PROSPECTS OF CLUSTER INITIATIVES IN RUSSIA AND THE WORLDWIDE IN DEVELOPMENT AND IMPLEMENTATION OF HIGH-TECH MEDICAL EQUIPMENT

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Introduction. Globalisation processess in world economy have a significant impact on the development of industries, regions, companies and their competitiveness. Almost all innovations demand some form of collaborative arrangement, for development or commercialization, but the failure rate of such alliances remains high. This forces companies, as well as regional policy makers, to reconsider their strategy, find new ways for collaboration and develop new activities. One of these new activities is the development of cluster building processes and their integration into the regions‘ innovation processes and strategies. Many publications (e.g. Michael Porter, 1998; Andersson et al. 2004 and others) discuss in detail academic and well defined approaches of the development, establishment and management of cluster structures. The author’s intention was to look through different ways of collaboration in various of technological fields and propose then the suitable form for medical and biotechnology industries basing on the world and russian market experience during last 10-15 years. Therefore, the aim of the current research can be formulated as defining the model of integration for companies and organizations which are involved in processing investigations and manufacturing biotechnological and medical equipment in Russian Federation according to results of international practice overview in the same and related fields.

Implementations of innovations. Firms collaborate for a number of reasons in order to implement innovations in high-tech fields of science and technology: to reduce the cost and/or risks of technological development or market entry; to achieve scale economies in production; to reduce the time taken to develop and commercialize new products; to promote shared learning. In any specific case, a firm is likely to have multiple motives for an alliance. However, for the sake of

analysis it is useful to group the rationale for collaboration into technological, market and organizational motives.

Technological reasons include the cost, time and complexity of development. In the current highly competitive business environment, the R&D function, like all other aspects of business, is forced to achieve greater financial efficiency, and to examine critically whether inhouse development is the most efficient approach. The rate of technological change, together with the increasingly complex nature of many technologies, means that few organizations can now afford to maintain in-house expertise in every potentially relevant technical area because of so called transaction costs [1].

In addition, there is a greater appreciation of the important role that external technology sources can play in providing a window on emerging or rapidly advancing areas of science. This is particularly true when developments arise from outside a company's traditional areas of business, or from overseas. Factors such as competitive advantage, market expansion and extending product portfolios are most important. Specifically, the most common reasons for collaboration for innovative product development are in response to changing customer or market needs. Therefore, it make sense to proceed with overview of existing forms of integration and discuss their strong and weak sides.

Forms of integration. No single form of collaboration or integration is optimal in any generic sense. However, in practice technological and market characteristics will constrain options, and company culture and strategic considerations will determine what is possible and what is desirable. For example, in the case of cross-border company acquisition, the potential for synergy and likelihood of success is greatest where there is some overlap in technologies, products or markets as this creates the potential for consolidation of R&D, production or marketing. In contrast, such overlaps are a major cause of failure of alliances because they create the potential for conflict and competition. Therefore firms should consider alliance partners with complementary technology, products or markets. Implementation of competitive partnership is also possible but not in each form of integration.

Table 1 presents a range of potential relationships between companies in integrated structures. To the data presented in [1], we added clusters in order to present the overview of all possible ways of collaboration. Alliances can be characterized in a number of different

ways. For example, whether they are horizontal or vertical. Horizontal relationships include cross-licensing, consortia and collaboration with potential competitors of sources of complementary technological or market know-how. Vertical relationships include subcontracting, and alliances with suppliers or customers. The primary motive of horizontal alliances tends to be access to complementary technological or market know-how, whereas the primary motive for vertical alliances is cost reduction. An alternative way of viewing alliances is in terms of their strategic significance or duration. In these terms, contracting and licensing are tactical, whereas strategic alliances, formal joint ventures and innovation networks are strategic and more appropriate structures for learning. However, it is important to relate benefits to the objectives of collaboration. For example, firms that entered into alliances specifically to reduce the cost or time of development often achieved this, whereas firms that formed alliances for other reasons were more likely to complain that the cost and time of development increased.

The research also found out a number of potential risks associated with collaboration without implementing cluster initiative, i.e.: leakage of information, loss of control or ownership, divergent aims and objectives, resulting in conflict ans some others less significant (Table 1).

