
How Innovation Cooperation Supports the Improvement of Health Care in the CEE Region: The Case of ECMO for Greater Poland

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Abstract:

Purpose: The main aim of this article is to present the development of innovation cooperation in the biopharmaceutical industry in the Central and Eastern Europe (CEE) region.

Design/Methodology/Approach: The authors present the role of R&D Innovation Ecosystem in the biopharmaceutical industry in the improvement of patient care in Poland. The article presents the results of qualitative research – focus group interview with representatives of the “ECMO for Greater Poland” program within the research grant of the National Science Centre (Poland) entitled “Analysis of Open Innovation Alliances and Strategic Partnerships in the Biopharmaceutical Industry in Poland and CEE countries”.

Findings: The authors present their own observations, contributions to the creation process and successful “ECMO for Greater Poland” program development.

Practical implications: It should be considered that nowadays due to pandemic COVID-19 the cooperation of all entities in the whole biopharmaceutical R&D innovation ecosystem is even more challenging and with high level of complexity.

Originality/value: R&D cooperation between academia, institutions and business can significantly increase the likelihood of creating better medical therapy for patients.

Keywords: R&D alliances, biopharmaceutical industry, open innovation, open innovation alliance, innovation cooperation, business-academia cooperation, ECMO.

JEL codes : 030, 032, 033.

Paper Type: Research study.

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1. Introduction

Over the last three decades we can observe that R&D cooperation has become a core aspect of the innovation strategy. We can find many interesting publications on R&D cooperation between companies in the economic and management literature considering the distinction between cooperation based on the transfer and exchange of technology, R&D arrangements, and joint ventures (Auster, 1987; Casson 1987; Chesnais 1988; Contractor and Lorange, 1988a). We can divide technological agreement from one-directional to the ones that are based on strong relationships between companies, e.g., joint-ventures, research corporations, on the other hand, those which involve less organizational dependencies (contractual arrangements such as joint R&D agreements or technology exchange agreements).

These types of technological cooperation have different effects on the nature of the sharing of technology, level of competitiveness, organizational aspects and the possible economic consequences for the companies involved in cooperation (Auster, 1987; Root, 1988; Contractor and Lorange, 1988b; Hagedoorn, 1990; Hagedoorn *et al.*, 2000; Gomes-Casseres, Hagedoorn, and Jaffe, 2006; De Man and Duysters, 2007; De Man, Duysters, and Neyes, 2009; Puślecki 2010). It should be considered that technological cooperation is an important channel of diffusion of knowledge in both sectors: public and private. Companies are using global strategic partnerships to strengthen competitive position, enhance core competencies and skills as well as acquire new technologies. By developing R&D alliances they can gain new opportunities to share the risk of the development of new technologies, on new, emerging markets (Puślecki, 2010; 2012; 2015) and have better innovation cooperation performance (Trąpczyński, Puślecki, and Staszaków 2018).

2. Development of R&D Cooperation - Theoretical Approach

Taking into consideration strategic alliances we can define them as a special mode of cooperation between at least two parties (competitors or partners) operating in the same or related sectors with the aim of achieving common goals which have been set up with the use of available resources, while preserving the autonomy of each partner, in a range of fields and areas which are not covered by the partnership agreement (Gomes-Casseres, 1996; Das, 2005). Regarding partners involved in the cooperation we can find that alliances are typically formed between two firms but can be also created with universities, research institutes, non-profit research organizations, or government institutions (Baum *et al.*, 2000, Puślecki and Staszaków, 2015). Strategic technology alliances are implemented mainly through joint ventures (an alliance of two or more participants forming a separate entity with the aim of achieving common goals), so-called equity alliances, or, within capital alliances and R&D cooperation agreements, so-called non-equity alliances. R&D alliances can be perceived as an innovation-based relationship formed by two or more partners who pool their resources and coordinate their activities to reach a common goal. In these type of relationships R&D activities represent a significant part of the collaborative effort

(Hagedoorn, 2002). They are also referred to as cooperative R&D, technological alliances, strategic technology partnering, strategic technology alliances, technological cooperative agreements, innovation cooperation (Puślecki, 2010; Narula and Martinez-Noya, 2015; Martinez-Noya and Narula, 2018). Technological alliances are understood as strategic when improving the long-term perspective of the product market combinations for at least one company involved in cooperation. Technological partnerships are defined as a form of cooperation including at least some innovative activity or an exchange of technology between partners (Duysters and Hagedoorn, 2000). The lack of uniformity in the definition of R&D alliances across the economic and management literature reflects the multidisciplinary of the subject (Martinez-Noya and Narula, 2018).

We can distinguish many different advantages offered by R&D alliances for partners involved in innovation cooperation, access to complementary resources required to develop new or improved products or processes, possibility of exploring new markets, achieving lower costs, mitigating risks, having more flexibility in partner selection or reducing time-to-market (Duysters and Hagedoorn, 2000; Hagedoorn *et al.*, 2000; Narula, 2001; Sakakibara, 2002). Analyzing the development and growth of R&D alliances (Narula and Dunning, 1998; Puślecki, 2008; 2010; Martinez-Noya and Narula, 2018) we can find in the literature that they have been explained through the lens of transaction cost theory taking a economization perspective into account (Pisano and Teece, 1989; Williamson, 1975; Hennart, 1988), or by taking a more strategic perspective, including number of other different theoretical approaches, such as the resource-based theory of the firm (Barney, 1991; Das and Teng, 2000; Wernerfelt, 1984), knowledge-based view and organizational learning (Kogut and Zander, 1993), social network theory (Gulati, 1995; Powell and Grodal, 2005), or even the dynamic capabilities approach (Teece *et al.*, 1997; Zollo and Winter, 2002).

