Project Deliverable

Project Number:	Project Acronym:	Project Title:
305532	Health-2-Market	From Health Research to Market - Advanced Services and Training Actions for the IPR Management and Business Exploitation of the EU-funded Research results in Health/life sciences

Instrument:	Thematic Priority
COORDINATION AND SUPPORT ACTION	HEALTH

Title

D5.1 Report on selection process with information on technologies mature enough for fostering

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Start date of project:	Duration:
September, 1st 2012	36 months

Organisation name of lead contractor for this deliverable:	Document version:
engage AG	1.0

Dissemination level (Project co-funded by the European Commission within the Seventh Framework Programme)		
PU	Public	X
PP	Restricted to other programme participants (including the Commission)	
RE	Restricted to a group defined by the consortium (including the Commission)	
CO	Confidential, only for members of the consortium (including the Commission)	

"Health-2-Market has received funding from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement No 305532"

Abstract: The report discusses status, contents, application and selection procedures for the advanced services in the Health-2-Market CSA project.

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Validated by: Q-PLAN INTERNATIONAL LTD & Eva Fadil, inno TSD

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"Health-2-Market has received funding from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement No 305532"

1. Introduction

The Health-2-Market (H2M) project has the goal of boosting the economic exploitation of EU-funded research results in the area of Health/life science by supporting researchers and entrepreneurs across Europe.
The major training and knowledge transmission activities –academies, seminars, online-learning– in the project are supported by direct and hands-on consultation, coaching and services.

The so-called Advanced Services (AS) concerned in this report form the most intense part of these additional measures to aid the researchers by giving access to a range of professional services offered by experienced members of the H2M consortium.

Figure 1 - AS in the H2M project (outlined)

The AS are specific and individually tailored services to help researchers move *their* commercialization cases and ideas a concrete step further towards successful valorisation. Currently, all participants in the H2M academies and seminars are eligible to apply for the AS.
The consortium has vowed to support at least 20 promising valorisation cases with these services. Nearly all partners have relevant expertise to contribute to this work package, though it stands out that engage, Q-PLAN, inno TSD, APRE and White Research are the main actors as they offer consulting and support to researchers on specific, commercialization-relevant topics more routinely.

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2. Preparation and case selection

To efficiently deliver the services to entrepreneurial researchers the consortium needed first of all to precisely define the three important questions, what, how and to whom. Meaning, the set of useful available service types offered to researchers needed to be determined, a method and process to identify and evaluate high-potential cases established and potential service recipients need then be informed of the existence of the services and the conditions of participation.

2.1. Types of services offered

To start, consortium members discussed which services they can offer to aid in research valorisation. It was found that most partners can perform a range of activities that could be very valuable to start-ups/commercialisation cases. Additional input to the discussion came from the Training Needs Analysis which was performed during the first phase of the project. When considering the identified beneficiaries and their needs, it is elemental to keep in mind, that in the primary analysis the focus was on training for groups of persons, yet the AS are individual and tailor-made. In the eyes of the consortium members, the AS thus should aim to be complementary to the educational contents, building on the output especially of the academies as the most comprehensive teaching format wherever possible. With this additional input, the initial service ideas were evaluated in order to be able to cover the whole range of potential needs.

As a result, these are the services currently offered to participants:

1. Application mapping and highlighting: With this service, potential areas of application on the market as well as specific examples of application are identified. In addition, potential partners from industry and science within the previously identified application areas are listed and the applicability of the invention in identified application areas is evaluated. Results are summarized in a conclusive presentation.

   Partners responsible: engage, inno TSD

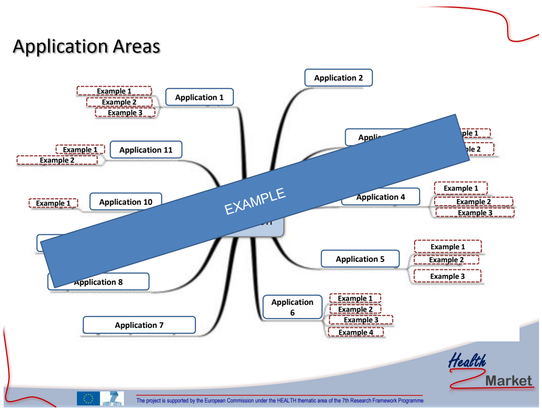

Figure 2 - Example of application mapping AS

2. Patent evaluation: With this service, the commercialization potential of individual patents or a patent portfolio is analyzed and the relative value of the researcher's patent(-s) is determined. An evaluation along the three critical axes technology (technology advancement, technical sophistication, technology cogency etc.), commerce (forward-/backward citation value, enforcement potential, partnering potential, crowdedness, competitive position etc.) and legal criteria (novelty, relevancy, claims, invalidities etc.) is performed. Furthermore the most similar patents can be ranked by relevancy which helps to identify potential patent buyers or licensing partners. The analysis is done with the help of specialized patent research software. Confer

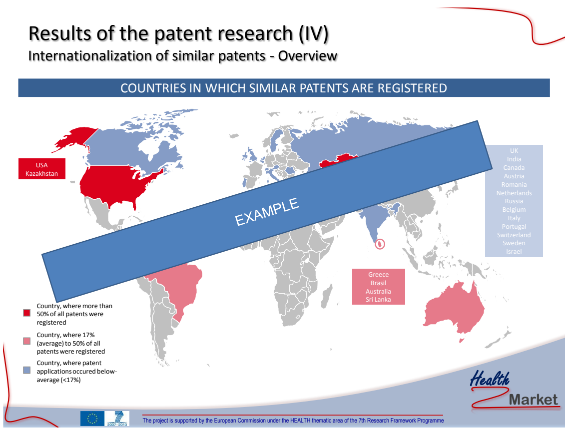

Figure 3 - Example of patent evaluation AS

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also the example in the addendum.

Partners responsible: engage

3. Market analysis: With this service we conduct a market analysis in a technology's specific application fields. This helps to narrow down the potential areas of application of a technology to the most promising ones and to give a first insight into the market value of the technology. Applicants receive a qualified recommendation how to further proceed with their project. A minimum of 10 talks are conducted with relevant experts to discuss any issues with the technology and receive valuable feedback from the market side. An example is included in the addendum as well.

   Partners responsible: engage, inno TSD, White Research, Q-PLAN

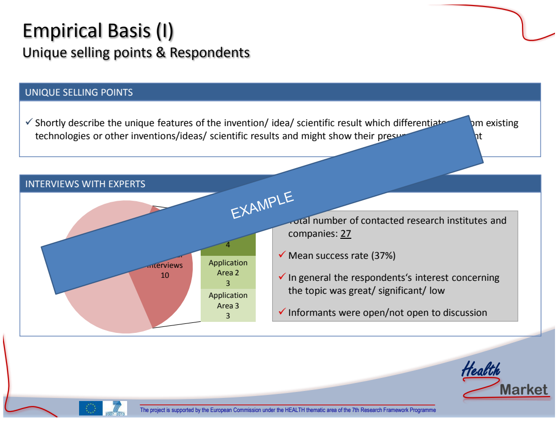

Figure 4 - Example of market study AS

4. Business plan formulation: With this service, experienced and creative professionals from the H2M team work along with Health Researchers and Entrepreneurs in order to translate their venture into a comprehensive business plan for successful commercial deployment or access to capital. H2M experts help clients to make the best out of this service in order to ensure that their business plan thoroughly assesses and demonstrates in a rigorous manner the commercial viability of the proposed venture. The plan covers all aspects of the business and will typically cover a five year planning period with emphasis on the first 18-24 months.

   Partners responsible: Q-PLAN, White Research

5. Business plan evaluation: With this service, the business plan is analyzed in detail and recommendations for optimization are given, taking into account the target group and purpose of the plan (e.g. banks, venture capital, own strategy, etc.). In particular, we scrutinize and check company purpose, problem definition, solution, timing, market size and dynamics, competition, product, business and revenue model, team composition, financials, as we all as overall presentation and layout.

   Partners responsible: engage, Q-PLAN, SKEMA, White Research

6. European legislation, standardization and certification issues related to medical technology: This service consists of analyzing the nature (basic characteristics and intended use) of the medical device under question, classifying it according to the directives' classification, determining the applicable directives / standards / requirements, providing a roadmap (i.e. procedure, costs, time schedules, main production requirements, certification process etc) for the appropriate assessment / certification route and (in more mature cases and for already operational entities) providing support for obtaining certification according to quality management system standards.

   Partners responsible: Q-PLAN

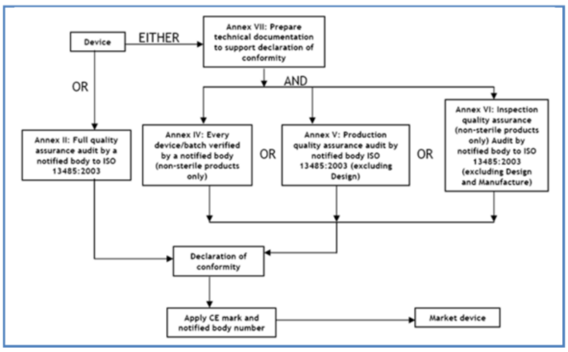

Figure 5 - Example figure from AS 5

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7. Support in obtaining further EU funds: This service aids researchers and entrepreneurs by identifying relevant R&I EU funding, by finding the most appropriate funding action among the relevant EU programmes and subsequently by supporting them in all stages of proposal preparation, e.g. project conception, consortium identification, budgeting, editing and review, etc.

   Partners responsible: APRE, White Research

8. Access to finance: Through our services the Health-to-Market users are supported in approaching banks, financial intermediaries, etc. to benefit from new financial facilities that have been introduced by the EU in 2014.

   Partners responsible: APRE

By design, the services cover different phases in the valorisation process, from the very early application mapping to the access to finance a suitable service exists for a project in any stage of the process as can be seen in the following diagram:

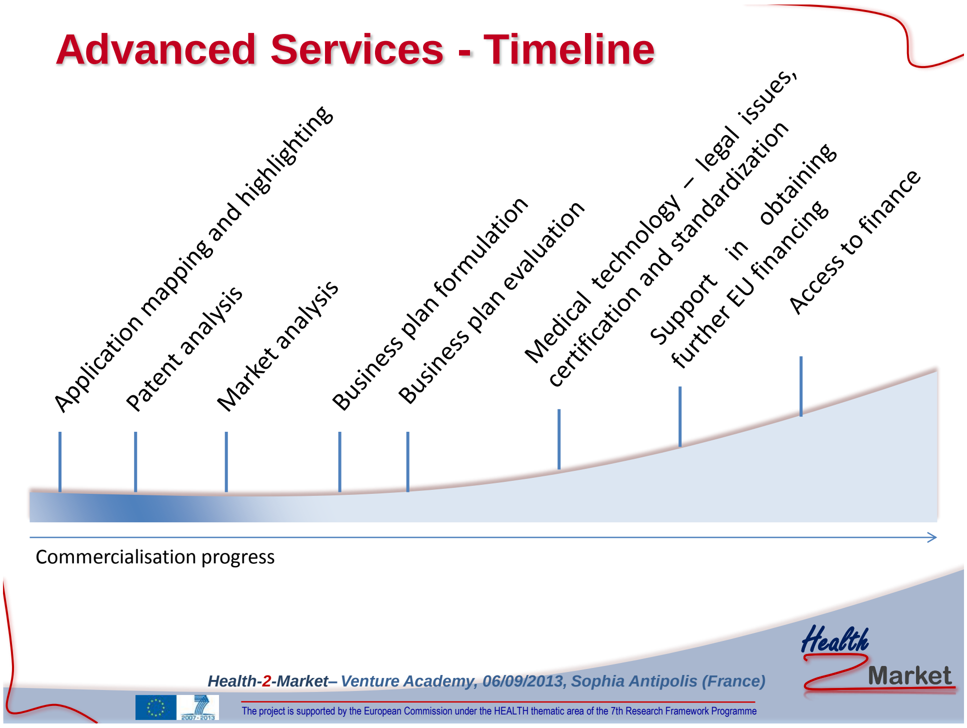

Figure 6 - Overview of different services with regard to their applicability in the commercialisation process

As partners are necessarily specialized, not all services can be offered by all partners. The following table from the initial project proposal gives an overview of partners competences:

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Health-2-Market Partners	Project Manage-ment	Health Research	E-training & e-learning	IPR / Asset Management	Business planning / new venture creation	Innovation management
inno AG	+	+		+	+	+
IE			+		+	+
UGOT		+	+	+	+	
SKEMA			+		+	+
Engage	+	+		+	+	+
APRE	+	+	+		+	+
Q-Plan	+			+	+	+
White Research		+	+		+	+
Europa Media	+		+		+	+
inno TSD	+			+	+	+

Table 1- Overview of partner's competences with regard to the major required skills in the H2M project

From these competences, it was worked out which partner has specific competence fields, as can be seen above.

2.2. Selection methodology

Whereas in the early stages of the H2M project a multi-stage application process (general application, IP & tech check / market check) was planned, this procedure was simplified to a single application. Currently, the preferred requirements for eligibility are:

1. Applicant has participated in an H2M training
2. Applicant has filled out the application form
3. Applicant has at least some form of tangible IP, e.g. patent or patent application, copyrighted materials, etc. preferably as a result of a FP- or EU-sponsored project

The reasoning for this structure is that receiving a free advanced service might be an additional motivator to participate in an academy, at the same time academy participants are motivated and engaged and can profit most from the services after having received initial information on related commercialisation topics in the academy. The requirement for "tangible IP" is that pure "ideas" should not receive advanced services as they are too speculative and far away from the market.

