

in4aha

INNOVATION SCALE-UP MODEL AND ROADMAP

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

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

<https://innovation4ageing.eu/>

<https://www.facebook.com/IN4AHA>

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More information about the EIP on AHA community and FUTURIUM platform:

<https://futurium.ec.europa.eu/en/active-and-healthy-living-digital-world>

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Executive Summary

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is an 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. Consequently, a roadmap was created to outline the activities necessary to facilitate successful scale-up.

The scale-up model is a tool meant for companies, especially SMEs, and industry support organisations. 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 may 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 in carrying out the necessary activities. At the same time, involving stakeholders gives the company a chance to raise awareness and support for its solution in the target market. Hence, it is crucial to identify the 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 whether scaling up is in tandem with 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 in the target market); **PILOT** (testing the solution); **PREPARE** (making preparations for 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, the target market, etc., different components might play a role. Links to additional information, tools and contacts are provided in this document, and companies can make use of the online step-by-step guide for the model on the IN-4-AHA website¹.

While the scale-up model mainly targets companies, the roadmap addresses three actor groups who have a major role in facilitating scale-up in the field of active and healthy ageing – **innovators, enablers and policy-makers**. However, it must be noted that AHA innovation can only be implemented efficiently if all relevant stakeholders are involved.

The innovators – companies that have an innovative solution and aim for internationalisation – must abide by three principals in their activities: **person-centered design, uptake of good**

¹ Link to the model on IN-4-AHA website

data management practices and impact assessment for their innovation. These principals are interconnected, and innovators can turn to enablers – clusters and industry organisations – for support.

The enablers' role in the roadmap is to offer innovators **AHA-specific business development services** and to create **focused accelerator and testing programmes**. Additionally, there is a need for a common **AHA innovation platform**. While public sector contribution to creating and running accelerators, testing programmes and the innovation platform would be beneficial, enablers are the organisations most suited to lead these activities.

The policy-makers, both at the European as well as the Member State level, can encourage AHA innovation by setting up **sandbox environments** and establishing **early-stage financing** initiatives for companies. **Raising competences** is another strategic focus area – there is a need to grow the skills of all relevant stakeholders, from the elderly and their families to medical professionals.

Harmonisation of regulations in the European Union, including approval, reimbursement and other aspects, would have the greatest impact on successful innovation implementation in AHA, especially for companies looking to target international markets. IN-4-AHA recognises that complete harmonisation might not be achievable in a reasonable timeframe; however, initiatives in specific areas and between individual Member States help companies greatly with their scale-up efforts.

Background

The 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 the WHO forecast², and 24.2% of the population of the European Union will be 65 or older³. This poses challenges for the society in general, but more specifically for health and social care. To address these changes, the European Commission created the European Innovation Partnership in Active and Healthy Ageing in 2011 with the aim to foster innovation in the field of active and healthy ageing.

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is an 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. The scale-up model and the roadmap are two of the main outcomes of the IN-4-AHA project. Both parts of the current report are 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 the project website at <https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/>

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

² Ageing and Health. WHO Fact Sheet, 2021. <https://www.who.int/news-room/fact-sheets/detail/ageing-and-health>

³ 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>

1. Scale-up Model

1.1. Assumption and Target Group

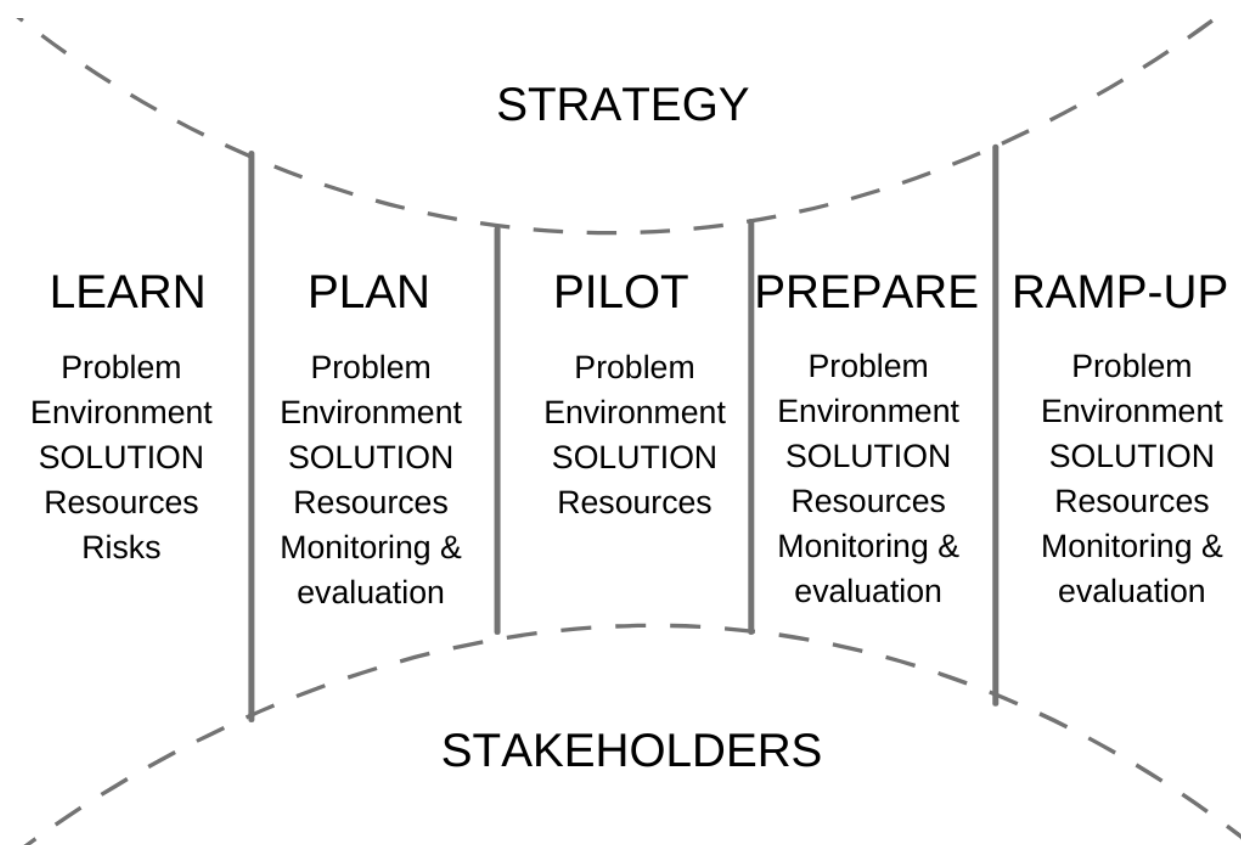
The scale-up model is intended for commercially driven entities whose innovative solution already has proof of feasibility on a local, regional or national scale but whose ambition is to expand, either internationally or into different regions. Small and medium-sized enterprises with none or little previous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

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

1.2. 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 set up a detailed plan to implement scaling up (PREPARE). Only when adequate preparations are made is it reasonable for the solution owner to enter the target market on a large scale (RAMP-UP).



