Managing Intellectual Capital and Innovation for Sustainable and Inclusive Society 27–29 May 2015 Bari • Italy

Management, Knowledge and Learning Joint International Conference 2015 Technology, Innovation and Industrial Management

# **BIOTECHNOLOGY CLUSTERS IN POLAND**

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#### Abstract:

Biotechnology is an area of strategic importance for Europe. It is widely considered a technology of key importance for strengthening the competitiveness and development of the European economy. European biotechnology companies are located in life sciences and biotechnology clusters in the northern and western regions of Europe, which has a long tradition of research in this field. Biotechnology clusters, being typical "intellectual" clusters based on knowledge flow, research generation and commercialization, enjoy a large interest from businessmen, politicians and scientists. They are perceived as innovation-boosting initiatives which stimulate growth of the local economies and draw investors. If they achieve their desired maturity, they constitute an effective platform of cooperation; information exchange and knowledge transfer, enabling the creation of innovative products and services. Ensuring their efficient operation requires a particular configuration of resources and operating conditions as well as proper management thereof. In the last ten years 12 biotechnology clusters have been established in Poland. In the majority of cases their creation was aided by European Union funds. The purpose of this article is to analyze the development process of the biotechnology clusters in Poland and to compare it to the development of similar organizations in Europe and worldwide. The analysis will include cases of Polish life sciences and biotechnology clusters which emerged in the last decade. The analysis will cover their structures, management models, strategies, business models and achieved results. Cluster initiatives are usually taken by the local governments, which want to demonstrate their active part in creating an environment facilitating entrepreneurship and innovation. However, ambitions and political will are not always sufficient to form cluster organization which are able to operate efficiently and effectively.

Keywords: management, cluster organization, biotechnology, regional cluster

### 1. SPECIFICS OF A BIOTECHNOLOGY CLUSTER

Michael Porter's classic definition describes cluster as "a geographically proximate group of interconnected companies suppliers, service providers and associated institution in a particular field linked by externalities of various types" (Porter 1998, p. 199).

When acting within the confines of a cluster, enterprises benefit in a number of way which are not accessible when conducting activities alone. Thanks to a network of contacts with other organisations active in the same field, they can obtain new technologies, access specialized staff or concentrated resources and absorb innovations more easily. It is a common characteristics of all clusters that organisations comprising the cluster compete and cooperate of the same time, whereas cooperation is restricted to those areas in which a synergy effect is possible as a result of the common activities. Competition between organisations does not exclude mutual interactions, yielding benefits and fuelling their growth.

Classic cluster definition accentuate the physical proximity of clustered organisations, perceiving it as the main source of the benefits. In the times where distance between two organisations is eliminated by means of a few mouse clicks, geographical proximity ceases to be of primary importance and clusters are perceived as a useful economic policy tool of regions and countries. It is visible particularly well with biotechnology clusters – a special variant of clustering, taking the form of innovation- and research-driven clusters.

Innovation-driven clusters can be defined as "...groupings of independent undertakings — innovative start-ups, small, medium and large undertakings as well as research organizations — operating in a particular sector and region and designed to stimulate innovative activity by promoting intensive interactions, sharing of facilities and exchange of knowledge and expertise and by contributing effectively to technology transfer, networking and information dissemination among the undertakings in the cluster." (Community Framework 2006).

Innovation-driven clusters often take the form of research-driven clusters, treating research and development activities as the main source of innovativeness and competitiveness. The features which differentiate them from other innovation-driven clusters are a strong R&D capability and the ability to commercialise the effects of their research. Clusters of this kind tend to develop around knowledge-generating areas with access to specialised information from particular fields of research. Apart from scientific and research institutions such clusters are joined by companies active at different stages of value chains, based on the technologies being developed and willing to tap the resources and opportunities generated by the cluster. A cluster on the correct growth path becomes an attractive "center of gravity", attracting further R&D institutions and companies after attaining a critical mass of resources and competencies relevant to the given industry (Innovation Clusters 2008).

