

Participatory Design Process Principles and the Needs of Innovation Up-scale Process in the Health and Care Sector

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

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

- <https://innovation4ageing.eu/>
- <https://www.facebook.com/IN4AHA>
- 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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1. Introduction

According to the WHO¹, the world's population will nearly double over a period of 60 years and the elderly population will grow rapidly. This is a huge demographic shift countries need to prepare themselves for in terms of the various aspects of health and care (prevention, treatment, and rehabilitation). Due to the ageing population, there is a bigger need to extend access to health and care, expand appropriate health services and scale-up innovative products and services worldwide. In recent years, the health crisis in the world, which started in March 2020, had a devastating impact within every sector of modern world economics, from manufacturing to travelling, but the harshest effect has been seen in the health and care sector. The corona virus epidemic has taken a deep toll on citizens' lives around the globe. The health crisis has clearly highlighted the urgent need for not only disruptive innovation but also the timely and uniform implementation of digital products and services in the health and care sector.

More sustainable and less resource-demanding health and care systems supported by the promotion of people-oriented and demand-driven innovation will bring real benefits to people and enable health and care systems to optimise costs and unlock business opportunities. Large-scale use of digital tools for citizen empowerment and person-centered care, highly relevant for active and healthy ageing (AHA), is dependent on active contributions from a variety of stakeholder groups, including local and regional ecosystems, industry, civil society, academia, and public administration.

The European Commission (EC), under the Horizon 2020 Programme (2014-2020) Coordination and Support Action (CSA) has supported initiatives such as EIP on AHA,² and the current project *Innovation Networks for Active and Healthy Ageing* (IN-4-AHA) is also supported by the Coordination and Support action. The project aims to tackle the abovementioned challenges of the health and care sector. By bringing together the supply and demand actors, the project will develop a practical validated innovation scale-up model that will facilitate the cross-border scale-up of innovative solutions in AHA.

The innovation scale-up model acts as a basis for an innovation roadmap meant to lead the actors through the bottlenecks towards efficient upscaling. To compile an innovation scale-up model, the IN-4-AHA project will analyse the necessary parts in detail. This report, for example, will take a closer look at the participatory design methods and tools—some of the model's key components for excelling in the formation of innovative products in health and care. It will explain the necessity of participatory design and provide readers with a set of useful methods for how to engage all relevant stakeholders in the process. In addition, the report will provide an overview of stakeholder needs for the innovation scale-up process in the health and care sector and address stakeholder expectations and requirements for creating accelerator programmes in the health and care sector.

¹ <https://www.who.int/news-room/fact-sheets/detail/ageing-and-health>

² The European Innovation Partnership in Active and Healthy Ageing (EIP on AHA) <https://digital-strategy.ec.europa.eu/en/policies/eip-aha>; https://ec.europa.eu/eip/ageing/about-the-partnership_en.html

The scale-up model and roadmap with instructions and guidelines will enable actors, in delivering innovations (including Reference Sites³), to design and offer successful regional acceleration programmes and to scale up products and services. Accelerator programmes serve as a great way to test and validate potential innovative solutions and to support their uptake and cross-border scale-up. This report provides guidelines and insight from the practical point of view.

The IN-4-AHA project has a wide range of activities and outputs, and the current report is an input into the toolkit of participatory design process which in turn will be an input into the scale-up model. With the next part we will give a more detailed overview of the development process and scope of the toolkit, scale-up model and eventually the roadmap for the scale-up model implementation.

Toolkit for participatory design process:

- The toolkit will be designed to encourage end-user involvement as well as high-level endorsement and buy-in from decision-makers and key stakeholders, also identified as the key audience for the toolkit. The toolkit will reflect the participatory methods and techniques, identify the needs and objectives of all stakeholders and act as a compilation of basic information.
 - Validation of the input for the toolkit (best practices, strategies)
 - Scope of the toolkit: evaluating and redefining the needs of the relevant stakeholders, explaining the tools for the work process
 - Testing the toolkit, toolkit gives an input for the scale-up model

- Scale-up model:
 - The innovation scale-up model should follow the general principles covering the entire cycle of the innovation scale-up process.
 - The model should embrace a participatory approach, enlisting the contribution of all stakeholders and relevant actors.
 - The model should take into consideration what currently exists and should be flexible in order to be applied in the diverse context of the respective location, region or area.
 - Endorsement of the model by the advisory board⁴ is relevant, as is validation by the tests carried out during the project.
 - Activities foreseen to implement the innovation scale-up model.

- Roadmap: To implement the **IN-4-AHA** innovation scale-up model, **a roadmap will be presented**. The roadmap is a reference document for all the stakeholders involved in order to scale-up innovative solutions in the health and care domain, which is also relevant for the preparation of policies, investment strategies, communication, and advocacy activities. The roadmap is a document that evolves over the time;

³ Reference Sites (RS) are ecosystems, delivering creative and workable solutions that improve the lives and health of older people and the entire community. RS are regions, cities, integrated hospitals or care organisations and their quadruple helix partners from industry, civil society, academia and government authorities that focus on a comprehensive, innovation-based approach to active and healthy ageing. <http://www.rscn.eu/>; https://ec.europa.eu/eip/ageing/reference-sites_en.html

⁴ The Advisory Board (AB) is a group of experts taking a supportive and guiding role in the project tasks. The AB includes a diverse set of stakeholder representatives, combining the key knowledge and connections necessary for project tasks.

continuation of the process will be reflected in the Deliverable 1.3 – the report combining steppingstones for project sustainability and plans for exploiting project results after its implementation period:

- ensuring the social impact of the scale-up model
- considering the long-term goals of AHA in the health and care domain.

The report combines two topics, chapter 2. *Insights into Participatory Design* and chapter 3. *Innovation scale-up process in the health and care sector*.

These topics have been addressed with this report because of the needs coming from IN-4-AHA project activities connected to the creation of scale-up model and roadmap. The scale-up model creation process on one side foresees co-creation and use of participatory design methods. Therefore, the participatory design process, methods and value are introduced to different stakeholders as well as used within the IN-4-AHA project since the consortium has set a goal to use participatory design process to co-create the outputs of the project together with relevant stakeholders. The consortium uses workshops as one of the main activities to involve a wider spectrum of stakeholders into co-creation activities. Workshops are used in all the seven work package activities, and this created the need to also introduce some of the methods that could be used to carry out participatory design workshops. Therefore, this report from the practical side focuses on different methods used for workshops. This is not the only possibility to involve stakeholders and the consortium also uses other methods to target specific stakeholder groups (i.e., interviews, focus groups and questionnaires etc.). These will not be covered with this report.

On the other side the innovation scale-up model and roadmap for AHA can be used as a tool in AHA acceleration programs and we hope to boost the innovation scale-up process, for this we have given an insight into creation of accelerator programmes and the needs of stakeholders in this process. The scale-up model would be a tool accessible for all reference site ecosystems and other parties developing accelerator programs or for scaling up different services for AHA.

2. Insights into Participatory Design

Participatory design empowers stakeholders to feel meaningful ownership over design outcomes.

Close involvement in the design process by a variety of stakeholders tends to generate better outcomes and a greater sense of ownership over the design outputs. The idea of stakeholder involvement in the design process is at the core of what is known as *participatory design* (hereinafter referred to as PD).

What is participatory design and why is it valuable?

With its conceptual roots in the 1980s workplace democracy movement in Scandinavia, PD is perceived as a democratic process (Hartson and Pyla, 2018). The core argument behind the early versions of PD states that all stakeholders should have input in designing the social and technological systems within which they operate (Hartson and Pyla, 2018) and that those whose interests are affected by new technology have a right to get involved in its design (Kensing and Blomberg, 1998).

The early versions of PD sparked the development of research communities and the adoption of PD by practitioners. The annual [Participatory Design Conference](#) (PDC), which started in

the 1990s and brings together an international community of researchers and practitioners across sectors, is one illustration of the multidisciplinary and evolving nature of the PD concept (Smith, Bossen and Kanstrup, 2017).

