EHMA
European Health Management Association

STRENGTHENING THE EUROPEAN VACCINE ECOSYSTEM: MANAGING THE DIGITAL TRANSITION

Published by the European Health Management Association (EHMA)
in January 2023.

This report is based on an independent research delivered by EHMA. It was supported by MSD. MSD has had no influence or editorial control over the content of this report, and the views and opinions of the authors are not necessarily those of MSD.

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EXECUTIVE SUMMARY

Vaccinations are a critical tool for primary prevention of disease and remain one of the most cost-effective public health measures available. Despite this track record of success, vaccination coverage in Europe reached a plateau before the COVID-19 pandemic and levels of vaccination coverage across the continent remain inconsistent. Administrative and financial barriers to accessibility, a lack of awareness about the importance of vaccination and the rising prevalence of misinformation about vaccines have caused public confidence in vaccination to wane, creating significant cause for concern and presenting a major challenge to public health professionals.

Within this context, this paper seeks to address the role that the ongoing 'digital revolution' in healthcare will have in shaping the future of Europe's vaccine ecosystem, and develops several recommendations to support a strong and sustainable vaccine ecosystem in Europe that can maximise the positive potential of the digital transition while avoiding an exacerbation of existing systemic inequity. These recommendations are aimed directly at policy makers at the EU and national levels, and health managers at all levels, who have critical roles not only in implementing modern digital technologies to support the vaccine ecosystem, but also in ensuring that these systems remain sustainable from the social, economic and workforce perspectives.

The policy recommendations presented in this paper were developed through a multi-stage, iterative process that includes input from existing scientific and grey literature, an expert focus group workshop, consultation interviews with stakeholders, and a survey of health managers to establish their feasibility in both national and European contexts. This process ensured that the final recommendations are grounded in both scientific evidence and health management practice.

As we work together to navigate the digital transition in health systems across Europe, including through the development of the European Health Data Space, it will be essential to consider the perspectives of every stakeholder who will be impacted by the decisions that are made. The recommendations developed in this paper should be thought of as a window into the perspective of health managers, who are often on the front lines of digital transition and responsible for the effective implementation of digital technologies.

To maximise the potential benefits of digital transition in the European vaccine ecosystem, it is critical to understand the specific challenges this transition presents to health managers, and the best ways to help them overcome these challenges.

EHMA RECOMMENDATIONS FOR MANAGING THE DIGITAL TRANSITION IN THE EUROPEAN VACCINE ECOSYSTEM

POLICY MAKERS AT THE EU LEVEL SHOULD:

1. **Consult** with vaccine researchers, health managers, industry leaders and national policy makers to ensure that the implementation of the **European Health Data Space includes provisions for collecting, sharing, and using relevant data** regarding vaccine development, deployment and effectiveness.

2. **Commit** to making vaccination data **accessible** in a way that promotes cross-border **interoperability**, innovation and evidence-based policy development while ensuring that **citizens retain ownership of their data**.

3. **Work towards broader European cooperation** on vaccines by creating provisions for non-EU states to access EU digital tools supporting vaccine research programmes, data collection platforms for vaccine surveillance and monitoring, research, and mutual learning facilitators like the EU Best Practice Portal.

POLICY MAKERS AND HEALTH MANAGERS AT ALL LEVELS SHOULD:

4. **Support** the implementation of **up- and re-skilling initiatives** for the healthcare workforce, such as the BeWell project, across Europe to ensure that health professionals have the training and resources they need to effectively adapt to digital transformation in the vaccine ecosystem.

5. **Create a framework** for transforming the infrastructure created for the EU Digital COVID Certificates into **broader digital tools supporting vaccination**, either through MyHealth@EU or a tailored national solution. This framework should facilitate cross-border data sharing and offer citizens information about schedules, accessibility, and safety for routine vaccinations to facilitate evidence-based communication strategies for overcoming existing obstacles to vaccination.

6. **Implement standards** for scaling up digital vaccine management, including the monitoring and maintenance of vaccine supply chains and storage facilities to facilitate efficient procurement, simplify logistics, and reduce waste.

7. **Support further research** exploring the **impact, efficacy** and **cost-effectiveness** of digital technologies in the European vaccine ecosystem.

INTRODUCTION

According to the World Health Organization (WHO), vaccination **prevents** an estimated of 3.5-5 million deaths worldwide each year, **reduces** disease-specific treatment costs and the use of antimicrobial treatments. (1) If every child in the world received a vaccine to protect against the streptococcus pneumoniae bacteria, this would prevent an estimated 11 million days of antibiotic use each year. (2) Vaccinations are a critical tool for **primary prevention** of disease and one of the most **cost-effective public health measures** available. In Europe, the advancement of vaccination technology and provision has eradicated previously deadly diseases like smallpox and has almost eliminated the spread of several other pathogens. (3)

Despite this track record of success, vaccination coverage reached a plateau before the COVID-19 pandemic and levels of vaccination coverage across Europe remain inconsistent. In recent years, several countries in the WHO European Region have faced unprecedented new outbreaks of vaccine-preventable diseases due to insufficient vaccination coverage rates. (4) **Administrative and financial barriers** to accessibility, a **lack of awareness** about the importance of vaccination and the rising prevalence of **misinformation** about vaccines have caused public confidence in vaccination to wane, creating significant cause for concern and presenting a major challenge to public health professionals.