In more recent R&D alliance literature we can find that alliances are not only the result of a cost minimization strategy, but also the result of value-enhancing considerations, related to market growth or inter-firm learning through alliances. From this perspective, based on strategic management theories, such as the resource-based view, firms form R&D alliances to enhance their technological and organizational capabilities (Das and Teng, 2000) as well as to create value by for example, acquiring complementary resources, leveraging existing resources, developing new (or improved) products and innovation capabilities, or entering new markets (Sakakibara, 2002). These strategies are important in new technological sectors (such as biotechnology and biopharmaceutical). The diversity of technological areas, turbulent and dynamic environment (now due to COVID-19 pandemic) high level of uncertainty as well as the complexity of alliance management requires from companies broader range of competencies (Granstrand *et al.*, 1997; Leiblein and Miller, 2003; Mol, 2005; Nicholls-Nixon and Woo, 2003; Quinn, 2000), which encouraged the use of a portfolio of R&D alliances in order to access complementary resources and capabilities (Hamel, 1991; Hong and Snell, 2013; Howard *et al.*, 2016).

Nowadays, both transaction cost minimizing, and value-enhancing motives are regarded as complementary to each other in the formation of R&D alliances, and as we can observe in the literature many studies combine both approaches (Lai and Chang, 2010) because very few alliances are distinctly driven by one motivation or the other (Martinez-Noya and Narula, 2018).

3. Development of Modes of Cooperation in the Biopharmaceutical Industry

Biopharmaceutical (pharma and biotech) companies have developed cooperation with universities for many years. At the beginning we can observe mainly individual, single projects, from small research projects to large clinical trials. Afterwards the companies developed alliances with individual academic institutions, including a wider range of cooperation, through research programs, clinical trials, and translational research. Companies also increasingly began to use different models of R&D alliances, from individual links in research projects to multilateral agreements involving multiple research projects, including various models for open innovation, for example where the main role of an academic institution was the coordination and sometimes funding of other institutions. Chesbrough (2003) defines "open innovation" as the paradigm stating that companies can and should use external and internal ideas, as well as internal and external paths to market.

According to the latest definition by Chesbrough open innovation is *“a distributed innovation process based on purposively managed knowledge flows across organizational boundaries, using pecuniary and non-pecuniary mechanisms in line with each organization’s business model”* (Chesbrough and Bogers, 2014). This concept can be applied in bilateral and multilateral alliances. Open innovation model is more dynamic than traditional alliances because partners in alliance are not identified in the conventional, purposeful way. Relationships are focused more on the exchange of knowledge and ideas during the period preceding the creation of the alliance. The main aim of open innovation alliances is to support the free flow of knowledge and ideas leading to the creation of partnerships aimed not only at joint innovation, but also at risk and profit sharing (Wilks and Prothmann, 2012). The results of research on open innovation have shown how firms are managing both the inflows and outflows of knowledge and how they are searching for partners and the innovations they provide (Culpan, 2014; West, 2014).

We can also observe how companies in specific industries (like biopharma) use the model of open innovation to establish open innovation alliances not only with firms from the same or other industry but also with universities, individuals, communities, or other organizations (Academia-Institutions-Business relations) (DeWitt and Burke, 2012; Wilks and Prothmann, 2012; Deloitte, 2015; 2017). It should be taken into consideration that the organizational fluidity of open innovation initiatives as well as multiparty relations increase the complexity in the alliance management. In open innovation alliances the alliance management plays a central role, particularly in

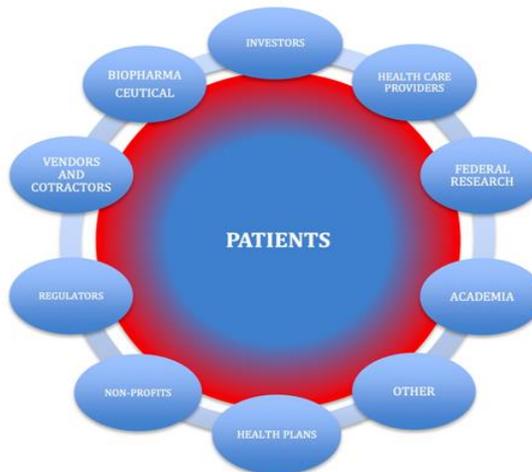
defining the alliance portal and framework. The use of open innovation model can significantly speed up the production process of new drugs and vaccines, which are in demand on the market because of COVID-19 pandemic (Chesbrough, 2020).

