

Executive Digest

Methods and tools to support digital health scale-up



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Relevance of this topic to Digital Health

Even though the COVID-19 pandemic accelerated the adoption of tech-based tools across the health sector, highlighting their role in maintaining continuity of care without physical interactions, the scaleup of digital health solutions encounters substantial challenges. In this context, the EU-funded project **Digital Health Uptake** (DHU) seeks to address these barriers by identifying and categorizing methods and tools that aid decision-makers and end-users in embracing digital health solutions.

DHU aims to facilitate the adoption and scale-up of digital health solutions across Europe, by aligning strategies, policies, and tools, addressing barriers that slow down the implementation of digital health innovations. The project includes several objectives, such as monitoring the use of digital health solutions, promoting knowledge exchange among stakeholders, and building capacity for the widespread adoption of these technologies. One key output of the project is the DHU Radar platform which aim at identifying, classifying, and sharing resources that help health authorities and organizations to overcome challenges in digital health adoption. The DHU Radar collects insights on various digital health innovations, allowing stakeholders to explore best practices, track emerging trends, and understand the digital maturity of different solutions. These resources are then synthesized to facilitate mutual learning and cross-border collaboration¹.

Differences between adoption, uptake and scale-up in the digital health context

In the context of digital health, adoption, uptake and scale-up represent different stages of integrating new technologies into healthcare systems, involving various roles for healthcare managers and end-users.

Adoption refers to the organizational commitment and decision-making required to implement a digital health solution. This phase is generally led by healthcare managers, hospital administrators, or policymakers, who evaluate the technology's fit within the existing system, ensuring its compliance with regulatory requirements and potential for enhancing healthcare delivery. The process is typically top-down, driven by the need for cost-effectiveness, alignment with clinical protocols, and broader organizational goals. Adoption includes steps such as integrating the technology into current systems, establishing new workflows, staff training, and ensuring the technology aligns with long-term strategic objectives².

Uptake focuses on the actual use and acceptance of the technology by end-users, including healthcare providers and patients. Uptake is more about the practical implementation and day-to-day use of the digital health solution. Success in this phase depends on how well end-users can integrate the technology into their routines, considering factors like usability, accessibility, and trust in the system. Uptake is often influenced by individual preferences and satisfaction, making end-user involvement crucial to ensure that the technology meets their needs and is effectively adopted in their workflows³.

Adoption and uptake are not just about technical issues but also involve overcoming broader challenges such as limited investments, inadequate regulatory frameworks, and a lack of implementation planning.⁴

Scale-up is the process to rollout the solution once the proof of concept or the early implementation has successfully finished, serving as an example of **transferability** with relevant adaptations. The

¹ Digital Health Uptake (2023). *Digital Health Uptake project deliverable D4.1: Ecosystem mapping and stakeholder analysis*. <u>https://digitalhealthuptake.eu/wp-content/uploads/DHU-D4.1-FINAL-1.pdf</u>

² DIGITALEUROPE (2024). DIGITALEUROPE recommendations for EU digital health policy 2024-2029: Policy paper.

https://cdn.digitaleurope.org/uploads/2024/02/DIGITALEUROPE-recommendations-EU-digital-health-policy-2024-29-policypaper.pdf

³ World Health Organization. (2021). *Digital health*. World Health Organization. <u>https://www.who.int/health-topics/digital-health/#tab=tab_1</u>

⁴ World Health Organization. (2021). *The impact of digital technologies on health service delivery*.

https://iris.who.int/bitstream/handle/10665/345091/Policy-brief-42-1997-8073-eng.pdf?sequence=1



importance of scaling up digital health innovations requires deliberate efforts to increase the impact of tested health technologies and addressing barriers such as funding and system sustainability.⁵

The scaling process requires strategic planning and careful execution to ensure sustainability, adaptability, and success across diverse regions and populations. Different strategies for scaling up digital health solutions vary based on the scope, speed, and degree of certainty regarding the technology's effectiveness.

