SEVENTH FRAMEWORK PROGRAMME

THEME : HEALTH.2013.4.1-4

Roadmap for Research and innovation in Health Technologies

Grant agreement n°602667

Summary of ITECH's Results

Prepared for the attendees of the *"Speeding up the development of Innovative Health Technologies, Closure event of the ITECH project"* January 27th, 2016 in Brussels.

20.1.2016

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FOREWORD

The purpose of this brief report is to provide information to the attendees of the *"Speeding up the development of Innovative Health Technologies, Closure event of the ITECH project"* January 27th, 2016 in Brussels of ITECH's main results and the methods used to reach these results. Its content originates from ITECH deliverables (especially D2.4 and D3.3).

ITECH contributes to the need of a Pan-European strategy for the optimisation of the uptake of research and innovation in the field of Health Technologies. It focuses in the fields of Medical Devices and eHealth applications. ITECH has carried out an extensive information gathering activity with the support of ITECH's Contact Nodes to identify and quantify existing national, regional and private funding instruments supporting Research & Innovation in Health Technologies. To guide the data collection and its analysis a 5-phase model describing the steps in transforming a scientific idea into a commercialized product (Idea-to-Market process) was created. During the 1st ITECH Workshop in October 2014, an analysis of the collected data was discussed resulting in the identification of 12 Gaps and Barriers in the Idea-to-Market process in Europe. After that a detailed analysis of the Gaps and Barriers by review of on-going activities, relevant literature and reports, and by selected interviews with key stakeholders and actors operating in the domain was carried out. Based on this a roadmapping exercise has been carried out to identify the issues and actions that are needed to optimize the uptake of research and innovation in the field of Health Technologies.

This resulted in *seven (7) issues in need of actions.* For four (4) of these roadmaps have been generated. These are:

- *eHealth taxonomy* as there is no widely accepted taxonomy for this innovative growth area;
- *Education and training* as that is the prerequisite for successful projects in Health Technologies; and
- *Clinical trials* as in addition to products being safe they must also be effective.
- *Adoption space and Human Factors Engineering (HFE)* as the pathway from idea to market is complex and the development process needs to be focused on identified user needs;

For the remaining three (3) issues a roadmap was not considered necessary as these issues are already included into the Medical Device Directive Reform (MDR). These are:

- *Health Technology Assessment,*
- *Post-market surveillance and*
- *Regulatory process.*

1 ITECH MODEL OF THE IDEA-TO-MARKET PROCESS

The ITECH model has been defined to capture the idea to market process in the field of health technologies and has been mapped to the TRL model, widely used in the industry sector where research and innovation are essential steps towards success.

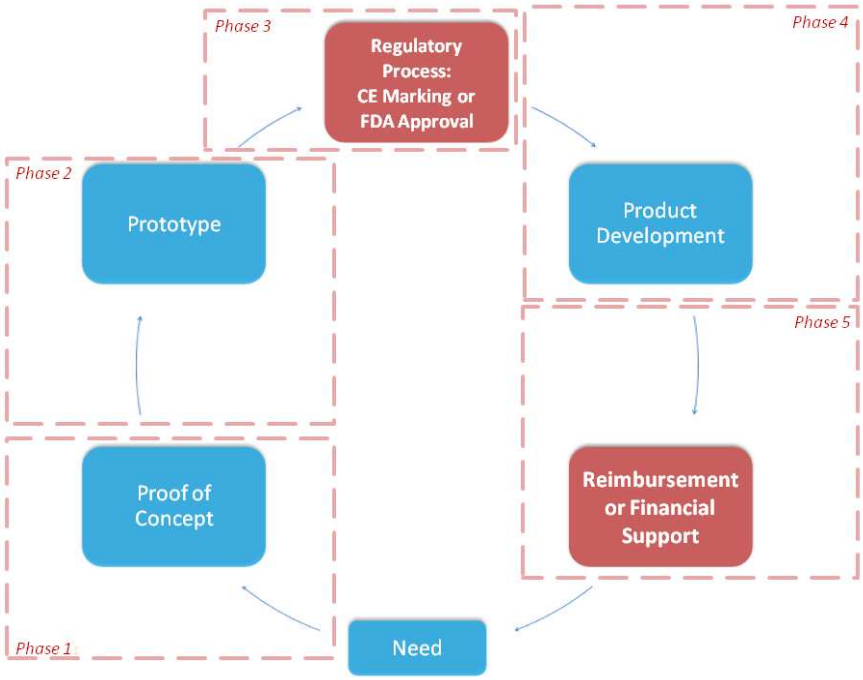

Figure 1. The ITECH Model of Idea-to-Market.