Biotechnology is one of the most fascinating and innovative areas of research and technology transfer. According to a commonly used OECD definition, biotechnology is "...the application of science and technology to living organisms, as well as parts, products and model thereof, to alter living or non-living materials for production of knowledge, goods and services" (Omiya & Noji 2013, p.4).

Biotechnology is used in manufacturing processes of wider and wider spectrum of products such as: pharmaceuticals, medical technologies, food, chemicals, textiles and energy. The biotechnology industry can be divided into three subsectors spanning: medicine and pharmacy (red biotechnology), industry, energy generation and environmentalism (white biotechnology) and food production with agriculture (green biotechnology).

Biotechnology is perceived as one of the science-based industries in which creation of networking between industries and universities is especially important for innovation (Meyer-Krahmer & Schmoch 1998). Biotechnology clusters tend to attract many different kinds of members, ranging from bodies of government through enterprises from above-mentioned sectors, research & development institutions, life sciences companies as well as financial investors. (Omiya & Noji 2014).

It is currently believed that biotechnology clusters are the main driving force behind the growth of the entire industry. Research identified a number of factors key to the success of a biotechnology cluster. Cooperation between research institutions and companies, well-developed ways of research

commercialisation and access to funding are the three key areas. Successfully clusters tend to find ways to bring the interested parties together (investors, research institutions and companies) by means of common interaction / collaboration platforms. SMEs are among the main beneficiaries of that system, as it provides them with access to both funding and research partners. Interaction often results in new projects and even creation of new research or commercialisation organisations.

The most desirable and expected outputs of creating and operating biotechnology clusters are: increased innovativeness of the cluster participants, ease of commercialisation of research outputs and knowledge transfer, creation of spin-off companies and innovative start-ups, attracting investors and funding as well as creating an environment facilitating development of common business ventures (Okamuro 2011).

#### 2. GLOBAL TRENDS IN THE BIOTECHNOLOGY INDUSTRY DEVELOPMENT

Biotechnology industry is considered to be one of the most promising industries in the process of development the knowledge-driven economy. Until recently it was the domain of the developed countries, but recently emerging economies started to show considerable interest in it. The landscape of global biotechnology industry has been marked by an activity and footprint shift of different countries: from the dominating role of the USA, Japan and Germany to China, Korea, Brazil and Russia (Global Life Sciences Cluster Report 2014).

The significance of large corporation (like the Big Pharma) seems to be decreasing in the biotechnology industry, as more and more important roles are played by small and medium companies. It is this group as well as highly specialised companies where stable, dynamic growth can be observed along with high level of activity in the market. They are responsible for most of the innovations in this industry – as their products gain momentum in the development cycle, they attract more and more interest with investors who often encourage them to float their companies. As the stock of biotechnology companies generally sells well and brings fast returns, even large industry investors, who remained quite careful during the 2008 – 2012 period, are starting to show more interest (Biotechnology Industry 2014).

In 2014 life science and biotechnology industry attracted investments of 104.2 billion USD, which is the second highest result only to the year 2009 when the investments totalled to 108.6 billion USD. Owing to a clear increase in industry attractiveness the number of newly floated companies doubled in 2014 (as compared to 2013) and amounted to 133 new companies (106 in the USA), attracting the capital of 11 billion USD (Biotech Industry 2014).

In recent years significantly more attention is drawn to the facilities of the biotechnology companies and their operations. Second only to the R&D expenditure, real estate and facilities cost have a high share of their cost structure. Many large and medium enterprises resort to consolidation, increasing the efficiency of resource utilisation and improving process efficiency as ways to lower cost. Clusters which are dominated by large organisations, based on large campuses centred on the headquarters of large pharmaceutical companies, are subjected to a currently dominant "right-sizing" law. Those clusters are witness to larger layoffs and manufacturing and distribution plant closures.

