INNOVATION SCALE-UP MODEL

IN-4-AHA Project - *Innovation Networks for Scaling Active and Healthy Ageing*

Work Package WP3 Co-designing AHA innovation model

Dissemination level: Public

2022

More information about the project can be found on the IN-4-AHA webpage and social media pages:

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017603

http://ec.europa.eu/digital-single-market/ehealth

Executive Summary

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is a EU-funded Coordination and Support Action that aims to contribute to the cross-border scale-up of tested and ready-to-use applications in health and social care. By bringing together a network of stakeholders, a scale-up model was developed to assist mainly small and medium sized enterprises with their international ambitions, and to provide industry support organisations with an additional tool to help their clients/members.

The model will be most beneficial if the company's solution already has some proof of feasibility. The proposed scale-up model takes the company through five phases from gathering preliminary information to ramping up on the target market. Although presented in a linear sequence, the company might need to move back and forth through the model, repeat some components and skip others, as new information is acquired.

The success of scaling up relies heavily on involving stakeholders from the very beginning – stakeholders provide valuable knowledge and can provide support carrying out the necessary activities. At the same time, it gives the company a chance to raise awareness and support for its solution on the target market. Hence, it is crucial to identify most significant stakeholders, and engage them accordingly at each phase and component of the model.

The scale-up process should be aligned with the company's strategy. Throughout the process constant review is necessary to evaluate if scaling up is matching the strategic outlook, as well as to adjust the strategy according to new knowledge gained.

The model outlines the following stages for scaling up – LEARN (acquiring general information), PLAN (setting up a pilot at the target market), PILOT (testing the solution), PREPARE (making preparations for a large-scale implementation) and RAMP-UP. Each phase is broken down in terms of aspects to consider, however, these lists are not exhaustive – depending on the characteristics of the company, its solution, target market etc., different components might play a role. There are also links to additional information, tools and contacts provided.

Background

World population is ageing at a rapid pace - by 2030, one sixth of the world population will be aged 60 years or older according to WHO forecast[1], and 24,2% of the population of the European Union will be 65 or older[2]. This poses challenges to the society in general, but more specifically to health and social care. To address these changes, the European Commission created the European Innovation Partnership in Active and Healthy Ageing in 2011, to foster innovation in the field of active and healthy ageing.

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is a EU-funded Coordination and Support Action that aims to contribute to the cross-border scale-up of tested and ready-to-use applications in health and social care. The project brings together a large and diverse group of stakeholders related to innovation and active and healthy ageing. One of the main outcomes of the IN-4-AHA project is the scale-up model outlined in the current document. The scale-up model is supported by other project outputs, including reports on participatory design, evaluation and assessment, adoption of services and products, data governance and investment. For more details on other reports, see project website at https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/

The scale-up model has been composed including contributions from a variety of stakeholders – feedback has been collected from IN-4-AHA partners and advisory board. The model has been validated through interviews with SMEs as well as through public consultations during workshops.

Assumption and Target Group

The scale-up model is intended for commercially driven entities whose innovative solution already has proof of feasibility on either local, regional, or national scale, but whose ambition is to expand, either internationally or into different regions. Small and medium sized enterprises with none or little previous international experience will benefit most from this model. Another pre-requisite is that the solution owner must be willing to change and adapt throughout the process, and as emphasised by the SME representatives interviewed, there must be commitment to the goal of scaling-up.

The model also serves as a tool for industry support organisations – clusters, accelerators, umbrella organisations etc., so they can assist their members/clients throughout the scale-up process. Support organisations often possess valuable networks and experience that the

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[1] Ageing and Health. WHO Fact Sheet, 2021. https://www.who.int/news-room/fact-sheets/detail/ageing-and-health

[2] Ageing Europe – Looking at the lives of older people in the EU. Eurostat, 2020. https://ec.europa.eu/eurostat/documents/3217494/11478057/KS-02-20-655-EN-N.pdf/9b09606c-d4e8-4c33-63d2-3b20d5c19c91?t=1604055531000

companies can benefit from during their preparations to scale-up, and they are more probable to make use of available tools in an efficient manner.

Proposed Model

Although the model is presented as a sequence of stages, it should not be seen as a linear process. According to new information acquired along the way, it might be necessary to trail back to previous components of the model, re-start activities, or run multiple components simultaneously. Some components at different phases of the scale-up model address the same questions - as the company moves through the process, they will have more information, contacts and experience that helps them re-define the answers and next steps.

The model consists of five phases, starting with general information gathering (LEARN), which is followed by concentrated efforts to prepare for a pilot project (PLAN). After testing the solution in the target market (PILOT), it is necessary to appraise all the information collected, and to set up a detailed plan to implement scaling up (PREPARE). Only when adequate preparations are made, it is reasonable for the solution owner to enter the target market on a large scale (RAMP-UP).
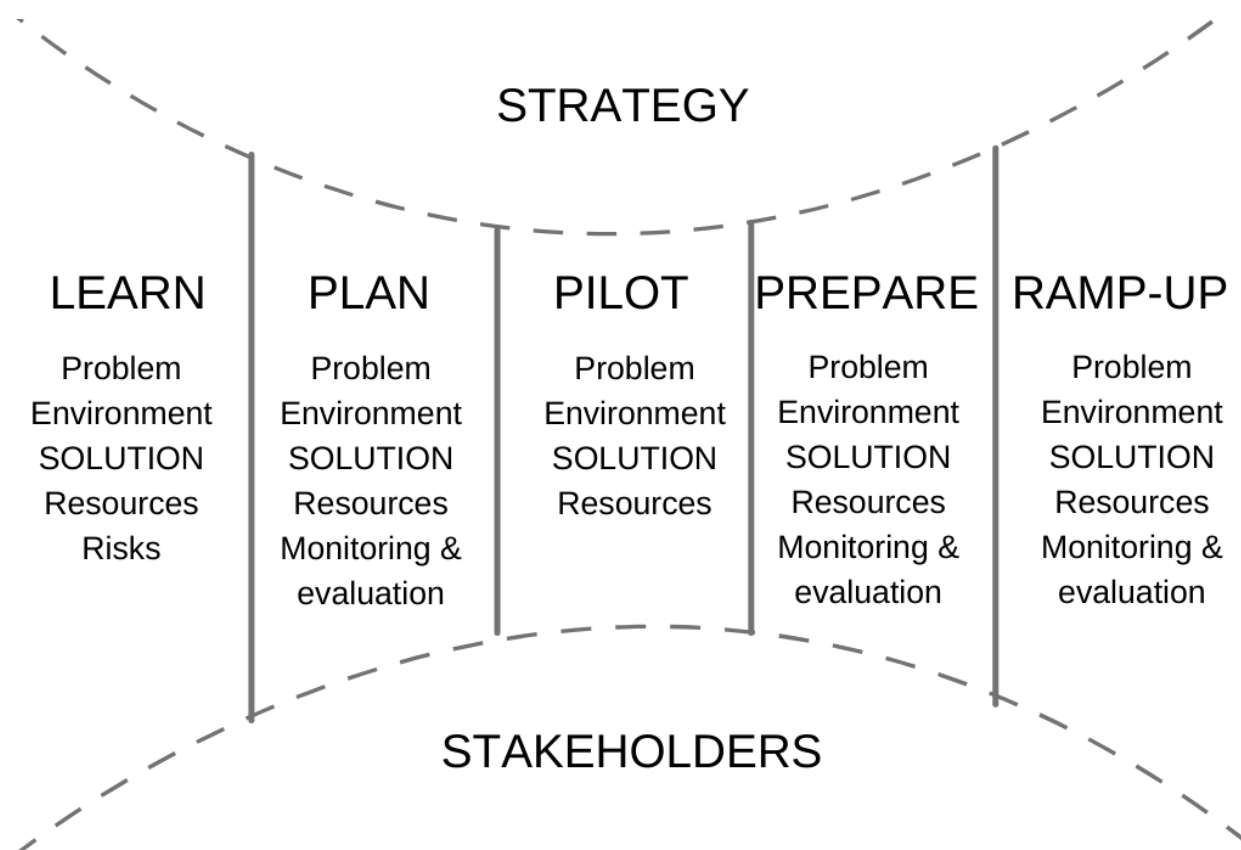
3 out of the 5 phases described by the model are about information gathering and planning. Although this may not seem to be "active" work on scale-up, collecting adequate information and analysing it is crucial. Each of these phases rely heavily on stakeholder involvement – stakeholders supply the company with valuable knowledge as well as contribute to the planning

