

in4aha

LIVING LAB TESTING AND INNOVATION SCALE-UP PLAYBOOK

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

Work Package: WP4 Service Tests and Adoption

Deliverable: 4.1 Living Lab testing and innovation scale-up playbook

Dissemination level: Public

Version: 2.0, 30.06.2022

2022



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

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

Innovation Networks for Active and Healthy Ageing (IN-4-AHA) is a project funded by the European Commission under the Horizon 2020 programme Coordination and Support Action (CSA), Grant Agreement No. 101017603.

This document has been prepared within work package 4 (Service tests and adoption) task 4.1 (Living lab testing and innovation scale-up model validation). This deliverable is to be reviewed and approved by the European Commission.

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>

https://twitter.com/EIP_AHA

<https://www.linkedin.com/groups/8912125/>

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

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

<https://digital-strategy.ec.europa.eu/en/policies/eip-aha>

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History of changes

Version	Date	Modifications
1.0	03.06.2022	
2.0	30.06.2022	Structural changes (e.g., separate chapters for tools) Add more experiences gained in the testing and scale-up process with IN-4-AHA pilot companies Language check Overall modifications for streamlining the text

Executive summary

Health and care systems are facing major challenges as the world's population ages rapidly. At the same time, digitalisation offers enormous opportunities to overcome these challenges and creates business potential for the development of scalable Active and Healthy Ageing (AHA) innovations.

Creating valuable and scalable innovations in the AHA field requires multidisciplinary collaboration of a wide range of stakeholders. One of the environments bringing stakeholders together is living labs, which can play an important role in assessing the relevance of innovations for the end-users. Living labs can act as intermediaries or innovation facilitators for collective learning in the co-creation processes.

Scaling up means deploying solutions on a larger scale. Scaling up is not a straightforward process because it may require going back to previous development stages or testing new aspects when seeking new customer segments or entering new markets. Startups should have their business model in mind already at an early stage, and especially their value proposition to end-users and customers, for guaranteeing a successful scale-up of digital health and care solutions.

The playbook highlights the learnings from the living lab testing and coaching process with pilot companies. Five pilot companies were selected in an open call, aimed at organisations that have a scalable digital or technology-supported innovative solution and wish to scale it up, promote it outside the domestic market, test it in co-creation with users in real-life environments in living labs, and receive business coaching for the idea from an international coaching team.

This playbook offers guidance on how to test innovative AHA solutions for scaling up. Guidance is provided to startups but also for all parties interested in living lab testing and scaling up AHA innovations. Moreover, guidance and advice for startups planning to scale up their AHA business into international markets is presented.

About the IN-4-AHA Project

Innovation Networks for Scaling Active and Healthy Ageing (IN-4-AHA) is an EU-funded project focusing on empowering the cross-border scale-up of tested and ready-to-use applications in the fields of health and care. Service providers such as startups, small and medium-sized enterprises (SMEs) and large industries need the support of ecosystems. IN-4-AHA brings together supply and demand actors to create sustainable models for innovation scale-up. Demand actors include, for example, health and care institutions and local governments who are responsible for providing services to ageing communities. The role of the ecosystem is to encourage supply actors – innovators – to step up and create user-centred strategies and transformative solutions. This may lead to the need for changes in ecosystem operations to gain success with digital solutions for AHA, smart age-friendly homes for independent living or chronic disease management. The goal of the project is to identify and encourage the interaction between ecosystem actors by addressing the challenges that innovators face in market uptake and expansion in the domestic and cross-border markets, and to enable digitally enabled, person-centred care solutions. The project addresses especially the challenges of implementing AHA solutions and scaling them up in the market. This Living Lab Testing and Innovation Scale-up Playbook summarises the experiences gained in the IN-4-AHA WP4 testing and coaching process. Under the project, an open call was arranged, aimed at organisations that have a scalable digital or technology-supported innovative solution and wish to scale it up. The living lab tests and validation activities of WP4 are described in detail in Appendix 1.

LIVING LAB TESTING AND INNOVATION SCALE-UP PLAYBOOK

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Introduction

Health and care systems are facing major challenges as the world's population ages rapidly. At the same time, digitalisation offers enormous opportunities to overcome these challenges and creates business potential for the development of scalable Active and Healthy Ageing (AHA) innovations. This Living Lab Testing and Innovation Scale-up Playbook (hereinafter “the playbook”) offers guidance on how to test innovative AHA solutions for scaling up. Guidance is provided to all parties interested in scaling up AHA innovations.

This playbook builds on two approaches which have become increasingly popular recently: design thinking and lean startup. Both approaches are based on the idea that the co-creation of innovations with customers and end-users leads to better results. When developing and scaling up innovations for AHA, it is important to ensure the involvement of all relevant stakeholders, including end-users and professionals, because these solutions can succeed only through joint efforts. Therefore, understanding ecosystems is essential.

The innovation process goes through different stages. With each stage, a deeper understanding accumulates of how to best meet the needs of end-users and how to link the innovation to existing systems. Testing is a natural part of the process, and it should take place in each phase and after each step – the only thing that changes is the object of testing.

Objectives and target groups of the playbook

The main objective of this playbook is to give advice on how to test AHA solutions for scaling up – for example, how to adapt solutions to different use cases, different contexts, different factors in technology, policy or regulatory conditions. Therefore, the main idea is to harmonise and find common ground for scaling up innovative solutions. Guidance is provided for startups, small and medium-sized enterprises (SMEs) and other *innovators* for testing and scaling up, but also for *clusters*, Reference Sites¹ and business accelerators on how to carry out the testing. In addition to these target groups, anybody interested in living lab testing or scaling up innovations can find this book interesting.

Creating valuable and scalable innovations in the AHA field requires multidisciplinary collaboration of a wide range of stakeholders from different backgrounds. One of the environments bringing stakeholders together is living labs, which can play an important role in assessing the relevance of innovations for the end-users. After this introduction, the first chapter of the playbook provides insights into living labs – what they are, what problems they can solve and how they can help innovators in the co-creation and testing of user-centred care solutions together with and for users. The second chapter focuses on the opportunities and challenges of scaling up innovations in the AHA sector and how to be aware of or overcome some of them. Both chapters are divided into sections with tips on how to design a testable AHA solution or a flexible business model, and practical tools for self-assessment.

¹ About Reference Sites see later section Where can they be found? Different types of living labs and similar concepts and <http://www.rscn.eu/>

Background

There is a major demographical change ahead, as the world's population ages at a much faster pace than ever before. According to the World Health Organization (WHO), by 2050, the number of people aged 60 years and older is expected to be 2.1 billion, and the proportion of people 60 years and older will almost double from 12% in 2015 to 22% in 2050. In addition, the number of years lived in good health has remained approximately the same as before, suggesting that any additional years are generally lived in poor health. (WHO, 2022). By 2060, one third of all Europeans will be over 65 years old, meaning that in this region the shift will be taking place even faster than globally (Michel et al., 2021; European Union, 2019).

This creates major challenges for the health and care systems with a triple aim: improving population health, enhancing user experiences and bringing down costs (Molema and van Egmond, 2017; Vereycken et al. 2019; Aanestad and Vassilakopoulou, 2019). The financial and organisational sustainability of European health and care systems and social security are at stake (Michel et al., 2021). The health and care sector will also face the challenge of not having enough workers in the future. The caregiver shortage is a global crisis, but it is also an opportunity for startups offering technology solutions allowing human caregivers to focus on the human aspects of caregiving, companionship and emotional support, while letting robots take care of manual work, such as laundry-folding (Etkin, 2022).

People will need more aids and technologies to enable them to live independently in their own homes for longer (Nordic infrastructure of test beds, 2017). "Ageing in place" is also the wish of the majority of older adults, who prefer to live in their homes for the rest of their lives. Therefore, the opportunities for living in one's own home and community safely, independently and comfortably, regardless of age, income or abilities, must be improved. Technology can help overcome these challenges, but ageing societies urgently need innovations to address these gaps. (Etkin, 2022).

Digitalisation is seen as one of the bases for innovation. Innovative solutions aim at people living longer in better health and with better quality of life, but also at establishing more sustainable, cost-efficient health and care systems. Information and communications technology (ICT) has the potential to cut age-related health costs, while simultaneously improving care services and increasing the social and economic role of the elderly in society (Mantovani and Turnheim, 2018).

Similarly, the demographic shift presents significant emerging market opportunities, referred to as the silver economy or the senior market. These market opportunities span from consumer goods and services targeted to the elderly population to devices and services supporting autonomy and home care, often combined with new technologies (e.g., artificial intelligence, big data) and customised medicine. (Michel et al., 2021; European Commission, 2018, 2018a). The ageing population creates a need to expand access to health and care services and to scale up innovative products and services. However, the elderly form a heterogeneous group. Age is just a number, and some 80-year-olds have the same physical and mental capacities as many 30-year-olds, whereas some people experience a significant decline in their health at a young age (WHO, 2022). To address this wide range of needs, health and care systems must become flexible, but at the same time, market opportunities for companies are vast.

These needs and aims can be supported by the promotion of user-centred, demand-driven innovation, which brings value to people and helps health and care systems manage their costs. Creating valuable and scalable innovations in the field of ageing requires multidisciplinary collaboration of a wide range of stakeholders from different backgrounds. One of the environments bringing stakeholders together are living labs. Living labs can play an important role in assessing the relevance of innovations for end-users. The living lab approach is a research methodology that involves the sensing, prototyping, validating and refining of solutions in real-life contexts. It has the potential to be particularly useful for developing solutions related to the health problems of older adults and improving the health of vulnerable groups (Kim et al., 2019).

Design thinking

In the past, development work was done within the research and development units of large companies. The innovation process was linear and driven by technological advances (“technological push”). End-users and their needs or demands played hardly any role. The current innovation paradigm differs from the earlier research and development traditions. This new process is based on an iterative or cyclic model driven by the demands of customers or end-users and by networks around innovations (“market pull”). In the new model, the potential customer or end-user can be involved in the innovation process from the beginning. In our fast-changing world, the traditional innovation process is no longer successful. The old approach has to go, also in the health and care sector. (Molema and van Egmond, 2017).

“Many of the organisations we support learn something more about the underlying problems which can send them back to the beginning. Making and testing very early stage ideas can be part of discovery. And in an ever-changing and digital world, no idea is ever ‘finished’. We are constantly getting feedback on how products and services are working and iteratively improving them.”
(Design Council, 2022).

For examining co-creation of user-centred innovations in living labs in the field of active and healthy ageing (AHA) and the scale-up of these innovations, this playbook builds on two approaches that have become increasingly popular in recent years. The first of these is design thinking and the second is lean startup. Design thinking is human- or user-centred (Marion et al., 2021). Both approaches are based on the idea of open innovation, according to which not all wisdom can be found inside the organisation, and actors can use both internal and external resources for their development work (Leminen, 2015; Guldemond and Geenhuizen, 2012; Chesbrough, 2003). Both design thinking and lean startup are based on the idea that co-creation of innovations with customers and end-users leads to better results (Marion et al., 2021).

Design thinking builds on the learning process and collaborative development. In addition to “thinking”, it emphasises practical skills, such as learning by doing, and a human approach, including empathy and listening. Design thinking is typically used for developing solutions and it is ideal in situations where there is not much information to begin with, or where the outcome or solution is yet to be discovered. There are various process models describing the design process, and they consist of four, five or six phases. The process is typically divided

into exploration of the problem space, exploration of the solution space, and iteration of these two phases (Santonen, 2020; Lindberg et al. 2011). *The double diamond model* proposed by the Design Council (2022) is one of the most well-known adaptations of this kind of process and it involves the following phases: (A) discover, and (B) define phases in the problem space, (C) develop, and (D) delivery phases in the solution space. At first, the problem is explored by widening the perspective and discovering, and then the real problem is further defined by focusing on it. It is only after having identified the real problem that ideation and solution development can begin – at first, by ideating and widening the perspective, and then by focusing on delivering the selected solution. (Design Council, 2007).

Design thinking has also been presented as a *Design Thinking 101* circle with the phases Understand, Explore and Materialise. Within these three phases there are six further phases: under Understand, Empathise and Define; under Explore, Ideate and Prototype; and under Materialise, Test and Implement. Empathise means conducting research to get to know what the users do, say, think and feel. In the Define phase, research results should be combined and the end-users' specific needs and problems should be observed. In the Ideate phase, there is a brainstorming of creative ideas addressing the unmet needs of end-users. In Prototyping, tangible representations of the ideas are built. In the Test phase, the prototype is presented to real customers to verify if it fulfils the goals. In the Implement phase, the vision is put into effect. (Gibbons, 2016; See Figure 1).

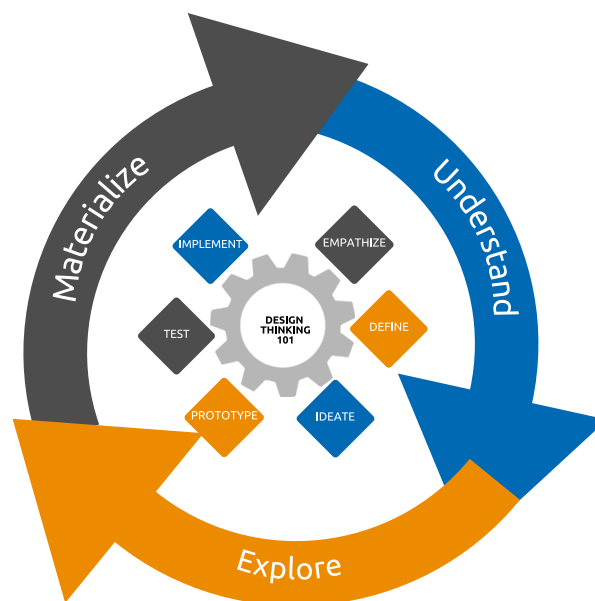


FIGURE 1. DESIGN THINKING. ADAPTED FROM GIBBONS (2016); ZURKUHLN ET AL. (2019).

All the various models involving design thinking emphasise that the process is iterative. It will likely be necessary to go back to earlier phases and revise them. Another issue in design thinking is that one must learn to tolerate uncertainty. The beginning of the process has been described as “the fuzzy front end”. Everything is uncertain until the solution has been finalised.

Design thinking and its methods place the users at the centre for enabling an empathic analysis and a deep understanding of their behaviour, values and non-obvious user needs, and for developing opportunities. (Marion et al., 2021). To be successful, an idea must be technologically *feasible* and economically *viable*, but also *desirable* for users. Many companies focus too much on technology and business perspectives while ignoring the viewpoint of the end-user. Consequently, many concepts fail because they do not solve an actual problem for the end-user. Those products are not desirable — nobody really needs or wants them, and nobody will buy them. (Mueller and Thoring, 2012; Brown, 2009). In fact, according to one estimate, 70% of innovative products and services cannot find a market because they do not meet user needs (Verloo et al., 2021).

There are many leading industry companies implementing design thinking-based co-development methods. One of these is Philips Healthcare with a process called Cocreate, targeted at innovating in collaboration with customers rather than developing innovations for them. (Marion et al., 2021).

Lean startup

Lean startup is another popular approach based on methods that aim to gain insight into opportunities through experimentation, testing and iterative learning with end-users and customers. The lean startup approach was developed in Silicon Valley by Steve Blank, and *The Lean Startup*, a book by Eric Ries (Ries, 2011), promoted these methods to a wider audience (Blank, 2013). In addition to startups, there are now also large companies trying to integrate this approach into their development work. (Marion et al., 2021). Earlier, lean principles have been used in manufacturing to make the production process efficient by reducing waste generated in the production process. They have also become popular in fields such as information technology development. The lean startup approach claims that the biggest waste is creating a product or service that nobody needs. (Mueller and Thoring, 2012).

According to Maurya (2012), what separates successful startups from their unsuccessful peers is not that they have a better initial plan (Plan A), but rather that they find a functional plan before they run out of resources. This can be accomplished by behaving according to the key phrase “Get out of the building”. The lean startup methodology is based on experimentation and validation with real potential customers and end-users, and for that purpose it uses the concept of *minimum viable product (MVP)*, which is used for gathering data from end-users and customers (Mueller and Thoring, 2012).

According to the lean startup methodology, successful startups develop in three stages. First, they try to find out whether there is a problem that is worth solving, whether customers are willing to pay for solving it, and whether the problem can be solved. This stage is called the “*problem/solution fit*”. Here the objective is to validate the problem and solution with potential customers. The second stage is called the “*product/market fit*”, where the solution is tested using an MVP. (Paakkinen, 2021; Maurya, 2012). The MVP is a product or service that only has the essential features that allow it to be introduced to potential customers or end-users for feedback, and no more (Ojasalo and Ojasalo, 2018; Ries, 2011). In early stages, the MVP can be, for example, a minimal landing page or application, a paper or cardboard prototype illustrating the features of a device or an early working prototype. (Mueller and Thoring, 2012).

The lean startup methodology presented by Ries (2011) builds on an iterative *Build-Measure-Learn* loop (Bortolini et al., 2021). In this iterative and incremental process, the MVP can be improved through repeated cycles (Ojasalo and Ojasalo, 2018). The entrepreneur can test their initial business model hypotheses by building experiments. Several types of methods can be used for this, including qualitative interviews, prototypes or MVPs. Measuring results means that the entrepreneur measures and monitors the results of their experiments and compares them with the hypotheses. Learning is the key concept and goal for a start-up. It implies accepting or declining hypotheses. (Bortolini et al., 2021).

Ecosystems thinking

Molema and van Egmond (2017) underline that for innovations and partnerships to emerge and grow in the health and care sector, a supportive environment is essential. An ecosystem is needed where people and organisations can get to know each other and experiment together, join forces, take risks and hope to gain from innovative ideas and entrepreneurs. Ecosystems can bring together four types of stakeholders relevant to health and care innovations, and these should be in proper balance: stakeholders necessary for scientific, technological, social, and business model innovations. Thus, innovation is about building entrepreneurial partnerships and thinking about who we need for success. (Molema and van Egmond, 2017).

Because health and care systems and their underlying sociotechnical aspects are complex, it is of utmost important to engage all key actors in the co-design and implementation of innovations to bridge knowledge gaps (Andersen et al., 2018). Especially in healthcare, it is essential to check if the innovation is a match with the current healthcare system (Molema and van Egmond, 2017). Taking all stakeholders into consideration helps to find a balance between desirability, viability and feasibility viewpoints and to not concentrate too much on technical feasibility, which can often dominate early decision making in complex projects (Marion et al., 2021).

Integrating design thinking and lean startup approaches into ecosystems thinking

Even though there are similarities, there are also differences in the design thinking and lean startup approaches. Both approaches are user-centred, non-linear, iterative and they emphasise learning. They are based on the needs of customers and end-users, testing and experimenting, and rapid development (Paakkinen, 2021; Lichthenthaler, 2020). Both approaches underline a “fail fast” approach, meaning that the sooner it is discovered that an idea is not working, the faster it can be updated and tested again, thus saving time and money. Lean startup emphasises the importance of incremental progress and taking small steps to speed up learning. (Mueller and Thoring, 2012; Ries, 2011). Iterative processes in both approaches mean that going back in the innovation process to an earlier phase should not be considered a failure. The most important aspect is to listen to the end-users and customers and discover how they behave, what their core problems are and to analyse which parts of the solution did not work. (Ojasalo and Ojasalo, 2018).

Lean startup takes a business model and an existing (product) idea as starting points, whereas design thinking emphasises idea generation and explores the problem and solution spaces more widely and with a more holistic service mindset. Design thinking often uses qualitative methods for studying people in their natural contexts, such as ethnography, observation and

interviews to understand people's behaviour, whereas the lean startup approach relies more on quantitative methods in measuring test results (Mueller and Thoring, 2012; Paakkinen, 2021; Lichthenthaler, 2020). The MVP concept has been seen as common ground for the two approaches, as design thinking also uses low-cost prototypes to test ideas with users. Typically, lean startup methods are considered to be more useful in a later phase in the product development process as opposed to design thinking methods. (Marion et al., 2021; Paakkinen, 2021; Lichthenthaler, 2020).

Taking these considerations into account, it seems that integrating these two approaches has the potential to obtain the best of both worlds, as Paakkinen (2021) referring to Korper et al. (2020) points out: start-ups using a service design approach have been observed to pay more attention to the value created instead of the technological solution, to larger sets of stakeholders essential to success, and to larger sets of innovation opportunities.

