FROM NANO4HEALTH TO SMARTHEALTH

BLUEPRINT AND STRATEGIC PLAN FOR A MULTI-DISCIPLINARY, INTERREGIONAL, X-SECTOR INNOVATION MODEL

THE MIX INNO MODEL

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I. Introduction

The healthcare management system (HMS) in many parts of the Western world is in a perfect storm. Never before so many significant factors have together impacted the HMS business space. An ageing population, global travel and migration, concentration of people in megacities, life style evolutions and consumerism impact an increasingly untenable healthcare cost. In order to keep the HMS cost sustainable, solutions for this trend lie in a paradigm shift from curative blockbuster driven medicine to **tailored prediction, prevention** and **precision medicine (personalised medicine)** and a further evolution **from a hospital-centric towards a home based patient-centric** care system. These evolutions are in part the direct result from radical technological breakthroughs in life sciences and from solutions brought about by advanced micro/nano-technology platforms.

In parallel to the above described trends we witness today the arrival of 'non-traditional' business players in the health space like consumer goods companies with wearables, food companies with precision nutrition and 'big data" companies developing digital health management tools based on the information shared through social media. The transition of the HMS requires the accommodation of these new actors as well as the adaptation of the existing ones to the new cross-disciplinary technology platforms and corresponding innovative business models that are emerging. Indeed, new industrial value chains will increasingly being configured and **a multi-disciplinary, interregional, X-sector innovation model (MIX model)** will significantly contribute to the awareness creation and understanding of regional healthcare actors towards the existence and the potential but also the limitations of associated technologies.

As innovation is likely to occur at the borderlines between different industries and technologies, facilitation and acceleration of new combinations along and across value chains represent a source for potential innovation and growth for the enterprises involved. This is exactly what drives the development of the MIX model. This blueprint for the MIX model focuses on a cross-sectoral collaborations between two worlds: nano/micro-electronics and biotechnology. The objective of the MIX model is to add an interregional dimension to the development of new value chains through the application of tailored innovation support services that have proven their validity across the individual regions of Flanders (BE), Auvergne-Rhône-Alpes (FR) and Saxony (DE) by the involved cluster organizations (respectively DSP Valley + FlandersBio, Minalogic + LyonBiopôle and Silicon Saxony + BioSaxony). The validity of the single-region X-sector innovation model has been set up and proven through the European CIP-projects Nano4Health (N4H) in Flanders, Health2Care (H2C) in Auvergne-Rhône-Alpes and CrossClusterCooperation (C3) in Saxony. The MIX model will offer interregional opportunities to companies whose activities are designed to supply innovative products and services in the fields such as *user centric precision healthcare* e.g. medical and surgical equipment and devices, personalised medicine information technology, clinical trials, as well as preventative care and general well-being. The MIX model focuses on collaboration between all kind of stakeholders with a special focus on SMEs, as they are the backbone of Europe's economy representing 99% of all businesses in the EU. In the past five years, SME's have created around 85% of new jobs and provided two-thirds of the total private sector employment in the EU. The partner organizations who were involved in the development of this blueprint daily witness the essential role SMEs and entrepreneurship play to ensure economic growth, innovation, job creation, and social integration.

It is well acknowledged that the emergence of technology oriented clusters has greatly contributed to the development, maturation and success of a number of high tech sectors like micro-electronics, nanotech and biotechnology. Indeed, clusters may improve the "factor conditions", the inputs that firms need in their operations, such as access to specialized labour and skills, targeted capital, infrastructure, technologies, research, education, and knowledge. Especially for smaller firms cluster membership is highly beneficial as these firms in general do not have the resources to find and

explore the technology, business and market knowledge on their own. This is particularly so in the emerging new industries combining different fields of science, engineering and technologies to facilitate new innovations based on an increasing convergence of physical and biological technology platforms. According to a PWC study for the European Commission, personalized medicine industries, the core domain of this Smart Health project, is one of the 7 key emerging industries for Europe, supporting breakthroughs in medical knowledge and technologies, "addressing major societal challenges (such as the threat of new diseases, pandemics or ageing), enabling greater choice and the customization of care and a move towards new Personalised Medicine lifestyles". Finally, differences in business models, market dynamics and service innovations and design across sectors further complicate the quick adoption of new technologies by companies when creating innovative solutions for patients and consumers. This MIX model capitalizes on the extensive experience the different cluster organizations involved have built-up in supporting R&D intensive companies active in the healthcare space and leverages on the relevant initiatives that have been taken at the respective regional, national and European level. SMEs in the smart health emerging industry need strong support and an innovation model focusing on cluster organizations proposes the right framework to pursue this objective.

The development of new industrial value chains in the healthcare management system calls for the collaboration and integration of different innovation actors, including large enterprises and especially SMEs, across different sectors towards the implementation of a joint vision. To achieve this, the group of clusters organizations from Belgium (Flanders), France (Auvergne Rhône-Alpes) and Germany (Saxony) mentioned above joined forces to collaborate on the development of the blueprint for this MIX model with a focus on multidisciplinary, interregional and cross-sectorial (X-sectorial) innovation targeting societal challenges in health. The participating clusters DSP Valley + FlandersBio, Minalogic + LyonBiopôle and Silicon Saxony + BioSaxony all integrate different innovation actors including SMEs and large enterprises as well as supportive organizations such as universities, research and development institutions, other knowledge and skills providers, financial actors, etc. Each cluster has a strong track record in supporting SMEs regional ecosystem by focusing on the growth and maturation of the involved SMEs and boosting the emergence of R&D collaborative projects and the SME development in the high tech sectors of micro/nanotechnologies and biotechnology). These sectors need specific attention as they are very innovative and expert driven, rapidly evolving and require very high costs for their development.

The MIX model capitalizes on the experiences gained in previous CIP projects in which all involved cluster organizations experimented on cross-fertilization approaches in the healthcare sector at regional level. Implementation of the MIX model can help:

- To build a cross-cluster, cross-regional, cross-KET openly accessible innovation ecosystem for companies active in the fields of digital technologies and life sciences, developing solutions for end user centric precision healthcare.
- To Facilitate and support the development of new industrial value chains in healthcare through a systemic approach that combines different resources, tools and instruments in setting up highly specialised, sustainable cross-KET innovation support processes for SME's.
- To Increase the technology readiness (TRL), operational readiness (ORL) and/or market readiness (MRL) of innovative products for patients and consumers including solutions for precision healthcare, active ageing, mobile and connected health, software and data capturing, data storage and interpretation.
- To Unlock cross-KET ideas by creating technology awareness, supporting project ideation and financing critical phases in technology or product development, prototyping and market deployment through vouchers for access to service innovation intelligence.
- To Leverage the company led projects by providing support on regional and European funding, access to regional and European infrastructure initiatives and pilot lines and prepare

for new products and solutions for deployment under real life conditions in Large Scale Demonstrators and/or living labs

Implementation of the MIX model will undoubtedly:

- Support the development of a new healthcare paradigm – from a hospital-centric to a patient-centric system; from standard treatments to increasingly precision diagnosis and cure; from treatment of acute and chronic diseases to preventive healthcare and health management
- Further pave the way towards a healthcare management systems with increased benefits for patients at a sustainable cort for society
- Improving the worldwide competitiveness of European SMEs in the field of smart health applications;
- Contributing to economic growth and employment in Europe; demonstrating at large scale the potential impact of innovative solutions to specific challenges

II. The concept of the MIX model

A. A concept based on 7 guiding principles

The MIX model can support open innovation on the borderline between nano-electronics and life sciences targeting specific healthcare related issues and aims at increasing the technology, operational or market readiness of an innovative project. It matches healthcare challenges with solutions enabled by a combination of life sciences and digital technologies. Relevant stakeholders from the participating life sciences clusters and nano-electronics clusters can be mobilized to collaborate together with healthcare specialists on future healthcare scenarios, development of concrete innovative solutions and the development of sound business models ready for deployment.

