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Executive Summary

The CONNECTINGHEALTH project is dedicated to fostering interconnected and inclusive innovation ecosystems across Europe, with a particular focus on maximising the value of innovation in the digital health sector. At its core, the project aims to contribute to the long-term sustainability and advancement of healthcare in the European Union and beyond.

With the use of inclusive development processes our approach has integrated collaborative input from diverse stakeholders and synthesises outputs from various project work packages and deliverables. Now, as a result of countless co-creation sessions, stakeholder validation sessions, and the completion of the Multi-Year Action Plan, the CONNECTINGHEALTH project Policy Recommendations aim to pave the way for an ideal future of (digital) health in Europe and beyond by 2030.

These recommendations are crafted with the intention of catalysing actionable steps that governments, healthcare organisations, academia, private-sector, and ultimately civil society can take to foster a connected and efficient health ecosystem. By addressing key issues such as funding and investment, interoperability and data sharing, and education and training, these policy recommendations seek to enable seamless exchange of health information, facilitate innovative digital health solutions, and ensure equitable access to healthcare services for all citizens in Europe. Embracing these recommendations will not only accelerate the adoption of digital health technologies but also assist in contributing to improved health outcomes, increased efficiency in healthcare delivery, and enhanced patient experiences on a global scale.

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List of Abbreviations

Abbreviation	Full Terminology
EU	European Union
GDPR	General Data Protection Regulation
SMEs	Small- and Medium-Sized Enterprises
WP	Work Package

1. CONNECTINGHEALTH Project Overview

The societal landscape of the contemporary era has undergone significant transformation, affecting numerous sectors, including healthcare. These shifts emphasise the imperative for innovative solutions that surpass conventional approaches. Notably, the fusion of digital technologies and data has emerged as a promising avenue for addressing societal concerns. Nonetheless, this integration has also brought to light discrepancies and deficiencies in the uptake and design of such technologies across diverse regions. This underscores the critical need to nurture innovation ecosystems that can effectively bolster the creation and deployment of solutions targeted at addressing societal challenges.

Through collaborative efforts among European nations and various stakeholder groups, innovation can be nurtured in the health sector, positioning the European Union (EU) as a frontrunner in health innovation on the global stage. This strategic approach not only enhances citizen well-being but also strengthens the EU's competitive edge in the digital health landscape. "CONNECTINGHEALTH - CONNECTing the dots withIN diGital HEALTH Innovation Ecosystems" therefore, emerges as a pivotal initiative aimed at laying the groundwork for joint programs among digital health ecosystem stakeholders in Europe and beyond. Aligned with the overarching objective of fostering interconnected and inclusive innovation ecosystems across Europe, the project seeks to maximise the value of innovation within one of the most promising sectors for growth and increased competitiveness: digital health, while recommending potential complementary policies for growth and development in the sector.

CONNECTINGHEALTH¹ is implemented by the small and agile core group, which consists of the European Connected Health Alliance (ECHAlliance) as a European partner and three organisations that are leaders of the digital health ecosystems in their regions: Scottish Enterprise (Scotland, United Kingdom), Pannon Business Network Association

¹ <https://echalliance.com/projects/connectinghealth/>

(Western Hungary) and Seinäjoki University of Applied Science (South Ostrobothnia, Finland).



Figure 1. CONNECTINGHEALTH project partners (ECHAlliance)

1.1 CONNECTINGHEALTH Objectives

1. To map the landscape of the digital health ecosystems in Europe and beyond including their stakeholders, resources, initiatives, projects and political frameworks.
2. To explore the current and future opportunities for growth of the digital health sector, and its competitiveness.
3. To engage a wide range of stakeholders from governments, industry, academia and society in the development of the multi-year action plan for the sustainable and thriving digital health sector in Europe.
4. To connect and interconnect the existing regional and thematic digital health ecosystems for better cooperation, learning, exchange of best practices and wider impact.

1.2 Work Package 6 Objectives

The objectives within Work Package (WP) 6 of CONNECTINGHEALTH are as follows:

- To plan the multi-year action in cooperation with the stakeholders,
- To identify the funding opportunities to finance the action,

- To validate the action with the key stakeholders (through meaningful policy recommendations) and,
- To ensure its sustainability through the submission of the application to one of the funding instruments available.

Through these coordinated efforts within WP6, the project aims to establish a solid foundation for the successful implementation and impact of its objectives within the digital health innovation ecosystem.