1. Full-scale rollout (Big bang): this approach involves deploying the solution across all targeted regions at the same time. It allows a shorter overall deployment time but implies a higher risk due to limited opportunity to identify and correct issues, a significant upfront investment in infrastructure, resources, and logistics, a possible overwhelmed support and operational systems if not properly prepared. This approach is suitable when the solution is already proven at a smaller scale and there is a high degree of confidence in its ability to perform well under different conditions.^{6,7}

2. Phased or stepwise rollout: this approach introduces the solution in stages, typically by region, customer segment, or product feature. It allows the possibility of adjustments and improvements between phases, a reduced risk of overwhelming operational resources, and the possibility to manage easier feedback and performance in a controlled manner. Deployment is usually slower, and each phase requires separate planning and potentially separate marketing efforts. This approach is suitable for complex products or services where localization, adaptation, or compliance is a key factor.⁸

3. Segment-based rollout: instead of focusing on regions, this method focuses on specific customer segments or market types. It allows a deeper understanding of customer needs at each stage, less risk and more focus on creating value for each customer group. On the other side, the process could slow down the overall growth if each segment takes longer than expected. This approach is suitable to be used for products that have distinct use cases or benefits for different customer segments like medical conditions.⁹

4. Parallel rollout: this approach is implemented in different regions simultaneously, but with independent teams managing each region's implementation. It allows combining elements of full-scale and phased rollout. On the other side, it requires a high coordination and management overhead and maybe there could be a risk of inconsistencies if different regions face unforeseen challenges. This approach is suitable when the organization has strong, independent teams capable of running parallel projects.¹⁰

5. Minimum Viable Scale (MVS): this approach is launched at a scale just large enough to test viability but small enough to pivot quickly if necessary. It allows balancing the need for significant data with the flexibility to change, as well as limited investment initially while still providing actionable insights. On the other side, if not carefully planned, it may not generate enough traction or feedback. This approach is suitable when there's uncertainty about the solution's ability to perform at scale.¹¹

Keywords

Digital health; Adoption; Uptake; Scale-up; DHU Radar; Rollout; Minimum Viable Scale

Current focus of policy, legislation, standards, emerging practices in this landscape

The European framework to stimulate digital health

⁵ World Health Organization. (2016). Scaling up projects and initiatives for better health: from concepts to practice. Copenhagen: WHO Regional Office for Europe. [pdf] Available at: https://www.euro.who.int/__data/assets/pdf_file/0004/318982/Scaling-upreports-projects-concepts-practice.pdf

⁶ Markus, M. L., & Tanis, C. (2000). *The enterprise system experience — From adoption to success*. In R. W. Zmud (Ed.), Framing the Domains of IT Management: Projecting the Future Through the Past (pp. 173-207). Cincinnati, OH: Pinnaflex Educational Resources. Somers, T. M., & Nelson, K

⁷ Somers, T. M., & Nelson, K. G. (2001). *The impact of critical success factors across the stages of enterprise resource planning implementations*. Proceedings of the 34th Annual Hawaii International Conference on System Sciences, IEEE Computer Society.

⁸ Project Management Institute (PMI). (2021). *A Guide to the Project Management Body of Knowledge (PMBOK Guide)*, 7th Edition. Newtown Square, PA: Project Management Institute.

 ⁹ Moore, G. A. (1991). Crossing the Chasm: Marketing and Selling Technology Products to Mainstream Customers. HarperCollins.
¹⁰ Office of Government Commerce (OGC). (2011). Managing Successful Programmes (MSP). The Stationery Office.

¹¹ Ries, E. (2011). *The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses*. Crown Business.



The digital transformation of health systems across Europe is essential to address the increasing pressures of ageing population, rising healthcare demands, and the need for resource efficiency. The European Commission (EC) has recognized the potential of digital health solutions, including telehealth, health data analytics, and interoperable platforms, to improve patient care, widen access to services, and streamline healthcare delivery. By promoting the adoption and scaling up of these technologies, the EC aims to foster resilient, equitable, and globally competitive healthcare systems, while encouraging member states to innovate and collaborate¹². Several major programmes reflect the EC's commitment to digital health, including the European Health Data Space (EHDS), the EU4Health, Horizon Europe (Cluster 1) and Digital Europe programmes that invest in digital health projects, such as telehealth, artificial intelligence in healthcare, and data-driven solutions, to improve healthcare systems' resilience and sustainability^{13,14}.

Two initiatives of the DHU project aim to cover the need of identifying methods and tools to support the implementation of digital health solutions and help stakeholders to avoid the high rate of failure. First, the **DHU Radar**, a unique platform that enables the discovery and learning about digital health innovations in Europe, their adoption and success. It publishes innovations and experiences, including methods and tools to support the implementation and uptake of digital health solutions. The Radar is implemented through an online survey which contains one category to report "Supporting tool and methodology for upscaling digital health solutions or services (e.g. management tool/impact assessment tool and methodology/etc.)". It is foreseen that the Radar will provide a number of methods and tools that will be further classified in the framework developed in this version.

