Study on Digital Health implementation in the EU

Final Report

April 2022

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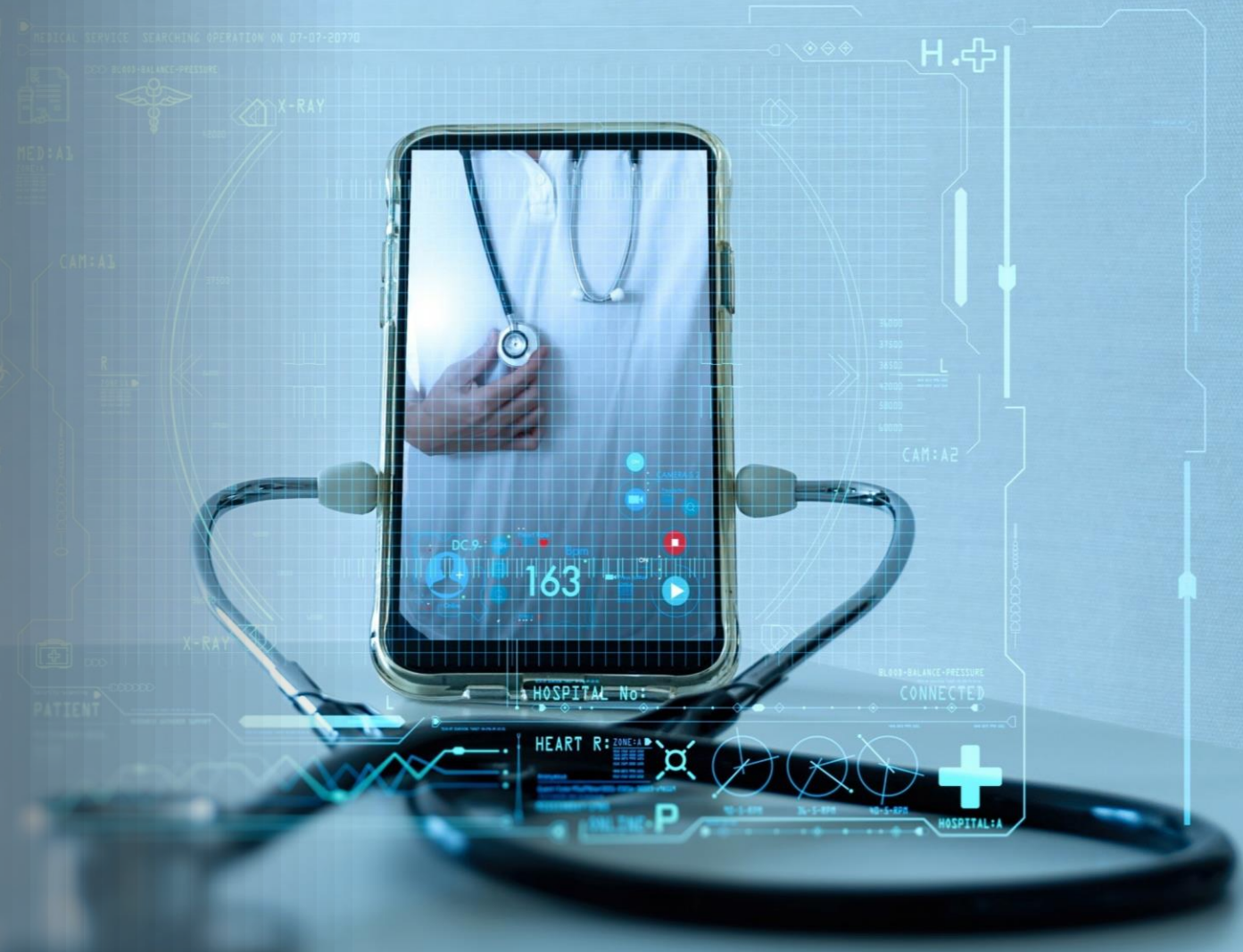
Executive Summary



Executive Summary (1/8)

Background

Healthcare is one of the most promising fields of application for digital technology. Indeed, it impacts all dimensions of the health system: care practices of health professionals, optimization of care pathways, research and development, etc. Last but not least, digital technology is a vehicle for empowering citizens, which means making them more responsible for managing their health and using their health data.