The MIX model has 7 common guiding principles:

1. It accommodates for multi-stakeholders, multi-discipline, multi-sector and cross-region collaboration.
2. It follows a lean and iterative approach allowing for learning by doing and pivoting.
3. It has to apply creative techniques to co-inspire and co-innovate.
4. It allows for framing challenges, connecting with partners, for cross pollination across partners and to co-create tangible solutions
5. It catalyzes cooperation or helps to coop with market inefficiencies by granting financial resources but the key driver for collaboration must be a sound business case rooted in a concrete market opportunity.
6. It applies a structured impact measurement & evaluation process to continuously support the innovation support process.
7. It creates synergy with and leverages on other existing support measures and instruments

The MIX model is based on year-long experience of the cluster organizations involed in supporting their ecosystems in becoming more competitive and creating value for their region. The development of the MIX model offers an ideal opportunity to combine the experience from 3 leading EU regions into one open innovation approach which can serve as a blueprint for other regions who want to apply an open, cross-sector, cross-discipline innovation approach.

B. Opportunities offered by digital and life sciences technologies

In the last 10 years the understanding and knowledge of human diseases and disorders has increased dramatically. Research on different disease patterns has been driven forward through the application of different –omics platforms but also more and more powerful visual detection technologies have allowed the more profound understanding of the physiological, molecular and genetic mechanisms driven different disease patterns. This results in a revolution of modern healthcare. For a lot of diseases different diagnostic tools have been developed and elucidate in a lot of cases the stratification of patient populations in different groups with different disease patterns. In addition these diagnostic tools also allow low cost and fast detection of the incidence of a disease or the genetic pre-disposition for a disease pattern. This evolution lays at the basis of a potential transformation of modern healthcare. Where traditionally healthcare systems were focused on cure-strategies based on broadly applied so-called blockbuster drugs, modern healthcare strategies start to focus on a more patient oriented prevention and personal cure and care strategy.

In parallel with the development of this more and more in depth understanding of different human disorders, also the micro-electronics sector continues to live through different waves of technological revolution. Miniaturization, ultra-low power electronics, better battery performance, wireless communication and interconnectivity are key trends which enable the development of added value products/devices in healthcare. These trends have resulted in very small technology platforms with increasing sensitivity and accuracy in a widening field of application domains for the healthcare sector. Major players in the medical technology field are investing massively in health applications based on new micro-electronics platforms. Currently this has resulted in health support diagnostic tools under the form of for example wearables to measure heart rhythm and blood pressure and other health determining values. Also the field of active implants leans heavily on these technological developments. The first applications on the combination of biotechnology and micro- electronics start to emerge. The combination of biomarker applications and micro-electronics form new diagnostic tools like biosensors, lab-on-chip, integrated small clinical labs. On the therapeutic side the combination of drugs and micro-electronics come up with smart pills and targeted drug delivery systems for example.

This merging of minds and combining of technologies is happening today because both knowledge platforms are mature enough to do this and because a number of research groups and entrepreneurs active in both domains have joined forces.

C. Leveraging on lessons learned from previous projects

The MIX model concept is based on extensive experience with innovation support methodology which the Smart Health consortium at local, regional level through 3 parallel CIP-funded projects (Nano4Health in Flanders, Health2Care in Auvergne Rhône-Alpes and C3-Saxony in Saxony).

The *Nano4Health project* has developed and applied a methodology called "Fast Track to Innovation[1]." Each case (carefully selected cross-KET) has been supported by different and complementary professional services in parallel, ranging from professional advice for business model innovation to product design services or manufacturing services. Financial support was provided through (European funded) vouchers and local Flemish SME-support tools. In total 9 projects were supported, leading to more than 25 bi-lateral collaboration agreements with competence providers.

[1] This methodology was inspired by the Fast Track to Innovation pilot program from the EC. To avoid confusion with this program this methodology is now called the X-Inno approach.

N4H CASE Company P

P is a plasmonics company that manufactures nanomaterials and turns them into bio analytical tools. They offer a platform that enables label-free screening using only a standard absorbance plate-reader. The technology uses gold nanomaterials in solution, which when conjugated to a specific protein, exhibit changes in optical density upon interaction with a protein ligand. These nanomaterials can be used in health monitoring devices, drug discovery screenings, … The interest for use of nanomaterials in cells is growing, but they did not enter the market of cell based screenings yet, mainly because of lack of in-house infrastructure to develop such assays. For the company it is important to gather more information to strengthen their unique selling point of their product on the market. The main challenge thus is a competition analysis for nanomaterial offerings and gaining a deeper insight in order to reduce costs. The project is at the interface of nanomaterials, bio-imaging and cellular assays. P started up seven different technological cooperations with competence providers of which four were awarded with a voucher. The fifth voucher was used by the creative industry to build a digital strategy. P evaluated the N4H outcome and impact on five levels. The first two related to the use of the vouchers and the Flemish SME scheme for the technological insights. The third as the building of a new ecosystem approach, the fourth for new contracts and grants and the fifth was a growth of a new internal awareness of other parameters, an impact on their production process and a change of the internal organisation of the company.

In Auvergne Rhône Alpes, 34 promising projects were identified through two calls for projects, of which 20 were presented to a jury of experts that selected 9 of them for vouchers (private co-financing of 30%). The *Health2CARE* consortium then had supported the selected SMEs in the definition of the use of their voucher in order to tailor as much as possible the service offered by the external experts. The services implemented have been mainly focused on market development needs (regulatory issues, CE certification, identification of clinician needs). In addition to the vouchers scheme, the partners organised cross-technological workshops on current hot topics such as the development of “Smart invasive medical devices: for a continuing patient monitoring”.

Health2CARE CASE

Avalun company – Voucher laureate

The company Avalun develops the LabPad a next generation mobile point of care (POC). Using the same imaging components as a smartphone to create a fully integrated miniature microscope, LabPad is a portable minilab that can perform many tests on the same device, such as blood coagulation, glucose or cholesterol. A patient or a healthcare professional just needs to insert the appropriate micro-cuvette in the device, draw a droplet of blood from the patient’s finger and deposit it on the micro-cuvette. The development of this technology is the result of over 10 years of research at CEA-Léti, a top French research institute in Grenoble. Design for e-health application, LabPad also is a communication device that strengthens the link between patients and healthcare professionals. The project implies studying different integration for the LabPad in different European healthcare system and related connection issues. Thanks to the Health2CARE voucher, Avalun has been able to study the reimbursement policies of 6 European countries. Moreover, the product involved key technologies, such as electronics, microfluidics, plastics, surface chemistry, biochemistry and IT; so linkage with potential new technology providers through the support of cluster organisations is crucial in the company development. This is why it participated actively in the H2C activities and workshops.