Phases 3 and 5 were acknowledged as most critical to transform a scientific idea into a commercialized product in the fields of eHealth and Medical Devices:

- The **Regulatory Process of CE Marking or FDA Approval:** certification of medical devices is a rather complex process that can delay or hinder the marketing of an R&D outcome. The last revision of the EU Medical Device Directive (MDD) 2007/47/EC has introduced additional requirements for certification and has broadened the definition of Medical Device covering categories, such as stand-alone software, not previously requiring CE marking prior to commercialization.
- The **Reimbursement** or **Financial Support**. Medical devices and eHealth services are usually prescribed by physicians or medical organizations and are then reimbursed by health insurance agencies, private or public. Reimbursement is highly regulated by public authorities and varies on a country to country basis. As a result, the development of a successful business model by a company in order to get financial support for an innovative product is a complicated, high risk task.

2 FUNDING OPPORTUNITIES

An extensive data collection process has been carried out regarding detailed funding opportunities for Health Technology in 21 European countries and Australia and Canada (Figure 2).

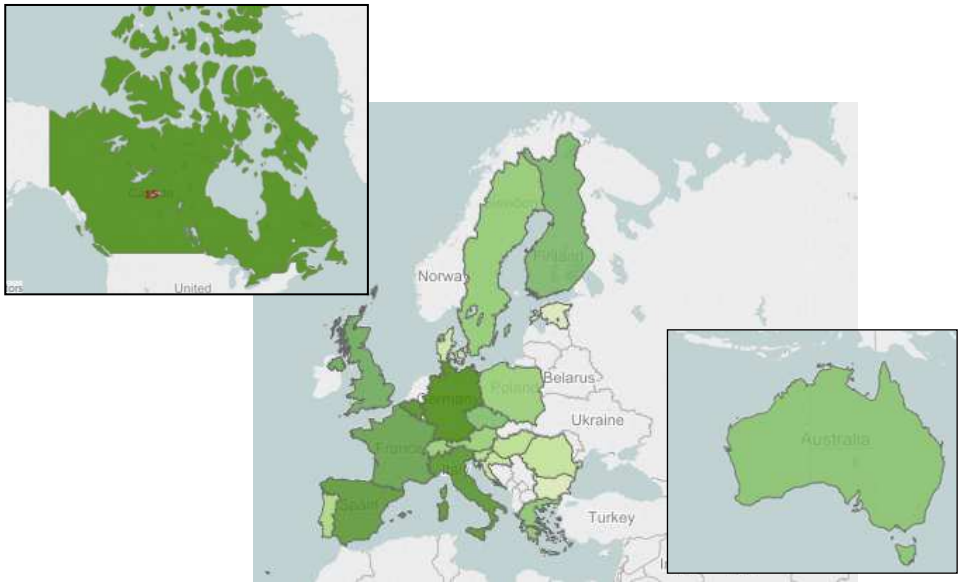

Figure 2. Map of participating countries

266 European, 14 Australian and 15 Canadian funding opportunities were identified. These have been mapped on the ITECH model to illustrate how funding is distributed among the five phases of the ITECH model (Figure 3).

