translational medicine.
- Increasing convergence in the sector, with further integration between drugs, devices and diagnostics.

- Increasing use of information technology to accelerate drug discovery, streamline clinical development and drive down costs.
- A growing tendency to search for novel therapies for unmet clinical needs.
- An unprecedented increase in biological data (of particular relevance to the fields of genomics and epigenomics) due to acceleration in the development of next generation sequencing technologies.
- Using artificial intelligence and machine learning in drug discovery processes.
- Using “omics” (transcriptomics, genomics, proteomics, metabolomics) based approaches in molecular diagnosis of disease.
- A move by electronics, transportation, retail, IT companies into the health and wellbeing arena.
- A move to holistic and preventative healthcare due to the rise of chronic, lifestyle disease and pressures on healthcare budgets.

AREAS OF EXCELLENCE IN POLISH LIFE SCIENCE ACADEMIC OUTPUT

> *"I can see some improvement in the quality of Polish science but we need to attract more world-class scientists to do their research in Poland"*
>
> *(Polish science expert)*
>
> *"The background might be grey but there are some real hidden gems"*
>
> *(Senior industry executive)*

KEY CONCLUSIONS

- Polish-based research groups are part of high impact research projects.
- The volume of high impact publications in top journals in Poland is significantly lower than in leading Western European countries but shows a clear upwards trend.
- Fields of research funded by Poland and the European Union are consistent.
- Polish research groups work in cutting edge scientific disciplines such as genomics, transcriptomics, epigenomics, molecular neuroscience, immuno-oncology, molecular biology of RNA or bioinformatics.
- Research fields and areas which form the basis for the development of new therapies such as molecular biology and biochemistry are represented by strong research groups in Poland.
- The number of European grants' applications in Poland is significantly lower than in leading Western European countries.

INTRODUCTION

Poland has made significant strides in boosting its scientific weight in the life sciences over the past decade. As a result of increased research funding and infrastructure investment, Poland's contribution to 68 leading science journals examined by Nature in 2018 rose 5.2% between 2016-17. Indeed Poland finds itself ahead its neighbours in Eastern Europe in terms of research output, bringing it closer to the top in worldwide rankings according to the Nature Index (2016-17). Poland is now ranked 24th in the world for quality research output[(4)].

When compared to the leaders in European life sciences academic output, namely the UK and Germany, Poland still lags behind. Bearing that in mind, we wanted to assess not just the quantity of Polish high-end research but also the areas top scientists based in Poland investigate in order to identify scientific strengths which could form the source of competitive technologies and start-ups for the future Polish economy.

A publication in a top academic journal is not the ultimate measure of scientific worth. Also, top journals are often accused of bias towards renowned academic centres and established authors with a track record of high-impact research[(5)]. Nevertheless, a publication in a top tier journal is a strong indicator of scientific quality due to the stringent peer review processes, international dissemination and competitive selection criteria. With this in mind we carried out an analysis of recent high-impact Polish publications.

RESULTS

For the purpose of our exercise we selected internationally renowned scientific journals with an impact factor greater than 30, namely:

- Nature including Nature Biotechnology, Genetics, Structural Molecular Biology, Cell Biology and Scientific Reports
- Science including Science, Science Advances, Science Translational Medicine, Science Signalling and Science Immunology
- Cell including Cancer Cell, Neuron, Structure, Molecular Therapy, Cell Host and Microbe and Cell Immunity

We also included eLife, a prestigious open-access journal publishing research in life and biomedical sciences.

Using PubMed (the online database of biomedical/life sciences journal literature from the U.S. National Institute of Health's National Library of Medicine), a search query was carried out to identify papers produced between 2013 and 2017 (inclusive) with the criterion that at least one of the authors or institutions participating in the research was based in Poland. In providing an estimation of Polish publication output into the wider scientific literature the total number of papers submitted and approved by the chosen publications was compared to the output by leading European countries, namely the United Kingdom and Germany (see Figure 2).

Following the wider international trend for increased life science publication, Germany and Poland have increased their publication output year on year since 2013 in the selected journals, with Germany leading Europe in this. As anticipated, Poland's output remains substantially lower than its western European neighbours, but is poised to continue its upwards trend.

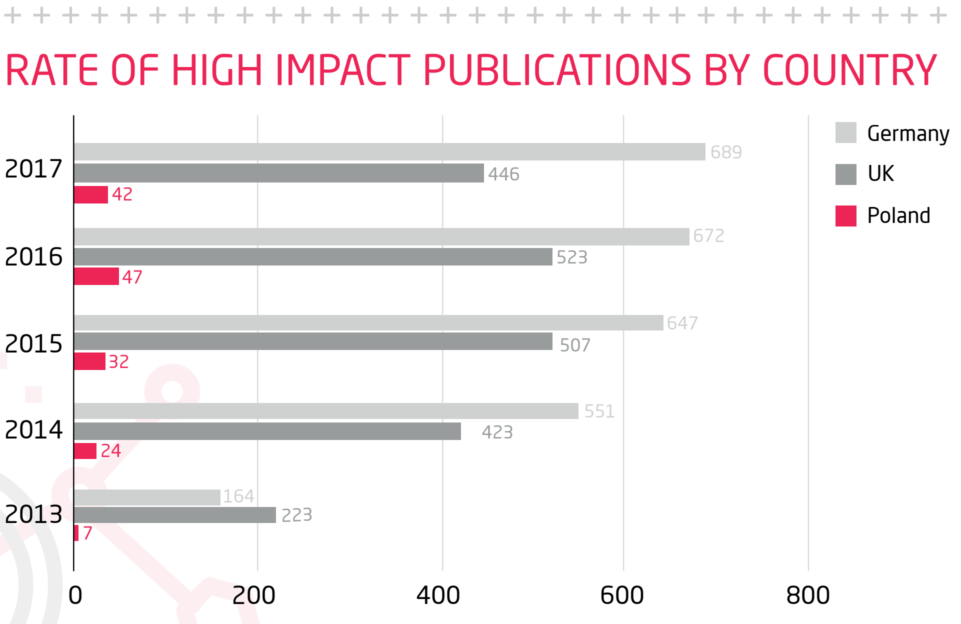


Figure 2. The number of high impact publications in Poland, Germany and the United Kingdom (2013 - 2017).

As a next step this primary dataset was manually filtered to exclude opinion articles, memorial pieces and papers from fields not related directly to bio-medicine. In order to analyse the output we developed our own methodology which assigned three different tags to each of the papers. A Scientific Tag (ST) - this tag describes the various scientific areas which are directly relevant to the content of the paper. An Industry Tag (IT) - which describes the implied or actual relevance of the paper to a specific stage of the therapeutics, diagnostics or medical device development process (data not shown). Finally we assigned each paper with a disease indication where this was clearly stated or could be anticipated based on the publication's abstract. A single paper could be assigned with multiple tags from each category.

Our results show that life science disciplines with particular strengths in Poland include molecular and structural biology. This includes molecular biology of RNA which is one of the most promising scientific areas in terms of developing new treatments which either target RNA or proteins involved in its cellular metabolism or use RNA as a therapeutic agent. Indeed the most prominent case study of commercialisation of research carried out by Polish scientists is within the area or RNA stabilisation for its use as an anti-cancer vaccine. The technology developed by the research group of Professor Jacek Jemielity from the University of Warsaw was acquired first by a German biotech company BioNTech and then bought by Genentech, an American subsidy of the Swiss pharmaceutical concern Roche.

Closely related to molecular and structural biology is bioinformatics which also appears as an important area. Polish bioinformaticians are world-leading experts in such disciplines as homology modeling of protein structures which is critically important e.g. in drug design. This represents a major opportunity for Poland to establish itself as a major player in the newly developing space between so called "wet" (laboratory based) life sciences and data science. Artificial intelligence is poised to revolutionize the pharmaceutical industry as we know it and its application to biological research and biotechnology innovation represents a major opportunity for new entrants into the life science innovation race.

Genetics including molecular genetics and genetic engineering also feature prominently in the results. These areas are primarily important for the study of gene and protein function and as such, form the basis for work on discovering new molecular mechanisms of disease and ultimately discovering novel protein targets for therapy.

It is worth noting that the "omics" disciplines (genomics, transcriptomics, epigenomics and metabolomics) also scored very high in our analysis. These disciplines are particularly important in the context of next generation diagnostic approaches as well as personalised medicine (Figures 3, 4).

Other cutting edge scientific disciplines with contributions from scientists working in Poland include molecular neuroscience, immuno-oncology or epigenetics all of which represent very dynamically developing scientific areas with strong relevance to deciphering molecular mechanisms of disease and creation of new therapeutic strategies.

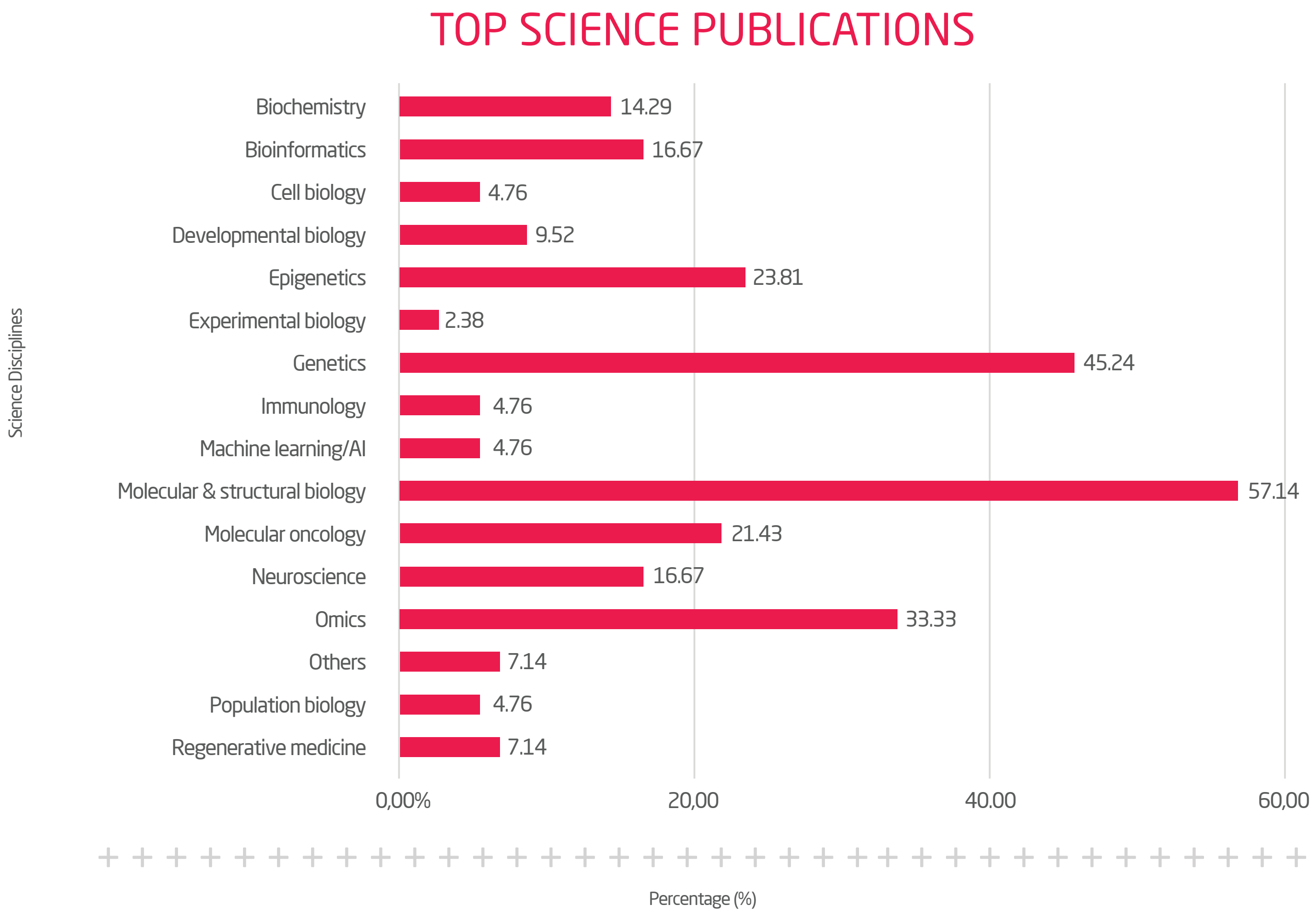


Figure 3. Prominent scientific disciplines with contributions from researchers based in Poland.