In *C3-Saxony* 44 projects were submitted in two calls for action. 21 of them received innovation vouchers. The projects were selected by an expert jury by the following evaluation criteria 1) soundness of the overall concept in regards of feasibility, uniqueness and unique selling point in comparison with existing products and processes, the level of innovation compared to the state of the art, and user benefit, 2) expected leverage effect & economic impact, and 3) Contribution to the RIS3 strategy [smart specialization „Sächsische Innovationsstrategie], quality and proposed implementation of cross-sectoral aspects. The degree of maturity, hence the current phase in-between conception and market launch was not taken in to account as an evaluation criteria. Though, the projects had to describe this point within their application in relation to their current project phase. The projects selected for vouchers got further the opportunity to apply the *Emerging Industry Price*. By doing so the projects holders had to qualify their ideas in terms of business developments. In support to the project owners a second workshop was offered, aimed to deliver a methodological overview to enhance and enable the several project ideas to qualify their descriptions towards more completeness and comparability. The following methods were quickly introduced and explained by giving useful and comprehensible examples: 2.1) Structured Executive Summary, 2.2) SWOT – Analysis; 2.3) Business Model Canvas and 2.4) Resource Roadmap. All projects – even without innovation vouchers – had the chance to contact the participating clusters to ask to support in IP-protection, business plan development, partner search, PR and internationalization. The deployed model proved very successful for the selected cases, bringing them to higher levels of TRL or MRL in an accelerated time frame. The current project aims at building an interregional dimension to the built-up experiences, wants to obtain further cross-fertilisation between the different experiences in the 3 regions, and wants to consolidate the achieved successes and experience in the long term.

C3 CASE

Project idea: Female Cycle Monitoring “OvulaRing”

The patented biosensor OvulaRing is the world's first system which is able to precisely determine a woman's fertile period as well as completely detect, map and evaluate individual fertility cycles. Knowing the exact timing of ovulation is essential for the targeted inducement of pregnancy or for practising natural, hormone-free contraception. OvulaRing is based on 40 years of scientific experience of one of the most renowned reproductive specialists in Europe and its approval as a medical device on the corresponding studies. In gynaecology and reproductive medicine OvulaRing enables better diagnosis for optimal fertility treatments with a higher chance of success. Through a web-based evaluation it allows the user to easily obtain an accurate understanding of their individual hormonal cycle.

What main entrepreneurial and innovation support needs did companies engaged in the crosssectoral collaborations have?

Integration of wireless data transfers into the system. The mobile front end design and app development to increase the usability at the point of care. Development of further technical solutions to integrate bio parametern into the sensor.

What entrepreneurial and innovation support did the identified projects and companies have access to (mentoring, coaching, IPR support, marketing, internationalisation etc.)?

IPR support, marketing, internationalisation

How where they provided this support and by whom (type of actors)?

In the framework of the voucher was financed a booth and the participation at the trade fair

MEDICA and a feasibility study for the implementation of an interface/API for the software.

The aim of this study is the implementation of an interface that can provide data and functions external modules available.

What were the main success factors?

The good networking in the region and a target-oriented management was the main factor for the success. The company was the third winner of the "emerging industries price" of the project C3-saxony. This price also helped for a better visibility of the company and their product.

D. Leveraging on existing, complementary support measures

In the MIX model support offered to SMEs could be reinforced and leveraged through other existing (financial) support instruments on as well a regional as a European level. Pursuing synergy with existing instruments is key in the implementation of the MIX model.

Relevant measures/instrument in the Flemish region

The Flemish government has developed several instruments to support SMEs developing and deploying innovative solutions. The instruments which are most relevant to include into the MIX model are:

- The 'KMO-portefeuille' an instrument through which an SME can receive financial support up to 15 000 Euro for advise and training.
- The 'KMO-haalbaarheidsstudies' an instrument through which an SME can receive financial support up to 50 000 Euro to evaluate the feasibility of new innovative ideas
- The 'KMO-innovatie projecten' an instrument through which an SME can receive financial support up to 250 000 Euro to gather and apply knowledge to create and develop new and innovative solutions.
- The 'O&O-bedrijfsprojecten' an instrument through which an SME can receive financial support above 250 000 Euro to gather and apply knowledge to create and develop new and innovative solutions. Priority is given to projects with a higher risk and with a greater potential economic impact in Flanders and possibly at the broader social level.
- Financial support up to 75 000 Euro through 'Flanders Investment and Trade' to support specific internationalization activities.
- Flemish Strategic Research Centers (e.g. IMEC, iMinds, Flandes Make, VIB, VITO) run ICON research programs. The ICON program is a formula for demand-driven, cooperative research. Over a period of typically two years, multi-disciplinary research teams of scientists, industry partners and/or social profit organizations work together to develop digital solutions that find their way into the market offer of the participating partners.

Relevant measures/instrument in the region Auvergne - Rhône Alpes

- Plan de développement à l'International (PDI). The Region Auvergne Rhône-Alpes supports the SMEs members of the regional clusters in their internationalisation strategy via the programme PDI. Thanks to the PDI, SMEs can get a small funding especially travel costs reimbursement for:
    - International business trips
    - Company mission

    - Booth on international fare trades
- Big Booster: BigBooster is a unique international non-profit acceleration program for early stage startups in Bio & Health, Informative Tech and Global Impact. BigBooster enables them to cross borders and take the leap to global markets.

  Organized around Lyon (France) and Boston (US), 2 worldwide renowned hubs with strong innovation ecosystems, BigBooster's distinctive model is based on 2 intensive 3-day Booster Camps, 1 in Lyon and 1 in Boston with top-notch mentors and experts, and in-between ad hoc mentoring.

- IDéclic Potentiel+. This regional programme facilitates young companies to access funding for their innovation project in the critical timeframe between the company creation and the first successful fundraising. The support is in form of a low-interest seed capital loan.
- IDéclic Innovation – Access to market. Regional support in form of repayable advance and funding for companies towards technological innovation. This tool supports industrial uptake i.e:
    - Prototyping
    - IP protection
    - Help on recruitment of talents
    - Purchase of business studies
- Easytech. The Easytech programme of IRT Nanoelec is run by Minalogic. Easytech transfers new technologies to the businesses that need them. The Easytech program leverages a market-pull approach to ensure that technology bricks are successfully transferred to small and mid-sized businesses—in other words; that they help meet real, identified customer needs. The programme offers support to companies that want to integrate micro/nano electronics bricks to their products. This support can be:
    - Consulting
    - Partner search
    - Co-development of new technological solutions with a R&D center partner of the programme.
- IRICE -Installations de Recherche et d'Innovation Centrées Entreprises (SME-centric R&I infrastructures) : This Regional call for projects is co-funded by the ERDF as part of the Smart Specialized Strategy for Innovation. Projects should fund the creation, modernization and improvement of strategic R&I infrastructures while guaranteeing primery access to Regional SME's. Access should help Regional innovative companies with:
    - Technology sourcing
    - Development of new processes
    - R&D , tests and qualification

Relevant measures/instrument in the region Saxen

In Saxony funding programmes in support of innovation and technology transfer for SMEs are available and useable for Smart Health.

- Technologietransferförderung Support of SMEs in terms of contract research, IP acquisition and protection and consulting for product and technology deployment. Acquisition financing 50 %.
- Förderung innovativer Ansätze im Bereich der Gesundheits- und Pflegewirtschaft (2014-2020) Funding of SMEs and research institutes to support research and innovation in the field of e-health. Acquisition financing up to 80% of the overall costs.
- FuE-Projektförderung Funding of innovative, technology driven R&D projects with acquisition financing up to 80%.
- HORIZON-Prämie Funding to support SMEs in the application process for Horizon 2020 projects with up to 5000 Euro.