In addition, it was agreed consortium members could nominate 1 "wild card" entry per partner, where the academy participation requirement was waived, to kick-start the process and have presentable successes as well as service examples on hand. 2 partners were able to identify high-potential cases, which were evaluated positively and thus received support. The researchers/entrepreneurs having benefitted from such Advanced Services were nevertheless encouraged to register for one of the Health-2-Market trainings, too, so as to complete the training.

An example of an application form can be found in the addendum.

Project partners have agreed to the following process to process applications and come to a conclusion on whether to support an applicant:

1. The filled-out applications are submitted to the work package leader engage AG who, in due time and usually no longer than four weeks, writes an initial evaluation and takes up contact with the applicant to clarify any open questions or gather more details where necessary. This is usually done via telephone. In the evaluation, one or more services are recommended and also discussed with the

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applicant. However, applicants mostly have a clear idea which service would be most useful to them and usually indicate this on the application form.

2. The evaluation is mailed to representatives from the other partners most involved in this work package (APRE, inno, Q-PLAN & White Research). Partners then discuss who can perform the requested service for the applicant, keeping in mind expertise, geographical distance, language and similarly influencing factors.

3. If partners disagree with an evaluation, they can seek the discussion and resolution in this forum - which thankfully hasn't happened yet. Similarly, if engage is unsure about an application, it consults this forum as well so that a joint solution can be found. Setting up a telephone conference is a suitable and welcomed option to solve any arising problems and has already been taken up.

4. Lastly, the agreed-upon partner contacts the applicant or is referred by engage and the service is delivered.

2.3. Promotion of the AS

Several venues were used to promote the academies and, in conjunction, the advanced services - even before their official launch.

1. The AS were promoted at each H2M academy:
    - Personal presentation during the pilot academy in Sophia-Antipolis (academy in conjunction with project meeting)
    - Explanation of advanced services by lecturers in Gothenburg during the 2nd Academy
    - Video conference and presentation in Madrid during the 3rd Academy
2. At each H2M seminar: Explanation of the H2M project and the AS, either in person, by the trainer or via video presentation
3. Project newsletter: The AS were featured in the H2M newsletter
4. Presentations at conferences and workshops. To mention only a few:
    - Presentation at the Workshop of our sister project Fit4Health, Vienna
    - Personal presentation of advanced services and individual explanation of projects benefits at the Innovationsakademie Berlin (Innovation academy)
    - Presentation of the H2M project at the incubator in Strasbourg
    - Presentation at the JPI Healthy Diet for a Healthy Life
    - Presentations at Europa Media's training programms and events
    - Information during the Entrepreneurship contests held by SKEMA
    - Presentation at the Horizon 2020 info days held by APRE
    - Presentation at the BioPartnering future Europe Conference
    - Presentation at the Health NCP net training events
    - And many more...
5. The AS are featured on the project website
6. The AS were featured on partners websites
7. In addition, project partners informed their relevant networks and contacts directly

Evaluating the different promotion channels shows that the personal presentation directly at the academy has had the most significant effect, however this form would also be the most costly due to travel costs and as such cannot be used in full force.

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It is also planned to use the overwhelmingly positive feedback from AS recipients more aggressively for the information of potential new candidates, e.g. in the form of testimonials or by featuring their cases in the newsletter and on the webpage.

3. Monitoring applications

The following list shows all cases that were evaluated positively:

Case #	Case	Desired Service	Service provided by	Service complete	Country
1	Marino -Skinteccelence	market study	engage	x	CH
2	DuMollard - Toxtest	market study	inno	ongoing	FR
3	Testi- Friedreich Ataxia	financing	APRE	ongoing	IT
4	DeLucrezia - Explora Biotech	patent eval	engage	x	IT
5	Schönthaler - ResQ Biotech	patent eval	engage	x	ES
6	Alterniity	business plan formulation	White Research	x	CH
7	BeNeSit Plus	business plan formulation	Q-PLAN	stalled	ES
8	Vidavo	medical tech regulation	Q-PLAN	x	GR
9	Wojdas - Aarhus	market study	White Research	ongoing	DK
10	Lindahl - Umea	market study	inno	ongoing	SE
11	Jonsson - Diago	market study	engage	ongoing	SE

Table 2 - Positive evaluations and respective services

As can be seen, 5 cases were already completed, with a number of cases still being worked on. If all cases can be successfully completed, the total number would stand at 10 cases.

Currently, 1 case is still under evaluation, while 1 application was rejected due to its high maturity (multiple products already on the market). Another team with a positive evaluation (BeNeSit plus) did decide not to go ahead with founding their project and thus retreated their application. In total there were 14 applications to date.

Considering the application under evaluation as well, a maximum of 11 cases could be completed at this point in time.

3.1. Current preliminary results

A number of conclusions can be drawn based on the above data:

1. Interest in the Advanced Services is lower than expected or the requirements are too high. Of course we must keep in mind that the actual training activities of the project have been running for less than a year.
2. Some services (e.g. market study) see more uptake than others (e.g. application mapping)
3. On a geographical level, there is some connection with the countries where the academies were hosted, but with at least 7 countries included so far, this seems reasonably well distributed.
4. With currently 11 completed cases in a best-case scenario, the project partners have one year left to deliver the remaining services. Considering the delivery times per case, partners will increase their efforts in this work package to deliver the minimum required number before the end of the project.

3.2. Planned adaptations

Consortium partners have identified a number of measures that will serve to make the AS more attractive and increase application numbers:

1. Increase promotional efforts by highlighting the AS more prominently on the web page, featuring them again in the newsletter and in presentation and personal talks
2. Include more seminar participants
3. Alter IP requirement to substitute IP for other success indicators or include other proof of being close to a successful exploitation, as this has caused confusion with groups relying on research data.
4. Further simplify application process where possible

Partners have discussed these ideas and came to the conclusion to go ahead with these ideas.

Partners are currently in discussion about the following ideas:

1. Make AS available for any recipient of FP funding or
2. Make AS available for users of the web courses as well
3. Offer “smaller” services to a larger number of applicants or offer different services (especially for those services where uptake has been low)

The partners will make decisions on these topics in the coming month.

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4. Confidentiality and use of H2M advanced service results

Health-2-Market is a project sponsored by the European commission. As such, the commission expects it to deliver a significant impact and benefit to the largest possible audience, either by addressing and involving people directly or through a domino-effect, which passes the results and new information forward.

Project partners have in co-operation with the project officer, undertaken additional efforts to ensure public benefits arise out of AS activities. This worthy goal is constricted to a degree by the innate nature of the AS themselves: Companies and companies-to-be disclose valuable and often mission-critical information – often only after signing a non-disclosure agreement – and rely on project partners not to carelessly disclose this information to potential or existing competitors or the public too early. As such, publication of the AS results is only possible where such relevant info is not included or mentioned. To still allow for publication, partners agreed to ask the recipients which parts of the delivered service may be published and to black mark confidential information within the AS report that is provided at the completion of each service. For an example of this, refer to the AS examples in the addendum. While this might hamper the readability for some case results, it mostly does not impact the value that can be derived from them.

In addition to publishing the direct results of the performed services, partners agreed to deliver a guide on how to perform specific services. The rationale behind this idea is to give interested parties, e.g. users of the web platform or technology transfer offices, the necessary tools to perform the services themselves and thus aid their commercialization projects. The guide will serve as an additional value-add of the H2M project and could be freely distributed.

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5. Conclusion and next steps

The AS form an important part of the H2M project and promise to be a key enabler of new ventures and driver of commercialization projects across Europe, as can already be seen with the completed cases. A range of suitable and valuable service types has been developed and is on offer to applicants. In tandem, a quick and fair evaluation procedure was designed and enacted.

Currently, the AS are at their halfway-mark in the overall project context, with about half of the WP-specific goal reached. Initial interest was high and has led to a range of successfully completed services.

Project partners have recognized the need to raise more interest for the AS and plan to enact these. A number of remedial measures have been outlined and are introduced. Further successfully completed cases will serve as an additional motivation and show the beneficial effects of the AS, enticing more researchers and entrepreneurs to come forward with their cases. Thus the consortium partners are optimistic that they can motivate enough high-profile applicants in the remaining project run-time – after all, the AS are still professional services free of charge.

6. Addendum

6.1. Application form

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H2M – Advanced services application form

Please fill out the questionnaire and send it back to h2m@engage-ventures.com. Please make sure to answer in all 5 categories (market, technology, people, financing, IPR). Based on your answers we will give you a qualified recommendation how to further proceed and which advanced service we would suggest. At the end of the questionnaire you can also indicate which advanced service you would like to receive if your case is selected.

1. General

Name:	Your name, title		
Institution:	Your host research institution		
Position:	(Lead) Researcher / Technology Transfer / etc.		
Tel.:	e.g. +49 (0) 721 91345-11	E-Mail:	e.g. a@b.cd

2. Market:

Which markets do you target (geographically, customer type, sector/ branch)?	
Geographical:	Please state whether national, European, ww or other market
Sector/ branch:	Please state whether therapeutic, diagnostic, biomedical device or other
What do you know about the market dynamic?	
Please give detail	
Is it a growth market?	
☐ Yes ☐ No	Other: Please explain
What do you know about market sizes/ volumes?	
Please state the size (in $/€) of the addressed markets	
Who is the customer, who needs to be influenced/addressed, who makes the buying decision?	
Please describe who is involved in the buying decision, whether there is only the end consumer deciding or whether others are involved such as government, health insurance, etc.	
How sensitive are the customers to price?	
Please indicate the price sensitivity of the customers	
What is important to the customer?	
Please indicate what is important to the customers (e.g. price, quality, accuracy, adverse events etc.)	
Has there been any feedback from the market side (e.g. when presenting results at a fair, talking to potential customers)?	
Please indicate if there is feedback from the market or interested parties for your product / service	
Have you or somebody else (TTO, etc.) already tried marketing the technology? What where the results?	
Please state whether the technology has been marketed already and if so, how successful this has been (e.g. lead to pilot customers etc.)	
Competitors. Who are they, what products/competing solution are they selling, what market position are they in, how do they compare to your technology?	
Competitors	Please name the competitors

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Products	Please name competing products
Advantages / Disadvantages	Please describe the (dis-)advantages of the competing technology
What knowledge do you have of special market mechanisms (market knowledge) and entry barriers (contractual, regulatory, financial, technical, …)?	
Market knowledge	Please give overview of your market knowledge
Entry barriers	Please indicate which market barriers there are and how "high" these are
What can you say about the pricing (costs/ market prizes) of your potential product and competitors technologies?	
Please indicate the price of your and the competitors technology	

3. Technology

What is the need your technology satisfies?
Please describe which concrete need(s) your technology satisfies
What is your technology's degree of maturity?
Please indicate, e.g. proof-of-concept, prototype, …
What are the technologies unique selling points?
Please describe the unique selling points
What limitations on your technology are there (e.g. special gear/tools/machines necessary, access to lab space necessary, etc.)?
Please describe the limitations of your technology
What are the necessary resources to create product (time, personnel, money, infrastructure, …)?
Please describe all resources which you need for production
How far ahead of the state of the art would you suppose the technology is?
Please indicate how novel, innovative your technology is
Will you need to conduct clinical/ human trials?
Please state whether you need to conduct clinical trials
What possibilities are there for further development?
Please indicate whether your technology can be further advanced to new products or expanded to different markets/sectors

4. People

What is your motivation to valorize your research? How convinced are you of your idea/ product/service?
Please explain
Who are the key persons involved?
Please name the key persons involved.
What is their background / experience?
Please describe their background
What can they bring to the proposed undertaking?
Please describe what each of the persons contributes to the undertaking

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When and how are they available?
Please also indicate whether they work fulltime or part time for the undertaking
Who is a candidate for management tasks?
Please indicate whether you have a candidate for management tasks
Are there professional contacts / networks that aid you with valorization?
Please indicate whether you have professional help

5. Financing:

Would you invest your own money in a company making your product?
☐ Yes ☐ No
Does a business plan exist?
☐ Yes ☐ No
Is an industry joint-venture possible?
☐ Yes ☐ No
Are you already in contact with investors?
☐ Yes ☐ No
How much is your own / your networks investment (family, friends, fools)?
Please enter

6. Intellectual Property Rights

Is the technology in any way protected? If so, please indicate the type of protection (patent, copyright, etc.)
Please detail type(s) of protection
Where is the technology protected (geographic scope)?
Please indicate in which regions the technology is protected
Which applications are currently covered?
Please indicate which applications / parts of your business are covered
Are there applications you plan to commercialize not yet covered by the protection?
Please explain.
Is the IP protection already - or can it still be - internationalized (at least in the US + most important markets)?
Please explain.
Have you published the underlying scientific results? When/where?
Please explain.
Is the protection still active (fees paid etc.)? How long will the protection still last?
Please explain.
Is it already licensed/used? By whom, where, for how long, to what conditions, ...?
Please explain.
Is the technology ready to be licensed / used or is follow-up research / development necessary?
Please describe.
What is the situation regarding norms, laws, GMP regulations etc. for the specific technology?
Please describe.