Second, the **DHU framework of methods and tools** which focuses on supporting the uptake of digital health solutions by categorizing and analysing methods and tools that are helpful for adoption, scale-up, and integration of digital health technologies.¹⁵

This Executive Digest features instruments for scaling up digital health such as the THCS transferability and implementation framework (see details below), instruments to assess the technological, business and service readiness levels, and the monitoring and assessment framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP).

Implications for digital health uptake

Developers

- Need to develop a scaling strategy able to impact product development cycles, market entry, and resource allocation.
- Guarantee technology's robustness, scalability and interoperability; compliance with regulatory standards during scaling to avoid market entry issues.
- Ensure rapid market penetration or incremental feedback collection and solution refinement.
- Guarantee the development of solutions easily adaptable across different healthcare contexts.
- Assess the readiness level of the technological maturity of their solutions.

Enablers

- Enhance the creation of ecosystems that support digital health scaling.
- Promote better monitoring of implementation and enable adjustments to regulatory frameworks.
- Promote rapid policy adaptations, particularly around data privacy and interoperability.

¹² European Commission. (2024). *Tracking framework for the implementation of the Commission communication on a comprehensive approach to mental health*. <u>https://health.ec.europa.eu/document/download/6317c605-5f5d-4d4f-9c8a-d5c93e869814 en?filename=ncd tracking-framework-mh en.pdf</u>

¹³ European Commission. (2024). *Annual Work Programme for EU4Health 2024*. Health and Digital Executive Agency (HADEA). <u>https://commission.europa.eu/document/download/0d742fe8-fa03-4037-b849-</u>

¹¹⁹fce66485b_en?filename=hadea_awp_2024_0.PDF

¹⁴ DIGITALEUROPE. (2024). *DIGITALEUROPE* recommendations for EU digital health policy 2024-2029: Policy paper. https://cdn.digitaleurope.org/uploads/2024/02/DIGITALEUROPE-recommendations-EU-digital-health-policy-2024-29-policy-paper.pdf

¹⁵ Methods and tools to support decision maker adoption and end-user uptake: <u>https://digitalhealthuptake.eu/resource/methods-and-tools-to-support-decision-maker-adoption-and-end-user-uptake/</u>

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- Engage diverse stakeholders, ensuring multi-perspective collaboration to tailor solutions to the local context.
- Foster co-creation environments and promote knowledge exchange between regions.

Payers and procurers

- Calculation of high upfront investments required and expected returns.
- Calculation of costs distribution over time and align investments with measurable outcomes.
- Evaluation of the solutions transferability.
- Evaluation of the feasibility analysis to ensure the solutions fit within the respective healthcare setting, ensuring they are cost-effective and sustainable over the long term.
- Assessment of the potential cost savings and health benefits of new digital health solutions, helping inform reimbursement decisions and investment in scalable technologies.

Users

- Ensure successful uptake of digital health solutions for all types of users (patients, caregivers, healthcare workforce, etc.).
- Provide more integrated access to care and personalized services.
- Ensure that digital health solutions meet all the requirements of trust and usability.
- Importance of person-centred development, ensuring solutions are adapted to the specific needs of healthcare providers and patients.
- Involvement of direct user in the co-creation process to ensure practical, beneficial solutions.

Remaining gaps and issues

Data-driven platforms often face significant obstacles in achieving compliance with diverse data protection laws, particularly when scaling across borders. These challenges complicate the task of safeguarding patient privacy and ensuring robust data security. Additionally, the lack of interoperability between systems interferes with the seamless exchange of data, which is crucial for platforms relying on real-time information flow among healthcare providers. The European Health Data Space (EHDS) is intended to address these cross-border complexities by establishing a framework that fosters secure and interoperable data sharing across EU member states. By setting standardized requirements for health data exchange, the EHDS aims to mitigate data fragmentation issues and facilitate access to and use of health data for both healthcare provision and research purposes.

In the case of telemedicine services, stronger collaboration with end-users is necessary to ensure services are tailored to different regions and user needs. However, barriers such as inconsistent regulatory frameworks, unequal access to digital infrastructure - especially in rural or underserved areas - and the prevalence of digital illiteracy could deepen healthcare disparities.