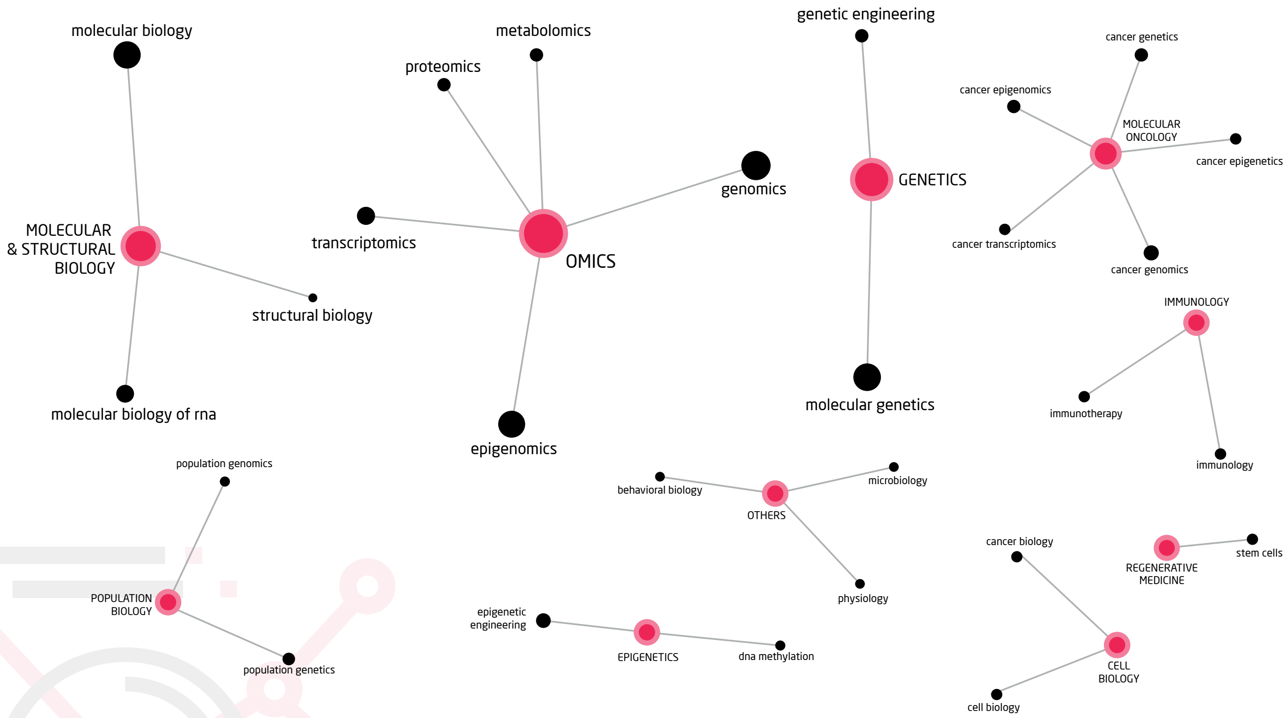


Figure 4. Diversity of cutting-edge life sciences disciplines with contributions from scientists working in Poland.

The disease indication tags we assigned show that over 35% of the papers had some relevance to cancer research. Interestingly a high proportion of the papers were also found to be relevant to understanding, diagnosing or treating the diseases of the Central Nervous System (CNS). This again demonstrates that neuroscience could be a potential area worth focusing on and where competitive strengths could be further expanded.

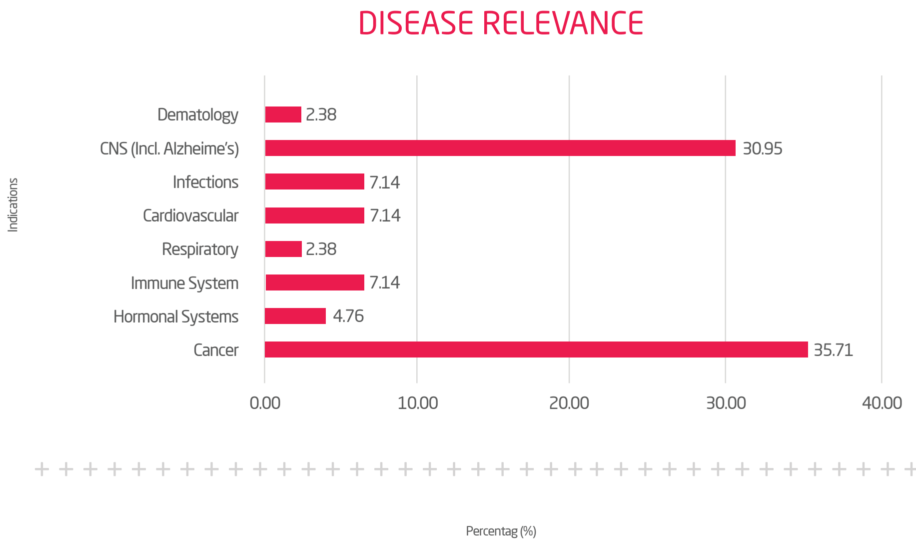


Figure 5. Disease indication relevance of selected publications co-authored by researchers based in Poland.

RESEARCH GRANTS

In order to see which areas of Polish science are strong we also looked at research topics and researchers who received some of the most prestigious scientific grant awards and prizes, that is the European Research Council (ERC) and European Molecular Biology Organization (EMBO) Young Investigator grants and EMBO Members awards over the past five years.

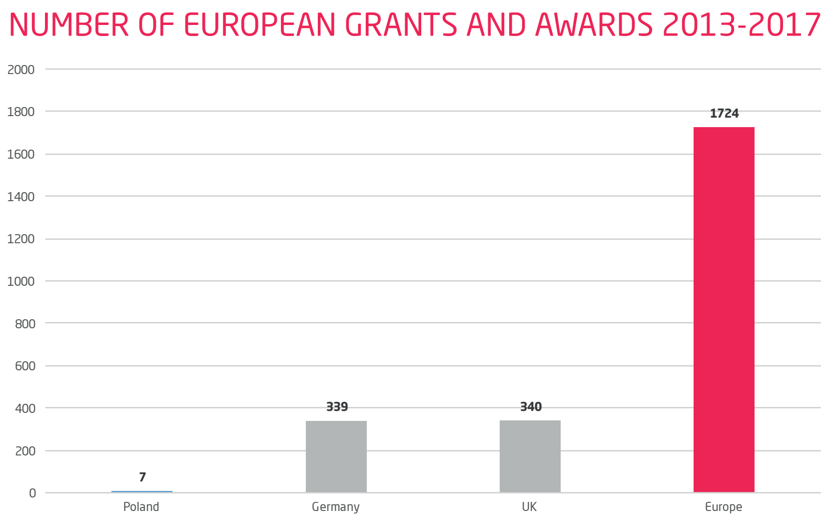


Figure 6. Number of ERC and EMBO Young Investigator grants and EMBO Members awards (2013-2017) in Poland, the UK, Germany and in Europe (total).

As the data in Figure 6. shows, Poland has a long journey ahead to catch up with major Western European countries in the number of grants and awards received. However, there has been more success over the last two years compared to earlier years when no such grants were received at all.

In terms of scientific areas of excellence based on this small dataset we can see that the ERC and EMBO awarded grants to Polish scientists in fields including: behavioral neuroscience, anticancer therapies, drug delivery, protein engineering, new antibiotics, bioinformatics and RNA modeling. This is consistent with our previous analysis to top research papers.

ERC STARTING GRANTS SUCCESS RATE

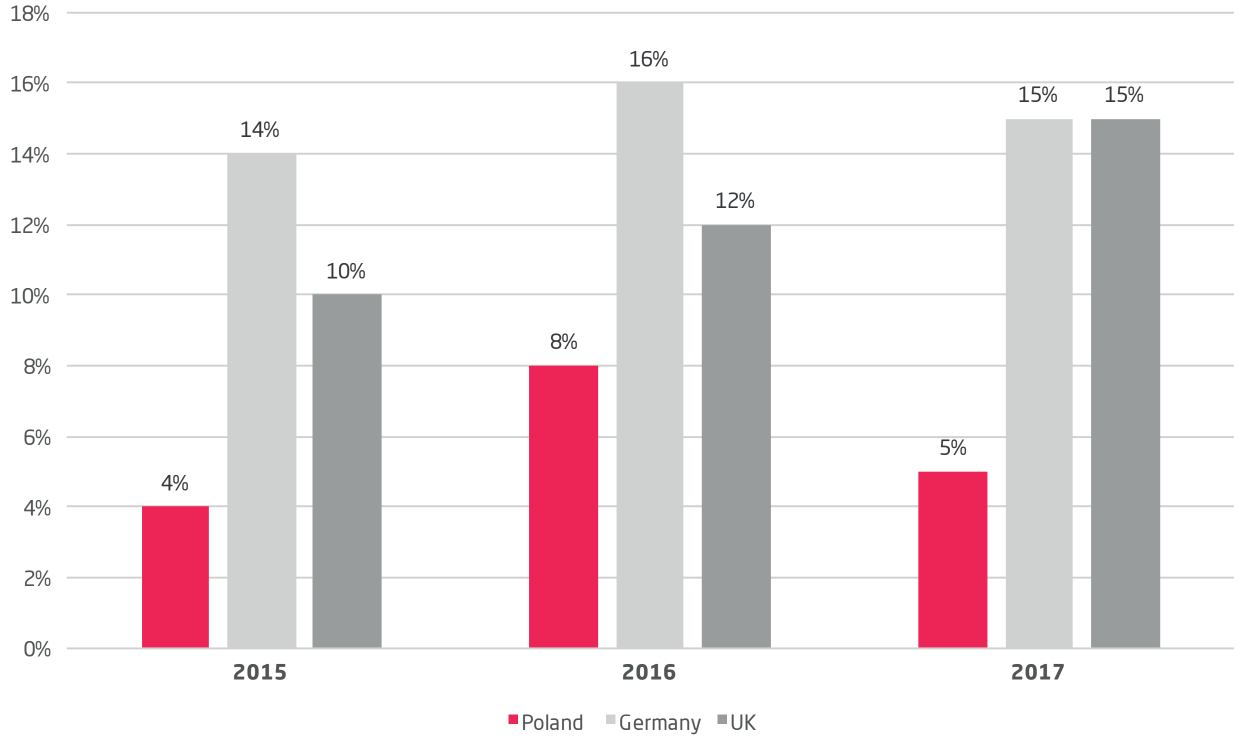
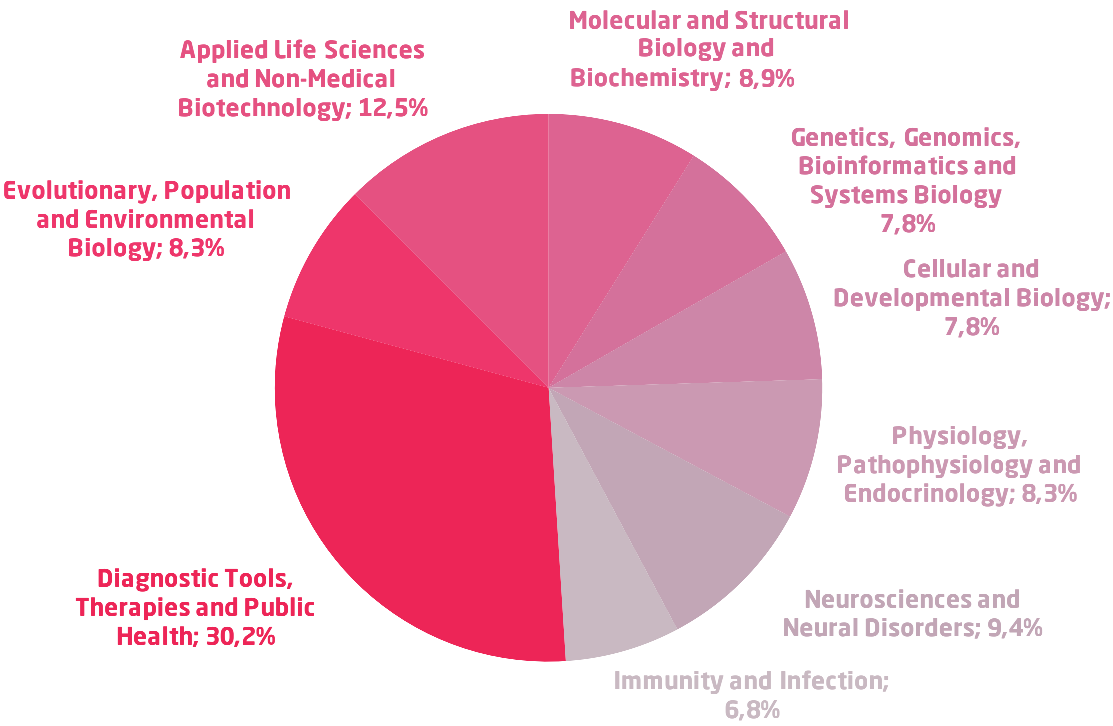


Figure 7. Analysis of the success rate for applicants applying for the ERC Starting Grants in Poland, Germany and the UK.

We also looked at the success rate for Polish applicants applying for the ERC Starting Grants. The analysis shows that while Polish researchers, when compared to their UK and Germany colleagues, are still less successful in obtaining European grants, there is a lower number of applications from Poland as well. For instance, in 2017 the number of ERC Starting Grants proposals from Poland equaled 39, compared to 450 for Germany in the same period.



SCIENTIFIC GRANTS IN POLAND

Figure 8. Major research areas funded by FNP and NCN grant programmes in Poland

We also looked at the grants awarded by the Foundation for Polish Science (FNP)[6]: MAB (2016-2017), MAB PLUS (2017), First Team (2017), Team (2017), Tech Team (2017) and the list of National Science Centre (NCN) grantees from OPUS 13 (2017), MAESTRO 9 (2017), SYMFONIA 4 (2016) and POLONEZ 3 (2016) programmes.