- Industriebezogene und netzwerkunterstützende Projektaktivitäten (INA) This funding program is aimed at advanced industrial topics. Within the funding period stakeholders from different sectors should exchange knowledge and competences. Application for funding is possible for SMEs, research institutes but also for cluster organizations. INA funds the project management as well as the implementation of expert symposia and conferences. The general cluster management is excluded from funding. Positive evaluated projects will be supported for two years with 100,000 EUR/year (50% acquisition financing).
- InnoExpert: The InnoExpert is a wage subsidy to employ external expert to get support in introducing innovation management in SMEs. The financial support covers 50% of the personal costs limited to 50.000 Euro per year and person). The duration of the funding is between 12 and 30 month.
- InnoTeam: InnoTeam is a cluster sectoral R&D funding program for consortia located in Saxony. Aim is to develop new products and technologies. The cooperation of at least one research institute with a SMEs is mandatory. Acquisition financing is up to 80 % (SME) and 100% research institutes.
- Innovationsprämie: Funding of contract research to accelerate product and service development. Acquisition financing 50% (maximum 20.000 Euro/year)
- KETs-Pilotlinien: Support of the implementation of research results into pilot lines in the area of Saxony with focus on KET - Key Enabling Technologies. Acquisition financing up to 80% (limited to 20 Mio Euro)
- Markteinführung innovativer Produkte und Produktdesign (MEP): Support of market deployment of innovative products (product design, marketing materials, serial specimens, prototypes). Acquisition financing 50% (limited to 100.000 Euro)
- Transferassistent: A funding program by the European Social Fund and the Free State of Saxony is the so called Transfer Assistant (TA). The TA is a person with relevant professional experience in science and industry. The task of the TA is the support of SMEs through information and consultation on technology transfer and product innovation. The financial support covers 50% of the personal costs (limited to 60.000 Euro per year and person). The duration of the funding is between 12 and 48 month.

EU Support Measures

The EU support measures offer opportunities for the individual SMEs. Some examples:

- Through the industrial leadership pillar of the Horizon 2020 program the SMEs can broaden their knowledge about technology and can build relevant IP to reinforce their business case.
- Through the access to risk finance instrument SMEsgain easier access, via financial instruments, to loans, guarantees, counter-guarantees and hybrid, mezzanine and equity finance.
- The SME instrument and the Fast Track to innovation allow entrepreneurs to prepare their market entry.

Also the MIX model can benefit from the EU initiatives, e.g.:

- The MIX model and strategic plan can be submitted for financial support under the H2020 Innosup program (“Cluster Facilitated Projects for New Industrial Value Chains”), which is exactly targeting the 3 dimension of MIX: multi-disciplinary, interregional and x-sectoral, and more over facilitated by clusters. It is also very interesting that part of the available budget should deliver direct benefits to SMEs, e.g. by using vouchers for stimulating the MIX-concept.

- Running projects on eHealth granted by the European Commission[2] . Those project offer a wealth of intelligence. Stakeholders can liaise with them concerning dissemination, synergies creation and common actions as much as possible.
- The COSME Go International program can help to further structure the access to market of SMEs in the cross digital and life sciences technology domain. Through dedicated activities more insight can be gain about opportunities on other continents and activities to open up those opportunities for EU companies can be set up.
- The three INTERREG strands of cooperation (cross-border, transnational and interregional) allow for reinforcing the Smart Health consortium as it allows for broadening the consortium with other regions, setting up specific activities with policy makers.

E. Application of creativity and design thinking methods

The MIX model aims at setting up collaboration between stakeholders from different and complex technology domains working on solutions for a better healthcare. As those stakeholders have to gain insight into each other's domain they have to open up their mind and have to become creative. This can be done through meetings, workshops, brainstorm sessions, training, conferences, coaching. All opportunities for the relevant stakeholders to meet up and start talking about joint opportunities. During all those gatherings one can apply creativity and design thinking techniques and methods to facilitate the participants into their thinking/learning process.

Design thinking to develop future scenarios

Design thinking is a formal method for practical, creative resolution of problems and creation of solutions, with the intent of an improved future result. In this regard it is a form of solution-based, or solution-focused thinking – starting with a goal (a better future situation) instead of solving a specific problem. By considering both present and future conditions and parameters of the problem, alternative solutions may be explored simultaneously. Design thinking identifies and investigates with known and ambiguous aspects of the current situation to discover hidden parameters and open alternative paths that may lead to the goal. Because design thinking is iterative, intermediate "solutions" are also potential starting points of alternative paths, including redefining of the initial problem.

Creativity techniques

To make people think out of the box creativity techniques will be used. There are plenty of useful techniques. They all come in different shapes and formats. But they have all one thing in common: people get acquainted, share thoughts and learn. Those creativity workshops are complementing the more business oriented gatherings (e.g. speed dating, pitching sessions) as they offer a more informal format to establish contacts and start talking, a prerequisite for setting up sound collaborations.

Some examples of creativity techniques which could be applied:

- Scenario analysis: A process that enables you to envision a diversity of futures for your market by distinguishing likely vs less likely transition scenarios and identifying the most important determinants towards those futures
- Storytelling: A creative method to communicate how users use a product

[2] Online Brochure: https://ec.europa.eu/digital-single-market/en/news/ehealth-projects-research-and-innovation-field-ict-health-and-wellbeing-overview

- Scenarios of use: Stories written in a natural language to describe how a persona uses a certain product or service
- Proxy technology assessment: A combination of interpretative and ethnographic methods used to detect the functional and contextual requirements of a new technology
- Thinking aloud protocol: A test method used to gather insights into the experiences, ideas and reasonings people have when executing a task or solving a problem
- Stakeholder mapping: A visual method to map interactions and relationships between the innovation and its stakeholders
- PESTEL analysis: A strategic framework to understand the macro-environmental factors in your environment

The support by the creative sector has already been set-up and validated in Flanders, where the 2 clusters DSP Valley and FlandersBio have been cooperating with Flanders DC (Flanders Districts of Creativity).

III. The MIX model: an operational view and a strategic plan "SmartHealth"

Turning the MIX model into an operational mode creates a strategic plan, which we baptized "SmartHealth".

The methodology for the "SmartHealth" strategic plan will be based on a systemic approach built thanks to the clusters that will bring together different tools and actors towards creating favourable conditions for project ideation, product creation and thus facilitate the development at a cross-border level of end user centric precision healthcare solutions enabled by a combination of digital and life sciences technology. The methodology in the strategic plan will try and keep creativity as a key to successfully blend knowledge and resource efficiency as a perpetual guideline in industrialization perspective.