Three out of the five phases described by the model are about information gathering and planning. Although this may not appear to be ‘active’ work on scale-up, collecting adequate information and analysing it is crucial. Each of these phases relies 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 in the target market, so it is a two-way movement.

Involving 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. A variety of tools are available for involving stakeholders. For example, one of the outputs of the IN-4-AHA project gives an overview of the principles of the participatory design process and suggests specific methods to be used⁴. 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 framework of the company’s strategic outlook. While start-ups are often more flexible in their perspective outlook, constantly checking whether the scale-up process is aligned with the company’s long-term goals keeps the progress on track. As with

⁴ Report ‘Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector’, compiled within 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

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 at 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 the company stands and what steps should be taken towards efficient scale-up.

1.3. Stakeholders

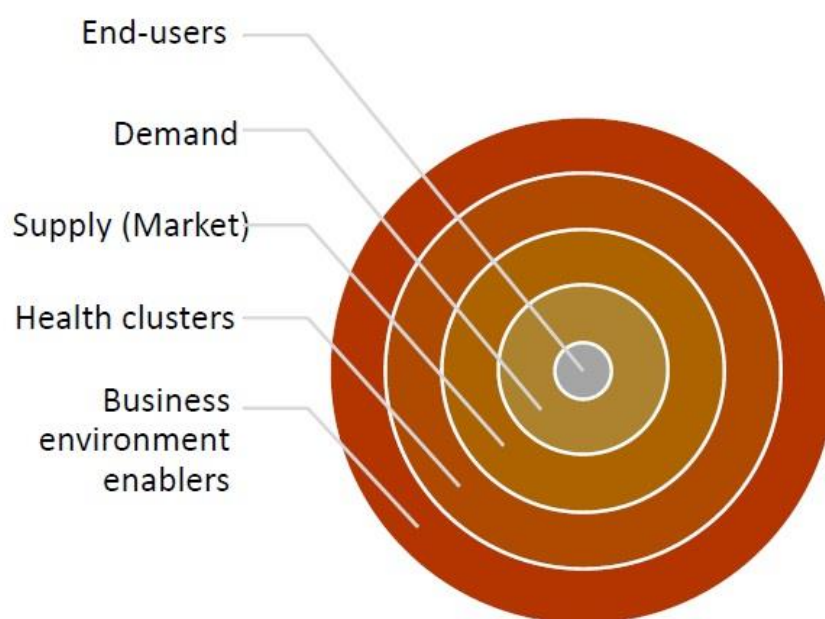
Involving stakeholders throughout the process of scaling-up is imperative – it ensures constant feedback for the entire scaling up process, provides better insight into the target market conditions and supports the company with acquiring the necessary approvals and achieving compliance with target market regulations. It also helps to ‘recruit’ supporters who champion the solution’s implementation in 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 design⁵.

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 policy-makers. The IN-4-AHA project recognises the importance of human-centeredness in the development and implementation of health and care solutions, especially when it comes to end users, who are often the elderly needing support with active and healthy living throughout the continuum. End users can also be family members, caretakers, medical professionals, etc.

In the healthcare sector there rarely exists a simple customer-supplier relationship, hence other stakeholders besides end users must be considered. The figure below demonstrates one way of viewing the layers of actors in the field. The needs of 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.

⁵ Report ‘Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector’, compiled within 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

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, SMEs, 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 a favourable environment for health technologies and to remove barriers in order to achieve 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 demand through healthcare providers and local, regional or national authorities (payers).

It is important to identify and involve the most significant stakeholders at every phase/component of the scale-up model. A variety of tools can be used for stakeholder participation, e.g. workshops. More information on this can be found in the IN-4-AHA report 'Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector'⁶.

⁶ Report 'Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector', compiled within 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

1.4. Phases and Components of the Scale-up Model

1.4.1. LEARN

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

Extensive research can be resource-consuming and can take the focus away from 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. This is also where industry/start-up support organisations can play a role – their knowledge and networks can provide a lot of the necessary initial information. Another option for starting to collect 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 idea as to whether scaling up is a feasible strategy and an initial understanding of whether and how their solution should be adapted to the target market. The decision the company must make at the end of this phase is whether to proceed or not.

1.4.1.1. Problem

The Scale AHA report concluded that one of the success factors for scaling up in AHA is addressing current healthcare needs⁷. To offer sustainable innovation to the market, the company must understand the problem they are targeting.

- 1) What is the problem the solution is designed to address in the current market?

An analysis of gaps in the AHA market was conducted within the framework of the IN-4-AHA project, after which it was suggested that instead of offering general solutions for the elderly, companies should focus on needs⁸ when designing their innovations. Hence, a well-defined problem, preferably from the point of view of the end user, lays a solid foundation for the entire scale-up process. The question to be answered is: which unmet need in the AHA market is the innovation aiming to alleviate?

- 2) Is the problem the same in the target market?

⁷ 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

⁸ Report 'Investment Readiness Assessment', compiled within 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

The same problem is not expressed in the same way in different environments, so it is not sufficient to assume that the unmet need in the target market is the same or similar. To gain a better insight, it is beneficial to start involving stakeholders as early as possible. Stakeholders are looked at in more detail in the following question.

3) Who is the need owner? What other groups are impacted by the problem?

Who is the individual, group or organisation that experiences the problem? Is the need owner in the target market the same or different from the current market? It must be noted that due to the nature of the health and care sector, the need owner is rarely the same as the customer and/or payer. Additionally, 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 several 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 project⁹.

4) What is the problem's impact?

What is the problem's effect, both qualitatively and 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 is it a significant disruption?

1.4.1.2. *Environment*

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

1) Regulatory and political environment

Health and care are part of a highly regulated field ensuring access to treatment and care and the health and safety of the population. Regulations vary between EU Member States and often between regions. EU-wide regulations might be relevant, e.g. 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

⁹ Report 'Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector', compiled within 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

assess how the scale-up process might work, anticipate upcoming regulatory changes and gain support from policy-makers.

2) Trends and demographics

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

3) End users and other stakeholders

The stakeholders identified during the analysis of the problem must now be described in more detail – what are their habits, abilities and perceptions towards new solutions? Which innovative solutions are they using? One option for describing the need owners and other stakeholders is to use personas¹⁰.

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, ageing, death, etc. can help avoid miscommunications. If necessary, the company should consult experts with knowledge of cultural differences and the elderly and their families/caretakers.

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 in the target market, for example what is the technological maturity level, what information systems are used for providing digital services, how do reimbursement schemes work, what are the procurement conditions for health and care providers?

