ITECH Project: Roadmap for Research and Innovation in Health Technology

The ITECH Project is focused on Research and Innovation in Health Technologies (Medical Devices and eHealth applications) and set out to identify gaps and barriers currently existing in all phases of the "idea-to-market" process. The aim of the Project is to propose a strategy to accelerate and support the process, with the ultimate goal of building a perennial network of referents in Healthcare Technologies. The process to transform a scientific idea into a commercialized product, devices or services is highly complex and heterogeneous due to the variety of stakeholders including institutional bodies, medical professionals, researchers, patients and consumers.

To capture and describe the **"idea-to-market" process** in the field of health technologies, the ITECH Consortium defined a **five phase model** shown below in figure 1. The five phases include: 1. Proof of Concept; 2. Prototype Development; 3. Regulatory Process; 4. Product Development and 5. Reimbursement. Additionally, **8 activities** can be identified in the phases: 1. Research (The term could entail different aspects within each phase, and includes: basic research, applied research, translational research and pre-clinical studies); 2. Technical Development; 3. Technical Evaluation; 4. User Experience; 5. Clinical Evaluation; 6. Patenting / IPR; 7. Business Intelligence; 8. Education.

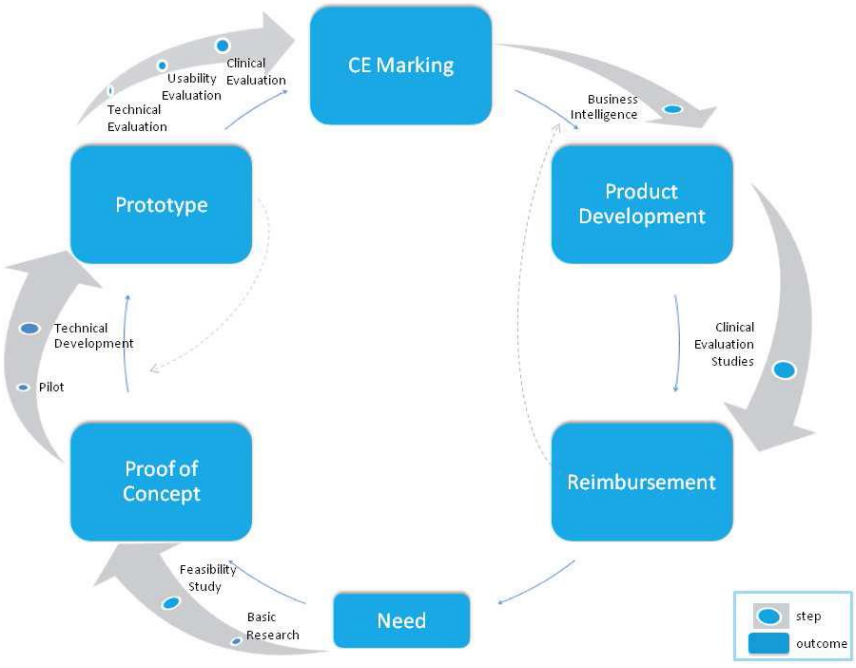

Figure 1: ITECH model of Idea-to-Market process (in all phases only key activities are represented)

Two of the phases, **3** (Regulatory Process) and **5** (Reimbursement) were identified as being most critical in the transformation process of a scientific idea into a commercialized product in the fields of eHealth and Medical Devices:

- The **Regulatory Process** involves the certification of medical devices and is a rather complex process that can delay or hinder the marketing of an R&D outcome. The most recent revision of the EU Medical Device Directive (MDD) 2007/47/EC introduced additional requirements for certification and has broadened the definition of what a Medical Device is to cover categories such as stand-alone software.

- The **Reimbursement** process involves the reimbursement of Medical Devices and eHealth services and is highly regulated by public authorities with the 'rules' varying from country to country. As a result, the development of a successful business model by a company in order to achieve financial support for an innovative product can be a complicated, high risk task.

Following an extensive data collection process across Europe, the ITECH Consortium described the different types of funding for the different phases of the model of figure 2 below. Findings indicate that research activities appear to receive higher support from the public funding agencies and that less attention has been paid to other critical issues like nomenclature, regulatory processes and reimbursement.