Are there any usage restrictions on the technology?
If so, please explain.
How freely can you access the technology (sole ownership, co-ownership, ...)?
Please describe.
Are other rights necessary to use the technology (background)?
Please explain.
Are the rights to the technology in any way under scrutiny (usage limitations, appeals, indictions, ...)?
If so, please explain.
Could you identify a violation of your rights? How easy would it be spot such a use of your technology?
Please explain.

7. Feedback / Input:

Please indicate which advanced service you would like to obtain:

Please indicate or leave blank.

Feedback:

Questions, comments, complaints, etc.

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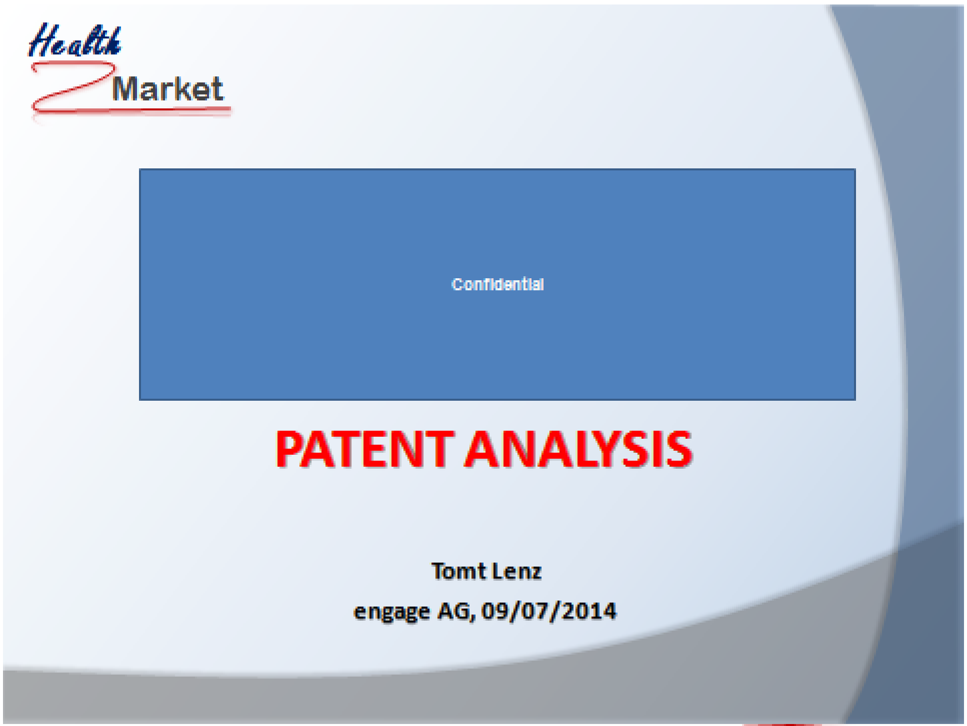
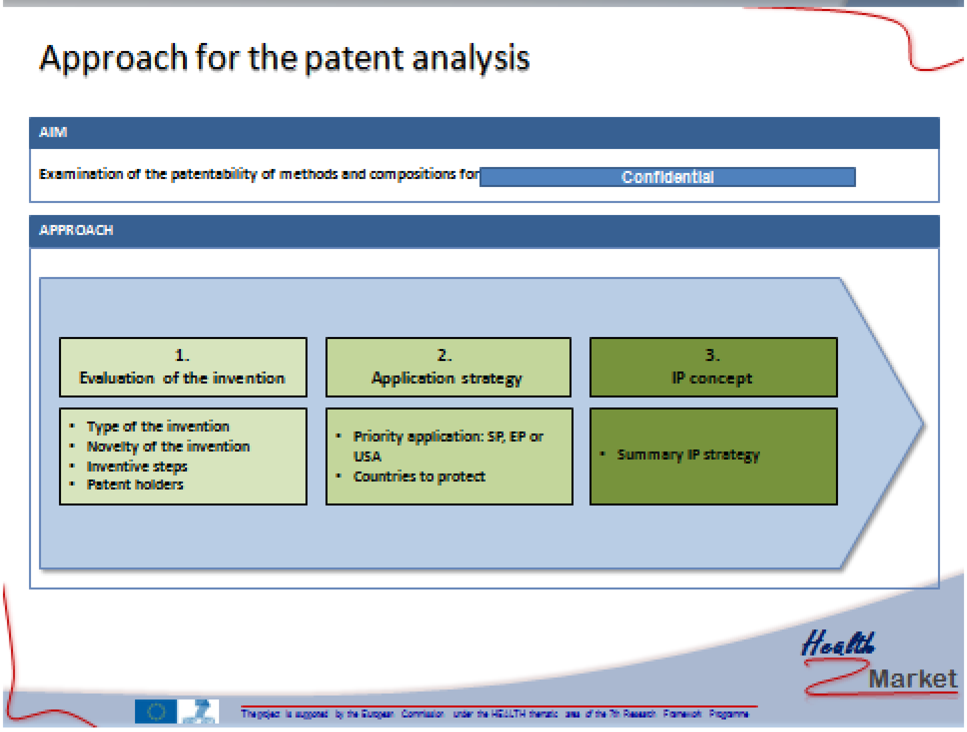
6.2. Service example: Patent evaluation





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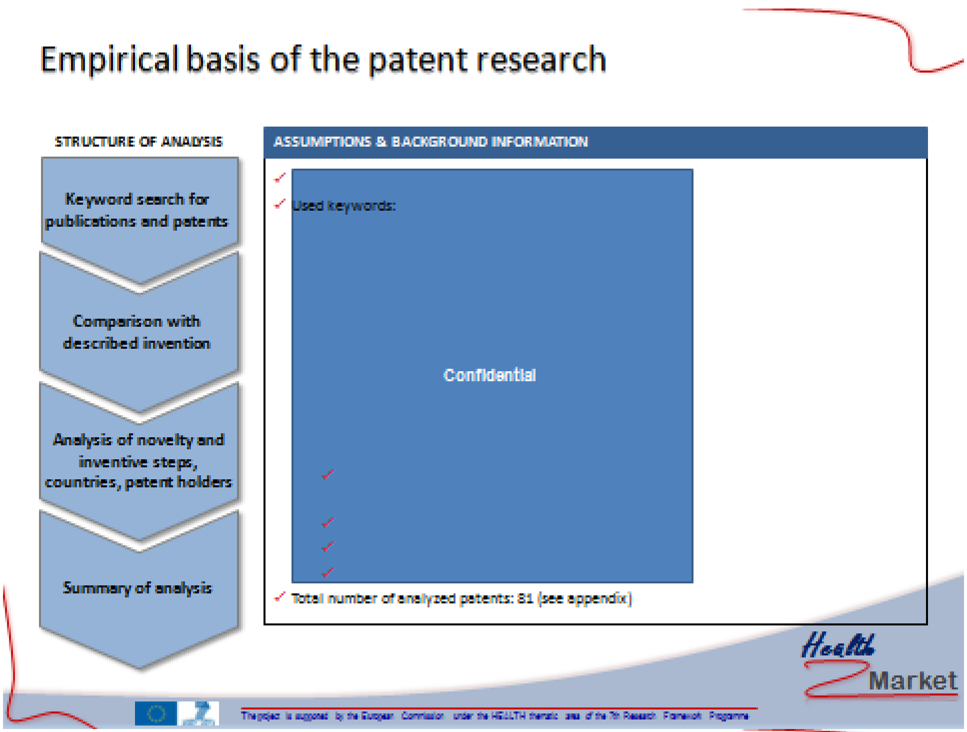

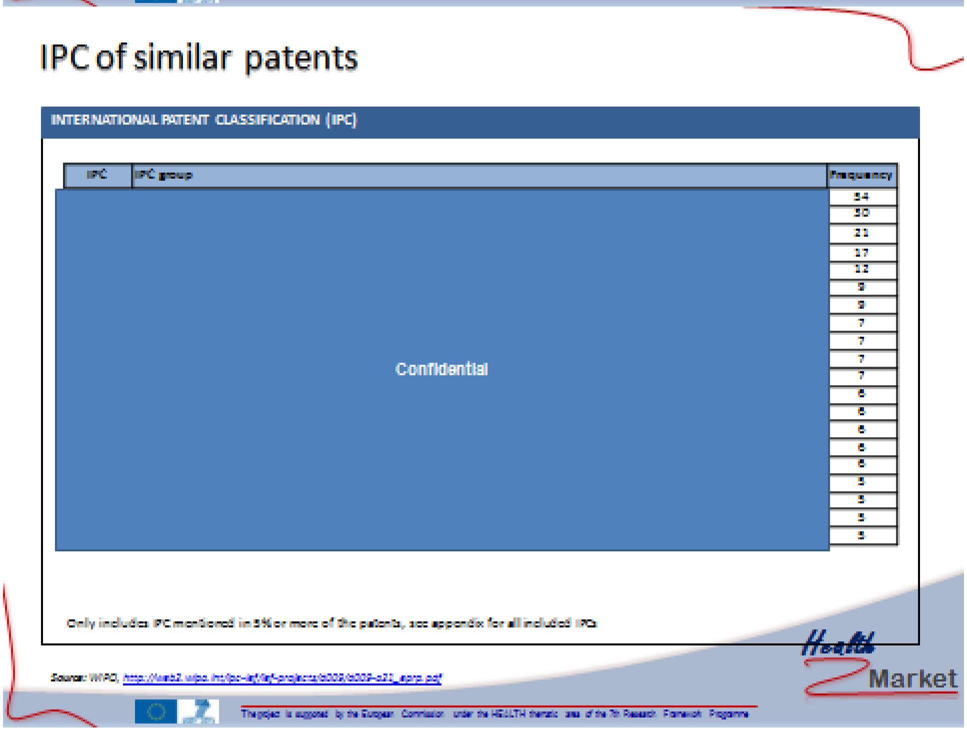

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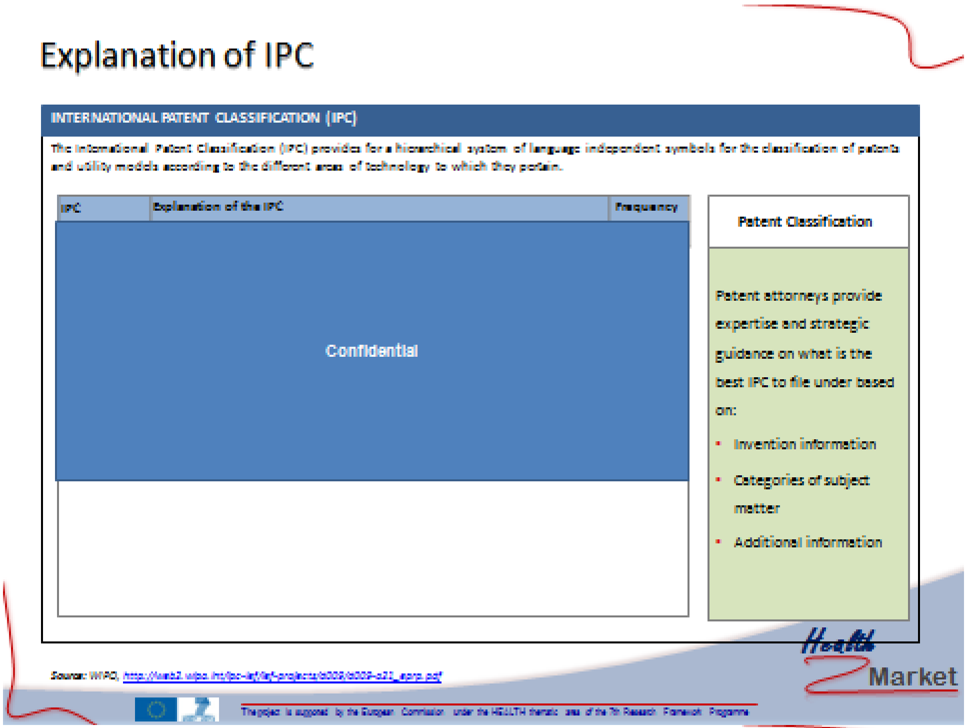

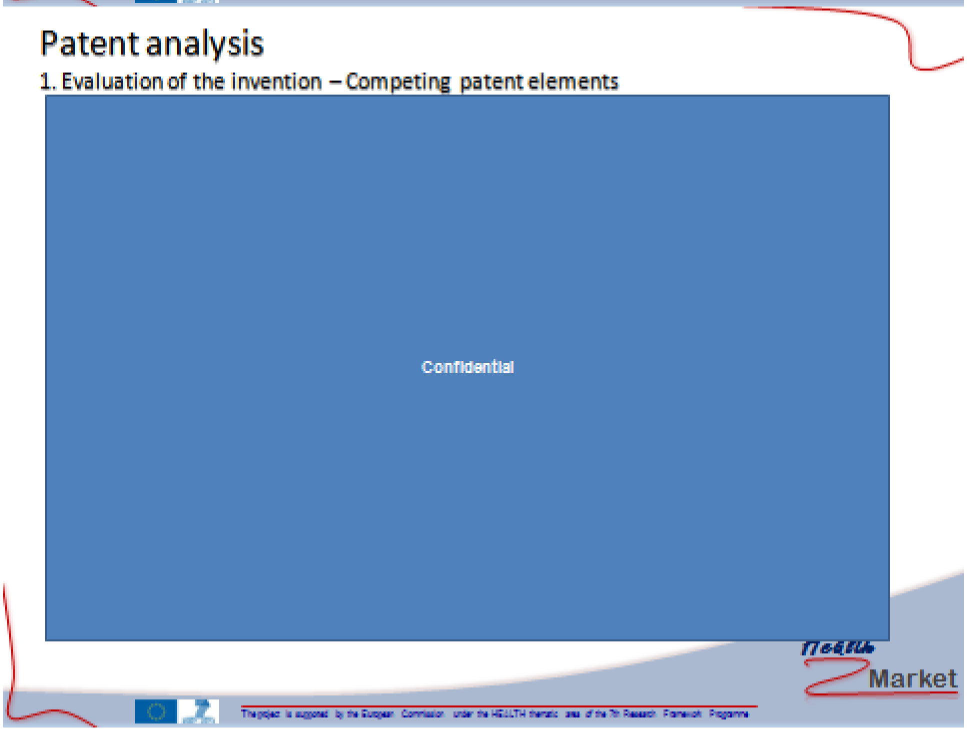

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Results of the patent research

