



## **D1.2 – Stakeholder Needs Analysis and KPI framework**

WP1 – EVOLVE2CARE experimentation  
space framework

March 2025 | Version 3.0



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## List of Abbreviations

KPI	Key Performance Indicator
LL(s)	Living Lab(s)
RI(s)	Research Infrastructure(s)
UC	Use Case

WP	Work Package
QoL	Quality of Life
FAIR	Findability, Accessibility, Interoperability, Reuse of Digital Assets

## Executive Summary

This deliverable outlines the activities and outcomes of Task 1.2: *Definition of Stakeholders' Requirements and KPI Framework*, conducted in the first semester of the EVOLVE2CARE project. The objective was to identify and analyse the needs of key stakeholders—researchers, Living Lab operators, end-users, and regulators—and to translate these into a practical and useful KPI framework.

The work builds on the barriers and enablers identified in D1.1 and maps stakeholder needs across two main dimensions: (1) the collaboration between Living Labs and innovators, and (2) the implementation of HealthTech solutions in transitional care. From this, two distinct KPI repositories were developed: the [Use Case Evaluation KPI Repository](#), focusing on individual collaborations and end-user alignment, and the [Impact Assessment KPI Repository](#), assessing broader impact dimensions such as regulatory readiness, financial sustainability, and social inclusion.

To ensure relevance and usability, the framework was validated through a stakeholder-driven process. Internally, an online workshop with EVOLVE2CARE partners gathered feedback to refine the initial design. Externally, three thematic webinars were held with stakeholders from healthcare, innovation, regulation, and Living Labs. These sessions included structured feedback tools and expert speakers, resulting in valuable refinements and the addition of new KPIs—particularly those related to regulatory flexibility, healthcare coordination, and social inclusivity.

Further input was gathered through a live session at the 14th Medical Conference of the Aristotle University of Thessaloniki, expanding feedback to include biomedical engineers. Additionally, collaboration with the GILL project supported the development of social KPIs, especially around gender-responsive innovation and inclusive healthcare.

This deliverable presents not only the validated KPI framework but also the methodology for stakeholder engagement and iterative refinement. The framework will guide the evaluation of HealthTech solutions within EVOLVE2CARE, balancing technical, clinical, regulatory, and social perspectives. Over the next project year, these KPIs will be further developed, tested, and integrated into ongoing use case activities, ensuring continuous improvement and practical applicability.

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# 1. Introduction

## 1.1. Project Overview

EVOLVE2CARE focuses on HealthTech experimentation practice to standardise and enhance the collaboration between Living Labs and innovators in the context of the Transitional Care sector. Challenges ranging from aging population to complexity of medical conditions and regulatory frameworks bring a growing recognition of the importance of experimentation practices. By subjecting innovations to real-world environments that involve end-users and stakeholders, EVOLVE2CARE provides innovators with access to services for testing and validating research and products.

The project focuses on three Use Cases (UC): i) Hospital discharge management; ii) Homecare monitoring solutions; and iii) Aging population & care transitions, engaging stakeholders across the whole value chain to examine complexities, barriers and enablers that regulatory framework poses to the development and commercialisation of healthcare innovations.

## 1.2. WPI Description

The main goal of WP1, led by AUTH is to design a scalable experimentation space. The specific objectives are:

- Identify drivers and barriers for the development of innovations.
- Define the specific requirements of the various stakeholders who can impact or be impacted from the outcomes of experiments.
- Design EVOLVE2CARE's experimentation space capitalising on AccelUP.
- Define the Use Cases reflecting solutions in the transitional care sector.
- Design an appropriate KPI framework for measuring experimental performance.

## 1.3. Purpose and scope of the deliverable

This deliverable presents the initial EVOLVE2CARE evaluation and impact assessment framework. The objectives for this framework are:

1. To assess the indirect technical, economic, environmental, and social impact of the project, which will be generated by the solutions selected through the EVOLVE2CARE Open Calls. This is the long-term expected impact of the project, which differs from the project's Key Performance Indicators (KPIs) that will be assessed during its duration



2. To be used for evaluating a wide range of experiments related to HealthTech innovation in transitional care.

Based on these two objectives, the evaluation and impact assessment framework define a KPI repository consisting of two subsets:

1. A broader set of KPIs designed to measure the indirect and envisioned impact of EVOLVE2CARE across technical, economic, environmental, and social aspects.
2. A KPI repository that supports HealthTech solutions in transitional care more broadly while also serving as a tool for evaluating the success of the Open Calls.

This repository includes:

- KPIs for Living Labs (LLs) that address the needs of innovators.
- KPIs for innovators that address the needs of patients, caregivers, healthcare professionals, and healthcare organizations.

## 1.4. Structure

The present deliverable is structured to provide a comprehensive and logical overview of the [Evaluation and Impact Assessment Framework](#) within the EVOLVE2CARE project. The document is organised into the following sections:

- **Section 2 Evaluation and Impact Assessment Framework:** This section outlines the methodology used to develop the KPI framework, describing its structure and the validation process conducted in collaboration with both internal project partners and external stakeholders. It explains how stakeholder needs were categorised into three main KPI repositories: the [Use Case Evaluation KPI Repository – Living Labs](#), the [Use Case Evaluation KPI Repository – End-users](#), and the [Impact Assessment KPI Repository](#), which evaluates broader dimensions such as regulatory compliance, financial sustainability, and social inclusion.
- **Section 3 Initial Framework:** This section presents the first version of the KPI framework before validation. It introduces the structure and intended purpose of the initial KPI repositories, laying the foundation for further refinement and validation activities.
- **Section 4 Results of Framework Validation and Refinement:** The validation process involved extensive stakeholder engagement activities, including three dedicated workshops and collaborations with key experts. This section summarises the key outcomes of the Workshop on Empowering Innovators to Transform Transitional Care, the Workshop on Aligning Innovation with Healthcare Stakeholder Needs, and the Workshop on Regulatory Requirements for Medical Devices in Digital Health. It also highlights the collaboration with the GILL project, which contributed to the development of social KPIs, particularly focusing on gender-responsive innovation and inclusive healthcare.

- **Section 5 Current Version of the Framework:** This section presents the updated KPI repositories, incorporating refinements and adjustments based on the feedback from the validation process. The revised framework ensures that KPIs align with real-world healthcare challenges and the broader objectives of EVOLVE2CARE, integrating technical, regulatory, financial, and social dimensions of healthcare innovation.
- **Section 6 Implementation of the Framework:** This section discusses the strategy for implementing the framework in EVOLVE2CARE project and how it will be promoted for wider adoption.
- **Section 7 Improvement Strategy and Next Steps:** To maintain relevance and usability, the KPI framework will undergo continuous refinement. This section outlines the strategy for ongoing improvements and the next steps in the project's implementation phase, ensuring alignment with stakeholder needs and emerging healthcare trends.
- **Section 8 Conclusions:** The document concludes by summarising key findings and emphasising the role of the stakeholder-driven validation process in refining the KPI framework. It highlights how this structured approach enhances innovation evaluation in transitional care and contributes to the long-term impact of the EVOLVE2CARE project.

## 2. Evaluation and impact assessment framework

The initial evaluation and impact assessment framework was developed based on EVOLVE2CARE's Deliverable 1.1 "Roadmap on navigating the complexities of enabling innovative technologies in transitional care". This deliverable analysed and presented the barriers and drivers that influence innovation within the realm of transitional care. By focusing on six key stakeholder groups, the deliverable provided a detailed examination of the factors that either drive or hinder innovation for each group. The identified stakeholder groups are as follows:

- **Innovators:** Individuals or organisations that develop new technologies and solutions aimed at improving transitional care.
- **Accelerators or Investors:** Entities that provide financial support, resources, or mentorship to facilitate the growth and implementation of innovative technologies.
- **Living Labs:** Real-life test and experimentation environments where users and producers collaborate to innovate and develop new products, services, and processes.
- **End-users (individuals):** Patients and caregivers (informal or formal) who experience the challenges of transitional care firsthand.
- **End-users (Care Units, Hospitals, Practitioners):** This group includes hospital administrators, clinicians, and healthcare professionals who provide valuable insights into the practical deployment and adoption of innovative solutions within healthcare systems.
- **Policy makers and Regulatory Bodies:** Government officials and regulatory bodies that shape policies and guidelines affecting the adoption and integration of innovative technologies in healthcare.
- **EU Initiatives:** European Union programs and projects aimed at fostering innovation and improving healthcare outcomes across member states.

The deliverable delved into how various factors, including regulatory, fiscal, technological, operational, and others, influence each stakeholder group.

### 2.1. Stakeholder needs analysis

The analysis of barriers and enablers in D1.1 provided a structured foundation for identifying stakeholder needs, categorizing them by group and purpose. These needs

serve two key objectives: assessing the broader technical, economic, environmental, and social impact of collaboration between Living Labs and tech innovators and directly addressing HealthTech solutions in transitional care.

This led to the development of two Key Performance Indicator (KPI) repositories. The Use Case Evaluation KPI Repository assesses how effectively Living Labs support innovators and how well innovators leverage these resources. It also ensures that innovations align with the needs of healthcare professionals, caregivers, patients, and healthcare institutions. Meanwhile, the Impact Assessment KPI Repository evaluates the overall contributions of EVOLVE2CARE in fostering technological advancements, financial sustainability, operational efficiency, and regulatory compliance.

By integrating insights from D1.1, this stakeholder needs analysis ensures that the KPI framework is rooted in real-world challenges, allowing for continuous refinement of solutions. This structured yet flexible approach strengthens the impact and scalability of EVOLVE2CARE, ensuring that innovations are both effectively developed and broadly sustainable.

## 2.2. Structure of the Framework

The barriers and enablers analysis conducted in D1.1 served as the basis for identifying the specific needs of each group. These needs were further analysed to determine which stakeholder group and category they belong to. We then identified the purpose each need serves:

1. The broader scope of technical, economic, environmental, and social impact of collaboration between Living Labs and Tech Innovators.
2. Directly addressing HealthTech solutions in transitional care

This led to the development of **two distinct Key Performance Indicator (KPI) repositories**:

1. **Use Case Evaluation KPI Repository** – Designed to **assess the effectiveness of individual collaborations** between Living Labs (LLs) and innovators, ensuring that innovations are effectively developed and validated.
2. **Impact Assessment KPI Repository** – Focused on **evaluating the overall impact of EVOLVE2CARE**, considering factors such as technological advancements, financial sustainability, operational efficiency, and regulatory compliance.

The **Use Case Evaluation KPI Repository** was structured based on two key stakeholder groups:

- **Collaboration between Living Labs and innovators:** Living Labs provide critical resources, infrastructure, and expertise to innovators. In return, innovators require targeted support to accelerate the development and adoption of their solutions. The corresponding **KPIs measure how effectively LLs support innovators** and **how well innovators leverage LL resources**.
- **Alignment with broader stakeholder needs:** Innovations must address the needs of healthcare professionals, caregivers, patients, and healthcare institutions. The corresponding **KPIs assess how well innovations align with real-world challenges** in transitional care.

The **Impact Assessment KPI Repository**, in contrast, evaluates EVOLVE2CARE at a broader level, measuring its contributions to:

- **Technological advancements** – How the program fosters innovation.
- **Financial sustainability** – The viability and scalability of solutions.
- **Operational efficiency** – How efficiently Living Labs and Innovators function.
- **Regulatory compliance** – The alignment of innovations with healthcare policies.

KPI repositories serve as guiding tools rather than rigid benchmarks, allowing innovators to refine their solutions based on structured feedback rather than compliance pressures.