Figure 2 below illustrates how we integrate the approaches of design thinking, lean startup, scaling up and ecosystems. When developing and scaling up AHA innovations, it is important to ensure the involvement of all relevant stakeholders, including end-users and professionals, because these solutions can only succeed through multidisciplinary and joint efforts. The innovation process goes through several stages. With each stage and based on learnings, a deeper understanding accumulates how to best meet the needs of end-users and customers and how to link the innovation to existing systems. (Schlieter et al., 2022). The qualitative approach of design thinking guarantees a comprehensive understanding of end-user needs, creating a solid foundation for the lean startup approach and testing of the business model. Testing is a natural part of the process, and it should take place in each phase and after each step – the only thing that changes is the object of testing (Mueller and Thoring, 2012). All phases are carried out inside the ecosystem and wider environment, and learning of this wider context should begin accumulating from the beginning.

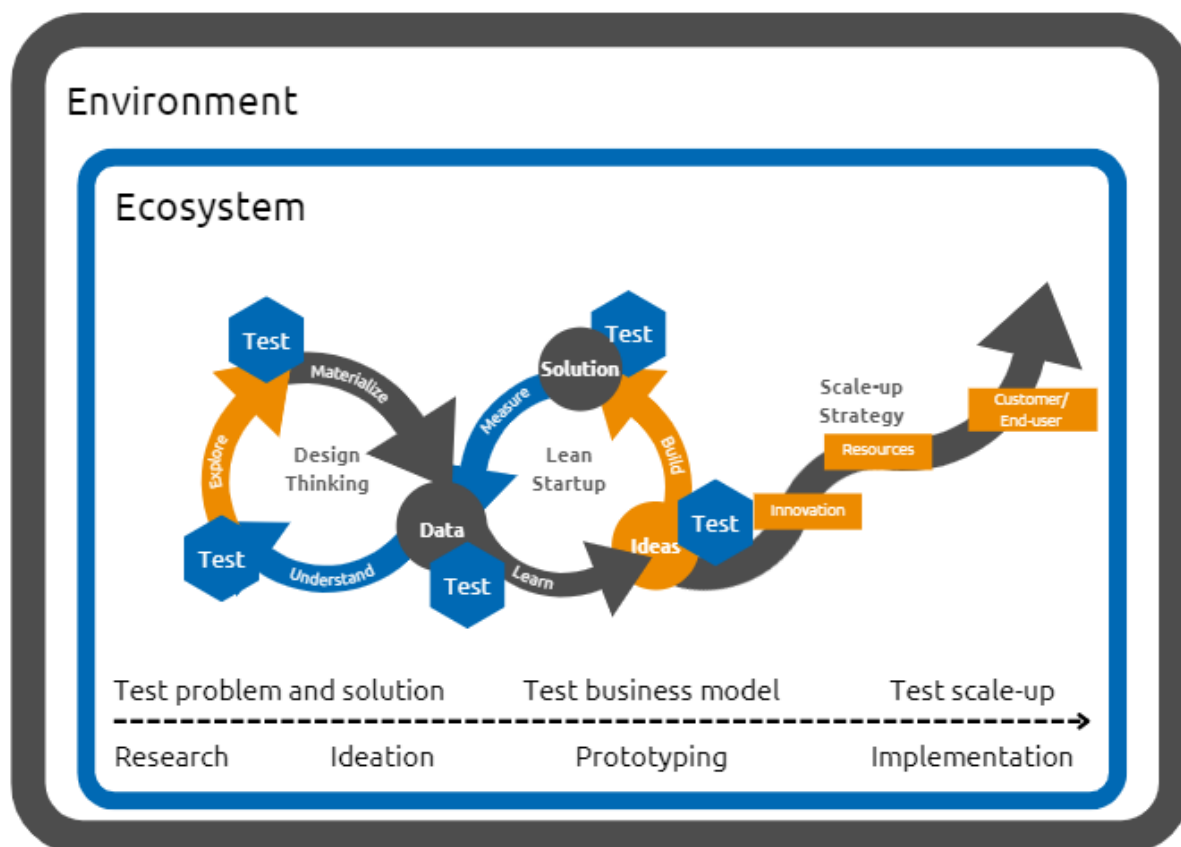


FIGURE 2. INTEGRATING THE APPROACHES OF DESIGN THINKING, LEAN STARTUP, SCALING UP AND ECOSYSTEMS. ADAPTED FROM GIBBONS (2016); ZURKUHLIN ET AL. (2019); MUELLER AND THORING (2012); OJASALO AND OJASALO (2018); PAAKKINEN (2021); CIMIT; RIES (2011); BORTOLINI ET AL. (2021); WHO (2010); GABRIEL (2014).

Chapter 1. Living lab testing

Key learnings of this chapter are:

1. Innovations can be co-created, tested and validated in living labs with real end-users and customers. Living labs can support the innovation process in different phases – from the early phases observing users’ problems or needs to product validation tests before market launch.
2. Living labs aim to remove barriers for collaboration, and to find better matches between new technology and end-user and customer needs. Living labs build on involvement of end-users, real-life environments and open networks bringing various stakeholders together to support a better and quicker adoption of innovations in the market.
3. The methods used in living labs can include, for example, focus groups, interviews, questionnaires, usability testing or lead user innovation.
4. Tools for startups and SMEs presented in this chapter are:
 - Tool 1: Preparation for Living lab tests: goals
 - Tool 2: Preparation for living lab tests: solution, prerequisites and testing needs
 - Tool 3: Estimation of values of person-centred care (PCC)
 - Tool 4: Tool for Technology Readiness Level (TRL) Assessment
5. Special issues to consider in living lab tests include ethical issues, medical device regulations and CE marking, data protection and intellectual property rights.
6. Advice for organisations planning to start a living lab is given in the end of the chapter.

Innovations are risky. Working on innovations is also expensive, time-consuming and unpredictable. It is important to minimise risks and maximise success factors. One way to achieve this is to improve market contacts and knowledge of the users’ problems and needs. Realistic use cases and better understanding of user behaviour are good ways to get results that are valid for real markets. Living lab is a concept created for supporting these contacts and knowledge. (Ståhlbröst and Holst, 2012). Accordingly, one of the main objectives of implementing living labs in the innovation process is to minimise the innovation risk and maximise the likelihood of successful market entry (Santonen and Julin, 2019).

Many stakeholders, such as universities, companies and cities, are involved in living labs. Living labs have become an increasingly popular tool to boost innovation in different areas, such as energy, health and ICT sectors. (Geenhuizen, 2015). Living labs can be particularly important for start-ups and SMEs, who typically have scarce resources and competences (Ståhlbröst and Holst, 2012). Living labs can complement the entrepreneurial team capabilities and provide multi-stakeholder input and real-life experience so that “it becomes possible to learn what customers really want, not what they say they want or what we think they should want” (Schuurman and Protic, 2018).

The living lab approach offers access to international markets already from the fuzzy front-end stage of innovation up to the stage when innovation has been introduced to the market. For AHA innovations, using this opportunity to test ideas and solutions is particularly important because the health and care sector is a highly regulated industry and healthcare systems, practices and legislation are different in each EU country (Ferreira et al., 2018). Entering a new country requires in-depth understanding of that particular market. (Santonen and Julin, 2019).

Until now, despite the growth of living labs in urban planning and civil design, living labs have not received as much attention in healthcare (Archibald et al., 2021). However, interest is growing towards living labs as a method to test and develop health and care innovations. In living labs, these innovations can be co-created with end-users and tested in practice. (Vereycken et al., 2019). The idea of living labs was born from insights based on the open innovation approach, according to which innovations should be tested in real-life situations and they should be co-developed with actual end-users (Vereycken et al., 2019; Almirall et al., 2012; Veeckman et al., 2013).

By using living labs, companies and health and care institutions can reach beyond their boundaries, apply the open innovation model and integrate outsiders into the co-creation of solutions. The proposed benefits of the open innovation model include more value for users, better innovation performance and lower costs (Leminen, 2015). Thus, living labs embody an encouraging approach for developing innovative solutions to the various challenges of the elderly population (Verloo et al., 2021). Guldmond and Geenhuizen (2012) note that although living labs are a relatively new instrument in enhancing open innovation, certain aspects of open innovation in the health and care sector are not new, such as co-design and co-creation, but living labs shift the user's role from research object to active co-creator.

The concept of living labs was created in the early 2000s when William Mitchell at Massachusetts Institute of Technology proposed that research activities should be moved from laboratories to *in vivo* settings, enabling the monitoring of users interacting with innovations in real life (Leminen, 2015; Geenhuizen, 2015).

What is a living lab?

There are various definitions of the concept of a living lab. There is no widely recognised definition, and Leminen (2015) found 70 different definitions in his review. In the literature, a living lab has been defined as a methodology, an organisation, a system, an environment and a systemic innovation approach, among others. (Verloo et al., 2021; Santonen, 2020; Ståhlbröst and Holst, 2012). The European Network of Living Labs (ENoll) defines living labs as *“user-centred, open innovation ecosystems based on systematic user co-creation approach, integrating research and innovation processes in real life communities and settings.”* (<https://enoll.org/about-us/>)

- *“Living lab is a multi-stakeholder driven user-centred open innovation approach to co-create and test novel solutions in real-life environments.” (Santonen, 2020)*
- *“Living labs are user-focused experimental environments in which users and producers co-create innovative solutions in real-life settings.” (Kim et al., 2019).*
- *“A key defining aspect of living labs is the real-life context, which allows the dynamics of everyday life to play a vital role in innovation processes.” (Schuurman and Protic, 2018).*

There is a rather wide consensus that living labs are *real-life environments* (referring to the “living” part of the name), or that they at least resemble them, but that they are also *research*

and design contexts where innovation experts develop and test innovations together with users (referring to the “lab” part of the name) (Fuglsang et al., 2021). Living labs can act as intermediaries or innovation facilitators for collective learning in the co-creation processes. Living labs can offer valid evaluations of innovations as they reach people in their real-life environments, and a realistic setting for co-creation. (Verloo et al., 2021).

The common elements in living labs include multi-stakeholder² participation and a multi-method approach (Kim et al., 2019; Montalva Colomer et al. 2014; Ståhlbröst and Holst, 2012). In the case of the health and care sector, faced with strong problem and actor complexity, the stakeholders in a living lab can include different types of users and other stakeholders, like elderly people living in care homes or at home, their family members, patients, doctors, care professionals and hospitals, insurance companies, regulatory agents, universities, large and small technology companies, public authorities, non-governmental organisations, etc., bringing in significant potential for finding solutions gained by cooperation. (Geenhuizen, 2015).

According to Guldemand and Geenhuizen (2012), all living labs share three main characteristics: involvement of users, a physical environment representing real-life environments and an open network bringing various stakeholders together to support a better and quicker adoption of innovations in the market. The main purpose of living labs is that fostering user involvement in the development process increases the maturity of a solution in terms of both technology and usability before introducing it to the market. (Montalva Colomer et al., 2014).

Where can they be found? Different types of living labs and similar concepts

There are many kinds of living labs. For example, research living labs focus on research, corporate living labs invite stakeholders to co-innovate, organisational living labs focus on co-creation in one organisation, and time-limited living labs close when the project ends (Ståhlbröst and Holst, 2012). There can be living labs offering factual real-life environments (home, care home, hospital) or test centres furnished like a real-life environment, or a mix of naturalistic environments and more controlled settings. The dilemma is to find the proper balance between research purposes and keeping close to authentic real-life practices. (Andersen et al., 2018). There are also differences related to the phase of the innovation process: while some living labs are more involved in the early phases of innovation processes, others serve as test beds or offer predefined, fee-based services to their clients (Schuurman and Protic, 2018).

For example, the IN-4-AHA consortium partner Cluster Saúde de Galicia (CSG) has a living lab network, ITGALL, which consists of several organisations providing services to the elderly. Most of them are social and/or healthcare centres hosting nursing homes, day care centres, home services and associations of elderly people. They are all located in Galicia, Northern Spain. Different criteria were used for selecting living labs for each IN-4-AHA pilot company, such as end-user type (physical and mental status, gender, age, etc.), services and

² Often the multi-stakeholder participation in living labs is referred to as the Quadruple Helix Model. This is an innovation model based on cooperation between citizens, government, industry and academia. See for example <https://enoll.org/about-us/>.

infrastructure of the living labs. For example, some of the pilot companies preferred living labs offering 24/7 nursing home services to the elderly, while others had the criterium that elderly people should have access to tablets. Table 1 illustrates some of the living labs of IN-4-AHA Project and their services and user profiles.

Living Lab	Country	Services	Users
Afaga	Spain	Day care centre	Elderly people diagnosed with different degrees of Alzheimer's disease
Atendo	Spain	Nursing home accommodation (24/7), day care centre and home care services.	Older people with different degrees of cognitive impairment
Red Cross (Cruz Roja)	Spain	Day care centre	Older people with different degrees of cognitive impairment
Saraiva	Spain	Nursing home accommodation (24/7) and day care centre	Older people with different degrees of cognitive impairment
Active Life Lab	Finland	Efficiency measurements and training groups in smart gym, wellbeing service development and test and research services for partner organizations	Senior citizens Working age citizens Professional athletes

TABLE 1. EXAMPLES OF IN-4-AHA LIVING LABS, THEIR SERVICES AND USER PROFILES

The literature on living labs underlines the importance of end-users, but depending on the situation, they can be passive or active, i.e. they can be research objects or subjects (Leminen, 2015; Almirall et al., 2012). Moreover, the research literature highlights the difference between user-driven living labs, with citizens or patients or their advocates as initiators trying to find better solutions to their problems, and company- or institution-driven living labs trying to bring inventions quicker to the market or use. (Geenhuizen, 2015).

Especially in Europe but also worldwide, the European Network of Living Labs (ENoLL) has promoted the introduction of an ICT-based living lab innovation approach (Geenhuizen, 2015; <https://enoll.org>). ENoLL was established in 2006. Currently (in 2022), the network has around 170 active members, and it has historically labelled more than 480 living labs globally. ENoLL facilitates knowledge exchange, joint actions and project partnerships. (<https://enoll.org/about-us/>). Its members operate all around the world, not just in Europe. On the ENoLL website, it is possible to search for living labs by country or sector. According to ENoLL, around half of the work done in living labs concerns health and wellbeing issues (Kim et al., 2019).

Many living labs and living lab networks have emerged in Europe with the support of the European Union, EIT Health (<https://eithealth.eu/>) or through initiatives at national, regional or local level by public and private actors (Michel et al., 2021).

While there is no universally accepted definition of a living lab, many similar concepts can also be found (Santonen, 2020). Test beds (or testbeds) and usability or field labs are cases where

user-involvement is more passive, and they can be considered similar concepts. A test bed can be defined as “a testing and validation environment for a product, in which transparent, measurable, and replicable studies can be conducted to assess the product design and performance” (Chernova and Konina, 2022). It has been argued that in test beds, for example, users act more passively promoting their thoughts, and they are not involved in co-creation (Geenhuizen, 2015; Almirall et al., 2012). In addition, the use of test beds in the field of healthcare and wellbeing industry is usually an iterative process, as most companies use the services more than once (Chernova and Konina, 2022). Usability labs have been proven successful for quick results in usability issues, but they are not necessarily based on the use of the technology in a real-life environment (Andersen et al., 2018).

EIT Health classifies living labs into two different types of facilities depending on the depth of end-user involvement and the activities they perform. Actual living labs focus on user ideation, co-creation and validation activities for new products and services, whereas test beds focus only on the validation of new products and services. (<https://eithealth.chronus.com/p/p2/about>). User validation labs, moreover, are EIT Health's European partners – they include living labs, accelerators, hospitals, and innovation centres – that offer connections between startups and product end-users, including patients and medical staff (<https://eithealth.eu/programmes/ulabs/>).

For the AHA sector, one particularly important similar concept is Reference Sites. Reference Sites are ecosystems delivering workable solutions that improve the lives and health of older people and the whole community. Over one hundred regional and local organisations were awarded Reference Site status in the 2019 call (<http://www.rscn.eu/reference-sites/>). They are regions, cities, integrated hospitals or care organisations and their quadruple helix partners cover industry, civil society, academia and government authorities. The focus is on a comprehensive, innovation-based approach to active and healthy ageing. The Reference Sites form a network named Reference Sites Collaborative Network (RSCN). (<https://digital-strategy.ec.europa.eu/en/policies/eip-aha>). Reference Sites benchmark each other. Therefore, if an organisation belongs to the ecosystem of one Reference Site, there are opportunities to test and scale up its innovation in another Reference Site.

To make the situation even more complicated, the lack of consensus on the basic characteristics of a living lab, such as methods and practices, creates confusion. Consequently, some research groups claim to be using a living lab approach even though they are not, but on the contrary, some research groups applying a living lab approach are not labelled as living labs. (Verloo et al. 2021).

For this reason, it is necessary to inspect the living lab or test bed more closely before deciding what kind of a lab it is. However, the proof of the pudding is in the eating – the startup, SME or other kind of innovator needs to identify their needs and only based on that can they decide which test environment and methods are the best options.

Instead of finding a living lab to test a solution, it can sometimes be possible to contact a care home, for example, directly for testing. If the care home is interested and motivated to test the solution, this route is also suitable. However, usually living labs have more experience of

the testing process and can produce an appropriate test report that can be used for development work and marketing.

- *“Testing with real users has been very important. Making decision in the public sector is slower but they are often more open to test, whereas private care homes are not easy to approach if the product is not finished. Now that the product is tested, we target first the private sector, because making decisions is easier there, with usually the owner being CEO.” (IN-4-AHA pilot company representative)*
- *“When you develop a solution, you need to think about co-designing it with professionals and end-users. You have to get out of your comfort zone, involve end-users, professionals, all stakeholders in the whole process. Otherwise, you will have a solution that no one wants to buy.... You have to have people by your side all the time. You should see the strength and wisdom in the elderly – not their sicknesses.” (IN-4-AHA Living lab network coordinator)*
- *“You have to be honest and ask: Does this answer a need and how can we validate that it responses the need? Designing a test is difficult. You need to invest. Your business model has to be clear, but do not finalise the product. Invest, invest, invest! Be prepared to get feedback and apply changes.” (IN-4-AHA Living lab network coordinator)*

Preparations for living lab tests

Better results are achieved if the objective has been clearly defined. Therefore, plans and expectations for the testing process should be defined as clearly as possible. If it has been possible to test the current solution or some other solution earlier, it is a good idea to think about the outcomes and learnings, what went well and what could have gone better.

Aspects to be tested can include, for example, usability or desirability of the solution for the test participants. In any case, the objectives for testing should be as clear as possible at this stage: what is being tested, why is it being tested, what is the desired learning outcome, who (which groups) is testing the solution, which tests/methods will be used, and how and where are the tests carried out. The solution can be tested in its entirety (as a minimum viable product, or MVP, or some other format), but it could also be narrowed down to test only some features (minimum viable features, MVF). Usually, it is better to keep things as simple as possible. A small test can be carried out first, and if everything goes well, a more comprehensive test can be carried out later.

- *“It is easy to write on paper that we want 50 test participants, but then you have to deal with the problems that arise from 50 people.” (IN-4-AHA pilot company representative)*
- *“We should have tested the testing protocol before the tests. This is valid for any kind of cooperation: the whole process should be pre-tested, because cooperation can stumble in rather simple things. We should be prepared to train the customer like that, too.” (IN-4-AHA pilot company representative)*

The following table illustrates some types of tests that can be carried out in AHA living labs based on tests for pilot companies in the IN-4-AHA Project.

Solution	Target groups	Living Labs	Tests
Operating concept for tablets that facilitates independent digital communication for beginners.	<ul style="list-style-type: none"> Professionals with sufficient knowledge in the use of technological tools. Senior people (65+), include members of both genders, and have little or no experience with digital applications. 	<ul style="list-style-type: none"> Day care centre Continuing education centre for the elderly Associations for the elderly and their relatives 	End-user tests where information was collected regarding end-users' understanding, reactions and attitudes towards the device.
A virtual assistant for active ageing designed for people with neurodegenerative mental illnesses.	<ul style="list-style-type: none"> Health professionals with knowledge in the use of technological tools. Senior people (65+) with varying degrees of cognitive impairment (Parkinson's disease, Alzheimer's or another dementia) 	<ul style="list-style-type: none"> Nursing home accommodation Home care services Day care centre Associations for the elderly and their relatives 	End-user tests by seniors and health professionals to co-create an enabling environment with end-users, so that solution can be validated in an everyday environment.
A software solution that integrates menus with user information for healthy eating.	<ul style="list-style-type: none"> Nutrition team professionals Professionals of the nursing team Professionals in the kitchen team Innovation team professionals 	<ul style="list-style-type: none"> Nursing home accommodation Day care centre Hospital 	<ul style="list-style-type: none"> Participatory design workshop for the company and end-users End-user tests where the behaviour and reactions in the user experience of the professionals who were testing the application were observed.