As the industry operating model evolves from a system driven by Big Pharma to a system where dynamic and innovative medium-size companies play the lead role, so changes the demand for the types and sizes of facilities. Large research and manufacturing campuses are divided into smaller modules to be used by one or many companies. Clusters centred on research institutions, those grouping several smaller tenants or created in the recent years Asian clusters, designed from the ground up as incubators and being the "trend-setters" of the industry are based on a similar "architecture". As Big Pharma companies is forced to keep axing their operating cost and the small-and medium-sized players will keep expanding the perspectives of strategic function outsourcing are more attractive and probable. (Global Life Sciences Cluster Report 2014).

In addition to the infrastructure the focus of biotechnology companies is also encompassing the internal process flow. Increasing efficiency through implementing new systems may result in cost decrease making it possible to dedicate more resources to research or other strategic purposes. However, for the time being the decision makers do not seem to take too radical decisions concerning this particular area. As biotechnology companies often produce pharmaceutical products for people,

they have to follow regulations and standards set for them by government bodies. The companies cannot tolerate any longer breaks in the manufacturing process, loss of consumers or loss of trust of the physicians who prescribe the medicines, so they usually do not revert to outsourcing of certain operations under GMP (Good Manufacturing Practices). Continuous technical progress in the infrastructure space combined with cost pressure may make the companies re-evaluate this option. Preventive Maintenance Optimization programs may be helpful in this context. They have been improved significantly in the recent years: they can be tailored and adapted to the facilities of a given company and its operational needs. They make it possible not only to confirm the compliance of existing processes with applicable regulations, but also to analyse their cost efficiency, which is quite important in light of shrinking margins in the recent years.

Apart from the change in relations between smaller and larger players some changes can be noticed in the geography of activity and demand. USA and Europe were until now the most embedded beneficiaries of added value in the development cycle (mostly in research and development of new products). In the recent years their leadership in the innovation space has been challenged, as many developing economies took significant action to improve their innovation potentials. Asian countries, led by Japan, Korea and China, dramatically improved their patent share as well as in number of Ph.D. and other degrees in science and engineering. USA remain the dominant player when it comes to life sciences patents, but its growth dynamics in this area is smaller and smaller every year.

Developing countries systematically expand foundations of knowledge-based economies. That will result in tangible successes most likely at the expense of the developed economies. This trend can be confirmed among others by the growing share of BRIC countries in the global R&D expenses. In the last three years China has increased their R&D expenses (as measured by the Global Expenditures on Research and Development indicator – GERD) by 10% year-over-year (Brazil: 6.5%, Russia 5.3%, India 4.5%). In 2014 China's R&D expenditures for the first time ever exceeded the EU countries' budget and reached over 60% of the expenditures of the leader, USA. Top ten countries with largest R&D expenditures, led by USA and encompassing the BRIC countries, are responsible for 80% of the global R&D (Global Life Sciences Cluster Report 2014).

Asian countries surpassed both North America as well as Europe when it comes to number of patent applications under the PCT (Patent Cooperation Treaty) system, reaching 79,000 (Europe – 58,100, North America 54,300). PCT applications related to life sciences and biotechnology accounted for 13.5% of the overall number. In this comparison North America emerges victorious (40.8% in 2012), but also here the trend of continuous decrease developed countries' share at the expense of the developed countries from Asia and Latin America is visible (Global Life Sciences Cluster Report 2014).

It is worth noting that developing countries, in the process of building knowledge-based economies, dedicate an increasingly larger part of their GDP to education and educate more and more people in science and engineering. China leads the statistics in absolute terms, producing more than 1.3 million Bachelor of Science and engineering degrees as well as close to 30,000 doctoral degrees whereas the latter number in the USA remains at almost 25,000, unchanged for a few years. (Global Life Sciences Cluster Report 2014).

### 3. BIOTECHNOLOGY INDUSTRY IN EUROPE

Biotechnology is perceived by most European countries as an area of strategic importance for their future growth, keeping their economies competitive and the life quality high. When considering the biotechnology industry potential Europe ranks second to the world's leader, USA. European biotechnology industry is generally composed of small and medium enterprises operating mostly in the field of healthcare and medical biotechnology. Until 2007 Europe witnessed a growing interest in investments in biotechnology companies. The subsequent financial crisis caused a downturn which lasted until 2013 when the investors gradually started to come back. (Omiya & Noji 2013).

