DEVELOPMENT, MANUFACTURING AND SALES OF IN VITRO DIAGNOSTIS MEDICAL DEVICES, EQUIPMENT, REAGENTS AND AGENTS AND SERVICES

GOOD PRACTICE - PROJECT

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Contents

Introduction to the Good Practice

Clusters have a high potential for innovations in the development of healthcare procedures and services, devices and agents. There are a few clusters specialized for biotech, biomedical and health industry among the several officially accredited innovation clusters in Hungary. These clusters have members from the biotech, pharma, medical device and ICT business, local and regional public authorities, universities and academia. Fortunately formal and informal care providers are also represented in these clusters through the clinics and clinicians of the university and the private care providers. Yet, the transfer of innovation needs and ideas from the small and medium size care providers (such as from the state owned hospital staff) to companies and universities was weak in Hungary and in Central Europe.

Problem:

1. Big university and hospital clinics have appropriate lab infrastructure for efficient and effective diagnosis, however, access to their services is often restricted (lack of functional medicine or personalized medicine, waiting lists, travel difficulties). Unfortunately smaller and/or private care providers might help to solve access inequalities, however, there was no appropriate lab infrastructure.
2. Big university and hospital clinics have appropriate lab infrastructure for taking part in clinical trials, and saving time and costs to test new reagents or molecules for new drugs and medicines or devices. However, smaller and/or private care providers – both on the industry side and the care provider side – don't have their own or shared efficient and effective lab infrastructure.

Solution:

Utilizing and further developing existing successful technologies (dominantly in development, manufacturing, and sales of immunodiagnostics, lab devices and equipment) and introducing new ones (genetic, genomic, in vitro and in vivo new trial models, products and services) the cluster members developed new products and services especially designed for the diagnostic infrastructure and activity of smaller formal and informal healthcare providers and business/industry actors. The accredited innovation cluster management – in partnership with and assisted by the R+D, education and techtransfer activities of the University of Pécs - provided its technology incubation background, and the cluster members shared their experiences in innovation, product and production design and marketing. The cluster is managed by a limited company owned by the Municipality of Pécs (county capital town).

Impact:

Cluster members managed to solve the problem by innovating and developing new, simple, cost effective and environment friendly solutions and products, and successfully stabilized and increased their domestic and export markets. The project paved the way for additional applications for OP grants and implementation of new projects of the cluster members and their partners.

1. Relevancy of the GP project

The "Relevancy of the GP project" section provides quick check and definition of its relevancy in regards to HoCare project objectives.

Good practice of quadruple-helix cooperation in R&I?	Yes, this GP project includes good practices of quadruple-helix cooperation in R&I
Good practice of delivery of Home Care R&I?	No, this GP project does not include good practices of delivery of Home Care R&I.
If not in Home Care R&I, description and proof of its potential for transferability to delivery of Home Care R&I	The project itself did not targeted home care. However, better diagnosis helps to develop innovative medicines for personalised/functional care providing appropriate solution and humane treatment with less pain and adverse reaction, and - in the best case – there is no noxious and unintended response to the drug selected or developed for cure. All these results lead to shorten hospital stay and increase the role of homecare by developing new drugs for outpatient care (e.g. for the dermatology practices of Hisztopatológia Kft.). Cooperation - among cluster members, cluster management and university as partner – helped to define real and unmet needs, problems and markets, which paved the way for innovation by using and further developing existing knowledge and technologies. The whole process was catalysed by the system of accrediting innovation clusters and supporting the joint technological innovation of cluster members, however, the budget allocated for the call for them was rather few comparing to the demand. There was no target sector, however, there was a strong requirement that only AIC members were allowed to apply for the grant. Although there were no requirements or benefits for Quadruple Helix cooperation, the cluster scheme fostered the actors to explore the advantages in co-operation. Therefore, the accreditation system could be replaced by defining requirements or benefits for Quadruple Helix cooperation and the learnings of the project may be transferred to other fields (e.g. Homecare) or regions.
Generation of innovation in home care through answering unmet needs identified by formal or informal healthcare providers?	Yes, this GP project includes good practices of innovation through answering unmet needs.
Generation of innovation in home care through public driven innovation?	No, this GP project does not include good practices of public driven innovation.
Generation of innovation in home care via quadruple-helix cooperation for quicker delivery to the market?	Yes, this GP project includes good practices of innovation via cooperation for quicker delivery to the market.