1. Evaluation of the invention - Patent holder of similar patents

CORPORATIONS AND INSTITUTIONS WITH SIMILAR PATENTS

Patent holder	# Patents
Single owners	17
UBE INDUSTRIES	6
MASSACHUSETTS INST TECHNOLOGY [US]	5
REPROGENESIS INC [US] (1)	3
BRIDGESTONE CORP [JP]	2
KABUSHIKIKAISHA KYOTO IRYO SEKKEI [JP]	2
SCIMED LIFE SYSTEMS INC [US] (2)	2
SENKO MED INSTR MFG	2
SUMITOMO ELECTRIC INDUSTRIES [JP]	2
TERUMO CORP	2
ADVANCED CARDIOVASCULAR SYSTEM [US] (3)	1
ANGEION CORP [US] (4)	1
ATRIUM MEDICAL CORP [US]	1
BIOACTIVE BIOMATERIALS LTDA [BR]	1
BIOATIS CO LTD [US]	1
BOSTON SCIENT CORP [US]	1
CENTRE NAT RECH SCIENT [FR]	1
CLEVELAND CLINIC FOUNDATION [US]	1
CORMATRIX CARDIOVASCULAR INC [US]	1
ETHICON INC (5)	1

Patent holder	# Patents
FEDERALNOE G BJUDZHETNOE UCHREZHDENIE NIINST KOMPLEKSNYKH SERDECHNO SOSUDISTYKH ZABOLEVANY SIB OTDEL	1
FOURTH PEOPLE S HOSPITAL OF WU [CN]	1
GUANGZHOU MEDPRIN REGENERATIVE [CN]	1
HARVARD COLLEGE [US]	1
I M S BIOPURU AG (6)	1
INDIAN INST OF TECHNOLOGY KANPUR [IN]	1
INST NAT SCIENCES APPLIQ [FR]	1
JAPAN GOVERNMENT [JP]	1
JAPAN RES DEV CORP [JP]	1
KANEGAFUCHI CHEMICAL IND [JP] (7)	1
LAB PEROUSE	1
LEPU BEIJING MEDICAL EQUIPMENT CO LTD	1
MEADOX MEDICALS INC [US] (2)	1
MEDTRONIC VASCULAR INC [US]	1
NAT CARDIOVASCULAR CT	1
NAT INST OF ADV IND & TECHNOL	1
NAT INST OF ADV IND & TECHNOL	1
NIPPON MEDICAL SUPPLY [JP]	1

Potential business targets

(1) Now Curis, Inc
(2) Now Boston Scientific Corp
(3) Now Abbott Cardiovascular Systems , Division of Abbott Laboratories
(4) Now MGC Diagnostic Corporation
(5) Part of Johnson & Johnson
(6) Now Gumit Holding AG
(7) Kaneka Corp
(8) Now Boston Scientific Corp

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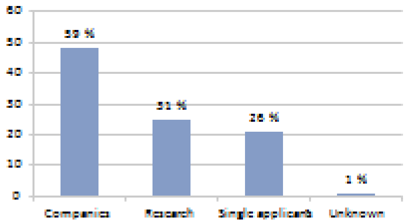
Results of the patent research

1. Evaluation of the invention - Patent holder of similar patents

CORPORATIONS AND INSTITUTIONS WITH SIMILAR PATENTS

Patent holder	# Patents
NIPRO CORP	1
OLYMPUS CORP	1
RIGAS TEHNISKA UNIVERSITATE [LV]	1
SANYO CHEMICAL IND LTD	1
SCIENCE HOME INC [KR]	1
SORIN BIOMEDICA CARDIO SPA [IT]	1
SULZER AG	1
SUNTECH CO LTD [KR]	1
TAPIC INT CO LTD [JP]	1
UBE NITTO KASEI CO [JP] (9)	1
UNIV BORDEAUX SEGALEN [FR]	1
UNIV CLAUDE BERNARD LYON [FR]	1
UNIV DONGHUA	1
UNIV HOKKAIDO	1
UNIV ILLINOIS [US]	1
UNIV JEAN MONNET DE SAINT ETIENNE [FR]	1
UNIV LIVERPOOL	1
UNIV NAGOYA	1
UNIV PITTSBURGH [US]	1
UNIV SOOCHOW	1
UNIV SYDNEY [AU]	1
UNIV TEXAS [US]	1
UNIV ZUERICH	1
VASCULAR GRAFT RESEARCH CENTER [JP]	1
XI AN REGE BIOTECH CO LTD	1



- 81 related patents, mostly from companies
- Indicates an already established market in which new innovative products can create a competitive advantage for established companies
- Companies focusing on cardiovascular products (in pink) like grafts and stents may be potential licensing partners

Potential business targets

(2) Now Boston Scientific Corp
(9) Now UBE INDUSTRIES

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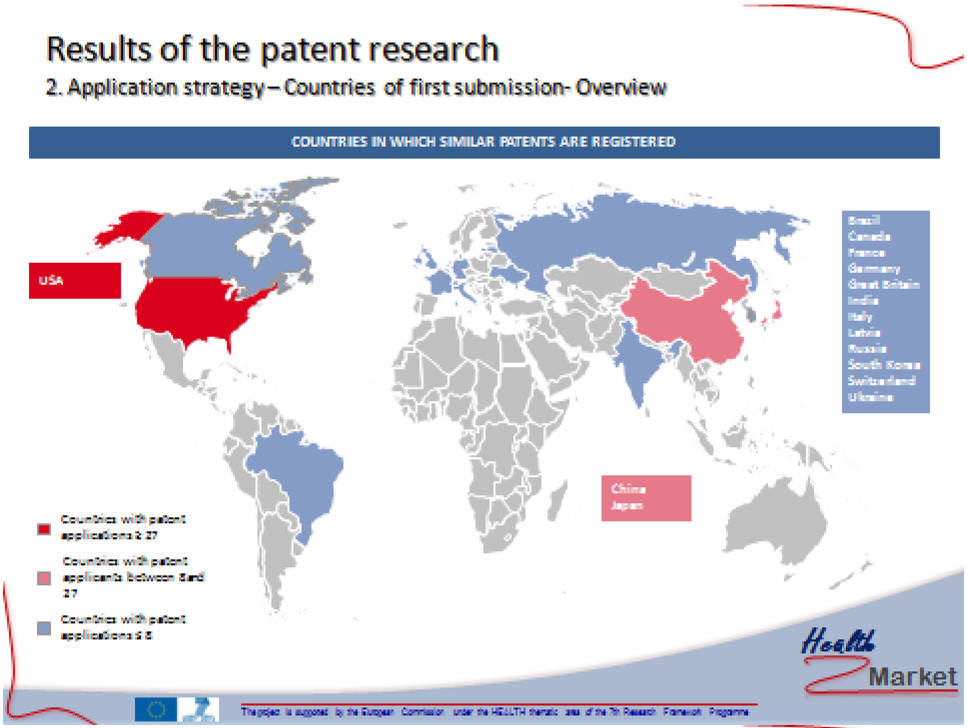
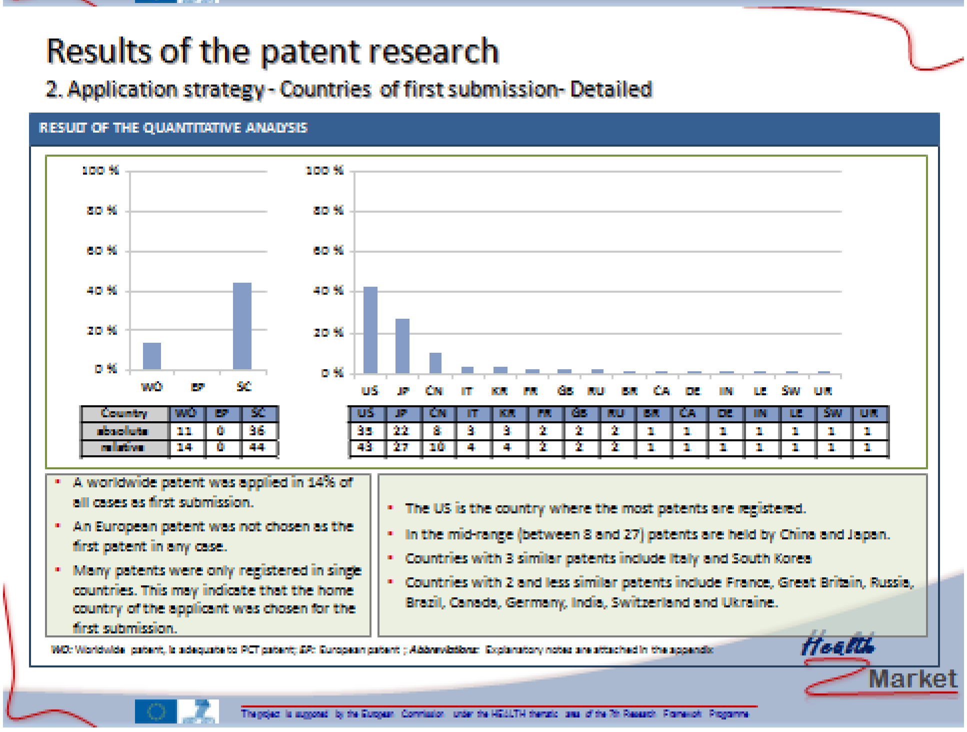
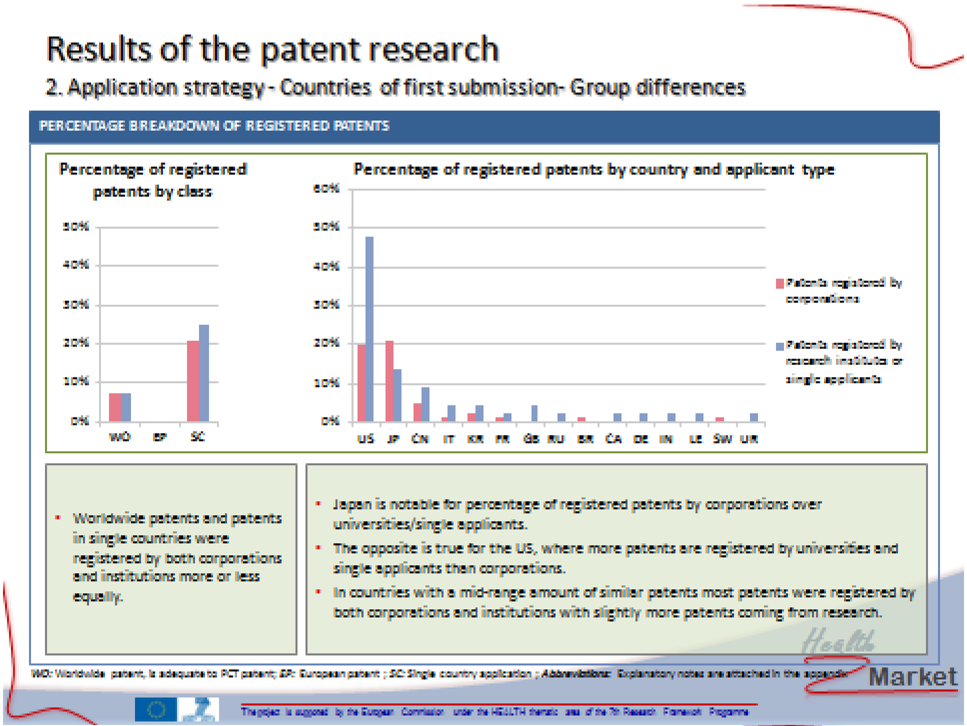
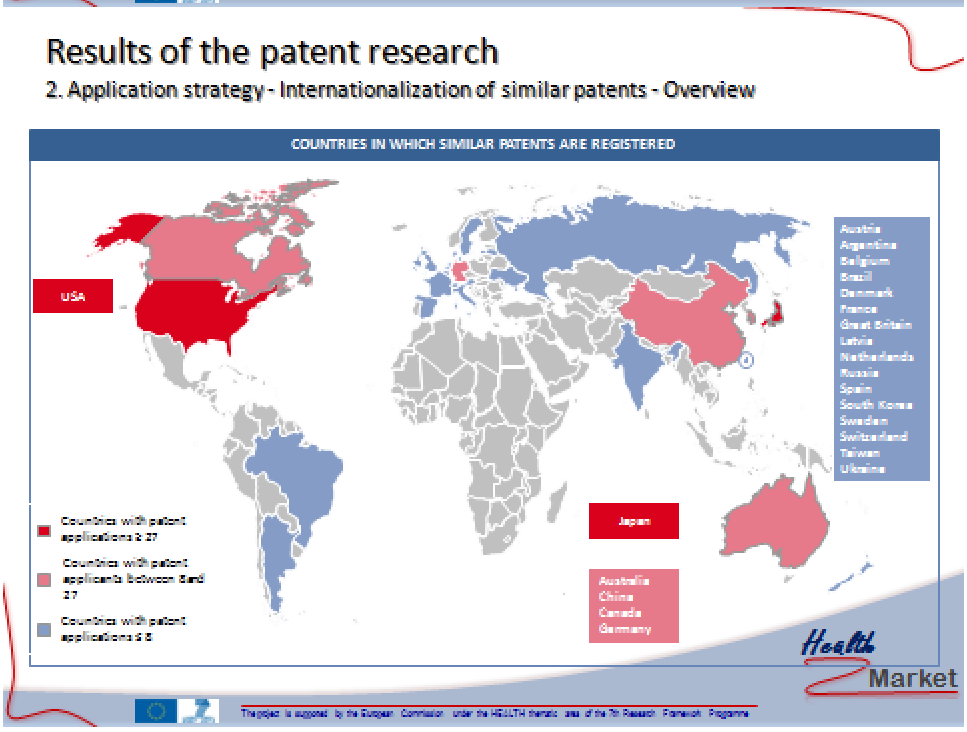




