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<p>This report presents the results of the first phase of the ecosystem analysis for Sano, providing preliminary insights into the framework conditions and actors, challenges, and drivers relevant for the development of computational medicine in Poland and the Malopolska region. Besides mapping the framework conditions and relevant stakes, it examines factors promoting and hindering innovation and detects potential challenges for the creation of Sano. Based on these insights recommendations for Sano are outlined.</p>
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# 1. Introduction

This report aims to provide an analysis of the ecosystem within which Sano is being established in Krakow, the Malopolska region and more widely in Poland. It covers the macro level of socio-economic development in Poland, the Polish healthcare system and the framework conditions for innovations, then zooms in on the meso level of the Malopolska region as well as the micro level of important stakeholder groups and their requirements. The paper concludes with drivers and barriers for computational medicine and recommendations for Sano. It is based on a literature review, analysis of publicly available data, interviews and a workshop with stakeholders. As the establishment of Sano proceeds, it will be updated in regular intervals.

Poland has a total population of approximately 38 million (2017) and is located in Central and Eastern Europe. It is a unitarian country with a high level of centralisation, giving high importance to state-wide regulations, structures and actors. Beneath the national level, there are 16 regions (voivodships) with limited autonomy. Regional authorities are elected in a separate ballot and are mainly in charge for regional planning. The national government appoints a governor (wojewody) for each region, responsible for supervising the activities of local self-government.

The Malopolska region, situated in southern Poland, is one of the smallest regions in the country, representing only 4.5% of the country’s territory. However, with 3.34 million inhabitants in 2017, it belongs to the most densely populated regions in Poland, with a significant concentration (762,500) in Krakow, the metropolitan centre of the region and the second largest city in Poland. Krakow is the main economic, academic and cultural hub of the region. Malopolska is located next to the Polish regions of Silesia (Śląsk), Holy Cross Province (Świętokrzyskie), Podcarpathia (Podkarpackie) and neighbouring the Slovak Republic in the South (see Figure 1).



Figure 1: Location of Malopolska region in Poland and neighbouring countries.



## 2. Socio-Economic Development in Poland

### 2.1 Main characteristics of economic development

During the entire post-communist transformation period, Poland experienced dynamic economic growth and made great progress in modernising the economy and infrastructure. Measured in real terms, the Polish GDP per capita in purchasing power parities in 2018 reached a level that was almost triple of that in 1990. However, it is well below that of countries such as Slovenia, Czech Republic, Slovakia and Estonia and the income gap with the EU's high-income countries, such as Germany, is still considerable (Figure 2).

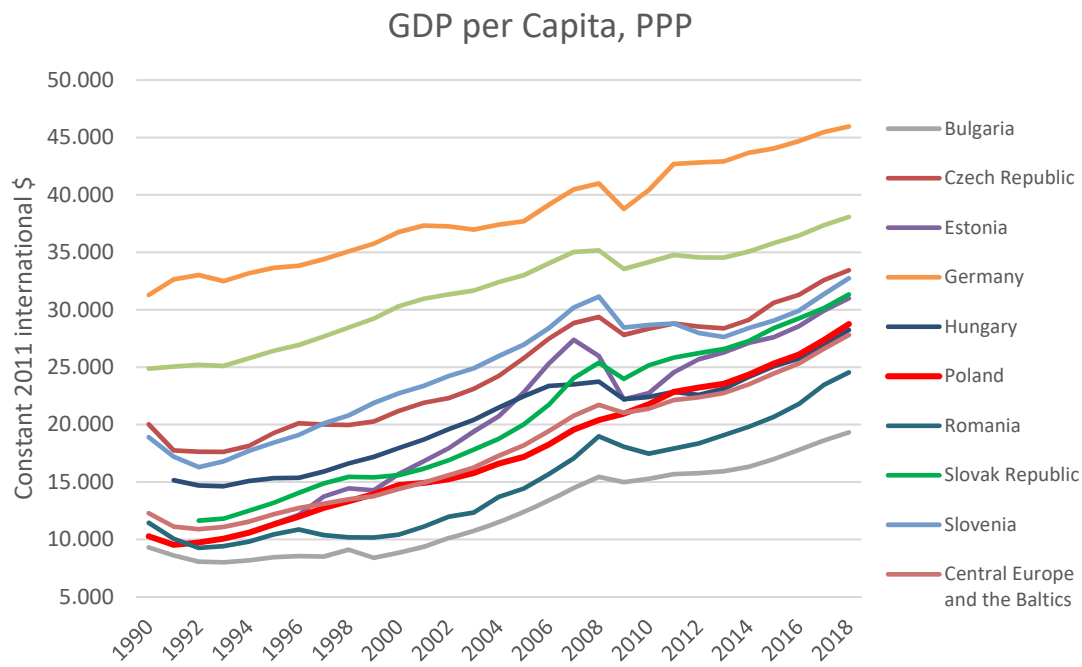


Figure 2: Development of the real income per capita in PPP. Source: World Bank Open Data.

So far, the growth success of the country has essentially been based on the exploitation of the extensive growth potential through a massive inflow of foreign direct investments, the intensification of trade and the associated expansion of productive capacities in manufacturing and service sectors, vast public investments supported by EU funds as well as continuously rising private consumption. They have been the country's key growth drivers (see Figure 2). Through outward investments, Poland has become successfully integrated into the European economy and the global supply chains. Since 2014, growth in services exports has outstripped those in goods exports due to the increasing importance of Poland for business process outsourcing and logistics for European and multinational enterprises (OECD Economic Surveys 2018).

Having started from a very low level in the 1990s, Poland experienced a robust productivity growth (Table 1, Figure 3 **Fehler! Verweisquelle konnte nicht gefunden werden.**) throughout the whole period, however, it was mainly driven by restructuring of the economy and moving from less to more productive sectors (OECD Economic Surveys 2018) and enhancing production capability by assimilating and adopting foreign technologies, (Radosevic 2017). Strong fluctuations in productivity



growth rates throughout the whole period shown in Figure 3 reflect to a large extent these restructuring processes. The productivity growth has so far not been innovation- and skill-based, so that the productivity gap with the leading EU countries is still significant: the real productivity per person employed in 2017 was only 35% of that of Germany's and 30% of Sweden's real productivity. Hereby, Poland belongs to the EU countries with the lowest level of productivity. In recent years, the productivity growth in real terms has been rather moderate: in 2017, its level was only 12% higher of those in 2008 (Figure 4). Small and medium enterprises show particularly low productivity.

*Table 1: Key economic data*

Indicator	Poland				Central Europe and Baltics				Germany				European Union			
	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018
GDP per capita, PPP (constant 2011 international \$)	14.733	21.771	28.752	32,1%	14.388	21.388	27.805	30,0%	36.765	40.429	45.959	13,7%	30.308	34.148	38.080	11,5%
Foreign direct investment, net inflows (% of GDP)	5,4	3,8	2,1	-46,5%	5,5	1,6	-2,1	-237,7%	12,7	2,5	2,6	4,6%	8,2	3,4	0,3	-92,2%
Export volume index (2000 = 100)	100,0	275,8	438,0	58,8%	..	..	..	..	100,0	137,6	158,3	15,0%	..	..	..	..
Exports of goods and services (% of GDP)	27,2	40,1	55,3	38,1%	38,1	52,3	65,5	25,1%	30,8	42,3	47,0	11,2%	34,3	38,3	44,8	16,9%
Real labour productivity per person, 2010=100	72,1	100,0	118,3	18,3%	..	..	..	..	94,3	100,0	106,1	6,1%	..	..	..	..
Final consumption expenditure (% of GDP)	81,7	80,7	75,9	-5,9%	..	..	..	..	75,8	75,2	72,0	-4,3%	..	..	..	..
Households final consumption expenditure per capita growth (annual %)	4,0	3,0	4,4	44,3%	3,4	0,5	4,6	746,2%	2,0	0,5	0,8	46,0%	3,1	0,6	1,4	145,6%
Medium high-technology manufacturing (% of manufacturing)	..	27,2	25,4	-6,6%	..	..	..	..	48,7	51	..	4,7%	..	..	..	..
High-technology manufacturing (% of manufacturing)	..	6,3	4,9	-22,2%	..	..	..	..	9,8	10,3	..	5,1%	..	..	..	..
Medium low-technology manufacturing (% of manufacturing)	..	31,4	36,5	16,2%	..	..	..	..	25	24	..	-4,0%	..	..	..	..
Low-technology manufacturing (% of manufacturing)	..	35,1	33,2	-5,4%	..	..	..	..	16,5	14,8	..	-10,3%	..	..	..	..
Knowledge-intensive market services (% of total business economy)	..	12,1	13	7,4%	..	..	..	..	19	21	..	10,5%	..	..	..	..
Ease of doing business index (1=most business-friendly regulations)	..	..	33,0	..	..	..	..	..	..	24,0	..	..	..	..	..	..
Start-up procedures to register a business (number)	..	7,0	5,0	-28,6%	..	6,2	5,6	-8,8%	..	9,0	9,0	0,0%	..	6,3	5,4	-14,3%

*Source: Eurostat, World Bank Open Data, own calculations*

Moreover, the share of sectors with low value added and technology and knowledge intensity, such as agriculture and forestry, mining, wholesale and retail trade, construction, accommodation and food service activities, food and beverages industries are significantly higher than in other European countries, which has a negative effect on the productivity growth of the Polish economy. Due to a favourable tax and social security regime for the agricultural sector, too many workers are engaged in small, low-productivity farms, while the employment share in high-tech sectors remains relatively low (OECD 2018c).

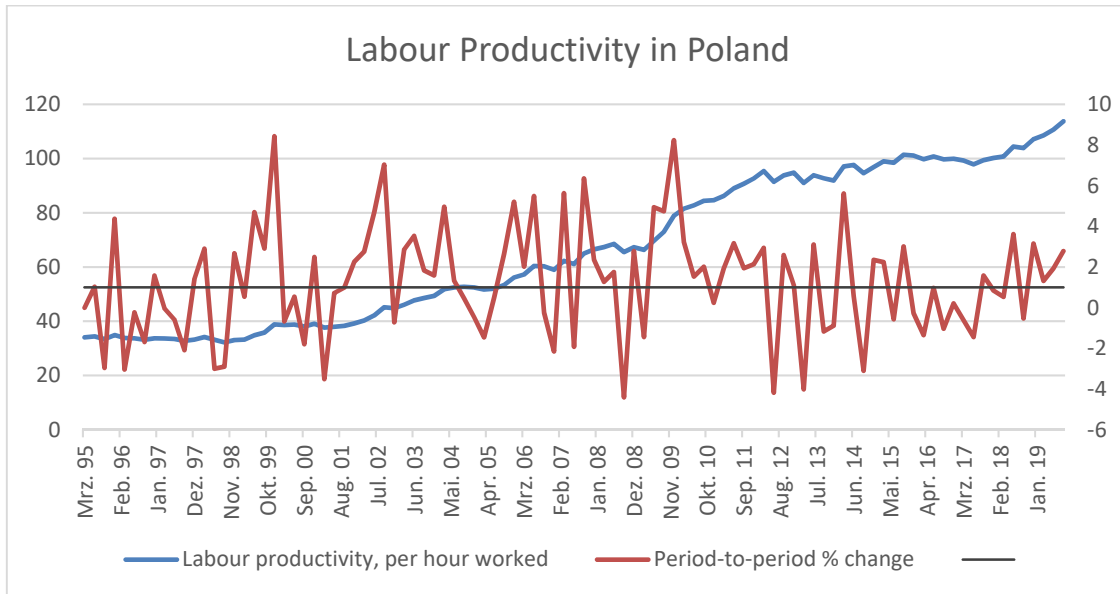


Figure 3: Labour productivity per hour worked, in chained-linked volumes based on the index of 2010. Source: European Central Bank.

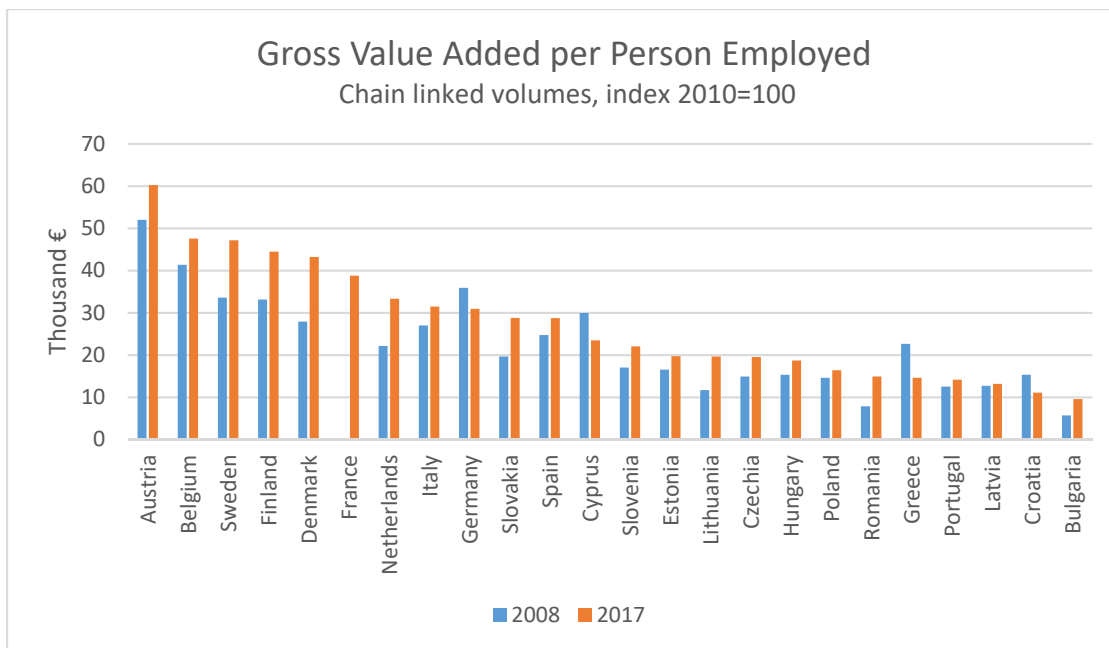


Figure 4: Real labour productivity of EU countries. Source: Eurostat, own calculations.

## 2.2 Industry Structure

Compared to the 1990s, the structure of the Polish economy has changed, moving away from traditional sectors to the higher value creating manufacturing and services. The Polish manufacturing sector is mostly dominated by low and medium-low technology sectors, collectively contributing about 70% to the total manufacturing value added (Table 1). Particularly the medium-low technology sector is playing an increasing role for the manufacturing sector, whereas the high technology and medium-high technology manufacturing contracted by approx. 22% and 6% each in 2018 compared



to 2010 (Table 1). The share of knowledge-intensive market services are continuously increasing, however somewhat less dynamically compared to the leading European countries. Overall, the structure of the Polish economy is predominantly characterised by labour-intensive, standardised activities with low technology and knowledge content offering fewer opportunities for R&D and innovations.

### *Structural Characteristics of SMEs in Poland*

The number of companies in Poland is higher than in many other EU countries, mostly due to the high share of micro enterprises. About 96.1% of the total 1.5 million enterprises employ fewer than 10 workers. Small enterprises (10-49 persons employed) make up 2.9% of all firms. The share of medium-sized enterprises (50-249 persons employed) is 0.8%. Only 0.2% of all firms are large enterprises (more than 250 persons employed) (European Commission 2019a). Compared with large companies, SMEs include far fewer industrial companies, and are more present in construction and trade. This is largely due to the necessity of industrial enterprises to operate under the condition of economies of scale and therefore most of the production takes place in large plants. The majority of Polish SMEs are in domestic hands - only 9.5% are firms with foreign capital. Thereof, 17% of all medium-size and 7.5% of small firms are foreign owned (Polityka Insight 2016).

67.1% of the working population in Poland are employed by SMEs, contributing collectively 52.9% to the total value added. The residual share of employees (32.9%) work in large enterprises that contribute 47.1% to the total value added. Large enterprises are highly integrated in the global production and service chains. They therefore account for a very high export intensity reflecting their orientation toward international markets. Overall, Polish SMEs contribute approx. 35% to the total intra-EU-goods-export value of the country. Polish microenterprises contribute only 6% to the total intra-EU-export, which is much lower than the EU-average (13.2%) (Eurostat 2017).

### *'Small Scale Trap' of Polish Microenterprises*

Polish micro and small enterprises (with less than 50 workers) are among the least productive in the EU (EBRD 2018). There is compelling evidence demonstrating the role of SMEs in the economic development of any country (e.g. Herr and Nettekoven 2017). Medium-sized companies are important for the growth as they create jobs, train young people and contribute to the competitiveness of countries and their regions through investment and innovation. They are an important factor for the continuous modernisation and economic dynamism of a country.

Microenterprises in Poland differ from other groups of enterprises as to the scale and nature of their activities. Although they play an important role in employment, there are some development traps related to business sectors dominated by microenterprises. Owners often lack either the ambition or the ability (or both) to gradually increase the scale of their operations, which is a significant barrier to business development in Poland. This phenomenon is called as the 'small-scale trap' (Polityka Insight 2016). The reasons for this development are manifold. One of the key hindrances for scaling up operations in small enterprises is the lack of availability of appropriately qualified staff. This relates not only to employees, but also to the management competencies and business knowledge of firm owners and managers needed for running and developing a business (Polityka Insight 2016). Another





problem is the particularly low level or entire lack of innovative activities of microenterprises in Poland. According to the Eurostat data, they account for only 10% of all business R&D expenditures, which is highly disproportionate considering their total share in the business sector. Lack of access to highly skilled employees is a considerable bottleneck to the development and strengthening of the innovation capability of small enterprises in Poland, as the availability of skilled and talented workers is necessary to be able to implement and drive innovations. Conversely, the availability and access to highly skilled employees would increase the willingness and motivation of the companies' owners to invest in innovations. Further reasons for the development trap of microenterprises and small businesses is their local scale of operation along with a high level of aversion to risk-taking. As a result, small(est) businesses are on the whole much less innovative and tend to grow more slowly than medium-sized and large enterprises in Poland (Polityka Insight 2016).

## 2.3 Development of innovation capability: main indicators

### Research and Development

Despite economic boom, the Polish R&D expenditure remained at a relatively low level throughout the whole transformation period (Figure 5). In real terms, the total R&D expenditure grew by 66% from 0.62% of GDP in 1995 to 1% in 2017 with a sizable shift towards business sector R&D spending amounting to 0.67% of GDP in 2017 as opposed to 0.24% in 1995. Although constantly increasing since the beginning of 2000s, the R&D investments of small and medium enterprises remain particularly low in European comparison (approx. 0.24% of GDP), reflecting their low absorptive capacity and innovative capability.

The most of the innovation activities in Poland were less related to actual innovations, but rather to the aspects referred to as 'improvements of production capability'. These are linked to the improvements in process engineering, quality improvements and management practices of the current production and business processes. Poland, along with the most countries in Central and Eastern Europe, focuses mostly on incremental innovations, cost-oriented process innovations and technology adoption (Radosevic 2017). This is reflected by the fact that more than 77% of Polish industry innovation expenditure is used for the acquisition of machinery and equipment. Only 12.9% of the overall innovation-related spending is used on R&D performed in-house and 5.5% for the R&D contracted out, whereas business companies in more advanced countries spend much more on R&D.<sup>1</sup>

Foreign companies in Poland contribute less to R&D-spending than in neighbouring countries. Throughout the whole period prior and after the EU accession, foreign direct investments in sectors classified as high and medium technology intensive have been rather high in Poland compared to a number of neighbouring countries. However, the R&D investments by the affiliates of foreign companies remained despite recent increases relatively low in the European comparison (OECD 2018c). As demonstrated in Figure 6, the real business R&D spending in high and medium technology intensive sectors in Poland are rather low in the European comparison. However, there has been a remarkable surge in R&D investments in information and communication services as well as professional, scientific and technical activities, largely due to the high investments made for the

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<sup>1</sup> <https://ec.europa.eu/eurostat/web/science-technology-innovation/data/database>



acquisition of modern technology and equipment. Overall, the share of enterprises that either introduced an innovation or have any kind of innovation activity is rather low in European comparison (Figure 7).

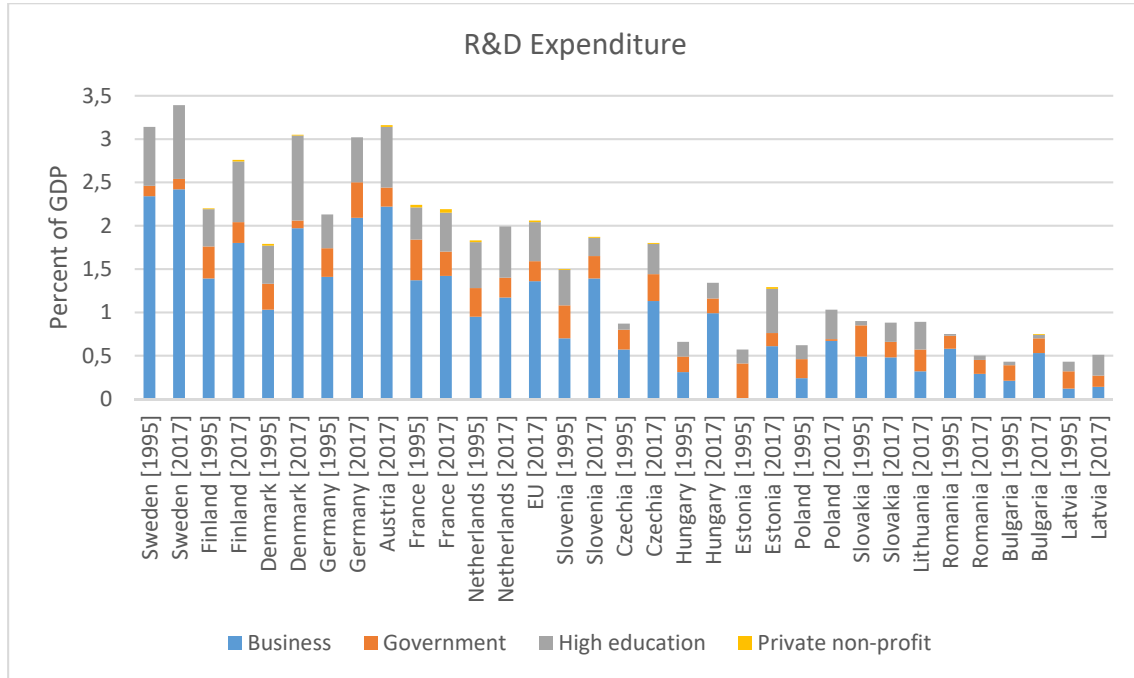


Figure 5: R&D expenditure by sector of performance. Source: Eurostat.

