INNOVATION STRATEGY IN R&D PROJECTS

A step by step guide

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FROM HEALTH RESEARCH TO BUSINESS

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement N°305532

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A step by step guide

Edited by: Svetlana Klessova (inno TSD, France)

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September 2015

This guide is available on-line: http://health2market.eu/results/step-by-step-guide

Preface

In September 2012, we started the "Health-2-Market" project. The goal was to help health and life science researchers across Europe, from both the public and private sector, to develop and reinforce an entrepreneurial mind-set and to enhance the commercial exploitation of their research results. We started to collect information from researchers and asked them a lot of questions. What are the relevant knowledge and skills you have? What do you expect to learn from successful entrepreneurs and experts? What barriers do you perceive and what are your ideas to overcome them? The demand for training was high and we rapidly collected a wealth of information: 637 European specialists answered our survey, 26 of them were additionally interviewed, two round tables were organised with researchers, entrepreneurs, technology transfer and IP experts. Based on the outcomes of this training needs analysis, we developed a training concept designed to meet the needs of researchers, including week long "boot camps", shorter seminars, e-learning courses, case studies, and hands-on individual consultancy.

A substantial support at all project stages was obtained from our Project Officer Antoine Mialhe, Health Directorate, the European Commission, and we are very grateful for it. Close to 30 events, spread over three years, provided an opportunity for more than 600 researchers and future entrepreneurs to learn from experienced trainers, discuss with innovation management leaders, share ideas, deliver plans, and address concerns through peer-to-peer discussions.

This work paved the way for this guide that became possible thanks to the 18 project contributors from all over Europe. The need for such a free, downloadable step-by-step guide was expressed by participants but the guide is not only for health specialists, but also for a larger audience since the topics addressed (commercialisation paths, business models or marketing strategy) are also relevant to other sectors as well. With the encouragement from the European Commission, we decided to prepare this brief guide for R&D specialists concerned with increasing the market and commercial impacts of their research. This is not an easy path to take but the results can be extremely rewarding.

We hope that this guide will be a valuable companion for you, and we wish you much success in your endeavours!

Svetlana Klessova
Director, inno TSD, France
Health-2-Market project coordinator

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We thank Amicis Arvizu, engage AG, and Dagmar Marron, inno TSD, for the proof reads of this document.

About the Health-2-Market project

Health-2-Market is a 3-year long Coordination and Support Action, funded by the Seventh Framework Programme of the European Commission (Grant Agreement No 305532), aiming at providing training and individual support to health and life science researchers in the process of transforming their research results into successful new business ideas. The duration of the project was 36 months (September 2012 – August 2015).

A portfolio of high-level services, training actions and tools were designed and offered free of charge (some of them are still available), escalating to address the needs of all potential target groups (health/life science researchers, European health research institutes, Technology Transfer Organisations, EU health-related companies and entrepreneurs, health/life sciences European networks, NCPs, etc.) A brief description of Health-2-Market services and assets developed during the project is presented below:

Health-2-Market trainings
17 Seminars and 7 academies free of charge for more than 600 participants

From October 2013 to July 2015, two types of trainings were offered free of charge by Health-2-Market: Weeklong highly intensive international business academies and 1-2 days regional training seminars to highly motivated health/life sciences researchers, entrepreneurs and technology transfer professionals on various topics. Several seminars were co-organised with or hosted by external partners such as higher education and research institutions, technology transfer structures and private companies in the field of health/life sciences, without extra fee-payment. For more info, statistics, testimonials and photos please visit http://www.health2market.eu/results/.

Health-2-Market academies at a glance

- **7 Academies**
- **132 Participants**
- **4 European cities**
  Sophia-Antipolis (FR), Gothenburg (SE), Madrid (ES), Rome (IT)
- **3 training topics**

Health-2-Market seminars at a glance

- **17 seminars (including 1 webinar)**
- **511 Participants**
- **11 European cities**
  Stockholm (SE), Madrid (ES), Sophia- Antipolis (FR), Thessaloniki (GR), Berlin (DE), Budapest (HU), Nicosia (CY), Naples (IT), Athens (GR), Gothenburg (SE), New Castle (UK), Braga (PT), Craiova (RO), Lisbon (PT), Rome (IT)
- **8 training topics**
- **8 co-organisers/ hosts**
  - Bayer HealthCare Pharmaceuticals
  - Cyprus Institute of Neurology and Genetics
  - National Cancer Institute Fondazione G. Pascale
  - Hellenic Pasteur Institute
  - RTC North
  - Creating Health- Research and Innovation funding, Institute of Health Sciences of the Universidade Catolica Portuguesa
  - Startup Braga
  - University of Craiova, Faculty of Physical Education and Sport, Kinetotherapy and Sport Medicine Department (Kinetoterapy - MedicinaSportiva)

Health-2-Market e-learning courses on “bringing research to market”

A valuable e-training web-platform was developed during the project and it is available free of charge on http://elearning.health2market.eu/, providing knowledge on a broad range of topics revolving around three thematic areas. E-learning courses constitute a valuable tool for researchers, aspiring entrepreneurs and start-ups in the field of health/life sciences and an educational opportunity for technology transfer officers, incubators staff, etc. Up to now, more than 400 active users benefit from Health-2-Market e-learning courses. E-learning courses are also accessible on smartphones –both IOS and Android- through the free of charge mobile Health-2-Market application, available on Google Play and the Apple Store.

Health-2-Market advanced services- Individually tailored commercialisation services

A significant offer of Health-2-Market was the provision of twenty, free of charge Advanced Services which were individually tailored commercialisation services to selected health research projects to help researchers move their cases and ideas a concrete step further towards successful commercialisation. Eight different services were offered, designed such as to cover different phases in the process of commercialisation of a research project. All cases were performed by experts of the Health-2-Market project consortium. For more info and testimonials, please visit http://www.health2market.eu/results/advanced-services.

MOOC on "Roadmap to Entrepreneurial Mind-set and Toolkit," available on Udemy

In the aim of disseminating the educational and training benefits of the Entrepreneurship and Business Planning Venture Academy (hosted by SKEMA Business School), a MOOC (massive open online course) was developed that reflects the combination of both the Venture Academy curricula and the Health-2-Market e-learning offer: https://www.udemy.com/entrepreneurial-mindset-and-toolkit/#/. Although the course has been developed with a health sciences focus, it is open to any researcher, coach and professional interested in grasping a better understanding of business opportunity development in the life sciences environment. Health-2-Market e-learning: http://elearning.health2market.eu/

Support tools for researchers and entrepreneurs for Horizon 2020

Apart from this practical guide on innovation strategy in R&D projects, an annotated template "Set of good practices to understand and write innovation related issues in Horizon 2020 proposals" is available free of charge on http://www.health-2market.eu/results/h2020-annotated-template and Health-2-Market mobile application. This guide gives hands-on advice on how to adapt a Business Model to a Horizon 2020 proposal, taking as a basis the standard application template of the European Commission of Research and Innovation Actions. With comments from innovation experts and R&D exploitation specialists, the guide specifically focuses on sections in which business aspects should be explained in more details.

If you want to find out more, visit http://www.health2market.eu or download from Google Play or the Apple Store the free of charge Health-2-Market mobile application.

The Health-2-Market project has been implemented by a consortium of 10 partners. For more information about Health-2-Market partners, see the last chapter of this guide.

PROJECT PARTNERS

COORDINATOR

INNO AG

PARTNERS

ie university · UNIVERSITY OF GOTHENBURG · skema · engage · APRE · Q-PLAN · WhiteResearch · europa media · INNO TSD

Introduction

During the course of the Health-2-Market project, the project team noticed that better awareness is needed with regard to the exploitation of R&D results. Indeed, it is not enough to start thinking about innovation strategy and exploitation roots at the end of a R&D project if there is a goal to bring the R&D results to market. The process should be understood and addressed from an early stage of the work. Therefore, the Health-2-Market team designed this guidebook to explain why and when an innovation strategy is required in R&D projects, and how it should be developed and implemented. Of course research valorisation is not only about commercialisation but also about bringing knowledge to society, which is primarily done through scientific publications and knowledge sharing; however, this guidebook focuses on how to bring results to market.

This guidebook on innovation strategy in R&D projects is designed as a practical "how-to" guide to support R&D projects practitioners (either working on collaborative projects or on the projects internal to the company) to bring research results to market. Concrete, real life examples are provided to illustrate each topic. These examples were developed throughout the Health-2-Market project and are therefore related to health sciences; however, methodologies to prepare and to implement innovation strategies are universal. The guide is designed to be relevant to everyone wishing to bring research results to market whatever the field of research, with or without previous experience in doing so.

In each chapter you will find:

- 5 most frequently asked questions about the topic
- Step-by-step process
- Major pitfalls and useful tips
- When relevant, concrete structures of the described documents (business plan, market analysis, etc.)
- 5 important points to remember.

The first chapter (Chapter 1) describes **key aspects of an innovation strategy:** what for, for whom and by whom!

Chapter 2 is intended to provide a useful overview and practical guide to develop an **innovation strategy**. It is for innovative leaders and practitioners in organisations large and small, each facing different innovation challenges. It can serve to assist all innovators whether they are health researchers, principal investigators, entrepreneurs or small teams in the identification, development and promotion of innovation to solve the problems of today and tomorrow.
Chapter 3 constitutes the central part of this guide providing you with a useful base of information to understand different **commercialisation routes** (Chapter 3.1) and to assist you in getting started with an **IP protection process** (Chapter 3.2), a **business plan** (Chapter 3.3), a **marketing strategy** (Chapter 3.4) and a **financing strategy** (Chapter 3.5). It will also give you some insights about **European legislation, standardisation and certification issues** (Chapter 3.6).

Chapter 4 will give you some insights on how to **follow-up and evaluate your innovation strategy** as it is a living document that needs to be adaptive and to evolve over time. Finally, Chapter 5 lists references that you may find useful for the design and implementation of your innovation strategy. At the end of the guidebook, you will find general useful links to go further in your innovation strategies.

It is not necessary to read all chapters and you can choose which ones are most important to you accordingly to YOUR innovation strategy; however, we recommend that you read Chapters 1, 2, 3.1 and 4 as they give information relevant to everyone who wishes to start a journey from research to market.

While this guide can help you get a start on identifying and managing your intellectual property or design a business plan, these topics can get quite technical and we are unable to cover such detail and broad subjects thoroughly enough. Professional help would most probably be needed and we encourage you to seek it.

We hope that this **how-to guide** becomes **your map** to **follow the road from your research to your market!**

Chapter 1 • Innovation strategy what for, for whom, and by whom?

5 most frequent questions asked about the innovation strategy:

- Why do I need an innovation strategy?
- What are the main characteristics of an innovation strategy?
- What is the best way to formulate an innovation strategy?
- Which main questions should be answered by an innovation strategy?
- Should the innovation strategy be revised regularly, and if yes, when?

Innovation has become one of those words that mean very different things to different people. Innovation may involve technologies, products, or services that are cheaper, simpler, and more convenient. Innovation can include real breakthroughs or simply be incremental improvements in existing products or services. On the formal side, the European Technical Specification (ONR CEN/TS 16555-1) defines innovation as "implementation of a new or significantly improved product (good or service), or process, new marketing method, or new organisational method in business practices, workplace organisation or external relations". In other words, the term innovation is employed to describe something original and more effective and, as a consequence, new, that "breaks into" the market or society[1]. In any case, the term innovation has a positive connotation: Innovation means an implemented novelty or improvement, which is beneficial at individual, institutional and/or societal level.

An initiator says: "I have a completely new idea."
An opponent says: "Well, then structure the whole thing systematically."
That's how innovations begin – or end.

- JÜRGEN HAUSCHILDT -

Why have an innovation strategy? Or Who needs an innovation strategy?

An innovation strategy is an instrument to make sure that you achieve your objectives in terms of ultimate impact. That is, an innovation strategy gives meaning to knowledge generation and ensures you can harvest a return on investment into knowledge generation.

Having an innovation strategy ensures that your efforts are given the right focus and support. More importantly, it also serves to identify and capture value that arises from your research and professional work. After all, the next innovation could very well be the elusive cure for breast cancer, bring a new diagnostic tool to the market, or provide a solution to any of the world's pressing problems. The genesis of any disruptive or sustainable innovation begins with formulating an innovation strategy.

Imagine for example that you are a principal investigator or scientist focusing on Alzheimer's. You have recently had a breakthrough and found that one of the small molecule compounds you have been testing on a mouse model acts on a receptor in the blood-brain-barrier in the most remarkable way. The scientist's first inclination and priority may be to publish the scientific results as soon as possible in a well-known scientific journal. In Europe however, once published the innovation becomes public knowledge to the benefit of all. Without having the foresight to protect the innovation or intellectual property before publishing, the scientist and the researcher's institute forfeits the right to commercially exploit the innovation. Granted, not all innovations or discoveries may warrant patent protection. Your goal may be to make your results part of the open source community as part of a larger adoption strategy. Either way, having an innovation strategy will assist you and your organisation to establish a process to adequately protect intellectual property, plan in advance, and allocate adequate resources.

[1] *Frankelius, P. (2009), Questioning two myths in innovation literature, Journal of High Technology Management Research, Vol. 20, No. 1, pp. 40–51.*

What is an innovation strategy?

Your innovation strategy constitutes a framework for establishing the innovation process, as well as the successful transition to bring innovations to the market. Succinctly put, innovation strategy is figuring out how to capture value from your innovations. More specifically, it outlines the expected ultimate achievement of an innovation project in clear, operational targets and documents the roadmap of how an organisation or a specific project shall be run.
In order to fully serve its function, a good innovation strategy should be characterised by at least the following features:

Your innovation strategy should be the guiding star for decision-making, investments and activities.

The innovation strategy will serve as the compass to adequately allocate or prioritise resources to meet the larger goal. The innovation strategy should not be a secret document. Instead, it should be fully embraced by at least all actors who are necessary to implementing the goal or target. Continuously competing demands for resources – time, financial resources (or constraints), as well as from external and internal stakeholders all need to be taken into consideration. Moreover, the innovation strategy should not be in conflict with the organisation's main hierarchy but instead be transparent to identify and solve conflicts as soon as possible. Therefore, in order to be successful, it is decisive to invite and integrate key stakeholders as early as possible in the innovation strategy development process to secure their contribution and commitment to the strategy. It is also recommendable to develop a plan on how to deal with potential conflicts, competing interests, and to mitigate risks along the way.

Your innovation strategy must clearly define the ultimate objective and the most decisive actions to achieve it.

All organisations are unique and therefore should have an innovation strategy that is tailored. The innovation strategy must be of high, integral quality, and should have clear goals or targets. In addition, it should be meaningfully connected with the "outside world" to develop its full impact. That is, you should not neglect to aim your efforts at the business concept so that you focus not only on the "what" but also the "who and how." By "who" we mean, who might eventually use your innovative product, service, or therapy, and what is the value proposition of your innovation? "How" refers to how you go to market or valorise your innovation for the greater public benefit as well as for you and your organisation. The strategy should be complete and as specific as possible.

This means that the innovation strategy must answer the following three key questions:

- What demand or problem will the innovation satisfy? Example: fighting a specific disease.
- What exactly should be achieved? Example: turnover with a new product which has the following characteristics: (a) in respect to medical effectiveness, (b) in respect to commercial results.
- How does the roadmap of exploitation look like? That is, what is the plan and what steps are required to bring your innovation to the market? In particular it is essential to outline different ways of exploiting the result. (E.g. setting up of a new company, selling of IP, production and marketing of products, etc.).

What is the best way to formulate an innovation strategy?

There is no best way of formulating a strategy. However, we suggest keeping some things in mind when doing so, including:

Respect the importance of strategy definition!

- Do not treat it as unnecessary paperwork. Dedicate time and resources to your strategy definition process.
- Do not do it alone, but integrate all those individuals and institutions that you envisage to be champions or crucial opponents (which cannot be overrun).

Strategy is top priority. Do not outsource strategy definition (neither to an external consultant nor to an internal department), but do look at inspiring examples.

A strategy must not be changed easily. However, if you detect major deviations between your expected and actual impact you should check whether your strategy needs some change. In addition, we recommend to continuously analyse whether major changes in framework conditions (e.g. regulatory changes, funding, change in important staff, etc.) endanger that your strategy will show the expected impact. In these cases, there is rational for changing your strategy. For more hands on advice, please consult chapter 4 in this guidebook.

5 things to remember why you should have an innovation strategy

- Your innovation strategy will boost impact orientation of all contributors to your innovation success. It allows you to define incentives and sanctions based upon contributions to strategy implementation.
- Your innovation strategy ensures dedication to exploitation of research results, which e.g. implies that knowledge will be systematically protected. For instance, patenting will be seen as a strategic investment and not a cost position.
- Your investments into knowledge generation and knowledge valorisation are based upon your strategic priorities. Thus, innovation becomes a cornerstone to your organisation.
- Your innovation strategy creates identity within your institution (strengthens team work) as well as reputation in the market place.
- Your innovation strategy will allow you to monitor deviations from expected impacts for early corrective measures, and will help you to identify and mitigate risks.

Chapter 2 • Innovation strategy preparation

5 most frequent questions asked about the innovation strategy preparation:

- When should the innovation strategy be formulated?
- What should an innovation strategy include?
- What are the main steps in preparing an innovation strategy?
- How do I get support for my innovation project or strategy?
- How do I get other people behind my idea and innovation strategy?

> *By failing to prepare, you are preparing to fail.*
>
> - BENJAMIN FRANKLIN -

Getting Started

The process of innovation is highly relevant to all innovators, yet it is a process that many struggle to master. An innovation strategy can be formulated within and for research, or other small work group, or it can be integrated into the operations and management of the larger organisation. Ideally it should include and be formulated with critical stakeholders such as senior management up through the hierarchy. This will ensure the innovation strategy you want to implement not only meets your needs but is also aligned with the overall goals or strategy of your organisation.

We have created a six-step innovation strategy preparation guide to help you answer these questions and to assist you in preparing your own innovation strategy. Because each innovation group or organisation is different and thus will require a unique innovation strategy, you will need to adapt the multi-step innovation process outlined below, adding or modifying to the six steps until they capture everything that you will need to do to achieve success. For example, you can add more detailed sub steps within each of the six main stages to customise it to your specific project, organisation, or need.

1 Set goals

Set goals for the innovation strategy which must be of high integral quality and be meaningfully connected with the outside world.

2 Identify resources & capabilities

Identify what resources and capabilities are required to accomplish your innovation strategy?

3 Assign and prioritize

Identify who the management process shall be defined, who is responsible to contribute with what resources, competencies and activities.

4 Develop timelines

Map out what and when you or your organization need to do to meet your goals and innovation strategy objectives.

5 Communicate strategy

Communicate your exploitation strategy effectively so all are on board.

6 Monitor

Establish evaluation procedures to monitor progress and be prepared to adjust when things go wrong.

Source: engage AG

Step 1 Setting goals

As Michael Porter once said, "*sound strategy starts with having the right goal.*" To do this, you will first need to bring together stakeholders and assemble your innovation strategy team. This may include your immediate co-workers but extend the invitation to all relevant stakeholders, including senior or executive management at the top of the hierarchy or others who will influence the strategy. The idea is to bring everyone on board so they understand where you are in the present and where you want to be (specific goal).

The word 'strategy' implies that you are talking about something with a potentially large impact on your organisation or research group. Therefore, you will want to develop a common understanding of the definition of the innovation strategy purpose.

Questions to ask

- Where do you want to go from here?
- What does innovation mean for you and your organisation?
- What are the innovation opportunities you can pursue?
- What steps are critical to advance innovations to eventually bring to the marketplace?
- How much effort do you and your organisation invest in the innovation process?
- What do you want to accomplish?

Most likely you will have an idea of where you are and where you want to be but the future is still unwritten. Clearly describe the ideal desired outcome for your organisation, project or team. Project forward, three, five, ten years. The greater clarity you have about where you want to be at a specific time in the future, the easier it will be for you to identify the unifying goal for your innovation strategy. As referenced in the prior chapter, the goal should be of high integral quality and be meaningfully connected to the outside world.

Innovation strategy goal tips

- Be specific about your future goals and desired outcome.
- Focus on problems and unmet needs.
- Take into account a potential business model that can support the innovation.
- Identify the key acceptance criteria in case trade-offs become necessary to evaluate the specific innovation opportunities.

In addition, innovators should be able to explicitly commit themselves to an innovation strategy focus area. For example, a medical practice area, research specialty, or targeting a specific need. Often this is intuitive but can also come out from brainstorming sessions if you are having trouble defining your focus area. Defining your focus area and setting a specific goal or goals will serve to guide the rest of your innovation strategy.

Step 2 Identify existing and needed resources and capabilities

After you have defined an innovation strategy with a specific goal that reflects the defined purpose and priorities, the next step is to assess key strengths and weaknesses. Ask what resources are missing? If funding related, what programs, grants, industry collaborations can be used to bridge the gap? Also look internally; you will want to begin to think about how different team members and other stakeholders can complement or contribute to the innovation strategy goal. You should also identify dependencies of other stakeholders under which the innovation strategy shall operate. For example, technology transfer office, patent professional, partner collaboration, investors, or the larger organisational entity.

Step 3 Assign and prioritise

That is, **define who is responsible** to contribute with what resources, competences and activities. Create a work plan that outlines the critical milestones for operationalising the strategy, linking them to other important milestones (e.g., R&D accomplishments, funding needs). Formalise this work plan into a comprehensive division of duties that clearly lays out who is responsible for what and by when. The responsibilities for each critical area should be mirrored in the organisational set up of the project.

Step 4 Develop timelines

Develop a **realistic timeline** for developing or advancing your innovation. If it is a new medical device for example, what R&D stages need to be completed before seeking clinical validation? What are the critical milestones for the innovation project and by extension the innovation strategy? When will you need to apply for more funding? When will you need to create a business plan? Your timeline should provide a macroscopic overview until your innovation strategy goal. This can be further broken down with greater detail or in phases based on your project and innovation strategy goal.

Step 5 Communicate

Once you have managed to formulate an innovation strategy, remember that you still have a major task – to communicate your innovation strategy effectively.

The best innovation strategy is not likely to succeed if it is not effectively communicated to all concerned parties. All organisations and teams are made up of social, communicative human beings who can achieve great things together only after they recognise that it is to their benefit to **come together cooperatively**. Consider to whom and how you will disseminate your strategy? How often will you collect and provide updates on progress? What communication channels will you use? Today there are many inexpensive media options. Find the best one that works for you and your organisation.

Step 6 Monitor

Even the best strategies and well thought out plans do not go as planned. Uncertainty is inherent when pursing any strategy but monitoring your plan will help you identify corrective courses. For example, R&D results may not go as planned, funding is suddenly jeopardised, an important team member is promoted or retires, or the need for further testing can push development timelines back. Almost anything can affect your innovation strategy in both positive and negative directions due to internal and external environments. Therefore it is important to establish evaluation procedures to monitor progress and be prepared to adjust when things go wrong (or right!). Use your innovation strategy as a guide for continually strengthening your innovation potential and capturing value from it. Monitor development timelines, resource usage, personnel, and if necessary, make strategic adjustments based on consensus.

5 things to remember about the innovation strategy preparation:

- Build strong teams and maintain this "investment" in human capital.
- Clarify and have specific innovation goal(s).
- Communicate early, often and widely.
- Be flexible about the innovation strategy preparation process, adapt to your needs.
- Emphasise the long-term benefits.

Chapter 3 • Innovation strategy implementation: a step by step guide

Chapter 3.1 : Commercialisation routes and business models

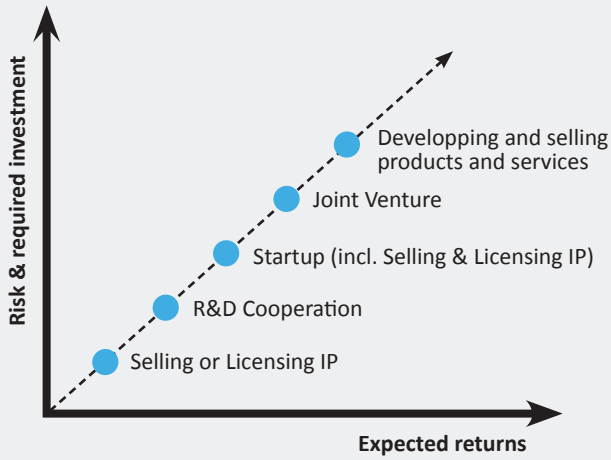
5 most frequent questions asked about the exploitation commercialisation routes and business models:

- What are the channels of commercialisation?
- How do you choose the right commercialisation path?
- Under what conditions should the innovation be developed, or should a new company be launched?
- What are the common myths about the commercialisation routes?
- What business model should you consider?