2. Deliverable Introduction

2.1 Deliverable objective and scope

Deliverable 6.3 (D6.3), Policy Recommendations, led by ECHalliance, is one of three deliverables a part of WP6 within the CONNECTINGHEALTH project. The objective of this document is to articulate needs-driven policy recommendations arising from key outputs of previous project deliverables, especially the Multi-Year Action Plan. These recommendations are intended to facilitate the implementation of CONNECTINGHEALTH project-identified and proposed initiatives and foster ongoing progress toward the envisioned digital health landscape in Europe by 2030.

The main concepts put forward in these policy recommendations have been validated amongst a diverse group of individuals during stakeholder-specific focus groups, and cross-sectoral consultation validation workshops, alongside project consortium and external review.

2.2 Key components of the deliverable

In addition to offering a concise overview of the methodology employed to formulate these policy recommendations and the project outputs that significantly contributed to this specific deliverable, the policy recommendations themselves will serve as the primary focus of this work. Within this, the following subsections and content will be explored:

- Key areas for action
- Collaboration and networking regulatory frameworks
- Funding and investment
- Interoperability and data sharing
- Education and training
- Rationale and justification for recommendations
- Challenges and risks with consideration to influencing implementation
- Implications on digital health innovation if no implementation

Following this, a brief summary will be provided outlining a call-to-action for the European Commission and next steps in order to promote effective progress on our suggestions.

2.3 Relation to other WPs and tasks/deliverables

D6.3: Policy Recommendations, spearheaded by ECHAlliance, draws extensively from the cumulative progress achieved across all project phases. Nevertheless, specific outputs from various tasks and deliverables have played a particularly significant role in shaping this project deliverable. Notably, inputs from activities such as the Future Scenarios Workshops (WP2), Focus Groups & Validation Consultancy Workshops (WP6), and Multi-Year Action Plan (WP6) have directly informed the content of this report and will be emphasised accordingly. The interplay between other work packages (WPs) and deliverables is detailed below:

Table 1. Relation to other WPs and tasks/deliverables

WP	Deliverable/Task	Relationship
WP2	D2.1	Map of the digital health ecosystems in Europe and beyond - providing the consortium insight on the current landscape which influences recommendations and accountability
WP2	D2.2	Paper: Scenarios for the digital health sector in 2030 - providing the ideal vision of digital health for the future which the Action Plan aims to work towards
WP2	D2.3	Paper: Lessons learned from other domains of health - providing insight to what has worked and what has not to contribute to useful and timely recommendations
WP3	D3.1	Report on the three focus areas - to reflect on opportunities for the digital health industry
WP3	D3.2	Paper: Lessons learned from the three focus areas - to reflect on opportunities for the digital health industry
WP4	D4.1	The body of knowledge - to understand the differences between regions and countries in relation to digital health implementation and the influence of economic and health policy in its role for future recommendations
WP4	D4.2	SWOT analysis - to understand the digital health landscape and opportunities that can be applied to the Multi-Year Action Plan

WP4	D4.3	Paper: Conclusions for further action - to help influence and prioritise next steps
WP5	D5.1	Map of the key stakeholders - to understand who is necessary to engage in the Multi-Year Action Plan
WP6	T6.1	Inclusive development of the plan - gathered feedback from all stakeholder groups to better understand dependencies and impact evolution of optimal future for digital health which is applied to this deliverable
WP6	T6.3	Validation and finalisation of the plan with stakeholder groups - to ensure that the key takeaways from T6.1 are relevant across stakeholder groups and can be applied to D6.1
WP6	D6.1	Comprehensive Multi-Year Action Plan - outlines objective, activities, and timeline for achieving specific goals for the next five years with respect to designing the optimal future for digital health in the European context

3. Background and Context of the Policy Recommendation

In tandem with nurturing innovation ecosystems, the CONNECTINGHEALTH project also places a strong emphasis on formulating policy recommendations to maximise the value of innovation in the sector of digital health and ensuring sustainable and thriving digital health sector in Europe. Policy recommendations coming from cross-sectoral co-creation are pivotal in driving meaningful change across diverse domains. By engaging stakeholders from various sectors such as government, industry, academia, and civil society, these recommendations reflect a comprehensive understanding of complex societal issues and potential solutions.

Through collaborative dialogue and shared expertise, cross-sectoral co-creation ensures that policy recommendations are inclusive, feasible, and aligned with the needs and aspirations of all stakeholders. This approach fosters a sense of ownership and commitment among participants, increasing the likelihood of successful implementation and sustainable impact. Policy recommendations forged through cross-sectoral co-creation serve as a catalyst for transformative change, enabling societies to address pressing challenges and achieve collective goals more effectively.

