

SCALE-UP MODEL COMPONENTS

/working document - summary/

BACKGROUND

*“Scaling up digital innovations in health and care services in Europe enables more EU citizens to lead healthy, active and independent lives while ageing, whilst improving the sustainability and efficiency of social and health care systems and boosting and improving the competitiveness of the markets for innovative products and services. By scaling up digital innovations, the EU Member States are responding to the ageing challenge at both EU and global level, while creating new opportunities for businesses.”*¹

There are several tools available to support planning and decision-making in the scale-up process, including ones focusing on the health and care sector. However, an analysis conducted in the framework of IN-4-AHA project concluded that they tend to lack one or more components necessary for comprehensive support, especially when it comes to human-centeredness. The partners of IN-4-AHA have developed a comprehensive model, taking into account both existing tools as well as input from actors in the field.

SCALE-UP DEFINITION

WHO defines scaling up as *“deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and programme development on a lasting basis”*²

ASSUMPTION

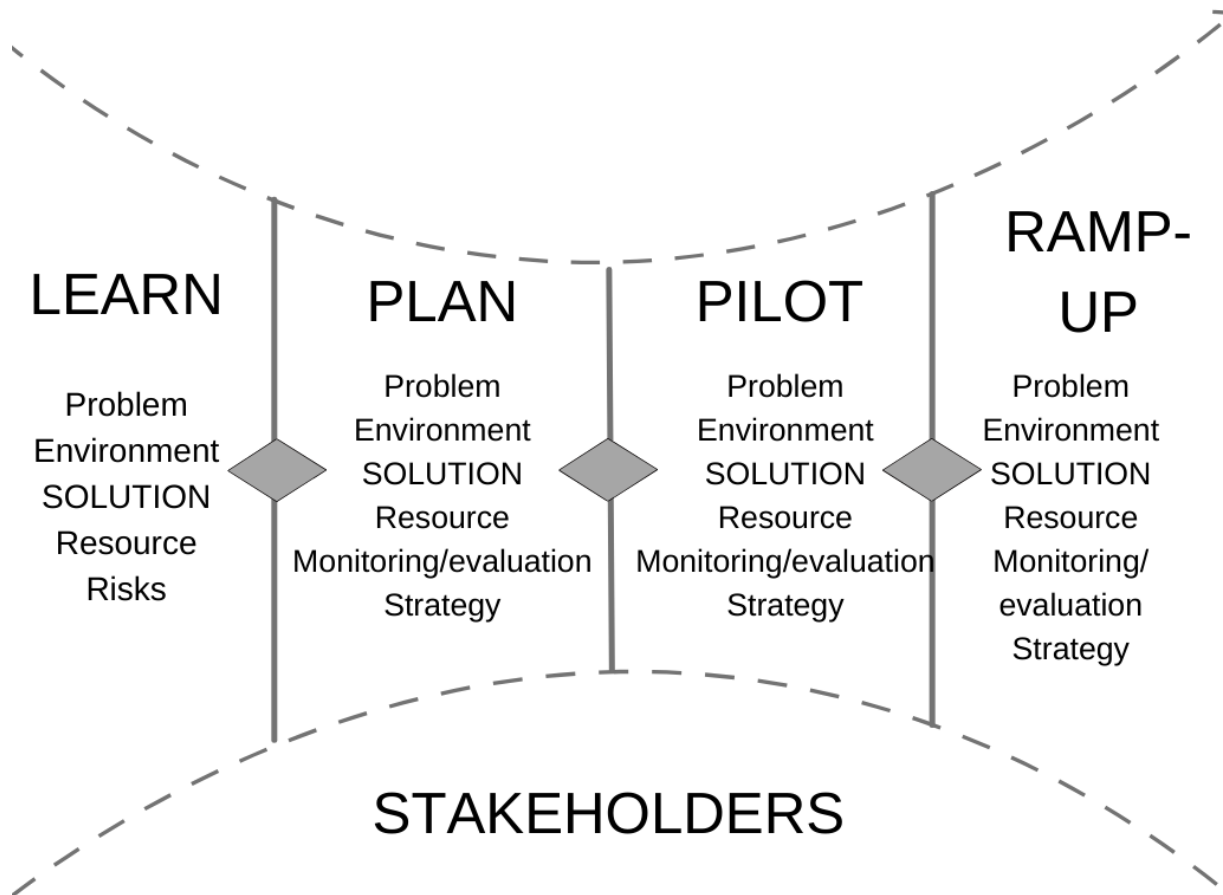
The scale-up model is intended for solutions that already have proof of feasibility on a smaller (local/regional/national) scale, but whose ambition is to expand (internationally).

The model also serves as a tool for industry support organisations – clusters, accelerators, umbrella organisations etc

¹ https://www.scale-aha.eu/fileadmin/documents/scaleaha_d5.4_finalstudyreport.pdf

² World Health Organization. Practical guidance for scaling up health service innovations. WHO, Geneva, 2009. http://whqlibdoc.who.int/publications/2009/9789241598521_eng.pdf

PROPOSED MODEL



Although the model is presented as a sequence of stages, it is not a linear process. As new information is acquired along the way, it might be necessary to trail back to previous components within the stages, re-start activities at a previous step or “run” multiple components simultaneously.