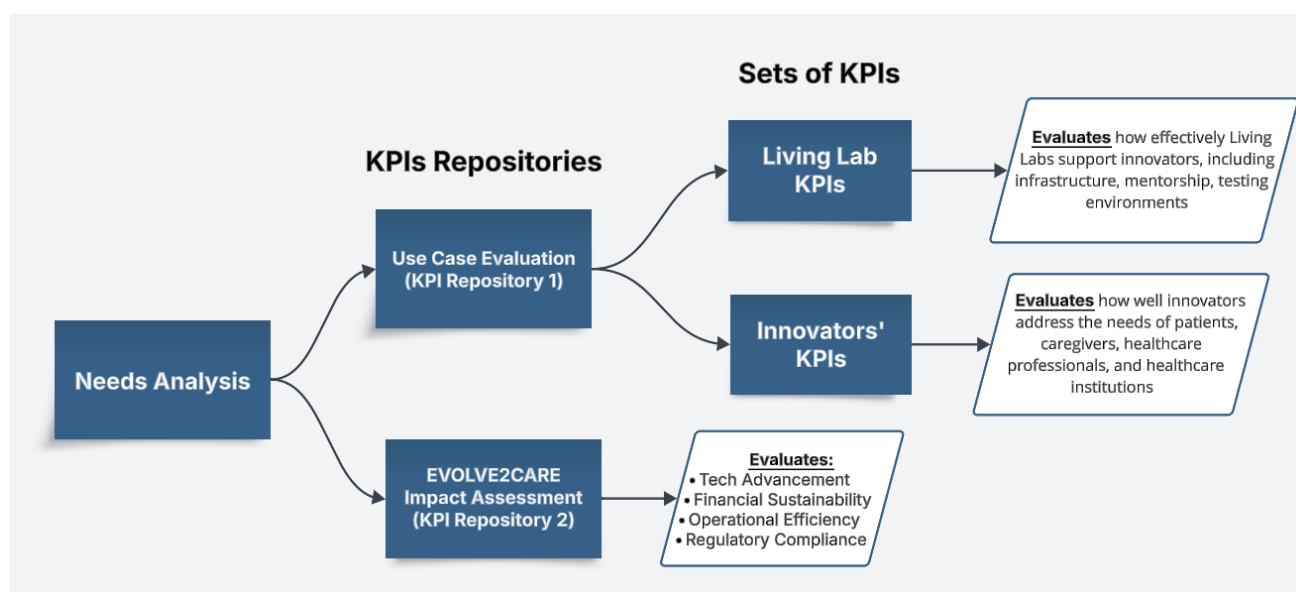


Figure 1 - KPI Framework Visualization

## 2.3. Framework Design

Various design approaches were employed for different components of the framework to capture the complexities of stakeholder groups and ensure a comprehensive representation of sources.

### 2.3.1. Use Case Evaluation KPI Repository – Living Labs

To understand what innovators expect from Living Labs, we used anonymised data collected as part of the Transnational Access activities of the VITALISE H2020 project. VITALISE provided researchers from around the world with the opportunity to visit Living Lab Research Infrastructures (LL RIs) and conduct part of their research. The project covered travel and accommodation expenses for the researchers at the hosting LL RIs, as well as the support provided by the LLs. However, the researchers did not receive any remuneration for their work. Participation in the Transnational Access activities was facilitated through an Open Call, with proposals evaluated based on their excellence, impact, and feasibility. All accepted researchers were asked to complete a questionnaire before their visit and another upon completion of their study.

As part of the EVOLVE2CARE framework, we analysed two qualitative questions. Specifically, we examined the question, 'What do you expect to gain from Transnational Access?' which was included in the expectations questionnaire before the visit, and the question, 'What did you appreciate most about the Transnational Access?' which was included in the evaluation questionnaire after the visit.

For the analysis we combined Thematic [1] and Content Analysis [2]. One researcher performed the initial thematic analysis. Specifically, after becoming familiar with the data by thoroughly reading through the responses to understand the overall context and tone, the researcher identified and labeled key words, phrases, or ideas that emerged from the data. The initial labels were then grouped into overarching themes, following an iterative refinement process. Once the themes were established, two independent reviewers matched the answers to the themes and suggested changes or additional themes where necessary, to minimise bias.

In total, we analysed the responses of 86 participants in the questionnaire before the visit and 80 participants in the questionnaire after the visit. Before the visit, the respondents came from 21 countries, with 47 females (54.65%) and 39 males (45.35%). After the visit, the respondents were also from 21 countries, with 43 females (53.75%) and 37 males (46.25%).

### 2.3.2. Use Case Evaluation KPI Repository – End-users

Building on the barriers and enablers identified in D1.1, we derived a set of general needs for the end-users, which were categorised into four main groups: 1) patients, 2) informal caregivers, 3) healthcare professionals, and 4) hospitals and care organisations. These overarching themes provided a broad understanding of the general needs of each group. To further refine and specify these needs, we conducted a comprehensive literature search to identify relevant indicators. We then triangulated our initial findings

with the literature, complementing and validating them by selecting what was most relevant to our context. This process ensured that the needs were both well-supported by literature and aligned with real-world evidence, thereby strengthening the robustness of our analysis.

The selected literature includes three highly influential literature reviews in the field of transitional care [3], [4], [5] and two well-established frameworks of transitional care [6], [7]. More specifically, we identified the following indicators:

#### **Patients:**

- Health indicators and outcomes: readmissions and rehospitalisation rates, length of stay in hospital, functional independence, health-related quality of life, adherence and knowledge to care plan, medication and follow-up, quality of life, patient satisfaction [3], [4], [5]
- Respecting patients' wills and their goals [7]
- Technology that offers understandable care models and processes [7]
- Ensuring that the medication management plan is based on evidence [7]

#### **Informal Caregivers:**

- Caregiver burden and satisfaction [3], [4]
- Active engagement in the caregiving process and shared decision-making [7]

#### **Healthcare professionals:**

- Job satisfaction, well-being and burden reduction [4]
- Assistive technologies that support the decision-making process with more information [6]
- Remote patient monitoring tools to assist them when they do not have access [6]

#### **Hospitals and care organisations:**

- Cost-effective innovations [3], [4], [5]

### **2.3.3. Impact Assessment KPI Repository**

The Impact Assessment KPI Repository builds upon the categorisation outlined in D1.1, dividing the KPIs into five primary categories: legal and regulatory, fiscal, technical, operational, economic and social ("Other"). The KPIs developed for these new categories aim to quantify the barriers and enablers identified in D1.1, offering a more comprehensive understanding of the factors influencing the project. Furthermore, this KPI repository is complemented by the analysis presented in the Impact Assessment section of the EVOLVE2CARE Grant Agreement, which is designed to capture the long-



term impact of the project's vision. This integration ensures that the repository not only reflects the current state of the project but also aligns with its overarching goals of fostering sustainable and transformative change in transitional care.

## 2.4. Framework Validation and refinement

Building on the initial framework design, which was based on D1.1 and further enriched by additional sources such as literature, data from previous projects, and the project's Impact Analysis, we entered a phase of framework validation and refinement. During this phase, we collected and integrated feedback not only from consortium experts but also from external stakeholders. This iterative process aimed to enhance the validity and robustness of our findings, ensuring the framework's relevance, accuracy, and alignment with the broader goals of the project.

## 2.5. Framework validation by the consortium

After the initial Evaluation and impact assessment framework was developed, it was presented to the entire consortium for feedback. AUTH organised an internal online workshop with the EVOLVE2CARE partners to validate the framework structure and gather input. The framework design strategy was also presented during this session. Feedback from the partners was then integrated into the proposal. A draft version of the framework was shared offline with the partners, allowing them several days to review and evaluate it. After incorporating their suggestions and revisions, we finalised the initial version of the framework (Section 3), which was subsequently presented to external stakeholders for further validation.

## 2.6. Framework validation by externals

To ensure the relevance and applicability of Key Performance Indicators (KPIs) for HealthTech innovation in transitional care, a structured validation process was designed. This methodology aims to integrate the perspectives of diverse stakeholders, including healthcare professionals, innovators, living lab practitioners, industry leaders, and policymakers. By integrating these insights, the KPI framework was designed to accurately reflect the complexities of real-world healthcare innovation, implementation, and scalability.

The validation process followed a [co-design methodology](#), actively engaging stakeholders in shaping and refining the KPIs through an iterative process. This approach combined [structured assessment tools](#) with [open discussions](#), enabling the collection of both **quantitative and qualitative feedback**. The iterative nature of this



process ensured continuous refinement, aligning KPIs with practical healthcare challenges and market needs.

To achieve this, a series of three online webinars were conducted as part of the EVOLVE2CARE *Accelerating Innovation in Transitional Care* initiative. These sessions served as platforms to present, evaluate and refine the KPI framework:

### **1<sup>st</sup> Workshop: Empowering Innovators to Transform Transitional Care**

- **Objective:** To explore the role of Living Labs in validating and scaling healthcare innovations, with an emphasis on innovators KPIs. This webinar validated the Use Case Evaluation KPI Repository – Living Labs.
- **Tools:** A structured Mentimeter session was conducted, where participants rated the relevance, feasibility, and applicability of proposed KPIs on a graded scale. This approach provided structured, quantitative feedback to guide further refinement.

### **2<sup>nd</sup> Workshop: Aligning Innovation with Healthcare Stakeholder Needs**

- **Focus:** Ensuring that healthcare innovation aligns with real-world challenges, integrating direct feedback from healthcare professionals. This webinar validated the Use Case Evaluation KPI Repository – End-users.
- **Tools:** A Miro board co-design exercise facilitated interactive discussions and refinements, enabling real-time input from clinicians and hospital administrators.

### **3<sup>rd</sup> Workshop: Regulatory Requirements for Medical Devices in Digital Health**

- **Focus:** Examining regulatory frameworks and clinical validation requirements to ensure compliance and market readiness. This webinar validated the Impact Assessment KPI Repository.
- **Tools:** Discussions with regulatory experts and innovators, researchers assessed the practicality of KPIs in real-world implementation.

To maximize the impact and depth of our discussions, we invited a highly relevant expert to each webinar. In the first workshop, we engaged a Living Lab expert who actively works with innovators and companies to validate and scale healthcare solutions. The insights helped refine the *Use Case Evaluation KPI Repository – Living Labs*, ensuring its relevance in real-world innovation ecosystems. For the second session, we brought in a healthcare expert, a practicing doctor who is also very experienced in designing and working with digital innovation. This ensured that the *Use Case Evaluation KPI Repository – End-users* accurately captured the priorities and challenges faced by healthcare professionals but also patients and caregivers. Finally, for the third session,

we collaborated with a regulatory expert specialising in EU policies on digital health and medical devices. Their expertise was crucial in evaluating the [Impact Assessment KPI Repository](#), aligning it with current regulatory frameworks and ensuring its applicability for compliance and market readiness. By integrating these expert perspectives, we not only enhanced the credibility of our framework but also ensured that the KPIs were practical, actionable, and aligned with the needs of innovators, healthcare professionals, and regulators.

Additionally, an interactive, face-to-face workshop was organised at the 14th Medical Conference of the Aristotle University of Thessaloniki to expand stakeholder engagement. This session gathered feedback not only from healthcare professionals but also from biomedical engineers, ensuring a broader and more interdisciplinary perspective on KPI applicability. This session focuses on Use Case Evaluation KPI Repository – End-users.