"Health-2-Market has received funding from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement No 305532"





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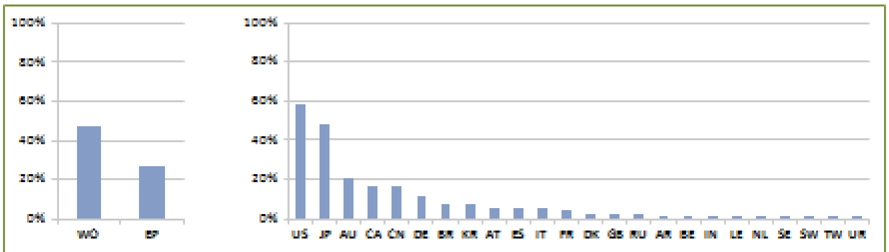
Results of the patent research

2. Application strategy - Internationalization of similar patents - Detailed

RESULT OF THE QUANTITATIVE ANALYSIS



Country	WO	EP
absolute	38	22
relative	47	27

US	JP	AU	CA	CN	DE	BR	KR	AT	ES	IT	FR	DK	GB	RU	AR	BE	IN	LE	NL	SE	SW	TW	UR
47	39	17	13	13	9	6	6	4	4	4	3	2	3	3	1	1	1	1	1	1	1	1	1
58	48	21	16	16	11	7	7	5	5	5	4	2	4	4	1	1	1	1	1	1	1	1	1

- A worldwide patent was applied in 47% of all cases.
- The results for European patents show lower numbers.

- The US and Japan are the countries where the most patents are registered in the mid-range (between 8 and 27) patents are held by Australia, Canada, China, and Germany.
- Countries with 6 similar patents or less include Austria, Argentina, Belgium, Brazil, Denmark, France, Great Britain, Korea, Latvia, Netherlands, Russia, Spain, Sweden, Switzerland, Taiwan, and Ukraine.
- It is noteworthy that while no patents were first submitted in Canada, it seems to be part of many internationalization plans.

WO: Worldwide patent, is adequate to PCT patent; EP: European patent ; Abbreviations: Explanatory notes are attached in the appendix

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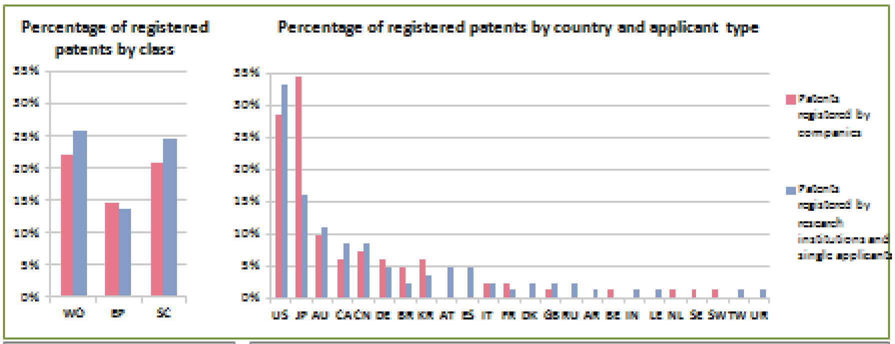
Results of the patent research

2. Application strategy - Internationalization of similar patents - Group differences

PERCENTAGE BREAKDOWN OF REGISTERED PATENTS



- Worldwide, European patents and patents in single countries were registered by both corporations and institutions more or less equally.

- Japan is notable for percentage of registered patents by corporations over universities/single applicants.
- For the US slightly more patents are registered by universities and single applicants than corporations.
- In countries with a mid-range amount of similar patents most patents were registered by both corporations and institutions.

WO: Worldwide patent, is adequate to PCT patent; EP: European patent ; SC: Single country application ; Abbreviations: Explanatory notes are attached in the appendix

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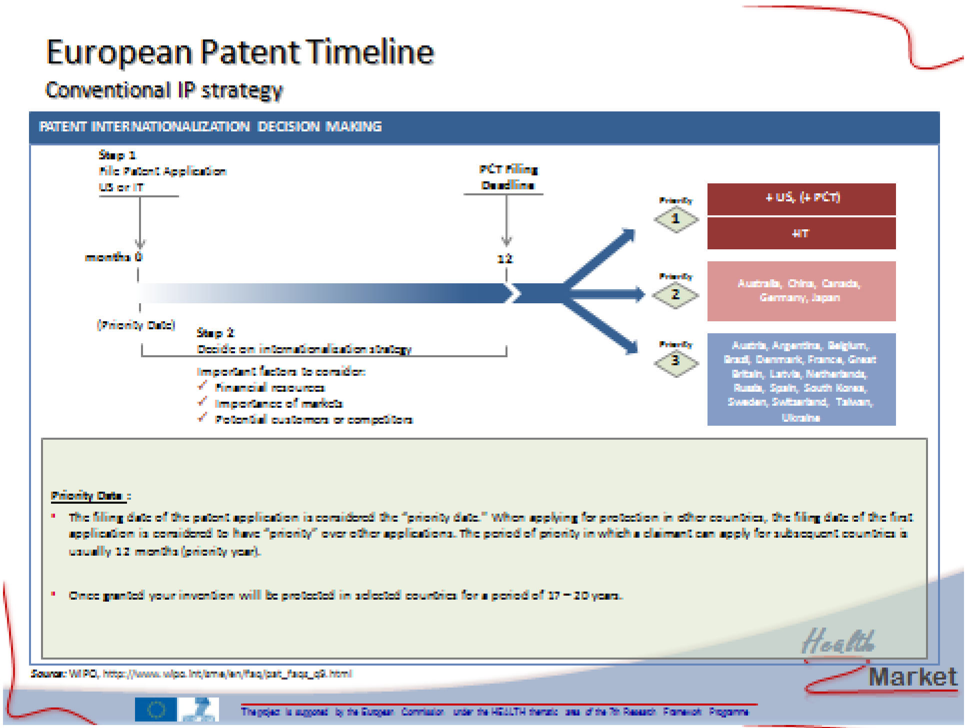

European Patent Timeline
Conventional IP strategy
PATENT INTERNATIONALIZATION DECISION MAKING
Step 1
File Patent Application
US or IT
PCT Filing
Deadline
months 0
12
(Priority Date)
Step 2
Decide on internationalization strategy
Important factors to consider:
Financial resources
Importance of markets
Potential customers or competitors
Priority
1
+ US, (+ PCT)
+IT
Priority
2
Australia, China, Canada, Germany, Japan
Priority
3
Austria, Argentina, Belgium, Brazil, Denmark, France, Great Britain, Latvia, Netherlands, Russia, Spain, South Korea, Sweden, Switzerland, Taiwan, Ukraine
Priority Date :
The filing date of the patent application is considered the "priority date." When applying for protection in other countries, the filing date of the first application is considered to have "priority" over other applications. The period of priority in which a claimant can apply for subsequent countries is usually 12 months (priority year).
Once granted your invention will be protected in selected countries for a period of 17 – 20 years.
Source: WIPO, http://www.wipo.int/sme/en/faq/pat_faqs_q8.html
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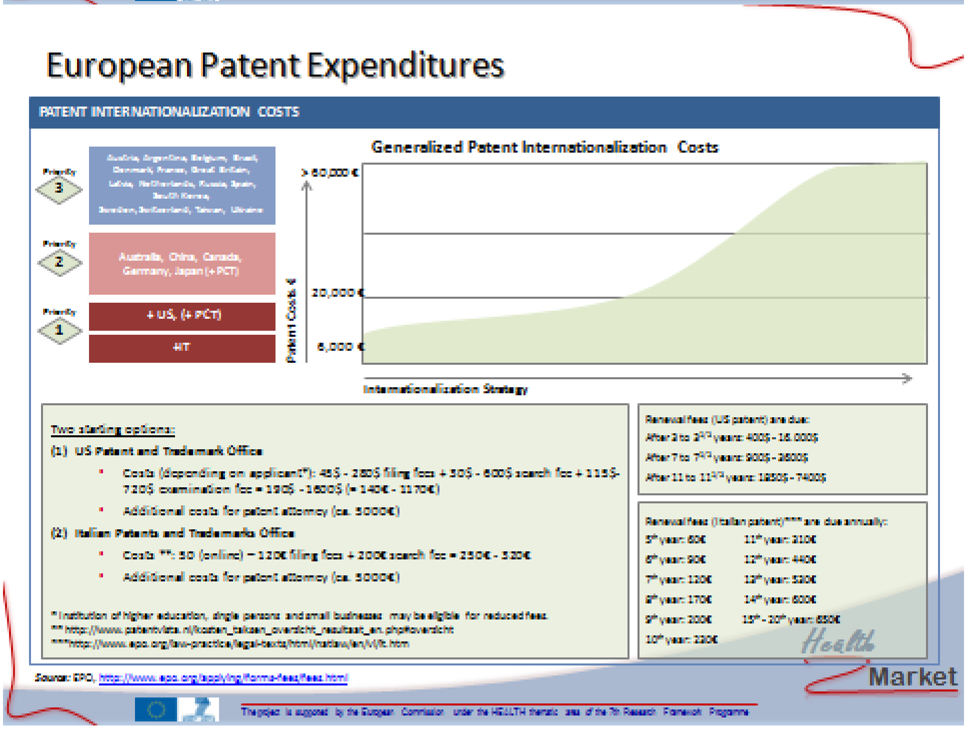

European Patent Expenditures
PATENT INTERNATIONALIZATION COSTS
Priority
3
Austria, Argentina, Belgium, Brazil, Denmark, France, Great Britain, Latvia, Netherlands, Russia, Spain, South Korea, Sweden, Switzerland, Taiwan, Ukraine
Priority
2
Australia, China, Canada, Germany, Japan (+ PCT)
Priority
1
+ US, (+ PCT)
+IT
Generalized Patent Internationalization Costs
> 60,000 €
20,000 €
6,000 €
Patent Costs €
Internationalization Strategy
Two starting options:
(1) US Patent and Trademark Office
Costs (depending on applicant*): 45$ - 280$ filing fees + 50$ - 600$ search fee + 115-720 examination fee = 190$ - 1600$ (= 140€ - 1170€)
Additional costs for patent attorney (ca. 5000€)
(2) Italian Patents and Trademarks Office
Costs **: 50 (online) – 120€ filing fees + 200€ search fee = 250€ - 320€
Additional costs for patent attorney (ca. 5000€)
* Institution of higher education, single persons and small businesses may be eligible for reduced fees.
** http://www.patentdata.nl/kosten_takaan_overzicht_resultaat_en.php#overzicht
***http://www.epo.org/law-practice/legal-texts/html/natlaw/en/vi/it.htm
Renewal fees (US patent) are due:
After 3 to 3 1/2 years: 400$ - 16.000$
After 7 to 7 1/2 years: 900$ - 2600$
After 11 to 11 1/2 years: 1850$ - 7400$
Renewal fees (Italian patent)*** are due annually:
5th year: 60€
6th year: 90€
7th year: 120€
8th year: 170€
9th year: 200€
10th year: 220€
11th year: 310€
12th year: 440€
13th year: 520€
14th year: 600€
15th - 20th year: 650€
Source: EPO, http://www.epo.org/applying/forms-fees/fees.html
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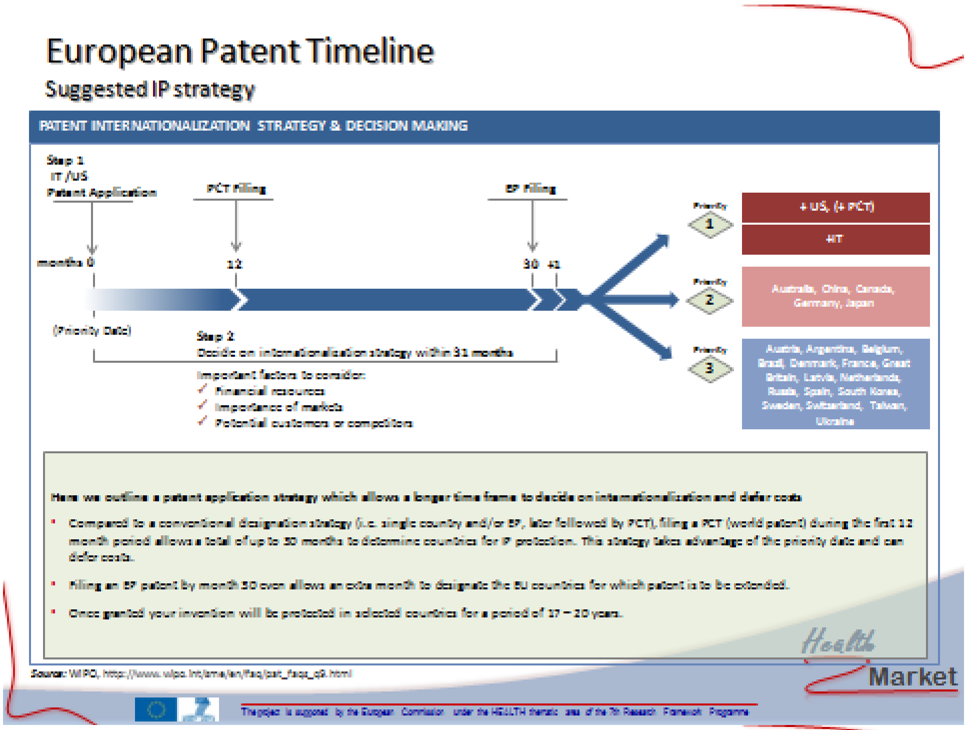