In addition, as a widely used concept in practice and research, the principles and methodology associated with PD are in continuous development and subject to various interpretations. As outlined by Hartson and Pyla (2018), in practice, PD has been applied in many forms and with various rules of engagement. For example, in some projects, participants' power is limited to the creation of input for the professional designers to consider. In other cases, participants are granted full access to sharing responsibility for the final outcome.

PD principles have also informed practices of widely applied [user-centred design](#) through a focus on the end-user and on nurturing a more creative development atmosphere (Rosenzweig, 2015).

Although the widespread adoption of PD methods has generated various interpretations of the definition and scope of the concept, the widely accepted core principles can still be identified. Luck (2018) outlines some of the guiding principles of PD that remain relevant today:

- **Democratising design and equalising power relations** – creating the opportunity for all stakeholders to participate in shaping the social and technological systems in which they operate. In large scale systems – such as health and care – PD also gives a voice to vulnerable communities such as patients.
- **Mutual learning** – emphasis on transforming the user and the designer through mutual understanding. Product teams need to practice openness and learning through engagement as well as the implementation of insights in their design process. PD calls for genuine curiosity in the needs and goals of all stakeholders.
- **Contextual awareness and actions** – engaging with stakeholders directly in their environment enables a deeper understanding of their situation. It is also crucial to tailor methods and engagement approaches to specific stakeholders and their respective contexts.
- **Development of tools and methodology** – PD represents an approach rather than a limited set of universal and standardised methods. The development of tools and methodology – like the concept itself – is an ongoing process. The choice of tools and methods at any given stage of the project needs to primarily help stakeholders express their needs and visions.

The conceptual mission of any design process is problem-solving – responding to the needs and goals of those using or impacted by the design of products and systems. Engaging with these stakeholders and creating avenues for genuine participation enables development and innovation for sustainable solutions that work. As such, the research team or the team leading the design process (also design team) needs to immerse themselves in the context of relevant stakeholders to acknowledge, understand and address all of their pain points and visions.

Who should the participants of participatory design be?

When considering the involvement of participants, project teams need to start by mapping out the stakeholders involved in the systems and/or products/services they are designing. While

user-centred design is primarily focused on engagement with ‘end-users’ (Barnum, 2021), PD adopts a wider perspective of the relevant stakeholders.

In the context of health and care, two wider categories of ‘end-users’ can be identified – **health and care workers** and **patients**, alongside their **families** and **informal caregivers**. The network of stakeholders involved, however, is wider. This includes groups such as **innovation solution providers** (including SMEs, start-ups, corporations, etc.), **investors**, **R&D institutions**, and the **wider health community** (including clusters, non-governmental organisations, policymakers, Reference sites and the AHA community).

As noted by Oprisan (UX Planet, 2021), value creation has become a matter of transversal output – that is, solutions which combine input from several disciplines, services and technologies. But transversal output requires multidisciplinary input (Oprisan, 2021). What is often seen, however, is siloed development across most sectors, including health and care, which leads to siloed solutions (see Sunil, 2019; Kelly et al., 2019). PD has the potential to remove siloed development by coordinating collaboration between all relevant stakeholders.

Effective coordination is key in producing design input for health and care solutions that stand the test of time. On an individual level, PD empowers all actors within a system to contribute and feel ownership over the design process as well as the design output. This is subsequently more likely to provide design input that reflects the truth of all stakeholders’ reality and thereby lead the design team towards more functional results. The design team comes from service provider or problem owner, or it can be the facilitator of the activity on behalf of service provider.

Furthermore, by connecting key stakeholders, the design team creates harmony within a given programme and creates solutions that can have an effect across wider systems. On a programme level, the design team becomes the coordinator of stakeholders that contribute to the mutually beneficial transversal output. Through the facilitation of meaningful collaboration and the development of functional solutions, this interaction produces value that can be elevated beyond the programme.

Expanding the perspective of relevant stakeholders illustrates that the pool of potential participants in designing for the health and care sector is vast and diverse. Importantly, however, not all stakeholders need to participate in all the workshops being organised. The final selection of stakeholders will depend on what any given workshop specifically aims to achieve and who is impacted by the workshop outcomes. Once the design team has identified all key stakeholders, they can move on to planning their PD facilitation process.

Design thinking and Service Design processes

An approach rooted in marketing studies, that is, Service Design (SD) has succeeded to introduce user-centered design principles to many organizations especially in the private sector, and provided a bunch of tools and techniques, many of which stem from PD (Saad-Sulonen, de Götzen, Morelli, and Simeone, 2020). According to Saad-Sulonen et al. (2020), Holmlid (2009) points out three themes in common for PD and SD fields: user involvement, cooperation, and emancipation. In the SD context, the expert designers no longer themselves create value, but engage users and communities in a participatory process of value co-creation,

helping them in defining their own needs and solutions. Due to tradition of PD in the public sector, it is the ground where SD and PD practices converge. (Saad-Sulonen et al. 2020).

SD is based on Design Thinking basing on the process of learning and collaborative development. Besides “thinking” it builds on practical skills, such as learning by doing, and human approach, including empathy, and listening, for example. Fundamentally, it is about being open to learning new things and questioning assumptions. Design Thinking is ideal in situations where there is not much information to begin with, or where the ideal outcome or solution is not known. Design Thinking is typically used for developing solutions. There are various process models describing the design process. Some of them have four, some five and some six phases.

For example, the Double Diamond model introduced by the British Design Council has four phases where, at first, you explore the problem by widening the perspective and discovering (British Design Council 2007). Then you continue with defining the real problem by focusing on it. It’s only after knowing the real problem that you can start ideating and developing solutions – at first, by ideating and widening the perspective, and then by focusing on delivering the selected solution.

The methods and activities used in SD processes are wide, not limited to workshops, and they include:

- 1) Discover phase: market research, user research, user journey mapping, diary, shadowing, service safari, managing and planning, design research groups
- 2) Define phase: design brief, personas, project development, project management, project sign-off
- 3) Develop phase: brainstorming, prototyping, multi-disciplinary working, visual management, development methods, business model canvas, service blueprint, testing
- 4) Deliver phase: design scenarios, final testing, approval and launch, targets, evaluation, feedback loops.

(Design methods for developing services, 2015)

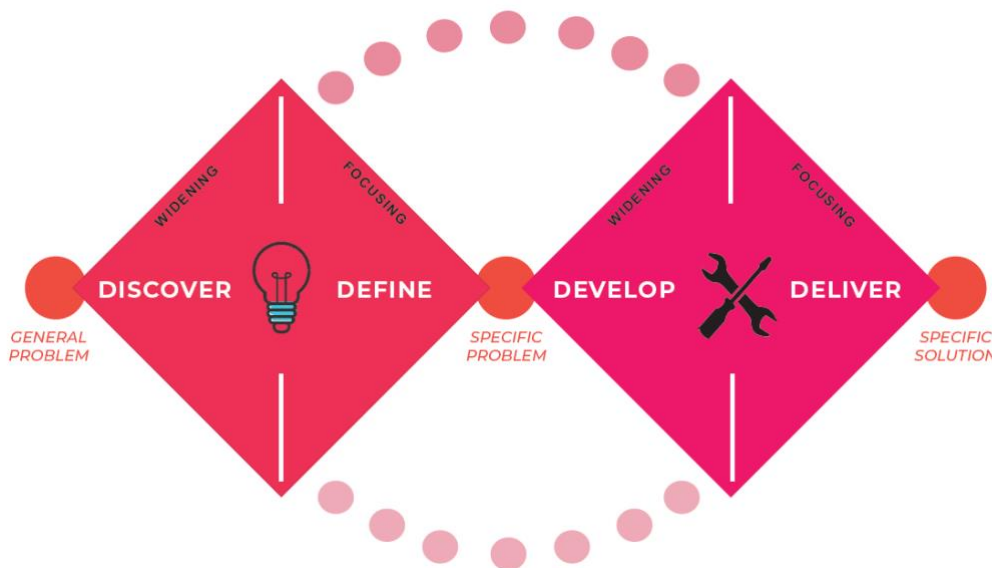


Figure: A four-phase Double Diamond model (Adapted from British Design Council 2007).