Furthermore, a dedicated workshop was conducted in collaboration with the [GILL – Gendered Innovation Living Labs](#) project. This session specifically contributed to the development of social KPIs, with a particular focus on gender-responsive innovation and entrepreneurship. These efforts ensured that the KPI framework promotes inclusivity and equitable healthcare access.

By integrating insights from these diverse validation activities, the final KPI framework reflects a holistic, stakeholder-driven approach, balancing business, clinical, regulatory, and social dimensions of healthcare innovation.

### 3. Initial Framework

Below we present the initial framework, as came out from the Framework Design process integrating also the feedback from EVOLVE2CARE partners.

#### 3.1. Use Case Evaluation KPI Repository – Living Labs

These KPIs assess how effectively Living Labs support innovators, including infrastructure, mentorship, testing environments, and validation frameworks. The categories came out from the thematic and content analysis of the VITALISE project data.

*Table 1 - Initial KPIs for Living Labs (LLs)*

Categories	KPI
<b>Business and scale-up support:</b> expand or get access to new markets, scale-up an existing solution	Innovations successfully expanded into new markets or scaled up for wider adoption.
<b>User recruitment and involvement:</b> get feedback from user, involve them in the process, handle the recruitment	Stakeholders from the 4-duple helix actively involved in the feedback process and innovation development.
<b>Collaboration and networking possibilities:</b> create new opportunities for collaboration, synergies and networking	New partnerships or synergies established through networking activities.
<b>Publications:</b> established evidence on the effects and efficiency of the innovation, provide proof and validity	Produce peer-reviewed publications demonstrating the effects and efficiency of the innovation.
<b>Access to existing data and data analysis methods:</b> either get access to existing data or collect a new dataset. It includes also the expertise for data analysis.	Innovators gain access to relevant existing data or have successfully collected new datasets for analysis
<b>Legal, regulation and safety standard support:</b> related to ethics, legal issues, privacy	Innovations meet legal, ethical, privacy, and safety standards throughout their development and deployment.

<b>Expert opinion and advisory services:</b> learn from experts, get guidance and support and expert opinion including from external stakeholders' network, refers to giving advice and consulting and not direct hands-on experience. Advice is from experts in another sector, different than yours	Advisory sessions or expert consultations received by innovators from external stakeholders or industry professionals
<b>Real life testing and experimentation:</b> all the activities that have to do with testing, piloting, experimenting and experimentation design	Real-life testing or experimentation activities that meet predefined goals or objectives.
<b>Physical space, equipment and facilities:</b> providing the technology, infrastructure resources and technical facilities to perform the work	Physical space, equipment, and facilities are open, available effectively utilized for innovation development.
<b>Knowledge acquired experience and learning:</b> get the knowledge, learn methodologies and experience the LL way of working, get insights or understanding that comes from active experimentation. Insights are from users and their perspective	Innovators gain new insights or methodologies through active experimentation.
<b>Diversity of opinions and new context:</b> cultural, social context, experience from new countries, language - multistakeholder	Innovators gain access and insights into feedback from diverse cultural, social, and geographical contexts
<b>Collaborative research and innovation</b> include new innovative ways of working, like openness, agility, collaboration, flexibility, iterative approach. It describes the work that is done in a new way other than what they have already experienced and know – core elements of LL work, the research plan is iteratively co-created	Innovation development is performed through collaborative, iterative, and flexible approaches.

## 3.2. Use Case Evaluation KPI Repository – End-users

The KPIs mentioned in Table 2 measure how well innovators address the needs of patients, caregivers, healthcare professionals, and healthcare institutions.

*Table 2 - Initial KPIs for End-Users*

Stakeholder	Need	KPI
Healthcare Professionals	Need innovations that reduce, rather than increase, their workload, streamlining processes and improving efficiency to allow for more focus on patient care.	<ul style="list-style-type: none"> <li>• <b>Decrease in time spent on administrative or repetitive tasks</b> due to the implementation of innovative solutions, measured through feedback or time tracking</li> <li>• No <b>significant increase in workload</b> following the introduction of an innovative solution, measured through feedback or time tracking.</li> </ul>
	Need centralized digital health platforms that integrate various services and data making access to information easy	<ul style="list-style-type: none"> <li>• New innovations are seamlessly integrated into <b>centralized platforms</b> instead of introducing a new platform every time.</li> </ul>
	Need decision support tools that enhance their knowledge by providing access to new, relevant information	<ul style="list-style-type: none"> <li>• Regular <b>use of decision support tools</b> by healthcare professionals</li> <li>• Healthcare professionals reporting <b>improved clinical decisions</b> because of</li> </ul>

		using decision support tools
Healthcare Professionals	Need wearables and assistive technologies that help them track more information, enhance patient monitoring, and support their work in real-time.	<ul style="list-style-type: none"> <li>Average rating given by healthcare professionals on the <b>usefulness of wearables/assistive technologies</b> in enhancing patient care and supporting their workflow, gathered through surveys or feedback</li> </ul>
	Need remote patient monitoring tools that allow them to track patients' health when they do not have direct access	<ul style="list-style-type: none"> <li>More <b>timely and continuous interventions for patients as a result of using remote patient monitoring tools</b>, reported by healthcare professionals</li> <li>Healthcare professionals report being able to respond to critical situations or patient changes that they would not have detected without the use of remote patient monitoring tools.</li> </ul>
Hospitals / Organizations	Need predictive analytics tools that help anticipate patient outcomes and risks, enabling proactive and data-driven decision-making	<ul style="list-style-type: none"> <li>Predictive analytics tools accurately forecast patient outcomes or risks</li> <li>Predictions lead to <b>proactive interventions</b></li> <li>Predictive analytics models incorporate data from multiple</li> </ul>

		sources (e.g., patient history, real-time monitoring, lab results) to enhance the accuracy and reliability of predictions
Hospitals / Organizations	Need scientifically validated solutions that are proven to be effective through rigorous research	<ul style="list-style-type: none"> <li>• <b>Peer-reviewed publications</b> demonstrating the scientific validation and effectiveness of the solution in real-world healthcare settings</li> </ul>
	Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions	<ul style="list-style-type: none"> <li>• <b>Improved proficiency and confidence</b> of healthcare professionals in using new technologies</li> </ul>
	Need innovations that streamline processes and enhance overall operational performance	<ul style="list-style-type: none"> <li>• <b>Reduction in time spent on administrative or repetitive tasks</b> due to improved workflows.</li> </ul>
	Cost-effective innovations that are proven through evidence to improve patient care and outcomes.	<ul style="list-style-type: none"> <li>• <b>Ratio of cost savings</b> to improvements in patient outcomes achieved by the innovation</li> </ul>
	Innovations should integrate smoothly into current hospital systems and practices, minimizing disruption	<ul style="list-style-type: none"> <li>• Average time taken to fully integrate an innovation into existing workflows, from introduction to full implementation</li> </ul>
	Need innovations that assist in creating and following discharge planning protocols, ensuring smooth transitions for patients	<ul style="list-style-type: none"> <li>• Patients <b>reporting better continuity of care and smoother transitions post-discharge</b>, due to the implementation of</li> </ul>

		discharge planning innovations.
Patients	Need innovations that prioritize their needs, involve them in decision-making, and encourage active participation in their care	<ul style="list-style-type: none"> <li>• Demonstrating respect for patients as partners in developing care plans reflective of their goals</li> <li>• Continuously evaluating patients' levels of engagement</li> </ul>
	Solutions that directly contribute to improved health outcomes	<b>Health indicators for transitional care</b> <ul style="list-style-type: none"> <li>• Quality of Life (QoL)</li> <li>• Re-hospitalization</li> <li>• Length of stay</li> <li>• Functional status and independence</li> </ul>
	Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions	<ul style="list-style-type: none"> <li>• <b>Improved proficiency and confidence</b> of patients in using new technologies</li> </ul>
	Need understandable care models and processes, along with effective medication management systems, to ensure they can follow their treatment plans confidently and manage their health effectively	<ul style="list-style-type: none"> <li>• Presenting <b>health information in easily accessible, accurate,</b> and usable formats</li> <li>• Monitoring to avoid medication errors</li> <li>• Ensuring that medication management plan is based on evidence</li> </ul>
	Ensuring that medication management plan is based on evidence	<ul style="list-style-type: none"> <li>• Ensuring that medication management plan is based on evidence</li> </ul>
	Personalized care that is tailored to their unique health conditions, preferences, and circumstances, ensuring more effective and individualized treatment.	<ul style="list-style-type: none"> <li>• Patients feel that their personal health needs and preferences are effectively addressed through the</li> </ul>



		personalized care provided, as measured through surveys or direct feedback.
Caregivers	Need support and resources to reduce the physical, emotional, and financial burden associated with caregiving	<ul style="list-style-type: none"> <li>• <b>Decrease in caregiving burden measured</b> through caregiver satisfaction surveys or specific burden assessment tools</li> </ul>
	Need to be actively engaged in the caregiving process, with opportunities for involvement in care decisions, training, and support systems	<ul style="list-style-type: none"> <li>• <b>Demonstrating respect for caregivers as partners</b> in developing care plans reflective of their goals</li> <li>• Continuously evaluating caregivers' levels of engagement</li> </ul>
	Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions	<ul style="list-style-type: none"> <li>• <b>Improved proficiency and confidence</b> of caregivers in using new technologies</li> </ul>

### 3.3. Impact Assessment KPI Repository

A broader set of KPIs has been designed to measure the indirect and envisioned impact of EVOLVE2CARE across technical, financial and budgetary (fiscal), environmental, social and regulatory aspects, ensuring a comprehensive evaluation of the project's effects. It is not essential to achieve impact in every domain, but rather to establish a method for measuring impact across various areas. The Key Performance Indicators (KPIs) outlined in Table 3 below represent the expected outcomes of the experimentation, providing a clear framework for assessing the specific impact in each domain.

*Table 3 - Initial KPIs for Impact Assessment*

Category	Need	KPI
Technical	Usability - Innovations should be user-friendly, visually appealing, and engaging to end-users.	<ul style="list-style-type: none"> <li>• Improving <b>user acceptance/usability score</b> and end-user engagement</li> </ul>

Technical	Interoperability- Seamless integration of innovations into existing healthcare systems and pathways, ensuring technical compatibility	<ul style="list-style-type: none"> <li>• <b>Integration Success Rate:</b> Percentage of innovations successfully integrated into existing healthcare systems without major technical issues.</li> <li>• <b>Time to Full Integration:</b> Average time required to achieve seamless interoperability between the innovation and existing healthcare pathways.</li> </ul>
	Standardization - Health tech innovations must adhere to established standards to ensure consistency, reliability, and compatibility across healthcare systems and devices.	<ul style="list-style-type: none"> <li>• <b>Standards Compliance Checklist Completion:</b> Percentage of required standardization criteria met by each individual innovation during development and deployment.</li> </ul>
	Privacy - Health tech innovations must ensure secure data ownership and protection, safeguarding users' personal and health information.	<ul style="list-style-type: none"> <li>• Technical implementation ensures <b>user and data privacy and security</b></li> </ul>
	Real-world Applicability - Health tech innovations must address the practical needs and challenges of stakeholders, ensuring they are relevant and valuable in real-world settings	<ul style="list-style-type: none"> <li>• Type and representativeness of stakeholders involved in <b>assessing the knowledge gaps</b> and needs addressed by the innovation.</li> </ul>
Fiscal	Faster development and launching of the innovations	<ul style="list-style-type: none"> <li>• Reducing by 3 months the time to market</li> </ul>

