

D1.1 End users need analysis and Service programme document



D1.1 End users need analysis and Service programme document

Project number	Project acronym:	Project Title:
727683	eHealth Hub	eHealth Hub, The European Hub for eHealth Business Support
Instrument:	Thematic Priority	
COORDINATION AND SUPPORT ACTION	H2020 CNECT. E-Health, Well-being and Ageing	
Title		
END USERS NEED ANALYSIS AND SERVICE PROGRAMME DOCUMENT		
Due Date:	Actual Submission Date:	
31-12-2016	17-02-2017	
Start date of project:	Duration:	
October 1st, 2016	36 months	
Organization name of lead contractor for this deliverable	Document version	
EDITO	Vs 03	
Work package No. and Title	WP1: Setup, monitoring and optimization of services delivery and internal processes: basis for sustainability	
Task No. and Title	Task 1.1 End users need analysis, services validation and setup	
Authors	<p>Author: Pascal Lardier, Principal, [édito]</p> <p>Contributors: Elena López and Jorge Gonzalez (TBM), Aline Noizet [édito], Patrick Cahill (QMUL), Veronic Sijstermans (UvA), Dario Mazzela (META Group), Marianne Baumberger (INNO TSD), Hicham Abghay and Mercedes Dragovits (STEINBEIS), Björn Hackbarth and Nicole Häusler (ENGAGE)</p> <p>Reviewer: Svetlana Klessova (INNO TSD), Myriam Martin (TBM)</p>	

Abstract

The present deliverable D1.1 is a report on the discovery phase that took place during the first 3 months (October 2016 - December 2016) of the eHealth Hub project. The objective of this research phase was to complement an initial study of our end-users' and stakeholders' needs led by the Consortium during the preparation of the grant proposal. While this initial study helped the Consortium shape relevant services to SMEs and the rest of the eHealth ecosystem, task 1.1's objective was to dig deeper into our stakeholders' needs and validate or adapt our approach in the delivery of our services as described in the project initial plan.

The online survey was designed to gather information from all end-users and validate our service delivery hypotheses with quantitative data. The survey was dynamic and jumping to a specific set of questions according to 5 main types of end-users and respondents: Health startups / SMEs, Insurers (public / private / complementary), Investors (Business Angels, VCs, Corporate Investors), Pharma (including biotech) and medical

devices, and Providers of health services (public/private hospitals, specialty clinics, regional health systems, nursing homes, care coordination networks, pharmacy groups).

The online survey allowed the Consortium to gather the insights and quantitative feedback of 285 key project stakeholders and end-users.

This report includes:

- a reminder of the project's objectives and services as proposed in the project initial plan;
- a detailed description of the goals of the project's discovery phase;
- the research methodology used for qualitative and quantitative information gathering from the ecosystem stakeholders;
- the main findings of the online survey and focus groups;
- an updated description of all the project services based on the discovery phase findings.

The updated service descriptions included in this report are to become the new reference for the definition of the eHealth Hub services and related activities, including more detailed information on the approach, the methodology, the selection criteria, and the deployment of the project services.

Dissemination level (Project co-funded by the European Commission within the Horizon 2020 Programme)

PU Public

X

Disclaimer

This document is provided with no warranties whatsoever, including any warranty of merchantability, non-infringement, fitness for any particular purpose, or any other warranty with respect to any information, result, proposal, specification or sample contained or referred to herein. Any liability, including liability for infringement of any proprietary rights, regarding the use of this document or any information contained herein is disclaimed. No license, express or implied, by estoppel or otherwise, to any intellectual property rights is granted by or in connection with this document. This document is subject to change without notice. eHealth Hub has been financed with support from the European Commission. This document reflects only the view of the author(s) and the European Commission cannot be held responsible for any use which may be made of the information contained herein.

Table of Contents

1	eHealth Hub: Objectives and Description	1
2	Research Methodology: Objective and Description	3
2.1	Objective: Researching and Analyzing Stakeholders' Needs	3
2.2	Research Methodology: Online Survey, Focus Groups and Interviews	3
3	Main findings of the users need analysis	9
3.1	General Findings	9
3.2	Detailed results	9
3.3	Business Modelling and Investment Readiness Training	11
3.4	Investment Platform	14
3.5	Commercialization Support	19
3.6	Legal and regulatory support	21
4	Service Document: Updated Service Descriptions	26
4.1	Service 1/ BUSINESS MODELING TRAINING	26
4.2	Service 2/ SOLUTION MATCH	30
4.3	Service 3/ INVESTMENT READINESS TRAINING	35
4.4	Service 4/ eHEALTH INVESTMENT PLATFORM	41
4.5	Service 5/ eHEALTH ROADSHOW	45
4.6	Service 6/ LEGAL GUIDANCE	48
4.7	Service 7/ REGULATORY GUIDANCE	51
5	Annexes	56
5.1	Main results of the first online survey: Preliminary Market research	56

List of Figures

Figure 1	Dissemination examples of the eHealth hub survey	4
Figure 2	Participants in the focus group held at Digital Health Venture Forum (DHVF) 25 th -10-2016	5
Figure 3	Level of annual revenues generated by your solution/organization?	9
Figure 4	Typology of the solutions	10
Figure 5	Current top priority (N=123)	10
Figure 6	Interest in participating in any of the following eHealth hub activities	11
Figure 7	Interest in participating in any of the following eHealth hub activities (N=33)	11
Figure 8	Benefit from expert guidance/support on (N=44)	12
Figure 9	Best positioned stakeholders to provide you with this guidance/support	12
Figure 10	Business plan readiness to pitch in front of investors (N=56)	12
Figure 11	Confident with pitching skills (N=56)	13
Figure 12	Participation in an investment readiness training program (N=56)	13
Figure 13	Most useful elements of this investment readiness program (N=24)	13
Figure 14	Importance of involvement of investors and/or key digital health stakeholders in investment readiness training program (N=24)	14
Figure 15	Raising a first round of external/risk capital investment (N=56)	14

Figure 16 Ticket amount (€) (N=21)	14
Figure 17 Actively looking for funding now (N=56).....	15
Figure 18 Ticket amount (€) (N=50)	15
Figure 19 Main challenge for this round of financing (N=50).....	16
Figure 20 Use an online platform to : (N=56).....	16
Figure 21 Use of online platforms to (N=28)	17
Figure 22 Importance to network and connect with other investors for co-investment/syndication opportunities (N=28)	17
Figure 23 Importance of the criteria provided when identifying a potential co-investor/syndication partner (N=28).....	18
Figure 24 Usefulness of a private and secure platform for verified investors to identify and network with new co-investment/syndication partners (N=28)	18
Figure 25 Information willing to share with other verified investors on this private and secure platform (N=28).....	19
Figure 26 Information acceptable for eHealth Hub to (N=28)	19
Figure 27 Interest in pitching in front of a panel of potential customers and/or corporate partners (N=89)	19
Figure 28 Key elements that would make it a successful/worthwhile event (N=89)	20
Figure 29 Piloted or implemented a digital health solution within your organization (N=33).....	20
Figure 30 description of scouting process and interaction with the digital health community (N=25) ...	21
Figure 31 Description of willingness to work/collaborate with digital health SMEs in the future (N=33) ..	21
Figure 32 Sought legal advice in the past (N=16)	21
Figure 33 If yes, what for (N=10)	22
Figure 34 If not, please explain (N=6).....	22
Figure 35 Regulatory/certification advice or support for your solution in the past (N=22).....	23
Figure 36 Please specify the type of support you received: (N=6)	23
Figure 37 Seeking for regulatory/certification advice or support on concrete topics (N=22)	23
Figure 38 Need for support for the following topics regarding reimbursement strategies (N=22).....	24
Figure 39 Need for support with software related regulatory topics (N=22)	24
Figure 40 Please specify (N=14):	24
Figure 41 Need for help in classifying your device (N=7)	25
Figure 42 Legal and/or regulatory questions investor have to face (N=28)	25
Figure 43 Percent of usefulness of receiving expert mentorship to	59
Figure 44 Favorite channel for receiving this expert mentorship.....	59
Figure 45 Access to finance services.....	60
Figure 46 What are 3 hardest sales connections to make and where would you welcome help	61
Figure 47 Percent of usefulness of... ..	61
Figure 48 Percent of usefulness of various channels for answering legal questions	62
Figure 49 Percent of usefulness of having... ..	62

List of Tables

Table 1 Survey Statistics	5
Table 2 Service 1: Business model training KPI	30
Table 3 Service 2: Solution match KPI.....	35
Table 4 Service 3: Investment readiness training KPI.....	41
Table 5 Service 4: eHealth investment platform KPI.....	45
Table 6 Service 5: eHealth Roadshow KPI	48
Table 7 Service 6: Legal service KPI.....	50
Table 8 Service 7: Regulatory and reimbursement service KPI.....	55

Table of abbreviations

AIMDD	Active Implantable Medical Devices Directive
CEO	Chief Executive Officer
CMO	Chief Medical Officer
CSA	Coordination and Support Action
DHVF	Digital health venture Forum
DoA	Description of the Action (Initial planning)
EU	European Union
FAQ	Frequently Asked Questions
ISO	International Organization for Standardization
KPI	Key Performance Indicators
MDD	Medical Device Directive
MDR	Medical Device Regulation
NCP	National Contact Points
Q&A	Questions and answers
QMUL	Queen Mary University of London
R&D	Research and development
SME	Small and Medium Enterprise
UK	United Kingdom
US	United States
UvA	University of Amsterdam
VC	Venture Capitalist

1 eHealth Hub: Objectives and Description

eHealth Hub is a new EU-funded initiative that is cross-border and exclusively focused on the digital health vertical. It will provide long-term support to the ecosystem stakeholders and address key challenges facing European SMEs in this space: fine-tuning a business model, securing investments, engaging the demand-side and accelerating commercialization, getting legal and regulatory guidance to develop solutions in compliance with a multi-layer complex framework.

eHealth Hub's goal is to provide high-quality, **vertically-focused and business-oriented** services tailored to the needs of European eHealth SMEs and stakeholders, and to secure their continuation after the project end via a sustainable support structure.

The eHealth Hub project will make progress towards this objective by:

- creating and maintaining a variety of activities helping to attract investment to SMEs;
- supporting the development of their successful business models and the acceleration of their commercialization;
- creating an EU-wide network of legal and regulatory guidance providers;
- and developing partnerships with healthcare organizations, major networks, investors and other stakeholders.

eHealth Hub will use **a demand-driven approach** to promote new business and collaboration opportunities for SMEs and key ecosystem stakeholders including healthcare provider organizations, investors, insurers, pharma and medtech groups.

Based on an initial research phase lead during the proposal preparation and based on the industry knowledge of the Consortium partners, the eHealth Hub project was designed to provide the following 7 services:

1. Business Model Training

A specialized training course helping eHealth entrepreneurs to optimize their Business Models. After the training programme, eHealth Hub will also support beneficiaries in validating their business hypotheses against the eHealth market.

2. Solution Match

eHealth Hub will support healthcare organizations interested in implementing an eHealth solution by gathering information about their exact needs, scouting and filtering solutions for fit, proposing a short list of the best matches, and connecting them with the vendors of these solutions.

3. Investment Readiness Training

eHealth SMEs seeking private funding will learn how to gauge their funding needs and what sources of funding are best for their specific situation, how to prepare before engaging in a serious conversation with eHealth investors and how to improve their pitches.

4. eHealth Investment Platform

An online brokerage tool will be made available to help eHealth SMEs and investors find each other in a more efficient way, and foster convenient online information exchange among investors to speed up deal flow.

5. eHealth Roadshow

Through the organization of agile networking events in conjunction with major eHealth conferences across Europe, SMEs with commercial traction will interact with potential customers, distributors and other eHealth stakeholders.

6. Legal Guidance

Within each European Member State there are different laws that SMEs have to comply with. A network of legal advisers will be set up across all EU countries, with nodes in each EU Member state, so that eHealth SMEs with legal challenges can access specialized, jurisdiction-dependent advice.

7. Regulatory Guidance

Within each European Member State there are different regulations that SMEs have to comply with. A network of regulatory advisers will be set up across all EU countries, with nodes in each EU Member state, so that eHealth SMEs with regulatory challenges can access specialized, jurisdiction-dependent advice.

The objective of Task 1.1 is to confirm some critical hypotheses and fine-tune the delivery approach of these services.

The eHealth Hub project is a Coordination and Support Action (CSA), carried out under the H2020 Framework programme (Contract No: 727683), and has duration of 3 years (1 October 2016 - 30 September 2019), with the ambition to continue support after 2019 through sustainable and scalable support structure.

eHealth Hub coordinator is TICBioMed, Spain, and core partners of the initiative include: [édito] in France, Queen Mary University of London (QMUL) in United Kingdom, University of Amsterdam (UvA) in the Netherlands, META Group in Italy, Inno TSD, France, Steinbeis-Europa-Zentrum in Germany, APRE in Italy and Engage AG in Germany.

For more information visit: <http://www.ehealth-hub.eu/>

2 Research Methodology: Objective and Description

2.1 Objective: Researching and Analyzing Stakeholders' Needs

In the eHealth Hub initial proposal, Task 1.1 proposed to organize in the first 3 months of the project:

- **a focus group** to collect feedback on the initial eHealth Hub support model and validate or generate suggestions to improve the initial design of initiatives with a sample population including eHealth SMEs, investors and other stakeholders - some of them coming from the Strategic Advisory Board.
- **a comprehensive online survey**, similar to the one presented in the proposal Annex 5.1, sent to SMEs but also to the relevant stakeholders involved in the project initiatives, and designed to quantify and prioritize the delivery options for the initial deployment of services.

Having already organized a focus group and lead a first online survey of eHealth stakeholders during the grant application phase, the goal of this second research phase was not to completely reinvent or rewrite the whole concept of our 7 services, but rather to confirm important hypotheses about the best ways to deliver and offer the most value to end-users through our activities.

The metrics and results of eHealth Hub's first online survey are attached as Annex 5.1. The questions asked in this first survey were not repeated in the second one. Each Consortium partner proposed a new set of questions for their stakeholders designed to validate, adjust and fine-tune the delivery of their services. This research phase also represented an opportunity for eHealth Hub partners to include our end-users in the co-design/co-creation of our activities.

The eHealth Hub sustainability and exploitation plan was not included in this second research phase as the Consortium believes it will be easier to ask stakeholders if they would be willing to pay for a specific service once we have already delivered this service to them. Questions related to the sustainability of eHealth Hub services after the funding of the European Commission will be asked in post-service delivery or post-event satisfaction surveys.

The results of eHealth Hub's second discovery phase have been used as the basis for the detailed service programme document that follows, precisating and adjusting the approach, the methodology, the selection criteria, and the deployment of the project services.

2.2 Research Methodology: Online Survey, Focus Groups and Interviews

2.2.1 Stakeholders Online Survey

The online survey was designed to gather information from all end-users and validate our service delivery hypotheses with quantitative data. The survey was dynamic and jumping to a specific set of questions according to 5 main types of end-users and respondents:

- Health startups / SMEs
- Insurers (public / private / complementary)
- Investors (Business Angels, VCs, Corporate Investors)
- Pharma (including biotech) and medical devices

- Providers of health services (public/private hospitals, specialty clinics, regional health systems, nursing homes, care coordination networks, pharmacy groups)

The eHealth Hub consortium has done a wide dissemination in order to reach as many stakeholders as possible:

- Personal emails: Over 350 personal emails were sent to SMEs and digital health stakeholders by [édito], asking them to take the survey.
- The survey was sent to specialised Health clusters.
- The survey information was also included in several newsletters including EU eHealth Newsletter, eHealthNewsletter.eu, Health 2.0 Europe and TICBioMed. Dissemination examples:
 - [EU eHealth Newsletter](#)
 - [eHealthNews.eu](#)
 - [Health 2.0](#)
 - [NN2.0](#)



Figure 1 Dissemination examples of the eHealth hub survey

- Dissemination Team APRE as WP3 Task leader on dissemination and communication activities also relayed the online survey to 1932 clients included in their internal database. Additional dissemination channels used by dissemination team APRE included networks such as HNN2.0 twitter account (including about 170 NCPs) and the EU DG connect website.
- Social media activities: the survey information was also relayed through LinkedIn posts and a series of tweets from the eHealth Hub and Consortium partners' accounts (The eHealth Hub twitter handle already counts 239 followers).

The online survey allowed the Consortium to gather the insights and quantitative feedback of 285 key project stakeholders and end-users. The break-down of survey respondents is below:

	Complete	Partial	Total
Health startups / SMEs	134	30	164
Insurers (public / private / complementary)	3	1	4
Investors (Business Angels, VCs, Corporate Investors)	30	2	32
Pharma (including biotech) and medical devices	8	3	12
Providers of health services (public/private hospitals, specialty clinics, regional health systems, nursing homes, care coordination networks, pharmacy groups)	21	8	29
Other	27	17	44
Total	223	61	285

Table 1 Survey Statistics

2.2.2 Investors Focus Groups

The two focus groups we organized with investors (one in-person, one online) aimed to gather more qualitative data and possibly bring out fresh ideas for our service delivery approach of the eHealth Investment Platform. Our 2 focus groups gathered the insights and qualitative feedback from over 12 specialized and active European investors in digital health.

The Consortium decided it did not make sense to gather all stakeholders in one focus group as the conversation would have been pulled in too many directions and would not have allowed to dig deeper into some of the stakeholders' insights.



Figure 2 Participants in the focus group held at Digital Health Venture Forum ([DHVE](#)) 25th-10-2016

Topics discussed and main findings

- Access to a more important pipeline is not a real priority for investors per se.

The Consortium discovered that most digital health investors, especially after some time in the industry, have enough pipeline - sometimes more than they can process efficiently.

Their main challenge is that this pipeline is not always of the expected quality and/or in line with their specific investment criteria.

- Co-investment and syndication are effective ways to invest.

Investors tend to co-invest to spread risks. The earlier the investment stage, the more co-investments take place. Angel and seed investors indicate that almost 100% of their investments happen through collaboration with other investors: co-investments or syndication.

Actually, a very effective mechanism to motivate investments is when a lead investor comes to other investors with an investment proposal. In this case, the chances that an investment comes through are very high.

Early stage investors are more open to share information about potential deals, while growth and corporate investors are much more cautious about making this information public. The latter will use personal connections and/or desktop research to find co-investors candidates if needed.