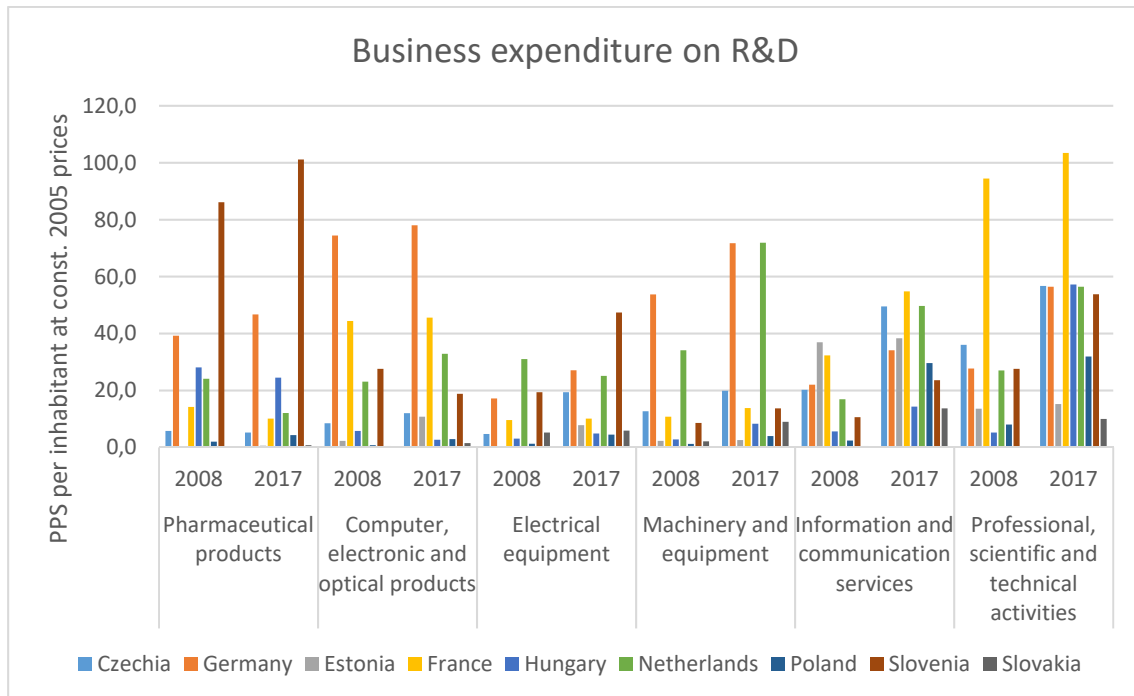


Figure 6: Business expenditure on R&D in selected high and medium technology intensive sectors, NACE Rev. 2. Source: Eurostat.

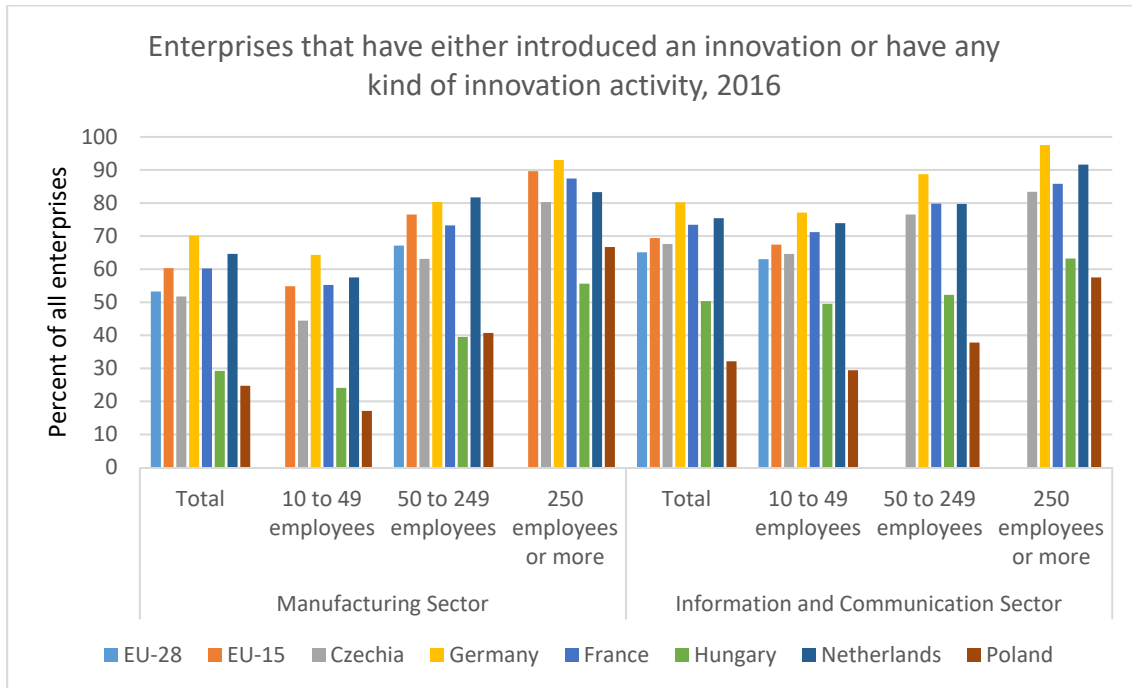


Figure 7: Share of Enterprises with innovative activities. Source: Eurostat, Community Innovation Survey (CIS).

Scientific and innovation output of Poland improves continuously, however, the relevant indicators remain well below the EU average level (Figure 8). Since 2010, the number of researchers in R&D per million people increased by 50% and of technicians in R&D<sup>2</sup> by almost 40%. Significant improvements in terms of scientific and innovation output is demonstrated by the rise in number of scientific publications<sup>3</sup> (+35%) and resident patent applications<sup>4</sup> (+32%) per million people in 2018 compared to 2010, whereas the number of patent publications by non-residents considerably decreased (-50%). The number of trademark applications is still very low in European comparison.

<sup>2</sup> Technicians and equivalent staff are people who perform scientific and technical tasks involving the application of concepts and operational methods, normally under the supervision of researchers. R&D covers basic research, applied research, and experimental development. Source: UNESCO Institute for Statistics (<http://uis.unesco.org/>).

<sup>3</sup> Scientific and technical journal articles refer to the number of scientific and engineering articles published in the following fields: physics, biology, chemistry, mathematics, clinical medicine, biomedical research, engineering and technology, and earth and space sciences. Source: National Science Foundation, Science and Engineering Indicators (<https://datacatalog.worldbank.org/>).

<sup>4</sup> Resident patent applications are those for which the first-named applicant or assignee is a resident of the State or region concerned. Source: World Intellectual Property Organization (WIPO), WIPO Patent Report: Statistics on Worldwide Patent Activity (<https://datacatalog.worldbank.org/>).

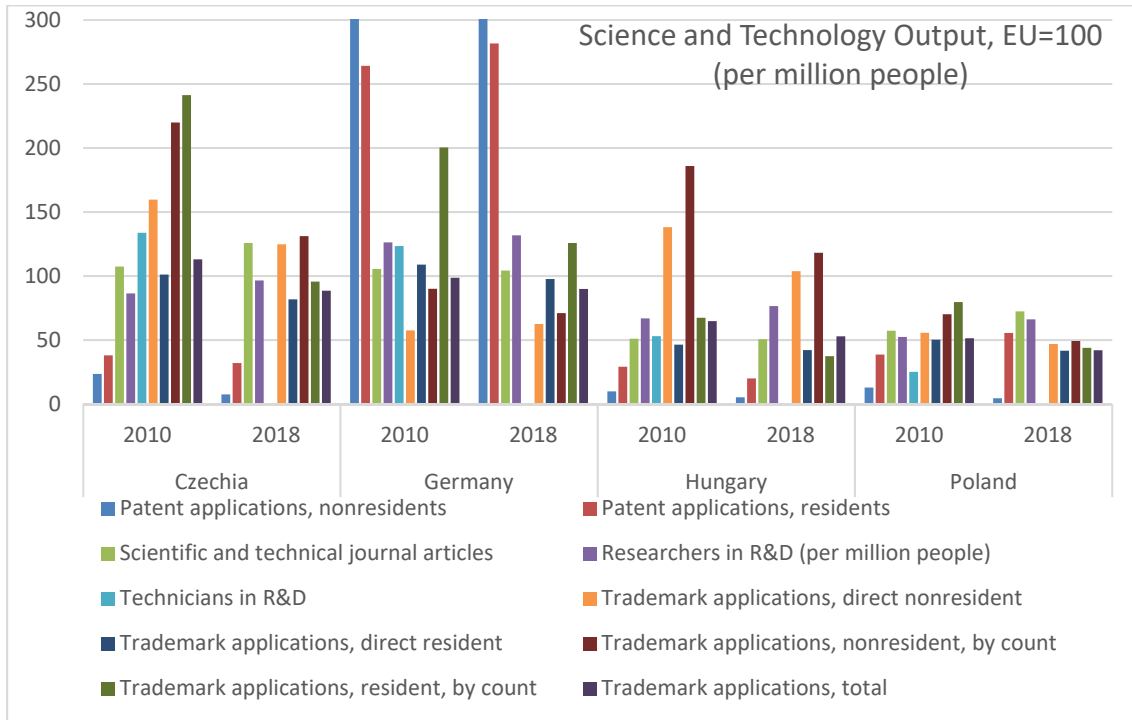


Figure 8: Scientific and Technology Output. Source: World Bank Data, own calculation.

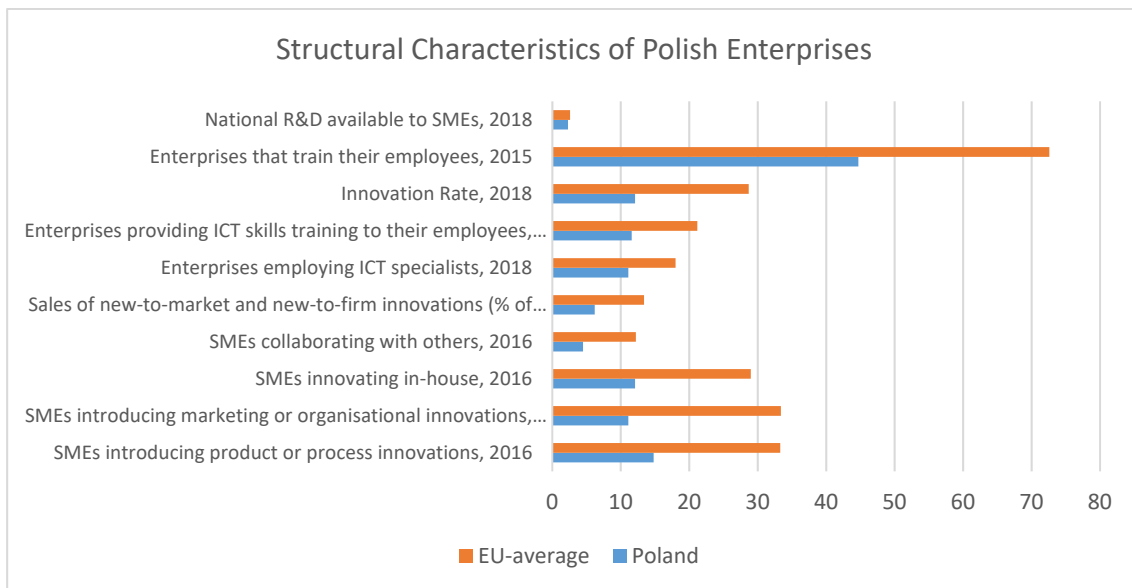


Figure 9: Structural Characteristics of Polish Enterprises, Source: (European Commission 2019).

As Figure 9, shows, Polish SMEs and enterprises on the whole score below average in many important business performance indicators reflecting their structural weaknesses compared to many other European countries. The percentage of SMEs that innovate in-house and introduce product and process innovations, remains well below the EU-average. As to the ICT skills demand, only 11% of enterprises located in Poland employ ICT specialists and only a slightly higher share (11.6%) provides ICT skills training to their employees. Although the lack of properly trained workers and specialists is one key bottleneck for the development of firms in Poland, only 45% of all enterprises in Poland provide training activities to their employees, which belongs to the lowest levels among EU-countries



(EU-average: 73%) (European Commission 2019a). Only a very small share of SMEs in Poland (4.5%) is currently engaged in cooperation with other organisations, such as universities and R&D institutions and other enterprises (EU-average: 12.2%).

Based on the Community Innovation Survey (CIS) 2016 results,<sup>5</sup> enterprises in Poland face many factors hampering innovation activities the most significant among them are high costs of innovations and lack of internal finance (Table 2). This is particularly true for small enterprises. Furthermore, enterprises are often confronted with difficulties obtaining public grants or subsidies. This is also reflected in a much lower participation rate of Poland along with other EU-13 countries in the European Framework Programmes (like Horizon 2020) per thousand researchers than in the EU-15 (European Parliament 2018). Based on a study conducted by the European Parliamentary Research Services, the most important reasons for reduced participation and non-fulfilment of the eligibility criteria of this group of countries result from a number of weaknesses of their innovation system and related effects, such as relatively low research and innovation activities and weak collaboration links between business sector and academia. Also the quality of proposals involving organisations from the EU-13, including Poland, is often lower than that of proposals from the EU-15, which reduces their chances to win European public grants, especially those linked to excellence (European Parliament 2018).

*Table 2 Factors hampering innovation activities of enterprises in Poland*

Size of enterprises	Lack of internal finance	Lack of external finance (credit or private equity)	High costs	Lack of qualified employees within enterprise	Lack of collaboration partners	Difficulties in obtaining public grants or subsidies	Uncertain market demand	High competition
Total	19,3	11,1	26,3	10	7	18,4	14,8	14,1
From 10 to 49 employees	21,1	11,2	27	10,8	8,4	18,5	16,3	15,4
From 50 to 249 employees	18,3	11,5	26,4	9,7	5,8	18,7	13,3	13,1
250 employees or more	13,6	8,9	22,8	6,7	4,3	16,8	11,5	10,1

Source: Eurostat, Community Innovation Survey (CIS) 2016.

## Education

Poland experienced an unprecedented tertiary education boom, but the quality of a number of its higher education institutions and the overall education and research output is rather weak by international standards (OECD Economic Surveys 2018). The highest share of degrees are achieved in business administration and law (24.3%), followed by tertiary graduates in engineering, manufacturing and construction (15.8%). With the graduate share of 3.6% in natural sciences, mathematics and

<sup>5</sup> <https://ec.europa.eu/eurostat/web/science-technology-innovation/data/database>



statistics and 3.5% in information and communication technologies, Poland belongs to the EU countries with the lowest level of tertiary graduates in these disciplines.<sup>6</sup>

There is a clear evidence of a large share of young tertiary graduates with very weak literacy (approx. 27%) and numeracy (approx. 35%) skills, which is among the highest levels in the EU (OECD 2018c). Among adults the share of top performers in technology problem-solving (19%) is much lower than in advanced European countries (e.g. Germany: 36%)<sup>7</sup>, although the situation is a bit better in the younger generation (OECD 2018c). The government spending on education is relatively low, compared to the standards of leading countries. Moreover, it was even lower in 2018 than in 2010 (Table 3).

Skills mismatches and inadequate on-the-job training are an increasingly severe bottleneck reported in business surveys. A reform in vocational training was implemented in 2013, though the unemployment rate for graduates of basic vocational schools remains high (43%) (EBRD 2018). The government has started to address quality gaps in tertiary education by strengthening accreditation, but more needs to be done in order to improve the quality of teaching and training in general. Public support for the development of human capital is primarily financed by EU Funds. Considering significant skill weaknesses and mismatches, there is a strong need for better guidance services to identify students with basic skills issues and refer them to education programmes that are better adapted to their abilities (OECD 2018c) and to ensure a better alignment to the market and regional needs.

Table 3: Key human development indicators

Indicator	Poland				Central Europe and Baltics				Germany				European Union			
	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018	2000	2010	2018	Change 2010-2018
Life expectancy at birth, total (years)	74	76	78	2,1%	72,719725	75,293966	77,033966	2,3%	77,926829	79,987805	80,990244	1,3%	77,158425	79,725637	80,991156	1,6%
GINI index (World Bank estimate)	38	33	32	-4,2%	..	..	..	..	29	30	32	5,0%	..	..	..	..
Age dependency ratio (% of working-age population)	46,2	40,2	48,3	20,1%	46,6	43,2	50,6	17,2%	47,4	51,8	54,0	4,3%	49,0	49,8	54,9	10,3%
Government expenditure on education, total (% of GDP)	5,0	5,1	4,6	-8,5%	..	..	..	..	4,5	4,9	4,8	-2,3%	..	..	..	..
Current health expenditure (% of GDP)	5,3	6,4	6,5	1,5%	5,7	6,8	6,7	-1,9%	9,8	11,0	11,1	1,2%	7,9	9,7	9,9	2,9%
Current health expenditure per capita, PPP (current international \$)	564,2	1.353,1	1.784,4	31,9%	562,7	1.397,5	1.784,4	27,7%	2.683,9	4.315,0	5.463,3	26,6%	1.774,8	3.158,2	..	..
Hospital beds (per 1,000 people)	4,9	6,5	..	..	6,7	6,5	..	..	9,1	8,2	..	..	6,3	5,4	..	..
Out-of-pocket expenditure (% of current health expenditure)	31,1	23,7	22,9	-3,2%	24,6	22,3	23,0	3,0%	12,1	13,9	12,4	-10,8%	14,2	15,1	15,7	4,1%

Source: World Bank Open Data, own calculations.

## 2.4 Summary

So far, Poland has experienced significant growth through the mobilisation and intensive use of production factors and continuous enhancement of production capacity, extensive public investments, foreign direct investments (FDIs) and the boost of private consumption. Innovation and economic research suggest that extensive growth sooner or later will reach its natural limits, as its sources are gradually exhausting, leading to the stagnation of economic growth. Indeed, economic growth is already slowing down in many Eastern European countries. The downward dynamics in

<sup>6</sup> [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Tertiary\\_education\\_statistics#Graduates](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Tertiary_education_statistics#Graduates)

<sup>7</sup> Cf. OECD 2018c.



Poland have so far been less distinct compared to many neighbouring EU-13 countries due to the economic advantages related to the size of the country and public policy efforts of recent years that aim at supporting the economy and social cohesion of the country. However, some clear signs of slowing down of the economic development are already apparent, which is reflected in the decreasing dynamics of FDIs and productivity growth. Theoretical and empirical evidence of innovation research suggests that only R&D and innovation driven growth accompanied by continuous technological upgrade ensure robust and sustainable income growth and rising living standards of countries (e.g. Freeman 2008; Hall and Rosenberg 2009). However, innovation activities in Poland are to a large extent associated with the adoption of foreign technology and are less focused on R&D and innovations generated by domestic players. This raises the question about the sustainability of the growth model and the long-term effectiveness of the present policy approaches in countries like Poland.

Poland needs to strengthen its innovative and technological capacity to be able to improve its productivity and generate a robust base for further economic and technological convergence. Of significant importance for the Polish economy is increasing the efficiency and innovativeness of the low productive small and medium enterprises.



### 3. Malopolska Region

#### 3.1 Brief overview of economic development

In absolute terms, the income level in PPP per inhabitant in Malopolska was in 2017 about 9% lower than in Poland as (Poland equals 63% of the EU average per capita income). However, Malopolska belongs to the Poland's regions with most dynamic and constantly rising economic growth. The unemployment rate was 7.7% of the total labour force in 2017 and has been steadily declining since 2012. Krakow is the most vibrant and wealthy economic part of Malopolska. In fact, the GDP in PPPs per inhabitant of Krakow was in 2016 83% higher than the average Malopolska GDP level, and 66% higher than the average national GDP (Figure 10).

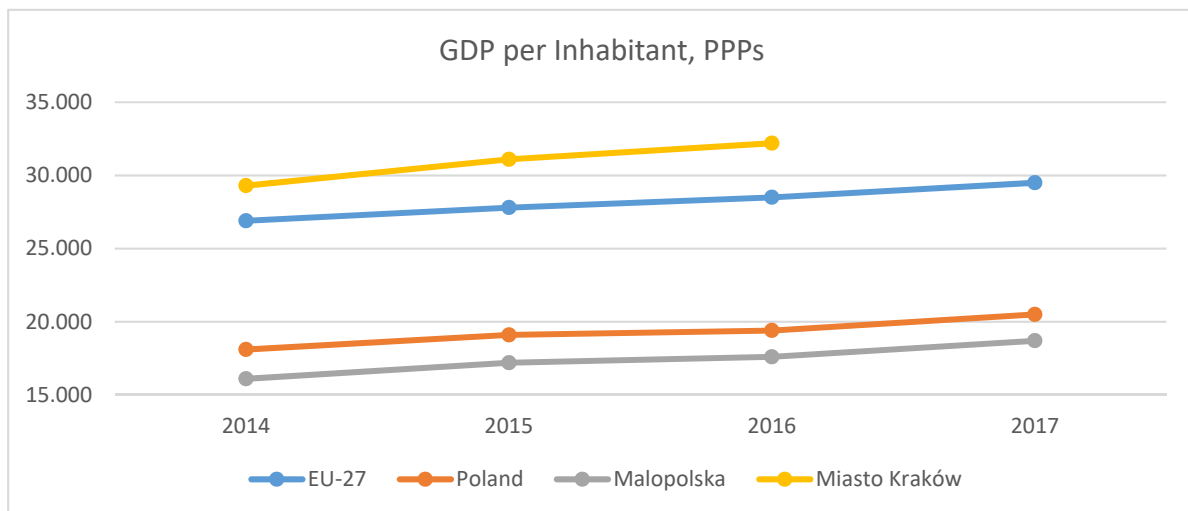


Figure 10: GDP per inhabitant in PPPs. Source: Eurostat.

Malopolska and Krakow have a high concentration of domestic and foreign-owned businesses. The foreign direct investments in Malopolska and Poland as a whole are largely associated with the cost motivated outsourcing of specific production and service operations of large enterprises in Western countries. Among the largest foreign companies with representations in Malopolska are BP Polska SE (fuel), Philip Morris International (tobacco), Coca Cola, Grupa Azoty - Tarnów (chemical industry), Synthos SA (chemical industry), Comarch (IT solutions), Motorola, MAN, Delphi, Valeo, IBM, Electrolux, Shell and Capgemini.<sup>8</sup>

According to the current data of regional statistics<sup>9</sup>, there are 398 609 economic entities in Malopolska. It belongs to the most dynamic Polish regions in terms of growth of new enterprises: there are around 10.000 newly established enterprises every year.<sup>10</sup> As of end of 2016, among all enterprises located in Malopolska, the highest share (355.100) have microenterprises (employing less than 10 people), followed by 13.300 small enterprises (between 10 and 49 people) and 2,700 medium and large companies.

<sup>8</sup><https://ec.europa.eu/growth/tools-databases/regional-innovation-monitor/base-profile/malopolskie>

<sup>9</sup> <https://businessinmalopolska.pl/en/about-the-region/statistical-data>

<sup>10</sup> <https://businessinmalopolska.pl/en/about-the-region/malopolska/kultura-ekonomiczna>





There is a dynamically developing start-up ecosystem in Malopolska and Krakow, ranking as second largest start-up centre in Poland. It has recently experienced a sharp increase in available venture capital funding, feeding a nascent start-up scene (OECD 2019d). Around 60,000 high-tech businesses are located in Krakow, 28,000 of which are ICT-related. In 2016, Malopolska was awarded the title of European Entrepreneurial Region by the EU's Committee of Regions.