These upcoming recommendations aim to bridge the existing disparities and deficiencies in technology uptake and design, ensuring equitable access and efficient deployment of innovative solutions. By fostering collaborative efforts among European nations and various stakeholder groups, these policy recommendations will not only propel innovation in the healthcare sector but also validate the EU's position as a global leader in health innovation. Through the implementation of strategic policies, CONNECTINGHEALTH aims to enhance citizen well-being while simultaneously fortifying the EU's competitive advantage in the digital health landscape.

As such, CONNECTINGHEALTH stands as a pivotal initiative poised to establish joint programs among digital health ecosystem stakeholders in Europe and beyond,

aligning with the overarching objective of fostering interconnected and inclusive innovation ecosystems across the continent.

4. Methodology

As mentioned in section 3.3 the formulation of this policy recommendation document draws upon the collective advancements made across all project work packages. However, certain outputs from critical tasks and deliverables have played a particularly influential role in shaping this forthcoming document - namely the various consultation outreach activities conducted and the creation of the Multi-Year Action Plan. Their insights and findings in particular will be highlighted to underscore their impact on the development of actionable policy recommendations.

4.1 Consultation process

The series of focus groups and validation workshops conducted between December 2023 and March 2024 played an important role in shaping the methodology of these policy recommendations. By engaging stakeholders from industry, academia, government, and civil society, these sessions aimed to uncover synergies and actionable steps toward building a desirable future of digital health.

Four stakeholder-specific focus groups (each for industry, academia, government and civil society) were held aiming to:

- (1) work to uncover and better understand the synergies between each of the focus groups and other focus groups with consideration to building a desirable future of (digital) health, and
- (2) to understand what actionable steps can be taken to achieve a desirable future - considering what needs to happen, and by whom. These sessions consisted of small group participation with anywhere from 4-15 participants present, including representation from varying EU and non-EU countries, and from various sectors across the Quadruple Helix.

Through these in-depth discussions and analysis of the collected data, insights were gained into stakeholder perspectives, priorities, challenges, and opportunities across regions and countries. This comprehensive approach facilitated the identification of key initiatives for policy recommendations, including the creation of multi-stakeholder

ecosystems, development of digital health-focused curriculum, expansion of awareness gatherings, and stakeholder mapping activities with a governmental focus.

Furthermore, the validation consultancy workshops held in-person and virtually in February and March 2024 provided a platform for stakeholders to consult and discuss the results from the focus groups, ensuring alignment and understanding of opportunities, enablers, and barriers across various sectors. These sessions also helped prioritise key initiatives for policy recommendations and establish next steps in digital health innovation implementation to inform the project's Multi-Year Action Plan. By synthesising insights from these consultation activities, this paper's methodology is enriched with a deeper understanding of stakeholder dynamics and informed strategies for advancing digital health in Europe and beyond. Thorough findings and analysis of this content can be found in the previously submitted project D6.1: Comprehensive Multi-Year Action Plan explained below in section 4.2.

4.2 Multi-Year Action Plan

The "Comprehensive Multi-Year Action Plan" (Deliverable 6.1) too, was pivotal in shaping this document's methodology for policy recommendations within the CONNECTINGHEALTH project. By setting strategic objectives for digital health in the EU and beyond, it provides a solid foundation for guiding policy formulation. Its emphasis on a five-year roadmap ensures forward-looking recommendations with tangible milestones aimed at designing the optimal future for digital health in the EU, capitalising on existing opportunities in digital health, and ensuring a future-proof approach. It includes the proposal of four main activity areas with potential outputs (seen in Figure 2 below) - listing relevant stakeholders, risk management and mitigation, and measures for continuous improvement.

Moreover, focusing on seizing digital health opportunities aligns with this paper's objectives, ensuring adaptability and relevance over time. Overall, the Action Plan serves as a guiding framework for responsive policy recommendations, contributing to the project's vision of advancing digital health in Europe and beyond.