TABLE 2. EXAMPLES OF TYPICAL TESTS, BASED ON TESTS CARRIED OUT FOR IN-4-AHA PILOT COMPANIES.

However, one should keep their mind open. Testing is always testing, and challenges and surprises are normal: if everything always went as planned, testing would never be necessary. The main purpose of testing is to learn new things and, based on what has been learned, continue the development work in a slightly different direction, and then test again. Or, if necessary, suspend the work and do something else.

In addition, each living lab is different. Therefore, before opening discussions with a living lab, it may be unclear what can be tested in the living lab. If the purpose is to test the solution outside the country, it is good to keep in mind that the co-design process is a market-specific process. So, it is quite normal that even if the solution has already been launched in the home market, it may be necessary to start from an earlier development phase in a new market environment. Moreover, not all living labs have the same facilities and resources, and therefore it may be necessary to make some compromises to match the living lab's resources, facilities and networks with the demands of the solution developer. For example, if the aim is to test the solution in a large hospital, it is worth noting that not all living labs have those in their living lab network. There are also technological thresholds one should be prepared for: for example, if mobile devices or open wireless internet connections are required for testing the solution, the reality can be that not all care homes of a living lab network have them available, nor do the elderly people living at home have them. In this case, it is a good idea to consider if the company could provide these for testing.

Furthermore, it is important to remember that research and development work in the health and care environment is highly regulated in most cases. In the IN-4-AHA Project, understanding ethical and data protection issues seemed to be challenging for some of the pilot companies. Testing most often requires some sort of ethical approval, for example a permission from an ethics committee. Most living labs have in-depth partnerships with the necessary bodies, enabling fast response to this kind of requests. (Santonen, 2020). However, one should be prepared for some potentially significant delays in the testing schedule due to permission issues. Data processing and storage should also be considered and how well the research complies with the requirements of the General Data Protection Regulation (GDPR), for example. Furthermore, not having a CE marking for a medical device can create an obstacle for testing the solution in some cases. Some living labs are willing to work with companies that are already going through the regulatory compliance process and have their documentation ready (Chernova and Konina, 2022). This could be observed in the IN-4-AHA Project, too, when selecting the best living labs for tests for some of the pilot companies. Read more about these things below in section “Special issues”.

Living lab testing process

Living labs can support the innovation process in different phases – from the early phases observing end-users’ everyday problems or defining end-users’ latent needs in focus groups to product validation tests before market launch. The living lab process can be described as a multi-disciplinary iterative learning process bringing scientific, technological, market and user knowledge into the innovation process, in which the solution is iteratively elaborated and refined based on feedback from the users. (Santonen, 2020).

“Living lab process is grounded on an idea of iteratively elaborating and refining the solution throughout the innovation process in which each iteration or round is making use of the findings from the previous rounds.... After each iteration round, researcher-developers have more information available, which reduces the risk of failure and enables flexible response if there is a need to make changes. Thus, living lab process can be considered as an iterative learning process...” (Santonen, 2020).

Living labs can conduct tests in different phases of the innovation process, but the tests differ depending on the phase in which the solution is in the market in question. Involvement of multiple stakeholders, including end-users, in the exploration, co-creation and evaluation of innovations in living labs within a realistic setting, aims at solutions that respond to the end-users’ real needs (Michel et al., 2021).

Depending on the phase, the methods used in living labs can also be different. The methods can include, for example, focus groups, interviews, questionnaires, usability testing or lead user innovation. (Santonen, 2020). The methods usually are qualitative and explorative research approaches, for example, ethnographic methods, co-creation sessions, field tests and idea scouting (Schuurman and Protic, 2018). Following the real-life approach, real end-users are involved in the process instead of relying on personas or other user representatives (Ståhlbröst and Holst, 2012).

Living labs cover a wide range of activities and different approaches to end-user involvement. The user as a research *subject* refers to user-driven co-creation of innovations, whereas if a user is a research *object*, it means that the user's needs and experiences are inspected, or solutions are tested or validated with users (user-centred model). (Leminen, 2015).

- *“Living labs remain underexplored and underdeveloped within health systems, and there appears to be an overemphasis on user roles as ‘testers’ of a prototype or service, rather than alternative roles, such as developers or designers of innovation.” (Archibald et al., 2021).*
- *“Despite the many inventions in medical technology and care, still a lot of R&D needs to be performed to bring healthcare inventions to market and to have them customized to user needs... efforts in which Living labs seem to be considerably helpful and have a large potential.” (Geenhuizen, 2015).*

In the following, a typical living lab testing process offered by a living lab network is described. This process was followed in the IN-4-AHA tests.

Preparation phase

The project starts with a preparation phase. The purpose of the preparation phase is to get to know the company and its solution to be tested, to introduce the living lab's facilities and potential tester groups to the company, to discuss and define the objectives the company has for the tests and the tester groups, to prepare the necessary documentation, such as questionnaires and informed consents, and to prepare for applying for the permissions required for the tests. After discussions between the living lab coordination team and company representatives, a project plan (and a contract) is drafted, reviewed and approved. The plan defines the timetable and describes the living lab testing process, including the living lab facilities to be used, targeted tester groups, as well as relevant stakeholders, methods and approaches for data collection. (Santonen, 2020; see also Figure 2).

Selection phase

The purpose of the selection phase is to determine the necessary requirements for testing in cooperation with the parties involved in the tests. During the selection phase, several discussions are held between the living lab network coordination team and the company's team of technology developers, and with those responsible for the living labs to determine the testing requirements. The result of this phase is the selection of the living labs that best suit the testing needs and the selection of the sample criteria necessary to carry out the testing process. To select the living labs, the requirements of each technological solution are taken into account so that the living lab network's coordination team can check the user profile of each living lab, the health and care professionals it employs and the frequency of the services it offers.

Reception phase

The purpose of the reception phase is to encourage a good reception of the testing of technological solutions among the testing stakeholders, especially in the participating living labs. This phase of innovation network orchestration is of utmost importance because it ensures that it is possible to implement the project according to the research plan. The living

lab approach is grounded on wide stakeholder collaboration, the use of multiple methods and real-life environments. This kind of research is not possible without motivating the key stakeholders, the personnel of the living labs – care homes, hospitals or associations – to join the project activities and gather a group of testers. Also, it is important to ensure that all the required testing and development facilities will be available during the project. (Santonen, 2020). This phase includes presenting the solution and project to the living lab personnel and handing out documentation (testing guide, brochure, informed consent form, etc.), delivering the necessary devices (if applicable), giving a demonstration on how to use the technological solution and holding training sessions if needed. The test schedule and other practical arrangements are also negotiated and agreed on with the living lab personnel.

Development phase

The purpose of the development phase is to gain understanding of the reactions and attitudes of end-users to the proposed solution and to observe their behaviour, which is made possible by testing solutions in real-life contexts. During the development phase, monitoring is carried out using the means of communication agreed with the participating living lab. This can be in person, via email or telephone. The objective is to collect experiences and record any incidents (device not working, connection breaks, end-user does not understand how the solution works, etc.) and to make changes in the testing process if needed. The person coordinating the living lab network is the one who communicates with the technology developer (startup, SME or other kind of service provider) of the project, collects the incident reports from the living lab where the technological solution is being tested and interprets possible anomalies.

Evaluation phase

After the development phase, the evaluation phase begins. The objective is to identify the main barriers and key factors of the user experience. For this purpose, project-specific questionnaires are carried out. A combination of qualitative and quantitative approaches can be used to collect information. The quantitative evaluation provides measurable results, and the qualitative evaluation gives a better understanding of the user experience.

Reporting phase

The process ends with the reporting phase. The purpose of the reporting phase is to compile the test results and the experience gained from the tests for the company. Additionally, the experiences gained from the conducted tests can be utilised in the further development of the testing process in living labs.

Services offered by living labs

Besides testing, living labs offer a wide range of services. *Project planning and management services* aim to support the planning and implementation of the user-centric living lab innovation process. *Co-creating services* aim to promote collaboration and interaction with various end-user and other relevant stakeholder groups for testing and developing user-centred services and products. *Testing and validation services* aim to offer opportunities to test and validate services and products with end-users in real-life contexts. The aim of *equipment and facility rental services* is to ensure that the required equipment, labs and other facilities are available for living lab testing and development activities. *Business support services* aim to support the business activities related to the solutions being tested and

developed at a living lab. (Santonen, 2020). Some living labs offer an incubation environment and access to stakeholders that are essential for commercialisation, which gives them the ability to enhance all phases of the commercialisation process. (Baltes and Gard, 2010).

Project planning and management services include, but are not limited to, the following:

- Grant writing and funding application support service
- Living lab project planning and management
- Funding services

Co-creating services include, but are not limited to, the following:

- Innovation network orchestration
- Hackathons and design sprints
- Interviews and focus groups
- Co-creation workshops
- Customer journey
- Panel research
- User personas

Testing and validation services include, but are not limited to, the following:

- Small-scale and large-scale real-life testing, experimentation and piloting
- Post-market surveillance and market acceptance testing
- Concept and proof-of-concept tests – feasibility studies
- Observation, shadowing and ethnography studies
- Clinical trials and regulatory approval tests
- Impact assessment and validation tests
- Idea selection and testing
- Usability testing
- Prototype testing
- Simulation tests
- Surveys

Equipment and facility rental services include, but are not limited to, the following:

- Offering equipment, labs and other facilities for rent

Business support services include, but are not limited to, the following:

- Market and competitor intelligence services
 - Competitor and market analysis and benchmarking
 - Foresighting (trends, weak signals and wild cards)
 - Stakeholder (and partner) analysis and mapping
- Business advice and management services
 - Expert opinion, sparring and advisory services
- Marketing and sales support services
- Public procurement support services
- Legal, regulation and safety standard support

As an example of business support services, the business coaching process for IN-4-AHA pilot companies consisted of 4-5 sessions with each project team. In the first meeting, the following topics were discussed: background of the entrepreneur(s) and enterprise and the development carried out so far, current state of business, short-term and long-term goals, planned next steps and analysis of the market position/current state of markets. In the second meeting, based on the analysis of the first meeting, the discussion focused on the main activities and goals for reaching the next market level or for progressing in the markets. In the third meeting, based on the broader view of the market dynamics and development, the discussion was about the actions that would be favourable to the company's scale-up. The immediate actions required of the company were listed and scheduled. In the fourth and fifth meetings, these actions were followed up on and the circumstances and market settings were discussed. The immediate next actions required of the company were also listed and scheduled. Later in the project, follow-up meetings were held to discuss the progress of the measures and development.

The following figure illustrates the living lab testing process integrated with the coaching process in the IN-4-AHA Project.

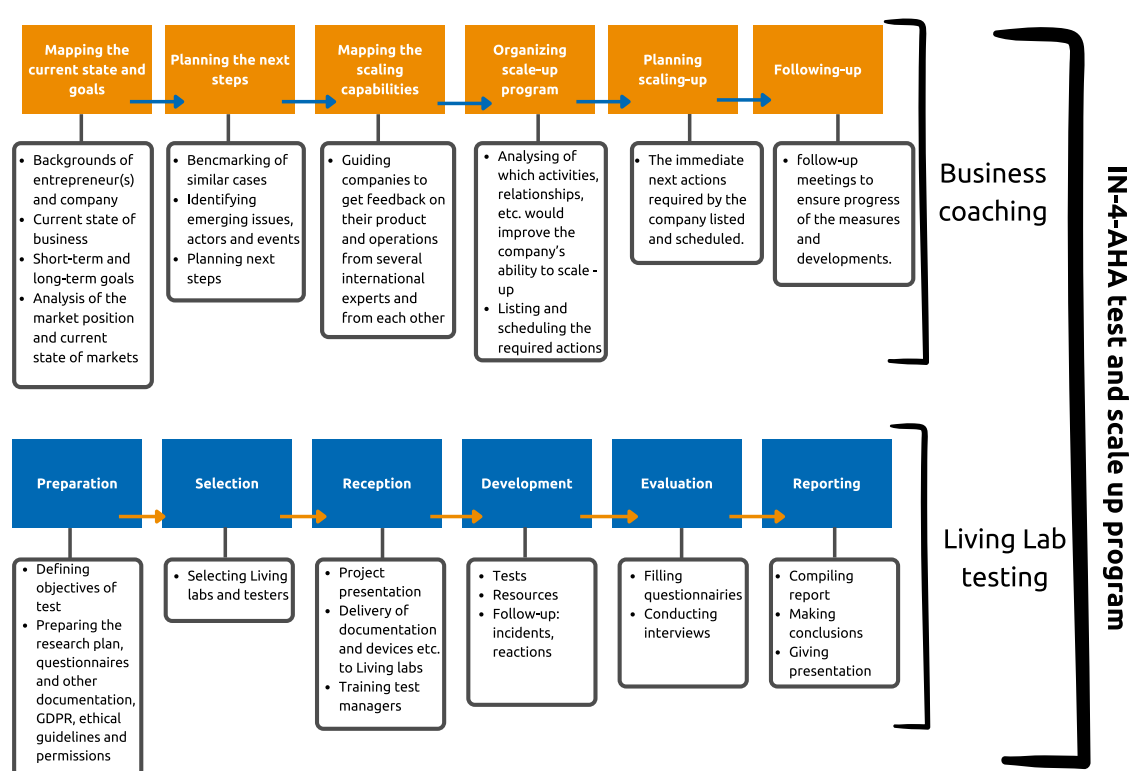


FIGURE 3. LIVING LAB TESTING PROCESS INTEGRATED WITH COACHING PROCESS. APPROACH USED IN THE IN-4-AHA PROJECT.

Tools for startups and SMEs for living lab tests

Tool 1: Preparation for Living lab tests: goals

Before the living lab process starts, the innovators must be able to define their aims, needs and expectations for the living lab testing. Typical questions the living lab representatives ask are the maturity level of the solution to be tested, business model, key customers, target markets for internationalisation and previous testing experience. (Santonen, 2020). Living lab coordinators in the IN-4-AHA Project used questions like the following to acquire information about the pilot solutions. These questions offer examples of issues innovators, for example startups and SMEs should consider before living lab tests.

Questions		Answers
Why?	Why should the solution be tested in a living lab and in this particular living lab?	
	Which research question the tests should answer?	
	What are the most important objectives for the tests?	
	What is the ideal outcome that can be achieved with the tests?	
	How will the tests improve the scalability of the solution?	
What?	What will be tested? (User needs, technical feasibility, solution usability, desirability, economic viability, something else?)	
	Which tests would be most valuable for scaling up of the solution?	
	Is the solution technologically mature enough for these tests? What is the TRL level? (See Table 6 below)	
How?	What kind of tests are needed?	
	What is the test set-up? (Instructions, devices, connections, something else?)	
	How long will the tests take?	
Who?	Who are the participants in the tests? <ul style="list-style-type: none"> ○ The target group/groups should be clearly defined. If the tests target elderly people, what kind of elderly people (age, gender, physical and mental state, other features)? If the tests target professionals, what kind of professionals? ○ How many participants will be included? (Usually, the fewer, the better, i.e. small test first.) 	
Where?	What kind of living lab environment is the best option? (Home, care home, hospital, some other environment?)	

TABLE 3. TOOL TO PREPARE FOR LIVING LAB TESTING: TESTING GOALS.

Tool 2: Preparation for living lab tests: solution, prerequisites and testing needs

Living lab coordinators in the IN-4-AHA Project used the following questions to acquire information about the pilot solutions. These questions offer examples of issues innovators, for example startups and SMEs should consider before living lab tests.

Questions		Answers
1. Information of the solution	Which problems of the users do you want to solve with your solution?	
	Who are the end-users of the solution?	
	Who are the beneficiaries of the solution?	
	What expectations do the end-users have when using your solution?	
	How would you define the user experience of your solution?	
2. Technical and competence prerequisites	Which technical resources are needed to use the solution? (Internet connection, tablets, mobile phones ...)	
	How can the solution be accessed (browser, app, server, cloud...)? Is a user account needed?	
	What skills are necessary to use the solution? Is training needed? Average time to become familiar with the solution.	
	Number of devices, wearables, products or licenses to be tested. How many devices / licenses / etc. can you supply for the testing process? When are they available for the tests?	
	Multilingual support (which languages are available)?	
3. Testing Needs	Objectives <ul style="list-style-type: none"> • What needs to be tested? • What do you want to learn through tests? • What are your most important objectives for the tests? 	
	Previous tests <ul style="list-style-type: none"> • What kind of tests have you carried out earlier? • What type of users did you have? • What results did you get? 	
	User profile <ul style="list-style-type: none"> • What user profile do you prefer for testing? Age, physical / mental health, level of digital literacy (low-medium-high), any other qualities? • How many test users are needed? • With whom do the users communicate through the solution, for example, with each other or with their caregivers? 	
	User needs <ul style="list-style-type: none"> • Real and latent needs • Information needs • Training needs 	

	<ul style="list-style-type: none"> • Motivations and trends 	
	Methods <ul style="list-style-type: none"> • Which methods will be used: observation, focus groups, interviews, questionnaires (paper/online), etc.? • Which questions will the users be asked in the test? Who answers / fills in the (possible) questionnaire(s)? List of indicators desired for testing. • How long-lasting test do you need? (Considering that the test persons get to know the solution and understand its purpose and benefits.) 	

TABLE 4. QUESTIONS TO CONSIDER WHEN PREPARING FOR LIVING LAB TESTING (SOURCE: IN-4-AHA TESTS).

Tool 3: Estimation of values of person-centred care (PCC)

Tests conducted in the IN-4-AHA Project for the pilot companies showed that the higher the degree of PCC present in the technological innovations, the higher the level of adoption by the end-user (Saborido Piñeiro, 2022). The following tool helps to estimate the PCC values.

Person-centred care (PCC) values	Definition	Your own estimate (0-100 points) Explain why you choose these points
Welfare	Technology must be geared towards generating the wellbeing of the people for whom it is designed and aligned with the framework of the ethics of person-centred care.	
Dignity	Technology contributes to respect and values the rights of the people who use it. It contributes to the dignified treatment of the individual.	
Autonomy	Technology should make it easier for the individual to decide on his or her own life project, facilitating access to and control over his or her personal data at all times.	
Independence	Technology must be understood from a dual approach, as technology can promote independent living for the people who use it and must be designed in such a way that it can be used independently, without external assistance.	
Personalisation	It is understood from a dual approach, as technological solutions must be customized according to the needs of users and allow for the adaptation of interventions to the needs of the people for whom they have been designed, providing added value to the person's life and respecting their privacy and intimacy.	
Empowerment	A technological solution empowers the user when the person is able to use it independently. And for this it is essential that its design is intuitive from the first interaction "without the need to read the user manual".	
Co-design and participation	Technological solutions must be co-designed and developed through participatory processes, taking into account the voice of the users themselves. For people and with people.	
Social inclusion	The capacity that technology brings to break down social gaps and generate opportunities for participation in the social and cultural life of their environment.	
User experience	Design of interactions throughout the acquisition, use and after-sales process. This should be designed in a user-friendly, inclusive and stimulating way, favouring interoperability and easy integration of solutions.	
Affordability	Person-centred technology must favour a balance between added value and price in order to be accessible to older people, families, administrations and organizations.	

TABLE 5. VALUES OF PERSON-CENTRED CARE. ADAPTED FROM CRITERIA DEVELOPED TOGETHER WITH FOCUS GROUPS FOR END-USER ACCESS AND READINESS FOR SERVICE ADOPTION IN CSG; SEE FULL VERSION OF THE TOOL IN APPENDIX 2 AND SABORIDO PIÑEIRO (2022), TABLE 15.

Tool 4: Tool for Technology Readiness Level (TRL) Assessment

The Technology Readiness Level (TRL) Assessment Tool groups nine technology readiness levels (TRLs) into four stages of technology development: 1 – Fundamental Research, 2 – Research and Development, 3 – Pilot and Demonstration and 4 – Early Adoption. This tool describes each TRL and provides checklists to determine if the technology is at that specific TRL. Here, the tool is adapted, and it is presented from the perspective of testing and scalability of an AHA innovation.