As shown in the Figure 8. the major research areas granted by Polish funding programmes are diagnostic tools, therapies and public health. Also, applied life sciences and non-medical biotechnology, neurosciences and neural disorders, molecular and structural biology and biochemistry are prominently featured.

Based on the analysis of the MAB and MAB PLUS (International Research Agendas) programmes, each worth ca. 7-10 mln EUR the following areas of focus can be identified:

- Immuno-oncology
- Anticancer vaccines
- Civilizational diseases’ therapies
- Cellular stress
- Neurodegenerative diseases and cancer
- Precision medicine
- Genetic mutations in cancers and Alzheimer’s disease
- Postzygotic mutations (PZMs)
- Biomaterials
- Radiopharmaceutical materials
- Computational medicine
- Bioinformatics

Our analysis of the top scientific publications and prestigious grants and awards is in line with the findings of the Polish Scientific Policy Committee (a government advisory group) on the “map of scientific excellence in Poland”, which identified the following areas where Polish biotechnology-related sciences are strong:

1. Structural biology (including determination of protein structures in complexes with small molecules).
2. Bioinformatics, including modeling of macromolecular structures, which is synergistic with structural biology.
3. Molecular neurobiology with neuropharmacology / neuropsychopharmacology, neurobiology of diseases of the central nervous system.
4. Molecular basis of civilization diseases.
5. Molecular biology of RNA.

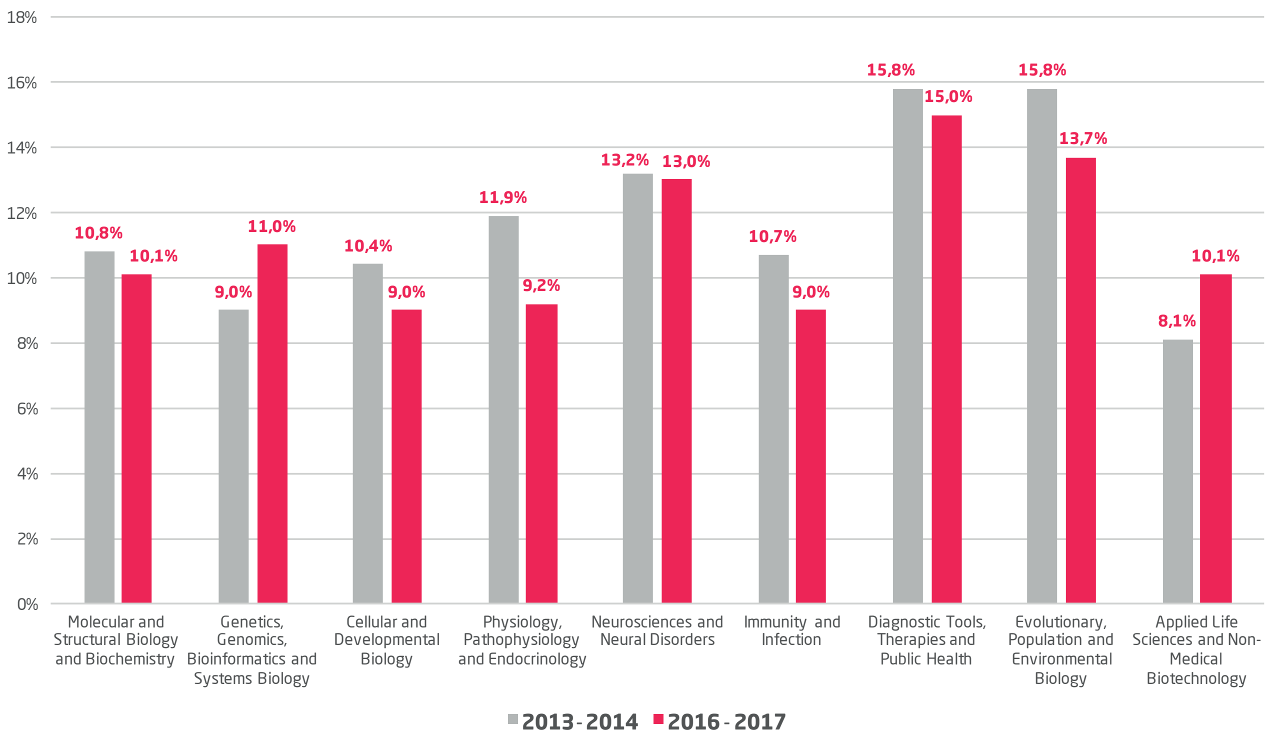


Figure 9. Scientific grants in EU countries, Switzerland and Norway (2013-2014 and 2016-2017)[7]

WHAT IS FUNDED IN THE EU?

In order to compare the trends in Polish science to general European trends we also looked at areas funded across the European Economic Area (EEA) (Figure 9). The analysis shows that European funding (namely EMBO and ERC) has not dramatically changed over the last 5 years. Among others, genetics, genomics, bioinformatics and systems biology are the scientific areas where we observed an increase in funding. Also applied biotechnology has gained more funding recently. Funding for neuroscience has stayed on a similar level in 2016-17 as it was earlier, but it constitutes one of the areas with the highest amount of funding. Based on the above data there seems to be an overall alignment of trends in Polish science with European and broader global research trends.

SCIENCE IN TRANSLATION: ACTIVITY OF UNIVERSITIES, STARTUPS AND SMES INVOLVED IN HEALTHCARE R&D IN POLAND

> *"Biotechnology firms generally lack for experienced management and specialists in their early stages of development"*
>
> *(Investor active on the Polish market)*

> *"It is the first time in history that a Polish biotech works on a truly innovative therapeutic"*
>
> *(Senior Industry executive)*

KEY CONCLUSIONS

- A third of biotechnology companies active in Poland focus on healthcare.
- There are currently two Polish companies with innovative clinical-stage asset.
- Polish companies are among key players in the biosimilars sector.
- There are strong local Polish players focused on digital health (telemedicine).

INTRODUCTION

In bringing a healthcare product to market, the biotech industry faces prolonged development costs and high regulatory burdens. As such healthcare-related innovative products are viewed as long-term investments with high risks and high rewards.

Startups are the vehicle by which academic institutions can "spin out" or commercialise research and technology through to market. SMEs (i.e. "grown up" startups) typically possess the resources to achieve pre-clinical validation (in vitro testing and animal trials to determine the mechanism of action as well as standard pharmacology and toxicology testing) of a therapeutic or technology and depending on financial resources early stage (first-in-man) studies. Following this, large pharmaceutical companies with significant financial resources and in-house expertise may acquire an asset or the SMEs itself to take a promising product or drug candidate to the market.

Life sciences/health/biotechnology startups are among the top five startup categories in Poland accounting for 13% of start-ups in 2016[8,9]. The overall number of biotechnology companies in Poland has trended upwards over the past 3 years according to GUS (Poland's Central Statistical Office) who found an increase from 2014 (124 biotech enterprises on the Polish market) through to 184 in 2016 (out of which 156 are SMEs)[10].

These early stage companies were categorised into subsets depending on their primary focus, which found 105 categorized as DBF (Dedicated Biotechnology Firms) – companies using biotechnological techniques, 118 companies were categorized as Biotechnology Research & Development Firms (i.e. engaged in R&D activities) comprising R&D only (73 companies) or R&D and manufacturing (45 companies) and 66 companies focused only on production and manufacture of biological products[11] (Figure 10).

BIOTECHNOLOGY RESEARCH & DEVELOPMENT FIRMS IN POLAND

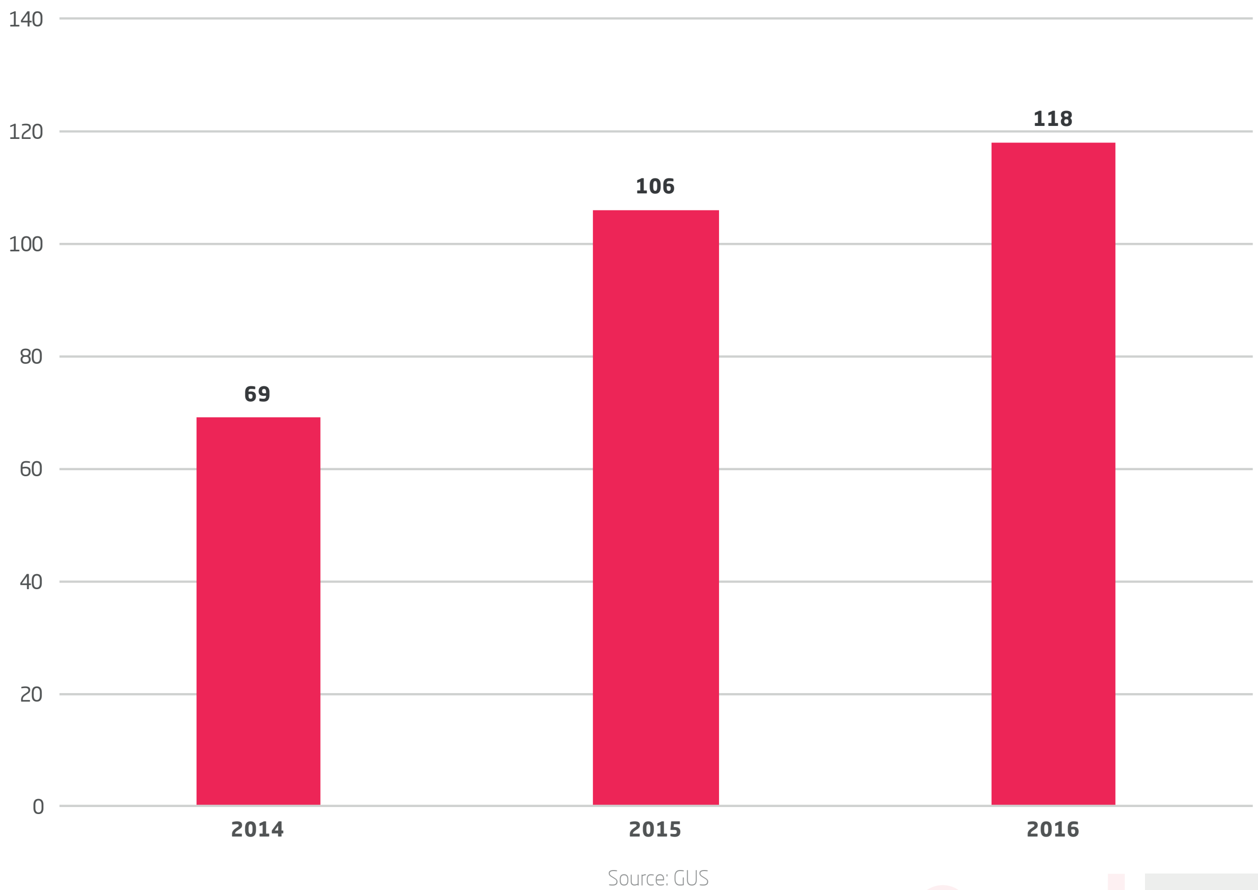


Figure 10. Increase in the number of biotechnology research and development firms in Poland (2014-2016)

BIOTECHNOLOGY COMPANIES BY APPLICATION

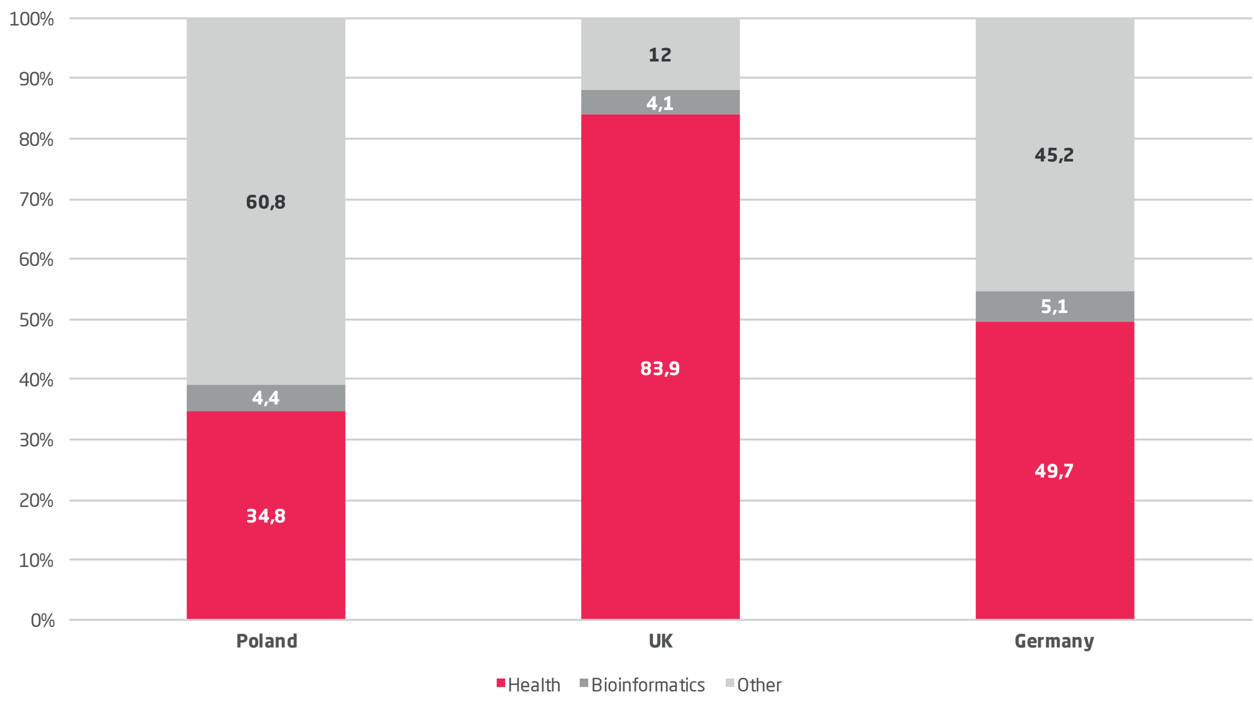


Figure 11. Biotechnology companies in Poland, UK and Germany by application. Data for Poland is from 2014, for Germany: 2015, UK: 2013 (the latest data available). Source: OECD. 'Other' applications include agriculture, food and beverages, natural resources, environment, industrial processing and other[12].