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 in the target market as well as alternative solutions. What is their value proposition? How are they 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?

¹⁰ 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/>

1.4.1.3. *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) 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 assessment¹¹, MAST for evaluating the medical, social, economic and ethical aspects of telemedicine solutions¹². An overview of some of the assessment methods was composed within the IN-4-AHA project¹³.

One of the outputs of the IN-4-AHA project is a framework for evaluating the person-centeredness of the innovation¹⁴. As person-centeredness contributes significantly to the 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.

2) Does the solution address the need in the target market?

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

3) Who is the primary target group?

The target group (individual, organisation or public authority) that the company intends to address in the target market is not necessarily the same as the need owner defined in the 'Problem' component. Instead, it could be a demand actor – health or care provider,

¹¹ Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing. <https://www.mafeip.eu/the-tool>

¹² 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

¹³ 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

¹⁴ Report 'AHA Innovation Assessment Framework', compiled within 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

insurance provider or other. What value would the solution have for them? Determining the target group sets the basis for the company's business model.

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

1.4.1.4. Resources

When investigating what kind of resources are necessary for implementing the innovation in the target market, it is essential to look at a broader perspective than simply finances. The 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”*¹⁵.

Below are examples of resources to be considered, but the list is in no way exhaustive. To define the needs more accurately, components 1.4.1.1. 'Problem', 1.4.1.2. 'Environment' and 1.4.1.3. 'Solution' may need to be revisited.

At the end of this component, the company can critically evaluate whether 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) Finances

What is the estimated budget needed 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)? An overview of different financing options available to companies in the field is presented in the IN-4-AHA report 'Investment Readiness Assessment'¹⁶. The same report provides a checklist for start-ups preparing to raise investment (See Annex 4).

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

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 knowledge of the organisation's capability and resources to engage in international markets, experiential market knowledge, and experiential knowledge of institutional frameworks¹⁷. If there are missing competences, they can be filled by either hiring staff or involving service

¹⁵ 'Scaling up health services: challenges and choices'. WHO Technical Brief, 2008.

https://www.who.int/healthsystems/topics/delivery/technical_brief_scale-up_june12.pdf

¹⁶ Report 'Investment Readiness Assessment', compiled within 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

¹⁷ Achtenhagen, L. Internationalization competence of SMEs. Entreprenörskapsforum, 2011. https://entreprenorskapsforum.se/wp-content/uploads/2011/12/internationalization-comp_webb.pdf

providers. Clusters and other support organisations can also offer advice on internationalisation.

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

3) Partners

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

4) Infrastructure and supply chain

The existing infrastructure and processes in the target market were analysed in component 1.4.1.2. ‘Environment’. Are there any gaps that the company must fill in? What effort is required for the solution to be compatible with the local healthcare system? What is necessary to set up a supply chain?

5) Licences and permits

What kind of certification must the company pass to operate in the target market? How long is the application process and what kind of resources are necessary?

1.4.1.5. *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 dimensions should be addressed in parallel¹⁸:

- 1) Clinical risk, including aspects on how the solution will be accepted and adapted, and whether it produces the expected results.
- 2) Market/business risk, for example if the unmet need in the target market is adequate and whether there are enough payers willing to purchase the solution for a sustainable price.
- 3) Regulatory risk – the kinds of regulation that must be adhered to, the kind of effort and cost required.
- 4) Technical risk, including how the technological advantage will be protected.

¹⁸ 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>

1.4.2. PLAN

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

In this phase, stakeholder groups must be included to ensure the quality of the pilot, but also to build strong collaborative relationships in 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, a patient association to support lobbying, a legal expert to interpret local regulations, an industry organisation to help navigate the local business environment. Each stakeholder group 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 and whether and how the solution must be adapted for the pilot. If the company decides to proceed, they will have a tactical plan along with a monitoring and evaluation plan in place.

1.4.2.1. *Problem*

1) Re-definition of the problem

Using information collected during the LEARN phase and additional contributions from stakeholder groups, the problem in the target market can be specified. All aspects described in the ‘Problem’ component of the LEARN phase 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, do other parties (policy-makers, other solution providers, patient groups, care providers, etc.) have intentions or proposals for solutions?

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 testing. Hence, a decision must be made on which elements are crucial and which ones can be addressed with the pilot project.

1.4.2.2. *Environment*

Using information collected during the LEARN phase, 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.

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 in the next phase, a distinction must be made between which requirements are a necessity for a pilot, which must be followed in the 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 Guidebook¹⁹ offers an overview of the EC regulations on data management and protection.

2) Health and care setting

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

3) Cultural and behavioural aspects

Stakeholders in 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 and their family members and caregivers. To evaluate the user-centered aspects of the solution, the evaluation framework outlined in Annex 1 can be consulted.

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.?

1.4.2.3. *Solution*

The innovation would most likely 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.

1) What is the value proposition for the target market?

Based on the definition of the unmet need, the end users and target group, and the potential of the solution (all identified during the LEARN phase), the company must determine what benefits would its solution deliver in the target market. It must be emphasised that different stakeholders perceive the value of the solution differently.

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

¹⁹ Report ‘Data Governance Handbook’, compiled within 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

2) What is the aim of the pilot?

To ensure that the pilot project provides 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.²⁰? Which features of the innovation will be tested? Does the solution need to be adapted (e.g. simplified) for the pilot?

1.4.2.4. Resources

During this component, the plan to implement the pilot is formed. When analysing the necessary resources, it is useful to do it simultaneously with the next component – 1.4.2.5. ‘Monitor and Evaluate’. A well-defined monitoring and evaluation plan ensures an efficient use of resources and high-quality results.

1) Scope and scale

The scope of testing is determined by the aims defined in the previous component – 1.4.2.3. ‘Solution’.

Will the pilot be carried out in one site or in multiple sites? In the case of 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 one²¹.

2) Regulations

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

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

4) Adaption

²⁰ 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>

²¹ 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>

Based on component 1.4.2.3. ‘Solution’, 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?

5) Stakeholders

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

6) Activities

What kind of activities are necessary for a successful pilot? An analysis of the accessibility and adoption of services and products conducted within the framework of the IN-4-AHA project concluded that the main factor contributing to success is person-centered approach²². 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 what is its capacity for implementing the pilot project? Where are additional resources needed?

7) Finances

What is the estimated budget for the pilot project? Will it be financed from the company’s own resources or is external financing required – public grants, reimbursement (patients, insurance, service providers or public reimbursement schemes), investors, lending? When considering grants, the company must critically evaluate whether 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.

1.4.2.5. *Monitoring and Evaluation*

To assess progress and improve decision-making, it is necessary to continually collect, analyse and use data. Therefore, it is important to have a good data strategy in place as early as possible. The Data Governance Guidelines²³ were developed during the IN-4-AHA project to support companies in their data governance processes.