The true scale of this challenge was highlighted by the outbreak of the COVID-19 pandemic in March 2020, during which both the strengths and weaknesses of existing global vaccine ecosystems were thrust into the spotlight. Europe witnessed the collaborative capacity of governments, industry, health professionals and experts from different sectors to discover, produce and distribute novel vaccines built with both new and traditional technologies in a historically short period of time. Europe's health systems were also able to quickly pivot towards **digital transition** to facilitate vaccination **communication**, **monitoring**, and **delivery**. (5) These strengths produced successes. As of September 2022, over 1.62 billion doses of COVID-19 vaccination had been delivered within the WHO European Region, which represents a mass vaccination campaign on a scale unprecedented in human history. (6) However, Europe also experienced the current limitations of digital vaccine infrastructure, with **challenges to local and regional supply chain management, a lack of interoperable data systems, and vaccine hesitancy and misinformation** disrupting the progress of vaccination campaigns and exacerbating existing health inequalities. (7)

PURPOSE OF THIS PAPER

This position paper builds on the global report produced in 2021 by the Economist Group's Vaccine Ecosystem Initiative (8), with a targeted focus on the European Context. Within this context, this paper seeks to **address the role that the ongoing 'digital revolution' in healthcare will have in shaping the future of Europe's vaccine ecosystem**. (9) Through an analysis of the existing political and technological landscape surrounding this issue, this paper develops several recommendations to support a strong and sustainable vaccine ecosystem in Europe that can maximise the positive potential of future digital transition while avoiding an exacerbation of existing systemic inequity. These recommendations are aimed directly at **policy makers** at the EU and national levels and **health managers** at all levels, who have a critical role not only in implementing modern digital technologies to support the vaccine ecosystem, but also in ensuring that these systems **remain sustainable** from the **social, economic and workforce** perspectives.

METHODOLOGY

The final policy recommendations presented at the end of this paper have been developed through a multi-stage, iterative process that includes input from existing **scientific and grey literature and consultation** with expert stakeholders. A literature review was initially conducted to develop a deep understanding of the European vaccine ecosystem, through which a set of preliminary **policy recommendations** were developed based on initial analysis. An **expert focus group** was then created, bringing together four professionals working with vaccine programming and holding high-level positions in academic, private sector, healthcare institution and government settings. This focus group was convened for a workshop during which the initial recommendations were compared against the practical experiences of the group members, resulting in several additions and reformulations.

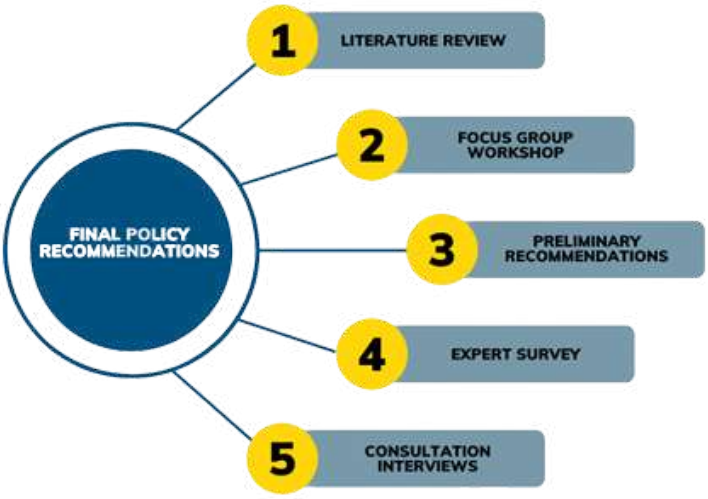

Figure 1. Methodology overview

The reformulated policy recommendations were then taken to the **broader community of European vaccination experts** through a survey, to establish their feasibility in both national and European contexts. This survey process was further supported by a set of five **intensive stakeholder consultations** with experts from Sweden, Germany, Latvia, Spain and Slovakia, selected strategically to provide diverse European perspectives. Following this process, the recommendations were revised for again to incorporate the feedback received, creating a **final set of policy recommendations** that are grounded in both practical and scientific evidence.

