PROJECT FINAL REPORT

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4.1Final publishable summary report

1. Executive Summary

Europe has a strong and enviable reputation for its excellent in science and innovation but, sadly, it has not been equally successful in translating scientific outcomes into commercially successful companies in spite of the significant investment by European and national agencies over many decades in supporting the translational processes. The process used to transform a scientific idea into a commercialised product (the *Idea-to-Market* process) can be highly complex, particularly in the field of health technologies, where a large number of actors and stakeholders are involved. The ITECH project was launched to propose recommendations which would accelerate the *Idea-to-Market* process associated with health technologies. The overall goal was to initiate procedures which would lead to improvements in the effectiveness and competitiveness of the European health technology industry on the global markets. To achieve the overall goal, the project set out the following objectives:

- To build and validate a model describing the phases associated with the *Idea-to-Market* process;
- To map existing national and European instruments supporting research & innovation and the *Idea-to-Market* strategy identifying the similarities and dissimilarities between countries
- To identify currently existing gaps and barriers;
- To propose solutions to overcome the identified gaps and barriers;
- To make recommendations for improvements;
- To create and network of artisans and to widely disseminate our finding, recommendations and associated action plans.

In order to achieve the objectives, the project went through the following steps: (a) definition of the *Idea-to-Market* model; (b) collection and analysis of funding opportunities; (c) identification of 12 gaps and barriers in the *Idea-to-Market* process; (d) detailed analysis of the above supported by interviews; (e) a prioritisation process to select the most important issues; (f) construction of roadmaps for the prioritized issues; and, finally, (g) generating recommendations and action plans. Based on the ITECH model, and restricting ourselves to information related to the domains of medical devices (MDs) and eHealth, we collected data on funding instruments and on the success and failures experienced by researchers in the translational process. From these data, seven issues were identified as requiring action to satisfy the project goals. Three of these are part of the ongoing Medical Device Directive Reform (MDR), namely health technology assessment, post-market surveillance and regulatory process, and therefore were not addressed within the scope of the ITECH project. For the remaining four issues, recommendations were made for eHealth taxonomy; Education and training; Clinical trials and Adoption Space (including Human Factors Engineering (HFE)).

Keywords. Idea-to-market, eHealth, medical devices, innovation, research & development, user requirements, adoption space, transition management, taxonomy, GMDN, regulatory requirements, CE marking, education and training, clinical trials, health technology assessment.

2. Summary Description of Project Context and Deliverables

Health technologies and pharmaceutical products are essential tools in the delivery of modern medicine and health services. They allow people to live longer, healthier and more productive lives. The industry is fuelled by SMEs and start-ups, providing high quality jobs and economic growth. In Europe[1], the market size of health technologies is estimated at roughly €100 billion while Europe represents about 30% of the global market. It comprises some 25,000 companies, of which 95% are SMEs, and it employs some 575,000 people. In 2013, Europe had a positive Health Technologies trade balance of €14 billion.

A central objective for Europe – which rests on strong academic research, a number of world-leading companies and a large number of SMEs – is to improve its performance in the commercialisation of innovative Health Technology products. The progress of an idea to the market (*Idea-to-Market* process) takes place within a framework that operates according to a set procedures. The procedures comprise, for instance, of a number of mandatory requirements considered necessary for market entry and consideration of what support (financial and other) is available under what conditions. Innovation and technology development are results of a complex set of relationships among actors in the system, which includes individuals, enterprises, universities and government research institutes. The European Union, national governments and regions play the role of coordinators with their policy and funding instruments.

In the case of health technologies at least two kinds of strategic capabilities are required:

1. In order to excel in the market place, ideas have to be at the forefront of technological progress while providing solutions to identified user needs (culture of swiftness or 'doing the right thing') and
2. To progress from an idea to a product compliant with a number of regulatory requirements (such as CE marking, FDA approval and reimbursement) at different points in the product development lifecycle is mandatory (culture of inertia or 'doing the thing right').

Furthermore, the current regulations are being overhauled in a process known as the Medical Device Directive Reform (MDR). Parallel to this, discussions are on-going on whether the use of health technology assessment (HTA) to evaluate the cost-effectiveness of health technologies is required.

The ITECH project[2] was launched in response to the conditions outlined above with the goal of proposing recommendations which would accelerate the *Idea-to-Market* process of health technologies, particularly in the domains of medical devices (MDs) and eHealth. To achieve the goal, the seven operational objectives as given below:

[1] www.medtecheurope.org/publications/133/64/Dynamic-infographics-Value-of-our-industry.

[2] ITECH (Roadmap for Research and Innovation in Health Technology) was a support action funded in FP7 from 2013-16.

- To build and validate a model describing the phases associated with the *Idea-to-Market* process;
- To map existing national and European instruments supporting research & innovation and the *Idea-to-Market* strategy;
- To identify the similarities and dissimilarities between countries;
- To identify currently existing gaps and barriers;
- To propose solutions to overcome the identified gaps and barriers;
- To make recommendations for improvements;
- To create and network of artisans and to widely disseminate our finding, recommendations and associated action plans.

Beginning with the specific Need associated with the *Idea-to-Market* process, ITECH defined a commercialisation model consisting of the five distinct phases as shown below in Figure 2.1. We further identified eight essential activities operating within and across the phases including: *Research (*entailing different aspects within each phase, such as: *basic research, applied research, translational research and pre-clinical studies); Technical Development; Technical Evaluation; User Experience; Clinical Evaluation; Patenting/IPR; Business Intelligence; Education.*

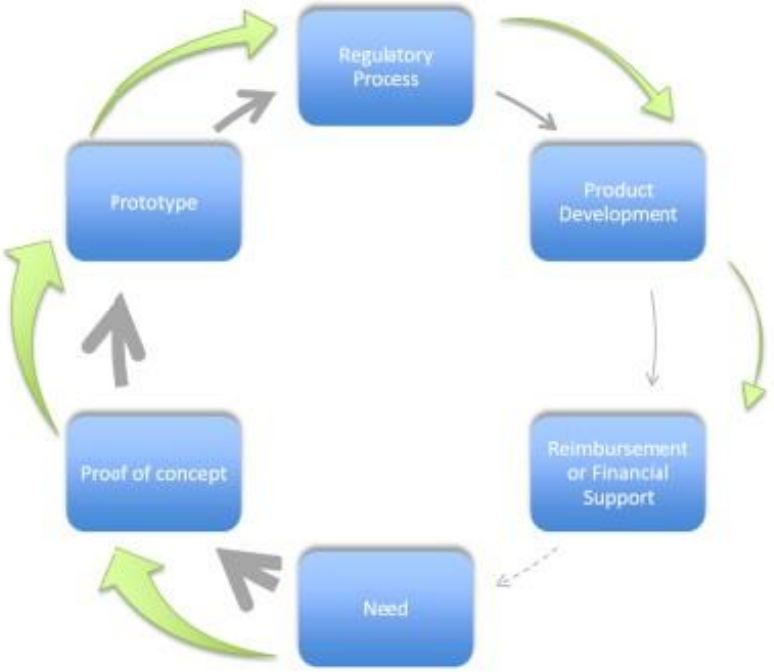


Figure 2.1: Funding support per phase in Europe, following the ITECH model (Black arrows are proportional to the number of funding bodies per phase. Green arrows are proportional to the mean amount of money available in each phase for one project).

For successful commercialisation all phases and activities must be properly resourced and finance plays a significant part at each stage in the process. Our research found that research-related activities appear to receive higher support from funding agencies while other critical phases including regulatory processes leading to CE Marking and Reimbursement or Financial Support are poorly supported in comparison as Figure 2.1 illustrates. It turned out that two of the phases, Regulatory Process and Reimbursement, while assessed as being critical in the transformational

process of a scientific idea into a commercialized product in the fields of eHealth and Medical Devices, had, proportionally, much less financial and other support than other key areas.

To ensure a full extensive data collection we generated a questionnaire and circulated it to 47 experts from across Europe, Australia and Canada. The responses provided[3] information on funding opportunities in different countries along with indications of success/failure experiences of the experts in the commercialization of health technology products and services. The experts attended ITECH's 1st Workshop, held in Brussels, for an in-depth analysis of these data and assisted the ITECH Consortium to identify a number of gaps and barriers to an efficient *Idea-to-Market* process.