2. Quick overview of the Good Practice (GP) project

The "Quick overview of the GP project" section provides initial overview of the good practice project (GP project) and enables readers to see if this GP project idea is relevant for possible transfer to their organization potential innovation activities.

Name of the GP project	Development, manufacturing and sales of in vitro diagnostic (IVD) medical devices, equipment, reagents and agents and services (GOP-1.2.1-08-2009-0020)
Region of origin of GP project	Hungary
5 keywords that best describe the content of the GP project	cluster, quadruple-helix, unmet needs of formal service provider delivery&transfer of innovation OP-support, transferable to homecare value chains and/or other regions
Relevant **Operational Programme name through which the GP project has been funded** (+ also in local language in brackets)	Economic Development OP (EDOP) Measure/Call: EDOP-121 Supporting joint technological innovation of Accredited Innovation Clusters *(Gazdaságfejlesztési Operatív Program, GOP-121 Akkreditált innovatív klaszterek támogatása komponens/pályázati felhívás)*
Relevant **support programme / intervention area name** of the GP project **through which it was funded** (+ also in local language in brackets)	New Széchenyi Plan (NSP) – Calls for proposals linked to NSP indirectly, originally designed and run under the New Hungary Development Plan 2007-2013 *(Új Széchenyi Terv - közvetett kapcsolódású pályázati konstrukciók - Új Magyarország fejlesztési terv 2007-2013)*
Single or multiple recipients of the GP project?	multiple recipients
Type of lead recipient (SME, LME, research centre, innovation centre, network/association, university/school, municipality, other public body, other (specify)	Project company: Biotechnológiai Innovációs Bázis Kft. (Biotechnology Innovation Base Cluster, Pécs) SME, main activities: Biotech RDI, Manufacturing & trading Professional leader: Hisztopatológia Kft., Pécs (SME, main activities: Clinical/translational RDI, Training, Manufacturing & trading + Dermatology practice)
Types of participating partners (list all participating partner types. E.g.: hospital, social house, senior house, patient association, networks, SMEs, LMEs, research actors, business supporting organizations, public institutions/regulators,	• "IMMUNOCHEM" Egészségügyi Szolgáltató Kft. (SME RDI, manufacturing) • PANNONIA Biotechnológiai, Környezetvédelmi, Egészségügyi, Műszaki és Informatikai Kutatási Park Kft. (project company, RDI) • HISTOPATOLÓGIA Kft. (SME: RDI, manufacturing, medical practise)) • PANNONPHARMA Gyógyszergyártó Kft. (SME: Manufacturing, RDI) • Proszilomed Kutató-Fejlesztő Kft. (SME: RDI) • University of Pécs – publc university (Education, RDI, clinical practise)

other (specify)	• Pécsi Egészségipari Innovációs Központ Zrt. (PEIK) (public RDI-promotion company)
Summary of the good practice	The project targeted on the delivery of a solution - based on immunodiagnostic method and the development, manufacturing and sales of in vitro diagnostic (IVD) medical devices, equipment, reagents and agents and services - for providing quick, reliable, accurate and cost effective diagnosis for both the patient and the medical doctors outside the big clinical and hospital environment. The project itself did not targeted home care. However, better diagnosis helps to develop innovative medicines for personalised/functional care providing appropriate solution and humane treatment with less pain and adverse reaction, and - in the best case – there is no noxious and unintended response to the drug selected or developed for cure. All these results lead to shorten hospital stay and increase the role of homecare by developing new drugs for outpatient care (e.g. for the dermatology practices of Hisztopatológia Kft.). Utilizing and further developing existing successful technologies (dominantly in development (RDI), manufacturing, and sales of immunodiagnostics, lab devices and equipment) and introducing new ones (genetic, genomic, in vitro and in vivo new trial models, products and services) the cluster members developed new products and services especially designed for the diagnostic infrastructure and activity of smaller formal and informal healthcare providers and business/industry actors. Early and correct diagnosis helps to make medical treatment of illnesses such as prostate, lung and breast cancer or malignus melanoma more successful and more affordable. The project - building on the results in the developments for routine diagnostics by antibody 'assemblage' – concentrated on the improvement of the laboratory capacity and the production of innovative medical devices and reagents essential for correct diagnosis, staging, prognosis and treatment. The technology was based on immunological nano/biotech methods to detect antigens characteristic of neoplastic and reactive cells or elements of cells. Nanotechnology helps developing medical devices and drug transport nanoparticles. In the focus of the whole method was the reagent family of 'HISTOLS'® products previously invented and registered by the HISTOPATOLÓGIA Kft. The project delivered new results in the utilization of HISTOLS products by light and electro-microscope in immune morphology to detect and localise certain molecules in cells and tissues 'in vitro'. These results assist in finding and defining varying biological parameters in unaffected or neoplastic tissues. This method can be used both for qualitative and quantitative examinations as it usefully assists to explore the origin and recognise the biological parameters of neoplastic cells in order to define target molecules for therapies. In addition the solution makes the procedure more stabile and less vulnerable to environmental effects. Cluster members managed to utilise the results of a previous EDOP project by validating innovative implants for abdominal wall surgery and repair having been developed