FRAMEWORK: A VACCINE ECOSYSTEM

Prior to further exploration of health management and digital transition in the context of a European vaccine ecosystem, the concept of a 'vaccine ecosystem' needs to be properly defined. This paper will adopt the detailed vaccine ecosystem framework developed by the Vaccine Ecosystem Initiative (8), which is based on five core pillars (see Figure 2). These pillars encapsulate the key stages in the life cycle of a vaccine, from research inception to administration, and are all interdependent, as a failure in one pillar can have negative consequences across the entire ecosystem.

Each pillar offers unique opportunities for strengthening through digital transition, helping Europe move towards a more resilient and sustainable European vaccine ecosystem.

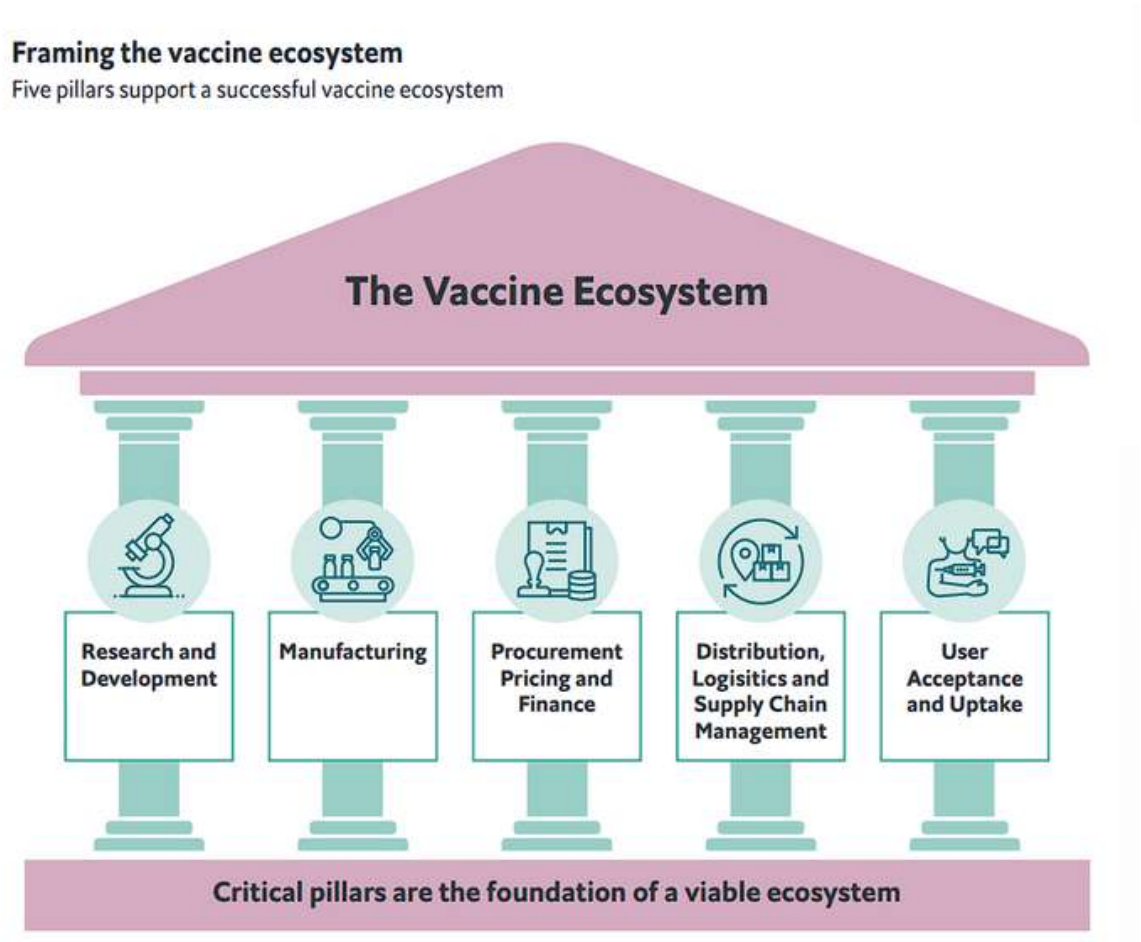

Figure 2. The Five Pillars of the Vaccine Ecosystem (8)

PILLAR 1: RESEARCH AND DEVELOPMENT (R&D)

This pillar includes the vaccine research process from the earliest stages of **laboratory research** up until the conduction of human **clinical trials**. This covers the entire framework surrounding R&D, from needs assessment to regulatory oversight of vaccine development to disease **surveillance** and monitoring to identify new **threats**, along with the framework of **policies**, **infrastructure**, **investments** and **partnerships** that surround the process of market access.

Digital technologies can be used to **accelerate the discovery** and development of new vaccines. *For example, with adequate access to quality data, researchers can use machine learning and AI to help identify new potential vaccine targets and assist in the design and optimisation of vaccines.*

PILLAR 2: MANUFACTURING

This pillar covers the factors involved in manufacturing vaccines at the scale necessary to meet demand. These include the **infrastructure, regulatory** oversight, **human resources, manufacturing** processes and **quality control** standards that must be in place to effectively produce safe and effective vaccines.