> *Success doesn't necessarily come from breakthrough innovation but from flawless execution.*
>
> - NAVEEN JAIN -

As a successful innovator you may have reached the stage where you are ready to commercialise your innovation or technology. Whether that is a new drug screening platform, therapy, medical device or otherwise, there are different factors and commercialisation routes to carefully consider. You should carefully ponder:

- your involvement and the commitment needed in terms of time, personal resources, passion, etc.,
- your appetite for risk,
- the investments needed and your organisation's ability to provide it or otherwise obtain it and of course,
- the potential earnings in monetary form or otherwise for both the innovator and your organisation.



Source: engage AG

In reality there are no clear boundaries between choosing the "right" commercialisation route since it will depend on an infinite number of variables unique to your specific case. Key variables that can affect this decision include the nature of the technology itself, the industry it will be applied to, and the personal objectives of the inventor. Moreover, different industries may prefer specific routes or a commercialisation route may simply be more realistic. For example, many research organisations form a R&D cooperation or joint venture with industry partners who are better prepared to understand market needs, end users, regulatory and certification processes, and who can provide funding for more capital-intensive innovation projects. In other cases, the innovator may be willing and have the drive to launch a start-up. In order to decide which route might be the most valuable for a specific technology, you need a general understanding of:

- the possible business models available to commercialise the technology as well as their market and revenue potential,
- the general aims and strategy of the research organisation, and
- the availability of suitable partners or people.

Experience indicates you need to assess the different routes in detail and not commit to any of them without a careful assessment of all available options. For example, you want to consider such issues as:

- How much effort are you willing to contribute to commercialisation activities?
- What are your competences and capacities to become engaged in commercialisation activities?
- What internal and external support is available to you?
- How much risk are you willing to take?
- At what stage and what type of technology do you seek to commercialise?
- How much additional R&D is needed in terms of resources, capital, before being market ready?

Often this requires seeking out professional assistance through your technology transfer office, consultants, and by networking with other professionals who can assess and provide feedback on your innovation potential. Below you will find a brief overview of the typical commercialisation routes you may consider.

3 myths about commercialisation debunked

There are a number of common misunderstandings and myths connected with the assessment of commercialisation routes that we would like to discuss.

A start-up is the silver bullet of technology transfer.
Often there is much hype around this idea, as well as some public support programs for this option. Although a start-up might be a valuable route, it may not be the best solution for all situations. Firstly, the risks are significantly higher; the business competences needed to successfully realise this option are not typically available to innovators from the research field. Moreover, the huge profits envisaged arrive only after many years, if at all. Indeed, many start-ups fail and do not succeed.

Selling or licensing IP frees the innovator from all the hassles involved with commercialising a technology.
Intellectual property coming from (public) research area is often at the earliest stage of commercialisation with further R&D needed for proof of concept, or testing in real world settings. Therefore, much effort is needed on the research side to convince a commercial actor to buy or license the technology. To successfully convince a company and to negotiate an attractive price requires a thorough understanding of the commercial value of the technology and how this value might be realised.

R&D collaborations are dull and financially not attractive.
Additional money for R&D can be just as valuable for a research organisation as proceeds from a sale or licenses since R&D is typically its core mission. Transferring the technology to a commercial partner where the research organisation can further support commercialisation efforts through know-how or additional R&D could be a mutually beneficial and financially rewarding option. This can be particularly true when private investments can be leveraged with public funding, thus reducing financial risk for industrial partners while advancing commercialising activities for greater public benefit.

Selling or Licensing IP

A sale or a license of the Intellectual Property Rights (IPRs) connected to a technology effectively transfers the rights to commercialise the technology to a company. In case of a sale, the IPR and all the connected rights will be transferred to the buyer. Without any additional agreements, the seller of the IPR loses all rights to the innovation including the right to use the IP for the seller's own further research. Usually this route is only available when patents are already granted and the IP protection is strong. The possible returns are lower than those of other commercialisation routes, but with significantly less risk involved. A quite common alternative is to negotiate a combination of a fixed up-front fee coupled with a success-based variable component such as a license or royalty.

A license grants the right to use the IP under the agreed terms and conditions in return for a combination of fixed up-front and variable, success-based fee. At minimum, the license should specify:

- regional limitations,
- defined fields of use or indications,
- the timeframe the license is valid for,
- fall-back options, particularly when a certain threshold for success or license fees is not reached,
- exclusivity vs. non-exclusivity element, and
- possible inclusion of other contractual restrictions or freedoms as negotiated.

The sale and licensing can be an attractive option because it takes advantage of the expertise, resources and market know-how of companies already operating in the field. Thus, it is improving the likelihood of your innovation reaching the market as well as receiving some commercial benefit. Licenses also allow for differentiated approaches for different fields of use or different geographical areas.

Although both commercialisation routes rely heavily on the buyer or licensee, the innovator and the research organisation must still have a detailed understanding of the market, possible business models, pricing options and competition. You need this knowledge to, firstly, convince a buyer or licensee to invest in the technology or innovation and, secondly, to support negotiations to receive fair prices and fees. Otherwise, the risk is that the licensee will capture value but not the innovator or his organisation.

Selling or licensing ownership of your technology could be a viable solution in the following situations:

- When there are established companies who control the market and will make launching a competitive business very difficult
- When your innovation could offer a competitive advantage to an established market player, who may offer to buy or license it in order to improve his product or service
- When there is only one market or when the market is too small, in which the innovation could be commercialised
- When the inventor wants to commercialise but does not have the resources or interest to develop a new business
- When the innovation applies to a variety of different markets, it can be licensed to different partners who will commercialise it in each of these markets and potentially create multiple revenue streams.

R&D cooperation

Since research-based IP is typically at the forefront of the state of the art, it often requires further R&D before it is market ready. Who else than the innovator that originally invented the technology is perfectly positioned to deliver the know-how to advance it further? Establishing a R&D cooperation with industry or commercialisation partner can be a mutually beneficial and rewarding commercialisation route. Firstly, research organisations can take advantage of their core competencies, namely innovative research-intensive functions. They can continue to focus on research and development but license out the technology to a commercialisation partner who is capable of bringing the technology to market.

Earnings from further R&D work, in combination with an IP sale or license, could prove to be financially more profitable with less risk than other commercialisation routes like, for example, forming a new venture. Moreover, potential earnings can be realised by the research organisation sooner than other kinds of revenue. In order to be successful with this commercialisation route, however, a research organisation may need to develop a "service-oriented" approach to be able to comply with the requirements of product development. By service-oriented we mean better aligning R&D activities with commercialisation efforts. This calls for carefully addressing and taking into account the needs and requirements of industrial product development. This may entail adjusting your research schedule to meet development milestones on time, focussing on robustness and costs instead of scientific excellence, developing stricter protocols to meet certification requirements, and accepting other restrictions regarding confidentiality. While this is often an adjustment of thought, the advantage is that your research innovation can develop further from concept to prototype, to a product that can benefit society at large.

Start-up

The most often talked about commercialisation route is to create a start-up. Creating a successful new company is very difficult and success is often heavily influenced by factors outside of your control. Although creating a new company to commercialise your technology holds the highest risk, it can also lead to high potential reward. The stark reality however is that a very large proportion of start-ups fail. As with all options, you must evaluate whether creating a start-up is the right option for you.

The transfer of the technology into a newly formed company should be your first step. This includes transfer of IP ownership or removing any freedom to operate concerns, and setting up a legal entity according to your local jurisdiction and laws. The research organisation and inventors can participate as shareholders. Often the research organisation transfers IP to the start-up as a direct sale, license, royalty element or combination thereof since shares of the start-up are converted into cash when the start-up is profitable, is sold to investors or goes public. The reality is that relatively few health or biotech start-ups succeed and if they do, it is frequently only after many years. A third source of potential income could be fees for using resources of the research organisation such as labs, expensive equipment or clean rooms and GMP rated facilities.

Setting up a new company to fully develop and market an innovation has the greatest risk but also is the most rewarding commercialisation route. Risk is found not only in the typical market risks associated with bringing an innovation to market, but also in the ability to acquire the necessary third-party funding and to manage all necessary processes efficiently and successfully. The core of the problem that many innovators face is that an excellent scientist is not likely to double as an excellent entrepreneur, and later-on, a highly efficient manager. Conflicts of interest stemming from the multiple roles of the entrepreneurs (inventor, scientist, employee, and entrepreneur) and the remaining influence of the parent organisation can hinder the process even more.

Moreover, you need to develop a deep understanding and competences in fields like management, financials, sales, marketing, manufacturing, technical, and administrative. Critical to the success of any start-up is to form a committed and enthusiastic founding team. Sooner rather than later, this will lead to the hiring of one or more experienced executives with an industrial background to navigate all the complex issues that may arise with a start-up.

Many innovators will consider starting a new company for the following reasons:

- The market potential for the opportunity is worth the added risk.
- You have the desire to participate in maximising the value of the innovation.
- You have contacts to create a business team and access to other support and resources.

Commercial services - joint venture or own commercial activities

The solution with perhaps the most intense involvement is to develop and market products and services based on the new technology on your own. This could be done within the research organisation itself, as a start-up, or with the help of a partner, e.g. in the form of a joint venture with an industrial partner or together with a support actor focused on technology commercialisation.

Admittedly, developing market ready products is not (yet) a common route for (public) research organisations because it deviates significantly from the main goal of generating research results and involves more risks, including financial ones, than other routes described above. This may change with the growing focus of commercialising research results. However, this may not be a viable alternative if a technology requires private third party funding, because there are no tradable assets to be transferred.

But there are situations when this route could prove to be the most rewarding one. This could include tech based services or even small lines of products which are still close to research activities. Also, if the expected market is rather small and fragmented or expensively equipped or highly specialised personnel are needed occasionally, it could be unattractive for a commercial partner or a spin-off. In order not to lose the business at all, providing commercial services could be a way out.

This route, in particular, holds a number of problems, which you should take into account early-on.

- Particularly for public research organisations there might be certain legal restraints preventing or hindering the organisation to engage in such activities. The general possibility for conflict of interest needs to be checked beforehand, if possible at all, a solution needs to be designed according to accounting rules, budgeting regulations, and pay scales.
- Tech transfer and commercialisation may not be goals shared by everyone in the research organisation. Support from parts of the organisation therefore can vary greatly, sometimes even resembling obstruction. Difficulties can arise from this e.g. when access to equipment, labs or other facilities is needed.
- Since a research organisations main goal is the advancement of science, typically there is not much investment or funding for commercialisation projects available. Most if not all of the tasks need to be done with in-house means.

For these reasons, a research organisation will most likely not tap the full commercial potential of an innovation. But if like mentioned above, the only other option is to forgo the opportunity altogether, this might be tolerable. To reduce risk and make management easier, setting up a separate business unit in form of a daughter company owned wholly or by the majority by the research organisation is an often-used option.

Business model

> *The business model is like a destination. The business plan is how you're going to get there.*
>
> - TIM BERRY -

An innovation by itself does not automatically guarantee economic success. Whenever an innovation project is commercialised, it either explicitly or implicitly employs a particular business model that describes the design for how the commercial entity (can be a start-up, joint venture, or other) will create, deliver, and capture the innovation's commercial value. In other words, the business model articulates the logic for how a business creates and delivers value to customers who are willing to pay. The business model includes such things as revenues, costs, and profits associated with the commercial entity delivering that value. In essence, a business model is a conceptual, rather than a financial model of a business. The commercialisation project should be coupled with the development of a business model that defines its 'go to market' and 'capturing value' strategies. Good business model design and implementation are necessary for commercial success. Figuring out how to deliver value to the customer, and to capture value from doing so are the key issues in designing a business model.

There are many different business models that can be employed. A classic example is the 'razor blade model'. If you've ever purchased razors and their replacement blades you are already familiar with this business model. The handheld razor is sold at a discount but the replacement blades are extremely expensive. In other words, the sale of the replacement blades is where the razor company captures value. This business model has been successfully adapted and is frequently used by clinical diagnostic companies who develop tests that run on proprietary platform instruments produced and manufactured by the same company. The principals are the same. The diagnostics company creates and sells a tool, the instrument or platform, and then perpetually sells specialised, high margin consumables (e.g. tests, biochips, etc.) to the same customer. There are many other business models and figuring out the 'right' business model involves some of the most difficult and frustrating issues that any innovator, entrepreneur and even established companies must address.

Figuring out how to capture value from innovation is a key element of business model design. However, a business model should be something more than just a good logical way of capturing value. It should be non-imitable in certain aspects, either by virtue of being hard to replicate or by the existence of complicated implementation steps or by strong intellectual property protection. Regardless of which business model you evaluate, good business model design and implementation involves assessing internal factors as well as external factors concerned with your customers, suppliers, competition, and the broader business environment.

The following mini-case study is taken from the Health-2-Market blog of Antonios Stamatogiannakis, Ph.D., Assistant Professor of Marketing at IE Business School, IE University, Spain. It serves to illustrate the challenges of commercialisation.

In previous posts, I have given examples on the complexity of deciding about Customers and Collaborators in the Health Industry. Now, I turn into discussing another important "C", namely Competitors.

In the final academy of the European Commission project Health-2-Market, a common confusion as to who can be considered as a competitor occurred. Specifically, two prospective start-ups, were dealing largely with the same problem. They were developing solutions to the Pharma industry regarding how to make more efficient the drug development process. A quick note here, this is a huge market; the development of a single drug can cost more than 2 billion euros!! Although both projects had the same objective, they used markedly different technologies. One project was based purely on novel chemical analysis, while the other was based on improving the already widely adopted HCS (high content screening).

As is the case for many entrepreneurs, these projects did not see each other as competitors, at least at the beginning. In their eyes, a competitor was someone who uses (or can use) the same technology as they. As both solutions were pretty novel, they both thought that at least for now, there was no competition. The problem became visible only when they had to present their marketing plan one next to the other. Then, it was obvious that they will be fighting for the same needs, and thus the same budget (for efficient drug development) of Pharma companies, so they had to consider each other as competitor. They were going towards the same target, but via different routes!

In general, many companies (especially smaller ones) fail to see that a competitor is not someone who does same things as they do, but someone who covers the same customer need as they do. In the example above, a competitor is not someone using the same technology, but someone aspiring to improve the drug development process, regardless of technology. In the same vein, a competitor for a canteen at Retiro, is not only other canteens at Retiro, but also canteens at Casa de Campo, as well as video game manufacturers, and subscription TV channels. All of those compete for the leisure time and money budgets of Madrid consumers. Realising how complicated competition can be (even for a canteen), drastically changes how one sees a business model and the challenges of commercialisation.

Extract from the marketing blog, Antonios Stamatogiannakis/IE Business School

Commercialising Publicly Funded Projects

Often, at the end of publicly funded R&D projects there is a technology or innovation that requires further development or commercialisation effort before it can be marketed. Project beneficiaries should come up with an "exploitation" or commercialisation strategy to ensure further dissemination and use of the knowledge generated by the project. Typically, the project coordinator or the exploitation manager of the project should take care of this task with the involvement of the partners where necessary. Defining a meaningful exploitation strategy is often difficult, and it is much more than business planning. The following guide and questions are intended to provide some guidance.

Identify the exploitable result[2]:

Definition: "***Achieved and Expected Results coming from the project which have commercial/social significance and can be exploited as a stand-alone product, process, service, etc.***"

By the end of your project you might have developed results as foreseen in the Description of Work - such as a process/process technology, methods, models, recommendations for standards, service/service technology, prototypes/pilots for a product, software codes, etc.; but not all of them could necessarily lead you to market oriented exploitation. As a first step, you should list all of the project results and identify the most promising ones from an exploitation point of view by answering the four questions below.

Does the result have a potential to be exploited?

If your answer is YES, further analysis is required. The coordinator, together with the project partners, should assess each party's interest in the further use of the relevant result, and define the characteristics of the result.

Did/does your organisation contribute to the generation of this result during the project's lifetime?

At this stage, the partners should identify and indicate their contribution to the generation of the relevant project result(s) and start thinking about the rights and obligations related to results within the consortium (e.g. ownership, protection, IPR, dissemination, exploitation, etc.). Subsequently, they should assess and identify whether or not there is need for negotiation between partners who are interested in the exploitation of results after the end of the project.

What is your interest in the exploitable result?

Partners should analyse each exploitable result individually and identify whether or not they are really interested in exploiting the given result (e.g. whether it fits into their actual and future product/service/process portfolio). The result can be important for a partner organisation for carrying out its activities after the project (e.g. spin-off, joint venture, further development/research, etc.), OR the partner(s) may also say that they have no interest in exploiting this result.

What is the best route for exploitation?

Try to foresee the best route(s) for exploiting the results. For example, commercial exploitation, exploitation for further research and development, exploitation via standards, exploitation via EU policies, etc.

In addition to the commercialisation routes referenced above and in this chapter, there are other options such as non-commercial exploitation routes. Non-commercial exploitation activities are mostly addressed to researchers, when the objective is to strengthen the network of contacts, or improve the related research product. Another example of non-commercial exploitation is when the result is directed towards schools or research institutions and universities for developing and evaluating new intervention plans or materials.

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[2] *The presentation of M.Caocci, Cimatec S.R.L, 29 April 2013 at an exploitation workshop organised by the EC; Exploitation tool introduced on a training organised by the TIPS project (Enhancing the capacity of EU transport projects to transform research results into innovative products and services)*

5 things to remember about the commercialisation routes and business models:

- Choose the most suitable commercialisation route based on your defined objective
- Is there a market of sufficient size to make your business concept feasible and worth the time and effort?
- Start-ups or spin-offs can be an attractive commercialisation route but is not right for everyone, nor is it necessarily the best route
- It is not only about facts and figures: what do you as a person want to do?
- Successful implementation of your commercialisation route requires the right competences and resources at hand. Do you have them? If not, can you recruit people and create a team that has these competencies and resources?

Chapter 3.2 : Intellectual assets and intellectual property

5 most frequent questions people ask (or ask themselves) about the intellectual assets/ intellectual property (IA/IP)

- Why should I want to identify and protect IP?
- How can I identify and protect IP?
- When should I patent in relation to publication or presentation of my research results?
- How can I check who else has patented in my field of research?
- How can understanding my research from an IA/IP perspective help me produce better research results?

The concept of property rights is one of the cornerstones of modern economy. In general, if you have a property right over something, tangible or intangible, you can: use the object of property; you can earn income from it; you can transfer the object of property to others; and you can enforce your property rights. Talking about this concept in the context of academic research is rather complicated because knowledge becomes the main object of property. These present some uncertainties, such as: "As a researcher, what exactly is it that I own?" "How can I gain control over what I own?" "How do I need to manage what I own?" This chapter gives you some practical tips on how to identify what valuable knowledge you have in a research project and how to systematise it (Intellectual Assets). Afterwards we discuss what legal means you have at your disposal to gain control over your assets (Intellectual Property) whereas special attention is given to patents. Understanding of the issues discussed in this chapter will give you practical insights of how to manage your research effectively.

Intellectual Assets Management in research projects

Any research project generates vast amounts of knowledge that may have potential commercial value. Whereas "knowledge" sounds somewhat diffuse, various parts of it can be described as methods, data, databases, software, etc. Approaching your research project as a set of assets will enable you to get a better grasp on the project activities and will lead to better decisions in relation to managing the research results. Intellectual Assets Management is a tool that turns intangible things into manageable assets. There are several steps you can follow to make the full use of your intellectual assets: identification; capturing; evaluation and structuring.

> *True wisdom is, knowing what you don't know.*
>
> - CONFUCIUS -

IA identification

An Intellectual Asset (IA) is something of value for your research project, meeting the criteria below:

- IA is possible to be conceptualised and described as an object - for example, "knowledge on how to extract tissue X from Y" is not an asset, whereas "a method for extracting tissue X from Y using equipment Z" is more objectified and can be considered as an asset;
- IA is specific and clearly defined – as opposed to being a high-level abstraction;
- IA is unique to the context of the project – as opposed to being generic and non-differentiating;
- IA is valuable in some meaningful way – in the sense of being useful for key research/utilisation activities;
- IA can be controlled by any stakeholder linked to the research activity.

Usually, a research project produces IAs belonging to one or several categories below:

IA category	Definition	Examples
Data	Potentially useful but unprocessed, raw information which can serve as a source for future insights or solutions.	Measurement or test data Experiments Notes and journals
Database	Structured and searchable data, which is collected, ordered and accessed in a systematic way.	Electronic databases (e.g. MS Excel, Access, etc.) Matrices
Data correlation	Conclusions derived from analysing empirical data or databases such as problem insights, design and process parameters.	Optimisations Trends and ranges Cause/effect relationships Dependencies
Theoretical framework	Generalised theories explaining technical phenomena, causes and effects.	Theoretical models Understandings and realisations
Technical solution	Solutions to technical problems and unique underlying ideas of new technologies.	Methods and processes Devices, units and apparatuses Compositions and designs Configurations and systems Technologies, inventions and solutions
Visualisations and simulations	Static or dynamic visual representations which go beyond typical drawings by being valuable in themselves	Designs, drawings and sketches CAD/CAM and prototypes Diagrams, graphs and photos Simulations, models and demonstrations
Instructions, manuals, algorithms	Instructions providing concrete directions to execute a specific procedure, e.g. a technical operation.	Algorithms, routines and procedures Guidelines, manuals and SOPs Recipes Recommendations
Software	A computer implemented and organised collection of data and automated operations, performing specified tasks	Systems, suites, and platforms Programs, applications, clients/servers Drivers, plug-ins, engines and GUIs Libraries, algorithms and scripts

Once identified, intellectual assets need to be clearly described. For each of the assets its function (what function does this IA have?) and utility (why is an asset valuable?) needs to be defined and listed. It will enable you to better understand how the IAs fit into your specific project.

Capturing IA

After you make an inventory list of your IAs you need to add a control dimension to your analysis. The basic questions at this stage are:

a) Who is (are) the potential owner(-s) of the asset?

b) What (potential) intellectual property rights could be linked to the asset?

The questions above are very straightforward, however answering them can be quite challenging. In most research projects there are multiple stakeholders involved: the principal researcher, students, PhDs, external consultants, collaboration partners, etc. Intellectual property laws follow the principle that anyone who contributed to an invention is entitled to some part of ownership. If not managed properly, having different people involved in creation of IAs throughout the project creates layers of potential ownership claims, which can lead to legal issues in the future. To avoid legal problems it is recommended to seek professional help with the contracts you sign throughout the project. Written sources, such as meeting minutes and protocols, day-to-day records, lab journals and other types of documentation are invaluable for settling possible legal claims. Therefore, it is highly important that you and your research team systematically keep records of all the research activities.

It is quite common that a research project is running under some type of collaboration agreement, as contracted research, or under various grants agreements. Since research collaborations are governed by contracts, which may include different provisions as to ownership rights to intellectual property created within the project, you need to make sure that you understand the implications contractual obligations and IA.
To see an example of conflicting ownership rights related to a research project, please look at the case "Prosound: Navigation Ownership and Rights Claims in Early Stage Research Utilisation", available at http://elearning.health2market.eu/course/3.[3]

IA Evaluation

During the evaluation process you determine significance of your assets and how much they worth against certain criteria. The process is individual and exact criteria for evaluation depend on your vision as to utilisation of your research.
Some typical questions you may ask during this process are as follows:

What is the value of asset X for commercial offering?

- how unique is X in relation to existing technologies?
- how well developed is X?
- does X help to solve some existing technical problem?

What is the value of asset X for continued research?

What is the value of asset X for future collaboration?

Structuring

A completed intellectual asset evaluation gives you good foundation for decision-making regarding next steps in utilisation process. For example, you will be able to see the potential of your assets to create value in different contexts (e.g. further academic research, collaboration, venture creation or license offering). The analysis also gives you an insight of how well each asset is developed.

Examples of the questions you would be able to get an answer to include:

What assets should be claimed as background in collaboration, license offering, venture creation or in other transactions?

What assets should we develop further in our research project?

Which assets should we develop through collaboration?

Benefits of Intellectual Assets Management

For a researcher, the IA approach represents another way of communicating the research externally as well as internally. Using this approach will enable you to communicate your message while talking to investors, research funding organisations, colleagues as well as to people having no specialised insight into the technology area you are working in. It also gives you a starting point prior to entering into collaborations with other actors, because it further clarifies what you may bring to the table in collaboration and what results you expect.

To learn more about the approach and see some examples, please see the case "Utilising Early Stage Research Results Through Intellectual Asset Portfolio Management" available at the Health-2-Market web-site. The case is available online at http://elearning.health2market.eu/case_studies/4.