activities. Concurrently, it gives the solution owner a chance to communicate, educate and mould potential users/clients/supporters at the target market, so it is a two-way movement.

Including stakeholder groups in the "active" phases of the scale-up process is also crucial, as their knowledge, contacts and infrastructure can proliferate the company's efforts. There is a variety of tools available for involving stakeholders. For example, one of the outputs of the IN-4-AHA project gives an overview of the principles of participatory design process and suggests a variety of specific methods to be used[3]. This report can be consulted during each stage of the scale-up process.

While stakeholder involvement is the foundation of the model, all activities should be conducted within the company's strategic outlook. While start-ups are often more flexible in their perspective outlook, constantly checking if the scale-up process is aligned with the company's long-term goals keeps the progress on track. As with stakeholder involvement, it is a two-way movement – obtaining new data and knowledge might lead to revising and adjusting the strategy.

The model offers several GO/NO GO points for the company. It is important to note that an informed decision to quit the scale-up process at any stage should not be seen as a failure. Rather, it can be a strategic decision that saves effort and resources in the long run.

As the full cycle of the model spans over a longer time frame, and potential users are companies in different stages in their life cycle, it might be appropriate to only focus on a certain stage or component at any given point. Clusters and support organisations can help define, where does the company stand and what should be the steps taken towards efficient scale-up.

STAKEHOLDERS

Including stakeholders throughout the whole process of scaling-up is imperative – it ensures constant feedback throughout the process of scaling up, provides better insight of the target market conditions, supports the company with acquiring necessary approvals and achieving compliance with target market regulations. It also helps to "recruit" supporters who would be championing the solution's implementation at the target market – SMEs interviewed during the validation model confirmed that including early adopters or "prophets" has been crucial in their internationalisation efforts. The benefits of stakeholder involvement are outlined in more detail in IN-4-AHA's report on participatory design[4].

The health and care sector has a large range of stakeholders, varying from individuals with existing or potential health conditions, and their families and caretakers, to care providers, public health institutions and policymakers. IN-4-AHA project recognises the importance of

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[3] Report "Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2021. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Revised_Updated_D3.1_Participatory-Design_-NeedsOfInnovation_Dec2021docx.pdf

[4] *Ibid.*

human-centeredness in the development and implementation of health and care solutions, especially when it comes to the end users, who are often the elderly who need support with active and healthy living throughout the continuum. The end users can also be family members, caretakers, medical professionals etc.

In the health and care sector there rarely exists a simple customer-supplier relationship, hence other stakeholders besides the end users must be considered. The figure below demonstrates one way of viewing the layers of actors in the field. The needs of the end users are often identified and empowered by the demand stakeholders (payers), and the needs are filled by the market. The process is supported by health clusters and other business environment enablers.

Figure. 1 Layers of actors in innovation scale-up
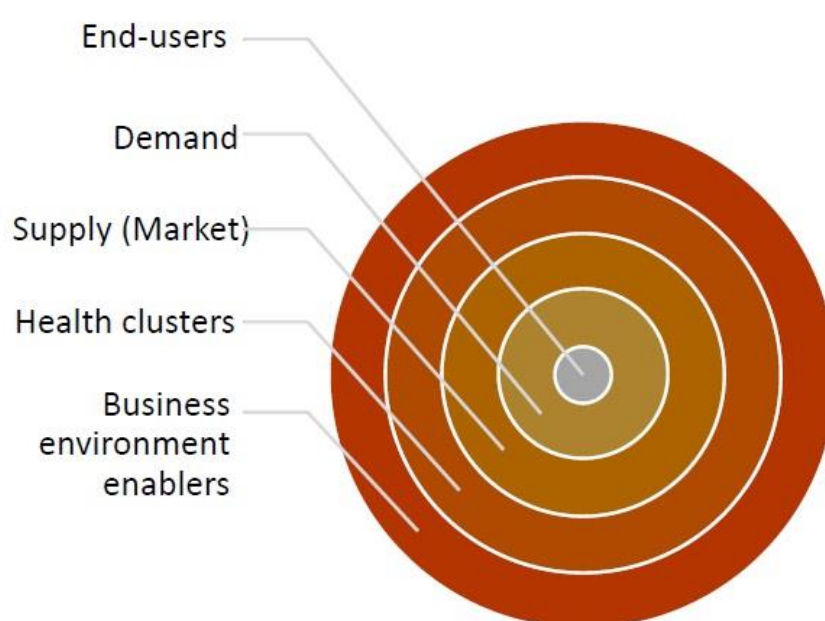
Business environment connects enablers such as EU grants and funds, private investors, EIP on AHA reference sites and similar networks, and industry organisations. Health clusters bring together start-ups, SME-s, large enterprises, research institutions and technology competence centres, health and care providers, as well as patient and physician organisations. Their common goal is to create favourable environment for health technologies and remove barriers to reach successful market uptake.

The market is guided by suppliers who are technology and service providers with successfully tested solutions. Suppliers need support in service adoption, including delivery protocols and testing for end-user readiness. Direct beneficiaries represent the demand through healthcare providers, local, regional or national authorities (payers).

It is important to identify and involve most significant stakeholders at every phase/component of the scale-up model. There is a variety of tools that can be used for stakeholder participation, for example workshops. More information on that can be found in IN-4-AHA report "Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector"[5].

1. LEARN

To start the scale-up process the company must collect information and analyse it to map scale-up potential and possibilities. It is a low-risk stage, but crucial for building the base for future activities and for minimizing risks and costs in the later stages. Aspects to be analysed during this phase are outlined below.

Doing extensive research can be resource-consuming and it can take focus off the company's daily operations, especially for start-ups/SMEs. Involving stakeholder groups can ease that burden, as they tend to have better knowledge of the different aspects of the target market. The SMEs interviewed during the validation of the model emphasised that international (target market) communication must start from the very beginning. Also, this is where industry/start-up support organisations can play a role – their knowledge and networks can provide a lot of the initial information necessary. Another option to start collecting new knowledge and contacts is participating in European projects and matchmaking initiatives.

At the end of the LEARN stage the company should have a better picture if scaling up is a feasible strategy, and initial understanding of if and how their solution should be adapted to the target market. The decision that the company must make at the end of this phase is whether to proceed or not.

1.1. Problem

The Scale AHA report concluded that one of the success factors for scaling up in AHA is addressing current healthcare needs[6]. In order to offer a sustainable innovation to the market, the company must understand what is the problem they are targeting to solve.