Another model was developed by Hasso Plattner Institute of Design at Stanford (2016), and it has five phases. According to this approach, you start with *empathizing* with the people to whom you are developing solutions, and then *defining* their needs and problems. Empathizing and defining helps you to achieve basic understanding on the situation, and after that, you can start *ideating* by exploring the environment and the possibilities and by challenging your assumptions. After ideating, you can create *prototypes* of the solution and *test* them. Also, this process must end with an implementation phase where you deliver the solution.

It is typical for Design Thinking processes that they are iterative. You may have to get back to earlier phases whenever needed. Another issue in Design Thinking and SD is that you have to 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 finalized.

Due to its popularity, it is possible that at least start-ups know the concept of Design Thinking or SD much better than PD.

How to pursue participatory design?

The most common form of participant involvement in PD is workshop facilitation. Many organisations use broad engagement strategies to increase participation in and commitment to strategic planning. In this section, we go beyond broad strategies, propose a concrete list of PD workshops, and give advice on common rules of engagement and how to select the right workshop method in accordance with the stage of your project.

The development of PD tools and methodology – like the PD concept itself – is an ongoing process. The selection we have compiled below represents the current best practice on a global scale.

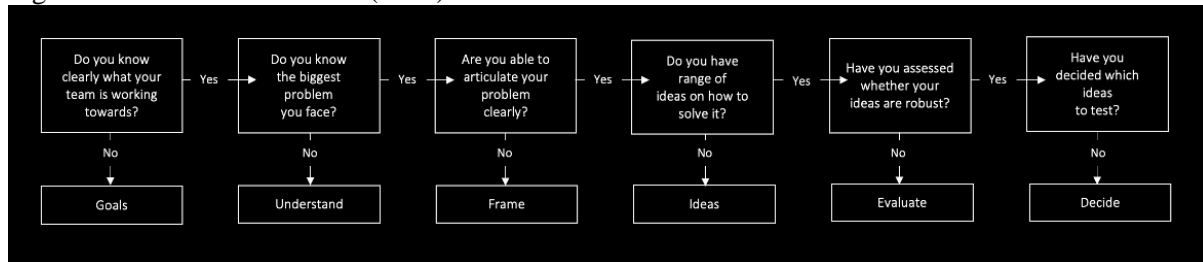
For the purpose of this chapter, the emphasis is on *best practice by practitioners*. With this, we aim to acknowledge the immense contribution of academic PD research, which has explored the ins and outs of some engagement methods in various contexts across sectors (for examples see: Dalsgaard, 2012; Hendriks et al., 2018; Østergaard, Simonsen and Karasti, 2018).

In line with our aim to provide the most practical and widely applicable hands-on guidance, however, we have chosen to compile a wider selection of the most popular actionable methods based on industry experience. There is other stand-alone methodology, such as interviews and focus groups, however with this report we introduce methods for workshops since these are also used as a common activity through the different work packages in the project.

Workshops create avenues for greater engagement for all relevant stakeholders. Creative workshops, such as those listed in this chapter, are also more likely to generate actionable input and engage people’s experiences and ideas in direct response to the research needs of the research team.

To structure your decision-making in line with the needs of your project, the following selection is structured around the decision-tree illustrated in Figure 1.

Figure 1. Source: Helen Kokk (2021)



When mapping out your PD strategy, start by asking the first question on the left side of the illustration (Figure 1). If your answer to the question is ‘yes’, feel free to follow the arrow to the next box. If the answer is ‘no’, follow the arrow down and explore the list of workshop formats listed under the relevant section below. Importantly, workshop selection is not dependent on the development phase of the innovation, but rather the resources and aims of the research team at any given phase.

The reason for providing a wider selection of workshop methods under each section is because of the general rule of thumb in workshop facilitation – that is, if one workshop is not producing the required results, then you try and use another one. Test out different shapes and forms until you meet the workshop goal. The selection of workshop methods are by no means exhaustive, but it has been specifically tailored to the context of the given project.

The ways in which the collected input and data are applied in future activities after the workshop largely depends on what happens during the workshop. As all workshops differ in terms of the aims that they are trying to achieve, there is no standard blueprint for how the input is to be used – this is for the research team to decide during the workshop facilitation process.

GOAL-setting workshops: Help answer the question ‘Do you know clearly what your team is working towards?’

Instil a sense of confidence and purpose by making the problem or goal clear *before* project kick-off. A goal-setting workshop exercise brings clarity, direction, and purpose to the team’s activities. It is a bonding exercise for teams and provides a clear picture of group priorities. Choosing an established method, like those below, provides the guidance and confidence needed to meet project aims efficiently and in-line with global best practice.

The power of proper framing cannot be underestimated. Once it has been skipped, there is no use in completing it retroactively. Agree on a desired end-state to work towards, so daily activity is moving in the right direction based on a mutually accepted roadmap. Choose a method for goal setting and if one of the methods does not work in the team set-up, then choose the next one:

Method	Description	Impact
G.R.O.W Duration: 1-2 hours	<p>The GROW method guides the team through specifying their goal and creating a roadmap towards achieving it. With this workshop, goal setting is context-based, considering the current reality, obstacles faced and what tangible actions can be taken to achieve the desired outcome.</p> <p>The GROW method was developed by Sir John Whitmore and colleagues in the 1980s. As of today, it is one of the most popular methods for strategic problem-solving and goal setting.</p> <p><i>Source and further guidance:</i> https://product.club/pages/grow</p>	Helps strategically compile a roadmap to achieve a specific goal.
Newspaper Headline Duration: 30 mins	<p>The Newspaper Headline method supports the team in defining the future of the project by predicting what the press might say about it. This creates space for participants to creatively dream about the future and thereby highlight the goals of the project. Based on the predictions, participants can then define the problems they aim to solve and the direction they should move towards.</p> <p><i>Source and further guidance:</i> https://product.club/pages/newspaper-headline</p>	Helps highlight the goals of the project by thinking about the future of the project creatively.
Sailboat Duration: 1 hour	<p>The Sailboat method is a great way to connect teams and stakeholders in order to achieve a mutual understanding of their goals as well as the drivers and barriers. This method can help identify what is slowing down the project or whether current goals should be tweaked according to stakeholder needs.</p> <p><i>Source and further guidance:</i> https://product.club/pages/sailboat</p>	Helps identify goals, the reasons behind them and the obstacles in the way of achieving them.
Sticky Steps Duration: 30 mins	<p>The Sticky Steps method supports the team in mapping a clear plan for achieving a specific goal. The method entails working backwards from the desired outcome. Reversing the plan-setting process can help transform seemingly unachievable goals into a tangible reality.</p> <p><i>Source and further guidance:</i> https://product.club/pages/sticky-steps</p>	Helps create a roadmap for your project by starting with the final outcome and working backwards.

Table 1: Goal-setting workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

UNDERSTAND workshops: Help answer the question ‘Do you know the biggest problem you face?’

If the team is struggling to articulate and/or agree on the primary problem they are trying to solve, one of the workshops from the selection below should be considered. The *understand* workshops help unpack the details of the problem being solved as well as discover insights with critical and analytical thinking exercises.