Moreover, having more interdisciplinary academic teams in the cooperation can also accelerate and support this process (Laviertes, 2012, Wilks and Prothmann, 2012). Companies have defined and implemented open innovation in several ways, including innovations for users, crowdsourcing, creation of joint development alliances or through building innovative ecosystems (Puślecki, 2015; 2016a; 2016b; Puślecki and Staszaków, 2015; Wilks and Prothmann, 2012).

4. Characterizing the Biopharmaceutical R&D Innovation Ecosystem

Collaboration within the biopharmaceutical R&D ecosystem enables important scientific breakthroughs in novel diagnostic technology and the definition of molecular targets for the development of personalized medicines. These advances have an impact on the current development of new drugs. Thanks to their commitment to cooperation, biopharmaceutical companies can develop targeted therapies and drugs needed to treat serious diseases and unmet medical needs (Deloitte, 2017).

Figure 1. Illustrative biopharmaceutical R&D innovation ecosystem



Source: Own elaboration based on (Deloitte, 2017, p. 11).

The biopharmaceutical R&D ecosystem consists of a varied group of stakeholders including, but not limited to: biopharmaceutical companies (e.g., large and small biopharmaceutical companies, biotechnology companies, and start-ups/incubators), investors including venture capital firms, health care providers, federal research organizations (e.g., the National Institutes of Health (NIH)), academic institutions, non-profits (including patient advocacy groups and disease-focused communities), services, regulators (e.g., the FDA and the Patent and Trademark Office), health plans,

and others (e.g., vendors providing health information, advanced engineering services, contract research and development execution, and others), and enables them to achieve together that which would be difficult acting as an individual entity. Biopharmaceutical companies in the R&D ecosystem have two functions, they are contributors as well as integrators of the ecosystem. They bring together diverse stakeholders offering distinct characteristics and contributions (Table 1) and having a common goal of improving patient health outcomes. In this case, patients are positioned at the ecosystem's hub as both key participants in driving patient-centered innovation and as the recipients of the value created because of cooperation in ecosystem (Figure 1).

Table 1. *Biopharmaceutical R&D Innovation Ecosystem - overview of typical contributions of various partners on innovation*

Partners involved in Biopharmaceutical R&D Innovation Ecosystem	Contributions to partnerships
<i>Biopharmaceutical/ Biotechnology/ Pharma Companies</i>	Support and/or lead the overall drug development process, including basic research, discovery, chemical compound synthesis, pre-clinical and clinical development, regulatory submissions, commercialization (delivery), etc., with scientific, operational, and/or financial input.
<i>Academia</i>	Perform basic research in areas of unmet patient need; advance scientific discovery in unsolved disease areas; develop new targets, drug technology platforms, compounds, etc., that can be tested in clinical settings.
<i>Federal Research</i>	Perform basic research, providing rationale and advancing scientific discovery to serve population health interests; develop new targets, drug technology platforms, and compounds that can be tested in clinical settings.
<i>Health Care Providers</i>	Advise innovators during R&D, clarifying patient needs and preferences (including methods for drug delivery and treatment), particularly in basic research, clinical studies, and epidemiological research; execute clinical trials.
<i>Investors</i>	Provide capital and strategic guidance for biopharmaceutical R&D innovation ecosystem players
<i>Non-profit</i>	Promote disease- or condition-specific discovery and research (including regulatory processes, value assessments, etc.); foster relationships with patients and health care providers to ensure the "patient voice" is heard throughout the drug development process.
<i>Regulators</i>	Evaluate safety and efficacy to approve critical, needed new therapies; provide public funding resources and tax incentives to support R&D to address unmet needs; shape health system regulations, uphold laws, and protect the interests of the public.
<i>Vendors and Contractors</i>	Supplement in-house resources, often providing specialized services such as data management and analysis, laboratory analytical services, clinical trial recruitment and execution, etc.

Source: Own elaboration based on (Deloitte, 2017, p. 13).

Analyzing examples of partnerships in biopharmaceutical industry we can observe different modes of cooperation open innovation alliances, public-private partnerships, consortia, pharma-university alliances, cross-industry alliances as well as different

entities involved in cooperation including governments, universities and research institutes, foundations, funds, banks, and organizations. An ecosystem model can be used as a lens through which it is possible to observe the biopharmaceutical innovation landscape. Deloitte (2017) defines ecosystems as “*symbiotic, cooperatively evolving communities comprised of multiple diverse players.*” This ecosystem consisting of highly specialized players make it possible to generate new biopharmaceutical solutions aiming at society’s medical and health needs. Considering current challenges impacting the biopharmaceutical R&D environment (COVID-19 pandemic), development of collaborative relationships can help partners in obtaining scientific and technological advances and offer new innovations (like new vaccines) to patients faster (Deloitte, 2017). This kind of constellation of partners is sensitive and difficult to manage, the problem of one entity or organization could affect all partnership and has negative effect on delivery of new drugs or new medical therapies. As multiparty alliances they require even greater competencies and skills of alliance managers and appropriate alliance management tools. Thanks to significant synergy effects participation in R&D Innovation Ecosystem gives the partners access to huge innovative potential and to more market opportunities, which helps them to innovate, accelerate growth and expand into new promising markets (DeWitt and Burke, 2012; 2013; Fraser, 2014).