- Importance to introduce and generate trust among digital health investors

The European digital health investment landscape is relatively young: investors have highlighted the need to know more about the actual investments in the space, and to get to know other investors to investigate future investment opportunities.

It is interesting to note that connections with other investors are sought in 2 main directions:

- horizontal: within the same investment range for co-investment or syndication opportunities
- vertical: at the next investment range, basically to identify whom they will sell their participation to.

This is the primary reason for their participation in events for investors like [Noah](#).

- Need to complement on-line interaction with physical gatherings.

As one of the investors put it, just an online platform would be 'too dry'. They welcome the idea of having a web space to identify other investors and follow the flow of digital health investments, but they would also like to get to know each other and network with liked-minded investors in physical gatherings.

If gatherings are co-located with events they plan to attend anyway, all the better as they will save time and money.

Also, in those gatherings they would value to be educated on a number of topics like:

- Regulatory changes
- Relevant laws in different EU countries (e.g. legal maps)
- Reimbursement processes

- Interoperability and standards
- What technologies are currently prescribed and why?

This information needs to come from recognized digital health experts.

- Need to know other profiles beyond investors and companies.

Apart from networking with new investors and building their pipelines, our participants also indicated that it would be helpful for them to meet other profiles, like experts that could help them assess companies and prepare due diligence, or experienced candidates that could reinforce the staff of the companies they invest in key positions such as financial manager, market strategy manager, etc..

Conclusions and adjustments to eHealth Hub investor-focused services

- The first release of the platform will focus on supporting investor-to-investor connections, increasing co-investments and attracting more investors to the sector. We will try to build a critical mass of investors before opening the platform to SMEs.
- The second release will incorporate SMEs and put a lot of attention on making the funds' investment criteria transparent. This criteria clarification will help SMEs save time and only contact investors that are a good fit for them at their current stage.
- Apart from investors and SMEs, and depending on budget availability, we will incorporate other profiles of interest that would add value and help promote investments in digital health in Europe.
- Since organizing networking events for investors was not included in the initial planning, it has no allocated funding. However, the Consortium partners will try to organize these events outside of the scope of the project to support trust-building and speed up the maturity of the ecosystem.

3. One-on-one interviews

The Consortium also led one-on-one interviews and informal discussions with end-users to validate eHealth Hub's hypotheses and approach, especially for our regulatory and reimbursement guidance and Solution Match services.

eHealth Start-up – Interviewer: ENGAGE

Summary of findings

- The ISO 13485:2016 update is going to "crush" the eHealth industry in the next few years, due to a lack of notified bodies (they must get authorized for the ISO update by the EMA; some have already been "shut down", e.g. in Austria) → This will probably result in only a very few certifications for medical products.
- In general, all the information you can find online about regulatory standards and certification of medical devices only tell you what they are about but not how you implement them or how to determine if your product is a medical device or not.
- The need for consulting regarding regulatory issues/certification processes for eHealth start-ups is more or less continuous and mostly provided by external consultancies (except in rare cases where the SMEs have an in-house regulatory expert).

eHealth Start-up – Interviewer: ENGAGE	
Summary of findings	<ul style="list-style-type: none"> Regulatory aspects are hugely overestimated by eHealth start-ups – people are extremely concerned about this topic. It would be really great and very helpful to have an expert that guides you through the best path to reimbursement in different countries. When working with pharma companies, they also do not know how to get reimbursement for a solution.
Institute on Medical Device Regulatory Services – Interviewer: ENGAGE	
Summary of findings	<ul style="list-style-type: none"> Most of the young companies are not aware of what efforts they will have to make to ensure compliance with regulatory requirements in the future, e.g. regarding the Medical Device Regulation. In its current version, the rule 10a makes software products of the class I practically impossible. As a consequence, rule 10a of the Medical Device Regulation will slow down the development of medical software as small manufacturers will find it very difficult to overcome the regulatory hurdles.
Research institute – Interviewer: ENGAGE	
Summary of findings	<p>Revision 4 of the guideline for clinical evaluation (MEDDEV 2.7/1) is only poorly taken into account and underestimated by many medical device producers. The revised guideline includes changes in the clinical evaluation of medical products and their documentation. A lot of medical devices will need to be recertified, which will represent significant additional efforts and costs for producers over the next years.</p>
Lawyers – Interviewer: ENGAGE	
Summary of findings	<ul style="list-style-type: none"> Considering reimbursement strategies early on together with regulatory issues is of utmost importance as going through the motions of the reimbursement processes in different health systems is very time-consuming -> many SMEs in the field of diagnostics start considering reimbursement too late. Some documentations - especially the ones focusing on clinical aspects - overlap with both certification and reimbursement.
Pharma company – Interviewer: EDITO	
Summary of findings	<ul style="list-style-type: none"> When they need a solution to a specific internal need, pharma groups tend to ask consulting companies like Accenture, Deloitte or clients with the required expertise. They don't normally work directly with SMEs as it represents a high risk for them. They are missing a space where SMEs and corporate stakeholders can meet and interact. Corporations could explain what they do and what they are looking for. It would make it easier for SMEs who don't always have time to approach corporations or find it difficult to identify the right point(s) of contact. SMEs should come up with innovative business models that don't necessarily involve equity.
Home care organisation – Interviewer: EDITO	
Summary of findings	<ul style="list-style-type: none"> They are interested in upgrading their offering by adding new services/solutions for the day to day care of their patients but they have no time to identify and research those solutions. Their budgets are also limited. Services offered and solutions implemented need to be cost-effective otherwise they would have to increase the price of their own service, which would result in a decline of their competitiveness. They would be interested in hearing use cases from other European countries

3 Main findings of the users need analysis

3.1 General Findings

The findings of our second online survey have served to fine-tune our service offerings but also to confirm and reinforce some critical hypotheses at the foundation of the eHealth Hub project:

- Building up the investment flow and accelerating the commercialization of eHealth solutions are the two key levers to boost the industry in Europe.
- The importance of increasing the engagement of potential buyers and investors confirms the relevance of eHealth Hub's demand-side driven approach.
- The digital health industry is still very young in Europe. Potential buyers and investors are asking for commercial traction and track records of successful implementations while many SMEs are still pre-revenues and in the pilot/proof of concept phase. Through careful participant selection, eHealth Hub needs to focus on European most advanced eHealth SMEs.
- The eHealth industry is very specific and eHealth Hub needs to offer very vertically-focused services involving buyers, investors and other digital health stakeholders as much as possible.

3.2 Detailed results

A good number of SME respondents are still pre-revenue or below 100K€ in revenues. The realization that the digital health industry is still very young in Europe, confirms the need to provide vertically-focused business modelling training.

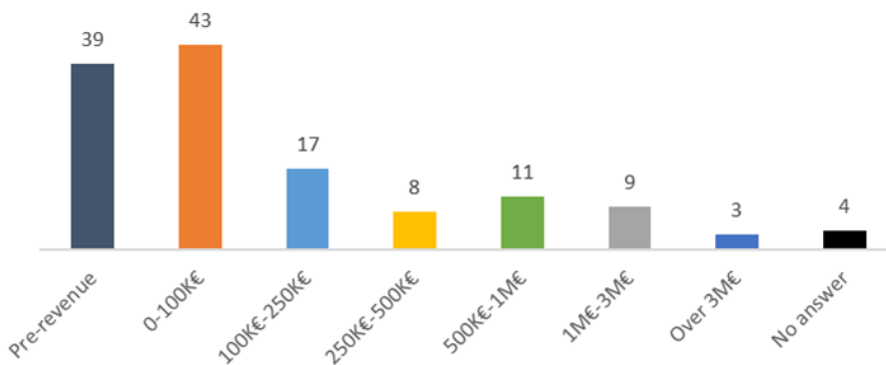


Figure 3 Level of annual revenues generated by your solution/organization?

Only a minority of the SME respondents are working on a B2C solution. Knowing that providers and payers are just starting to engage with SMEs and look into digital health solutions, this validates the Consortium approach to accelerate commercialization focusing on the needs of demand-side stakeholders.

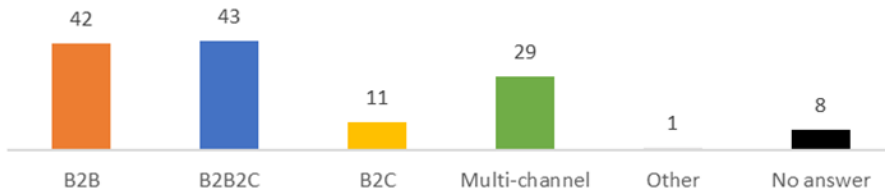


Figure 4 Typology of the solutions

The top priorities for SMEs remain in order to:

- accelerate the commercialization of solutions;
- secure financing,
- fine-tune their business models;
- and find answers to legal and regulatory questions.

Very few respondents answered they had a different priority, which confirms that eHealth Hub services are focusing on the right needs. In this 'Other' category, respondents mentioned: building or further developing and testing a solution, validating a proof of concept or building evidence through a clinical trial.

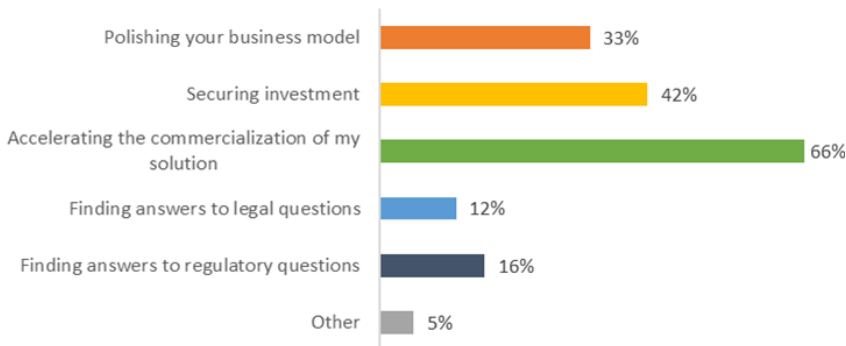


Figure 5 Current top priority (N=123)

The project's focus on the right priorities for SMEs was also confirmed by the last question of the survey, asking respondents if they would be interested in eHealth Hub specific services:

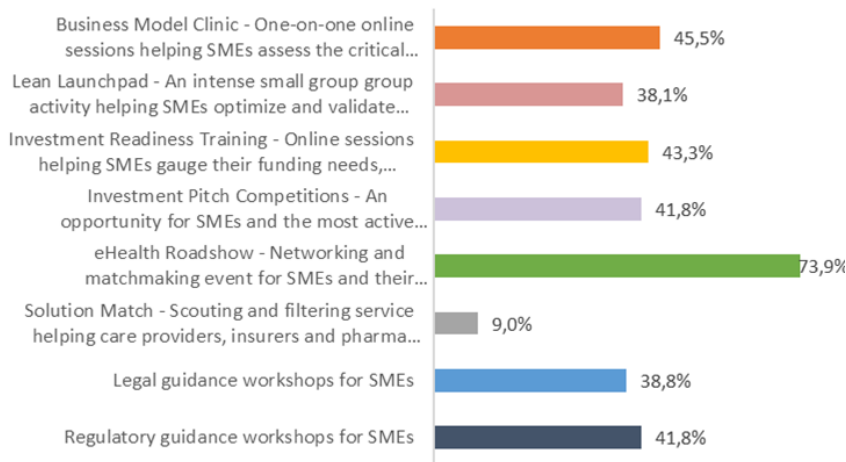


Figure 6 Interest in participating in any of the following eHealth hub activities

The relatively low percentage of respondents interested in Solution Match can be explained by the fact that only 20 survey respondents represented the main end-users of this service: health care providers, insurers and pharma/medtech companies.

Analyzing their isolated response to this question, we realize that Solution Match is actually of high interest to most health care providers, insurers and pharma/medtech companies.

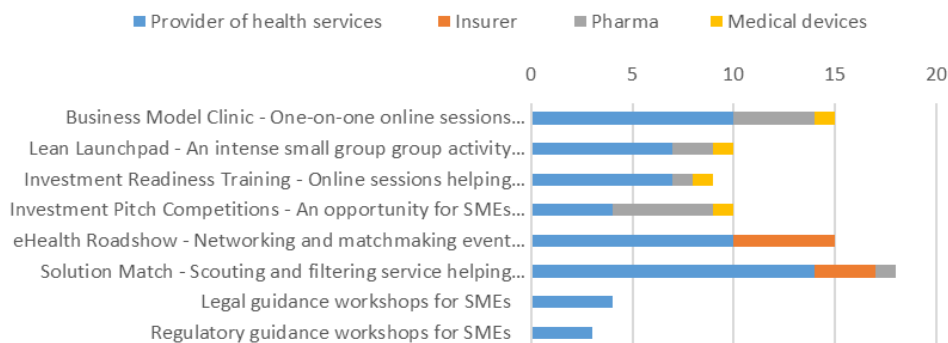


Figure 7 Interest in participating in any of the following eHealth hub activities (N=33)

3.3 Business Modelling and Investment Readiness Training

When asked where they could benefit from expert guidance, SMEs responded:

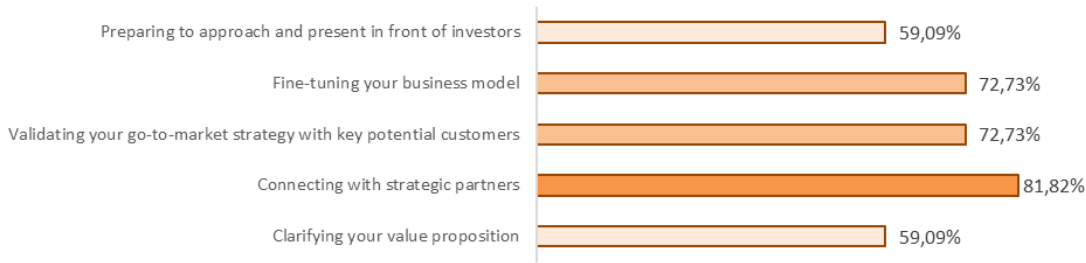


Figure 8 Benefit from expert guidance/support on (N=44)

SME respondents believe the best positioned to provide them with this guidance/support are industry stakeholders and digital health experts: potential strategic partners, potential customers, industry experts and potential investors. The Consortium will make sure eHealth Hub services, activities and training programs are very focused on the digital health vertical and include these demand-side stakeholders as much as we can in our services and activities.

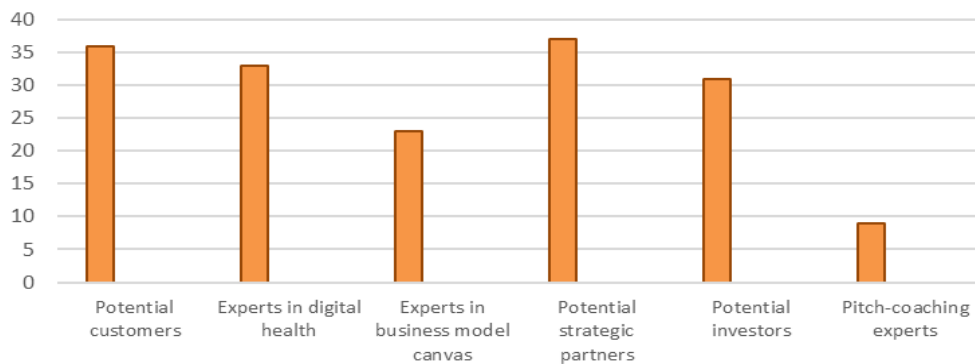


Figure 9 Best positioned stakeholders to provide you with this guidance/support

SMEs are generally confident with the readiness of their business plans and with their pitching skills.

71% of respondent felt ready (4 on a scale from 1 to 5) or very ready (5 on a scale from 1 to 5) to present their business plans in front of investors.

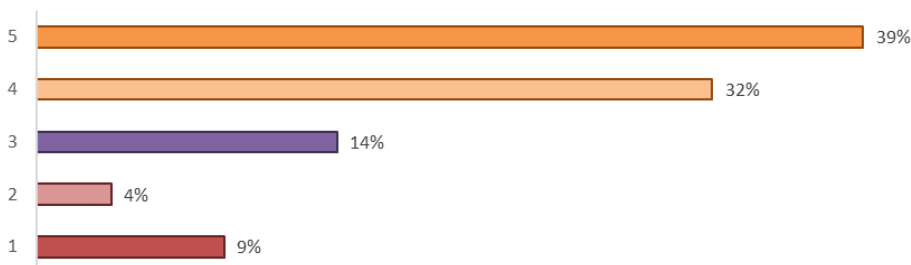


Figure 10 Business plan readiness to pitch in front of investors (N=56)

84% of respondent felt confident (4 on a scale from 1 to 5) or very confident (5 on a scale from 1 to 5) with their pitching skills.

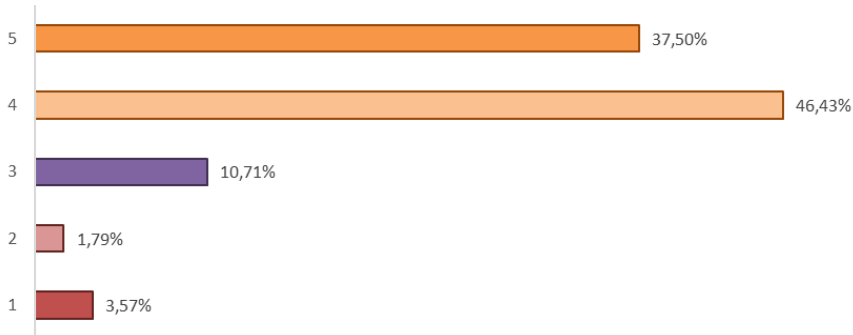


Figure 11 Confident with pitching skills (N=56)

However, these results need to be put in perspective with the point of view of investors who always mention that SMEs need to fine-tune their pitch presentations and work on their pitching skills.