²² Report ‘Mapping of Accessibility and Adoption of Services and Products’, compiled within 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

²³ 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

Setting up the monitoring and evaluation plan is determined by the aims and objectives of the pilot defined in component 1.4.2.3. ‘Solution’. There are numerous tools available 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.

1.4.3. PILOT

A pilot project is a small-scale adoption of the solution, either in one setting or in 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 of 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, therefore relying on a successful pilot alone 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 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, whether and how the solution must be adapted.

1.4.3.1. *Problem*

- 1) Does the problem appear the same as that defined in the earlier stages?

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

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

- 2) With the new information gained during the pilot, are any additional venues for the solution opening up?

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

1.4.3.2. *Environment*

The company should monitor the same environmental aspects outlined in the LEARN and PLAN phases 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, finer and less obvious details will likely start playing a larger role (cultural, behavioural, process-related aspects).

1.4.3.3. *Solution*

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

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?

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.

1.4.3.4. *Resources*

This component is also based on the monitoring and evaluation set up in the PLAN phase. Comparing initially planned resources with what was needed provides input into planning for scaling up. Aspects to analyse include the resources outlined during the PLAN phase.

1.4.4. 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 minimise risks, the company must prepare extensively before committing to large-scale efforts. The 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 sufficient evidence before proceeding.²⁴

The PREPARE phase might be more time-consuming than the previous stages depending on which activities are necessary. For example, it might be necessary to build awareness, improve data interoperability, set 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 in the target market.

1.4.4.1. *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

²⁴ Nine steps for developing a scaling up strategy. WHO and ExpandNet (2010).
https://www.who.int/immunization/hpv/deliver/nine_steps_for_developing_a_scalingup_strategy_who_2010.pdf

addressing. The problem definition will be one of the fundamental pillars of the scale-up plan.

1.4.4.2. *Environment*

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

1.4.4.3. *Solution*

1) Aims and goals

Before setting up a plan for scaling-up in the next component, what the company considers a successful scale-up must be defined. Well-established aims and goals will be the base of both planning as well as monitoring and evaluation. Furthermore, the strategy for scaling-up must be determined. The WHO distinguishes between the following strategies for deliberate scaling²⁵:

- Horizontal – the company implements its solution in different geographical areas or in different or wider target groups. 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 policy-makers in the target market.

2) Market-ready innovation

Using data from the pilot project and factoring in feedback from stakeholders, the company should understand what the solution to be implemented on a large scale is exactly. If any modifications are needed, it will be tackled during the next component – 1.4.4.4. “Resources”.

3) Value proposition to stakeholders

The roles and expectations of different stakeholders have been analysed throughout the model. Now, the focus is on stakeholders who are potential 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 the potential value of the innovation to stakeholders helps to plan specific activities in component 1.4.4.4. ‘Resources’.

²⁵ Practical guidance for scaling up health innovations. WHO, 2019.
http://apps.who.int/iris/bitstream/handle/10665/44180/9789241598521_eng.pdf;jsessionid=7EF06593A38D3F3AFEEBBF658BCC0AF3?sequence=1

1.4.4.4. *Resources*

Along with component 1.4.4.5. ‘Monitoring and Evaluation’, 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.

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.

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.

3) Integration

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

4) Competences and capacity

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

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-up²⁶.

1.4.4.5. *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 out in component 1.4.4.3. ‘Resources’, constant monitoring and evaluation enables the company to prevent and minimise potential risks.

1.4.5. 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

²⁶ 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>

abrupt and society and culture are under constant transformation. Persistent monitoring and an ability to adapt contribute to the sustainability of the innovation.

2. Roadmap

The aim of the roadmap is to propose a set of actions to set up a favourable environment for the companies to scale-up their AHA solutions. Throughout the IN-4-AHA project, innovation in AHA was analysed from multiple aspects, such as person-centered design, data, investment, user involvement, etc. Several barriers to the efficient scale-up of novel services and products were identified and solutions for how to tackle these issues were proposed.

2.1. Barriers

IN-4-AHA identified a list of hurdles that hinder the implementation and internationalisation of AHA innovations. A detailed overview of the barriers pointed out can be found in Annex 5. Most of the challenges arise in the following areas:

- 1) Perception, awareness and acceptance
- 2) Understanding stakeholders
- 3) Accreditation and approval
- 4) Reimbursement and financing
- 5) Data

There is significant overlap between areas and many of the issues are interconnected. More details on the barriers can be found below.

2.1.1. Perception, awareness and acceptance

One of the crucial spheres where problems arise is the lack of understanding of innovation in AHA. Low awareness, misperceptions and lack of acceptance were pointed out as issues throughout all stages of IN-4-AHA. This applies to all stakeholder groups, from policy-makers²⁷ and health and care providers to the elderly and their families.

Focus groups and expert roundtables run within the framework of IN-4-AHA concluded that both public authorities and health and social care professionals have an insufficient understanding of innovative solutions in the AHA field. It is difficult for decision-makers and health and care workers to find accurate information about new services targeting the elderly and about how they compare to existing treatments. They do not realise the benefits of new solutions nor how those benefits are distributed between stakeholder groups.

The same applies to the elderly and their families. In addition to not understanding the value new solutions might provide, senior citizens might be more reluctant and distrusting of

²⁷ Report 'Recommendations on public-private collaboration', compiled within the framework of the project 'Innovation Networks for Active and Healthy Ageing', 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/Report-D3.2_IN4AHA_v4_29_6_final.pdf

change in general. They might fear that digital solutions will replace human contact or that they do not have skills to use the services and there is no-one to help them²⁸.

One of the reasons behind these problems is the lack of impact assessment and management. Due to the complexity of the health and social domain it is difficult to identify how to evaluate the impact of solutions, which aspects should be considered, and which tools should be used. Additionally, digital solutions add additional angles to be addressed, such as privacy and data protection for example²⁹. To conduct an efficient impact assessment, relevant, sufficient and high-quality data is needed – data-related problems are outlined in section 2.1.6.

The lack of understanding is also caused by lacking digital skills and communication. These aspects will be investigated in later sections.

2.1.2. Understanding stakeholders

Lack of awareness and understanding goes both ways. As the health and care sector has a large and diverse range of stakeholders, innovators do not always grasp what different groups, especially the elderly, need and think. The elderly as a population group tends to be stigmatised and there may be negative connotations to ageing. Companies frequently segment target markets by age; however, such groups can consist of very heterogeneous individuals^{30,31}. Innovators who are usually tech-savvy also misjudge the level of digital skills of the elderly and their caretakers as well as their accessibility to new solutions³². The latter includes devices and technical support, but also affordability.

An analysis of accessibility and adoption of novel solutions³³ was performed within the IN-4-AHA project, involving different stakeholder groups such as the elderly, their caregivers, social care and healthcare professionals and living lab professionals, and looked at case studies. The analysis concluded that the major problems for users stem from technical issues, interoperability problems and difficulties signing up.

