Development, manufacturing and sales of in vitro diagnostic (IVD) medical devices, equipment, reagents and agents and services

Category: project

Sub-objective: generation of innovation via addressing unmet needs identified by formal or

informal providers of healthcare

Country: Hungary

Subsidized by: Economic Development OP (EDOP-121 Supporting joint technological

innovation of Accredited Innovation Clusters)

Rate of subsidy: 50% (42.5% EDRF + 7.5% National Budget)

Eligible costs of the project: ~2 M EURO

Intro:

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.

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 valorizing 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)

Main objective:

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.

Problem:

- 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.

Unmet needs:

- 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.

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.