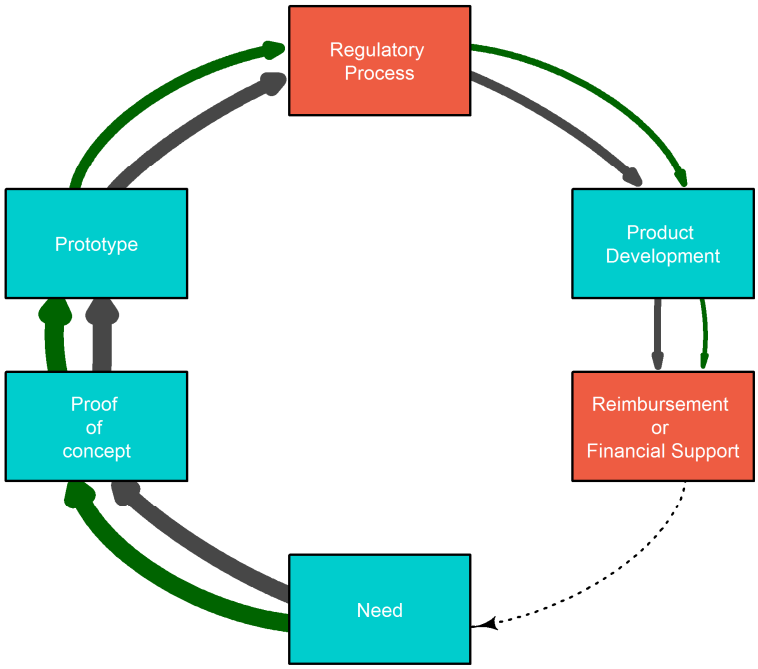

Figure 3. Funding support per phase in Europe, following the ITECH model (Black arrows are proportional to the number of funding bodies per phase. Green arrows are proportional to the mean amount of money available in each phase for one project).

The graphs above show significant decrease in funding opportunities and the corresponding decrease in the sum of money each phase receives, following the ITECH model (Figure 3), as well as the actual number of funding opportunities and sum of funding per project each phase receives, following the TRL system, mapped to the ITECH model (Figure 4).

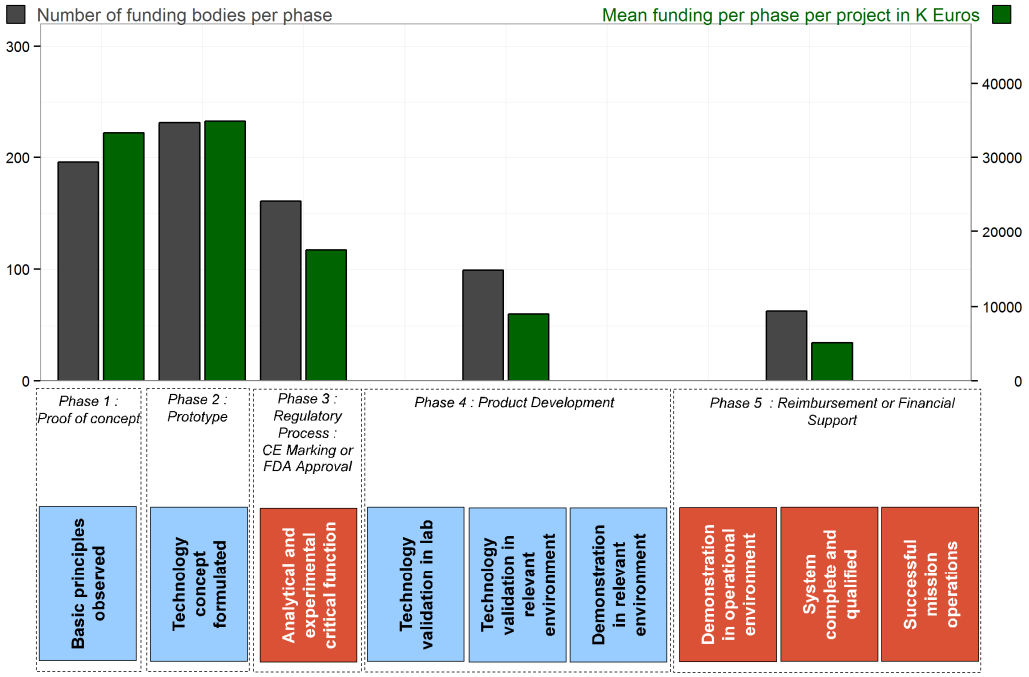

Figure 4. Funding support per phase in Europe, following the TRL model.

Our findings indicate that funding is not uniformly spread throughout all the phases of the ITECH model. The first two phases concerning research focused activities seem to receive higher support than the three following phases, namely Regulatory Processes, Product Development and Reimbursement. There seem to be barriers in activities such as clinical evaluation, CE marking and IPR.