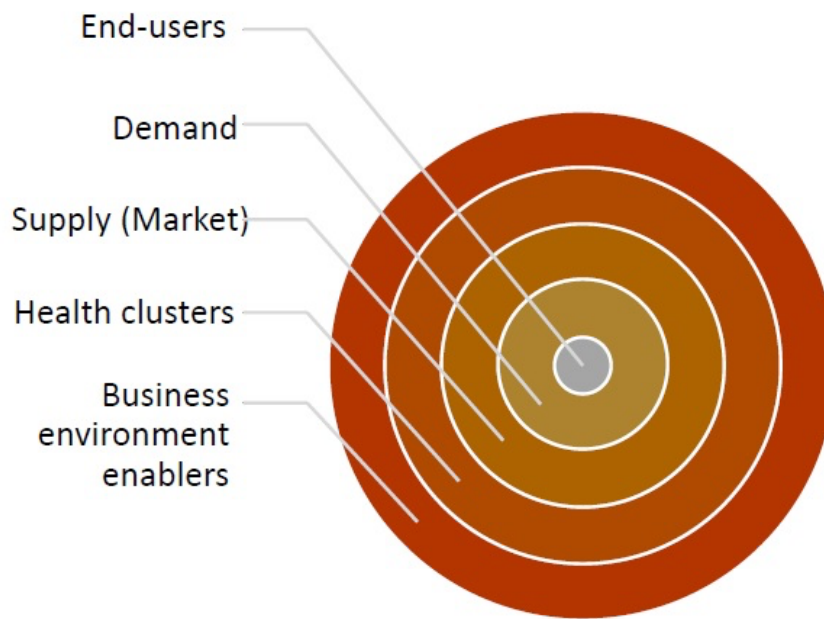
The model offers several GO/NO GO points, and it is important to note that a well-informed decision to quit the scale-up process at any stage should not be considered a failure. Rather, it is a strategic decision that saves wasted effort and resources in the long run.

0. STAKEHOLDERS

Including stakeholders throughout the whole process of scaling-up is crucial. The health and care sector has a large range of stakeholders, from individuals with existing or potential health conditions, and their families and caretakers, to care providers, public health institutions and policy-makers.

IN-4-AHA project recognises the importance of human-centeredness in the development and implementation of health and care solutions, especially when it comes to the end users. The end users have been defined as the “*elderly who need the support with active and healthy living throughout the continuum.*”

Figure. 1 Layers of actors in innovation scale-up



It is important that the most significant stakeholder groups are identified and involved at each component and stage.

1. LEARN

The first stage consists of collecting information and analysing it to map scale-up potential and possibilities. It is a low-risk stage, but crucial for assessing the scale-up opportunities. Doing extensive research might be resource-consuming and it can take focus off the company's daily operations, however, done well it decreases potential losses in the future.

1.1. The problem

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

1.1.2. Is the problem the same in the potential market(s)?

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

Different stakeholders perceive and experience the problem differently, therefore it is important to include a wide range of stakeholders already at this stage.

1.1.4. What is the problem's impact, both quantitatively and qualitatively?

1.1.5. What is the problem's breadth and level of criticality?

1.2. The environment.

1.2.1. Regulatory environment

1.2.2. Cultural differences

1.2.3. Existing relevant infrastructure and processes

1.2.4. Trends and demographics

1.2.5. Direct users/beneficiaries and involved stakeholders, what are their habits, abilities, perceptions towards new solutions etc,

1.2.6. What are the existing and potential competitors and alternative solutions? What is their value proposition? What is their business model? How are these solutions currently financed?

1.2.7. Which stakeholders can help in understanding different aspects of the environment?

1.3. Solution

1.3.1. What is the solution? How has its feasibility been proven - is there a reference case, proven data, established processes to back it?

1.3.2. Does it address the problem at the target market? If not, where are the gaps? What are the main features that would address the target market?

1.3.3. Who is the primary target group (individual, organisation, public authority)? What is the value proposition towards them?

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

1.3.4. What is the current business model?

1.4. Resources

1.4.1. What kind of resources are necessary to implement the solution in the new setting? (finances - costs, financing options), managerial competences, institutions and companies needed for partnering, competences needed for adapting the solution, activities to be conducted during the next steps (training staff, raising awareness, lobbying, fundraising), processes to be developed, infrastructure to be built, licences/permits/certificates to be acquired etc.

1.5. Risks

Based on the previous components, both external and internal risks must be analysed. The CIMIT Healthtech Innovation cycle suggests the following four dimensions of risks, and emphasises that all dimensions should be looked at in parallel³.