	by Proszilomed Kft. and a Biotechnológiai Innovációs Bázis Kft. This validation work was based on the IVD use of the nanometric reagents. The project to delivered innovation for every-day use of research results in diagnostic devices and materials, especially in: - Immunodiagnostic reagents; - Surgical implants; - Zebrafish models of human disease for pre-clinical drug discovery; - Embryonic stem cell body model; - Culevit – Supplementary food additive for patients with malignant tumour; - Intra-operative device for collecting histological sample during surgical staging.

3. Transferability

The "Transferability" section provides more detailed review of strengths and weaknesses of this GP project including description of necessary basic conditions for region and leading organization to potentially transfer it. At the end of the section, the key threats in the successful transfer open up possibility to focus on specific relevant issues important for the successful transfer.

Strengths and weaknesses of the project

What are the GP project strengths? Why it was funded?	• The project met the needs of care providers and addressed a wide range of patients suffering from diseases. • The results are important in functional/personalised medicine and have positive impact on access to care services. • The delivered solution and products help manufacturers to develop their new additional medical products. • The cluster structure and the grant system forced cooperation among stakeholders of the value chain in the production and use of diagnostic devices and materials and surgical implants.
What are the **key weaknesses of the GP project**?	From the point of view if home care, this project did not delivered outputs directly used in the field. The learning shall be translated for the homecare industry. The cooperation among cluster members could be widened both in planning (project and application) and implementation. The project companies lost their importance after closing the project, and cluster members went on doing their business mostly on their own.

Basic conditions for successful transfer

Why is this GP project transferable? – innovation,	Cooperation - among cluster members, cluster management and university as partner – helped to define real and unmet needs, problems and markets, which

impact, financial, legal, and timeframe aspects	paved the way for innovation by using and further developing existing knowledge and technologies. The whole process was catalysed by the system of accrediting innovation clusters and supporting the joint technological innovation of cluster members, however, the budget allocated for the call for them was rather few comparing to the demand. There was no target sector, however, there was a strong requirement that only AIC members were allowed to apply for the grant. Although there were no requirements or benefits for Quadruple Helix cooperation, the cluster scheme fostered the actors to explore the advantages in co-operation. Therefore, the accreditation system could be replaced by defining requirements or benefits for Quadruple Helix cooperation and the learnings of the project may be transferred to other fields (e.g. Homecare) or regions.
What are the **basic conditions the region needs to have** to be successful in transferring this good practise?	Grants and any other resources invested in innovation are used in a more effective and efficient way if the market accepts it quickly. The end users' market needs services instead of pure products, therefore, it's important to realise that service oriented innovation (either executed in quadruple helix cooperation or in clusters of less stakeholders) should be supported.
What are the **basic conditions the leading recipient from the region needs to have** to be successful in transferring this good practice?	The innovation in the service of health care providers (e.g. new treatment procedures) and the technological development shall be integrated in the same project/programme and supported in coordinated way or in the same grant scheme. Home care, rehabilitation and hospital care (both acute and chronic) shall be integrated in a single functional/personalised approach.

Key threats in GP project transfer

What are the **key potential threats for the GP project transfer?**	• Altering solutions more favourable for big laboratories appear in the diagnostic market; • The spread of functional/personalised medicine wouldn't be as fast as desirable;

4. Description of the GP project

The "Description of the GP project" section provides more detailed information on the Good Practice project (GP project) and enables readers to get further detailed inspiration and easy ready-to-use information for possible innovation transfer to other project applications. This includes: tackled problem, time length of the GP project, objectives, phases, activities and deliverables of the GP project, its main innovation and target group.