Implementation of joint activities between all the partners, including appropriate alliance management tools and multiparty alliance strategies can contribute to the dynamic development of the biopharmaceutical industry in Poland and in the CEE, as well as better use of research and innovative potential of all parties, involved in cooperation (Staszków, Puślecki, and Trąpczyński, 2017; Wach, 2005), in delivering new products, services, better therapies and health care of patients. This can be very well observed in the “ECMO for Greater Poland” program operating in Poland. In the next section the results of qualitative research (focus group interview) with representatives of the “ECMO for Greater Poland” program will be presented, which was conducted within research grant of the National Science Centre (Poland) entitled “Analysis of Open Innovation Alliances and Strategic Partnerships in the Biopharmaceutical Industry in Poland and CEE countries”.

5. “ECMO for Greater Poland” as a Result of Innovation Cooperation

5.1 ECMO Support

Extracorporeal Membrane Oxygenation (ECMO) is currently the most widely used extracorporeal blood oxygenation technique using an oxygenator responsible for gas exchange and a pump that moves the blood. The prototypes for ECMO were the artificial heart-lung machine used for extracorporeal circulation during cardiac surgery. The concept of ECMO was initiated in the 1960s by Bartlett *et al.* (1976).

Depending on how the cannulas are connected to the patient's vascular system, the extracorporeal blood oxygenation system may be used to improve arterial blood

oxygenation or to support the circulatory system in the event of heart failure. In the case of venous-venous cannulation (VV-ECMO), venous blood returning to the right heart is oxygenated. The work of the lungs is replaced, and the technique can be a bridge in the treatment of the most severe forms of refractory respiratory failure (including Ah1N1 and COVID-19 patients). In the case of venous-arterial cannulation (VA-ECMO), oxygenated blood is introduced directly into the arterial part of the circulatory system, replacing both the functions of the lungs and the circulatory system.

5.2 ECMO Renaissance

Currently, ECMO is experiencing a kind of renaissance in the world and in Europe in last 30 years with significant intensity firstly in 2009 with the real spectrum of the new influenza pandemic - AH1N1 and in recent months because of SARS-CoV-2 pandemic. From December 2019 to March 2020, COVID-19 evolved from a cluster of pneumonia cases in China into the first coronavirus-caused pandemic surpassing 54.0 million cases and 1.3 million deaths in ten months and is still not under control (COVID-19 Situation Update, 2020). Although estimates the 3-5% of all cases progress into critical illness (Auld, 2020) but invasive mechanical ventilation is necessary for both hospitalized and critically ill (2.3-33.1% and 29.1-89.9%, respectively) (Wunsch, 2020). In cases with refractory hypoxemia unresponsive to lung-protective ventilation the World Health Organization (WHO) provisionally recommends ECMO emphasizing access to expertise in extracorporeal membrane oxygenation. Up to date, more 3,500 applications of ECMO in COVID-19 reported into the Extracorporeal Life Support Organization (ELSO) registry.

The use of VV-ECMO in the treatment of acute respiratory failure (ARDS) has found its permanent place in intensive care – National Consultant in the field of Anesthesiology and Intensive Care guidelines were updated in 2017 (Lango *et al.*, 2017). Along with the growing experience in the use of extracorporeal techniques, ECMO in the venom-arterial configuration (VA-ECMO) is increasingly used also outside cardiac surgery departments. This form of support has become a recognized technique in the treatment of hypothermia; severe heart failure; resistant cardiogenic shock; pulmonary embolism; severe poisoning and all other critical conditions with a potentially reversible cause. The use of VA-ECMO in extended cardiopulmonary resuscitation - E-CPR has been proven to significantly increase the survival rate of patients in in-hospital cardiac arrest (Tonna *et al.*, 2016).

In addition to the classic indications for supporting the treatment of patients in critical conditions, it is also possible to use regional organ perfusion using ECMO (nECMO) in the deceased due to irreversible cardiac arrest - for kidney, liver, and lung donation. Since 2009, the Polish act on transplantation (the Act on the collection, storage, and transplantation of organs), following the example of other countries in the world, extends ex mortuo organ donation to include such a group.

It should be emphasized that ECMO is not a therapy, it is only a temporary prosthesis, replacing the work of the inefficient lungs and/or heart until their function improves, allowing them to work independently. The key criterion for the inclusion of extracorporeal techniques in the treatment of critical conditions, in addition to other specific inclusions and exclusions, is the potential reversibility of the process that led to lung or heart failure.

5.3 ECMO Center Model-HUB

The main ELSO recommendation to improve outcomes in that therapies are to consolidate ECMO treatment to specialized high-volume centers and minimum ECMO cases for good outcomes is 6 per year but providing more than 30 annual adult support showed a significantly lower ECMO mortality. Therefore, the centralized therapies in dedicated centers are strongly recommended with the use of specialized ECMO transportation (Linden *et al.*, 2001; Barbaro *et al.*, 2015). To obtain the best possible results, it is necessary to bring the patient to a center with comprehensive and advanced treatment. Hence, the concept of "HandS - Hub and Spoke" was introduced by Combes *et al.* (2014). A high reference center integrates the regional hospitals applying only conventional therapeutic methods using high qualified transportation.