The manufacturing potential of the biotechnology industry in Europe encompassed 2083 companies in 2013, out of which 168 were publicly listed, employing over 55,000 people. Those companies generated combined revenues of 21 billion USD and posted 1.033 billion USD profit. The European biotechnology sector can be characterised by high research intensity – R&D budgets reach 23% of their revenues (Biotechnology Industry Report 2014).

Today, biotechnology companies are typically concentrated in biotechnology clusters, spread across mostly Northern and Western Europe. In terms of revenue as well as absolute number of companies Germany leads the ranking, followed by UK, Denmark, France and Sweden. (Omiya & Noji 2013).

For quite some time Europe has been trying to create a significant capability in the field of biotechnology. Initial effort aimed at setting up clusters dates back to 1994 – 96 and was concentrated around leading research institutes (universities) with pre-existing strong ties to pharmaceutical and biotechnology research as well as good connections to related industries. Until today, the clusters are still fulfilling their primary task very well, which is bringing together research institutes and industry to facilitate knowledge transfer and commercialisation. (Omiya & Noji 2014).

The above mentioned activities are also in focus of the European Commission. It has authored a number of initiatives focussing on enabling tighter cooperation between universities and the industry. EC initiatives support also different kinds of collaboration networks, better knowledge base and funding.

One of the key characteristics of biotechnology clusters in Europe is the importance of unified and standardized approach to cluster development: establishment of trans-regional, trans-national clusters and pan-European networks. Another key characteristic is the varied initial forces behind cluster establishments: biotechnology clusters in the UK were largely encouraged by market players, on the contrary, government program and policy-driven forces provided the impetus to the growth and development of biotechnology clusters in France and Germany. (Omiya & Noji 2014)

Another factor important to the development of bio-clustering in Europe is that small and medium companies in this sector have to stand up to huge challenges of attracting means necessary to master the next-level technology or to perform subsequent research stages for new drugs. Cluster governing bodies are actively attracting financial investors offering a scale of different forms of legal partnership. On top of that, combining traditionally separated areas of activity (such as diagnostics and targeted therapeutics) start to play an important role in existing European clusters' strategies – clusters make it easy to take advantage of those potential opportunities.

There are five main factors that seem to contribute to the growth of biotechnology industry in Europe. Economic stability contributes to stable organic growth, the large common market area makes it easy to find niches and explore different segments, technology advances make it possible to lower the operations cost and large number of market players enable takeovers and mergers. (Omiya & Noji 2013, p.14).

### 4. BIOTECHNOLOGY CLUSTERS CREATION IN POLAND

Emergence of clusters in Poland is caused by this form of cooperation being considered a priority in the overall strategy of boosting the innovativeness of the Polish economy and of contributing a significant part of the means earmarked to cluster creation and development in the EU programmes perspective of 2007 - 2013.

As a result of those activities over 220 cluster initiatives across all 16 major administrative regions emerged in Poland. The industry structure of Polish cluster initiatives shows that they are created both in industries considered innovative (28 ICT clusters) as well as in those more traditional (27 tourism, 20 food industry clusters). 12 new biotechnology / life sciences clusters have also been created, out of which 5 are located in Warsaw. Out of the 12, 4 were established between 2006 and 2008 and the other 8 – between 2011 and 2014. This time gap demonstrates that creation of biotechnology clusters is slightly different than others and – compared with traditional industries - it requires specific mechanisms and strategies (Klastry w Polsce 2012).

First to emerge was the Life Sciences Cluster in Cracow, which brought together 32 different institutions, among others the leading Cracow universities and hospitals. The BioFarmKo - Biotechnology, Pharmacy and Cosmetics Cluster of Gdansk created at the same time survived only 3 years in its original form and was transformed into the Pomeranian Bio-Eco-Chem Bio-cluster of a different scope and participant list. Third oldest biotechnology cluster in Poland is NUTRIBIOMED – a scientific-industrial consortium in Wroclaw, since its inception focused on applying advanced technologies in the production of diet supplements, nutraceutics and biomedical compounds.