These are listed below in Table 2.1.

Table 2.1 List of identified Gaps and Barriers

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

The findings that emerged from the 1st Workshop were further considered by an additional, and specifically selected, group of experts across a wide spectrum of commercialisation actors including industry, funding and innovation agencies and entrepreneurs experienced in the technology transfer and commercialisation process

[3] Full details can be found in Deliverable D2.2

for health technologies. The resulting comments, along with further research in the form of a desk-based research programme using the most recent literature reviews and reports, were analysed to produce a set of 61 significant issues which were identified as needing to be addressed in order to make the *Idea-to-Market* process more effective. The 61 issues were mapped into 7 ITECH Recommendation categories through a prioritising procedure to represent the most important issues (and actions) to further analyse and take forward to produce project roadmaps. Figure 2.2 summarizes the procedure followed in developing the 12 gaps and barriers into the issues making up the ITECH Roadmaps with the recommendations and action detailed in section 3.

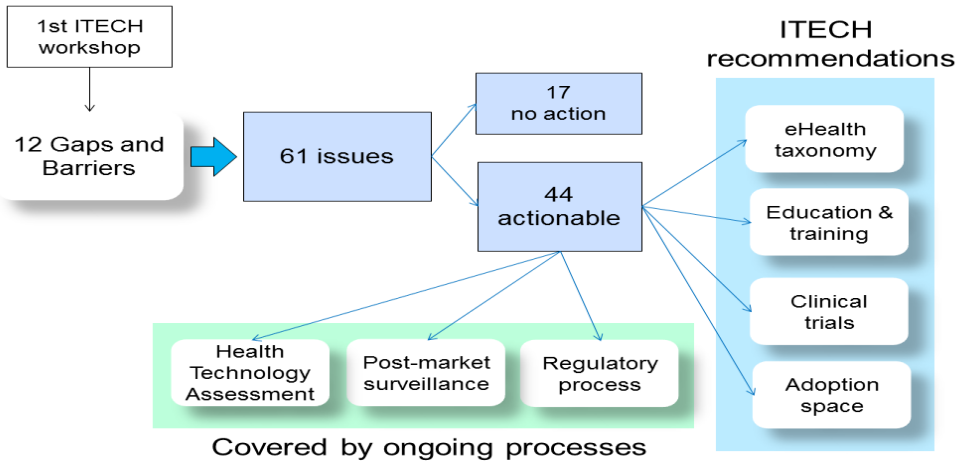


Figure 2.2: Prioritising Procedure used to develop Roadmaps

Of the seven recommendation categories, three are part of the on-going Medical Device Directive Reform (MDR), namely *health technology assessment*, *post-market surveillance and regulatory process*, and therefore, to avoid duplication, were not addressed within the scope of the ITECH project. For the remaining four categories, specific recommendations and actions were developed with the overall aim of accelerating the Idea-to-Market process based upon users' needs. The four categories include:

Clinical trials: with the intention to create a culture of clinical evaluation, both quantitative and qualitative, of Health Technologies;

eHealth taxonomy: arguing that Health Technologies 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 final version of the product;

Education and Training: with the aim of making relevant education and training in all steps of the *Idea-to-Market* process of Health Technologies available in Europe to individuals participating in the development of an idea to a commercialized product;

Adoption Space & HFE: identifying the difficulties associated with the diffusion products and devices in mainstream usage a new and unified systematic process based on Adoption Space principles is required that may accelerate the successful uptake of Health Technologies into mainstream healthcare.

3. ITECH Results

3.1. Introduction

The ITECH project contributes to two major EU initiatives:

- The European-wide strategic plan for Health Technologies with an objective of contributing to the Horizon 2020 Common EU Strategic Framework for Research and Innovation as outlined in the Europe 2020[4] strategy; and,
- The Innovation Union[5] flagship initiative, focusing on the grand societal challenge.

Specifically, it considers the relatively poor European performance in translating scientific research and outcomes in commercially realizable products and services; the, so called, *Idea-to-Market* process. Within the domain of medical devices and eHealth technologies, the ITECH project was launched to identify gaps and barriers in the *Idea-to-Market* process with the overall goal of making recommendations which would lead to improvements the effectiveness and competitiveness of the European health technology industry on the global markets.

The essential research question asked by the Project was: *"What is the best strategy to adopt so that strong research can be successfully translated into Health Technology products and services"?*

To address the research question several operational objectives were developed:

- To build and validate a model describing the phases associated with the *Idea-to-Market* process;
- To map existing national and European instruments supporting research & innovation and the *Idea-to-Market* strategy identifying the similarities and dissimilarities between countries;
- To identify extant gaps and barriers currently existing;
- To propose solutions to overcome the identified gaps and barriers;
- To make recommendations for improvements;
- To widely disseminate our finding, recommendations and associated action plans.

The ITECH project achieved these goals through a number of key actions including:

- Enrolment of experts in the domain willing to contribute to the description and optimisation of the *Idea-to-Market* process for Health Technologies in their own countries and at the European level;
- Extensive coverage of European countries;
- Commitment of major scientific/industry organisations of the domain to support the initiative;

[4] Europe 2020. A strategy for smart, sustainable and inclusive growth. COM (2010) 2020
[5] Europe 2020 Flagship Initiative Innovation Union. COM (2010)

- Commitment of a number of national / international networks already working on the description / optimization of the *Idea-to-Market* process of Health Technologies, or of significant segments of this process;
- Design of a proper and efficient methodology to coordinate the experts from all countries in order to:
    - collect, analyse and formalize the knowledge on the state of affairs of this process in European countries,
    - foster constructive and innovative ideas to harmonize and optimize this process at a European level,
    - elaborate distinct communication strategies to reach each targeted stakeholder.

To meet these challenges, experts from 21 European countries were recruited by the Project PI, INSERM. All experts, hereafter referred to as "contact nodes", agreed to actively participate in the project and to contribute *pro bono*. Similarly, the commitment of the European Alliance for Biomedical Engineering and Science (EAMBES) and of the European Clinical Infrastructures Network (ECRIN) committed[6] along with other national and internationally relevant networks to the project.

3.2. The ITECH Model

In order to map the *Idea-to-Market* process ITECH defined the model shown in Figure 3.1 to highlight all the phases and outcomes that are necessary to transform a scientific idea into a commercialised product and identify the evolutions already in-progress. By way of definition, this model describes three attributes; outcomes, phases and activities as follows:

- An *outcome* is defined as the end result of a phase, the consequence of the activities within each phase, setting the termination of the phase. An *outcome* is a result that can be identified for itself, by a paper, a document, a device or software at any stage of development
- A *phase* is defined as a period of time leading from one outcome to another, during which several activities take place to produce the results defined as the outcome.
- *Activities* are defined as the generic processes which operate within each phase. They could be supported by a funding body for a phase to be implemented and an outcome produced.

The model's starting point is when professionals, patients, or healthcare organisations come up with an idea and identify a particular Need and these requirements are delivered to the following *phases*. Each *phase* in the ITECH model produces an *outcome*.

The ITECH model defines five (5) *outcomes*:

[6] http://www.semantichealthnet.eu/

- Proof of Concept
- Prototype
- Regulatory Process: CE Marking and/or FDA Approval
- Industrial Development
- Reimbursement and Commercialisation.

As shown in Figure 3.1, the five (5) *phases* are shown leading from one outcome to another as:

- 'Need' to the 'Proof of Concept'
- 'Proof of Concept' to 'Prototype'
- 'Prototype' to the 'Regulatory Process (CE Marking or FDA Approval)'
- 'Regulatory Process (CE Marking or FDA Approval)' to 'Industrial Development'
- 'Industrial Development' to 'Reimbursement and Commercialisation"

In each *phase,* 8 *activities* can be identified with their importance varying according to the project, but some of them are present and it is essential to identify their presence within each *phase* and include: Research[7]; Technical Development; Technical Evaluation; User Experience; Clinical Evaluations; Patenting / IPR; Business Intelligence ; Education.

In the Healthcare Technology domain, it does not seem possible to identify one *phase* with one *activity,* as is proposed in many models (for example, the PIPAME Model or the TRL model). For this reason, ITECH has included the same 8 *activities* in all 5 *phases*.