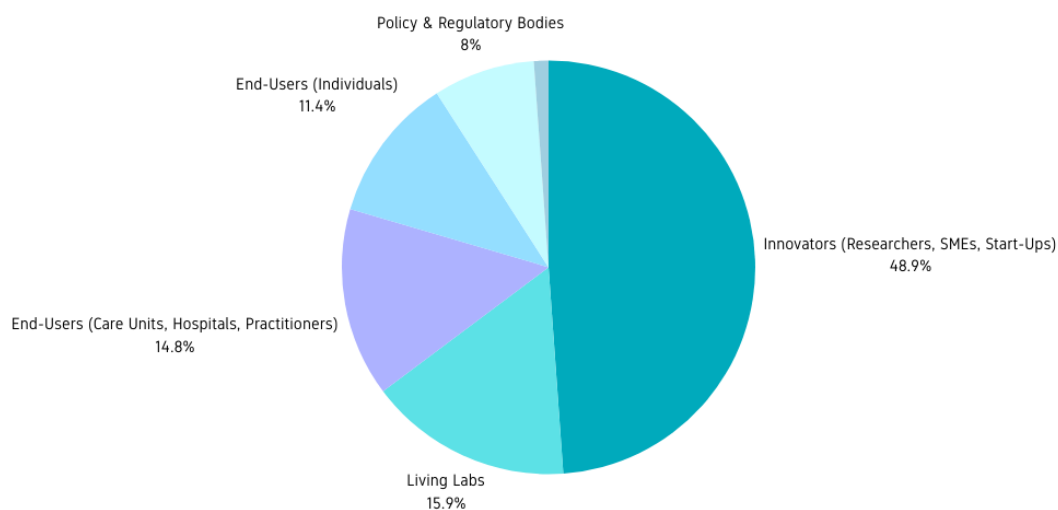
	Lower the high upfront costs of design and implementation of implementation of new innovations	<ul style="list-style-type: none"> <li>• <b>Lowering development costs of products/services</b> by 5%</li> </ul>
	Innovators and innovations need to prioritize equity and access, ensuring that products are available to all populations, while also having investment and commercialization pathways that are free from territorial inequalities, allowing for fair distribution across regions.	<ul style="list-style-type: none"> <li>• <b>Integrate Partnership results on national/regional/ local strategies,</b> programmes, and plans supporting synergies across policy areas towards health and care systems transformation.</li> </ul>
	Stimulating investment in innovative care models and experimental approaches.	<ul style="list-style-type: none"> <li>• <b>2M€ Unlocked</b> in Healthcare Savings</li> </ul>
<b>Environmental</b>	Innovations need to prioritize eco-friendliness by promoting responsible consumption and production practices, minimizing environmental impact throughout their lifecycle.	<ul style="list-style-type: none"> <li>• <b>Sustainability Compliance:</b> innovations should adhere to <b>eco-friendly standards,</b> demonstrating responsible consumption and production practices throughout their development and lifecycle.</li> </ul>
<b>Social</b>	Innovations should be designed to be culturally sensitive, inclusive, and accessible, addressing social and psychological factors to overcome stigma and cultural barriers for patients	<ul style="list-style-type: none"> <li>• <b>Number of people from different</b> backgrounds involved (in testing or co-creation).</li> </ul>
<b>Regulatory</b>	Innovations need to align with both European and local legislations and regulations to ensure compliance and smooth integration into healthcare systems.	<ul style="list-style-type: none"> <li>• Innovations should <b>fully comply with relevant European and local legislations</b> and regulations during</li> </ul>

		development and deployment
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## 4. Results of Framework Validation and Refinement

Each session was structured to enable a participatory methodology, ensuring that every voice was heard and that diverse perspectives were integrated into the framework. The aim was to create an inclusive environment where sector-specific challenges and expectations were addressed, and all relevant viewpoints were considered. Through this collaborative approach, we ensured that the KPIs would meet the practical needs of all stakeholders involved in the innovation process.

A total of 105 participants from diverse stakeholder groups registered for the validation process across three online workshops and one in-person session. Representing [Greece](#), [Spain](#), [Portugal](#), [Switzerland](#), [Tunisia](#), [the UK](#), and [Bulgaria](#) participants brought a wide range of expertise, including [healthcare professionals](#), [researchers](#), [Living Lab representatives](#), [policy advisors](#), [startup founders](#), [industry representatives](#), and [biomedical engineers](#), as shown in Figure 2. This broad representation ensured that the validation process was comprehensive and that the KPIs considered the varying needs and challenges across sectors.



*Figure 2 - Workshop Participants*

The largest group, Innovators (i.e., researchers, SMEs, startups), accounted for 43 participants, reflecting their critical role in developing and scaling new solutions. Living Labs followed with 14 participants, emphasizing the importance of co-creation environments in testing and validating new concepts. End-users were divided into two key groups: Care Units, Hospitals, and Practitioners (13 participants), and Individuals (10 participants) ensuring that both organisational and personal perspectives on healthcare

innovation were represented. Policymakers and Regulatory Bodies (7 participants) provided essential insights into compliance and policy alignment, while Accelerators/Investors (1 participant) brought forward considerations for funding and market readiness.

The validation process gathered real-time feedback on the [relevance](#), [feasibility](#), and [applicability](#) of the proposed KPIs. This quantitative data laid the foundation for subsequent discussions, highlighting key areas for improvement. Following the quantitative feedback, open discussions facilitated the exchange of qualitative insights, personal experiences, and sector-specific challenges. These dialogues helped refine the KPIs, ensuring they aligned with scalability, regulatory compliance, and market adoption.

## 4.1. Workshop on Empowering Innovators to Transform Transitional Care

The first session in the "Accelerating Innovation in Transitional Care" workshop series, titled **"Empowering Innovators to Transform Transitional Care"** took place on the 4<sup>th</sup> of March 2025 and brought together over 15 innovators, researchers and Living Lab experts to explore the role of Living Labs in driving innovation and real-world experimentation. [Teemu Santonen](#) from [Laurea University](#) shared insights into the Living Lab approach, highlighting how Laurea Living Lab is testing health monitoring sensors, providing a hands-on perspective on HealthTech advancements. The session emphasized how Living Labs bridge research and market adoption, the importance of co-creation, rapid prototyping, and validation, and strategies for iterative development to meet regulatory and user needs.

Through an interactive quiz and discussions, participants engaged with the EVOLVE2CARE Use Case Evaluation KPI Repository for Living Labs, providing feedback on key metrics for evaluating the impact and scalability of HealthTech innovations. The session emphasized the importance of co-creation, rapid prototyping, and iterative development to meet both regulatory and user needs, offering hands-on strategies for refining innovations to ensure successful market integration.



Figure 3 - 1st Webinar on Empowering Innovators to Transform Transitional Care

A Mentimeter survey conducted during the session and provided valuable **quantitative validation** of these KPIs.

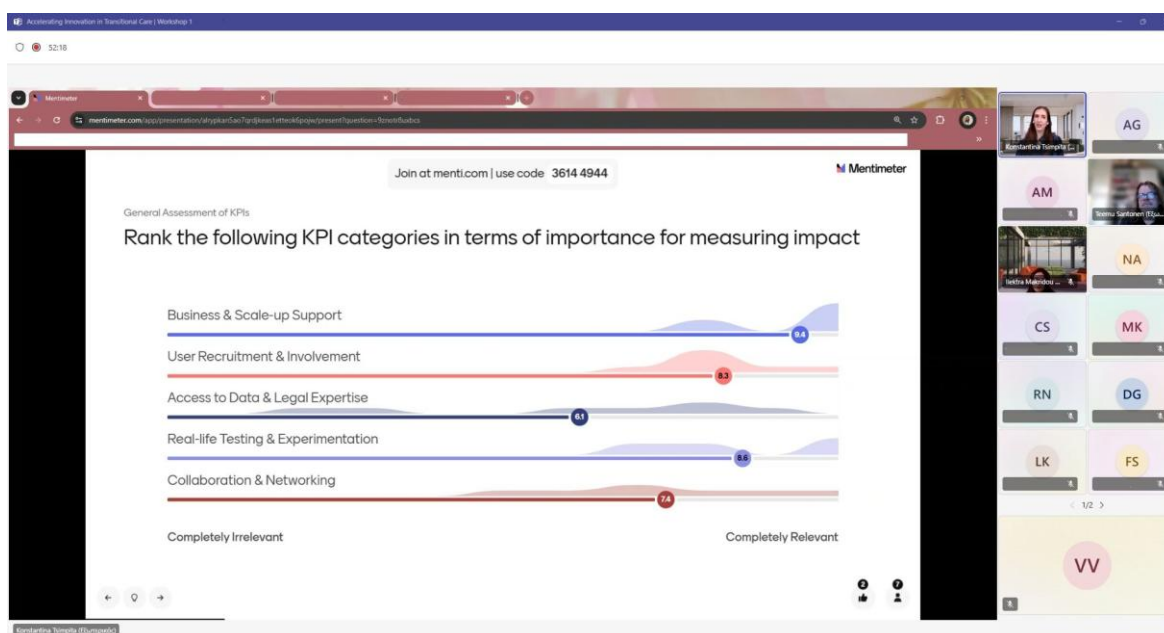


Figure 4 - KPIs Validation through Mentimeter

The results from the Mentimeter survey, shown in Table 2, indicated that user involvement and real-life testing were among the most critical factors in ensuring successful innovation adoption. Participants agreed that end-user engagement must be embedded throughout the innovation lifecycle to support continuous refinement and iterative development.

Table 4 - KPIs for Innovators Ratings from 1st Workshop

KPI Category	KPI Description	Average Rating (Out of 10)
<b>Business and Scale-Up Support</b>	Innovations successfully expanded into new markets or scaled-up for wider adoption.	<b>8.5</b>
<b>User Recruitment and Involvement</b>	Stakeholders actively involved in the feedback process and innovation development.	<b>9.2</b>
<b>Collaboration and Networking</b>	New partnerships or synergies established through networking activities.	<b>8.8</b>
<b>Publications</b>	Peer-reviewed publications demonstrating the effects and efficiency of the innovation.	<b>7.6</b>
<b>Access to Data &amp; Analysis Methods</b>	Innovators gain access to relevant existing data or successfully collect new datasets for analysis.	<b>8.9</b>
<b>Legal, Regulation &amp; Safety Standards</b>	Innovations meet legal, ethical, privacy, and safety standards throughout development.	<b>9.1</b>
<b>Expert Opinion &amp; Advisory Services</b>	Advisory sessions or expert consultations received by innovators from external stakeholders.	<b>8.3</b>
<b>Real-Life Testing &amp; Experimentation</b>	Testing or experimentation activities that meet predefined goals.	<b>9.0</b>
<b>Physical Space &amp; Facilities</b>	Technology, infrastructure, and	<b>7.8</b>



	facilities available for innovation development.	
<b>Knowledge &amp; Learning</b>	Innovators gain new insights or methodologies through active experimentation.	<b>8.7</b>
<b>Diversity of Opinions &amp; Context</b>	Access to feedback from diverse cultural, social, and geographical contexts.	<b>8.4</b>
<b>Collaborative Research &amp; Innovation</b>	Innovation development performed through iterative, flexible, and co-creative approaches.	<b>9.0</b>

The results showed that KPIs related to [collaboration, networking, and co-creation with stakeholders](#) were highly rated, further reinforcing the role of Living Labs in bridging the gap between [research, industry, and real-world applications](#). Additionally, participants emphasized that the ability to measure knowledge exchange and stakeholder involvement in the innovation process is crucial for ensuring that solutions meet real-world needs.