Activities	Outputs
<p><u>Activity 1:</u></p> <p>Creation and nurturing of one multi-stakeholder cross-border ecosystem in Europe</p>	<ol style="list-style-type: none"> 1. Stakeholder Identification Report 2. Stakeholder Partnership Development Strategy 3. Government-Specific Stakeholder Mapping Exercise 4. Government-Specific Stakeholder Engagement Strategy 5. Stakeholder Engagement Workshops and Meetings 6. Online Collaboration Platform 7. Cross-Border Networking Events 8. Initiation of Cross-Border Projects 9. Best Practice Sharing Guidelines 10. Policy Briefs 11. Advocacy and Lobbying Campaigns 12. Stakeholder Engagement Metrics, Evaluation and Monitoring Framework
<p><u>Activity 2:</u></p> <p>Development and implementation of digital-health-focused curriculum for current healthcare students and pre-existing healthcare practitioners for European contexts which request support</p>	<ol style="list-style-type: none"> 1. Development of Curriculum Framework 2. Development of Curriculum Modules and Lesson Plans 3. Digital Learning Resources 4. Teacher Training and Professional Development Workshops 5. Pilot Implementation Programs 6. Quality Assurance and Accreditation Guidelines 7. Evaluation and Assessment Tools 8. Community Engagement and Outreach Activities
<p><u>Activity 3:</u></p> <p>Roll-out and expansion of gatherings that improves awareness and visibility of digital health initiatives</p>	<ol style="list-style-type: none"> 1. Event Speaker Recruitment and Program Development 2. Event Planning and Logistics 3. Marketing and Promotional Materials 4. Participant Registration and Engagement 5. Content Creation and Documentation 6. Evaluation and Impact Assessment. 7. Sustainability and Scaling Strategies 8. Continuous Improvement and Iteration

<p>Activity 4:</p> <p>Creation of a knowledge-sharing database and/or open marketplace Europe wide for cross sectoral, multi-stakeholder use</p> <p><i>(i.e., for industry to find funds/testers/etc., for academia to have their innovations uptaken by industry, for civil society to be included in consultations at initial innovation phases, for the government to support with enabling policies, etc.)</i></p>	<ol style="list-style-type: none"> 1. <i>Creation of a strategy for designing, operating, and maintaining database</i> 2. <i>Database Design and Architecture</i> 3. <i>Content Curation and Aggregation</i> 4. <i>User Interface and Experience Design</i> 5. <i>Platform Development and Implementation</i> 6. <i>Quality Assurance and Testing</i> 7. <i>Community Engagement and Onboarding:</i> 8. <i>Monitoring and Analytics Tools</i> 9. <i>Governance and Moderation Policies</i>
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Figure 2. CONNECTINGHEALTH Multi-Year Action Plan Framework Main Activities & Output

5. Policy Recommendations

5.1 Key areas for action

Taking into consideration the previous project-led research, conclusions, and deliverables, we feel that to advance digital health innovation within the EU framework, key policy recommendations across varying levels should be:

- Prioritise the creation and nurturing of a multi-stakeholder cross border ecosystem;
- Develop and implement a digital-health-focused curriculum;
- Create an expansion of gatherings aimed at improving awareness and visibility of digital health initiatives.

Across EU countries at a national and continental level, we recommend that key policies must first prioritise the creation and nurturing of a multi-stakeholder cross-border ecosystem. This involves fostering collaboration among various stakeholders, including governments, healthcare providers, technology developers, and academic institutions, to facilitate the exchange of ideas, resources, and best practices across borders. By establishing partnerships and networks, the EU can harness collective expertise and resources to drive innovation and address common challenges in digital health. Based on our data collected, national governments are recommended to take the lead in creating regulatory frameworks that enable collaboration among various stakeholders. This may involve European-led efforts in streamlining approval processes for cross-border initiatives and incentivising participation through funding or other means.

Additionally, recommendations for **national policy across Europe are aimed at focusing on the development and implementation of a digital-health-focused curriculum which is relevant to their nation's needs.** Once there is more equitable coverage for this form of established curriculum across European regions, then, it could be useful for the EU to support some form of standardisation on the evolution of the curriculum Europe wide. This involves integrating digital health education and training programs into existing healthcare professional curricula to ensure that

healthcare workers are equipped with the necessary skills and knowledge to leverage digital technologies effectively in their respective professions. By investing in workforce development, the EU can work to build a robust digital health workforce capable of driving innovation, delivering high-quality care, and improving health outcomes for citizens. Improved health outcomes can represent improved economic benefits. Healthier societies consist of more people that are able to be economically active members of society for longer and can thus represent more positive sustainable and budgetary outcomes from less people drawing on health services.

Furthermore, **policies made at a national and regional level first should prioritise the expansion of gatherings aimed at improving awareness and visibility of digital health initiatives.** This includes financially supporting the creation and implementation of conferences, workshops, and networking events that bring together cross-sectoral stakeholders to share knowledge, showcase innovations, and foster collaboration. Following this, alongside national and regional initiatives, it would be beneficial for the EU government to also build complementary policies to do the same across borders. By promoting awareness and engagement, the EU can stimulate interest and investment in digital health innovation, ultimately accelerating the adoption and implementation of digital health solutions across the region in order to influence local, regional, and national strategy documents and policy, and to promote their implementation.