*Digital technologies can be used to **improve the efficiency** and scalability of vaccine production, including using digital manufacturing techniques to increase the speed and flexibility of production, and enable the rapid scaling up of production to meet demand.*

PILLAR 3: PROCUREMENT, PRICING AND FINANCE

This pillar includes every aspect involved in the purchasing and pricing of vaccines, as well as the financing required for vaccine R&D, innovation and the implementation of vaccination programmes. It also covers the procurement, pricing and finance systems that govern access to vaccines at the international level and the affordability of vaccines at the local level.

Digital technologies can be used to **streamline the procurement process** for vaccines. *For example, using digital platforms can enable more efficient and transparent procurement by allowing for the automated submission and evaluation of bids, and providing real-time visibility into the status of procurement and pricing activities.*

PILLAR 4: DISTRIBUTION, LOGISTICS AND SUPPLY CHAIN MANAGEMENT

This pillar relates to the mechanisms that enable the **distribution** of vaccines from manufacturing facilities to the locations where they are administered. This includes the **infrastructure** and systems required to distribute vaccines both within and between countries, the development of human resources capacity through the training of health care professionals, and the **effective management of vaccine supplies**.

Digital technologies can be used to **improve the tracking** and distribution of vaccines. *For example, using digital logistics systems can help to ensure that vaccines are delivered to the right place at the right time, and enable real-time monitoring of vaccine stock levels across regional and national jurisdictions.*

PILLAR 5: USER ACCEPTANCE AND UPTAKE

The final pillar covers the factors that govern **individual decision-making** regarding vaccination. It includes **health literacy**, **accessibility** and **affordability** of vaccination services, building **public trust** in vaccines, and the **design** of vaccination programmes.

Digital technologies can be used to **improve the administration** of vaccines, *for example by using Health apps that can help people find and book vaccination appointments and remind them when they are due for a booster. By tracking vaccination coverage through digital solutions, vaccination campaigns can also optimise the allocation of resources and identify population trends of vaccine hesitancy.*

THE LANDSCAPE OF THE EUROPEAN VACCINE ECOSYSTEM

To evaluate the current state of the European vaccine ecosystem, each pillar must be analysed in context. For an accurate picture, this analysis must consider the **uniquely European factors** that influence the structure of each pillar at the local, regional, national and international levels. These include major influences like the multiple **governance frameworks** provided by the European Union and broader **geopolitical influences** such as the continent's access to strategic resources, but they also encompass micro-level factors like the regional availability of health care resources and the impact of cultural context on attitudes towards vaccination.

THE IMPORTANCE OF THE EU

As a unique transnational governance structure integrating 27 European Member States, the EU has the largest influence on the wider European vaccine ecosystem of any stakeholder, especially in economic and regulatory terms. This was demonstrated when the circumstances of the COVID-19 pandemic pushed the EU to make several large investments in digital vaccine research infrastructure, including the European Corona Vaccine Trial Accelerator Platform (**VACCELERATE**) to establish an international clinical research network and facilitate vaccine clinical trials (10), and **TRANSVAC2**, which offers technical vaccine and development services to researchers at no cost. (11) Although these examples were motivated by an acute public health crisis, they highlight the existing capacity of the EU to **support digital transition in R&D**, **procurement and distribution** to promote a resilient vaccine ecosystem, especially in pandemic contexts.

> A major challenge will be to **continue sustained investment** in digital transformation across the vaccine ecosystem as Europe moves towards a post-pandemic era. The majority of the EU's political energy and financial resources related to vaccines are still directed towards COVID-19, with less attention being given to future-facing, sustainable initiatives that can improve the ecosystem surrounding routine vaccinations. The EU can support Member States in adapting existing EU-funded COVID-19 vaccination projects for use with routine vaccination strategies, creating **permanent digital improvements** to the European vaccine ecosystem.

The EU also has an impact on the vaccine ecosystem through the **EMA regulatory process**, including direct influence on the conduction of **clinical trials** and **manufacturing standards** and an indirect impact on purchasing, procurement, supply and distribution. (12) The decision-making process of the EMA also shapes the way that scientific and real-world vaccine data is collected across Europe, potentially laying the foundations for unified European standards for digital vaccine data.

THE INTERSECTION OF REGIONAL, NATIONAL, AND INTERNATIONAL POLICY LEADERSHIP

The EU's role in establishing frameworks within the European vaccine ecosystem creates complications for coherent multi-level development of digital vaccine infrastructure. While the EU, and to a lesser extent, WHO Europe, have a large role in setting data standards and managing cross-border emergencies in Europe, **the final authority over vaccination services remains with individual states or regions**.