Therapy with the use of ECMO is expensive and not a routine procedure in Poland, and only in some places such treatment is provided as part of grassroots initiatives, there is no systemic solution (Puslecki *et al.*, 2019). "HandS" conception is realized in 4 centers (Cracow, Lublin, Warsaw, Opole) with transportation "on yourself" conception and since COVID-19 pandemic developed there are 5 dedicated centers for VV ECMO support in COVID patients (Lublin, Warsaw, Cracow, Gdansk, Wroclaw). The developing epidemic provoked the launch of air transport (HEMS - helicopters and planes) in Poland, and for several months transport by helicopter has been available 24 hours a day in five Polish HEMS stations.

It is difficult to estimate the demand for extracorporeal techniques, considering epidemiological needs. Pediatric ECMO support is usually incorporated in Hospitals with pediatric Cardiac Surgery departments. Pediatric transfer in Poland is marginal - there are individual case-study reports.

6. ECMO Reactivation in Greater Poland – "ECMO For Greater Poland" Program

In 2016, in Greater Poland, thanks to the employees and units of the Poznan University of Medical Sciences, in cooperation with the Medical Simulation Center, the Voivodeship Emergency Station in Poznan, as well as with the support of the Polish Society of Medical Simulation and the Medical University of Warsaw, the "ECMO for Greater Poland" program was implemented (Puślecki *et al.*, 2017) and is coordinated by the Department of Cardiac Surgery and Transplantology, PUMS. The main goal of the nonprofit program is to implement extracorporeal techniques of

supporting vital functions with the use of ECMO in the population of 3.5 million people in the Greater Poland region.

The main application areas of the Program are, use of ECMO in patients with hypothermia, reversible respiratory failure, or other critical conditions (refractory cardiogenic shock, pulmonary embolism, acute poisoning, E-CPR). Additional application of ECMO to regional organ perfusion in the deceased in the mechanism of irreversible cardiac arrest (DCD - donation after circulatory death) to obtain potential donors of organs for transplantation. Such a wide range of application of perfusion techniques, despite the regional scope, is unique in the country, comparable to the best and few centers in the world.

Before the program was launched, until 2016, ECMO was not used in the treatment of adult patients with reversible respiratory failure or hypothermia in Greater Poland. Nationally, ECMO has never been used for organ perfusion in donors who have died from irreversible cardiac arrest (DCD). Such therapy is an established procedure that allows to increase the pool of organs available for transplantation.

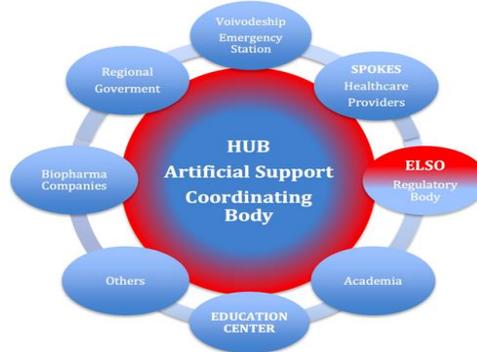
The ambition of the Poznan University of Medical Sciences and the creators of the "ECMO for Greater Poland" program is to create a Regional Extracorporeal Therapy Center - HUB in the academic structures, based on the experience of clinical teams. The functioning of the Center should improve the care and therapy of patients in critical conditions, increase the safety of patients undergoing therapy, and develop regional transplantology through bridging treatment of patients awaiting heart and/or lung transplantation, as well as increase the number of potential organs that can be used for transplant. Temporary Center is developed on available hospital center in SKPP UMP Hospital and was first in Poland affiliated center in ELSO. Extracorporeal Life Support Organization (ELSO, Ann Arbor, MI, USA, www.elseo.org) is a worldwide patronage organization of more than 900 centers providing ECMO-assisted therapy. The main mission of ELSO is to improve outcomes, collect registry of ECMO treatments and provide guidelines associated with ECMO treatment, also for ECMO transport (ELSO).

7. “ECMO For Greater Poland” Innovation Ecosystem

The “ECMO for Greater Poland” innovation ecosystem enables a varied group of stakeholders to achieve together that which would be difficult for any individual member of ecosystem. The role of the HUB – Artificial Support Coordination Body is the integration of external partners, coordination of innovation cooperation, knowledge transfer and diffusion of knowledge, monitoring, management and control of the ecosystem, continuous improvement of existing procedures, improvement of qualifications, skills within a dedicated education platform to develop common necessary competencies. This cooperation enables several benefits both for HUB as well as for partners (Table 2), development of innovative projects and allows significant synergy effects and helps easier respond to changes in the environment

(COVID-19 pandemic). The involvement of all partners in the cooperation can have positive effect on innovation cooperation performance of the whole “ECMO for Greater Poland” Innovation Ecosystem (Figure 2) (Trapczyński, Puślecki, and Staszaków, 2018) as well as can enable the development of new modes of cooperation (Puślecki, 2015; Puślecki and Staszaków, 2015).

Figure 2. “ECMO for Greater Poland” Innovation Ecosystem



Source: Own elaboration.