Technology Development Stage	TRL	Definition	Description	Methods	Checklist	Yes	No	Not Relevant
Fundamental research	1	Basic principles observed	Scientific research begins with properties of a potential technology observed in the physical world.	<ul style="list-style-type: none">• Desk research• Interview• Survey• Observation	Basic research activities have been conducted and basic principles have been defined.			
	2	Technology concept formulated	Applied research begins with identification of practical applications of basic scientific principles.		Principles and findings have been published in the literature.			
					Applications of basic principles have been identified.			
					Applications and supporting analysis have been published in the literature.			
Research and development	3	Experimental proof of concept	Active research and development begin. The applications are being moved beyond the paper stage to experimental work.	<ul style="list-style-type: none">• Co-creating workshop• Interview• Hackathon• Design sprint• Concept and feasibility testing	Proof of concept and/or analytical and experimental critical function has been developed.			
	4	Technology validated in lab	Basic technological components are integrated “ad-hoc” to establish that they will work together in a laboratory environment.		Separate components have been validated in a laboratory environment.			
					“Ad-hoc” integrated components, sub systems and/or processes have been validated in a laboratory environment.			
					It is understood how “ad-hoc” integration and test results differ from the expected system goals.			
					Semi-integrated component(s)/ subsystems or processes have been validated in a simulated environment.			
	5	Technology validated in relevant environment	The integrated basic technological components are performing for the intended applications in a simulated environment.		It is understood how the simulated environment differs from the expected operational environment and how the test results compare with expectations.			
Pilot and demonstration	6	Technology demonstrated in relevant environment	A model or prototype, that represents a near desired configuration, is being developed at a pilot scale, generally smaller than full scale. Testing of the model or prototype is being conducted in a simulated environment.	<ul style="list-style-type: none">• In-house testing• Unit testing• Expert opinions• Usability testing• Integration testing• System level and large-scale piloting• Clinical trials	Pilot scale model or prototype is developed.			
					Pilot scale model or prototype system is near the desired configuration in performance, and volume but generally smaller than full scale.			
					Pilot scale prototype or model system has been demonstrated in a simulated environment.			
	7	System prototype demonstrated in relevant environment	A full-scale prototype is being demonstrated in an operational environment but under limited conditions (i.e., field tests). At this stage, the final design is very close to completion.		It is understood how the simulated environment differs from the operational environment, and how results differed from expectations.			
					Full-scale prototype with ready form, fit and function is developed.			
					Full-scale prototype demonstrated in an operational environment but under limited conditions.			

					Final configuration of the technology is developed.			
					Final configuration successfully tested in an operational environment.			
	8	System complete and qualified	Technology is being proven to work in its final form and under expected conditions. This stage commonly represents the end of technology development. At this stage, operations are well understood, operational procedures are being developed, and final adjustments are being made.		Technology's ability to meet its operational requirements has been assessed and problems documented; plans, options, or actions to resolve problems have been determined.			
Early adoption	9	Actual system proven in operational environment	Actual application of the technology in its final form is being conducted under a full range of operational conditions.	<ul style="list-style-type: none"> • Interview • Survey • Observation 	The technology has been successfully deployed and proven under a full range of operational conditions.			
					Operational, test and evaluation reports have been completed.			
Commercially available		Technology development is complete	Technology is openly available in the marketplace and/or has been sold directly to a buyer in the public or private sector, in its current state or service offering for non-testing or development purposes.	<ul style="list-style-type: none"> • Interview • Survey • Observation 	The technology is openly available in the marketplace and/or has been sold in its current state of service offering for non-testing or development purposes.			

TABLE 6. TECHNOLOGY READINESS LEVEL (TRL) ASSESSMENT TOOL. ADAPTED FROM TECHNOLOGY READINESS LEVEL (TRL) ASSESSMENT TOOL (2021); CIMIT; SANTONEN (2020).

Special issues

Below, we discuss some of the special issues that startups typically face when developing digital solutions for the health and care sector or when testing them in living labs.

Ethical issues

The importance of ethical awareness is obvious for companies who offer solutions for elderly end-users. These concerns were discussed with all the IN-4-AHA pilot companies. It has also been observed that if ethical concerns are not addressed correctly, this may lead to a denial or slow adoption of technology solutions (Mantovani and Turnheim, 2018; European Commission, 2007).

Co-creation as a key living lab process can succeed in an open and safe environment where people feel respected. (Nevmerzhitskaya, 2020). Several studies show that older adults are happy to actively participate in the testing process of an innovative solution that will be beneficial for them in the future. This is also true for older adults with dementia. They are glad to contribute with their pragmatic knowledge. (Verloo et al., 2021). In the IN-4-AHA living lab tests, this enthusiasm could be observed in those tests where older adults with dementia were involved. However, it could also be observed that also these participants must understand the reason why they participate in a test – if they do not see the point, they will not continue with the tests. And they have every right to withdraw, too. Informed consents related to elderly and vulnerable people are not just a one-off formality but become a continuous process that must be repeated constantly. (Sainz, 2012).

As mentioned above, living lab testing often requires ethical approval, for example a permission from one or more ethics committees, but most living labs can see to resolving these requirements (Santonen, 2020). However, it is advisable to be prepared for arising ethical issues and at least some delays due to them in living labs before, during and after testing periods that involve companies offering solutions for elderly end-users. It is important to plan and be ready to resolve these issues. Therefore, both strategies and tools should be in place for handling ethical issues in living labs and in companies. (Sainz, 2012).

When involving end-users in activities, informed consents are essential, meaning that all participants must be fully informed and agree on the purpose, type of data collected, how data will be used and by whom (Nevmerzhitskaya, 2020). Until recently, many studies concerning older people excluded those with reduced cognitive ability because it was thought that they cannot give informed consent. However, the general opinion is leaning towards a view according to which most people with moderate dementia are able to give informed consent. (University of Sheffield, 2015). It is possible to overcome the challenges of participants' cognitive impairments by using such concepts as fluctuating consent, process consent or rolling consent. This means that the vulnerable people's will to participate can and should be monitored continuously. (Verloo et al., 2021). However, in some cases where activities require the participation of end-user groups who are unable to give informed consent, such as people with advanced dementia, a legally authorised representative can provide consent (Nevmerzhitskaya, 2020). It should also be ensured that the methods of involvement used in living lab testing are selected and built taking into account the elderly people's needs, motivations and their contexts (Eisma et al., 2004).

Medical devices and CE marking

Due to the strict requirements for designating an innovation as a medical device, developers need to carefully consider the distinction between health and wellness products and medical devices (Herron, 2022). The new criteria in the European Medical Device Regulation (MDR 2017/745) brought a variety of new products and devices without a specific medical purpose into its scope (Takhar, 2021). The MDR is an ambitious project aiming to protect the end-user by placing their safety and anonymity at its core (Chernova and Konina, 2022). For example, many mobile health applications now count as medical devices, especially if they make recommendations by measuring physiological signs (Stevovic, 2019).

CE marking is the manufacturer's claim that a product meets the requirements of the relevant regulations, such as safety and performance requirements of the MDR. CE marking was established to harmonise product requirements across Europe, making it more straightforward for companies to trade across Europe. It is also a legal requirement for placing a device on the market in the EU. (Hinkkanen, 2020).

To understand which requirements must be met, the device's MDR classification must first be identified. Annex VIII of the MDR should be consulted to classify the device according to its risk profile (Rish, 2020). After these steps, the next step is to identify the relevant European standards and other essential requirements, and if notified bodies are necessary to obtain the CE marking. In addition, the necessary quality management system and technical documentation must be compiled. Many medical device companies use ISO13485 as a guideline for building a quality management system. The necessary documentation can include, for example, product specifications, manufacturing information, risk management, tests, assessments, product inspections and audits. (Rish, 2020). The higher the risks of the device are, the stricter are the regulations. In case of Class I products, the medical device can be self-certified, and it is up to the developing company to check and test that the device complies with the technical requirements. However, products in other MDR classes must be certified using a notified body who conducts an audit of the technical documentation. (Herron, 2022).

A notified body is a company – in practice, auditing or standards organisation – that the European Union has accredited to be competent to conduct audits of medical device companies, their products and systems. Once the medical device is certified, the developing company must create and sign a declaration of conformity, which is a document stating that the device meets all the essential requirements laid out by the EU MDR and any other applicable regulatory requirements. At this point, the CE marking can be included, and it should be visible on both the device and the packaging. The final steps include completing registration with a national competent authority and submitting data to the European Database on Medical Devices (EUDAMED). (Takhar, 2021; Rish, 2020; Obelis Group, 2019).

To handle this complex process, companies developing solutions should commit significant resources to safety and compliance. Practical tips include investing in regulatory intelligence and stakeholder engagement, planning with partners, external advisors and stakeholders across the value chain, and allowing products to be assessed at an early stage. (Herron, 2022).

Data protection and GDPR

Collection of sensitive individual end-user data is a key function of many companies developing digital solutions for health and care. Companies are responsible for ensuring that their customers' and end-users' data is protected (Stevovic, 2019). The EU's General Data Protection Regulation (GDPR 2016/679) applies to all companies handling personal data of EU citizens. The GDPR defines personal data as information relating to an individual, and data concerning health is personal data on the physical or mental health of a person. (Moore and Poitras, 2020). The GDPR gives several rights to data subjects, and these are enforced with tough fines. Health data receives special protection under the GDPR. (Stevovic, 2019).

There are seven principles in the GDPR: 1) Lawfulness, fairness and transparency, 2) Purpose limitation: data only for specified, explicit and legitimate purposes, 3) Data minimisation: only data that is necessary to provide service, 4) Accuracy: data is true and correct, 5) Storage limitation: not for longer than necessary, possibility to delete data if requested, 6) Integrity and confidentiality: data security, 7) Accountability: complying with the principles of the GDPR, and ability to demonstrate the compliance (Extra Horizon, 2022).

Managing sensitive data, such as health data, in compliance with the GDPR requires paying special attention to administrative and technical measures. For example, the solution company must be able to provide and store consent forms for users, carry out impact assessments, employ specific staff, such as a Data Protection Officer, and ensure staff training. Technical infrastructure requirements include authentication and access control procedures, secure data transfer between the solution and cloud infrastructure, data encryption and audit logs. (Extra Horizon, 2022).

There are important links between the MDR and the GDPR. For example, if a mobile application falls under the MDR and it collects end-users' personal data, then it also falls under the GDPR (Stevovic, 2019). In 2020, the Medical Device Coordination Group (MDCG) of the European Commission published *Guidance on Cybersecurity for medical devices*, providing medical device manufacturers guidance on how to meet the cybersecurity requirements provided in Annex I to the MDR. Annex I lists concerns about devices that incorporate software: the software should be developed and manufactured taking into account risk management, including information security, verification and validation, hardware, IT network and security measures, and devices should be designed and manufactured to prevent unauthorised access. (Liguori and Stefanini, 2021). For a company, it is worth considering GDPR and MDR compliance from the beginning of development, because the more these are postponed, the greater the cost of compliance becomes (Stevovic, 2019).

Careful elaboration of data protection policies is valuable as these policies show a company's approach to the collection and use of customer or end-user personal data. A policy can guide actions with detailed steps. The legal motivation for using policies is very important, but inadequate data protection policies also carry practical and commercial risks. (Anneraue, 2021).

For further information on data protection see D5.3. Data Governance Guidebook (Kütt et al., 2022), where for example, a basic consent template for companies is provided in Annex 2.

Intellectual property rights (IPR)

There are several types of intellectual property (IP), for example, copyrights, patents, trademarks and trade secrets. It has been estimated that one third of all research and development efforts is spent on inventions that already exist. Therefore, existing solutions in the field should always be checked – what solutions are already on the market and what IPRs have been registered? For example, in the case of medical devices, the ideation phase should include an IP analysis. The testing phase should apply non-disclosure agreements, inspect the patent landscape and patentability and later apply for patents and design and trademark protection. The production phase should record copyright in packaging and instruction materials. Finally, the market phase should consider customs protection and develop anti-counterfeiting strategies. (Rajendra and Smillie, 2014). As most European countries are part of the European Patent Convention, software as such is not patentable in Europe. However, there are some exceptions: when a computer programme solves a technical problem, it can be patentable.

(https://en.wikipedia.org/wiki/Software_patents_under_the_European_Patent_Convention).

The European IP Helpdesk (https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk_en) provides free-of-charge first-line support on IP-related issues to European SMEs for managing their IP issues in the context of international business or EU research and innovation programmes.

Advice for organisations planning to start a living lab: how to build a living lab (network)?

Evaluation of digital solutions developed for AHA requires collective efforts from multiple stakeholders, including health and care providers, companies who develop the solutions and authorities (Guo et al., 2020). It is crucial to involve end-users as well as other stakeholders in the innovation process. Today, open innovation and consequently living labs as open innovation environments are seen as an important instrument for advancing innovations in knowledge-based economies (Schuurman and Protic, 2018; Guldemon and Geenhuizen, 2012). Living labs are a response to many contemporary trends including the shift in user role from passive to active, a shorter time to market and the globalised market. (Ståhlbröst and Holst, 2012).

- *“Real-life settings can involve a vision of meeting users or citizens on ‘equal grounds’” (Fuglsang et al., 2021).*
- *“Open innovation can be perceived as the systematic encouragement and exploration of a wide range of internal and external sources of innovation opportunities, consciously integrating that exploration with organizations’ capabilities and resources.” (Guldemon and Geenhuizen, 2012)*

Living labs are considered as means to respond to the demands for cost reduction and a quick market introduction in global competition. These demands have also driven many universities, technology institutes and companies to adopt models of open innovation. (Guldemon and Geenhuizen, 2012). Living labs have also become important regional policy instruments in cities and rural areas. Common elements of living labs are active end-user

involvement, real-life settings, co-creation, multi-method approaches and multi-stakeholder participation. (Schoorman and Protic, 2018).

Living labs are intermediaries or innovation facilitators for the co-creation process where they provide structure and governance. They involve people in real (or realistic) environments, thereby providing more valid evaluations of innovations in context. Collective learning and thinking taking place in a living lab should contribute to both theory and practice. (Verloo et al., 2021).

Research has defined critical factors for building a successful living lab or living lab network. Geenhuizen (2015) points out six factors worth considering. They are related to user involvement, real-life environments, network and management, innovation process, the role of ICT and practical values and requirements.

- Perhaps the most important factor to take into consideration is user involvement, including the selection and motivation of users, and guaranteeing that they have sufficient capabilities to succeed in their roles, and especially in the case of elderly users, considering appropriate measures to deal with vulnerable users.
- There are also other less critical issues concerning real-life environments, such as ensuring access to facilities and ensuring adequate infrastructure.
- Network and management issues include building a network of all the relevant (but not too many) stakeholders, promoting openness and neutrality as well as a multisector and multidisciplinary approach, managing different roles and building trust and commitment. Guldmond and Geenhuizen (2012) note that because there are multiple actors in living labs – typically universities, research institutes, user groups, SMEs, large firms, non-profit institutions and local or regional authorities – living labs are in a dynamic multi-actor situation where good management is needed.
- The innovation process in a living lab must have an adequate selection mechanism of projects, with transparent go/no-go decisions.
- ICT should not be the main driver. Instead, it should be used efficiently for monitoring and analysis of user responses.
- Issues related to practical values and requirements include paying adequate attention to ethical and legal issues, such as liability and intellectual property issues, as well as the values of user groups, such as privacy, cultural identity and self-determination. (Geenhuizen, 2015).

In connection with regional development work, Kolehmainen and colleagues (2015) point out that, because each actor in the collaborative network has their own vision, it is important to establish joint processes for formulating shared visions. The following ten themes have been identified as essential building blocks in generating and maintaining an innovative and co-creative co-learning environment: great beginnings, art of projects, building to last and expand, networks for talent hunting, investing in networking, co-creative collaborative thinking, informal ways of working, transparency, identifying enablers and being visual. In addition to the above-mentioned themes, three basic pillars – trust, respect and joy – can be identified as the foundation for the collaborative culture and innovative environment. (Rajahonka et al., 2015).

Especially concerning end-user involvement, building of trust has been seen as a success factor for collaborative innovation processes: trust ensures stability and commitment, but trust is also needed for end-users to share their honest opinions and experiences about the solutions they test. Respect and sharing of power contribute to trust and promote commitment to the innovation process among stakeholders, which in turn has a positive impact on motivation. (Ceasar et al., 2017). Co-creation and active end-user involvement are not possible without strong cooperation and openness towards different actors (Schuurman and Protic, 2018).

“Elderly users do not have experience in using technologies, they are insecure or afraid, unless a professional can introduce the solution in a proper way... you have to gain their trust. You have to take into account their culture, you cannot use complicated language...” (IN-4-AHA Living lab network coordinator).

Living lab business models are grounded on the possibilities and restrictions arising from the surrounding partners and ecosystem. According to Santonen (2020), who studied 15 health and care living labs, the most important partners of these living labs were research and education institutions, regional public organisations, care organisations and municipalities. Key activities included project management, education and training as well as testing and co-creation. The value proposition was usually to offer research and development services in unique infrastructure and with real end-users. The most important customer segments were education and regional public organisations, device manufacturers and digital service providers. Santonen (2020) suggests that a partnership strategy based on widespread partnerships is the best choice for living labs. Supporting startups in developing solutions, i.e., relying on entrepreneurship and venturing, brings living labs closer to sustainable business models. This also demands good relationships with private funding, such as venture capitalists, for which living labs can deliver high-potential investment opportunities. (Katzy, 2012). However, currently most living lab projects are funded by public grants (Santonen, 2020). Santonen and Julin (2019) studied SMEs’ needs for living lab services and concluded that testing was clearly the most often mentioned need among the interviewed SMEs. Therefore, the authors recommend living labs to adopt the testbed approach. In addition, marketing and sales support, research and development services for new ideas, networking and collaboration, as well as access to various types of end-user groups and market knowledge were identified as services that SMEs most often expect living labs to provide.

There are different types of living labs, and they offer different types of services. Accordingly, there are multiple business model options for living labs. (Santonen and Julin, 2019). Business models must be built on openness and neutrality, avoiding situations where one actor plays a key role and discourages other stakeholders from participating (Guldmond and Geenhuizen, 2012), and there should only be one business model applied.

The European Network of Living labs (ENoll) facilitates knowledge exchange, joint actions and project partnerships between living labs (<https://enoll.org/about-us/>). The members operate all around the world, not just in Europe. The ENoll website includes various resources, publications, policy briefs, playbooks, toolkits and toolboxes – for example, 20 tips and tricks

for building a sustainable living lab (<https://www.iscapeproject.eu/wp-content/uploads/2020/02/Tips-Tricks-for-Living-Labs.pdf>).

There are several interrelated challenges that living labs may face. These include transition challenges, as a living lab in most cases is only a minor part of the activities of, for example, a care home. This same issue often leads to a lack of resources and time for the personnel as well as commitment challenges for the personnel but also for other stakeholders. There can also be challenges in scaling, as this requires even more resources. There are also day-to-day technical and practical issues, such as communication, that must be solved as they emerge. These demand time and resources. Technical challenges may be so significant that there is a need to define what constitutes a real-life setting. As participation is and should always be voluntary, getting end-users motivated to participate in co-design and testing activities may be a challenge. It can also be the case that unclear roles cause conflicts and misunderstandings, and therefore, there is a need to define roles and tasks. (Andersen et al., 2018). Moreover, sustainability and lack of sustainable funding is a typical challenge for living labs, as many living labs do not survive beyond the first financed project. (Verloo et al., 2021).

“The key point is to have a clear idea of what you can offer, what differentiates you from others. We are good at public-private-people collaboration, offering diverse user profiles, putting together protocols etc. There should be two or three things you are good at and there should be a neutral umbrella organisation, who understands the ecosystem. It is important to have good relationships to user associations, regulators, and private procurers.” (IN-4-AHA Living lab network coordinator)

Here is a short checklist to ensure successful ecosystem cooperation. The following aspects must be defined and established:

- Strategic, major challenge common to everyone
- Identification of the right actors
- Shared vision
- Common metrics
- Decision-making, decision-makers and decision criteria
- Goals for each actor – described and communicated openly (what each actor wants to achieve)
- Roles and capabilities of each actor – described and communicated openly (the contribution of each actor)
- Use of tools for service design and agile development
- Continuous facilitation digitally and face-to-face to keep the big picture clear and address challenges effectively
- Commonly agreed rules of the game, standards and agreements (Motiva, 2020)

Chapter 2. Scaling up

Key learnings of this chapter are:

1. Scaling up means deploying solutions on a larger scale. In this way, the solutions also provide more benefits. Scaling up can mean not only the implementation of a solution in a new context or by new users, but also a more intensive use of the solution by the same users. (Motiva, 2020).
2. Scaling up is not a straightforward process because it may require going back to previous development stages or testing new aspects when seeking new customer segments or entering new markets.
3. Startups should have their business model in mind already at an early stage, and especially their value proposition to end-users and customers, for guaranteeing a successful scale-up of digital health and care solutions. Following lean startup principles can help. According to lean startup approach, scaling up means that after reaching the product/market fit the company aims at rapid growth. The solution has been proven good enough for the masses, evolving from an MVP to a scalable product. (Paakkinen, 2021; Maurya 2012; Mueller and Thoring, 2012). Preparations for scaling up can be done by sketching a business model with Lean Canvas.
4. For being easily scalable, the innovation should be credible (tested), observable, relevant, better than existing practices, easy to understand, compatible, and testable without complete adoption (WHO, 2010). In addition, the technological implementation should be easy to scale (software, cloud, etc.) and the solution should be based on person-centred care (PCC) principles.
5. The scalability of the innovation can be improved, among other things, by simplifying a complex innovation, completing an incomplete innovation, or redoing a pilot project under circumstances more characteristic of the scale-up setting (ExpandNet, 2010).
6. Tools for startups and SMEs presented in this chapter are:
 - Tool 5: Key points of a business model (Lean Canvas)
 - Tool 6: Evaluation of scalability of an innovation
 - Tool 7: Enhancement of scalability of an innovation
 - Tool 8: Questions to consider when scaling up: Why, what and how?