> As the only stakeholders with direct contact with the end users of vaccines, national and regional governments are ultimately responsible for their own systems of procurement, logistics, distribution, and administration of vaccines and need to be supported in managing the digital transition of these systems. (13)

The challenges inherent to the existing division of healthcare competences within the European vaccine ecosystem were another reality exposed by the COVID-19 pandemic. As powerful as the EU is within the European vaccine ecosystem, the pandemic exposed the need for strengthened cross-border public health cooperation between both Member and non-Member States. Data about case numbers, the risks posed by travel, hospital and health workforce capacity, and vaccine supply chains was instrumental to creating effective cross border policy responses. As the spread of vaccine-preventable pathogens is not bound by national borders, this experience emphasises the need for ongoing collaboration on vaccines and related data between EU institutions, Member States, and other European states, which can potentially be achieved through the emerging European Political Community. (14) (15)

Greater data interoperability across different levels of European governance is also needed due to the importance of consistent messaging about vaccinations in the battle to combat vaccine hesitancy. When reports surfaced about possible dangerous side-effects associated with some COVID-19 vaccines, many European countries began to change their vaccination recommendations while others maintained that the vaccinations were safe. (16) This type of **inconsistent messaging** and **contradictory information** about vaccination from officials at different levels of government and across countries risks exacerbating **vaccine hesitancy** in Europe, but could be largely corrected with effective and accessible digital data systems that provide legitimate evidence to decision makers. (17)

The need for greater collaboration across levels of governance is also reflected in the pursuit of an international instrument on pandemic prevention, preparedness, and response by the World Health Assembly. (18) In giving the green light to start negotiations on an international pandemic treaty, the European Council explicitly recognised the importance of sustained political engagement, integration across policy areas, and a stronger international health framework that includes a stronger vaccination ecosystem for global pandemic preparedness. (19)

EUROPEAN VACCINE HESITANCY: LOCAL DIFFERENCES AND WIDER CHALLENGES

Europe has an incredible diversity of cultures across regions and nation-states, which makes it impossible to offer broad generalisations. However, the level of integration and free movement that define the nature of modern European economy mean that the vaccination challenges experienced in one country can easily spill over into its regional neighbours and even have impacts on the entire European vaccine ecosystem. The spread of vaccine-preventable, communicable diseases is not bound to follow the border regulations between EU and non-EU countries, so it is critical to consider the vaccine ecosystem of the entire region as a whole.

> Measles presents a valuable case study of the European vaccination experience. Measles is an extremely contagious disease that is preventable with a safe and effective vaccine, normally received as two doses during infancy in combination with rubella and mumps vaccine (MMR). However, in 2021 the WHO European Region had only 91% coverage of a second dose of measles-containing vaccine, below the 95% necessary to achieve herd immunity. (20) As a result of this sub-optimal vaccination coverage, many European countries have had a resurgence in measles cases in recent years, with Serbia, Ukraine, Georgia, Greece, Romania and Italy all having outbreaks of over 55 cases per million population between 2017 and 2018. (21) (22).

One of the most significant barriers to optimal vaccination coverage in Europe is vaccine **hesitancy** and **lack of awareness**, and the level of **distrust** of vaccines has wide variation across countries and even within countries. (23) Less than 10% of people in Finland agree with the statement “I think vaccines are not safe”, but that figure rises to 45.5% in France, indicating a degree of cultural influence on individual attitudes towards vaccination. (24) The widespread prevalence of vaccine hesitancy in Europe also had a significant influence on the progress of vaccination campaigns against COVID-19. As an example, Germany, Austria and Switzerland were largely successful in procuring vaccine doses and making them easy for citizens to access, but saw their vaccination coverage progress halted by social, rather than logistical or administrative barriers. (25) The cases of measles and COVID-19 indicate that **vaccine hesitancy is endemic to the entire European vaccine ecosystem** and that solutions to address it need to be developed to address regional and cultural differences.

Beyond a lack of confidence in vaccines, vaccine hesitancy is also influenced by the existence of local obstacles to vaccination affecting their **availability, affordability** and **accessibility.** (26) It is equally important to consider the impact that these administrative barriers to vaccination have on overall vaccination coverage in Europe. Ongoing projects like the European Health and Digital Executive Agency’s 'Service Contract to Identify Obstacles to Vaccination of Physical, Practical or Administrative Nature and Develop Recommendations' will be an important step towards understanding and overcoming these barriers, but it is essential that the recommendations generated are seriously considered by policy makers to overcome vaccine hesitancy in Europe. (27)

DIGITAL TRANSITION IN HEALTHCARE

Digital transition refers to the integration of digital technologies into all aspects of healthcare, including clinical care, administration, and communication. This can include the use of electronic health records (EHRs), telemedicine, mHealth, and other digital tools to improve patient care, reduce costs, and increase efficiency. Digital transition in healthcare can lead to improved patient outcomes, streamlined processes, and better collaboration among healthcare professionals. It can also help to reduce administrative burdens and enable patients to have more control over their own health. (28) Furthermore, the promising possibilities of personalized medicine will be enabled through the deployment of different digital solutions.