1.1.1. What is the problem that the solution is designed to address in the current market?

An analysis of gaps in the AHA market was conducted in the framework of IN-4-AHA project, and it was suggested that instead of offering general solutions for the elderly, companies should

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[5] Report "Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector", compiled in the framework of the project "Innovation Networks for Active and   Healthy   Ageing",   2021.   https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Revised_Updated_D3.1_Participatory-Design_-NeedsOfInnovation_Dec2021docx.pdf

[6] Stroetmann, V., Birov S. *et al.* Study on support to scaling-up of innovations in Active and Healthy Ageing. A study prepared for the European Commission DG Communications, Networks Content & Technology, 2017. http://www.scale-aha.eu/fileadmin/documents/scaleaha_d5.4_finalstudyreport.pdf

focus on needs[7] when designing their innovations. Hence, a well-defined problem, preferrable from the point of view of the end user, lays a solid base for the whole scale-up process. The question to be answered is which unmet need in the AHA market is the innovation aiming to alleviate?

1.1.2. Is the problem same in the target market?

The same problem does not express the same way in different environments, so it is not sufficient to assume that the unmet need at the target market is the same or similar. To get better insight, it is beneficial to start involving stakeholders already. This aspect is described in question 1.1.3.

1.1.3. Who is the need owner? And who are other groups impacted by the problem?

Who is the individual, group or organisation that experiences the problem? Is the need owner at the target market the same or different from the current market? It must be noted that due to the character of the health and care sector the need owner is rarely the same as the customer and/or payer. Also, the problem might have an indirect but significant impact on individuals or organisations connected to the need owner. Hence, different stakeholders must be identified, and their experience and perception of the problem must be analysed.

There are different ways to include stakeholders in the process. Some examples of co-creation workshop methods are outlined in an overview of participatory design methods and tools, a report developed within the IN-4-AHA project.[8]

1.1.4. What is the problem's impact?

What is the problem's effect, both qualitatively as well as quantitatively? The impact must be studied on multiple levels, from individuals to socioeconomic influences. How many people or organisations are impacted by the problem? What is the problem's breadth and level of urgency? Is the impact marginal or a significant disruption?

1.2. Environment

There is a multitude of environmental aspects that impact the scale-up process, and it is not possible to identify and/or describe them all. However, a thorough knowledge of the details of the target market is necessary for building a sustainable scale-up strategy. Below are some examples of environmental factors to consider.

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[7] Report "Investment Readiness Assessment", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/FInal_D6.1-Investment-readiness-assessment.pdf

[8] Report "Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Revised_Updated_D3.1_Participatory-Design_-NeedsOfInnovation_Dec2021docx.pdf

1.2.1. Regulatory and political environment

Health and care is a highly regulated field in order to ensure access to treatment and care, and the health and safety of the population. Regulations vary between the EU member states, and often between regions. EU-wide regulations might also be relevant, for example the Medical Device Directive. To examine the regulatory framework, the company can either turn to local regulatory authorities or use the services of legal consultants.

In addition to specific regulations, the general set-up of the healthcare/social security system and policy framework must be considered. Understanding strategic policy priorities helps to assess how the scale-up process might work, anticipate upcoming regulatory changes, and gain support from policymakers.

1.2.2. Trends and demographics

What specific trends are prevalent on the target market that are relevant to the problem? This could include population trends, dynamics of healthcare spending, prevalent health concerns etc. Also, the ethical principles prevalent in the target market must be researched.

1.2.3. End users and other stakeholders

The stakeholders identified in question 1.1.3. must now be described in more detail – what are their habits, abilities, perceptions towards new solutions? Which innovative solutions are they already using? One option to describe the need owners and other stakeholders is to use personas[9].

It is important to acknowledge cultural differences, as health and ageing can be a very sensitive subject. Being aware of how the target market perceives different aspects of health, care, aging, death etc. can help avoid miscommunications. If necessary, the company should consult with experts with knowledge of cultural differences, and with elderly and their families/caretakers.

1.2.4. Infrastructure and processes

The solution must fit into a larger health and care framework. What kind of infrastructure and processes are currently in place at the target market, for example what is the technological maturity, what information systems are used for providing digital services, how do reimbursement schemes work, what are the procurement conditions for health and care providers etc.

1.2.5. Competitors and alternatives

To better define the value proposition and business model at the later stages of this model, it is necessary to have an overview of existing and potential competitors at the target market, as

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[9] Examples of personas have been suggested by the "Smart and Healthy Ageing through People Engaging in Supportive Systems – SHAPES 2020" project (https://shapes2020.eu/deliverables/shapes-personas/), and the Blueprint on Digital Transformation on Health and Care for the Ageing Society https://blueprint-personas.eu/persona-library/

well as alternative solutions. What is their value proposition? How are the currently financed? How do they fit into the health and care system, and how have they been accepted by the end user and other stakeholders?

1.3.   Solution

To enter new target markets, the company's innovation must at least have proof of feasibility. It is essential that the company has a good data strategy in place as early as possible, to back up the value claims of its innovation.

1.3.1.   What is the solution?

How has the innovation's feasibility been proven in the target market - is there a reference case, sufficient proven data, established processes etc? Is the solution safe, efficient, and advantageous compared to other innovations in the same field?

A range of tools are available to help with appraising the solution, for example MAFEIP for health and economic impact assessment[10], MAST for evaluating the medical, social, economic, and ethical aspects of telemedicine solutions[11] etc. An overview of some of the assessment methods was composed within the IN-4-AHA project[12].

One of the outputs of the IN-4-AHA project is a framework to evaluate person-centeredness of the innovation[13]. As person-centeredness contributes significantly to successful uptake of the solution, the company can make use of questionnaires targeting different groups (service providers, service users and facilitators) in Annexes 1-3.

1.3.2.   Does the solution address the need at the target market?

It is highly improbable that the innovation in its current state covers the need on the target market fully. Where are the gaps, and which are the main features that would address the target market? Stakeholders identified in 1.1.3. should be included to find answers to these questions, as well as business, scientific and legal experts.

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[10] Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing. https://www.mafeip.eu/the-tool

[11] Kidholm, K., Ekeland, A.G., Kvistgaard Jensen, L., Rasmussen, J., Duedal Pedersen, C.D., Bowes, A., Flottorp, S.A., Bech, M. "A Model for Assessment of Telemedicine applications: MAST." International Journal of Technology Assessment in Health Care 28 (1): 44-51, 2012. https://www.researchgate.net/publication/225056446_A_Model_for_Assessment_of_Telemedicine_applications_MAST

[12] Report "Overview of Evaluation Toolkits", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2021. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/D5.1-Report_IN-4-AHA-toolkits.pdf

[13] Report "AHA Innovation Assessment Framework", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/AHA-innovation-assessment-framework-ver-2.0-FINAL_280322.pdf

1.3.3. Who is the primary target group?

The target group (individual, organisation or public authority) that the company intends to address at the target market is not necessarily the same as the need owner defined in 1.1.3. Instead, it could be a demand actor – health or care provider, insurance or other. What value would the solution propose to them? Determining the target group sets base for the company's business model.

During the process of scale-up, this is the first effort to define if and how the innovation must be adapted to the intended market. It must be constantly reviewed throughout the cycle.

1.4. Resources

When investigating what kind of resources are necessary to implement the innovation in the target market, it is essential to look at a broader perspective than just finances. WHO has emphasised that *"more resources alone are rarely enough to ensure successful scale-up. There are many other kinds of constraints to be tackled, including unsupportive law, weak management systems or limited demand from clients"* [14].