[3] *Access to the cases requires registration for e-learning modules, it is provided free of charge.*

Intellectual Property Rights

When speaking about intellectual property it is important to understand that this term refers to notion of "property". In a broader sense "property" is something that belongs to its owner and it is solely up to the owner to decide how to dispose it. For example you can sell your property, rent it out, or use it as collateral. Unlike physical items, intellectual property relates to intangible creations. Whereas, you can get back your flat after the renting contract expires, you will never be able to regain your knowledge once you have shared it with someone. Another important characteristic of knowledge is that it is non-conflicting, meaning that different people may possess the same knowledge at the same time.

Intellectual property means the legal rights resulting from intellectual activity. More or less, all activities you pursue in a research setting can be claimed as intellectual property rights (IPRs). Usually, an IPR is described as a monopoly, in other words, a right to block others from using your knowledge. At the same time IPRs play a major role in constructing research collaborations, consortiums and open platforms. Open Source, for example, is built upon copyright and Creative Commons represents a licensing structure. Another example can be a situation when you enter a research collaboration where you give the partners access to your technology and get access to theirs in exchange. Regardless of whether you plan to commercially utilise your research results or want to make your knowledge available to everyone in order to contribute to scientific community you should consider getting proper protection for your IP. In a commercial context, this is necessary to have control over your assets that would be used for generating profit. In non-commercial settings, the control dimension can also be important because it prevents others from using your research in an inappropriate way, as well as, allows different actors the possibility to build sustainable IP portfolios partially based on your IP.

There are several major forms of intellectual property rights that may be relevant for your project. The table below summarises and gives a brief overview of different intellectual property rights.

IPR	What is protected	Requirements	Duration
Patent	Technical function	Patentable subject matter, novelty, inventive step, industrial applicability	Normally, up to 20 years
Trademark	Graphically representable means of identification	Distinguishable Non-descriptive	Indefinite if mark continues to be distinctive
Copyright	Literary and artistic works, computer programs	Originality	Normally, the lifetime of the creator + 70 years
Design	Form/appearance of a product	Novelty and individual character	Up to 25 years (Registered community designs)
Trade secret	Unique process, formula, pattern, device, etc.	Maintaining secrecy	As long as secret is kept from becoming common knowledge

The main focus described in more detail is on patents, which can be the most important form of protection for research results.

Patents

Whether it is a scientific discovery, new process, product design, invention or apparatus, your innovation may be intellectual property that has economic value. Intellectual property can include the innovations and other creative expressions of your ideas that you created. Therefore, you can and should pursue legal protection of your inventions by filing a patent. A patent is a set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed public disclosure of an invention. Patents confer the right to prevent third parties from making, using or selling the innovation without their owners' consent. If you do not protect your intellectual property, others will be able to use your innovation and potentially profit from it.

Why should I patent my innovation?

Patents can be extremely powerful business tools and are necessary for any commercialisation endeavour. Patents normally have a lifetime of 20 years and during this time the intellectual property is the sole property of the owner. The patent enables its owner to prevent others from making, using, selling or importing the technology or invention claimed in the patent.

Developing and maintaining an effective intellectual property strategy is challenging but essential and should be included in your overall innovation strategy (see chapter 1). While understanding the ins and outs of intellectual property law and practice is essential to the successful implementation of innovations, it can often seem monumental. While it is recommended that you seek professional help from intellectual property professionals such as patent lawyers, the following is intended to provide a useful base of information to help you understand the IP landscape better, the patent process, and to develop an IP strategy and implementation plan as part of your innovation strategy.

IP Protection Process

1. Evaluate the innovation/invention

To figure out whether your new invention, product or process is unique and qualifies for patent protection, begin by asking yourself these simple questions:

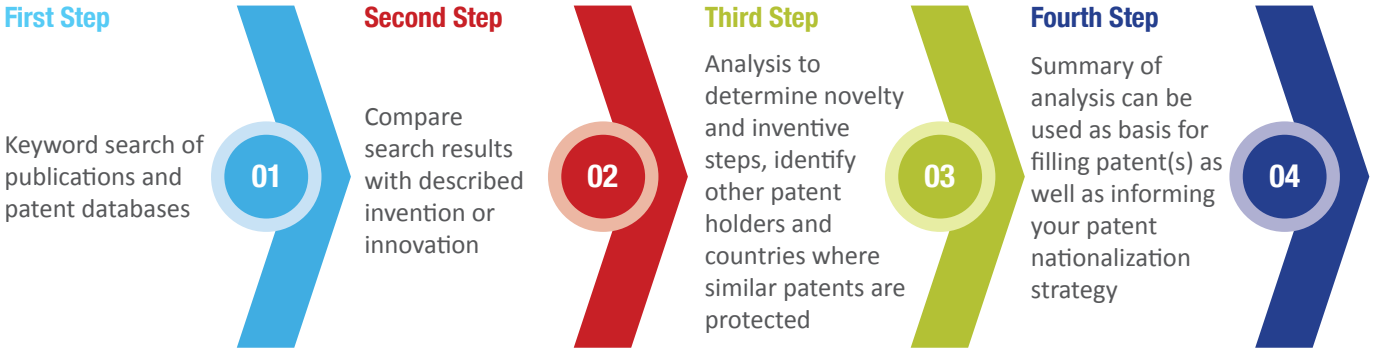
- **Is it novel or unique?**
- **Is it non-obvious?**
- **Is it industrially applicable?**

If your initial answer to all three questions is yes, there is a good chance that your innovation is patentable. The next step is to evaluate your assumptions.

A key part to further evaluation if your innovation is patentable is, knowing what patent references exist in the area of invention. This begins with patent searches to identify key patents and patent applications. Patent searches should be performed early in the innovation process to help an innovator understand the IP landscape and assess **freedom to operate** in the field. "Freedom to operate" is usually used to determine whether a particular action, such as commercialising a product, can be done without infringing on valid intellectual property rights of others.

Beginning this process early in the innovation process can help shape ways of thinking about the claims for your innovation, developing strategies to work around prior state of the art, challenge existing patents, obtain licenses if need be, or avoid wasted investment. An explanation of how to perform these searches is included below. The Health-2-Market website http://health2market.eu/results/step-by-step-guide also includes an indicative template (PowerPoint) for conducting your own patent analysis.

Structure of Patent Analysis



Source: engage AG

Keyword Search

Search for key words related to your innovation. You may also use keywords from information collected through prior searches, scientific publications, and other sources.

Where to search for patent analysis:

- **USPTO databases** - http://patft.uspto.gov/
- **Google Patents** - www.google.com/patents
- **Espacenet** - http://worldwide.espacenet.com/
- **Pubmed** - http://www.ncbi.nlm.nih.gov/pubmed
- **World Intellectual Property Organisation (WIPO) PATENTSCOPE:** https://patentscope.wipo.int

Or another search engine

You can compile your search results in a tabulated spreadsheet. Most patent search databases will allow you to export your search results. We recommend exporting such information as:

- title of patent,
- publication number,
- publication date,
- priority date,
- inventor,
- applicant,
- patent type,
- and protected country or countries.

This will not only organise your search results for future reference but more importantly, compare and analyse your patent search results. Because new IP is published every week, and other prior state of the art is regularly published, keeping an IP landscape up-to-date is a constant challenge. It is however important to understand and stay informed of the competitive landscape and continue to evaluate the technology and IP of competitors as your innovation progresses through technology readiness levels. Once the patent search process has been completed once, new patent search inquires can be completed on a quarterly basis or as needed.

Hint Documentation and key words may have been prepared for other uses that can be valuable in patent search and analysis. For example, journal articles, papers and theses, invention disclosures, grant applications, and research notes could all be useful.

Compare and analyse novelty

Once you have searched and found similar patents you can compare your innovation with your patent search results. Determine what elements of your innovation, in whole or in parts, are novel compared to existing patents. Identify and compare the inventive steps, process, designs, etc. against your search results.

The goal of the analysis is to determine if your innovation is considered to be novel and does not form part of the state of the art. You should find and compare patent claims from another inventor that are currently in force and that may cover your purported innovation, a component of it, or methods of making or using your innovation. For any claim that appears to read on a feature of a search patent result, assess each word and clause of the claim carefully to determine if it applies completely or in part to your purported innovation. Interpret words in the claim in the context of their definitions (and diagrams) in that patent. If you can demonstrate that even a single feature or element is unique to your innovation, or that is not included in the patent, then your innovation will likely not infringe.

Summary of analysis

The outcomes from your patent search and comparison will serve to validate the novelty of your innovation, how defensible your innovation is if filed as a patent, identify possible freedom to operate concerns, and will contribute to formulating your patent filing and IP internationalisation strategy.

2. Formulate application strategy

Many factors need to be considered when deciding when and where to file patent applications. Some factors relate to the business development or marketing of the innovation, and other factors relate to the legal status of the invention. When properly managed, your application strategy can afford many strategic and economic advantages. However, implementation requires careful planning, coherent organisation, and a thorough knowledge of your innovation's potential.

For example, critical considerations include market potential (both in terms of monetary and geographical factors), the presence or absence of competitors, and the overall patent protection regime (in terms of laws and enforcement) in the various nations or regions where the innovation might be used, sold, produced, or marketed. Having carefully weighed these considerations, options for patent protection can then be evaluated. For example, patent applications can be filed within national (for example the U.S. Patent Office), regional (for example the EPO), or international systems (for example the PCT), each with advantages and disadvantages, depending on the objectives and resources of the organisation. Whatever course is taken, coherent planning is essential, and a thorough knowledge of all relevant parameters is fundamental.

Moreover, the cost of filing patent applications in every country in the world can add up quickly. So can maintenance fees to keep patents current. Therefore, it is important to work together as a team in collaboration with an IP attorney who truly understands your organisation, business, strategy and plans for the future, as well as the timing of its operating milestones.

Here are some questions to consider when formulating your patent application strategy:

- How big is the market for your innovation in a particular country?
- How big is the market for your innovation in a particular region?
- Where are the emerging markets?
- Where are your potential competitors operating and in what countries are their patent applications?
- Do you have limited time? Resources?

This list is not exhaustive but you should be able to answer these questions.

3. File for patent protection

Once a decision has been made to file a patent application, there are different routes to patent protection and the best route will depend on your innovation, available resources, and market entry strategy.

The formal requirements for preparing and filing a patent application will vary by patent authority. Patents are generally granted by a national patent office, or a regional one like the European Patent Office. Patents are valid in individual countries for specified periods. If you are seeking protection in only a few countries, it may be best to apply directly for a national patent to each of the national offices. Or you may seek more broad protection by filing for a regional patent (e.g. European Patent Office (EPO), Euroasian Patent Convention (EA)) or by a so called international patent such as the Patent Cooperation Treaty (PCT). These options provide a unified and simplified procedure for filing multiple foreign patent applications via a single initial application.

While any person can file a patent, hiring a patent attorney or patent agent who can assist you in navigating the complexities and nuances of filing a patent correctly, will meet your strategic need. This professional should have deep, first-hand experience with patent filings—ideally in the domain of the invention as well as with IP strategy and protection. The best way to identify a qualified patent attorney or professional is through a referral from a trusted source. You can also network with professionals in the field and ask for assistance in meeting and choosing an IP attorney. If affiliated with a university, the technology transfer office should be able to provide information as well as referrals related to IP issues.

5 things you need to remember about intellectual assets/ intellectual property (in the process "to advance research results to market"):

- More or less all academic activities have the potential to be claimed as intellectual property.
- Intellectual property protection is an ethical obligation when the research results require further investment to support utilisation and value creation in society.
- The objective of protecting intellectual property is to encourage the creation of innovative ideas and to facilitate its commercialisation.
- Understanding research results as intellectual assets/intellectual property will help generate better research applications and funding opportunities in additional to more utilisation opportunities.
- Intellectual property is more than a tool to commercialise, it is a way to regulate openness among different stakeholders.

Chapter 3.3 : Business Plan

5 most frequent questions asked about the business plan:

- What should be the ingredients to put into the business plan to convince investors?
- What is the difference between a business model and a business plan?
- Should I have different business plans for different audiences?
- What comes first, the business plan or the business model?
- What will investors check the most in a business plan?

Getting Started

You have your eyes set on your commercialisation goals and have carefully thought out your business model. Now it is finally time to put your business ideas on paper and effectively plan your way towards the successful commercialisation of your innovative research results. To this end, the current chapter will guide you through the process of writing an effective business plan with a focus on the purpose of acquiring external financing.

What is a business plan?

A business plan is a written document that provides a broad overview of a business including its mission, objectives, strategy, market and financial forecasts for the foreseeable future. It can serve as a roadmap for new entrepreneurial ventures and long-established firms alike, outlining their goals, making a strong case about why they are within reach and laying out the plan that will lead to their successful achievement.

In simpler words, the business plan is a blueprint of how your business is going to work and how you, along with all the people involved in the (novel) venture, will make it succeed.

> *A goal without a plan is just a wish*
>
> - ANTOINE DE SAINT-EXUPÉRY -

Why do you need to prepare a business plan?

It is common knowledge that the development of a business plan may require a lot of work. However, what is more often than not disregarded by many is the fact that preparing a business plan is hardly a waste of time. Indeed, business plans are considered key for successful commercialisation and are more likely to guide and facilitate your exploitation efforts in the frame of a R&D project, rather than hinder the progress of your research.

The principal objective of a business plan is typically to construct a compelling case to secure external financing (e.g. venture capital, grants, bank loans, etc.). However, it also serves as a valuable tool that can effectively support you to fine-tune and realise your business model while at the same time minimising the risks involved as well as maximising the return on your investment (both in terms of time and money).

Indeed, the business plan is inextricably connected to your business model, and as thus, any changes to your model will definitely imply changes to your planning as well. With this in mind, a well-prepared and consistently updated business plan can guide your commercial venture throughout its life cycle, addressing all aspects of the business planning process such as vision declaration, mission statement and strategy alongside with sub-plans to cover marketing, operations, human resources, financing as well as a plan for Intellectual Property (IP) protection and regulatory aspects, if required. Therefore, the business plan will essentially serve as a comprehensive operating manual of your business that will pave the way towards not only the successful introduction of your R&D outcomes to market but also the achievement of your long-term business goals.

All in all, the business plan is effectively the first sales brochure of your innovative, new product, process or service for both internal (e.g. employees, colleagues, etc.) and external (e.g. investors, suppliers, customers, etc.) stakeholders, and investing time to prepare one is as necessary as the need for patents and publications in a scientific journal. In addition, it is also a meaningful tool for monitoring your business performance and keeping it on track, as it can and should be continually updated based on changes made to your business model due to changing market conditions and new, emerging opportunities and threats.

5 myths about the business plan debunked

- ***I do not need a business plan*** – This wildly popular myth could not be further from the truth. Your business plan will provide the details of your business model, as well as set the strategy for bringing it to life. Thus, the process of developing your plan, which will make you think through the details of your business model in order to choose the best strategic pathway, is vital for the success of your commercial endeavour.

- ***It is too soon to develop a business plan*** – It is never too soon to start thinking on the commercial prospects of your R&D project. The sooner you start planning, the sooner you will be able to test and reassess your assumptions and potentially even unveil new business opportunities such as new application areas for your innovative solution which you hadn't thought previously.

- ***The business plan has to be a long document*** – Overly large documents of 50 pages or more is the idea of a business plan that many people frequently have. In practice, however, a business plan does not necessarily have to be that long. A reasonable length for a business plan aimed at attracting the attention of prospective investors is about 15 to 30 pages. This length should provide you with enough space to compellingly present your business case as well as with evidence to effectively support it.

- ***A business plan is only necessary for acquiring funding*** – It is true that the majority of businesses typically develop business plans to procure external financing. However, this is by no means the only reason. A business plan can serve as a beacon for young and long established companies alike, detailing their business goals, outlining the strategy for achieving them and monitoring its implementation.

- ***A business plan is a static document*** – Falling for this particular business plan myth can prove fatal for a commercial venture. In a rapidly changing business environment, you need to continuously update your business plan as your business evolves, taking into account emerging opportunities and threats.

When should the business plan be written and who should contribute?

History is filled with examples of promising inventions and innovative research results that never made it to the market due to faulty business plans that were prepared at the last minute. In this context, the development of an effective business plan from the early stages of the R&D project can considerably raise the chances for successful commercial exploitation as it serves as a concrete roadmap for your market-oriented endeavour.

The business plan should be developed after formulating the business model since it builds upon the focus of the latter. Given that the business plan will provide the details of your business model, the sooner you start working on it, the sooner you will start talking the commercialisation language, evaluating the feasibility of the proposed venture and reconsidering your assumptions based on in-depth investigations of several business and marketing aspects such as protection of IP, market of operation, target customers and competition – just to name a few.

With the above in mind, it becomes evident that drafting a business plan is a process that implies the collection of information from numerous sources, and it is highly unlikely for any one person alone to be able to provide all the answers required. Therefore, in the case of existing firms inputs should be obtained from several departments such as R&D, manufacturing, finance, sales, human resources, etc. Individual prospective entrepreneurs and/or researchers who may lack relevant expertise and/or resources may acquire input and support from appropriate external sources such as collaborators, innovation intermediaries, and consultants.

Finally, as with any project, when writing a business plan it is essential to effectively and timely inform all contributors about its main aims, objectives and requirements, and ensure their commitment as well as to provide all participating authors with easy-to-understand guidelines and realistic deadlines.

5 steps to prepare a business plan

- ***Determine the purpose and target group of the business plan*** – Start by determining the reason why you are developing your business plan as well as your target audience, as both can have a great impact on its content. For instance, if you are targeting prospective investors to acquire external funding then you might want to keep the plan concise and highlight the market potential and expected profitability of your proposed commercial endeavour. Conversely, if you aim to use it for internal purposes then you may want to prepare a more detailed plan that will guide your everyday operations.

- ***Research*** – The next step towards preparing your business plan should be a thorough research of your potential market. To this end, a market study can be of great value as it can enable you to develop an evidence-based marketing strategy for your innovation (see Chapter 3.4). In addition, you should also orient your research towards collecting information on other crucial business aspects, such as start-up (if applicable) and operating costs required, personnel needs and availability, etc.

- ***Assess your business model and outline your business plan*** – In light of the findings of your market research, this is the perfect time to assess the viability of your business model and potentially even the business idea itself. Should you decide to move forward with your commercial venture, then you should start outlining the business plan. In this respect, you could use as a guide a template of a business plan outline such as the one provided later on in this chapter.

- ***Write your business plan*** – With the outline of your plan at hand, is now time to finally write the narrative of the business plan, based on the evidence you unveiled through your market research as well as on your chosen business model. You may want to involve other people in the writing process as well. Therefore, it is vital to figure out who is more appropriate to be involved, and to provide them with meaningful guidelines and realistic deadlines. The last step of the writing process is to develop the executive summary, which will summarise the entire business plan in a couple of pages with a goal to hook prospective readers to your business idea from the very start.

- ***Set up a regular update schedule for your business plan*** – Finally, as your business evolves and you gain new information about your target market, you should constantly update your business plan and/or model if necessary. To this end, establishing a regular review and update schedule will ensure that you stay on track and, more importantly, allow you to timely react in case of significant deviations from your plan.

Which topics are to be covered and what questions should be answered?

The exact content and format of a business plan should be determined by taking into account the unique nature and particularities of the business it aims to describe. However, there are key elements that should not be missing from any plan. Below, an outline of typical topics and respective sections that should be included in a business plan oriented towards procuring external financing is provided along with indicative questions that should be answered, and indicative length of each chapter (the length always depends on the specific case particularities). The indicative length of the overall document is 15-30 pages.

1. Executive summary (1-2 pages)

This section aims to provide a summary of the overall content of the business plan. It is one of the most important sections of the plan as it is the first (and maybe the only) one that will be read by your prospective investors and as thus, it must concisely present a convincing case for the proposed commercial venture. The executive summary is typically the last section of the plan to be written.

2. The Product / Service – Value proposition (2-3 pages)

2.1 Problem statement: In this section, you should provide a description of the problem that the proposed venture is trying to address. Moreover, you should explain in a clear manner how this problem translates into a promising business opportunity by identifying a specific social challenge to be tackled and/or a market gap to be filled such as a latent or unsatisfied demand.

2.2 Solution: This section should present, in detail, the solution that will be marketed in order to solve the problem that you described in the previous section. The description of the solution should include technology characteristics and innovative features as well as any complementary services that you plan on offering. In the case that the business plan is targeting investors that might not be entirely familiar with technical terms, the language used for describing the solution should be simplified (to the degree possible).

2.3 Value proposition: The value proposition is the formulation of your innovative offering in a way that it values the benefits for your customer(s). This part of the plan should also include an explanation of how your innovation is different from the competition focusing on its competitive advantages and unique selling points as well as explaining how they create value for the customer(s).

2.4 Technological environment: Here, you should elaborate on the position of the innovation in a technological framework. Simple explanations should be prepared and included for any specialised terminology and concepts. **Indicative questions:** *What is the "state of the art" in the field? How is the solution positioned in relation to what already exists in the market and how should it evolve in the future in order to remain competitive at a technological level?*

2.5 Research & development: This section should reflect the current status of your R&D project including details with respect to the time and budget required for completion and market launch. **Indicative questions:** *What is the current status of R&D? What additional R&D work is required? How is this work organised? Will there be any external partners required (e.g. research and technology organisations, living labs, etc.)? What are the risks associated with R&D and what measures are foreseen to minimise them?*

2.6 Intellectual property rights: The strategy regarding protection of Intellectual Property Rights (IPR) should be the focal point of this section. Details should include any patents that the R&D project team holds or has applied for as well as any trademarks or other rights which are currently owned or will be sought in the future. **Indicative questions:** *Does the R&D team hold any patent(s)? What are the geographical limitations? Who holds the patent(s)? What are the budgetary requirements for effective IP protection?*

2.7 Standards and regulation: This section should summarise any legal standards or regulations that may affect the development and commercialisation of your innovation. For instance, you may want to create a table comprising the principal standards pertaining to your innovation and its application and describing any possible implications. **Indicative questions:** *Which elements of the innovation are standardised or regulated by relevant legislation? What are their implications for R&D and marketing?*

3. Market & Competition (2-5 pages) described in detail in chapter 3.4 of this guidebook

3.1 Description of the market: A general description of the market that your innovation is targeting should be provided here along with its anticipated future development and main growth drivers. **Indicative questions:** *What are the size and key features of the market under consideration? Which segments exist and what dynamics do they exhibit? What is the estimated potential for growth?*

3.2 Customers: In this section, potential customer groups for your innovation should be identified and described. **Indicative questions:** *Which homogeneous groups of customers can be identified for the innovation? What are the common, identifiable characteristics of these customer groups?*

3.3 Market structure: Here, you should elaborate on the relationships that exist between the various actors in your market (e.g. customers, suppliers, etc.) and on factors that may influence purchase behaviour. **Indicative questions:** *How does the market work? Who are the main actors in each customer group? Which is the typical purchasing process: who is involved and what are the key criteria for each one (price, quality, etc.)? Is the end-user also the decision-maker and/or the payer? What are the implications?*

3.4 Competition: This section should provide an **assessment of the competition** operating in the target market. **Indicative questions:** *How are the needs of target customers satisfied now? Are there any major competitors who already market the same (or quite similar) technology/product/service? What are their market shares, competitive advantages, growth rate and/or any recent developments, etc.?*

4. Marketing Strategy (2-5 pages)
described in detail in chapter 3.4 of this guidebook

4.1 Product: The exact product offering should be defined here. **Indicative Questions:** *Are we selling a product, a service, or a full solution? Do we have different offerings for different segments? Are there any bundling possibilities?*

4.2 Segmentation and targeting: In this section, potential customers should be grouped in homogenous segments, each of which should be described in terms of economical size, needs and requirements, trends, etc. with a view to targeting the most appealing one(s). **Indicative questions:** *What criteria can be used to divide prospective customers into homogeneous segments (e.g. geographic, customer size, etc.)? Which segments are the most appealing and why?*

4.3 Positioning: This section should describe the desired market position of the innovation as well as outline your planned strategy to achieve it. You should prepare a positioning statement that will clearly communicate (internally and/or externally) the position that your solution is aiming to occupy within the mind of your targeted customer(s). **Indicative questions:** *How will we differentiate our offer from the competition and how are we going to achieve this (e.g. unique selling points, reputation, branding, etc.)?*

4.4 Sales and distribution strategy: This section should define your sales objectives and lay out the strategy to reach them. The methods that will be employed to realise sales should be included here as well (e.g. own sales force, distributors, local sales representatives, etc.). **Indicative questions:** *What are the sales targets and chosen channels of distribution (e.g. by customer segment)? Are there any special services (e.g. after sale support, credit, etc.) that will be provided for customers and/or intermediaries? Can we use the same channels for different segments, or should we diversify?*

4.5 Price: Here, you should define and justify the pricing of your innovative solution. **Indicative questions:** *What is the price that target customers have to pay at the moment to satisfy their need for our innovation? What are the price trends that are currently dominating in the market? Based on these, what pricing policy should we adopt per target segment?*

4.6 Promotion: The strategy and actions to be implemented in order to widely increase awareness on the innovation and establish (initial) contacts with prospective customers will be presented here. **Indicative questions:** *What message should we communicate? What marketing and communication tools will be used (by customer segment)? What promotional activities are planned (e.g. internet presence, advertising campaign(s), trade fairs, etc.)? What monitoring mechanisms are in place? Should there be variations across target segments?*

5. Management (1-2 pages)

The aim of this part of the business plan is to concisely describe the management team of your venture, proving that you possess the expertise and skill-set required to successfully drive its commercial success. Therefore, it should include the personal qualifications, track records and role of all the key people involved as well as the degree of their commitment. Important information that should also be presented includes former relevant positions and skills related to the particular job they will fulfil in the frame of the proposed venture. Qualifications should not be limited to scientific expertise, but also include business skills, project management, etc. **Indicative questions:** *Do the members of the proposed management team have relevant experience and competences? Have they worked together before? Are they clear about their future roles? Are they fully committed to the undertaking?*

6. Company structure (1-2 pages)

As suggested by the title, in this section the structure of the company that will introduce the innovation to the market should be defined, ideally, with the help of an organisational chart. A concise description of key personnel and their qualifications should be included to demonstrate their capacity to perform their assigned role. The time-wise creation of the structure of the company (and potentially of its legal structure too), including milestones and interrelations of actions, should be presented as well.