[7] The term "Research" could entail different aspects within each phase, such as basic research, applied research, translational research and pre-clinical studies.

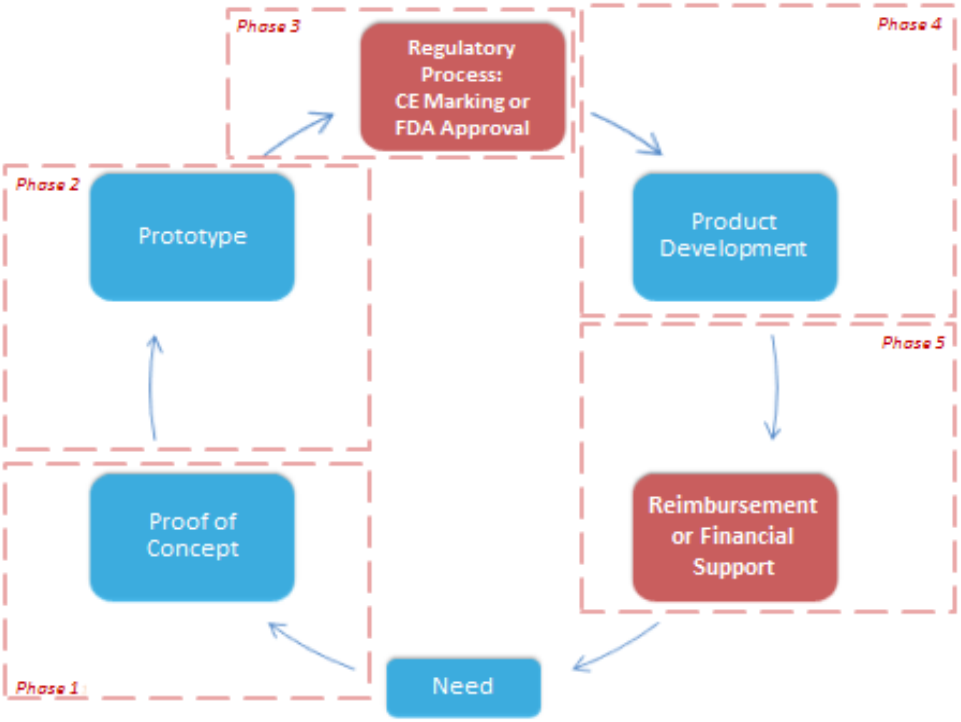


Figure 3.1: The ITECH Model

When studying the ITECH model, the *outcomes* "Regulatory Process: CE Marking or FDA Approval" and "Reimbursement or Financial Support", took on particular importance so as to be considered more significant milestones than the others for a Medical Device and/or an eHealth service.

3.3. Mapping of European Instruments

Figure 3.2 shows the extent of the ITECH data collection. In all, 21 contact nodes from European Countries plus Canada and Australia, collected data on their national, regional, public and/or private organisations, agencies or authorities that fund and/or offer validation/certification instruments in support of the *Idea-to-Market* process. We refer to these as Funding Bodies. In addition, for each country, we collected information regarding funding opportunities, as exhaustively as possible; i.e. information for each call/program for tender that is offered by a funding body.

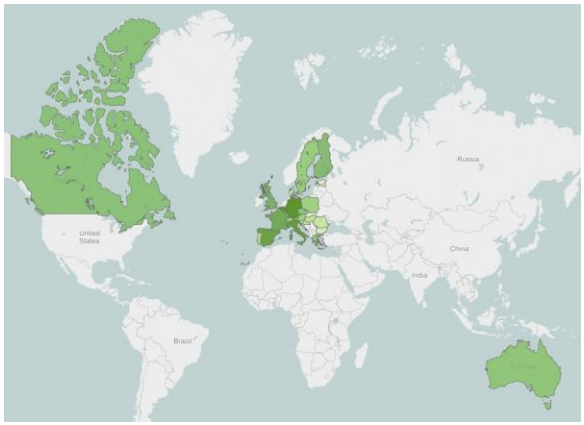


Figure 3.2 : Map of participating countries

eHealth services in Australia and Canada are widely used and developed and therefore have been chosen as the non-European partners in order to compare the European experience with the strategy of other continents. Shading in Figure 3.2 designates the number of funding opportunities per country; the darker the colour, the higher the number of funding opportunities.

The dataset consists of data for 223 distinct funding bodies, providing detailed information on 295 funding opportunities. Figures 3.3 and 3.4 show the number of funding bodies and number of funding opportunities, respectively, collected for each country on which our analysis is based upon.