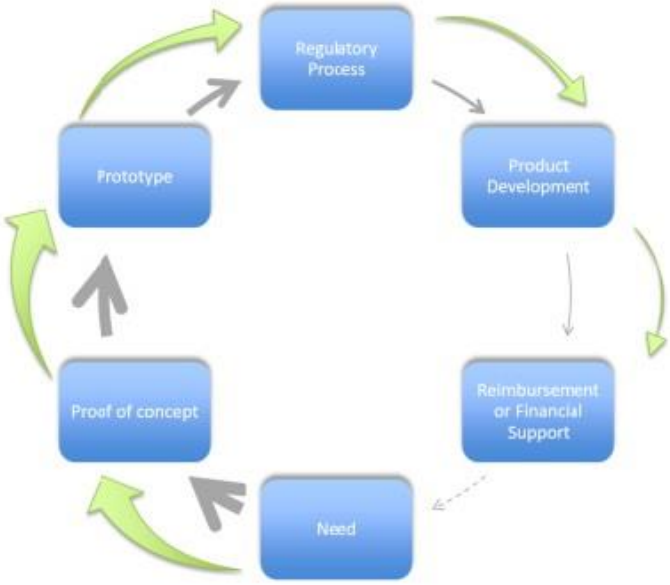

Figure 2: Funding support per phase in Europe, following the ITECH model (Black arrows are proportional to the number of funding bodies per phase. Green arrows are proportional to the mean amount of money available in each phase for one project).

47 experts from across Europe, Australia and Canada, attended the 1st ITECH Workshop for an in-depth analysis of these results and assisted the ITECH Consortium to identify **12 main Gaps and Barriers** to an efficient "idea-to-market" process as listed below in Table 1.

GAP 1	Lack of common and well-shared definitions and classifications of MDs and eHealth applications
GAP 2	Limited calls for projects on Healthcare Technologies
GAP 3	Limited number of multidisciplinary projects
GAP 4	Regulation: lack of knowledge, lack of experts, differences between countries
GAP 5	Problems with patents and intellectual property rights
GAP 6	Limited regard of applied and translational research on the evaluation of researchers and academics
GAP 7	Difficulties on Technology Transfer
GAP 8	Delayed involvement of industries in the process
GAP 9	Methodological difficulties and limited funds for clinical trials on Healthcare Technologies
GAP 10	Difficulties in obtaining reimbursement
GAP 11	Lack of education
GAP 12	Recognising the importance of usability / user experience / usages / ergonomics

Table 1. List of identified Gaps and Barriers.

The 12 Gaps and Barriers were analysed in detail as part of a desk-based research programme using the most recent literature reviews and reports. Additionally, targeted interviews were carried out with a spectrum of commercialisation actors including industry, funding and innovation agencies and entrepreneurs experienced in the technology transfer and commercialisation process. In total, 61 issues were identified as hampering the Idea-to-Market process. A prioritizing procedure selected the issues (and actions) that were taken forward to produce project roadmaps.

The prioritizing process resulted in ***seven issues*** *classified as* ***in need of actions***. For four of them, roadmaps were generated: *eHealth taxonomy*; *Education and training*; *Clinical trials* and *Adoption space and Human Factors Engineering (HFE).*
For the remaining three issues a roadmap was not considered necessary as these are already included in the Medical Device Directive Reform (MDR). These are: *Health Technology Assessment, Post-market surveillance and Regulatory process.*

The roadmaps and action plans can be downloaded at: www.itech-project.eu

Figure 3 summarizes the process from the 12 Gaps and Barriers to the issues making up the ITECH Roadmap.