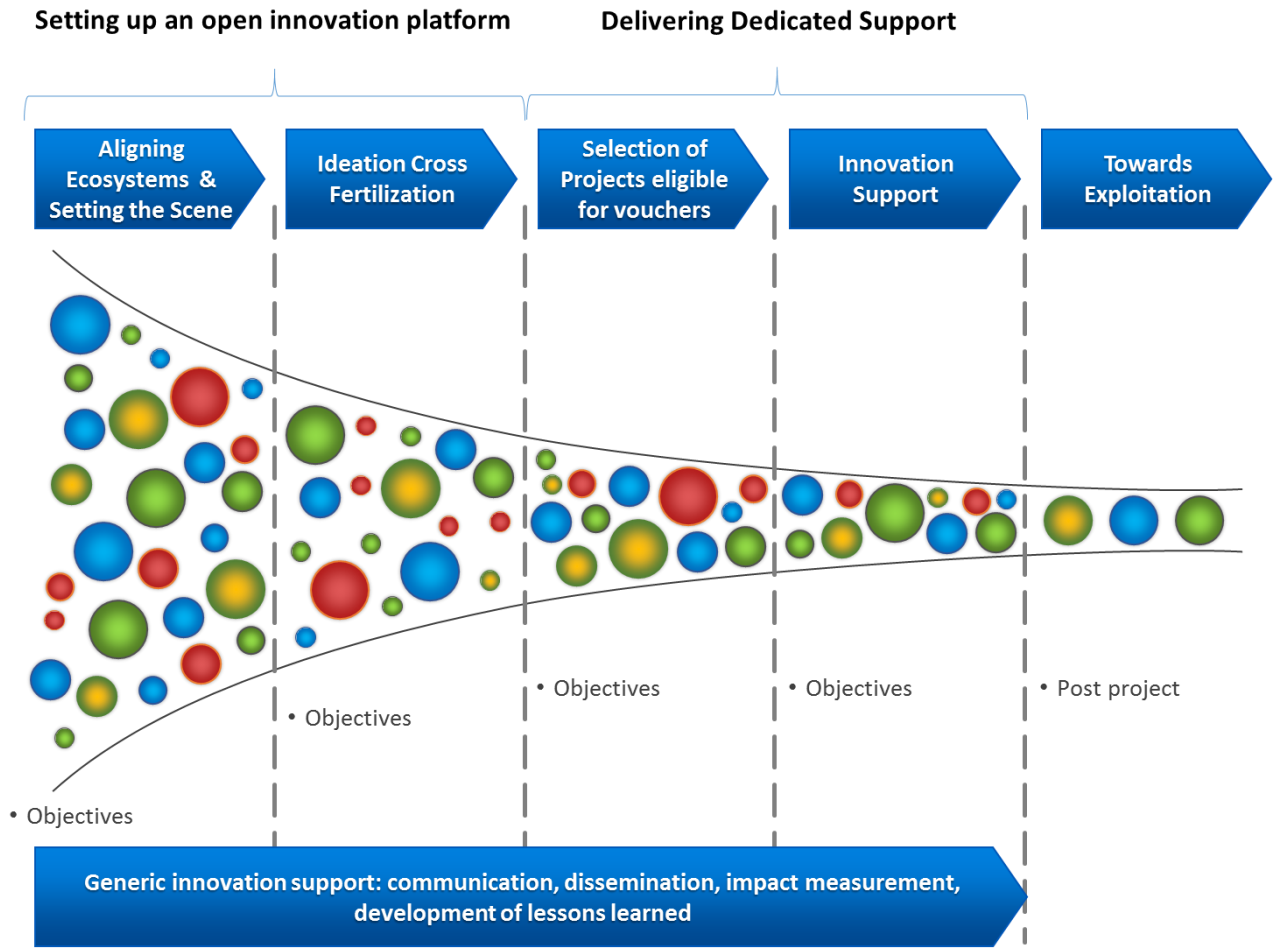


Figure 1

The MIX model concept will be operationalized through a coherent approach in a strategic plan. This strategic plan aims at as much impact as possible by creating as much opportunities as possible for stakeholders to be involved in MIX model activities and by creating as much synergy as possible with other existing initiatives. The approach in the strategic plan consists of 3 major parts.

1. Setting up the open innovation platform
2. Delivering dedicated support to SMES
3. Organizing generic innovation support

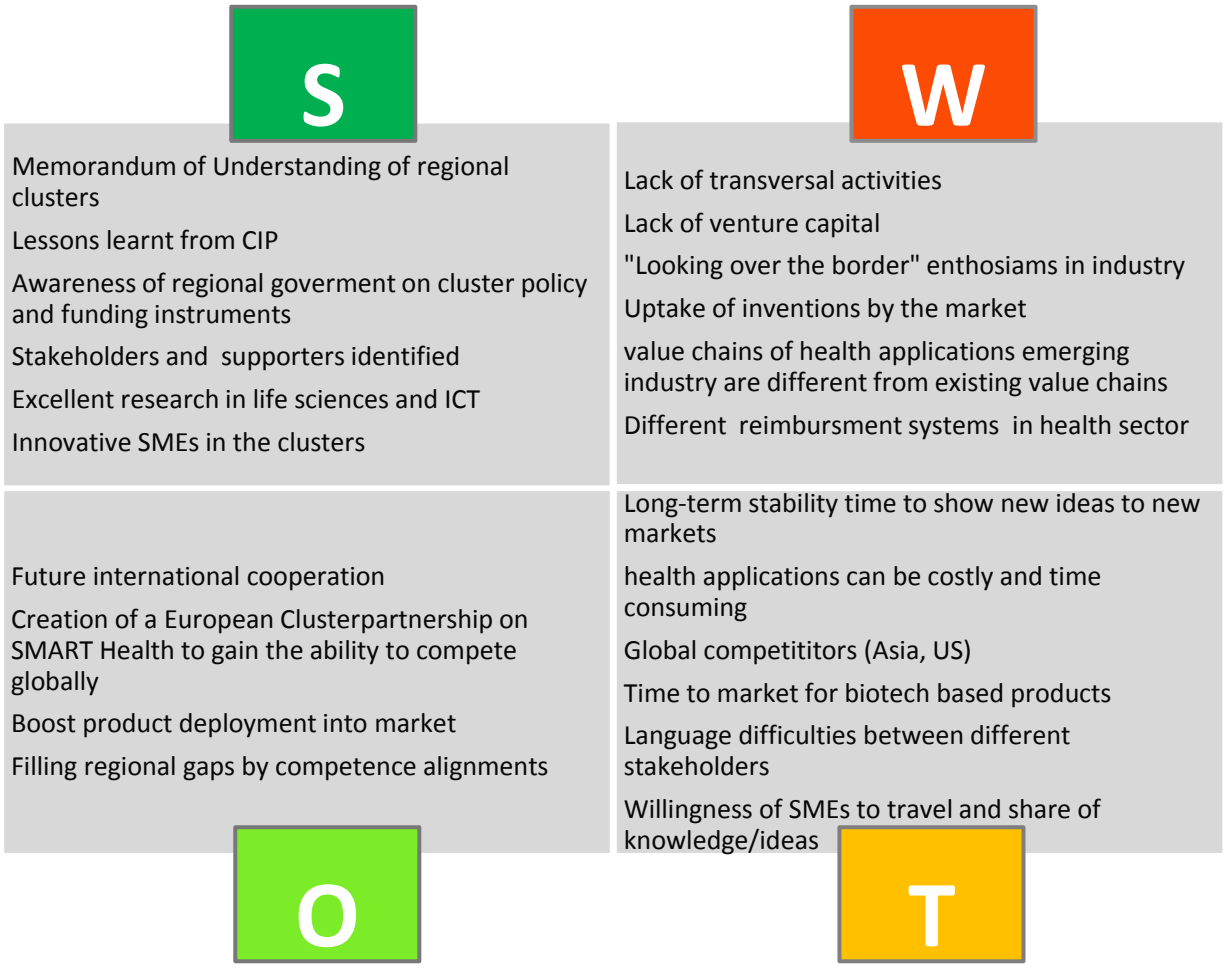
A. Setting up the open innovation platform

This part of the methodology of the MIX model and the SmartHealth strategic plan will set up the cross regional, cross digital technology/life sciences, open innovation platform. A platform where people can meet, discuss, learn and co-create innovative products and services within the focus domain of the SmartHealth strategic plan.