Additionally, **policy made at an EU, national and regional level is recommended to consider and incorporate elements of the following topics in order to create and maintain the most optimal environment for a desired future for digital health in Europe (and beyond)** – as outlined in sections 5.1.1 through 5.1.4.:

- Collaboration and networking regulatory frameworks
- Funding and investment
- Interoperability and data sharing
- Education and training

The key policy recommendations per domain can be seen below in Table 2 and are explained in more depth in sections 5.1.1 through 5.1.4.

Key Domain	Key Policy Recommendations
Collaboration and networking regulatory frameworks	1. Establish robust collaboration mechanisms among EU regulatory authorities, industry, healthcare providers, and research institutions
	2. Develop standardised EU-wide regulatory frameworks for digital health to ensure clarity and consistency
	3. Implement adaptable frameworks for continuous evaluation and adjustment to match the pace of technological advancements
	4. Foster partnerships between regulators and industry for innovative yet safe digital health regulations
Funding and investment	1. Prioritise funding allocation across the digital health innovation lifecycle, from research to market
	2. Emphasise public-private partnerships in EU, national, and regional policy development for impactful investment
	3. Explore diverse financing mechanisms like venture capital and innovation funds to attract private sector investment
	4. Address investment barriers such as regulatory uncertainty and market fragmentation to foster a conducive environment for digital health innovation
Interoperability and data sharing	1. Prioritise development and implementation of interoperability standards across EU, national, and regional levels for seamless health data exchange
	2. Emphasise governance mechanisms and data sharing agreements to ensure responsible and secure health data sharing, while protecting patient privacy
	3. Promote adoption of open standards for transparent and accountable data exchange among stakeholders
	4. Address technical and organisational barriers to interoperability and data sharing to foster collaboration and innovation in EU digital health
Education and training	1. Prioritise national-level development of tailored education and training programs for the evolving healthcare workforce in the digital era, followed by EU-level initiatives
	2. Emphasise lifelong learning and continuous professional development for healthcare professionals in national and EU policy
	3. Foster collaboration among academic institutions, healthcare providers, and industry stakeholders to create practical education and training programs at all policy levels
	4. Address disparities in education and training access across underserved populations and regions in EU policy implementation

Table 2. Key Policy Recommendations per domain

5.1.1 Collaboration and networking regulatory frameworks

In the context of continued digital health innovation and uptake in the EU, collaboration and networking regulatory frameworks play a crucial role in facilitating cross-border cooperation and harmonisation of regulations. **EU policy makers in the domain of collaboration and networking regulatory frameworks should focus more on establishing robust mechanisms for collaboration among regulatory authorities, industry stakeholders, patients/service users, healthcare providers, and research institutions across EU member states alike.** This involves creating platforms for information sharing, dialogue, and mutual recognition of regulatory approvals to streamline the process of bringing innovative digital health technologies to market. More specifically, by working to enforce regulatory alignment, EU policy makers can try to better align regulatory standards and requirements across member states to minimise discrepancies that could hinder cross-border collaboration. In order to do this, regular assessments would be recommended looking at the existing regulations while actively seeking input from stakeholders to identify areas for greater interoperability across borders. Additionally, by implementing more agile regulatory processes (while facilitating cross-sector partnerships across borders), EU policymakers should work to further explore strategies which can adapt and keep pace with technical advancements – regularly expressed as a barrier to meaningful innovation amongst our sessions. This could involve piloting different regulatory approaches (i.e. sandbox environments) which can be beneficial to academia or private sector innovation implementation.

EU leaders, in conjunction with national politicians, should aim to build policies that prioritise the development of standardised regulatory frameworks that provide clarity and consistency in digital health regulations across the EU. Harmonising regulations and standards can reduce barriers to market entry, enhance interoperability, and promote innovation by providing a level playing field for digital health companies operating within the EU. Additionally, these **frameworks should focus on incorporating mechanisms for ongoing evaluation and adaptation to keep pace with rapid advancements in digital health technologies and evolving regulatory landscapes.**

Moreover, both in the context of EU and national politicians, **policy should assert the importance of fostering partnerships between regulatory authorities and industry stakeholders to co-create regulatory frameworks that balance innovation with patient safety and data protection to assure ideal future scenarios.** By involving both patients/users and industry stakeholders in the regulatory process, policymakers can ensure that regulations are practical, proportionate, and conducive to innovation while safeguarding public health and privacy. Ultimately, collaboration and networking regulatory frameworks are essential for creating an enabling environment that promotes digital health innovation and uptake across the EU, driving improvements in healthcare delivery and patient outcomes.