Method	Description	Impact
Assumption Collecting Duration: 1 hour	<p>The Assumption Collecting method helps your team uncover the assumptions they may have about the project. By declaring what is thought to be true at the start of the project, participants can better identify potential upcoming pitfalls. Having everyone’s assumptions visible early on removes surprises in the future.</p> <p><i>Source and further guidance:</i> https://product.club/pages/assumption-collecting</p>	Helps narrow down a problem by collecting and addressing the assumptions that reflect your team’s thoughts on the project.
Service Map Duration: 1-2 hours	<p>If you are working on a specific service, the Service Map method guides your team through creating a map for the associated processes. This workshop helps your team better understand the service and identify opportunities for improving the processes involved.</p> <p>The service map considers both the front- and back-stage players in a service. As such, it also helps understand the interactions between all stakeholders, which can subsequently reveal bottlenecks or areas for improvement.</p> <p><i>Source and further guidance:</i> https://product.club/pages/service-map <i>Similar guidance can also be found via:</i> https://www.nngroup.com/articles/service-blueprinting-faq/</p>	Helps better understand a service and identify opportunities for improving associated processes.
Five Whys Duration: 30 mins - 1 hour	<p>Best conducted after an unexpected challenge during the project, the Five Whys method helps the participants dig deep to the root cause of a problem that is affecting your flow. This method is inspired by your inner curious toddler and asks ‘why?’ five times to get to the heart of the issue. Identifying the root cause helps the team save time as they can better prioritise their actions.</p> <p><i>Source and further guidance:</i> https://product.club/pages/five-whys</p>	Helps identify a root problem that is affecting your project.

Table 2: Understanding workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

FRAMING workshops: Help answer the question ‘Are you able to articulate your problem clearly?’

Move on to *framing* workshops once all the goals are set up and obstacles unpacked through understanding. Framing the problem that you are trying to solve is particularly useful. This process helps avoid solutions that are based on intuition or what someone ‘wants’ rather than what will be effective. The workshop should be selected according to what you need to achieve.

Method	Description	Impact
Value proposition Duration: 1 hour	A value proposition statement is <i>crucial</i> – it’s the <i>mission</i> of your project in written form. The Value Proposition method not only helps articulate this but also helps identify who your project is for and why your approach is unique. <i>Source and further guidance:</i> https://product.club/pages/value-proposition	Helps articulate the aim of your project, who the beneficiaries are and what makes your approach unique.
Problem Statement Duration: 1 hour	Every project sets out to solve a problem. How the problem is articulated is the key to success on the path to finding a solution. The Problem Statement enables your stakeholders to analyse the real challenge your customers/end-users are facing. Throughout this process, the participants may uncover more problems than initially expected, but they will be well-articulated and organised so your team can tackle them one by one. <i>Source and further guidance:</i> https://product.club/pages/problem-statement <i>Similar guidance can also be found via:</i> https://www.nngroup.com/articles/how-might-we-questions/	Helps articulate a problem statement that captures the project’s aims and challenges as well as helps outline measurable success criteria.

Table 3: Framing workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

IDEAS workshops: Help define the question ‘Do you have a range of ideas on how to solve the problem?’

Once all the steps above have been covered, it is time to work on solutions in response to your specified problem. The workshop selection below helps guide your team through extensive ideation for possible solutions.

Method	Description	Impact
Mind Map	Mind Maps help organise your thoughts into an interconnected map. Filling out a blank page with new ideas can be difficult. Letting ideas branch off from initial thoughts can lead to new and unexpected pathways for	Helps structure all your ideas as input for

<p>Duration: 30 mins</p>	<p>innovative solutions. This is a great warm up to get the team’s creativity flowing. <i>Source and further guidance:</i> https://product.club/pages/mind-map <i>Similar guidance and further background materials can also be found via:</i> https://www.nngroup.com/articles/cognitive-mind-concept/</p>	<p>coming up with concrete solutions.</p>
<p>Storyboard Duration: 1-2 hours</p>	<p>Storyboard helps your team map out your solution by writing it up as a story. By connecting a sequence of moments and real-world interactions, it is easier to understand how your solution might work. Through this, your team can also identify pitfalls or spot new details that need to be considered. <i>Source and further guidance:</i> https://product.club/pages/storyboard <i>Similar guidance and further background materials can also be found via:</i> https://www.nngroup.com/articles/storyboards-visualize-ideas/ https://www.nngroup.com/videos/ux-storyboard/</p>	<p>Helps map out your solution by thinking of it in a story-telling sequence.</p>

Table 4: Ideation workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

EVALUATE workshops: Help answer the question ‘Have you assessed whether your ideas are robust?’

Having articulated your problem and arrived at a collectively crafted solution, the next step is to assess problems or ideas against certain criteria to better understand them. The evaluation process can help refine your ideas and uncover insights that have thus far remained hidden.

Method	Description	Impact
<p>SWOT analysis Duration: 1-2 hours</p>	<p>Conducting a SWOT analysis with your team is a powerful method for identifying the strengths, weaknesses, opportunities and threats related to your project. This is another classical method to get stakeholders together and evaluate your project from multiple dimensions. <i>Source and further guidance:</i> https://product.club/pages/swot-analysis</p>	<p>Helps thoroughly evaluate your project by identifying strengths, weaknesses, opportunities and threats for a desired end state.</p>
<p>Premortem Duration: 1 hour</p>	<p>The Premortem method invites your team to think about the ways that the project might go wrong. Anticipating potential pitfalls from the start can help you stop mistakes from happening. <i>Source and further guidance:</i></p>	<p>Helps evaluate and refine your idea by considering what may go wrong.</p>

	https://product.club/pages/premortem	
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Table 5: Evaluation workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

DECIDE workshops: Help answer the question ‘Have you decided which ideas to test?’

By now, the team should be following a specific roadmap. Nonetheless, at certain stages of your project, you may find yourself stuck when choosing which ideas to prioritise. Prioritisation should always be based on stakeholder needs. Refer to the methods below for guidance in this process:

Method	Description	Impact
Priority Map Duration: 30 mins - 1 hour	The Priority Map method helps your team identify the criteria most relevant to your group. This workshop encourages constructive debate to arrive at the most important focus point in any given context. <i>Source and further guidance:</i> https://product.club/pages/priority-map	Helps prioritisation by outlining the most relevant criteria important to the group.
Impact Effort Map Duration: 30 mins - 1 hour	The Impact Effort Map invites participants to group ideas based on the effort they require to carry out and how they will impact the achievement of your aim. By analysing the impact relative to the effort, your team can better decide which ideas are worth pursuing. Prioritisation allows you to focus on what is going to be the easiest, yet most valuable path to pursue. <i>Source and further guidance:</i> https://product.club/pages/impact-effort-map	Helps prioritise ideas by outlining the effort they require relative to the impact they have on achieving your aim.
Blind Vote 30 mins	The Blind Vote method guides your team through a democratic decision-making process. This method is ideal to avoid group dynamics getting in the way of finding the idea that is most likely to work best. Blind voting neutralises dominating opinions in the decision-making process and supports finding the most effective solution. <i>Source and further guidance:</i> https://product.club/pages/blind-vote	Helps prioritise ideas by encouraging a democratic decision-making process.

Table 6: Prioritisation workshop methods from Product Club, available at: <https://product.club/pages/workshop-tactics>

For more resources on the design process, you can also refer to:

- Design Council: <https://www.designcouncil.org.uk/>
- Nielsen Norman Group: <https://www.nngroup.com/>
- Future London Academy: <https://futurelondonacademy.co.uk/>
- Interaction Design: <https://www.interaction-design.org/>

Planning your workshop

In addition to selecting the method that is most relevant to any given stage of your project, there are a few other aspects to consider when planning your PD strategy. Beyond the basic practicalities of organising a workshop, such as booking a venue and recruiting participants, research teams should map out the flow of their activities to ensure that they achieve the input they need.

Example outline for the flow of your PD strategy:

1. Start by introducing the topic and the participating members.
2. List the skills and/or topics you will cover.
3. Decide on the order of the topics.
4. Select an appropriate workshop method and determine the ground rules.
5. Decide how you will wrap up the **workshop**.