7. Company projections (1-2 pages)

Here, you should outline the overall objectives and envisioned development of the venture within the business planning horizon as well as provide your views for the long-term future. Measurable values should be included when possible, together with the assumptions used to derive these values. Visionary aspects may be provided as well.

8. Risks and success factors (1-2 pages)

In this section, you should identify and describe any potential risks (e.g. operational, legal, regulatory, etc.) as well as factors (e.g. market or technological developments) which might influence the success of the proposed venture. Being objective here is important. Ignoring or underestimating potential risk factors will have a very negative impact to potential investors. **Indicative questions:** *What risks can be identified that might threaten the success of the venture? How will the team deal with these risks, and minimise their impact (e.g. contingency planning)? What are the requisites for success? What is the plan in case these requisites are not realised?*

9. Financing (4-7 pages)

9.1 Assumptions: This section should describe in a comprehensive summary, all the assumptions that you made in order to develop the financial forecasts of the business plan.

9.2 Financial analysis results: Here you will demonstrate the financial viability and robustness of the proposed venture by presenting the results of all the financial analyses that were running including: financial forecasts, pro forma profit and loss statement and balance sheets, break-even analysis, cash flow statements, etc. Indicative templates you can use for this section are annexed to this guidebook.

9.3 Capital requirements: The capital requirements of the venture within the time frame of the business plan should be explained here. **Indicative questions:** *How many steps of financing are necessary? For what period is the financing required?*

9.4 How funds will be used: In this section, you should describe in detail how the funds that will be obtained by external investors are going to be used / invested. **Indicative questions:** *Is the amount of capital requested going to be used for e.g. R&D, capital equipment, marketing, general working capital, etc.?*

9.5 Exit / payback strategy: This section should explain how and when your prospective investors are going to "*cash out*" their investment. The projections should indicate that the invested funds will enable you to generate the revenue required for payback and exit of your investors.

5 tips for preparing a compelling business plan

- **Consider your target audiences** – You should tailor the business plan to the specific audience (e.g. investors, employees, clients, etc.) at which it is aimed, as they each have their own particular requirements.
- **Research your market** – A firm understanding of your target market is key for preparing a compelling business plan. In fact, prospective investors will pay considerable attention to your knowledge of the market and as thus, the need for market research cannot be overemphasised.
- **Keep it concise but pay attention to detail** – No reader would like to read an overly long business plan. Therefore, try to keep your plan short and to the point, but at the same time, make sure you include enough evidence and details to convince the reader of your business case.
- **Visualise key elements of your business plan** – A continuous wall of text will tire and discourage most readers. In order to avoid this, you can use visuals (e.g. images, figures, graphs, charts, etc.) with the goal to bring key elements of your business plan to life. Including a creative element in your business plan can help you stand out, provided you avoid excessive visualisation.
- **Keep it real** - You should set realistic objectives and timeframes in your plan, considering the challenges and opportunities within your market. Being realistic also implies presenting assumptions and financial projections that are not overly optimistic. As such, you will provide your plan with increased credibility.

The case of 'Alterniity'

The concept of Alterniity (www.alterniity.com) was born at the ARTORG Research Center for Biomedical Engineering of the University of Bern in Switzerland, where a team of world-class researchers had the vision to provide seniors and elderly people with an effective solution to delay or even prevent the onset of cognitive decline and counteract the degenerative process of dementia. In order to realise their ambitious vision, however, they needed a compelling business plan that would enable them to procure the financing required to kick-start their entrepreneurial endeavour. This is what led the Alterniity team to enlist the commercialisation support services of the Health-2-Market project on September, 2013. At the time, the team was still exploring their business prospects and had yet to devise a concrete business plan. In order to kick-off the development of their business plan, a meeting was scheduled between the team and Health-2-Market experts. During this telco, the team introduced Alterniity and its promising market potential, tasks and responsibilities were allocated and a provisional time plan for the completion of the plan was sketched.

With respect to the drafting of the business plan, the emphasis was initially placed on developing a simple but appealing description of the solution for external investors as well as on investigating the target market. In fact, gaining a deeper understanding of the target market proved essential at defining an appropriate business model. The demanding regulatory requirements and the intricate mechanisms of the business to business (B2B) healthcare market could potentially prove fatal for the entrepreneurial venture. Therefore, it was decided to initially market the solution directly to consumers (B2C) and through this business avenue, generate the necessary revenue to fund the development of a tailored solution for the B2B market. Based on the results of the market study, a tailored marketing strategy and plan were prepared along with a suitable company structure, risks and success factors were identified and the necessary financial analyses were run to evidence the viability of the proposed venture. Communication was continuous and virtual meetings where scheduled at frequent intervals, in order to discuss on work done and plan the next steps to complete the business plan.

Overall, the process of writing a business plan significantly helped the Alterniity team in their commercial endeavour. The investigation of several vital business aspects revealed valuable insights which led the researchers to adapt their business model and prepare an appropriate business plan. Now, the concept of Alterniity has been successfully introduced to the market through XtremeVRI AG, which was established on January, 2014 as one of the first medtech gaming consoles designed to promote healthy aging solutions.

5 things you need to remember about the business plan:

- The business plan is the detailed description of the relevance and the planned implementation of your business model.
- The business plan is the roadmap that formalises the reality of the opportunities you address.
- The business plan is the first promotional tool of your project.
- The business plan formalises the legitimacy of your business model towards employees, partners, clients, suppliers.
- The business plan is anchored into the business model, meaning it will evolve as the business model evolves.

Chapter 3.4 : Marketing strategy

5 most frequent questions asked about the marketing strategy

- I have an excellent product or service; do I really need a marketing strategy?
- Is a marketing strategy necessary if I do not plan to do any advertising?
- What exactly is a marketing strategy? What are its different steps?
- Do I need a different marketing strategy for every segment that I target?
- Should I have a low starting price in order to attract customers?

Getting Started

Marketing is a key element of success in practically any commercial endeavour, even more so when it comes to bringing highly innovative solutions to market, be they products, services, or complete solutions. It is essential for businesses of all sizes, ranging from budding start-ups to multinationals. In other words, marketing and innovation are like a set of gears that work in tandem to drive business success. With this in mind, the current chapter of this guidebook aims at introducing you to basic marketing concepts, clearing out some common misconceptions in this respect. Furthermore, it aims at showing you how to design an evidence-based marketing strategy which can then be employed as an effective lever in order to substantially raise the likelihood of the successful commercial exploitation of your promising innovation.

> *A business has two basic functions – marketing and innovation.*
>
> - PETER F. DRUCKER -

Do I really need a marketing strategy in order to commercialise my innovation?

After working long and hard on your R&D project, you have finally developed a great product or service and now you are thinking of going down the path of commercial exploitation. However, will the excellence of your research outcome suffice for its successful commercialisation? The truth is that simply having an excellent product or service does not necessarily guarantee your success in today's highly globalised and competitive environment, where innovations are born, marketed and become obsolete at a hitherto unprecedented rate. There are two reasons for this, both of which can be addressed with careful marketing strategy. First, there is a multitude of competitors (of all forms and sizes) that one-way or another can satisfy the needs of your customers. Second, potential customers have specific needs, and may not be willing to settle for anything than the best. Example: A pharmaceutical company needs to reduce the costs of the development of medicine. This can be accomplished in many ways, e.g., with the adoption of new types of molecule analyses, with the improvement of existing analyses, or simply by hiring experts in drug development. For a biotech company aiming to help this pharmaceutical company reduce costs, all the above are potential competitors, and thus threats to commercial success.

In this context, developing and adopting a suitable strategy for marketing your innovation(s) is vital and can considerably contribute to your business success. In fact, an effective marketing strategy will enable you to realise the full potential of commercially exploiting your research results by emphasising on the in-depth understanding of the market environment in order to properly position your products and/or services in the market.

Is developing a strategy for marketing necessary if I do not plan to do any advertising?

Many people often erroneously confuse marketing with advertising. In reality, marketing is a broad organisational function that envelops almost everything a company does with a view to targeting and reaching the most suitable customers and profitably providing them with well-tailored products and/or services. This includes pricing, sales, distribution, promotional efforts and advertising among others. Thus, advertising is only a small part of a much broader blend of marketing tools (also known as the marketing mix) that work in tandem to satisfy the needs of your customers while at the same time nurturing long-term and mutually beneficial relationships with them.

What is a marketing strategy exactly, and how can I design one that will allow me to successfully market my innovative solution?

In a nutshell, marketing strategy is a process that (a) sorts out which customers to target after finding out what has value for them, (b) then determines the most suitable way to successfully generate and deliver this value and (c) finally captures some of this value in return. **The three basic steps** which, if properly followed, will enable you to design an evidence-based strategy for your marketing efforts are provided below.

1. **Understanding your market**
2. **Designing the marketing strategy**
3. **Implementing the marketing strategy**

5 marketing strategy myths debunked

- ***A marketing strategy is only required when you plan on advertising*** – The truth is that advertising is only a marketing tool. Marketing strategy encompasses all the operations of a company that aim at profitably and sustainably addressing the needs of its target customers (e.g. sales, distribution, promotion, etc.)

- ***Marketing strategy is only for big companies*** – An effective marketing strategy can greatly help in making sound strategic decisions. Any business, of any size, in any market, will find that invaluable.

- ***I cannot afford a marketing strategy*** – More often than not, the opposite is actually true. A lack of marketing strategy will probably waste your limited resources. In today's highly competitive business world you cannot afford not to have an effective marketing strategy. Even though you should consider it as an investment and not as an expense, there are ways to affordably develop an evidence-based marketing strategy (e.g. through a simple search of free, online information).

- ***If my competition doesn't have a marketing strategy, then neither should I*** – Just because your competitors do not employ an aggressive advertising campaign, this doesn't mean that they do not invest in marketing at all or that they are not planning to do so in the future. Even if in your market marketing strategies are inadequate, the first company that implements them well will dominate the market. It'd better be yours!

- ***Low prices constitute the best marketing strategy*** – By no means do all customers prioritise price. There are also other determining factors that affect their purchase decision such as quality as well as emotional and occasional factors that can be revealed and exploited with the appropriate marketing strategy. Remember that every euro you lower your price, is a euro lost.

Step 1 Understanding your market and identifying potential opportunities

The first step towards designing an effective, evidence based marketing strategy is gaining a firm understanding of the market that the innovation is aimed at addressing and identifying potential opportunities on which you can capitalise. The standard tool you can employ to this end is a **market study**.

A market study is an organised effort to collect and analyse information regarding your target market with a view to mining valuable marketing intelligence on what is widely known as the **5 Cs**, namely **Customers, Company, Competitors, Collaborators and Context**. The table below provides further details on these key elements of your market along with indicative questions that the market study should aim at addressing for each one.

1. Customers

An integral element of any market study is determining who your prospective customers actually are, and unveiling their particular needs which you will aim at satisfying. The key areas where your study should focus in this respect, are the (i) market size, growth and segments; (ii) benefits that your customers are seeking; (iii) motivation behind their purchases; (iv) purchase process including purchase frequency and quantity; (v) usage - *when, where, how*, and *how much* do people use the product; and finally (vi) customer trends.

Especially when looking into the needs of your customers, it is important to go beyond simple functional needs (e.g. we buy a watch to tell the time or a pen so that we can write something with it). There are also symbolic and emotional needs which you may identify and aim at addressing, which are deeper and less transparent emotional needs (e.g. we may buy a gold watch or an equally expensive pen to showcase our income level or social status). **Example 1:** In the US, a high proportion of cheerleaders find a job after college as medical visitors. Clearly, this is not because they can communicate to doctors clearly the benefits of different drugs. Rather, pharmaceuticals have realised that many doctors, spending their days between pain and death, have a desperate need of someone cheering them up. **Example 2:** Developing a medical examination that can diagnose cancer very early, can be of interest for a prestigious private hospital mainly because it is new and fancy, not because it saves more lives.

Indicative questions: *Who are our customers and what are their needs? Why would they purchase our innovation? What process do they follow to purchase similar products or services? Where do they search for relevant information? Where does the customer actually purchase the product or service? How does the customer use the product? Where, when, with what and for what purpose are they going to use our innovation? How could the needs and preferences of our customers change over time? How can we "lock" them, in the longer run?*

2. Company

After determining the needs of your customers you will need to **assess your current situation** and whether you can effectively address those needs. A useful tool that you can employ in this respect is a **"SWOT" analysis**. The term "SWOT" stands for **Strengths** (e.g. as innovative products or services, key expertise and competencies, efficient processes, etc.), **Weaknesses** (e.g. lack of adequate financial or human resources, etc.), **Opportunities** (e.g. an emerging customer trend that will favour the commercial uptake of your innovation), and **Threats** (e.g. a potential competitor that is about to launch a similar innovation to the market, new legislation that will decrease the size of the market for your innovative technology, etc.). The "SWOT" analysis will allow you to identify and carefully think about your weak and strong points as well as any potential opportunities and threats of the external environment that may influence the success of your commercial endeavour.

Indicative questions: *Who are we? What can we do well? What do we currently offer? What are our key competencies? What makes us better than others? What don't we do well or efficiently? What knowledge and/or skills are we missing? What market opportunities are present today? What is missing from the market? What obstacles do we face right now or may arise in the future? What is the competition doing that might cause us difficulties?*

3. Competitors

The careful assessment of the competition is another crucial part of the market study. You need to identify and examine actual or potential competitors, their offering and positioning in the market as well as their strengths and weaknesses. When researching your competition, it is important to keep in mind that a competitor may not be only someone who does the same thing as you do, but may also be someone who aims at addressing the same customer needs as you. Thus, you will have to determine who competes with your company in meeting your target customers' needs.

Example: An appetite reduction medicine competes not only with other similar drugs, but also with bariatric surgery, gyms, and sports clubs because people who decide to lose weight may decide to do so using different means.

Indicative questions: *Who are our competitors? Are they active at the moment or do they pose a potential threat in the future? What can they do well? What do they currently offer and to whom? What are their strengths and weaknesses? What can we do better than them?*

4. Collaborators

In the course of marketing your innovative solution, you may have to cooperate with several organisations and/or people who do not belong to your company such as distributors, suppliers, etc. Identifying the most suitable partners with which to collaborate is key in a commercial venture. This is even more true for young start-ups, the available resources of whom are more often than not rather limited and who thus are often 'forced' to collaborate with other organisations in order to operate and/or better market their products or services. A good collaborator can provide you with expertise, financial resources, networking, a developed clientele, managing skills, etc. However, a collaborator can turn to a competitor, if he/she thinks that this is more profitable for him/her. Choosing your collaborators wisely involves identifying those whose skills and expertise are different/complimentary to yours, and who are not likely for any reason (e.g. personal connection, lack of interest or resources) to learn from you, and then become your competitor. **Example:** A small start-up can provide genetic diagnoses to optimise the lifestyle (exercise, nutrition, etc.) of obese people. Cooperating with many individual dieticians will require much effort, but is safer. Cooperating with a large private clinic can provide easy and fast access to clients, but the clinic may develop similar diagnoses, if it sees that this service is highly profitable. Balancing between threats and opportunities is important here.

Indicative questions: *What skills and competencies do we seek in our collaborators? What is our current relationship with our collaborators? Are we satisfied and if not, why? Can we ask for improvements or do we have to change certain collaborators? What would be the consequences in the case of a change? What further alliances should we establish (e.g. through licensing out/in intellectual property, joint ventures, etc.)?*

5. Context

Your market study would not be complete without shedding some light on the context within which you (will) operate and market your innovative solution, including the following aspects of the external environment: (i) Political and regulatory (e.g. governmental policies, regulations, legal issues, taxation, etc.); (ii) Economic (e.g. business cycle stage, inflation rate, interest rates, etc.); (iii) Social and cultural (e.g. demographics, trends and fads, culture, etc.); and (iv) Technological (e.g. emerging technological developments, etc.). The investigation of the aforementioned aspects of the environment is also known as a "**PEST**" analysis. **Example:** Insurance policies begin to cover preventive treatment for a disease. This provides a huge opportunity for companies that can offer these treatment regimes. At the same time, it is a huge threat for companies that sell medicine for this disease, as those who actually get the disease will be a lot fewer.

Indicative questions: *What aspects of the political and legal environment can affect the valorisation of our innovation? Do we have the freedom to operate and if not what licenses are required? Is the economic situation of our market favourable for our business? What are the demographics of our market? Are there any trends that we can exploit to better market our innovation? What cultural factors are there that we have to take into account in our marketing efforts? Is the technology in our field developing rapidly or slowly? Can we follow the pace of development or even lead? Is there any risk that our innovation will become obsolete in the near future and if so what can we do so as to remain at the state of the art?*

In order to collect information to fuel the development of your market study, you will need to perform some market research, which can build upon both secondary and primary sources of information.

Secondary market research is based on existing data that has been previously collected for other purposes by someone else. It can be as simple as asking a friend who is knowledgeable on the market you are about to enter. Some free online sources you may consult include synopses of market research reports, websites and published annual reports of competitors, government websites and statistics as well as the press including newspapers and popular business journals. Secondary market research has the advantage of saving you valuable time and money but inherently implies the risk of the data collected not perfectly fitting your needs.

Primary market research is original market research conducted by either you or a professional you may hire (e.g. a market research company) to collect data specifically for your commercial objective. You may choose to launch a survey, conduct interviews, run a focus group, or even carry out some behaviour observation and experimental activities. In the case of primary research, the information that you will collect may be precise but the costs and time required will scale accordingly.

By no means is primary market research always preferable to secondary. The choice depends on how one wants to resolve speed versus accuracy trade-off.

Especially for budding entrepreneurs and young start-ups, it is advisable to begin with more affordable means before moving to advanced market research techniques that typically necessitate increased resources. Contrary to primary research, a good search through secondary data sources will take only a fraction of your budget and time. As such, more often than not, the rewards of secondary market research tend to outweigh its costs while the collected information will help you avoid any potential redundancies in case you decide to also perform primary market research. Finally, a market study is often presented in the form of a written report or presentation (typically as a component within a marketing plan). You should present the findings of your study in a specific and actionable manner so as to facilitate the subsequent design of appropriate marketing strategies and actions.

Step 2 Designing your marketing strategy

The market study has allowed you to gain a better understanding of your market. Once this is over you should:

(a) Have readily available all the knowledge regarding tour market that you could assemble, in a structured way (The 5 Cs)

(b) Have pinpointed important information that you were not able to collect, and for which you should make your own assumptions.

Now, it is time to set the strategy that will guide your marketing efforts towards the successful commercial uptake of your innovative solution. The **process for designing your marketing strategy** is depicted by the figure that follows.

Segmentation: Customers within any market differ in terms of needs, characteristics and/or behaviours and thus require differentiated marketing strategies and actions. The logic of market segmentation is that no company can profitably offer to all its customers exactly what they want, at a price they are willing to pay. Thus, market segmentation is the process by which you will utilise the findings of your market study to divide your market into homogeneous and actionable customer segments, comprised of either individual consumers or other organisations/companies. An "acceptable" segment is one that can be effectively addressed with products and/or services that fit their particular needs. Indicative criteria that you can employ as basis for segmenting your customers are provided by the following table:

Segmentation criteria	Examples
Geographic	> Countries, regions, states, cities, etc.
Demographic	> Age, gender, income level, etc.
Behavioural	> Benefits sought, occasion and rate of usage, etc.
Psychographic	> Personality traits, lifestyle choices, social status, etc.

Example: A lab offering genetic analyses can segment its market first between individuals and companies (hospitals etc.). Then, it can divide the market based on geography (e.g. individuals from the North; Hospitals in big urban centres), demographics (e.g. married females 35-50 years old; Hospitals with more than 100 employees), behaviour (e.g. individuals on a diet; hospitals who perform a specific treatment), or psychography (e.g. individuals who want to do genetic analyses for their families, hospitals who want to communicate that they are "cutting edge").

After identifying the most suitable way to segment your market, a (brief) profile should be prepared for all the resulting customer segments with the key characteristics of each one in order to facilitate the next phase of designing your marketing strategy, namely targeting. Remember: Strictly speaking, there is no "right" or "wrong" segmentation. A good segmentation is simply one that helps the company engage into profitable marketing activities.

Targeting: Based on the profiles that you have prepared during the segmentation phase, you will have to evaluate the attractiveness of each identified customer segment and ultimately decide which one(s) you should try to address, and which ones you should not. In this respect, a meaningful question that will help guide you towards making the right choice is: *Which customer segments can we serve best?* This implies not only being able to effectively address their needs but also being able to do so better than the competition, while at the same time taking into consideration the finite resources at your disposal.

Example: A small company based in a large city and producing bulky hospital equipment may be better off targeting hospitals in the region around it, rather than hospitals all over the country. In the latter case, high transportation costs could reduce profit margins. Of course, this does not mean that if a hospital based in the other side of country makes an order, the company should neglect it. In fact, that may signal that hospitals in that region are not served well by competition, so they could be a good future target segment, willing to pay prices that at least partially absorb the extra transportation costs.

Positioning: Next to choosing the segments of your market which you will target, you must also decide on a suitable positioning strategy for your innovation elaborating on how it will provide distinct value for each of your target segment(s). In fact, the principal aim is to make your innovative offering occupy a distinctive and desirable place in the mind of your customers when compared to competing offerings.

To this end, you may greatly benefit from developing a **positioning statement** with key messages and customer value propositions to be used internally across the organisation. The positioning statement is essentially a concise description of how you want your innovative product and/or service to be perceived by your target market in relation to your competition, and it should guide all the subsequent marketing activities. A basic template for writing an internal positioning statement is provided below.

> For [insert target market], the [insert our product/service] is the [insert point of differentiation] among all [insert frame of competitive reference] because [insert reason to believe].

The point of differentiation should explain how your innovation can benefit customers in ways that differentiate it from competing products/services (e.g. the key benefit offered to prospective customers). The frame of reference refers to all your competitors, as they are perceived by the particular segment which you are targeting. The reason to believe should be a statement that will offer a compelling reason why your target customers should actually believe you. It can range from hard scientific evidence, to customers' testimonials or experts' opinions, or anything else that makes your point of differentiation believable.

Example: For [young, rational, well-educated, health-conscious Germans seeking personalised medicine & healthcare], [Geneses] is the [only 100% German Genetic Diagnosis Company], that [does comprehensive Genetic Analysis tailored for German consumers], [based on its own exclusive and constantly updated databases, which are representative of the German population].

The positioning statement is an internal tool, which can guide your marketing efforts enabling you to maintain focus on how to best tailor your innovative offering and its value proposition to your target customer segments while you develop your marketing strategy and tactics. Although it can be similar to an advertising message, it should not be used as such. If you are targeting different segments, then you need a different (even slightly) positioning statement for each segment.

Step 3 How do I implement my marketing strategy?

Now that you have set your marketing strategy, it is time to implement it. To effectively execute your marketing strategy, you will have to make decisions about the appropriate "marketing mix" for your innovative product or service. The term "**marketing mix**" refers to a set of tactical marketing tools that are widely known as the **4 Ps**, namely (i) **Product**, (ii) **Price**, (iii) **Place** and (iv) **Promotion**, as illustrated in the following figure.