1.5.1. Clinical risk

1.5.2. Market/business risk

1.5.3. Regulatory risk

1.5.4. Technical risk

At the end of this stage the company should have a better picture if the idea of scaling up is a feasible strategy, and initial understanding on how their solution should be adapted to the target market. -> **GO/NO GO**

2. PLAN

During this phase gathering information and evaluating it is more specific. Preparations are made to move to pilot phase. Deeper stakeholder involvement is necessary, most importantly - who will be the primary target group and allies on the target market. While planning, a strategic perspective must be kept in mind, however there must be readiness to change as new knowledge and experience is gained.

2.1. Problem

2.1.1. Based on information collected during the previous stage, and additional contribution from stakeholder groups, the problem must be re-defined (refined).

2.1.2. Who are the problem owners? Are they the same as the end user? How does the problem impact different stakeholder groups?

2.1.3. Is the problem perceived as a problem in the target market, are there proposed strategies/intentions for solutions by other actors?

2.2. Environment

2.2.1. Is it possible to run the pilot in the current legal setting? Which permits, certificates, regulatory classifications are necessary? What legal procedures must be adhered to?

2.2.2. Is it possible to run the pilot in the current health and social care setting? (Processes, infrastructure)

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<https://www.cimit.org/documents/173804/228699/Navigating+the+HealthTech+Innovation+Cycle.pdf/2257c90b-d90b-3b78-6dc9-745db401fbc6>

2.2.3. Which cultural and behavioural aspects will impact the pilot?

2.2.4. Which organisations/institutions/companies are main actors in the field? Who are the potential cooperation partners, support providers?

2.3. Solution

2.3.1. What is the value proposition? What impact does the solution propose? What kind of data and references are there?

2.3.2. Which features should be adapted for the target market? Which features are to be tested during the pilot?

2.3.3. What is going to be tested with the pilot (validation, verification, performance)?

2.4. Resources

What does it take to set up and run a pilot?

2.4.1. What is the scale of the pilot (timeframe, one vs multiple sites, consecutive or simultaneous pilots?).

2.4.2. What effort is needed to comply with laws and regulations, and established processes?

2.4.3. What effort is needed to develop and implement new processes?

2.4.4. What effort is needed for adjusting the solution?

2.4.5. Which target groups must be reached? Which partners service providers are necessary (including their capacity)?

2.4.6. Does the team have the capacity to run the pilot?

2.4.7. What kind of communication activities are necessary?

2.4.8. What are the costs? How to finance them (public support mechanisms (grants), reimbursement, investors)?

2.5. Monitoring & Evaluation

2.5.1. Set up monitoring and evaluation plan for the pilot

2.6. Strategy

At the end of this stage there is an understanding if the company should proceed to the pilot, and if yes, a plan to run it - > **GO/ADAPT/NO GO**

3. PILOT

A pilot project is a small-scale adoption of the solution, either in one or multiple settings to test different features, environmental aspects and/or target groups. This phase enables to collect additional information, test the feasibility of the solution and build credibility, while keeping activities at a lower risk and exhausting less resources.

It is important to keep a long-term perspective throughout the pilot, at the same time being cautious, as pilot projects have their limits, they are not a smaller copy of the full system.

3.1. Problem

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

3.1.2. Is there a difference between how stakeholders perceive the problem and how they experience it?

3.1.3. With new information available, might there be additional venues opening up?

3.2. Environment

3.2.1. What environmental aspects do come into play during implementation? Was there something that has been overlooked/neglected until now?

If comprehensive information has been gathered during the previous stages, most probably finer and more hidden details start playing a larger role (cultural, behavioural, process-related aspects).

3.3. Solution

3.3.1. How does the solution work in the testing environment? Is it easy to implement/use/understand by the users/target group?

3.3.2. How have the stakeholders accepted the solution – how do they perceive it, how do they behave?

3.3.3. Which features have proved to be most significant, where are the shortcomings?

3.4. Resources

3.4.1. Based on the pilot, what kind of resources are necessary for a large-scale implementation?

3.4.2. How will the scale-up be financed?

3.5. Evaluate

3.6. Strategy

Set up strategy and roadmap for scaling-up. WHO suggests the following types of deliberate guided scaling up⁴:

- Horizontal scale-up: solutions are replicated in different geographical areas or to target larger or different target groups. or targeting a larger population.
- Diversification or functional scale-up: adding new features, services or processes to the existing solution.
- Vertical scale-up: policy-makers decide to adopt the solution in their area of responsibility.

Phased, gradual or rapid implementation?

GO/ADAPT/RE-PILOT/NO GO

4. RAMP-UP

4.1. Problem

With the information available so far, is there a possibility to expand into different segments?

4.2. Environment

Continue surveying the environment, as circumstances can change:

- Legal environment
- Technological development and acceptance
- Demographic and social trends
- Competition, alternatives

4.3. Solution

Continuation of collecting data, adjusting and improving.

Generating evidence that the product achieves clinical, social, economic or behavioural benefits

4.4. Resources

4.5. Monitoring and evaluation

4.6. Strategy

RETRACT/FOCUS/EXPAND/DIVERSIFY