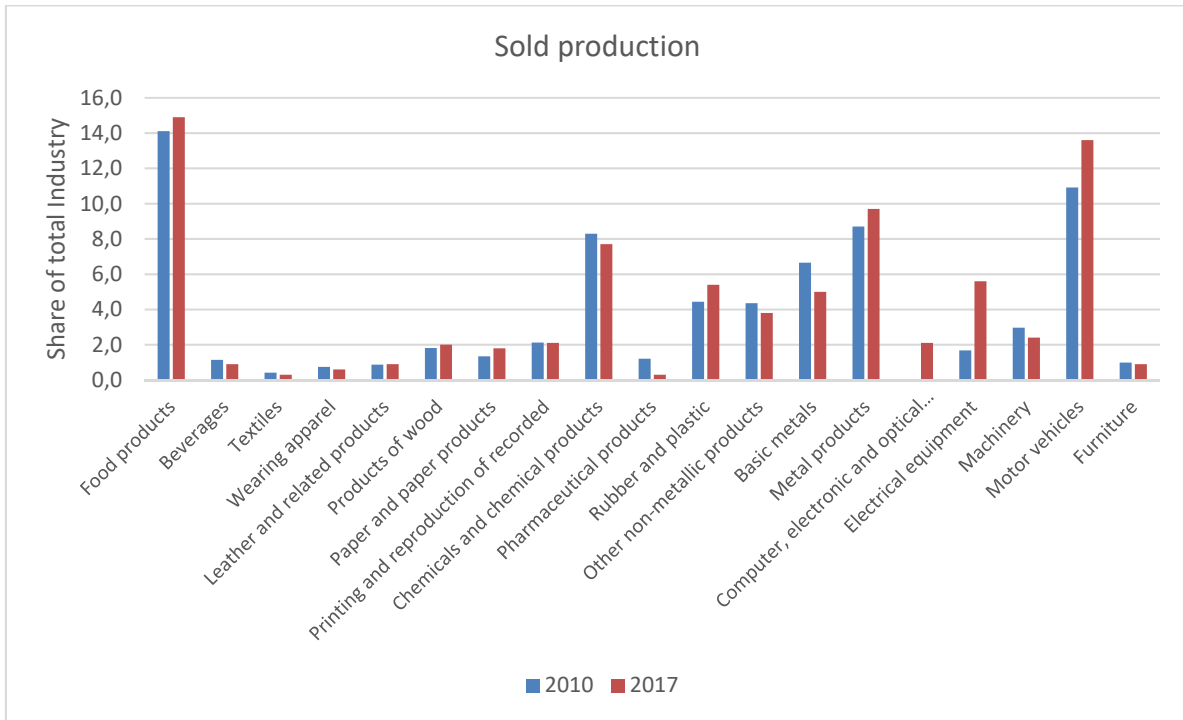
However, some further evidence suggests that Malopolska and Poland as a whole still underperform in terms of the number of high-growth firms compared to other regions in Central and Eastern Europe and Western European countries. However, in the life sciences, digital and IT sectors there is a number of companies, which according to the Deloitte Technology's 'Fast 50 Central Europe 2016' belong to the fastest-growing tech companies in Central and Eastern Europe (OECD 2019b).

### 3.2 Structural characteristics

The industrial structure of the Malopolska voivodship is diversified. This diversity is an asset helping the region to mitigate possible shocks. Many sectors of the medium-low and low technology continue to play a very important role for the economy of the region (Figure 11). Between 2010 and 2017, the share of sold production by sectors representing high- and medium-high manufacturing industries, such as the manufacturing of motor vehicles and electrical equipment, further expanded. Employment in manufacturing in Malopolska grew between 2008 and 2017 by a total of 9% (as opposed to 2% for Poland as a whole). The industry sectors represent 26.5% of the total employment in the region (OECD 2019c). Small and medium enterprises play an important role for the economy of Malopolska. 36% of all industrial production sold on the market is attributable to them.

Statistical data of Eurostat provides evidence that there has been a significant increase in the number of local business units between 2008 and 2017 in many medium- and high technology manufacturing sectors, such as manufacturing of pharmaceutical, computer and electronic products and electrical equipment. Considerable growth of local business units accompanied by growth in employment emphasising their increasing significance for Malopolska took place in the information and communication service sector, particularly in computer programming, consultancy and related activities, information service activities, but also in activities related to scientific research and development.

The development of the region has been primarily defined by the regional smart specialisation strategy since 2014. Through the selected priority areas based on the region's strengths and comparative advantages it is intended to enhance the innovation potential and competitiveness of the regions. This is described in more detail in section 4.1. The ICT and life science sectors are among the most dynamic sectors of the region offering a considerable potential for promoting innovation and technological and scientific advance.



*Figure 11: Industrial structure of Malopolska by sold production at current prices in 2010 and 2017. Based on data from Statistical Yearbook of Małopolskie voivodship 2018.*

### ICT Sector in Malopolska

The ICT sector plays a very important role in Malopolska having grown continually in recent years. According to the Eurostat data, the number of active enterprises in the Information and Communication sector in Malopolska has doubled between 2008 and 2016. At the end of 2017, 10,792 (3.1% of all business entities) were operating in the voivodship, in which the declared predominant activity is in the ICT sector (Business in Małopolska 2019a). Krakow is the core centre of ICT sector, where more than 50% of all Malopolska's ICT entities are located. Among them are about 100 start-ups (Foundation Institute for Eastern Studies 2018). Moreover, Malopolska in general and Krakow in particular is one of the most important destinations in Poland for the outsourcing of ICT business services for globally operating companies. Among large foreign capital based firms are subsidiaries of global ICT companies, such as Akamai, Cisco, CD Project, ComArch, Ericsson, Google, IBM, Luxoft, Motorola.

The most of the ICT enterprises are related to the ICT services: web portals (32.5%) as well as data processing and hosting (22.8%). Meanwhile, 21.2% firms are active in the production of computers and peripherals. 58.1% of all entities are located in Krakow. The large majority of the identified companies are microenterprises (95.4%), 3.6% are small, 0.8% - medium and 0.2% - large enterprises (Business in Małopolska 2019c). The majority of employees (52%) work in Polish companies. Most foreign companies come from the United States, including large American corporations such as Motorola Solutions, Cisco, IBM or Saber. They employ a total of 27.2% of all ICT specialists (Business in Małopolska 2019a). Malopolska is ranked second among the voivodships in Poland with the highest employment share in the ICT sector. Among all IT jobs, the highest demand is registered for software



developers, programmers, analysts and administrators in the field of software and databases. Businesses are increasingly facing a shortage in these specialisations (Business in Małopolska 2019a).

Main products of the ICT firms operating in Malopolska are solutions such as apps/platforms including those concerning health, air pollution, education, satellite data/navigation, e-health, e-hospital, e-government, Internet of Things, 3D printing, information management, data analysis (Foundation Institute for Eastern Studies 2018).

#### Life Science Sector in Malopolska

In Malopolska, a sizable business and academic community related to the life science disciplines has been established. There are about 10.566 enterprises and institutions operating in this sector. 56,5% of the entities are located outside of Krakow (Foundation Institute for Eastern Studies 2018). Life science is a broad concept, which encompasses disciplines such as medicine, biology, biotechnology and biochemistry. One major branch of life science involves products, technologies and services used in the treatment, diagnosis and prevention of diseases and help improve the quality and standard of life. Since 2016, there is a growing trend in terms of the number of enterprises indicating focusing on activities in health protection, including health protection with the use of rDNA technology, bioinformatics and the environment (Business in Małopolska 2019b).

One of the most dynamically developing sector in Malopolska is the biotechnology sector. Between 2012 and 2017, the number of enterprises active in the field of biotechnology increased from 3 to 17. Among them are ten small companies employing less than 50 people and seven have more than 50 employees. The most of the biotechnology companies conduct R&D activities. Their cumulated investments in R&D grew from approx. 7 Mio. € in 2012 to 15.5 Mio. € in 2017. The main areas of biotechnology companies' activities are: human health with and without rDNA technology, bioinformatics, industrial processing, environmental and genetically modified agricultural biotechnology.<sup>11</sup> Biotechnology, medical technology and biomedical markets are considered to have a large growth potential due to their breakthrough potential and the economic relevance.

#### Electrical Engineering and Machine Industry

The electrical engineering and machinery industry sector is one of the most important export sectors of the region. It focuses on the production of electronic and optical products, electrical and mechanical equipment as well as the production of vehicles, means of transport and their components. As of 2018, 3.227 companies from the electrical engineering and machinery industry operated in the region. 54.7% of all entities are located outside of Krakow (Foundation Institute for Eastern Studies 2018). A high percentage of enterprises operating in this sector is involved in some kind of innovation activities.

The core technologies in the regional sector that have relevance for computational medicine involve devices for medical therapy and diagnostics, medical engineering technologies and artificial organs. Apart from this, companies specialise in modern machines for agricultural and forestry sectors, means

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<sup>11</sup> According to the data base from the Statistical Office of Poland  
<https://bdl.stat.gov.pl/BDL/dane/podgrup/temat>



of transport and transport systems, physical and chemical sensors as well as biosensors and sensor networks, intelligent textiles, personal electronics, process automation, third generation solar cells, optoelectronic devices and systems and optical networks (Region of Malopolska 2018).

### 3.3 Innovation Ecosystem in Malopolska

Scientific, research and innovation potential

In the Regional Innovation Scoreboard of European regions, Malopolska is categorised as a 'moderate innovator'. This means that its innovation performance is between 50% and 90% of the European average (European Commission 2019b). The performance of the Malopolska region has improved over the past few years. Malopolska outperforms the country's level in the majority of innovation related performance indicators, highlighting the relative strengths of the region (Figure 12). When compared to the country's average, Malopolska performs particularly well on R&D expenditures of the business sector and the PCT patent publications (70% higher), lifelong learning (more than 50% higher) and international scientific publications (43% higher). However, compared to the EU-average, there is still some catching-up to do, especially with regard to the patent output, research excellence and lifelong learning.

R&D expenditure indicates direct research and development efforts of a country or region. In Malopolska, R&D expenditure has increased nearly fivefold since 2000, principally boosted by the business sector demonstrating an unprecedented growth in R&D investments (Figure 13). It equals to 1.5% of the regional GDP, which is one of the highest scores in Poland. It was rising by an average annual growth rate of 18% between 2000 and 2016. In 2016, the real expenditure in purchasing power standards per inhabitant of Malopolska amounted to more than twice that of the country's average. Most R&D expenditure was carried out in Engineering and technology (54%), Natural sciences (26%) and Medical sciences (8%).<sup>12</sup> As to the type of activities, the highest share of R&D expenditures is dedicated to experimental development research<sup>13</sup> (51%), followed by basic (36%) and applied research (13%). Of the total expenditure on activities related to innovation, Malopolska's industry currently spends approx. 43% on actual R&D, which is significantly higher compared to the national level. Further 41% are spent on the acquisition of machinery and equipment (Figure 14). In 2016, almost 17% of all enterprises in Malopolska invested in innovation.

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<sup>12</sup> Calculations in this paragraph are based on data provided by the Statistical Yearbook of the Małopolskie Voivodship (Urząd statystyczny w Krakowie 2018).

<sup>13</sup> Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed (OECD Glossary).

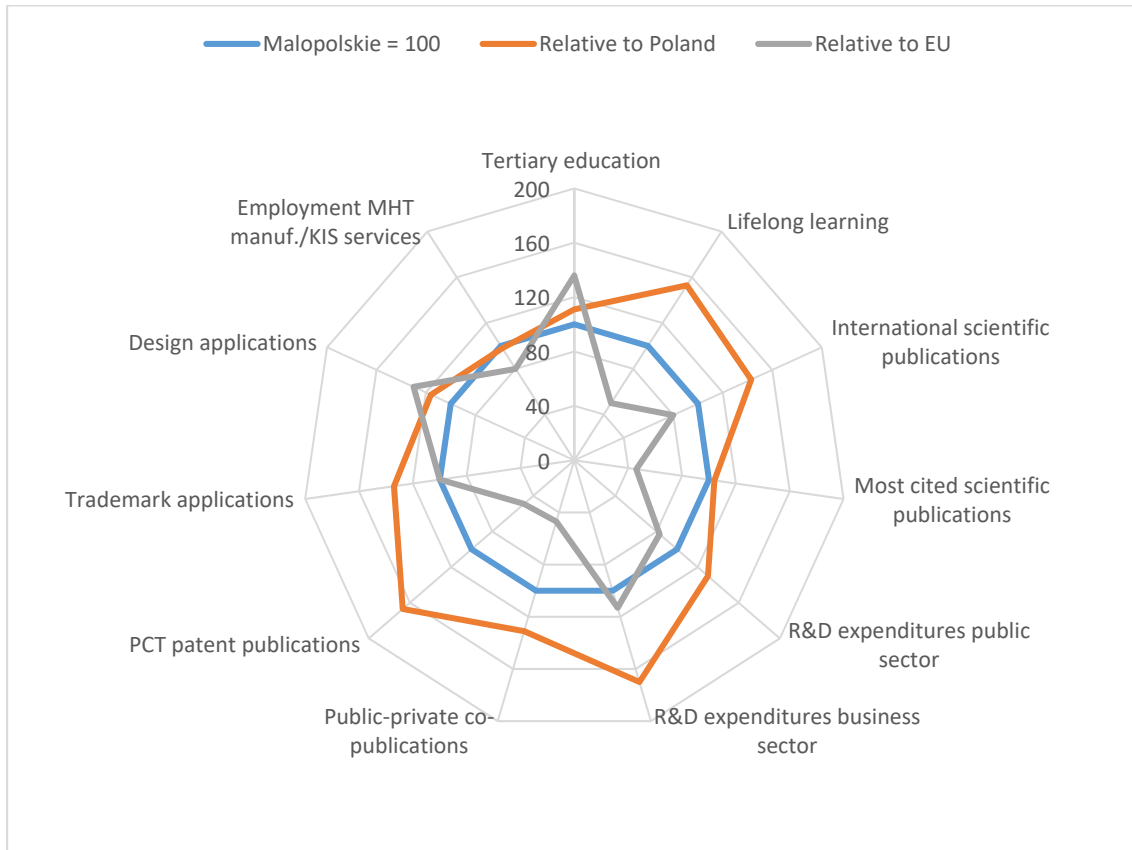


Figure 12: Malopolska - Innovation-Related Performance 2019. Source: Regional innovation scoreboard 2019: [https://ec.europa.eu/growth/industry/innovation/facts-figures/regional\\_en](https://ec.europa.eu/growth/industry/innovation/facts-figures/regional_en)

Large companies ( $\geq 250$  employees) recorded the highest rate of innovation-based sales (12.75% of total revenue in 2016); which have been increasing over several years. Medium-size companies (50–249 employees) had a share of 5.5% (less than in 2015) and small enterprises (10–49 employees) reached 2.6% respectively.<sup>14</sup>

An economy’s ability to create new knowledge and stimulate innovation relies on the availability of highly qualified research professionals. In Malopolska, the share of researchers in total employment increased between 2000 and 2016 by a total of 70%. This is twice of the increase at national level. Owing to the rapid growth of the R&D expenditures of the Malopolska business sector, its share of researchers in total employment has expanded to a greater extent than in Poland as a whole, approaching the average EU level. The business enterprise and the higher education and business enterprise sectors are the main employers of researchers. Higher education institutions account for 55% of all employed researchers, whereas business enterprises employ further 40% of researchers. Also the share of persons with tertiary education (ISCED) employed in science and technology as well as of scientists and engineers have been rising faster in recent years compared to the national level.

<sup>14</sup> According to the data base from the Statistical Office of Poland: <https://bdl.stat.gov.pl/BDL/dane/podgrup/temat>

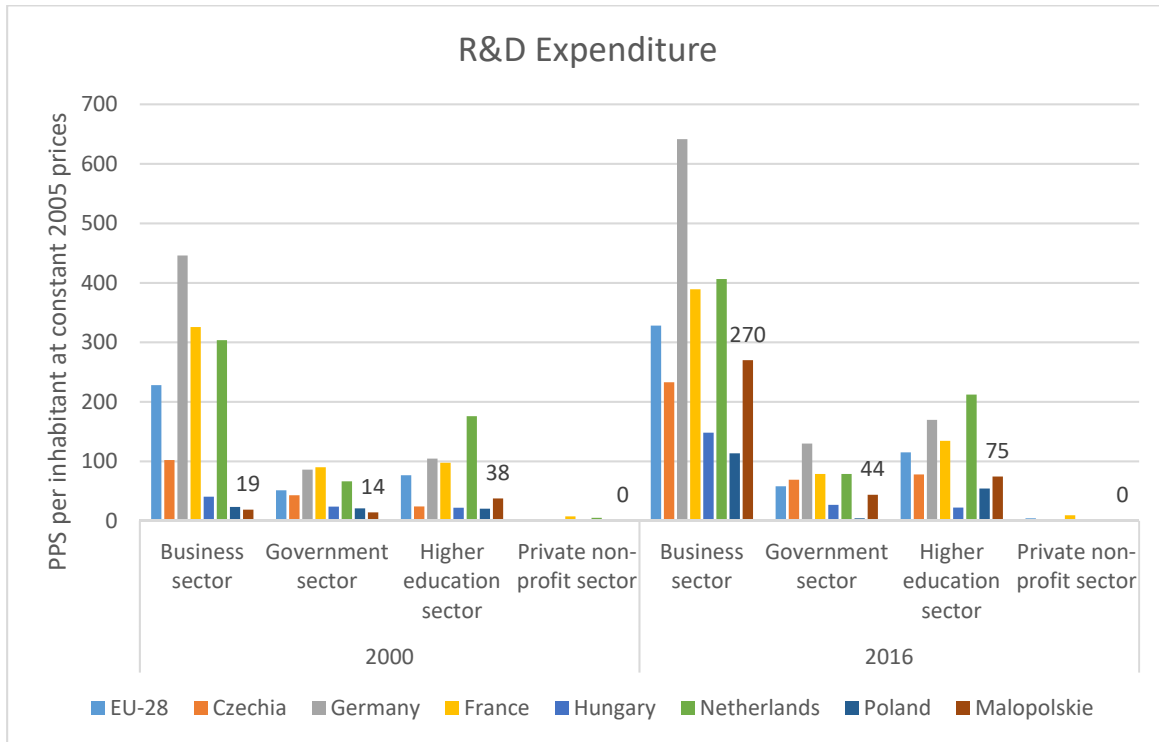
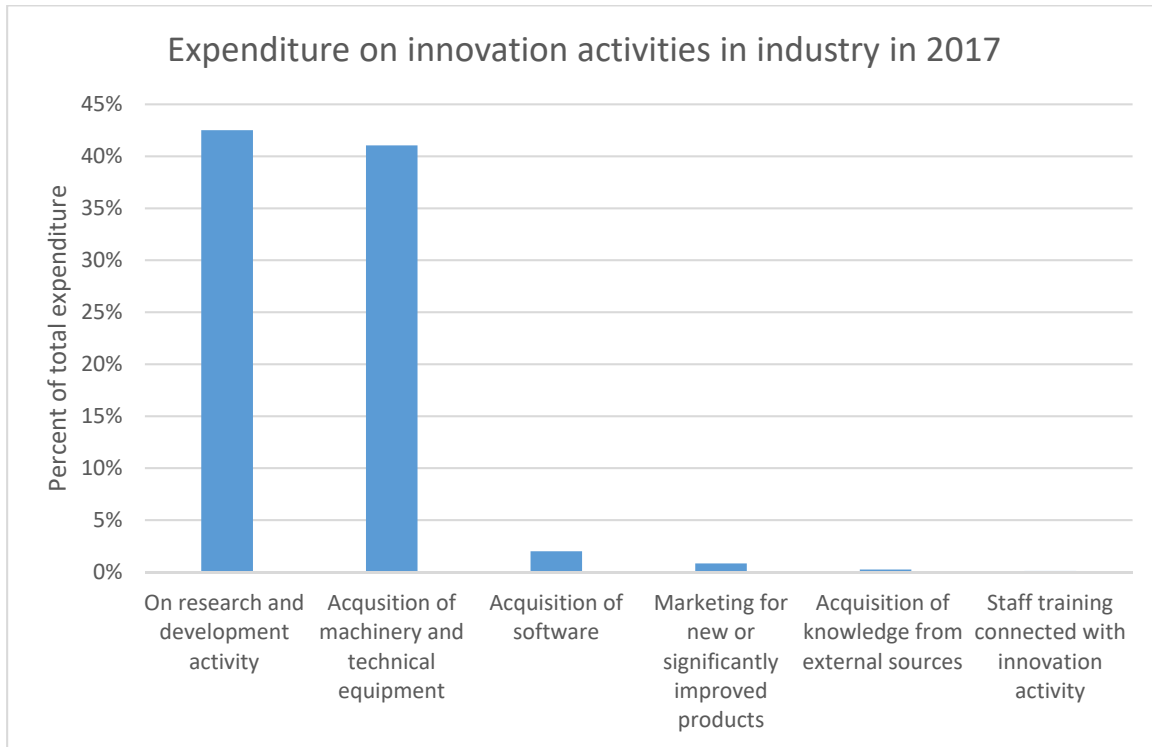


Figure 13: R&D Expenditure by Sector of Performance. Source: Eurostat.

Country-wide, Malopolska demonstrates a very strong position in the science fields related to computational medicine as the scientific publication analysis confirms.<sup>15</sup> The academic organisation with the highest level of publications is the Collegium Medicum of the Jagiellonian University in Krakow, which is outperformed only by the Polish Academy of Sciences consisting of numerous research institutes.<sup>16</sup> The Jagiellonian University and AGH University of Science and Technology are further organisations showing a high level of scientific activity in this area. Additionally, the Institute of Pharmacology of the Polish Academy of Sciences, located in Krakow, has an established publication record.

15 The searches in Scopus were conducted using the key words "in silico", "computational medicine", "computational modelling", "data mining" and "data modelling" in context of medicine, medical technology, drug discovery, pharma or biotechnology.

16 In this case a clear delineation was not possible, as some publications were reported by individual institutes, whereas others were subsumed under the umbrella of the Academy of Sciences.