Participants also raised concerns regarding [data accessibility and standardization](#). Many stakeholders highlighted limited access to structured healthcare datasets and interoperability issues between existing systems. This led to the proposal of KPIs that evaluate data availability, usability, and compliance with regulatory and ethical requirements. These challenges were particularly evident for startups and innovators working with sensitive healthcare data, where obtaining and processing structured datasets remains a significant barrier.

Another area that emerged as a point of interest was the [importance of validating market readiness and sustainability](#). While participants acknowledged the necessity of scaling innovations beyond the pilot phase, most agreed that [traditional business-oriented KPIs do not fully capture the complexities of scaling healthcare innovations](#). Instead, sustainability-focused KPIs were suggested to track [long-term viability, adoption rates, and financial feasibility](#) within real-world healthcare

## 4.2. Workshop on Aligning Innovation with Healthcare Stakeholder Needs

The second workshop **‘Aligning Innovation with Healthcare Stakeholder Needs’** was conducted on March 11, 2025, engaging 22 participants and focusing on **key healthcare challenges**, highlighting how innovation can better align with stakeholder needs. **Dr. Constantinos Bakogiannis**, a distinguished Cardiologist, shared insights on the global rise in cardiovascular diseases, particularly during the pandemic, and discussed their clinical and economic impact in Greece. He emphasized the role of digital innovation, distinguishing between clinical reality and user-centered solutions. He stressed that education and healthcare literacy are essential for maximising the impact of new technologies.

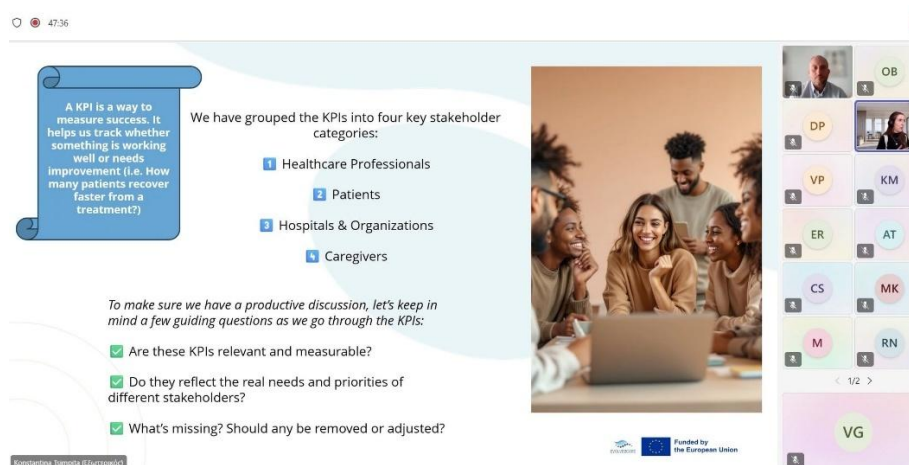


Figure 5 - 2nd Webinar on Bridging Innovation with the Needs of Healthcare

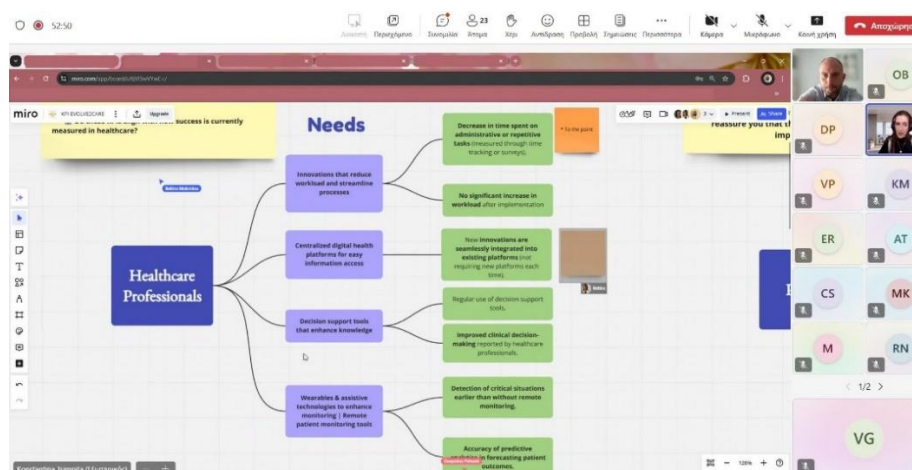
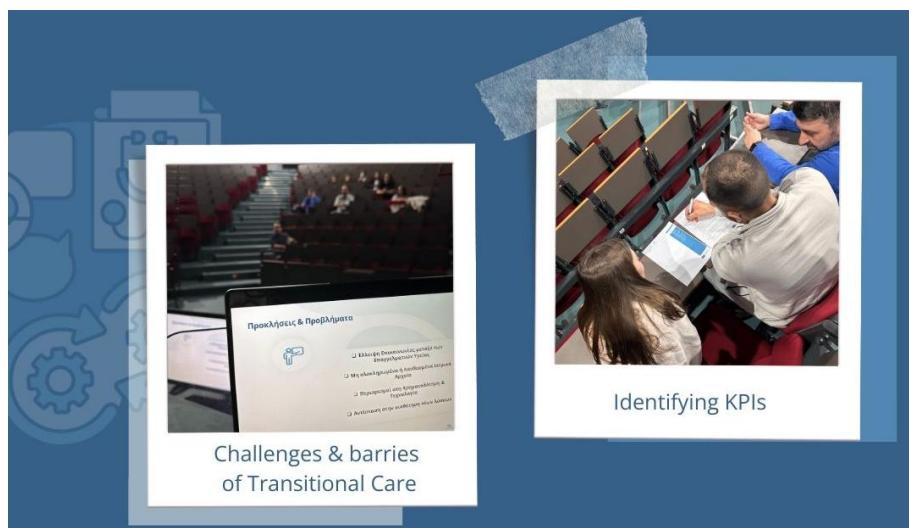


Figure 6 - Healthcare KPIs Validation Interactive Activity with Miro

The second phase of validation of the Use Case Evaluation KPI Repository for End-users consolidated feedback from 10 healthcare professionals, hospital administrators, and 6

biomedical engineers through structured stakeholder engagement sessions and clinical validation at the 14th Medical Conference of Aristotle University of Thessaloniki. The emphasis was on ensuring that KPIs align with real-world clinical workflows, efficiency, and impact.



*Figure 7 - KPIs Validation during the 14th Medical Conference*

The insights from both sessions were analysed and summarised collectively as they addressed the same questions. In both sessions, healthcare professionals prioritised the **development of centralised digital health platforms**, emphasizing that innovations should reduce, rather than increase, administrative burden. Many participants highlighted that current digital systems are fragmented, requiring KPIs that assess system integration efficiency, reduction in documentation time, and overall user satisfaction.

Hospitals and organisations focused on the need for cost-effectiveness KPIs, particularly in demonstrating how innovations reduce operational costs while maintaining or improving patient outcomes. Participants stressed that KPIs should evaluate the ratio of cost savings to patients' outcome improvements, ensuring that financial indicators align with healthcare quality metrics.

Patients and caregivers emphasized the importance of treatment adherence, quality of life, and usability of digital health tools. Many healthcare stakeholders agreed that KPIs should capture patient-reported satisfaction and confidence in navigating digital health innovations. Medication management was also highlighted, with professionals advocating for KPIs that assess medication adherence rates, reduce prescription errors, and accessibility of treatment plans.

While the KPIs broadly aligned with healthcare needs, the workshop reinforced that measurement methodologies require further refinement. Healthcare professionals

emphasized the need for real-time data collection mechanisms, allowing for continuous monitoring of KPI effectiveness in different care settings.

*Table 5 - Feedback on Healthcare KPIs*

Issue Identified	Proposed KPI Refinement	Stakeholder Input
<b>Fragmented Digital Systems</b>	KPI for system interoperability, reduction in documentation time, and improved data exchange	Clinicians and hospital administrators emphasized that disconnected systems increase workload, create redundant tasks, and hinder smooth coordination among care teams.
<b>Cost-Effectiveness of Innovations</b>	KPI for cost savings to quality-of-care improvements ratio	Hospitals stressed that new solutions must be financially viable, demonstrate a clear return on investment, and show measurable improvements in patient outcomes.
<b>Patient Adherence &amp; Digital Health Usability</b>	KPI for medication adherence, prescription error reduction, treatment compliance, and ease of treatment plan access	Patients and caregivers highlighted challenges in navigating digital tools, reporting confusion around complex interfaces, and inconsistencies in treatment adherence.
<b>AI Decision-Support Systems</b>	KPI for diagnostic accuracy improvements, reduction in cognitive workload, and real-world impact on clinical decision-making	Clinicians emphasized that AI should assist human decision-making, providing actionable insights rather than replacing expertise, and must be tested for ethical AI bias.

<b>Challenges with Digital Literacy</b>	KPI for user-friendly digital tools for elderly caregivers	Older caregivers struggle with new technologies, requiring more intuitive digital health solutions.
<b>Human-Centric Care</b>	KPI for balancing digital tools with direct patient interaction	Patients fear losing human connection; tools must be integrated without reducing physician engagement.
<b>Challenges with Digital Literacy</b>	KPI for user-friendly digital tools for elderly caregivers	Caregivers often struggle with new technologies, requiring more intuitive digital health solutions.

### 4.3. Workshop on Regulatory Requirements for Medical Devices in Digital Health

The final workshop on **‘Regulatory Requirements for Medical Devices in Digital Health’**, took place on March 18<sup>th</sup>, engaging 34 participants in the validation process. The session featured an insightful keynote presentation by [Mrs. Aikaterini Zisaki](#), Quality and Regulatory Director at PKNM Solutions Sàrl, who expertly guided participants through the complex regulatory landscape for medical devices and digital health solutions in Europe. Mrs. Zisaki’s presentation provided participants with a comprehensive understanding of the current regulatory environment, focusing on the intricacies of [CE Certification requirements](#), the [Medical Device Regulation \(MDR\)](#), the [In Vitro Diagnostic Regulation \(IVDR\)](#), and the evolving framework surrounding the [AI Act](#).

This session was particularly valuable for innovators, researchers, and healthcare professionals aiming to navigate the complex regulatory processes necessary to bring healthcare solutions to the market. Key messages highlighted during the session included the importance of regulatory planning from the early stages of development, particularly from the proof-of-concept stage. Mrs. Zisaki stressed the significance of engaging with notified bodies early in the process to streamline the certification and compliance journey, ultimately reducing time to market and minimizing regulatory risks.

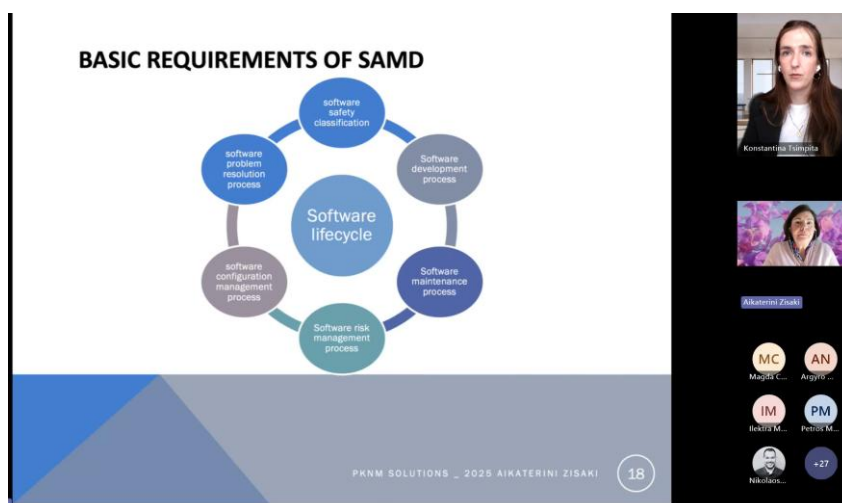


Figure 8 - Webinar 3 on Regulatory Requirements for Medical Devices in Digital Health / Challenges and Opportunities

One of the most crucial takeaways from the workshop was the emphasis on Rule 11 of the MDR, which governs the compliance requirements for digital health solutions. Participants learned how aligning their innovations with these regulatory requirements can accelerate market access while ensuring patient safety and regulatory approval. The session underscored the value of collaboration between innovators, investors, and regulatory experts as a key strategy to reduce risks and speed up bringing medical devices and digital health technologies to the market.