Below are examples of resources to be considered, but the list is in no way exhaustive. To define the needs more accurately, components 1.1. "Problem", 1.2. "Environment" and 1.3. "Solution" might need to be revisited.

At the end of this component the company can critically evaluate if it has the capacity to proceed with scaling-up, as well as what kind of resources it needs to gain to be more successful.

1.4.1. Finances

What is the estimated budget to enter the target market? Which options can the company use to finance the scale-up (investors, payors, grants, lending, self-financing or a combination of these)? Overview different financing options available to companies in the field is presented in the IN-4-AHA report "Investment Readiness Assessment"[15]. The same report provides a checklist for start-ups preparing to raise investment (See Annex 4).

Also, clusters and other support organisations can usually suggest which specific financing opportunities are obtainable and assist in applying for grants or raising investments.

1.4.2. Competences and capacity

It has been suggested that for successful internationalisation the management of a start-up should have the following competences – personal international orientation, experiential

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[14] "Scaling up health services: challenges and choices". WHO Technical Brief, 2008. https://www.who.int/healthsystems/topics/delivery/technical_brief_scale-up_june12.pdf

[15] Report "Investment Readiness Assessment", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/FInal_D6.1-Investment-readiness-assessment.pdf

knowledge of the organisation's capability and resources to engage in international markets, experiential market knowledge, and experiential knowledge of institutional frameworks[16]. If there are missing competences, they can be filled by either hiring staff or involving service providers. Clusters and other support organisations can also offer advice on internationalisation.

Another aspect to consider is if the company with its current staff has enough capacity to scale-up. It might be necessary to hire additional staff or spend effort on training collaboration partners at the target market.

1.4.3. Partners

The need owner, stakeholders and target group were defined in questions 1.1.3. and 1.3.3. Now the company must analyse which organisations, companies or institutions it needs to collaborate with to succeed on the target market – a legal office, an insurance provider, a health authority or a social services provider etc.

1.4.4. Infrastructure and supply chain

The existing infrastructure and processes at the target market were analysed in question 1.2.4. Are there gaps that the company must fill in? What effort is required for the solution to be compatible with the local health care system? What is necessary to set up a supply chain?

1.4.5. Licences and permits

What kind of certification must the company pass to operate at the target market? How long is the process to apply, and what kind of resources are necessary.

1.5. Risks

Based on the previous components, both external and internal risks must be analysed before proceeding. The CIMIT Healthtech Innovation cycle suggests the following four dimensions of risks and emphasises that all the dimensions should be looked at in parallel[17]:

1.5.1. Clinical risk, including aspects on how the solution will be accepted and adapted, and does it produce the expected results.
1.5.2. Market/business risk, for example if the unmet need at the target market is adequate, and are there enough payers willing to purchase the solution for a sustainable price.
1.5.3. Regulatory risk – what kind of regulations must be adhered, what kind of effort and cost is required.

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[16] Achtenhagen, L. Internationalization competence of SMEs. Entreprenörskapsforum, 2011. https://entreprenorskapsforum.se/wp-content/uploads/2011/12/internationelization-comp_webb.pdf
[17] Navigating the healthtech innovation cycle. CIMIT (Consortia for Improving Medicine with Innovation and Technology). https://www.cimit.org/documents/173804/228699/Navigating+the+HealthTech+Innovation+Cycle.pdf/2257c90b-d90b-3b78-6dc9-745db401fbc6

1.5.4. Technical risk, including how will the technological advantage be protected.

2. PLAN

If the company has decided to proceed towards scaling up at the end of the LEARN phase, gathering and evaluating information will be more focused now. The focal point of the PLAN phase is to prepare for a pilot project by setting up a clear protocol for it.

In this phase stakeholder groups must be included to ensure the quality of the pilot, but also to build strong collaborative relationships at the target market. The company must identify which individuals, groups or organisations will be most relevant to assist in conducting a pilot, for example a living lab, a care provider to test the solution at, a patient association to support with lobbying, a legal expert to interpret local regulations, an industry organisation to help navigate in the local business environment etc. Each of the stakeholder groups must be approached differently.

When planning a pilot, the company must have a strategic perspective in mind. However, it is necessary to be ready to change according to new knowledge and experience gained.

At the end of the PLAN phase the decision to be made is whether to continue to the pilot project or not, and if and how the solution must be adapted for the pilot. In case the company decides to proceed, they will have a tactical plan along with a monitoring and evaluation plan in place.

2.1. Problem

2.1.1. Re-definition of the problem

Using information collected during the LEARN phase, and additional contribution from stakeholder groups, the problem on the target market can be specified. All aspects described in 1.1. should be included – who are the problem owners, are they the same as the end user? How does the problem impact different stakeholder groups on different levels (from individual to socioeconomic impact)? Is the problem perceived as a problem in the target market, and if yes, are there intentions or proposals for solutions by other parties (policymakers, other solution providers, patient groups, care providers etc)?

2.1.2. Which aspects of the problem will be addressed with the pilot?

As pilot projects are limited, it is often not possible to tackle the problem fully during the testing. Hence, the selection must be made, which elements are crucial, and which ones can be addressed with the pilot project.

2.2. Environment

Using information collected in component 1.2., environmental aspects should be analysed from the point of view of the planned pilot project. Some factors that could impact the testing are outlined below.

2.2.1. Legal setting

Is it possible to implement the pilot in the current legal setting? What kind of permits, licences and certificates are necessary prior to entering the market? Are there any post-marketing requirements? When setting up the plan for executing the testing (component 2.4.), a distinction must be made which requirements are a necessity for a pilot, which must be followed in long-term perspective (scale-up), and which legal aspects, while not necessarily compulsory, might add to the value proposition of the solution.

As regulations in a foreign market might be difficult to comprehend, it might be useful to involve legal experts or consult the relevant authorities. The IN-4-AHA Data Governance Guidebook[18] offers an overview on EC regulations on data management and protection.

2.2.2. Health and care setting

Is it possible to implement the pilot in the current health and care framework? Are there established infrastructure and processes in place that the solution is compatible with?

2.2.3. Cultural and behavioural aspects

Stakeholders on the target market can help identify which cultural and behavioural factors might impact the pilot project. It is especially important to focus on the end user, their family members, and caregivers. To evaluate the user-centered aspects of the solution, the evaluation framework outlined in Annex 1 can be consulted.

2.2.4. Main actors in the field

Which organisations, companies or public institutions would be relevant to the testing – potential sites, collaboration partners, service providers, support organisations etc.?

2.3. Solution

Most probably the innovation would have to be adapted for the pilot project. However, this adaption should be done considering how the solution should be adjusted for large-scale implementation.

2.3.1. What is the value proposition for the target market?

Based on the definition of the unmet need, the end users and target group (component 1.1.), and the target group and the solution's potential (component 1.3), the company must determine what benefits would its solution deliver at the target market. It must be emphasised that different stakeholders perceive the value of the solution differently.

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[18] Report "Data Governance Handbook", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/06/D5.3_Data-governance-guidebook_full-text_final.pdf

Describing the value proposition in this phase also includes determining what features of the innovation should be adapted for the target market.

2.3.2.   What is the aim of the pilot?

To ensure that the pilot project high-quality evidence into the scale-up process, the company must start by setting clear aims and objectives. For example, does the company intend to validate or verify the solution, test performance, load, or integration etc.?[19] Which features of the innovation will be tested? And does the solution need to be adapted (for example, simplified) for the pilot?