43% of SMEs have already been part of an investment readiness training program:

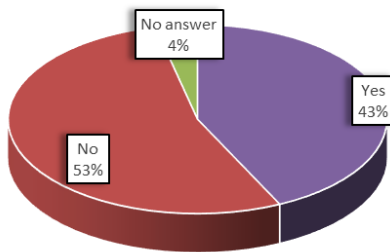


Figure 12 Participation in an investment readiness training program (N=56)

SMEs that participated in one of these investment readiness trainings thought the most useful elements of these programs were the opportunity to clarify their business models or to improve their pitching skills:

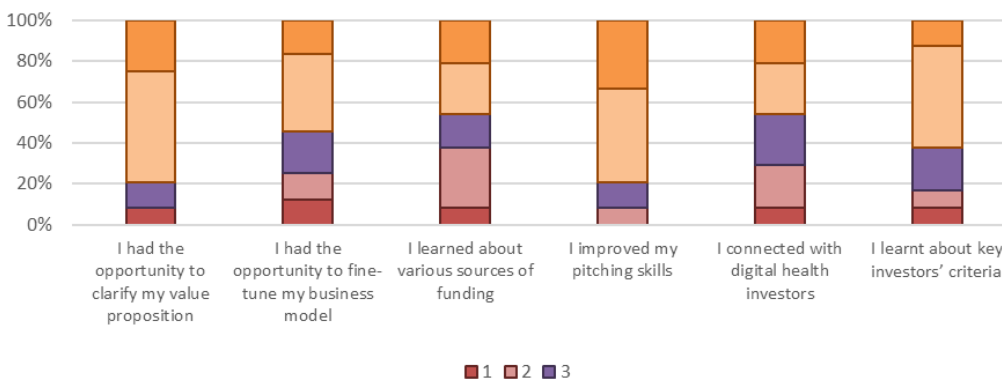


Figure 13 Most useful elements of this investment readiness program (N=24)

A question that was more specific to investment readiness training confirmed the importance of involving investors and key digital health stakeholders in these programs. 75% responded their involvement was important (4 on a scale from 1 to 5) or very important (4 on a scale from 1 to 5):

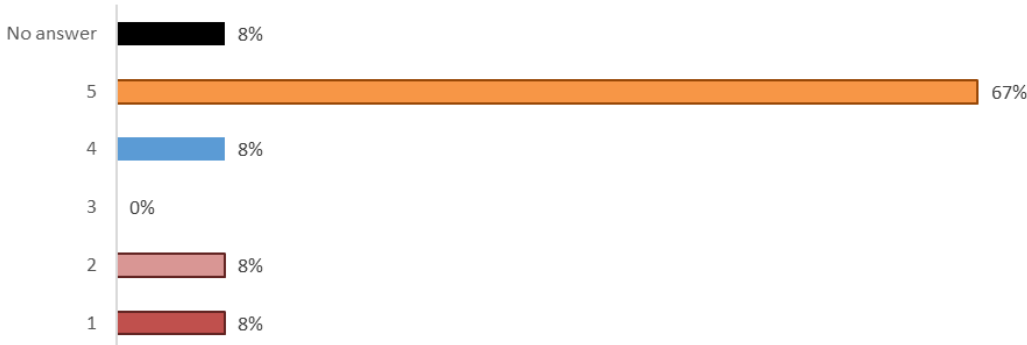


Figure 14 Importance of involvement of investors and/or key digital health stakeholders in investment readiness training program (N=24)

3.4 Investment Platform

37% of SME respondents had already raised a round of external capital:

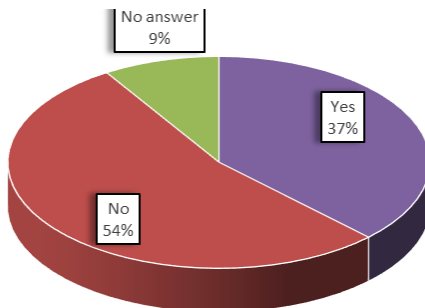


Figure 15 Raising a first round of external/risk capital investment (N=56)

Over 38% of these SMEs that had already been financed raised over 1M€.

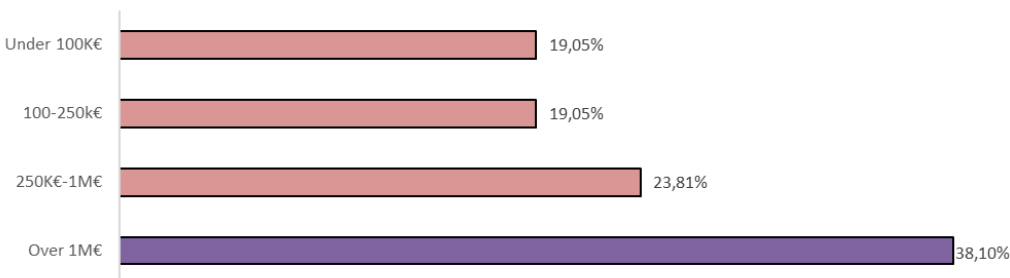


Figure 16 Ticket amount (€) (N=21)

83% of SME respondents are currently actively looking for funding:

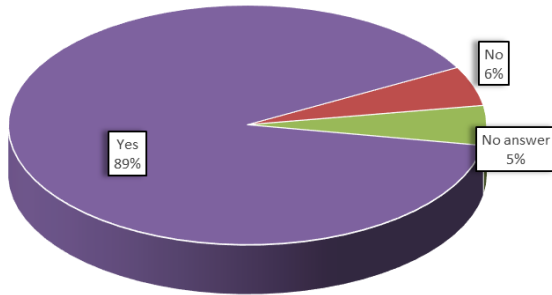


Figure 17 Actively looking for funding now (N=56)

72% are currently looking to raise between 100K€ and 1M€ and 28% are currently looking to raise more than 1M€:

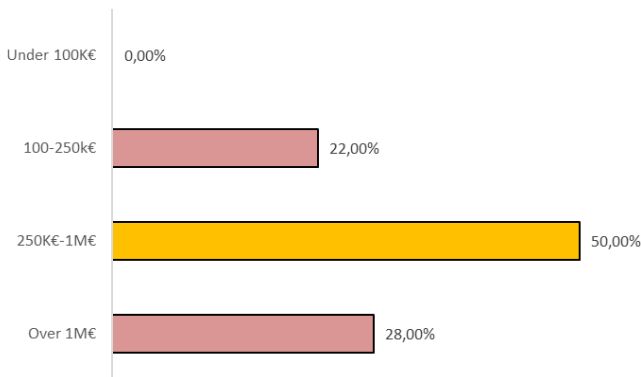


Figure 18 Ticket amount (€) (N=50)

Since 50% of SMEs currently looking for investment are trying to raise between 250K€ to 1M€, eHealth Hub will particularly pay attention to this bracket.

In their current search for investment, the main challenge of SMEs is about identifying and connecting with the right investors, which confirms the hypothesis that the eHealth Hub platform needs to have a strong focus on making investors' criteria public and transparent:

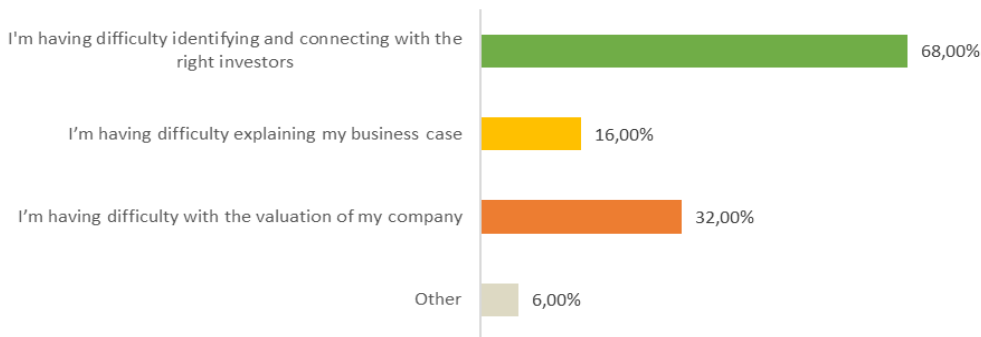


Figure 19 Main challenge for this round of financing (N=50)

SMEs use available online platforms primarily to follow startup and industry news and to increase their own visibility. Identifying and connecting with the right investors comes in 3rd position, as most online platforms are not specifically designed and built for this purpose. eHealth Hub plans to propose a platform that will focus on this activity.

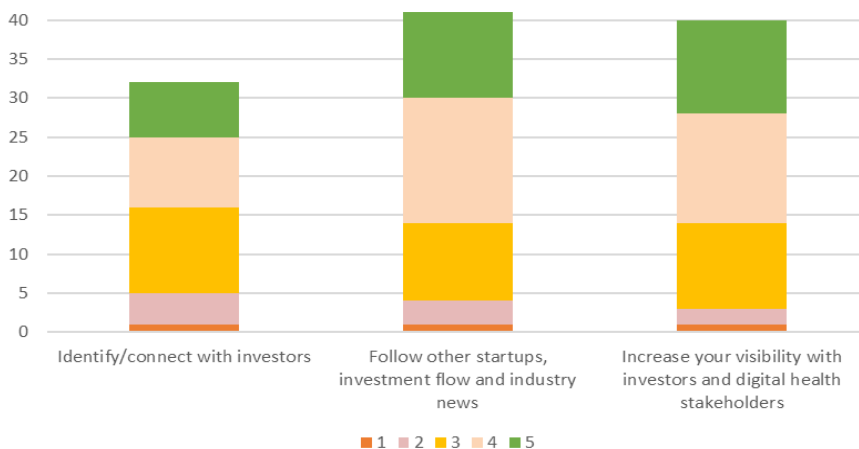


Figure 20 Use an online platform to : (N=56)

When asked what could make these platforms more useful to SMEs, their responses included:

- A focus on the health/digital health vertical;
- More detailed information about investors (deal history/portfolio, specific areas of interest) and a way to identify and connect with the most relevant ones;
- Additional services including legal advice, healthcare news, investment deals, reports, case studies;
- An easier way to upload/update information targeting investors;
- An algorithm to make matches between startups and investors.

A majority of investors also use online platforms to follow industry news, build their pipeline and increase their visibility:

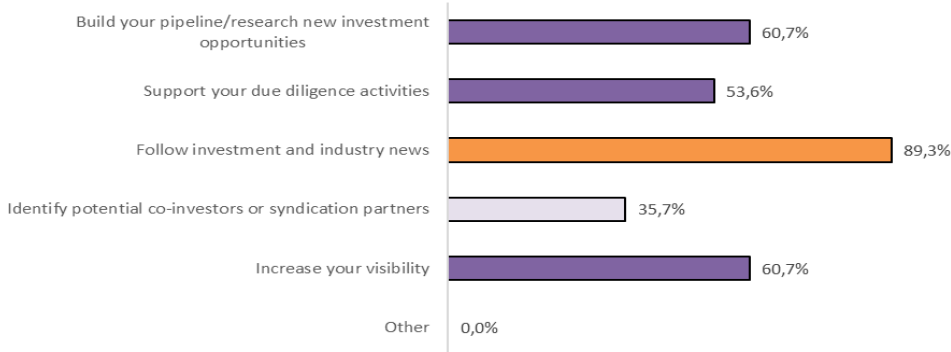


Figure 21 Use of online platforms to (N=28)

The main reason for using online platforms is to stay informed of investment and industry news. Only 35,7% of investors use online platform to identify potential co-investors or syndication partners. However, most of them use these platforms to understand who's investing in what.

Although not happening directly through online platforms, connecting with other investors remain important (4 on a scale of 1 to 5) or very important (5 on a scale of 1 to 5) for 89,3% of respondents.

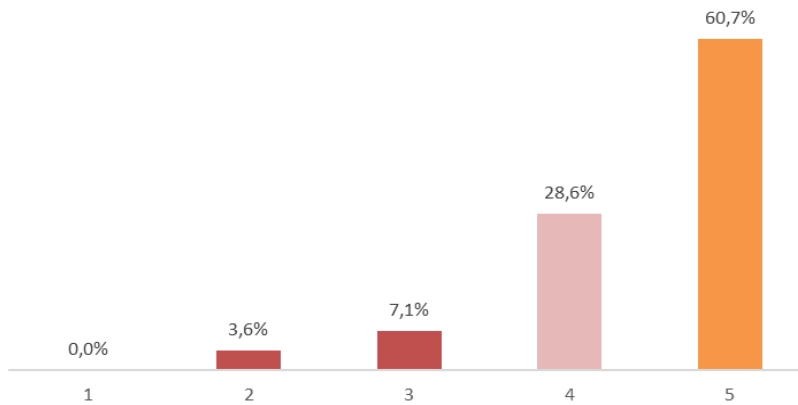


Figure 22 Importance to network and connect with other investors for co-investment/syndication opportunities (N=28)

Trust and knowledge are the two most important criteria for connecting to a potential co-investment or syndication partner:

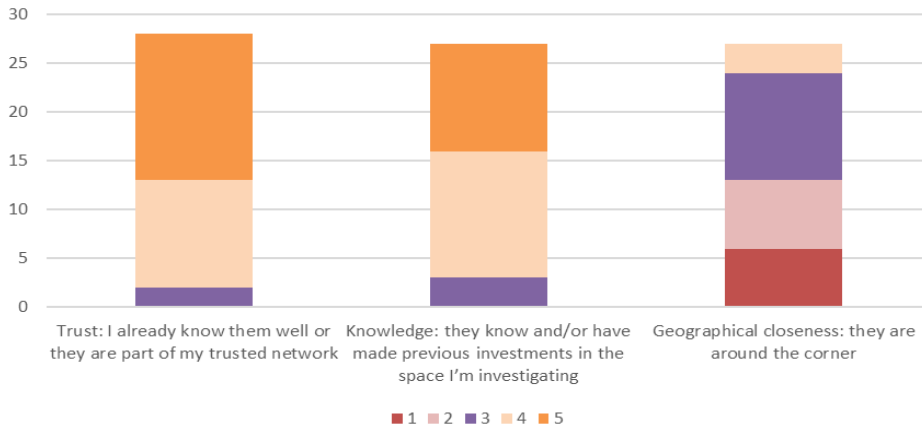


Figure 23 Importance of the criteria provided when identifying a potential co-investor/syndication partner (N=28)

Although this is not how they describe their main use of existing online platforms, 63,6% of Investors would be interested in joining a private and secure platform for investors only where they could easily identify and network with co-investment and syndication partners.

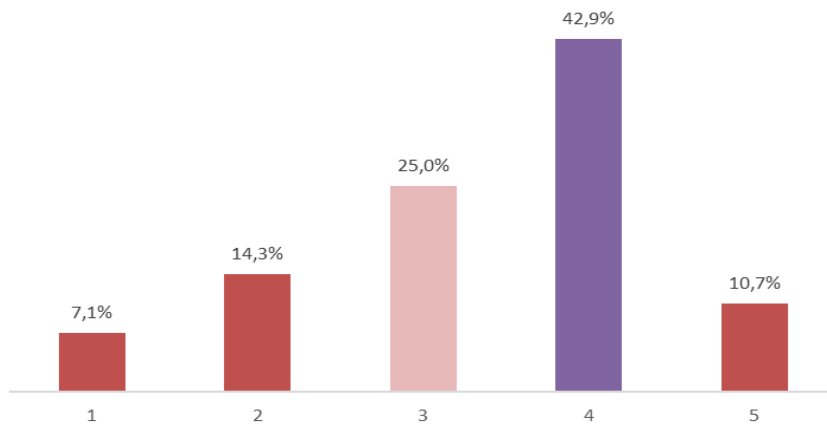


Figure 24 Usefulness of a private and secure platform for verified investors to identify and network with new co-investment/syndication partners (N=28)

On this private and secure platform, investors would be ready to share information on ticket amounts, investment criteria, categories of solutions of particular interest, previous investments in digital health, main point of contact, contact details including email addresses and phone numbers)

They are more reserved about sharing info on current/open investment opportunities. On this question, there is an important difference between business angels and VCs. Business angels are a lot more open to sharing information about current/open deals than VCs.

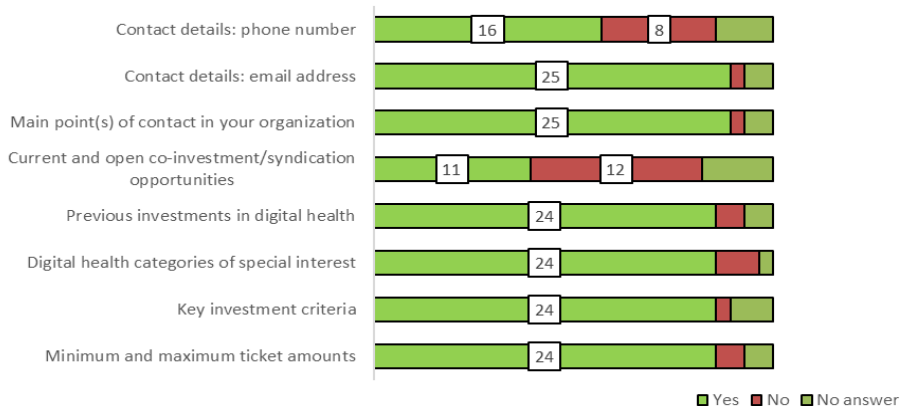


Figure 25 Information willing to share with other verified investors on this private and secure platform (N=28)

Investors would accept to share a more basic profile with SMEs and other stakeholders that would not including personal contact details:

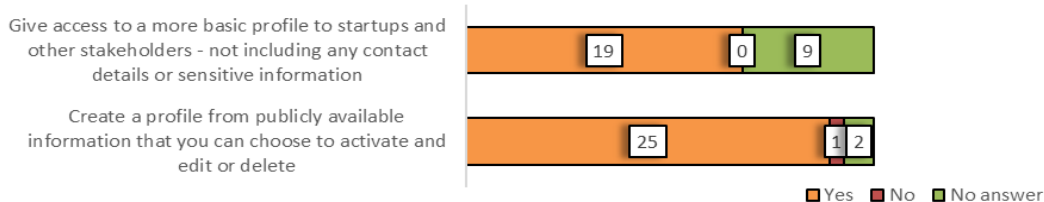


Figure 26 Information acceptable for eHealth Hub to (N=28)

3.5 Commercialization Support

The survey revealed a strong interest of SMEs in pitching in front of potential customers and/or corporate partners, which is in line with 2 of our services: Solution Match and eHealth Roadshow.