“For the pilot companies, Slush startup event was a living lab, too – for testing their business model.” (IN-4-AHA Living lab network coordinator)

What is scaling up?

There are several definitions of scaling up. The concept comes from manufacturing, meaning the aim to grow and economies of scale (Gabriel, 2014). The term has been used especially in the health sector – in addition to the increase of service provision or outcomes, it has also been used for describing the increase or more efficient usage of inputs (budgets or workforce) and for scaling small projects to wider audiences. Scaling up can be smooth, stepwise or a great leap (WHO, 2008). The WHO ExpandNet defines scaling up as: *“deliberate efforts to increase the impact of successfully tested... innovations... to benefit more people...”*. (WHO, 2010)³.

According to lean startup approach for startups, scaling up means reaching a point where the company aims at rapid growth. At this point, the company has reached a product/market fit, and both the company and the investors have the same goal – growth. Therefore, precisely this point is a convenient time to raise additional funding (Jureen, 2014; Maurya, 2010).

Phases of a successful startup:

1. Problem/solution fit: Find out whether there is a problem that is worth solving, that customers are willing to pay to be solved, and that can be feasibly solved. Validate the problem and the solution with real potential customers and end-users. This is a bootstrapping stage financed by friends, family and angel investors.
2. Product/market fit: Test the solution and its ability to solve the problem with a minimum viable product (MVP) released to the market. The MVP includes a minimal set of features for solving the core problem. The results lead to pivot or persevere: change or keep the MVP. The goal of this phase is to test if a) the customer is willing to pay for the product, b) there is an economically viable way to get customers, and c) the market is large enough. This is the seed stage, in which a startup often works in an accelerator or incubator and gets its first paying customers.
3. Scale: Build organisational structures, turn startup into a corporation. This is the customer creation and growth phase with venture capital funding. This phase starts once the solution has been proven good enough for the masses, thus evolving from minimum viability to a scalable product. (Paakkinen, 2021; Maurya 2012; Mueller and Thoring, 2012).

Preparations for scaling up: sketching a scalable business model with Lean Canvas

Because the environment is uncertain and startups have no history, writing lengthy traditional business plans is not sensible. Therefore, presenting the business model in a one-page visual representation has become a popular approach for startups. A business model describes how a company creates and delivers value to its customers and captures a market share so that the business model becomes economically sustainable (Maurya, 2022d; Bortolini et al., 2021; Teece, 2010).

The business model can be presented using the Business Model Canvas (Osterwalder et al., 2010) or Lean Canvas (Maurya, 2012). Both illustrate the business model in nine subparts that can be separately tested. The benefit of using these canvases is that they aid in identifying

³ ExpandNet is a network of public health professionals and scientists that focuses on scaling up health service innovations that have been tested in experimental, pilot and demonstration projects. The website includes guidance tools to assist countries in scaling up. See more: <http://www.expandnet.net>.

quickly the key points of the business model and iterate towards an improved business model (<https://www.pimcy.nl/business-model-canvas-lean-canvas-and-strategy-sketch-compared/>).

The elements of Lean Canvas are presented in Figure 4. The elements of the Business Model Canvas are the following:

- Customer segments: Which customers do I serve and which “activities” are carried out by my customers?
- Value proposition: What is the value I offer to the customer? What does the customer achieve by using my product or service?
- Channels: How can customers be reached?
- Customer relations: What kind of relationship do I have with my customers? How can I acquire customers?
- Revenue streams: What are customers willing to pay and how?
- Key resources: What resources (time, money, etc.) am I using to create value?
- Key activities: What activities should be done to create value?
- Key partners: Which partnerships are necessary?
- Cost structure: What are the resulting costs? Are they fixed or variable?

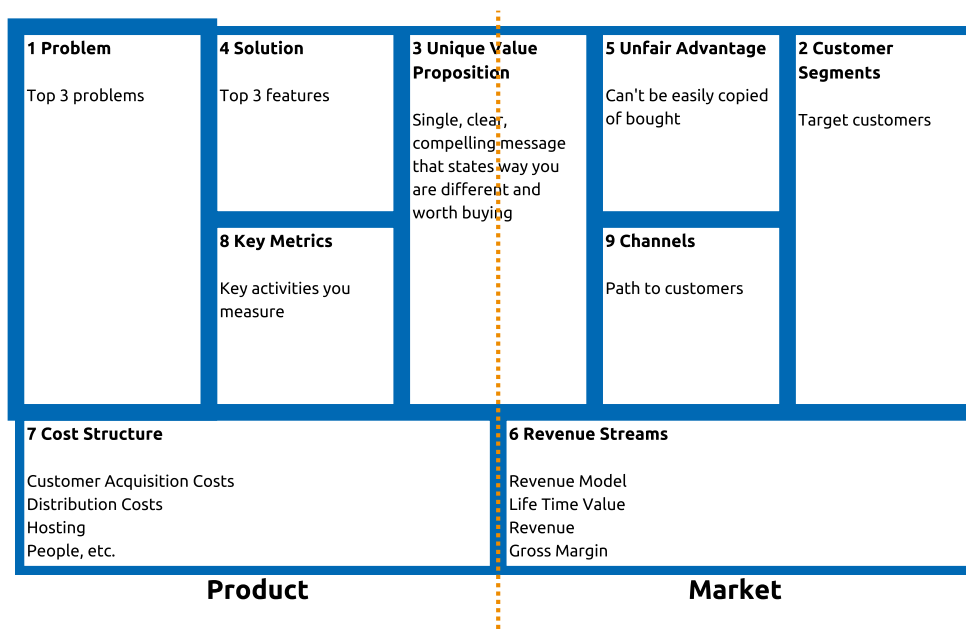


FIGURE 4. LEAN CANVAS. ADAPTED FROM MAURYA (2012).

Since business models function in a specific context, the following areas need to be mapped using the so-called Environment Map:

- Market forces: growing or shrinking customer segments, pains and gains
- Key trends, such as technology innovations, regulatory constraints, social trends
- Industry forces, namely key actors, such as competitors, value chain actors, technology providers
- Macroeconomic forces, such as global market conditions

In any case, the most important success factor for a startup is the ability to modify its business model dynamically (Bortolini et al., 2021; Blank, 2013). Successful startups go quickly from failure to failure, at the same time adapting, iterating and improving their original ideas while learning constantly from their customers (Ojasalo and Ojasalo, 2018).

Identifying customer values is vital, but this is not enough for transforming them into an economically sustainable business. For that, the company needs a scalable and profitable business model. (Ojasalo and Ojasalo, 2018). Actually, a startup has sometimes been defined as an organisation founded with the aim of building a scalable business model (Jureen, 2014; Bortolini et al. 2021; Blank, 2006). Therefore, for a startup it is important to know what the characteristics of a scalable business model are, how to build one and how to scale one up. An important feature of a scalable business model is that the model is self-enforcing, i.e., it creates feedback loops or virtuous cycles that continuously strengthen the business model, expanding both value creation and capture (Casadesus-Masanell and Ricard, 2011).

In the sample of five IN-4-AHA pilot companies representing very different types of companies, it was recognisable that all firms in the iterative process simultaneously developed a more accurate picture of the problem and, on the other hand, of the solution. At the same time as they better identify the details of the end-user's and customer's problem and are able to provide a solution to them, as an outcome, it creates feedback loops or virtuous cycles that continuously strengthen the business model, expanding both value creation and capture.

[Lean Canvas, point 1: Understanding the customer problem](#)

It can be observed that startups fail if they are not able to create a sufficient understanding of customers and their problem and to build a solution that is wanted by the market. This means that these startups either work on a problem that is not defined correctly or significant enough, or they are not able to build solutions that solve the problem in a feasible and viable manner. An MVP is built and re-built for the purpose of learning as much as possible from a small group of customers and continuously improving the product. (Paakkinen, 2021; Mueller and Thoring, 2012).

Before reaching the product/market fit, focus should be placed on learning from customers and pivoting. After reaching the product/market fit, the focus shifts towards growth and optimisation. Pivots are for changing direction and finding a plan that works, while optimisations are for accelerating that plan. (Maurya, 2012).

[Lean Canvas, point 2: Who is the customer?](#)

Defining the right customer segments is not always easy in the AHA sector. It has been argued that the role of the customer is not as clear in health and care as it is in a regular retail value chain, for example. Thus, startups such as medical device companies, can get confused. Who should they serve? Is it the doctor, the hospital, the municipality, the elderly end-user, the family member, the insurance company or someone else? Moreover, each stakeholder has a different focus, and even the payment systems can be divided so that payments are split to multiple parties – i.e. the elderly end-user pays one part, and the municipality or insurance company another part. And to make the situation more complicated, these constellations in

the kaleidoscope can vary in different countries or even case by case, and they can change over time. (Cecere, 2014).

To make the situation a bit clearer it is a good idea to start by brainstorming the list of possible customers for the solution, then distinguishing between customers and end-users. If there are multiple user roles in the solution, the customers should be identified. A customer is someone who pays for the solution, but an end-user is not always a customer. Broad customer and end-user segments should be split into smaller ones, because it is impossible to build, design and position a solution that fits everyone. (Maurya, 2012).

Lean startup and customer development approaches distinguish between different types of customers: end-users, influencers, recommenders, economic buyers and decision makers (Mueller and Thoring, 2012; Maurya, 2012). Even when the aim is to build a mainstream solution, it is best to start with a specific customer in mind. It is necessary to identify *who has the pain*, who are the early adopters that really want the solution urgently. Finding the top two or three customer segments the company understands well or finds most promising is a good start. All customer segments should be placed on the same canvas at first, but later sketched onto a separate canvas for each customer segment. The elements of the business model may vary significantly by customer segment. (Maurya, 2012).

A value proposition canvas can be used to clarify links between customer profiles and solution values: the solution should be able to solve customer problems. However, focus should always be kept on what the value-based outcomes for the elderly end-user are, because other stakeholders in the care circle or value chain also benefit from them. The benefits in the value chain should be aligned, but sometimes it is the company's job to show the stakeholders that they are aligned because a lack of alignment can be a barrier to progress. (Cecere, 2014).

While some older adults purchase technology-based solutions for themselves, some rely on family members or advisors to help them with their decisions, as well as with the set-up the solution or technical support. Besides family members and professional advisors, private and public organisations providing care for the elderly are important stakeholders, and most probably at least some of them are the company's customers as they pay for the solution. Besides solutions for elderly care, business-to-business solutions can also be offered, such as software for care home resident engagement. This means that stakeholders of AHA solutions are not just older adults but the entire care circle – the entire value chain. This includes family members, national, regional and local governments, as well as healthcare and other service providers, who purchase solutions that benefit the ageing population. (Etkin, 2022).

It can be noted that also in all of the five IN-4-AHA pilot companies, although they represent very different types of companies, several stakeholders and their opinions and actions have to be taken into account when producing the solution.

The (paying) customers of the solution in the AHA sector could be:

- Seniors (Which specific age groups and physical or mental characteristics?)
- Families (Informal caregivers, who specifically?)
- Private organisations providing services to seniors (Which specifically?)
- Public organisations providing services to seniors (Which specifically?)

- Local government (Which specifically?)
- Regional government (Which specifically?)
- National government (Which specifically?)
- Insurance companies (Which specifically?)
- Others, who/which?

The end-users of the solution in the AHA sector could be:

- Seniors (Which specific age groups and physical or mental characteristics?)
- Professionals (Formal caregivers, doctors, nurses, researchers; who specifically?)
- Families (informal caregivers, who specifically?)
- Private organisations providing services to seniors (Which specifically?)
- Public organisations providing services to seniors (Which specifically?)
- Others, who/which?

Besides end-users and customers, other key stakeholders to approach should be considered. Depending on the situation, they can include national, regional or local decision makers, or NGOs advocating necessary policy changes. The pilot company cases of the IN-4-AHA Project support previous research findings. In the five IN-4-AHA pilot companies, all of the above stakeholders had to be taken into account when designing a scalable solution and operation.

Thinking about who will pay for the solution, and what their interests are, is fundamental to a successful scaling strategy. The benefits of health and care innovations are often distributed – some concern individuals, some concern institutions and others concern the wider society. Therefore, customer segments can be direct customers – individuals or companies who buy the solution because it benefits them – or indirect customers who buy the solution on behalf of others, such as public sector institutions buying services for taxpayers. Therefore, it is important for the innovator to engage with the stakeholder communities and find out what they want. It is reasonable to release an MVP into the market and shape it with the help of stakeholder communities. (Gabriel, 2014).

It is important to keep an open mind regarding the variety of areas to which the solution could be applied. For a technologically advanced solution, it is quite common that the company starts by advocating and selling the solution, for example, for research purposes, then to professionals, and after validating and simplifying the solution enough, to consumer mass markets. Another route is developing and testing solutions first for veterinary markets, and only after getting the required approvals, for human health and care markets. Using these routes, startups can guarantee at least some income flow from paying customers at an early stage. These models have been applied also by some of the IN-4-AHA pilot companies.

Customer development (Blank, 2006) is a method to increase the success of product development through better understanding of customers before scaling up the business model (Bortolini et al., 2021). This method is based on iterative and incremental development and feedback from customers. Customer development refers also to innovating for new customers and creating a new market, thus resembling the blue ocean strategy introduced by Kim and Mauborgne (2004). In this process, a minimum viable product (MVP), with only the core features that allow the product to be introduced to potential customers for feedback, is improved through iterative cycles. A rather similar approach is called rapid

prototyping, which starts with the designer's best guesses and goes on to iterate at a fast pace and low cost until the solution meets expectations. (Ojasalo and Ojasalo, 2018). Even though customer development is perhaps not as easy and straightforward in the AHA sector as in regular consumer product markets (Jureen, 2020), developing end-users, customers and other key stakeholders by training and advocating can be of utmost importance in the AHA sector, especially.

"You have to get out and directly engage customers. The key takeaway from customer development can be summed up as: Get out of the building!" (Maurya, 2012).

Some examples of the important issues related to the end-users or user organisations and required actions to increase the potential for scaling up success are the following:

- Strengthening need or motivation through advocacy using formal and informal channels
- Identifying, working with and mobilising advocates or champions who are ready to speak for the innovation (lead users, etc.)
- Identifying any opposition to the innovation, and trying to reduce it
- Identifying areas where implementation capacity is stronger
- Strengthening the implementation capacity by offering support for implementation (training of end-users or personnel, etc.)
- Advocating for needed policy or legal changes
- Identifying possible negative impacts and finding ways to prevent them
- Maximising opportunities and minimising constraints of changes required for implementation. (WHO, 2010; WHO, 2021)

Lean Canvas, point 3: Unique value proposition

Unique value proposition is one of the most important boxes on Lean Canvas, but it is also one of the hardest to get right. The unique value proposition should be short and explain how the solution is different and why that difference matters. The key is to derive the value proposition from the customer problem being solved. Value propositions must be evaluated from the perspective of the customers' value creation (Ojasalo and Ojasalo, 2018). Therefore, the value proposition should

- Target early adopters first because the product is probably not yet ready for mainstream customers
- Be clear and specific
- Focus on customer benefits – not features – and use the customer's language to explain how the solution will benefit the customer
- Use the formula "Result the customer wants" + "Time period" + "How to deal with objections"
- Answer the questions *what*, *who* and *why*
- Mirror the value propositions of leading brands. (Maurya, 2022a).

Thinking about a unique value proposition is vital for a startup. To succeed, an idea must be desirable, viable and feasible. Too many startups focus on viability and feasibility, starting with a business model or technological invention, but do not consider how the end-users feel

about it. The main reason why concepts fail is that they do not solve any relevant problem for the end-user, meaning that they are not desirable. Nobody wants them, and nobody will buy them. (Mueller & Thoring, 2012).

Lean Canvas, point 4: Solution – is the innovation scalable?

There are aspects related to the solution that should be considered before trying to scale up, such as the technological maturity of the solution (TRL, see Table 6 above), novelty of the solution and if it has to be protected with IPR, compliance with regulations and necessary approvals or certificates, etc. Before attempting to scale up, the scalability of the innovation should also be assessed. Scalable innovations tend to be relevant beyond their initial context, relatively simple, clearly better than the alternatives, provide value for money (less expensive than alternatives), and they do not rely solely on the talent of specific individuals. (Gabriel, 2014).

- *“The world is full of ‘gold plated pilots’” (Gabriel, 2014).*
- *“Pilots are an experiment in an ideal world where the constraints of the real world are not considered...There should be at least a roadmap for scaling after a successful pilot which should be discussed before the pilot.” (Chernova and Konina, 2022).*

WHO (2010) listed eight points (“CORRECT”) for evaluating the scalability of an innovation. We propose adding another “T” and a “P” to the list: *technological implementation* and *person-centredness*, because these aspects are very important to take into account when scaling AHA innovations. If necessary, the scalability of the innovation should be boosted by improving the points above. This can be achieved, for example, by collecting further evidence or documenting and communicating test results more clearly. (WHO, 2010). (See Tool 6).

The barriers for scaling up AHA innovations, in particular, include the following: lack of communication, lack of awareness, resistance to change, low digital literacy, barriers related to organisational structures, lack of technical infrastructure and connections, lack of interoperability and system integration, as well as financial, time and effort barriers. (Stroetmann et al., 2015). All five of the IN-4-AHA pilot companies, representing different types of companies, identified these barriers to scaling as very significant. Although they were in slightly different situations in development, they had to take into account and develop these qualities.

The scalability of the innovation can be improved, among other things, by modifying it in the following ways: a complex innovation should be simplified before scaling up; an innovation lacking an essential component should be completed before scaling up; and a pilot project carried out with various external inputs or in special settings should be redone under circumstances more characteristic of the scale-up setting. (ExpandNet, 2010). (See Tool 7).

Lean Canvas, point 5: Unfair advantage

The fact is that most entrepreneurs do not have an unfair advantage to start with. The most mentioned unfair advantage is first mover advantage. However, being first to market is a disadvantage, because it requires not only building a solution, but also having to build a

market. Therefore, a fast follower can overcome this advantage. Examples of unfair advantage include insider information, dream team, personal authority, network effects, community, existing customers and their loyalty. Other relevant concepts are sustainable or competitive advantage, where the idea is to think about how to stand out from the competition. (Maurya, 2022b). This is also a good moment to think about business potential, market needs and trends. Is the market opportunity wide or limited? Do the trends support the opportunities? The difference between a unique value proposition and unfair advantage is that the former is intended for the customers, while the latter relates to the competitors (Maurya, 2022c). Potential cultural differences in the new market area should also be considered. Unfair advantages in one market area are not necessarily the same in another.

Lean Canvas, points 6 and 7: Revenue and costs

It has been claimed that healthcare startups must be prepared to maintain the company financially for at least five years before being able to secure the first profitable deal. An industry as conservative as healthcare is unwilling to trust young startups. (Sinhasane, 2020). The financing of operations until the first paying customers is something that must be planned in advance. In addition, the timeframe for getting the first customers, the size and growth of the potential market, as well as the growth rate and market share of the business should be defined. Pricing options can be tested first based on what customers say and after that based on what they do (Maurya, 2012).

There are various revenue and pricing models to try. There are some that come with a one-time license fee and others that are subscription-based. These have different benefits: for example, one-time payments are more suitable for monitoring tools and wearables, whereas cloud-based software providers usually use subscription model, as lower initial fees can lead to more customers. Subscription-based models can have different pricing models – for example, in a freemium model some features are available for free, but the customer has to pay for the key functionalities; in flat rate pricing, users get complete functionality for a fixed price. Other pricing models include the pay-as-you-go model, where price is based on use metrics, and tiered pricing, where there are multiple fixed prices depending on the features used, or the price could be based on the number of users per account. (Demigos, 2022).