2.4.   Resources

During this component the plan to implement the pilot is formed. When analysing resources necessary, it is useful to do it simultaneously with component 2.5. A well-defined monitoring and evaluation plan ensures an efficient use of resources and high-quality results.

2.4.1.   Scope and scale

The scope of testing is determined by the aims defined in 2.3.2.

Will the pilot be carried out in one or multiple sites? If the latter, will the testing take place simultaneously or consecutively? What is the planned timeframe for testing? One option is to use Rapid Cycle Improvement, by running multiple consecutive tests, each being larger in scale than the previous one[20].

2.4.2.   Regulations

Based on the analysis conducted in 2.2.1., what effort is necessary to comply with the legal requirements? Which certificates are necessary to operate, which add extra value (for example credibility) to the solution? While it might not be feasible to obtain certificates in the piloting phase, it is useful to plan activities and documentation according to the specific requirements. Legal experts should be involved if necessary.

2.4.3.   Integration

What effort is necessary to integrate the innovation into the target market framework? If there are gaps, which resources are needed to set up and implement new infrastructure and processes?

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[19] A guide to good practice for digital and data-driven health technologies. UK Department of Health and Social Care (2019). https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#have-a-clear-value-proposition

[20] Barker, P.M., Reid, A. & Schall, M.W. A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. *Implementation Sci* 11, 12 (2015). https://doi.org/10.1186/s13012-016-0374-x

Are there any recommended standards for technical and semantic interoperability of digital solutions?

2.4.4. Adaption

Based on question 2.3.2, which resources are necessary to adapt the solution for the pilot project? If modifications are made, how will the results of testing be applied to large-scale roll-out?

2.4.5. Stakeholders

Which partners are needed to implement the pilot project – host sites, service providers, medical professionals etc.? What are their competences and capacity to participate in testing? How to approach them? How should end users and other related stakeholders be involved?

2.4.6. Activities

What kind of activities are necessary for a successful pilot? An analysis of the accessibility and adoption of services and products conducted in the framework of the IN-4-AHA project concluded that the main factor contributing to success is person-centered approach[21]. Some examples of activities include communication for awareness-raising, training of caregivers, patient recruitment, setting up data strategy, hiring etc. What are the company's competences and capacity to implement the pilot project, and where additional resources are needed?

2.4.7. Finances

What is the estimated budget for the pilot project? Will it be financed from the company's own resources, or external financing is required - public grants, reimbursement (patients, insurance, service providers or public reimbursement schemes), investors, lending? When considering grants, the company must critically evaluate if the financing scheme is aligned with market needs – otherwise the company will be distracted from the scale-up strategy by fulfilling financing conditions. Investors often contribute to the companies they invest in with their competences and networks, hence approaching them must be done strategically.

2.5. Monitor and Evaluate

To assess progress and improve decision making, it is necessary to continually collect, analyse and use data. Hence, it is important to have a good data strategy in place as early as possible.

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[21] Report "Mapping of Accessibility and Adoption of Services and Products", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022 https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/06/D4.2.-Mapping-of-accessibility-and-adoption-of-services-and-products-finalversion_.pdf

A Data Governance Guidelines[22] was developed during the IN-4-AHA project to support companies with their data governance processes.

Setting up the monitoring and evaluation plan is determined by the aims and objectives of the pilot defined in question 2.3.2. There are numerous tools available to use for that purpose, depending on what exactly needs to be evaluated. Companies could also use the aspects described in the PILOT component as part of their monitoring and evaluation, making sure both qualitative and quantitative aspects are assessed.

3. PILOT

A pilot project is a small-scale adoption of the solution, either in one or multiple settings to test different features, environmental aspects and/or target groups. Running a pilot enables to collect information, test the feasibility of the solution, and build credibility, while lowering risks and exhausting less resources. In the context of the current scale-up model it is assumed that the pilot takes place in the target market.

Throughout the planning and conducting the pilot, a strategic perspective must be kept in mind. Pilot projects have their restrictions – they are not miniature models of the target market, but rather represent limited aspects of it. When implementing the innovation on a larger scale, the company will most probably experience numerous factors that did not appear during the pilot, hence relying on a successful pilot only does not guarantee sustainability.

Below is a list of aspects to be taken into consideration during the pilot project and upon its completion. These aspects could be part of the monitoring and evaluation; however, assessment should not be limited to the questions below. At the end of PILOT-phase the decision point is whether to continue the process of scale up and if yes, if and how the solution must be adapted.

3.1. Problem

3.1.1. Does the problem appear the same as defined in the earlier stages?

The pilot will help to refine the problem definition from the perspective of stakeholders involved in testing. For example, it might appear that there is a difference between how stakeholders perceive the problem and how they experience, and additional communication activities are necessary (component 3.4.).

The problem definition might still have to be adjusted with input from other stakeholder groups for a more complete picture during component 4.1.1.

3.1.2. With new information gained during the pilot, are there any additional venues for the solution opening up?

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[22] Report "Data Governance Handbook", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/06/D5.3_Data-governance-guidebook_full-text_final.pdf

In addition to the original problem, pilot projects might help identify other potential market opportunities to be explored.

3.2. Environment

The company should monitor the same environmental aspects outlined in components 1.2. and 2.2. throughout the pilot, with a focus on which factors had the largest impact? Was there something that had been overlooked/neglected until now? Assuming that comprehensive information has been gathered during the previous stages, most probably finer and less obvious details start playing a larger role (cultural, behavioural, process-related aspects).

3.3. Solution

Understanding the solution's performance relies heavily on the monitoring and evaluation set up during component 2.5 and implemented during and at the end of the pilot. Questions to be considered may include the following:

3.3.1. Stakeholders and acceptance

Was it easy for the end users and/or target group to understand and use the innovation? How have the stakeholders accepted the solution; how do they behave?

3.3.2. Which features proved to be most significant?

This also includes the analysis of shortcomings, to help understand how to improve the solution before large-scale implementation.

3.4. Resources

This component is also based on the monitoring and evaluation set up during component 2.5. Comparing which resources were initially planned with what was actually needed provides input into planning for scaling up. Aspects to analyse include resources outlined in questions 2.4.3.-2.4.7.

4. PREPARE

Pilot projects are conducted in a relatively controlled environment, hence information obtained during the pilot is not directly transferrable to scaling-up activities. To minimize risks, the company must prepare extensively before committing to large-scale efforts. WHO's advice for developing a scale-up strategy includes a warning not to rush into scaling-up, even if initial pilot results are promising. Rather, the company should collect enough evidence before proceeding.[23]

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[23] Nine steps for developing a s scaling up strategy. WHO and ExpandNet (2010). https://www.who.int/immunization/hpv/deliver/nine_steps_for_developing_a_scalingup_strategy_who_2010.pdf

The PREPARE phase might be more time-consuming than the previous stages, depending which activities are necessary. For example, there might be a need for awareness-building, improving data interoperability, setting up regulatory adherence etc. During the PREPARE phase the company actively sets up a tactical plan for initiating and running a large-scale implementation of its solution at the target market.

4.1. Problem

Consolidating the results from the pilot project, and feedback from stakeholders, the company should have a comprehensive understanding of the problem their innovation will be addressing. The problem definition will be one of the fundamental pillars of the scale-up plan.

4.2. Environment

If the company has done adequate research, and included stakeholders from the target market, they should have an extensive comprehension of the environment they intend to operate in.