Table 2. Benefits for HUB and for partner as a result of innovation cooperation

Partner description in innovation cooperation	Benefits for HUB	Benefits for partner
<i>HUB – Temporary SKPP PUMS (Mobile ECMO Team and ECMO Team)</i>	<ul style="list-style-type: none"> cooperation exchange of experience backup for personnel and equipment resources 	<ul style="list-style-type: none"> cooperation exchange of experience backup for personnel and equipment resources
<i>HUB – Pediatric SKKJ PUMS</i>	<ul style="list-style-type: none"> cooperation exchange of experience backup for personnel and equipment resources 	<ul style="list-style-type: none"> cooperation exchange of experience backup for personnel and equipment resources
<i>PUMS</i>	<ul style="list-style-type: none"> know how brand and background for publications 	<ul style="list-style-type: none"> international meetings POWER funds promote PUMS brand publications
<i>Voivodeship Emergency Station Poznan (WSPR)</i>	<ul style="list-style-type: none"> transportation vehicle mechanical chest compression devices Emergency Medicine staff prehospital algorithm of patient inclusion 	<ul style="list-style-type: none"> WSPR brand improvement in Poland New procedures: <ul style="list-style-type: none"> DCD ECPR
<i>Center for Medical Simulation (CSM) PUMS – Center for</i>	<ul style="list-style-type: none"> building, equipment, rooms for the ECMO Center translational simulation 	<ul style="list-style-type: none"> CSM brand improvement in Poland first ELSO certified Training Center in

<i>Artificial Life Support and Patient Safety</i>	<ul style="list-style-type: none"> • procedure creation • procedure implementation • skills improvement 	Central and Eastern Europe
<i>Extracorporeal Life Support Organization (ELSO) Family</i>	<ul style="list-style-type: none"> • certification • world knowledge flow • support for meetings 	<ul style="list-style-type: none"> • ELSO brand in Poland improvement • patient's registry • new guidelines creation
<i>Spoke – Referral Hospital</i>	<ul style="list-style-type: none"> • patients pool 	<ul style="list-style-type: none"> • support on every step of treatment • patient transportation “on himself”
<i>E-learning Platform</i>	<ul style="list-style-type: none"> • part of POWER Program 	<ul style="list-style-type: none"> • knowledge platform
<i>Promote Platform</i>	<ul style="list-style-type: none"> • indexing • brand ECMO for Greater Poland building 	<ul style="list-style-type: none"> • indications and potential procedure for patients
<i>Biopharma Companies</i>	<ul style="list-style-type: none"> • devices, medical equipment delivery and technical support • access to new knowledge 	<ul style="list-style-type: none"> • cooperation during project duration • company brand improvement
<i>Crisis Management of the Greater Poland Voivodeship</i>	<ul style="list-style-type: none"> • support • transportation priority 	<ul style="list-style-type: none"> • regional health care improvement
<i>Helicopter Emergency Medical Service</i>	<ul style="list-style-type: none"> • cooperation 	<ul style="list-style-type: none"> • POWER course, training • Cooperation
<i>Marshal Office of the Wielkopolska Region</i>	<ul style="list-style-type: none"> • support 	<ul style="list-style-type: none"> • regional health care improvement
<i>Greater Poland Voivodeship Office</i>	<ul style="list-style-type: none"> • support 	<ul style="list-style-type: none"> • Priority for ECMO Program

Source: Own elaboration.

8. Translational Simulation in ECMO Transportation

Translational simulation is a proper term describing the part of simulation activities focused on improving healthcare processes and outcomes. It can be realized through diagnosing safety and performance issues and delivering simulation-based intervention, irrespective of the location, modality, or content of the simulation (Brazil, 2017). Translational simulation can be best probing mechanism in improving safety in ECMO implementation. In high sophisticated activity the result depends on the frequency and preparation of the team, and the circumstances under which the patient transfer occurs. High fidelity medical simulations with all partners involved in the cooperation gave opportunity to create and test procedures and checklists developing situational awareness and entrusting such tasks to specialized teams, prepared, and trained in each field.

The “ECMO for Greater Poland” program uses, as a superior, proprietary tool allowing to create previously non-existent procedures, high-fidelity simulation. It

allows for high-quality personal and procedural training in an accessible and repeatable way. In the case of rare, complicated, and expensive procedures, it allows for “probing” standardized and repeated training, skills improvement, and their verification. In addition, it allows to improve Healthcare Service, communication for best patients’ outcomes (Brazil, 2017). The role of medical simulation in the educational process is invaluable and still underrated. The economic result of simulation training is an optimized cost of improving theoretical and practical skills.

In “ECMO for Greater Poland” program several high-fidelity simulation scenarios were created for ECMO Team and Mobile ECMO Team - in every application of program arm (DCD, hypothermia, ECPR, RRF) including transfer of patient (mannequin) with implanted ECMO console. This probing simulation allowed us to control the deployment of qualified medical personnel, know what equipment was needed in the ambulance and during in-hospital ECMO support. The above simulations were performed in such a scope and form for the first time in Poland and Europe, and they have become an excellent training tool allowing to create procedures that have not been carried out so far. In addition, for the first time, medical simulation has been transferred to the areas of clinical application in the form of an in-situ simulation of a 48-hour training platform at the Department of Anesthesiology and Intensive Care. The experience gained during the simulations and the first transports enabled us to redesign first in Poland ECMO Standard Operating Procedures, algorithms, proper checklists and equipped the most modern container ambulance dedicated for ECMO transport (the first ECMO ambulance in Poland) (Puslecki *et al.*, 2016; 2017; 2019)