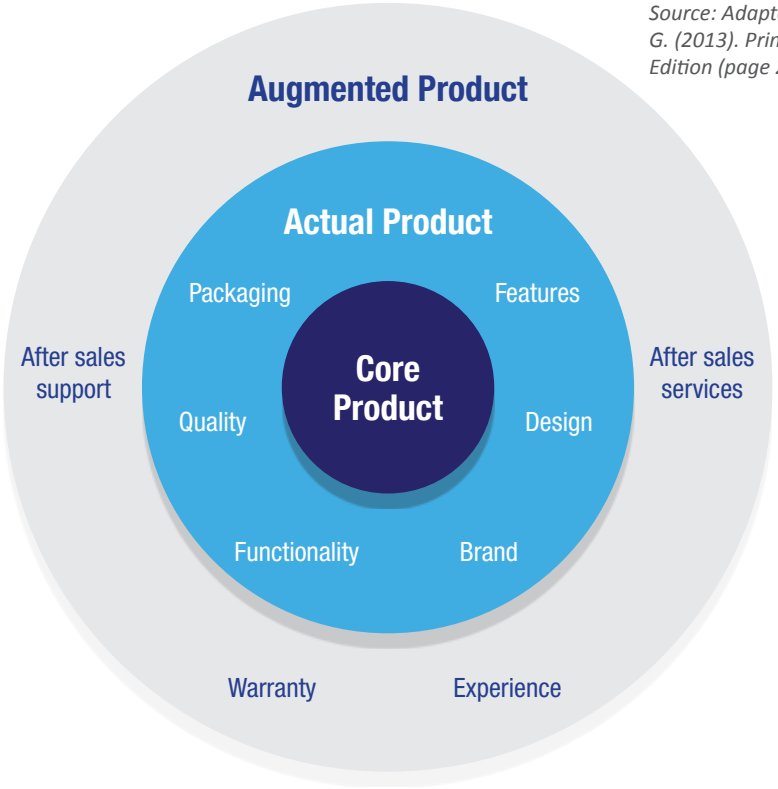
No ingredient of the marketing mix works in isolation. Product, price, place and promotion, all work in tandem aimed at successfully bringing your marketing strategy to life. As such, all of them should be developed in parallel. A good marketing mix is one that implements seamlessly the designed marketing strategy. Below you will find some meaningful insights about the 4 Ps of the marketing.

Product: *What exactly are we offering?*

When thinking about a product, more often than not, the first thing that comes to mind is the image of a tangible object. However, in marketing the term "Product" means much more than just physical products. In fact, it is used to refer to anything that might be offered to a market in order to satisfy a desire or need. Therefore, it may refer to both tangible, physical products (e.g. pens, necklaces, clothes, cars, tablets, smart phones, etc.) as well as services (e.g. hotel, travel, retail, banking services, etc.).

In order to design a customer-driven offering, your Product must be in proper alignment with your marketing strategy with characteristics tailored to the particular needs and wants of your target customers. In this respect, you will have to think of your Product at three different levels, with each one adding more value to your target customers, as depicted in the figure that follows.

Source: Adapted from Kotler, P., & Armstrong, G. (2013). Principles of Marketing 15th Global Edition (page 250). Pearson.



The **Core Product** reflects the main benefit/reason for which your target customers will purchase your product or service. **Example:** A hospital buying a bulky machine, is actually buying the services that this machine can provide, potentially allowing the hospital to improve its efficiency. An individual doing a diagnostic analysis is actually buying "security", "prevention", or "well-being". Knowing what the core product is, allows a company to make the right offering to its customers. The **Actual Product** refers to the tangible product and its characteristics such as technical features, design, quality level, packaging, functionality, etc. Finally, the **Augmented Product** encompasses elements that enhance your offering such as after sale services and support, warranty, experiences, etc. Typically, a company can develop different types of product offerings, by developing several augmented products. These augmented products should then be supported by appropriate promotion, distribution (place), and pricing decisions.

HINT

When designing the Product ingredient of our marketing mix, first identify the key benefits that your Product should provide to your customers, then subsequently design the (unique) characteristics of your actual Product and finally, determine and leverage ways to augment your Product (e.g. through services, experiences, etc.).

Example: A start-up has developed a diagnosis kit that can accurately diagnose a potentially lethal infection in 3 hours, whereas the existing technology does that in 2 days. The "core product" is what this diagnostic kit offers to the hospitals that will use it. This can be, for example, "less people in the intensive care unit, thus fewer costs". The "actual product" is the way that the company will decide to deliver the core product. For instance, it can choose to keep the kit, and only sell to interested hospitals the diagnosis. Or, it can sell the whole kit to the hospitals. Or, it can bundle the kit with all the "disposals" that will be needed for its operation for 6 months. The choice depends on what each hospital is really interested in. Several "extended products" can be "selling the kit with free service every 3 months" or "selling the kit with 5 years warranty".

Price: *How much will we charge for our offering?*

Price refers to the amount of money you will charge for your product or service and amongst all the ingredients of your marketing mix, it is the only one which generates revenue. All other elements are costs. With this in mind, it becomes evident that the pricing strategy you will decide to follow is vital for capturing value from your target customers, and thus crucial for the successful commercialisation of your innovation.

Broadly speaking, pricing should reflect the value that your product generates for the customer. For instance, suppose that you sell to a hospital a diagnostic kit, the production of which costs you 4 000 Euros. If (based on your estimates, or the discussions with the hospital managers and doctors) this kit can save the hospital 50 000 Euros of costs/month from people remaining unnecessarily long in the intensive care unit, you should try to capture some of this value for yourself. From this perspective, and assuming that you have convinced the hospital for the effectiveness of your kit, you could consider a "renting" model in which you will lease your kits to the hospital for a certain price – e.g., 20 000 Euros per month. Although this number may sound a bit too high compared to the cost, it is justified by the money that the hospital saves, and the absence of a comparable competitive offering.

Choosing an appropriate pricing strategy for the introduction of your novel product or service to the market can prove to be quite challenging, as it will be the first time you will be setting a price for it. The basic trade-off is if you are going to chase larger margins, even if that means losing potential customers, or if you are going to chase as many customers as possible, even if that means cutting your margins. In this respect, there are two broad pricing strategies which you may choose to follow, namely **market-skimming** and **market-penetration**:

Market-skimming involves charging a high introductory price for your new product or service with the goal to maximise revenues from customer segments which are able and willing to pay a high price. This strategy implies fewer sales but with a higher profit margin (i.e. fewer but more profitable sales). A market-skimming pricing strategy is more suitable for

- a new product/service...
- which is highly distinctive…
- of high quality or image…
- the main target segment(s) values the above characteristics of the product enough to pay a premium price…
- cases in which competitors are not able to easily and quickly imitate your offering or else they might undercut your higher prices.

A market-penetration pricing strategy entails setting a low price for your new product or service in order to attract a considerable number of buyers and thus quickly secure a large market share. This strategy implies increased sales but with a relatively lower profit margin (i.e. more but less profitable sales). In order for a market-penetration strategy to work:

- your target customers must be price-sensitive and thus readily willing to buy a lower quality/ lower price product compared to a higher quality/ higher priced one.
- the low price of your offering must prevent the competition from entering the market.
- you must be able to sustain the low price of your product/ service, or otherwise your price advantage will not last for long.

The pricing strategy that you will opt for should be dictated by your marketing strategy. In this context, you should also keep in mind that low prices are not always the best option for success. Every cent by which you reduce your price, is a lost cent. In fact, sometimes setting a low price for your product may result into lost profits or even cheapen your innovative offering from the perspective of value-seeking customers by signalling a lower level of quality.

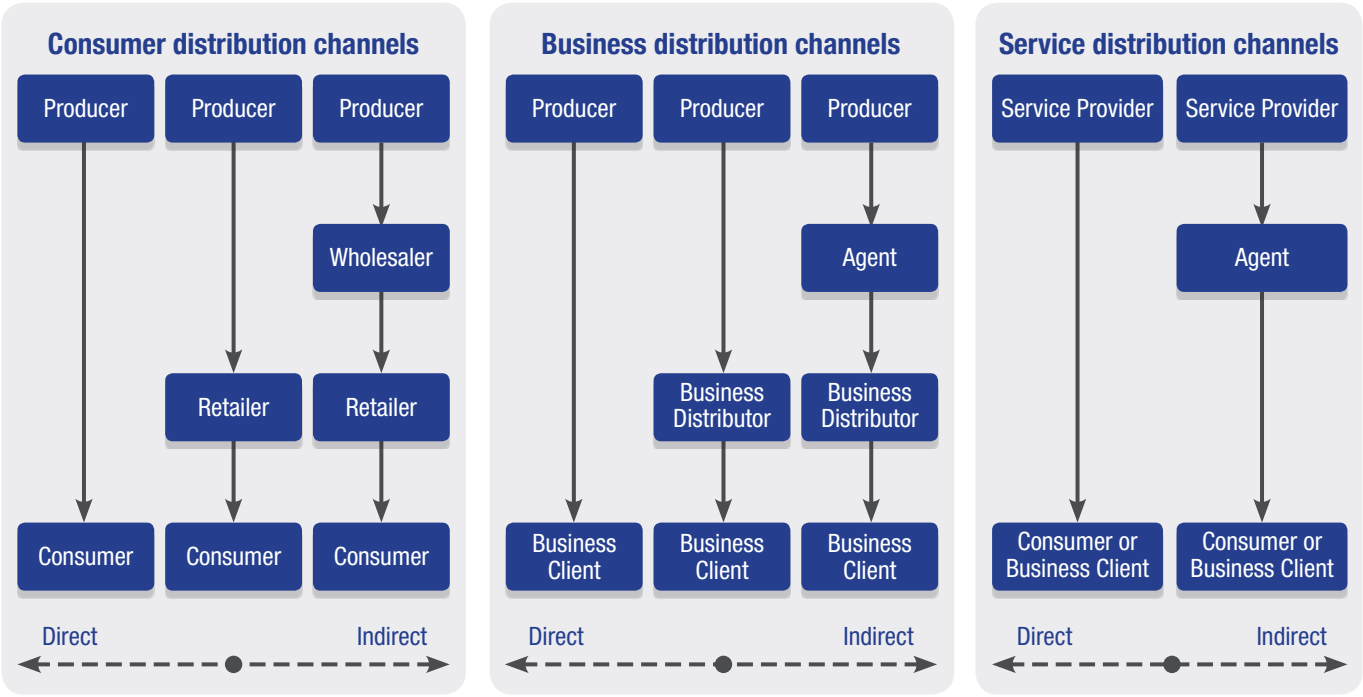
Finally, it is common practice to switch from a market-skimming to a market-penetration strategy as the market matures.

Example: The company selling the diagnostic kits described above, first targets big and fancy private hospitals and charges a high price. As the competition catches up, they can gradually lower the price, and also start doing business with smaller hospitals at the same time.

Place: *How will you deliver your offering to your customers?*

Place is the ingredient of your marketing mix that will enable your innovative product or service to be made timely and conveniently available to your target customers, be they consumers (Business to Consumer – B2C) or business clients (Business to Business – B2B). It involves the design and management of your distribution channels, a chain of interconnected organisations and /or individuals (i.e. intermediaries) which bridge the gap between you and your target customers.

A distribution channel may encompass any number of intermediaries, ranging from none to several. In fact, based on the number of intermediaries involved, distribution channels are characterised either as direct or as indirect, as illustrated by the following figure.



Source: Adapted from Kotler, P., & Armstrong, G. (2013). Principles of Marketing 15th Global Edition (page 365). Pearson.

Choosing a direct distribution channel implies that you will be selling directly to your target customers, whereas indirect distribution channels require the utilisation of one or more levels of intermediaries, such as wholesalers, retailers, agents, business distributors, etc. In general, a direct channel allows for better control, but can be effectively applied for customers that are big and easily reachable (e.g., geographically concentrated). An indirect channel is more expensive (as each participant maintains a separate profit margin), less controllable, but can be the only choice for a company that has many, small, and hard to reach customers.

In practice, you may have to employ a mix of different channels in order to effectively distribute your product or service to your target customers. To this end, it is vital to have a deep understanding of the buying preferences and behaviours of your customers as well as ensure that the intermediaries you choose are able to support the sales of your innovative solution.

Distribution channels are key for the successful implementation of your marketing strategy. Indeed, a unique mix of distribution channels can be a great way to differentiate your product or service from the competition enabling you to develop a sustainable competitive advantage.

Example: Chemical compounds for research laboratories are frequently very similar for all the companies that offer them. In this case, a company selling chemical compounds to research labs that also offers guaranteed fast and reliable delivery at the location of the lab can gain a significant competitive advantage, even if it sells exactly the same product at slightly higher prices. To do that, of course, it is necessary to establish a network of collaborators that ensures fast and reliable delivery.

Promotion: *How are you going to communicate the benefits of your offering?*

You have designed a well-tailored set of products or services (Product), set an attractive price for it (Price) and determined the most appropriate way to distribute and make it available to your target customers (Place). At this stage, you still have one problem: How will your target customers know that you are doing such a great job for them? If you are to successfully reap the benefits of your marketing efforts so far, all the aforementioned ingredients of your marketing mix need to be effectively communicated to your customers. In this respect, the Promotion element of your marketing mix, encompasses the design and coordination of all activities aimed at reaching, communicating, and interacting with your target customers.

The basic objective here is to communicate a message that is desirable for your target segment, different than that of the competitors, and deliver it in ways that your target customers will listen. In terms of *promotional message*, this is a direct consequence of the positioning statement as described above, presented in a more "customer friendly" way.

Example: For the company selling chemical compounds described above, the promotional message should focus on the fast and reliable delivery, and not on the chemical compounds themselves. The former, but not the latter, is a valuable part of the offering, different than what the competitors offer.

In terms of *ways to communicate the message*, many people, erroneously believe that the focus of Promotion is solely on advertising. However, Promotion entails more than just advertising. Indeed, it is comprised of a blend of activities and tools called the promotional mix that can be leveraged in order to raise awareness about the benefits of your innovative product or service, boost sales, as well as to nurture a loyal customer base. The choice of the specific tools that you are going to use depends again on what matches well with your marketing strategy and the other marketing mix elements, and on what communication channels is your target segment likely to attend to.

The following figure depicts the main elements of the promotion mix.

Source: Adapted from Kotler, P., & Armstrong, G. (2013). Principles of Marketing 15th Global Edition (page 431). Pearson.

Advertising: A typically paid type of promotion in the form of (non-personal) presentation of marketing messages, physical products and/or services. Advertising means including mass media (e.g. newspapers, magazines, the radio, TV networks, etc.), brochures and outdoor placements (e.g. billboards, posters, etc.) as well as more contemporary channels such as the internet, mobile advertising, etc. Advertising will enable you to reach a lot of people quickly but is typically one-directional and may be considered impersonal.

Example: Big Pharma companies that advertise directly to medical doctors.

Sales promotion: Short-term strategic tools which aim to provide potential customers with incentives to encourage a boost in sales. Examples of sales promotion tools include seasonal discounts, samples, coupons with expiration dates, contests, demonstrations, etc. Sales promotions can achieve rapid results but their effects tend to be short-term, unless the offering is really superior to competition, and facilitating its trial helps demonstrate this superiority.

Example: A company selling chemical compounds has developed a compound that is really superior to everything else, but also a bit more expensive. It may consider giving small samples of it for free, or sell it at a lower price for a limited period of time, hoping that the users will see its superiority and continue buying it even after the promotion is over.

Personal selling: Personal interactions between your sales force and target customers for the purpose of realising sales. Interactions may be in person, over the phone, through (video and/or voice) chat, etc. This mode of promotion is the most effective when it comes to building trust and establishing long-term relationships with your target customers.

Example: Pharmaceutical companies use medical visitors. SMEs' members or employees visit big clients (e.g. big hospitals) in order to convince them to cooperate.

Public relations: This mode of promotion aims at stimulating favourable publicity in influential media outlets as well as successfully handling negative attention. Media outlets may include traditional channels (e.g. newspapers, magazines, TV, etc.) as well as modern ones such as social media, blogs, etc.

Example: A company that has developed a really innovative solution for fighting dementia. Instead of promoting it directly, they may want to apply to many health start-ups competitions, and hope that they will create a buzz by doing a good job there.

Direct marketing: Activities targeted at carefully selected, influential potential customers with a view to inviting immediate results and nurturing lasting relationships with them.

Example: Social Media is an example of direct-marketing. The company mentioned above that has developed a really innovative solution for fighting dementia can use social media to communicate the benefits of its solution to important players in the market that otherwise are hard or costly to reach (e.g., the families of the people suffering from dementia). It can also combine this channel with sales promotions (e.g., give a discount to those that will share the content posted at the company's Facebook page), hoping to become visible to as many people as possible that are interested in fighting dementia.
Clearly, this channel of direct marketing is not equally suited for all the potential targets. E.g., targeting doctors through Facebook may not work. A direct-marketing activity aimed at doctors could be a 1-day mini conference, in which the scientific evidence behind the solution would be presented.

In conclusion, each promotion tool has its own unique pros and cons. Therefore, when designing your promotion mix, you should take into careful consideration the particularities of your target audiences in order to effectively stimulate their interest and persuade them to choose your offering instead of competing ones. A well-tailored and carefully planned and executed promotion mix can provide you with a high return on your marketing budget.

What comes after the design and implementation of the marketing strategy?

Once your marketing strategy has been defined, the specific ingredients of the marketing mix that will enable you to reach your target customers and successfully meet their needs should follow as a consequence. However, by no means should you consider this as a one-off process. You should constantly monitor the effectiveness of your marketing strategy and make any adjustments required to maintain its success by expecting and timely responding to changes in customer perceptions and demand. These adjustments can be both planned (e.g., will enter a new market in 18 months, and a new marketing strategy is needed for that), or unplanned (e.g., the target segment is more price-sensitive than anticipated, so we have to lower the price a bit). This continuous process will also enable you to identify additional or entirely new and emerging markets that you may successfully target.

The case of 'SKINtecCELLence'

SKINtecCELLence is comprised of a team of highly experienced researchers in the field of life sciences who managed to develop an innovative technique to grow large patches of skin from a patient's own cells. This new skin graft can be used to treat damaged or disfigured skin tissue (e.g. caused from burns or skin cancer). The core benefit of this new skin graft is that it allows for the growing of large pieces of skin tissue in the laboratory instead of transplanting smaller patches of skin from another area of the patient thus, reducing the number of reconstructive surgeries while being less invasive. In addition, it has the benefit of growing with the patient as with normal, healthy skin, which is very important to reconstructive paediatric surgeons. Initial feedback from prospective customers - reconstructive surgeons - based on published preclinical results was positive. In fact, the research team behind SKINtecCELLence was convinced that their therapeutic benefits were far superior to the state of the art and their unique selling proposition (i.e. reduced amount of necessary reconstructive surgeries with minimal invasiveness), would enable them to capture a premium price from their target customer segment, namely reconstructive surgeons. In other words, they held the belief that reconstructive surgeons were not sensitive to price.

In order to substantiate their belief with real marketing evidence, the team employed the advanced commercialisation support services of the Health-2-Market project to conduct a market study. As such, they would be able to not only test their assumptions but also to evaluate their target customers' willingness to pay. Plastic and trauma surgeons were interviewed and findings indicated that there was indeed a demand for improved skin grafts and therapeutic options. The majority of the interviewees ranked improved scar quality or minimised scarring to be the most important. In addition, they were also concerned with pigment irregularities which provided a new insight with a promising business potential. More importantly, however, the professionals that were interviewed turned out to be more price sensitive than anticipated, citing low reimbursement from health authorities and high upfront costs of current products. This finding underlined the need to market the product emphasising on the unique selling points of improved scarring and reduced overall cost in relation to competitors while pursuing strategic reimbursement strategy from health regulatory bodies.

It is evident that the market study greatly benefited the SKINtecCELLence team in understanding their target market and especially in unveiling their particular customer needs so as to develop an effective, evidence-based marketing strategy based on the most suitable selling points of their solution. At the same time it prevented them from going down a path that could potentially gravely endanger the success of their commercial venture.

EXAMPLE POSITIONING STATEMENT: For [*Reconstructive Surgeons who care about minimally invasive surgeries, without pigment irregularities, at an affordable price*], [SKINtecCELLence] is the [only option] that allows [growing of large pieces of skin tissue in the laboratory instead of transplanting smaller patches of skin from another area of the patient thus, reducing the number of reconstructive surgeries], as supported by a [multitude of published preclinical results].

5 things you need to remember about the marketing strategy

- Marketing strategy is a process. You cannot simply do parts of it.
- Marketing strategy always starts with a market study, which can include both simple (e.g., a Google search and talking to a knowledgeable friend) and complex (e.g., an elaborate survey or qualitative study) tools.
- Choosing a target segment is necessary. Choosing also means deciding that you will NOT target some segments.
- Understand well all the needs of your target segment(s). These can be functional or symbolic and emotional. All categories are important, do not assume that only function matters.
- Streamline your actions. Identify a segment and the needs of which you can satisfy better than the competition. Build an offer that satisfies exactly those needs, so that you are profitable.

Chapter 3.5 : Financing

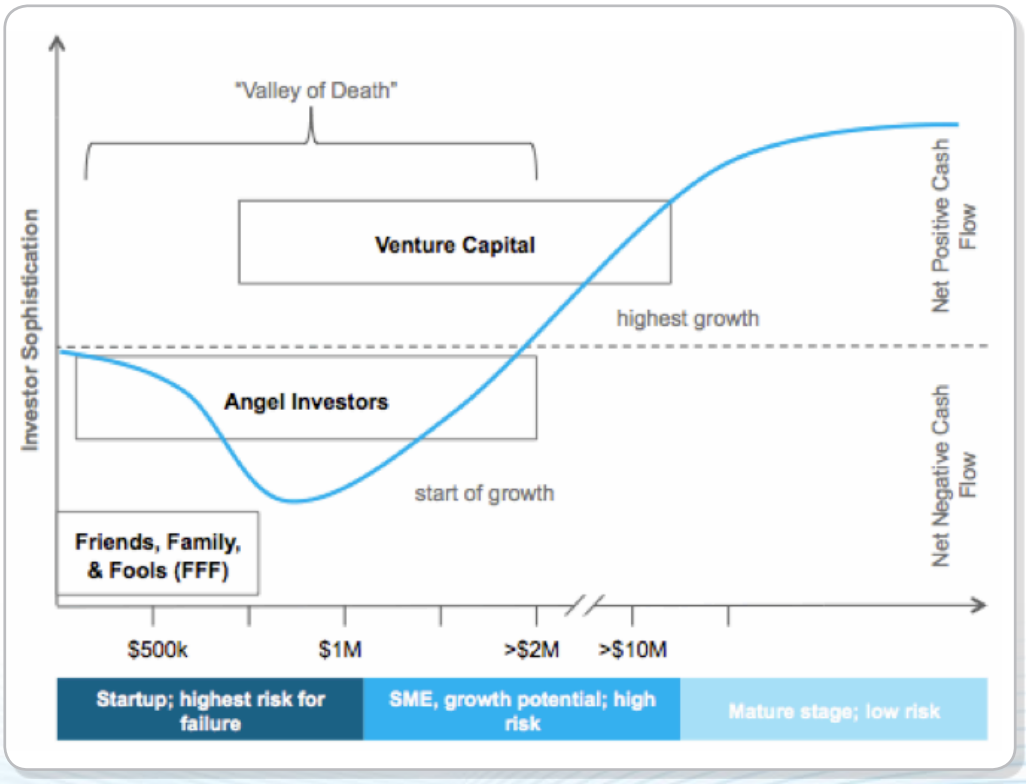
5 most frequent questions on financing

- Where can I find funding for commercialisation?
- How difficult is it to raise funding?
- What will private investors ask in return?
- What do I need to do to prepare?
- How much should I rise?

> *If you always do what you always did, you will always get what you always got.*
>
> - ALBERT EINSTEIN -

A commercialisation project will almost certainly need some kind of financial support to successfully get started and progress beyond the concept stage. As public funding does not generally cover exploitation, outside investment and investors play a crucial role in order to establish an innovation in the market. However, making investments at the earliest stages of development involves significant risk and uncertainty. Many commercialisation projects and in particular start-ups struggle to raise the vital money in what is known as the funding gap or "valley of death".

Financing by risk and investor sophistication



Source: engage AG illustration following Volkmann, Tokarski & Grünhagen (2010) and Smith & Smith (2004)

Because of this high-risk association, new ventures are severely limited by traditional capital sources such as bank loans to see their ideas to fruition. Thus start-ups and new ventures must rely on outside financiers or backers. A variety of new venture financing sources appears below. Depending on the stage of development and the merits of the venture, outside investors may include the entrepreneur's immediate social network, e.g. friends, family, fools (FFF) to more sophisticated investors such as venture capital.