Description of the tackled problem

What was the **problem / challenge tackled** by the project?	1. Big university and hospital clinics have appropriate lab infrastructure for efficient and effective diagnosis, however, access to their services is often restricted (lack of functional medicine or personalized medicine, waiting lists, travel difficulties). Unfortunately smaller and/or private care providers might

	help to solve access inequalities, however, there was no appropriate lab infrastructure. 2. Big university and hospital clinics have appropriate lab infrastructure for taking part in clinical trials, and saving time and costs to test new reagents or molecules for new drugs and medicines or devices. However, smaller and/or private care providers – both on the industry side and the care provider side – don't have their own or shared efficient and effective lab infrastructure.
What were the **reasons for the problem?**	Unmet needs: 1. Smaller formal and informal healthcare providers needed available solution for quick, reliable, accurate and cost effective diagnosis to assist the work of their staff and satisfy their patients. 2. Smaller business/industry actors needed own or shared lab infrastructure to assist in saving time and costs of developing and testing new procedures, devices, drugs, molecules.

Time length of the GP project

What was the **time length** of the GP project in months?	52 M 2009-Sept – 2013-Dec

Objectives of the GP project

Describe the **overall and specific objectives** of the GP project	The project targeted on the *delivery of a solution - based on immunodiagnostic method and the development, manufacturing and sales of in vitro diagnostic (IVD) medical devices, equipment, reagents and agents and services - for* providing quick, reliable, accurate and cost effective diagnosis for both the patient and the medical doctors outside the big clinical and hospital environment.

Phases, activities and deliverables

List all **main phases** of the GP project including their time length	2009-Sept - 2010-Jun: - Creating of development- product- and trade plan of immunodiagnostics - Defining existing products that could be used for further development - Development of new solution in the use of existing and new materials and equipment for immunodiagnostics - Hernia mesh development and development of further implanting aids in animal models 2010-Jul - 2010-Dec: - Development of new production methods - Quality management system ISO 9001 for production and sales 2011-Jan - 2011-Jun: - Experimental production of immunodiagnostics - Testing of immunodiagnostics

	- High throughput screening technology for in vivo pharmacological testing of angiogenesis oncological drug candidates 2011-Jul - 2011-Dec - Product-preparation of immunodiagnostics, instrumental adaptation - Marketing tasks of immunodiagnostics for domestic market 2012-Jan - 2012-Jun: - Validation of the new solutions and products - Closure of development phases 2012-Jul – 2012-Dec: - Marketing tasks of immunodiagnostics for export market - Production-preparation 2013-Jan - 2013-Jun: - Testing the results of production-preparation - Bio-informatics developments 2013-Jul – 2013-Dec: - Closure of the project
List and describe all **main activities** that were implemented by the GP project	Main activities in the project: Infrastructure: Development of laboratory for cluster members Work: • Medical device prototyping and turning invented agents, reagents and devices into production, sales and use (by involving cluster members and their partners); • Integrating clinical research into product development cycle, market segment creation, uptake of R&D results and valorising innovation, techtransfer (by involving cluster members and their partners); • Cooperation among care providers, universities and business - backed by incubation entity and local public authority, intellectual property management, shared facilities. (by involving cluster members and their partners)
List all **main deliverables** of the GP project	- Development of new solution in the use of existing and new materials and equipment for immunodiagnostics - Development of new production method - Training procedures and material

Main innovation of the GP project

What was the **main innovation** of the GP project?	**Solution:** Utilizing and further developing existing successful technologies (dominantly in development, manufacturing, and sales of immunodiagnostics, lab devices and

	equipment) and introducing new ones (genetic, genomic, in vitro and in vivo new trial models, products and services) the cluster members developed new products and services especially designed for the diagnostic infrastructure and activity of smaller formal and informal healthcare providers and business/industry actors. The accredited innovation cluster management – in partnership with and assisted by the R+D, education and techtransfer activities of the University of Pécs - provided its technology incubation background, and the cluster members shared their experiences in innovation, product and production design and marketing. The cluster is managed by a limited company owned by the Municipality of Pécs (county capital town).