Electronic Health Record (EHR) platforms face similar challenges, particularly in terms of standardization and system interoperability. This makes it difficult for healthcare providers to efficiently share and access patient data across different regions or systems. Moreover, the high upfront costs and ongoing maintenance required for these platforms pose financial sustainability issues for payers and procurers, as the return on investment is often delayed. The EHDS seeks to overcome these limitations by enabling consistent data access and streamlined sharing, allowing healthcare providers to efficiently exchange patient data access systems. Additionally, the EHDS framework could reduce some financial sustainability issues associated with EHR platforms by promoting shared infrastructure and reducing duplicative investments, thus supporting payers and procurers in maximizing their return on investment.

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Legislative, regulatory, policy or standardisation instrument, or good practice
Title
THCS Transferability and Implementation Framework
Instrument status
Published
Publisher or source
THCS Transforming Health and Care Systems
URL or reference
https://www.thcspartnership.eu/kdocs/2130453/d4.4_first_draft_of_the_thcs_transferability_and_im
plementation_framework.pdf
Summary of the instrument

The THCS Transferability and Implementation Framework is designed to support the transfer and implementation of health solutions across diverse contexts, including different health and care systems.¹⁶ The framework consists of three key components:

- 1. Aligning and Organizing Development Activities: this component focuses on the preliminary steps for initiating the development process, which includes identifying challenges, involving key stakeholders, and gathering relevant data. The main goal is to establish a shared understanding of the problem and align goals among all parties involved. The framework suggests performing a transferability analysis to assess whether an existing solution can be adapted effectively to a new context. This step includes evaluating factors such as the cultural, legal, and health infrastructure differences between the original and new settings.
- 2. Adapting a Solution Developed Elsewhere: this component emphasizes the process of localizing it to fit the new context. This involves modifying certain elements of the solution to align with the unique characteristics of the new healthcare environment, such as local workflows, cultural norms, and regulatory requirements. Developers are encouraged to engage in co-creation with local stakeholders, including healthcare providers, patients, and administrators, to ensure the solution remains practical and relevant.
- 3. **Implementing the Adapted Solution:** after adaptation, the framework outlines steps for the actual implementation of the solution. This includes creating a detailed implementation plan, testing the solution through rapid iteration (e.g., using prototyping and feedback loops), and evaluating the outcomes. The focus is on ensuring the solution is fully integrated into everyday practice, while also maintaining flexibility for further adjustments based on real-world performance. Sustainability is a key aspect of this component, with emphasis on ensuring the solution remains viable in the long term through continuous monitoring and adaptation.

These three components together ensure that digital health solutions can be effectively transferred, adapted, and implemented across different healthcare settings, while maintaining relevance and achieving sustainable change.

 $^{^{16}\,}D4.4\,THCS\,Transferability\,and\,Implementation\,Framework:\,https://www.thcspartnership.eu/deliverables/deliverables.kl$



Legislative, regulatory, policy or standardisation instrument, or good practice

Title

Technological Readiness Level (TRL), Business Readiness Level (BRL), Service Readiness Level (SRL) Instrument status

Published

Publisher or source

TRL: Mankins, J.C. (1995). *Technology Readiness Levels: A White Paper*. NASA Office of Space Access and Technology.

European Commission (2014). *Technology Readiness Levels (TRL)*. Horizon 2020 Work Programme General Annexes. This document outlines the TRL scale used in European Union funding programs.

BRL: Access2EIC Consortium. (2020). *A2EIC toolbox guidelines: Guidelines for the Access2EIC toolbox.* **SRL:** Hughes, J., Lennon, M., Rogerson, R. J., & Crooks, G. (2021). Scaling digital health innovation: Developing a new 'Service Readiness Level' framework of evidence. *International Journal of Environmental Research and Public Health*, *18*(23), 12575.¹⁷

URL or reference

TRL¹⁸: <u>https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf</u>

BRL¹⁹: <u>https://access2eic.eu/wp-content/uploads/2020/09/A2EIC-Toolbox-Guidelines.pdf</u> SRL²⁰: <u>https://www.mdpi.com/1660-4601/18/23/12575</u>

Summary of the instrument

The Technology Readiness Level (TRL), Business Readiness Level (BRL), and Service Readiness Level (SRL) frameworks are well-established instruments used to guide the scaling-up process of digital innovations. These frameworks have been developed and refined across multiple sectors, including healthcare, to evaluate the feasibility, viability, and scalability of new technologies and services. Each framework focuses on a specific dimension of the project's development - TRL for technological maturity, BRL for business viability, and SRL for service implementation - ensuring a comprehensive approach to scaling up. These tools are now commonly used in innovation-driven industries to help decision-makers assess risks and readiness at each stage of project development, from concept to full-scale market deployment.