5.1.2 Funding and investment

Robust funding and investment mechanisms are indispensable for driving research, development, and adoption of cutting-edge technologies when considering the future of digital health innovation in the EU. **Key policy recommendations in this domain direct EU and national bodies to prioritise the allocation of adequate funding resources to support digital health innovation across the entire innovation lifecycle, from early-stage research to market commercialisation.** This entails establishing dedicated funding programs, grants, and incentives tailored to incentivise investment in digital health startups, scale-ups, and small- and medium-sized enterprises (SMEs), fostering a vibrant ecosystem of innovation and entrepreneurship.

Furthermore, **policy development at EU, national, and regional levels is recommended to highlight the importance of leveraging public-private partnerships to maximise the impact of funding and investment in digital health innovation.** Collaborative initiatives between government agencies, industry stakeholders, academic institutions, and healthcare providers can pool resources, expertise, and networks to accelerate the development and adoption of transformative digital health solutions. Additionally, **policymakers across European nations should explore novel financing mechanisms, such as venture capital funds, impact investment vehicles, and innovation funds, to mobilise private sector capital towards high-potential digital health ventures.**

Policies at EU, national, and regional levels should aim to address barriers to investment, such as regulatory uncertainty, market fragmentation, and reimbursement challenges, to create a favourable investment climate for digital health innovation in the EU. This involves implementing regulatory reforms, tax incentives, and reimbursement frameworks that incentivise investment in digital health technologies while ensuring patient safety, data privacy, and quality of care. By fostering a supportive funding and investment environment, policymakers can catalyse innovation, drive economic growth, and improve healthcare outcomes for citizens across the EU.

5.1.3 Interoperability and data sharing

In the landscape of digital health innovation and uptake within the EU, interoperability and data sharing are pivotal for facilitating seamless exchange of health information across borders and healthcare systems. **Key policy in this realm should be built to prioritise the development and implementation of interoperability standards and frameworks at the regional, national, and EU level that enable seamless integration and exchange of health data between different electronic health record systems, medical devices, and digital health applications.** This entails synchronising technical standards, data formats, and protocols to ensure compatibility and interoperability across diverse digital health technologies and platforms.

Furthermore, policy makers at the EU and national level should build out **policies that emphasise the importance of establishing governance mechanisms and data sharing agreements to facilitate responsible and secure sharing of health data while safeguarding patient privacy and confidentiality.** This involves defining clear rules, protocols, and consent mechanisms for accessing, sharing, and using health data in compliance with EU data protection regulations, such as the General Data Protection Regulation (GDPR). Additionally, **policymakers across national and EU levels should promote the adoption of open standards and interoperability frameworks that enable seamless data exchange while ensuring transparency, accountability, and trust among stakeholders.**

Moreover, **it is recommended that regional, national and EU policy makers address technical and organisational barriers to interoperability and data sharing, such as legacy systems, proprietary technologies, and siloed data repositories, to foster a culture of collaboration and data-driven innovation in digital health across the EU.**

This involves investing in infrastructure, interoperability testing facilities, and capacity-building initiatives to support the implementation of interoperable solutions and enable data-driven decision-making in healthcare delivery and research. By prioritising interoperability and data sharing, policymakers can unlock the full potential of digital health technologies to improve patient care, enhance healthcare outcomes, and drive innovation in the EU.

5.1.4 Education and training

Education and training play a vital role in equipping healthcare professionals and stakeholders with the necessary skills and knowledge to leverage digital technologies effectively. **Within this domain, it is recommended to first direct change at a national level (followed by EU level) to prioritise the development and implementation of comprehensive education and training programs tailored to address the evolving needs of the healthcare workforce in the digital age (and in its digital transformation).** This involves integrating digital health literacy, data analytics, telemedicine, and health informatics into existing healthcare student and professional curricula to ensure that healthcare providers are proficient in utilising digital tools and technologies to deliver high-quality care when in the field – no matter the stage of their professional life they are in.

It would be **beneficial if policy made by the national and EU politicians stress the importance of lifelong learning and continuous professional development to enable healthcare professionals to stay on top of emerging digital health trends and innovations.** This entails providing ongoing training opportunities, workshops, and certifications to support skill acquisition and knowledge transfer in digital health. Additionally, **policymakers at all levels (regional, national, and EU) should aim to foster collaboration between academic institutions, patients/users, healthcare providers, and industry stakeholders to co-create and deliver education and**

training programs that are relevant, practical, and responsive to the needs of the healthcare workforce.