By addressing the practical aspects of regulatory compliance, the third workshop provided participants with essential knowledge to navigate the challenges of scaling healthcare innovations within the European market. This session also offered participants the opportunity to engage in discussions regarding how **regulatory strategies** can be effectively integrated throughout the **innovation lifecycle**, ensuring that products evolve in line with legal requirements, thus avoiding costly delays in market entry.

Table 6 - Feedback on Regulatory KPIs

Regulatory KPI Expansion	Description
<b>Regulatory Readiness Tracking</b>	Ensuring innovations align with EU and national regulations at early stages to prevent costly compliance delays. This KPI helps innovators integrate regulatory strategies from the outset, reducing risks of market entry rejections.
<b>Compliance Integration into</b>	Embedding regulatory considerations within product development processes

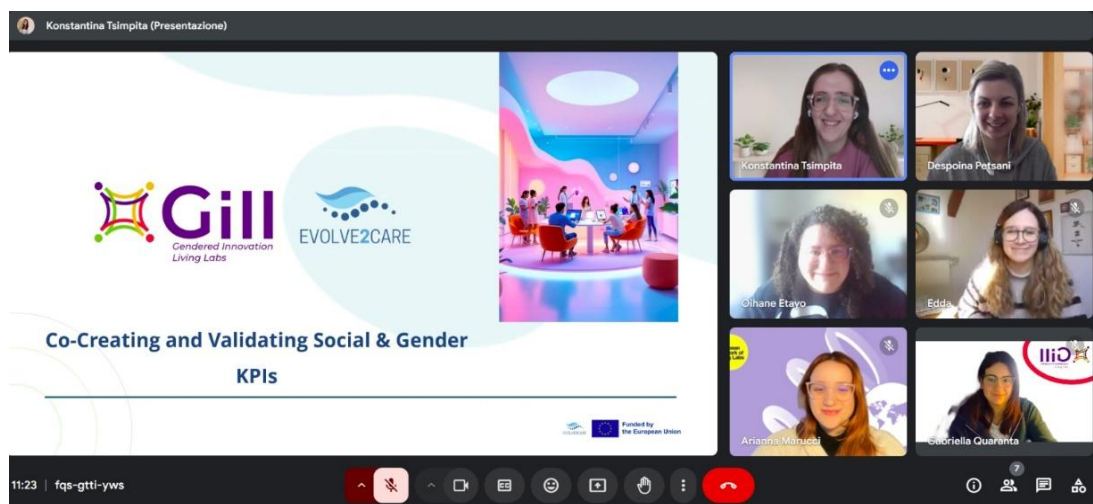


<b>Innovation Pathways</b>	ensures that innovations evolve with legal requirements, avoiding last-minute redesigns that could hinder commercialization.
<b>Market Entry Preparedness and Certification Alignment</b>	Ensuring that startups and healthcare innovators understand the full compliance journey, including necessary certifications, clinical trials, and documentation standards for approval.
<b>Assessment of Clinical Validation Milestones</b>	Measuring progress toward regulatory approval, including rigorous clinical testing, technical documentation compliance, and alignment with industry safety standards.
<b>Regional Adaptability</b>	Ensuring flexibility in adapting to national-level variations within the broader EU regulatory framework, allowing innovations to meet country-specific compliance while maintaining EU-wide market viability.
<b>Regulatory Readiness Tracking</b>	Ensuring innovations align with EU and national regulations at early stages to prevent costly compliance delays. This KPI helps innovators integrate regulatory strategies from the outset, reducing risks of market entry rejections.
<b>Compliance Integration into Innovation Pathways</b>	Embedding regulatory considerations within product development processes ensures that innovations evolve with legal requirements, avoiding last-minute redesigns that could hinder commercialization.

During discussions, experts emphasized that regulatory compliance is often overlooked until late in the innovation process, leading to costly delays. The importance of early-stage regulatory engagement was reinforced, leading to KPIs that measure how well regulatory expertise is incorporated throughout the innovation lifecycle.

## 4.4. Collaboration with GILL – Gendered Innovation Living Labs project.

To deepen our understanding of the social dimensions of Key Performance Indicators (KPIs), particularly in relation to gender inclusivity and impact assessment, we organized a webinar with the coordinators and key partners of the GILL - Gender Innovation Living Labs Project. This session provided valuable expertise on structuring KPIs that account for gender dynamics within innovation ecosystems. The discussion covered critical aspects such as measuring gender representation, assessing inclusivity in decision-making processes, and ensuring that innovation initiatives address diverse societal needs. By engaging with experienced stakeholders from GILL, we gained practical insights into developing a more holistic and socially conscious KPI framework.



*Figure 9 - Validating Social & Gender KPIs in collaboration with GILL Project*



## 5. Current version of the Framework

Following the validation process, discussions, and feedback gathered from end-users during the webinar sessions, new needs and KPIs were identified as critical for ensuring the practical impact and relevance of healthcare innovations. Also, some changes and adaptation were made to the initial framework based on the feedback received. In the sections below we discuss the changes that were applied to the framework based on the feedback received. The current version of the framework can be found in ANNEX 1.

The developed tables for the current version of the framework are as follows:

- **Table 7:** Use Case Evaluation KPI Repository – Living Labs (Section 5.1)
- **Table 8:** Use Case Evaluation KPI Repository – End-users (Section 5.2)
- **Table 9:** Impact Assessment KPI Repository (Section 5.3)

### 5.1. Use Case Evaluation KPI Repository – Living Labs

Our results show that all the identified KPIs were validated as important for the stakeholders. In the new framework we present the KPIs prioritized based on the rating received by the workshop participants.

Regarding **User Recruitment and Involvement** which was the top-rated category, the inclusion of a KPI to measure the level of user involvement was deemed essential. Living Labs can tailor their measurement approach based on their strategic objectives. Some examples include to measure the participation rate (percentage of invited users who actively engage in Living Lab activities), the co-creation Involvement (number of user-generated contributions) or the user retention rate (percentage of users who participate in multiple activities within a given timeframe). These metrics can be further refined based on the specific needs of a project or innovator.

Feedback was also received regarding the **Access to Data & Analysis Methods**, specifically concerning data availability and compliance with regulatory and ethical requirements. Two key KPIs that can be tracked in this regard are: 1) FAIR Data Compliance, ensuring that Living Lab data adhere to the FAIR principles (Findable, Accessible, Interoperable, and Reusable) and 2) Regulatory and Ethical Compliance, verifying that data collection processes within Living Labs align with relevant regulatory and ethical requirements.

Feedback was also received regarding **Collaboration and Networking**, emphasizing the importance of measuring knowledge exchange within these activities. A key KPI that can be tracked in this regard is: Quantifying Knowledge Exchange by assessing the extent of knowledge transfer in collaboration and networking activities. This can be measured through indicators such as the number of joint publications, co-created project proposals, shared best practices, or formalized partnerships resulting from networking efforts.

Regarding **Business and Scale-Up Support**, the importance of assessing market readiness was emphasized. A new KPI in this area is: Validating Market Readiness by evaluating the maturity and commercialization potential of solutions using frameworks such as the Market Readiness Level (MRL). This assessment can be based on structured evaluations, pilot deployments, stakeholder interest (e.g., industry partnerships or investor engagement), and the progression of solutions toward commercialization.

## 5.2. Use Case Evaluation KPI Repository – End-users

**Healthcare professionals** emphasized that new innovations must reduce workload rather than add to it, streamlining processes, enhancing efficiency, and providing meaningful insights to improve patient care. They highlighted the need for tools that seamlessly integrate into existing healthcare systems and enable more proactive decision-making. Based on this feedback, two new KPIs were introduced to assess the effectiveness of predictive analytics tools, measured through control group comparisons, and to track re-admission and complication rates as indicators of how innovations contribute to improved patient health and more effective transitional care.

**Hospitals and organisations** stressed the importance of minimising disruptions when introducing new technologies. For smooth adoption, innovations must align with strategic implementation approaches, optimize operational workflows, and integrate seamlessly into existing hospital systems. To ensure this, two new KPIs were added: one measuring the time required for personnel to adapt to new systems and workflows, assessing how quickly healthcare staff become proficient in using innovations, and another evaluating the effectiveness of adoption strategies. This comparison between top-down implementation, where leadership mandates innovation, and user-driven adoption, based on satisfaction and engagement, ensures that innovations are not only introduced efficiently but also embraced meaningfully by healthcare professionals.

**Patients** raised concerns about the growing role of digital solutions in healthcare, particularly the fear that increased automation and remote care might reduce human

connection. While digital innovations can enhance care quality, they emphasized the need to preserve personal interactions with healthcare providers to maintain trust and individualised care. In response, a new KPI was introduced to measure the perceived balance between digital solutions and personal interaction, assessed through direct patient feedback, ensuring that innovations support, rather than replace, the essential human element in healthcare.

**Caregivers**, who play a vital role in patient care, expressed the need for better educational tools and platforms to help them manage their responsibilities more effectively. They highlighted that a lack of adequate training and resources can increase their emotional, physical, and financial burden. To address this, a new KPI was introduced to measure the impact of caregiver-focused educational tools, assessed through satisfaction surveys, to determine how well these resources help caregivers feel more confident, supported, and prepared in their role.

Following the regulatory and social discussions during the validation process, several new needs and KPIs were identified to ensure healthcare innovations are both **socially inclusive and regulatory-compliant**. These updates address gender inclusivity, cultural sensitivity, regulatory flexibility, and market readiness, ensuring innovations align with real-world healthcare systems and societal needs.

The **social dimension** emphasized the need for culturally sensitive, inclusive, and accessible innovations that address stigma and psychological barriers. A new KPI was introduced to **integrate social inclusivity indicators** into innovation impact assessments, ensuring healthcare solutions promote equity and accessibility.

On the **regulatory side**, stakeholders stressed the importance of early compliance tracking to prevent costly redesigns and delays. A new KPI now evaluates regulatory flexibility, allowing innovations to be tested in controlled settings before full compliance. Additionally, a new KPI measures regulatory adaptability, ensuring policies support emerging technologies without compromising safety.

### 5.3. Impact Assessment KPI Repository

In response to the feedback received during the validation process and ongoing discussions with key stakeholders, the final Key Performance Indicators (KPIs) for the Impact Assessment Repository have been refined and expanded. Table 9 in the Annex presents the finalised Key Performance Indicators (KPIs) for the Impact Assessment Repository, derived from the feedback and validation process. These KPIs have been identified to assess the technical, fiscal, environmental, social, and regulatory impact of healthcare innovations. Each KPI aims to evaluate key aspects of innovation

effectiveness, including usability, interoperability, privacy, real-world applicability, and more. This comprehensive set of KPIs ensures a holistic assessment of innovations, guiding their development, deployment, and long-term sustainability in healthcare environments.