The Technology Readiness Level (TRL) assesses the technological maturity of an innovation from the research and concept phase to full market readiness. It is divided into three main phases:

- 1. TRL 1-3 (Research and Concept Validation): Involves early-stage research, formulating technology concepts, and conducting feasibility tests.
- 2. TRL 4-6 (Prototype Development): Focuses on building and testing prototypes in controlled environments that resemble real-world conditions.
- 3. TRL 7-9 (System Integration and Commercial Readiness): Involves operational testing, manufacturing optimization, and market launch of the technology.

The Business Readiness Level (BRL) framework evaluates the commercial viability and operational readiness of an innovation:

- 1. BRL 1-3 (Business Concept and Planning): Involves formulating the business concept, assessing market size, and developing a business plan.
- 2. BRL 4-6 (Product Fit and Compliance): Ensures product-market fit, business model feasibility, and regulatory compliance.
- 3. BRL 7-9 (Operational Readiness and Market Launch): Involves establishing a procurement framework, testing in real-world conditions, and transitioning to full commercial operations.

The Service Readiness Level (SRL) framework assesses the readiness of a service innovation to be adopted by stakeholders and scaled within organizations:

1. SRL 1-3 (Service Demand and Feasibility): Focuses on analyzing market demand, assessing user needs, and determining the feasibility of service innovations.

¹⁷ Hughes, J., Lennon, M., Rogerson, R.J. and Crooks, G., 2021. Scaling Digital Health Innovation: Developing a New 'Service Readiness Level'Framework of Evidence. International Journal of Environmental Research and Public Health, 18(23), p.12575.

¹⁸ TRL was originally developed by NASA in the 1970s for assessing the maturity of technologies in space exploration. Over time, it has been adapted for broader use in many industries, including healthcare, defense, and energy sectors.

¹⁹ BRL is a relatively newer concept compared to TRL, and its development is attributed to several innovation and business development frameworks, particularly within the UK government's Innovate UK programs. It is commonly used to evaluate business viability and operational readiness for scaling up.

²⁰ SRL has emerged from the European Commission and various service design disciplines. It is designed to assess the maturity of service-based innovations and their scalability.



- 2. SRL 4-6 (Prototype Testing and Adoption): Involves stakeholder co-design, pilot testing, and assessing service viability within the organization.
- 3. SRL 7-9 (Evaluation, Scaling, and Implementation): Includes thorough evaluation, business case development, and the full-scale implementation of the service.

Legislative, regulatory, policy or standardisation instrument, or good practice Title MAFEIP Instrument status Published Publisher or source MAFEIP Tool URL or reference https://www.mafeip.eu/the-tool https://futurium.ec.europa.eu/sites/default/files/2021-10/Blueprint%20guide%20on%20MAFEIP.pdf Summary of the instrument The MAFEIP (Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing) instrument is a decision-analytical modelling tool that has achieved a high level of maturity through iterative improvements and collaboration among stakeholders. Applied in the context of multiple research and innovation projects as well as large-scale pilots, MAFEIP has become a flexible, web-based tool designed to estimate the health and economic outcomes of various ICT-enabled social and health innovations, including new care pathways, devices, surgical techniques, and organizational models. It allows users to estimate the incremental cost-effectiveness and societal impact of healthcare interventions compared to current care: users input data - whether from clinical studies, expert opinions, or estimations - on two scenarios, the existing care pathway and the intervention being assessed. The tool then calculates changes in healthcare resource use, societal costs, and healthrelated quality of life (QoL) to determine the intervention's efficiency and effectiveness. The tool's flexibility allows for its use in a variety of healthcare innovations, including digital health

solutions, new care pathways, medical devices, and surgical techniques. By modelling the outcomes of these interventions, MAFEIP assists in assessing how well an innovation may improve patient outcomes, reduce healthcare costs, or provide societal benefits. Its use extends to real-world evaluations, including large-scale pilots and early assessments of technological solutions.