Facilitating a workshop remotely? If your selected method mentions sticky notes, online tools can bring the hands-on workshop experience to a distributed team remotely. Current best practice points to tools such as:

- **Miro** – a visual collaboration tool available at: <https://miro.com/>
- **FigJam** – a virtual whiteboard space available at: <https://www.figma.com/blog/introducing-figjam/>

Workshop roles

Furthermore, great product teams don't happen by chance, they happen by *design*. To achieve a collaborative workshop environment, research teams should assign specific roles to workshop facilitators. There are five responsibilities to consider:

Facilitators	The facilitator guides the conversation and activities, follows rabbit holes when they emerge and brings everyone back on track when necessary. The facilitator is a full-time leadership job for the duration of the workshop.
Co-facilitators	The co-facilitator's role is to support the facilitator, who is actively involved in leading the group's activities. As such, co-facilitators function as a special force that can go anywhere and do anything, helping keep the group in motion.
Collectors	The collector documents the workshop outputs. Like the facilitator, collecting is a full-time position. As such, for any workshop, you will need at least two people: one to facilitate and a second to collect.
Participants	Participants are your stakeholders and therefore almost always the people outside your design team. Participants ask questions, answer questions and participate in activities with the aim of co-designing the given project.
Listeners	Some workshops may also have listeners. Usually, listeners come from the broader design team – their job is to be quiet and listen. Workshop

	participants are expected to ask and answer questions, listeners are encouraged to hold back and only interject when necessary.
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Table 7: Workshop roles and responsibilities, <https://www.agux.co/workshops/roles/overview>. For further info also see Customer Insight Leader available at <https://www.customerinsightleader.com/others/role-definition-workshops-from-tasks-to-the-roles-needed-part-2/>

Workshop engagement

As a final step, before executing your plan of action, it is important to settle on basic ground rules for engagement. Introducing a framework of mutually understood principles tailored to the specific group of participants and their context can help immensely in conditioning the group for successful collaboration. As proposed by Gottesdiener and Addison-Wesley (2002), these rules may include the following:

- Assume best intentions, but do not assume anything else – Asking questions to better understand participants’ input is highly encouraged throughout the workshops.
- Listen when others speak – Genuine engagement can only be achieved through active listening.
- Develop in-depth insights by building on participants’ input – In addition to asking questions to further understand the input that comes up, facilitators should follow up on the considerations that emerge. Ask other participants for their opinions to achieve more depth and gather everyone’s opinion on the topic.
- Share your views and concerns in the room – All participants should be encouraged to actively engage in the activities and as such, share their observations whenever they have anything to contribute.
- Treat one another with kindness and tolerance first – Especially in the ideation phase; participants should feel comfortable and safe to express their needs and goals.
- Take care of yourself – Participants, and indeed all stakeholders taking part in the PD activities, should also be encouraged to check in on themselves to ensure they are in the right state of mind to contribute.
- And finally, have fun!

Source and further ideas on the EBG Consulting resource:

<https://www.ebgconsulting.com/Goodies/Assets/WrkshpGroundRules.pdf>

As evidenced from the workshop methods and tools outlined above, PD is often facilitated through a creative and playful environment. While the research team aims to retrieve significant input for their design process, all PD methods should be approached for what they are – an opportunity to create space for genuine human interaction, through which to uncover the needs and goals of all associated stakeholders.

PD is therefore especially valuable for fostering innovation in the health and care sector, as it brings together the diverse group of stakeholders needed in the process. Facilitating collaboration based on PD methods will increase the sense of ownership over the innovation process and its outcomes. While the design team executes a specific strategy to guide the process, they also need to maintain the readiness to pivot when necessary. The primary focus should always remain on stakeholder needs and fostering an environment in which these can surface.

Participatory Design methods used in IN-4-AHA project

This subsection gives some examples of the PD workshop methods that have been used and that will be used within the IN-4-AHA project activities. The project uses workshop as the main format, still it is important to notice that although workshops methods are introduced within the report, the project also uses other alternatives to engage with stakeholders such as interviews, focus groups, questionnaires, webinars. In total there are seven work packages dedicated to different topics and workshops are commonly used in all work packages. Not all events that are organized within IN-4-AHA project are of participatory design workshops (there are also webinars to empower and share knowledge and to engage with stakeholders). The participatory design and service design methods are used mainly within the activities of work package 4 that covers living lab testing, innovation scale-up model validation and end-user access for service adoption. For this part we have given detailed info since some of the activities involve end users in testing of actual AHA services/products. PD methods are used also in other activities for the co-creation of the AHA innovation scale up model and roadmap but for these activities, stakeholders are involved to create project outputs which are tools and model not services or products directly. More insight is given below on specific activities.

For the work package 1 (WP1 - Project Management and Coordination) this is mainly activities to organize the work within partners and inside the consortium. We have used some of the workshop methods and tools as Miro to gather input and organize the work for and within the consortium itself.

For the work package 2 (WP2 - AHA scaling up troubleshooting with stakeholders' engagement) interviews have been used to gather feedback of the needs and interest of different stakeholders. Therefore, based on the feedback and needs of the stakeholders and needs from the project, webinars are carried out on relevant topics. Beside this there are four workshops that are carried out through the project and there are several interconnections with different tasks. Two joint workshops have been already organized together with other work packages to get input for scale up model and for impact assessment and data governance topics.

For the work package 3 (WP3 - Participatory Design of IN-4-AHA Innovation Scale-up Model) the consortium has planned several co-creation activities to prepare innovation scale-up model in AHA and practical roadmap. Mainly workshop methods are used for the scale up model creation activities. Up to 15 different workshops will be organized during the project for this topic to better raise knowledge and empower stakeholders, involve different stakeholders into discussions and group work, to get input and feedback of their needs and co-create the tools together. Specifically, five participatory design process formulation and validation workshops will be organized, four online workshops are organized for developing the toolkit for participatory design process in the health and care sector and four workshops organized for the co-creation of the scale-up model to enable an exchange of viewpoints among all stakeholders. Two workshops are held to get feedback for private-public collaboration models. Some workshops are organized jointly with other work packages (WP2, WP5, WP6). So far mostly IDEAS workshop methods have been used, specifically Mind Map or DECIDE workshop method, specifically Priority Map. Miro has been used as a tool for structuring and collecting ideas. Also, other PD methods are used that are not described in this report, specifically for participatory design process toolkit we also carry out interviews and have used

written feedback form to access SMEs and service providers. For the innovation scale-up model, focus groups and workshop methods could be used in co-creation process as well.

Work package 4 activities (WP4 - Service Tests and Adoption) involve testing of real AHA services with end users in living labs.

Five start-up companies' solutions (pilots) were selected for living lab testing in IN-4-AHA. The main purpose of the testing was to get user feedback for the selected companies. The assumption was that the technological maturity was a TRL 5 or higher, the pilots should be ready for their (prototype) testing phase. So, especially useful for the companies would be DECIDE workshops and methods described there. Also, Priority Mapping and Impact Effort Mapping can be used for deciding the scope of the tests – for example, which traits of a company's mobile phone app to include in the user tests. The stakeholders involved in these workshops in IN-4-AHA pilot cases were typically representatives of each pilot company and representatives of the living lab arranging the testing. In addition, separate discussions between the living lab and representatives of the user groups were organized to get the users' insights on how to arrange the tests, too.

The testing phase in living labs with users can be understood as a separate PD process starting from UNDERSTAND workshops. Here for example Assumption Collecting, Service Map and Five Whys methods can be useful for the person collecting feedback from the users testing the solution in case.

In particular, together with the technology developers, using GOAL-SETTING workshop methods, which helped us to solve the biggest problem we encountered, which was to define the profile of the older people participating in the testing according to each of the projects, as each one required a different profile, autonomous or people with different levels of cognitive or physical impairments.

To do this we used Service Map and the Five Whys methods. Once we were able to articulate the problems we were facing, we proposed to the technology developers a series of ideas to help solve the problem, defining the profile of the older people participating in the testing. To do this we used Mind Map and Storyboard methods.

The business coaching part of the living lab testing used also EVALUATE , IDEAS , and FRAMING approaches and workshops. Here the parties involved in the sessions were representatives of each pilot company and the business coach, and methods such as Value Propositions, Storyboards, and SWOT analysis were used. Also, various SD methods were used in the co-creation workshop with five selected pilots to find an answer to a question: 'How a software company could find its way to the Finnish and Nordic healthcare market?' and 'How to introduce digital solutions to the Nordic healthcare sector: opportunities and barriers, collaboration prospects etc.?'