Table 1. Forms of integration

Type of collaboration	**Typical duration**	**Advantages (rationale)**	**Disadvantages (transaction costs)**
Subcontract/ supplier relations	Short term	Cost and risk reduction, reduced lead time	Search costs, product performance and quality
Licensing	Fixed term	Technology acquisition	Contract cost and constraints
Consortia	Medium term	Expertise, standards, share funding	Knowledge leakage, subsequent differentiation
Strategic alliance	Flexible	Low commitment, market access	Potential lock-in, knowledge leakage
Joint venture	Long term	Complementary, know-how,	Strategic drift, cultural mismatch

		dedicated management	
Network	Long term	Dynamic, learning potential	Static inefficiencies
Cluster	Flexible	Expertise, standards, share funding, Complementary, know-how, quality management	Sensitive to number and size of members

Source: [1-3]

Nowadays, regions and regional companies face the challenges provided by the global market. The competitiveness of a region is not determined by single companies, but more and more by the innovative activities of entire industries and branches.Therefore, it is especially important that clusters is more flexible structure which also establish international networking and they act as a bridgehead in the promotion of regional and cross-border cooperation. In comparison with networks, cluster initiatives can provide following potential benefits for companies and regions encourages governments and other public actors:

- Increased productivity (through specialised inputs, access to information, synergies, and access to public goods);
- Faster innovation (through cooperative research and more intense competition);
- New business formation (filling in niches and expanding the boundaries of the cluster map).

Author can propose that cluster initiatives is the next level of innovations network development. Cluster initiatives help regions govern their economic development and recruiting efforts. It also encourages communities to refocus their efforts on existing industries. Strong domestic cluster initiatives also assist the regions in attracting foreign investments, that is very important for new investigations in biotechnology field, as well as medical equipment implementation and manufacturing. This fully applies to medical industry companies (MIC).

We would like to note that the main specific features of the MIC are relatively small sales volume, high risk of development of innovative high-tech medical devices caused by market changes, complex and time-consuming procedure in the practical implementation

and necessity to conduct a significant amount of medical - biological and clinical research, etc.

However, the strategy for the any MIC management must involve providing positive financial performance, causing stability, instability and even his critical condition, taking into account the market environment functioning [2, 3]. Ineffective management causes unstable or critical condition of the enterprise, product diversification and leads to reorganization or liquidation, therefore seleting integration strategy is very crucial for MIC.

Strategies for integration in healthcare, biotechnology and biomedical equipment sector. Successful strategies of cost leadership or differentiation are associated with internal development of processes and product technologies.

However, in highly dynamic environments, characterized by market uncertainty and technological change, like biotechnology, sourcing technology externally is a superior strategy to relying entirely on internal capabilities. This pattern of collaboration is observed in a range of sector studies, for example, high levels of collaboration in the information and communications technology and biotechnology industries, but lower levels in more mature sectors. In the more high-technology sectors, organizations generally seek complementary resources – for example, the many relationships between biotechnology firms (for basic research), and pharmaceutical firms (for clinical trials, production and marketing and distribution channels). In the pharmaceutical sector the number of exploration alliances with biotechnology firms is predictive of the number of products in development, which in turn is predictive of the number of exploitation alliances for sales and distribution.

Firms in higher technology sectors tend to favour horizontal relationships with their peers and competitors, whereas those in more mature sectors more commonly have vertical relations with suppliers and customers. A sector is usually defined as ‘high technology’ on the basis of the industry average R&D intensity (R&D expenditure/turnover).

Clusters are important because they create tangible economic benefits. The benefits of a cluster come in three dimensions [3- 5]:

- Firstly, companies can operate with a higher level of efficiency, drawing on more specialised assets and suppliers with shorter reaction times than they would be able to in isolation.

- Secondly, companies and research institutions can achieve higher levels of innovation. Knowledge spillovers and the close interaction with customers and other companies create more new ideas and provide intense pressure to innovate while the cluster environment lowers the cost of experimenting.

- Thirdly, the level of business formations tends to be higher in clusters. Start-ups are more reliant on external suppliers and partners, all of which they find in a cluster. Clusters also reduce the costs of failure, as entrepreneurs can fall back on local employment opportunities in the many other companies in the same field.

Due to these criteria, clusters seems to be most suitable solutions for integration strategies in sectors of biotechnology and medical equipment.

Implementation of cluster policy abroad and in Russian Federation. As there are several definitions used in connection with cluster initiatives, it is necessary to point out following definition and differentiation: cluster is vertically and horizontally related economic partners of a certain industrial sector in a defined region with international competitiveness.