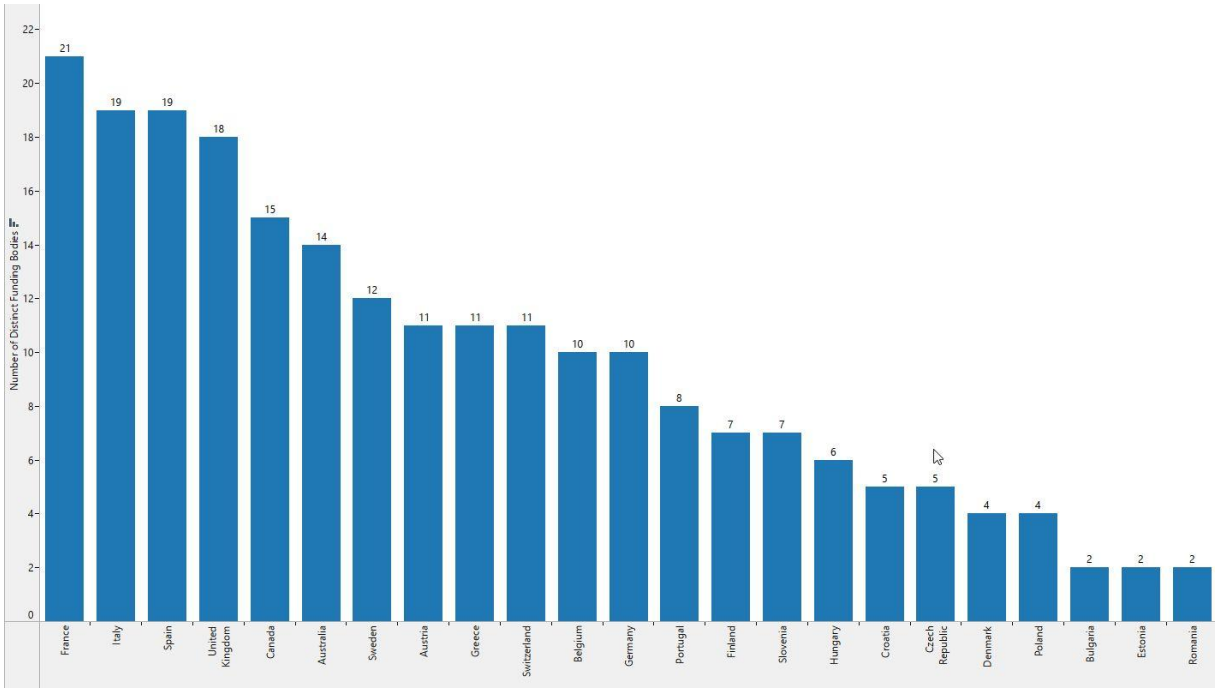


Figure 3.3: Number of Distinct Funding Bodies per country

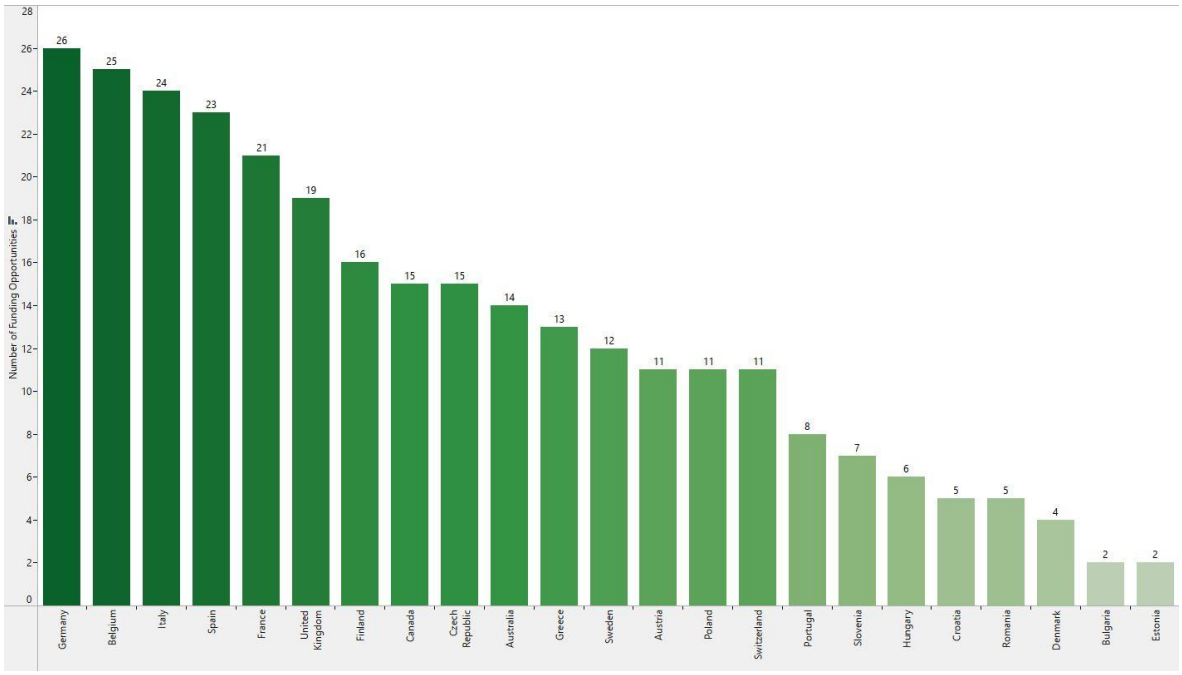
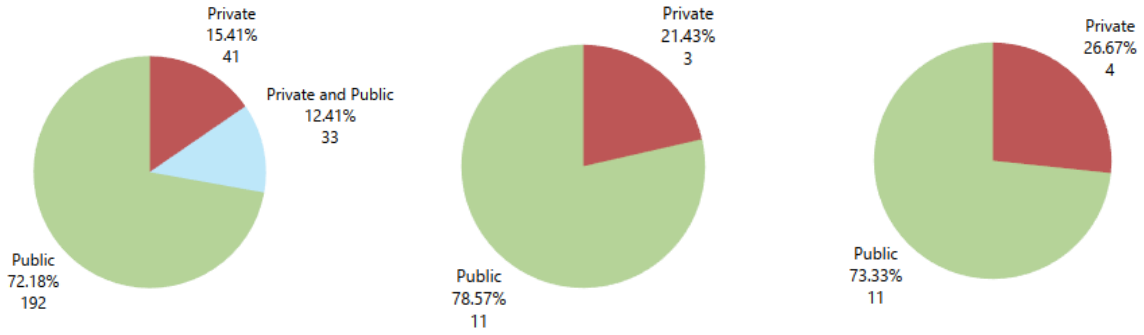


Figure 3.4: Number of Funding Opportunities per country

In total, 266 funding opportunities were identified throughout the 21 European countries. The pie charts of Figure 3.5 below present the distribution of the type of funding opportunities in Europe, together with the total number of funding opportunities within each type. The data shows that research and innovation funding in Europe is heavily supported by public funding bodies, whereas less than 16% of the funding is private. A similar pattern is also observed in the 14 funding bodies existing in Australia, where more than 75% of the funding bodies are public and over 70% of funding bodies in Canada are public.



(a) (b) (c)

Figure 3.5: Types of funding opportunities in (a) Europe, (b) Australia, and (c) Canada.

At the country level, Figure 3.6 presents the type of distribution of funding bodies arranged by the highest percentage of *public* funding opportunities. The data show that most of the countries have at least half of the funding opportunities from public sources; most Eastern European Countries offer exclusively public funding, whereas Portugal has the highest percentage of Private funding bodies.

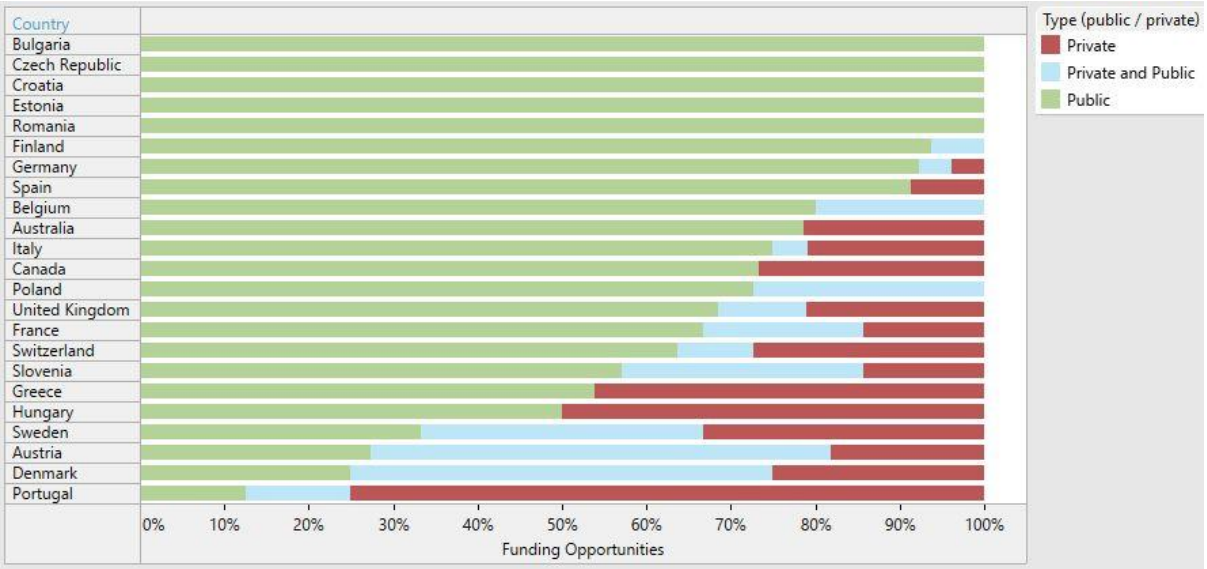


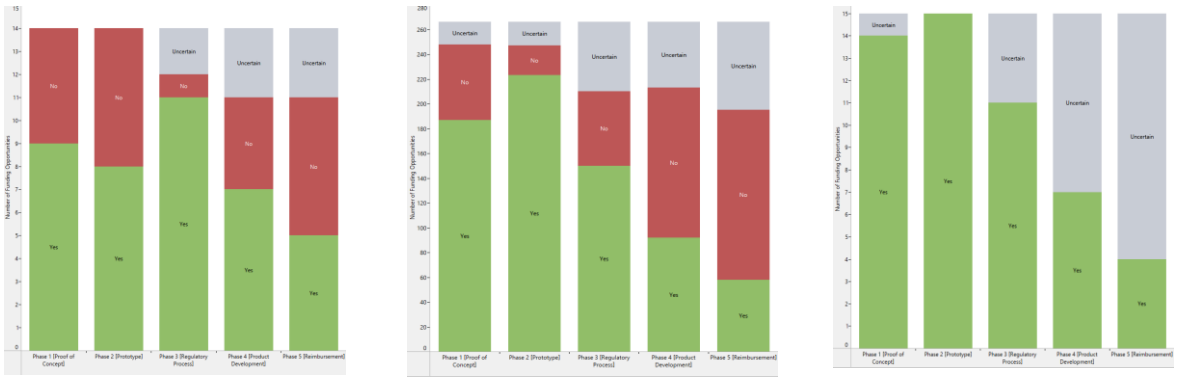
Figure 3.6: Type distribution per country

ITECH has identified 5 phases in the *Idea-to-Market* process of medical devices and eHealth services. Figure 3.7 below shows how the number of funding opportunities

are distributed in each phase in Europe, Australia and Canada. All countries have at least one funding body supporting *phases* 1 and 2, namely proof of concept and prototype development. In subsequent *phases* (i.e. phases 3, 4, and 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. Figure 3.7(a) shows that 83% of the collected funding bodies support *phases* 1 or 2 which are more "research" focused. However, it is also worth noting that there is an increased uncertainty concerning the funding opportunities of the later *phases*, i.e. in *phases* 3, 4 and 5.