4.3. Solution

4.3.1. Aims and goals

Before setting up a plan for scaling-up in component 4.4. it must be defined what the company considers a successful scale-up. Well-established aims and goals will be the base of both planning as well as monitoring and evaluation. Also, the strategy for scaling-up must be determined. WHO distinguishes between the following strategies for deliberate scaling[24]:

- Horizontal – the company implements its solution in different geographical areas, or in different or wider target groups. However, it is not copying the same innovation, but analysing and modifying it if necessary.
- Functional – the current solution is improved by *"adding new features, services or processes"*.
- Vertical – the push to implement the solution comes from policymakers in the target market.

4.3.2. Market-ready innovation

Using data from the pilot project and factoring in feedback from stakeholders, the company should have an understanding, what exactly is the solution to be implemented large-scale. If any modifications are needed, it will be tackled during component 4.4.

4.3.3. Value proposition to stakeholders

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017603

http://ec.europa.eu/digital-single-market/ehealth

The role and expectations of different stakeholders have been analysed throughout the model. Now, the focus is on stakeholders who are potentially the catalysts for implementation. It could be an insurance provider looking to optimise costs, a professional association rooting for a change in healthcare, a care provider seeking more efficient ways to provide services, reference sites etc. If they see benefits in the scaling up of the solution, they are more likely to support the company's efforts. Determining what value does supporting the innovation provide to them helps planning specific activities in component 4.4.

4.4. Resources

Along with component 4.5., setting up a plan to ramp up is the most crucial stage in the scaling up process. Some aspects to be considered, are listed below, however the list is in no way comprehensive.

4.4.1. Scope and scale

The company must choose the pace of scaling up – whether it will be phased, gradual or rapid implementation, as well as the timeframe and reach for it.

4.4.2. Regulations

Does the innovation meet all the standards and requirements needed for market entry? What are the post-marketing obligations? To ensure compliance, relevant institutions for accreditation and notification should be consulted.

4.4.3. Integration

What effort is necessary to ensure the solution will be integrated and running in the target market framework sustainably?

4.4.4. Competences and capacity

Does the company possess the necessary competences and capacity to run the scale-up, or they must include stakeholders and additional resources?

4.4.5. Financing

What is the long-term strategy for financing the scale-up? As in the EU, public reimbursement mechanisms vary greatly between member states, and are complex and time-consuming, it is suggested to have a phased approach to financing scale-up[25].

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[25] Brinkman-Sass, C., Richter, L., Silberzahn, T., Somauroo, A. The European path to reimbursement for digital health solutions. McKinsey & Company, 2020. https://www.mckinsey.com/industries/life-sciences/our-insights/the-european-path-to-reimbursement-for-digital-health-solutions

4.5.   Monitoring and evaluation

A large-scale implementation is a high-risk strategy, hence thorough monitoring and evaluation procedures should be established. Based on the aims and goals set in 4.3.1., constant monitoring and evaluation enables the company to prevent and minimize potential risks.

5. RAMP-UP

When the innovation has entered the target market, the company must continue to monitor and evaluate all the components described in the earlier phases of the model. Technology and its applications are rapidly evolving, new innovations are emerging, changes in policy can be abrupt, and society and culture are in a constant transformation. Persistent monitoring and ability to adapt contributes to the sustainability of the innovation.

Annex 1: Innovation assessment questionnaire for end-users

Adapted from report "AHA Innovation Assessment Framework", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/AHA-innovation-assessment-framework-ver-2.0-FINAL_280322.pdf

Facilitator – profile description

Professionals in health and care institutions (hospitals, social and healthcare centres, assisted living communities, etc.) who provide professional support for the elderly person (65+) in connection of service which is being evaluated.

Family members, relatives, or other informal care givers who assist the elderly person to improve their health condition and/or help.

Living Lab coordinators who assist the elderly in the process of testing the service.

Any other person who directly assists the elderly person to improve their health conditions and/or helps.

Service provider – profile

Service provider is a representative of the team (company) who has developed the service (technology, solution) and has designed its delivery process. The service provider has put the service on the market and has defined the target group(s) of users.

User – profile

People who use or are intended to use the service:

Professional users (including health and care professionals) if the service is meant to benefit their work with the elderly (persons aged 65+).

End-users (persons aged 65+) if the service aims to improve their health condition or help receive care/assistance.

DOMAIN 1: Autonomy

<u>Health outcomes</u>

Are you actively involved in developing a plan to improve your health status while using the service? *Yes/No/Other*

Does the service give enough information to help you make decisions about your health status? *Yes/No/Other*

Does the use of the service enable you to take responsibility for your health status? *Yes/No/Other*

Involvement

Are you involved (are you motivated to be involved) in the development or improvement of the service (e.g., giving feedback)? *Yes/No/Other*

Would you like to give feedback on the use of the service (e.g., by questionnaires, tests)? *Yes/No/Other*

Responsibility

Do you feel better informed about your health after using the service? *Yes/No/Somewhat informed*

Do you feel that you received full support throughout the service? *Yes/No/Other*

DOMAIN 2: Coordination and cooperation

Service coordination

Do you feel like your input is valuable to the improvement of this service? *Yes/No/Other*

Have your family members/caregivers been involved in developing or improving the service? *Yes/No/Other*

Target group coordination

Have you (or a family member) signed a written consent to use the service? *Yes/No/Other*

DOMAIN 3: Empowerment

Targeted service

Has your need to use the service increased or decreased during the period of using the service? *Increased/Decreased/Has not changed*

If living at home, do you think the service will help you to live longer at home? *Yes/No/Other*

Do you think that using the service will enable you to maintain your current state of support longer? *Yes/No/Other*

Early detection

Do you feel that using the service has helped you better manage your health? *Yes/No/Other*

Do you feel that the service has helped to reduce your need for other medical interventions? *Yes/No/Other*

DOMAIN 4: Personalization

Accordance to needs

Do you feel that all your different needs were considered when providing the service? *Yes/No/Other If no, please specify*

Have your assistance needs been satisfied by formal (health and social care professionals) or informal caregivers (family, volunteers, etc.)? *Formal care system/Informal care system/Both/Neither*

Has your overall quality of life changed after using the service? *Has improved very much/Has improved a bit/Has not changed/Has become worse a bit/Has worsened very much*

Usability and accessibility

Do you have any physical needs (for example blindness, hearing loss, etc.) that make it difficult for you to use the service? *Yes/No/Other*

Do you have any psychological needs (for example the need for orientation, need for self-esteem enhancement, etc.) that make it difficult for you to use the service? *Yes/No/Other*

Do you have any social needs (for example need for social isolation, need for interactions, etc.) that make it difficult for you to use the service? *Yes/No/Other*

Do you have any environmental needs (for example need for availability of home services, need for reasonable living conditions, etc.) that make it difficult for you to use the service? *Yes/No/Other*

Have you considered discontinuing the service because it seems too complicated to use? *Yes/No/Other*

Did you feel safe while using the service? *Yes/No/Other If no, please specify*

Would you be willing to pay for this service? *Yes/No/Other If yes, sum in EUR*

Trust and respect

Did you feel that you were treated with dignity and respect during using the service? *Yes/No/Other*

Have you been asked to give personal data (data that allows you to be identified – e.g., name, picture, address, fingerprint, etc.) to use the service? *Yes/No/Other*

Did you feel that your data was handled securely? *Yes/No/Other*

Have you been given information about how your personal data will be used? *Yes/No/Other*

Annex 2: Innovation assessment questionnaire for facilitators

Adapted from report "AHA Innovation Assessment Framework", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/AHA-innovation-assessment-framework-ver-2.0-FINAL_280322.pdf

Facilitator – profile description

Professionals in health and care institutions (hospitals, social and healthcare centres, assisted living communities, etc.) who provide professional support for the elderly person (65+) in connection of service which is being evaluated.