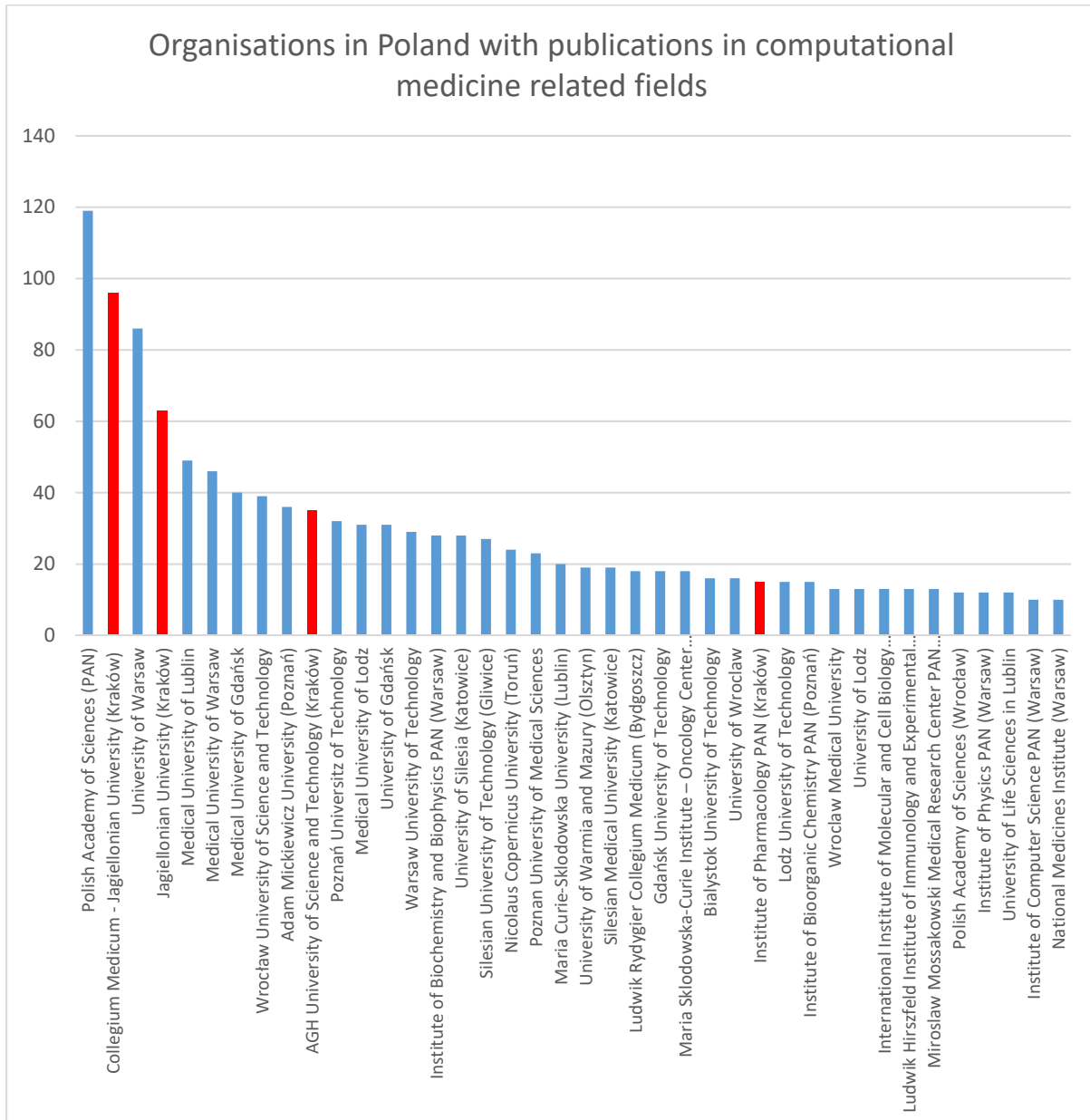


*Figure 14: Expenditure on innovation activities of industry in Malopolska in 2017 by type of activities. Own calculations based on data from Urząd statystyczny w Krakowie (2018).*

#### Education

The Malopolska region is the second largest academic centre in Poland, after Warsaw. In the 2017/18 academic year, more than 157,000 students studied in 30 higher education institutions with headquarters in the region, 23 of which are located in Krakow. In addition, they recorded 11,000 post-graduate students and 6,300 PhD students (Urząd statystyczny w Krakowie 2018). In 2016, Malopolska demonstrated the highest regional rate in proportion of graduated when compared to the population density. However, there is a somewhat downward trend in the number of students since 2009 (OECD 2019b). By type of higher education institutions, the highest share of students in Malopolska (including foreign students) have universities and higher schools of technology (25% each) (Figure 16).

In particular, there is opportunity for the development of technologies related to computational medicine based on IT, life science and engineering skills developed in the Krakow universities. In the 2016/2017 academic year, 6.4% of all students in Malopolska studied in the fields related to ICT. However, there has been a noticeable decline in the number of students in this field of study in recent years, largely due to the changes in educational preferences. The university with the largest number of students studying ICT-related faculties is the University of Science and Technology, AGH. The AGH University has been taken a leading position in the IT faculties ranking of the “Perspektywy” Foundation in the category of technical fields of study (Business in Małopolska 2019a).



**Figure 15** Number of total publications in science areas fields to computational medicine. The graph shows all organisations with at least 10 publications in total. Source: Scopus

Life science has a significant share in the education profile of Malopolska, which is demonstrated by a high share of students in the fields of medicine, biology, agriculture and environmental protection. Some evidence indicates that the supply of regional graduates in life science disciplines exceeds the actual demand of companies so that the regional market is not able to absorb all young specialists and many are forced to go abroad or change their specialisation (Business in Małopolska 2019b)

On the whole, there is a regular supply of well educated, skilled workers provided by its numerous higher education institutions in Malopolska. Universities increasingly pay attention to the skills needs and requirements for the industry trying to address them. However, cooperations of higher education institutions with business enterprises still remain at a rather low level. Evidence suggests that universities need to focus more on providing business skills to graduates and to existing SME managers (OECD 2019b) as well as on stimulating creativity and the entrepreneurial mind set of young people.



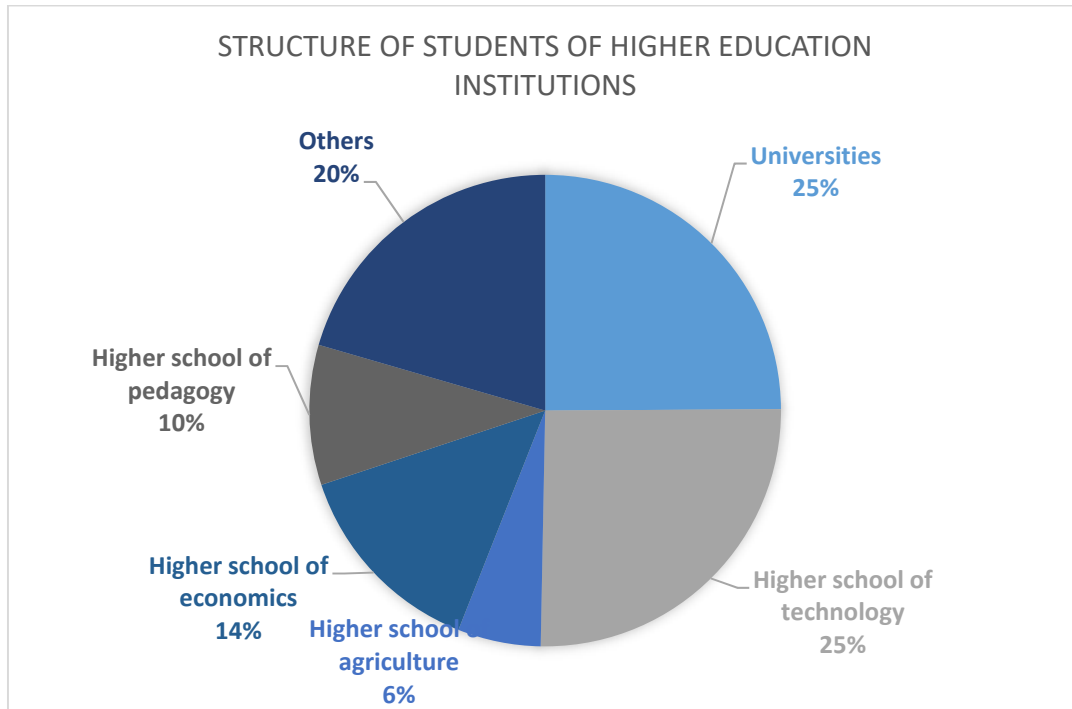


Figure 16: Structure of students of higher education institutions by type of institutions in Malopolskie in 2017/18. Source: Statistical Yearbook of Malopolskie voivodship 2018.

#### Socio-cultural factors

The innovation system might be also shaped by the socio-cultural context. The remaining sections briefly highlight potentially relevant dimensions: the impact of social capital and long-term historical effects.

Besides the absence of a favourable institutional environment (see Geodecki et al. 2012), Batorski (2013, p. 81) argues that one reason for the low level of innovativeness in Poland is the lack of social capital - where Poland ranks below most other European countries (Lackowska-Madurowicz and Swianiewicz 2013, p. 1404; Herbst 2008b).

At the same time, current research has pointed to the different types of social capital and its impact (Swianiewicz et al. 2008). Malopolska is characterized by rather low levels of bridging capital (i.e. orientation outwards/to unknown people), but high levels of bonding capital (inward orientation). While this constellation is found to exhibit a positive effect on the speed of absorption of EU funding (Lackowska-Madurowicz and Swianiewicz 2013), the orientation towards hierarchies and inward orientation might be less facilitating for innovation, compared to the comparatively more open Lower.<sup>17</sup> A look at registered patents by the national office (per 100,000 inhabitants) supports this claim (see Figure 17). In most years, Malopolska was close to the national average and lagging behind Lower Silesia. However, this gap has vanished and even reversed in the years 2016 and 2017.

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<sup>17</sup> This might be reinforced by the high levels of religiosity in the region, a factor that is considered in other contexts to facilitate a rather negative attitude towards innovation (Bénabou et al. 2015).

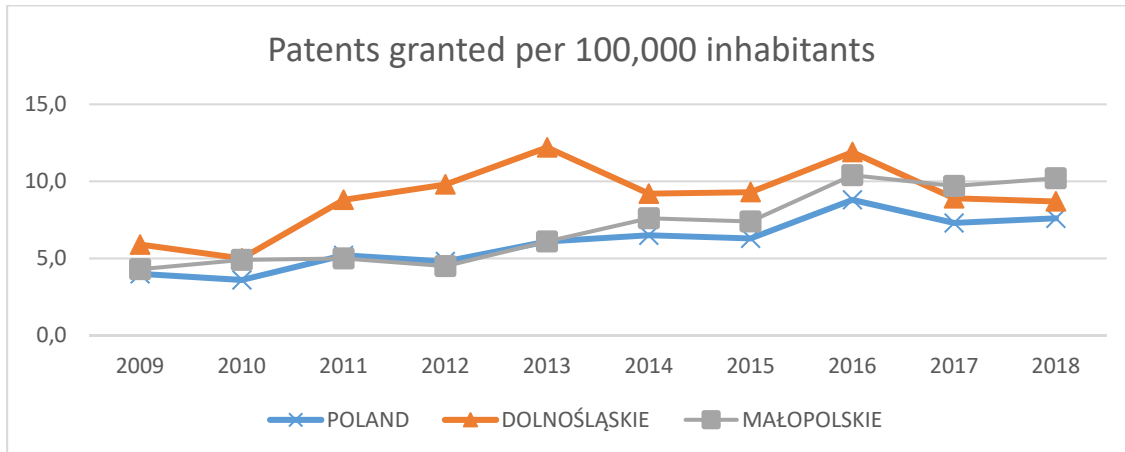


Figure 17: Number of registered patents at Polish Patent Office per 100,000 inhabitants. Own compilation based on data provided by Polish Statistical Office/Bank Danych Lokalnych.

Secondly, there is a wide range of studies arguing that the partition of Poland in 18<sup>th</sup> century has long-term effects, affecting a wide variety of factors, such as economic determinants, societal aspects, voting behaviour and electoral turnout (Herbst 2008a; Wysokinska 2017).<sup>18</sup> Malopolska almost exclusively belonged the Austro-Hungarian Empire. This is usually considered to provide more favourable conditions compared to parts under Russian rule. Contrary to Western Polish, it did not experience a major exchange in population after 2<sup>nd</sup> World War due to westward shift of boundaries (see Figure 18).

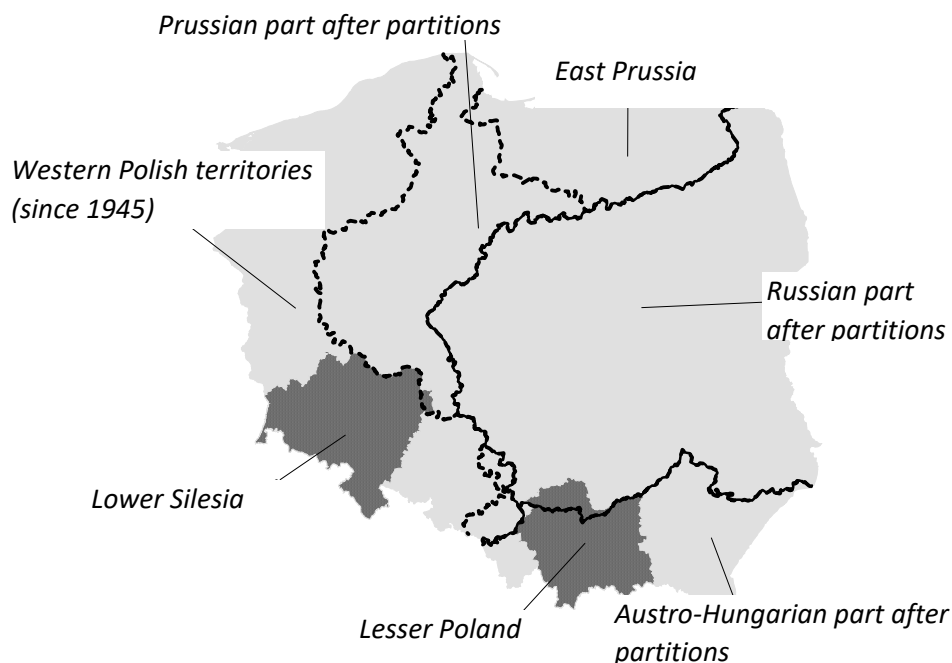


Figure 18: Polish partitions and regional boundaries. Figure from Herbst (2008b, p. 52) with own translations.

<sup>18</sup> For graphical illustrations see: <https://www.politico.eu/article/polands-past-marks-its-present/>



### 3.5 Summary

Malopolska is one of the fastest growing regions in Poland with Krakow as its economic, scientific and cultural centre. The economic structure of the region is very diverse. Through a high concentration of entities operating in the field of life science, IT, electrical engineering, machinery and automotive both in the production and service areas, the share of businesses investing in innovation activities is above the national average. Besides Malopolska is characterised as one of the most important education and research centre in Poland with a number of nationally renowned universities and research institutes.

Malopolska demonstrates a strong position in the fields of Life Science and ICT, which contributes to the potential of the future development of Computational medicine in the region. However, although Malopolska is continuously improving its innovation and R&D indicators, it still scores below the EU-average far below the levels of advanced EU-countries, like Germany. Indeed, evidence suggests that - although significantly higher than the national average - the actual intensity of R&D and innovations is much lower compared to other European countries and the less sophisticated R&D activities and activities linked to the adoption and absorption of foreign technologies prevail. A large share of small businesses shows a particularly low innovation and absorptive capability. This emphasizes the need of the region in upgrading technology and the shift towards more technology, knowledge and skill intensive activities.



## 4. Institutional setting and policy instruments for innovation

Having provided an overview over the economic context and the strength of innovation in Poland and Malopolska, in particular, this section focuses on structures and instruments supporting economic development and innovation activities. Relying on the OECD taxonomy of policy instruments,<sup>19</sup> the paper reviews the following areas: governance structures, direct financial support, indirect financial support, collaborative structures, and guidance/regulation/incentives.

### 4.1 Governance structures

Despite the centralized character of the Polish state, there are multiple responsibilities for economic development and innovation. There have been attempts by the current government to overcome the dispersed responsibilities for innovation policy that was observed in the past and that was considered as an obstacle to implementation (Kapil et al. 2013, p. 2). On the one hand, the creation of a new inter-ministerial Council for Innovation (see Figure 19) is considered as 'a big step forward' (European Commission 2017, p. 5) that increased policy coordination between different ministries and delineating responsibilities (OECD 2018c, p. 13, 2018b, p. 114). However, there have been also critical remarks about the lacking capacity/personnel replacements, the on-going existence of overlapping responsibilities and different priorities (Breznitz and Ornston 2017; European Commission 2017, p. 5; OECD 2018a, p. 18).

There is a number of different agencies (PARP, NCN, NCBiR, FNP, PFR) being subordinated to the ministry of Science and Education and the ministry of Entrepreneurship and Technology. The Polish Development Fund (PFR) is a newly established umbrella organization to unify offers by the BGK (State development bank), PARP and other actors and provide a more coherent access for enterprises and local administration for funding (OECD 2018b, p. 114). NCBiR focuses on applied research with a stronger focus on private organizations. Its priorities rely on the National Research Program (KPB) from 2011 that highlighted seven interdisciplinary areas (including 'civilisation diseases', new drugs and regenerative medicine) with approximately 70 research themes (European Commission 2017, p. 24). Finally, the National Science Centre (NCN) focuses on Higher Education Institutes (HEIs) and researchers supporting individuals and research institutions - a task that is complemented by the activities of the independent Foundation for Polish Science.

Whereas the national government is in charge of providing the main strategic orientation (such as the National Strategic Reference Framework for EU Cohesion Policy) and the majority of financial resources, regional authorities are in charge of strategic planning and the implementation of Regional Operational Programs (ROPs) of EU Cohesion Policy. The absence of independent sources of revenues, however, limits the autonomy of regions to act independently.<sup>20</sup> Regional innovation strategies (RIS) are part of the long-term regional development strategies and are embedded in the system of EU Cohesion Policy. The Malopolska RIS contains seven smart specialisation areas (OECD 2019c) that

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<sup>19</sup> [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/STP\(2019\)17&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/STP(2019)17&docLanguage=En)

<sup>20</sup> The public co-financing of regions is provided by the central government via so-called voivodship contracts (Churski 2018).

define the priorities for investments in the ROP. Besides three more 'traditional' areas of production (chemicals, manufacturing of metals and metal products, electrical engineering and machine building), life sciences and information and communication technologies (ICT) are among the new areas of specialisation (also sustainable energy, creative/leisure-related industries).<sup>21</sup>

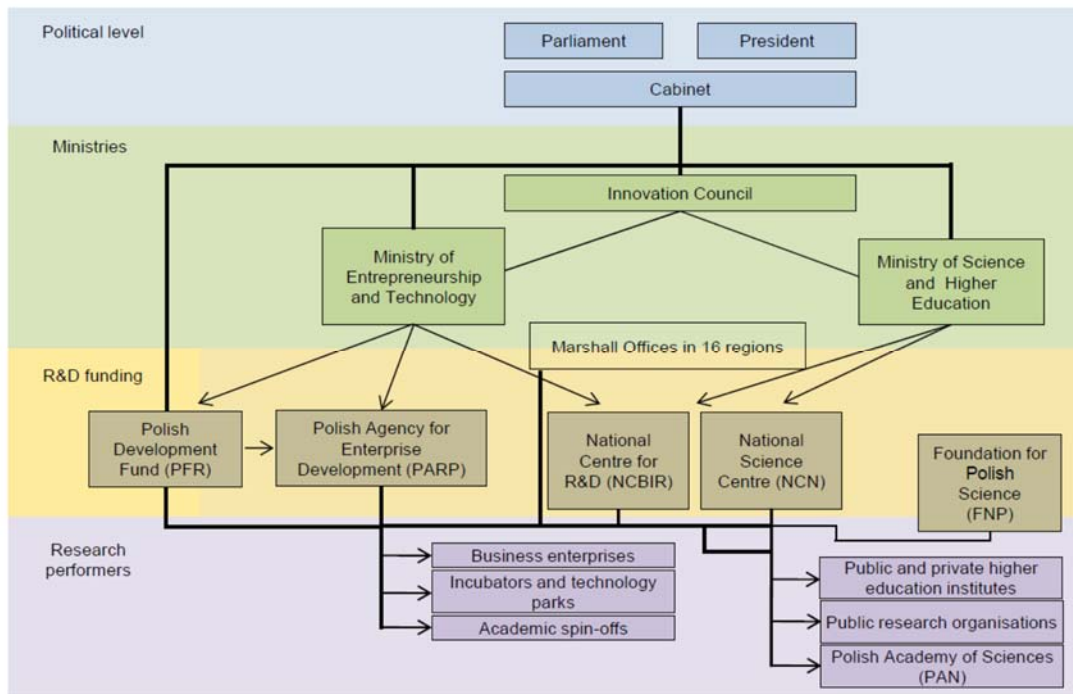


Figure 19: Institutional setting for research and innovation support in Poland (Figure from OECD 2018c, p. 13).

The development of innovation strategies at the regional level is supported by the Malopolska Innovation Council that is headed by the regional president and comprises representatives from enterprises, academics and territorial entities. For each of the specialisation areas there is an own working group that serves as a source of information and consultation for the definition of regional priorities. The impact of this working group in life sciences has been rated differently in interviews carried out with policy makers and public sector employees. While it is appraised that the smart specialisation strategies have helped to overcome existing boundaries (Nadolny et al. 2012, p. 137), there remain multiple points of criticism. This includes the poor linkage between knowledge generation in universities/research centres with the areas of smart specialisation and education of sufficiently skilled specialists (OECD 2019c, 19, 65), or the -despite improvements (OECD 2018c, p. 14) - still lacking coordination between different institutional levels in the implementation of policies.

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<sup>21</sup> Life sciences involves the following thematic fields: active and healthy life, medical products, modern therapy and diagnostics, digital health, new therapeutic and supportive medical devices, Innovative health centre, health food and nutrition, new balanced agriculture, environmental health resources, and bio-economy.



## 4.2 Direct financial support

The sharp increase in R&D spending of the business sector in Poland has been closely tied to the massive inflow of EU funds in the past years (Kapil et al. 2013, p. 28), summing up to almost 25 bln. EUR in the current funding period (2014-2020, see Figure 20). According to OECD data, roughly 85% of funds to support innovation in the private sector and SMEs is linked to EU Cohesion Policy (OECD 2018b, p. 17), while universities and public research organizations can access EU funds for research activities. Besides programs managed by the central government (above all the Operational Program Smart Growth) and some EU-wide programs (Horizon 2020 - research, COSME - SMEs, *NER 300* - reducing emissions), Regional Operational Programs are the second source for financing innovation. The ROP of Malopolska includes funding for innovation activities equalling roughly 340 million EUR (priority axis 1: “Strengthening research, technological development and innovation” and priority axis 3: “Enhancing the competitiveness of SMEs”).<sup>22</sup> After 2022 the availability of EU funds might diminish considerably and it is not clear how the further financing will be provided (OECD 2018c).

Interviews indicate that in practice there are often limited differences between regional and national programs, with applicants applying where they see the greatest chances for success (see also Klimczak et al. 2019, p. 13). At the same time, there seemingly is no lack of resources for innovation in general, but rather as argued by some interviewees a lack of good projects.<sup>23</sup> Finally, it is important to note that there are usually no resources reserved for specific sectors. In case of ROPs, all potential beneficiaries belonging to a certain area can apply for funding, but are competing with applicants from other smart specialisation areas. The re-orientation in EU funding towards SMEs and a greater role of equity-based instruments in the current funding period (2014-2020) instead of relying primarily on

Programme	Total financing (EUR billion)	Total financing (% of 2015 GDP)	Share of EU financing	Domestic financing (% of 2015 GDP)
<b>A. Smart Growth (of which)</b>	10.2	2.4	84.5%	0.4
I. Support for R&D activity of enterprises	4.6	1.1	84.5%	0.2
II. Support for the environment and capacity of enterprises for RDI activity	1.2	0.3	84.5%	0.0
III. Support for innovation in enterprises	2.6	0.6	84.5%	0.1
IV. Increasing the research potential	1.4	0.3	84.6%	0.1
V. Technical Assistance	0.4	0.1	84.6%	0.0
<b>B. Regional programmes<sup>1</sup></b>	7.0	1.6	84.6%	0.3
<b>C. Eastern Poland<sup>1</sup></b>	0.8	0.2	85.0%	0.0
<b>D. National Rural Development<sup>1</sup></b>	6.3	1.5	63.6%	0.5
<b>E. Maritime and Fisheries<sup>1</sup></b>	0.3	0.1	74.7%	0.0
<b>Total (A+B+C+D+E)</b>	24.7	5.7	79.1%	1.2

1. Refers to European Structural and Investment Funds with thematic objectives “Research & Innovation” and “Competitiveness of SMEs”. Source: European Commission (2016). ESIF Finance dataset.