1. Aligning the ecosystems and setting the scene

The first action – aligning the ecosystems and setting the scene - starts from the lessons learned and the analysis in other initiatives (e.g. the Health2Care, C3- Saxony and Nano4Health project) and combines this information to align the consortium partners, create a common interregional vision and related priorities. Based on those lessons learned the stakeholders can develop a common

SWOT matrix related to the development of solutions for user centric precision healthcare enabled by a combination of digital and life sciences technologies. The following was developed based on the experience of the C3, H2C and N4H project.



This common SWOT is key to align stakeholders and to optimize the support which will be delivered to SME through this SmartHealth Strategic Plan. SmartHealth will deploy a support portfolio which aims at implementing support scenarios based on the common SWOT. Those support measures will include access to adequate competences, access to funding, access to market, access to technology, access to infrastructure, access to living labs. This first action aims at aligning the 3 regions involved into this 'access to X' principle so that efficient use of existing support measures can be facilitated.

Throughout the implementation of the SmartHealth strategic plan, according to the MIX model, additional business intelligence (as well technology as market related) on local, European and global level will be gathered as input to the other modules but also from the outputs of the other modules. This intelligence can be generated through:

- desk research,
- stakeholder consultations,
- focus groups,
- surveys and
- workshops.

2. Ideation and cross fertilization

As second action in setting up the open innovation platform the stakeholder ecosystem will be mobilized through ideation and cross fertilization activities. This action in the strategic plan starts from the intelligence gathered. Stakeholders involved will be able to have a clearer vision of the state of the art and trends around disruptive technologies and innovation that could be applied to user centric precision healthcare solutions. So from these statements, the stakeholders will use their experiences and strengths for mobilizing their respective communities from different sectors in order to address personalised healthcare challenges. The ideation and cross fertilization activities aim at generating concrete ideas between players from different technological or application backgrounds for the emergence of future relevant projects that will be then be supported in through dedicated support (vouchers, cluster services…). This action consists in bringing bring people together and initiate a learning process. This learning process is key because the MIX model combines complex domains (life sciences, digital technologies, incl. nano-electronics) into solutions for user centric precision healthcare. Experts coming from the clusters' various ecosystems and from different types of organisations have to gain insight and have to understand each other to collaborate together on solutions. Furthermore, the ideation and cross fertilization aim at mobilizing a broad group of stakeholders (entrepreneurs, researchers, policy makers, healthcare professionals, investors, cluster organisations, service providers, companies,..). Thanks to the expertise of networking process, the clusters will use as much creativity techniques during the ideation and cross fertilization workshops to unlock as much ideas and insights as possible. The objective is to support open innovation in a cross sectorial context. Thus the MIX model will use stakeholder experience and techniques experimented in projects with the aim to inspire the participants and actively bring them together to nurture each other. To lead this activity, the clusters involved will organise different types of activities at a regional and inter-regional level, such as:

- Matchmaking capacities between the respective ecosystem
- Inspiration and cross-fertilisation sessions,
- Brainstorming sessions on dedicated pre-identified topics (WP2)
- Hackathons / pitch presentations etc.
- Inspirational sight-seeing..

According to the selected topics, the organisation of such activities might involve the participation of designers or creativity professionals that would support the participants to go beyond their own discipline.

This ideation process is strongly linked to the 'Delivery of innovation support' in which the most promising ideas emerging from these activities will be able to apply to the call for projects to receive vouchers or external support.

3. Delivering dedicated innovation support to SMEs

The key objective of the SmartHealth strategic plan, according to the MIX model, is to support innovation actors in the development of their projects. As well early stage (TRL 2-5) as projects which are close to market introduction (TRL 6-9) will both be considered. The MIX model innovation support will allow for individual support which can be enabled by vouchers as well as for collective support which will be delivered by the cluster organisations involved. Both types of support could be technology and/or business related.

a) Selection of projects eligible for vouchers – organizing the individual innovation support

A blueprint of a voucher call and granting procedure that will be developed and implemented in MIX model graphically displayed in the figure below. In short, the procedure starts with a call for projects

targeting stakeholders that may have been involved in the ideation workshops and that have developed know-how, IP and/or technology in the KET domains of life sciences/biotechnology and/or digital technology in the broader sense (hard-and software with applications in the health domain) and want to make use of individualized support through the voucher scheme. Applicants (SMEs and larger enterprizes, see further) will be asked to describe carefully their project and the type of support/competences they need in order to bring their project a step further. The projects will be evaluated by one (interregional) evaluation committee consisting of relevant independant external stakeholders. The evaluation committee will make a first ranking/selection of projects based on a set of eligibility criteria. Projects co-submitted by life sciences companies and technology companies will be especially appreciated. Selected projects will be invited to present at one of the regional project evaluation sessions in front of the evaluation Committee. The evaluation committee will then make a final decision on which projects will be eligible for support. The aim is to select projects in the relevant domain of focus, i.e. **end-user centric precision health and care**.

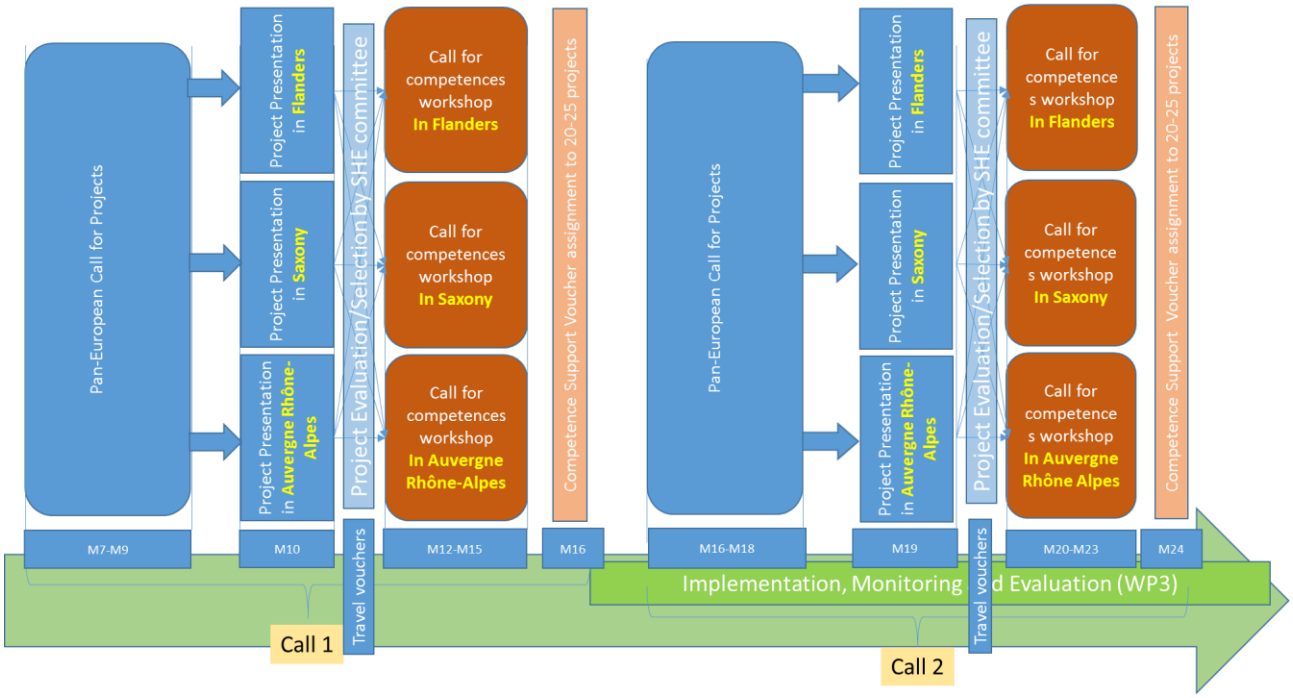


Figure 2: Schematic overview of the calls that will be launched in the SMART Health project