In other words, *even if appropriate instruments exist to fund research outcomes so that they can proceed to certification, product development and reimbursement, they seem not to be known to the researchers and experts in the fields of medical devices and eHealth.*

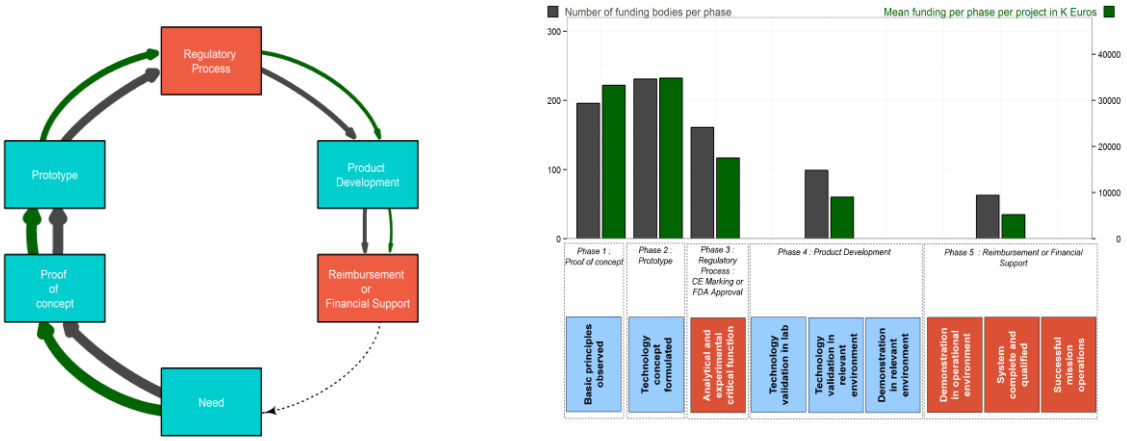
Similarly in Australia we observe that although number of funding opportunities increases in *phase* 3, uncertainty is again on the rise for the *phases* 3, 4 and 5.



(a) Europe (b) Australia (c) Canada

Figure 3.7: Funding opportunities per phase in Europe, Australia and Canada.

In comparing the ITECH model with the TRL system as in Figures 3.8(a) and (b) below, a similar pattern emerges.Figure 3.8(a) shows a significant decrease in funding opportunities and the corresponding decrease in the sum of money each phase receives, following the ITECH model. Similarly, as shown in Figure 3.8(b), the actual number of funding opportunities and sum of funding per project each phase receives, following the TRL system, mapped to the ITECH model.



(a) ITECH Model **(b) TRL System**

Figure 3.8: Support per phase in Europe

During data collection from each country, it has not been possible to gather information on the total amount of funding spent to support research and innovation. However, the contact nodes have been able to provide an average range of funding per project offered for each funding opportunity recorded. This has allowed us to derive some indicative results on the number of funding opportunities in each funding range per project, the average amount of money offered per project within each country, as well as the number of funding opportunities for each funding range per project, in each phase.

Figure 3.9 shows that the highest number of funding opportunities in Europe exist to fund projects in the range of €100-300k within *phases* 1, 2, and 3, whereas smaller projects of less than €100k are mostly supported during product development and reimbursement (i.e. *phases* 4 and 5).

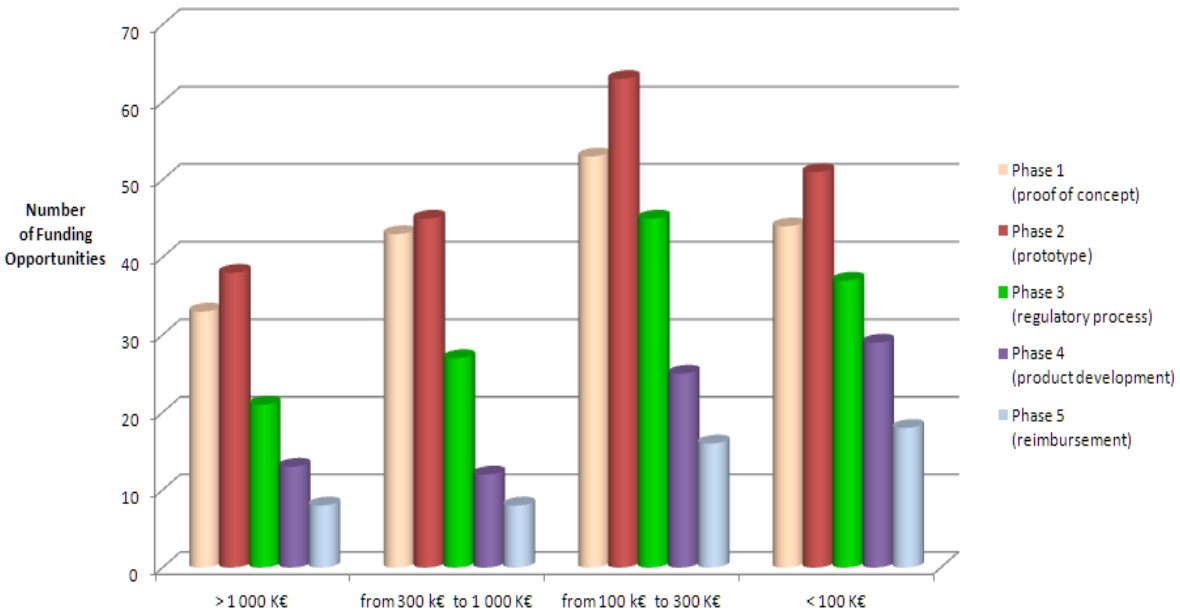


Figure 3.9: Funding range for each phase in Europe

3.4. Identify gaps and barriers

A critical part of the research work was carried out in WP2 as described in Deliverable D2.4. Analysis of the data collected in WP2, 12 gaps and barriers that were assessed to negatively impact the *Idea-to-Market* process were identified. These gaps and barriers emerged from two essential sources: directly from the data itself; returned from the questionnaire circulated to all contact nodes and affiliates, and from widespread discussions that took place as part of the 1st ITECH Workshop in Brussels with 47 experts from academia, industry and government, to validate the data. The 12 gaps and barriers presented and described briefly below in Table 3.1 and are as previously reported in Deliverable 2.4

Table 3.1 Identification and Description of the 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).

The gaps and barriers identified represent the broad or generalized attributes in the commercialization process that our research considered as inhibiting effective and efficient operation. Further research work was undertaken to identify specific issues from within each of these broad categories that contribute to the overall gap or barrier. By analysing the gaps and barriers themselves we were able to identify 61 specific issues which need to be addressed and, by incorporating a roadmapping methodology were able to make overall recommendations as to what needs to be done.

3.5. From the Gaps to the Recommendations: Road mapping

Roadmapping is a flexible technique that is widely 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. The scope of roadmaps is often broad, covering a number of complex conceptual and human interactions. The use of roadmaps can be approached, for example, from both company and multi-organisational perspectives. Company roadmaps may allow technology developments to be integrated along with business planning. In a multi-organisational context their contribution may take place in the form of capturing, on the environmental landscape, threats and

opportunities for a specified group of stakeholders in a technology or application area[8].

Roadmaps can take many forms, but generally comprise multi-layered time-based charts (see Figure 3.10).

The roadmap layers can be tailored to fit the particular context. The can layers align markets or environment ("know-why"/purpose) with applications ("know-what"/delivery), and resources ("know-how"). These aspects are projected on a temporal dimension (horizontal axis, "know-when"). Another key element of the roadmap chart is vision, which can be understood as a temporarily locked target that is systematically verified and re-formulated, either based on an organisation's strategy clock or when a critical need, such as a change in the environment, emerges.