Figure 20: Summary of EU Structural and Investment funds for innovation spending of enterprises in Poland (OECD 2018, p. 119).

<sup>22</sup> Based on interviews there does not seem to be a clear delineation between national and regional programs. Applicants usually apply where they see the greatest chances for success.

<sup>23</sup> Only in one case, it was noted that the available sum a company can obtain for projects do not match the financial requirements in the biotech area.



grants and focusing on large companies and infrastructure investments<sup>24</sup> (OECD 2018a, p. 18; Kapil et al. 2013, pp. 3–4)<sup>25</sup> has been welcomed however, with some reservations. While addressing criticism about the previous funding period past (OECD 2019c, p. 46; Nadolny et al. 2012, p. 143; PARP 2013, p. 60), the re-orientation might be too radical in its character and result in a low level of policy continuity.

Breznitz and Ornston warn of the pitfalls of the 'innovation tsunami' (2017, p.5). The large quantities would more than double private R&D expenditure and are at risk of imposing too great a demand on public administration for administering the implementation process. The main concerns with regard to the current funding mechanisms are too narrow a focus on activities (R&D), actors (SMEs), and instruments (venture capital investments) (p. 36), the lack of capacity and question whether there is sufficient demand for spending the massive inflow of money appropriately (p. 26-27). Brandt (2018c, pp. 21–22) in this context criticises that investments in technology start-up are high, but overlook the need to create adequate structures in higher education and research as a foundation. So far, the effects of the orientation towards SMEs has yielded rather mixed results (OECD 2018b, p. 116).

Access to financing in general has increased, placing Poland above the EU average (European Commission 2017, 79). In total there are three main sources for preferential loans: National Capital Fund (KFK), Corporate Venture programmes run by several companies (KGHM, TVN), and Crowdfunding platforms (a total of 25 platforms in Poland). Access to finance for SMEs has also improved over time: Poland makes considerable use of loan-guarantees for SMEs, adding up to more than 14.5 bln PLN (OECD 2018a, pp. 16–17). With regard to financial service entities the OECD (2019c, pp. 45–46) reports a total of almost 2,000 financial entities, placing Malopolska in a comparatively weak position, though the total number increased since 2009 by 40%.

There have also been efforts to increase the role of Venture capital at different stages of the business cycle (e.g. the Polish Development Fund PFR; 'Start in Poland', approx. 2.8bln PLN, or the BRIDGE Alfa programme). However, it remains unclear whether there is sufficient demand (OECD 2018b, p. 50) and there have been legal and tax uncertainties in the past (OECD 2018a, p. 25). The current structure of public procurement is not yet in condition to incorporate quality criteria and support innovation (OECD 2018b, p. 97).

### 4.3 Indirect financial support

The recent innovation laws strengthened to possibilities for tax deductions for R&D expenditures and thus complemented the predominant focus on direct support for innovation (OECD 2018a, p. 10).<sup>26</sup> Prior to 2015 the reliance on these instruments has been very small, it increased strongly afterwards and accounts for 2% of total (direct and tax) support of the Polish government (see Figure 21). At the same time, there is a need for the clarification of rules (eligible costs, regulations) and for a careful

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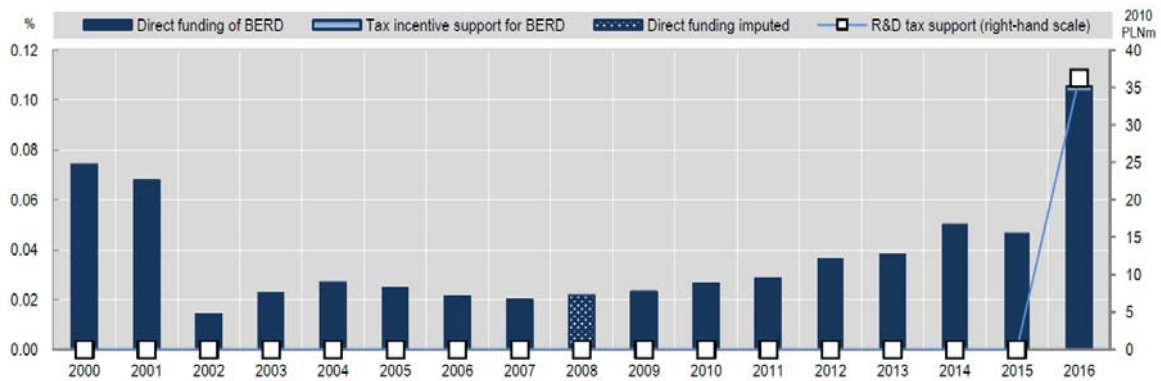
<sup>24</sup> Larger companies tend to have advantages when applying for grants, as these can rely on internal resources or external support for application procedures that are rather complex (Nadolny et al. 2012, p. 136; Nadolny et al. 2018, p. 81).

<sup>25</sup> For a summary over spending priorities in the past funding period see the appendix.

<sup>26</sup> In contrast to EU funds these also allow for innovation at the enterprise level.



review, in order to analyse the risk of abuse of current rules and whether young and innovative firms/SMEs benefit from these specific measures (OECD 2018b, pp. 50–51, 2018a, pp. 20–22).



Source: OECD, R&D Tax Incentive Database, <http://oe.cd/rntax>, March 2019.

*Figure 21: Direct funding of business R&D and tax incentives for R&D, Poland, 2000-2016 (OECD 2019c, p. 2).*

Moreover, SMEs were addressed with specific tax measures and a reduced tax rate. The chosen approach, however, has been criticized for creating size thresholds that might act as an obstacle to firm growth. These thresholds create problematic incentives and introduce arbitrary cut-off points by e.g. ending exemption from contribution to social security system rather abruptly (OECD 2018b, p. 121). Among current measures, there has been the introduction of an Innovation Box regime by 1<sup>st</sup> of January 2019.

#### 4.4 Collaborative infrastructure for business development/innovation

There is a range of actors aimed at supporting the transfer of knowledge and facilitating the realization of innovative developments. Especially the inflow of EU funding has fuelled the emergence of clusters, technology parks and other structures supporting innovation activities with reaching its peak around 2013 and decreasing since then (Mitka et al. 2018, p. 76).<sup>27</sup> However, given the fuzzy definitions, the dynamic environment and changes over time, a clear delineation is often not possible, leading to considerable differences between different reports (Mitka et al. 2018; SOOIP 2018)

However, the emergence of such structures has not been without criticism, questioning the impact and effects of these structures and their match with entrepreneurs' needs (Kapil et al. 2013, p. 61; OECD 2018c, p. 28, 2019c, pp. 85–86)<sup>28</sup>, a finding that also applies to Malopolska in general (OECD 2019c, p. 89). This is also reflected by an evaluation of the Regional Innovation System in Malopolska that suggests that there is a declining/limited role of business intermediaries (IOBs), as actors prefer direct contacts (Nadolny et al. 2012, p. 137).

<sup>27</sup> A clear delineation and identification of business environment organizations is difficult due to rather fuzzy criteria, varying activities, and changes over time (see Mitka et al. 2018, pp. 75–79).

<sup>28</sup> In some instances, such organizations may even create additional complexity like in the case of Technology Transfer Offices (OECD 2019c, p. 88). These offices often suffer from a lack of funding and qualified personnel (OECD 2018c, p. 20).





Among the 560 centres for innovation and entrepreneurship in Poland existing in 2017 (SOOOIP 2018), 45 are located in Malopolska, ranking fifth in absolute numbers (behind Masovia, Wielkopolska, Silesia, Lower Silesia). Like in all Polish regions, the majority of institutions is located in the regional capital, Krakow.

*Table 4: Business environments institutions*

Type of intermediary	Poland	Malopolska	Krakow
Innovation centres	39	3	3
Technology Transfer Centre	55	4	3
Seed funds	88	10	8
Loan funds	58	4	3
Guarantee funds	52	2	1
Business incubators	37	5	1
Technology incubators	22	2	0
Training and consulting centres	151	11	4
Technology parks	37	2	2
Academic incubator	20	4	3

*Source: Own compilation based on <http://www.sooipp.org.pl>*

#### 4.5 Regulations, incentives, and guidance

The process for the approval of medical products as a crucial part of technology regulation will be discussed in greater depth in Section 5.3. The legal IP framework in Poland is embedded into the system of the European Union, with regulations having being harmonized with the European Patent Conventions. One particular obstacle, however, might be the enforcement of contracts. Taking the Doing Business Index of the Worldbank (2019) as a benchmark, Poland among all categories absolute scores are particularly low in the area contract enforcement, lagging considerable behind the best performers (35 percentage points). The main reason for this is the low speed of court proceedings (ibid., pp. 51-56).

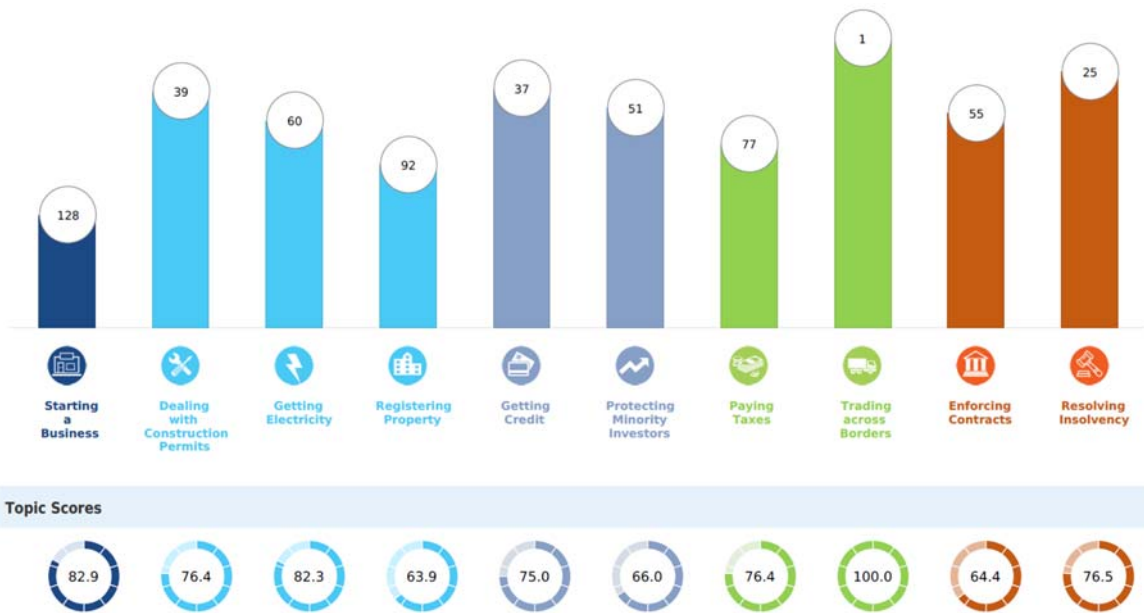


Figure 22: Rankings and scores of Doing Business Index for Poland (2019, p. 4).

### 4.6 Summary

The character of Polish innovation policy has been massively shaped by the inflow of EU resources, marking the beginning of a new period of innovation policy in Poland (Jasiński 2018, p. 231). This has an impact on both the available instruments and the emergence of new actors. This includes the growing importance of regional authorities as bodies being in charge of implementing parts of EU Cohesion Policy, as well as the creation of business intermediaries/support organizations that were financed from EU resources.

Despite the centralized character of Poland, there is a multi-level structure with activities of multiple actors at the national level and regional authorities in economic development and innovation. At the same time, it is highlighted that that '[t]he region is becoming more innovative largely as a result of government action rather than through a natural tendency of firms and individuals to innovate' (OECD 2019c, pp. 35–36), suggesting that the process is strongly top-down driven, suffering from a lack of bottom-up initiatives.



## 5. Healthcare system and healthcare provision in Poland

### 5.1 Context of health care in Poland

Poland is increasingly confronted with rapid aging. The age dependency ratio<sup>29</sup> rose by 20% in 2018 compared to 2010 and expected to do so further due to a recent decision of the government to lower the retirement age, putting more pressure on the labour force. Health spending has increased, however, Poland belongs to the EU countries with the lowest health expenditures both absolutely and relatively. The out-of-pocket expenditures are still among the highest in the. A third of the population reports skipping medical consultations as a result of high costs (Domagała and Klich 2018).

The total population of Poland was approximately 38 million in 2017, but is decreasing as a result of a low birthrate. However, in some regions, an increase in population can be registered, among them the Malopolska region. Figure 23 shows the current population structure as well as the projected structure for 2050. This is partially due to domestic migration (Statistical Office Krakow 2019).

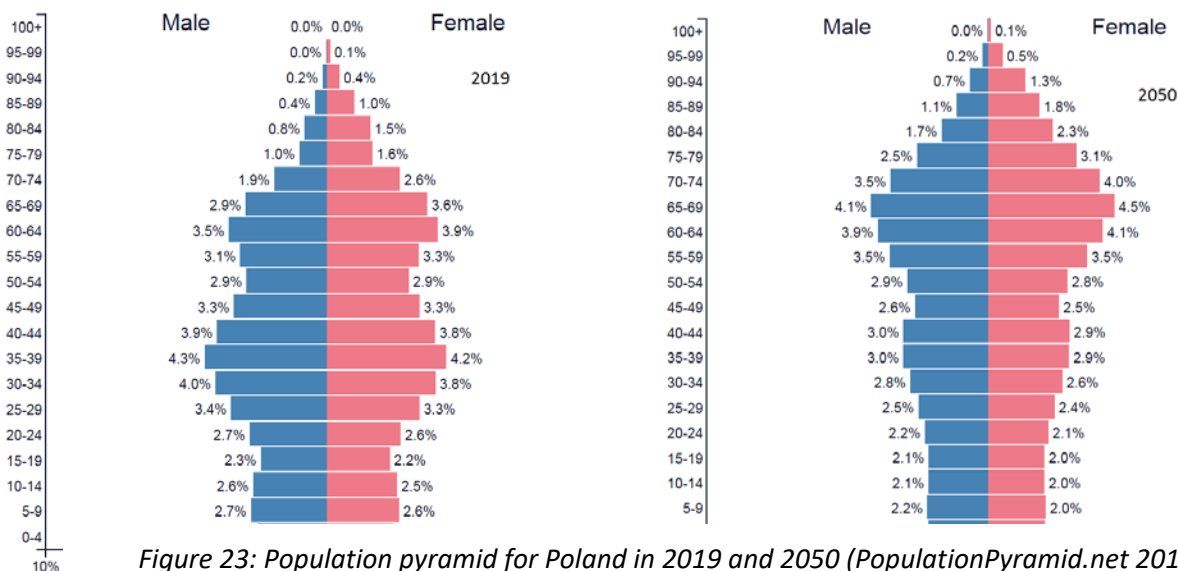


Figure 23: Population pyramid for Poland in 2019 and 2050 (PopulationPyramid.net 2019).

Figure 24 shows the development of Polish population size in general compared to the development of the population aged over 65 years. The percentage of people 65+ is shown in a dashed line and is steadily increasing. People aged over 65 currently make up about 7% of the population, but receive 44% of health care benefits (Statistics Poland 2019).

Average **life expectancy** in Poland was 78 years in 2016, which is three years less than the EU average. Worryingly, the number differed up to 16 years between social groups within Poland. Of the average 78 years, Poles can expect to live 60 in good health; however, their mortality is 25% higher than the EU total, differing between regions, with Malopolska one of the two districts with the lowest mortality rate (934 compared to 1,036 deaths/10,000 inhabitants/year). Among the main causes of death are circulatory diseases and ischemia, responsible for almost half of deaths; cancer causing a quarter of deaths, and bronchus and lung diseases. 34% of the population reported health problems lasting

<sup>29</sup> Ratio of people younger than 15 or older than 64 to the working-age population those ages 15-64 (World Bank Open Data).



longer than six months (Sowada et al. 2019). The prevalence of dementia is lower than the OECD average with about 10 cases per 1,000 inhabitants (OECD Health Division 2017), but is likely to be a result of a lower life expectancy.

In general, Poland faces problems that have direct health implications such as a relatively high alcohol consumption rate or a high exposure to air pollutants (Sowada et al. 2019).

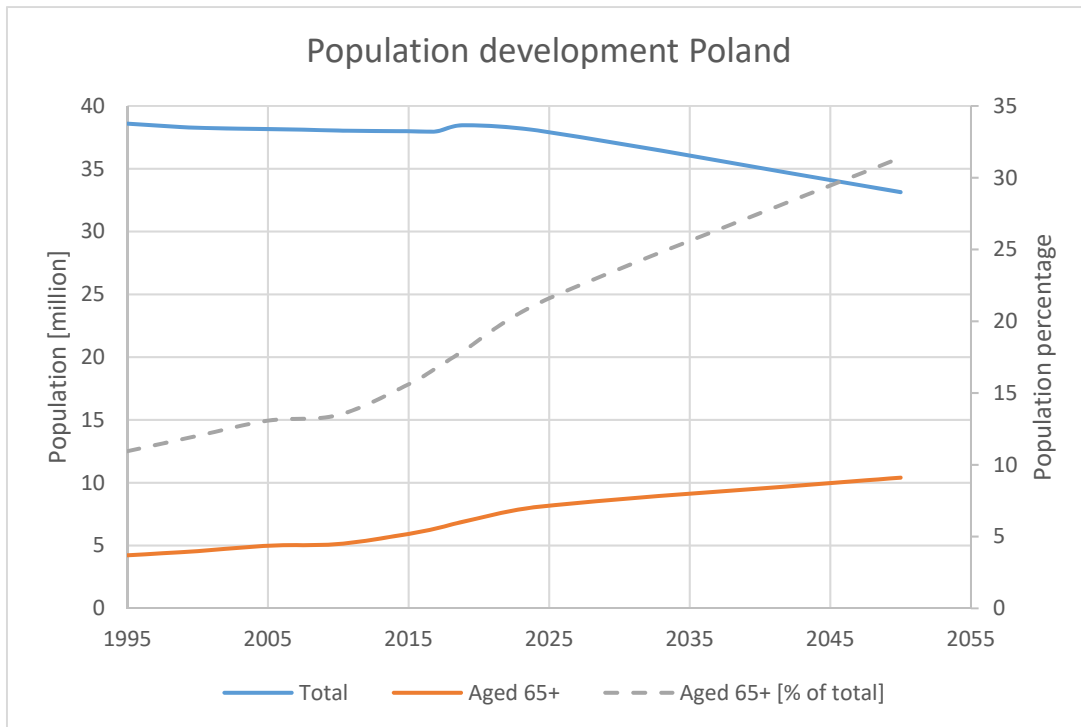


Figure 24: Population development in Poland (Statistics Poland 2019). Projected data based on PopulationPyramid.net

## 5.2 General structure and functioning of the health care system

The health care in Poland is free for insured people and is delivered through a public system. It is a combination of the Bismarck and Beveridge models of healthcare systems: Elements from the Bismarck model, which is found e.g. in Germany and France, include the way medical services are financed and activity of healthcare providers is regulated as well as freedom of choice in provider. An element taken from the Beveridge model, to be found in the UK or in Sweden, is there being only a single payer that decides on contract details and prices of medical services.

The Polish healthcare system consists of the following central institutions (see Figure 25): the Ministry of Health; organs of control (the Chief/State Sanitary Inspectorate *Sanepid*, the Chief/State Pharmaceutical Inspectorate, the Patient Rights Ombudsman), the National Health Fund (NFZ), voivodeships, counties/districts (*powiaty*) and municipalities (*gmina*) and the healthcare services provided at these different levels, last but not least the actual beneficiaries, the patients who need or utilise public-funded health care (Fal 2016).

The Ministry of Health's role in health care is mainly that of governance of the sector and its organisation. The Minister of Health sets out the country's health policy orientation and works with national consultants operating in various medical specialisations. The Ministry of Health also serves as



supervisor for hospitals, the training of health care personnel, funding of very expensive medical equipment, and the compliance with health care standards. Additionally, it supervises the Chief Pharmaceutical Inspectorate, the Office for Registration of Medicinal Products, Medical Devices and Biocides and the Chief Sanitary Inspectorate, the Medical Centre of Postgraduate Education and the Agency for Health Technology Assessment and Tariff System (AOTM, see Figure 25) (Panteli et al. 2011; Fal 2016)(Fal 2016, Panteli 2011). The role of the National Health Fund (NFZ) is described below.

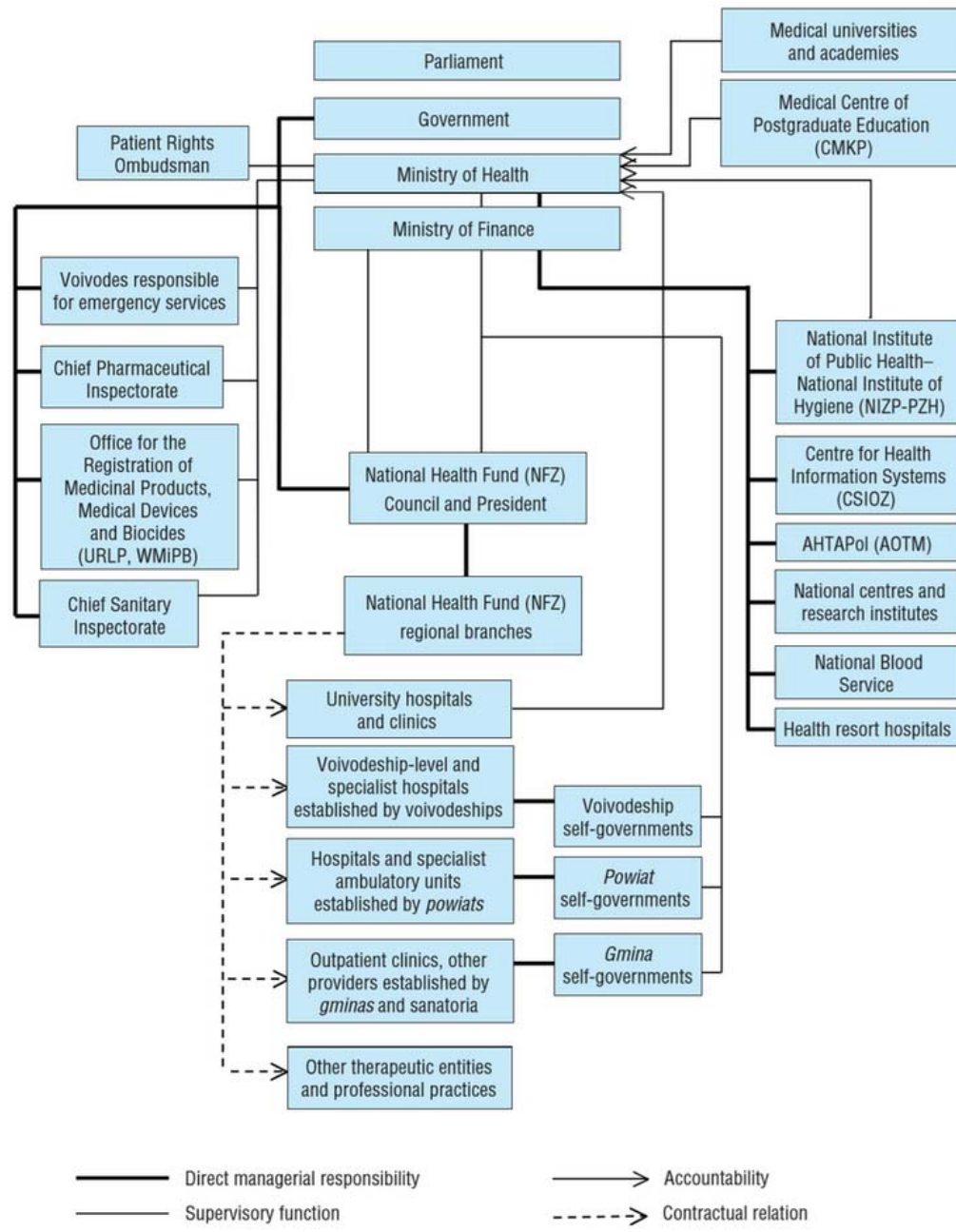


Figure 25: Relations in the Polish Health Care System (Jasinski 2015).