Classical methodologies such as interviews and focus groups have also been used. These focus groups were carried out to map the accessibility of end users. Families, professionals, older people, and consortium members participated. In total four focus groups were conducted.

When compiling Living Lab testing and innovation scale-up playbook we will use workshops, interviews and focus group discussions with the pilot companies, investors, living lab facilitators, end-users and their representatives.

For work package 5 (WP5 - Impact Monitoring and Evaluation) diverse range of methods has been used to collect insights from stakeholders. A web-based survey was conducted among

service providers (product owners who have brought innovative solutions to the market) to explore their usage of impact evaluation. Another survey was disseminated among service providers to map current practices in data management.

The surveys brought some insight on the challenges and needs of service providers on a European scale. A focus group of service providers was conducted to discuss both topics (impact evaluation and data management) with the specific stakeholder group. Miro platform was used to prepare questions for discussion and guide the ideation and discussion process.

One participatory workshop was held jointly with WP3 to present the initial structure of data management guidebook and solicit feedback from stakeholders on what topics could best address their challenges and to reflect on prepared questions to facilitate the sharing of practical experiences.

Three more workshops will be organized during the project on WP5 themes to validate the deliverables and collect input to formulate recommendations in the roadmap.

For the work package 6 (WP6 - Long-term Investment and Cost Efficiency) one participatory workshop was organized together with WP3 activities to involve SMEs and investors but also other stakeholders into the discussions about the long-term investment and funding possibilities with the aim to gather insights both to the investment strategy that is created by the end of the project as well as the scale up model to which the investment strategy is connected to.

For the work package 7 (WP7 - Dissemination and Communication) one part of the activity is also compiling the policy recommendations as a result of project outcomes. For this, one participatory workshop will be organized during the second year of the project. The aim of this workshop is to gather a multi-stakeholder representation to get feedback and validate specific actions and policy recommendations of the project. The specific method will be agreed and decided based on the needs, prior to the activity.

This second chapter concludes the first part of the report that is connected to the compilation of innovation scale up model in connection to the participatory design process activities in theoretical and practical part as well as insight to the IN-4-AHA project context and activities.

The next, third chapter, is connected to the innovation scale up model in a quite different angle as already explained in the introduction. The next chapter will give more general overview of the stakeholder needs and background info in the context of creating an accelerator program for the AHA to put the model into practice and boost the scale up of innovative solutions.

3. Innovation scale-up process in the health and care sector⁵

The growth area of knowledge-based health and care sector technology encompasses a wide range of products, services and business models that affect human health, from medicines, diagnostics, treatments and medical devices to welfare, prevention, and public health programmes.

⁵ EIT Health Scandinavian analysis for Program RABBIT 'Support material for Digital Sandbox call to access biobanks and health registers in

Scandinavian region' <https://connections.eithealth.eu/documents/21805/0/Supporting+document+for+EIT+Health+Digital+Sandbox+Call/f90019e4-57c2-9f9e-c50f-e3dba1594341?version=1.0>

It is realistic for Europe to be a developer and exporter of new high value-added knowledge-intensive health technology. This report sees the following sub-areas as the main growth engines for European health and care economy⁶:

- **Public health and wellbeing and silver economy**

Development and deployment of real-world data-based health and care solutions for improved screening, prevention, and wellbeing.

- **Telemedicine and remote services to promote digital literacy and services**

Digitisation of the diagnostic and treatment route, development and implementation of synchronous and asynchronous communication tools, development of tools for empowering the patient/consumer/user decision-making process.

- **Biomedicine and related applied life sciences to support healthy ageing**

Development of tools and medicines for prevention, diagnosis, detection, and treatment in the personal and precision medicine sector based on deep molecular profiles, such as genomics, transcriptomics, methylomics, proteomics, metabolomics, microbiomics, and similar.

Public health, consumer health and wellbeing and Silver Economy

The health and care sector is a fast-growing industry worldwide, driven by the growing consumer focus on health and care. The health and care economy encompasses all health and care solutions developed outside the ‘pharmaceutical economy’ that use new technology, data and business models and focus not only on treatment of diseases but also on prevention and improvement of quality of life. It is also necessary to stress the importance of the growing European Silver Economy (the economy of the population over 50) which would be the third largest economy in the world behind the USA and China according to the European Commission study conducted by Technopolis and Oxford Economics (2018).⁷

The rapid growth of the health and care sector is driven by the movement of new market participants into the end-user health and care solutions market. These include global technology platforms, equipment manufacturers and the pharmaceutical industry with significant market power. This in turn has triggered a massive concentration of technology, capital, data and talent in the health and care market. Care solutions must become more data and citizen need driven as well as focus on early prevention of disease through managed lifestyle programmes. Furthermore, management of chronic ailments should become completely data-centred and personalised through smart digital tools.

Telemedicine, digital literacy, and remote services

The European Commission defines remote services in health and care (or telemedicine)⁸ as the provision of health and care remotely using information and communication technology (ICT), including the secure transmission of medical data and information in text, audio, video or

⁶ More info: [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI\(2021\)690548_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI(2021)690548_EN.pdf); https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf

⁷ <https://digital-strategy.ec.europa.eu/en/library/silver-economy-study-how-stimulate-economy-hundreds-millions-euros-year>

⁸ https://ec.europa.eu/health/sites/default/files/ehealth/docs/2018_provision_marketstudy_telemedicine_en.pdf

another form to prevent, diagnose, treat and monitor diseases. Remote health and care services are divided into synchronous (remote reception, remote therapies, remote monitoring) and asynchronous (messaging) communication, but also include solutions where a person receives health and care without the involvement of a health and care professional (so-called patient decision support, reminders, notifications).

Biomedicine and related applied life sciences to support healthy ageing

Biomedicine is a theoretical and transitional field of medicine that studies and describes the development of diseases through a variety of biological causes, including hereditary (genetic) and molecular causes. Biomedicine seeks and develops solutions to problems in applied medicine using laboratory and computational tools in molecular biology, genetics, genomics, microbiome and metabolomics, with the aim of improving early detection of diseases (e.g. through screening) and the quality and effectiveness of patient care. Biomedicine is a highly interdisciplinary field, i.e., the development of the necessary solutions often requires the cooperation of top specialists from many disciplines. It is also important to emphasise that biomedicine is a very capital-intensive field and that the innovative solutions developed in this field that can be implemented outside research institutions have higher added value.

Ecosystem properties necessary for the successful development and implementation of digital innovation in the health and care sector

In recent decades, Europe in general has only systematically dealt with the development of the knowledge creation and transfer ecosystem centred around academic research, provided that other parts of the business ecosystem develop spontaneously as a result. While the technology sector in general has seen many successes, the start-up ecosystem for the health and care sector is lagging quite substantially behind compared with the overall level of digitalisation in Europe.⁹

To boost technological innovation in the health and care sector, Europe as a whole needs to address the following questions:

- how to engage private investors in health and care financing, while health care and elderly care are interpreted as social responsibility
- how to support innovation transfer and build an entrepreneurship ecosystem that supports health and care and social care tech solutions to take into consideration economic returns and savings in health and care from the early stages of start-up business development
- how to overcome the regulatory barriers in innovations, targeting personalisation and personal data usage
- how to monitor and evaluate in the long-term perspective the socio-economic benefit

It is worth mentioning the following details separately:

- The existing knowledge ecosystem is largely focused on the development of knowledge transfer, but this has not led to the development of other subsystems.

⁹ <https://carnegieendowment.org/2020/07/09/europe-and-ai-leading-lagging-behind-or-carving-its-own-way-pub-82236>;

https://www.euro.who.int/_data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf

- The level of generality of the existing ecosystem is low or extremely low and this is reflected in the statistics¹⁰ on the establishment of start-ups.
- In a region the size of the European Union, it is very difficult to build innovation and an international growth-supporting ecosystem built on the principle of geographical proximity without significantly stronger integration into international networks, cross-border knowledge change and the need to establish operational gold standards as well as build financing networks (similarly to US East coast (Boston/Cambridge) and West coast (Seattle/San Francisco/San Diego)).¹¹
- The regulatory environment (including the system of public procurement and ordering of health and care services) today does not give start-ups the opportunity to pilot their solutions in neither the domestic nor the broader EU market. The regulatory aspect should focus on removing barriers to scale-up across borders, addressing issues such as health data privacy, licensing and reimbursement of innovative health and care services. One common and integrated regulatory framework (research ethics, medical device approvals and similar) would provide strong support for an innovation transfer ecosystem.