All countries have at least one funding body supporting phases 1 and 2, namely proof of concept and prototype development. In the following phases (i.e. phases 3-5) the number of countries with at least one funding body supporting each phase decreases, leaving only 15 out of the 21 European countries providing funding support in phase 5.

Furthermore, 52 case stories were collected describing projects that either progressed or not, to commercialization.

3 GAPS AND BARRIERS

The 1st ITECH Workshop in October 2014 discussed the ITECH model and the funding opportunities and resulted in the identification of *12 Gaps and Barriers* in the Idea-to-Market process of Health Technologies (Table 1).

Table 1. Gaps and Barriers.

GAP 1: Lack of common and well shared definitions and classifications of Medical Devices and eHealth	• There is no unique and unified international classification (although efforts have been underway for some years). • It is difficult to identify which Health Technologies are implemented in different research projects; and which technologies are used for the diagnosis, treatment, management and surveillance of different diseases.
GAP 2: Limited calls for projects on Healthcare Technologies	• Calls are often generic or directed towards the management of medical diseases and not specifically oriented towards Heath Technologies. • Limited coordination between funding agencies • SMEs (and particularly the smallest ones) have limited human resources, are not aware of all existing facilities offered and prefer to concentrate on their immediate needs. Targeted calls for SMEs involved in Health Technologies need to be continued and strengthened in HDW work programs for 2016-17. • Lack of information on the global amount and budget for research in Health Technologies
GAP 3: Limited number of multidisciplinary projects	• Health Technologies are multi-disciplinary and necessitate the collaboration of different teams. Given the complexities associated with a multi-disciplinary project, further and significant consideration must be done to ensure that evaluators and industrials have the necessary and specific expertise to ensure every part of the project is properly assessed.
GAP 4: Regulation: lack of knowledge, lack of experts, differences between countries	• Regulations are different from one field of Health Technology to another (e.g. concerning risk classification and implementation of regulations). • Different approaches and interpretations amongst certified bodies that participate into the CE Marking process • There is a lack of experts capable to undertaking the requirements of the very complex standards applied to Health Technologies.
GAP 5: Problems with patents and intellectual property rights	• The cost of the patenting or IPR procedure is important for both academic institutions and SMEs, and is even much higher when patents need to be defended. Besides the money-back issue for public institutions, other criteria should be considered such as long-term effects (employment, taxes paid, leverage effect).
GAP 6: Limited regard of applied and translational research on the evaluation of researchers and academics	• For academics and researchers, their evaluation criteria need to include applied translational research and entrepreneurship.

GAP 7: Difficulties on Technology Transfer	• Organizations that support technology transfer activities in a variety of ways do exist but academics and industrial companies often suffer from a paucity of certain information which would ensure successful and rapid transfer of technology such as:
	  ◦ Lack of information on mentoring facilities
	  ◦ Guidelines on "how to conduct technology transfer"
	  ◦ Support and knowledge of good practices

GAP 8: Delayed involvement of industries in the process	• Technology transfer occurs late in prototype/product development • There are difficulties for accessing funding of prototypes, to develop business plans and to perform market studies and post

	market studies.
GAP 9: Methodological difficulties and limited funds for clinical trials on Healthcare Technologies	• The methodology of clinical trials for Health Technologies is different from those in pharmaceutical trials and necessitate specific competencies. • The industrial companies are mostly SMEs or VSMEs and support with difficulty the cost of randomized multi-centre clinical trials.
GAP 10: Difficulties in obtaining reimbursement	• Rules and procedures differ from country to country • Lack of transparency on the necessary requirements for obtaining a decision of reimbursement • SMEs do not have a clear understanding of the reimbursement process
GAP 11: Lack of education	• In educational curriculums (M.Sc., MD, PhD, etc.), engineers, researchers and healthcare professionals interested in the domain of Health Technologies should be trained in all aspects of the Idea-to-Market process.
GAP 12: Recognising the importance of usability / user experience / usages / ergonomics	• Lack of awareness in stakeholders regarding the requirements for Human Factors Engineering in the regulatory process • There is no specific funding for Human Factors (HF) or usability activities for Medical Devices and eHealth. • Lack of methodological support to implement usability harmonized standard (e.g. IEC 62366).