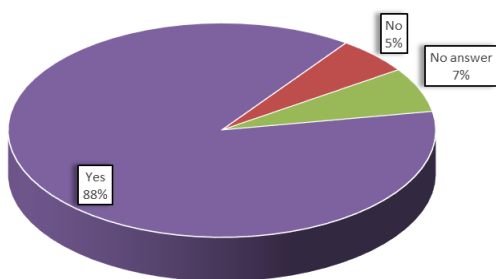


Figure 27 Interest in pitching in front of a panel of potential customers and/or corporate partners (N=89)

The quality of the panel of potential customers and/or corporate partners and the possibility to pre-arrange one-on-one meetings onsite are key for the success of this type of events:

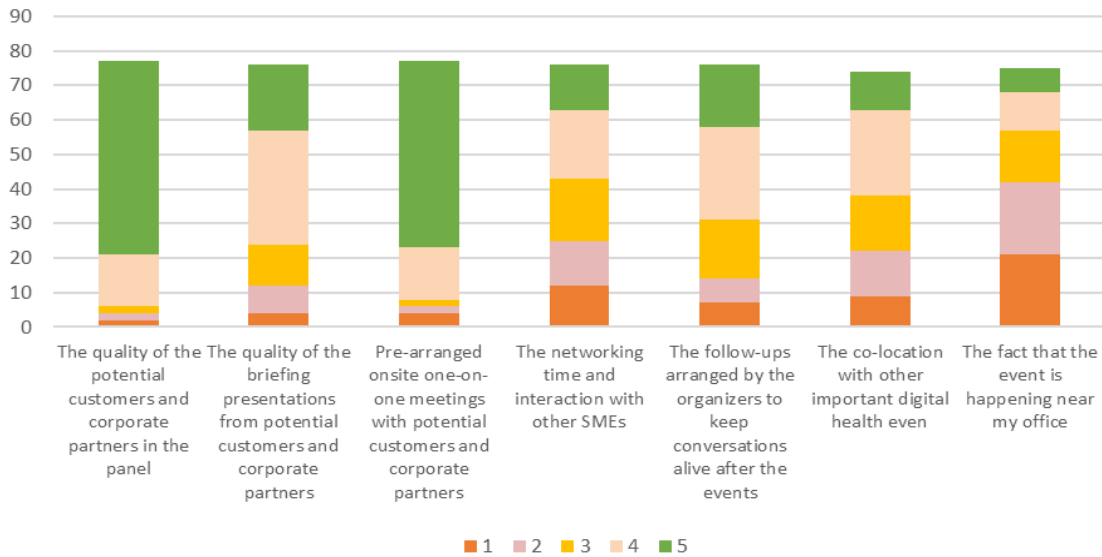


Figure 28 Key elements that would make it a successful/worthwhile event (N=89)

Surveying demand-side stakeholders (healthcare providers, insurers, pharma/medtech companies), 76% of respondents had already implemented a digital health solution.

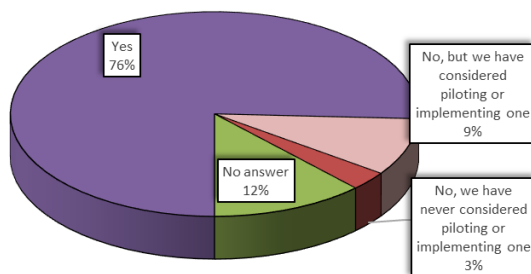


Figure 29 Piloted or implemented a digital health solution within your organization (N=33)

Although they would not completely outsource the process, they admitted they were missing detailed information and a broad view on the market, and found the scouting and filtering process time-consuming:

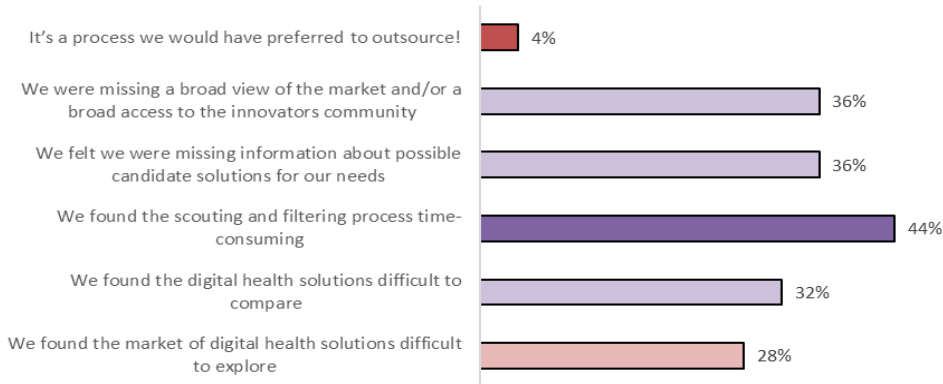


Figure 30 description of scouting process and interaction with the digital health community (N=25)

However, they remain willing or very willing to interact and work with startups and SMEs in the future:

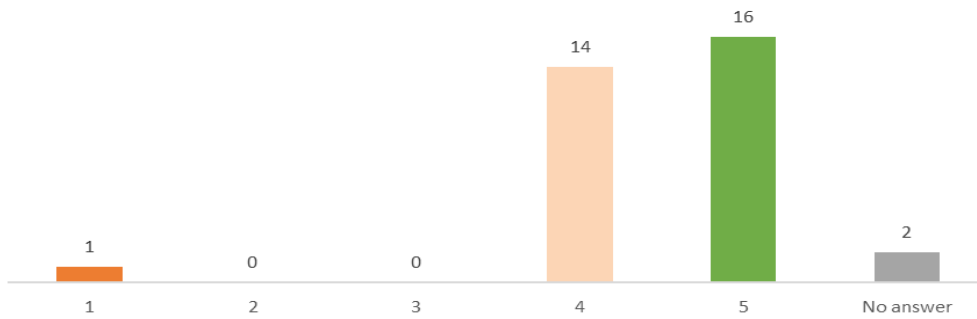


Figure 31 Description of willingness to work/collaborate with digital health SMEs in the future (N=33)

3.6 Legal and regulatory support

A majority of SMEs had already sought legal advice in the past.

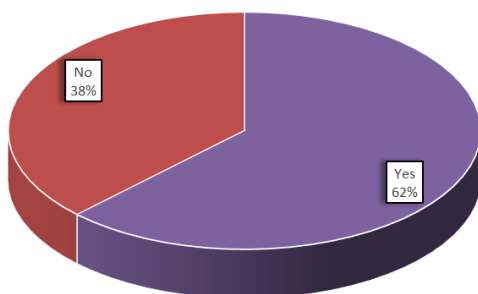


Figure 32 Sought legal advice in the past (N=16)

When asked about specific legal topics, 80% of SMEs declared they had sought legal advice on privacy policy/data protection and intellectual property. Their response has helped us shape the content of our legal workshops.

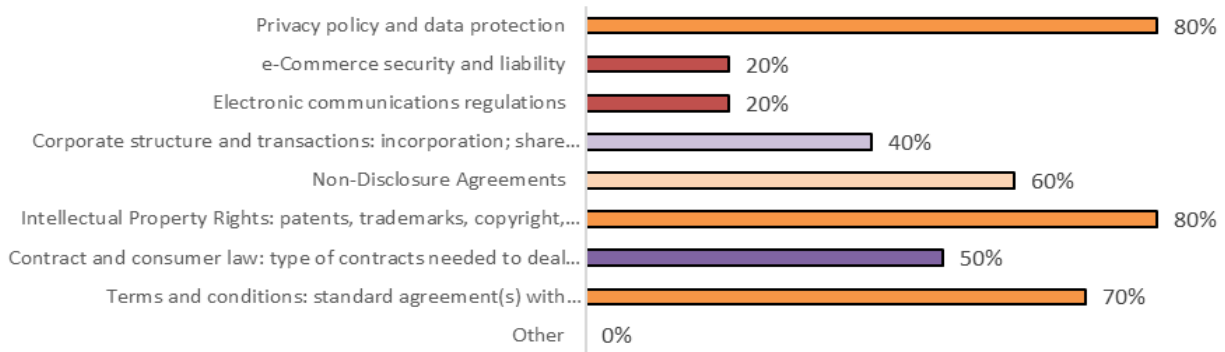


Figure 33 If yes, what for (N=10)

The respondents who had never sought legal advice were asked why. Budget restrictions and not knowing where to find the right legal advice were the two main reasons, which validated eHealth Hub's plan to establish a network of 'legal nodes' across member states.

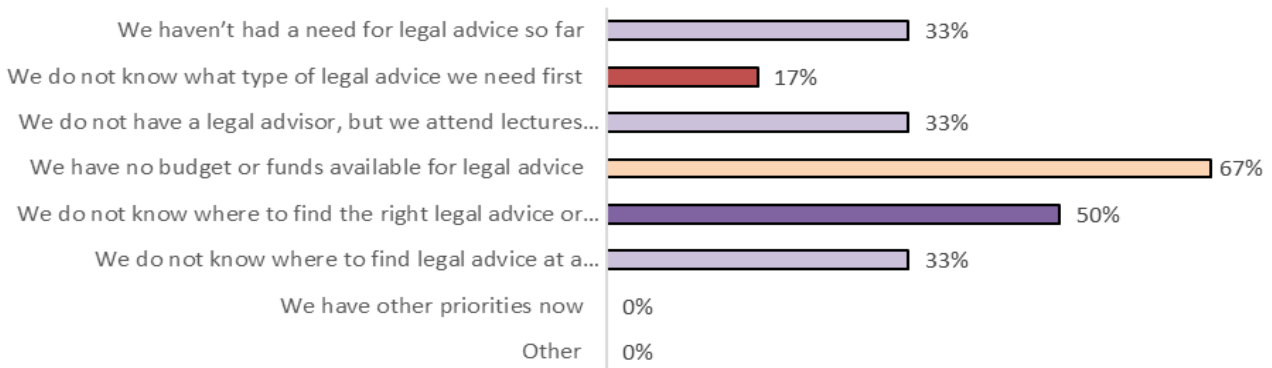


Figure 34 If not, please explain (N=6)

The survey featured a specific set of questions about regulatory guidance.

Only 27% of respondents had sought regulatory guidance in the past, while over 50% of respondents were likely to seek regulatory guidance in the future, mainly on general medical device certification, standards related to medical device software and quality management systems for medical devices. Their response has helped us shape the content of our regulatory workshops.

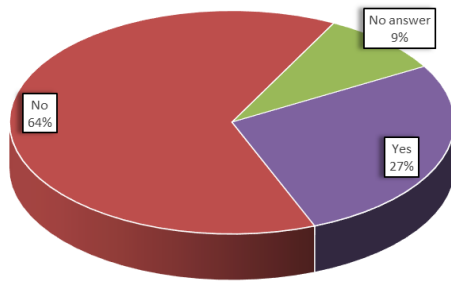


Figure 35 Regulatory/certification advice or support for your solution in the past (N=22)

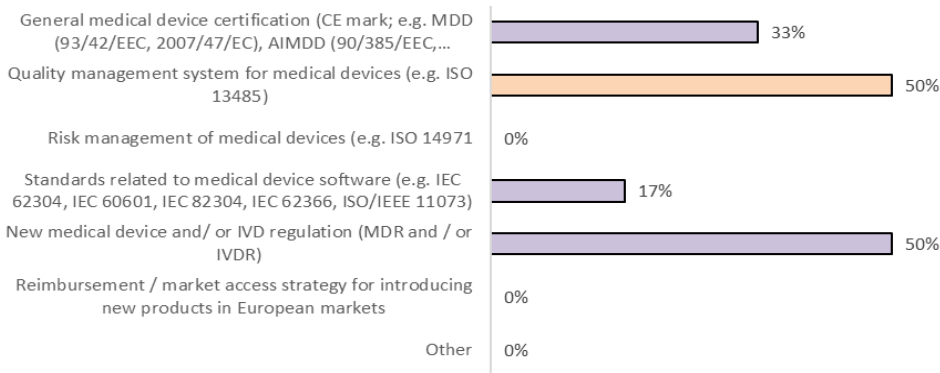


Figure 36 Please specify the type of support you received: (N=6)

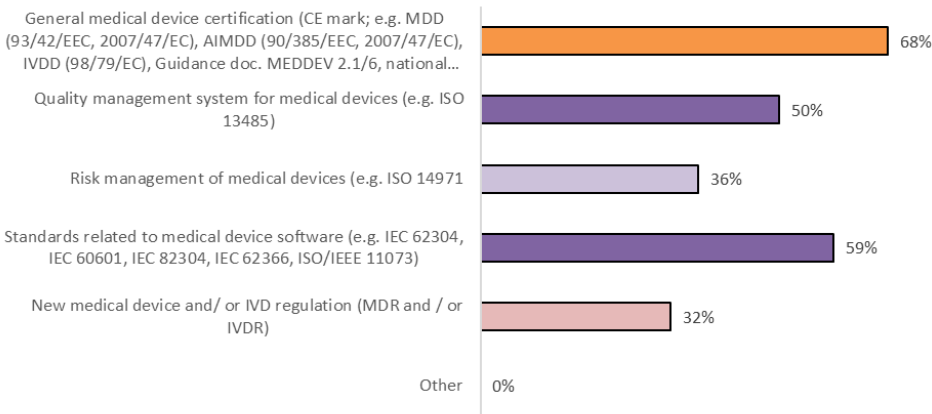


Figure 37 Seeking for regulatory/certification advice or support on concrete topics (N=22)

68% of SMEs responded they would welcome support in better understanding pathways and mechanisms of reimbursement across Europe. eHealth Hub has decided to include this topic – not in the project’s initial scope of work - in its mission of regulatory guidance and support.

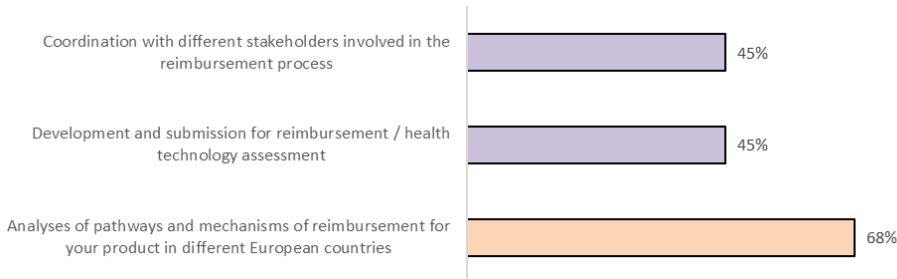


Figure 38 Need for support for the following topics regarding reimbursement strategies (N=22)

64% of SMEs stated they would welcome support with software-related regulations.

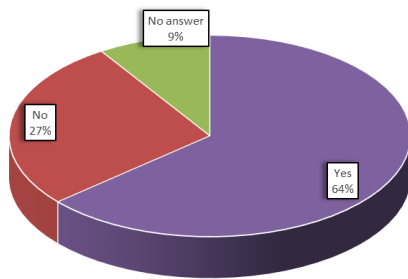


Figure 39 Need for support with software related regulatory topics (N=22)

We asked these 64% respondent to precise the type of software-related regulatory support they would welcome:

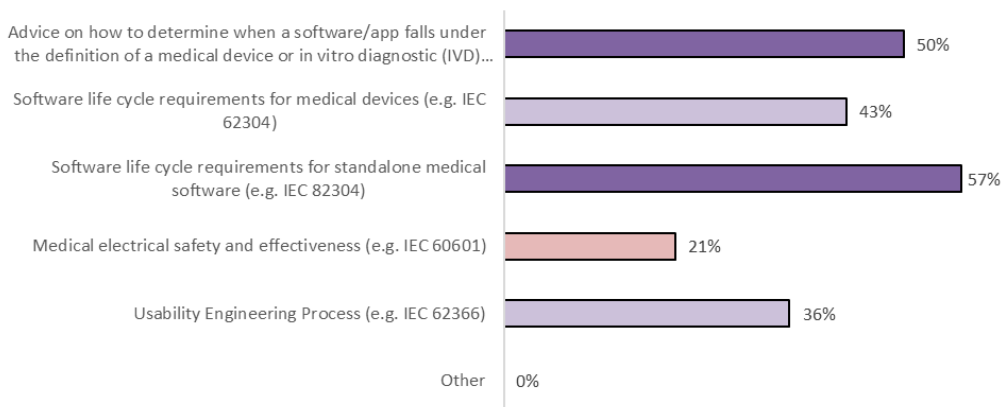


Figure 40 Please specify (N=14):

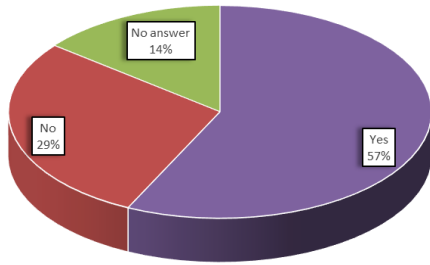


Figure 41 Need for help in classifying your device (N=7)

The survey also confirmed an interest of investors, already identified in the focus group, in learning more about legal and regulatory requirements across Europe.

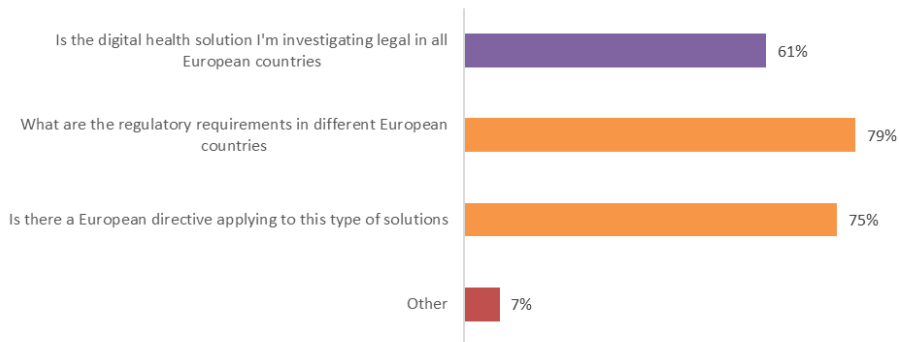


Figure 42 Legal and/or regulatory questions investor have to face (N=28)

4 Service Document: Updated Service Descriptions

Following the project research and discovery phase led in Task 1.1, the following Service Document D 1.1 aims to become the new reference for the definition of the eHealth Hub services and related activities, including updated service descriptions and more detailed information on methodologies, stakeholders' selection criteria, and timing for the roll out of all project activities. Each description includes Key Performance Indicators (KPIs) for the 3-years project period.

4.1 Service 1/ BUSINESS MODELING TRAINING

1. Service code, name and brief description

Business Modeling Training - The business modeling service aims to take participating teams through the right steps to rapidly develop and test novel solutions by gathering feedbacks, developing a goal-oriented and well-planned business model for exploitation and dissemination of key results and solutions. The Lean Startup approach and methodology will be used and adapted to specific participants' needs. Throughout the process participants will be mentored by industry experts and coaches.