²⁸ Report ‘Recommendations on public-private collaboration’, compiled within the framework of the project ‘Innovation Networks for Active and Healthy Ageing’, 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/Report-D3.2_IN4AHA_v4_29_6_final.pdf

²⁹ Report ‘AHA Innovation Assessment Framework’, compiled within 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

³⁰ Report ‘Investment Readiness Assessment’, compiled within 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

³¹ Report ‘Living lab testing and innovation scale-up playbook’, compiled within the framework of the project ‘Innovation Networks for Active and Healthy Ageing’, 2022. <https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/D4.1-Living-Lab-testing-and-innovation-scale-up-playbook-FINAL.pdf>

³² Report ‘Recommendations on public-private collaboration’, compiled within the framework of the project ‘Innovation Networks for Active and Healthy Ageing’, 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/Report-D3.2_IN4AHA_v4_29_6_final.pdf

³³ Report ‘Mapping of accessibility and adoption of services and products’, compiled within 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

IN-4-AHA focus groups also pointed out that companies tend to misunderstand the specifics of the health and care sector, especially the needs and competences of the medical professionals, care workers and decision-makers of those institutions.

2.1.3. Accreditation and approval

The fragmentation of jurisdiction between Member States is a significant barrier for scale-up of innovation in general³⁴. Getting acquainted with new target markets in Europe is already a significant effort due to the differences in health and care sector set-ups as well as language and cultural differences. In addition, companies need to make sure that they have the competence and resources necessary for understanding different regulatory requirements. Regulatory processes in health and social care are complicated, time-consuming and resource intensive. Furthermore, due to the novelty of digital health applications, regulations have not always caught up with the surrounding technology and issues.

When approval has been obtained in one target market, it does not carry over to other Member States, so innovators must start processes all over again, spending more time and resources.

2.1.4. Reimbursement and Financing

Reimbursement schemes are complicated to comprehend and navigate; and established compensation measures for digital products do not always exist. Additionally, reimbursement schemes not only vary between Member States but also between regions. Just as with the regulatory fragmentation, it is a significant hindrance to the implementation of novel solutions in new target markets. Due to the lack of impact assessment and low general awareness of innovative services and the AHA field, the payors find it hard to understand the benefits of new solutions.

Reimbursement is not the only finance-related issue innovators come across. There is a lack of financing options in general, especially in the early stages of operations. Innovators can make use of general research and development support measures, but when it comes to business development and market entry there are limited public schemes and private investments available. Furthermore, the long perspective on return on investment and the general lack of understanding of AHA mean that private investors are hesitant to get involved. As the implementation cycles in the AHA field are long, companies need resources to carry them over the gap from development until they either raise investments or earn their first revenues³⁵.

2.1.5. Data

The lack of knowledge and skills in data management often turns out to be a pitfall for companies. Relevant and high-quality data is necessary for development, implementation and impact assessment. Innovators do not always possess the necessary competences – in addition

³⁴ Report ‘Investment Readiness Assessment’, compiled within 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

³⁵ *Ibid.*

to traditional data management, aspects such as privacy, consent, security, etc. must be taken into consideration when it comes to AHA³⁶.

The regulatory environment is difficult to navigate for companies. As with approval and reimbursement schemes, the application of regional, national and EU-level data-related regulations is complicated for innovators. Getting access to existing data in biobanks and registries is a complicated, lengthy and bureaucratically heavy process. Interoperability and quality of data pose another set of barriers – using and integrating datasets from different sources, cleaning and updating/enriching data, etc³⁷.

2.2. The Proposed Roadmap

Throughout IN-4-AHA, a variety of solutions were suggested to address the outlined issues – a detailed overview can be found in Annex 5. Analysing both sides, it is evident that barriers are often interconnected, and the solutions proposed directly or indirectly impact more than one issue.

Hence, instead of focus areas, the roadmap identifies three main stakeholder groups – innovators, enablers and policy-makers – to implement activities necessary for successful scale-up in AHA. Innovators are companies, usually SMEs, with international ambition and an (early-stage) innovative solution. Enablers include clusters, industry organisations, reference sites, living labs, incubators and other organisations working with companies, supporting them with development, implementation and internationalisation. Policy-makers include European, national and regional level decision-makers.



³⁶ Report 'Data Governance Handbook', compiled within 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

³⁷ *Ibid.*

The roadmap proposes a set of activities for each group, with overlap in several areas; however, each group has a different time perspective to consider. Innovators need to implement proposed activities from the beginning of their undertaking. Although these activities must be ingrained in their strategic outlook, they are presented as short-term to mid-term, as it is necessary to implement these principals daily.

Enablers operate on a mid-term timescale, as carrying out their activities requires longer planning, involving stakeholders and often building consensus between the latter. The same applies to most of the activities proposed to the policy-makers, especially as the processes related to them can be complicated and time-consuming.

All three actors must be in constant communication with each other. Successful scaling-up depends heavily on all relevant stakeholder groups, so stakeholder involvement is a common theme for all three actor groups and their activities. There is a wide range of methods available that can be used to involve stakeholders – some are suggested in the IN-4-AHA report ‘Participatory Design Process Principles’³⁸.

2.2.1. Innovators

Innovators in the AHA field can be companies at different phases of development; however, what is common between them is their commercial goals and international ambition. The scale-up model described in the first half of the current report provides companies with step-by-step guidance on how to proceed towards large-scale implementation with their solutions and offers references to tools that can be used for strategic decisions as well as tactical planning. While the scale-up model describes the journey to scaling-up in more detail over time, the roadmap focuses on three principal activities that are essential throughout the process: adopting a person-centred approach, implementing good data management practices as early on as possible, and conducting impact assessment. These activities are interconnected and give the best results in synergy with one another.

2.2.1.1. *Adopt a person-centered approach*

The IN-4-AHA project concluded that one of the main factors contributing to success in AHA is a person-centered approach to innovation³⁹. This means that product development should start from targeting needs instead of demographic groups⁴⁰, and users and other stakeholders should be considered and involved from an early stage. In turn, this means that the focus should not only be on the elderly, but also on caretakers, medical professionals,

³⁸ Report ‘Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector’, compiled within 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

³⁹ Report ‘Mapping of Accessibility and Adoption of Services and Products’, compiled within 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

⁴⁰ Report ‘Investment Readiness Assessment’, compiled within 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

healthcare providers, etc. The involvement should be iterative and continuous throughout the development and scaling-up process.

IN-4-AHA provides companies with some tools for implementing a person-centred approach, such as a participatory design toolkit⁴¹ to analyse which stakeholder groups are relevant and in which stages they should be involved. Another IN-4-AHA report suggests specific techniques for stakeholder involvement through workshops⁴². Companies can make use of the person-centred measurement tool developed within the framework of IN-4-AHA⁴³. Testing solutions in living labs is an excellent way to refine innovations and include stakeholders – the IN-4-AHA project provides guidance to start-ups and SMEs on how to prepare and conduct living lab testing⁴⁴.