Family members, relatives, or other informal care givers who assist the elderly person to improve their health condition and/or help.

Living Lab coordinators who assist the elderly in the process of testing the service.

Any other person who directly assists the elderly person to improve their health conditions and/or helps.

Service provider – profile

Service provider is a representative of the team (company) who has developed the service (technology, solution) and has designed its delivery process. The service provider has put the service on the market and has defined the target group(s) of users.

User – profile

People who use or are intended to use the service:

Professional users (including health and care professionals) if the service is meant to benefit their work with the elderly (persons aged 65+).

End-users (persons aged 65+) if the service aims to improve their health condition or help receive care/assistance.

DOMAIN 1: Autonomy

Health outcomes

Have you actively guided the end-users to participate in the development of an outcome plan (to improve their health condition or address the need for assistance)? *Yes/No/Other*

 While using the service, are guidelines and adequate information materials available for the end-user to help them participate in their health/care related decisions? *Yes/No/Other*

Has the end-user indicated how they would like to engage in making decisions on their health and care? *Yes/No/Other*

Involvement

Are you involved in the development or improvement of the service (e.g., by giving feedback)? *Yes/No/Other*

Have you guided the end-user to give feedback on the service (e.g., by questionnaires, tests)? *Yes/No/Other*

Responsibility

Do you consider the end-user to be the most responsible person for their own health? *Yes/No/Other*

Do you feel the end-user is better informed about their health after using the service? *Yes/No/Somewhat informed*

Do you feel that you offered full support to the end-user throughout the service? *Yes/No/Other*

DOMAIN 2: Coordination and cooperation

Service coordination

Do you feel like your input is valuable to the improvement of this service? *Yes/No/Other*

Has there been any service-related cooperation activities with the health and social care system representatives and service providers during the service design and/or delivery phases? *Yes/No/Other*

Target group coordination

Are channels provided for end-user communication and feedback? *Yes/No/Other*

Has the user given informed consent to use the service? *Yes/No/Other*

DOMAIN 3: Empowerment

Targeted service

Have the needs of end-users increased or decreased over time of using the service? *Increased/Decreased/Have not changed*

If the end-user is currently living at home, do you see that using this service will help the end-user live longer at home? *Yes/No/Other*

Do you think that using the service will enable the end-user to maintain their current state of support longer? *Yes/No/Other*

<u>Early detection</u>

Has using this service helped to better manage the health of the end-user? *Yes/No/Other*

Does the service have potential for the end-user to reduce the need for other medical interventions? *Yes/No/Other*

DOMAIN 4: Personalization

<u>Accordance to needs</u>

Do you feel that all the different needs of the end-user were considered when providing the service? *Yes/No/Other If no, please specify*

Have the assistance needs of the end-user been defined by formal or informal care systems? *Formal care system/Informal care system/Both/Neither*

Has the overall quality of life changed for the end-users after using the service? *Has improved very much/Has improved a bit/Has not changed/Has become worse a bit/Has worsened very much*

<u>Usability and accessibility</u>

Does the end-user have physical needs (for example blindness, hearing loss, etc.) that make it difficult to use the service? *Yes/No/Other*

Does the end-user have psychological needs (for example the need for orientation, need for self-esteem enhancement, etc.) that make it difficult to use the service? *Yes/No/Other*

Does the end-user have social needs (for example the need for social isolation, need for interactions, etc.) that make it difficult to use the service? *Yes/No/Other*

Does the end-user have environmental needs (for example need for availability of home services, need for reasonable living conditions, etc.) that make it difficult to use the service? *Yes/No/Other*

Has the end-user reported not feeling safe while using the service? *Yes/No/Other If yes, please specify*

Do you consider the cost of the service appropriate for the end-user? What price would you consider appropriate for the service? *Yes/No/Other If no, sum in EUR*

<u>Trust and respect</u>

Do you feel that you were treated with dignity and respect during using the service? *Yes/No/Other*

Do you feel that the end-user was treated with respect and dignity during using the service? *Yes/No/Other*

Annex 3: Innovation assessment questionnaire for service providers

Adapted from report "AHA Innovation Assessment Framework", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/AHA-innovation-assessment-framework-ver-2.0-FINAL_280322.pdf

Facilitator – profile description

Professionals in health and care institutions (hospitals, social and healthcare centres, assisted living communities, etc.) who provide professional support for the elderly person (65+) in connection of service which is being evaluated.

Family members, relatives, or other informal care givers who assist the elderly person to improve their health condition and/or help.

Living Lab coordinators who assist the elderly in the process of testing the service.

Any other person who directly assists the elderly person to improve their health conditions and/or helps.

Service provider – profile

Service provider is a representative of the team (company) who has developed the service (technology, solution) and has designed its delivery process. The service provider has put the service on the market and has defined the target group(s) of users.

User – profile

People who use or are intended to use the service:

Professional users (including health and care professionals) if the service is meant to benefit their work with the elderly (persons aged 65+).

End-users (persons aged 65+) if the service aims to improve their health condition or help receive care/assistance.

Introduction: Define all the end-user groups who will benefit from the service. What is the share of 65+ aged users out of all service users? *0 – 100%, step by 5%*

DOMAIN 1: Autonomy

Health outcomes

What is the estimated share of 65+ aged end-users who are actively involved in defining their health outcomes? *0 – 100%, step by 5%*

How many different guidelines and information materials are available regarding the service, that help the end-user make health/care related decisions? *Nr*

Have you asked end-users how they want to engage in decision-making concerning their health? *Yes/No/Other*

Involvement

What share of end-users give feedback (questionnaires, tests, etc.) to the service? *0 – 100%, step by 5%*

Responsibility

Does your service encourage the end-user to take responsibility for their own health? *Yes/No/Other*

Is the service aiming to improve the end-user's awareness on their own health? *Yes/No/Other*

Do you feel that you offer comprehensive support for the end-users throughout the service? *Yes/No/Other*

DOMAIN 2: Coordination and cooperation

Service coordination

How many elderly persons (65+) are involved in service development process? *Nr*

How many formal caregivers are involved in service development process? *Nr*

How many informal caregivers (family, volunteers, etc.) are involved in service development process? *Nr*

How many family members are involved in service development process? *Nr*

Please list service-related cooperation activities with health and social care system representatives (institutions, individuals) during the service development. *Add text*

Target group coordination

Are channels provided for end-user communication and feedback? *Yes/No/Other*

Is the informed consent given by the end-user and integrated in the service delivery process, as regulated by law? *Yes/No/Other*

DOMAIN 3: Empowerment

Targeted service

What is the estimated proportion of the elderly whose service needs have increased during the period of using the service? *0 – 100%, step by 5%*

What is the estimated proportion of the elderly whose service needs have decreased during the period of using the service? *0 – 100%, step by 5%*

What share of end-users live in their homes while using the service? What share of users live at home after having completed using the service? *While using the service: 0 – 100%, step by 5% After completing using the service: 0 – 100%, step by 5%*

Early detection

What percentage of end-users have reported that thanks to the service they manage their health better? *0 – 100%, step by 5%*