The second step in the procedure is the participation of the project owners in regional "call for competences" workshops (of which at least 1 outside of their region). The "call for competences" workshops aim at matching the project owners with the right competence providers from either their own region or (preferably) from one of the other participating regions. They will consist of a project pitching part complemented with active tools to match the projects with the essential competence providers (e.g. business model canvas). Project owners that were successfully matched can submit voucher applications to the interregional "Voucher Assignment Committee" (VAC) that will do a final evaluation before granting the vouchers. The vouchers will be awarded on the basis of strict criteria. in line with regional/national and EU regulations that may exist.

This step-wise procedure will stimulate the interregional co-operation in different ways:

1. As a result of the mandatory requirement for selected projects to pitch in "call for competences" workshops of which at least 1 located outside of their region.

2. By awarding contracts between companies (and their projects) and selected competence providers from another region with a higher support %.
3. By stimulating projects to (also) make use of general support activities outside of their region (.
4. By issuing travel vouchers to support the interregional travel financially.

A few features distinguish the SmartHealth vouchers from normal grants.

- Firstly, the SmartHealth vouchers need to be used to buy access to external expertise seeking to initiate and foster professional relationships with external competence providers such as research institutes, universities and consultants. They cannot be used to fund innovation efforts like personnel costs, private R&D costs or even investment in generic hardware and software directly for the recipient company.
- Secondly, the SmartHealth voucher system should be developed into a flexible funding vehicle that can be obtained with greater speed and ease compared to grants. Their funding volume is much smaller, but the conditions which regulate their use to buy external expertise make them ideal instruments for lowering the barriers to first contact with external knowledge providers.
- Finally, the SmartHealth vouchers will target a well defined set of competence groups who can assist companies with answering concrete technical, market related, legal or regulatory questions in order for their projects to be taken to a next TRL, MRL and/or ORL level. Vouchers will not provide full-scale innovation support or finance companies marketing activities. Vouchers are awarded against invoices and cover a percentage of the service given and charged in the invoice. The % coverage will vary based on the size of the company buying the competence and based on other incentives as defined in WP6 (e.g. interregional collaboration). Vouchers cover costs excluding VAT if this is applicable to the invoice covering the service.

Once projects and competences are matched and SmartHealth vouchers are awarded, actions will be defined to monitor the project and possibly identify other support these projects may need for further development.

b) Organizing the collective support through Cluster organisations

The projects which will be supported through vouchers do have at least one thing in common: they want to develop a new user centric precision healthcare solution by combining digital and life sciences technology. Through the vouchers they have access to tailored and dedicated competences but as they are also part of the MIX model ecosystem they can also benefit from the expertise of the other selected projects. The MIX model team will facilitate (pro) actively the cross fertilization between the different project by organizing a number of workshops. Those workshops will address some the specific needs which the project owners are confronted with. This can include (but is not limited to):

- To prepare for access to funding, e.g. Organisation of training (How to prepare a good pitch for investors? How to structure a private equity deal? What does an investor expect? How to find the right investor? How can I access government support programs?), Organisation of Business to finance matching sessions.
- To support the companies in addressing market challenges, e.g. Organisation of training (How to access a specific market? What is the regulation to take into account when accessing a market? What about reimbursement?), Organisation of stakeholder consultations (e.g. meetings with healthcare professionals to better understand the ins and outs of the healthcare sector)
- To support the companies in their internationalization strategy, e.g participation in international exhibitions, etc.

- To make the ecosystem work by organisationing cross fertilization workshops between the projects and their competence providers
- And finally to foster business collaborations by offering the right opportunities and the last push into new markets in brokerage events and Open Innovation Challenges

4. Generic innovation support

According to the MIX model, he SmartHealth innovation platform and innovation support activities delivered through this platform will be supported further through some generic support activities.

1. The SmartHealth team will implement a continuous learning process through gathering lessons learned and deploying structured impact measurement and evaluation. Continuous learning is a key success factor when bringing different ecosystems together. All stakeholders have to gain insight to be able to collaborate on joint, innovative solutions. The project will start with aligning stakeholders and setting the scene. Through a process of gathering lessons learned additional intelligence will be gathered to further optimize the MIX model innovation support. Impact measurement will allow to set priorities on those activities which will, most likely, have the most impact on competitiveness of those stakeholders involved in developing solutions enabled by digital and life sciences technologies. It allows also policy makers to further optimize their instruments and create prosperity in their region through open and collaborative innovation.
2. All disclosable results from the SmartHealth innovation cases will be disseminated to an as broad as possible audience. Through focused communication and dissemination activities:
    a. The MIX model / SmartHealth Services will be promoted
    b. Stakeholders will be engaged to join MIX model / SmartHealth activities.
    c. Project supported by MIX model / SmartHealth gain visibility and credibility
    d. More stakeholders will be engaged in shaping their future through open and collaborative innovation.

B. A Europe wide open innovation platform for digital technology – life sciences innovation

The ambition of the SmartHealth clusters team is to create a Europe wide open innovation platform in which user centric precision healthcare solutions enabled by a combination of digital and life sciences technologies can mature. This innovation space allows for collaboration of experts from different domains, for developing promising ideas, for creating prototypes, for building large scale demonstrator, for validation with end users, for deployment into the market.

With the creation of this open innovation platform, the MIX model approach goes far beyond the current innovation support measures:

- Most of the innovation support measures in place focus on supporting individual stakeholders in their innovation activities. Few existing measures focus on collaboration between innovation stakeholders. A MIX model approach goes beyond existing measure by its focus on cross sector innovation by fostering collaboration between digital technologies and life sciences cluster.
- MIX model recognizes that innovation does not stop at the borders of a country. The digital technology and life sciences sectors are global sectors. People worldwide are working on solutions enabled by those enabling solutions. Solutions which probably can be implemented globally. MIX model takes advantage of this global activity by combining expertise from leading regions in both domains and by combining best of all regions involved. It offers local experts the opportunity to share expertise and make use of experience from people in other regions.
- Most innovation measures are 'one shot' measures, supporting one aspect of innovation. MIX model organizes its support by starting from a full innovation value chain: from ideation through deployment and exploitation. Insight in each step of that value chain is needed to speed up innovation. The MIX model Innovation support is organizing it support in a transversal way, building step by step insight in each step of the innovation value chain, combining all expertise from all relevant stakeholders.
- MIX model will create an innovation platform which is open. Participation of and reach out to other relevant stakeholders will be actively stimulated. The openness of the platform allows also to adopt new ideas, adapt vision based on technology and market trends, target other markets and even continents. The open minded approach is key to learn, develop and implement solutions for a European future.