As Europe moves towards a post-pandemic era, there is a clear need for a **more robust health management framework** at all levels of governance to properly address existing challenges to vaccine provision. Europe's pandemic response demonstrated the power of **collaborative health leadership** to achieve public health goals, and by strengthening its capacity for cooperation Europe can expand upon this success and tackle the most complex obstacles to vaccination. It is also evident that there is an interconnected need to **harness** the benefits of Europe's accelerated **digital health transition** towards **improved accessibility, availability, interoperability** and **efficiency** across the vaccine ecosystem.

With these two lessons in focus, there is a significant opportunity for **policy action** that will harness digital transition to foster a sustainable vaccine ecosystem to safeguard good health and wellbeing for every person in Europe.

DIGITAL TRANSITION IN THE EUROPEAN VACCINE SYSTEM

Several aspects of the European vaccine ecosystem underwent a **digital transition** to adapt to the circumstances created by the pandemic, including the dissemination of immunisation information, the monitoring and surveillance of disease spread, the facilitation of vaccination programmes, the monitoring of adverse reactions to vaccines, and the documentation of vaccine delivery. This transition is exemplified by the European Centre for Disease Prevention and Control's (ECDC) COVID-19 vaccine tracker, which provides extensive data on COVID-19 vaccination coverage across different countries, regions and demographic groups. (29)

A significant aspect of the digital transition was a growing **interconnection of digital vaccination information systems** at regional, national and EU levels, allowing for greater data interoperability and coordination across governance systems. (5)

An important example of how digital transition was effectively leveraged to strengthen the European vaccine ecosystem is the implementation of EU digital COVID-19 **vaccination certificates**. These allowed for a streamlining of vaccination records and monitoring of adverse events at the population level, and in most cases a certificate issued by one European state or region was recognised as valid in international contexts. (5) As the infrastructure for these digital certificates was developed at the national level, they offer an opportunity for Member States to expand the use of this technology in a manner that is tailored to their unique environments.

> This could include the adaptation of the existing digital tools to incorporate health literacy campaigns, vaccine schedule information for routine vaccinations, and other evidence-based vaccination strategies suited to local contexts.

Efforts are already taking place to build upon the EU digital COVID certificates in the form of pilots for the implementation, integration, deployment and operation of Member State services in **MyHealth@EU**. These pilots seek to take advantage of the widespread use of smartphones and QR code technologies to facilitate cross-border healthcare covering the ePrescription and Patient Summary services, although vaccination history is not yet included. (30) The WHO Global Strategy on Digital Health 2020-2025 and OpenSky are both supporting these efforts by mapping the current state of digitalization in Europe, including the level of digital literacy among healthcare workers and the public, the availability of digital health services, and government support for digital health initiatives. (31) (32) The growing use of digital tools can have benefits across the vaccine ecosystem, but it will be critical to **foster uptake and public trust** by creating explicit distance between new digital vaccination services and existing negative perceptions associated with the EU digital COVID certificates, including their association with creating barriers to travel and public spaces.

Public trust is also a critical component of another major shift driven by the pandemic, the shift towards digital **data sharing** tools for the purposes of vaccine development, such as the OPENCORONA platform. (33) The fledgling European Health Data Space (EHDS) is grappling with this issue directly, as its development has come alongside constant questions about its ability to operate effectively while protecting individual rights and freedoms accorded under the General Data Protection Regulation (GDPR). (34)

> However, the **EHDS also represents the potential to ensure interoperability across the European vaccine ecosystem** by unifying the efforts of national and regional surveillance and monitoring systems for emerging pathogens and the sharing of data across borders to facilitate research innovation and the conduction of clinical trials. (35)

Despite the challenges to be overcome, it is clear that the development of the EHDS would benefit from policy considerations and provisions specific to **vaccination to ensure that the vaccine ecosystem is not left behind**.

ANALYSIS: THE CRITICAL ROLE OF HEALTH MANAGERS

Looking at the landscape of the European vaccine ecosystem and the lessons learned from our experiences with COVID-19, **deeper collaboration across stakeholder groups** appears to be one of the most essential concepts to target for intervention. As leaders in many of these groups, the responsibility for **facilitating this collaboration often falls to health managers**. In the aftermath of the COVID-19 pandemic, there is broad opportunity for the establishment of **new research and financing networks**, supported by enhanced digital tools that enable effective data sharing and co-creation. Health managers are uniquely placed to **coordinate these networks** in a way that capitalises on digital transition and strengthens the vaccine ecosystem. (36)

Health managers are well placed to identify existing **best practices for digital transition** within the European vaccine ecosystem and advocating for their adoption. As professionals who work across government, industry, academic, healthcare, and civil society settings, health managers have a uniquely broad overview of health system functioning and an inherent ability to identify practices and processes that might produce transferable results. (36) This role is essential for ensuring that concepts critical to successful digital transition, such as interoperability, are included in policy and practice development.