To help identify which organisations and individuals should be involved, companies can turn to clusters and industry organisations. Enablers often have extensive networks and experience working with similar SMEs, so in addition to giving recommendations they can provide access to their contacts internationally.

A person-centred approach is not limited to gaining insights from stakeholders during development – communication must work two ways and should be continuous. Throughout development and implementation, it is important for the solution owners to communicate, raise awareness and support all relevant groups in order to ensure that their solution is understood, favoured and used⁴⁵.

2.2.1.2. Implement good data management

For successful scale-up, data on effectiveness, impact and feasibility is essential. The companies need proof-of-feasibility before they start scaling up; there are regulatory requirements for implementation in clinical and social settings and good data management facilitates many other processes when it comes to implementation. Therefore, good data practices should be implemented as early as possible. IN-4-AHA considers data management as a feedback loop that creates value and includes multiple functions – planning, designing

⁴¹ Participatory design toolkit, composed within the framework of the project “Innovation Networks for Active and Healthy Ageing”, 2022. <https://innovation4ageing.tehnopol.ee/toolkit/>

⁴² 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

⁴³ 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

⁴⁴ Report “Living lab testing and innovation scale-up playbook”, compiled in the framework of the project “innovation Networks for Active and Healthy Ageing”, 2022. <https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/D4.1-Living-Lab-testing-and-innovation-scale-up-playbook-FINAL.pdf>

⁴⁵ *Ibid.*

and enabling, creating or obtaining, storing and maintaining, using, enhancing and disposing⁴⁶.

Developing AHA solutions means that innovators must take a large variety of aspects into account, starting from data infrastructure but also privacy, consent, security, etc. When planning data strategy, it is important to consider both internal factors as well as the environment – existing infrastructure, available databases, and regulatory setting. Companies can consult IN-4-AHA’s ‘Data Governance Guidebook’ for more details⁴⁷.

2.2.1.3. *Conduct impact assessment*

To raise awareness, build favourability and succeed in implementing the solution, impact assessment is crucial. It is necessary to evaluate the potential health and quality-of-life effects of the solution as well as analyse the economic, social, environmental and other impacts. Impact assessment can be both qualitative and quantitative and use a variety of inputs, from (potential) user feedback to clinical data. A range of tools are available to help with appraising the solution, for example MAFEIP for health and economic impact assessment⁴⁸, MAST for evaluating the medical, social, economic and ethical aspects of telemedicine solutions⁴⁹, etc. An overview of some of the assessment methods was composed within the IN-4-AHA project⁵⁰.

When planning an evaluation, it is important to consider the purpose of the assessment (for example, contribute to achieving regulatory approval, help convince healthcare providers to adjust their processes, supply information for elderly and their families) and select the most appropriate methods. Clusters, industry organisations and other enablers can help companies by suggesting suitable tools and partners for conducting impact assessment.

2.1.2. *Enablers*

Clusters and industry support and representation organisations play a major role in supporting innovation in the AHA field. Through their experience with different companies, they possess competences and contacts that individual companies, especially start-ups, lack. The task of the enablers is to guide innovators to target markets, offer business development advice,

⁴⁶ Report ‘Data Governance Guidebook’, compiled within 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

⁴⁷ Report ‘Data Governance Guidebook’, compiled within 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

⁴⁸ Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing. <https://www.mafeip.eu/the-tool>

⁴⁹ 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

⁵⁰ Report ‘Overview of Evaluation Toolkits’, compiled within 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

share information on funding opportunities and use their own networks to support the companies' activities towards scaling-up.

These organisations serve as a connection point between innovators and policy-makers and many other stakeholders. Their ability to understand different groups empowers them to mediate between stakeholders and represent and communicate the companies' interests and needs to authorities, investors and the health and social care sector. Additionally, their competences and networks mean they are suitable partners for the public sector in initiating and implementing activities and programmes meant to facilitate innovation in AHA.

2.1.2.1. AHA-specific business development support

While the clusters and industry organisations have been offering companies a large variety of business development services, they need to be more focused on the specifics of the AHA field. While there are plenty of service providers on the market to offer companies target market and regulatory advice, they often lack either the bigger picture or the AHA-specific competence.

The role of enabler is both to provide support to individual companies and to develop the AHA innovation community in general. Providing information on target markets, directing to approval and reimbursement schemes and networking are just a few of the functions that clusters and other organisations fulfil. Based on the conclusions of the IN-4-AHA project, enablers must turn special attention to two aspects when it comes to AHA – financing and testing. Testing will be looked at in section 2.2.2.3.

As companies often struggle with finding financing, it is up to enablers to provide them with information on public support schemes as well as train innovators for investor-readiness. Clusters can also work in the other direction – involving and educating the investor community in AHA and its benefits and setting up contacts for companies.

2.1.2.2. AHA innovation platform

The IN-4-AHA project concluded that the information on AHA initiatives and best practices in Europe is currently fragmented. To ensure that the field develops from individual activities to a movement, a common platform is necessary. The AHA innovation platform should connect all related stakeholders from companies and investors to health and social care providers, representatives of elderly users and public authorities and provide information on existing solutions, best practices, collaboration, financing opportunities and more^{51,52}.

While the initiative should include all relevant parties, and setting it up requires public sector support, it is the enablers who are most fit to implement such a platform. With their networks and experience, they have the most comprehensive overview of what needs to be included,

⁵¹ Report 'Recommendations on public-private collaboration', compiled within the framework of the project 'Innovation Networks for Active and Healthy Ageing', 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/Report-D3.2_IN4AHA_v4_29_6_final.pdf

⁵² Reference to policy recommendations (will be available from December 2022) <https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/>

which functions the platform should serve and how to make sure that the platform is useful, usable and sustainable.

2.1.2.3.AHA-specific accelerator and testing programmes

Enablers often have extensive experience supporting the commercialisation of innovative technologies; however, not all programmes designed for technology uptake suit the AHA field. When it comes to novel solutions in health and care, there is a gap of understanding between commercialisation and social responsibility, and the journey from development to implementation is lengthy. Hence, AHA-specific accelerators and testing programmes are necessary. These could be conducted with support and contributions from the public sector.

IN-4-AHA recommends that accelerator and testing programmes in AHA include practicing experts, data training, legal mentoring, access to real-world data, access to real-world testing environments, such as living labs, proof-of-concept funding initiatives, support for market access and contact with investors⁵³. The IN-4-AHA playbook on living labs gives recommendations on how to plan and conduct AHA innovation testing in living labs, which are multi-stakeholder testing environments portraying real-life conditions⁵⁴.