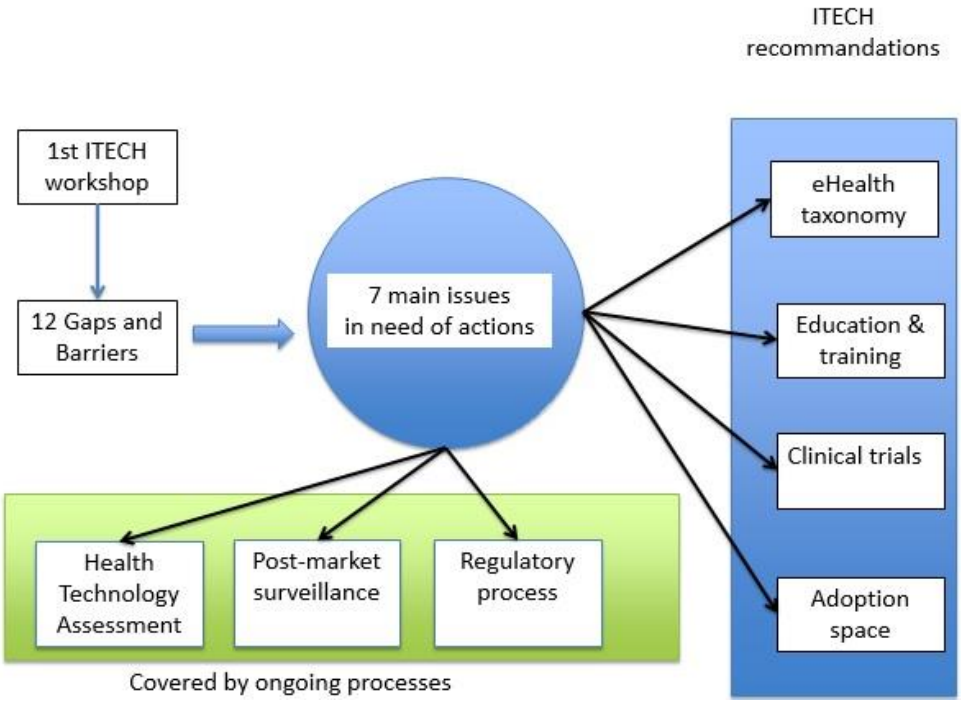

Figure 3: The process from the Gaps and Barriers to the issues that will be roadmapped.

The ITECH recommendations

1. From **IDEA** to market: **importance of nomenclatures and classifications**.

There are currently more than 200,000 Medical Devices available in Europe. It seems obvious that all these devices have to be correctly identified and registered in a common database.

That is why ITECH supports current efforts aimed at identifying, in a unique manner, the Medical Devices through the work of GMDN and **recommends** that the European Commission support the creation of a European Board to propose a first **classification of eHealth**, under the form of a taxonomy, usable by academics, developers, and industrials. This Board will associate scientific societies (as EFMI, IMIA) and industrial representatives, to build this first classification of eHealth.

2. From **IDEA** to market: **importance of education and training for all the parties**.

Most of the researchers, trainees and industrials working in the domain of Medical Devices and eHealth are not aware of the extent and complexity of the knowledge necessary to push an idea to market: regulations, industrial property rights, technology transfer, industrialization, commercialization, clinical trials etc.

ITECH **recommends** developing harmonized courses within European Universities to offer accreditation of competences and map specific knowledge to the different educational levels in order to bridge the existing gap between the professionals graduating from universities into industry; adopt an evidence-based approach; progress from mature knowledge to more innovative knowledge.

3. From Idea to **MARKET**: **The importance of comparative clinical trials**.

The “access to market” requires decision makers, buyers, physicians, healthcare professionals, and, more frequently, patients to be convinced of the benefits of the device or the eHealth application. This is best achieved through comparative, well-managed clinical trials.

ITECH **recommends** developing a methodologically guided approach to help physicians and industrials in the design, realization and interpretation of high-quality medical trials able to prove the efficacy, effectiveness, and benefits of innovative Medical Devices and e-Health applications. CE Marking and reimbursement require every increasing numbers of clinical trials creating a problem for SMEs who cannot always find the necessary funding for clinical research. **Funding support for Clinical trials of Medical Devices seems absolutely necessary**.

4. From **IDEA to MARKET**: **Adoption Space.**

The adoption of a new technology and the success of this technology in the marketplace are not obvious. The industrialization and the commercialization process should use “Adoption Space” principles that may lead to better diffusion of products into mainstream healthcare usage by addressing the most prominent issues that emerged from our research work. It is difficult to know which innovation leads to a real application sold on the healthcare market. This may depend on attributes like technical quality, human factors, specific timing or socio-technical factors. However, it is clear that we need better interaction between actors, a more flexible approach to monitoring progression and more appropriate involvement of all key stakeholders in the commercialization cycle.

ITECH, therefore, **recommends** developing the commercialisation pathway to include recent research with reference to the principles identified in the concept of adoption space; to enhance the collaboration with and between Usability labs and Living labs to encourage a deeper integration and sharing of technology and expertise across Europe; to develop an information HUB allowing information sharing of all the parties (researchers, academics, developers, industrials, experts) and permitting the connection and collaboration between different European partners.