Cluster policy should include strategic positioning within the region, definition of objectives, tasks and activities, definition of responsible body / legal entity, establishment of a project team, establishment of a cluster advisory board, Information and communication concept, Project management standarts implementation.

The underlying concept of clusters dates back to the 1890-s and the work of Alfred Marshall. In recent times, the term cluster was introduced and popularised through Michael Porter's book from 1990: "The competitive advantages of nations". As a consequence, none of the countries have used cluster policy explicitly before this. The methodology behind cluster mapping goes back to the model developed in US by Professor Michael Porter and implemented in the beginning of 21-th century. In 2003, the U.S. model was brought to Europe by Professor Örjan Sölvell, Dr. Christian Ketels, and Mr. Göran Lindqvist [5].

The number of countries adopting cluster policy in the time periods from 1990-1994, 1995-1999, 2000-2004 and from 2005 is fairly equal. A slight overweight of countries started to use the concept in the period from 1990-1994, i.e. early adopters, and in the period from 2000-2004. Considering the fact that around half the countries used cluster policy for the first time in the period from 2000 until today, the policy

area is still at an early stage in many countries. There is also a notable distinction between countries from Eastern and Western Europe. Among the adopters after 2000, many of them are small in population size and/or from countries in Eastern Europe [6, 7]. Table 2 presents information available about abroad clusters involved in biotechnology, pharmaceuticals and medical equipment research and development.

Table 2. Abroad cluster initiatives

Cluster	Country or region	Year of foundation	Field or speciality	Size or members
Biovalley[1]	Germany, France, Switzerland	1995-2011	Biotechnology, pharmacy	50 000 employes
FlandersBio[2]	Belgium, Flanders	2008	Biotechnology	15000 employes
Der Medizintechnik-Cluster (MTC) [3]	Austria	2002	Medical equipment	177 members
Kansai Bio Cluster [4]	Japan	2001	Biotechnology,Medical equipment	619 members
Kobe Biomedical Cluster[5]	Japan	2005	Biotechnology,Medical equipment	35 members
BIO.NRW Cluster Biotechno-logie NordrheinWestfalen[6]	Germany	2008	Life science, biotechnology	95 members, 5700 employes

Source: [3, 12]

[1] http://www.biovalley.com/academia/biovalley-services#
[2] http://flandersbio.be/
[3] http://www.gesundheits-cluster.at
[4] http://www.biobridge-kansai.com/
[5] http://www.ibri-kobe.org/

[6] http://www.bio.nrw.de/

There is a huge variation among the countries when it comes to how many and what kind of national ministries that are responsible for the implementation of cluster policy. Specially ministries or their combinations are mostly used as implementers of cluster policy abroad: ministry of industry and/or the ministry of finance/economy and/or ministry of science and research [7].

In Russia the Ministry of economic development provides the national cluster policy since 2007 when Job project "Cluster Policy Concept in the Russian Federation" and "Methodical recommendations for the implementation of the cluster policy in the subentities of the Russian Federation" were developed. At the moment cluster policy in Russia is provided according to the following documents: "The concept of long-term socio-economic development in in Russia up to 2020" and "Innovative Development Strategy of Russia up to 2020" [8, 9]. Table 3 consists information about Russian Federation innovation territorial clusters in the field of biotechnology, pharmaceuticals and medical equipment research and development. The author is participating at the moment in implementation of functional model of Bio-medical technology cluster (BMT-C) and would like to find out if it is more efficient than regional/territory model, while modern communication possobilities make it much easier to organize clusters interactions processes. But here additional researches should be obtained in order to formulate criteria of membership in functional cluster.

Table 3. Russian Federation cluster initiatives

Cluster	**Country or region**	**Year of foundation**	**Field or speciality**	**Size or members**
"AltaiBio"[7]	Biysk, Barnaul, Novoaltaisk	2010	Biotechnology, pharmacy	35 members, 7400 employes
Kaluga pharmaceutic	Kaluga region	2009	Biotechnology, pharmacy	40 members

[7] http://www.altaybio.ru; http://www.altkibd.ru/ackr/

al cluster (NP «KPhC»)[8]				
Innovative territorial cluster “Zelenograd” [9]	Zelenograd distrcit, Moscow region	2011	Micro & nanoelectronics (electronic component base); devices and apparatus for medicine; integrated technical IT systems	150 members, 12900 employes
Innovative territorial biotechnological cluster “Pushchino” [10]	Moscow region	2005	Medicine, pharmaceutics, biotechnologies	More then 30 members
Cluster “Fizteh XXI” - Severny[11]i	Dolgoprudny i, Moscow region	App. 2012	Biophysics, innovative medicines, new technologies for drug delivery and treatment; individualized medicine	More then 12 members
Innovative [12]cluster	Novosibirsk region	2013	Informational and	About 130 members