In view of the above, it is necessary to make decisions for the development of a new type of knowledge-based health technology business ecosystem, which would also provide an opportunity to amplify the achievements of the knowledge creation and transfer ecosystem.

More specifically, it is important to develop the following ecosystem properties and functions fully and equally to support knowledge-based health and care products and services:

- **Knowledge creation and transfer ecosystem** – Universities, academic research organisations, knowledge-dense commercial organisations. Important to support public-private partnerships and knowledge transfer through policy, public funding.
- **Incubators and business accelerators ecosystem** – Public and private mentoring programmes, incubator programmes and data/research/business accelerators. Important to have well-connected and knowledgeable mentors' network with practical experience.
- **Regulatory and policy ecosystem** – Local and EU-wide laws and regulations around data protection, data privacy (including cloud computing), ethical review boards, regulations and procedures to obtain CE-mark and market approvals as medical devices (therapeutical, digital or devices).
- **Digital-health ecosystem** – Digitalisation of all health and care services and data, including procedures, treatments, outcomes and management of patients.
- **Venture and other financing ecosystem** – Local and regional networks of angel investors, venture funds and institutional investors. Important to develop public funding programmes to support knowledge and labour transfer between academia and industry. Furthermore, it is important to educate private investors on the peculiarities of knowledge-dense business models.

¹⁰ <https://medium.com/speedinvest/digital-health-in-europe-analysis-of-600-european-startups-from-the-last-decade-642e97c75478> and <https://nobel-project.eu/the-community/healthtech-in-europe/> and <https://www.medtecheurope.org>

¹¹ More background info can be found at: <https://www.cipherbio.com/blog/2020-biotech-funding-us-europe-and-asia/> and <https://www2.deloitte.com/us/en/insights/industry/health-care/health-tech-private-equity-venture-capital.html>

Long-term strategic goals for knowledge-based health and care innovation programmes

Forward-looking innovation ecosystems need to work towards building and developing the innovation support system towards a platform that could be characterised by higher generativity – the ability of new enterprises to co-create and re-create within the ecosystem – and higher growth potential, easier market validation and access and improved survival rates of start-ups.

The implementation roadmap for scaling up innovation in the health and care sector should prioritise the implementation of the following changes, central operational principles and objectives:

- Health technology used through e-health systems has become an integral part of the health and care system.
- Health and care technology developed in academia finds wide application in the context of everyday health and care economy empowered by public-private partnerships.
- The health and care system is increasingly using health technology to facilitate access to medical services and alleviate the shortage of doctors and nurses through telemedicine, remote services and a high level of digitalisation.
- The local ecosystem has launched new Accelerator and Incubator service models to the market that help bring knowledge-based health technology and products and services to market faster and more successfully, including business concept validation, prototyping, testing, validation and business development services in line with international best practices.
- Straightforward and transparent processes – laws, consents regulations and technological solutions – have been implemented for access to and secondary use of real-world health and care data for the development of new types of medicines as well as medical devices (including so-called digital medical devices) and a broader range of health technology for start-ups, small-medium-sized enterprises and multinational corporations.
- Workshops, policy forums and guidelines have been developed and implemented in order to significantly improve the understanding of ‘health management literacy’ in society, which in turn amplifies the change in public health for the better, including the indicator of healthy life years.

Stakeholder expectations and needs towards health and care sector technology innovation

Compared with other innovation and economic verticals, the health and care sector has the broadest set of stakeholders with their respective roles, expectations, needs, contributions and decision-making powers in the ecosystem.¹² The health and care sector is very highly regulated to offer citizens the best products/services whose effectiveness on improved health outcomes is evidence-based and safe for patients. Regulations, processes and data protection laws need modernisation in light of wide-spread digitalisation, rapid technology development and priority

¹² <https://www.karger.com/Article/Fulltext/481301>

shifts in stakeholder expectations towards health and care. The COVID-19 pandemic has very sharply brought out the need for innovation in the health and care technology sector. Stakeholders' main expectations can be summarised as follows:

- **Policy-makers** – Enable the state-of-the-art treatments, procedures and services that enable the delivery of cost-efficient services to patients and citizens. A high level of generality among health and care sector stakeholders for the improved, timely and cost-efficient implementation of knowledge-dense and evidence-based solutions in practice. Strong public private partnerships to develop the health and care ecosystem and support stakeholders that drive disruptive technology and solutions with great potential for export. Broad and rapid adaption to policy documents, regulatory framework and priority areas by all health and care sector stakeholders.
- **Health and care providers, professionals and the health community** – Access to state-of-the-art treatments, procedures and services that enable the delivery of the best service to patients. Available funding and policy that support testing and implementation innovative products and services as standard of care. Dedicated efforts towards a higher level of digitalisation in the health and care sector to enable effective use of resources – both specialist time, exploitation of infrastructure and finances (value-based health and care). Available training programmes to learn and adapt to changing standards, tools and services due to the wide adaption of technology in the health and care sector. Career models in clinical work that allow part or full-time industry sabbatical to develop innovative solutions without harming prospects for clinical career. Outreach programmes at educational institutions starting from kindergarten throughout primary and secondary school to advocate the importance of jobs in the health and care sector.
- **Patients, Consumers and Users** – Easy and timely access to state-of-the-art treatments, procedures and services. Transparent and clearly communicated priorities in health and care policy with flexibility to adapt to changing priorities or realities. Expectation towards higher adaption of digitalisation, remote services and telemedicine in general. Easy-to-use digital products and services with improved user experience similar to the commercial none-health and care sector.
- **Academia and research organisations** – Public funding programmes that support exploratory research on basic concepts in science. More flexibility in funding programmes and evaluators to change topics due to shifted research priorities. Similarly, availability of funding for knowledge and technology transfer towards commercialisation in collaboration with industry. Career models in academia that allow part or full-time industry sabbatical to develop innovative solutions without harming prospects for academic career. More specifically, major change is needed among academics and the public more generally towards public-private partnerships and academics transferring to industry.
- **Start-ups, SMEs and Industry** – Transparent and straightforward processes for developing, testing, validating and commercialisation of innovative products/services. The main expectation is being on a clear path to certification and market approval as well as business models and payment models. Available policy documents which set the priorities for innovation transfer in the health and care sector and access to mentors, data custodians and funding networks to accelerate innovation process.
- **Funding organisations and Investors** – Available sustainable policy documents for understanding the market needs and long-term future trends in the health and care

sector. Academic and public Training programmes, Accelerators and Incubation networks that support entrepreneurs on the innovation path and enable the development and launch of competitive products and services.

Real World Data as a key driver in health technology innovation

The main motivations for start-ups, small-medium-sized enterprises and broader industry to have access to individual level real-world health and care data can be summarised as follows:

- Extensive data mining, such as hypothesis-free mining of health data against new molecular endophenotype profiles or comprehensive genomic profiles.
- The interest in applying or developing innovative analytical methods, such as machine learning and artificial intelligence, requires in-depth data to acquire new knowledge.
- Ensure and implement industry standards for schedules and procedures to enable efficient use of data.
- Perform market studies and develop products and services based on real-world needs and according to current/future standard of care and data models. Real-world data access and understanding of processing standards is mandatory for developing products and services that meet the EU General Data Protection Regulation (GDPR)¹³ and the Medical Device Regulation (MDR).¹⁴

National laws, different standards in informed consent protocols and lengthy approval processes for ethical and regulatory review boards make access to individual-level health and care data for third parties difficult, if not impossible, especially for developing commercial products/services purposes. Access to primary data is easily granted to academic research teams, but to a lesser extent if the application involves the collection of a larger field of data and longitudinal health data. The main reason for this being the lack of laws and regulations surrounding the secondary use of real-world health and care data from national registries, databases and biobanks. Opinions on ensuring wide access to the industry vary widely and, in general, remain very conservative.