The Patient Rights Ombudsman investigates if patient rights might have been violated, initiates new laws and raises awareness for patient rights.



The territorial self-governments, i.e. regional, county, and municipal governments, are responsible for health care and service provision assessment, as well as for promoting health and preventing diseases and outbreaks. On voivodship-level the respective government plans health care according to the population's needs and organizes the medical emergency services.

According to the 2011 Law of Therapeutic Activity, health services can be provided by either therapeutic entities or professional practices. The therapeutic entities include private entrepreneurs, independent public health care facilities (SPZOZ), budgetary entities, research institutes, foundations, associations and churches. Among the professional practices are those of physicians, dentists, nurses, midwives, laboratory diagnosticians as well as pharmacies. All practicing professionals are obliged to be a member of their respective professional chamber (Panteli et al. 2011).

Concerning changes in the health care system, a National Health Programme (NPZ) is issued every five years. It sets out strategic and operational objectives and the most important tasks to improve health and quality of life. The most recent National Health Programme covers the time from 2016 to 2020 (Witold Chodzko Institute of Rural Medicine 2020).

#### Financing

The financing of the Polish health care system is legally based on the right to equal access to public health services, as granted in Article 68 of the Constitution. The health system is mainly financed by mandatory health insurance contributions that are dependent on the income; paediatrics and emergency services are financed from general taxes (Sowada et al. 2019). According to the OECD '[i]n Poland, employees bear the brunt of social contributions [...]'. In 2015 health financing was sourced mainly from social insurance contributions, a fifth through transfers from government domestic revenues and only 5% through voluntary prepayment by the patients (OECD Health Division 2017).

All public health providers are paid by the National Health Fund (NFZ). The Fund receives money from the districts and the National Health Ministry. This 'central and highly monopolistic' structure is criticized by Nieszporska (2017), who calls it the 'most important organizational problem of the Polish health care system' and 'utopian'. The National Health Fund creates contracts with generalists and specialists in private practices and with hospitals, assigning how much money will be paid for a certain treatment. That way the number of treatments in a facility or practice is limited and more treatments will not be done, even if there were sufficient capacities and patients in need - the Fund would not pay for it. As soon as the treatment contingent is fulfilled, patients have to wait for a long time (Hreczuk 2017). However, some health care services are reimbursed regardless of such contingents (e.g. cardiologic interventions, transplantations, births, cancer diagnoses and treatment). In primary health care an annual capitation payment per patient registered with a general practitioner is paid in monthly instalments. Concerning secondary care in outpatient specialist care, a fee for service rates is reimbursed; in hospital treatment the payment is based on the respective cases, while emergency wards receive a daily lump sum; in long term, palliative and psychiatric care the facilities are reimbursed per diem (Bulankowski 2016).

In addition to the NFZ, 17 sickness funds exist - one in each region plus a separate fund for the uniformed services. As per the 2004 'Act on Health Care Services Financed from Public Sources' no complete private health insurance is allowed; however private supplementary insurance in the form



of subscriptions with private health care providers ('quasi-insurance') can be acquired. These subscriptions are not considered insurance products and are therefore less heavily regulated. The market of private health subscriptions is ever growing (Sowada et al. 2019). According to Alicja Sobczak (2016) '[t]hese subscriptions mainly provide faster access to and better quality of outpatient services'. Examples include ambulatory specialist consultations and procedures, diagnostic procedures, inpatient treatment as well as rehabilitation, medical treatment, nursing treatment and dental care.

#### Expenditure

In 2018 health expenditure consumed 6.3% of GDP and as such was lower than the OECD average at 8.8%. However, between 2013 and 2018 it had increased faster than the OECE average (4.3% vs. 2.4%). In total numbers the per capita health expenditure was 2,056 \$ per person, a number far lower than the OECD average of 3,992 \$per person (OECD).

In 2016 health expenditure by financing type was distributed as follows (OECD Health Division 2017):

- 61% compulsory health insurance
- 23% out of pocket
- 9% government schemes
- 5% voluntary health insurance.

According to Nieszporska (2017) about 70% of this private, out-of-pocket expenditure was spent on medication, about a third on outpatient health care and 2.3% on hospital treatment. The share of expenditure on over-the-counter medicines for patients is particularly high. The expenditure on long-term care is remarkably low, probably due to a lot of patients being cared for by unpaid relatives. Many outpatient clinics, dispensaries and doctor's practices do not appear in the public health expenditure statistics, as they are largely in private hands (Nieszporska 2017).

In 2015 health expenditure by type of service was distributed as follows (OECD Health Division 2017): 36% inpatient care, 30% outpatient care, 23% medical goods, 6% long-term care, 4% collective services.

#### Reforms

In 1999, the financing source of health care shifted from general taxes to an insurance system composed of sickness funds. In 2003 these were complimented by the National Health Fund. In 2011 the controversial Commercialization Reform aimed to resolve the grave indebtedness of Polish hospitals and established that, if a district-owned hospital loses money and the district is unable to pay the loss, it has to be transformed into a company. Effects were limited and reforming efforts were delayed and postponed due to protests from doctors and human rights activists (against strict abortion laws) in recent years (Sowada et al. 2019). In 2012, the law was tightened so that people now lose their social and health insurance if they fail to pay their contribution; however, according to the OECD Health Division 'uninsured people who need medical care, utilize emergency hospital services, where they will be encouraged to obtain insurance'.



Recent reforms aim to increase the number of nurses and midwives, as well as that of medical graduates (HSPM 2019). In the OECD Health Division's report the number of medical graduates was indicated as rising, if partly due to international students. The reforms also include the objective of increasing the wages (Sowa-Kofta 2018). Very recently the nurse-to-bed ratio has been set higher than before (0.6 to 0.9 nurses per bed), resulting in a decrease in hospital beds (HSPM 2019). The Act on the Network of hospitals adopted in 2017 established a network of hospitals of particular importance for ensuring access to healthcare services to patients, with financing to be guaranteed by the government. The majority of funding (91%) is allocated to hospitals that meet the requirements to be part of the network, leaving the approximately 50% of hospitals not involved with potential difficulties in providing services (Dubas-Jakóbczyk et al. 2019).

#### Numbers of health care providers

In 2017 there were 1,058 hospitals in Poland This results in 6.6 hospital beds per 1,000 people, which is above the OECD average of 4.7 beds (OECD 2019a).

About a fifth of doctors are generalists. Specialist treatment is organized by Koordynowa Opieka Specjalistyczna (KOS, Coordinated Specialist Care) and provided mostly by hospitals. A shift from inpatient to outpatient care is taking place and as mentioned above waiting times for specialists can be very long (up to eleven months for endocrinologists or over a year for cataract treatment). Waiting times for surgeries are longer than in other OECD countries (OECD Health Division 2017).

'There is no information on the split between various care settings (e.g. share of specialists working in their own practices and specialists working in outpatient departments of hospitals)' (Sowada et al. 2019).

As in Western European countries the number of hospital beds per inhabitants is declining - 75% of those beds are dedicated to curative care and 25% to rehabilitation care (OECD Health Division 2017).

#### Supply with medical technology and IT-infrastructure

The number of MRI (magnetic resonance) units was only half the OECD average with 7.6 units per million inhabitants, that of CT scanners 17.2/million inhabitants compared to an OECD average of 25.7 (OECD Health Division 2017). Both values serve as an indicator for the grade of supply with medical technology.

According to Kautsch et al. (2016) '[a]lthough developments of IT and E-Health solutions in the health sector have been official priorities for over a decade, in practice, implementation has been slow and patchy'. Although between 38% and 53% of health care providers have an IT strategy for the years ahead, only up to 13% currently use decision support systems. The usage of telemedicine such as e-diagnostics or tele-consultations is between 10.9% in ambulatory care providers, 22.7% of long-term care providers and up to 40.4% of hospitals (HSPM 2019).

In the OECD Health Division's report the poor integration of primary and secondary care is attributed to the low level of IT use in health care. The organization, management and coordination of IT systems is regulated by the 2011 Act on Information Systems in Health Care. The development of e-health solutions have been a priority in this. According to (Sowada et al. 2019) access to IT has significantly improved, but the implementation of e-health has been slow. They cite as reasons a lack of reliable





analysis and coordination among national, regional and local IT, as well as a delay in the development of regulations.

'In general, computers with Internet access are used in the vast majority of health care providers [...]. In ambulatory care units they are mainly used for registering patients and other administrative purposes. Use of IT solutions during medical consultations in primary and specialist ambulatory care is low, particularly in solo doctor practices and small to mid-size ambulatory care units. Implementation of IT solutions is more advanced in the hospital sector compared with out-patient care, yet still requires much progress.' (Sowada et al. 2019)

Table 5 gives an overview on the state of digitalization in the Polish health care system.

The attitude of the users is also very important in introducing e-health technologies. According to the Polish Ministry of Administration and Digitalization in 2015 around a quarter of the population was digitally excluded - mainly the elderly, so the part of the population that would benefit from e-health solutions and telemedicine the most. The Jagiellonian University spin-off 'Dane i analizy' (Data and analytics) identified doctors as a group resistant to e-health, the reasons being fear of job-loss and a decrease in their performance quality. Contrarily patients, especially younger ones, were seen as very accepting of e-health solutions (Data and analyses 2015).

*Table 5: Progress in implementing IT solutions by type of provider, 2018*

	Ambulatory care	Hospitals	Long-term care
	Providers with a positive answer [%]		
<b>IT strategy</b>	37.9	53.1	46.2
<b>IT infrastructure, that allows e-documentation</b>	53.2	66.3	50.6
<b>e-service cooperation with other providers</b>	14.8	24.2	15.6
<b>e-registration</b>	27.7	46.7	24.0
<b>Decision support systems (medical)</b>	4.5	7.8	5.5
<b>Decision support systems (management)</b>	4.1	13.2	8.7
<b>telemedicine</b>	10.9	40.4	22.7

*Source: Sowada et al. 2019*

## Challenges

The Polish health care system is stricken by challenges such as old and obsolete infrastructure in hospitals, public hospital indebtedness and emigration of medical staff due to low salaries, long working hours and lack of specialisation opportunities for doctors (Sowada et al. 2019). The number of specialists per 1000 inhabitants is 2.2, compared to 4.3/1000 in Norway (Nieszporska 2017). The share of employment in health and social work is declining and was 6 % of the work force in 2015, compared to a 10 % OECD average (OECD Health Division 2017).



Compared to other OECD countries, Poland exhibits the lowest population coverage with insurance for core health services. 33 out of 100 doctor consultations are skipped due to concerns about having to pay medication out of pocket (OECD average = 10.5/100 appointments), which is an indicator for actual financial **access** - pharmaceuticals often have to be paid at the patient's expense. The OECD Health Division lists other problematic indicators such as a low concern for patient safety as measured by obstetric trauma and a high rate of avoidable hospital admissions.

According to Nieszporska (2017) the centralized organization of the insurance market results in lengthy waiting times for a specialist consultation (see above) and supply with cheaper, older generation drugs. She holds organisational problems responsible for discontinuous care and mentions other issues such as a high fluctuation in the price for medication and the poor state of patient rights in courts.

### 5.3 Health Technology Assessment in Poland

Since 2005 the Agency for Health Technology Assessment and Tariff System (AOTMiT) has served as an advisory body to the Ministry of Health and has been setting tariffs for health care services since 2015. The AOTMiT is tasked with controlling and testing medicines, health care services and public health policy programmes. The AOTMiT also issued guidelines for Health Technology Assessment, listed in the bibliography (The Agency for Health Technology Assessment and Tariff System of Poland 2016). The agency cooperates with other international health technology assessment organizations (Sowada et al. 2019).

Figure 26 displays a flow chart of the approval process by the AOTMiT. If a new product is innovative or its use for a new clinical indication is applied for or if the price is to be increased, an additional report on the expected economic impact and the impact on the health system as well as on social consequences must be submitted. After the initial health technology assessment, the Transparency Council assesses the product independently. The AOTMiT has nothing to do with reimbursement of a product, which must be negotiated with the Economic Commission of the Ministry of Health.

'For a few years, the Polish health care system has been recording numerous actions connected with implementation of modern information technology systems. The works aimed at placing the system in the teleinformatic area are going in different directions, the most important of which are: administrative side of hospital operation, supporting current work of physicians in the area of diagnosing, counseling and therapy and making data on patients and latest achievements of the world.' (Nieszporska 2017).

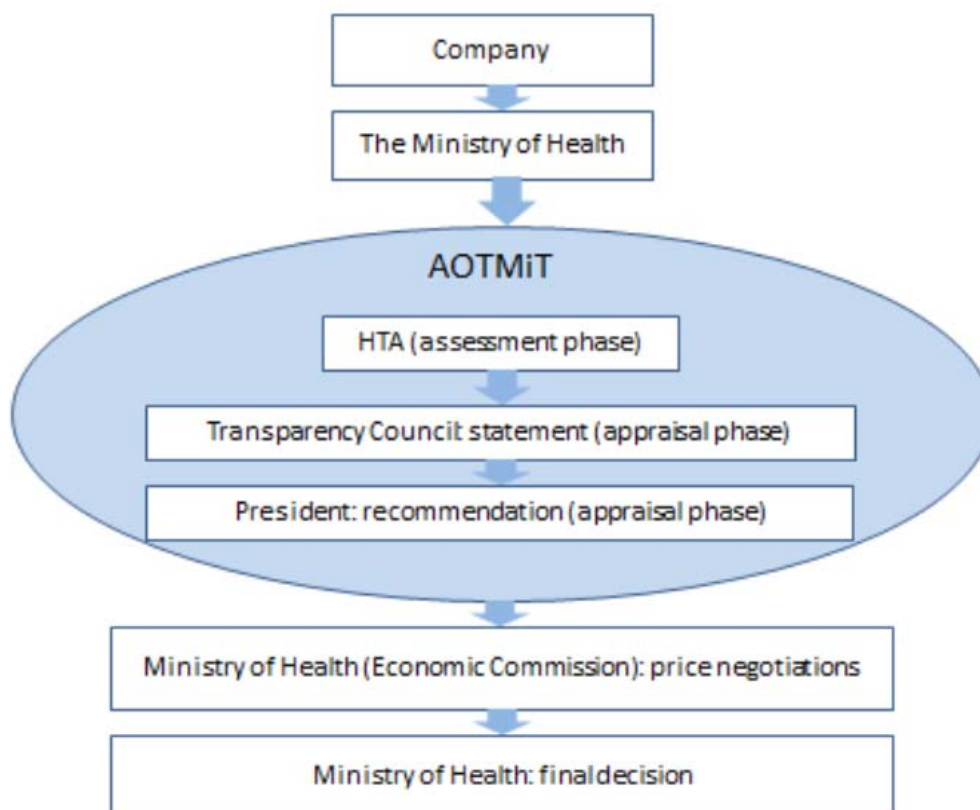


Figure 26: Flowchart of Approval Process via AOTMiT (van Wilder et al. 2015).

## 5.4 Healthcare in the Malopolska region

The population in the Malopolska region saw an increase in the past few years due to natural population growth and a positive net migration rate. As mentioned previously, the region also enjoys the lowest mortality rate in Poland and the highest life expectancy (Sowada et al. 2019) .

Table 6: Medical personnel in the Malopolska region in comparison to general Poland.

Year	Doctors per 10,000 people		Nurses and midwives per 10,000 people	Pharmacists total		Increase pharmacists
	2005	2017	2017	2004	2017	2004-2017
Poland	33	38	71	22,170	29,330	32%
Malopolska	33	39	77	2,185	2,562	17%

Source: Statistics Poland 2019

The following statistical differences to Poland in general are derived from the Polish Statistics Agency's Local Data Bank:<sup>30</sup>

There were less self-paying patients in health resort facilities (24% compared to 35%). The number of patients per bed in general hospitals in Malopolska declined stronger between 2005 and 2017 than in

<sup>30</sup> <https://bdl.stat.gov.pl/BDL/start>



Poland overall, but was higher in total (from 213 to 207 in Poland; from 235 to 226 in Malopolska) - this indicates that the medical provision in hospitals is improving in the region.

Table 6 shows some data on medical personnel in Malopolska and how their numbers developed. The numbers in the table can serve as an indicator that while some indicators for health provisions changed similarly in Malopolska compared to the rest of Poland, while others differed somewhat.

## 5.5 Summary

Poland has relatively low health care spending compared to other countries in Europe, manifesting itself in a below average life expectancy (although this has increased since 2000). However, compared to other countries with similar level of spending on health care, Poland is able to achieve better outcomes.

Overall, the health care system is overstretched, suffering among others from a lack of professionals and an ageing population. Malopolska is one of the regions performing better on these indicators.

There is a reliance on private health care services due to long waiting times in public facilities. This results in high out-of-pocket expenses for patients.

Like many other countries, the Polish health care system is running on a partially obsolete infrastructure. While e-health has been declared a priority, in practice only a small proportion of healthcare providers make use of it. This is one of the contributing factors to a fragmented health care system, i.e. a weak degree of coordination between inpatient and outpatient care.

While conditions for computational medicine may not be ideal with regards to the overall level of computerisation and interoperability, there is also an urgent need for more efficient health care and improved outcomes.



## 6. Stakeholders

### 6.1 Stakeholder mapping

Sano's success within the ecosystem depends on its ability to integrate within the existing stakeholder landscape. The section builds upon the insights of the previous sections, desk research, the qualitative interviews and a patent and publication analysis. Besides providing an overall assessment of the strengths of individual stakeholder groups in the ecosystem, it identifies key players in the field.

#### Academia

In Malopolska, there are three higher education institutions offering various training courses and conducting R&D related to the ICT sector: AGH University of Science and Technology,<sup>31</sup> Krakow University of Technology and Jagiellonian University, established in 1364. Additionally, there are several scientific institutes of the Polish Academy of Sciences. Universities in Malopolska are characterised by a relatively high level of scientific research.<sup>32</sup> Drawing insights from the publication analysis (see Section 3.3) especially the Jagiellonian University, the AGH, and the Pharmacological Institute of the Polish Academy of Sciences appear as key players in the relevant fields in the Malopolska region. Moreover, there is the Malopolska Biotechnology Centre that deals with scientific research in biotechnology, food safety, nutrigenomics and related fields (Business in Małopolska 2019c).

Research and development actors in engineering include the Institute of Advanced Manufacturing Technology and the Research and Development Centre operating within Zakłady Mechaniczne Tarnów S.A (Region of Malopolska 2018).

#### Industry

In Malopolska, there is a large group of companies that owing to their focus of specific thematic business activities offer a considerable potential for applications of Computational Medicine solutions in future. This critical mass of companies is necessary to booster competition in the region, which could lead to new business opportunities for advanced technologies, including Computational Medicine. A large number of companies in Malopolska is operating in the areas, which are of potential relevance for this field of technology:

- pharma and biotechnology
- medical technology and medical equipment
- diagnostics/E-Health
- clinical research
- medical services.

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<sup>31</sup> The AGH University was founded in 1919. It offers numerous courses in modern technical disciplines like Industrial Computer Science, Electrical Engineering, Automatics, Computer Science and Biomedical Engineering, Electronics and Telecommunications, Mechanical Engineering and Robotics, Physics and Applied Computer Science, Advanced Materials and Nanotechnology. CYFRONET Academic Computer Centre, operating as organizationally and financially an autonomous unit of the AGH University is one of the largest supercomputing centres in Poland.

<sup>32</sup> See also <https://www.timeshighereducation.com/world-university-rankings>



Selected companies with potential relevance in the area of Computational Medicine are listed in appendix II.

#### Health care providers

Within Malopolska Krakow in particular has numerous healthcare facilities. In 2017, there were 13 regional hospitals, independent healthcare units, 19 powiat (i.e. county) hospitals and 8 departmental hospitals that are either linked to state authorities (army/Ministry of the Interior), specialised institutes (cancer research, lung diseases) or are linked to the Jagiellonian University in Krakow. Besides the majority of these hospitals, there is a number of private hospitals. Whereas the hospitals Sw. Rafała (Scanmed), Nowy Szpital (Grupa Nowy Szpital Holding S.A.) and Sw. Jana Grandego (Zakonu Bonifraterek) is part of the hospital network of the NFZ and thus receive public reimbursement, there are other private institutions (Szpital na Klinach - Krakow; American Heart of Poland - Charznów). According to data provided by the health report of the region of Malopolska, advanced technological equipment can be mainly found in the hospitals in Krakow (Urząd Marszałkowski Województwa Małopolskiego 2017, pp. 42–43).

Jagiellonian University Medical College is Malopolska's foremost teaching hospital and is responsible for the university hospitals. These are The University Hospital, considered to be one of the best in the country the biggest health care institution in Poland; the Children's University Hospital, the Orthopedic-Rehabilitation University Hospital (Zakopane) and the University Dental Clinic. Together these provide a wide range of services to the Malopolska region and beyond and are actively involved in national and international collaborations.

#### Intermediaries

As noted in Section 4.4, there been a growing number of business intermediaries and institutions aimed at facilitating cooperation, knowledge exchange, commercialization of research results and providing financial services. At the same time, the overall number of entities does not allow yet insights into the effectiveness and role of those intermediaries, given the aforementioned problems.

In some there are few actors being specialised on the field of activities of Sano as such, as most business intermediaries pursue a rather general approach. The outstanding example is the the Klaster LifeScience Krakow that is considered as 'a model cluster in the country' (OECD 2019c, p. 89; similar Mitka et al. 2018, p. 172) and since 2016 receives funding of the national program for key clusters (Krajowe Klastry Kluczowe). It exhibits an orientation towards start-ups and almost half of its members are SMEs. Moreover the Jagiellonian Centre of Innovation, as a subsidiary of Jagiellonian University, operates the Krakow Life Science Park including a Clinical Trial Centre and lab space for rent.

Moreover, there are two thematic-specific clusters in South-Eastern Poland. In Tarnów there is the MedCluster being specialised on healthcare offers. A review of involved companies indicates a greater emphasis on companies focusing on customer-oriented solutions. Moreover, in close proximity to the Malopolska region there is the MedSilesia Cluster, containing mainly companies from the Silesia regions. It specializes on four main groups of products: rehabilitation, surgery and orthopedic tools, diagnosis tools and IT solutions for hospitals.

Among more generally oriented actors the following can be highlighted:



The Krakow Technology Park (Krakowski Park Technologiczny) as a joint project of national, regional and local stakeholders focuses primarily on larger enterprises. It is considered as a viable point for interaction between stakeholders and potential investors (OECD 2019c, p. 109). While not exhibiting a specialisation in the health sector, the Malopolskie ICT Park (MPTI) provides office space, labs and advisory services for IT companies.