4 ITECH'S ROADMAPPING METHODOLOGY

Roadmapping is a flexible technique used to support strategic and long term planning. It provides a structured means for exploring and communicating the relationships between e.g. evolving and developing markets, products and technologies over time. In the ITECH project, we adopted a System Transition Roadmap structure[1] (Figure 5).

The temporal dimension of the System Transition Roadmap is divided into three systemic development phases: Emergence, Diffusion and Consolidation. The content of the System transition roadmap can be understood as an action plan describing the steps required to enable the desired transition. The actions are portrayed on three levels: Landscape, Regime, and Niche.

The roadmapping process can be divided into three main phases: Scoping, Roadmap Creation and Action Plan. The purpose of the Scoping phase is to gather background information on past and ongoing activities of a similar nature, elicit views and advice from stakeholders, and finally, articulate and present options.

The Scoping phase sets boundaries for the actual Roadmap Creation phase. It involves literature reviews, interviewing experts and stakeholders, and it may also include a scoping workshop or similar activity with the most important stakeholders or sponsors of the process. This phase is iterative and includes stakeholder engagement.

[1] Auvinen, H., Ruutu, S., Tuominen, A., Ahlqvist, T., Oksanen, J. (2015) Process supporting strategic decision-making in systemic transitions. *Technological Forecasting & Social Change*, vol. 94, pp. 97-114.

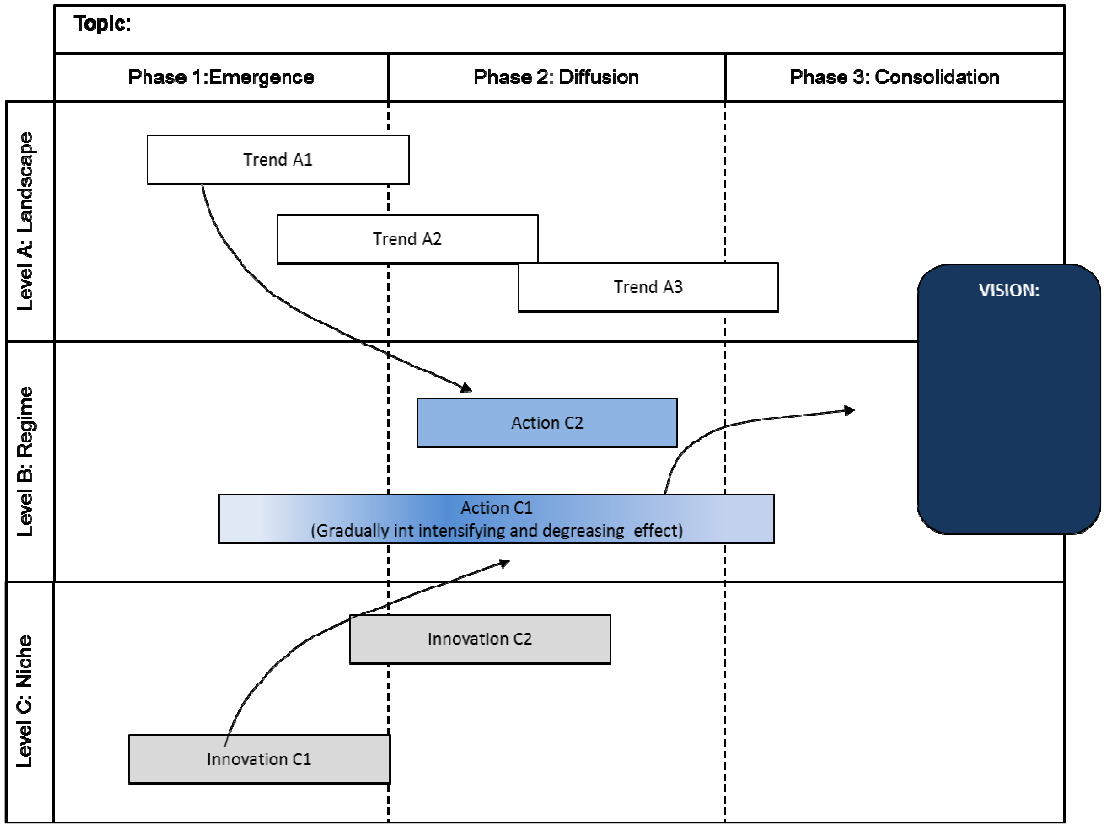

Figure 5. A generic structure of System Transition Roadmap.