Figure 11 shows the share of dedicated biotechnology companies by application in Poland, the United Kingdom and Germany according to the OECD. Regarding bioinformatics ventures the percentage of companies is similar across countries with the UK dominating in regard to health-related companies which constitute just above a third of Polish companies and nearly half of biotech firms in Germany.

RESULTS

PROJECTS FUNDED BY THE NCBiR

In order to asses the activity of university groups, startups and SMEs involved in translational research in life sciences we examined projects which received funding from the biggest public funder of applied science in Poland, the National Centre for Research and Development (Pol. NCBiR).

We analysed 248 projects submitted to the NCBiR by universities, startups and SMEs in the last 10 years which received at least 3 Million PLN in grant funding. Using a similar approach as described in the previous chapter we manually reviewed and assigned all projects with two categories of tags: industry area, and disease indication.

Our analysis reveals that over one third of the projects were found to relate to drug discovery. This shows the potential for building a robust downstream pipeline of novel drugs. If these projects can be developed further and reach the late pre-clinical or early clinical stages this could create opportunities for partnerships with the large pharma players. An important factor here is, however, the level of innovativeness of these new therapeutics as drugs against a well known molecular target often face competition from other industry players and are often referred to as "me too" drugs. We did not analyse this aspect of the projects in detail, however, based on the opinions of experts we have interviewed a significant portion of the small molecule projects would fall into the "me too" category. Interestingly, however, a number of the new therapeutics projects also relate to cell and gene therapy which is a novel, innovative area with high growth potential.

Medical and diagnostic devices were an important area of funding by the NCBiR, which is a feature of Polish SME activity and seen to be an area where science can more readily be translated into attractive business ventures. Over 20% of projects were related to devices. Based on our discussions with industry insiders a number of those devices are being developed for niche/ specialised applications. This could create competitive advantages but also might be the basis for low commercial potential if the markets addressed are not large enough.
Additionally, a high number of projects funded by the NCBiR relate to clinical studies or improvements in pharmaceutical manufacturing. This is in line with the interests of the large pharmaceutical companies operating in Poland which largely focus their activities in these two areas (see next chapter).

INDUSTRY AREA - NCBiR FUNDED PROJECTS

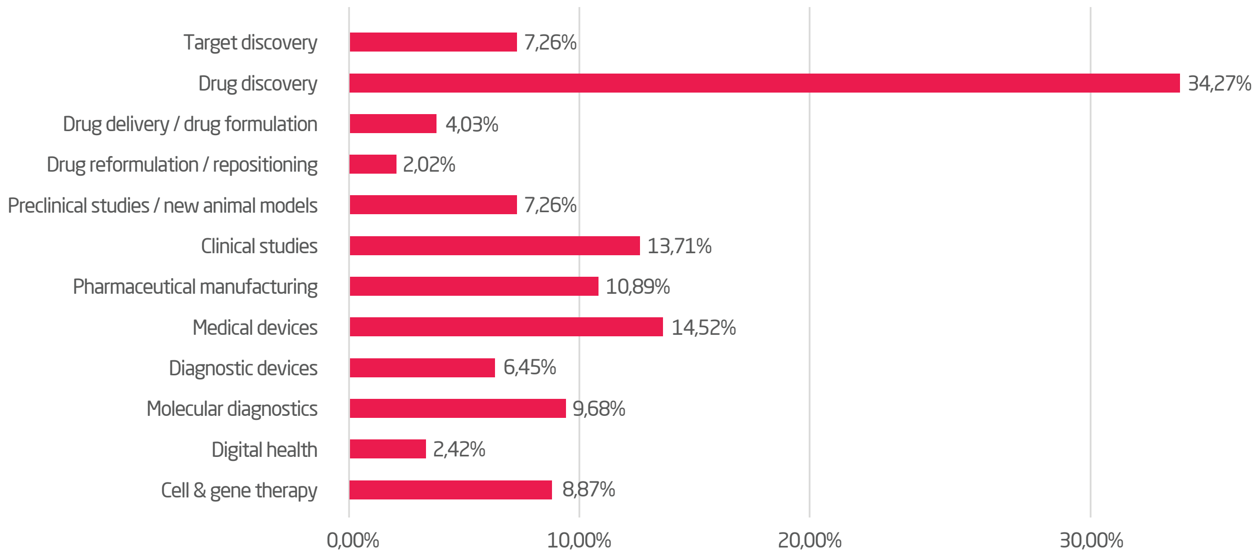


Figure 12. Industrial R&D area and stage of projects funded by the National Centre for Research and Development (NCBiR)

Cancer, cardiovascular diseases and diseases of the Central Nervous System (CNS) are seen to be the strongest areas of development in all large-scale grants approved, along with the wider category of diagnostics, imaging and drug delivery (Figure 13). The weighting of research to cancer and cardiovascular disorders mirrors a larger world-wide trend towards these diseases as they constitute large and growing pharmaceutical markets.

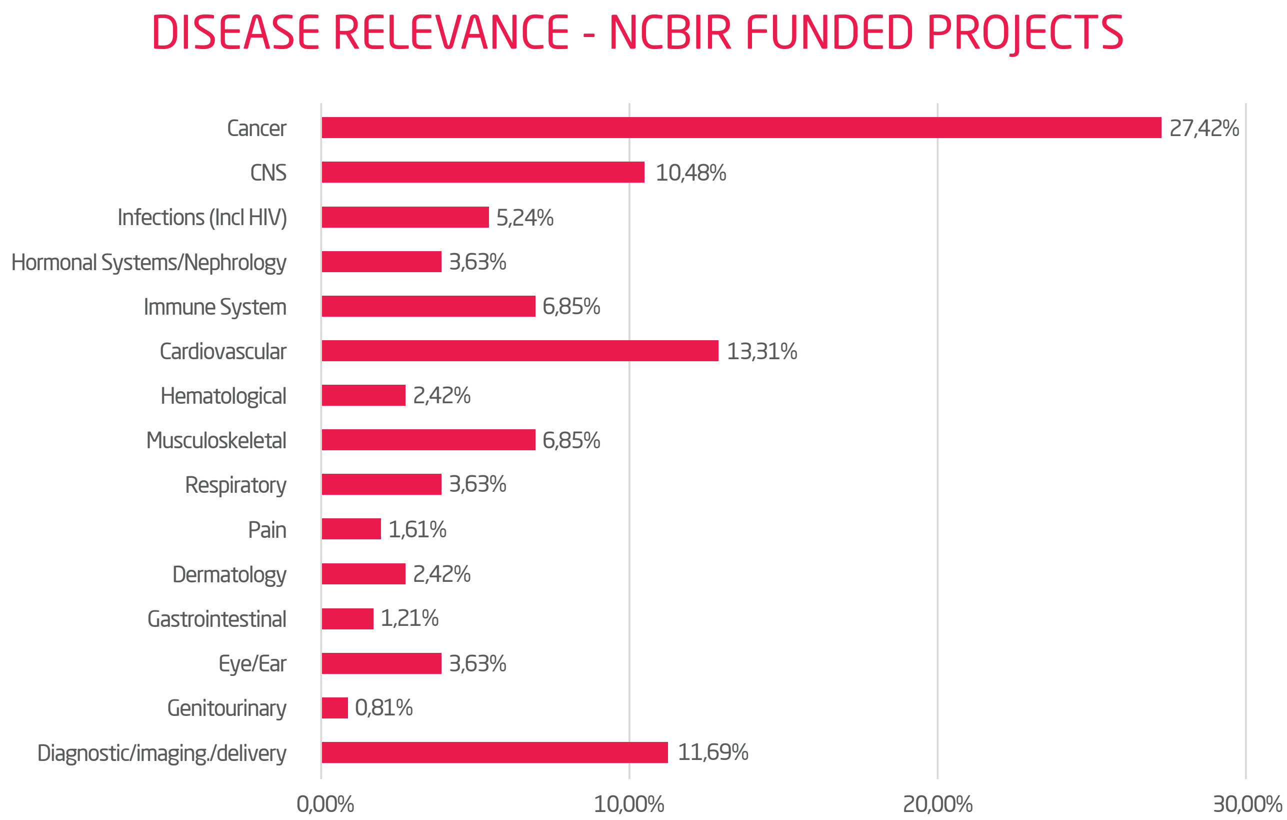


Figure 13. Disease indications targeted by projects funded by the NCBiR

ACTIVITY OF MATURE STARTUPS AND SMEs

Poland has multiple domestic medium sized bio-pharmaceutical companies. A number of those companies specialise in generic drug manufacturing, however recently there has been an increased investment by several players into innovative drug discovery. As a result, for the first time in history companies based in Poland have advanced to early clinical trials with innovative drugs developed in-house. The frontrunners among Polish companies with a dedicated research and development pipeline delivering first-in-class molecules to the clinical trials stage are Selvita and OncoArendi. Both of them are now mature companies with multiple sites across different geographies and both are publicly traded. OncoArendi's R&D pipeline currently includes three discovery programmes and four molecules with an immuno-oncology asset in a late stage of preclinical development and their most advanced molecule focused on respiratory disorders completing phase 1 clinical evaluation.

Worth noting is that some of the bigger domestic companies are also active in the newly developing space of digital health. Notable examples are Medicalgorithmics developing mobile cardiac telemetry, but also Adamed which, besides its activity in drug manufacturing, discovery and development, treats telemedicine as a strategic focus area, with the goal that it can help the company to compete against bigger players.

CASE STUDY: SELVITA S.A.

Selvita S.A. is a Polish-founded and Poland-based drug discovery company developing novel oncologic therapies. Established in 2007 the company is headquartered in Krakow with international offices located in the US, as well as in Cambridge (UK). An international player the company has engaged in partnerships with multiple international SMEs and intensive R&D partnerships with Merck, H3 Biomedicine, and Nodthera Therapeutics/Epidarex Capital. Selvita closed a €100M licensing deal with Menarini Group in March 2017.

Selvita also offers a wide range of integrated drug discovery services assisting pharma partners to discover and develop new drugs. The company's most advanced R&D program is SEL24, a Phase I/II dual PIM/FLT3 kinase inhibitor for use in relapsing acute myeloid leukemia, along with several drug discovery platforms in immuno-oncology, immunometabolism and cancer metabolism.

BIOSIMILARS

Another area with a strong presence from Polish companies is the development of biosimilar assets. According to the report on the global biosimilars market, in 2017 the market value exceeded 4 bln USD and it is expected to reach more than 23 bln USD in 2023[(13)]. Among the crucial global players are Pfizer, Amgen, Samsung Biologics, Sandoz, Teva Pharmaceuticals, Stada.

The European Union market is well regulated regarding approval of biosimilars. The first EU approval was in 2006, since then EU approved the highest number of biosimilars worldwide. At the end of May 2018 European Commission proposed the 'export manufacturing waiver' amendment to Supplementary Protection Certificate (SPC). The purpose of the amendment is to allow EU bio-pharma companies to develop generics and biosimilars of SPC-protected reference biological medicines during the term of certificate only if exported to countries outside the EU where patent protection already expired or there is no protection at all.

"A Supplementary Protection Certificate ('SPC') - an intellectual property right, available in EU Member States, that extends by up to five years the legal effects of a reference ('basic') patent which pertains to a medicine or a plant protection product that has been authorised by national or EU regulatory authorities. (...) SPCs are intended to compensate for the 'loss' of effective patent protection caused by lengthy compulsory testing and clinical trials required before a medicine is authorised to be placed on the EU market." Source: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. 28.05.2018

The market leader among Polish companies in the biosimilars segment is Polpharma which invested heavily in its biologics research site in Gdansk. Other notable companies are Mabion or Adamed (Table 2). Polpharma Biologics, is currently developing biosimilars in different therapeutic areas, including eye diseases, multiple sclerosis, psoriasis, psoriatic arthritis and Crohn's disease. Mabion, recently receiving substantial investment from the European Development Fund, is working on biosimilars in oncology, autoimmune and metabolic diseases with a Phase I/II clinical trial underway for a biosimilar to the Roche therapeutic rituximab.

Table 2. Activity of key small and medium-sized bio-pharmaceutical companies in Poland.