Moreover, **policy implementation across all levels must address disparities in access to education and training opportunities, particularly for underserved populations and regions within the EU.** This considers investing in infrastructure, digital literacy programs, and capacity-building initiatives to ensure equitable access to education and training in digital health across the EU. By prioritising education and training, policymakers can empower healthcare professionals and stakeholders to embrace digital transformation, drive innovation, and improve healthcare delivery and outcomes for citizens across the EU.

5.2 Rationale and justification for recommendations

The policy recommendations listed above are essential for promoting a positive future for digital health innovation and implementation in Europe due to several key reasons. As such, in justifying the above, the following rationale can be taken into consideration:

- Firstly, **collaboration and networking regulatory frameworks are crucial to facilitate cross-border cooperation and alignment of regulations.** By establishing robust mechanisms for collaboration among regulatory authorities, industry stakeholders, patients/users, healthcare providers, and research institutions across EU member states, these frameworks ensure streamlined processes for bringing innovative digital health technologies to market. This fosters a conducive environment for collaboration, knowledge exchange, and mutual recognition of regulatory approvals, ultimately driving innovation and improving patient outcomes.
- Secondly, **funding and investment are vital for driving research, development, and adoption of digital health technologies.** Adequate funding resources and incentives are needed to support innovation across the entire lifecycle, from early-stage research to market commercialisation. By establishing dedicated funding programs, grants, and incentives, policymakers can incentivise investment in digital health startups, scale-ups, and SMEs,

fostering a vibrant ecosystem of innovation and entrepreneurship. This, in turn, promotes economic growth, job creation, and competitiveness in the global digital health market.

- Thirdly, **interoperability and data sharing are essential for enabling seamless exchange of health information and promoting data-driven decision-making in healthcare.** By establishing interoperability standards and frameworks, policymakers can ensure compatibility and interoperability across diverse digital health technologies and platforms, facilitating seamless integration and exchange of health data between different electronic health record systems, medical devices, and digital health applications. This promotes care coordination, enhances clinical decision-making, and improves patient safety and outcomes.
- Lastly, **education and training are critical for equipping healthcare professionals and stakeholders with the necessary skills and knowledge to leverage digital technologies effectively.** By integrating digital health education and training programs into existing healthcare professional curricula, policymakers can ensure that healthcare providers are proficient in utilising digital tools and technologies to deliver high-quality care. This promotes a culture of digital health literacy, fosters innovation adoption, and drives continuous improvement in healthcare delivery and outcomes for citizens across Europe.

5.3 Challenges and risks with consideration to influencing implementation

Implementing policy recommendations for promoting a positive future for digital health innovation and implementation in Europe faces several challenges and risks.

One challenge relates to establishing effective collaboration and networking regulatory frameworks across EU member states. Varying regulatory environments and legal frameworks may hinder coordination efforts, leading to delays in standardisation and interoperability. Additionally, conflicting interests among

stakeholders and regulatory authorities may pose challenges to consensus-building and alignment, further complicating the implementation process.

Another challenge pertains to securing adequate funding and investment for digital health initiatives. Limited financial resources, competing priorities, and economic uncertainties may constrain funding opportunities, hampering innovation and inhibiting the scalability of digital health solutions. Additionally, the complex nature of digital health investments, coupled with the long-term horizon for returns, may deter investors from committing capital, thereby impeding the development and deployment of innovative technologies.

Furthermore, ensuring interoperability and data sharing presents significant challenges in the digital health landscape. Technical complexities, data privacy concerns, and regulatory requirements may hinder seamless exchange of health information across disparate systems and platforms. Cultural and organisational barriers within healthcare institutions too may impede collaboration and hinder data-sharing initiatives, limiting the potential for interoperability and data-driven innovation.

Lastly, addressing the education and training needs of healthcare professionals poses challenges in promoting digital health innovation and implementation. Resistance to change, inadequate resources for training, and a lack of standardised curricula may hinder efforts to build a digitally competent workforce across the continent. Additionally, disparities in digital literacy and access to training opportunities may exacerbate workforce shortages and impede the adoption of digital health technologies. Overcoming these challenges requires concerted efforts from policymakers, industry stakeholders, and healthcare providers to address regulatory, financial, technical, and educational barriers, thereby paving the way for a positive future for digital health innovation and implementation in Europe.