2. Service leader

META Group S.r.l

- Dario Mazzella (d.mazzella@meta-group.com)
- Andrea Di Anselmo (a.dianselmo@meta-group.com)

2. Target audiences and participants

The Business Modeling Training service targets early-stage startups and SMEs within the eHealth sector. The service includes a wide array of expert one-to-one coaching and will be customized to fit the specific needs of each participant. In general, it is expected that the participating teams bring the same passion that they have for their idea or startup into the service.

4. Where and how does it take place?

The Business Modeling Training service will take place 5 times over the next three years. The goal of the Consortium is to bring the service into 5 different countries, by making strategic partnerships with key international events in the eHealth sector.

Locations and specific dates are still to be determined, but the first service iteration will most likely be delivered in June 2017 at ICEEfest in Bucharest (to be confirmed).

5. Context and initial challenge hypotheses

Many of the solutions developed within the eHealth sector fail to have a meaningful impact, as startups fail to validate their ideas early on with real-life customers. To mitigate that, entrepreneurs attending eHealth Hub Business Modeling Training will learn how to apply the lean start-up approach: getting "out of the building", identifying real pain points, searching for unmet needs or niche market segments, and validating their impact-related assumptions.

Lean Startup is a new, field-tested philosophy that provides researchers and entrepreneurs with a toolset to minimize failure and increase chances of success for their projects.

The main idea is learning how to rapidly develop and test ideas by gathering massive amounts of user feedback. Our coaches, with a wide expertise in the eHealth market, will guide teams through assumption identification, customer interviews, rapid experimentation, and new exploitation opportunities. eHealth Hub training will push teams outside of their “comfort zone” and change the way they look at research results for maximum impact.

6. Value proposition

The Business Modeling Training service will strengthen the launch and commercialization process of participating teams and increase the chances of the business proposition to become a success.

Presented poorly, a great idea no longer appears to be great. Working with a value proposition is much more useful than trying to write the perfect business plan very early on in the development of an innovative idea. We will provide teams with the tools and frameworks to manage innovation in conditions of extreme uncertainty, allowing breakthrough ideas to prosper.

The service has been designed and adapted to the European context, thanks to the unique knowledge that META developed in complimentary fields:

- Managing co-investment funds for early stage startups in Italy, Slovenia and Poland;
- Running exploitation seminars for +400 EU-funded research projects, with a total of 6000+ researchers involved;

7. Validation methodology

The service is centered around the LEAN Startup approach and takes the participants through the following elements:

- Customer discovery
- Validating assumptions
- Getting out of the building
- Business modeling
- Understanding investors

FIRST STEP: Idea generation → What to learn from startups

- The mindset: Start small. Experiment.
- Involve customers. Fail. Iterate.

SECOND STEP: Validation → Idea development and testing out of the building

- Getting customer feedback with fast-made prototypes of an idea
- Testing business models and validating results
- Pivoting

8. Main research findings and needs’ analysis

To reduce failure among early stage startups in the eHealth sector, we need to properly assess customers’ needs and reduce the uncertainty related to the launch of a new product. By doing so,

we can help startups save time and money by focusing on developing products that actually fulfill customers' expectations.

The Consortium's second online survey revealed that:

- 38,2% of the participants showed interest in being involved in intense small group activities helping SMEs optimize and validate their business models by interacting with the market.
- 65,85% of participants said they would need help accelerating the commercialization of their solution.
- 58,54% of participants said they would need help clarifying their value proposition.
- 80,49% of participants said they would need help connecting with strategic partners.
- 70,73% of participants said they would need help validating their go-to-market strategy.
- 73,17% of participants said they would need help fine-tuning their business models.
- 60,98% of participants said they would need help preparing their approach of investors.

9. Updated Description of the Service:

9.1. Updated methodology

The methodology used during on-site training will be based on the Lean Startup and the flipped classroom approach with an important focus on the expertise of the industry mentors.

Participants will be pushed to share their experiences, to re-think their current business approach focusing on solving customers' needs, and to get out of the building to validate their assumptions.

The Lean methodology has proven to considerably reduce the incidence of failure, while increasing the chances of successful commercialization of innovative ideas. Through these courses startups will:

- Get a unique opportunity to validate impact assumptions as well as exploitation prospects in real market conditions;
- Gain invaluable knowledge from peer interaction and access to expert coaches;
- Learn realistic, common-sense validation principles and acquire hands-on experience in product and customer development within a real business environment;
- Interact with experienced and competent industry mentors and advisors, meet with investors and enter their networks.

9.2. Number of events/service iterations

The Business Modeling service will be delivered 5 times over the 3 years of the eHealth Hub project. The service will be implemented as plug-in of international events in the eHealth sector, to leverage the engagement of entrepreneurs from all over Europe.

- The first edition is likely to be delivered in June 2017 in Bucharest during ICEEfest (to be confirmed). Exact dates will be announced soon.
- The second one will be delivered in the second half of 2017 in Spain.

9.3. Selection criteria for participants

Teams eligible to participate in this service need to be from early-stage startups or SMEs within the eHealth sector, headquartered in Europe, and with an existing solution to build their business model around. Only the most promising proposals will be chosen to participate in this service.

Proposals will be evaluated based on:

- Innovation & competitive status
- Market & customers
- Team & network
- Technology
- Resources and costs
- Future of the company
- Needs and motivation
- Financing

A selection of the most promising SMEs having previously participated in the project's Business Model Clinic will be invited to participate in the follow up Business Modeling Training service. SMEs will need to demonstrate their willingness to commit to a 10-week programme (online/physical meeting) and to participate at least in one live event to meet other SMEs and mentors .

Each application will be evaluated by at least two specialists from the eHealth Hub project consortium. All evaluators will declare the absence of a conflict of interest.

9.4. Dissemination activities and recruitment process for participants:

The eHealth Hub website will be the one stop shop with all key information for eHealth entrepreneurs, while social media and the websites/networks of partner events will become dissemination multipliers.

Dissemination activities and recruitment process for startups will go through active social media campaigns (involving key multipliers such as StartupEuropeClub and others), email marketing and website visibility.

The eHealth Hub Consortium will leverage its databases and transnational networks of contacts to involve entrepreneurs, mentors, investors and stakeholders.

9.5. Link with other eHealth Hub activities

The Business Modeling Training service is intended as a first step for early stage SMEs that may be interested in the future in pitching to investors and taking advantage of our Investment Readiness Academy.

9.6. Follow-ups and traction monitoring with service participants

Follow-ups and progress monitoring will be done through the evaluation of revised key documents after the training sessions (e.g. business plans, pitch decks, lean canvas) and on the expression of interest to continue working together toward the opportunity to pitch in front of investors.

9.7. Service-related publications for broader knowledge-sharing

At the end of the project, a white book with lessons learned, and a video containing clips from participants and training sessions (ex-ante and ex-post) will also be made available to a wider audience of digital health stakeholders through publication on the eHealth Hub website and a dissemination campaign through the Consortium and key partners' channels.

9.8. Updated KPIs

Business Model training (BMT) courses organized, each module of 3 days duration	5
Entrepreneurs and SME representatives attending the 5 BMT	50+
Projects supported by the online eHealth Business Model Clinic coaching (recruitment activity)	60
Multiplicator report "Library of successful eHealth business models in Europe" available on-line	1
Download of the multiplicator report "Library of successful eHealth business models in Europe"	1000
Positive feedback from participants of Business Model training courses	90%+
SMEs and entrepreneurs that optimized their business models and/or validated their business hypotheses	90

Table 2 Service 1: Business model training KPI

4.2 Service 2/ SOLUTION MATCH

1. Service code, name and brief description

Solution Match - Solution Match is a personalized service for health care providers interested and ready to implement a digital health solution, helping them gather and clarify their exact requirements; research and compare available solutions developed by European SMEs; dress a list of the most relevant solutions ('Solution Report'), and facilitate introductions & networking with solution owners during live events ('Solution Match Live'). Starting with the providers' needs, Solution Match will also benefit European eHealth SMEs by connecting them to key potential customers.

2. Service leader

[édito]Health

- Pascal Lardier, Principal (pascal@editohealth.com)
- Aline Noizet, Partner (aline@editohealth.com)

3. Target audiences and participants

Solution Match is designed for healthcare providers interested in implementing a digital health solution within their organizations and ready to engage in serious discussions with digital health SMEs offering relevant solutions. Health care providers are broadly defined as public and private hospitals, clinics, primary and specialty care providers, nursing homes, care coordination networks, HMOs, pharmacy groups, etc. Although designed primarily for providers of healthcare services, Solution Match is also proposed to payers (public and private insurers), pharma and medical device companies.

4. Where and how does it take place?

Most health care providers find the eHealth marketplace crowded and time-consuming to research. eHealth Hub is here to provide a framework and do the heavy lifting. Solution Match follows 6 easy steps to clarify health care providers' needs, research the offering, and connect them with the most relevant SME solutions:

- Step 1: **Need Analysis** - Thorough and comprehensive analysis of client's needs and requirements.
- Step 2: **Research** - Search of eHealth Hub online platform complemented by desktop research and a broad call for applications using the project database and networks.
- Step 4: **Filtering for Fit** - Filtering of the researched solutions through the client's exact needs and requirements.
- Step 5: **Solution Match Report** - Summary report highlighting the top 5 solutions and their close match with the client's exact needs and requirements.
- Step 6: **Solution Match Live** - Live events where providers get a chance to present their organizations, listen to deep-dive solution presentations, and arrange private one-on-one meetings with the most relevant ones. Depending on the providers' preferences, Solution Match Live will either take place at their premises or be co-located with key European digital health conferences.

5. Context and initial challenge hypotheses

A majority of health care providers is currently looking to implement a digital health solution. However, the market is constantly evolving and difficult to navigate for those looking for the perfect match to a concrete need:

- Most providers lack a broad access to the European innovators' community;
- Scouting for specific solutions is time-consuming and most providers don't have the human resources to dedicate to this task;
- Gathering, evaluating, comparing information and filtering potential candidate solutions for fit requires a framework that is often missing;
- Providers are also missing a space where they can meet and discuss with innovators, and exchange experiences and references with other providers with similar needs.

Our initial hypothesis is that health care providers would collaborate more with SMEs if they had an easier and broader access, and a time-efficient way to engage with them.

6. Value proposition

Through Solution Match, eHealth Hub provides an efficient method, a painless process and a live/online platform for health care providers to scout and connect with European eHealth innovators. A free service, Solution Match takes care of the time-consuming processes and helps them:

- Get access to a large network of European innovators;
- Filter solutions for fit, according to their exact needs and requirements;
- Connect with top vendors in person through Solution Match Live;
- Connect with other health care providers with similar challenges and needs.

7. Validation methodology

The Consortium hypotheses were validated through:

- An online survey, filled out by 20 healthcare providers, 7 pharma and 3 insurance companies across Europe;
- One-on-one interviews with health care providers.

The survey questions were designed to confirm the end-users' need for the Solution Match service but also to validate the Consortium's hypotheses regarding the best way to deliver this service.

8. Main research findings and needs' analysis

- 63% of online survey respondents were currently looking to implement a digital health solution in their organization.
- 90% of online survey respondents were 'very willing' to work with digital health SMEs.
- 50% of online survey respondents found the scouting process of eHealth solutions time-consuming.
- 36% of online survey respondents found that either the solutions they found were difficult to compare, or that they were missing information about the solutions, or that they were missing a broad access to the market.
- 70% of online survey respondents considered 'very important' for SMEs to demonstrate a successful track record and/or present customer references.
- 80% of online survey respondents would be interested in accessing a database of digital health solutions.
- 63% of online survey respondents would be interested in getting a report of the most relevant solutions for their specific needs.
- 63% of online survey respondents would be willing to attend a live event where they would meet relevant digital health SMEs
- 42% of online survey respondents would prefer that event to be public, including other providers looking for similar solutions

9. Updated Description of the Service

9.1. Updated methodology

Solution Match aims to support healthcare organizations seriously looking to implement a digital health solution in the near future but with limited access to European innovators and limited human and financial resources to dedicate to scouting, filtering for fit, and meeting innovators in person.

The consortium's extensive reach into the European innovators' community will be key to support these healthcare procurement executives who usually have limited views on the available eHealth solutions across Europe, especially those developed outside of their geographic reach, and only little time to dedicate to that time-consuming scouting of matching solutions.

The service will also look at needs that are still 'unmet' or not well covered by the market: it will initiate matches when there is a solution and/or create new business opportunities for SMEs when the need is unmet.

The Consortium will follow 5 steps:

- **Step 1: Need Analysis** - During interviews with the health care provider, eHealth Hub will lead a thorough and comprehensive analysis of their needs and requirements.
- **Step 2: Research** - To identify potential matching solutions, eHealth Hub will simultaneously lead:
 - A search through the eHealth Hub database of solutions
 - A call for applications, widely disseminated through the Consortium's networks
 - A complementary desktop research
- **Step 3: Filtering for Fit** - The Consortium will compare the results of the research phase with the health care provider's exact needs and requirements and dress a list of best matching solutions.
- **Step 4: Solution Match Report** - eHealth Hub will produce a Solution Match Report highlighting the top 5-10 solutions according to the health care providers specific needs and criteria. This Solution Match Report will also be shared through the Consortium network for the benefit of additional providers and digital health stakeholders.
- **Step 5: Solution Match Live** - The Consortium will propose to host live events where health care providers will get a chance to present their organizations, needs and requirement, listen to deep-dive solution presentations, and arrange private one-on-one meetings with the most relevant ones. Depending on the providers' preference, Solution Match Live will either take place at the providers' premises or will be co-located with key European digital health conferences. Following the results of our online survey, these events will be open to other providers with similar needs and interests

9.2. Number of events/service iterations

eHealth Hub is planning to have at least 8 iterations of the full Solution Match service, including a Solution Match Live, and to produce 12 Solutions Reports as we consider that some healthcare organizations will not be ready or willing to host or participate in a live event. The iterations of Solutions Match Live will either take place at the healthcare providers' premises or as a satellite event of a major European digital health conference.

The first Solution Match Live event will take place on April 3rd at Hospital Bernal in Murcia – our first healthcare organization client of Solution Match. The following life event will most likely take place on May 3rd as part of Health 2.0 Europe 2017.

9.3. Selection criteria for participants

Solution Match will involve SMEs as well as health care providers and other types of demand-side stakeholders with a strong interest in implementing a digital health solution: payers/insurers, pharma and medtech groups from Europe but also from the US.

Primary target - Selection criteria for Solution Match demand-side clients:

- Providers, payers, pharma and medtech groups from Europe and the US
- Serious intention to implement a specific digital health solution within their organization (The Consortium will ask demand-side stakeholders to sign a MOU prior to starting the service)
- Dedicated budget to implement that solution

- Willingness to work with the Consortium on defining and clarifying their needs and requirements
- Willingness to participate in a live event, either at their premises or at a major European digital health conference, to meet the vendors of the best matching solutions

Secondary target - Selection for participating SMEs:

- European SMEs (headquarters or main offices located in Europe)
- A working solution, closely matching the demand-side client needs and requirements
- Readiness to pilot and/or implement the solution with the demand-side client
- Willingness to participate and present the solution in a live event, either at the premises of the demand-side client or at a major European digital health conference

9.4. Dissemination activities and recruitment process for participants:

Although the service will be widely advertised through the Consortium dissemination channels, we expect the recruitment of healthcare providers and demand-side stakeholders will mainly happen through personal connections and one-on-one conversations.

Dissemination and recruitment process for Solution Match demand-side clients:

- Personal contacts with prospects in the Consortium network
- Recommendations from the Advisory Board
- Promotion of the service through eHealth Hub website
- Dissemination through email newsletters and social media - using the Consortium channels but also key partners channels

Dissemination and recruitment process for SMEs:

- Research of Consortium partners' proprietary databases, and later in the project research of the eHealth Hub online database of SME profiles
- Call for applications through eHealth Hub website and through email newsletters and social media - using the Consortium channels but also key partners channels
- Complementary desktop research
- Personal communications with the solutions best matching our clients' specific needs and requirements

9.5. Link with other eHealth Hub activities

The Consortium is planning to leverage the eHealth Roadshow service to identify additional potential demand-side stakeholder clients for Solution Match. eHealth Roadshow represents an interesting pipeline as it also targets healthcare providers, insurers, pharma and medical device companies.

When further developed, the Consortium will also invite health care providers and demand-side stakeholders to use the online platform to scout and research solutions. We will monitor their activity and contact those most active on the platform to propose our Solution Match service.

9.6. Follow-ups and traction monitoring with service participants

A post Solution Match Live online survey will systematically be sent to participating SMEs. A follow up debrief call will also be arranged with health care providers and demand-side stakeholders to get more in-depth feedback on Solution Match as a service. We will take the opportunity of this debrief to propose follow up meetings with the SMEs offering the solutions that best match their needs and requirements. Afterward, the Consortium will periodically check in with demand-side stakeholders and SMEs to track progress and promote serious conversations.

9.7. Service-related publications for broader knowledge-sharing

A press release will be disseminated through eHealth Hub and key partners' channels for each Solution Match Live event, presenting the need and requirements of the procurer and the top pre-selected solutions.

The Solution Match report written for each iteration of the service and featuring the top pre-selected solutions will also be made available to a wider audience of digital health stakeholders through a publication on the eHealth Hub website and a dissemination campaign through the Consortium and key partners' channels.

9.8. Updated KPIs

Solution Match Live	
Number of Solution Match iterations and number of demand-side stakeholders supported	8
SMEs presenting at each event	6
Total number of SMEs participating in Solution Match Live	48
Solution Match Reports	
Solution Match Reports available for download to the wider European eHealth ecosystems, highlighting each time 8 to 10 SMEs and their solutions.	10
Total downloads of 10 Solution Match reports	1000
Satisfaction	
Positive feedbacks from participants of Solution Match Live events	+90%
Sustainability	
Business model for Solution Match service.	1
Traction	
Solutions implemented/SMEs involved in serious commercial conversations by project end.	8

Table 3 Service 2: Solution match KPI

4.3 Service 3/ INVESTMENT READINESS TRAINING

1. Service code, name and brief description

Investment Readiness Academy - Securing funding can be essential for the success of SMEs and more generally for the development of the eHealth industry in Europe. The Investment readiness training program aims to prepare European early-stage startups and SMEs within the eHealth sector

to approach and collaborate with investors. During the training, entrepreneurs will focus on six key elements of investment readiness:

- Traction
- Team
- Market
- Model
- Product
- Advantage

The training will be a mix of online support (4 weeks) and one face to face event, linked to the project's Pitch Events where entrepreneurs will be able to share the latest version of their pitches with the most active investors in digital health.