COMPANY	BIOSIMILAR/GENERIC	NEW DRUGS	DISEASE/INDICATIONS	CLINICAL TRIALS ACTIVE
Selvita		☑	Oncology	Y
OncoArendi Therapeutics		☑	Oncology, Inflammation	Y
BioFarm	☑		Allergy, Cardiovascular, Gastroenterology, Gynecology, Neurology, Psychiatric, Oncology	N
Polpharma	☑		Oncology, Immunology	Y
Celon Pharma	☑	☑	Oncology, Neurology, Inflammation, Metabolism	Y
Mabion	☑		Oncology, Autoimmunology, Metabolism	Y
Synektik	Imaging		Radiopharmaceutical	N
Adamed	☑	☑	Oncology, Neuropsychiatry	N
Pure Biologics	Manufacturer/Discovery	☑	Oncology, Autoimmunology, CRO	N
Ardigen	Bioinformatics	☑	CNS, Microbiome, AI, Immunology, Bioinformatics	N
Bioton	Recombinant insulin		Diabetes	N
GLG Pharma		☑	Oncology	Y

OPPORTUNITIES FOR POLAND TO DEVELOP BIOSIMILARS

- Expiring patents; 'patent cliff' for many currently protected and commonly used drugs.
- EU regulations - the EU is a global leader regarding biosimilars' approvals.
- Biosimilars are cheaper to manufacture and commercialise than the biological medicinal products.
- Polish companies are already developing biosimilars with existing infrastructure.

CASE STUDY: POLPHARMA

Polpharma Group is a leading generic drugs player based in Poland, operating across Europe, the Caucasus and Central Asia, with manufacturing subsidiaries in Poland, Russia and Kazakhstan. It is among the top 20 generic drug manufacturers in the world with annual sales of approximately $1 billion. The Polpharma Group portfolio includes nearly 600 products with another 200 in development. It is also one of the leading European API producers, delivering products for pharmaceutical companies worldwide. In order to provide patients with more affordable access to modern biologic drugs, Polpharma Group has decided to focus on biosimilar products. It has created a state-of-the-art R&D and production centre and established strategic partnerships in addition to expanding its capabilities in the development and commercialization of biosimilars.

Polpharma manufactures a wide range of prescription drugs and pharmaceuticals for in-patient care, used in cardiology, gastroenterology, CNS and other indications.

ACTIVITY OF MULTINATIONAL PHARMACEUTICAL COMPANIES IN POLAND

"Invention has no nationality. We will setup research sites wherever we can find the best science."

Senior Executive, pharmaceutical company

KEY CONCLUSIONS

- Multinational pharmaceutical companies focus their activities in Poland on clinical trials, manufacturing and sales of drugs.
- There has been a recent increase in innovation related activities by big pharma in Poland.
- There is a need of governmental incentives which will link the drug reimbursement policy with innovation policy and prioritise those drugs which both have the best clinical outcomes and have been (at least partially) developed in Poland.

INTRODUCTION

The pharmaceuticals market in Poland has grown continuously for the last decade and now accounts for around 1 percent of the national GDP. The Polish market represents the largest consumer market in Central Europe and the sixth largest in the European Union. It has grown thanks to a strong domestic demand for generic drugs and increasing consumer spending power. Pharmaceutical exports, especially to Western Europe, have been strong and on the rise, as local producers have increased their focus on more advanced-medicine markets(12). According to McKinsey estimates, the value-added breakdown in pharmaceuticals ranges from 70 to 90 percent in manufacturing, with up to 15 percent in distribution (retail and wholesale), and 3 to 5 percent in logistics[(14)]. Poland has established a solid reputation and the fundamentals in the manufacture and marketing of pharmaceutical products.

Traditionally, activities of multinational pharmaceutical companies operating in Poland have been focused on late stage clinical trials as well as manufacturing and distribution of drugs. Several modern manufacturing plants are operating in the country with a skilled labour pool that is salary-competitive with specialists from other countries[(15, 16)]. The plants are situated in attractive locations conveniently sited in close proximity to Western, Central, and Eastern European markets (Table 3.).

While the aforementioned activities are still dominating, global pharmaceutical companies including Roche and AstraZeneca have increased their research and development operations within Poland, particularly in IT and earlier stages of clinical trials. Roche has invested over 130M USD in a bioinformatics centre[(17)] and recently together with the Maria Skłodowska-Curie Institute of Oncology in Warsaw opened a unit devoted to early stage (first-in-man) clinical trials. In March 2017, AstraZeneca expanded their global R&D hub located in Warsaw.

This investment makes Poland one of the key countries for AstraZeneca's operations. Soon Poland will be home to more than 1100 AstraZeneca employees. In 2011, the company established a global Clinical Research Center in Warsaw as the first in this part of Europe and currently one of six in the world.

Table 3. Multinational pharmaceutical companies with significant service and manufacturing activity in Poland.

MULTINATIONAL COMPANY	ACTIVITY IN POLAND
GlaxoSmithKline	Focuses on pharmaceuticals, vaccines and consumer healthcare with manufacturing and clinical trial management in Poland based sites.
Johnson and Johnson	Sales and marketing site with clinical trial support roles based in Warsaw. Collaborating with innovators from CEE region.
Roche	Maintains Medical Department and Clinical Trials hub in Poland, hired more than 150 bioinformaticians, invested 130 M USD in a bioinformatics centre, which among other things, will work on machine learning applications in drug discovery.
Novartis	Operates pharmaceutical and consumer health production sites in Rzeszów, Gorzów Wielkopolski and Pruszków. In total, Novartis employs over 1500 people in Poland including investment in a new generics production and logistics facility in Stryków.
Sanofi	Has major manufacturing sites for Sanofi Aventis, Sanofi Pasteur and Zentiva (all part of the Sanofi Group) and a Clinical Trial management group and R&D project site in Warsaw.
AstraZeneca	In 2011, the company established a global Clinical Research Center in Warsaw which was expanded in March 2017. The company also announced Warsaw as the location for one of the three global financial and HR centers. AstraZeneca also expanded their global R&D hub located in Warsaw.
Pfizer	Focuses on pharmaceuticals, vaccines and consumer healthcare with clinical trial management in Poland. Cooperates with Polish academia.
Valeant	Comprises four companies and plants: Jelfa Pharmaceutical Company, ICN Polfa Rzeszów, EMO-FARM, Valeant Med and operates as a CRO with Polish production plants providing contract manufacturing services for worldwide clients.
Baxter	Is headquartered in Warsaw and maintains a warehouse and technical service in Błonie and a modern factory in Lublin employing in total about 400 people.
Tekada	Runs a production facility in Łyszkowice, sales center in Warsaw and a financial center in Łódź.
Biogen	Maintains a manufacturing site based in Warsaw.

CLINICAL TRIALS IN POLAND

The key purpose of clinical trials is to confirm that a new medicine which is to be handed over to doctors and patients is safe and effective. Clinical trials are a major component of the drug development process: approximately two-thirds of the average cost of the molecule route to the market is allocated to clinical trial, and as such, international manufacturers are looking for sites across the globe with large patient populations, skilled workforce and lower wages. Owing to the growing complexity of medical technologies used in modern medicines and the necessity to adapt to increasingly strict standards of the safety of use of medicinal products, the role of clinical trials and the related costs have been steadily growing, and this trend is expected to continue in the nearest future(18).

A typical process consists of four phases of clinical trials (preceded by a phase of preclinical trials, when the concept of a new therapeutic method is tested on cellular and animal models). According to Good Clinical Practice (GCP) standards, these phases are as follows:

- Phase 1: Initial testing of drug safety and pharmacological properties, involving 50-100 healthy volunteers;
- Phase 2: Dose-ranging tests and initial analysis of drug safety and efficacy, involving 300-600 patients with specific conditions;
- Phase 3: The lengthiest and costliest part of trials, involving from 1,000 to 3,000 patients, which aims to confirm the safety and efficacy of a drug and enable its registration and introduction in the market;
- Phase 4: Additional post-registration testing aimed to confirm the long-term safety and efficacy of a drug.

In reaching phase 3 a new drug will be approved for market and made available for patients. According to a report by PwC "Clinical Trials in Poland – Key Challenges": Poland was ranked 10th in the world and 1st among emerging (and CEE) markets in terms of number of clinical trials sites. The structure of Polish clinical trials market differs from the wider global model and showcases the modern tendency for CROs to operate the majority (70% by volume; 53% by value) of trials as opposed to traditional in-house trial management(19).

RESULTS

New and emerging therapies were examined on international clinical trial databases to account for novel drugs that stem from Polish based clinical trial sites and are sponsored by industrial partners with a research management site within Poland.

Non-commercial clinical trials are also an important component of the market. Typically, these trials do not aim at introducing a new drug into the market, but concern medicines which have already been authorized for marketing. Non-commercial trials focus on the analysis of drug efficacy with respect to various groups of patients (e.g. in children), different dosage or previously unspecified use. As such these trials were a large proportion of total trials carried out in Poland however were excluded from the data.

For the purposes of examining novel pharmaceutical innovation and development in Poland, the 10 largest multinational pharmaceutical companies with a research & development arm bringing novel molecules to market were analyzed in terms of their domestic clinical trial output within Polish sites.

A total of 1,095 studies were found to be, as of 2018, recruiting, not yet recruiting (i.e. in planning), active, not recruiting (i.e. underway) or enrolling by invitation. These studies were all based in Poland at Early Phase 1, Phase 1, Phase 2, and Phase 3 with industry sponsors.

Table 4. The top 10 clinical trial sponsors in Poland. Source: clinicaltrials.gov.

SPONSOR COLLABORATORS	NO. OF STUDIES ACTIVE WITH POLISH RESEARCH SITES
Hoffmann-La Roche	90
Janssen Research & Development, LLC	64
AstraZeneca	59
Novartis Pharmaceuticals	58
Bristol-Myers Squibb	57
AbbVie	48
Eli Lilly and Company	48
Bayer	40
Pfizer	39
Sanofi	28

Of the 531 trials shortlisted (Table 4) five multinational companies with a Polish research and development presence (active project management or clinical trial management facility) have a total of 167 trials ongoing. These trials included biosimilars and drug repurposing which predominated the data analysed.

DISEASES INDICATIONS FOR NOVEL DRUG CLINICAL TRIALS IN POLAND

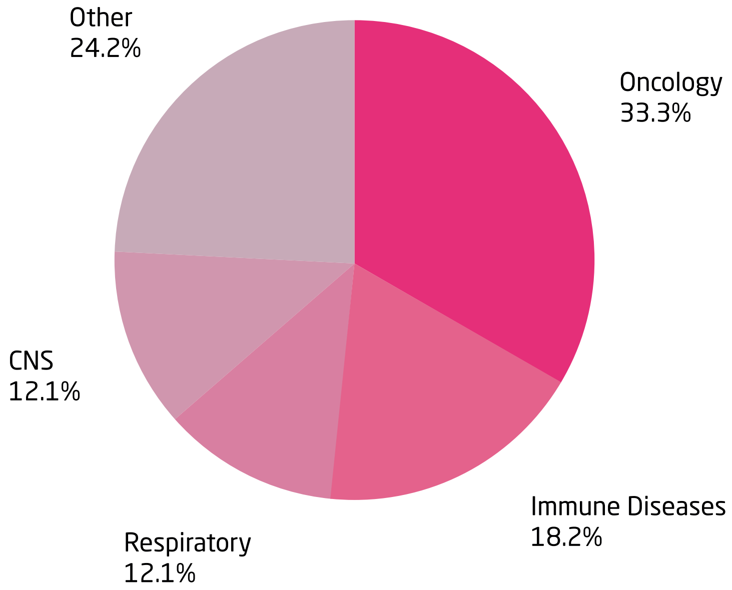


Figure 14. Disease indications of active clinical trials for novel drugs carried out by companies with project management or clinical trial management facility in Poland (June 2018). Source: clinicaltrials.gov.

Out of these studies, trials of novel and first-in-class drugs in Phase 1-3 sponsored by these top pharmaceutical companies being carried out in Poland constitute below 20% of all trials. Within the analysed dataset the highest number of trials are in oncology (34%) followed by immune diseases (19%), respiratory (13%) and CNS (13%) disorders (Figure 14.).

BIOTECHNOLOGY INVESTMENT LANDSCAPE

'Without world-class science to invest in, even the most idealized investment landscape won't be of much use"

(Industry expert)

"Public money is good but too much of it can be dangerous"

(Cambridge-based serial entrepreneur)

KEY CONCLUSIONS

- There is a significant amount of early stage Proof of Principle and Proof of Concept public funding for translating science into innovation.
- Most investors into biotech in Poland are active at early seed to seed stages (50 000 - 500 000 USD).
- There is a clear gap in the investment landscape at a Series A venture capital round (1M USD to 5M USD).
- PFR is the only large investor in the life sciences sector in Poland with a total investment budget of just over 80 M USD (300 M PLN) and a ticket size of 8M USD to 13 M USD (30 to 50 M PLN).
- There is a strong need of "smart money" at all stages of the investment cycle (from early seed stage to IPO) as most investors in Poland do not have the biotechnology domain expertise and networks necessary to support the projects they invest in.
- Given the lack of domestic specialist investors in the life sciences sector, there is an opportunity for foreign investors to fill in the gap.