DOMAIN 4: Personalization

Accordance to needs

Are you willing to customize the service according to the person's needs? *Yes - please indicate potential modification that you are willing to undertake/No/Other*

Which needs are you ready to customize for? *Add text*

Usability and accessibility

What is the estimated share of 65+ aged end-users who are unable to use the service due to individual physical needs (for example blindness, hearing loss, etc.)? *0 – 100%, step by 5%*

What is the estimated share of 65+ aged end-users who are unable to use the service due to individual psychological needs (for example need for orientation, need for self-esteem enhancement, etc.)? *0 – 100%, step by 5%*

What is the estimated share of 65+ aged end-users who are unable to use the service due to individual social needs (for example need for social isolation, need for interactions, etc.)? *0 – 100%, step by 5%*

What is the estimated share of 65+ aged end-users who are unable to use the service due to individual environmental needs (for example need for availability of home services, need for reasonable living conditions, etc.)? *0 – 100%, step by 5%*

What share of end-users (including 65+ age group and other users) have declined or discontinued the service because the service has proved to be too costly? *0 – 100%, step by 5%*

Trust and respect

What share of end-users have reported that they experience respect and dignity when using the service? *0 – 100%, step by 5%*

What safeguards do you provide to handle personal data in a secure way?

1) Using adequate information security measures for technology

2) Using relevant data protection safeguards

3) Other security measures, please specify

Annex 4: Checklist for start-ups preparing to raise investment

Source: report "Investment Readiness Assessment in the AHA Market", compiled in the framework of the project "Innovation Networks for Active and Healthy Ageing" 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/FInal_D6.1-Investment-readiness-assessment.pdf

As the investment landscape for AHA is developing and more generalist private investors are looking to invest in AHA-related companies, the sector specific criteria for start-ups are quickly starting to disappear and AHA solutions are more and more being viewed as being part of the mainstream tech sectors.

Things the founders should consider before searching for the investor:

- Founders should realistically determine their financing needs and the basis for these
- The advantages and disadvantages brought by investors to the company in its present situation should be assessed in advance
- Founders must decide whether they are ready for equity dilution
- Founders should understand the way and the principles under which business angels, venture capital funds and other entities/organisations/programmes invest
- After taking care of the above, it is helpful to determine the ideal investor profile: What kind of investor is desired for the company? What know-how and networks are needed? How much of the investor's time is required?

Checklist – what founders should have ready before approaching investors

- **Establish a legal company.** You cannot give away shares of your business in exchange for investment unless you have a legal entity with shares.
- **Founders' Agreement** is a legally binding contract, usually in writing, that outlines the roles, rights, and responsibilities of each owner in a business. The agreement sets the terms if one founder decides to exit the business. Furthermore, it shows investors that you have a serious business.
- **Business plan**: you will need a detailed case for your business that includes market research, traction to date, financial forecasts as well as the amount of investment being sought and for what.
- **One pager**: prepare a short summary of what you do.
- **Pitch deck**: prepare two versions of it – one that could be sent out as a reading material and other that you can present standing in front of an investor.
- **Share capitalisation table** will set out the structure of shares for your company before and after the investment. You may need to seek some help from a lawyer to help prepare your share capitalisation table (CAP table).

AHA sector specific things to consider:

- **Long money needed:** Today's active tech funding landscape and quick to market business models let early-stage investors expect that they can exit already after 4-5 years. However, the longer to market time and slower initial market traction means that the potential exit time for investors will be significantly longer and up to 10+ years. Even more so if the company is developing a hardware device or operates in the medical sector. There are investors who are willing to invest in such businesses with longer exit periods. When looking for investors the start-up should take this into account when looking at investor profiles.

- **Problem to be solved**: Is your product or service solving a clear real-world problem the user has or is it just a nice to have solution offering extra comfort? For applications aimed at the general 53 public, nice-to-have solutions can be very successful as there's clear willingness to pay for convenience. AHA market on the other hand is facing problems with customer adoption and willingness to pay. Therefore, customers are mostly interested in only solutions that solve a clear problem for them. For example, voice-first computing has been hyped for its potential for serving the elder community. However, as of yet very few solutions have emerged solving a real-life problem and most applications have been just nice to have convenience features which explains why there's limited market traction for the voice first computing among the elderly.

- **Technology use case and design:** while the user experience should focus on the needs of an older generation, neither the purpose nor the marketing of the product should solely feed into the elderly storyline. People are very quick to reject products or services that make them feel old and helpless. Similarly, seniors don't want to feel spied on even if it's by loved ones. This means that even though the product might solve a necessary problem for the person themself of their family member it still might be rejected if designed and marketed on the wrong premise.

- **Business plan:** Is it clear how you will make money with your invention? Who will pay for it? Does the business case need reimbursement or purchases by either public or private insurers or social service providers? If so, do you have any proof of willingness to pay from insurers or social service providers? Do you have a clear roadmap on how to achieve reimbursement or first purchases? Investors have pointed out that many start-ups are too reliant on the technology and don't turn much attention to how to get regulatory approval, and public sector financing if the business model requires it.

- **Reaching customers and users:** Is the payer and end-user of your solution the same. In many cases for age tech solutions the payer and end-user might be different. For example, the case described above where the insurance provider pays for the solution. Similarly the payer and user might be different if an adult child purchases a solution for their elderly parents. In this case investors want to see some kind of traction or feedback from both the payer and user to be sure that both stakeholders see the value of the solution.

- **End-user testing and piloting:** As in many cases neither the founder nor the potential investor are the target group for the product or service for the elderly then in order to assess market and product/service match. Many AHA investors have explicitly stated that they expect to talk to the potential end-users and first customers of the company as they themselves can't evaluate the product/service. This means that the company must

have at least the first prototype of the service or product that can be tested by the end-users before approaching the investor.

- **Marketing and sales channels:** companies targeting the young or adult population leverage different social media channels for marketing and e-commerce channels for sales. However, this is significantly less effective for age-tech solutions and traditional media should be used to target the elderly customers. This means average customer acquisition cost per customer is significantly higher for age-tech companies.

Guidelines for venture capital due diligence process

During the investment negotiations Due Diligence (DD) is carried out by the investor to understand the investability of the company. It is used to verify information, expectations, and data about an investment. In the process of Due Diligence different documents (e.g., business plan, intellectual property) need to be provided. It is recommended to arrange the documents in a virtual data room (e.g., Google Drive) for more 54 convenient management. The data room structure (folders, documents) should match the structure of DD checklist.

There is no standard process for Due Diligence and most investors have defined their own process and criteria to assess the investment target. The depth and the format of Due Diligence differs from investor to investor. High level checklist of Due Diligence focus areas is presented below.

DD focus areas: what investors want to know and verify

- **Key risks** – risk analysis
- **Management team** – show co-operation and leadership
- **Technology** – prove that team knows what they are building
- **Product/Solution** – prove that someone needs it
- **Go-to-market strategy** – what is the vision
- **Intellectual property** – is there something to protect and is it protected
- **Competition** – current situation, entry

- **Market opportunity** – what is the perspective
- **Financials** – whether the founders have feet on the ground
- **Funding** – how the founders will achieve their goals
- **Legal** – critical issues
- **Deal terms** – realistic returns for the investors
- **Alignment** – do the investors and founders see the future the same way
- **Exit** – how the investors will get out

Focus areas can vary from investor to investor

Early-stage companies by their nature have little information to analyse and therefore Due Diligence might be centred around some key topics like:

- Team
- Market potential
- Contracts and agreements and legal risks
- Intellectual property (depending on the business)