2.1.3. Policy-makers

Considering current demographic trends and the implications, AHA is an extremely important area for policy-makers to focus on. Novel solutions not only promise improvements in health and quality of life for elderly individuals but also have significant social and economic benefits that are distributed between stakeholder groups – families, caretakers, health and social professionals, healthcare systems, etc. As policy-makers have a comprehensive and long-term view of health and social care, they must recognise the necessity to facilitate the implementation of new products and services in AHA.

Two activities in which the public sector should take initiative and/or participate in collaboration with the enablers were outlined above: creating a common AHA innovation platform and running AHA-specific accelerators and sandboxes. Four more focus activities are suggested by the roadmap: setting up sandboxes, providing early-stage funding options for innovators, raising skills and competences, and working towards the harmonisation of regulations in the EU. The latter is a long-term aim that requires a great deal of political consensus and efforts. Creating sandboxes, funding options and improving competences are activities that can be conducted in a shorter timeframe, but they still have compelling effects

⁵³ Report ‘Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector’, compiled within 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

⁵⁴ Report ‘Living lab testing and innovation scale-up playbook’, compiled within the framework of the project ‘Innovation Networks for Active and Healthy Ageing’, 2022. <https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/D4.1-Living-Lab-testing-and-innovation-scale-up-playbook-FINAL.pdf>

on innovation in AHA. More detailed policy recommendations can be found in the relevant IN-4-AHA report from December 2022⁵⁵.

2.1.3.1. Government-backed sandboxes

In addition to innovators' own efforts and enablers' contributions, the public sector can support stakeholder involvement and human-centered design in AHA with specific initiatives. IN-4-AHA suggests that governments set up sandbox environments, where companies could work on pre-defined health and social care problems, create stakeholder networks and refine their innovations. Such sandboxes would not only help innovators already active in the AHA field but also encourage other companies to explore the potential of silver economy⁵⁶.

2.1.3.2. Early-stage financing

As development and implementation cycles are long in AHA, it is often difficult for companies to finance their scale-up ambitions. Public support mechanisms are available for initial development, and it is easier to attract investors after the first reference of implementation, but the gap in between must be covered by public support mechanisms, such as targeted project calls, innovative tenders, incubators and increased emphasis on innovation procurement⁵⁷.

Public financing of AHA innovations would show the importance of the sector and encourage investors to participate. Another way that policy-makers could build the trust of the investor community is by developing AHA-centered investment platforms.⁵⁸

2.1.3.3. Literacy, skills and competences development

While innovators and enablers work on communicating and educating on the general public and their stakeholders, strategic technology and AHA-related education should be carried out by the public sector. Three areas should be focused on: general digital literacy of citizens, digital skills of health and care professionals, and data management skills of innovators and health and care providers.

General digital literacy can help citizens feel less intimidated by technology and increase trust in new interventions in general⁵⁹. Improving the digital skills of health and care professionals creates more understanding of the value provided by new innovations as well as

⁵⁵ Reference to Policy Recommendations (will be available from December 2022)

<https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/>

⁵⁶ Report 'Investment Readiness Assessment', compiled within 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

⁵⁷ Reference to policy Recommendations (will be available from December 2022)

<https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/>

⁵⁸ Report 'Investment Readiness Assessment', compiled within 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

⁵⁹ Reference to Policy Recommendations (will be available from December 2022)

<https://innovation4ageing.tehnopol.ee/tools-and-outputs/project-outputs/>

increases demand for novel services. Updating data-related education helps innovators create better solutions, enables better uptake of those innovations and builds general confidence in how the health and personal data is used.

2.1.3.4. Harmonisation

The long-term aim for the European Union should be the harmonisation of policies and procedures, covering approval as well as reimbursement. It should start with Member States and the EC reviewing current regulations to ensure that information is accessible by innovators and that the requirements and procedures are understandable and efficient. Member States should be collaborating in conducting such reviews, as they could identify common features in their policies. This would ideally eventually enable innovators that have their solution approved in one Member State to enter the market in another Member State via a more simplified procedure.

While complete harmonisation might not be realistic in a reasonable timeframe, especially when it comes to reimbursement, regulators could start working on smaller-scale initiatives in specific areas such as research ethics, medical device approvals, data sharing practices etc.⁶⁰. Some initiatives in the abovementioned fields have already been started, e.g. the European Health Data Space^{61,62}.

⁶⁰ Report 'Participatory Design Process Principles and the Needs of Innovation Scale-Up in the Health and Care Sector' compiled within 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](https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Revised_Updated_D3.1_Participatory-Design_-_NeedsOfInnovation_Dec2021docx.pdf)

⁶¹ Report 'Data Governance Guidebook', compiled within 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

⁶² European Health Data Space, European Commission. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

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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

Health outcomes

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*

Early detection

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

Accordance to needs

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*

Usability and accessibility

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*

Trust and respect

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 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 themselves or 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 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.



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)

Annex 5: Barriers to AHA scale-up and proposed solutions

CHALLENGES	PROPOSED SOLUTIONS
Awareness, perception and acceptance	
<ul style="list-style-type: none"> ▪ Lack of understanding of healthy ageing⁵ ▪ There is a stigma associated with getting old/the older generation⁷ ▪ Low awareness and knowledge of digital solutions and how they compare to traditional treatments⁴ ▪ The value of implementing innovation is not clear to users in the public sector² ▪ The lack of recognition by central authorities that digital health applications are a new entity which must be approved and prescribed by the practitioners⁴ ▪ Lack of acceptance by healthcare professionals⁴ ▪ Weak digital skills of health and care workers² ▪ Stiffness of the public medical systems and inertia towards adopting new digital tools and processes² ▪ No reference for where to find accurate information about the devices that meet the needs and preferences of the elderly⁴ ▪ Senior citizens might be against new services by default, people do not trust new solutions, they might be scared of new techniques, they might not have anyone to help them² 	<ul style="list-style-type: none"> ▪ Initiatives to change attitudes via education and intergenerational contact⁷ ▪ Create an ecosystem with all stakeholders involved^{1,3,5,7} ▪ Demand-driven: there has to be a strong need identified by the user, the innovation has to be a solution to a problem² ▪ A move towards needs-based solutions, rather than aged-based, shifting from healthy ageing to healthy living⁷ ▪ Co-creation: the solution has to be developed/piloted between the demand and the supply side, and there has to be a commitment from the end-user to acquire the solution if the pilot is successful² ▪ Informing and teaching stakeholders in order to accept a new solution, customer development^{2,3} ▪ Training programmes to learn and adapt to changing standards, tools and services due to the wide adaption of technology in the health and care sector^{1,4} ▪ Healthcare professionals need to receive benefits from the use of digital health applications⁴ ▪ Building trust between inventor and customer, finding new approaches via repurposing existing techniques²
Understanding stakeholders	
<ul style="list-style-type: none"> ▪ Innovators lack understanding of their stakeholders⁷ ▪ Digital solutions are often not user friendly² ▪ Products and services do not meet user needs³ ▪ Accessibility barriers⁸ 	<ul style="list-style-type: none"> ▪ Create an ecosystem with all stakeholders involved^{1,3,5,7} ▪ Companies need to perform comprehensive stakeholder analysis⁷ ▪ Demand-driven: there has to be a strong need identified by the user, the innovation has to be a solution to a problem²