Potential sources of new venture financing

	Life Cycle				
Sources of Financing	Seed	Startup	Early Growth	Rapid Growth	Exit
Entrepreneur					
Friends, Family, Fools (FFF)					
Crowdfunding (reward, donation, pre-order, etc.)					
Crowdinvesting					
Angel Investors					
Venture Capital					
Banks and Financial Institutions					
Acquisition					
IPO					
Dark grey shading indicates primary focus of investor type. Light grey shading indicates secondary focus, or focus of a subset of investors.					

Source: engage AG adapted from Smith & Smith (2004)

Raising funds for a venture is a process not completely unlike that of obtaining grants for research. Not only you need to identify and approach the right funding bodies (and ascertain that you are eligible and understand how much money is available) but also what the application guidelines are and how to tailor your application to best appeal to evaluators and showcase your research so you have the best chance of getting an award. Seeking outside investment from private investors such as angel investors or venture capitalists works much the same way. Below you will find two methods, part one is focused on readying your strategy for private investment, while part two provides information on how to seek and apply for EU funding.

Financing from Private Investors

Step 1 Prepare your Business Plan

The transformation of an innovative idea into a profitable business is rooted in an adequate business model. Your business model is the basis for which you will prepare your business plan which will inform how you plan on succeeding as business. Especially regarding financing, your business model must convince beyond doubt. The information for deciding on a business model and writing a business plan are covered more in depth in chapters 3.1 and 3.3 and will not be reiterated here. However, to convince potential investors, your business plan must have a detailed financing strategy including milestones, timing and overall financing need which should be included in your business plan.

In addition, assessing the valuation of your business can be critical to investors and founders. Your valuation may be part of the negotiation with investors and can be used to split the value, ownership, and control of your company between the founders, previous investors (or IP owners), and the next round of investors. It can take into account comparable businesses, value of IP, total addressable market size, maturity of your business idea, and many other factors. While determining the valuation of your business is important exercise and can assist in negotiating with investors, in the end, it is only an estimate. You should remain open and flexible when negotiating with investors. If an investor values your business lower, listen and take note of their rationale. You may find in subsequent financing rounds, or as your innovation develops, your business valuation may increase significantly.

Step 2 Research and select investors

Based on your company's stage of development, consider the different types of investors. Some investors, for example, may specialise in early stage health or medical device start-ups while others will only invest in later stages. Consider whether to approach business angels, venture capital, or another investment vehicle such as business incubator. Use your personal network and those of your co-founders/ employers to search for proper investors. Be diligent, assertive, and creative in seeking referrals to appropriate investors.

HINT

Lawyers, accountants, industry collaborators, consultants, and other professional service providers with whom you have worked with can be an excellent source for potential investors, and be able to provide an introduction.

After determining from which types of investor(s) to seek funding, consider the advantages and disadvantages of each type of funding. In addition to capital, some investors may be able to provide mentorship or greater access to follow-on financing or customer network. Other investors may be able to provide additional services beyond financing such as assistance with marketing, legal aide, or provide access to IT infrastructure. The idea is to assess the potential fit between your business and the investor's interests and requirements.

Step 3 Define your strategy and approach investors

After selecting suitable investors, define a reasonable strategy. Most experts recommend starting with a group of ten potential investors and keeping seven to eight active at any given time. Whenever possible, you should leverage personal and professional connections for introductions to investors. Otherwise you may try contacting investors directly but be concise. Start with a subject line that is informative and to the point, include a brief introduction as well as an executive summary.

Keep in mind that any potential investor you approach will want a clear and concise overview of what the company does, why it should be interesting, and why it would eventually be profitable investment. Therefore, at this point you should be well prepared to follow up with a well-articulated elevator pitch, be able to present a business plan or prototype. You should also be prepared and anticipate questions they will ask. These questions could span the market size and potential, founding team, business model, customer acquisition strategy, competition, regulatory pathway, clinical strategy, risks, intellectual property, financials and other topics depending on your business. The failure to have well thought out and prepared answers from investors will decrease your likelihood of being funded. In essence, you want to make sure that your potential investor(s) immediately realise the benefits in supporting you. In return for their investment, the investor will typically ask for an equity stake or shares in the company. These shares will be exchanged for cash in subsequent rounds of financing or during an exit (e.g. company is purchased by a competitor, or goes public through an IPO).

Public funding options: How to seek and apply for EU funding for your research and innovation project

Recognising that small to medium enterprises and start-ups pay dividends in job creation and economic development, many regional and national governments, as well as public, private foundations are offering programs of support. The level of support can vary substantially and there are too many to provide an exhaustive list here. Therefore, please refer to your local or national government bodies for list of opportunities that you may be eligible to apply to.

Another option, and the focus of this chapter, that you may want to consider is to investigate the opportunities offered by the **European Union's Horizon 2020 (H2020) Framework Programme for Research and Innovation**.

Running from 2014 until 2020 with a budget of nearly €80 billion, H2020 is the biggest multinational research programme in the world. It funds research and innovation in all areas and there may be opportunities to participate. Since, an organisation of any type or size can participate in H2020 you may be able to benefit from being part of a pan-European consortia sharing knowledge, skills, experience while further developing your innovation.

Reasons to apply for Horizon 2020:

- achieve something that's too big to do alone;
- collaborate across a value chain;
- utilise your organisation's technology and/or know-how that is essential to a solution;
- gain access to science and technology;
- gain access to skills and expertise you don't have;
- find opportunities to trial innovative solutions.

Examples of funding schemes for H2020 are: Research and Innovation Action, Innovation Action, SME Instrument, Fast Track to Innovation... Some of the schemes are described below – for more information, refer to H2020 documents and calls. The level of EC funding depends on the Technology Readiness Level (TRL), a measurement of the maturity level of specific technologies. TRL could vary from 1 (basic principles observed) to 9 (actual system proven in operational environment). The level of funding is indicated in the call documents.

Research and Innovation Action (TRL 2 to 5)

This is an action primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment. Projects may contain closely connected but limited demonstration or pilot activities aiming to show technical feasibility in a near to operational environment. Funding rate is 100%

Innovation Action (TRL 6 to 8)

This is an action primarily consisting of activities directly aiming at producing plans and arrangements or designs for new, altered or improved products, processes or services. For this purpose they may include prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

Often such projects involve a validation of technical and economic performance at system level in real life operating conditions provided by the market. Projects may include limited research and development activities. Funding rate is 70%, except for non-profit legal entities, for which a rate of 100% applies.

Dedicated opportunities for SMEs:

Supporting Entrepreneurship is a H2020 motto and it is also why the new programme has seen the launch of a dedicated instrument for SMEs (SME Instrument, and Fast Track to Innovation) which among other opportunities, could respond to the needs of companies (SMEs, spin offs, start-ups, etc.) who require funds to further develop their products, business plan, or proof of concept.

SME Instrument

The SME instrument is targeted at all types of innovative SMEs showing a strong ambition to develop, grow and internationalise. It provides staged support covering the whole innovation cycle in three phases complemented by a mentoring and coaching service. Transition from one phase to the next will be seamless provided that the project proves to be worth further support in a subsequent evaluation. Phase I (feasibility study); Phase II (demonstration, piloting, prototyping, market replication activities) and Phase III (Support to final commercialisation). Each phase is open to new entrants.

During the first two years of H2020 (2014-2015), in Societal Challenge 1 "Health, wellbeing and demographic change", the SME instrument has a specific regulation compared to other Societal Challenges and Programmes, and targets proposals with more research and thus lower TRL (topic "Clinical validation of already identified biomarkers and/or Diagnostics", TRL 3-6) and more public funding (up to 100%), while in other sectors of H2020 the SME instrument is always requiring for a higher TRL (6-8) with up to 70 % funding.

Fast Track to Innovation

The Fast Track to Innovation (FTI) pilot provides funding for bottom-up proposals for close-to-market innovation activities in any area of technology or application. This thematic openness – combined with the possibility for all kinds of innovation actors to work together and deliver innovation onto the market and/or into society – should nurture trans-disciplinary and cross-sector cooperation. The aim is to reduce time from idea to market, to stimulate the participation of first-time applicants to EU research funding, and to increase private sector investment in research and innovation. The TRL is 6-9 and the EC funding level is 70%.

Beside the SME Instrument or Fast Track to Innovation young companies could be part of other type of collaborative projects where the leading part could be also for public/private research organisations, hospitals, larger companies and more mature SMEs.

There were a number of simplifications in H2020, for example the introduction of a new simplified system of allocation of project costs and the elimination of the negotiation phase preceding the conclusion of contracts. This was done in order to facilitate and accelerate the disbursement of public funds.

In case Horizon 2020 looks like a good opportunity to develop your business, you should then approach in different steps the funding programme, especially getting advices in your own country from the National Contact Points (NCP). These are individuals nominated by their governments with the mandate to spread awareness, provide advice and on-the ground guidance on specific funding opportunities within Horizon 2020 and ensuring that the programme is readily accessible to all potential applicants. There are NCPs in various thematic topics - health, information and communication technologies, food security, energy….You can find "your" NCP via the EC portal:

http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html

and some NCPs have dedicated web sites related to the specific thematic.

Example: Health NCPs can guide anyone interested in applying for European funding in health research to identify the right call, guide and support through the different stages of an application process. Health NCPs in your country can be identified via: http://www.healthncp.net/health-ncp-net-hnn-20.

If you plan to participate in the Horizon 2020 competitive calls, here are the steps you should follow:

Step 1 Find a suitable Call for Proposals

The European Commission publishes on the Participant Portal all the Calls of its research and innovation programmes H2020 divided by themes, such as Health, Transport, Environment, ICT, etc. In the same Portal you can also have access to past programmes to search for previous EU funded projects (Seventh Framework Programme (FP7) and Competitiveness and Innovation Programme (CIP). In addition you can find information about some additional calls in the Other Funding Opportunities section. Besides, you can search according to your research topic with key words and set filters in the calls list.

Step 2 Find project partners or apply as an individual

Collaborative projects: most of the EU funded projects are collaborative projects with at least 3 organisations from different EU Member States or Associated Countries. Various partner search services help you to find organisations that would like to participate in the proposals. You can also post your collaboration offers there.

H2020 also aims to enhance EU international research cooperation so there are more opportunities for cooperation with and participation by researchers from non-EU countries.

Individual researcher or team: It is also possible to submit your proposal as an individual researcher, team or organisation. Such opportunities are mainly funded under the H2020 European Research Council (ERC) grants and the Marie Skłodowska-Curie actions (MSCA). Individual SMEs can apply to the H2020 SME instrument.

Step 3 Create an account on the portal

If you already have a Participant Portal account or so-called ECAS account, you can use it for any future submissions. You only need one account for any of the Participant Portal secured services.

If you do not have an account yet, you need to create it clicking on REGISTER on the top menu on the right.

Step 4 Register your organisation

Check first on the Organisation Register page if your organisation is already registered. Only if you do not find your organisation there, you should start its registration by clicking on the Register.

If you want to participate in a project proposal, your organisation needs to be registered and have a 9-digit Participant Identification Code (PIC) that is the unique identifier of your organisation and will be used as a reference by the Commission in any interactions.

Step 5 Prepare your proposal

This is the major part of the work, requiring a lot of preparation and - for collaborative projects - exchanges with the members of your consortium. Follow the guidelines for applicants and be in touch with the relevant National Contact Point in case of questions! Also, there are many valuable sources that can help you to write good proposals.

Step 6 Submit your project proposal to the European Commission

To submit your project proposal, you need to go to the section Electronic Proposal Submission on a specific topic page that belongs to a call. You need to be logged in with your Participant Portal account to start filling in standard forms and submit your proposal to the Commission.

5 things you need to remember about financing:

- Obtaining private funding can be extremely difficult; exhaust all public funding opportunities first to develop your innovation as far as possible.
- Be sure to understand the expected return from each private investor.
- Be prepared to answer tough questions from investors about all aspects of your business.
- Not all funding or investors are equal.
- Opportunities for obtaining public funding should also be explored both as standalone options and in conjunction with private funding.

Chapter 3.6 : European legislation, standardisation and certification issues

(focus on medicinal and medical device technologies)

Medicinal products and devices are amongst the most stringently regulated products in Europe and abroad. As complex as these regulations are, as necessary it is that you actively address them throughout your innovation processes.

As you may well be aware of, legislation and regulations are governed by different requirements depending both on the sector you are acting in, and the target market. For example, a healthcare biotech SME seeking to bring a new medicinal product to market in the EU has to follow many different EU (and national) regulations and directives on Advanced Therapy Medicinal Products (ATMP), pharmacovigilance, manufacturing, clinical trials, etc. It is decisive to adhere respectively align your commercialisation efforts to all relevant regulations from development to market authorisation in order to avoid endangering successful commercialisation. Throughout all stages, product development activities must be conducted in accordance with the related regulatory requirements to avoid costly delays in bringing your products to the market. This requires that you define and implement a regulatory strategy specifying what and how necessary regulatory information must be collected, evaluated and be translated into planned action prior - or at least in parallel - to the initiation of the early development steps. In other words, following all relevant legislation, standardisation and certification issues will streamline your development activities and help you to develop a product that is safe and effective for its intended use and that meets the regulatory standards of your target market.

If you are a potential newcomer to the subject, you will most likely find these regulations overbearingly complex. This chapter will help you not to give up. It introduces you to the basic principles and provides a broad overview so that you can appreciate the importance of regulatory affairs and compliance. As the topic of European legislation, standardisation and certification issues is sector-specific and can be complex, this chapter focuses on the medicinal products and medical devices sectors. The goal of this chapter is **to raise awareness about the importance of regulations and aligning your commercialisation efforts to legislation, standardisation and certification issues in the innovation strategy for R&D projects.** The chapter also provides additional informational sources where you can look for more information; it is not meant to be and cannot be an exhaustive guide of references, though. While this guide offers a first overview, we highly recommend seeking professional advice or consultation for any innovation project involving regulatory compliance.

Medicinal and Medical Device Regulatory Overview

The table below provides an overview of regulations, which should help you to understand the regulatory systems from a top down approach. Medicinal products are covered on the left, while medical devices are on the right hand column.

To begin, the top level is denoted by international regulatory bodies such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF) and represents the most important regulators worldwide, e.g. European Medicines Agency (EMA), US Federal Drug Administration (FDA), etc. These international bodies seek to achieve greater harmonisation to ensure that safe, effective, and high quality medicines and medical devices are developed and registered in the most resource-efficient manner. The web portals of these bodies offer important libraries of resources: be sure that you consult them regularly during development and implementation of your Innovation Strategy.

The second level serves to demonstrate the most important regulations in the European Union. When planning a new business or developing a new medicinal product or medical device, it is important to identify the applicable regulatory requirements for your product. Again, seeking professional advice in the beginning is strongly recommended. After looking into EU regulations, you should find out which are the applicable national regulatory requirements (the third level). Your products need to obey to regulations at all three levels!

Medicinal and Medical Device Regulatory Overview Table

	Medicinal Products		Medical Device, Active Implantable Medical Devices, in-vitro-diagnostics	
Top-Level	**ICH**	"Early Warning System"	**IMDRF**	"Early Warning System"
	International Conference on Harmonisation	Key Regulators from EU, USA, J, WHO as well as from nearly all Western countries	International Medical Device Regulators Forum (in the past GHTF Global Harmonisation Task Force)	Key Regulators from EU, USA, J, WHO as well as from nearly all Western countries
International	**EU**	Follow-up	**EU**	Follow-up
	• EudraLex • EudraVigilance • EudraCT • EudraGMDP • EudraPharm • EU CT Registry • GCP & Clinical Trials • EMA Inspectors Working Groups (e.g. GCP)		• AIMDD 90/385/EEC • MDD 93/42/EEC • IVDD 98/79/EC • Harmonised, product relevant EU Norms / Standards (EN ...), for Clinical Trials or EN 14155-1/-2	
For information & advice, e.g.:	• EMA – European Medicines Agency • EMA micro-, small- and medium-sized enterprises (SMEs) office and its related information, such as "User guide for micro, small and medium-sized enterprises on the administrative and procedural aspects of medicines legislation" • Guidelines from COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) • European Federation of Pharmaceutical Industries • EUnetHTA (EU network of HTAs) • Private service providers		• European Commission – Growth – Sectors – Medical Devices • European Commission - Dialogue between interested parties • Notified Bodies • Notified Bodies Operations Group • Recommendations-NB-MED • MEDDEV Guidelines • EUnetHTA (EU network of HTAs) • EUCOMED Association of Medical Device manufacturers	
National	**European Economic Area** (EU and Iceland, Liechtenstein, Norway)		**European Economic Area** (EU and Iceland, Liechtenstein, Norway)	
	• Drug Laws • Their Ordinances • Applicable regulatory requirements		• Medical Device Acts • Their Ordinances • Applicable regulatory requirements	
For information & advice, e.g.:	• Regulators Innovation Office(s) • HTA (e.g. GBA (D), HAS (F)) • Innovation Offices of SHIs • National Federation of Pharmaceutical Industries • Private service providers		• European Commission - Dialogue between interested parties • Notified Bodies • Recommendations-NB-MED • MEDDEV Guidelines • HTA (e.g. GBA (D), HAS (F)) • National Associations of Medical Device Industries • Private service providers (example: **Emergo Group and others**)	

Expected Regulatory Changes

The year 2015 marks the 50th anniversary of the adoption of the first law on the authorisation of pharmaceuticals at EU level, which set the basis for some of the key principles that are still valid today: http://ec.europa.eu/health/human-use/50years/index_en.htm. However, the current EU Medical Devices Directives will soon be replaced by a new regulation. The new regulation is expected to be adopted and published in 2015 with implementation through 2018. This will have significant impact on clinical, biocompatibility, preclinical performance and other technical requirements. Therefore, it is of vital importance to continuously follow this process in order to stay updated on upcoming changes to legislation. Bear in mind that the typical development of a therapeutic product takes 10 to 12 years (and sometimes longer). Below we provide two examples of recent respectively upcoming regulatory changes, in the two sectors we focus on: medicinal products and medical devices.

Notable Regulatory Changes

Medicinal Products

A number of regulatory changes and new regulations have been implemented. This includes the repeal of the Clinical Trials Directive on clinical trials on medical products for human use (Directive 2001/20/EC) which was replaced by REGULATION (EU) No 536/2014.

All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive (126 KB) until the new Clinical Trials Regulation (CTR) EU No 536/2014 (875 KB) will become applicable, which will be no earlier than 28 May 2016. For further information please visit the EMA's information on the Clinical trials Directive and the transition period.

Other useful information for SMEs working in the pharma sector:

To understand the EU legal framework for medicinal products it is important to know the applicable provisions of the legislation itself. The Compendium of EU pharmaceutical law is an E-Book published by the European Commission in May 2015 and is provides the most recent versions of the key legal instruments on medicinal products for human use. It offers a useful overview for stakeholders, especially the pharmaceutical industry, regulatory authorities, legal practitioners, but also interested citizens, patients and healthcare professionals.

For information on administrative and procedural aspects of the pharmaceutical legislation: SME User Guide - European Medicines Agency - Europa.

Medical Devices

In September 2012, the European Commission launched a revision process that is expected to substantially change the Regulatory and Legislative Framework about medical devices. Till now, the following legislative documents have been adopted:

- The Communication on safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals.
- The Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.
- The Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

The above documents have been submitted to the European Parliament and the Council. In order to become binding Union law, Parliament and Council need to adopt the texts by ordinary legislative procedure. More information can be obtained through the following link: *http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm*

For information on the whole spectrum of EU policies, legislation, programmes and initiatives relevant to Europe's SMEs, from the European Commission: European portal for SMEs.

Focus on medicinal regulatory pathway

The development of a new medicinal product (i.e., a new drug or biologic) is a long, complex and expensive process which typically takes 10 to 12 years from product identification to commercialisation. The typical development process can be broken down into 5 broad steps:

1. **Discovery and research:** Identification of a target therapy for the diagnosis, cure, mitigation, treatment or prevention of a disease or condition.
2. **Development:** This includes the necessary non-clinical research, clinical studies and chemistry, manufacturing and controls development to support clinical trials.
3. **Regulatory review and approval:** Submission of data for regulatory review to demonstrate product safety, efficacy and quality for its proposed indication.
4. **Market Access:** Getting reimbursement for the product by the relevant regional and national authorities.
5. **Commercialisation and marketing:** Ongoing regulatory compliance through safety reports and other required submissions (e.g., product renewal).

Let us focus on step 3 – regulatory review and approval. The approval of medicinal products is harmonised in the European Economic Area (EEA) - medicines can be authorised by the centralised authorisation procedure[1] or national authorisation procedures:

1. **Centralised authorisation procedure** – it allows the applicants to obtain a marketing authorisation that is valid in all EU countries, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. The centralised procedure is mandatory for medicinal products manufactured using biotechnological processes, for orphan medicinal products and for human products containing a new active substance which was not authorised in the Community before 20 May 2004, i.e. date of entry into force of Regulation (EC) No 726/2004, and which are intended for the treatment of AIDS, cancer, neurodegenerative disorder or diabetes. The European Medicine Agency, EMA, is responsible for the centralised authorisation procedure for human and veterinary medicines.
2. **National authorisation procedures** - each EU Member State has its own national authorisation procedures, within their own territory, of medicines that fall outside the scope of the centralised procedure; these procedures are usually described on the website of the national medicine authority in the relevant country.

There are also two possible routes available to companies for the authorisation of these medicines in several countries simultaneously:

- **Decentralised procedure:** companies can apply for the simultaneous authorisation of a medicine in more than one EU country if it has not yet been authorised in any EU country and it does not fall within the mandatory scope of the centralised procedure.
- **Mutual-recognition procedure:** companies that have a medicine authorised in one EU Member State can apply for this authorisation to be recognised in other EU countries.

Source: European Medicines Agency

Your strategy will therefore depend on the nature of a given medicinal product, the target country(-ies), previous authorisations etc.

[1] *http://ec.europa.eu/health/authorisation-procedures-centralised_en.htm*

Advice for SMEs

The medicinal and medical device market changes frequently in terms of technology, risk potential and marketing. Lack of adequate planning and regulatory strategy for a chosen market can cause higher development costs and unexpected delays resulting in a longer development cycle. It is therefore paramount to ensure that the product to be developed is correctly classified within each jurisdiction and well aligned with an appropriate market entrance strategy. As referenced above, SMEs in particular fail more often than large pharma companies in obtaining final Market Authorisation. SMEs at the minimum should therefore plan to:

- Formulate a regulatory action plan and strategy
- Employ dedicated personnel to cover regulatory and certification issues
- Secure Regulatory Affairs resources
- Establish high quality internal and external training to ensure full compliance to the more stringent requirements (i.e., biocompatibility and clinical data)
- Monitor and prepare for new regulations (see ICH, IMDRF where new planned regulatory changes are made public) that may cause higher costs for the overall assessments and submission fees
- Prepare for longer review times for all medicinal products and medical devices
- Be prepared for clinical evaluation for all device types, classes IIa, b and III mandatory, for class I dependent on risks (see medical device directives)
- Follow the required Quality Management System (QMS), e.g. GxP (medicinal products) or EN 13485 (medical devices) and its SOPs (Standard Operating Procedures) to the word.

Depending on the type of product being developed there may be other processes that an SME should be aware of and integrate into its regulatory action plan and strategy. However, there are special incentives and forms of assistance for European SMEs developing human or veterinary medicines. For example, the European Medicines Agency (EMA) Micro-, small- and medium-sized-enterprise (SME) Office has the explicit aim of promoting innovation and development of new medicines by SMEs. In particular, it helps to identify and address the concerns of SMEs in relation to EMA's regulatory processes from development to marketing - this includes scientific advice and reduced fees among other support. In 2014, EMA reported expansion of its incentives to support SMEs through the regulatory process and broadening its fee incentives to the post-authorisation phase. An overview of EMA's fee incentives available to SME applicants can be found online on the EMA web site. It is important for SMEs to engage in an **early** dialogue with the EMA on all aspects of development, including quality management.

The EMA is also the primary contact point for issues such as orphan designation, pediatric investigation plans, pan-European scientific advice, filing an application for marketing authorisation through the centralised procedure, and EudraVigilance. The SME Office at the EMA can provide assistance and serve to identify the appropriate point of contact for a particular issue. The EMA also gives scientific advice to research-based companies on the development of new medicinal products and develops guidelines on quality, safety and efficacy testing requirements. Furthermore, SMEs can access financial assistance (in the form of fee reductions and deferrals) and administrative assistance from the EMA.

EMA related information for micro-, small- and medium-sized enterprises (SMEs)

The EMA's SME Office – an initiative of the European Medicines Agency - regularly publishes the information for SMEs, issues news bulletins and provides annual reports with an overview of experience with applications for centralised marketing authorisations submitted by SMEs. These and other documents are available on the EMA's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000116.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580024b9c

According to the EMA, to date, **the success rate of SMEs applying for MAA has been below the average** when compared against all companies applying for MAA. Some of the reasons SMEs fail to win approval is the need for additional clinical data to support the application, better quality management and documentation, or **premature filing**. Moreover, **many SMEs are seeking advice too late in development stages** rather than at the beginning.