2. Service leader

META Group S.r.l

- Dario Mazzella (d.mazzella@meta-group.com)
- Andrea Di Anselmo (a.dianselmo@meta-group.com)

3. Target audiences and participants

The Investment Readiness service targets early-stage startups and SMEs within the eHealth sector looking to connect with investors now or in the near future. The service includes a wide array of one-to-one coaching that can be customized to fit the needs of each specific participant. In general, it is expected that the participating teams bring the same passion that they have for their solution or organization into the service.

4. Where and how does it take place?

The Investment Readiness Academy will happen 5 times over the next three years. In order to make this training more impactful for startups, the Consortium partners have decided to link it with our Pitch Competition events: startups and SMEs will be required to participate in the Investment Readiness Academy in order to present at the Pitch Competition. Locations and specific dates of the five iterations are still to be determined, but the first service will be delivered in May 2017 leading up to Health 2.0 Europe 2017 (May 3-5, 2017 in Barcelona).

During the 4-hour live training events, participants will learn:

- how to gauge their funding needs and what sources of funding are best for their specific situation (VCs and private equity, grants, development against equity, state agency funding, the 3 types of crowd funding, etc.);
- how to tailor their approach to a specific source of funding;
- how to pitch and how to prepare before engaging in a serious conversation with eHealth investors (due diligence, business plan, valuation, etc.).

Prior to the training course, participants will be sent a pitch template and asked to read guideline documentation to optimally prepare a 4-minute investment pitch. Their pitch will have to highlight

all the key information for investors. They will also be able to benefit from online mentorship prior to the live training course.

As part of the training session, each participant will deliver their pitch and receive feedback from the training team and guests. Know-how and lessons learnt will be systematically captured to produce the 'How to effectively seek funding in the European eHealth sector' multiplier report.

5. Context and initial challenge hypotheses

Being investment ready can make or break a business. Many of the solutions developed within the eHealth sector are based on a large amount of research and R&D activities. In order for these solutions to be successfully brought to market, external funding is most often needed to finance the development of the product, build the clinical evidence and support its early commercialization. It is therefore crucial for health entrepreneurs and SMEs to identify and approach the right investors, better understand what they are looking for, and learn how to negotiate and collaborate with them.

The training is designed to fill the knowledge gap about equity as an alternative source of finance for innovative SMEs:

- what equity is and the benefits it may bring;
- the limitations of debt funding;
- the different types of equity providers in the market and their specific focus;
- how to access the right investor;
- equity investors' evaluation process and decision-making criteria;
- the investor's perspective;
- determining realistic funding needs for the future.

6. Value proposition

The Investment Readiness Academy is a unique way to prepare entrepreneurs for reaching out, collaborating and negotiating with investors, which can be crucial for the success of businesses within the eHealth sector.

The Investment Readiness Academy addresses key challenges facing eHealth entrepreneurs and startups in Europe:

- the lack of vertically-focused programs promoting investment readiness across Europe;
- the low awareness of available financing options amongst entrepreneurs;
- the low awareness of eHealth investors' specific criteria;
- the lack of framework and opportunities for entrepreneurs to sharpen their pitching skills;
- the weak "investability" of many of the companies approaching investors;
- the difficulty of matching innovative companies with specialized investors.

7. Validation methodology

The Investment Readiness Academy methodology is based around the LEAN Canvas, investment readiness practices and the official Pitching Guidelines of META Group S.r.l.

Leading up to the live workshop, the participating teams will undergo an array of preparation sessions based on these methodologies. During the live training session they will get further training along with one-on-one coaching to fine-tune and further improve what was already prepared during the online sessions.

The training will emphasize:

- Information provision → Entrepreneurs do not know about the advantages of equity finance, what is required to attract equity investors, the criteria that investors use to assess investment opportunities or how to sell their investment proposal to investors.
- Personalized Support → delivering personalized coaching to help entrepreneurs meet these standards.

8. Main research findings and needs' analysis

Being able to properly pitch your idea in front of investors, and thus communicate the value proposition and business opportunity behind it, is crucial to raise external/risk capital.

The central objective of the Investment Readiness Academy is to raise the quality of investment opportunities and provide vertically-focused training for eHealth entrepreneurs and startups.

The eHealth Hub online survey revealed that:

- 80,49% of respondents would welcome support in connecting with strategic partners
- 60,98% of respondents would welcome support in preparing their approach with investors
- 43,1% of participants said they would be interested in attending an investment readiness program
- 42,3% of participants said they would be interested in attending/presenting at pitch events
- 75% of participants said that involving investors and/or key digital health stakeholders in the investment readiness training would be critical

Updated Description of the Service:

9.1. Updated methodology

The methodology used will rely on the previous experience of META Group in managing early stage venture funds across Europe.

Common training:

- Understanding the different types of investors
- Principles of Investment Readiness
- How to pitch
- Tips on company valuation

One-to-one coaching:

- Review of pitch deck (reflecting key points for investors)

This methodology will put entrepreneurs at the center of the stage:

- what are the entrepreneur's aspirations?
- how experienced is the entrepreneur and management team?
- does the entrepreneur know the market?
- is the product/service proprietary or can it be protected?
- has the product/service been tested in the market place?
- how competitive is the product/service?
- can the entrepreneur articulate how the finance will be utilized?
- what is the likely rate of return on investment?
- is there the likelihood of an exit strategy?

9.2. Number of events/service iterations

The Investment Readiness Training will be delivered 5 times over the 3-year period of the eHealth Hub project and will be linked to the project's Pitch Competitions.

The first service delivery is planned for May 2017 leading up to the Health 2.0 Europe 2017 conference, which will take place on May 3-5 in Barcelona. There will be a part of one-to-one online support (4 weeks) prior to the event, and then a physical gathering on May 3rd in the morning.

The next Investment Readiness Training will be likely delivered in the second half of 2017.

9.3. Selection criteria for participants

The participating teams need to be early-stage startups or SMEs within the eHealth sector, with the ability to present a relevant solution to build the Investment Readiness training around. Only the most promising proposals will be chosen to participate in the service.

Pitch competition participants will have to go through this training process, ensuring that only the most promising proposals are chosen to be part of the Investment Readiness Academy.

The applications will be evaluated based on the following aspects:

- Innovation & competitive status
- Market & customers
- Team & network
- Technology
- Resources and costs
- Future of the company
- Needs and motivation
- Financing

Primary target: Selection of SMEs previously participating in the business modeling academy and selection of SMEs applying to present at one of our Pitch Competitions.

- European SMEs
- Solution clearly indicating a business opportunity
- Already showing traction
- Willingness to participate in a live event to meet other SMEs, mentors and investors

Each application will be evaluated by at least two specialists from the eHealth Hub project consortium. All evaluators will declare the absence of a conflict of interest.

9.4. Dissemination activities and recruitment process for participants:

The eHealth Hub website will be the one stop shop with all key information for e-Health entrepreneurs, while social media and the websites of partner events will become dissemination multipliers.

Dissemination activities and recruitment process for startups will go through active social media campaigns (involving key multipliers such as StartupEuropeClub and others), email marketing and website visibility.

The eHealth Hub Consortium will leverage its databases and transnational networks of contacts to involve entrepreneurs, mentors, investors and stakeholders. Investors will receive personalized email invitations.

9.5. Link with other eHealth Hub activities

The Investment Readiness Academy will represent a second step for high-performing companies that already took part in the business modeling academy, and an entry point for mature startups raising capital on the market and willing to pitch in front of investors.

The Investment Readiness Academy will be closely linked to eHealth Hub's Pitch Competition events, and will happen right before in order to increase the quality of the performances of startups participating.

9.6. Follow-ups and traction monitoring with service participants

Follow-up and monitoring will be done on expression of interest received by startups from investors.

A post Investment Readiness online survey will systematically be sent to participating SMEs. Follow up calls will also be arranged with entrepreneurs indicating they are in contact with potential investors to help them in the first steps, and later on to track progresses.

9.7. Service-related publications for broader knowledge-sharing

At the end of the project, a white book with lessons learned, and a video containing clips from participants and training sessions (ex-ante and ex-post) will be made available to a wider audience of digital health stakeholders through publication on the eHealth Hub website and a dissemination campaign through the Consortium and key partners' channels.

9.8. Updated KPIs

Number of Investment Readiness Academy training	5
Total number of SMEs participating in the Investment Readiness Academy	50+
Pitch competitions organized, as part of the recruitment activities	5
Total number of SMEs taking part in pitch competitions	60+
Multiplicator report on "How to effectively seek funding in the European eHealth sector"	1
Downloads of the report "How to effectively seek funding in the European eHealth sector"	1000
Positive feedback from trainees	90%+
SMEs in serious conversations with investors	10

Table 4 Service 3: Investment readiness training KPI

4.4 Service 4/ eHEALTH INVESTMENT PLATFORM

1. Service code, name and brief description

eHealth Hub will build an online platform that aims to become the map of the European digital health landscape.

The platform will include different types of profiles (e.g. investors, SMEs, legal and regulatory service providers) that will be able to access relevant information to promote relationships and business opportunities.

In particular, the platform will initially bring transparency to the investment criteria of private investors, so it will be easier to both SMEs and other investors to identify if an investor is of interest. The list of investors can be filtered under several criteria, so that SMEs can easily assess whether they should contact a particular investor because they fall under their investment criteria (ticket amount, geographic area of interest, etc.). For investors, it will be also much easier to spot potential co-investors.

Further functionalities will be investigated after interacting with the relevant stakeholders of the European digital health landscape.

2. Service leader

TICBioMed.

- Elena López (elena.lopez@ticbiomed.net)

3. Target audiences and participants

- Investors of different types (e.g. Business Angels, Venture Capital firms, Corporate VCs, etc.) interested in investing in European eHealth companies,
- European eHealth SMEs seeking private funding,
- In the near future, other relevant actors: Healthcare providers, (clinical or market) experts, legal and regulatory service providers, accelerators, etc.

4. Where and how does it take place?

Online.

5. Context and initial challenge hypotheses

The digital health market is difficult to navigate since it is quite young and constantly evolving due to its technological nature which can result in a lack of clarity that can discourage actors' interaction and cooperation. This, together with the existing difficulties of SMEs to find funding and the urgent need to increase the level of private investment in European digital health, explains the necessity to create an online map that provides clearer information and encourages interaction among the actors in the sector.

Though there are already several online platforms that support private investments, our hypothesis is that they are not very effective for the systemic increase of private investment in digital health. The reason for this is that they lack specialization in this category and fail to build an entire digital health network. There is, therefore, a need to favor and accelerate the pace of private investment so the whole sector can grow faster and smarter.

6. Value proposition

By identifying the key European eHealth actors, the platform will enhance transparency in the sector and, therefore, enable information exchange and stakeholders' interaction to promote and accelerate business growth.

For SMEs, it will:

- Provide a more efficient way to find funding since investment criteria is much more transparent.
- Gain visibility among investors that have explicitly stated their interest in digital health.
- Save time by connecting only with the investors that match their funding needs.

For investors, it will:

- Facilitate and accelerate co-funding opportunities, one of the most effective channels to increase investment.
- Let them know what is going on (who is investing where) and what are the relevant trends.
- Give visibility and recognition to the top performers so they can increase their reach, both to companies and other investors.
- Attract more funding in the eHealth sector by providing a tool that facilitates scouting of opportunities.
- Provide contacts with relevant expertise to facilitate their internal decision processes (e.g. experts in specific technologies or market niches).

7. Validation methodology

We have already used one to one interviews and focus groups with investors from different stages (seed, early, growth, corporate) to analyze needs. We have also included related questions in the survey.

Besides, during the development, the platform will be validated through cherry picked investors that will provide feedback for improvements.

8. Main research findings and needs' analysis

- A focus group revealed that investors are mainly building their pipeline through other investors which highlights the need to find their peers in the sector. Actually, in the survey 63.6% of investors stated that they would be interested in joining a private and secure platform for investors only where they could easily identify and network with co-investment and syndication partners.
- In the same focus group, investors stated that they are not only interested in online interaction but also physical such as networking events.
- For SMEs, when asked what could make these platforms more useful to SMEs, their responses included additional services including legal advice, which supports the addition of other stakeholders in the future.

9. Updated Description of the Service:

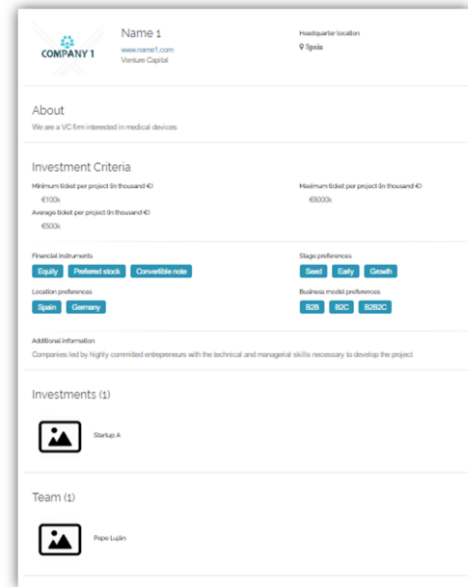
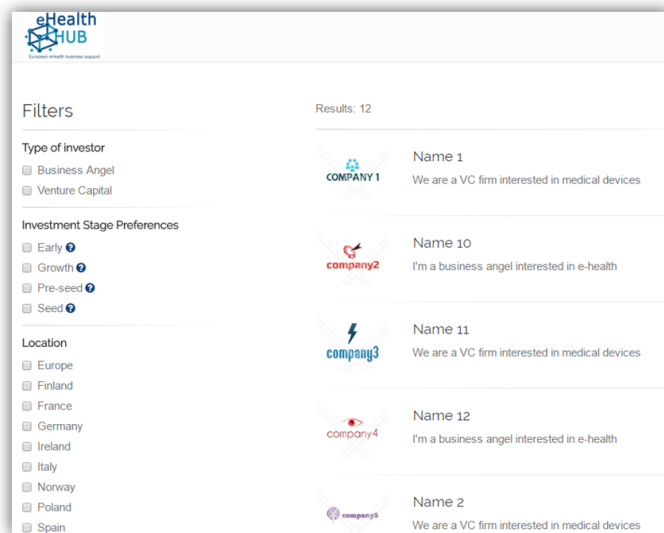
9.1. Updated methodology

The online platform features:

- A pipeline of digital health opportunities for investors in the form of 'SME profiles'. Investors will be able to sort/filter the SME profiles, request additional info about companies matching their criteria, and connect directly with them. To make sure the pipeline is easy to browse, we will impose a profile format that follows investor criteria and summarizes the key information they need to see before engaging in a conversation. To guarantee quality, SME profiles will be reviewed and approved by the consortium before going live.
- SMEs will be able to look at investors' profiles and request an intro to the ones with criteria that fit their investment profiles. Investors profiles will also help SMEs better understand who are the truly active ones in digital health (listing the firm's' past investments). Investor profiles will be reviewed and approved by the consortium. We will complement the information published by investors with other relevant public sources of information.
- The platform will be initially populated with public information about investors interested in eHealth, including information gathered during the GET project. After obtaining critical mass of quality 'investor profiles', the registration will be open for European eHealth SMEs.
- A news section will publish the data on European deal flow and other relevant information.

To build the online platform momentum, SMEs, investors and other stakeholders interested in joining any of our investment readiness activities will be required to create an online profile. Privacy and data protection issues will be properly addressed as explained in section 2.2.3 of the initial planning.

Although the main format of delivery will be the online platform itself, the tool will not replace the facilitation of one on one interaction. Regular follow-ups with SMEs and investors alike will make sure both parties are actively engaged in making the most of the Platform. In particular, investors inquiring about specific solutions or commissioning Multiplier Reports will be offered one on one meetings with SMEs of interest, and SMEs will be encouraged to follow up with investors after each interaction with investors including the Pitch Competitions.



Data and statistics gathered during the deployment of the service will be disseminated through the consortium channels, in particular the project newsletter.

9.2. Number of events/service iterations

None. The number of iterations does not apply to the online platform.

Nevertheless, as it was suggested by the investors' focus groups, we are considering organizing events for private investors only. These events would be coordinated with the organizers of the Pitch Competitions and Investment Readiness Academy, and perhaps also with the Legal and Regulatory teams (to propose speakers on these topics).

9.3. Selection criteria for participants

- Primary target: investors and European eHealth SMEs.
- Secondary target: other stakeholders like healthcare organizations, legal and regulatory nodes, pharma and medical devices groups, etc.

9.4. Dissemination activities and recruitment process for participants

Initially, the dissemination will be done through personal contact, databases from the GET project, email marketing and social media campaigns, using the project's own channels but also the Consortium partners' networks.

9.5. Link with other eHealth Hub activities

Those related with funding, but potentially all the other services.

9.6. Follow-ups and traction monitoring with service participants

We will mainly track and analyze access data. We will also interview key stakeholders for qualitative feedback.

9.7. Service-related publications for broader knowledge-sharing

We could produce statistics based on the data we produce that feed other funding related reports.

9.8. Updated KPIs

300 SME profiles and 150 Investor profiles created in the Investment Platform by end of project.	450
SMEs in serious conversations with investors brokered by eHealth Hub	40

Table 5 Service 4: eHealth investment platform KPI

4.5 Service 5/ eHEALTH ROADSHOW

1. Service code, name and brief description

eHealth Roadshow - The eHealth Roadshow offers an opportunity for leading European eHealth SMEs to benefit from targeted networking with demand side stakeholders from across Europe. This helps SMEs raise their visibility and gather direct feedback from high-calibre stakeholders, who can in turn provide access to potential customers and procurement executives.

2. Service leader

Steinbeis-Europa-Zentrum der Steinbeis Innovation gGmbH

- Hicham Abghay (abghay@steinbeis-europa.de)
- Dr. Mercedes Dragovits (dragovits@steinbeis-europa.de)

3. Target audiences and participants

The eHealth Roadshows have a primary and a secondary target audiences:

- The primary target audience is made up of **demand-side stakeholders** including procurement managers at hospitals and clinics, healthcare providers, insurances and medical technologies/pharma companies.
- The secondary target audience consists of **SMEs**, mainly highly innovative companies with novel eHealth solutions and products.

4. Where and how does it take place?

The eHealth Roadshows will be organized in 9 locations throughout Europe as satellite events of major eHealth conferences. The Roadshows start with 5 minute pitches from eHealth SMEs presented in front of a panel of high-calibre stakeholders. After a networking break, a Q&A session takes place where the committee can ask questions to every presenter and give them their inputs and feedback.