5.4 Implications on digital health innovation if no implementation

The absence of implementation of policies focused on collaboration and networking regulatory frameworks, funding and investment, interoperability and data sharing, and education and training would have profound implications for digital health innovation in Europe. Without collaborative regulatory frameworks, fragmented regulations across EU member states would persist, hindering interoperability and standardisation efforts. This fragmentation could greatly impact innovation efforts and impede the development and adoption of new digital health technologies, limiting their potential impact on improving healthcare delivery and patient outcomes at a population level.

Inadequate funding and investment in digital health initiatives would restrict innovation and hinder the scalability of digital health solutions. Without sufficient financial support, digital health startups and SMEs would struggle to access the resources needed to develop and commercialise innovative technologies, slowing the pace of technological advancement and limiting access to transformative healthcare solutions. Additionally, the lack of funding may lead to missed opportunities for economic growth and job creation in the digital health sector, hindering Europe's competitiveness in the global market.

Without prioritising interoperability and data sharing, siloed health information would remain a significant barrier to seamless care coordination and data-driven decision-making. The inability to exchange health data securely and efficiently between different systems and stakeholders would impede care delivery, hinder innovation, and limit the potential for personalised and predictive healthcare solutions.

Finally, neglecting education and training initiatives would perpetuate digital health literacy gaps among healthcare professionals, impeding their ability to leverage digital technologies effectively and adapt to evolving healthcare practices and population needs. This would result in a workforce ill-equipped to harness the full potential of digital health innovation, ultimately undermining efforts to improve healthcare quality and accessibility in Europe.

6. Conclusion

6.1 Summary

To advance digital health innovation within the EU framework and create a thriving environment, **key policies should focus on creating a multi-stakeholder cross-border ecosystem, developing a digital-health-focused curriculum, expanding gatherings for improved awareness, and furthering stakeholder mapping activities.** These recommendations, outlined in the CONNECTINGHEALTH project, aim to foster collaboration, support workforce development, and enhance visibility of digital health initiatives across the EU.

There is a need for common understandings and goals supported by jointly-built strategies (across organisations, regions, and nations). Healthcare is somewhat fragmented, and still sometimes far away from technology which poses challenges. Therefore, a wider range of stakeholder and ecosystem involvement could assist moving forward. Collaboration and networking regulatory frameworks are essential for facilitating cross-border cooperation and harmonisation of regulations, promoting innovation and addressing common challenges in digital health. Funding and investment mechanisms are vital for driving research, development, and adoption of digital health technologies, fostering a vibrant ecosystem of innovation and entrepreneurship. Interoperability and data sharing are crucial for facilitating seamless exchange of health information and promoting data-driven decision-making in healthcare, enhancing care coordination and improving patient outcomes. Education and training initiatives are critical for equipping healthcare professionals and stakeholders with the necessary skills and knowledge to leverage digital technologies effectively, promoting digital health literacy and driving continuous improvement in healthcare delivery and outcomes.

However, implementing these recommendations for future policy face several challenges and risks, including regulatory complexities, limited funding opportunities, technical barriers, and workforce shortages. Overcoming these challenges requires concerted efforts from policymakers, industry stakeholders, and healthcare providers

to address regulatory, financial, technical, and educational barriers, thereby paving the way for a positive future for digital health innovation and implementation in Europe. Failure to implement these policies would result in fragmented regulations, restricted innovation, limited access to transformative healthcare solutions, and an ill-equipped workforce, ultimately undermining efforts to improve healthcare quality and accessibility in Europe.

6.2 Call-to-action for the European Commission

In light of the transformative potential of digital health innovation, the CONNECTINGHEALTH project consortium urges the European Commission to prioritise the swift and effective implementation of policy recommendations aimed at fostering improved and ideal futures of digital health innovation and implementation in the EU.

The time to act is now. Collaboration and networking regulatory frameworks, funding and investment, interoperability and data sharing, and education and training are critical pillars that require immediate attention and action. By establishing succinct regulatory frameworks, increasing funding and investment opportunities, promoting interoperability and data sharing, and enhancing education and training initiatives, we can unlock the full potential of digital health innovation to revolutionise healthcare delivery and empower citizens to take control of their health and well-being across Europe - and beyond.

Considering our work in the CONNECTINGHEALTH project and the policy recommendations provided herein, we urge the European Commission to spearhead policy reforms, foster cross-sectoral collaborations, and invest in digital health infrastructure to foster innovation and growth. Together, let us seize this opportunity to build a brighter and healthier future for all Europeans through the power of digital health innovation.