Chronologically, since 2006, following bio-clusters emerged in Poland:

- 1. Klaster Life Science [Life Science Cluster] Cracow;
- Bio-Eco-Chem Pomorski Bioklaster [Pomeranian BioEcoChem Bio-cluster] (earlier Klaster Biotechnologii, Farmacji i Kosmetyków BioFarmKo [BioFarmKo Biotechnology, Pharmacy and Cosmetics Cluster]) – Gdańsk;
- 3. NUTRIBIOMED Cluster Wrocław;
- 4. Centrum Zaawansowanych Technologii BioTechMed [Centre of Advanced Technologies BioTechMed]- Łódź;
- 5. Klaster Nauk Medycznych i Biomedycznych [Cluster of Medical and Biomedical Sciences] ALICE-Med (Advanced Laboratories in Centre of Excellence) Warsaw;
- 6. Bioregion Wielkopolska [Bioregion Greater Poland] Poznań;
- 7. Klaster Biotechnologiczne Centrum Wdrożeniowe BioCeW [Biotechnological Implementation Centre Cluster BioCeW] Warsaw;
- 8. Klaster Centrum Inżynierii Biomedycznej CIBio [Centre of Biomedical Engineering Cluster CIBio] Warsaw;
- 9. Mazowiecki Klaster Peptydowy [Mazovian Peptide Cluster] Warsaw;
- 10. Klaster Biotechnologiczny BIOPARK [BIOPARK Biotechnological Cluster]– Gdańsk
- 11. Mazowiecki Klaster BioTechMed [BioTechMed Mazovian Cluster]- Warsaw;
- 12. Polski Klaster Biotechnologiczny LINUM [LINUM Polish Biotechnological Cluster]– Wrocław.

All of the above cluster initiatives included, since its inception: scientific research institutions (including universities), medical services institutions, companies and business environment institutions. For details related to member structure, legal form of the cooperation and their coordinators please see Table 1.

In most cases creation of a biotechnology cluster was a common initiative of the local government, universities and companies. Apart from the willingness to confirm the region's potential in advanced technologies and granting it a status of a knowledge-based region, a clear motivation was the access to financial support from the EU funds for cluster initiative development. Measure 5.1 of the "Innovative Economy" Operational Programme as well as Measure 1.6 of Regional Operational Programmes were used to that extent.

In spite of the rather low number of new biotechnology cluster initiatives, they can be characterised by relatively high diversity when it comes to their strategy and functional models. There are cluster with a wide field of activity (Life Sciences Cluster in Cracow, Bio-Eco-Chem Cluster in Gdansk) as well as initiatives focused on a very narrow field (NUTRIBIOMED, Mazovian Peptide Cluster, LINUM Cluster). This diversity stems from different founding approaches: wide-spectrum clusters were created by integrating a dispersed research & development potential and by seeking to define a common plain of cooperation whereas specialised clusters resulted from singular initiatives of research teams attempting to attract potential partners to implement results of their research.

Cluster name	Year of	Cluster members			Legal form of	Cluster
	establis	Universities / research	Com- panies	Business environment	cooperation	coordinator
	nment	institutes	P	institutions		
Klaster Life Science	2006	22	30	19	participants	dedicated
(Krakow)					agreement	foundation
Bio-Eco-Chem	2006	8	17	10	participants	joint venture of
Pomeranian					agreement	universities
Biocluster (Gdańsk)						and
						administration
Klaster	2007	8	40	3	consortium	technological
NUTRIBIOMED						park
(Wrocław)						
Center of Advanced	2008	8	7	2	consortium	university
Technologies						-
BioTechMed (Łódź)						
Alice-Med.	2011	10	12	1	participants	research

Table 1: Biotechnology Clusters in Poland.