Target group of the project

Who was the main **target group** of the GP project? (SME, LME, research organization, university, public institution, healthcare provider, business supporting organization, other (specify)	Patients suffering from and care providers for prostate, lung and breast cancer or malignus melanoma Producers of drugs / medicinal devices
Describe the main target group	The project targeted on the delivery of a solution - based on immunodiagnostic method and the development, manufacturing and sales of in vitro diagnostic (IVD) medical devices, equipment, reagents and agents and services - for providing quick, reliable, accurate and cost effective diagnosis for both the patient and the medical doctors outside the big clinical and hospital environment. Results lead to shorten hospital stay and increase the role of homecare by developing new drugs for outpatient care (e.g. for the dermatology practices of Hisztopatológia Kft.). Utilizing and further developing existing successful technologies (dominantly in development (RDI), manufacturing, and sales of immunodiagnostics, lab devices and equipment) and introducing new ones (genetic, genomic, in vitro and in vivo new trial models, products and services) the cluster members developed new products and services especially designed for the diagnostic infrastructure and activity of smaller formal and informal healthcare providers and business/industry actors.

5. Impact

The "Impact" section provides more detailed information on the effect of the GP project implementation and dissemination of major outputs.

Impact

What was the level of **geographical impact** of the GP project? (village, city, county, country, international, other (specify)	county, country, international
What were the final **impact indicators including their quantification**?	N/A
Describe the **changes resulted from the project** activities	Clusters have a high potential for innovations incapacity the development of healthcare procedures and services, devices and agents. There are a few clusters specialized for biotech, biomedical and health industry among the several officially accredited innovation clusters in Hungary. These clusters have members from the healthcare providers, biotech, pharma, medical device and ICT business, local and regional public authorities, universities and academia. Fortunately formal and informal care providers are also represented in these clusters through the clinics and clinicians of the university and the private care providers. Yet, the transfer of innovation needs and ideas from the small and medium size care providers (such as from the state owned hospital staff) to companies and universities was weak in Hungary and in Central Europe. The accredited innovation cluster management – in partnership with and assisted by the R+D, education and techtransfer activities of the University of Pécs - provided its technology incubation background, and the cluster members shared their experiences in innovation, product and production design and marketing. The cluster is managed by a limited company owned by the Municipality of Pécs (county capital town). Cluster members managed to solve the problem by innovating and developing new, simple, cost effective and environment friendly solutions and products, and successfully stabilized and increased their domestic and export markets. The project paved the way for additional applications for OP grants and implementation of new projects of the cluster members and their partners. Improving diagnostic capacities and capabilities of the smaller formal and informal healthcare providers opens doors for easier access to cure, care and rehabilitation services.

Dissemination of outputs

Describe **dissemination activities** of the project outputs carried out during the GP project	Articles, Conferences, Training and education curses

6. Risks

The "Risks" section provides more detailed review of potential risks of this GP project implementation including their defined mitigation strategies to eliminate them.

Describe **risks involved** in implementing this GP project including their **mitigation strategies**	-sustainability of operation after minimum 5 years sustaining period ends because of weak financial conditions of the SMEs to finance IP, marketing and investment costs -access to clinics and SMEs being difficult in some regions and for some partners due to local situation and weak networks

7. Budget

The "Budget" section provides more detailed review of costs regarding the project implementation as well as operational sustainability after its end. In addition, if relevant, public tenders within the project and additional generated incomes by the project are showed and explained.

Budget

What was the **overall budget** of the project **in EUR**?	1 853 000 EUR (HUF 574 430 000 at 310 EUR/HUF) Rate of support gained from the OP: 50%
List relevant **budget lines of the project including their % share** from total budget	N/A

Additional income generated by the project

Did the project create any **additional income**?	yes, the GP project generated additional income
If yes, specify **which type of income and what amount in EUR?**	N/A

Public tender

Did the project include any **public tender**?	no, the project did not include a public tender
If yes, specify **what kind of contract** (specific contract, general contract, other)	N/A
If yes, specify in **what amount** in EUR	N/A
Describe the **public tender subject**	N/A

Financial sustainability after GP project end

Was there an **operational financial sustainability plan** in the project **after its end**?	yes, the GP project included an operational financial sustainability plan
If yes, specify **where the operational funds** after project end **came from?**	From the beneficiaries' budget (sales)
If yes, specify the **amount of operational funds** in EUR	N/A

8. Other information

In this section, specific additional information about the GP project could be revealed.

Please describe **any other relevant information about this GP project** (if relevant)	http://www.histopat.hu/ http://www.histopat.hu/index_base.aspx?lang=en http://www.peik.hu/Home/Details/bib_klaszter

9. Information gathered by …

The information about this good practise (GP) project has been gathered for the purpose of the HoCare project (Interreg Europe Programme) by the following organization:

Region	Hungary
Organization name(s) (+ in local language in brackets)	National Healthcare Service Center (ÁEEK)
Name of the **contact person(s)**	CSIZMADIA, István
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