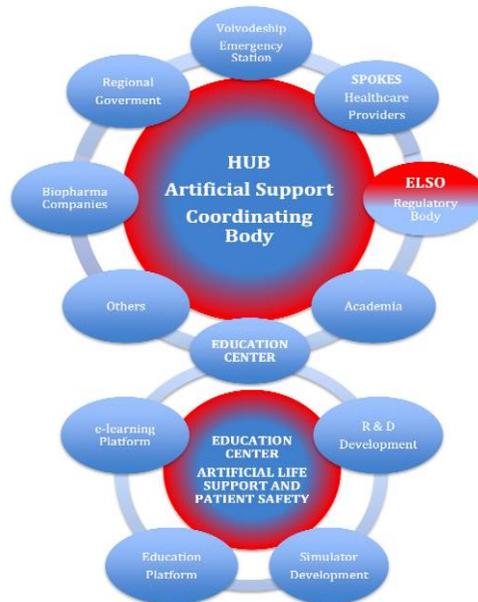
9. Development of Innovation Cooperation in “ECMO for Greater Poland”

The aim of the "ECMO for Greater Poland" program is to create systemic procedures for the identification, notification, and transportation of potential candidates for extracorporeal support to conduct therapy at the highest possible level. It is possible with improvement of the Medical Rescue System coordination, sophisticated training of medical personnel and ECMO team’s creation. Permanent funds obtained during the program implementation were funds for the purchase of 15 devices for automatic mechanical chest compression devices for the Voivodeship Emergency Station (WSPR) in Poznan. Before the program was launched, there were no such devices in Greater Poland. In addition, at the end of 2017, the most modern medical ambulance in Poland, dedicated to highly specialized transports, including ECMO, was designed and purchased for WSPR in Poznan.

As a result of innovation cooperation - to constantly improve qualifications, develop skills, and exchange knowledge between partners, an Education Center in artificial support techniques was established (Figure 3), which has, among others, education platform and e-learning platform. Thanks to the education center, it is possible to improve the existing procedures, monitor individual ECMO cases, and constantly improve the qualifications of all ecosystem participants, and thus develop better safety

and patient care. Additionally, as part of the education center, R&D cooperation is undertaken to develop a ECMO human patient simulator and IT software. It should be considered that this Education Center is unique in Poland and CEE region – under ELSO auspicious. One of the creative activities is the creation of innovative procedures and guidelines, especially for the care of ECMO supported patients and the transport of such patients.

Figure 3. R&D Development: „know-how and knowledge transfer” in Education Center of Artificial Support in „ECMO for Greater Poland” Innovation Ecosystem



Source: Own elaboration.

Because part of “ECMO for Greater Poland” is an education intention a course about “Artificial Life Support with ECMO” was developed and the “Center of Artificial Life Support and Patient Safety” was created within a University Medical Simulation Centre. It is first in Central Europe certificated ELSO center. The project will be implemented in 2019-2021 at the Poznan University of Medical Sciences. The project was awarded funding from a POWER competitive national grant (POWR.05.04.00-IP.05-00-006/18) by the Polish Ministry of Health for a total of 2.750.000 USD (PLN 10.974.708,60). The program will be offered to 264 physicians from Poland specializing in anesthesia and intensive care, cardiac surgery, cardiology, thoracic surgery, vascular surgery, transplantology, emergency medicine, and other physicians in training from all over Poland. An important part of education 3 days program is ECMO transportation subject with lectures, transfers checklist creation and intra and interhospital transfers simulation scenarios. Since 2019 130 physicians from Poland finished the ELSO endorsed Course.

10. Results of Successful Innovation Cooperation

Thanks to the successful innovation cooperation in “ECMO for Greater Poland” Innovation Ecosystem we can distinguish organizational, educational, and clinical results of cooperation.

10.1 Organizational Results

The creation of the concept of the "ECMO for Greater Poland" program is aimed at popularizing the use of extracorporeal ECMO perfusion to support the treatment of critically ill patients in the regional dimension - using the existing infrastructure and equipment base. All arms of the "ECMO for Greater Poland" Program are implemented simultaneously with the increasing experience in the use of ECMO. The "ECMO for Greater Poland" program was entered into the Priorities for the Regional Health Policy of the Wielkopolskie Voivodeship for the period from June 30, 2016 to December 31, 2018 by the order of the Greater Poland Voivode.

10.2 Educational Results

The summary of the organizational activity and popularizing the techniques of extracorporeal life functions support with the use of ECMO was the organization in 2016 ("ECMO for Greater Poland") and 2017 ("ECMO CHALLENGES") of nationwide scientific and training conferences with workshops on practical skills based on simulation exercises. The last international meeting "ECMO CHALLENGES 2019 - VA / ECPR", was devoted to extracorporeal techniques used in critical circulatory failure, not only as support after cardiac surgery but also as a form of support for the therapy of critical conditions resulting in severe circulatory disorders and cardiogenic shock.