The first eHealth roadshow took place in the context of the WOHIT Conference & Exhibition on 22. Nov. 2016 in Barcelona, Spain.

5. Context and initial challenge hypotheses

Current technology transfer support services or open innovation platforms are either sector non-specific or tend to be a database of mismatches. This makes it difficult for major stakeholders to interact with mature and innovative eHealth SMEs in dedicated networking events (and viceversa).

6. Value proposition

There is a need for an eHealth service that fulfils the requirements of this specific target group in that they get access to potential clients from the demand side. The latter have the opportunity to present their needs and requirements while accessing a pool of novel technologies and solutions that could be potentially implemented in their respective institutions

7. Validation methodology

An online survey has been carried out to assess the needs of both SMEs and high calibre pharma /medtech companies as well as healthcare providers and investors (s. table 1: survey statistics, p. 5)

8. Main research findings and needs' analysis

- 73,9% would be interested in the eHealth roadshow service
- 88% SMEs pronounced a strong interest in pitching their solutions to potential customers
- 66% SMEs indicated that commercializing digital solutions is one of their top priorities
- 15 out of 20 healthcare providers are keen on learning about new solutions.

9. Updated Description of the Service:

9.1. Updated methodology

The eHealth Roadshow will represent an added value for stakeholders/investors. When contacting framework event organizers, the eHealth Hub Service Team will highlight this added value to the organizers, who will be asked to refer potential panelists to the Roadshow, thus helping the Team with the recruitment activities.

The registration form sent to interested pitchers will ask for quantifiable information to help the team with the selection process. At the same time, it will contribute to its transparency and objectiveness.

The Roadshow duration will in future include a coffee break to offer the panelists to engage in bilateral conversations with pitchers. The total duration of the whole event would be around 3 hr. beginning with the pitch-presentations, followed by the coffee break/bilateral meeting session and finally the Q&A round.

9.2. Number of events/service iterations

9 eHealth Roadshows will be organized throughout the project duration. The events are planned to take place every 4-6 months, depending on the timing and prestige of existing potential framework events.

9.3. Selection criteria for participants

The selection of the primary target group of the eHealth roadshow i.e. Providers, payers, pharma and medtech / groups from Europe are:

- Serious intention to implement a specific digital health solution
- Willingness to work with potential partners on defining and clarifying their requirements
- Willingness to participate in a live event to meet the SMEs with a solution matching their requirements

The selection of the secondary target group of the eHealth roadshow, namely SMEs are:

- Established European SMEs active in the eHealth sector
- Solution closely matching the demand-side client requirements
- Readiness to pilot and/or implement their solution with the demand-side client
- Willingness to participate in a live event to meet the primary target group with a clear demand that matches the requirements of the latter

Each application will be evaluated by at least two specialists from the eHealth Hub project consortium. All evaluators will declare the absence of a conflict of interest.

9.4. Dissemination activities and recruitment process for participants:

Demand side stakeholders will be recruited through personal contacts or selected in conjunction with the organizers of host events. SMEs will be recruited through broader communication campaigns including: announcement through the project website, email marketing campaigns, dissemination via social media (all partners will be involved and will re-tweet or share posts through their own accounts), mailing to partners' networks (e.g. Enterprise Europe Network, Fit for Health 2.0), partners' event calendars, partners' own websites, posts in social media groups related to digital health.

9.5. Link with other eHealth Hub activities

Participants who are not mature enough to participate in the eHealth Roadshow will be signposted to profit from our business modelling training services. Participants who have been selected and have successfully pitched could be signposted for the Investment Readiness Academy.

9.6. Follow-ups and traction monitoring with service participants

Whenever, the service team will approach the participants directly after the networking session at the event to collect the first impressions.

One to two days later, a feedback survey will be sent to all to find out if or how many conversations with stakeholders/SMEs have the potential of turning into a future cooperation/investment opportunity.

Participants involved in serious conversations will be contacted via email and/or telephone to assess if an agreement was reached. In case one or more agreements were reached, the participants will be asked to make a statement on the relevance of the eHealth HUB in their success. If they agree, the success story will be published via different channels (e.g. partners' newsletters, project website, social media).

9.7. Service-related publications for broader knowledge-sharing

Publication of success stories on the website and in press releases, e.g. partners' electronic newsletters distributed among their client networks.

Release of a short guide on effective pitching.

9.8. Updated KPIs

The eHealth HUB aims at organizing 9 eHealth Roadshow events as a platform for innovative SMEs to pitch their innovative solutions in front of a panel of high-caliber stakeholders. The project partners will produce a document summarizing recommendations on how to effectively pitch in this type of events to attract investments.

Target amount of pitching SMEs	108
Target number of panelists	100
Target amount of serious commercial conversations by project end	20
Publication of a "Short guide to effective pitching"	1
Target number of downloads of the "Short guide to effective pitching"	1000

Table 6 Service 5: eHealth Roadshow KPI

4.6 Service 6/ LEGAL GUIDANCE

1. Service code, name and brief description

Legal Network - The eHealth Hub legal network will provide European eHealth SMEs with the professional contacts necessary to receive paid for legal advice across the European Union. The legal advice will provide them with the understanding necessary to grow and develop their business, new products and services within the legal framework of each member state.

Please note that this is not a free legal service unless legal advice is requested in The Netherlands or United Kingdom.

2. Service leader

CLINIC, University of Amsterdam - Veronic Sijstermans (V.M.H.Sijstermans@uva.nl)

Queen Mary University of London - Patrick Cahill (p.cahill@qmul.ac.uk)

SMEs interested in this service should e-mail lac@qmul.ac.uk together with info@clinic.nl with their name, address, telephone number and a detailed description of their legal issue(s). They should quote eHealth Hub in all correspondence

3. Target audiences and participants

The eHealth Hub legal network is open to all European eHealth SMEs on a first come, first served basis.

4. Where and how does it take place?

Once an SME has made an enquiry to us, we will contact them to assess their legal needs and suggest partners within the eHealth Hub legal network who may be able to help them with paid-for legal assistance. Where possible, these will be specialist legal advisers in the areas the SME requires assistance with. If their legal issue relates to UK or Dutch law, then we may be in a position to help for free, subject to capacity.

5. Context and initial challenge hypotheses

European eHealth SMEs face legal issues, across one or often, numerous jurisdictions. The eHealth Hub legal network will make the provision of good quality, affordable legal advice more seamless for eHealth SMEs. Often navigating legal services can be complicated, time consuming and difficult, particularly in jurisdictions which are outside of where SMEs are located.

6. Value proposition

eHealth SMEs face particular legal challenges that are sector-specific. The eHealth Hub legal network will provide a critical mass of lawyers in jurisdictions across EU Member States that are familiar with the challenges that eHealth SMEs face. In some jurisdictions (UK and The Netherlands), free assistance will be offered to a certain number of eHealth SMEs. eHealth Hub will also deliver free workshops detailing current legal issues facing eHealth SMEs.

7. Validation methodology

An online survey was developed which asked SMEs a number of questions relating to the service and investors what legal issues they faced.

8- Main research findings and needs' analysis

The survey included a question which asked SMEs, if they had sought legal advice in the past. 43% of respondents had not and the reasons given for not receiving legal advice in the past included: Not having a need (33%), not knowing what legal advice is required first (17%), not having a legal adviser (33%), not having the budget (67%), not knowing where to find the right legal advice (50%); and not knowing where to find legal advice at a reasonable price (33%). Investors were asked what legal questions they are facing and responses included: (i) Is the digital health solution legal in all EU countries; (ii) Is there a European Directive applying to these types of solutions; and (iii) how is data regulated across the EU.

9. Updated Description of the Service:

9.1. Updated methodology

eHealth SMEs and start-ups will receive support on their legal issues.

After the initial assessment in Task 1.1, the service team will start building the eHealth Hub Legal Network by recruiting the 60 legal nodes (at least 1 per member state).

When the Legal Network gets critical mass, the service team will launch the following actions:

- Co-development of the online tools to collect SME requests to be available on the project web site.
- Interact with the SME requesters to assess their legal challenge and provide initial legal guidance (not specific to their jurisdiction).
- If requested, facilitate the contact information of Network legal service providers specialized in their area of law and jurisdiction.
- Deliver direct support when their challenge is within the jurisdiction of the service team (UK and NL) and the SME requests it.
- The quality of the support delivered by the nodes of the network will be regularly assessed in coordination with Task 1.2 team.

9.2. Number of events/service iterations

eHealth Hub legal network is planning three legal and regulatory workshops during the 3 years of the project. The first legal and regulatory workshop will be delivered as part of the Health 2.0 Europe 2017 partner event. eHealth Hub legal network will also create the nodes in the network and begin to guide SMEs to the nodes. To date, the eHealth Hub legal network has already solved the legal issues of one SME in the UK.

9.3. Selection criteria for participants

The eHealth Hub legal network is open to all European eHealth SMEs on a first come, first served basis. There are no criteria for selection.

9.4. Dissemination activities and recruitment process for participants

The legal network as well as the free legal workshop will be widely advertised through all the Consortium's channels: information on the eHealth Hub website, email marketing, social media campaigns, inclusion in newsletters.

9.5. Link with other eHealth Hub activities

There is some overlap with the eHealth Hub regulatory activity as it is envisaged that the legal and regulatory workshops will be held together on the same day and therefore jointly organized, facilitated and advertised.

9.6. Follow-ups and traction monitoring with service participants

SMEs will be sent an online questionnaire following legal and regulatory workshops. SMEs who are assisted by the Network will also be asked for feedback through an online questionnaire on the service that they have received.

9.7. Service-related publications for broader knowledge-sharing

- Legal maps will be developed to answer investors questions and
- A report covering: 'Guidelines to Frequent Legal and Regulatory Challenges of European eHealth SMEs' will be published on the eHealth Hub website.

9.8. Updated KPIs

Legal nodes created by project end	60
SMEs assisted by the nodes by the end of the project	60+
Startups and entrepreneurs receiving direct support and mentoring services free of charge from eHealth Hub partners	10+
Legal Awareness workshops organized	3
Total participants in Legal Awareness workshops, at least 20 attendees per workshop	60
Demand-driven « Legal maps » available on line	1
Downloads of legal maps document	800
Multiplicator Report "Frequent legal and regulatory challenges of European eHealth SMEs"	1
Downloads of this report by the end of the project	1000

Table 7 Service 6: Legal service KPI

4.7 Service 7/ REGULATORY GUIDANCE

1. Service code, name and brief description

Regulatory Network - This service will help European eHealth SMEs comply with regulatory requirements and develop reimbursement strategies across the European Union. Our network of European experts in medical device regulation and reimbursement will support them in obtaining market authorization and market access.

Please note that this not a free regulatory service. SMEs will negotiate the conditions with the regulatory service provider.

2. Service leader

Engage Ventures

- Björn Hackbarth (b.hackbarth@engage-ventures.com)
- Dr. Nicole Häusler (n.haeusler@engage-ventures.com)

Interested SMEs should e-mail them with their name, address, telephone number and a detailed description of their regulatory issue(s). They should quote eHealth Hub in all correspondence.

3. Target audiences and participants

- European eHealth SMEs looking for regulatory guidance
- Regulatory and reimbursement consultancies that will provide the services

If you are interested in joining eHealth Hub's network of regulatory and reimbursement consultancies, please contact the Engage team. You must have experience on EU and national regulatory requirements and/or reimbursement strategies for medical devices, in particular in combination with medical information systems.

4. Where and how does it take place?

Once you have made an online enquiry to us, we will contact you to assess your regulatory and reimbursement needs and suggest partners within the eHealth Hub regulatory network who may be able to help you with paid-for regulatory and reimbursement guidance.

If your regulatory issue relates to German regulations, then we may be in a position to help for free, subject to capacity.

5. Context and initial challenge hypotheses

To obtain CE certification and to get reimbursement for innovative medical devices are crucial challenges that have to be met by digital health SMEs. CE certification gets more complicated and costly due to several renewals in European standards and regulations. Tackling reimbursement challenges often is started rather late in the life cycle of a medical device although decision making can delay launching of the product. Accordingly, reimbursement strategies should be addressed early on together with certification. Standards and regulations are implemented in various ways across EU member states. European markets are diverse, there are as many reimbursement systems for medical devices as there are countries. In order to launch a product in a new market, SMEs need to know the local policy environment, how a system is funded, how reimbursement decisions are made and how long decisions take.

6. Value proposition

We offer specialized and tailored regulatory and reimbursement guidance services for eHealth SMEs to overcome their challenges in CE certification and reimbursement for developing and commercializing new medical devices in various European countries. Based on their specific challenges, we will guide SMEs to appropriate regulatory and/or reimbursement nodes within our network that will deliver individual and high quality support.

As a reward for becoming a member of our network, we enable the regulatory and reimbursement service providers to be a part of a pioneer 60 nodes European regulatory and reimbursement network specialized on the fast-growing digital health sector and to get direct access to more than 700 European eHealth SMEs in order to increase their EU-wide visibility and customer base.

7. Validation methodology

We conducted one-on-one interviews (via phone or face-to-face) with five digital health start-ups, one digital health accelerator and two regulatory experts, one of them being a renowned specialist on regulatory consulting for software related medical devices and a member in international regulatory standards boards. Additionally, we included service relevant questions in the eHealth Hub online survey to gather additional quantitative information on SMEs' needs regarding regulatory and reimbursement challenges.

8. Main research findings and needs' analysis

The main results are as follows (more detailed description follows below):

- The majority of digital health SMEs need advice on certification and reimbursement strategies
- Regulatory compliance of SMEs is crucial for investors to decide on investments
- CE certification gets more complicated and costly due to new European standards and regulations which is extremely critical for small medical software producers like app developers and start-ups.
- There is a high demand for reimbursement consultancy services - reimbursement should be addressed early on together with certification

Main findings of one-on-one interviews

The digital health start-ups and regulatory experts from our one-to-one interviews mentioned huge challenges in CE certification and reimbursement when developing and commercializing new medical devices in Europe.

CE certification gets more complicated and costly due to several renewals in European standards and regulations, as already pointed out in our challenge hypothesis.

The new Medical Device Regulation (MDR) is going to replace the current Medical Device Directive (MDD) and Active Implantable Medical Devices Directive (AIMDD). The MDR requirements regarding the technical documentation, clinical evaluation and classification of medical devices are more detailed, complicated and stricter. In particular, rule 10a of the MDR implies that the majority of stand-alone software has to be declared as class 2a, 2b or 3 devices. Only a very few exceptions might be declared as class 1 device. Consequently, **in most cases producers have to involve notified bodies and establish a quality management system** which has to be certified. Efforts and costs are multiplied which is extremely influential and difficult for small producers like app developers and start-ups. ("Rule 10a will aggravate the development of medical software products

to an extent that small manufacturers can barely overcome the regulatory hurdles”, Johner Institut, Regulatory Consultancy for software-related medical devices).

Furthermore, the updated version of the quality management system standard, ISO 13485:2016, leads to more complicated and time-consuming audit processes. Several notified bodies will be shut down which limits the availability of the remaining notified bodies for auditing medical device producers. This will probably result in only a very few certifications for medical products in the next years (“The ISO 13485 update is going to crush the eHealth industry”, Fredrik Dejong, CEO, MySugr).

Moreover, revision 4 of the guideline for clinical evaluation (MEDDEV 2.7/1) is only poorly taken into account and underestimated by many medical device producers. The revised guideline includes changes in the clinical evaluation of medical products and their documentation. A lot of medical devices will have to be recertified which will lead to high efforts and costs for the producers over the next years.

There is a high demand for reimbursement consultancy services.

Not only certification issues are a major challenge (“Regulatory aspects are overestimated by start-ups. People are extremely concerned on this topic.”, Martijn Grinovero, co-founder and CMO, Amiko), reimbursement strategies also have to be considered. Start-ups and their cooperation partners, even big medical companies, often do not know how to get reimbursement for new solutions. Additionally, as mentioned in our challenge hypothesis, reimbursement systems differ in each EU member state. Reimbursement strategies should be addressed early on together with certification as reimbursement is also crucial for getting market access. Hence, reimbursement consultancy would definitely add value for European eHealth SMEs (“It would be really great and very helpful to have an expert that guides you to the best path to reimbursement in the different countries”, Martijn Grinovero, co-founder and CMO, Amiko).

Main findings from online survey

(1) SMEs

- 21 of 123 SMEs (17%) pointed out that finding answers to regulatory questions is one of their current top priorities, confirming our hypothesis that this is a highly relevant topic
- 5 of these 21 SMEs (23,8%) had already received regulatory advice in the past, referring to the general medical device certification (2 of 5), quality management system (3 of 5) and the new Medical Device Regulation resp. In Vitro Diagnostic Medical Devices Regulation

(2 of 5) → none of the SMEs had received advice on reimbursement strategies

- the majority of the 21 SMEs need certification advice, in particular for the general medical device certification (71%), standards related to medical device software (57%) and quality management system (52%)
- the majority of the SMEs also need support regarding reimbursement strategies, in particular for analyzing pathways of reimbursement for the product in different European countries (14 of 21, 67%). Furthermore, the other 2 categories (development of reimbursement/health technology assessment and coordination with different stakeholders in the reimbursement process) are of high relevance as well (43% of respondents for each of them)
- most of the SMEs (13 of 21, 62%) need support with software related regulatory topics. Especially relevant is advice on how to determine when a software is a medical or in vitro

diagnostic device (54% of these 13 SMEs) and software life cycle requirements for standalone medical software (54%)

- the majority of the SMEs which need advice on the decision if the software is a medical or IVD device, also need help in classifying the device (4 out of 7, 57%)

(2) investors

- the majority of the investors respondents (24 of 30, 80%) are faced with questions on regulatory requirements in different European countries and if there is a European directive applying to the type of solutions of the SMEs (22 of 30, 73%)
- 20% of the investors seek guidance from a digital health regulatory expert to get their regulatory questions answered. The majority of the investors (63%) uses own research methods (23%) or requests help from an in-house/partner regulatory consultant (40%)

Furthermore, focus groups and events with investors, e.g. the Digital Health Venture Forum in Valencia (25th Oct. 2016), revealed that investors always consider regulatory compliance of SMEs for their investment decisions. It is one of the first criteria they check before making that investment.