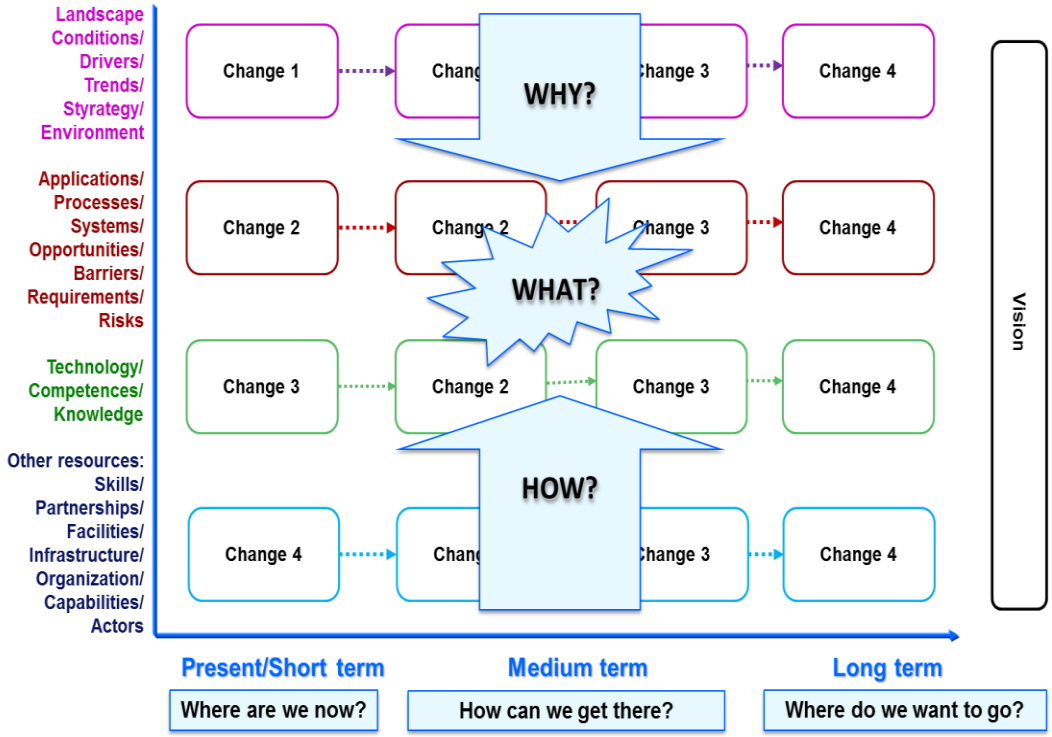


Figure 3.10: A generic roadmap structure

[8] Phaal, R., Farrukh, C.J.P. & Probert, D.R. (2004) Technology roadmapping—A planning framework for evolution and revolution. *Technological Forecasting & Social Change*, vol. 71, pp. 5 – 26.

Roadmapping is inherently a flexible technique, in terms of the following[9]:

- The wide range of aims that roadmapping can contribute toward;
- The timeframe covered by the roadmap (past and future);
- The structure of the roadmap, in terms of layers and sub-layers, which can be adapted to fit the particular application;
- The process that is followed to develop and maintain the roadmaps;
- The graphical format that is selected to present information and communicate the roadmap.

Following the identification of the 61 issues we classified each into one of four priority groups based upon two criteria: Relevance and Response time. Relevance was evaluated against the ITECH goals, i.e. the acceleration of the *Idea-to-Market* process of Health Technologies. Response time refers to the time required to make an impact on the above mentioned goals.

Table 3.2 Scheme used to as a Prioritising 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

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. Priority group 4 comprises of issues that eventually were considered to be inappropriate or irrelevant in the context of the ITECH project.

From these results, we were able to identify and classify thirty important issues to be included into the following suite of four roadmaps[10]:

- *Clinical trials* (comprising 4 of the original issues)
- *eHealth taxonomy (*comprising 4 of the original issues*)*
- *Education and training* (comprising 4 of the original issues)
- Adoption space and Human Factors Engineering (HFE) (comprising 18 of the original issues)

[9] Phaal. R., Farrukh, C.J.P. & Probert, D.R. et al. (2007) Strategic roadmapping: A workshop-based approach for identifying and exploring strategic issues and opportunities. *Engineering Management Journal* vol. 10 No. 1, pp. 3–12.

[10] Full details can be found in Deliverables D3.3 and D3.4

Additionally, eleven other issues considered as important were assigned to three other categories (Health Technology Assessment, Post-market surveillance and Regulatory process) but were not considered for roadmapping since they are issues already included into the Medical Device Directive Reform (MDR). Lastly, two original issues suggested that a book might be needed describing the Idea-to-Market process based on the work done in ITECH. Figure 3.11 shows the distribution of the issues into categories and those selected to be roadmapped.

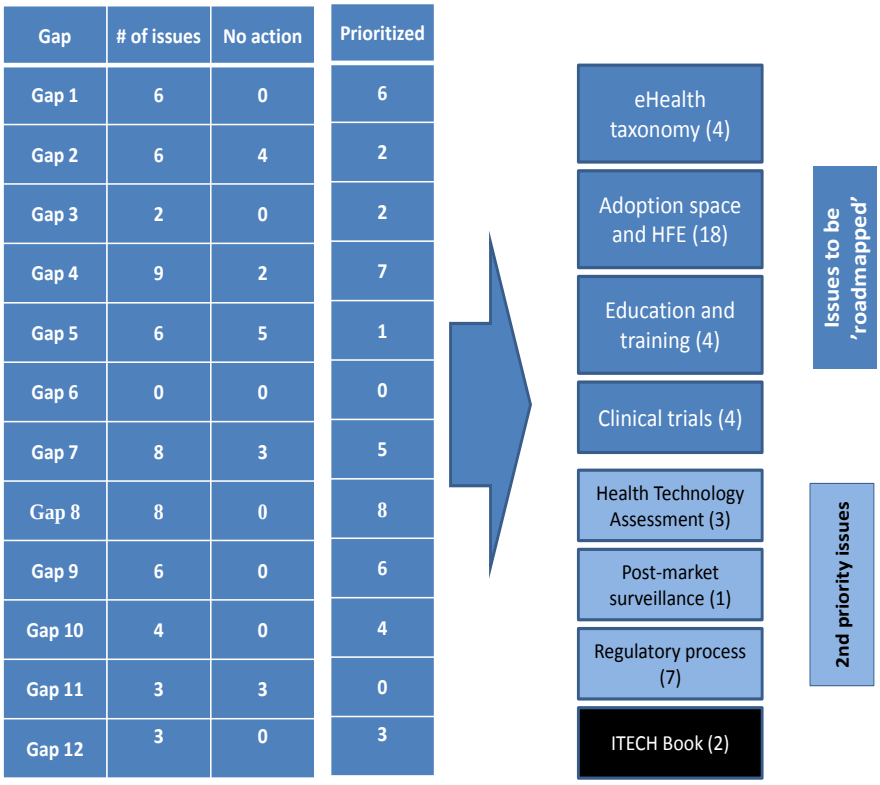


Figure 3.11: The regrouping of the original issues into those that will be roadmapped.

3.6. Recommendations

Following the process described in section 3.5 above, the issues contained within the four categories to be roadmapped were analysed in order to identify a specific set of recommendations and associated actions.

In the following tables we identify fourteen (14) recommendations and nineteen (19) associated actions. These are detailed in Tables 3.2 (a) - (d).

Collectively the four sets of recommendations and actions contribute to the overall ITECH vision of 'Acceleration of the Idea-to-Market process based on users' needs'. Individually, each roadmap was accompanied by a Vision Statement which summarised the effective goal(s) hoped to be achieved by the recommendations and actions plan:

Table 3.2 (a) Clinical Trials

Clinical Trials Vision: To create a culture of clinical evaluation, both quantitative and qualitative, of Health Technologies	
Recommendation	**Actions**
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 MDs. 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)
For eHealth To provide a methodological guidance for the clinical evaluation of eHealth applications. To identify which eHealth applications 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 eHealth. 2 To create a database of evaluation studies
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.