European Patent Timeline
Suggested IP strategy
PATENT INTERNATIONALIZATION STRATEGY & DECISION MAKING
Step 1
IT /US
Patent Application
PCT Filing
EP Filing
months 0
12
30
31
(Priority Date)
Step 2
Decide on internationalization strategy within 31 months
Important factors to consider:
Financial resources
Importance of markets
Potential customers or competitors
Priority 1
+ US, (+ PCT)
+IT
Priority 2
Australia, China, Canada, Germany, Japan
Priority 3
Austria, Argentina, Belgium, Brazil, Denmark, France, Great Britain, Latvia, Netherlands, Russia, Spain, South Korea, Sweden, Switzerland, Taiwan, Ukraine
Here we outline a patent application strategy which allows a longer time frame to decide on internationalization and defer costs
Compared to a conventional designation strategy (i.e. single country and/or EP, later followed by PCT), filing a PCT (world patent) during the first 12 month period allows a total of up to 30 months to determine countries for IP protection. This strategy takes advantage of the priority date and can defer costs.
Filing an EP patent by month 30 even allows an extra month to designate the EU countries for which patent is to be extended.
Once granted your invention will be protected in selected countries for a period of 17 – 20 years.
Source: WIPO, http://www.wipo.int/sme/en/faq/pat_faqs_q9.html
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Your contacts
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Tel. +49 721 91345-11
t.lenz@engage-ventures.com
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Appendix - List of abbreviations

Abbreviation	Meaning
AR	Argentinia
AT	Austria
AU	Australia
BE	Belgium
BR	Brasil
CA	Canada
CN	China
DE	Germany
DK	Denmark
EP	European Patent
EPO	European Patent Office
ES	Spain
FR	France
GB	Great Britain
IT	Italy
IN	India
JP	Japan
KR	South-Korea
LE	Lettia
NL	Netherlands
RU	Russia
SE	Sweden
SW	Switzerland
TW	Taiwan
US	USA
UR	Ukraine
WIPO	World Intellectual Property Organisation
WO	Abbreviation for a PCT patent (valid worldwide)

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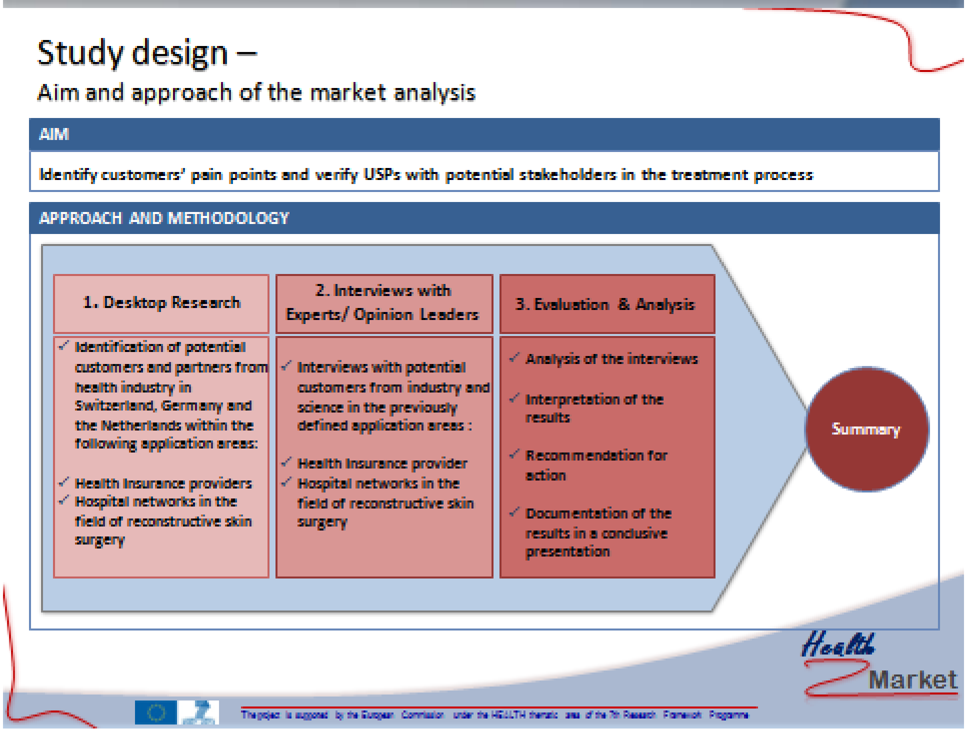
6.3. Service example: Market study



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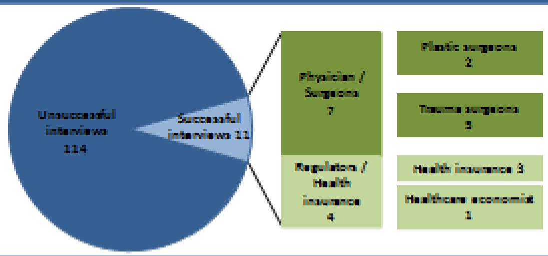
Empirical Basis (I)

Unique selling points (USPs) & Respondents

UNIQUE SELLING POINTS

Confidential

INTERVIEWS WITH EXPERTS:



- ✓ Total number of contacted clinics and companies: 125
- ✓ Extremely low success rate (8%)
- ✓ In general the respondents' interest concerning the topic was significant – once we got hold of someone
- ✓ Informants were not that open to further discussion

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Empirical Basis (II)

Questionnaire

LIST OF QUESTIONS FOR HOSPITALS (PHYSICIANS / SURGEONS)

Questions about the status quo

1. What procedures and products are you currently using to treat patients with large and medium full-thickness skin defects (e.g. burns, scar removals, tumors etc.)?
2. How many patients with full-thickness skin defects are you treating per year?
3. How satisfied are you with your current solution in terms of
   - Number of surgeries to conduct
   - Duration of hospitalization
   - Costs for the treatment
   - Quality of life of patients?
4. Are there any requirements the current solution cannot accomplish?

Evaluation of the competencies of SKINtechCELLence

5. Could the new customized skin graft from SKINtecCELLence be of interest to you? If not, why?
6. Which requirements must be fulfilled to use this product for the treatment of full-thickness skin defects such as burns and scar removal (e.g. reimbursement by health insurances etc.)?
7. How much would you be prepared to pay for this product (financial dimension)?

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Empirical Basis (III)

Questionnaire

LIST OF QUESTIONS FOR HEALTH INSURANCE PROVIDERS

Questions about the status quo

1. Which procedures and products are currently reimbursed for the treatment of patients with full-thickness skin defects (e.g. burns, scar removal, tumors etc.)?
2. How satisfied (unsatisfied, undecided, satisfied) are you with these current solutions in terms of
    - Medical efficacy
    - Costs for the treatment
    - Quality of life of patients?
3. Are there any requirements the current solution cannot accomplish?

Evaluation of the competencies of SKINtechCELLence

4. Could the new customized skin graft from SkinTecCellence be of interest for reimbursement? If not, why not?
5. Which requirements must be fulfilled to decide to what extent the new product is reimbursed?

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Empirical Basis (IV)

Overview on the interview experts

Pyramide Klinik am See

Universitätsklinikum Carl Gustav Carus

Techniker Krankenkasse

ERGO DKV

UKSH Universitätsklinikum Schleswig-Holstein

VISANA

UMM Universitätsmedizin Mannheim

Merian Iselin

Immungenetics – Jürgen Blume, Health economist

BG Klinik Berufsgenossenschaftliche Unfallklinik Tübingen

Klinikum Nürnberg

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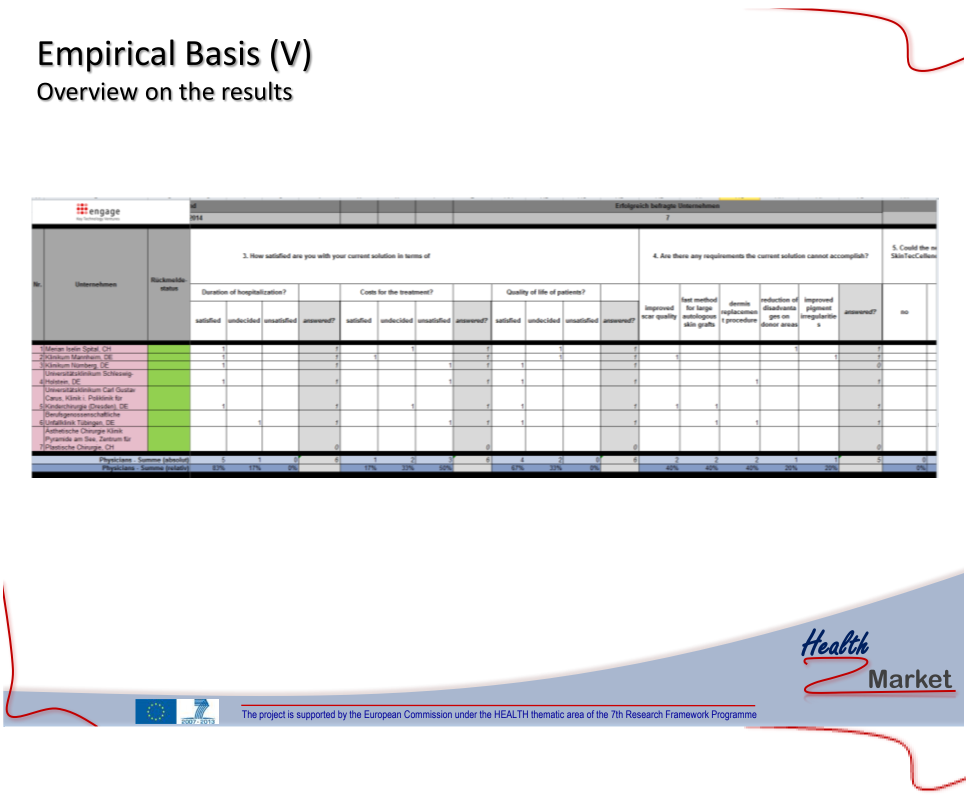
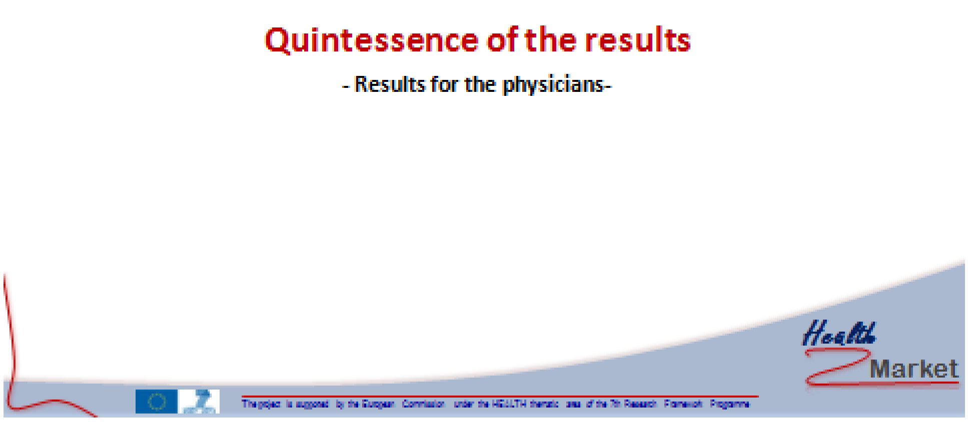