[8] http://www.pharmclusterkaluga.ru/
[9] http://www.technounity.ru/
[10] http://www.psn.ru
[11] http://phystech21.ru/; www.pharmcluster.ru
[12] http://icnso.ru/en/clusters/cluster_of_biomedicine_technology/index.html

"Sibacademsoft"			biopharmaceutical technologies	
Cluster of Medical, Ecological Tool Engineering and Biotechnologies[13]	St. Petersburg	2005	Medical industry, pharmaceuticals, radiation technology	About 150 members
LLC Tomsk Invest[14]	Tomsk	2011	Pharmaceuticals, medical equipment and information technology	39 members, about 3000 employes
"Bio-medical technology cluster" – BMT-C "Technomed"[15]	Moscow, Zelenograd, Saint-Petersburg	2015	Medical equipment and information technology	11 members

Source: [8-10]

Evaluating and increasing effectiveness of cluster structers and their prospects in healthcare field. Cluster Initiatives are organised regional sectorial networks among economic partners aiming at improving innovation performance and international competitiveness, i.e. "tool for innovation policy". Cluster initiatives have become a central feature for improving the growth and competitiveness of clusters. They are an increasingly popular approach to develop and strengthen clusters in following directions (fields): information and communication, training and qualification, co-operations, marketing and PR, internationalisation. These define the role of specialized

[13] www.clustermedtech.ru; www.21mpp.ru
[14] www.fmt.innoclusters.ru
[15] http://www.cyberneticworld.ru/rus/bmt_k_rus.html

company – operator of cluster and possible members, as well as their competences. At the same time, cluster initiative should be open to all companies due to low threshold, low member fees, minimum commitment (e.g. participation at meetings), etc. At the same time it was shown in several studies that a cluster initiative should comprise at least 30-50 members (companies and other actors) to achieve a critical mass. Efficiency of cluster is also sensitive to size of companies members. This limits the selection of cluster sectors [6-10].

The role of cluster specialized company (CSOC) is extremely high because of its coordination role inside the integrated structure and communication with near and far surroundings, determiming the quality management of processes and products. As part of the European Cluster Policy there is a system of evaluation of quality management in clusters (within ECEI program) - «Quality mark of the cluster organization management system» designed to encourage continuous improvement in the quality of cluster initiatives governance. «Quality Mark» is an independent assessment system, the methodology followed by the methodology of the «European Foundation Quality Management» (EFQM) and is based on the quality indicators applicable to different types of clusters in the EU as well as in other countries. This methodology allows managers to clearly see the areas of improvement of their activities, to understand the strengths and weaknesses of their work and the characteristics of the controlled object. Specialized companies of clusters consistently improve their ranking with the initial stage of the bronze to gold, and the process duration may take from 6 months to 2 years [11]. European Cluster Excellence Foundation (ECEF) as well as the European Secretariat for Cluster Analysis (ESCA) are outcomes of efforts by the European Commission to support cluster organisations in Member States on their way towards cluster management excellence under the European Cluster Excellence Initiative that was supported by the Directorate-General “Internal Market, Industry, Entrepreneurship and SMEs”. Many Member States and regions have turned these recommendations into policy actions and programmes [11, 12].

Integration strategy to Bio-medical technology cluster (BMT-C) must be adjusted to unfavorable factors, should provide a high rate of production development based on the stabilization of the organizational-economic stability and increase the competitiveness of the enterprise, while reducing the threat of bankruptcy. Medical industry enterprises and companies should harmonize financial

performance, taking into account development strategies of healthcare institutions and facilities acting towards them as consumers, which will increase efficiency, both clinics and public health.Implementing quality management system into cluster operation processes is extremely important for clusters dealing with pharmaceuticals and medical equipment in order to fulfill ISO 13485 requirements as well as GMP and GLP standarts. To estimate progress of cluster specialized company list of criteria can be evaluated according to recommendadtions prepared by OECD [13].