5 THE SCOPING PHASE

The gaps and barriers were analysed in detail using available literature and reports. Selected 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. These included large companies along with SMEs and VSMEs in the sector and European and national industry associations. Finally two questionnaires were created and sent to the Contact Nodes, one on education and training and the other on nomenclatures and taxonomies for Medical Devices and eHealth applications. Altogether 61 issues were identified that are hampering the Idea-to-Market process.

Table 2. Prioritizing matrix.

	Short time to make an impact	*Long time to make an impact*
High Relevance	Priority 1: Short term impact	Priority 2: Long term impact
Low Relevance	Priority 3: Possibly	Priority 4: No action

A workshop was organized to rank the 61 issues into four priority groups based upon two criteria: Relevance and Response time (Table 2). Relevance was evaluated against the ITECH goals, i.e. the acceleration of the Idea-to-Market process of Health Technologies and increasing the capabilities of academic R&D teams and health technology companies to carry

out this process. Response time refers to the time required to make an impact on the above mentioned goals.

Priority groups 1 and 2 contain the highly relevant issues. Priority group 3 contains those issues that are determined to have a higher impact uncertainty or low relevance profile demanding more careful assessment. Group 4 comprises of issues that were considered to be inappropriate or irrelevant in the context of the ITECH project.

The last part in the scoping phase was to use the results of the prioritizing workshop to select the issues (and actions) that will be roadmapped. Figure 6 summarizes the scoping process from the 12 Gaps and Barriers to the issues making up the ITECH Roadmap.

This resulted in *seven (7) issues in need of actions.* For four (4) of these roadmaps have been generated. These are:

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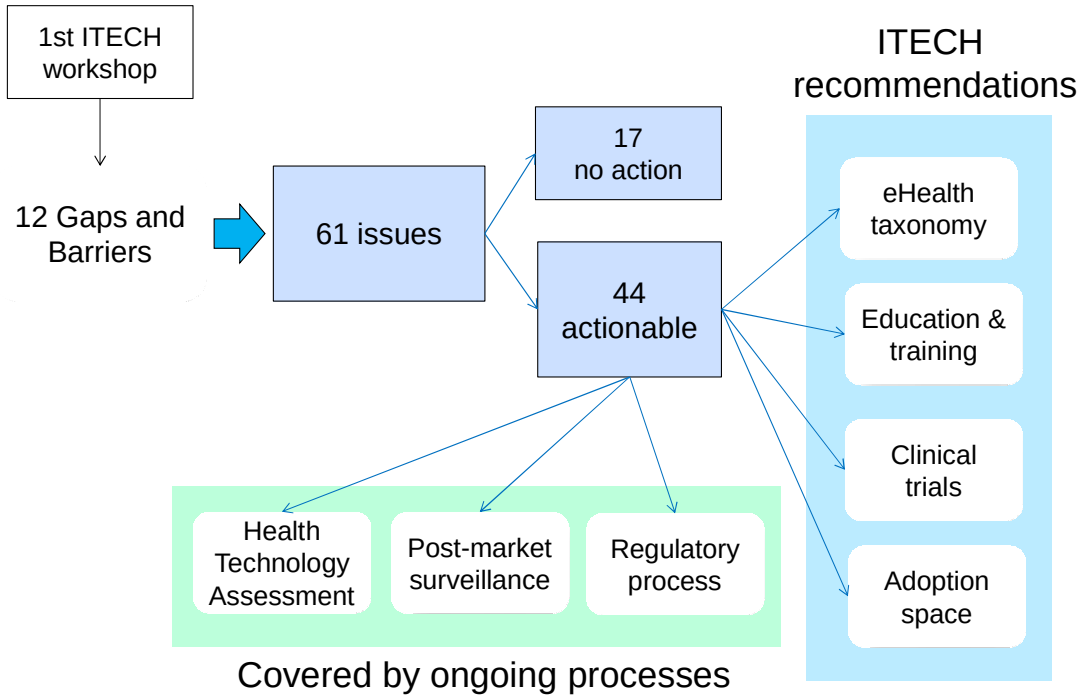

Figure 6. The process from the Gaps and Barriers to the issues that will be roadmapped.