Extract from the Annual Report 2014 from the EMA's SME Office:

"The SME Office of the EMA conducted a follow-up analysis on the issues encountered in applications from SMEs for human medicines during 2011 and 2013 at day 120 of the evaluation process. Compared with earlier findings, the analysis revealed the following:

- Deficit areas in the quality and clinical modules of the dossiers continue to be identified. Approximately 46% of major objections were on the quality documentation, 47% on the clinical efficacy and safety documentation and 7% on the non-clinical development. Positive dossiers experience an average of 6 major objections (range: 0-18) and negative/withdrawn files, an average of 12 (range 18-24).
- When comparing outcomes for biologics and chemical entities, an increase in the average number of major objections is noted, with biologics experiencing an average of 15 major objections per dossier vs. 6 for files containing chemical entities. 51% of objections encountered in MAAs for biologics were on quality topics vs. 41% in dossiers for chemical entities.
- The most frequent problem areas in the quality documentation related to manufacturing process validation, control and/or characterisation data of active substance/finished product, stability/compatibility data/shelf life and pharmaceutical development.
- Deficits in the pre-clinical development programmes were identified on toxicity study design, pharmacodynamic and pharmacokinetic studies, and reproduction toxicity. Toxicity study design and pharmacodynamics were more frequently raised in biologics applications than in dossiers for chemical entities.
- Major deficiencies in the clinical documentation related to the analysis/robustness of pivotal data, inconsistent data on clinical efficacy, study design and safety issues.

SMEs applying through the centralised authorisation procedure seem to have been experiencing more favourable regulatory approval rates in the past four years. However, deficit areas in the quality and clinical modules of dossiers continue to be identified.

The uptake of scientific advice by SMEs is now significant and it is encouraging to note an increased number of SMEs utilising a broader range of regulatory scientific advice services such as biomarker qualification. There is need to increase awareness of other incentives such as parallel scientific advice with health-technology-assessment bodies.

Initiating dialogue early and repeating it at major milestones is important to decrease the quality and clinical failure rate at time of marketing authorisation review. Compliance with the advice should also be emphasised as an important factor in increasing the outcomes of regulatory submissions."

Source: Annual Report from the SME Office - 2014; reference: EMA/699351/2014 (Link)

HINT: Explore which advice and information is available from relevant institutions and associations !

Institutional:

- EMA - European Medicines Agency
- FDA - U.S. Food and Drug Administration
- HMA - Heads of Medicines Agencies
- IMDRF – International MD Regulators Forum
- IMDEC - International Medical & Dental Ethics Commission
- The European Association for Medical Devices of Notified Bodies
- WHO - World Health Organisation

Associations:

- AAPS - American Association of Pharmaceutical Scientists
- TOPRA - The Organisation for Professionals in Regulatory Affairs
- The Cochrane Collaboration
- DIA - Drug Information Association
- ICH - International Conference on Harmonisation
- IFPMA - International Federation of Pharmaceutical Manufacturers Associations
- MEGRA - Mitteleuropäische Gesellschaft für Regulatory Affairs
- RAPS - Regulatory Affairs Professionals Society

HINT: Get guidance documents available from the relevant authorities!

In August 2014, the SME Office of the European Medicines Agency (EMA) published the revised User guide for micro, small and medium-sized enterprises on the administrative and procedural aspects of medicines legislation that are of particular relevance to SMEs. The guide focuses primarily on the requirements for authorising innovative medicinal products for human or veterinary use, it provides explanation on the EU regulatory framework and data requirements for licensing new medicines, and facilitates understanding of the main aspects of medicinal product legislation. More specifically, the guide provides an overview of the scientific data requirements for obtaining an EU marketing authorisation, summarises the regulatory procedures in place to optimise development and obtain it, provides references to existing national provisions for SMEs applicable to the pharmaceutical sector and gives links to numerous sources with additional information.

EMA also published brief notes on major research and financing initiatives launched at the EU level to support SMEs during the research and development phase. This information is available on the EMA website:

Summary of EU Initiatives for Research (updated in January 2015): EMA/748291/2014 (Link)

Overview of current initiatives at EU level to assist SMEs with financing (updated in December 2014): EMA/748284/2014 (Link)

Remember: be proactive, seek advice, and establish an early dialogue with relevant organisations!

Focus on medical devices

To help entrepreneurs like yourself that are developing new medical devices, the following chapter aims to present the regulatory status-quo that governs the development of medical devices in Europe and give guidance regarding regulatory compliance in related activities. Medical devices are considered to be a vital subsector of the wider medical technology sector and were deemed by the authors as a representative example of the concepts and principles that apply to regulation, certification and standardisation in the medical sector.

Getting started

Medical devices play a pivot role in ensuring a high level of public health care. Covering a wide range of products, from simple bandages to the most sophisticated life-supporting products, the medical devices are essential in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities. The EU, in order to ensure the highest level of patient safety while promoting the innovation and the competitiveness of this sector, has established a comprehensive legal and regulatory framework that provides a set of specific requirements for the manufacturers of medical devices.

Innovative companies like yours that are seeking to bring new medical products in the European Market must be familiar with the applicable legal, regulatory and certification framework and be able to integrate its requirements into their products from the early development stages.

> *CE marking makes Europe's market yours.*
>
> - EC COMMUNICATION -

5 most frequent questions people ask about Medical Device Directives and CE Marking

- What is CE Marking?
- Which are the EU Directives?
- What is the CE Marking process?
- Why do you need a Notified Body for CE marking?
- What are the benefits of CE Marking?

EU MEDICAL DEVICE DIRECTIVES

General

In 1985 a European Council Resolution on a new approach to technical harmonisation and standards proposed a radical change in regulating the technical aspects of industrial products. The new ap-proach involves the development of legislation specifying only the essential requirements that are general and mandatory. These general requirements are assembled in so-called Directives. These Directives address a wide range of industrial products (e.g. machines, electronics). The **European Regulatory and Legislative Framework for medical devices**, is comprised of three EU Directives:

- **Medical device Directive** (MDD) 93/42/EEC;
- **In Vitro Diagnostic Device Directive** 98/79/EC and
- **Active Implantable Device Directive** 90/385/EEC.

All medical devices must meet the applicable 'essential requirements' on safety, performance and labelling as outlined in Annex I of the MDD. Safety requirements are not restricted to patients but include users and, where applicable, other persons. You as the entrepreneur or CEO of a med tech company have to demonstrate the fulfilment of the essential requirements for all devices whether they are new devices or whether they have already been on the market in former times. You can do this by showing that your product fulfils all relevant harmonised standards that are associated to the Directives. An overview over the harmonised standards can be found here: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/index_en.htm

What is CE Marking?

CE Marking is a mandatory conformity marking for certain products sold within the European Eco-nomic Area[2]. The CE Marking is the manufacturer's declaration that the product meets the essential requirements of the applicable EC Directives (of the Medical Device Directives in the case of medical devices) on safety and efficacy and thus enables its free movement within the European market. **Note:** medical devices intended for clinical investigations are exempted from the CE Marking obligation.

CE Marking allows you to sell your products in the countries of the European Economic Area (EEA). By implementing the requirements you may also find that your product is safer and more reliable; you therefore reduce the risk of customer dissatisfaction.

CE Marking is not a distinction of quality or a mark of consumer assurance.

Which products are considered medical devices?

Before engaging in the CE Marking process, **it is very important to ensure that your product is really a medical device and to verify which Directive governs your product's market entry**. As a starting point, you can look at the first articles of the Directives, which contain the definitions and exclusions. For example, according to the Medical Device Directive a medical device is:

…any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnos-tic and/or therapeutic purposes and necessary for its proper application, intended by the manufactur-er to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation or compen-sation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process, con-trol of conception,*
- *and which does not achieve its principal intended action in or on the human body by pharma-cological, immunological or metabolic means, but which may be assisted in its function by such means*.

Some examples of products that are not considered medical devices are:

- medicinal products;
- cosmetic products;
- human blood and human blood products;
- human plasma;
- human transplants, tissues and cells;
- animal origin transplants issues and cells.

[2] *The European Economic Area (EEA) consists of the member states of the European Union, Norway, Iceland and Liechtenstein.*

What are the steps that lead to CE certification?

The following paragraphs outline the process that you should follow to enter the European market in accordance with the Medical Device Directives. This process goes through several stages and involves some choices. The main steps are:

1. Identify the applicable Directive(s)
2. Risk Classification
3. Contact a Notified Body as soon as possible
4. Select the conformity assessment route
5. Demonstrate the safety and efficacy according to harmonised standards
6. Prepare the required Technical Documentation
7. Draft the Declaration of Conformity

These stages are the subject of the next sub-chapters.

Step 1 Identify the applicable Directive(s)

As explained in a previous paragraph, you should determine if a Medical Device Directive applies to your product based on the relevant definitions that can be found in the first articles of the Directives. A first step is to determine whether your solution is a diagnostic tool involving human specimen or it is an active implant. If neither of them applies, then check the MDD. At this point is also necessary to determine if further Directives have to be taken into account (EMC, machinery directive).

Step 2 Risk Classification

The **classification system** that has been developed under the Medical Device Directive, divides the medical devices into **four classes** based on the risk factor involved and the intended use to be made of the product:

- **Class I** for low-risk devices: This includes hospital beds, incontinence diapers, ordinary Band-Aids, external splints, spectacle glasses, examination gloves, reusable surgical tools, non-invasive electrodes etc. Class I devices are further divided into **Is** (sterile devices) and **Im** (measuring devices).
- **Class IIa** for medium-risk devices: This includes catheters, ultrasound equipment, blood filtration equipment, standard contact lenses, surgical gloves, dental fillings, hearing aids etc.
- **Class IIb** for medium-risk devices: This includes haemodialysis equipment, standard intra-ocular lenses, drug administration devices, anaesthetic apparatus, contact lens fluids, blood bags, X-ray equipment etc.
- **Class III** for high-risk devices: This includes cardiac valves, neurological catheters, implants with a biologically active coating etc.

A set of 18 rules that are elucidated in Annex IX of the MDD help you classify your product. Be aware: The result of the risk classification determines the complexity of the conformity assessment process. Therefore, you better discuss your classification with a Notified Body as early as possible. A Notified Body can change your risk classification und thus the entire conformity assessment process. Unexpected changes can threaten your entire financing!

Step 3 Contact a Notified Body as early as possible

A Notified Body is a certification organisation which the national authority (the competent authority) of a member state designates to carry out one or more of the conformity assessment procedures described in the Medical Device Directive. Lists of Notified Bodies, the tasks and responsibilities which have been assigned to them, and their unique four digit identification number are published and updated in the Official Journal of the European Communities.

A Notified Body is not needed for every product. Keep in mind that Notified Bodies are not your opponents. They are your partners on the long and sometimes cumbersome way into the market. They confirm (or challenge) your initial risk classification and help you plan the conformity assessment procedure (time, costs). This procedure comprises all activities to demonstrate the compliance with all relevant harmonised standards. As each product demands a specific selection of harmonised norms, a Notified Body can help you identify the standards you will need to comply with.

Step 4 Select the conformity assessment route

The Medical Device Directive specifies a **set of possible conformity assessment routes** for the CE certification of medical devices. In general, the conformity assessment has 2 aspects:

- Evaluating the design of the device to determine if it meets the requirements of the Directives;
- Assessing your ability as a manufacturer to mass produce conforming devices and to fulfil your regulatory obligations.

You must choose the appropriate conformity assessment route based on the classification of the device. Choosing the most suitable assessment procedure is of strategic importance as poor choices can lead to extended delays or increased costs required to obtain CE certificates and possibly lead to deadlock. The following table maps the possible conformity assessment routes, described in the respective Annexes to the Medical Device Directive with the various classes of the medical devices.

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
ANNEXES	I	Is	Im	IIa	IIb	III
II (+ Sect. 4)						✔
II (- Sect. 4)				✔	✔	
III					✔	✔
IV		✔	✔	✔	✔	✔
V		✔	✔	✔	✔	✔
VI		✔	✔	✔	✔	
VII	✔	✔	✔	✔		

Step 5 Demonstrate the safety and efficacy according to harmonised standards

Once the route to conformity assessment has been determined, the concrete tasks to fulfil the harmonised standards can be initiated. The Medical Device Directives define **essential requirements** and characteristics for medical devices such as risk assessment and patient safety. In order to permit flexibility and encourage innovation, the Directives do not define specific technical requirements. Instead, the EU develops and publishes (in the Official Journal of European Communities) **European Harmonised Standards** that can be used by manufacturers like yourself to demonstrate compliance with the essential requirements. The use of European Harmonised Standards is voluntary. However, conformity of EU Harmonised Standard is deemed to satisfy the applicable essential requirements.

In particular, the safety and efficacy of your product needs to be evaluated. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances under normal conditions of use of the device and the evaluation of the undesirable side effects must be based on 'clinical data'. According to Article 1, the clinical data must be based on:

- clinical investigation(s) of the device concerned; or
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated; evaluation of this data (clinical evaluation) must follow a defined and methodologically sound procedure.

For clinical investigations the rules laid down in Article 15 and Annex "X" (ten) of the MDD apply and the performance of clinical trials is recommended to follow the standard EN 14155. Besides that, each other functional aspect of your med tech product needs to fulfil the harmonised standards to fully comply with the MDD. But before testing and verifying each and every component, you together with the Notified Body better check which of the standards really are binding for you. You need to verify each exclusion of the harmonised standards in case of an audit. Over the last five years, the aspect of usability as described in IEC 62366 has grown in relevance for the med tech industry. So, analogously to the technical document, you need to setup a similar procedure to guarantee that your product is easily and safely usable.

Step 6 Prepare the required Technical Documentation

After evaluating the medical device according to Essential Requirements, you must compile a **Technical Documentation** (device master file, technical file, design dossier) to demonstrate its conformity. Typically, technical files are compiled for Class I, Class IIa and Class IIb medical devices; design dossiers are drafted for Class III medical devices. Your Technical Documentation shall be available for Competent Authority post-market surveillance purpose and shall be maintained for a period ending at least five years after the last product has been manufactured.

Step 7 Draft the Declaration of Conformity (DOC)

The DOC is a one-page document used to "declare" your "conformity" to the Essential Requirements of the European Medical Device Directive. DOC is a legally binding document that should be signed by a senior executive of your company. DOC is obligatory regardless the class of the medical device and the assessment route.

The DOC serves as a formal statement in which you declare publicly that you have met all regulatory obligations necessary to market your device in Europe. It's important to note that the DOC should be signed after all regulatory compliance requirements have been met.

When DOC is signed by the CEO (personal liability) you declare that the product fully complies with the med tech directives, i.e., all relevant harmonised standards are fulfilled! Depending on the risk class of the med tech device, the company is expected to have fully documented the fulfilment of the requirements (external test protocols) or is requested to have a Notified Body check each shipment of its products. Essentially the organisation must have conducted a clinical evaluation of the med tech product in accordance with annex X. (Annex I part I, 6a of Directive 93/42/EEC).

Quality systems standards for medical device manufacturing

What are standards?

The formal definition of a standard that should be adopted in the medical device domain is given by the ISO organisation:

"Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose".

Standards establish prescriptive, design, performance and management specifications for products, processes and services.

Recent years have seen the development and application of what are known as "generic management system standards", where "generic" means that the standards' requirements can be applied to any organisation, regardless of the product it makes or the service it delivers, and "management system" refers to what the organisation does to manage its processes. Two of the most widely known series of generic management system standards are the ISO 9000 series for managing quality systems, and the ISO 14000 series for environmental management systems. ISO 13485 is a specific ISO quality systems standard for medical device manufacturing.

What is ISO 13485?

Based on the approach of ISO 9001, **ISO 13485 specifically addresses quality management systems related to medical device manufacturers as yourself.** The standard can be used by you to demonstrate conformity with applicable regulatory requirements as well as by your suppliers and other supporting organisations. As mentioned previously, the MDD requires from you as a medical device manufacturer to implement a quality management system as part of the conformity assessment procedure. ISO 13485 can be used by you in the design, development and implementation of your quality management system. Certification with ISO 13485 by Notified Bodies can be used to meet the regulatory requirements of the MDDs. **In fact, although not mandatory, ISO 13485 certification has been established as the "golden standard" to meet the quality system requirements** of the European Medical Device Directive (93/42/EEC), In Vitro Medical Device Directive (98/79/EC) and Active Implantable Medical Device Directive (90/835/EEC) with less difficulty.

Which are the ISO 13485 requirements?

In order to achieve compliance with ISO 13485, you must **develop and follow documented procedures** for the following functions:

- Risk management and risk analysis procedures (ISO 14971)
- Document and record controls
- Internal auditing procedures
- Controls for non-conformance
- Corrective and preventative actions
- Process and design controls
- Record retention
- Accountability and traceability.

Most common myths about certification and standardisation

To anyone even remotely involved with certification and standardisation issues, it is clear that the various myths and misunderstandings about these issues act as a barrier to the adoption and use of standards and in addition they constitute the greatest cause of frustration and diminished benefits on the part of users. In this section we will try to identify and address the most common myths about certification and standardisation.

Certification does not add value, but I am obliged to have one just to comply with the relevant regulations and market trends.

Points to consider:

- Certification of your innovative products is a value driver for the entire company as it is a prerequisite for market entry (milestone of company strategy) and an inevitable step towards reimbursement by the national health care system (Europe).
- If you market an innovative product without a CE certification, you put the entire organisation at risk (e.g. risk of compensation for loss suffered, penalty for distortion of competition).
- Without a certified product, the CEO is personally liable for any damage caused by the product.
- Quality management systems focus on the customer needs and strive for continuous improvement of the whole organisation and its products/services.
- Certification and standardisation provide bottom-line cost savings and improved profitability and performance through embedded preventive practices.
- Certification and standardisation assist organisations to avoid mistakes and save resources, time, and money.
- Organisations that are not achieving value from their management systems may not be clear on their true purpose and may be just going through the motions.

Certification is a net cost to my organisation.

Points to consider:

- Studies have shown that preventing a problem is less expensive - and in many cases much less expensive - than dealing with the consequences after a problem occurs.
- If you create a system that you are unwilling to work with on a daily basis, it will provide little or no value, and, in fact, may be a net cost to the organisation.

Standards do not allow my organisation to be flexible and innovative.

Points to consider:

- Standards provide best practices to demonstrate the compliance with the applicable Regulatory and Legislative Framework.
- During management system planning, the organisation will need to make decisions that allow it to remain flexible where flexibility is important, while at the same time providing enough structure to ensure good discipline where discipline is needed.

Certification and standards do not guarantee product quality.

Points to consider:

- Nothing can absolutely guarantee product quality. However, management systems can go a long way toward preventing problems from occurring in the first place, thus providing dramatic improvements in results while reducing costs.
- Management systems do create a monitoring and measurement system of processes and products, or services that substantially increase your ability to produce consistent quality.
- While management systems do not assure absolute results, the preventive steps embedded in management systems will dramatically increase the likelihood of consistent product and overall business success.

Conclusion

Put simply, management systems prevent problems. They work efficiently and effectively whenever organisations can get past the myths addressed above. A clear understanding that the end result may be a fundamental change in how the business operates will help organisations make the transition from reactive management to preventive management. Use of management systems standards and the associated accredited certification process should reduce costs, improve results, improve customer satisfaction and provide confidence to customers, stakeholders, and organisations.

5 things you need to remember about certification and standardisation

- CE Marking is not a distinction of quality or a mark of consumer assurance.
- CE Marking is a kind of trade passport for the European marketplace.
- The CE Marking affixed to a product is a declaration by the person responsible that: (1) The product conforms to all applicable EU legislation, and (2) The appropriate conformity assessment procedures have been completed.
- How easy or difficult is to get CE Marking depends on the classification of your product. Note that you must determine the classification, but a Notified Body has the authority to challenge and/or change the classification.
- ISO certification is not obligatory, however in the long run the easiest way **to meet the quality management system requirements** of EU Directives is to develop a full quality system based on ISO 13485 and have it certified by a notified body.

The case of VIDAVO

VIDAVO S.A. is a high tech company that operates in the field of e-Health and specialises in **health telematics.** The company was established in 2002 in Greece by a group of experienced scientists. VIDAVO develops innovative mobile applications, assisting citizens on-the-move and medical professionals to better manage health and wellness. The company addresses health & social care providers, policy makers, insurance companies, ICT companies wishing to differentiate and specialise, patients, telecom operators and any health related stakeholder group.

Recently VIDAVO S.A. developed a new innovative product, namely a wireless **electrocardiograph (ECG).** The device communicates with a PDA, cellular phone, interactive television or PC, thus allowing acquisition and transmission of data from the patient to a special web-based data centre. The device is intended for monitoring symptoms that may suggest abnormal heart rhythms: skipped beats, pounding heart (palpitations), racing heart, irregular pulse, faintness, light-headedness, or a history of arrhythmia.

VIDAVO, in order to place its product in the EU market had to demonstrate compliance with Europe's Medical Device regulatory framework and especially, as a medical device, with the **Directive 93/42/EEC**. This is where Health-2-Market offered to VIDAVO SA specialised support services to ensure the compliance of its new product with the legal and regulatory framework for medical devices. These services consisted of:

- Identification of the legislative requirements and documentation appropriate for the product.
- Classification of the device according to MDD Annex IX.
- Selection of Conformity Assessment Route.
- Identification of Harmonised Standards.
- Overseeing of the development of risk assessment, procedures, monitoring system and documentation required according to EN ISO 14971:2012.
- Identification of VIDAVO's Quality Management System elements that needed to be modified to ensure compliance to the specific requirements for the product.
- Overseeing of the preparation of the technical file demonstrating compliance with the MDD.
- Support for selecting the Notified Body.
- Attendance of Notified Body's audit and support for the implementation of subsequent corrective actions.
- Overseeing of the preparation of the Declaration of Conformity.

VIDAVO S.A., thanks to Health-2-Market services, managed to get CE Marking for one of its most important products.

The important element in the process is to **choose the right risk classification**. An « easy » conformity assessment procedure could in a "worst case scenario" threaten the company's strategic product development and marketing plan: closely to market entry, the Notified Body can reject the risk classification of the product and thus make a lot of prior work obsolete. This would destroy financial planning of the company. In such cases, it is important to get in touch as early as possible with the Notified Body to prevent such risky situation.

Chapter 4 • Innovation strategy follow-up and evaluation

5 most frequent questions asked about the innovation strategy:

Are the goals you have set for your innovation strategy still relevant? Is there a need for updating the goals/targets?

Is this innovation still going to benefit you, your organisation and the society at large? Are the goal/targets still meaningfully connected with the "outside world"? Did the target groups/end-users, which might eventually use your innovative product, service, or therapy, change? Is the value proposition of your innovation still appropriate?

Are the required resources and capabilities available as planned? Is the timeline for developing or advancing your innovation still realistic?

Do I have to reconsider resource allocation? (Time, financial resources (or constraints), human resources and responsibilities, external and internal stakeholders involved in the implementation of the strategy)

Are there any changes in the technological and economic environment?

Has there been any advancement in the current state of the art in R&D in the relevant domain? Are there any new solutions in the market that were not previously foreseen? Is my innovation still patentable? Are there any barriers to the implementation of the valorisation route identified? Is my business plan and business model still convincing for the investors? Is the amount of capital/financial source available as planned? Are there any new financial solutions out in the market?

Are there any changes in the legislation, standardisation and quality standards related to my innovation?

Have there been any new national, European or international directives, regulations, guidelines, codes of conduct or standards enacted that may have an effect on your innovation strategy?

Are there further results or new technological advancements in your project?

Have you in the meantime generated new R&D results or enhanced components or systems relevant for your innovation? Have you developed/invented an entirely new service/process/product, which may affect your current innovation strategy?

> *However beautiful the strategy, you should occasionally look at the results.*
>
> - WINSTON CHURCHILL -

Getting started

After reading the previous chapters, you may agree with us that to start thinking about the innovation strategy and exploitation routes at the end of your R&I project is already too late, if there is a goal to bring the R&I results to market. The process should be well defined since the early stage of the work and exploitation activities and objectives have to be followed up and evaluated from time to time.