(Warszawa)					agreement	institute
Bioregion	2011	2	10	3	association	private
Wielkopolska						company
(Poznań)						
Klaster BioCeW	2012	1	6	1	participants	foundation
(Warszawa)					agreement	
Biomedical	2012	17	29	2	participants	university
Engineering Center					agreement	
Cluster CIBio						
(Warszawa)		-				-
Mazowiecki Klaster	2012	2	4	1	participants	research
Peptydowy					agreement	institute
(Warszawa)			1.5			
Biotechnology	2013	4	12	3	participants	private
Cluster Biopark					agreement	company
(Gdańsk)						
Mazovian	2014	7	16	1	partnership	dedicated
Bio I echMed Cluster					with	company
(Warszawa)					management	
					tirm	
Polish Biotechnology	2014	2	8	1	association	foundation
Cluster Linum						dedicated
(Wrocław)						

Source: Klastry w Polsce, 2012, clusters' own websites.

Most cluster initiatives are basing the internal cooperation on agreements between different participants – only few formalised it as an association or a consortium. The "looser" form of cooperation resulted from the unwillingness of cluster participants to be bound by too strict regulations and their fear of being subjected to additional liabilities. This formula was sometimes due to unequal financial position of the participants: public universities and research institutes play a significant role in clusters next to private companies and the funding potential of the former are usually quite limited. However, in the opinion of the cluster governing bodies loose ties among the cluster participants contribute to low quality of the cooperation and low efficiency of the cluster structures.

A significant difference between organisational models of the bio-clusters under analysis is the form of coordination of their activities. Several models have been applied: four consortiums assigned the responsibility for coordination to the leading institution (usually a university or a research institute), four other initiatives gave this function to a business support unit who at the same time is a cluster participant (university implementation centre, foundation, technology park), four further clusters founded companies designated to coordinate cluster activities.

Assigning coordination activities to a research institute or a university does not seem to guarantee efficiency and effectiveness of cluster activities, owing mainly to the particularities of their organisational and management culture which make managing of a completely different organisation, composed of independent institutions with different objectives and expectations, quite difficult. This observation seems to be confirmed by the outcomes of the clusters' activities – initiatives coordinated directly by universities and research institutes seem to exhibit limited level of activity, raising only in the event of a possibility of attracting new, subsequent instalments of cluster development support funds.

Entrusting a business environment institution with coordination activities proves equally risky. Those companies tend to run multiple projects in parallel and not all of them can find and implement a strategy that would ensure real cooperation of all cluster participants. The Life Sciences Cluster has adopted a unique approach: in the beginning cluster coordination role was given to the implementation company of the leading university partner and after 7 years a dedicated foundation (Life Sciences Cluster Foundation]) was commissioned. This foundation, as a leader and coordinator of cluster activities, is the legal entity behind the cluster and fulfils tasks benefiting all cluster participants (group purchases, information access, human resource attraction and development, common marketing activities etc.). This approach seems to be the model for cluster coordination activities as the cluster grows and matures.

An innovative biotechnology cluster requires a special approach to management, in particular when creating its organisational culture, defining the strategy and executing subsequent projects. Its ultimate success, measured by transitioning in a natural way through the subsequent cluster maturity phases and attaining a repeatable synergy effect, depends mostly on the ability to skilfully configure the potentials of cluster participants, bringing together the right management team and obtaining a leader which is able to successfully balance interests, competences and resources of all cluster participants.

Many clusters created in Poland did not make it through the first "embryo phase" of its development. Part of them solidified in this preliminary shape while waiting for another instalment of the cluster support funds. One can hope that thanks to the support scheduled for the 2014-2020 period they will be able to reach a development level allowing independent functioning.

Based on the conducted analyses it can be concluded that more or less a third of the cases under analysis shows symptoms of correct growth and has enough resources at their disposal to transition into true, efficiently functioning biotechnology clusters. The most basic, organic obstacle that is prohibiting them from reaching higher levels of development and efficient fulfilment of their mission is predominantly the fact that the scientific community is not prepared well for direct cooperation with the business and for commercialisation of their research. Creating cluster structures without a simultaneous change in the attitude of the scientific community and without changes to regulations for how research institutions should function will not automatically result in emergence of an environment that creates innovations, even in such an innovative industry as biotechnology.

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