INTRODUCTION

Despite trailing behind its Western European counterparts in life science innovation and intellectual property generation the number of biotechnology companies in Poland is growing, driven by an improving academic output and substantial investment in infrastructure[20]. Many of these nascent companies are relatively young, with the potential for further growth still to come.

The development of the Polish life science and pharmaceuticals sector has been in part stimulated by increasing funds for innovative products, both from EU bodies and financial institutions created by the central government. Beyond government development funds, innovative startups rely on the expertise, capital and influence of private investors, both individual (angel networks) and institutional (Seed/Venture capital) to drive their own R&D and commercialisation efforts.

RESULTS

Based on our discussions with senior figures in the investment circles, the current low density of biotechnology firms and immature investment landscape hinders the drawing of wholesale conclusions. However, in principle, most of the early stage funding available in Poland is linked to various government programmes and funding agencies. The programme (funded by the National Centre for Research and Development), which was designed to draw in private capital for high risk, high return innovation investments is called Bridge Alpha (BA). In this scheme 80% of the investment capital comes from the government while only 20% is private money. We analysed those BA funds which have active portfolios and which received additional government funding in the 2017 edition of the programme (see Figure 15).

Majority of the 30 funds analysed (73.4%) do not have any, or have only limited interest in biotechnology startups. Out of the funds which have clear interest in biotech (26.6%) only half (13.3%) are dedicated biotechnology investment vehicles (Figure 15).

BRIDGE ALFA FUNDS: LEVEL OF INTEREST IN BIOTECH

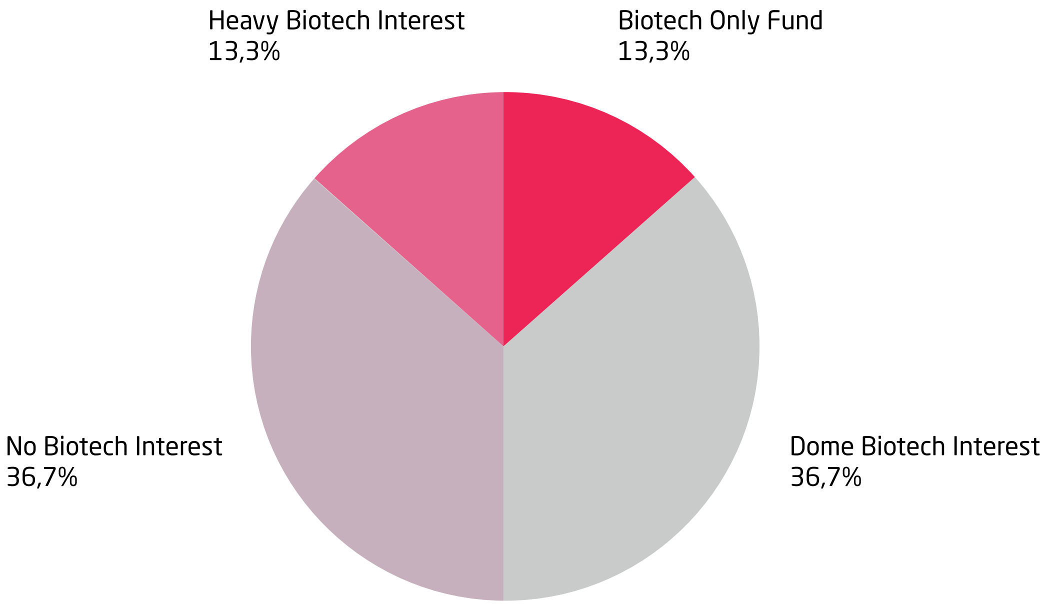


Figure 15. Analysis of the level of interest in Biotechnology amongst selected seed funds backed by the Bridge Alfa programme

Out of the BA funds analysed, 11 had current investments in 24 Polish biotechnology, pharmaceutical or related companies between them.

INVESTMENT PORTFOLIO BREAKDOWN FROM 11 ACTIVE BIOTECHNOLOGY SEED FUNDS

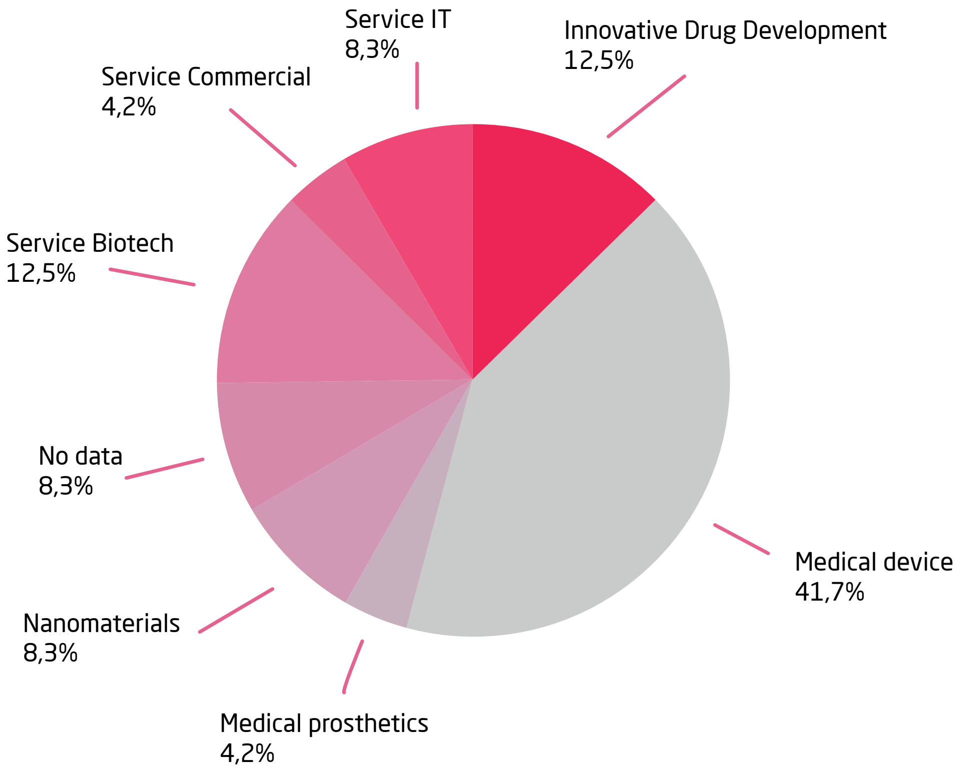


Figure 16. Investment portfolio breakdown from 11 active biotechnology seed funds in Poland

Out of the biotech related investments of the BA funds analysed, the most significant area of activity is within medical devices (41.7% for the funds analysed) (Figure 16). Based on our discussions with industry insiders, this feature of the investment preferences can be explained by the lack of seasoned biotechnology specialist investors with sufficient depth of expertise among the funds' personnel. Hence, the BA funds currently operating in Poland are less likely to tolerate the high attrition rate and longer term returns offered by drug development projects. Medical devices are offering a shorter and more easily understood route to market[21]. Also, due diligence on medical devices prototypes is easier and cheaper to carry out. As such, these projects can be seen as less risky investments by an inexperienced investor with a limited investment budget. Novel drug discovery projects constitute just over a tenths of the analysed portfolios (Figure 16), with startups exploring innovative medicines focused predominantly on oncology and immunotherapy. This focus area is in line with global trends as cancer and especially immuno-oncology are very attractive investment spaces[22] with large deals precedence and even larger hopes for future growth.

An important finding we have made is that there are currently no established players in the biotechnology investment space who provide follow on funds for those projects which receive the initial seed level investment.

There is a clear gap in the investment landscape at a Series A venture capital round (1M USD to 5M USD). PFR is the only large investor in the life sciences sector in Poland with a total investment budget of just over 80 M USD (300 M PLN) and a ticket size of 8M USD to 13 M USD (30 to 50 M PLN). Unless the gap we have identified is filled by private or public funds the startup companies will find themselves starved out of cash before they can reach sufficient milestones to secure larger rounds.

Also importantly, there is another gap on the market at a late series A-B stage (15M USD and above) with currently no biotech investors in this space. Because of that, companies find themselves in a position where they need to go to the stock markets and seek an early Initial Public Offerings (IPOs) in order to continue growing. The option of floating on the public market is a useful tool that Polish companies have, however it also poses a number of serious risks. Firstly, compared to specialist biotech Venture Capital, stock market investors are generally less likely to be aligned with and able to understand a biotech company's science-driven vision, which often requires significant upfront R&D investments before delivering any increase in value. Secondly, due to the long timelines and high failure rate for such companies to be able to achieve specific milestones which will enable a large deal with a multinational pharma company (e.g. asset or company acquisition) there is a risk that non-specialist investors will lose patience and become disappointed with the entire biotech sector (see Table 5).

Table 5. A healthy mix of funds for biotechnology sector growth versus the current investment landscape in Poland. The traffic lights system indicates areas which are well developed (green), need attention (yellow) and are a serious threat (red).

	IDEATION	SEED	SERIES A	SERIES B +	EXIT
Source of Funds (healthy mix)	Government institutions, research bodies	Individual angels, early stage VCs	Angel Networks, VCs	Specialised VCs & Private Equity Funds	Stock market, M&As
Source of Funds (Poland)	Government institutions, research bodies	Government backed vehicles (BA funds)	PFR	Stock market	Stock market

INFRASTRUCTURE

"In order to grow we will have to build our own R&D facilities."

Executive, Biotech company

KEY CONCLUSIONS

- There is world class research infrastructure at key Polish universities.
- Infrastructure at universities is difficult to access by biotechnology companies.
- There is a strong need to open the existing academic infrastructure to high-end commercial R&D companies (this process should be selective based on the quality of science).
- Most technology parks with lab space dedicated to biotechnology are full.
- There is a need to develop more commercial infrastructure to accommodate for the growth of the sector and individual companies' expansion.

INTRODUCTION

As with other high knowledge sectors, the life science industries rely on high value and complex infrastructure requirements including basic research facilities, process plants, packaging, and distribution capabilities. A distinguishing feature of the life sciences industries, in contrast to the wider innovation sector, is the requirement of well equipped, and therefore costly laboratories already at an early stage of the product development cycle. This is a complicating factor in the general infrastructure landscape required for a health life science and pharmaceutical sector as infrastructure expansion and operation requires constant investment.

In that respect intensive rounds of EU funding have helped to improve existing laboratories and foster the creation of new science and technology parks across Poland.

The capital city Warsaw is the country's main research hub with numerous pharmaceutical companies making it their base in Poland. In terms of R&D infrastructure expansion the main Warsaw based universities completed major projects. These include the creation of the Centre of New Technologies at the University of Warsaw (CeNT UW) which is an interdisciplinary research institute dedicated to the understanding of important biological, chemical and physical phenomena. Another project is the Centre for Advanced Materials and Technologies (CEZAMAT) at the Warsaw University of Technology.

The centre is one of the largest investments in Poland in the field of high-tech R&D funded largely through EU grants. The project envisages the establishment of a network of interdisciplinary laboratories equipped with state-of-the-art tools. The goal of the centre is to conduct applied research with the aim to produce new commercial products and solutions. It is worth to note that Warsaw currently does not have a commercial incubator or laboratory facilities for biotechnology companies.

Other cities have also seen an increase in research facilities investment. One of the most prominent developments is The Małopolskie Centre of Biotechnology in Krakow build by the Jagiellonian University which received €24 million in EU-financed structural funds. Another significant development is the PORT science campus with over 2,000 square meters of laboratory space which received over €200 million in EU and public funding[23]. It is one of the few research centres which offers facilities and research equipment for industrial use with the aim to allow the industrial companies to innovate in collaboration with academic institutions in Wroclaw which is the seat of the institute.

There are over 80 other dedicated science and technology parks in Poland with a focus on strategic Polish sectors including biotechnology, however, only a handful of dedicated life science/biotechnology parks totalling 6 biomedical and biotechnology clusters and 8 dedicated technology parks for pharmaceuticals and life science research[24].

RESULTS

In order to determine how easy or difficult it would be for a biotech company to rent a suitable commercial research laboratory we contacted the main Science Parks and Research Centres (Figure 17, Table 6).

Of the 17 science and technology parks and centres interviewed, 88% offered dedicated laboratory space suitable for life science research, however some of these (15%) did not offer basic equipment necessary for standard molecular biology research. Five of the sites interviewed (29%) had lab space available for rent at the time of asking however all of those institutions except the EIT+ (PORT) had at least 75% of their laboratory space already occupied and the total space still available for rent was not more than 300 sq. meters per site. This lack of available laboratory space is echoed in the findings of the Cluster Benchmarking in Poland (2014) - General Report[25], which also concluded in the survey of clusters and occupying companies that while office space is in plentiful supply, access to fixed assets (i.e. capital equipment was rated "very difficult" for over 27% of cluster users. If the research parks and centres are to be an important factor supporting the R&D and innovative activity in the Polish economy, laboratory resources need to be considerably improved.

Additionally, it is worth noting that despite the substantial investments made by various leading academic institutions in Poland, the existing research centres are difficult to access by external commercial biotech companies as they are either exclusive to the various universities' members, spin-out companies, or are running at full capacity. An important reason for the hindered access to university based infrastructure are legal definitions of assets. According to the OECD Economic Survey: Poland 2018[26], university assets such as IP, technology licenses and designs but also laboratory infrastructure and equipment are subject to classification as public goods and applicable to public finance law, which is significantly disadvantaging industry collaboration[27].