6 SUB-ROADMAP: EHEALTH TAXONOMY

Vision: A Medical Device must be clearly and simply identifiable with a limited number of key words through all the phases of the Idea-to-Market process from the definition of the project to the definition of the system reimbursed or bought by the global population.

Recommendation	Actions or action plan	Responsible actor	Other stakeholders	Desired impacts
To develop a classification / taxonomy for eHealth that is currently not available. The classification has to be usable by both academics and industrials.	1 A task group is necessary to identify the different dimensions of eHealth applications: - technical - application domain (clinical, ambient-assisted living, Wellbeing) - users - others 2 To propose a CSA action within H2020 Programme.	European Commission	Scientific societies (e.g. EFMI*, EAMBES*, IMIA*) WHO European medical organisations Industries International experts	MDs and eHealth systems (including telehealth and personalised health) will play a major role in the diagnosis, procedures and treatments of patients. A common language and common keywords, will support the communication and collaboration between researchers, developers, industrials and stakeholders; improving the projects' interdisciplinarity. A standard taxonomy will facilitate the categorisation of projects and assist in focusing on specific calls and funds. This will contribute to the economic growth (through funding and reimbursement process) of the domain. Classification/taxonomy effort is a continuous process open to new ideas and devices.
To continue the current efforts to organize a European Medical Devices classification (or taxonomy) that should be used by all Member States based on GMDN and UDI.	1 To standardize keywords for research, innovation, industrialisation and commercialisation. 2 To propose a simplified Medical Devices nomenclature, based on GMDN, providing keywords for an unambiguous identification of the MDs research, innovation, industrialisation and commercialisation.	European Commission	Scientific societies GMDN* WHO European medical organisations International experts Industrial organisations	
To consider a way of linking Medical Device and eHealth nomenclature with DRGs and reimbursement to facilitate a more consistent coding system.	The classification will support the integration of Health Technologies in the reimbursement phase.	WHO National Authorities	EU organisations of professionals International experts	

* EFMI = European Federation for Medical Informatics
* IMIA = International Medical Information Association
* EAMBES = European Alliance for Medical and Biological Engineering Sciences
* GMDN = Global Medical Device Nomenclature

7 SUB-ROADMAP: EDUCATION AND TRAINING

Vision: Education and training in all steps of the Idea-to-Market process of Health Technologies is available in Europe to individuals participating in the development of an idea to a commercialized product.

Recommendation	Actions or Action plan	Responsible actor	Other stakeholders	(Desired) Impacts
In educational curricula (MSc., MD, PhD, etc.), engineers, researchers and healthcare professionals interested in the domain of Healthcare Technologies should receive specific training during their study courses in what is required to comply with all aspects encountered in the Idea-to-Market process; such as regulatory requirements, industrial property rights, HTA, managing clinical trials, as well as the technology transfer process both in Europe and globally. In addition to specialised courses, should be offered placement/ internships/ fellowships within principal EU associations and/or industry.	Set up a working group with representatives of the responsible actors to explore the possibility of a European curriculum based on eLearning or a MOOC, which will also offer accreditation for professional competence. Create a HUB with a pool of courses. Use platforms for wide educational possibilities such as the Google Scholar in collaboration with this HUB.	Academia, the Commission, Industry and Scientific societies to map specific knowledge qualifications to different educational levels and provide 'qualifications'	European Commission Professional organisations EAMBES to help with preparation of curricula IMIA recommendations on education on medical informatics	Common training in all aspects of the Idea-to-Market process to support communication/ collaboration between researchers, developers, industrials and stakeholders, eventually bridging the existing gap between professionals getting out from universities to industry. Increase the likelihood of multi-disciplinary schemas with high added value at the innovation axis Understanding the meaning of the TRLs from the industry and product developers

8 SUB-ROADMAP: CLINICAL TRIALS

Vision: Create a culture of clinical evaluation, both quantitative and qualitative of Medical Devices and e-Health applications.