Nr.	Unternehmen	Rückmeldestatus	3. How satisfied are you with your current solution in terms of												4. Are there any requirements the current solution cannot accomplish?						5. Could the ne SkinTecCellen
			Duration of hospitalization?				Costs for the treatment?				Quality of life of patients?										
			satisfied	undecided	unsatisfied	answered?	satisfied	undecided	unsatisfied	answered?	satisfied	undecided	unsatisfied	answered?	improved scar quality	fast method for large autologous skin grafts	dermis replacement procedure	reduction of disadvantages on donor areas	improved pigment irregularities	answered?	no
1	Merian Iselin Spital, CH		1			1		1		1		1		1				1		1	
2	Klinikum Mannheim, DE		1			1	1			1		1		1	1				1	1	
3	Klinikum Nürnberg, DE		1			1			1	1	1			1						0	
4	Universitätsklinikum Schleswig-Holstein, DE		1			1			1	1	1			1			1			1	
5	Universitätsklinikum Carl Gustav Carus, Klinik i. Poliklinik für Kinderchirurgie (Dresden), DE		1			1		1		1	1			1	1	1				1	
6	Berufsgenossenschaftliche Unfallklinik Tübingen, DE			1		1			1	1	1			1		1	1			1	
7	Ästhetische Chirurgie Klinik Pyramide am See, Zentrum für Plastische Chirurgie, CH					0				0				0						0	
	Physicians - Summe (absolut)		5	1	0	6	1	2	3	6	4	2	0	6	2	2	2	1	1	5	0
	Physicians - Summe (relativ)		83%	17%	0%		17%	33%	50%		67%	33%	0%		40%	40%	40%	20%	20%		0%



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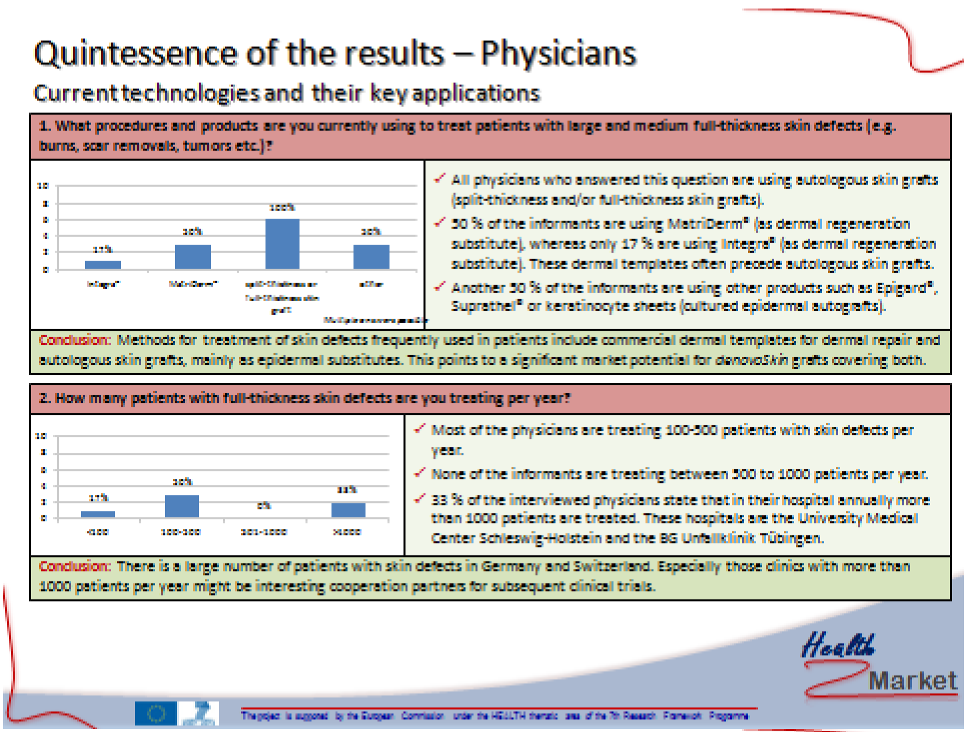
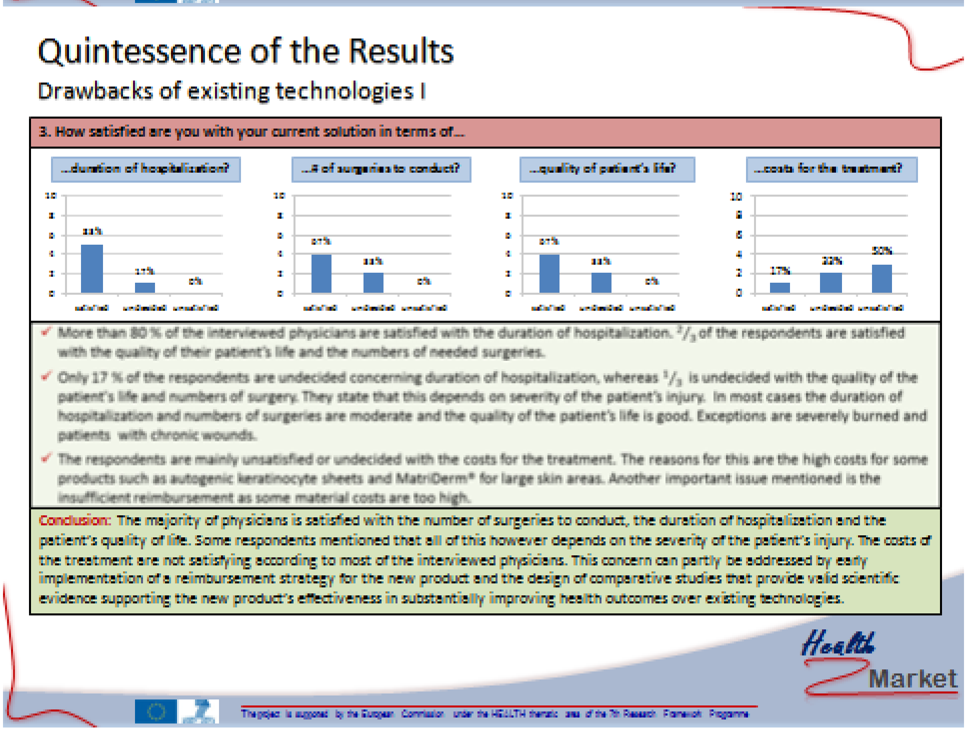
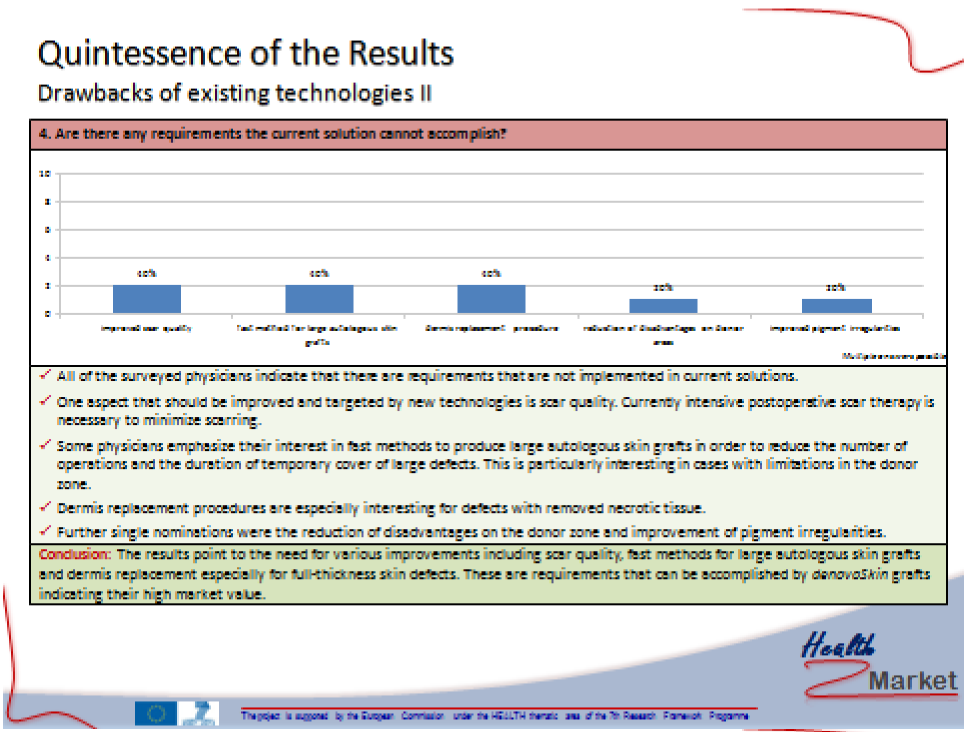
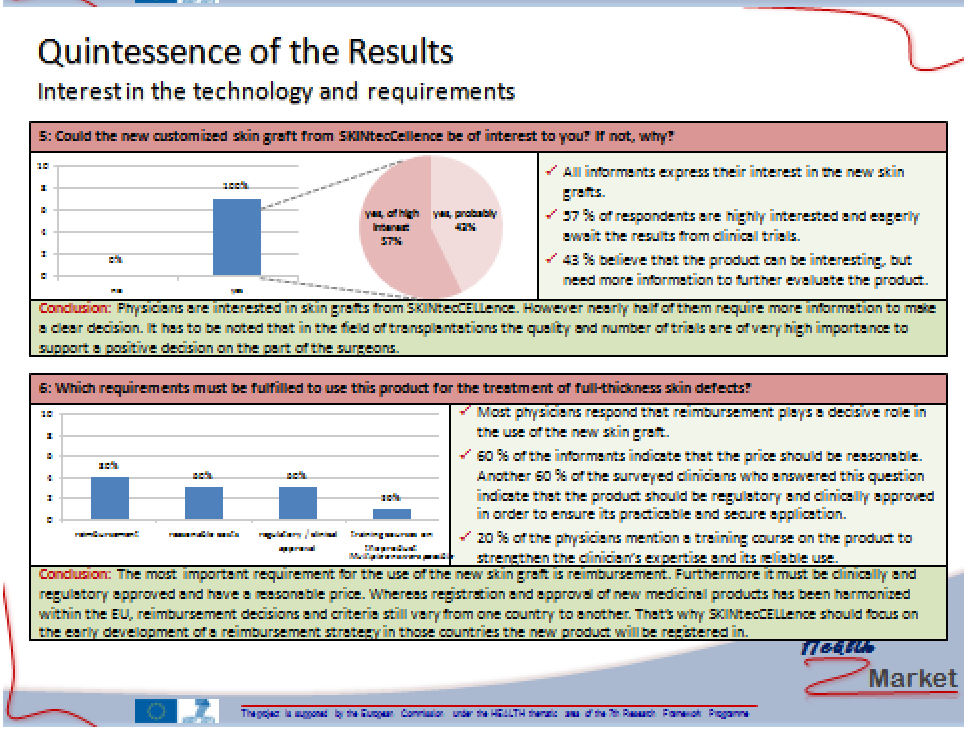




"Health-2-Market has received funding from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement No 305532"

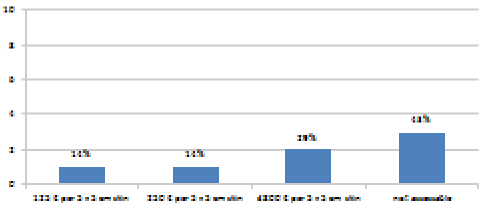

Quintessence of the Results
Drawbacks of existing technologies II
4. Are there any requirements the current solution cannot accomplish?
All of the surveyed physicians indicate that there are requirements that are not implemented in current solutions.
One aspect that should be improved and targeted by new technologies is scar quality. Currently intensive postoperative scar therapy is necessary to minimize scarring.
Some physicians emphasize their interest in fast methods to produce large autologous skin grafts in order to reduce the number of operations and the duration of temporary cover of large defects. This is particularly interesting in cases with limitations in the donor zone.
Dermis replacement procedures are especially interesting for defects with removed necrotic tissue.
Further single nominations were the reduction of disadvantages on the donor zone and improvement of pigment irregularities.
Conclusion: The results point to the need for various improvements including scar quality, fast methods for large autologous skin grafts and dermis replacement especially for full-thickness skin defects. These are requirements that can be accomplished by denovoSkin grafts indicating their high market value.
Health 2 Market


Quintessence of the Results
Interest in the technology and requirements
5: Could the new customized skin graft from SKINtecCellence be of interest to you? If not, why?
yes, of high interest 57%
yes, probably 43%
All informants express their interest in the new skin grafts.
57 % of respondents are highly interested and eagerly await the results from clinical trials.
43 % believe that the product can be interesting, but need more information to further evaluate the product.
Conclusion: Physicians are interested in skin grafts from SKINtecCELLence. However nearly half of them require more information to make a clear decision. It has to be noted that in the field of transplantations the quality and number of trials are of very high importance to support a positive decision on the part of the surgeons.
6: Which requirements must be fulfilled to use this product for the treatment of full-thickness skin defects?
Most physicians respond that reimbursement plays a decisive role in the use of the new skin graft.
60 % of the informants indicate that the price should be reasonable. Another 60 % of the surveyed clinicians who answered this question indicate that the product should be regulatory and clinically approved in order to ensure its practicable and secure application.
20 % of the physicians mention a training course on the product to strengthen the clinician's expertise and its reliable use.
Conclusion: The most important requirement for the use of the new skin graft is reimbursement. Furthermore it must be clinically and regulatory approved and have a reasonable price. Whereas registration and approval of new medicinal products has been harmonized within the EU, reimbursement decisions and criteria still vary from one country to another. That's why SKINtecCELLence should focus on the early development of a reimbursement strategy in those countries the new product will be registered in.
Market

Quintessence of the Results

Price for the product

7: How much would you be prepared to pay for this product ?