Table 3.2 (b) eHealth Taxonomy

eHealth Taxonomy Vision: Health Technologies must be clearly and simply identifiable with a limited umber of key words through all the phases of the Idea-to-Market process from the definition of the project to the final version of the product.	
Recommendation	**Actions**
To develop a classification / taxonomy for eHealth to be usable by both academics and industrials.	1. A task group to identify the different dimensions of eHealth applications. 2. To propose a CSA action within H2020.
To continue the current efforts to organize a European Medical Devices classification/ 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 MDs nomenclature, based on GMDN, providing keywords for an unambiguous identification of the MDs research, innovation, industrialisation and commercialisation.
To consider a way of linking MD and eHealth nomenclature with reimbursement procedures apart from DRGs.	The classification will support the integration of Health Technologies in the reimbursement phase.

Table 3.2 (c) Educatio and Training

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 commercialised product.	
Recommendation	**Actions**
Specific training to comply with all aspects of Idea-to-Market process, in educational curricula for engineers, researchers and healthcare professionals interested in the domain of Healthcare Technologies. Propose placement/ internships/ fellowships within principal EU associations and/or industry.	1 Set up a working group to explore the possibility of a European curriculum based on eLearning or a MOOC, which will also offer accreditation for professional competence. 2 Create a HUB with a pool of courses. 3 Use platforms for wide educational possibilities such as the Google Scholar in collaboration with this HUB.

Table 3.2 (d) Adoption Space & HFE

Adoption Space & HFE vision: A unified systematic process based on Adoption Space principles that accelerate the successful uptake of Health Technologies into mainstream healthcare.	
Recommendation	**Actions**
Establish a virtual HUB to provide a communication and information platform for all involved the Idea-to-Market process.	Set up a Working Group with representation from across the sector to determine the specific plan, structure and content of the HUB.
Develop the commercialisation pathway to include recent research particularly with reference to the principles identified in the concept of adoption space.	Review funding approval processes to include on-going and post-project 'impact' criteria which could be used to inform continuation of project funding and future allocations of funding for new projects. Introduce/enhance the assessment of 'impact' as a feature of approving applications for project funding.
Enhance the collaboration with and between Usability and Living labs to encourage a deeper integration and sharing of technology and expertise across Europe.	Provide appropriate funding to encourage the semi-formal linkages of research centres, usability and living laboratories involved in the Medical Device and eHealth sectors as a way of sharing of expertise and good practice

3.7. Results Summary

The ITECH project started with 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 and innovation in Health Technologies. A 5-phase model describing the steps in transforming a scientific idea into a commercialized product (*Idea-to-Market* process) was created to guide the data collection and its analysis. In 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 followed by a detailed analysis of the Gaps and Barriers complemented with reviews of on-going activities, relevant literature and reports, and by selected interviews with key stakeholders and actors operating in the domain. Based on these, a roadmapping exercise was carried out to identify the recommendations and actions needed to optimize the uptake of research and innovation in Health Technologies.

The issues were classified into seven categories in need of actions were identified. For the three following, a roadmap was not considered necessary as they are already part of the ongoing Medical Device Directive Reform (MDR) process:

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

Roadmaps along with vision statements, recommendations and action plans were created for the following four categories:

- *Clinical trials* as in addition to products being safe they must also be effective;
- *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
- *Adoption space and Human Factors Engineering (HFE)* as the development process from Idea-to-Market requires a complex set of competences and the needs to be focused on identified user needs.

The ITECH project uncovered a comprehensive picture of the extant instruments at national levels, identifying a number of inadequacies. This mapping provided the evidence-base to permit ITECH to propose new initiatives for inclusion in the commercialization process across Europe that will optimise the whole path from *Idea-to-Market*.

According to the objectives of the project, ITECH achieved the following results:

- An overview of the current European situation regarding all steps in the *Idea-to-Market* process in Health Technologies. The diversity of supporting actions throughout European countries is a factor contributing to the complexity of the domain of Health Technologies;
- The identification of 12 gaps and barriers that slow down and sometimes block the successful completion of the *Idea-to-Market* process;
- A list of recommendations intended to overcome some of the identified gaps and barriers;
- The creation of the *Idea-to-Market* Roadmap;
- The elaboration of a Strategic Plan for the *Idea-to-Market* process with special emphasis in making it usable for different stakeholders including Universities, R&D organizations, SMEs and large industries.

In summary, ITECH has achieved all its objectives providing an up-to-date picture of national instruments and, where necessary, suggests additional instruments and initiatives required to optimise the European innovation *Idea-to-Market* process with the objective of significantly increasing the number of European champion SMEs. Additionally, the ITECH project offers a strategic plan dedicated to support the *Idea-to-Market* strategy across Europe.

4. Impact

Impact of the development of well conducted Clinical Trials for Medical Devices and eHealth

In the EU regulatory system, and according the Medical Devices directives, the government of each member state is required to appoint a Competent Authority responsible for Medical Devices. The competent authority acts on behalf of the government of the Member state to ensure that the requirements of the Medical Devices directives are transposed in the National Law and applied.

The Medical Devices directives, as well as the guidance documents that accompany the directives, describe the processes and essential requirements in terms of safety and clinical evaluation.

Performing a clinical evaluation basically means looking at the available clinical data and assessing the safety and performance. Clinical data are derived from: a critical evaluation of the literature, or a critical evaluation of the results of all the clinical investigations made, or a critical evaluation of the combined data provided.

When the available data are not sufficient to draw valid conclusions about the device's safety and performance, clinical investigations (clinical trials) are required.

In a recent report[11], it is stated that "the critical issue is that Good Clinical Practice for medical devices is not supported by a specific process description on how to collect new clinical data for every new product. Altogether, the regulatory authorities have neither a basic rationale or conceptual framework nor methodological requirements to provide sufficient evidence or additional benefit".

In the USA, the FDA premarket notification application involves a series of studies starting with first clinical use and culminating in a multicenter, prospective (randomized) control trial. Typically, FDA requires randomized studies in which the new device is compared against current controls treated with current best medical practice. The harmonization between the two approaches is searched through the GHTF study group, in collaboration with WHO. The number and quality of clinical trials in the field of medical devices and eHealth are real challenges to ensure access for European innovations to international markets.

[11] Evaluation of new technology in health care, Royal Netherlands Academy of Arts and Sciences, ITZ Comitee, June 2014

ITECH propose an increase in the number of European call for proposals and the number of European projects dedicated to:

- Defining a coherent methodology of clinical evaluation and clinical investigation of innovative medical devices;
- Elaborating methodologies for the evaluation of eHealth applications;
- Promoting multicenter clinical trials (clinical investigations) of innovative medical devices;
- Promoting multinational, multicenter evaluation of eHealth applications (particularly in the domain of mHealth, connected objects, etc.);
- Promoting the development of platforms to stimulate the clinical investigations and reinforce the cooperation between academic centers for evaluating industrial products (e.g. ECRIN or F-CRIN).

Such platforms, developed at the European or national level, appear essential for developing a culture of evaluation and assessment of Health Technologies. They have to be reinforced, funded, and coordinated, to provide scientists, industrialists and regulatory bodies, the necessary information and competences for high quality evaluation studies of medical devices and eHealth applications within Europe.

The impact of these actions will contribute to building a coherent, robust and transparent model of evaluation of medical devices in order to build evidence of the risks (safety), performance and benefits of medical devices for healthcare.

They will help innovative industries, start-ups, SMEs, to identify evaluation platforms where they will find the necessary competences and support for building good-quality clinical trials with the perspective of publishing their results in high-ranked journals and bring to buyers and users an evidence-based approach.

With this support a European Network of Evaluation Platforms dedicated to the clinical investigation of medical devices can be organized to promote multicentre studies.

The economic impact should be important as the researchers and industry are looking for such competences, easily available and reachable.

Impact on the development of Classifications GMDN and eHealth Taxonomy.

In the domain of Medical Devices, GMDN is the de-facto tool to provide a classification for a growing set of medical technologies. The importance and potential utility of GMDN is now highly recognized by all. Medical Device Regulators may specify the use of the GMDN to their specific country or region. For example, regulators in the European Economic Area (EEA), request the use of GMDN to support the Conformity Assessment process required for CE marking. In the USA the FDA have introduced the use of the GMDN as part of their UDI Rule. The medical device Regulators in 65 countries are using the GMDN to support patient safety and beginning to require the use of the GMDN Code in their medical device listing / approval process.