Start-up Incubators: the main start-up incubators in the region are: Hub:Raum, KPT, JCI Ventures, Business Link, and BiznesLab (Mitka et al. 2018, p. 35). At the national, especially Startup Hub Poland and StartUp Poland can be considered as relevant (European Commission 2017). In Krakow there are attempts to enhance exchange and opportunities within the start-up community OMGKRRK which is partly financed by the Municipality of Krakow. Especially in Krakow there is a number of venture capital/seed funds (e.g. SATUS, JCI Venture, Innovation Nest)

Financial entities with a region-focus - besides credit line of e.g. MARR - are the Małopolski Regionalny Fundusz Poręczeniowy Sp. z o.o., Inicjatywa MIKRO Sp. z o.o., the Entrepreneurship Development Fund, Rabka Region Development Fund, the Local Government Centre for Entrepreneurship and Development, the Local Self-Government Loan Fund, and the Malopolskie Credit Guarantee Fund

There is a number of public business intermediaries aimed at supporting the activities of enterprises. The Małopolski Centrum Przedsiębiorczości (MCP) is responsible the implementation of several program lines of Regional Operational Programme with focus on Innovation and ensuring the linkage to the smart specialisation priorities. There are several business incubators working in different cities of the region.

Regional development internal is supported by the Malopolska Regional Development Agency (MARR). As a regional development agency, it is non-specific in focus, part of several of previous organizations (Technology Park, etc.), offering infrastructure, loans and subsidies for business development, advisory services and educational programs, implementing EU-funded programs. In contrast, the Business Centre in Malopolska (CeBIM), a joint cooperation of regional government and Technology park aimed at attracting investors to Malopolska and supporting efforts for export.

There are totally ten business incubators, seven Technology Transfer Centres and four Knowledge Transfer Centres located in Malopolska. With one exception, these are located in Krakow and are mostly associated with universities. Among the thematically closest bodies are the Malopolska Center for Biotechnology (Jagiellonian University) and the Center for Smart Information Systems (AGH). The AGH, the agricultural university and the politechnical university moreover established special purpose vehicles for the commercialization of research results, a step that is also planned by the Jagiellonian University (Mitka et al. 2018, pp. 80–81)

#### Public authorities

There is a considerable push for innovation from public actors. Especially EU funds play a pivotal role shaping the still dominating role of direct investments. While the central level through state-wide agencies (NCBIR, NCN, PARP, PFR) and operational programs (especially OP Smart Growth) has considerable leverage, the analysis should not ignore the growing importance of regional authorities, especially of the regional government. This is also confirmed by the assessment of the OECD (2019c, p. 16), attesting the regional government of Malopolska a high level of engagement that also



manifests itself in the organization of specific events like the annual innovation week. Furthermore, there is a number of intermediaries that are closely linked to regional authorities that are actively engaged in regional development policies (e.g. MARR, MCP).

The fact that Sano directly relates to one of the regional smart specialisation areas implies that there is not only support through regional authorities and the ROPs managed by them, but also that there is a high strategic interest in Sano. As confirmed during one interview with a regional policy-maker, the emergence of Sano has profound implications for the smart specialisation strategy as it can reinforce this priority and strengthen the role of life sciences in the region.

Civil society and non-governmental organisations

The bigger NGOs and patient organisations are organised at national rather than regional level. The Federation of Polish Patients (FPP) is an umbrella organisation that brings together representatives of other patient organisations to represent their interests ([www.federacjapp.pl](http://www.federacjapp.pl)). Besides illness-specific organisations (and their territorial sub-units) and foundations dealing with health at a national level, there is a number of foundations and organisations whose activities can be considered to be more local..

According to data of the Institute for Patients Rights and Health education, there were a total of 593 organisations dealing with health preservation/prevention and 118 patients' organisations in Lesser Poland. For instance, in the case of cancer, the database lists a total of 14 organisations that are active in the Malopolska region. Depending on the future priorities such organizations might be valuable partners for gathering detailed informations about the specific needs of patients and requirements for a successful implementation of computational medicine.

Moreover, in 2009 the position of ombudsman (commissioner) for patients' rights, who is directly subordinated to the prime minister, was created. Tasks include the initiation of procedures in case of a violation of patients rights, the analysis of patients complains and the preparation of reports to promote patients rights. Since 2017, the position has been held by Bartłomiej Chmielowiec.

Civil society organisations that Sano could possibly engage with are listed in appendix III.

## 6.2 Needs for computational medicine and stakeholder requirements

In order to better understand the ecosystem in which Sano will operate and the factors shaping the potential success of Sano, Fraunhofer ISI in cooperation with the Klaster LifeScience Krakow and University of Sheffield held a workshop in November 2019 in Krakow . It was attended by 24 clinicians, researchers and entrepreneurs. Discussions took place in a large plenary session and smaller working groups, facilitating the exchange of thoughts between different groups of stakeholders.

The discussions during the workshop underlined that computational medicine could potentially address a multitude of healthcare, research and industry needs. These include uncertainties in diagnostics, treatment and monitoring, a general lack of prevention, increasing efficiency in healthcare processes (e.g. by the use of chatbots), a lack of data and tools to develop targeted products and therapies, the high cost of bringing such products to the market, limitations in human clinical trial populations or difficulties in identifying patterns in large research data sets. These needs are embedded in a general trend towards personalised medicine arising from healthcare provider side





and demands from patients. Technical developments in computational processing, machine learning, app development as well as in life sciences increasingly enable advanced computational tools.

A broad range of different needs and existing gaps was identified by the workshop participants that computational medicine solutions could help to address. The overall need for diagnostic support and clinical decision support as well as for post-treatment monitoring and prevention of disease was emphasised by both clinicians and researchers. Of particular importance was the ability to identify hidden patterns and gain a better understanding of links between different phenomena, which is otherwise difficult to achieve. Moreover, with the help of computational medicine (in particular AI solutions) the experts expect that they will be able to better embrace the potential of precision medicine. Apart from the need to improve precision and efficacy of diagnosis and treatment, the use of computational medicine should free up primary care physicians' time and enable more efficient allocation and use of resources. In addition, new technological solutions are required, such as virtual assistants and chatbots to answer patient's questions, collect important information and help reduce unnecessary hospital visits.

Business representatives stressed the importance of the availability and access of database, of faster and more accurate user-friendly algorithms and models that can be used in their business practice to validate and design better-fitting medical devices and to be able to provide higher added-value products and services.

The workshop participants are also aware that for the successful implementation of computational medicine solutions, a number of essential requirements has to be met. One of the key requirements is the availability and accessibility of meaningful high quality data. To be able to exploit the potential of computational medicine, access to large integrated databases are key. CM applications make use of data that is often sensitive and private and are therefore subject to legal protection. The participants pointed out that there is an urgent need in terms of regulatory, legal and technological clarification and support (e.g. through effective anonymization techniques and secure data storage) perspectives to ensure secure use of data (e.g. for research purposes). Furthermore, the availability and access to expertise in computational medicine, in particular the interdisciplinary expert knowledge that combines relevant disciplines (engineering, computer science, medicine etc.) are highly important.

Trust, acceptability and understanding of how the technology works and the benefits it provides are essential. The dissemination of basic knowledge to all target groups (patients, clinicians) and communication with the general public would help understand computational medicine and discover its benefits, uses as well as its limitations. Further important preconditions are consistent digitalisation of all relevant areas, interoperability and standardisation in IT systems as well as the availability of significant computing power for the analysis of large and complex data sets.

### 6.3 Summary

Sano is being established within a rich and mostly favourable ecosystem with a multitude of stakeholders. This includes a good academic environment, the presence of a number of large international companies as well as local companies and start-ups. There are also various business intermediaries and as a result of the dual structure (regional and national) public actors are also represented. Several large hospitals as well as patient organisations and other civil society



organisations can play a pivotal role in ensuring that the needs of patients and healthcare professionals are met.

Computational medicine can potentially help to address pressing needs such as diagnostic uncertainty and trial and error approaches, a lack of prevention or lengthy and costly development processes for pharmaceuticals and medical devices. Stakeholders have also provided valuable insights into requirements to be fulfilled by Sano for the Centre to become a success.



## 7. Opportunities and Challenges of the Malopolska Innovation System

Through our data analysis and literature review and using the insights from the interviews (n=10) and the stakeholder workshop, a number of strengths and opportunities, but also bottlenecks for the emergence of computational medicine could be identified in Malopolska. The following sections provide a synthesis of the insights gathered and serve as a foundation for formulating recommendations for the future development of Sano. The multiple sources of data allow for a triangulation of results.

### 7.1 Opportunities and strengths

The analysis confirmed that Malopolska possesses a number of strength that can support the uptake of computational medicine. Firstly, there is a large number of skilled graduates educated at nationwide highly ranked universities in terms of educational quality, such as the Jagiellonian University, the Krakow University of Technology and the AGH University of Science and Technology. In the workshop on needs and challenges with respect to the implementation of computational medicine in the region, experts emphasised the high human and talent potential in Malopolska. In fact, there are many fields of study and specialised training programmes in computer science, medicine, biotechnology, robotics, automation, mechatronics, etc. which can contribute to the development of computational medicine in the region. As became evident in the stakeholder analysis, this is complemented by a number of specialised research centers and institutions. Furthermore, there is a relatively high level of innovation activity in Malopolska, which academic and business organisations are involved in. Among them is a large share of innovation activities related to the computational medicine field.

Moreover, there is a good infrastructure in terms of hospitals and technical assets such as the supercomputer. Besides a good cost/quality ratio in European comparison, also the attractiveness of Krakow has led to an increasing internationalisation in the past years, further enlarging the available talent pool and number of enterprises.

The rise of the life science sector fits into the smart specialisation strategies of the regional authorities, focusing on life sciences as one of the priorities. This has led to a massive inflow of EU funds to research and business development and fostered the emergence of a wide variety of business intermediaries such as business incubators, innovation and support centres, technology and industrial parks and clusters (see Sections 4.4 and 6.1) aiming to support business development. In consequence, also the framework conditions of the ecosystem can be considered to have improved over time. In consequence, smart specialisation strategies are an important tool for engaging enterprises in regional development projects, including research collaborations with potential to strengthen smart specialisation activities (OECD 2019c). EU funding at the regional and national level has also facilitated the emergence of additional sources of finance, for private equity and venture capital investment in the region and nationally allowing access to finance for businesses (OECD 2019c). Moreover, there is evidence that considerable improvements could be also achieved with respect to the coordination of innovation policies and its efficiency (OECD 2018c). The overall improvement of framework conditions has been also confirmed in interviews with company representatives.

Finally, the interest of large Polish IT companies to move towards the health sector, an emerging start-up and spin-off culture, the readiness of venture capitalists to invest in relevant projects and the



availability of resources and support from regional authorities for the field can be considered as factors supporting the development of computational medicine in Krakow. An additional push factor has been highlighted by clinicians, noting the relative openness of patients in the region towards computational medicine.

## 7.2 Challenges and bottlenecks

The potential success of Sano depends to a large extent on its capacity to utilise the innovativeness of the regional and national ecosystem. Despite various positive developments and improvements in recent years, a lot of barriers and hindrances still remain. This section highlights the key challenges in the regional innovation system of Malopolska and barriers in the field that might affect the impact potential and spill-over effects from the Centre's activities. We distinguish between two main dimensions of challenges: those directly affecting Sano and its development, and those that might indirectly affect Sano through its potential cooperation partners.

Among those factors that might directly affect the development of Sano, interviews and the discussions in the workshop especially highlighted the following issues.

### Lack of cooperation and trust

The low level of cooperation between academia and businesses and general exchange of ideas is a main weakness of the Malopolska's innovation system. One of the most significant development constraints of Polish business - the lack of access to modern technologies - is among others a consequence of non-existing links to research organisations of the majority of business companies. Particularly outside Krakow, the networking potential is used too little. One of the key barriers for more interaction is the lack of trust between businesses. Many local stakeholders argue that relationships between firms are often characterised by a lack of trust and people are afraid of exchanging ideas. Top-layer firms such as Selvita find that there are not many companies in the region which they trust and which they want to collaborate with (OECD 2019c). This could represent a huge challenge to Sano as it relies heavily on close cooperation and links to businesses. A similar picture was painted in interviews with regional authorities: trying to facilitate cooperation by the design of funding schemes such as innovation vouchers only brought limited effects, as there has not been considerable demand for this kind of funding.<sup>33</sup> Apparently, the problems are more deeply rooted and cannot be easily addressed by the creation of new institutions alone.

The lack of trust and cooperation activities were highlighted by the workshop participants as central challenges when developing and adopting computational medicine technologies. The need for trust and the intensification of cooperation was identified for multiple arenas. On the one hand, one needs to increase trust of patients and doctors in the daily routine. Because of the consequences of potential mistakes, the stakes in healthcare are high. An accurate validation of technology and rigorous testing before adoption is therefore absolutely critical to ensure trust and overall acceptance. This is related to the 'black box problem' - the difficulty to understand, how the system has come to the conclusion,

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<sup>33</sup> A more positive conclusion, however, is found by an evaluation arguing that beneficiaries of ROP programs were more active in cooperation, keeping them often (86%) even beyond the realization of the project (OECD 2019c, p. 82).



to validate the outputs of computational medicine and to identify errors and bias in them. Additionally, clinicians might fear the replacement of scientific knowledge/expertise by big data and see the risk of being challenged in their professional authority. Thus, the adoption of computational medicine requires a change in the mindset. Here the main challenge arises from the difficulties to disrupt the maintenance of the status quo in healthcare models established decades ago.

On the other hand, a lack of trust and the existent framework limits the cooperation among researchers and between researchers and enterprises and hinders the translation of knowledge between different areas. In consequence, there is no established culture of cooperation, and exchange of ideas and knowledge is still relatively rare, so that innovations often do not meet demands and cannot easily be applied on a larger scale. This manifests itself in the unwillingness to share data or opt for open data concepts, limited capacities and resource constraints for translational research, the fear of loss of intellectual property and risk aversion in enterprises, expecting successful examples of implementation as a foundation for decision-making given the high financial investments.

#### *Data and technical infrastructure*

To fully exploit the potential of computational medicine, the availability and accessibility of meaningful high quality data is a precondition. In many cases, the scarcity of useable data is a serious problem. This includes the sheer quantity of data required, the access to data, its often siloed nature and associated regulatory requirements (privacy/data security), possible inconsistencies in the data, the need for standardisation and interoperability as well as anonymisation/pseudonymisation. Only if the data sets used are sufficiently large to be representative and are of good quality, can the products based on them be trusted and make a valuable contribution to healthcare. The workshop participants pointed out that there is an urgent need in terms of regulatory, legal and technological clarification and support (e.g. through effective anonymization techniques and secure data storage) perspectives to ensure secure use of data (e.g. for research purposes). At the same time, this requires the existence of up-to-date digital infrastructure and computing technology capable of integrating new technological solutions. A lack of interoperability and standardisation in IT systems can prove a serious hindrance to computational medicine.

#### *Skill mismatch*

The Malopolska region is rightly characterised by its relative high density of well-educated persons. However, there is an increasing shortage of IT specialists in the region, particularly of software developers, programmers, analysts and administrators in the field of software and databases. Moreover, the emerging field of computational medicine results in shifting requirements with regards to the skills of physicians and researchers. Interdisciplinary expert knowledge that combines relevant disciplines (engineering, computer science, medicine etc.) gains importance - contradicting the increasing silosiation of many research disciplines and funding/evaluation schemes. While there are high intrinsic and career motivations for researchers to work at the intersection of these emerging fields and spill-over effects from advancements in other areas (e.g. apps, machine learning, image processing), workshop participants pointed out that there are still cultural barriers between different disciplines of engineering/computer science, biology/biotechnology, and clinicians that are an obstacle for understanding and that make cooperation difficult. Educational institutions and their training programmes in Poland and other countries are also not adequately prepared to respond to



the challenge by offering specialised courses for the development of interdisciplinary competencies needed in this field of technology.

Further limiting factor is a very low level of participation of employees in the lifelong learning. Only a small share of enterprises provides training activities to their workers. This in conjunction with reported very low digital skills of a large proportion of workers (OECD 2019c) represents a serious problem when adopting new digital solutions. Furthermore, there is evidence indicating that in the higher educational institutions the development of soft skills enabling young specialists to work independently, be able to work in a team, being concerned about quality and to manage a project is not sufficiently provided (Center for Evaluation and Analysis of Public Policies 2013).

### *Regulation*

Official regulation and approval are further main challenges. Computational medicine, especially when it includes self-learning algorithms, cannot be adequately covered by current market approval and post-market surveillance processes and regulation has not kept up with the speed of technological developments. This means that regulatory adjustments are necessary to ensure optimal patient safety and at the same time accelerate the entry of advanced computational medicine technologies in the medical practice.

At the same time, desk research highlighted a number of additional challenges for companies. While Sano cannot directly address these problems, they need to be kept in mind as potential risks for the development.

### *Business scale-up constraints*

One of the most serious bottlenecks for innovations and business development in Malopolska and Poland in general identified in the literature is the lack of scale-up ambitions and related strategies for sustainable growth of businesses, which are highly important to the productivity upgrading and industrial diversification in the region (e.g. Polityka Insight 2016; OECD 2019c). The reasons for it are manifold. First of all, they lie in the insufficient entrepreneurial and management skills of university graduates, lack of ability to generate new business ideas and of insufficient motivation of the management to develop own business through investment in innovation and skills. Another problem is that available skills often do not match those required for potential scale-ups. At the same time, small companies are often unable to identify the skills they need to be able to scale up and develop their businesses. Many business owners have poor awareness of opportunities that innovative products and processes offer them and often lack ambition to develop more innovative products and to sell outside of the Polish market. This represents a further potential barrier for the development of the highly innovative, dynamic and investment-intensive market segment, such as computational medicine.

### *Heavy dependence on the EU funding and lack of genuine motivation to invest in R&D*

The next problem, which can have a negative effect on the development of the entrepreneurship ecosystem in the field of computational medicine is heavy dependence on the EU funding and lack of genuine motivation to invest in R&D. In fact, the huge share of technological and research activities in Malopolska and Poland in general rely on the EU funding. Continuous financing from European Funds



may also produce an undesired side-effect - resulting expectation of the reliance on external funds and insufficient willingness to make own investments. The higher involvement in innovation activities of the local stakeholders is largely the result of incentivising mechanisms making investments related to innovation activities attractive rather than driven by the inner motivation of business enterprise owners to invest in innovations. This raises the question about the investment readiness of businesses and public institutions in innovative technologies like computational medicine and their implementation after the expected future reduction of the EU financing

#### Access to finance

Access to finance is of major importance for innovative businesses and limited financial opportunities may pose a serious challenge for those business owners who are willing to invest in new technologies and innovations. As mentioned earlier, access to finance for entrepreneurship and innovation has improved significantly in recent years in the region and nationally. However, there is an evidence that SMEs are still confronted with a lack of knowledge of financing opportunities and complexity of systems to access public financing support. To get external finance for the proof of concept and commercialisation of innovations seems especially problematic (OECD 2019c).

#### Organisational readiness and economic risks

This challenge, to which the industry representatives pointed out in the workshop, does not relate to the particular situation in Malopolska, but rather has a more general character and should be taken into account when studying framework conditions for the adoption of new technologies. Industry needs a clear evidence of positive return of investment through proof of concept and multiple real business cases. This is related to the major challenge of ensuring that the new solutions are well tested, accurate and failsafe enough. Companies usually do not want to take the risk implementing the technology first. They therefore prefer a 'second mover strategy'. One question that is frequently asked is 'Who used the technology before me?', i.e. before implementing it within their own organisations, companies usually need to see success stories clearly demonstrating that the technology and its implementation strategy really work. Basically because of this challenges and problems related to the lack of trust and acceptance, it is still difficult to get potential users on board.

Costs to adopt CM technologies are the further hurdles for the uptake and broad adoption of computational medicine. At the current stage, the adoption is associated with high costs and heavy investments representing quite a burden for many organisations.



## 8. Insights and recommendations for Sano

Sano is being established within a vivid ecosystem alongside multiple existing players and a regional specialisation in the area of life sciences and ICT. It benefits from its own supercomputer, international partners, funding over a sufficient period of time and ambitious research and development plans. The existence of this ecosystem requires Sano to actively address a number of different stakeholders at different levels simultaneously and its success depends on being able to integrate into this ecosystem.

The establishment of Sano has been welcomed by stakeholders and a window of opportunity now exists to maximally benefit from this enthusiasm. The workshop and interviews showed that there are high hopes and expectations connected with the creation of Sano. However, stakeholders beyond potential early adopters should also be made aware of the opportunities offered by computational medicine and the role of Sano. **Raising awareness of computational medicine and creating visibility for Sano** will therefore be an ongoing early task. Sano should continuously undertake efforts to spread information via different channels to increase the awareness of the potential of computational medicine and to enhance trust in these technologies. This implies also a closer collaboration with patients, civil society and clinicians in their daily routines in order to better understand their needs. The insights obtained in this process can also fruitfully fed back into formulating demands for technology development and to ensure that solutions address real problems. Thereby, Sano can help further foster demand-driven R&D associated with the improved products and processes (Radosevic 2017) generated in Malopolska.

The ecosystem workshop highlighted the key role of collaboration and trust building - one of the current weaknesses of the innovation system of the Malopolska region in general. This provides both a risk and an opportunity for Sano. A risk of being equally affected by a lack of willingness to cooperate and the opportunity of becoming an intermediary, **bringing together stakeholders from different groups and creating opportunities for meeting and exchanging experiences and ideas through its specific offers**. As put by one interviewee, there is no lack of new institutions, but a lack of opportunities that meet the real needs. Sano therefore has to invest considerable efforts of not repeating mistakes of the past and strive for a close integration of different areas of activities and different groups of stakeholders.

Therefore, Sano might position itself both via the contents offered as well as an approach that addresses the existing problems of cooperation between different fields. This requires an approach of seeking actively the involvement of various stakeholders and the readiness to invest in networking. For this, Sano needs to **engage with industry, academia and health care providers in a collaborative process to identify future needs and skills** and collaborators to ensure that their needs and requirements are adequately taken into account when developing and implementing computational medicine technologies.

The healthcare system in Malopolska and Poland is facing numerous challenges that are also common in other European healthcare settings. Some of these issues are more pressing, however, due to an urgent lack of staff and below average health outcomes. A number of advanced healthcare facilities exist in Malopolska, and **Sano needs to continue and extend its collaboration with such healthcare providers to help them become early adopters of computational medicine in Poland**.

Sano fits neatly into the regional development strategies and the smart specialisation area of life sciences. The interviews with regional policy-makers revealed a high strategic interest in Sano and its





(future) activities. Therefore, **Sano should use the opportunity for a more intense exchange with regional authorities.** Regional authorities do not only provide resources via Regional Operational Programs but also shape regional development strategies. A closer collaboration could be of mutual benefit, also by ensuring sufficient provision of support for potential collaborators of Sano.

Additionally, longer-term changes in the ecosystem can be instigated and supported by Sano. Collaborations with academia could help to **ensure that curricula cover the necessary interdisciplinary skills required by Sano and industry**, and work placements in the Centre can help to promote it as an attractive employer. During the ecosystem workshop the possibility of an industry-based PhD was raised, which would allow for a close integration of the research and business environment. By taking a coordinating role in this process, Sano could strengthen its position as an intermediary between different fields. By doing so, Sano at the same time could address potential risk arising from the limited capability of absorbing highly skilled personal (OECD 2019c) and securing the supply of skilled workforce with interdisciplinary knowledge and understanding.