9. Updated Description of the Service:

9.1. Updated methodology

Our services will mainly be delivered as described in the Initial planning. Additionally, we will include reimbursement consultancy providers in our network as described in our challenge hypothesis and value proposition above. Hence, the regulatory network will consist of service providers that have consulting experience on EU and national regulatory requirements (certification, software standards, quality management systems etc.) and / or on reimbursement strategies for medical devices (in particular in combination with medical information systems) in different countries. Thus, we will make sure that we cover both challenges, CE certification and reimbursement for medical software products.

9.2. Number of events/service iterations

Continuous service support during project lifetime: At least 60 regulatory services will be delivered by our regulatory network, 15 of them free of charge.

3 regulatory awareness workshops are planned during the project lifetime. The first regulatory workshop will take place on 04/05/2016 as part of the Health 2.0 Europe 2017 partner event.

9.3. Selection criteria for participants

The services of our eHealth Hub regulatory network are open to all European eHealth SMEs, in particular start-ups resp. early-stage SMEs are encouraged to apply.

Regulatory and reimbursement consultancies that want to become part of our network must have experience on EU and national regulatory requirements and/or reimbursement strategies for medical devices, in particular in combination with medical information systems.

9.4. Dissemination activities and recruitment process for participants:

Next to partner dissemination activities we are exploring digital health accelerators and networks for identifying digital health SMEs and startups. Furthermore, our 3 regulatory awareness workshops will represent important activities to recruit SMEs and startups in the digital health sector.

For our regulatory and reimbursement network, experts are identified via partners' networks and desktop research. They will be contacted by mail and telephone.

9.5. Link with other eHealth Hub activities

There is some overlap with the eHealth Hub legal support activity as it is envisaged that the legal and regulatory workshops will be held together on the same day and therefore jointly organized, facilitated and advertised.

9.6. Follow-ups and traction monitoring with service participants

When at least ten SMEs have utilized the regulatory and / or reimbursement guidance service, respectively (noting that not all ten may have received advice), they will be sent a survey which we will ask them to complete. The survey will be sent periodically every 4 months thereafter to all SMEs who have received regulatory and / or reimbursement guidance. The survey will include questions on the quality, usefulness, affordability and communication, timeframe of the advice and responses will be on a sliding scale of 1 to 10 (with 10 being excellent). Similarly, regulatory and reimbursement nodes will be approached periodically every six months. Their survey will additionally include questions on clarity of description of the regulatory and / or reimbursement challenges and accessibility of the advised company.

Workshop attendees will be sent a similar survey including overall quality of the workshop, relevance of the content, impact of the workshop and improvement suggestions.

9.7. Service-related publications for broader knowledge-sharing

The key document for dissemination and broader knowledge sharing will be the multiplier report "Guidelines to Frequent Legal and Regulatory Challenges of European eHealth SMEs", comprising the main identified regulatory and reimbursement challenges, providing indications and best practices on how to address these challenges. Insights provided by highly-qualified experts and practitioners (both internal and external to the consortium) will also be incorporated.

Further means for publication: communication of lessons learned on webpage. Mail to network nodes on main results of quality assurance survey and if required improvement suggestions

9.8. Updated KPIs

Number of regulatory nodes created throughout Europe by project end	60
Regulatory workshops for awareness raising and recruitment	3
Total number of participants in regulatory workshops (20 participants per workshop)	60
SMEs assisted by the regulatory guidance network	60+
Start-ups and entrepreneurs getting direct support and mentoring services free of charge from eHealth Hub partner Engage	15+
Positive feedback from beneficiaries (affordability, quality of services... - both from the project team and/or from the network nodes)	90%+
Sustainable business model for the Regulatory Network	1
SMEs that solve their regulatory challenges	30

Table 8 Service 7: Regulatory and reimbursement service KPI

5 Annexes

5.1 Main results of the first online survey: Preliminary Market research

5.1.1 Survey

In order to validate our hypotheses and proposed services, the Consortium conducted a comprehensive quantitative survey of digital health startups and SMEs to confirm their challenges, needs and preferred methods of service delivery for business modeling and investment readiness training, investor and demand side stakeholder networking and matchmaking, legal and regulatory guidance.

50 people from 14 countries responded to our survey that was sent to 130 contacts. 24% are based in Spain while 18% are based in the UK, 18% in Germany and 12% in Slovenia. Two thirds have a B2B solution (1/3 B2C). All levels of revenue are represented from pre-revenue (10%) to over 3M€ (14%), the 0-100k€ and 250-500k€ being the most represented (25% and 19% respectively). **The results therefore cover a wide range of SMEs' profiles.**

5.1.2 Questions

Profiling questions

1/32 Headquarters Location?

2/32 Is your solution B2B, B2C or other?

3/32 If you have checked other to the previous question, please specify.

4/32 What is approximately the level of revenues generated by your e-health solution/company?

- I am pre-revenue
- 0-100 k€/Year
- 100 k€ -250 k€/Year
- 250 k€ -500 k€/Year
- 500 k€ -1 M€/Year
- 1-3 M€/Year
- Over 3M€/Year

Business Modelling

5/32 Please rank the usefulness of receiving expert mentorship to get early validation on the commercial viability of your solution and check potential customers' acceptancy (readiness to use/purchase)

6/32 Please rank the usefulness of receiving expert mentorship to finetune an already existing business model

7/32 Please rank the usefulness of receiving expert mentorship to develop your minimum viable product

8/32 Please rank the usefulness of receiving expert mentorship to create a killer elevator pitch

9/32 What would be your favorite channel for receiving this expert mentorship?

- One on one personalized mentorship
- A small group live workshop focused on your category of solution
- An online webinar focused on your category of solution
- Access to an online toolkit and case study/best practices resources

Access to finance

10/32 Are you or will you be looking for funding in the near future? *If so, please indicate how much you are/will be raising.*

- 0-250 k€
- 250 k€-1 M€
- 1-3 M€
- Over 3 M€

11/32 Would it be helpful to have access to an online library of eHealth focused public and private investor profiles detailing their specific interests, criteria and past investments?

12/32 Would it be useful to have your own investment profile on an online platform where it could be searched by eHealth investors according to their specific interest and criteria (confidential/sensitive information would only be available upon investors' request to you

13/32 Would you subscribe to a paid news service on the European eHealth investment market: investment trends, what types of solutions are getting funded, for what amount, and by whom?

14/32 If you already have a subscription to this type of newsletter, please indicate which one(s).

Acceleration of Commercialization

15/32 Are you planning to enter new markets within the next 24 months?

16/32 If so, please list your top 3 target countries:

17/32 Will you need legal support for your internationalization plans?

- Yes
- No
- I am not sure

18/32 In your experience, what are the 3 hardest sales connections to make and where would you welcome help:

- Private sector customers

- Public sector customers
- Domestic distributors
- Foreign distributors
- Strategic partners (insurer, pharma, medical device groups)
- Other

19/32 If you have answered other, please specify

20/32 How would you rate the usefulness of having your own solution provider profile on an online platform where it could be searched by potential customers, strategic partners or distributors?

21/32 How would you rate the usefulness of participating in networking events organized around the specific needs of potential customers, strategic partners or distributors?

Legal Counsel

22/32 Please select the top 3 legal challenges your business is facing:

- Commercial contracts (sales/distribution agreements)
- Intellectual property
- Data protection
- Business formation and incorporation
- Employment (domestic and foreign)
- Tax/VAT (domestic and foreign)
- Other

23/32 If you have selected other, please explain:

24/32 How would you rate the following channel for answering your legal questions: Access to a free list of peer-reviewed lawyers within each European member state, specialized in advising eHealth SMEs:

25/32 How would you rate the following channel for answering your legal questions: A free live workshop hosted by legal experts.

26/32 How would you rate the following channel for answering your legal questions: A free webinar workshop hosted by legal experts

Compliance and Certification

27/32 Do you need help to comply with the European medical device directive?

- Yes
- No
- I don't know

28/32 Please rank the usefulness of having a compliance telephone/internet hotline

29/32 Please rank the usefulness of having an online compliance FAQ and decision tree

30/32 Please rank the usefulness of having an online library of compliance case studies and best practices

31/32 Please rank the usefulness of having a small group live workshop focused on your category of solution

32/32 Please rank the usefulness of having an online webinar focused on your category of solution

5.1.3 Results

Business Modeling

Among the expert mentorship services proposed, they all received over 50% of positive marks (very useful + extremely useful) with **the validation of the solution's viability** being the most appreciated (76%) followed by **finetuning an already existing business model** (71%) and **creating a killer elevator pitch** (66%). Their favorite channel for receiving this expert mentorship is by far the **one on one personalized mentorship** (63%) followed by small group live workshops focused on their category of solution (28%). The online webinars and online toolkits obtained very low adhesion scores (7% and 2% respectively).

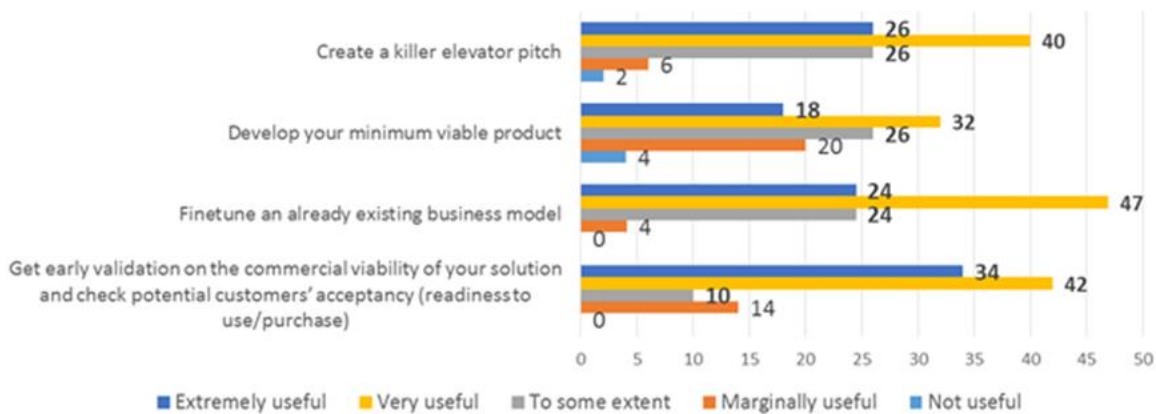


Figure 43 Percent of usefulness of receiving expert mentorship to

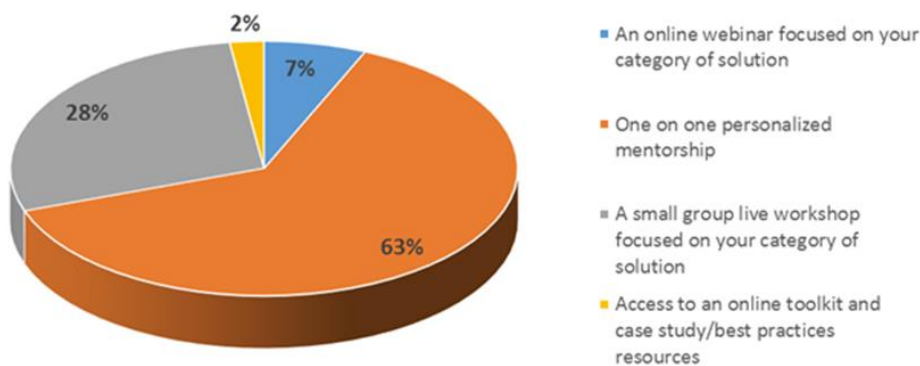


Figure 44 Favorite channel for receiving this expert mentorship

Access to finance

82% of the respondents will be looking for funding in the near future, the majority looking for 1 to 3 M€ (38%).

Respondents consider that it would be helpful to have **access to an online library of eHealth focused public and private investor profiles detailing their specific interests, criteria and past investments** (98%) as well as useful to have their **own investment profile on an online platform where it would be searched by eHealth investors according to their specific interest and criteria** (88%); however, the majority would not subscribe to a paid news service on the European investment market (66%). Only 3 already have a subscription to a similar service (CB insights, Startup Health and Assobiomedica).

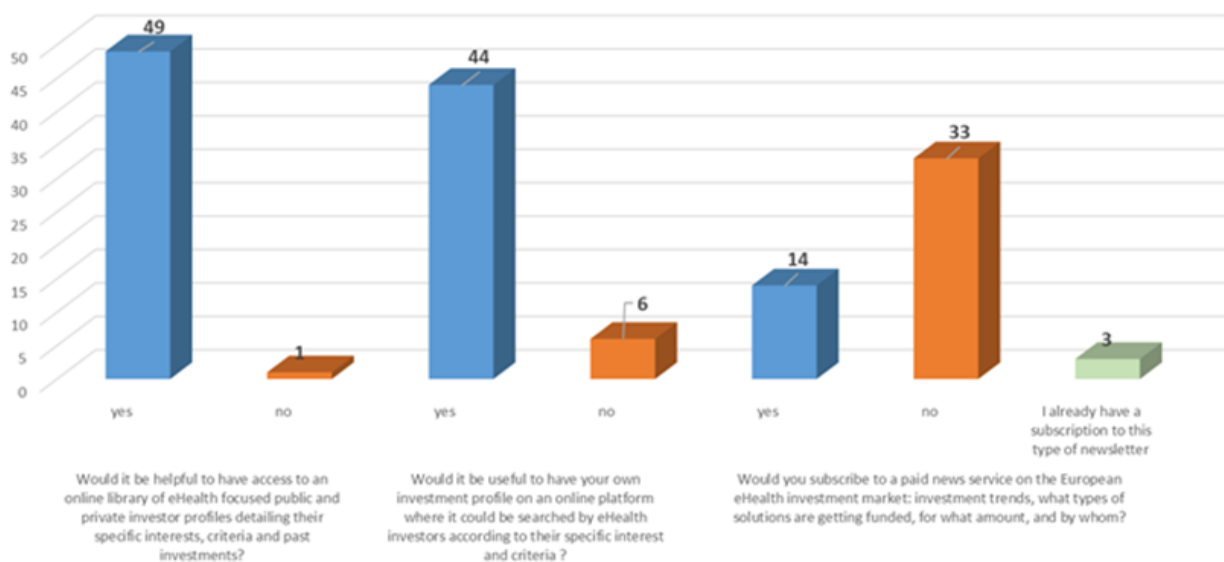


Figure 45 Access to finance services

Acceleration of commercialization

88% of respondents are planning to enter new international markets within the next 24 months. Most mentioned markets included the USA (15%), Germany (14%), the UK (14%), France (8%), Spain (7%) and the Netherlands (4%).

68% mention that they will **need legal support for their internationalization plans** while 18% are actually not sure.

The top **3 hardest sales connections to make are with public sector customers** (36%), **private sector customers** (29%) and **foreign distributors** (25%).



Figure 46 What are 3 hardest sales connections to make and where would you welcome help

68% think that participating in **networking events organized around the specific needs of potential customers** would be extremely useful (28%) or very useful (40%). Respondents are a little less enthusiastic to having their own solution provider profile on an online platform where it could be searched by potential customers (48% find it either extremely or very useful).

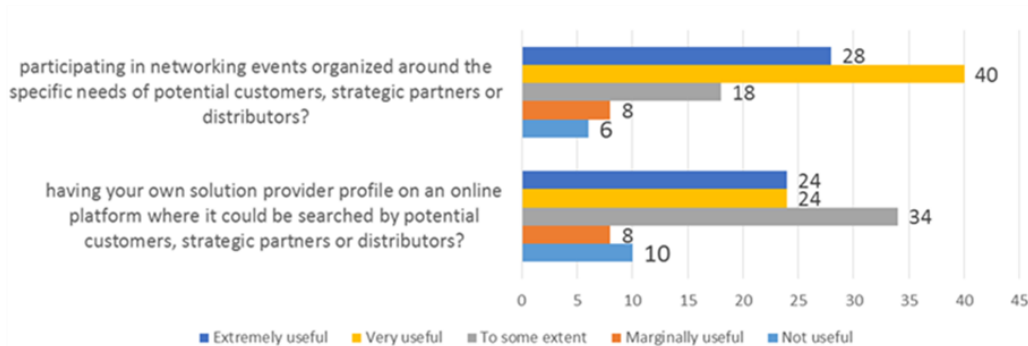


Figure 47 Percent of usefulness of...

Legal Counsel

Respondents indicated that their top legal challenges are commercial contracts, data protection and intellectual property. The most appreciated service is the access to a free list of peer-reviewed lawyers within each European member state, specialized in advising eHealth SMEs (54% find it extremely or very useful). Workshops hosted by legal experts are preferred to webinars (46% versus 26%).

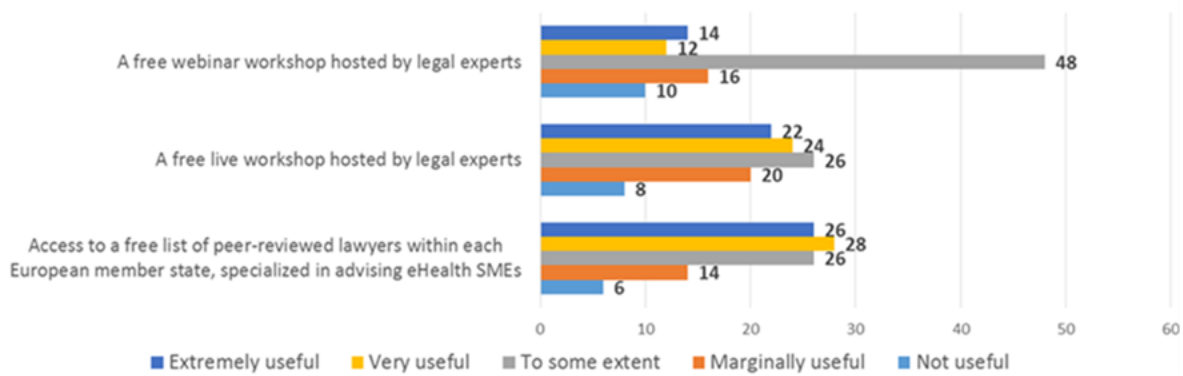


Figure 48 Percent of usefulness of various channels for answering legal questions

Registration and certification

51% of respondents considered that they don't need help to comply with the European Medical device directive while 37% think that they do. Respondents offer widely different responses about the services proposed; however, the **online library of compliance case studies and best practices, the online compliance FAQ and decision tree and the small group live workshop were the most appreciated** (55%, 55% and 53% respectively). Webinars and hotlines only convinced a little over a third of the respondents (36% and 38% respectively).



Figure 49 Percent of usefulness of having...