HINT:

A strong innovation strategy is inspirational, ambitious, grounded in reality and adaptive

"**The innovation strategy needs to be adaptive and to evolve over time** allowing adjustments to the desired goals/targets. An innovation strategy and the respective execution should be capable of adapting the moment there are new insights, even if that requires moving in multiple directions to raise the aspiration you had at the beginning. After all, Rome was not built in a day. Likewise, innovation sometimes requires more time than originally estimated." [5]

[5] *InnovationManagement.se; 5 Key Points to Consider when Developing an Innovation Strategy, Wouter Koetzier & Christopher Schorling*

Step 1 Evaluate the goals/targets set for the innovation strategy

HINT: Before deciding how to play the innovation game, organisations have to decide where to play. Is my playground still there

The most strategic question that you should ask yourself: "Are the goals set for the innovation strategy still relevant?" From time to time, you need to come back to basics, consider the whole strategy again and decide if this innovation is still going to benefit you, your organisation and your target group. During the execution of the strategy, internal/external conditions may have changed, requiring a revision of the ultimate goal or certain elements of the strategy. You must always remember that your targets shall remain realistically connected with the "outside world". You also have to make sure that your innovation is still a solution to a problem, meeting unmet needs, and monitor whether someone else has already come up with a more feasible solution. The changing needs and the expectations of the target group may also be a relevant factor, and you must consider whether the target group/end-users, which might eventually use your innovative product, service or therapy, has altogether changed? If any of these factors is applicable and that there are changes in framework conditions, the overall innovation strategy or its constitutive parts should be revised and updated accordingly.

HINT:
The right kind of failure is success.

Step 2 Monitor the availability of resources and capabilities and verify your timeline

The most strategic question that you should ask yourself: "Are the goals set for the innovation strategy still relevant?" From time to time, you need to come back to basics, consider the whole strategy again and decide if this innovation is still going to benefit you, your organisation and your target group. During the execution of the strategy, internal/external conditions may have changed, requiring a revision of the ultimate goal or certain elements of the strategy. You must always remember that your targets shall remain realistically connected with the "outside world". You also have to make sure that your innovation is still a solution to a problem, meeting unmet needs, and monitor whether someone else has already come up with a more feasible solution. The changing needs and the expectations of the target group may also be a relevant factor, and you must consider whether the target group/end-users, which might eventually use your innovative product, service or therapy, has altogether changed? If any of these factors is applicable and that there are changes in framework conditions, the overall innovation strategy or its constitutive parts should be revised and updated accordingly.

HINT:

Adjust the innovation plan: If the current strategy is not viable anymore, and another approach might be, change the approach and begin experimenting again.

Step 3 Follow up your technological and economic environment

The innovation strategy is mainly built on the characteristics of the technological and economic environment that will accommodate your innovative product, service, or therapy. What if the conditions and the characteristics have changed? Then you have to adapt your strategy. One of the most important considerations is the actual state of the art in R&D. New research results may change the angle of your strategy and you may have to come up with an updated plan for execution. New competing solutions might be launched in the market by a competitor, which may force you to reinforce your position by focusing on different advantages of your innovation. In such a situation, you should ask yourself: Is my innovation still patentable? Has anyone else patented a similar innovation in my field of research? Accordingly, you may consider modifying your technological solutions.

IP issues are not the only issue that may be relevant due to the variable technological and economic environment. You also need to evaluate if there are any barriers to the implementation of the valorisation route identified. Is this still the best way for you? The relevance of your business plan should also be assessed and improved. Why? Because you have to make sure that your business plan and business model are still convincing for the investors. Assuming that your valorisation strategy and business plan are still appropriate, you should then consider whether there are any financial bottlenecks. You should assess carefully if the resources for the necessary investment are still available as planned. New financial solutions with better conditions may also be available, inducing changes in your financial plan, bringing added value to your execution procedure.

Step 4 Double check the policy environment and the framework conditions

HINT:

The key is to make decisions rapidly in order not to lag behind the changing framework conditions.

Market exploitation of the research results – especially in the health and life sciences fields – is highly dependent upon the policy environment and the framework conditions. Understanding the legal and regulatory framework and the specific requirements is one of the first steps when you are developing your innovation strategy; but the follow-up and the monitoring of these factors are equally important. European legislation, standardisation and certification procedures, as well as quality system standards related to medical devices are not changing rapidly, yet even a minor change in the framework conditions may affect the execution of the innovation strategy. Therefore, it is advisable to monitor the legislative environment and relevant standards from time to time and adopt corrective measures if necessary.

Step 5 Discover the new results and technological advancements in your project

HINT:

If there is no clear path forward, move on to other projects until something else changes.

R&I projects may generate new, previously unforeseen results and technological advancements that might have potential for market exploitation through setting up of new business ventures. In this case, commercialisation of the new result needs to be considered in light of the existing innovation strategy. You should examine if this new result is in line with or complementary to the opportunities and possibilities formulated in your innovation strategy, or this new idea is representing a different angle that requires a complete restructuring of your strategy. Clearly, this is an important decision that should come out from a consensus of the internal and external stakeholders involved in the execution of the innovation strategy. But keep in mind that you have to be realistic about how many and which kind of innovation strategies you can drive simultaneously.

If any of the above mentioned cases, situations happens to your institution or your project team you can always take a step back and evaluate your innovation strategy. The specific chapters of this guidebook will always help you to revise and adapt your strategy and may provide you with a new insight that will assist you to overcome these challenges.

5 things you need to remember about the follow-up and evaluation of your innovation strategy:

- Check continuously if you are on a good way and your objectives are still relevant.
- Monitor development timelines, resource use, personnel, and if necessary, make strategic adjustments based on consensus.
- Follow up the status of R&I, keep an eye on your competitors and continuously assess the relevance of your valorisation routes.
- Make sure that your innovation strategy is in compliance with the applicable rules, directives and meeting the requirements of the quality system standards.
- New, unforeseen results can boost your innovation potential; however, significant efforts will be required for the adjustment of the existing innovation strategy. Be realistic!

Chapter 5 • Useful references

This chapter suggests some useful references related to the topic of the guidebook. The links have been sorted by categories to help you find what you are looking for. This list is not exhaustive. Other useful links are indicated throughout the various chapters of the guidebook, and additional sources are often available from the web portals of national authorities and support organisations.

Support to exploitation of research results and to SMEs' participation in European research and innovation projects

The Health-2-Market consortium developed useful resources described in the chapter "About the Health-2-Market project" (page 5-6 of this guidebook). These and other materials are available free of charge on the web site www.health2market.eu and as Google Play or the Apple Store Health-2-Market mobile applications.

- **E-learning courses** on "Bringing research to market": http://elearning.health2market.eu/
- **ARIaT – Horizon 2020 Annotated Research and Innovation Actions Template** - "Innovation dimension in Horizon 2020 proposals: Set of good practices to understand and write innovation related issues both in Research and Innovation Actions (RIA) and Innovation Actions (IA)": http://www.health2market.eu/results/h2020-annotated-template
- **MOOC on "Roadmap to Entrepreneurial Mind-set and Toolkit**," available on Udemy: https://www.udemy.com/entrepreneurial-mindset-and-toolkit/#/

In addition to Health-2-Market, other European projects aim at providing support for the exploitation of research results. These include:

Fit for Health 2.0: http://www.fitforhealth.eu/
Fit for Health 2.0 aims to sustainably enhance the participation of European industry, in particular research intensive, high-technology small or medium-sized enterprises (SMEs), in the health-related theme of H2020. SMEs and researchers are supported by targeted, cost-free support measures during the entire innovation cycle and all phases of research projects, including first orientation, consortium building, proposal writing, project management and lastly efficient exploitation of project results.

Entente: http://entente-health.eu/
The Entente project aims at strengthening knowledge transfer offices in universities, public research organisations and hospitals and at promoting transnational collaboration between industry and academia in the health sector through networking activities between all the key stakeholders within knowledge transfer in the health sector in Europe.

Learning materials

Nowadays, many online platforms have been developed to offer various learning materials on topics such as entrepreneurship and business planning or marketing. A few examples of such platforms are:

Udemy: https://www.udemy.com/
Udemy is an online learning marketplace. Each course is given by an expert instructor, and is available on-demand. Thus, students can learn at their pace on any device and fit learning time in their schedules.

Coursera: https://www.coursera.org/
Coursera provides universal access to the world's best education, partnering with top universities and organizations to offer courses for anyone to take, for free.

edX: https://www.edx.org/
EdX offers free online courses and classes from the world's best universities.

Open Education Europa: http://openeducationeuropa.eu/
The main goal of the Open Education Europa portal is to offer access to all existing European Open Educational Resources in different languages in order to be able to present them to learners, teachers and researchers.

IPR support

IPR is a complex topic for which many different supports exist. Besides the national patent offices present in every country, information and support can be found here:

IPR Helpdesk: https://www.iprhelpdesk.eu/
The European IPR Helpdesk offers free of charge, first-line support on IP and IPR matters to beneficiaries of EU funded research projects and EU SMEs involved in transnational partnership agreements, especially within the Enterprise Europe Network (EEN).

WIPO: http://www.wipo.int/portal/en/
WIPO is the global forum for intellectual property services, policy, information and cooperation.

WIPO: Case Studies on Intellectual Property (IP Advantage): http://www.wipo.int/ipadvantage/en/
The case studies in the IP Advantage database offer insights into how IP works in the real world, and how its successful exploitation can contribute to development.

INNOVACCESS: http://www.innovaccess.eu
INNOVACCESS is a network of National Intellectual Property Offices. INNOVACCESS aims to co-ordinate and build synergies with other Intellectual Property Rights (IPRs) related partners and projects in order to enhance the competitiveness of SMEs, to empower them to integrate IPRs into their business strategies, and to improve their capabilities within the area of enforcement.

Drug evaluation and regulation support

For a drug to access market, it needs to be approved by the European Medicines Agency (EMA). As this can be extremely complex for SMEs, the agency provides some specialised support.

European Medicines Agency: www.ema.europa.eu
The European Medicines Agency is a decentralised agency of the European Union responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. The European Medicines Agency publishes a wide range of documents, including press releases, guidance documents, annual reports and work programmes.

Micro-, small- and medium-sized-enterprise (SME) Office of the European Medicines Agency: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000059.jsp&mid=WC0b01ac05800240cc
The SME Office has been set up within the Agency to address the particular needs of smaller companies. The office aims to facilitate communication with SMEs through dedicated personnel within the Agency who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs.

Ethics support

The field of health and health care raises numerous ethical concerns, related to, for example, health care delivery, professional integrity, data handling, use of human subjects in research, and the application of new techniques, such as gene manipulation. Support to research and SMEs is available:

Ethics Helpdesk: http://ec.europa.eu/research/participants/portal/desktop/en/support/other_help_services.html#ohs4
Ethics Helpdesk provides information on ethical issues and offers consultation on the ethical aspects of EU-funded research and innovation projects.

World Health Organisation (WHO): http://www.who.int/topics/ethics/en/
WHO provides general as well as technical information about ethics and health.

Funding and partnering opportunities:

To support research and health care development, many programmes and organisations provide funding or partnering support:

EASME: http://ec.europa.eu/easme/en
The Executive Agency for Small and Medium-sized Enterprises (EASME) has been set-up by the European Commission in order to provide support for SMEs.

Participant Portal: http://ec.europa.eu/research/participants/portal/desktop/en/home.html
This Participant Portal was established as an Internet portal for the stakeholders of the EU research and innovation programmes. It provides you a set of services to facilitate your participation in the programmes.

Horizon 2020 Helpdesk: http://ec.europa.eu/research/index.cfm?pg=enquiries
Provides answer to questions about any aspect of European research in general and the EU Research Framework Programmes in particular.

EIT Health KIC: http://eit.europa.eu/eit-community/eit-health
The goal of EIT Health is to contribute to increasing the competitiveness of European industry, improve the quality of life of Europe's citizens and the sustainability of healthcare system.

EIP on Active and Healthy Ageing: https://webgate.ec.europa.eu/eipaha/
This platform is a communication and information hub for all actors involved in Active and Healthy Ageing throughout Europe; the place to promote news and events, to meet and exchange ideas with peers and potential partners on innovative projects in this challenging field.

Ambient Assisted Living Joint Programme: http://www.aal-europe.eu/
The AAL JP is a funding activity that aims to create better condition of life for the older adults and to strengthen the industrial opportunities in Europe through the use of information and communication technology (ICT).

Innovative Medicines Initiative (IMI): http://www.imi.europa.eu/
The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

Third EU Health Programme: http://ec.europa.eu/health/programme/policy/index_en.htm
The Third EU Health Programme is the main instrument that the Commission uses to implement the EU Health Strategy. Annual work plans of the Programme set out priority areas and the criteria for its funding actions.

Appendices

> Appendices are available on the H2M website: http://health2market.eu/results/step-by-step-guide

They include the following:

- Appendix 1: Indicative template for patent analysis
- Appendix 2: Indicative templates for pro forma financial statements

About the contributors
(in alphabetical order)

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Alexandros Altsitsiadis is a physiotherapist with an expertise in neurological rehabilitation. He also holds a Sports Science degree and is an MBA candidate. He has experience in health research both in lab and field settings and has worked on several healthcare business cases as a specialist. He has extensive training in education with people with disabilities while his primary interest is health entrepreneurship and how to trigger the entrepreneurial mindset in fellow health researchers.

Jürgen Blume, health economist, is Director Medical Research & Regulatory Affairs at Immungenetics, a German SME developing novel therapeutics. He has over 25 years of progressive knowledge and experience in clinical trials, including setting-up a new CRO and consulting in the restructuring of a clinical trial center. He has considerable knowledge and experience with EU and national regulations concerning clinical trials, market approval and market access for Medical Devices and Pharmaceuticals. His practical experience is completed by his record of developing and maintaining cooperations and partnerships with enterprises, institutions, administrations and public authorities as well as of negotiating at all levels of the aforementioned groups.

Kostas Bougiouklis is a partner at an international business consultancy firm and co-founder of a Brussels-based start-up focusing on market research. He has an engineering background combined with an MBA and has been working as an innovation management expert for European start-ups and SMEs since 1998. Kostas is a co-author of two books focusing on SMEs and innovation strategy and has supported more than 100 European start-ups and SMEs in setting up their business and innovation plans.

Caterina Buonocore has started her carrier in 2001 with managing the Innovation Relay Centre project (IRC) by DG Enterprise and then has been managing several projects dedicated to foster Small and Medium Enterprises involvement during FP5 and FP 6. She joined APRE in 2001 and is currently Italian National Contact Point for Societal Challenge Health, Wellbeing and demographic change and for Joint Research Centre for HORIZON 2020, and Head of Unit for Horizon 2020 Italian National Contact Point network and Institutional relations. She has worked in the Health European Commission Programme Committee for Health during FP7. She is involved since 2010 in the Health National Contact Point Network called HEALTH-NCPNET dedicated to the strengthening of National Contact Point Skills all over the Europe and outside.

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Dimitrios Daskalakis is Founding Partner and Director at Q-PLAN INTERNATIONAL, Greece. He holds a diploma in Mechanical Engineering and is a certified Quality System Senior Consultant and Auditor. His fields of expertise since 1996 include (i) Implementation and auditing of management systems to be certified or accredited (more than 50 completed projects), where his experience covers a very broad spectrum of standards (e.g. ISO 17025, ISO 9001, ISO 14001, OHSAS 18001, EMAS, ISO 13485, ISO 27001) for Innovation Agencies, Academic/Research Organisations, industry, service sector, laboratories; (ii) Quality management in several large scale projects (e.g. studies, R&D, demonstration & support projects, implementation of management systems in large organisations with great geographical distribution of their sites); (iii) Project Management and Senior Advice in several RTD and support projects (FP6, FP7, LIFE+, etc); and (iv) Lecturing in Quality Management.

Kostas Giagtzoglou holds a Master in Business Administration (M.B.A.) backed by a BSc in Accounting and Finance. Since 2013 he has been working for Q-PLAN INTERNATIONAL and has been actively involved in the implementation of innovation studies on behalf of the European Commission (EC) as well as FP7 support actions in the fields of innovation and research valorisation. His main areas of expertise include: (a) Elaboration of business plans for highly innovative and entrepreneurial ventures with emphasis on innovation and commercialisation aspects; (b) marketing strategy formulation, implementation and monitoring; and (c) design, implementation and follow-up of large-scale surveys including the development of targeted questionnaires designed to mine insights of both qualitative and quantitative nature as well as data analysis powered by the use of advanced statistical tools.

Dilney Goncalves is an assistant professor of marketing, since 2010, at IE Business School - IE University, in Madrid, Spain where he teaches Marketing, Consumer Behavior, Decision Making, and Market Research and conducts research activities associated with the Customer Loyalty Chair. He holds a PhD in Marketing from INSEAD. His current research interests lie in the area of judgment and decision making. In particular, his research focuses on consumer choices, social comparison processes, and their effects on well-being. His work has been published in Human Resource Management as well as in several international conference proceedings like those of the Society for Personality and Social Psychology, the Society for Consumer Psychology, and the Association for Consumer Research.

Peter Häfner is senior innovation manager with engage AG, Germany, and head of engage's Leipzig and Berlin offices. He is specialised in innovation management and technology commercialisation. His main focus are projects concerning the stimulation and support of technology-oriented spin-offs from higher education and research institutions. Prior to joining engage AG in 2010, Peter Häfner studied Physics and Business Administration with a focus on marketing, innovation management and psychology. He gained his first entrepreneurial experiences in 1992 by founding a company in the social sector. Since 2003, Mr. Häfner supported university spin-offs and was involved in the training of entrepreneurs. He was in charge of setting up structures for efficiently identifying commercially relevant technologies and supporting particularly technology-oriented spin-offs from several universities as CEO of SAXEED Center for Entrepreneurship.

Christoffer Hermansson is Project Manager at the Centre of Intellectual Property (CIP), the joint development center for knowledge-based business development between University of Gothenburg and Chalmers University of Technology. One of his key areas is to develop education and educate students from interdisciplinary backgrounds in law, business, life-science and engineering focusing on knowledge based business development and management. Mr. Hermansson is currently teaching in master level educations at both the University of Gothenburg and Chalmers University of Technology. Mr. Hermansson holds a Master in Law from the University of Gothenburg with a specialization in intellectual capital management and strategic business development.

Peter Heydebreck co-founded the inno group in 1991 and, ever since, has been responsible for expanding the networks of public partners and research labs to match their needs and demands to those of industrial players. He mentors and advises national and regional governments and multi-national organisations (EU, OECD, UNIDO) in the field of innovation policy and competitiveness. His experience covers the public and private sector and is dedicated to boost the return on investment for private and public innovation. Peter is Chairman of the innoveas Board and chairman of the Advisory Board of HZDR Innovation GmbH, he has also served as a member of the Research Commission of the German Science Council. He holds a professorship for Innovation Management and Entrepreneurship at the University of Malmö (Sweden), as well as, a professorship for Waste-Technology at the University of Lulea (Sweden).

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Pavel Kopylov is a specialist in IPR strategy and project coordinator at Sahlgrenska School of Innovation and Entrepreneurship at the University of Gothenburg. He is responsible for project management as well as teaching at master level educations. Previously, Pavel worked as an in-house lawyer, and a business coach for technology-based projects. He holds a master's degree in business design and entrepreneurship from Chalmers University of Technology and a master's degree in law.

Lars Krüger is Chief Executive Officer, Gensoric, Germany. His motivation is to unlock the full potential of electrochemistry in diagnostics. As the head of the Gensoric team, he always strives to find new scientific and business applications of this powerful discipline. His special abilities comprise designing new applications, finding the right partners and financing and eventually turning cutting-edge ideas into reality. Lars studied Industrial Engineering and holds an MBA of HHL Leipzig / EADA Barcelona. He is an alumni of MIT Sloan School of Management's Entrepreneurship Development Program.

Séverine Ouvry is senior consultant at inno TSD, France, and an expert in innovation. Her background as a researcher in the United States, where she completed her PhD in 2005, and her experience in a French Innovation Agency has allowed her to gain experience to help SMEs, academic researchers and other stakeholders build multi-disciplinary research projects and innovation services. She regularly supports SMEs and academic researchers to determine the best financial path to fund their projects, including European funding opportunities, such as research and innovation actions, innovation actions, SME Instrument, Fast Track to innovation Instrument.

Mr. Petros Papadionisiou is partner and Head of Management Systems Department at Q-PLAN INTERNATIONAL. He holds a diploma in Electrical Engineering, a Master in Business Administration and is a certified Quality Systems Auditor. In the last 14 years, Petros Papadionisiou has designed, developed, supported and audited Management Systems according to internationally acclaimed standards (e.g. ISO 9001, ISO 14001, ISO 17025, OHSAS 18001) for more than 100 companies of various industries. Furthermore, he provides commercialisation and business development services to research, industrial and public organisations, including SMEs, in a broad range of business sectors. He participated in several large scale national and European research projects and in the elaboration of specialised Research, Development & Innovation studies on behalf of the European Commission.

Antonis Stamatogiannakis has been a professor of Marketing at IE Business School - IE University since 2011. He holds a PhD in Management from INSEAD. His research has been published in the Journal of Consumer Research, and Human Resource Management, as well as in numerous international conference proceedings. Antonis has received external funding from several international organisations (European, Asian, and American), as well as from industry sources in order to carry out both research and management training. At Health-2-Market, Antonis was the Scientific Coordinator for IE Business School-IE University. He coordinated all the marketing and decision making training of the program, including 6 one-day seminars and 2 week-long academies, as well as the respective on-line training.

Krisztina Varga-Toth, Project Manager at Europa Media, has six years of experience in the development and management of EU-funded projects under FP7 and CIP-IEE programmes. Previously, she acted as the National Contact Point for Twinning at the National Development Agency of Hungary, where she has gained hands-on experience in international affairs and EU policies. Ms. Varga-Toth is the coordinator of the Horizon 2020 MY-WAY project (MY-WAY: Strengthening the web entrepreneurship ecosystem and the services offered across the chain of actors by actively engaging student networks and student entrepreneurship centres) which aims at integrating student networks into the web entrepreneurship ecosystem to support the next generation of tech entrepreneurs.

About the Health-2-Market consortium

inno AG, Germany
www.inno-group.com

inno AG is a European innovation and technology transfer consultancy practice specialised in helping major private and public stakeholders to design and implement R&D and innovation projects worldwide, with a twenty-year track record in providing hands-on support to actually generating large returns on investments in research and innovation.

IE Business School - IE University, Spain
www.ie.edu

IE University is a major part of the IE Higher Education (IE), a leading international group of higher education and research institutions also including IE Business School and IE Foundation.

University of Gothenburg, Sweden
www.gu.se, ssie.gu.se

Sahlgrenska School of Innovation and Entrepreneurship (SSIE) at Sahlgrenska Academy, University of Gothenburg provides one of the leading educational programs in Sweden in the field of entrepreneurship and management of innovation. Through collaboration with the Centre for Intellectual Property (CIP) at UGOT, various research and healthcare organisations, industry and governmental agencies, SSIE aims at becoming a link between academia, society, government and healthcare.

SKEMA Business School, France
www.skema.edu

The School of Knowledge Economy and Management (SKEMA) is a leading European Business School in Knowledge Management and Innovation offering Bachelors, Masters, and Phd programs. SKEMA aims to be a global business school, located on five continents with a unique international strategy, training management leaders in the knowledge economy.

engage AG, Germany
www.engage-ventures.com

engage AG is focused on IP asset management and in founding and supporting start up companies. It supports research institutions and European research endeavors in creating commercial value from IP and scientific results.

APRE, Italy
www.apre.it

APRE, the Agency for the Promotion of European Research, is an Italian non-profit private research organisation that provides information, assistance and training for participation in national and European programmes and collaborative initiatives (today, with particular reference to Horizon 2020) in the field of Research, Technological Development and Innovation (RTDI) and in the transfer of research results.

Q-PLAN INTERNATIONAL, Greece
www.qplan-intl.com

Q-PLAN INTERNATIONAL is an innovation and management consulting company that focuses its activities in the provision of innovation and business support services to researchers, entrepreneurs, start-ups and SMEs operating in several business sectors (e.g. Manufacturing, ICT, Health, Transport, Agro-food, Environment, Energy, etc.) and their related research and technological areas.

White Research, Belgium
www.white-research.eu

White Research is a social research enterprise based in Brussels, specialising in consumer behaviour in the ICT, health, transport and other related sectors and sub-fields. The company employs several collective intelligence research methods and techniques such as crowd sourcing and co-creation workshops and specialises in the design and evaluation of innovation and business modelling with a careful eye on social innovation and entrepreneurship.

Europa Media, Hungary
www.europamedia.org

Europa Media is a Hungarian non-profit SME. Europa Media has vast experience in EU-funded research and innovation projects as well as in developing and delivering on-line platforms and e-learning infrastructures.

inno TSD, France
www.inno-group.com

inno TSD is the French branch of the inno group, specialised in innovation and research support services to public and private actors - including the exploitation of research results and support to entrepreneurship – and in economic development consultancy.

INNOVATION STRATEGY IN R&D PROJECTS

A step by step guide

Health 2 Market
FROM HEALTH RESEARCH TO BUSINESS

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement N°305532

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