Computational medicine raises various issues in terms of market approval and reimbursement. **Collaboration with regulators at national and EU-level** and within existing working groups can help pave the way for this emerging field to be adequately represented within relevant regulations. Another important issue for the broad adoption of computational medicine is the support of open standards principles for software interoperability, data and document formats that enable sharing of data, communication with other systems, help avoid vendor 'lock-in' and enhance new opportunities for innovations. By actively contributing to work on standardisation and setting a positive example by sharing information on innovation projects, particularly those with public funding involvement, Sano can contribute to creating a culture of open innovation.

Sano's initial activities should **focus on activities that both provide a useful foundation for later work and demonstrate early value to stakeholders.** Given the high demand from the side of different stakeholders, a first area for activity for Sano could be engagement in the field of data, by bringing together different groups of stakeholders and developing appropriate offers (workshops, possibly a Sano data repository). This would have the benefit of simultaneously addressing the problems of cooperation and technological challenges. This would provide Sano with both the opportunity to strengthen its ties with local stakeholders and gathering a critical mass of actors.

In order to address a reluctance by businesses to take risks by investing in computational medicine early on, Sano could provide support by **demonstrating typical business cases for computational medicine.**

While striving for a close cooperation with the academic, public, and economic actors in the region, **Sano should maintain a close relationship with partners outside of the region and outside of Poland**, especially in the field of academia. Within Poland especially the Masovia region is an academically and economically strong region, but also the neighbouring Silesia offers opportunities for cooperation. Cooperation with international actors should also be continued and extended. Gaining international visibility could be also an asset for potential regional collaboration partners of Sano such as SMEs and start-ups, which they could not achieve independently. This fact underlines that different levels of engagement should not be treated in isolation, but they reinforce each other.



In conclusion, **Sano right now benefits from the momentum of an emerging field and an ecosystem that can support the further development of Sano and the field of computational medicine.** Therefore, **Sano should opt for a demand-oriented multi-stakeholder approach** that makes use of the regional strengths and potentials by developing activities that are able to attract relevant stakeholders. By doing so, Sano has the unique opportunity to establish itself as a key player and provide regional, national, and international benefit through the development and diffusion of computational medicine solutions.



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## Appendix

## Appendix I: Types of support for innovation during the funding period 2007-2013

		University / RDIs			Firms	
		Basic and scientific research	Applied research and development	Company formation	Capital investment	
Direct support	Grant	3.209 7.8%	5.070 12.3%		12.6 30.7%	49.6%
	Loan				0.1 0.2%	0.2%
	VC/PE			0.97 2.4%		2.4%
	Tax		0.056 0.1%		0.011 0.02%	0.1%
	Total	7.8%	12.4%	2.4%	31.0%	53.4%
		Human capital	Research infrastructure	Incubators / tech offices / specialized services	Cooperation and organization	
Indirect support		2.647 5.5%	9.043 21.9%	5.914 12.4%	1.516 3.7%	46.4%

Figure from Kapil et al. (2013, p. 26)

Appendix II: Selected companies with potential relevance for computation medicine<sup>34</sup>


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**Pharma and Biotechnology**

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- ACCESS PHARMA SP. Z O.O. (<http://accesspharma.eu/pl/>): Development and production of dietary supplements and medical devices with development plans for drug production. Products: OTC drugs for sore throat, swelling and bruising, and diosmine.
- BIOCENTRUM SP. Z O.O. (<http://www.biocentrum.com.pl/pl/>): Biotechnology company conducting pre-clinical studies of medicines. Manufacturer of highly purified and highly active enzymes, inhibitors and other biologically active preparations. Provides research and development services.
- BIOMANTIS SP. Z O.O. (<http://www.biomantis.pl/>): Production and distribution of biologically active dressings, i.e. containing larvae of the fly species *Phaenicia sericata*, for difficult-to-heal wounds (ulcers, sores, postoperative, post-burn and infected wounds).

<sup>34</sup> Based on: Klaster LifeScience Krakow (2017) and desk research .



- BIOPHAGE PHARMA S.A. (<http://www.biophagepharma.pl/>): Advisory services on the development of medicinal products with the use of bacteriophages. R&D in biotechnology, natural sciences and engineering, and the production of basic pharmaceuticals.
- CHEMICZNO-FARMACEUTYCZNA SPÓŁDZIELNIA PRACY ESPEFASP. Z O.O. (<http://espefa.com.pl/>): Pharmaceutical manufacturer. Products: medicines and dietary supplements. Services in: laboratory tests in the field of physicochemical analysis of raw materials and medicinal products - tests are conducted in accordance with FP, EuPh and USP.
- DACLÉ POLSKA S.A. (<http://www.dacle.eu/>): Conducts research on drugs, and is involved in wholesale and retail sale of medicines.
- FARMA PROJEKT SP. Z O.O. / RECORDATI POLSKA SP. Z O.O. (<http://recordati.pl/>): Research, development and production of pharmaceutical products. Products: specialised and OTC medicines and dietary supplements; research on the production of drugs used in urinary system disorders.
- FARMINA SP. Z O.O. (<http://www.farmina.pl/index.php>): Manufacturer of generic drugs (Rx and OTC) and dietary supplements.
- INSTYTUT BIOTECHNOLOGII SUROWIC I SZCZEPIONEK BIOMED S.A. (<http://www.biomed.pl/>): Manufacturer of prebiotics, vaccines, dietary supplements and diagnostic preparations, substrates and indicators. Conducts R&D activities.
- JAGIELLONIAN CENTRE FOR EXPERIMENTAL THERAPEUTICS (<http://jcet.eu/new/>): External unit of the Jagiellonian University, a centre for drug R&D. It conducts interdisciplinary research in pharmacotherapy.
- LANGSTEINER SP. Z O.O. (<http://www.langsteiner.eu/pl/>): Manufacturer of medical devices and dietary supplements. It conducts educational activities promoting a healthy lifestyle.
- MONTELIN FARMACEUTICI POLSKASP. Z O.O. (<http://www.molteni.com.pl/>): Manufacturer and wholesaler of medicines; part of the Italian listed corporation. The company focuses on drugs used in palliative care, diabetes and addiction.
- MPS LABS SP. Z O.O. SP. K. (<http://www.mpslab.com.pl/>): Manufacturer of prescription drugs, medical devices, OTCs and dietary supplements.
- SELVITA S.A. (<http://www.selvita.com>): Leader of the Polish biotechnology market. Company operates in the area of drug discovery and development. Research focuses on design and development of oncology drugs, developing molecules that can be used in the treatment of leukemia, lymphoma and colorectal cancer in the future. Selvita also provides R&D services and offers IT solutions to support innovative projects.
- TACTICA PHARMACEUTICALS SP. Z O.O. (<https://tactica.pl/>): Manufacturer of medicines, diet supplements, foods for special medical purposes, medical devices and cosmetics. Its product range includes prescription and OTC drugs.
- TEVA PHARMACEUTICALS POLSKA SP. Z O.O. (<http://www.teva.pl>): Manufacturer of generic drugs used to treat cardiovascular, nervous, transplant, and oncology and dermatological diseases.
- ZAKŁAD FARMACEUTYCZNY AMARA SP. Z O.O. (<http://amara.pl/>): Manufacturer of medicines, dietary supplements and pharmaceutical formulas. Conducts R&D activities.





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### ***Medical Technology and Equipment***

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- AFISEN JERZY SUPERATA: The company specializes in bio-sensors, developing new products - chemosensors and biosensors – i.e. micro analytical devices. It offers also services in the area of chemical analysis techniques, including the complete configuration of equipment, training, development and validation of separation methods: chromatography, capillary electrophoresis and sample preparation.
- abcMED Sp. Z O.O.: Manufacturer of medical and surgical equipment and orthopaedic appliances.
- ALBERT Polska Sp. Z O.O.: Manufacture of medical and surgical equipment and orthopaedic appliances.
- ASPEL SP. Z O.O. (<http://www.aspel.com.pl/>): Manufacturer of electronic medical apparatus. The company offers: electrocardiographs, Holter ECG systems, exercise systems, cardiological rehabilitation equipment, EEG, intensive medical surveillance equipment.
- BARDOMED SP. Z O.O. (<http://www.bardomed.pl/>): Manufacturer and distributor of rehabilitation and medical equipment, including; laser therapy, ultrasound, magneto therapy, shortwave diathermy, lymphatic drainage devices, Rosetta ESWT shock wave equipment and high power lasers.
- EM-MED SP. Z O.O. (<http://www.emmed.pl/>): Manufacturer and distributor of medical devices for patient heating, minimally invasive and non-invasive, hemodynamic monitoring, vascular diagnostics, neonatology. The company manufactures infusion fluids, fabric heaters and infusion fluids.
- FINDAIR SP. Z O.O. (<http://findair.pl/>): Primary product is an intelligent device for asthma detection Findair ONE. The device is mounted on top of the drug container and transfers data after each use to the corresponding monitoring application.
- GRUPA PHARMATECH SP. Z O.O. (<http://pharmatech.com.pl/>): Manufacturer of fittings (valves, agitators), hoses, seals, connectors for the pharmaceutical, cosmetic and food industries. Production of RABS enclosures for machines and insulation systems.
- INOVAMED SP. Z O.O. (<http://inovamed.pl/>): Manufacturer of orthopedic and rehabilitation equipment: orthopedic shoes, prostheses, corsets and orthopedic accessories. It helps patients requiring non-standard complex solutions based on German components to select the right equipment. In 2013, the company took over Krakowskie Zakłady Sprzętu Ortopedycznego.
- GPS LIFESP. J. (<http://www.gpslife.pl/pl/>): Provides a tool that enables to monitor the whereabouts of the people who are equipped with it. It is dedicated to people who may have difficulty in returning to their place of residence and to their carers.
- HAND-PROD SP. Z O.O. (<http://www.hand-prod.com.pl/>): Manufacturer of devices for the diagnosis of blood glucose, dietary supplements and pharmaceuticals. Manufacturer of Evercare genius glucometer. The device can be connected to a computer with Internet access.
- LABSYSTEM EWA SUPERATA(<http://www.labsystem.pl/>): The company supplies equipment, including laboratory equipment, furniture, laminar chambers, centrifuges, reagents and small laboratory equipment to many manufacturers both Polish and foreign.



- MEDICAL SIMULATION TECHNOLOGIES SP. Z O.O. (<http://www.mstech.eu/>): The company supplies medical technology; it is in the process of implementing a simulator, which can be used to train physicians specialised in transesophageal echocardiography (TEE), one of the basic diagnostic methods in cardiology. K.
- MES SP. Z O.O. (<http://www.mes.com.pl/>): Manufacturer of medical equipment: spirometers, pulse oximeters, rhinometers, capnographers, treadmills, bicycles and a number of other appliances used in respiratory function tests.
- MRI-TECH SP. Z O.O. (<http://www.mri-tech.pl/>): Manufacturer of Cirrus 0.2T, a low-impact magnetic resonance imaging (MRI) systems for medical applications. With the use of resonance imaging technology, the device produces high quality images at the low field.
- PRACOWNIA ORTOPEDYCZNA PIOTRLEWKOWICZ (<http://lewkowicz.com.pl/>): Company deals with the preparation of prostheses and orthoses for disabled persons, which are individually tailored to the needs of the patients.
- PRODRobot (<http://prodromus.pl/product/prodrobot-standard/>): Manufacturer of a rehabilitation robot, an automatic gait trainer. It is a medical device designed for the rehabilitation of the lower limbs of patients with gait dysfunction.
- SEMIC®BIOELEKTRONIKA (<http://www.semic.cracow.pl/>): Producer of biological, zoological, medical, veterinary and agricultural laboratory equipment. Key words: laboratory equipment, lab equipment.

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### *Diagnosics / E-Health*

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- AUTOIDS. A. (<https://www.autoid.pl/>): Company provides solutions based on OCR, RFID, bar codes and biometrics for the pharma and medical sectors.
- ARDIGEN S.A. (<http://www.ardigen.com>): Bioinformatics company, part of Selvita S.A. The company's focus is on three business areas: LIMS class information management systems, and bioinformatics systems for sequencing nucleic acids and proteins -CLC bio.
- BIOTE21 ADAM MASTER (<http://www.biote21.com/>): Company provides services in the field of: synthesis and sequencing of nucleic acids, genetic engineering, silencing and amplification of gene expression, diagnosis of predisposition to hereditary diseases including cancer, paternity testing for clients, as well as forensic medical examinations for prosecutors and courts.
- CENTRUM BADAŃ MIKROBIOLOGICZNYCH I AUTOSZCZEPIONEK SP Z O.O. IM. JANA BOBRA SP. Z O.O. (<http://www.cbm.com.pl/>): Microbiological tests, production of auto vaccines, manufacture of diagnostic discs, research and development work. Performing microbiological analyses of aerobic and anaerobic bacteria, yeast-like fungi and dermatophytes.
- COMARCH HEALTHCARE S.A. (<http://www.comarch.pl/healthcare/>): The company is part of the Comarch Capital Group. It offers IT management systems for medical documentation, hospital software, remote medical care and own devices used in telecare.
- CONSONANCE SP. Z O.O. (<http://consonance.com.pl/>): Company develops consumer electronics for the medical industry in Europe and the United States.



- COSMETIC SCAN SP. Z O.O. (<http://cosmeticscan.tech/>): Mobile application - a personalized shopping assistant that allows you to choose cosmetics for people with allergies as well as those who want to control the composition of the cosmetics they use.
- DATA COMPLEX SP. Z O.O. (<http://www.datacomplex.pl/>): The company offers trend analysis, OOT / OOS prediction, scheduling and implementation of stability studies, microbiological monitoring of the environment, process validation / CPV, tracking of parameters. Creation and implementation of IT systems for data analysis.
- DIAGNOSTYKA SP. Z O.O. (<http://diag.pl/>): The largest network of diagnostic laboratories in Poland.
- ERICSSON SP. Z O.O. (<https://www.ericsson.com/>): The company provides software for medical facilities. The company is a manufacturer of the eWUŚ software, which allows patients to verify their rights to public medical services.
- DR OMNIBUS SP. Z O.O. (<http://www.dromnibus.com/pl/>): Manufacturer of a complex tool to support children with developmental and/or behavioural disorders (including autism, Down syndrome, ADHD, mental retardation) in the form of tablet applications.
- HARIMATA SP. Z O.O. (<http://harimata.pl/>): The company is the author of the first medical application, which supports the diagnosis of autism in children.
- GENBIOINFOSP. Z O.O. (<http://www.genbioinfo.pl/>): This entity provides bioinformatic solutions for the industry and science sectors.
- KRAKOWSKIE CENTRUM INNOWACYJNYCH TECHNOLOGII INNOAGH Sp. Z O.O. (<http://www.innoagh.pl/>): Manufacturer of the remote interactive medical consultation systems TeleDICOM II (which uses the TeleCARE IT system), which enables continued medical care of a large number of patients after they are released home.
- KARIOGEN BOGUSŁAWA KRZYKWA (<http://www.kariogen.pl/>): Studies of cytogenetics in karyotypes; Research scope: prenatal diagnostics (amniocytes from fetal water, chorionic gonadotropin) and maternal study after miscarriage.
- MEDAPP S.A. (<http://medapp.pl/>): The company specialises in the area of innovative mobile solutions for the medical industry, dealing with mHealth applications.
- MREH SP Z O.O. (<http://mreh.pl/>): The company offers a system for remote mobile rehabilitation. The system includes a sensor kit for the patient, a dedicated mobile application and a web platform for professionals.
- ONCOGENE DIAGNOSTIC SP. Z O.O. (<http://oncogene.pl/>): The company carries out research in the field of molecular diagnostics and genome analysis, specializing in the analysis of selected types of cancer and genetic diseases. In addition, it performs breathing tests to detect an active Helicobacter pylori infection. The company is a subsidiary of Diagnostyka Sp. Z O.O.
- PAGA SOLUTIONS SP. Z O.O. (<http://www.ratunek.eu/o-nas.html>): The company has created the Ratunek application, integrated with the system used by the Mountain Volunteer Rescue.
- PERKINELMER POLSKA SP. Z O.O. (<http://www.perkinelmer.com/>): The company implements modern methods of diagnosis of infectious, oncological and foetus diseases. It also scans genetic diseases in children with the use of a single drop of blood.
- PRACOWNIA ANALITYCZNA MAGDALENA SZELĄGOWSKA (<http://www.pracownia-analityczna.pl/>): The company deals with laboratory analyses, research and diagnostics.



- SENSINUMSP. Z O.O. (<http://sensinum.pl/>): IT company, which provides solutions for programming web and desktop applications, with experience in the field of life sciences. It designs the solutions that make up the ambient intelligence and the contemporary Internet of Things.
- Silvermedia (<http://www.silvermedia.pl/contact/>): applications for the needs of telemedicine, algorithms for biomedical signal evaluation supporting diagnostics and monitoring of the patient's health status in the field of cardiology, audiology, geriatrics and allergology.
- TELEMEDYCYNĄ POLSKA S.A. (<http://telemedycynapolska.pl/>): The company specialises in cardiology telemedicine. It has a branch in Krakow. It offers the Kardio teleservice – a 24-hour cardiopulmonary telecare service; provision of a personal, portable ECG device for sending heart performance test results via telephone; ECG results consultation.
- 32WYDAWNICTWO INTERAKTYWNE MEDUTOOLS SP. Z O.O. ([www.medutools.pl/](http://www.medutools.pl/)): The company designs, implements and implements products and services integrating medical knowledge with modern technologies in mobile applications. The company offers 3 applications: MeduSzczepienia -mobile vaccination calendar, MeduFit -traffic control system under control and MeduCards -application for medical and pharmaceutical students.
- VERACOMP SA (<http://www.veracomp.pl/>): Veracomp supplies solutions in the area of: telecommunication, IT, storage and server security; management of IT infrastructure, audio visual systems and digital signage, digital document flow.
- VOXEL S.A. (<http://www.voxel.pl/>): Voxel runs a national network of Diagnostic Medical Centres specializing in imaging diagnostics. It provides teleradiology services and supplies hospitals and diagnostic centres with IT systems; implementation of projects involving equipping diagnostic laboratories.

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### ***Clinical Research***

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- ACCOVION SP. Z O.O. ([www.clinipace.com/](http://www.clinipace.com/)): The company provides clinical trial services. It is part of the international clinical trial research group Clinipace.
- CENTRUM BADAŃ KLINICZNYCH JAGIELLOŃSKIEGO CENTRUM INNOWACJI SP. Z O.O. (<https://www.cbkjcj.pl/>): The Centre is specialised in conducting clinical trials, conducting comprehensive research and development projects in the field of medicine and related sciences.
- KCRISPÓŁKA Z O.O. (<http://kcri.org/>): The company designs clinical trials and provides full support in their proper implementation. It also represents companies wishing to conduct clinical trials before pharmaceutical regulatory institutions.
- LANDA KATARZYNA ŁANDA (<http://smo.com.pl/>): The company conducts clinical trials for R & D, pharmaceutical companies and global CROs.
- MONIPOL SP. Z O.O. (<http://www.monipol.com/pl/>): Monipol deals with clinical trials, from the feasibility study and design phase to the final reporting of results. The second aspect of the company's business is carrying out audits of clinical trials conducted by other entities.



- SKIN LAB INTERNATIONAL SP. Z O.O. (<http://skinlab.pl/>): The company conducts dermatological, application and implementation studies for the cosmetic and chemical industry, and specialised research for the light industry. Key words: research in cosmetics.

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### ***Medical Services***

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- BIOSPEKT BADANIA I EDUKACJA SP. Z O.O. (<http://biospekt.pl/>): The company deals with the chemical analysis, including the determination of element concentrations, as well as with the consultancy for sewage treatment plants, mycological analysis, natural valorisation and research and development in the field of life sciences.
- CENTRUM BADAWCZO-ROZWOJOWE MEDINET SP. Z O.O. (<http://medinet.com.pl/>): The Centre conducts projects in the field of aerosology, respiratory physiology, respiratory rehabilitation, psychoneuropharmacology and immunology. It conducts research aimed at understanding the role of the brain in somatic diseases and the effect of inhalation drugs on selected brain functions in asthmatic patients.
- LABORATORIUM IVFS.C. (<http://www.laboratoriumivf.com.pl/>): Distributor of laboratory materials. The company runs a sperm bank.
- PROGENIS SP. Z O.O. (<http://progenis.pl/>): The company deals with the storing of stem cells.

### **Appendix III: Civil society organisations with potential relevance for Sano**

- THE INSTITUTE OF HEALTH FOUNDATION (<https://www.fioz.info/>): The Foundation supports health care, counteracts social pathologies and conducts broad research and development activities in biomedical and social sciences.
- WATCH HEALTH CARE (WHC) FOUNDATION ([www.korektorzdrowia.pl/o-whc/](http://www.korektorzdrowia.pl/o-whc/)): The foundation provides reliable, evidence-based information on health-related data and medical procedures that are difficult to access.
- PUBLIC HEALTH FOUNDATION (<http://www.fzp.com.pl/>): The foundation implements the public health development program in Poland and conducts consultancy and educational activities by organizing courses and trainings. It also organizes or sponsors a number of events and uses the funds raised during these events to purchase medical equipment for hospitals.
- FOUNDATION FOR THE DEVELOPMENT OF ORTHOPAEDICS AND TRAUMATOLOGY IN KRAKOW: The aim of the foundation is to implement new methods of treatment ensuring progress in orthopedics and traumatology.
- MEDICAL ASSOCIATION IN KRAKOW (<http://krakowskietowarzystwomedyczne.pl/>): The association is active in supporting local communities in the fields of health care and protection, prevention of social pathologies and broadly understood social assistance.
- POLISH SOCIETY FOR BIOMATERIALS (<http://www.biomat.krakow.pl/>): The association was founded at the instigation of a group of people involved in the production and research of materials for the medical sector. It realizes its goals through scientific and educational activity.



It publishes the 'Engineering of Biomaterials' quarterly and actively participates in numerous scientific events.

- POLISH ASSOCIATION FOR THE STUDY OF PAIN (<http://ptbb.pl/>): The company organizes conventions, symposia and scientific events. It conducts pain treatment training for doctors, cooperates with other related associations, financially supports its members to participate in pain medicine conferences, and publishes the 'Ból' quarterly and other newsletters.
- POLISH SOCIETY OF HOSPITAL INFECTION ([www.ptzs.org.pl/](http://www.ptzs.org.pl/)): The society brings together people whose professional activity is directly related to the practice of controlling hospital infections. It publishes the 'Zakazenia' bimonthly.
- POLISH SOCIETY FOR FIGHTING ALLERGIC DISEASES ([www.ptzca.pl/](http://www.ptzca.pl/)): The objectives of the society include: assistance in solving problems of patients with allergies, their access to medicines and specialised treatment; development of health education through publishing activities and events such as the Allergy Days ('Dni Alergii'); supporting the development of interdisciplinary counseling and allergy treatment.
- POLISH SOCIETY OF MECHANICAL ENGINEERS AND TECHNICIANS (SIMP) (<http://www.krakow.simp.pl/>): The society brings together engineers and technicians of all specialisations and related professions. Its mission is to contribute to science, technology and the economy, the upgrading of professional qualifications of engineers and technicians, the promotion of employment, vocational re-orientation and job search assistance, and the creation of a forum for exchanging information on science, technology and economic and social issues.