This highlights the importance for scientists, industrialists and pharmacists and clinicians to have at their disposal coherent, recognized and, if possible, exhaustive classifications.

eHealth is a rather new technology with a very broad application domain, but there is no available classification or taxonomy able to represent the importance and the complexity of the field. ITECH recognizes this as a significant gap and proposes to create a working group in EFMI and IMIA for the purpose of proposing a draft taxonomy, publish the results of the work and introduce a nomenclature that may be used by all to classify eHealth products and projects.

The first action will be a Working Group with the support of EFMI during the MIE Congress in Munich, August 2016. This Working Group will be organised with the support of the EVAL working Group of EFMI (Chair: Elske Ammenwerth). The objective of this workshop is defined as following.

Expected impact.

It is expected that eHealth applications will be prescribed by physicians and potentially reimbursed by medical insurances and social security. When physicians prescribe a drug, this drug is referenced in a list of medications (this list differs from one country to another) and can be identified through a coding system, i.e. the ATC Codes (WHO). When physicians prescribe a medical device, this device is referenced in a list of available medical devices. In the future, a Unique Device Identifier will be available for each medical device.

A similar arrangement needs to be made for eHealth products. It is unacceptable not to have such a classification allowing the identification of the eHealth applications, including technical characteristics, ergonomics, connectivity, utilisation of the captured information, potential benefits for the user (healthcare professional or patient).

The benefits of such a classification will be:

- A clear identification of the eHealth application;
- The possibility to analyse the potential risks for the user (particularly if the user is a patient);
- Provision to developers and industrials with a clear understanding of which eHealth apps are regulated;
- Allowing the development of clinical evaluation and particularly clinical investigations;
- Identifying the risks attached to the connectivity of such systems in terms of: confidentiality, security, protection of data, protection against intrusion and hacking;
- Allowing the reimbursement of such systems by medical insurances and national social security systems through clear and complete information of the experts and decision makers;
- Allowing the technical and medical follow-up of these systems by medical authorities.

All these elements are significant prerequisites for the industrial and economic development of eHealth considered as a very innovative technology for new approaches in the diagnostic, treatment and monitoring of patients and users.

Impact of Education and Training

During the ITECH Project, it has been highlighted that the education and training of the actors participating and influencing the *Idea-to-Market* process is not satisfactory for, *inter alia*, the following reasons:

- Researchers are not aware of the regulations in the field of medical devices and eHealth;
- Developers and Industrials (particularly SMEs, and VSMEs) are not always aware of the regulations necessary for CE Marking and reimbursement;
- Clinical trials are indispensable, but the methodology of clinical trials in the field of medical devices is not harmonized or standardized;
- The poor quality of medical trials is sometimes an obstacle towards the reimbursement of Health Technologies.

Moreover, as part of the curriculum of medical students, the time devoted to describe the methods for the evaluation of medical devices is always poor (between 0 and 2 hours per 6 years). In the curriculum of scientific students, even during the masters the time and effort devoted to the training of scientists to medical devices and eHealth is not satisfactory as the number of class hours to the methods of clinical evaluation of medical devices is limited to a few hours.

This forms part of the reason why Education and Training of both medical, engineering and scientific students appeared to be essential in the strategic plan of the European Project ITECH.

One of the impacts of ITECH can be the harmonization of these curricula and to obtain a European Blueprint (through ERASMUS) to facilitate both the training of scientific students and medical students in Biomedical Engineering and eHealth throughout Europe.

The impact to an organisation of such training would go beyond the academic world. On one hand it would increase the number of people who will be educated during their formative years, in different phases of development of a medical device or eHealth application.

Continuous training of developers, engineers, and stakeholders working in SMEs or VSMEs is also necessary, particularly in the domains of regulations and evaluation.. Currently, companies are feeling the need for skills in the field of regulations (European or international) governing medical devices and eHealth applications. This concerns both the CE marking, FDA approval and reimbursement procedures.

Some aspects require methodological and statistical knowledge, particularly in the clinical studies necessary for CE marking and reimbursement procedures.

SMEs and VSMEs cannot have, in-house, all the skills needed to answer those questions, these constraints, or the establishment of clinical research protocols. But they have to be aware of these constraints and procedures through education and training.

Continuous training, including eTraining, must be made available on these topics so that the necessary information required by industrials and developers to overcome obstacles is provided if their products and innovations are to reach the market on the

right time. New types of companies will develop to provide this expertise to industrials or startups aware of the importance of these topics.

The harmonization of curricula of European universities and schools should allow for developing a common reference for teaching, to install a common language between scientists, industrials and caregivers, and promoting by walkways transdisciplinary training.

Impact of applying Adoption Space principles to the ITECH project

The ITECH project began with the widely held assumption that the extant translational processes of new medical device and e-health technologies were littered with gaps and barriers that inhibited successful adoption. ITECH recognised the need to remove the gaps and barriers that prevent discoveries reaching the market in the form of innovative products and services. Our research work confirmed the existence of many of these gaps and barriers and went on to identify 12 specific Gaps and Barriers of particular relevance. Our research work further uncovered some deeper and, not-as-well understood, problems which one researcher described as 'the ridged and anaemic logic of evidence-based medicine using tightly defined concepts of clinical and cost-effectiveness and cost utility ….'[12] so highly valued, has, in itself, failed to realise the policy goal of rational technology adoption in healthcare. In addition to addressing the specific Gaps and Barriers the overall process requires innovation and a new, more inclusive, way of thinking. In addressing this matter, ITECH explored current research in the field and proposed the inclusion of the conceptual Adoption Space model as described in the Deliverable 3.4. Originally, the expected impacts of the ITECH proposal included a primary impact where new initiatives would be proposed and, a long-term impact to significantly increase the number of European Health Technology champions. The application of Adoption Space principles supports both of these expectations in the following manner:

Primary Impact: As part of the research work, the ITECH project confirmed the very complex nature of the *Idea-to-Market* process noting that it involved an increasing variety of artisans, different disciplines, varying national strategies and difficulty in identifying 'winner' products and services. Our work further showed that, if a technology was to be successfully transformed and taken-up into mainstream usage, and hence secure reimbursement, an number of issues not addressed by the traditional Health Technology Assessment or Clinical Trials procedures were exceedingly influential. Adoption Space principles enable the examination of these 'other' issues and give the possibility of quantifying there influence.

Given the complexity of the process, ITECH has proposed a modest of number recommendations based on Adoption Space principles in order to test out their effectiveness. We expect these to yield two benefits; firstly to provide a methodology to allow for the engagement of all or any actor, influential in the

[12] Technology Identity: The role of sociotechnical representations in the adoption of medical devices. Ulucanlar, S.; Faulkner, A.; Pierce, S.; Elwyn, G. Social Science and Medicine 98 (2013) 95-105

diffusion process, to engage appropriately and, secondly, to encourage the weighted inclusion of all relevant contributions to the overall process.

Long-Term Impact: Our research work identified a number of significant national research programmes looking at various ways in which to improve the uptake of medical devices into mainstream usage. Our desk-based research and face-to-face discussions with both funding agents and co-workers identified communications with and between those involved in the overall process, along with connecting different policies and decision-making processes, as the single-most important factor: people need to be given the opportunity for discussion, to share ideas, to learn from mistakes and to emulate good practice. Too often, such communication is absent leading to duplication of effort, repeating of errors, lack of innovation and misunderstanding. The major principle of Adoption Space theory is that different actors in the overall process each have a specific identity and influence on the outcome. The notion of an electronic communication platform in the form of a HUB, implemented incrementally as actors learn to share experience and information, will eventually remove the communication barrier. We expect the inclusion and development of an electronic HUB to greatly facilitate appropriate and inclusive communication. It will also help industry, the health services, clinicians and academics collaborate and to focus on and respond to future patient needs.

In summary, the inclusion of Adoption Space principles as ITECH recommendations, if fully implemented, will have a major overall impact on the scientific and industrial competitiveness for the European Medical Devices and eHealth industries. It will enhance the implementation of the Innovation Union 2020 strategy, through the deployment of R&D capacity and will make the transformational process of the *Idea-to –Market* more efficient, while at the same time, more rigorous. It will further offer the opportunity for all actors in the emerging medical devices and eHealth technology to share in the developments and mainstreaming of new and innovative products along with off-shoots of healthcare cost containment and reduction of health inequalities in Europe.