Conclusions. Following estimations can be made after the conducted research:

1. Cluster initiatives in the field of medical industry development must take into account several factors: first - the creation of clusters in the medical industry should implement a functional model of Bio-medical technology cluster (BMT-C); second – participation of national banks and financial institutions, insurance companies is preferable to increase the capitalization of the project and its attractiveness to other investors and to coordinate financial streams; third - the usage of project financing methods, providing the ability to minimize the risks and increase the profitability of the project as a whole.

2. Increasing the attractiveness of an innovative project in the medical industry includes the creation of competitive advantages due to the high standards in the field of high-tech medical care and the creation of new types of medical equipment, others institutional targets. Important questions here are selection of the development direction (early diagnosis and rehabilitation, use of laboratory, genetic analyzes, etc.), pricing and marketing policy, introduction and implementing of innovative technologies, quality guarantee and service, financial engineering support of innovation, and so on.

3. All over the world, as well in Russian Federation, the role of specialized company is very high, quality management is necessary also for international cooperation and certification needs as well as for implementing of ISO, GMP and GLP standarts.

REFERENCES

1. Managing innovation: integrating technological, market and organizational change / Joe Tidd, John Bessant, Keith Pavitt.– 3rd ed, 2005. 602 p.

2. Gertsik Yu.G. Analysis of factors affecting the competitiveness and organizational-economic sustainability of medical industry companies/ European Social Science Journal, 2015. № 7. – P. 29-36

3. Cluster Programmes in Europe - Report September 2015. EU Cluster Portal: European Cluster Observatory [internet resource]. Access mode: http://ec.europa.eu/growth/smes/cluster/observatory/. Accessed in 1 December 2016

4. Cluster policy in Europe. A brief summary of cluster policies in 31 European countries Europe Innova Cluster Mapping Project Oxford Research AS, January 2008 [internet resource]. Access mode: http://www.innova-europe.eu/. Accessed in 1 Novemver 2016

5. Cluster Management Guide – Guidelines for The Development and Management of Cluster Initiatives [internet resource]. Access mode: http://www.interreg4c.eu/uploads/media/pdf/2_Cluster_Management_Guide_CLOE.pdf. Accessed in 1 December 2016

6. The Concept of Clusters and Cluster Policies and Their Role for Competitiveness and Innovation: Main Statistical Result and Lessons learned [internet resource]. Available at: http://ec.europa.eu/enterprise/policies/innovation/files/clusters-working-document-sec-2008-2635_en.pdf. Accessed in 1 Novemver 2016

7. Perfect Cluster policy and Cluster Program [internet resource]. Available at: http://regx.dk/fileadmin/user_upload/Perfect_Cluster_Program_final_120411.pdf. Accessed in 1 Novemver 2016

8. Official internet resource of Ministry of economic development of Russian Federation [internet resource]. Available at: http://economy.gov.ru/en/home. Accessed in 1 December 2016

9. Russian cluster observatory [internet resource]. Available at: http://cluster.hse.ru/. Accessed in 1 December 2016

10. RVC report «Quality management for specialized operating companies of innovative regional clusters in Russian Federation» [internet resource]. Available at: https://www.rvc.ru/upload/iblock/946/201403_management_companies_clusters.pdf. Accessed in 1 Novemver 2016

11. European Foundation for Quality Management (EFQM). Cluster Organization Management Excellence Label [internet resource]. Available at: http://www.efqm.org/the-efqm-excellence-model. Accessed in 1 December 2016

12 Müller, L., Lämmer-Gamp, T., Meier zu Köcker, G., Christensen, T.: Clusters are Individuals, Vol. II, New Findings from the Clustermanagement and Clusterprogramme Benchmarking. Berlin: VDI/VDE-IT GmbH, 2012. Available at: http://www.cluster-analysis.org/downloads/ClustersareIndividualsVolumeIIAnnex.pdf. Accessed on: 1 December 2016.

13. OECD. DAC Criteria for Evaluating Development Assistance [internet resource]. Available at: http://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm. Accessed in 1 December 2016

GLOSSARY

BMT-C - Bio-medical technology cluster;
CPCRF - Cluster Policy Concept in the Russian Federation;
CSOC - cluster specialized operating company;
EFQM - European Foundation Quality Management;
ECEF - European Cluster Excellence Foundation;
ESCA - European Secretariat for Cluster Analysis;
GLP – good laboratory practice
GMP – good manufacturing practice;
ISO – International Standart Organisation;
MIC - medical industry companies;
RVC – Russian venture company;
OECD - Organisation for Economic Cooperation and Development.