Importantly, health managers play a critical role in protecting health data privacy by implementing and enforcing policies and procedures to safeguard patient information. This includes ensuring compliance with national and EU regulations and implementing existing standards for protecting the confidentiality, integrity, and availability of protected health information. Health managers may also be responsible for conducting regular audits and risk assessments to identify potential vulnerabilities in the organization's information systems and implementing security controls to mitigate these risks. They are also responsible for training the health workforce in privacy and security best practices and ensuring that third-party vendors, such as electronic health record providers, comply with data security regulations. (37)

Health managers also have the essential task of **steering the conversation** around public health messaging and ensuring consistent, evidence-based communication during public health emergencies while avoiding messages that introduce further polarisation into the political climate surrounding vaccines. This role extends to providing healthcare providers sufficient **training in public communication and digital tools** to ensure that they can effectively adapt to digital transition and serve as effective agents of public health communication. (38)

For these reasons, the insight of health managers is already welcomed in ongoing stakeholder consultations for European digital health initiatives like the EHDS and important forums for discussion of these topics such as the Digital Health Society (DHS) & European Institute for Innovation Through Health Data (i~HD) Round Tables. (39)

This is also why it is important to **properly capture the perspectives of health managers** from across the European vaccine ecosystem and present them as a cohesive set of policy recommendations that can be referenced as we work to maximise benefit from digital transition.

THE HEALTH MANAGEMENT PERSPECTIVE: RESULTS FRPM THE SURVEY AND EXPERT CONSULTATIONS

Following the completion of the literature review and a workshop with the expert focus group, the following preliminary recommendations for policy makers and health managers were developed. To further refine these recommendations, they were put to health managers across Europe through a survey and a set of five individual consultation interviews to determine which recommendations fit which contexts, and if there was general agreement about the value of each recommendation at both the national and European levels. The survey received responses from 31 health managers representing professional practice in 27 different European countries, with five additional consultation interviews across five countries selected to provide a broad European perspective (see Figure 3).

The content and structure of the consultation interviews was largely driven by initial survey results indicating that certain recommendations were resonating much more with health managers than others. In particular, the first two recommendations presented about expanding the mandates of TRANSVAC2 and VACCELERATE and about changing the mandate of the EMA's Digital Business Transformation Task Force received a majority of negative or neutral responses compared with the other recommendations which all received a majority of positive responses.

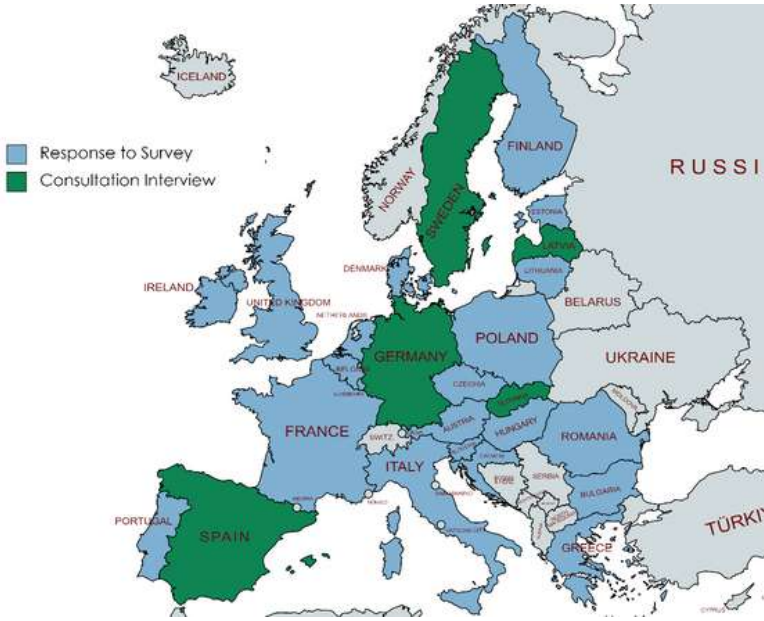

Figure 3. Geographical coverage of health manager survey and stakeholder consultations

The individual stakeholder consultation interviews allowed for a deeper dive into the factors that health managers consider as they navigate digital transition in the European vaccine ecosystem. It became clear through their responses that policy recommendations based on specific platforms or services offered little practical value to their day-to-day work with vaccination programmes. Only one of the experts consulted had any experience with the TRANSVAC2 and VACCELERATE platforms, and all agreed that specific platforms should not be a direct focus of policy action. The experts also all agreed that the EMA's Digital Business Transformation Task Force was not the right vehicle for ensuring a fit-for-purpose EU regulatory environment, preferring support for existing national initiatives over EU-level oversight.