Recommendation	Actions or action plan	Responsible actor	Other stakeholders	Desired impacts
For Medical Devices To make researchers, developers, academics, industrials, pharmacists, hospitals professionals, aware of the different steps conducting first from a prototype to a CE marked product then from a CE marked product to a reimbursed product.	1 To provide a methodological guidance for the clinical evaluation of Medical Devices, including: - regulation of clinical trials - methodologies of clinical trials - management of confidentiality and security of medical records. - bio statistical analysis - clinical trials for CE marking - clinical trials for Reimbursement 2 Consideration should be given to methodologies that facilitate the harmonisation of clinical trial procedures across Europe. 3 To identify centralised facilities and to create a database for evaluation studies which could be used as a harmonisation vehicle to improve the communication practices and strategies (between payers, providers and manufacturers)	EAMBES, scientific societies, COCIR, EUCOMED, ECRIN Academics, Industry, companies Policy makers Health care managers	Pharmacists, Clinical organisations, Clinical trial portals	As in other domains of medicine, the use of Medical Devices and eHealth must become evidence-based. This will contribute to a safer usage of Health Technologies improving the quality of care and participation and empowerment of patients. To make difference between Health care and Wellbeing To make a link with Health Technology Assessment
For eHealth To build a new methodology to evaluate eHealth systems (including mobile and personal Health) To identify which eHealth systems must obtain CE Marking To identify necessary clinical trials for reimbursement To evaluate the "general public" products sold for welfare, wellbeing and better health.	1 To provide a methodological guidance for the clinical evaluation of e-Health including: - regulation of clinical trials - methodologies of clinical trials - management of confidentiality and security of medical records. - bio statistical analysis - clinical trials for CE marking when necessary clinical trials for reimbursement when possible - clinical trials for clinical evaluation of a "general public" market - HFE aspects (Usability and Usage) 2To create a database of evaluation studies	Big companies working in this sector (Orange, SFR, Google, Biotronik, Medtronic, Sorin…) Regional and National platforms National agencies Universities – research organisations Scientific societies ECRIN	Patient organisations Professional and clinical organisations Scientific societies Wellbeing Sport federations (which have a "health leitmotiv")	
To increase the number and quality of clinical trials in Health Technologies	1 Delineation of well-defined funding sources to cover the large research costs on evidence development on Health Technologies. 2 Funding support to help SMEs in the development of their products.	European commission Member states Industry	Academics Start-ups/Industries Research organisations Hospitals	

9 SUB-ROADMAP: ADOPTION SPACE AND HFE

Vision: An inclusive systematic commercialisation process that accelerates the successful adoption of Medical Devices and eHealth applications into mainstream healthcare.

Recommendation	Actions or Action plan	Responsible actor	Other stakeholders	(Desired) Impacts
For Medical Device and eHealth technologies, refocus the commercialisation pathway so as to maximise adoption into mainstream healthcare.	Fund a proposal to consider/validate Adoption Space principles for their application to the Medical Device and eHealth domains;	European Commission; Government Bodies; Relevant Funding Bodies; Researchers	Professional and Commercial Associations; Industry; HTA and EBM Associations	Provides validation (or otherwise) of Adoption Space principles when applied to the Medical Device and e-Health Domains Provides an enhanced process based upon empirical evidence; Within the commercialisation process introduces more appropriate decision-making and engagement through the inclusion of decision-making points (Gates) at appropriate location;
Develop an effective communication platform to network all actors in the Medical Device and eHealth Idea-to-Market process.	Fund the creation of a flexible and expandable electronic HUB to include the following attributes: • A Database of Medical Device and eHealth projects; • Structured to operate at a variety of levels including International, National, Regional and local and organised in a domain specific manner; • Provide a reservoir for case-based studies.	Industry Associations; Academia;	European Commission; Governments; Regional Development Agencies; Professional and Trade Associations.	Operates as a decision tool to interrogate processes and progress providing adaptive feedback for changing User Requirements; Provides opportunity for further intervention studies using case-based data; Facilitates a specific interconnection between and across artisans; Provides a data repository for case studies and user/reviewer experiences; Enables signposting throughout the commercialisation pathway; Offers a platform to enable artisans to critically evaluate research, policy and procedures on a regular basis to inform future decision-making; Supports the possibility of regular conference/workshops to present latest results, policy developments and procedures