With regards to the commercial research parks, industry insiders whom we have interviewed also pointed out that many of those parks which are currently full do not make plans for further expansion despite high demand from the biotech sector. These are important issues which should be further investigated and addressed as the lack of access to infrastructure could seriously damage the growth potential of the Polish biotech sector.

Figure 17. Availability of R&D infrastructure for rent by commercial biotechnology companies.

Table 6. Availability and capacity of commercial laboratory facilities in Poland.

NAME	DO YOU HAVE IN YOUR OFFER A LABORATORY SPACE AVAILABLE FOR RENT TO BIOTECHNOLOGY COMPANIES?	DOES YOUR LAB SPACE HAVE THE BASIC MOLECULAR BIOLOGY EQUIPMENT (PCRS, FUME HOODS, CENTRIFUGES)?	WHAT IS THE TOTAL LABORATORY AREA FOR RENTAL?	WHAT PERCENTAGE OF YOUR TOTAL LAB SPACE IT IS STILL AVAILABLE FOR RENT?
Białystok Science and Technology Park	Yes	Yes	1 800 m2	0%
Bionanopark - Lódź	Yes	Yes	6 000 m2	0%
Centre of New Technologies University of Warsaw (CeNT UW)	Yes	Yes	Information not provided	Difficult to access/occupied
PORT	Yes	Yes	2,000 m2	Information not provided
Gdansk Science and Technology Park	Yes	Yes	6 000 m2	0%
Kardio-Med Silesia	Yes	Yes	Information not provided	Information not provided
Krakow Life Science Park	Yes	Yes	7 500 m2	0%
Krakow Technology Park	No	N/A	N/A	N/A
Lublin Science and Technology Park	Yes	No	1 300 m2	0%
Olsztyn Science and Technology Park	Yes	No	937 m2	23%
Pomeranian Science and Technology Park Gdynia	Yes	No	1500 m2	0-1%
Poznan Science and Technology Park of Adam Mickiewicz University Foundation	Yes	No	4 000 m2	0%
Science and Technology Park Poland-East in Suwałki	Yes	N/A	N/A	N/A
Puławy Science Technology Park	Yes	Yes	1 100 m2	20 - 25%
Wielkopolska Centre for Advanced Technologie	Yes	Yes	2 000 m2	10 - 15%
Wrocław Technology Park	Yes	Yes	7700 m2	2%
YouNick	Yes	No	400 m2	0%

SWOT ANALYSIS

STRENGTHS

- Polish science follows global trends and can already produce world-class results.
- Poland has a robust higher education system producing 2000 biotechnology graduates every year.
- Poland has a strength in mathematical sciences and informatics which are at the core of industry 4.0 (connectivity, AI) currently transforming the biotech sector.
- First Polish companies start developing novel, "first-in-class" therapeutics, hence obtaining critical "know-how".
- Poland is a leading CRO market and has a high number of professionals working in the clinical trials sector.
- There is a significant amount of early stage Proof of Principle and Proof of Concept public funding for translating science into innovation.
- There is significant amount of world class research infrastructure at key Polish research universities.
- Polish government treats innovation and the biotech sector as key priorities.

WEAKNESSES

- The volume of top quality science is an order of magnitude lower than in leading EU countries.
- Polish ecosystem still did not generate the critical mass of later-stage startups developing innovative products which could attract the interest of multinational bio-pharma companies. Biotechnology firms lack for experienced management and specialists in their early stages of development.
- There is a clear gap in the investment landscape at a Series A venture capital round (1M USD to 5M USD) and also at later stages (15M USD +).
- PFR is the only large investor in the life science sector in Poland with total investment budget of just over 80 M USD (300 M PLN) and ticket size of 8M USD to 13 M USD (30 to 50 M PLN).
- There is strong need of "smart money" at all stages of the investment cycle (from early seed stage to IPO) as most investors in Poland do not have the biotechnology domain expertise and networks necessary to support the projects they invest in.
- There is a luck of diversity of funding options for biotech companies with public funding dominating the sector.
- Infrastructure at universities is difficult to access by biotechnology companies. The majority of technology parks with lab space dedicated to biotechnology are full.

OPPORTUNITIES

- There is a large number of young Polish scientists working in top global research universities. Additionally the global research system produces many more PhD and Postdoctoral scientists versus the number of available faculty positions. Poland should aim to attract young and promising Postdoctoral fellows from leading international universities and especially from leading established laboratories who should be given an early opportunity to setup independent research groups for example under the umbrella of the Virtual Research Institute/ PORT.
- Poland should leverage its strengths in computer sciences and mathematics to develop new research fields on the cross-section between molecular and structural biology, omics (genomics, transcriptomics, proteomics, epigenomics) and data science. In particular we see artificial intelligence applied to target and drug discovery and development as a major opportunity for Polish scientists, innovators and companies.
- The manufacture and development of biosimilars to novel biologics is an important area where Poland could excel. These "copycat" drugs are sophisticated biological equivalents of existing biological drugs that have already been approved for medical use through clinical trials and therefore have a better risk profile. A significant R&D effort is needed to develop an equivalent version of the original moiety providing a high entry barrier to potential competitors. Poland's skilled workforce typically comes with a lower price tag than the workforces in Western Europe's pharmaceutical hubs in Switzerland or Germany, while possessing the know-how, manufacturing infrastructure, and quality assurance needed for these products.
- Brexit can be an important event in Poland's favour also in the biotech sector. A number of skilled scientists and managers who gained experience at top British universities and in leading companies will consider returning home if the Polish sector can offer them attractive opportunities to either find jobs or start up their own ventures. Additionally, the biggest recipients of EU funds are UK and Germany. Assuming that the UK will discontinue or decrease its participation in financing of EU research programmes, Brexit presents a chance for Poland and other EU countries to leverage funds previously directed towards major British universities.

THREATS

- Over-reliance on public funding and lack of diversity of other sources of capital can lead to a collapse of the sector in economic downturn (i.e. due to lower tax revenues and necessary cuts to public spending) or in the case of countries like Poland in case of the failure to secure substantial funding from the EU budget.
- Biotech companies which go for an IPO prematurely due to the lack of other sources of capital may disappoint stock market investors leading to a long term damage to the financing of the sector due to investors becoming overly risk averse towards biotech. Such scenario took place in the UK in the early biotech days in the 1980s and 1990s.

CASE STUDIES: INTERNATIONAL ORGANISATIONS DEDICATED TO CATALYSING INNOVATION

The models used for transferring knowledge, know-how and technology from research universities to the industry have undergone a quiet revolution in the past 5 years. Traditional Technology Transfer Offices (TTOs) are still predominant, but leading universities, research organisations and industrial companies are establishing new structures which take a more holistic and connected approach to science translation. Such structures will become critical in integrating and developing science and innovation ecosystems. Hence, we are presenting three distinctive case studies which can be used as benchmarks for establishing an operational model for their Polish equivalent, the Virtual Research Institute (Pol. Wirtualny Instytut Badawczy, WIB).

CASE 1 - VLAAMS INSTITUUT VOOR BIOTECHNOLOGIE (VIB)

1) What is the purpose/problem the organisation is trying to solve?

Created in Belgium in 1995 as an initiative of the Flemish government, VIB (Vlaams Instituut voor Biotechnologie) is a unique example of a non-profit support structure for a particular scientific domain (biotechnology) working towards both excellence in research and transformation of the results of such research into economic growth.

What is the mission and vision?

VIB's mission is to conduct frontline biomolecular research in life sciences for the benefit of scientific progress and the benefit of society.

What is the added value of the organisation?

VIB provides the Flanders region with the following:

- an opportunity to invest in technology
- attraction of young & high potential scientists
- conducting commercial exploitation of scientific results
- nurturing startups
- providing advanced research facilities for industry
- improving science communication to the community

2) How does it function?

A) Scientifically:

It is a decentralized institute with departments, labs and research facilities at universities throughout Flanders.

How does VIB select scientists?

VIB increasingly puts efforts into attracting the world's leading scientists. Calls for international projects are made among young scientists seeking to create independent research groups within VIB.

How scientists are evaluated?

1. Evaluation or research groups is done by independent external exerts.
2. Lack of productivity leads to loss of affiliation (no tenure).
3. The evaluation criteria are:
    - the number of publications
    - patents
    - income from industrial collaboration
    - creation of start-ups
    - authoring of PhD theses
    - and capacity to attract industrial and international funding

B) Operationally:

What is the organisational structure:

Recent reorganization of VIB involved the clustering of former departments and independent research groups in 8 research centers. Their role will be to increase the efficiency of support from VIB headquarters and from the universities.

How/by whom was the institution set up?

VIB was funded by the Flemish Government and works in close partnership with five universities: University of Gent, KU Leuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University.

Who governs it, who makes decisions?

VIB is a non-profit, autonomous research institute, headed by a general assembly and a board of directors from which:

1. The general management is responsible for running VIB on a daily basis.
2. The scientific directors scientifically lead the institute and head the VIB research departments.
3. The institutional advisory board assists VIB in its institutional policy.
4. The general assembly is the organisation's most senior body and consists of 35 members from academic, public and industrial circles.

Who provided the initial funding/who provides ongoing funding?
VIB is a non-profit, autonomous research institute initially funded by the Flemish Government. Currently significant proportion of VIBs funding comes from independent grants, industry collaboration and science commercialisation.

Do the scientists and partners need to move to a single location or is it more virtual?
VIB provides research laboratories but not all scientists and partners need to relocate to the institution.

3) What are the key structural elements of the organisation/activities the organisation is performing? (e.g. basic science research, acceleration of companies, incubation of companies, etc.)

VIB's key activities can be divided into four:

- Basic research and technological advances in the whole region of Flanders: VIB concentrates on diffusing the institutional knowledge and advance technology in the entire Flemish academic and industrial community. VIB focuses on developing and attracting advanced technologies which must not only be integrated in VIB's research laboratories but also be advantageous to the whole of Flanders.

- Commercial exploitation: The results obtained in their research laboratories are exploited through submission of patents, collaboration with industry and the creation of innovative companies. A dedicated team is concerned exclusively with technology transfer. Income from these activities exceeds 10% of the VIB budget and all profits are immediately ploughed back into research.

- Creation of start-ups: The five-year contract signed with the government includes the creation of at least one start-up each year. VIB has its own dedicated acceleration programme.

- Incubation of companies: VIB offers fully licensed laboratory and office facilities for life sciences companies in its bio-incubators in Leuven and Ghent. However, these incubators are not designed exclusively for use by companies emanating from the VIB but are in fact open to all young companies active in biotech R&D, including foreign companies.

CASE 2 - THE BIOINNOVATION INSTITUTE

1) What is the problem the organisation is trying to solve?
The Novo Nordisk Foundation (NNF) has established the BioInnovation Institute (BII) in order to improve research translation by bridging the commercialisation gap between academia and industry. Despite having a strong focus in life-science research, Denmark has shown limited success in translating excellent research discoveries into new products and services due to limited support and resources dedicated to it. Therefore, BII aims to help the most talented researchers and entrepreneurs in developing and maturing research projects until they can attract capital on market terms. BII is expected to open its facilities, labs and office space in the second half of 2018.

What is the mission and vision?
BII is a Danish initiative with an international perspective. The vision is to position Denmark as a leading international life sciences research, innovation and entrepreneurship ecosystem. The mission is to promote research-based innovation within biotechnology, biomedicine and related disciplines, and translate this into novel biomedical and biotechnological solutions, products, start-ups and companies.

What is the added value of the organisation?
The Bioinnovation Institute will:

1. act as an open portal in the Copenhagen Bioscience Cluster for entrepreneurs from all Danish and international universities.
2. seek to establish synergy with existing national innovation initiatives from industry, hospitals and Government.
3. create a functional bridge between novel research-based innovation and start-up companies.

2) How does it operate?

A) Scientifically:
How does it select scientists and partners?

- Open calls: BII will publish open calls for programs in the second half of 2018.
- Scouting: BII will also actively scout for research projects which, upon evaluation, are to be invited in to BII from academia, research hospitals and industry.

Evaluation committees will evaluate and prioritise applications for Discovery and Transition/ Incubation programmes (explained below in "Key structural elements of the organisation"), and also oversee project development. On top of robust scientific excellence, the selection process will prioritise people and projects on the basis of entrepreneurial, open and ambitious personality, commitment, drive and potential.

How scientists are evaluated and rewarded:

- Evaluation: Projects will be evaluated by the Discovery Evaluation Committee or the Incubation Evaluation Committee, each of which will consist of 4-6 members selected by the Board, with supplementary support from relevant experts and between committees when required.

- Reward: if mutually agreed milestones are achieved, the most promising projects and committed teams will receive continued funding and support. BII offers a number of grants and convertible loans to successful project teams:

a The Discovery Grant: it provides up to DKK 1 million per year over 5 years, with a further DKK 5 million to pursue novel research ideas developed within the Discovery programme.
b Proof of Concept Grants: up to DKK 1 million will be available to projects developed within the Discovery programme, and also to external investigators via open call.
c Accelerator Grant: in the Business Acceleration Academy, up to DKK 0.6 million is available to support items such as salary, consultancy and travel expenses.
d Financial support for projects entering the Incubation programme (from within or outside BII) will be given as convertible loans attached to the two sub-programmes: the Creation House and the Traction Factory. Creation House loans will be up to DKK 10 million and Traction Factory loans will be up to DKK 5 million, both over a period of up to 18 months.