The most widely agreed recommendations, both through the survey and the consultations, were those related to the **inclusion of vaccine-specific considerations** in the development of the **EHDS** and the creation of frameworks for **managing digital transformation at a national level**. Health managers expressed the need for digital systems that are adequate for the practical demands of their work, and specifically pointed to the need for accessible databases that are connected and interoperable, both within and across national borders. These interoperable databases would ideally allow for broad data sets to be stratified and consulted based on the exact needs of a planned vaccination initiative, giving health managers access to European data and best practices on how to

improve vaccination coverage for specific populations. The platforms used to host these databases also need to be developed in consultation with the professionals who will be using them to ensure that they are fit-for-purpose. One expert outlined the importance of **pilot testing the eventual EHDS platform** in different regional contexts to allow for necessary practical adaptations between different healthcare systems, as there is a wide variance in current digital capacity across European states.

> The need to consult health managers in the development of digital platforms extends to the importance of ensuring a smooth transition for the health workforce. Digital transformation will not be successful without **proper up- and re-skilling of healthcare professionals**, which requires adequate strategic planning.

Health managers also expressed the importance of **including the right vaccination data** in new digital systems. Several case studies emerged through these discussions, highlighting a general lack of information about the availability of certain vaccines and vaccination practices in different countries. With larger migrant flows and the re-emergence of diseases like tuberculosis and diphtheria in Europe, health managers need easy access to up-to-date information about how these diseases are being in other contexts and which vaccines they might have access to in case of an outbreak. A general lack of dialogue between health managers and industry about the status of the wider vaccine pipeline also disrupts the planning of public health initiatives, as health managers are often unable to anticipate vaccine shortages or the emergence of new products on the market. Having additional access to European data about efficacy, safety and cost-effectiveness would allow for further granular planning at the local level.

To further support the practice of health managers through the digital transformation, several experts expressed the need for **continuous, ongoing evaluations** of commonly deployed digital tools such as apps for monitoring and surveillance, digital communications to support vaccination programmes, and **digital monitoring** of adverse effects to vaccines.

> In many national and local contexts, financial and logistical support is needed to conduct these evaluations and ensure that new digital initiatives are having the desired positive impacts on vaccination rates and citizen well-being.

FINAL POLICY RECOMMENDATIONS

The Vaccine Ecosystem Initiative outlines four guiding themes around which clear recommendations for actionable change to vaccine ecosystems can be structured. Although the European context differs in several ways from the global context in which these themes were developed, they still provide a meaningful framework for providing policy recommendations based on the discussion included in this paper. These themes are a focus on **political will**; enhancing leadership and collaboration; fostering and enabling vibrant **innovation** efforts to increase system-wide **preparedness**; and nurturing **trust** in vaccines.

Based on these themes and supported by a comprehensive literature review and analysis, a focus group workshop, a survey of health managers across Europe and individual expert consultations, we believe the final policy recommendations presented below will promote the continued expansion of **evidence-based policy on digital transformation and strengthen the European vaccine ecosystem**. These recommendations will be disseminated through various health management practice networks and at relevant events.

Policy makers at the EU level should:

1. **Consult** with vaccine researchers, health managers, industry leaders and national policy makers to ensure that the implementation of the **European Health Data Space includes provisions for collecting, sharing, and using relevant data** regarding vaccine development, deployment and effectiveness.
2. **Commit** to making vaccination data **accessible** in a way that promotes cross-border i**nteroperability**, innovation and evidence-based policy development while ensuring that **citizens retain ownership** of their data.
3. **Work towards broader European cooperation** on vaccines by creating provisions for non-EU states to access EU digital tools supporting vaccine research programmes, data collection platforms for vaccine surveillance and monitoring, research, and mutual learning facilitators like the EU Best Practice Portal.

Policy makers and health managers at all levels should:

4. **Support** the implementation of **up- and re-skilling initiatives** for the healthcare workforce, such as the BeWell project, across Europe to ensure that health professionals have the training and resources they need to effectively adapt to digital transformation in the vaccine ecosystem.
5. **Create a framework** for transforming the infrastructure created for the EU Digital COVID Certificates into **broader digital tools supporting vaccination**, either through MyHealth@EU or a tailored national solution. This framework should facilitate cross-border data sharing and offer citizens information about schedules, accessibility, and safety for routine vaccinations to facilitate evidence-based communication strategies for overcoming existing obstacles to vaccination.
6. **Implement standards** for scaling up digital vaccine management, including the monitoring and maintenance of vaccine supply chains and storage facilities to facilitate efficient procurement, simplify logistics, and reduce waste.
7. **Support further research** exploring the **impact, efficacy** and **cost-effectiveness** of digital technologies in the European vaccine ecosystem.

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