Defining the costs and cost structure means, firstly, defining which costs are variable and fixed costs. Fixed costs remain the same, whereas variable costs change based on the amount of output produced. Fixed costs are, for example, facilities, equipment, insurance, internet and phone services and bank fees, and variable costs can include materials, cloud hosting and outsourced services (Demigos, 2022). The usual advice for a startup making financial plans is that it is best to keep fixed costs to the minimum. This means that it may be a good idea to prefer cloud solutions and outsource distribution and manufacturing operations to a third party, for example. (Upcounsel, 2021).

Lean Canvas, point 8: Channels – how is the solution integrated into the larger service delivery system?

Ecosystem thinking is essential for planning the integration of the solution into the bigger service delivery system – for example, a homecare system, a care home's elderly care system, a hospital's treatment system or associated ICT system. The regulatory environment in the AHA sector is complex, and legal requirements applying to both the company's location and

target markets must be met. For interoperability of data, it is necessary to ensure that the solution under development meets interoperability standards. (Sinhasane, 2020).

“Exporting companies also need to comply with regulations adopted in the countries where they are distributing their products. For instance, if they distribute in the U.S., they need to satisfy the requirements of the Food and Drug Administration. Finally, they also need to comply with regulations from the industries that intercross healthtech. The process of regulatory compliance may be lengthy and complicated.” (Chernova and Konina, 2022).

The user organisation and its capacities to adopt the solution must be assessed. What is the best way to assist the organisation in the implementation process? For the purpose of scaling up, the following questions should be considered:

- Are there any relevant technical or regulatory questions or requirements?
- Which organisations are expected to adopt the innovation or have already implemented it?
- Are these organisations different from the organisations that tested the innovation earlier?
- At which level will the solution be adopted (national, regional, local, etc.)?
- If a user organisation has not yet been selected or if the level has not yet been decided: which options exist, and which steps need to be taken?
- If there are several user organisations that will jointly implement the innovation, which is the lead organisation? Is there coordination between the organisations?
- How can a sense of ownership be promoted in the user organisation(s)?
- What is the customer problem, i.e., is there a need for the innovation in the user organisation(s)? Is it a priority?
- Who are advocates/champions of the innovation in the organisation(s)? Is there any opposition?
- Does/do the user organisation(s) have the capacity to implement the solution? Does/do it/they have, for example, resources needed, technical skills, personnel to take on the new tasks implied by the innovation, physical facilities or values and orientation supportive of the innovation?
- Can the solution be implemented without endangering the organisation’s provision of existing services?
- Are there process/workflow descriptions, and do they need to be adapted?
- Is further testing required?
- What can be done to ensure the funding of the scale-up phase?
- What will be the probable challenges? Are there ongoing changes in the organisation or the environment that might affect the success of scaling up? (WHO, 2021).

Lean Canvas, point 9: Metrics

Metrics are used to help a company to improve and to focus on essential issues. Without metrics it is hard to reach goals and measure progress towards them. The best suited metrics

change over time: before reaching product/market fit, it is best to use engagement metrics and quality feedback from customers, but once the solution is working and growing, focus can be shifted to growth and revenue metrics. (Parikh, 2015). However, for a health and care startup, in addition to the regular metrics used in business development, indicators developed for assessing health and economic outcomes of different innovations are important metrics to observe. And the most important focus to aim at is person-centred care.

For further information on how to find metrics for person-centred care, see D5.1. Overview of evaluation toolkits (Paat-Ahi et al., 2021), D5.2. AHA innovation assessment framework (Paat-Ahi et al., 2022), and D4.2. Mapping of Accessibility and Adoption of Services and Products (Saborido Piñeiro, 2022). See also Tool 3 above.

How to scale up?

There are different ways to scale up an innovation. The aim can be, for example, to increase the user volume, modify the solution for different customer segments or enter new markets, i.e., cross-border use. Increasing the number of users has sometimes been called quantitative or horizontal scaling – therefore, qualitative scaling could be trying to scale the impacts of the innovation. Functional scaling would mean offering complementary innovations targeting, for example, important policy aims. Each of the different ways to scale up requires different capacities to tackle different challenges. In any case, scaling up will require several ways of working and several skills and competences. All this will most probably force an organisation to change their culture in a way that can feel uncomfortable. (Gabriel, 2014; WHO, 2009).

When developing a scale-up strategy, the questions of *why*, *what* and *how* to scale up must be answered. *Why* means defining goals for scaling, *what* means establishing what will be scaled up, and *how* means choosing the routes to scaling up and delivering the strategy. These aspects are linked together. (Gabriel, 2014).

The following principles can help in the development of a scale-up strategy:

- Ecosystems thinking – being aware that the scale-up of innovations is carried out in a complex network of relations and systems. Relationships between the innovation and the team behind it, and the end-users and user organisations as well as other key stakeholders and the larger environment including infrastructures and ICT systems, where the scale-up takes place, create a complex network where a change in one element affects the others.
- Building on sustainability – taking into account regulations, policies, guidelines, budgets and health and care systems and their reforms, and aligning innovations and scaling up with them.
- Enhancing scalability – taking scale-up into consideration already at early stages.
- Participatory approach and person-centredness. Scaling up should be guided by participatory and person-centred approaches. It should ensure attention to human dignity, the needs and rights of vulnerable groups and promote access to quality services. (WHO, 2010).
- Testing at all stages – testing activities continue throughout the development and scale-up process, however, the object of testing and with whom the testing is carried out change (Mueller and Thoring, 2012).

“When organisations grow, they often have to change not just their leadership but also their culture and structures.” (Gabriel, 2014).

Why?

The planning of the scale-up must begin by asking the question “why?”. For the solution to gain acceptance, people need to understand the purpose of the solution and believe what the developer believes. Thus, having a clear vision is an important starting point in scaling up. Finding the answer to “why?” can be made easier by first defining the target customers: how many people will benefit from the innovation and what is realistically possible to achieve. It is necessary to recognise the full potential of the idea. (Gabriel, 2014). For questions to consider at this stage include see Tool 8.

What?

Scaling up will be successful only if the solution is superior to the alternatives in significant respects and if someone is willing to pay for it (Gabriel, 2014). This means that the company should be able to identify and understand the customer problem and develop a solution solving the problem, as well as an MVP for testing whether the problem can be solved and whether the customer is willing to pay for it. For focusing on important issues and communicating and transferring knowledge about the innovation to others, it is useful to identify the core or essence of the innovation – what is fixed and what is flexible in the model, scaling routes and goals. Building of an MVP helps here. (Gabriel, 2014).

The relationship between the innovation and the wider context affects scalability. This means that timing is important: scaling up is easier if the company is able to ride a trend of interest. It is also useful to define whether the innovation is sustaining or compatible, i.e., it creates better ways of doing something and strengthens the existing system, or whether it is disruptive, radical or systemic, i.e., it creates new ways of doing things and at the same time challenges the existing system. The latter types of innovations are harder to implement and scale as they require changes in attitudes and systems, and because they challenge existing dynamics. It is easier to scale if there is a proper fit with the existing structures, systems or home environment, and if the innovation is “plug and play” compatible with them. (Etkin, 2022; Gabriel, 2014). For questions to consider at this point see Tool 8.

How?

There are various routes to scale up an innovation – and they can be applied at the same time. Optimal approaches to scaling up can also change over time. The first option is to expand the organisation: set up new branches, build team and staff capacities, raise funds and develop the organisation’s resources and systems. This option seems to be the most obvious and straightforward approach for innovators. It also allows for the most control over how the innovation is implemented and it usually best guarantees receiving a proper return on investment. It is the most appropriate way if the innovation involves a lot of tacit knowledge and would require significant knowledge transfer for others to replicate. If this is not the case, secondly, scaling up could be achieved through building strategic partnerships or delivery networks. (Gabriel, 2014).

Strategic partnerships include mergers and acquisitions, joint ventures and piggybacking on larger organisation's infrastructures or platforms. Building a delivery network involves delivery contracts, licencing and franchising. Yet another route – a more indirect one – is to influence and advise through campaigning, dissemination and advocacy via social or traditional media, engaging with policymakers, or consulting and training others. Nurturing demand can be thought about from various perspectives: there are people who will pay, people who will take part, use and benefit, people who will advocate for the solution and devote their time to make it happen. Tighter control could guarantee quality but allowing for adaptation through licencing or franchising, for example, might increase effectiveness and create greater local ownership. Usually, all routes require at least some level of knowledge transfer and process codification, as well as building a brand and identity for the innovation. (Gabriel, 2014). For questions to ask at this point see Tool 8.

How may the organisation need to change?

Thinking about the team behind the solution is important in the scale-up stage. Whereas a clear vision and passion to change the world are important in a startup, vision and strategy become even more important in the scale-up stage. In addition, the company must be able to deliver the vision. Motivation, experience and reputation of the team, advisors and networks are important. It is important to think about the strengths and weaknesses of the team, how to strengthen the team and where to find the missing competences. Is there a need for additional training or should new members be added to the team? Are there resources available to support the team and how can flexibility be ensured to respond to the changing needs? It is not always necessary to recruit a person – instead, the services can be bought from experts. The company should consider whether key team members are likely to stay for as long as scale-up is ongoing and how to motivate them to stay. (WHO, 2021).

Although many of the required skills and competences have changed over time, creativity and innovativeness, participatory approach, user-orientation and understanding customer problems and needs are as important as before. All decisions should be tested before implementation. Access to financial and technical resources becomes more important, and it is useful to try to locate any existing networks offering them.

At the scale-up stage, the following attitudes and skills are important:

- strong commitment
- strategy, leadership and management
- resource mobilisation
- communication skills: ability to communicate with customers and other stakeholders
- training, dissemination and advocacy
- monitoring and evaluation
- scale-up experience
- quality of care
- technical skills
- process management
- legal skills, public procurement (WHO, 2021)

Thus, after selecting the scale-up approach, the next question concerns the changes the organisation requires. Scaling up is challenging because it requires change management, development of organisational capacity to scale and shifting from a startup to a mature organisation. Core aspects include leadership, management, governance, staffing, resources and culture. Growth means shifting from passionate multitasking and flat organisational structures to clearer reporting responsibilities, role specialisation and recruiting specialists. (Gabriel, 2014).

Questions to ask at this point include the following:

- What are the main skills gaps in the team? Which competences will be needed and where can they be found?
- How does governance need to change?
- How to establish a shared purpose and culture as the organisation changes?

Tools for startups and SMEs for scaling up

Tool 5: Key points of a business model (Lean Canvas)

The elements of the Lean Canvas are described in the following tool. You can use the tool for thinking about the answers, and after that, collect your answers on the canvas (Figure 4).

Element	Question	Answer
Problem	What are the top three problems that the customer has, that are worth solving and that I want to solve?	
Customer segments	Where can I find customers, and especially the so-called early adopters?	
Value proposition	How do I solve the customer's problems?	
Solution	How do I deliver value?	
Unfair advantage	What do I have to offer that cannot easily be copied by others (competitors)?	
Revenue streams	What is my revenue and pricing model?	
Costs	What are my fixed and variable costs?	
Key metrics	How do I measure success? (This does not always have to be a financial metric.)	
Channels	Which paths do I use to reach the customers?	

TABLE 7. TOOL FOR IDENTIFYING THE KEYPOINTS OF THE BUSINESS MODEL WITH LEAN CANVAS.

Tool 6: Evaluation of scalability of an innovation

With the following tool the scalability of the innovation can be assessed. This should be done before attempting to scale up.

Attribute	Questions	Your evaluation (Give points 1-10)
Credibility	Is your innovation based on sound evidence? Is the innovation tested in pilot or experimental projects in the type of setting where it will be scaled up?	
Observability	Can the potential users or other stakeholders see the results in practice?	
Relevance	Does the innovation address persistent needs or problems?	
Relative advantage	Is the innovation better than existing practices, is it more cost-efficient?	
Easiness	Are there needs to change current practices, or for additional resources; Is the level of technical sophistication too high or apt to arise conflicts?	
Compatibility	Is the innovation compatible with the potential users' values, norms, systems and facilities?	
Testability	Can the potential user (organisation) test the innovation in stages without complete adoption?	
Technological implementation	Is the technological implementation scalable? Hardware vs. software; cloud; supply chain.	
Person-centredness	Is the innovation based on person-centred principles? (See above Tool 3)	

TABLE 8. ATTRIBUTES FOR EVALUATING THE SCALABILITY OF AN INNOVATION. ADAPTED FROM WHO (2010).

Tool 7: Enhancement of scalability of an innovation

The scalability of the innovation can be improved, among other things, by modifying it in the following ways (adapted from WHO, 2010).

Category	Possible action	Relevant: Yes / No	Doable: Yes / No
Add credibility	Test in different settings Bring stakeholders to pilot sites		
Simplify	Determine the core of innovation with stakeholders		
Rely on the strengths of users	Arrange initial scaling where champions / early adopters are available		
Address constraints	Organise meetings with stakeholders to discuss barriers of adoption		
Advocate policy commitment	Link scaling up to national health sector reforms or other similar opportunities		
Speed up timetable	Search for lead districts that can act as demonstration sites		
Cost reduction	Collaborate with similar initiatives and benefit from economies of scale		
New partners	Seek support and commitment from agencies working in the area		
Dissemination and training	Develop and offer training modules Assure quality		
Diversification	Test added components		
Spontaneous scaling up	Arrange focus group discussions to inspect if innovation spreads from individual to individual		
Suppliers and logistics, other value chain partners	Assure functional value chain and logistics		
Monitoring and evaluation	Create a simple monitoring system		
Strengthen the team	Add someone with strong advocacy skills to the team		

TABLE 9. ASPECTS TO CONSIDER FOR INCREASING THE SCALABILITY OF A SOLUTION. ADAPTED FROM WHO (2010).

Tool 8: Questions to consider when scaling up: Why, what, and how?

When developing a scale-up strategy, the questions of *why*, *what* and *how* to scale up must be answered. *Why* means defining goals for scaling, *what* means establishing what will be scaled up, and *how* means choosing the routes to scaling up and delivering the strategy. These aspects are linked together. (Gabriel, 2014).

Questions		Defined: yes or no	Answers
Why?	What is the goal the company is trying to achieve?		
	What is the size of the opportunity?		
	What are the company's financial targets?		
	Are the company's practices sufficient to meet that goal?		
	What are the company's values?		
What?	Who will pay for the innovation?		
	Who will use the innovation?		
	Who will benefit from the innovation?		
	Does the company have evidence that the innovation works?		
	Does the innovation fit in with the existing systems and structures? Does it support or challenge them?		
	Is there a viable business model and a clear idea of costs and revenues?		
	Are the company's processes capable of operating at higher volume?		
What? (Standards of evidence)	Is the company aware of the value its customers will gain? Can the company describe what it does and why it matters?		
	Does the company collect data that shows positive change?		
	Can the company demonstrate causality by using a control group?		
	Does the company have replication evaluations confirming conclusions?		
	Does the company have manuals, systems and/or procedures ensuring replication and impact?		

How?	Which routes for scaling up the innovation are reasonable?		
	What are the potential risks and benefits of different routes (for example, quality issues)?		
	What types of scaling activities fit the company's capabilities?		
	Can new partners be found who can support or implement the scale-up, and can they be involved in the process in a more participatory way?		
	Can the company identify key decision makers?		
	Can the company use political, personal, or other informal channels and relationships to convince new areas (regions, municipalities, etc.)?		
	Can the company design clear and concise messages on the key aspects of the innovation, customised to different audiences?		
	Can the company use various ways of communication: mass media, reports, policy briefs, training, technical assistance, peer-to-peer support, materials, etc.?		

TABLE 10. ASPECTS TO CONSIDER FOR SCALING UP. (GABRIEL, 2014; WHO, 2010).

Challenges of scaling up – the perspective of IN-4-AHA pilot companies

The health and care sector is undergoing a change from traditional approaches towards increasing use of digital solutions for prevention, diagnosis, treatment, monitoring and management of health-related issues and lifestyle behaviours that impact health. At this stage, there are still remarkable barriers in legislation, regulation and finance hindering the successful scale-up of digital health and care innovations. Some examples of this are liability issues, the generally lacking innovation-friendliness of the system and inadequate funding or reimbursement. On the micro-level – the level of end-users – lacking resources, motivation and trust can be barriers. For example, professionals as end-users can feel that they will be loaded with additional work, they may see digital innovations as a threat, or there can be challenges if the usability of solutions has not been considered. Likewise, integration and interoperability aspects can hamper the innovation if not sufficiently considered. (Schlieter et al., 2022). A major factor slowing down scale-ups are the national health and care systems, practices and legislation, which differ significantly between the European Union countries. Thus, for entering a new country, a deep understanding of that particular market is needed. (Santonen and Julin, 2019; Ferreira et al., 2018).

Startups should have their business model in mind already at an early stage, and especially their value proposition to end-users and customers, for guaranteeing a successful scale-up of digital health and care solutions. Important success factors include flexibility and learning by using a stage-wise innovation process as well as the involvement of all relevant stakeholders, including professionals and elderly end-users. (Schlieter et al., 2022).

The pilot companies in the IN-4-AHA Project see that there are several strategies that small startups can use to enter the markets or scale up digital solutions, for example by cooperating with larger companies or developing solutions first for professionals. However, they have faced many of the challenges mentioned above.

- *“We need bigger companies to go along, but small companies have just a tiny part and cannot decide how to proceed. This is the biggest challenge in the sector.” (IN-4-AHA pilot company representative)*
- *“Solutions developed for professional usage is a step towards consumer markets. When the solution is simplified enough, you can sell it to consumers.” (IN-4-AHA pilot company representative)*
- *“The health and care sector has limited capabilities to take innovations into use. We should find right people and get them enthusiastic to use the solution. The solution must be simple and tangible, easy to adopt and use – it should be as easy as measuring of blood pressure.” (IN-4-AHA pilot company representative)*
- *“A small company has scarce resources. We should find financing partners who would boost the development.” (IN-4-AHA pilot company representative)*
- *“Public procurement is a problem for small companies. You have to assure the government that you can implement – this is a problem for small companies and that is why small companies go with bigger companies.” (IN-4-AHA pilot company representative)*

Some of the pilot companies have experiences of the importance of positioning the solution carefully.

“There is a big difference between developing solutions for health and wellbeing – if your solution is a medical device and a CE mark is necessary, you face problems, because health CE mark is very difficult to get and expensive. In terms of trying to make a small product from a startup it is better to keep it in wellbeing. There are less requirements about CE mark and in the market.” (IN-4-AHA pilot company representative)

Customers are not a challenge.

- *“Customers are no different in the AHA sector than other sectors I know – users are old users but anyway you have to know what your client is and adapt your solution to that.” (IN-4-AHA pilot company representative)*
- *“You have to convince the workers in the institution, that the product helps their work. They decide if it is successful, because real users cannot give feedback.” (IN-4-AHA pilot company representative)*

The pilot companies also see the EU as a good place to do business.

- *“The EU makes a common structure. It should be easy to sell solutions here. But we do not yet know if it works like this or not. There are differences in national health systems, but there is a 350 million people market in Europe.” (IN-4-AHA pilot company representative)*
- *“I am happy how things are going. The sector is accelerating. Success is straightforward. Health insurance could fund our solution. For some people it is possible to finance themselves, if they can afford it, or relatives.” (IN-4-AHA pilot company representative)*
- *“The EU is a good place. People are getting older and how to support their health is a question. Healthcare is expensive, so new solutions are needed.” (IN-4-AHA pilot company representative)*
- *“The EU is a good place to do business, because we have a regulatory umbrella, and business understanding is the same. There are other kinds of barriers elsewhere.” (IN-4-AHA Living lab network coordinator)*

However, preventive solutions are not always easy to sell.

- *“There is a challenge. Local municipalities and family members start thinking only after first accidents. We should change this mindset. It is difficult to answer how to change the mindset. Maybe by giving real examples... what technology can provide... but it is a slow process.” (IN-4-AHA pilot company representative)*
- *“The healthcare system is changing – however there should be a change in preventive care, too. When organisations find out what the benefits are, they are eager to adopt our solutions. But the problem is how to raise awareness, find the right marketing channels, and so on. There should be a forum for promoting preventive care at the EU level, which would present new technology solutions for preventive care. If you think the European markets, marketing must be country-specific, and therefore there should be an umbrella or platform making marketing at the EU level easier.” (IN-4-AHA pilot company representative)*

Market logics and market information: How to approach new markets abroad?

There are many names for digital solutions markets targeting active and healthy ageing. Among other names, they have been called “silver economy”, “Age-Tech” and “longevity economy”. There are at least three types of solutions developed for this sector: solutions purchased by older people themselves; solutions purchased on behalf of older people, and solutions delivered to future older people. Even the most conservative estimates place the active and healthy ageing markets at around 20% of the global gross domestic product (GDP).