	<ul style="list-style-type: none"> ▪ A move towards needs-based solutions, rather than aged-based, shifting from healthy ageing to healthy living⁷ ▪ Focus on person-centered care³ ▪ Continuous testing³ ▪ Government-backed sandboxes to facilitate stakeholder relations⁷
Accreditation and approval	
<ul style="list-style-type: none"> ▪ The AHA market is deemed as highly fragmented in the EU^{5,7} ▪ Regulatory barriers¹ ▪ Lack of legislation and protocols to integrate digital technologies in providing health and care services² ▪ SMEs/start-ups have difficulty understanding what is necessary and beneficial for approval⁴ 	<ul style="list-style-type: none"> ▪ The regulatory aspect should focus on removing barriers to scale-up across borders, addressing issues such as health data privacy, licencing and reimbursement of innovative health and care services¹ ▪ One common and integrated regulatory framework (research ethics, medical device approvals and similar)¹ ▪ Transparent and straightforward processes for developing, testing, validating and commercialisation of innovative products/services, clear path to certification and market approval, as well as business models and payment model¹ ▪ If a digital product has been approved in one EU country, it should be possible to use it in other Member States too. This process would require trust and automation since it would require the transfer of data and licences.⁴ ▪ Initiate small-scale collaboration between individual Member States⁴ ▪ In the context of a fragmented EU market, companies should place a bigger emphasis on well-defined action plans and on ways to address sudden changes in legislation and requirements⁷
Reimbursement and financing	
<ul style="list-style-type: none"> ▪ The payer does not understand the distribution of the benefits of a digital solution between the payers, the clinicians and the patients⁴ ▪ Returns on investments, financial benefits of digital applications are difficult to estimate⁴ ▪ There is a gap in discourse – private investors seeking commercial returns 	<ul style="list-style-type: none"> ▪ Initiatives to encourage investor activity in the AHA market (accelerators, EU-launched AHA investment platforms, novel venture capital models)⁷ ▪ Focus on sustainability-driven investment strategies⁷ ▪ Favour innovation in public procurement⁵

<p>while health and elderly care are seen as a social responsibility¹</p> <ul style="list-style-type: none"> ▪ Lack of funding, especially beyond the functional prototype/early product version⁵ ▪ Reimbursement models differ between Member States⁴ ▪ Lack of investor activity in the AHA field⁷ 	<ul style="list-style-type: none"> ▪ Public funding programmes to support knowledge and labour transfer between academia and industry¹ ▪ Educating private investors on the peculiarities of knowledge-dense business models¹
Data	
<ul style="list-style-type: none"> ▪ Wide range of regulations on privacy protection and data use at EU and national levels – hard to follow for solution providers^{1,6} ▪ Data access: challenging to get access to health data in registers and biobanks for product validation, unclear procedures^{1,6} ▪ Quality of data: complicated to get input for digital solutions – different data formats, fragmented information, data is not in machine-readable format⁶ ▪ Narrow consent to use data – consent for using data to provide care and consent for using data for research are separate⁶ ▪ Data interoperability: challenges of interoperability (bringing different datasets together, integration from different sources), organisation-specific policies and practices vary (different data user classes and exchange protocols, different terminology, data security and ways of identifying people etc.)⁶ ▪ Data management capabilities: need for new skills and updated curricula in both biomedical and data science (such as digital literacy, basic genomics, machine learning, AI) for all health care providers⁶ ▪ Lack of proper and suitable data for impact assessment and management for policy-making, regulatory bodies and healthcare regions for digital health solutions⁶ 	<ul style="list-style-type: none"> ▪ Innovations with scaling potential would benefit from national and EU level decisions on harmonising how personal health information can be shared. The European Health Data Space (EHDS= supplements the GDPR with additional rights and mechanisms related to using and sharing personal data.⁶ ▪ Standardising patient health files and ensuring that electronic health data is interoperable and can be accessed across the block⁶ ▪ Responsible data-sharing initiatives driven by industry, promoting open technologies such as the Open Electronic Health Record and appropriate encryption tools and security standards⁶ ▪ It is recommended to disseminate semantics and other data standards developed by industry networks. Policy-makers should coordinate their use in public as well as private procurement of services⁶ ▪ Citizens as data subjects must be able to decide autonomously on the use of their data. The competences of a citizen in dealing with their own health data should be raised by awareness and training activities.⁶ ▪ Actors in the health and care ecosystem, including service providers and technology providers should get access to training on data management. Organisational data management capabilities need to be strengthened by support programmes and dedicated funding⁶
Other	

<ul style="list-style-type: none"> ▪ Lack of business support for AHA start-ups in the early stages⁷ ▪ Clinical implementation barriers⁵ ▪ No proper plan for evidence-generation³ 	<ul style="list-style-type: none"> ▪ National and EU level initiatives to support start-ups in AHA markets⁷ ▪ Dedicated efforts towards a higher level of digitalisation in the health and care sector to enable effective use of resources¹ ▪ Specialised accelerators and sandboxes for AHA businesses^{1,7}
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Sources:

¹ IN-4-AHA report "Participatory Design Process Principles and the Needs of Innovation Scale-Up in the Health and Care Sector", 2021. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Revised_Updated_D3.1_Participatory-Design_NeedsOfInnovation_Dec2021docx.pdf

² IN-4-AHA report "Recommendations on public-private collaboration", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/Report-D3.2_IN4AHA_v4_29_6_final.pdf

³ IN-4-AHA report "Living lab testing and innovation scale-up playbook", 2022. <https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/08/D4.1-Living-Lab-testing-and-innovation-scale-up-playbook-FINAL.pdf>

⁴ IN-4-AHA expert roundtable "Digital health applications' frameworks for the Nordics: focus on DiGA", 24th November 2021

⁵ IN-4-AHA expert roundtable "'Challenges in scaling up innovation for active and healthy ageing", 7th April 2022.

⁶ IN-4-AHA report "Data Governance Guidebook", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/06/D5.3_Data-governance-guidebook_full-text_final.pdf

⁷ IN-4-AHA report "'Investment readiness assessment of the AHA market", 2022. https://innovation4ageing.tehnopol.ee/wp-content/uploads/2022/04/Final_D6.1-Investment-readiness-assessment.pdf

⁸ IN-4-AHA focus groups on accessibility to technological solutions, 2022.