Individual-level data is often confused with personal data, e.g., information enabling identification, such as full name, home address, personal identification number or social security number, etc. Rather, individual access means the ability to perform complex queries and analyses in real time without the need to directly involve national health system-linked registry, database or biobank staff. Such procedures usually result in summary descriptive metadata or deep mechanistic knowledge of how the biomarker relates to health and disease.

Modern IT (information technology) offers a number of solutions to provide secure and functional access to sensitive data. For example, one approach would be password-managed virtual servers with an interactive link to raw health and care data and the ability to use containerised cloud computing solutions. Data lakes where different phenomena have made deep phenotype data available in a shared environment without compromising data security. An additional audit function could be achieved through the introduction of blockchain-based technology, which provides solutions to ensure data integrity and uncompromisingly record all analytical steps and procedures. Blockchain technology is used, for example, in Estonia to

¹³ <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>

enable services provided by the state and to enable RSA-based authentication solutions for digital signatures, encryption and e-voting.

Current EU data privacy laws and regulations have made it a lengthy and bureaucratically heavy process to get access to and process special personal data, such as health and care data as well as genetic profiles, in public cloud environments such as Google Cloud Platform, Microsoft Azure, Amazon Web Services and similar by requesting very stringent rules around data encryption and key managements systems. As health data (including health and care data and genetic profiles) are becoming enormous in size and modern computational techniques, such as machine learning and artificial intelligence-based modelling, require high computational volumes, it is mandatory for local knowledge-based health and care innovation ecosystems to develop both legal and technological solutions for the secondary use and processing of real-world health system data.

A very detailed analysis and overview of the Nordic digital health data landscape, including national registries, databases and biobanks, has been carried out by the European Institute of Innovation and Technology (EIT) Health. The same documents outline various motivations and value propositions for various stakeholders as well as the main modes for collaboration between public and private sector organisations.¹⁵

Specific requirements for Health and Care sector Accelerator Programmes

Innovation acceleration in health and care vertical-focused programmes is more complex and resource demanding compared with, for example, the B2B (business to business) SaaS (Software as a Service) technology sector due to extensive regulatory requirements, the public sector as a main market and diverse stakeholder expectations towards developed novel products and services. In Europe, there is an urgent need for a new generation of Health Tech Accelerators that can support entrepreneurs with tailored programmes throughout the ideation phase until finding a product-market fit and commercial expansion.

While existing Accelerators have very strong programmes and mentor networks, the focus is almost always on growth, sales and marketing, which perfectly matches and supports technology-focused (SaaS, IoT (Internet of Things), hardware and similar) start-ups as their core product/service has already been developed and product-market fit largely found. Such approach is suboptimal for health and care sector start-ups as the development of products/services needs to follow a specific set of guidelines imposed by Healthcare Sector Regulators. Detailed documentation – including but not limited to product/service development process and steps, statistical evidence and models, ethics and other approvals, validation study designs and outcomes – is necessary to obtain certificates and approvals from respective regulatory bodies. Only then does a product/service become market-ready and a sector start-up ready to join a Business Accelerator focused on sales and growth.

Development process from ideation to certification/approval-ready product/service can take several years (up to 10 years in the case of therapeutic molecules) – without the timely implementation of the appropriate processes and documentation principles, no certification/approval can be applied, thus fast amounts of resources (time, talent, finances) are wasted. Furthermore, pivoting to a completely different product/service and/or business plan

¹⁵ EIT Health Scandinavian analysis for Program RABBIT

<https://connections.eithealth.eu/documents/21805/0/Supporting+document+for+EIT+Health+Digital+Sandbox+Call/f90019e4-57c2-9f9e-c50f-e3dba1594341?version=1.0>

is common for technology-focused teams. At the same time, such structural changes are not possible on the HealthTech track due to the same strict regulations and the way products/services reach market (and client/patient) readiness.

Thus, for health and care sector entrepreneurs, significant gaps exist in almost every EU innovation ecosystem, as very early stages of product/service development are not supported by most University Technology Transfer Offices, Accelerators or Incubators. In order to remove the discussed major innovation bottlenecks, the following tracks need to be integrated into health and care vertical-focused Accelerator programmes:

1. Health and care-specific mentoring programmes by practicing experts (including medical, research, policy, law etc.)
2. Data Science training programmes and practical workshops focused on sensitive health and care and patient data (including health and molecular data-based workshops and hands-on programmes, data privacy and high throughput computing in cloud environments, best practices and gold standards in statistical modelling and evidence building)
3. Health and care sector-specific legal mentoring programmes and practical problem-solving workshops (including data privacy and data protection, regulations for certification and market approvals – the most important being the EU CE-mark, the In Vitro Device Regulation (IVDR) and Medical Device Regulation (MDR) certification systems and how a given product/service is categorised)
4. Access to real-world patient health and care, molecular and behavioural data for developing, validating and testing products/services (including national health system registries, databases and biobanks of longitudinal real-world treatment data)
5. Access to functional living labs and real-world testing environments, including engagement by real patients, consumers and users (including Consumer research, Co-creation spaces, Rental of hardware and software for testing, Living laboratory ecosystem for large-scale user testing)
6. Implementation of proof-of concept funding programmes to support development activities in early-stage start-ups to grow the product and company for investor readiness (close the financing gap between TLR levels from 4 to 7)
7. Functional support framework for market access in local, regional and global markets, including growth models, regulatory framework and standard of care (cross-border mentoring, living labs and commercialisation networks as well as Reference Sites). Furthermore, the need for investors who understand the peculiarities of developing and commercialisation of knowledge-dense products/services in the health and care sector. Similarly, training programmes and support networks for researchers and innovators to connect with relevant investors and funding mechanisms.

4. Summary and Conclusions

The objective of this report was to give an insight into participatory design methods and tools and an overview of the specific needs and expectations of stakeholders for innovation scale-up processes in the health and care sector.

The first part of the report provides an overview of what participatory design is, why it is important and who the participants of this process should be.

The most common form of participant involvement in participatory design is workshop facilitation. To structure your decision-making process in line with the needs of your project, there is a wide selection of workshop methods under each section to choose from.

For each decision-making step we have added several methods along with a description and impact overview and the possibilities to look for additional information. It is important to know a wider range of workshop methods to use because, as pointed out in the report, if one workshop is not producing the required results, then another method should be used until the workshop goal is achieved. The selection of workshop methods is by no means exhaustive, but it has been tailored to the context of the given project.

Part of the concept of design process is responding to the needs and goals of those using the product or system; therefore, it is important to map out the stakeholders involved in the products or systems you are designing at the beginning of the process.

In the end, the main goal is to engage the relevant stakeholders to participate in the design process in order to develop sustainable and valuable systems or products for the end-users that solve their problems or offer better solutions that meet their needs.

The report also gives an insight where and how in the project context the workshop methods are used. Since during the preparation of this report, the project is still ongoing, the list of chosen methods for workshops is not final.

The third part of the report gives an overview of what is important for the successful development and implementation of digital innovation in the health and care sector and more specifically the requirements for creating accelerator programmes in the health and care sector. It gives an overview of the ecosystem properties and functions that are important and should be developed to support knowledge-based health and care products and services. One part of this also addresses the importance and value of real-world data.

The health and care ecosystem is very complex and has a broad set of stakeholders, so for each stakeholder group identified by the project consortium, it was important to give insight into their expectations in the field of health and care technology innovation.

The IN-4-AHA approach is to use participatory design for the engagement of business environment actors and enablers for innovation scale-up model creation and roadmap-building. The report will be an input into the practical innovation scale-up model and a roadmap to guide the practical activities related to the scale-up of the innovations that will be created by the end of the project as the main outcome. The report will be also made public and accessible to relevant stakeholder via IN-4-AHA webpage and other social media channels.

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