Thus, the gap in the country's conference offer was filled, allowing for the consolidation of the medical community dealing with therapies used in states of extreme circulatory and respiratory failure. An additional achievement are numerous national and international scientific publications on the "ECMO for Greater Poland" program and the application of teaching techniques based on high fidelity simulations in peer-reviewed national and international journals.

As part of the project, an Internet platform (<http://ecmo.pl>) was created, where you can find information about the "ECMO for Greater Poland" program, about the extracorporeal technique itself and its limitations, current guidelines, and indications for perfusion treatment, and allows contact with the team.

10.3 Clinical Results

The benefit of the simulation and training activities of the Program, during the first years of the project, was the creation of a unique ECMO-DCD algorithm, the first on

a national scale, and the procedure for applying extracorporeal regional perfusion of organs (kidneys) in a donor who died because of irreversible cardiac arrest was performed for the first time in Poland (Puslecki *et al.*, 2016).

Another positive effect was the successful application of perfusion therapy to patients with cardiac arrest and hypothermia in two different hospitals in Poznan, where the temperature of patients was restored to normal values as planned. These were the first cases of using perfusion therapy in hypothermia in Greater Poland.

2017 brought a breakthrough in the treatment of acute respiratory failure in our region. Thanks to the use of high-fidelity simulation, it was prepared to transport a patient from a neighboring hospital connected to the ECMO system. Such preparation, in close cooperation with the Voivodeship Emergency Station and the Medical Simulation Center, made it possible to successfully carry out such transport several times in the following months. Throughout 2017, as part of the project, ECMO therapies were performed in patients with ARDS for the first time in Greater Poland.

The concept of extended cardiopulmonary resuscitation (ECPR) for the Poznan agglomeration is a part of the development of the "ECMO for Greater Poland" program. The development of ECPR concept was based on the experiences of predominantly single centers (Belohlavek *et al.*, 2012) and was adapted to local protocols in 2019 as first organized program in Poland as – Poznan out of Hospital Cardiac Arrest (POHCA). It should be considered that currently the ECMO mobile team was created on a voluntary basis. Thanks to the program it was possible to equip emergency teams in the region with 15 mechanical compression devices and one dedicated ambulance for transport of ECMO supported patients. In last 4 years 13 uneventful transfers of ECMO-supported patients have been performed and more than 50 ECMO-supported patients were treated in Temporary Poznan ECMO Center (both adult and pediatric).

In the time of pandemic COVID-19, in recent month "ECMO for Greater Poland" mobile ECMO team performed two transfers: one patient with suspected COVID-19 infection and one patient – two weeks after COVID-19 infection (currently with negative PCR test result) using ECMO-dedicated ambulance. Transfer and ECMO implantation were properly prepared according to developed checklists, including team division in "cold" and "hot" zone and application of personal protective equipment (PPE). For the purposes of precise separation of units and equipment, rational use of PPE and to prevent contamination of the equipment and transport bags, an additional vehicle with a driver was provided. Both patients' ECMO transportations were uncomplicated.

Due to the difficult situation of the COVID-19 pandemic in Poland, from November 2020 the Minister of Health prepared a proposal to expand the existing network of centers dedicated to ECMO COVID-19 patients and dedicated transportation solution,

including HEMS. Unfortunately, current data regarding COVID-19 patients' support and transportation are not available.

11. Conclusions

Biopharmaceutical companies look for various forms of cooperation that will minimize the risk and will share the costs of R&D investment. In addition to partnerships within the industry, they establish relationships with universities or research institutes as well as more often cross-industry alliances and public-private partnerships. Cooperating with academic institutions, particularly in the model of open innovation alliances they can significantly increase the likelihood of better medical therapy for patients. It should be considered, that as multiparty alliances they require greater competencies and skills of alliance managers and appropriate alliance management tools, particularly in the selection of potential partners, as well as in creation and maintenance of alliance networks.

Thanks to diversity of modes of cooperation and alliances it was possible for biopharmaceutical companies to obtain a much more advanced research results in both preclinical and clinical stages. The effect of such actions can be jointly developed new drugs proposals (Wilks and Prothmann, 2012; Burke, 2013) as well as new vaccines, which are currently in high demand in the fight against COVID-19. Thanks to the creation of the partnership and use of various tools and partners, firms may use the resources, competencies, technology and knowledge from partners, and thus easier respond to changes in the environment, and most of all, quickly launch new services and products as well as offer better health care of patients in the CEE region.

Considering the results of innovation cooperation of "ECMO for Greater Poland" program, the effectiveness of training activities based on simulation, practical and theoretical training developed under the program should be confirmed with full responsibility. They have a direct impact on the effectiveness in the implementation of such complex procedures as perfusion therapies at the highest possible level in a thoroughly prepared manner, which has a direct impact on the safety of treated patients.

List of abbreviations: *ECMO* – extracorporeal membrane oxygenation; *ECPR* - extended cardiopulmonary resuscitation; *ELSO* – Extracorporeal Life Support Organization; *COVID-19* – coronavirus disease; *VV* – venovenous; *VA* – venoarterial; *HandS* – hub and spoke; *RRF* – reversible respiratory failure; *DCD* – donor after circulatory death; *SOP* – standard operating procedure.

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