- Most of the clinicians refer to the prices of competing products such as Integra® and MatriDerm®.
- In general they are not prepared to pay as much as for the dermal template Integra® which costs around 800 € per 5 x 5 cm skin.
- One of the surveyed physicians is prepared to only pay 125 € whereas another one is willing to pay 250 € per 5 x 5 cm skin.
- 43 % are not able to estimate the financial dimension for the product.
- Some of the physicians emphasized however that the price is not important if the product is reimbursable.

Conclusion: The quoted prices are significantly lower than the envisioned price for *denovoSkin* grafts. The statement that the price is negligible if the product is reimbursed again underlines the importance of an early implemented reimbursement strategy.

Quintessence of the results

- Conclusion for the health insurance provider -

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Quintessence of the results – Health insurance

Current reimbursement system

1. What procedures and products are currently reimbursed for the treatment of patients with full-thickness skin defects (e.g. burns, scar removal, tumors etc.)?

German health insurance providers (2)

- ✓ Reimbursement is allowed as lump compensation for procedures according to G-DRG system (German diagnosis-related- groups maintained by the InEK[1]) and not for specific medicinal products (see example).
- ✓ There is a time lag between the availability of a new procedure and rate adaption (or available new coding) in the G-DRG which might hamper the adoption of new procedures. The update of the G-DRG by InEK is done yearly however based on the data from the previous 2 years.
- ✓ Therefore InEK has created an "on-top" funding process for innovative products: Hospitals can apply separately for using a new procedure under the NUB[2] process especially if the DRG lump compensation does not cover the expenses of the new procedure. The reimbursement for NUBs is negotiated with the SHI[3].

Swiss health insurance provider (1)

- ✓ According to the benefits in the SHI (Krankenpflege-Leistungsverordnung, KLV) of the EDI[4] (as at January 2014):
  - ✓ Skin autografts with cultured keratinocytes*
  - ✓ Treatment of hard-to-heal wounds with approved grown autologous or allogenic skin grafts**

Conclusion: Reimbursement systems differ from country to country, but in Europe they "protect" between 88 and 95% of the population. Following the German system the procedure must be covered by the G-DRG system. The mechanism allowing innovation within the G-DRG system is the NUB procedure which each hospital can apply individually for. The Swiss health insurance provider Visana Service AG explains that skin grafts under given circumstances can be reimbursed according to EDI.

<u>Example: Costs G-DRG system 2014</u>
Burns with skin transplantation (2014): ca. 6.000 - 40.000 € (hospitalization time 2 to 48 days)
Large skin transplantation (2014): ca. 14.000 - 55.000 € (hospitalization time 8 to 64 days)

Source: http://www.g-drg.de/cms/inek_site_de/layout/set/standard/G-DRG-System_2014/Fallpauschalen-Katalog/Fallpauschalen-Katalog_2014

[1] Institute for the Hospital Remuneration System
[2] New examination and treatment method
[3] Statutory Health Insurance
[4] Swiss Department of Internal Affairs

*[illegible]
**after unsuccessful conservative therapy

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Quintessence of the results – Health insurance

Current technologies and requirements

2. How satisfied (unsatisfied, undecided, satisfied) are you with these current solutions in terms of medical efficacy, costs for the treatment, quality of life of patients?

3. Are there any requirements the current solution cannot accomplish?

- ✓ Health insurance providers cannot answer these question as they do not get feedback from the hospitals and the patients. In general the major focus is the well-being of the patients and not the costs of the procedure.
- ✓ One private German health insurer stated that, in total, skin drafts make up for less than 1 % of insurance costs. Given the small amount of cases, it is not interesting whether one treatment is more cost efficient than the other because the changes are negligible for the overall costs for the insurance.

4. Could the new customized skin graft from SkinTecCellence be of interest for reimbursement? If not, why?

- ✓ Health insurers cannot provide definite answers to that question as they act in accordance with the DRG catalogue.
- ✓ They further state that new methods have to offer clear medical improvement.

Conclusion: Insurers cannot comment due to not being the responsible ones. Fundamental is the well-being of the patient and not the costs. In general the new technology must represent a substantial clinical improvement relative to existing technologies.

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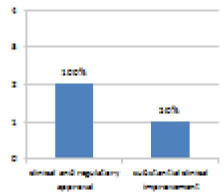
Quintessence of the results – Health insurance

Requirements for reimbursement

5. Which requirements must be fulfilled to decide to what extent the new product is reimbursed?



- ✓ The surveyed health insurance providers state that health insurances are not the decision makers during the reimbursement decision-making process.
- ✓ Key criteria which have been mentioned are the new technology being clinically and regulatory approved. Furthermore one health insurance professional also stated that substantial clinical improvement must be shown over existing procedures or technologies.

Conclusion: Health insurances do not decide about reimbursement. Essential criteria for reimbursement are clinical and regulatory approval and substantial clinical improvement.

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Quintessence of the results

- Conclusion for the health economist-

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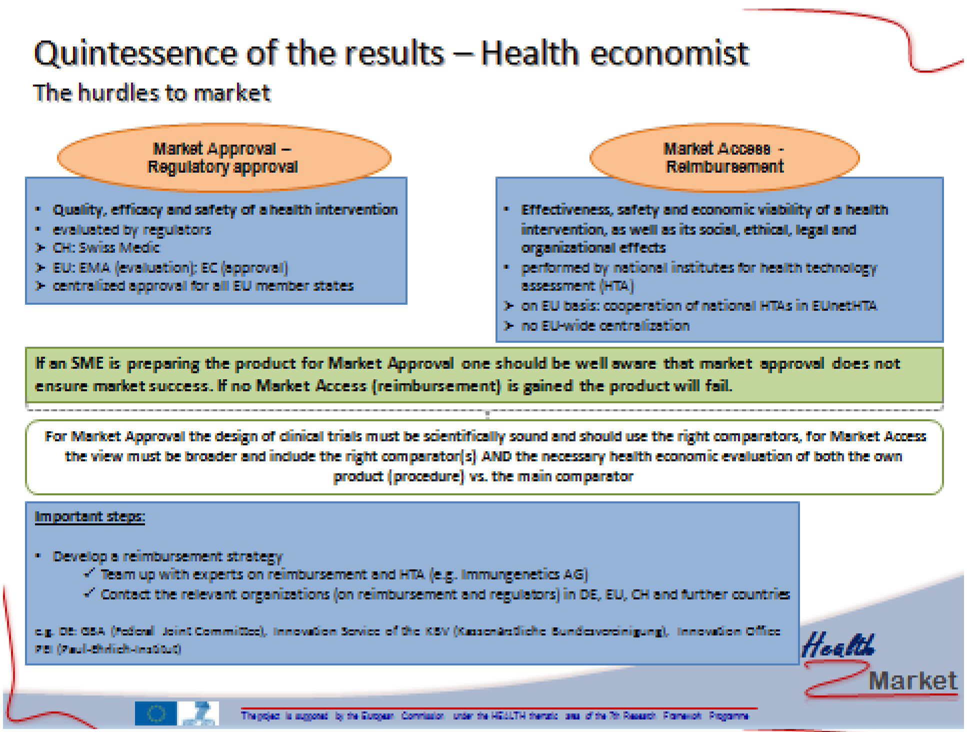
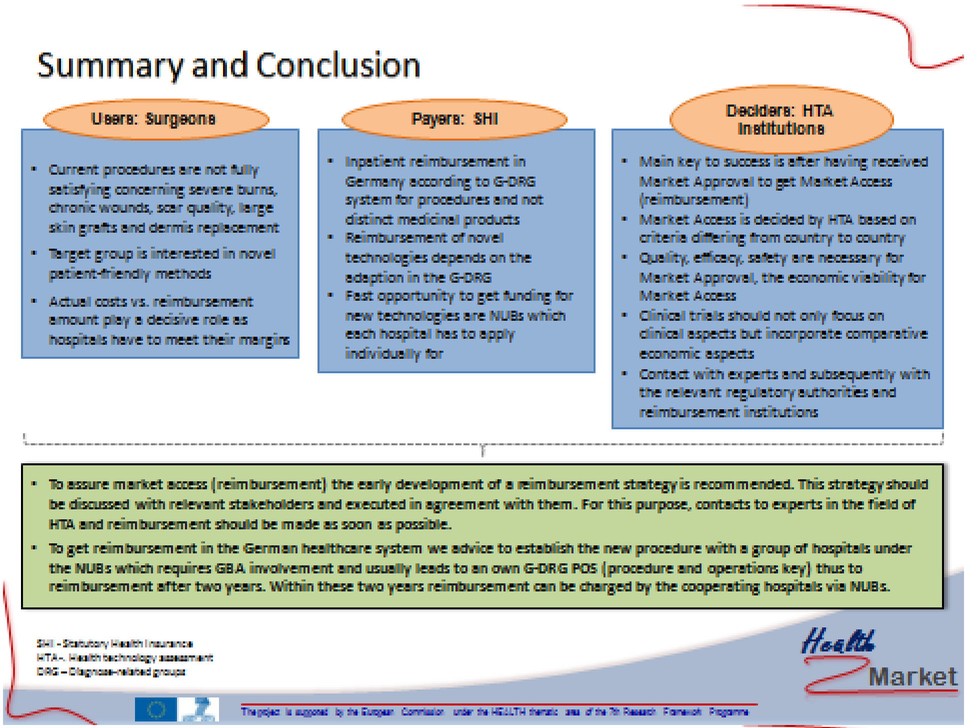
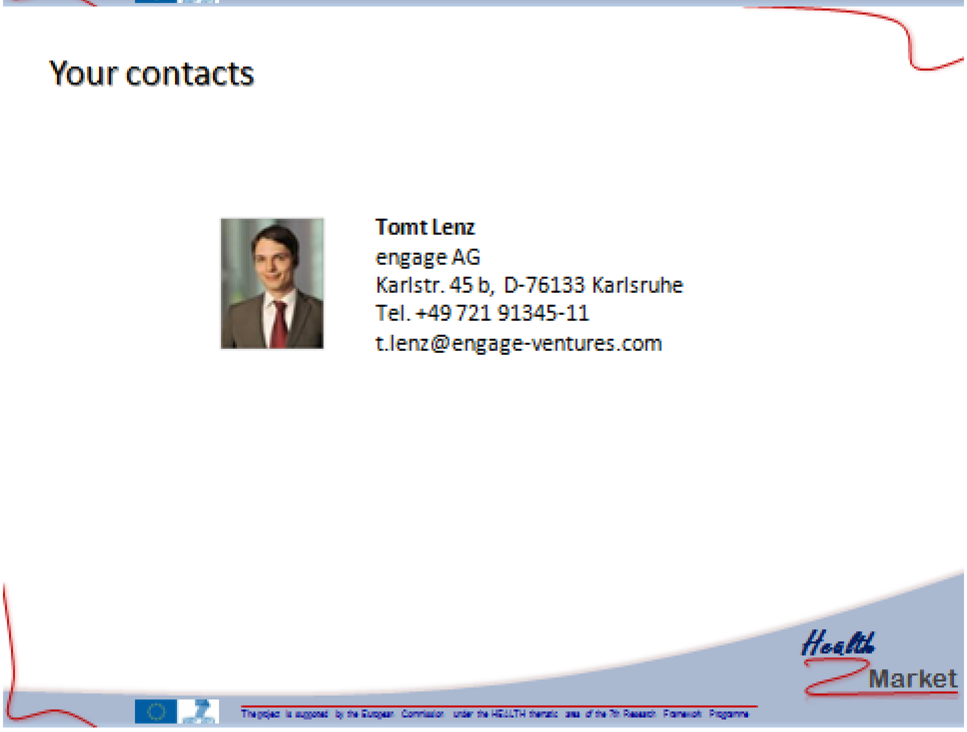


Quintessence of the results – Health economist
The hurdles to market
Market Approval – Regulatory approval
• Quality, efficacy and safety of a health intervention
• evaluated by regulators
➢ CH: Swiss Medic
➢ EU: EMA (evaluation); EC (approval)
➢ centralized approval for all EU member states
Market Access - Reimbursement
• Effectiveness, safety and economic viability of a health intervention, as well as its social, ethical, legal and organizational effects
• performed by national institutes for health technology assessment (HTA)
➢ on EU basis: cooperation of national HTAs in EUnetHTA
➢ no EU-wide centralization
If an SME is preparing the product for Market Approval one should be well aware that market approval does not ensure market success. If no Market Access (reimbursement) is gained the product will fail.
For Market Approval the design of clinical trials must be scientifically sound and should use the right comparators, for Market Access the view must be broader and include the right comparator(s) AND the necessary health economic evaluation of both the own product (procedure) vs. the main comparator
Important steps:
• Develop a reimbursement strategy
✓ Team up with experts on reimbursement and HTA (e.g. Immungenetics AG)
✓ Contact the relevent organizations (on reimbursement and regulators) in DE, EU, CH and further countries
Health 2 Market

Summary
Health 2 Market





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