## 6. Implementation of the Framework

This framework is designed to support the diverse stakeholders involved in HealthTech innovation within transitional care. To address the varying perspectives, it is structured into three distinct sections, each aligned with the specific stakeholders that the KPIs are intended to serve. This section provides an overview of how the framework can be utilised both within the EVOLVE2CARE project and more broadly to support HealthTech innovation in transitional care.

### **Use Case Evaluation KPI Repository – Living Labs**

These KPIs are designed to address the needs of innovators by assessing their collaboration with Living Labs. As such, they should be tracked by Living Labs to ensure continuous improvement and alignment with their strategic goals. Based on the prioritization and validation conducted within this framework, Living Labs can determine which KPIs are most relevant to their strategic planning and service offerings. Tracking these indicators can help Living Labs build an attractive portfolio to engage innovators and demonstrate their value. Additionally, the KPIs can be tailored to specific projects. During the intake and matching process with innovators, Living Labs can identify the most critical aspects of collaboration to track, ensuring a meaningful evaluation of the partnership's success.

Within EVOLVE2CARE, Living Labs participating in the Open Calls will be required to demonstrate how they address the needs of innovators. This framework will serve as a guide on what to track and how to showcase progress effectively. The EVOLVE2CARE consortium will explore the integration of these KPIs into the AccelUP platform to highlight successful and compelling examples of collaborations between Living Labs and innovators.

### **Use Case Evaluation KPI Repository – End users**

When innovators or entrepreneurs venture into the world of HealthTech in transitional care, they often face a key challenge: understanding what stakeholders truly need to develop a solution that effectively addresses these needs. The Use Case Evaluation KPI Repository for End Users offers a comprehensive, structured approach to clarify what is essential for various stakeholders and what they expect from innovative solutions. This framework provides actionable, quantifiable guidance on how innovations can meet real-world demands, enabling innovators to align their solutions with the most pressing needs of patients, caregivers, healthcare professionals, and care organizations.

We envision this KPI repository as a central reference point for HealthTech innovations in transitional care, facilitating a shared understanding among all stakeholders. By

tracking and reporting on these KPIs, innovators can demonstrate that their solutions not only meet regulatory and technical standards but also fulfil the actual needs of end users. The KPIs offer a powerful tool to validate and prove that an innovation is making a meaningful impact, ultimately ensuring its long-term success and adoption in the healthcare ecosystem.

Within the EVOLVE2CARE project, innovators participating in the Open Calls will be encouraged to utilise the KPI repository as a valuable tool for tracking and measuring the outcomes of their innovations. Innovators will have the flexibility to adapt and customize the KPIs to effectively demonstrate how their solutions address the specific needs of stakeholders, while also quantifying the progress made throughout the support provided by the Living Labs during the EVOLVE2CARE Open Calls. By leveraging these KPIs, innovators can clearly showcase the impact of their work, track improvements over time, and ensure that their solutions align with the evolving demands of the transitional care sector.

### **Impact Assessment KPI Repository**

The Impact Assessment KPI Repository encompasses a set of KPIs designed to support the HealthTech innovation ecosystem in ensuring that innovations are progressing in the right direction. These KPIs are intended to evaluate the overall ecosystem, rather than individual companies, Living Labs, or stakeholders. They are crafted to guide the assessment of initiatives that facilitate the successful adoption of innovation in transitional care. For example, policymakers can use these KPIs to assess whether innovations are aligned with the desired goals and are contributing effectively to the advancement of transitional care. This comprehensive approach helps to monitor the broader impact of innovation and ensures that efforts are focused on achieving meaningful, sustainable change across the ecosystem.

Within EVOLVE2CARE, we aim to measure a significant impact on several of these KPIs for the mini-consortia participating in the Open Calls. Our primary objective is to assess how effectively Living Labs can contribute to the advancement of innovations in transitional care. The specific KPIs to be measured will be further refined once the precise goals of each mini-consortium are defined. For instance, measuring improvements in usability would only be relevant if a project explicitly targets that objective. This approach ensures that the KPIs align with the unique focus and goals of each mini-consortium, enabling a more accurate and impactful evaluation of their contributions.

## 7. Improvement Strategy and Next Steps

To ensure the continuous improvement and widespread adoption of the EVOLVE2CARE framework, we will focus on engaging a broad spectrum of stakeholders, aligning the framework with the needs of key players in the HealthTech ecosystem, and incorporating valuable feedback from various perspectives. The following strategic steps will guide the process:

A critical step in the improvement process is extending the framework to the relevant stakeholders. This will involve targeted dissemination efforts to achieve wider adoption and gather insightful feedback on its effectiveness.

- **Living Labs Engagement:** The Living Lab KPI repository of the framework will be shared with the Health & Wellbeing Working Group of the European Network of Living Labs (ENoLL).
- **End-Users Integration:** To ensure that the framework remains user-centric, we will aim to connect with EIT Health to explore the possibility of circulating the End-User KPI repository within their network, which could facilitate the adoption of the framework in relevant calls. Additionally, we plan to engage with HADEA (Health and Digital Agency) of the European Commission to assess the framework's relevance to ongoing and future initiatives.
- **Wider Impact and Solution Deployment:** For broader adoption and real-world application, the framework will be presented to organizations focused on the deployment and adoption of healthcare solutions, such as EHTEL (European Health Telematics Association) and Era4health partnership. These organizations are pivotal in shaping the dialogue around digital health solutions and ensuring that frameworks like EVOLVE2CARE are effectively integrated into national and international health strategies.

To ensure the framework's continuous improvement and broader adoption, we will establish feedback channels with stakeholders to refine the KPIs and framework elements, ensuring alignment with the healthcare sector's evolving needs. Strategic partnerships with organizations like EHTEL, EIT Health, and HADEA will help expand the framework's reach and facilitate its implementation. Additionally, monitoring the adoption and effectiveness of the framework will be crucial, allowing us to track its impact, gather reports, and identify areas for improvement.



This framework will be further refined during the project's evolution and integrated into project activities. This framework outlines a comprehensive set of Key Performance Indicators (KPIs) designed to offer flexibility and allow for adaptation as the project progresses. We will actively monitor the needs of innovators to identify whether new elements should be added to the Living Lab Repository, ensuring that it remains up-to-date with emerging insights and requirements. The Living Lab Repository will be also integrated into the Accelup experimentation space. The end-users repository will be presented to applicants of the Open Call, allowing them to tailor it to the specific needs of their individual projects. To Impact Assessment repository, we will analyze the application data, identifying areas for adaptation and refinement based on how the framework is applied in practice.

The culmination of this process will be the development of the final version of the needs and KPI framework for EVOLVE2CARE. This finalized framework, as shown in Figure 10, will be presented in Deliverable 1.5, titled "Stakeholder Needs Analysis and KPI Framework – Final."

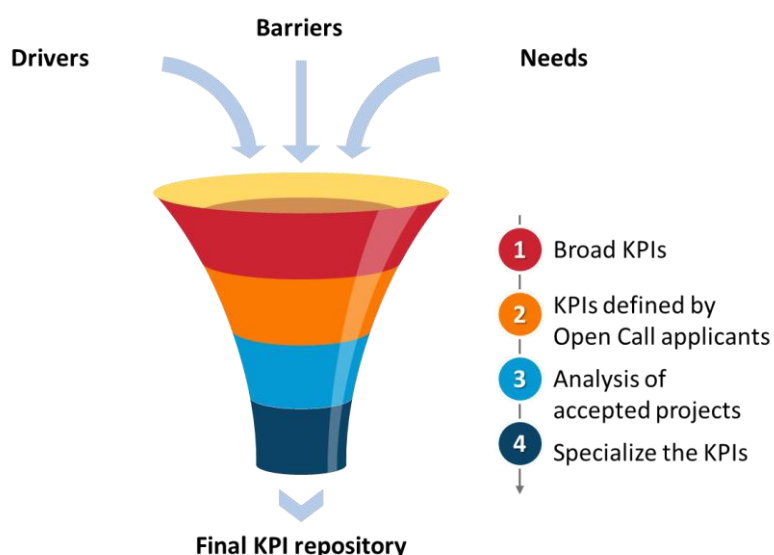


Figure 10 - Final KPI Repository



## 8. Conclusions

This deliverable presented a stakeholder-informed KPI framework developed through a rigorous, iterative process within the EVOLVE2CARE project. By identifying key needs across Living Labs, end-users, and the broader healthcare ecosystem, the project translated those insights into measurable indicators that support evaluation, refinement, and scaling of HealthTech innovations in transitional care.

The framework stands out for its participatory approach—engaging diverse stakeholders from academia, healthcare, innovation, business and policy to ensure relevance and usability. It includes three repositories tailored to distinct user groups and use cases, offering clear guidance for both innovators and evaluators.

Validation workshops and expert input led to refinements that enhanced the framework's inclusivity, regulatory applicability, and real-world alignment. As a result, the KPIs now better capture success factors like user involvement, regulatory readiness, social inclusivity, and clinical impact.

This is a living framework. It will evolve with the project, supporting Open Call participants and contributing to the long-term impact and sustainability of HealthTech innovation in transitional care across Europe.

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# Annex

## Final KPIs for LL

Table 7 - Final KPIs for LLs

Categories	KPI
<b>User recruitment &amp; involvement:</b> get feedback from user, involve them in the process, handle the recruitment	<ul style="list-style-type: none"> <li>• <b>Stakeholders from the 4-druple helix</b> actively involved in the feedback process and innovation development.</li> <li>• <b>Measure the level of involvement</b> of stakeholders in Living Lab Activities</li> </ul>
<b>Legal, regulation &amp; safety standard support:</b> related to ethics, legal issues, privacy	<ul style="list-style-type: none"> <li>• <b>Innovations meet legal, ethical, privacy, and safety standards</b> throughout their development and deployment.</li> </ul>
<b>Real life testing &amp; Experimentation:</b> all the activities that have to do with testing, piloting, experimenting and experimentation design	<ul style="list-style-type: none"> <li>• <b>Real-life testing or experimentation activities</b> that meet predefined goals or objectives.</li> </ul>
<b>Collaboration &amp; Networking possibilities:</b> create new opportunities for collaboration, synergies and networking	<ul style="list-style-type: none"> <li>• <b>New partnerships or synergies established</b> through networking activities.</li> <li>• <b>Quantify Knowledge exchange</b> in collaboration and networking activities</li> </ul>
<b>Access to existing data and data analysis methods:</b> either get access to existing data or collect a new dataset. It includes also the expertise for data analysis.	<ul style="list-style-type: none"> <li>• Innovators gain access to relevant existing data or have successfully collected new datasets for analysis</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>FAIR Data compliance</b> for Living Lab data (Findability, Accessibility, Interoperability, and Reuse of Digital Assets)</li> <li>• <b>Regulatory and Ethical Compliance</b> for Living Lab data</li> </ul>
<b>Knowledge acquired experience &amp; Learning:</b> get the knowledge, learn methodologies and experience the LL way of working, get insights or understanding that comes from active experimentation. Insights are from users and their perspective	<ul style="list-style-type: none"> <li>• Innovators gain <b>new insights or methodologies</b> through active experimentation.</li> </ul>
<b>Business &amp; Scale-up support:</b> expand or get access to new markets, scale-up an existing solution	<ul style="list-style-type: none"> <li>• Innovations <b>successfully expanded into new markets or scaled up</b> for wider adoption.</li> <li>• <b>Validating market readiness</b> using frameworks like Market readiness level</li> </ul>
<b>Diversity of opinions &amp; New Context:</b> cultural, social context, experience from new countries, language - multistakeholder	<ul style="list-style-type: none"> <li>• Innovators gain access and insights into feedback from <b>diverse cultural, social, and geographical contexts</b></li> </ul>
<b>Expert opinion &amp; Advisory services:</b> learn from experts, get guidance and support and expert opinion including from external stakeholders' network, refers to giving advice and consulting and not direct hands-on experience. Advice is from experts in another sector, different than yours	<ul style="list-style-type: none"> <li>• <b>Advisory sessions or expert consultations</b> received by innovators from external stakeholders or industry professionals</li> </ul>
<b>Physical space, equipment &amp; facilities:</b> providing the technology, infrastructure resources and technical facilities to perform the work	<ul style="list-style-type: none"> <li>• <b>Physical space, equipment, and facilities are open</b>, available effectively utilized for innovation development.</li> </ul>