1. Why this domain

In the last 10 years the understanding and knowledge of human diseases and disorders has increased dramatically. Research on different disease patterns has been driven forward through the application of different –omics platforms but also more and more powerful visual detection technologies have allowed the more profound understanding of the physiological, molecular and genetic mechanisms driven different disease patterns.

This results in a revolution of modern healthcare. For a lot of diseases different diagnostic tools have been developed and elucidate in a lot of cases the stratification of patient populations in different groups with different disease patterns. In addition these diagnostic tools also allow low cost and fast detection of the incidence of a disease or the genetic pre-disposition for a disease pattern.

This evolution lays at the basis of a potential transformation of modern healthcare. Where traditionally healthcare systems were focused on cure-strategies based on broadly applied so-called blockbuster drugs, modern healthcare strategies start to focus on a more patient oriented prevention and personal cure and care strategy.

In parallel with the development of this more and more in depth understanding of different human disorders, also the micro-electronics sector continues to live through different waves of technological revolution. Miniaturization, ultra-low power electronics, better battery performance, wireless communication and interconnectivity are key trends which enable the development of added value products/devices in healthcare. These trends have resulted in very small technology platforms with increasing sensitivity and accuracy in a widening field of application domains for the healthcare sector. Major players in the medical technology field are investing massively in health applications based on new micro-electronics platforms. Currently this has resulted in health support diagnostic tools under the form of for example wearables to measure heart rhythm and blood pressure and other health determining values. Also the field of active implants leans heavily on these technological developments. The first applications on the combination of biotechnology and micro- electronics start to emerge. The combination of biomarker applications and micro-electronics form new diagnostic tools like biosensors, lab-on-chip, integrated small clinical labs. On the therapeutic side the combination of drugs and micro-electronics come up with smart pills and targeted drug delivery systems for example.

This merging of minds and combining of technologies is happening today because both knowledge platforms are mature enough to do this and because a number of research groups and entrepreneurs active in both domains have joined forces.

2. Why is collaboration needed

Life Sciences based knowledge has traditionally been translated in health solutions that involve the development and registration of therapeutic drugs or diagnostic tests. These developments are typically done over a period of 8-12 years from early discovery and as a result of the regulatory compliance requirements can cost between 300 Million and 1Billion Euro.

Medical Technology applications based on micro-electronics follow a different registration process (e.g. in EU the so called CE registration) and takes 3-8 years depending of the complexity of the technology and the health application they address. The cost for a global registration of a Medtech solution is …-… Million Euro.

Developments of micro-electronics based solutions are typically much faster (aanvullen) and follow a registration process which varies with the application domain both in complexity, timelines and cost.

These fundamental differences in resource needs, development timelines but also in value capture mechanisms applied in the business models typically applied in the life sciences or micro-electronics ventures has also resulted in parallel financing bodies (both in public and private circles) that do not overlap, do not understand the business dynamics of the cross-over field and have very little

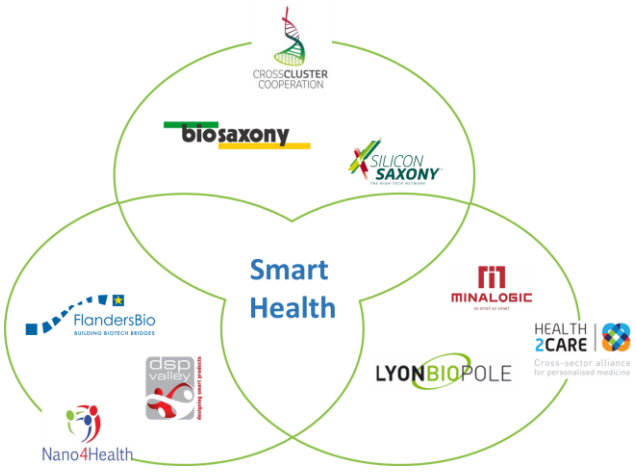
interaction. Just like scientists in this field like to 'cocoon' in their own field, also financiers in this field like to focus on their area of specialization and feel uncomfortable to explore ventures with business elements from the other side. The education/training on knowledge of both worlds will need to be stimulated both in public and private financing bodies.

In parallel with this education process of the financing bodies for this new industry, we need to identify and train 'the (combined) competences of the future' needed for the roll-out of this industry. This has to be realized within the public research bodies active in both fields but also within the early private movers in this field. This education will be implemented by the SMART Health consortium by gathering intelligence throughout the project, involving as well researchers as first movers in to a cross-intelligence bath and have them gaining insights by collaborating on joined projects.

We need to nurture the 'first mover advantage' these companies offer us, in order to identify the key success and risk factors for these ventures and use that as a basis for a next phase roadmap. The selected success stories in this young field will be used as a basis to prepare a second wave of cross-over initiatives amplifying the combinations of technologies that drive new developments but also the application domains tackled in this novel health solutions. The parallel learning derived from these initiatives need to form a constant basis of development and optimization of the service portfolio supporting the roll-out of this new cross-over industry.

3. Why this "SmartHealth" cluster team

The SmartHealth strategic plan is the 2nd step towards a 'digital technology – life sciences open innovation platform'. Before, the 6 cluster partners of the team were all involved in CIP funded projects which aimed at setting up collaboration on a regional level. With this SMART Health strategic plan, the team of these six clusters wants to take a next step in the evolution towards this Europe wide open innovation platform by joining forces and elaborating on an innovation support model which support SMEs with promising ideas in shortening the time to market for cross digital technology/life science solutions.



This strategic plan aims at creating an interregional dimension for 3 related projects, previously funded under the EC Competitiveness & Innovation Program (CIP), namely Nano4Health, Health2Care and C3-Saxony, in which a policy for cross-KET innovation cooperation has been developed and applied successfully for stimulating emerging industry in health applications on a regional level. Using these methodologies, they demonstrated at regional level that it was possible for clusters to help develop new cross-sectoral industrial value chains, specifically building on the innovation potential of SMEs.

Combined, the 3 consortia identified more than 50 promising projects and distributed 40 vouchers. They experienced different challenges in doing so that will be addressed in this new proposal which aims at leveraging on the impact of the first regional round of projects to help develop new transnational cross-sectoral industrial value chains with the objective to place new products in the market meeting the needs of users: patients and healthcare professionals, therefore generating new jobs and contributing to the emergence of a Healthcare economy 4.0.

IV. Future Ambitions and Funding

After ending the different CIP-funded projects in the 3 participating regions, the “SmartHealth” team of six clusters will search for continuation in funding for the implementation of this strategic plan. This can be achieved at both levels of the individuals regions and at European interregional level.

In Flanders, the MX-cooperation (Multi-disciplinary / X-sectorial) is already continued in the XKET4HEALTH project, aiming at unlocking additional innovation cases in the “SmartHealth” domain.

At European level, the team of the 6 cluster partners intend to submit this strategic plan as a project proposal in a suitable H2020 call. The Innosup scheme seems to fit perfectly to the ambitions of this SmartHealth strategic plan. The Innosup scheme is offering several time windows: the EC has announced annual calls for Innosup “Cluster facilitated projects for new industrial value chains”. For these calls, the EC is targeting a budget of 5M€ for each granted project, of which at least 75% must be at the direct benefit of the SMEs in the participating clusters.