The most important principle is to design solutions that are valuable for all age groups and not viewed as “products for old people”. Another important aspect is personalisation: because people are more and more diverse, it will be increasingly important to develop solutions that are adaptable to the specific needs of each group. It is important to remember that there are regions where the number of older adults is high, and some of these regions are expressing their interest to become “Silicon Valleys” of silver economy. These regions are worth exploring. Older adults can still be reached through many of the “traditional” channels and media that have been otherwise losing their importance in the digital economy (Woods, 2019).

“When you are scaling technology, you should start with person focus. It is an advantage that you respond to their needs. But people are really different in different countries, so you need personalisation.” (IN-4-AHA Living lab network coordinator)

Frameworks for analysing international markets

When entering a new market, there are several general frameworks for analysing the macroeconomic environment. One of the most used is PEST analysis in its various forms. The basic analysis includes four factors: “P” refers to political factors such as political stability, infrastructure, legal framework of the country and government’s impact on people’s health and education. “E” refers to economic factors, such as economic growth, inflation and interests. “S” stands for social or social-cultural factors, such as cultural aspects and

population age distribution⁴. “T” refers to technological factors, such as research and development activity, automation and technological change. More comprehensive versions of the analysis add ELE to the factors, whereby the first “E” brings in environmental factors, that is, ecological and environmental aspects like weather, climate and climate change. “L” stands for legal factors, such as consumer and employment law, and health and safety laws. The second “E” refers to ethical issues, such as corporate social responsibility, ethical principles and moral or ethical challenges that can arise in a business. All these factors affect the demand for a company’s solution, but also how it operates and its costs. (<https://www.professionalacademy.com/blogs/marketing-theories-pestel-analysis/>).

“The environment refers to conditions and institutions that are external to the user organisation but fundamentally affect the prospects for scaling up.” (WHO, 2010)

One way to analyse a company’s microeconomic environment is to use Porter’s (1979) five forces model. It too has many variants, but mostly referring to bargaining power of buyers and suppliers, new entrants, substitutes, the industry dynamics and rivalry. It could also be worthwhile to study trends in the health and care industry, technology and culture as well as consumer behaviours – both globally and at country level, as there are several governmental and consulting agencies studying these issues, in addition to web tools such as Google Trends.

Special features of the health and care market

In the case of the healthcare industry, the WHO (2010) points out that issues in the environment worth considering include the health sector, policy and politics, bureaucracy, socioeconomic and cultural contexts, and people’s needs and rights. It has been claimed that the healthcare industry is one of the toughest areas for a startup. Most of the issues creating challenges in the healthcare market also apply to the AHA market. Besides fierce competition, challenges include a conservative market and long sales cycles; regulatory, security and privacy demands; interoperability of health data; and complexity of stakeholder relationships and trust building. All the challenges listed above have been met by the sample of IN-4-AHA pilot companies. In addition, many other companies have experience in a number of fields and that the health sector and its requirements is one of the most challenging.

In this conservative market, not all older adults as end-users are accustomed to using digital solutions, and professionals need convincing proof that digital technologies will make both their work easier and improve the quality of care, until they will be reassured that new solutions will not complicate their lives. (Sinhasane, 2020). Holgersson and Söderström (2019) found five categories of factors leading to elderly individuals’ digital exclusion: fear and negative attitude towards using digital technologies, feeling too old to learn, lack of knowledge and experience, and language-related problems, i.e., not understanding digital terminology. However, the situation with older adults is changing, because older adults have begun to adopt technology at increasingly growing rates (Etkin, 2022).

⁴ There is a tool for comparing cultural differences between two or more countries on Hofstede Insights’ website: <https://www.hofstede-insights.com/country-comparison/>

Although all the pilot companies in the IN-4-AHA Project had experienced the challenges of the older population in using the new digital services, they had also identified that at least some older people were interested in learning and adopting the new digital services.

The health and care industries are infamous for their bureaucracy and long sales cycles. It has been claimed that startups must be ready to maintain the company financially for at least five years before being able to secure the first profitable deal. The regulatory environment is complex and there are multiple levels – international, national, regional – and legal requirements applying to both the company’s location and target markets must be met. The conservative sector is unwilling to trust young startups and not all people are ready to place their trust in remote or digital health and care services (Sinhasane, 2020). So, it is necessary to raise awareness and build a reputation: relationships with key stakeholders, hospital chains, insurance companies and other technology companies must be built to proceed. Also, startups should have resources for training and supporting stakeholders in their change processes (Sinhasane, 2020). It is also vital to show that the solution is validated, safe and complies with regulations and standards. (Demigos, 2022).

Steps to enter a new market

To enter a new market, the following steps are required:

1. Studying the market:
 - Target audience – end-users, health and care providers, insurance companies, available technologies. Naming the people and/or organisations that want to buy the solution.
 - Determining the needs and problems of the target audience and defining whether the pains are significant enough. Discussing with relevant people (end-users, professionals) to get to the bottom of the issue.
 - Limitations of the market: Are there issues that prevent the audience from adopting the solution? The limitations could be slow internet connections, low digital literacy or paper-based processes in care homes. Most of the AHA technology solutions require high-speed internet, which is not available in almost half of the world’s countries, rural areas being the most problematic regions (Etkin, 2022). There can also be cultural differences. A good way to get to know these limitations is testing.
 - Competition, i.e., companies that have tried to solve the same problems – successful, unsuccessful or indirect competitors.
2. Hiring an advisory board (member) with expertise on the market
3. Creating and testing a business plan and scale-up strategy for the market
 - Defining goals, expectations, risks, dependencies with other systems; then testing.
4. Starting with an MVP
 - Testing the idea, core features and revenue model with a minimum viable product (MVP) — a simplified version of the solution with bare-bones functionality.
 - Focusing on the critical functionality, features that solve the main problem.
5. Choosing and testing the revenue model
 - One-time payments are suitable e.g. for wearables, whereas software providers tend to use recurring payments because lower initial fees bring more users.
6. Ensuring compliance with regulations and safeguarding cybersecurity

- Evaluating ICT and administrative structures and policies, identifying the personal health information being processed and evaluating the risks of the systems, implementing technical safeguards.
 - Ensuring compliance with laws and data security practices by looking up compliance management tools and/or hiring a professional auditing company.
 - Checklist: legal conditions (legal form, registration), ethical issues, certificates, licenses, approvals, IPR protection, data security, insurance, adequate resources for handling these issues.
7. Promoting the solution to the target audience and other stakeholders
 - Preparing scientific evidence to back up the solution.
 8. Releasing the solution to the market
 - Using the feedback on the MVP to modify the technical specifications before full-scale development.
 - Building the application with scale in mind: replacing hardware with software and using cloud-based infrastructures for flexibility and modular architecture with upgradable modules. (Demigos, 2022).

Success factors of scaling up outside the home market

According to Oviatt and McDougall (1994), startups can be categorised based on their international intentions into four groups, namely to geographically focused startups, export startups, multinational startups and global startups. Strong entrepreneurial orientation empowers a startup to deal better with foreign market challenges. *Entrepreneurial orientation* encompasses proactiveness, innovativeness and risk taking. Proactiveness can be understood as the ability of identifying opportunities and market trends. Innovativeness covers creativity, generation of new ideas and development of solutions for relevant market problems, and risk taking is the ability of making decisions in unpredictable situations. (Farooq, 2020; Wach, 2015). It is also worth noting that opportunities are recognised by individuals, not companies, and that *networking* skills and social ties – i.e., not necessarily only business ties – play an important role in recognising opportunities (Farooq, 2020; Ellis, 2011).

Market-driven management drives the international success of a startup. Research has shown that especially customer knowledge at individual level, and not just general-level market knowledge, creates a competitive advantage in foreign markets. Knowledge must be gathered from the customers about the technological and solution features that best suit the particular market. Therefore, customer knowledge enables a startup to develop a proper product/market fit. Customer knowledge also links to strategic alliances with partners. Besides networking with customers and partners, networking with competitors can be highly endorsed. (Farooq, 2020; Gneccchi, 2009; Ruokonen, 2008).

Cultural similarity between the home and international market has been shown to play an important role in success, because based on cultural similarity, a startup can assess market changes and its competitors appropriately (Farooq, 2020; Fan and Phan, 2007). For success, it is important to customise solutions taking into account local languages and customer and end-user behaviours. Culture affects the marketing and positioning of the solution. Any strategies to eliminate cultural distances – for example by networking – are effective in

creating success. Startups succeed only by placing the customer in the centre and by considering, at the same time, the right positioning of the solution on the market. However, there are some indications that culture might not play as big a role in successful internationalisation of health and care solutions as is the case for other sectors' solutions. One possible explanation could be that innovative health solutions are in demand across cultures. (Farooq, 2020). Then again, it has been claimed that for health and care startups, the best market would be the USA, because the country spends almost 17% of its GDP on healthcare, making it the world leader in healthcare expenses. Moreover, North America dominates the digital health market. (Demigos, 2022). However, Europe is the world's second-largest medical device market with almost 500 million people.

The IN-4-AHA pilot companies were aware of the fact that the cultural similarity of the European-wide international market can be viewed from two different perspectives. In the short term, cultural similarity in a pan-European market seems to be beneficial. In the longer term, however, the weight of pioneering markets such as the United States in shaping international market habits and standards may take over and previous strong cultural competences in nearby markets may fade away. The IN-4-AHA pilot companies took this into account at an early stage when planning their operations.

There has been a distinction between stepwise internationalisation and born-global strategy, where companies following the former can gradually expand their domestic innovations to global markets, whereas born-global companies aim to develop solutions directly for the global market (Santonen and Julin 2019; Archibugi and Iammarino, 2002). However, it is typical for startups to have rather limited possibilities due to several internal and external barriers. These include a lack of distributors, negotiation power, target market knowledge, international experience, competitive advantage and resources, or political instability, legal issues, insufficient demand or problems in entering the market. (Santonen and Julin 2019; Paul et al., 2017).

It is worth emphasising that networking with end-users and other stakeholders, even online networking, can significantly help startups with establishing themselves in foreign markets. It is important to build trust among stakeholders. Besides social networking, business networking is important in the health and care sector; it increases the probability of approval of new solutions by health professionals, leading them to convince consumers. To summarise, being more entrepreneurially oriented and connecting with stakeholders helps a startup to build an international market presence more quickly. (Farooq, 2020).

It is necessary to dedicate time to market and competitor research (Demigos, 2022). Positioning the solution in the market and locating the competition may be easier by inspecting how the companies have been categorised into market segments, for example, on the AgeTech Market Map (Etkin, 2022). On the map, there are companies belonging to health, wellness, insurtech, independence, cognitive care, end-of-life planning, housing categories, etc. Challenges acknowledged in the sector that startups could develop solutions to include health and cognitive health issues, social connectivity, mobility and transportation, and daily living activities. (Etkin, 2022). If possible, it is useful to define and name the competition – direct and indirect competitors and those offering substitutes for the solution.

“More and more startups, as well as big tech companies, are building tech for older adults. These technology solutions are designed with older adults not only in mind, but also in practice. This doesn’t mean big buttons and loud audio; it means putting older adults (and other stakeholders) at the center of the design process, and aiming to meet their needs and aspirations.” (Etkin, 2022).

Why scaling up may fail?

Nevertheless, there are several reasons why startups may fail. The main reason is a lack of demand: it has been estimated that 70% of the innovative products and services cannot find a market because they do not meet user needs (Verloo et al., 2021). This happens if a startup wants to solve a problem that seems interesting but it is not big enough to require a general solution (not desirable). Similarly, a startup may identify a relevant problem, but its technology cannot solve it (not feasible), or the business model cannot solve it in an economically sound and scalable way (not viable). In addition to these main reasons, there are several other reasons, for example insufficient networking and marketing: companies that cannot communicate their value do not survive. A startup should recognise who needs its product, what are the target audience’s pain points, and how to solve them better than the competitors. Then, it must communicate all this, i.e., the value proposition must be adapted to the audience.

Moreover, the company may fail if it does not have a proper plan for evidence-generation. This can be easily avoided if discussions with stakeholders are held already in the beginning, whereby the startup will get to know what kind of data they appreciate, and which are the right methods for evidence generation. Lack of flexibility and sticking to the initial business plan can hamper the company’s ability to recognise opportunities and respond to market dynamics. Therefore, the team should be continuously open to learning, gathering input from stakeholders and studying the customers’ and end-users’ reactions. For AHA startups, varying reimbursement policies can be a challenge if they make health and care providers turn away from new solutions. Then, of course, it is worth considering if the team consists of the right people. Customers, healthcare providers, authorities and investors often look for and respect certain personal qualities in a team. (Demigos, 2022).

Investor relationships

Compared to the more generic healthcare technology, much fewer startups and venture capitalists focus on the AHA segment, making the segment significantly underserved. However, it is obvious that there will be many unicorns in this sector soon. Five key steps to getting an AHA startup funded are the following: 1 – finding a viable niche; 2 – understanding core needs; 3 – offering solutions for areas where technology can have a major positive impact in the lives of older adults, including access to healthcare, telemedicine, healthy lifestyle and wellness, cognition, cognitive health, employment, independence, mobility, nutrition, monitoring, communication and staying connected; 4 – considering all stakeholders; and 5 – raising awareness and promoting customer development. (Sullivan, 2022).

The experience of the IN-4-AHA pilot companies with funders confirms that funders’ assessments and decisions are based on economic facts, not on whether the senior market

offers exceptional business opportunities. Thus, evaluating the company's ability to create a scalable business in the elderly market is based on the same laws of scalable business as anywhere else.

For further information on investor relationships, see D6.1 Investment readiness assessment (Jankauskaitė et al., 2022).

"Private capital investors do not like AHA. You have to call it differently. They do not like AHA products." (IN-4-AHA Living lab network coordinator)

Part C. Conclusion – the best models for international business

These concluding remarks discuss the learnings from the living lab testing and coaching process with the IN-4-AHA pilot companies. Although they do not present coherent “models” for international business, they gather some principles that – based on our learnings from the IN-4-AHA living lab testing and scale-up program and our best understanding – could help startups planning to scale up their AHA business into international markets.

Person-centred care – involving end-users

In our fast-changing world, the traditional innovation process is no longer successful. The potential customer or end-user must be involved in the innovation process from the beginning. Many concepts fail because they do not solve an actual problem for the end-user. Those products or services are not desirable, and nobody will buy them. (Mueller and Thoring, 2012; Brown, 2009). It has been shown that designs with a more person-centred approach have higher adoption rates and satisfaction among end-users (Saborido Piñeiro, 2022).

Involving all relevant stakeholders

The stakeholders of AHA solutions are not just elderly end-users, but the entire care circle, that is, the whole value chain. This includes family members, national, regional and local governments, healthcare and other service providers, who purchase solutions that benefit the ageing population. (Etkin, 2022). The entire value chain should be included in the solution development work – as early as possible – to guarantee that the solution actually solves relevant problems of the stakeholders and can be smoothly integrated into their systems. Wicked problems can only be solved in collaboration. It is difficult to know what the various stakeholders in the value chain need without discussing it with them (Chernova and Konina, 2022).

Iteration and learning

The business, regulatory and technological environment is constantly changing. This is especially true in the complex and highly regulated health and care sector. Despite efforts and achievements in integration, there are many cultural and regulatory differences between European countries. One example is that, in France, medical devices can only be marketed to healthcare professionals. (Lucey, 2022). There are always things to learn, which is why keeping an open mind and proceeding step by step is crucial.

Flexibility: preparing for bootstrapping and surprises

It has been claimed in the healthcare sector that the founders of a startup have to be prepared to support the company financially for many years before they are able to secure the first profitable deal (Sinhasane, 2020). This means years of bootstrapping, characterised by the founder working to turn an idea into a business with the help of networks and operating with a minimum amount of investment while relying only on customer revenue (Paakkinen, 2021). Maurya (2012) proposes “Right action, right time” as a philosophical definition of bootstrapping: “Startups are inherently chaotic, but at any given point in time, there are only a few key actions that matter. You need to just focus on those and ignore the rest.” There are always surprises around the corner, and one must be prepared to take them as opportunities to learn and change direction (pivot).

Testing, testing and testing

If we could offer just one take-away based on this playbook, it would be this: testing, testing, testing. Even testing of testing. Testing is necessary at all stages even though objectives and names vary: when defining the needs and problems of the customers and end-users it may be called co-creation, when developing the solution to them it may be called testing, and when developing the business model and trying to scale up the business it may be called validation. Even when the solution is already on the market, the company should keep their eyes and ears open and observe and listen what the customers and end-users feel and say. Keeping an open mind and continuous learning are key.

Customer development: raising awareness and training

The phases of the customer development model are, firstly, customer discovery, where the aim is to understand customer needs, establish a problem/solution fit and develop an MVP; secondly, customer validation, where the aim is to establish a product/market fit and find a viable business model; thirdly, customer creation where the solution developer drives end-user demand; and fourthly, company building, where the company transitions from discovery to efficient execution. (Schuurman and Protic, 2018; York and Danes, 2014). In the health and care sector, working closely with customers and end-users and investing in raising awareness and training are many times necessary because a lack of awareness, resistance to change, inflexible organisational structures and systems, among other factors, create barriers (Stroetmann et al., 2015). If the company takes a proper attitude and thinks of itself as a lean startup, the idea of customer development resembles the blue ocean strategy (Ojasalo and Ojasalo, 2018), meaning that there will be less competition if the company manages to create its own markets in this way.

Relying on expertise

It is always wise to know oneself and one's strengths, and also be aware that no one knows everything. Therefore, experts should be involved in the development process as early as possible. It is an excellent idea to have those experts on the board of directors or advisory board. If not, it is wise to build networks or hire a person with the required expertise. Many tools have been developed, for example, for managing regulatory compliance, but finding the right tool for the company's needs can also be difficult without expert knowledge.

Market research – how to position the solution (blue ocean or red)

Startups succeed only by placing the customer in the centre and by considering, at the same time, the right positioning of the solution on the market. Time should be dedicated to market and competitor research (Demigos, 2022). If possible, it is useful to define and name the competition – direct and indirect competitors and those offering substitutes for the solution. The key is to find a viable niche, understand core needs, offer solutions for areas where technology can make a significant positive impact on the lives of the elderly, consider all stakeholders, and rely on raising awareness and promoting customer development (Sullivan, 2022).

Resources

Living labs

<https://digital-strategy.ec.europa.eu/en/activities/testing-and-experimentation-facilities>

<https://enoll.org/>

<https://www.living-labs.org/our-goal>

EU markets

https://european-union.europa.eu/live-work-study/doing-business-eu_en

- Doing business in the European Union

<https://eithealth.eu/>

<https://startups.eithealth.eu/dashboard?applyDefaultFilters=true>

- EIT Health

EU markets, legislation and health policies are very different in different countries.

Overviews can be found from EU websites:

- [Summaries of EU legislation on health](#)
- [EU health policy and actions](#)
- [Health profiles for EU countries](#)
- Publication: [State of health in the EU \(2019\)](#)

Medical devices

A medical device is a tool, device or equipment (including software) that a manufacturer has developed in order to make a diagnosis or to prevent or treat diseases or problems (van Drongelen et al. 2018). There are resources with which you can evaluate if your solution is a medical device or not.

- Navigate the EU medical device regulation: <https://www.oxfordglobalguidance.com/>
- Harmonised standards in the EU: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en
- https://ec.europa.eu/health/medical-devices-sector_en

CE mark

- https://ec.europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm
- https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en
- https://ec.europa.eu/health/medical-devices-topics-interest/overview_en
- <https://ec.europa.eu/tools/eudamed/#/screen/home>
- https://ec.europa.eu/health/medical-devices-topics-interest/notified-bodies_en
- https://ec.europa.eu/health/index_en

GDPR

<https://gdpr.eu/>

- Complete guide to GDPR compliance

https://edps.europa.eu/data-protection/our-work/subjects/health_en

- European Data Protection Supervisor (EDPS)

https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_fi

- MDCG 2019-16 - Guidance on Cybersecurity for medical devices

IPR

https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk_en

- IP Helpdesk

<https://www.epo.org/index.html> and <https://www.epo.org/searching-for-patents.html>

- European patent office

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Appendix 1. Living lab tests and validation activities in WP4

WP4 of IN-4-AHA focused on living lab tests and validation activities necessary to design scalable solutions, assessing the accessibility and adoption of services and products, providing protocols that increase service accessibility to end users and further promoting the adoption innovation standards. WP4 facilitated the testing and validation activities necessary to design scalable solutions, providing protocols that will increase service accessibility to end users (patients and care givers) and further promoting the adoption innovation standards. For organising living lab tests and innovation scale-up model validation, an Open Call was arranged, aimed at organisations that have a scalable digital or technology-supported innovative solution of technology readiness level (TRL) 5 or higher for AHA, and that want to scale it up and expand outside the home market, test it in co-creation with users in real-life environments in living labs, and receive business coaching for the idea from an international coaching team.