<b>Publications</b>	<ul style="list-style-type: none"> <li>• <b>Peer-reviewed publications demonstrating the effects</b> and efficiency of the innovation.</li> </ul>
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## Final KPIs for End-Users

Table 8 - Final KPIs for End-Users

Stakeholder	Need	KPI
<b>Healthcare professionals</b>	Need innovations that reduce, rather than increase, their workload, streamlining processes and improving efficiency to allow for more focus on patient care.	<ul style="list-style-type: none"> <li>• Decrease in time spent on administrative or repetitive tasks due to the implementation of innovative solutions, measured through feedback or time tracking</li> <li>• No significant increase in workload following the introduction of an innovative solution, measured through feedback or time tracking.</li> </ul>
<b>Healthcare professionals</b>	Need centralized digital health platforms that integrate various services and data making access to information easy	<ul style="list-style-type: none"> <li>• New innovations are seamlessly integrated into centralized platforms instead of introducing a new platform every time.</li> </ul>

	Need decision support tools that enhance their knowledge by providing access to new, relevant information	<ul style="list-style-type: none"> <li>• Regular use of decision support tools by healthcare professionals</li> <li>• Healthcare professionals reporting improved clinical decisions as a result of using decision support tools</li> </ul>
	Need wearables and assistive technologies that help them track more information, enhance patient monitoring, and support their work in real-time.	<ul style="list-style-type: none"> <li>• Average rating given by healthcare professionals on the usefulness of wearables/assistive technologies in enhancing patient care and supporting their workflow, gathered through surveys or feedback</li> </ul>
<b>Healthcare professionals</b>	Need remote patient monitoring tools that allow them to track patients' health when they do not have direct access	<ul style="list-style-type: none"> <li>• More timely and continuous interventions for patients as a result of using remote patient monitoring tools, reported by healthcare professionals</li> <li>• Healthcare professionals report being able to respond to critical situations or patient changes that they would not have detected without the use of remote</li> </ul>

		patient monitoring tools.
	Need predictive analytics tools that help anticipate patient outcomes and risks, enabling proactive and data-driven decision-making	<ul style="list-style-type: none"> <li>• Predictive analytics tools accurately forecast patient outcomes or risks</li> <li>• Predictions lead to proactive interventions</li> <li>• Predictive analytics models incorporate data from multiple sources (e.g., patient history, real-time monitoring, lab results) to enhance the accuracy and reliability of predictions</li> <li>• Re-admission rates and complication rates as indicators of improved outcomes.</li> </ul>
<b>Healthcare professionals</b>	Need scientifically validated solutions that are proven to be effective through rigorous research	<ul style="list-style-type: none"> <li>• Peer-reviewed publications demonstrating the scientific validation and effectiveness of the solution in real-world healthcare settings</li> </ul>
	Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions	<ul style="list-style-type: none"> <li>• Improved proficiency and confidence of healthcare professionals in using new technologies</li> </ul>

<b>Hospitals / Organisations</b>	Need innovations that streamline processes and enhance overall operational performance	<ul style="list-style-type: none"> <li>Reduction in time spent on administrative or repetitive tasks due to improved workflows.</li> </ul>
	Cost-effective innovations that are proven through evidence to improve patient care and outcomes.	<ul style="list-style-type: none"> <li>Ratio of cost savings to improvements in patient outcomes achieved by the innovation.</li> </ul>
	Innovations should integrate smoothly into current hospital systems and practices, minimizing disruption	<ul style="list-style-type: none"> <li>Average time taken to fully integrate an innovation into existing workflows, from introduction to full implementation.</li> <li>Time for personnel to get used to new systems and work efficiently.</li> </ul>
	Adoption is based on strategy (top-down vs User Satisfaction).	<ul style="list-style-type: none"> <li>Comparison of adoption effectiveness based on top-down strategy vs. user satisfaction.</li> </ul>
	Need innovations that assist in creating and following discharge planning protocols, ensuring smooth transitions for patients	<ul style="list-style-type: none"> <li>Patients reporting better continuity of care and smoother transitions post-discharge, due to the implementation of discharge planning innovations.</li> </ul>
<b>Patients</b>	Need innovations that prioritize their needs, involve them in decision-making, and encourage active participation in their care	<ul style="list-style-type: none"> <li>Demonstrating respect for patients as partners in developing care</li> </ul>



		<p>plans reflective of their goals</p> <ul style="list-style-type: none"> <li>Continuously evaluating patients' levels of engagement</li> </ul>
	Solutions that directly contribute to improved health outcomes	<ul style="list-style-type: none"> <li>Health indicators for transitional care</li> <li>Qol</li> <li>Re-hospitalization</li> <li>Length of stay</li> <li>Functional status and independence</li> </ul>
	Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions	<ul style="list-style-type: none"> <li>Improved proficiency and confidence of patients in using new technologies</li> </ul>
	Need understandable care models and processes, along with effective medication management systems, to ensure they can follow their treatment plans confidently and manage their health effectively	<ul style="list-style-type: none"> <li>Presenting health information in easily accessible, accurate, and usable formats</li> <li>Monitoring to avoid medication errors</li> <li>Ensuring that medication management plan is based on evidence</li> </ul>
<b>Patients</b>	Ensuring that medication management plan is based on evidence (TCC)	<ul style="list-style-type: none"> <li>Ensuring that medication management plan is based on evidence</li> </ul>

	Personalized care that is tailored to their unique health conditions, preferences, and circumstances, ensuring more effective and individualized treatment.	<ul style="list-style-type: none"> <li>Patients feel that their personal health needs and preferences are effectively addressed through the personalized care provided, as measured through surveys or direct feedback.</li> <li>Direct measurement of perceived balance between digital solutions and human interaction.</li> </ul>
<b>Caregivers</b>	Need support and resources to reduce the physical, emotional, and financial burden associated with caregiving	<ul style="list-style-type: none"> <li>Decrease in caregiving burden measured through caregiver satisfaction surveys or specific burden assessment tools</li> </ul>
<b>Caregivers</b>	Need to be actively engaged in the caregiving process, with opportunities for involvement in care decisions, training, and support systems	<ul style="list-style-type: none"> <li>Demonstrating respect for caregivers as partners in developing care plans reflective of their goals</li> <li>Continuously evaluating caregivers' levels of engagement</li> </ul>

	<p>Need training and education on new technologies to enhance their skills and improve the effective use of innovative solutions</p>	<ul style="list-style-type: none"> <li>• Improved proficiency and confidence of caregivers in using new technologies</li> <li>• Measurable impact of educational tools in reducing caregiver burden.</li> </ul>
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## Final KPIs for Impact Assessment

Table 9 - Final KPIs for Impact Assessment Repository

Technical	Usability - Innovations should be user-friendly, visually appealing, and engaging to end-users.	<ul style="list-style-type: none"> <li>Improving <b>user acceptance / usability score and end-user engagement</b></li> </ul>
	Interoperability- Seamless integration of innovations into existing healthcare systems and pathways, ensuring technical compatibility	<ul style="list-style-type: none"> <li><b>Integration Success Rate:</b> Percentage of innovations successfully integrated into existing healthcare systems without major technical issues.</li> <li><b>Time to Full Integration:</b> Average time required to achieve seamless interoperability between the innovation and existing healthcare pathways.</li> </ul>
Technical	Standardisation - Health tech innovations must adhere to established standards to ensure consistency, reliability, and compatibility across healthcare systems and devices.	<ul style="list-style-type: none"> <li><b>Standards Compliance Checklist Completion:</b> Percentage of required standardisation criteria met by each individual innovation during development and deployment.</li> </ul>
	Privacy - Health tech innovations must ensure secure data ownership and protection,	<ul style="list-style-type: none"> <li><b>Technical implementation</b> ensures user and data privacy and security</li> </ul>

Fiscal	safeguarding users' personal and health information.	
	Real-world Applicability - Healthtech innovations must address the practical needs and challenges of stakeholders, ensuring they are relevant and valuable in real-world settings	<ul style="list-style-type: none"> <li>• <b>Type and representativeness of stakeholders</b> involved in assessing the knowledge gaps and needs addressed by the innovation.</li> </ul>
	Faster development and launching of the innovations	<ul style="list-style-type: none"> <li>• <b>Reducing by 3 months the time to market</b></li> </ul>
	Lower the high upfront costs of design and implementation of implementation of new innovations	<ul style="list-style-type: none"> <li>• <b>Lowering development costs of products/services by 5%</b></li> </ul>
	Innovators and innovations need to prioritize equity and access, ensuring that products are available to all populations, while also having investment and commercialization pathways that are free from territorial inequalities, allowing for fair distribution across regions.	<ul style="list-style-type: none"> <li>• <b>Integrate Partnership results</b> on national/regional/ local strategies, programmes, and plans supporting synergies across policy areas towards health and care systems transformation.</li> </ul>
	Stimulating investment in innovative care models and experimental approaches.	<ul style="list-style-type: none"> <li>• <b>2M€ Unlocked in Healthcare Savings</b></li> </ul>

<b>Environmental</b>	<p>Innovations need to prioritize eco-friendliness by promoting responsible consumption and production practices, minimizing environmental impact throughout their lifecycle.</p>	<ul style="list-style-type: none"> <li>• <b>Sustainability Compliance:</b> innovations should adhere to eco-friendly standards, demonstrating responsible consumption and production practices throughout their development and lifecycle.</li> </ul>
<b>Social</b>	<p>Innovations should be designed to be culturally sensitive, inclusive, and accessible, addressing social and psychological factors to overcome stigma and cultural barriers for patients</p>	<ul style="list-style-type: none"> <li>• Percentage of innovations incorporating <b>cultural sensitivity assessments</b>, ensuring inclusivity in design and accessibility.</li> </ul>
<b>Regulatory</b>	<p>Innovations need to align with both European and local legislations and regulations to ensure compliance and smooth integration into healthcare systems.</p>	<ul style="list-style-type: none"> <li>• <b>Documentation and audits confirming adherence to European and national legal requirements.</b></li> </ul>
	<p>Regulatory Readiness Tracking: Ensuring early compliance alignment with EU and national regulations to prevent costly market entry delays.</p>	<ul style="list-style-type: none"> <li>• <b>Number of innovations that successfully meet regulatory milestones</b> without compliance-related delays.</li> </ul>
	<p>Measuring progress toward regulatory approval, including clinical validation milestones, technical documentation compliance, and industry safety standards alignment.</p>	<ul style="list-style-type: none"> <li>• <b>Completion rate of key clinical validation milestones</b>, ensuring adherence to technical and industry safety standards.</li> </ul>