B) Operationally:

How/by whom was the institution set up?

In 2015, the NNF Board of Directors investigated how to position Denmark as a leading international innovation ecosystem within the life sciences. This led to the preparation of the vision paper for BII after extensive engagement with key stakeholders in Denmark and worldwide. Inspired by the strongest bioscience research hubs and incubators in the US, Asia and Europe, common factors for success were identified and adapted to the Danish life-science innovation ecosystem. The scope and potential impact of BII were defined, and the vision paper was approved by the NNF Board of Directors in December 2016.

Who governs it, who makes decisions?

Two main teams lead the decision making in BII:

- The BII Board: it consists of 6-8 members, representing the entire BII value chain and providing a thorough understanding of the environment in which BII operates. The Board sets the vision, strategy and direction of BII, holds overall responsibility for budgets, and is responsible for hiring the BII leadership team.
- The BII leadership team: it will consist of 8 members, including director, head of operations, head of science and technology, head of business and entrepreneurship, lead investigators and lead entrepreneurs. The current director is Thomas Nagy.

Who provided the initial funding/who provides ongoing funding?

- Initial funding: BII is a long-term, 10 years initiative. The NNF has awarded BII a grant of DKK 392 million to cover the 3-year establishment phase (2018-2020). By 2020, the BII is projected to have established its team, developed the framework for the programs, opened the facilities, laboratories and office space, published calls for programs, and awarded the first grants and loans.
- Ongoing funding: After the establishment phase is evaluated, the NNF Board of Directors will decide whether to establish BII as an independent foundation for years 4 to 10.

Do the scientists and partners need to move to a single location or is it more virtual?

BII activities will be located in the Copenhagen Science City in central Copenhagen to create synergy with the existing research environments and laboratory facilities.

3) What are the key structural elements of the organisation/activities the organisation is performing?
BII will be structured into four phases, each of which is comprised of specific programmes:

1. Discovery: Idea generation and research, thereby providing a pipeline of interdisciplinary projects for entry into subsequent phases.
2. Transition: Proof of concept for promising projects from Discovery and outside BII, along with hands-on educational programme on business formation and early planning.
3. Incubation: Business formation and solution refinement, backed by loans.
   Growth: Offers opportunity for start-ups to continue to benefit from mentoring, facilities and networking opportunities offered by BII.

4) What are the elements/ pillars supporting science translation? How they are organised?
In order to support science translation, BII is building a community of scientific, technical and commercial experts as well as support staff. They will provide the following:

1. Support: full-time employed experts will be engaged with BII start-ups, and provide general research and problem solving. External consultants may be engaged where specific sector skill sets are necessary.
2. Partnership: BII will actively seek partnerships with other internationally renowned institutions such as ETPL, QB3, LabCentral and the Wyss Institute in the form of staff exchanges, joint conferences, events and research activities.
3. Collaboration for research: BII will facilitate access to existing specialised infrastructures via collaborations with universities and other research institutions.
4. Collaboration with industry: BII will be very open to collaboration with industry.

CASE 3 - THE MILNER THERAPEUTICS INSTITUTE

1) What is the problem the organisation is trying to solve?
The Milner Therapeutics Institute is a global therapeutic alliance based in Cambridge (UK), dedicated to the conversion of basic science into therapies. It is a new paradigm for an academic Institution, based on bridging the gap between academia and Industry. The institute is the hub of 65 Affiliated Organisations worldwide and will have its own Research Labs within the Capella building at the Biomedical Campus from the University of Cambridge, due to open at the end of 2018.

What is the mission and vision?

The institute represents a new paradigm, in which an academic institution harnesses a global therapeutic alliance to deliver better therapies.

Its mission is delivered through three distinct avenues:

1. by connecting academic institutions with pharmaceutical and biotech companies,
2. by enabling collaborative research projects throughout Cambridge, and
3. by accelerating the formation of new biotech companies with a therapeutic outlook.

What is the added value of the organisation?

The added value of the Milner Institute is realised through creating synergies between various stakeholders in the therapy development ecosystem:

- a partnership of 3 Cambridge academic Institutions and 7 pharmaceutical companies who have signed an agreement to engage in pre-competitive research in Cambridge (the Therapeutics Consortium);
- a set of 14 Affiliated Institutions and 39 Affiliated Companies enjoy networking opportunities within the ecosystem;
- 2 Affiliated Venture Partners help to mentor entrepreneurs setting up biotech companies
- Additionally, the Milner Institute organises networking events, symposia and workshops to enhance interactions within the alliance.

The Therapeutics Consortium has been active since June 2015 and, as mentioned previously, it is based on a research agreement signed by three academic centres in Cambridge--the University of Cambridge, the Sanger Institute and the Babraham Institute-- and seven pharmaceutical companies-- Astex, AstraZeneca, GlaxoSmithKline, Shionogi, Pfizer, Elysium and Johnson and Johnson. The agreement is designed to facilitate the speedy exchange of reagents and information and to underpin research collaborations leading to publications.

This Consortium will provide researchers with the potential to access novel therapeutic agents (including small molecules and antibodies) across the entire portfolio of drugs being developed by each of the companies, in order to investigate their mechanism, efficacy and potential.

2) How does it operate?

A) Scientifically:

How does it select scientists and partners?

Scientists based or affiliated with the Milner Institute are selected by an independent panel of experts based on the scientific and translational merit of their research.

Partners are vetted based on their international reputation as leading research and innovation organisations.

How are scientists evaluated and rewarded?

Scientists are evaluated on the basis of their academic publication output. Additionally, collaborations with the industry partners are taken into consideration. Only the best performing research groups can maintain their affiliation with the institute.

B) Operationally:

How/by whom was the institution set up?

The Institute was founded by the University of Cambridge. The therapeutics concept and mission was developed following the establishment of the Therapeutics Consortium by Tony Kouzarides.

Who governs it, who makes decisions?

- Boards: The Milner Institute has a number of Boards and Committees to provide advice and guidance on science, strategy, policy, funding, and administration. Board members include representatives of industrial companies who belong to the Consortium, Scientific Advisors and representatives of the University of Cambridge.
- Direction: The Milner Therapeutics Institute is directed by Professor Tony Kouzarides. Kathryn Chapman is the Executive Manager responsible for day to day management of the institute.

Who provided the initial funding/who provides ongoing funding?

- The Initial funding was provided by a businessman and philanthropist Jonathan Milner (a donation of £5 Million) and the University of Cambridge
- The ongoing funding will be based on competitive research grants as well as income from industry via the Milner Therapeutics Consortium. The institute does not have any core funding.

Do the scientists and partners need to move to a single location or is it more virtual?
The Milner team are based at the Gurdon Institute, but will move to the Research Laboratories when they are built, both within the University of Cambridge, UK. Partners and other scientists are not obligated to move into the new facilities, but are able to rent laboratory space to conduct research there. Most of the members of the Consortium signed rental agreements with the institute.

3) What are the key structural elements of the organisation/activities the organisation is performing? (e.g. basic science research, acceleration of companies, incubation of companies, etc.)
The Milner Institute is trying to:

a. Connect industry and academia - The goals of the Milner Institute are realised through a global therapeutic alliance of industry and academia partners (mentioned in question 2A) who have signed an agreement to engage in pre-competitive research in Cambridge (the Therapeutics Consortium);
b. Enable collaborative research - The Milner Institute enables collaborative research by lowering the barriers of engagement between industry and academia, also via the Therapeutics Consortium agreement;
c. Accelerate biotech spin-offs - The Milner Research Labs aim to provide such opportunities for budding entrepreneurs.

4) What are the elements/pillars supporting science translation? How they are organised?

Thanks to the Therapeutics Consortium agreement, the research labs of the Milner Institute will have academic and industry funded researchers working together, providing a unique research environment for science translation and therapeutic development.

Additionally, in 2018 additional research capabilities will be provided in the Milner Research Labs on the Cambridge Biomedical Campus. The labs will house computational biology, disease modeling, phenotypic drug screening and an entrepreneurial program for the development of biotech companies.

RECOMMENDATION FOR AN OPERATIONAL MODEL FOR WIB TAKING INTO CONSIDERATION THE LOCAL LANDSCAPE AND DEVELOPMENT OPPORTUNITIES

> *"The Institute will be a "virtual" platform for cooperation of scientists from all over the country who, working at universities in various Polish cities, e.g. in Szczecin, Krakow or Lublin, as well as abroad, will apply to the Polish Center for Technology Development (PORT) for financing of their projects. They will form virtual teams connecting various research centers, creating a real, top-notch research value. We want for this cooperation to lead to the creation of breakthrough technologies and products, which is why intellectual property management and effective commercialization will be the foundation of this unique enterprise."*
>
> *- Piotr Dytko, President of the Board of the Polish Center for Technology Development PORT.*

KEY RECOMMENDATIONS:

- WIB needs to support the highest level, globally competitive science addressing fundamental biological problems as only through this activity breakthrough, disruptive knowledge can be created.
- WIB needs to work closely with funders of Polish science (e.g. the Foundation for Polish Science or the National Science Centre) and develop programmes to attract young ambitious postdoctoral scientists who should be able to setup independent research groups in Poland. The process for doing so should be seamless and the funding for research and benefits packages should be globally competitive.
- WIB should develop a network of science scouts searching globally for the best young scientific talents with the intent to attract them to Poland.

  WIB needs to avoid focusing on translational science as its core scientific activity as this will only lead to incremental (process focused) innovation with low competitive potential on the global stage.
- WIB needs to avoid becoming a contract research centre for the industry but can function alongside a comprehensive scientific services environment which can also be leveraged for the benefit of basic research.
- WIB should aim to attract industry partners (small, medium and large companies), who should be able to rent research and office space and work next to academic scientists. The selection of industry partners should be strict and only R&D focused activity should be allowed ideally at the early research stages.

- WIB needs to develop a new model of "co-working" between the industry and academic scientists where both work on independent basic research projects but share research and office facilities. Through these new relationships and cross-fertilisation of ideas can be achieved. Intellectual property in such an environment can be protected by suitable confidentiality agreements as is practiced at the Milner Institute (University of Cambridge).
- WIB needs to create world-class support structures for efficient science dissemination and translation into innovative products or services (such structures would include an accelerator, a translational science conference, a global network of innovation brokers).
- WIB should seek early partnerships with similar international organisations such as the VIB in Belgium, the Milner Institute in the UK or the BII in Copenhagen. Such partnerships should be based on joint funding programmes to finance collaborations within specific scientific areas (e.g. artificial intelligence in drug discovery).
- Science areas which should be of particular interest to WIB should include machine learning / artificial intelligence applied to structural biology, genomic, proteomic, epigenomic and metabolomic analyses as well disciplines related to molecular neurobiology.

POLICY RECOMMENDATIONS FOR THE POLISH BIO-INNOVATION SECTOR BEYOND WIB

STRATEGIC

- The government should finance countrywide programmes of genome sequencing especially in various patient populations. The anonymised data coming from such population genomics programmes should be deposited in a network of bio-banks and freely available to academic researchers but also to innovative R&D companies based in Poland. Such approach would allow to boost Polish science and innovation especially in areas which can leverage the use of artificial intelligence in large genomic data set processing such as functional studies of genes and proteins. This would also provide a competitive advantage to Polish companies involved in the discovery of novel therapeutic targets and innovative drugs.
- The government through its relevant funding agencies should also create a dedicated funding scheme for university researchers and innovative companies working on solutions for increased data safety and anonymity, e.g. solutions based on the blockchain technology as well as dedicated grants aimed at further development of the core machine learning technology with application to healthcare and other sectors.
- Incentive schemes for patients sharing their genomic, epigenomic, metabolomic (etc.) data should be designed and piloted at leading hospitals.
- In parallel an extensive campaign explaining to the public the benefits of sharing anonymised biometric data with the research, healthcare and innovation sectors should be designed and implemented.

OPERATIONAL

- There is a need to modify the law such that university infrastructure is not subject to stringent audit rules under the public finance law and universities are given maximum flexibility in pricing the usage of such infrastructure depending on market demand.

  In parallel the relevant government agencies responsible for funding science and innovation in partnership with NGOs such as the Foundation for Polish Science should organise a series of roundtable meetings between the leadership of universities, the biotechnology and pharma sector and policymakers aimed at clarifying the rules within existing legislation and encouraging collaboration.
- There is a need to coordinate government policies designed to support innovation and entrepreneurship with policies related to healthcare provision. Those companies which can develop in Poland innovative products and solution leading to improved clinical outcomes should be able to get reimbursements for such products.
- Poland should join the European ELIXIR network set up to coordinate, integrate and sustain bioinformatics resources across its member states and enable users in academia and industry to access important streamlined R&D services related to managing and safeguarding the increasing volume of data being generated by research.
- The government through its relevant agencies should support Polish companies wishing to take part in international trade shows as well as support organisation of leading conferences and trade shows in Poland. These events should create a platform to showcase top quality Polish bio-science and innovation.

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