Open Call process

For the Open Call, the selection criteria were agreed on prior to launching the Open Call. The application form included questions on the team, solution (name and description, IPR, TRL, users, when it was first launched), scalability (value proposition, competitive advantage, current and targeted markets, resources needed for scaling), business potential (revenue model, income, challenges), and plans for tests (most suitable tests, expected outcomes, issues for coaching).

25 finalized applications (+ 5 unfinished applications) from 11 countries were received. The selection process was conducted from the 15th to the 31st of May 2021. The selection committee, consisting of representatives of the IN-4-AHA partners and invited members representing end-users and business life, scored the applicants thoroughly and impartially based on technical quality and the evaluation criteria.

The following guidelines were sent to the selection committee members beforehand:

- Go through and rate the applications. Use the attached evaluation scorecard. Please let us know if you have any requests for additional information.
- Select your own candidates for the top 5 finalists.
- You can find the evaluation criteria in the Open Call launch document.

The evaluation criteria based on the Open Call were used in the selection.

Thresholds:

- The applicant is legally registered in a member state of the European Union or in a Horizon 2020 associated country.
- The solution is a digital or technology-supported innovation for active and healthy ageing.

1–5 points are awarded to the following criteria:

Team behind the solution (weight 25%)

- Clear vision and strategy.
- Skills and competences. Motivation, experience and reputation of the team, advisors and networks. Strengths versus weaknesses of the team.
- User-orientation. Understanding users' capacities and limitations.
- Access to financial and technical resources.

Solution (25%)

- Novelty of the solution. IPR.
- Person-centred care (PCC) focus.
- Minimum viable product (MVP) offered to real users.
- Technological maturity: technology readiness level (TRL) 5 or higher.
- Investment readiness.

Scalability (weight 25%)

- Credibility, evidence: Service tested in pilot or experimental projects or available in the market with real users.
- Observability: potential users see the results in practice. Feasibility for the users.
- Relevance: addresses persistent problems.
- Relative advantage: better than existing practices, costs < benefits.
- Easy to install and understand.
- Compatibility with the potential users' values, norms and facilities.
- Testability without complete adoption. Impact of the tests on scaling. ("CORRECT" adapted from WHO 2009, 11)
- Quality of the plan for scaling and testing.

Business potential (weight 25%)

- Market needs and trends. Is the market opportunity limited or propelled by trends?
- Size and growth of the potential market. Similarities and differences in European markets.
- Probability that the business will produce revenues when scaling up.
- Current and potential market share, current and potential number of users. Is the growth accelerating?
- Loyalty of users.

The selected five pilot solutions were the following:

1. Tecnologías Plexus SL, AVECEN

AVECEN is the virtual assistant for active aging of people with neurodegenerative mental illnesses. The objective of the project is the development of a distributed platform that allows self-management of neurodegenerative diseases by patients as well as decision-making by medical professionals and caregivers of their environment. For this, the creation of a dynamic virtual assistant is proposed that continuously monitors and evaluates the execution of certain clinical and lifestyle routines. The assistant is also making recommendations adapted to the patient's condition and evaluating their frequent or habitual behavior at all times, allowing to understand its evolution over time. AVECEN is a project led by Plexus Tech, an IT products and services consultancy with more than 20 years of experience in the sector. Other project partners are Arcade Consultores and Insati Innovation.

2. Novos Sistemas SI, Coquus

COQUUS is a software for integrating menus with user-specific informing for healthy eating. The goal of Coquus, developed by Novos Sistemas de Información, is better nourished and happier elderlies. Coquus is a software integrating different menus with their technical sheets, allergens, costs and nutritional assessments with the characteristics of diners such as allergies and tastes, and by combining both decides what each person should take.

3. Enna

Enna is an operating concept for tablets to facilitate independent digital communication for beginners. Enna enables digital beginners to communicate independently digitally and to access and use digital content such as entertainment and support. For this purpose, tablet is extended with a haptic operating concept.

4. Myontec

MYONTEC utilizes muscle activation technology in smart clothes for active ageing. Myontec develops smart clothes to motivate elderly people to keep their muscles activated and maintain good balance. Myontec is the cutting-edge wearables company which takes muscle activation technology – electromyography (EMG) – out of the lab, for a new dimension in understanding muscles behaviour.

5. TempID Smart Patch

TempID Smart Patch is a body temperature logger with mobile application. It is a reusable body temperature logger with mobile application for early detection of health risks, potential infection and other health related issues. The aim is to support remote care and increase efficiency.

How to arrange an open call: lessons learned

Here are some general insights of the challenges concerning the IN-4-AHA Open Call process. These points could be taken into account when planning similar open calls in the future.

- There are many kinds of calls going on at the same time, and therefore it can be challenging to recruit applications. Are these kinds of Open Calls attractive enough for the potential applicants? How can the potential applicants be reached?
- The criteria and selection scorecard must be clear and simple; this is necessary both for the applicants and the judges.
- Do the applicants see the benefits of applying, for example, do they trust that the testing process will be efficient and effective?
- Many of the applicants are still developing their solutions, and therefore, they avoid telling their business secrets. They write their applications so round and vague that there is a danger that we did not recognise the best innovations.
- Probably the most innovative ideas do not apply because they do not need us: they go directly and quickly to investors and market. To be more attractive, there could be investors involved in the open call process.
- Most of the solutions were for monitoring and for the health sector and there were less solutions to activate ageing people themselves or to make their daily lives easier. How could we attract multidisciplinary solutions better?
- The application form was rather long and detailed, and it is possible that we missed applications for that reason. However, from the applicants' part, there might also be some lack of skills in writing good applications.

Testing environments and living labs in the IN-4-AHA Project

With the selected five finalists, user-centred cross-border testing was done in e-environments and physical spaces in Finland and Spain. The testing environments in Finland and Spain differ from each other a lot, but both are already established, and have validated procedures concerning technical, legal and organisational requirements to integrate third parties in testing projects. In Finland there is a quite small and preventive healthcare focused Living Lab (Xamk Active Life Lab (ALL)), compared to the Galician Health Cluster (CSG) in Spain, which is based on wide cooperation amongst the Spanish Galician healthcare and social care ecosystems with several types of testing environments.

Spain / Galician Health Cluster (CSG)

The CSG is a professional platform for public-private cooperation, acting as a catalyst for the competitiveness of the health and social care industries, and contributing to the economic

and social development of the region of Galicia. There are several types of housing testing environments among the CSG members: international big care homes group (DOMUSVI), medium-sized residencies with broad services, day care centre and full accompaniment of the user (SARAIVA), home help in supervised flats (ATENDO) or community housing (O Lecer). CSG Ecosystem also counts with day care centres and programs that focus in autonomous or dependent seniors and caregivers (ATEGAL, AFUNDACION). These CSG Living Labs are based on person-centred care and are spread all over Galicia in both rural and urban settings.

Living Labs in CSG network have the following user profile:

- Dependent elderly people
- Autonomous elderly people
- Older people with disabilities
- Family caregivers of the elderly
- Professional caregivers of social and health centres.

Finland / Xamk & Xamk Active Life Lab

Active Life Lab (ALL) is a research and development unit of the South-Eastern Finland University of Applied Sciences (Xamk), established 2018 in Mikkeli. Its mission is to increase people's health through effective wellbeing services, and the mission is carried out by systematically gathering information on the effectiveness of wellbeing services, conducting research to develop services, and applying this knowledge in practice with partners. Research and development projects form the foundation of its activities. Besides, ALL offers expert services in cooperation with partners and serves as a learning environment for Xamk students. The facilities of ALL offer possibilities to measure the effectiveness of activities targeted to improve human wellbeing. The information collected will help companies to develop new solutions that have a measured impact on human wellbeing. The testing can take place in various environments depending on the target group and the service or product to be tested, for example, end-users' daily life (with e.g. apps, wearable tech), end-users' home (with devices) or ALL Smart Gym.

Living lab testing process

The objective of living lab tests is to co-create an enabling environment with end users, so that solutions can be validated in an everyday environment, and to gather useful information for technology developers so that they learn to make improvements to better adapt their solutions to the real needs of users. Living lab tests – especially in CSG's living labs – also aimed to evaluate how person-centred care (PCC) approach was realised in the tested solutions. The aim was to identify key user experience factors and barriers – and depending on the tested solution – for example, to test whether the application improved the perceived quality of life of the test group or facilitated their self-management. Tests in living labs are based on user experiences, which are defined as the set of factors and elements related to the user's interaction with the tested solution. These interactions result into generation of a positive or negative perceptions of the solution. A generalised testing and adoption process is detailed in the figure presented below (modified from CSG's living labs' testing process).

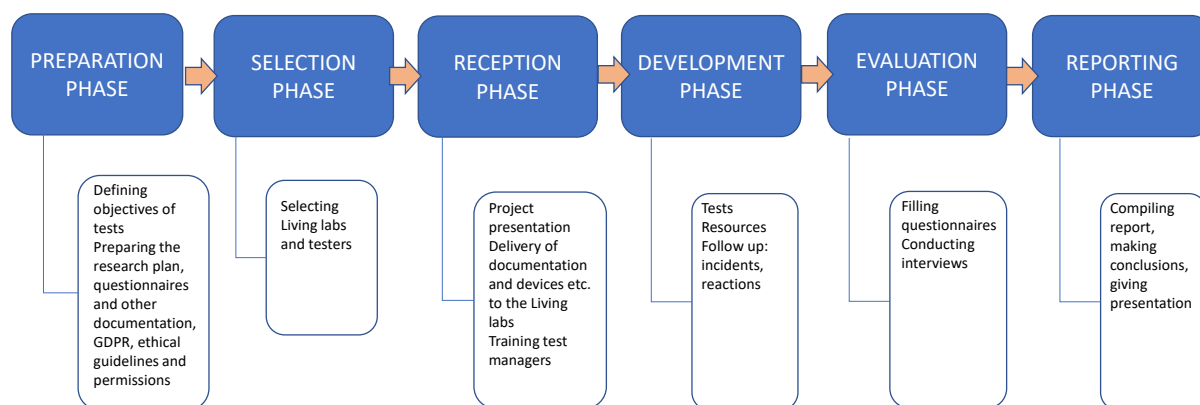


FIGURE 5. LIVING LAB TESTING AND ADOPTION PROCESS (SOURCE: MODIFIED FROM CSG'S LIVING LABS' TESTING PROCESS)

Lessons learned in the living lab testing process

Testing highlights were cross-border cooperation between living labs in Spain and Finland, but also cooperation between Finnish and Estonian organisations. The test settings (tests done and user profiles, for example) were different in Spain and Finland. The solutions have been tested with different user groups (for example, in care home and professionals vs. with independently living elderly and their relatives), and different environments (care home vs. home), with different methods (user test vs. workshop). For example, one solution was tested by CSG with users to collect data and user experiences, and the test was continued in Finland by analysing the data in Xamk ALL.

There were several challenges faced in the tests, for example, the maturity of some of the solutions was lower than expected, or some companies had challenges in getting their solutions ready for testing due to lack of components caused by the chip crisis. Also, some of the companies had difficulties in defining the objectives of the tests or which the most appropriate tester groups would be. In some applications there were errors causing incidents and also need to modify the tests. On some occasions, companies lacked resources, for example, due to Covid-19 pandemics. Some pilot cases demanded more resources than expected from the living labs because of time consuming work phases. There were also cultural differences causing difficulties in communication between companies and living labs.

It is not always clear for companies what can be tested in a living lab and that the participatory co-design process is a market-specific process. Scaling up is not straightforward because you may have to go steps backwards or test different things when entering new markets. There can be gaps between companies' demands and living labs' resources, facilities and networks, for example, if a company wants to test the solution in a big hospital, and there are no big hospitals in the living lab's current network. Or if for example mobile devices or open wireless internet connection are needed for testing the solution, all care homes or elderly people living at home do not necessarily have them available. Also, ethical issues and GDPR data protection issues seemed to be challenging for some of the companies developing digital solutions.

There has been tight cooperation between Xamk and CSG throughout the project. Xamk representatives visited and benchmarked CSG's living labs in Galicia. A new model of collaboration and division of labour between living labs was created in this project. The tests were conducted differently in Spain and Finland in all the pilot cases. Tests are useful and

bring valuable insights in every phase of participatory design process. Thus, living labs may conduct tests in different phases of the process, but these tests are different depending on the development stage the solution is in the market in question. This model helps the companies to scale-up their innovations more than just repeating the same test in two countries.

Business coaching

Business coaching was offered to the five selected pilot companies as a part of the test and scale-up program. Based on the discussions on the needs of the companies, 4–5 tailored coaching sessions arranged for each of the pilot companies. Main coaching themes in these sessions were market logics and market information and how to approach new markets abroad, scale-up models, business strategy, as well as investor relationships. In addition, the pilot companies were offered an opportunity to attend Slush startup event and its side event in Finland, where also a joint information session and workshop was arranged for the companies related to Nordic healthcare markets. The visit included coaching by investors and experts, and meetings with stakeholders in the sector: potential partners, suppliers and customers. Slush allowed benchmarking and testing the company's own business idea in a global environment, creating a continuum to the living lab testing process, i.e. "a living lab" for testing the company's business model.

Lessons learned and feedback from the pilot companies about the test and scale-up program, including visit at Slush included sharpening of business strategy and getting insights on how to take important decisions, learning the right way to scale a business internationally and different means of achieving a solid customer base, and finding ways of doing business in the Nordics. Learnings from Slush were the following, for example:

- New technologies: eHealth, diagnostics, quantum technology.
- New ways of assessing the maturity of a technological solution.
- Business models: Lean thinking applied to business models.
- Networking: New ways of networking in start-up events.
- Stages and milestones in venture capital investment process.
- How to approach new markets abroad.
- Insights into the Finnish and Norwegian healthcare system.
- Contacts, ideas, inspiration.

The themes of the business coaching sessions were as follows.

Session	Theme
First meeting	Backgrounds of entrepreneur(s) and an enterprise and the development until now. Current state of business. Short-term and long-term goals. Planned next steps. Analysis of the market position/current state of markets.
Second meeting	Based on the analysis of the first meeting, which are the main things to do/achieve to enter to the next level in the markets/to progress in the markets. How can those be achieved? What is needed? How could the project help to support the next step(s)?

	<p>In order to have a broader view of company progress as part of the market progress/development, some examples/benchmark cases were reviewed. A company's ability to scale depends a lot on how it can take advantage of rising issues. The team must be able to identify emerging issues, actors, events and situations in which it is worthwhile to integrate one's own work in order to quickly improve one's market position.</p>
Third meeting	<p>Based on the broader view of the market dynamics and development, which actions would be particularly favorable to the company scaleup in the market conditions and settings.</p> <p>An open discussion and in-depth analysis of which activities, relationships, etc. would improve the company's ability to scale and expand the fastest and how the company should use its existing resources and achieve its position to realize those functions and relationships. Also a discussion on how the company will be able to leverage the measures and status of this project to make those things happen. The analysis draws on examples that have promoted scaling in previous cases. The immediate actions required by the company are listed and scheduled.</p> <p>A scaleup program organised in connection with Slush</p>
Fourth and fifth meeting	<p>The follow-up of the immediate actions taken and the circumstances and market settings that have arisen for the implementation of the following actions. The immediate next actions required by the company are listed and scheduled.</p> <p>Later during the project, follow-up meetings will be held on the progress of the measures and developments.</p>

Appendix 2. Tool designed by CSG to measure PPC: Indicators and questions for end-users

(Source: Saborido Piñeiro, L. 2022. D4.2. Mapping of Accessibility and Adoption of Services and Products. IN-4-AHA Project - Innovation Networks for Scaling Active and Healthy Ageing. Table 15.)

Tool for assessing accessibility and UCD				
Values	How it is applied	Indicators	Questions	Level Of Compliance (% of affirmative responses from test participants)
Welfare	Technology must be geared towards generating the well-being of the people for whom it is designed and aligned with the framework of the ethics of person-centred care.	Percentage of people who have a better perception of their quality of life after the use of the technological solution on a social, functional, psychological or physical level. 2. Percentage of people who have felt good about using the technology solution	1. Has your perception of your quality of life improved while using the technological solution? <i>Yes/No</i> If yes, in which aspects has your quality of life improved? <i>physically/psychologically/functionally, cognitively/otherly?</i> 2. Did you feel good about using the technological solution? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Dignity	Technology contributes to respect for and values the rights of the people who use it. It contributes to the dignified treatment of the individual.	1. Percentage of people who feel safe while using the technology solution 2. Percentage of people who experience respect and dignity when using the technology solution	1. Did you feel confident using the technology solution? <i>Yes/No</i> 2. Did you feel that you were treated with dignity and respect during the use of the technology solution? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Autonomy	Technology should make it easier for the individual to decide on his or her own life project, facilitating access to and control over his or her personal data at all times.	1. Percentage of people who use the technological solution to improve their autonomy. 2. Percentage of people who trust that their data is handled securely	1. Does the technological solution facilitate your day-to-day decision-making? <i>Yes/No</i> 2. Do you consider that your personal data has been handled securely? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Independence	Technology must be understood from a dual approach, since technology can promote independent living for the people who use it and must be designed in such a way that it can be used independently, without external help.	1. Percentage of people who have needed help to start using the technological solution. 2. Percentage of people who have been able to use the technological solution independently. 3. Percentage of people who have needed help during the use process on an ad hoc basis.	1. Did you need help in getting started with the technology solution? <i>Yes/No</i> 2. Have you used the technological solution yourself? <i>Yes/No</i> 3 Have you needed help to resolve any doubts or incidents that have arisen during the testing of the technological solution? <i>Yes / No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low

Personalisation	It is understood from a dual approach, as technological solutions must be customised according to the needs of users and allow for the adaptation of interventions to the needs of the people for whom they have been designed, providing added value to the person's life and respecting their privacy and intimacy.	1. Percentage of people who can adapt the technological solution to their needs (physical, cognitive, organisational, etc.). 2. Percentage of people who are able to adapt the technological solution to their tastes and preferences 3. Percentage of people who consider that the technological solution adapts to their life routines.	1. Do you consider that the technological solution is adapted to your needs (physical, cognitive, organisational...)? <i>Yes/No</i> 2. Do you consider that the technological solution suits your tastes and preferences? <i>Yes/No</i> 3. Do you consider that the technological solution adapts to your daily routines? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Empowerment	A technological solution empowers the user when the person is able to use it independently. And for this it is essential that its design is intuitive from the first interaction "without the need to read the user manual".	1. Percentage of people who feel empowered by using the technology solution	1. Do you feel that your self-esteem has improved since you have started using this technological solution? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Co-design and participation	Technological solutions must be co-designed and developed through participatory processes, taking into account the voice of the users themselves. For people and with people.	1. Percentage of people providing feedback on the development or improvement of the technology solution 2. Percentage of users who have been part of the co-design of the technological solution.	1. Has your feedback been collected to improve the technological solution? <i>Yes/No</i> 2. Have you actively participated in the improvement of the technological solution? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Social inclusion	The capacity that technology brings to break down social gaps and generate opportunities for participation in the social and cultural life of their environment.	1. Participation of people in their environment.	1. Has using the technology solution increased your involvement in your community? <i>has increased/decreased/not changed</i>	<ul style="list-style-type: none"> High has increased No change Medium It has decreased low
User experience	Design of interactions throughout the acquisition, use and after-sales process. This should be designed in a user-friendly, inclusive and stimulating way, favouring interoperability and easy integration of solutions.	1. Percentage of people who consider the technological solution to be intuitive 2. Percentage of people who find the technology solution easy to use 3. Percentage of people who find the technological solution useful 4. Percentage of people recommending the technology solution to others	1. Do you consider the technological solution to be intuitive? <i>Yes/No</i> 2. Do you find the technological solution easy to use? <i>Yes/No</i> 3. Do you consider the technological solution to be useful? <i>Yes/No</i> 4. Would you recommend the solution to others? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low
Affordable	Person-centred technology must favour a balance between added value and price in order to be accessible to older people, families, administrations and organisations.	1. Percentage of people who would be willing to pay for the service of the technology solution 2. Percentage of people who can afford the technology solution	1. Would you be willing to pay for the service of the technology solution? <i>Yes/No</i> 2. The technological solution has a price of X, could you afford it? <i>Yes/No</i>	<ul style="list-style-type: none"> 70 - 100 - High 50 - 69 - Medium >49 - Low