The COVID crisis has only heightened awareness of this reality and has indirectly contributed to the credibility of e-health initiatives, both among professionals and the general public, as shown by the skyrocketing of teleconsultations in the last 2 years.

However, digital health raises many side questions, notably about ethics. The massive use of personal health data means that their protection and proper use must be secure. At the same time, access to digital technology is still very unequal among the general public, and the goal of inclusiveness must be embedded into public policies that are intended to develop digital solutions "designed for and by citizens" and in accordance with shared ethical values.

The subject is therefore becoming pivotal in the health strategy of States and, during its EU Presidency, France has wished to promote an ambitious drive for the development of digital health, building on the achievements and lessons learned from the many existing initiatives, and paying close attention to ethics, which is a prerequisite for the legitimacy of digital applications.

To set the stage, the Ministerial Delegation for Digital Health of the French Ministry of Solidarity and Health, in coordination with the EU's DG SANTE, has tasked EY with performing a comprehensive overview of Digital Health in Europe, focusing on ethics and highlighting best practices

Executive Summary (2/8)

Methodology

The study was carried out in 3 stages:

- First, we took stock of the regulations in force at European level re: digital health
- Second, the development of Digital Health was studied in 29 European countries (the 27 Member States + Scotland and Norway) to provide an overall assessment of the current state of play in Europe. This work has been mostly based on desk research and on the knowledge of each national context by our network of EY European health experts.
- Lastly, we looked deeper into ethical issues, by interviewing national Digital Health representatives of 15 countries reflecting European diversity (size, geographical location, organization, etc.)

The state of play is based on an analysis grid which revolves around the five guiding principles of a digital health strategy: (1) Digital health governance (2) Security and interoperability of information systems (3) Deployment of core digital services (4) implementation of digital platforms for the use and sharing of health data (5) Support for innovation and the buy-in of all stakeholders involved.

In order to draw up a picture that is both comprehensive and based on objective, comparable factors, the five guiding principles have been broken down into 120 criteria.

Ethics cuts across all five of these guiding principles and has been analyzed from four complementary perspectives: (1) Base Digital Health on humanistic values (2) Enable individuals to manage their Digital Health use and data (3) Make Digital Health inclusive and accessible to all (4) Implement eco-responsible Digital Health.

The current state of the 29 countries has been summarized on four sheets per country, which we call a “country profile”. This country profile is our best assessment as an outsider as we did not have enough time to contact national representatives and get formal confirmation from the relevant public authorities.

It is a snapshot of a moment in time. Indeed, this analysis should not be perceived as a value judgment on the relevance of the approach or the ambition of each country in digital health. It is a state of play, not a benchmark!

Executive Summary (3/8)

European regulations in force

As for the European regulations in force, we have identified a base of 44 regulatory documents governing digital health in Europe, related to 7 major topics: Ethics, funding, governance, interoperability, data management, data privacy, and security. They have been broken down by coerciveness: Binding legislation, binding acts, non-binding frameworks, and Advisory and information documents. On this basis, we have ranked the topics by their level of regulation maturity.

The most mature areas are security, data protection, and data management. They are largely covered not only by general regulations but also by principles specific to the health sector.

Conversely, governance and funding of Digital Health are associated with relatively few regulations, which is attributable to the fact that Healthcare falls under the responsibility of Member States. However, areas for improvement at the European level were identified.

Interoperability sits in between these extremes.

Finally, this analysis underlines that ethics remains largely unexplored at the European level, even though some cross-sectoral regulations are observed and applied to Healthcare. Thus, this first snapshot on regulations highlights how necessary it is to address ethical dimensions.

Executive Summary (4/8)

Overall state of play (1/2)

Let’s note that digital health is a stated priority in all European countries, and is already a reality even though the available features and their effective use vary considerably from one country to another. This is obviously not a surprise, especially since the pandemic drove patients and providers to adopt digital health services, heightening awareness of the value of digital technology to both the healthcare system and the patient.

Its deployment is therefore proceeding at a particularly brisk rate, although still uneven in terms of the objectives pursued, its scope of application, the governance and management bodies and mechanisms in place, the services offered to citizens and patients, and also, and perhaps above all, the rate of actual use of these services by citizens.

Each country has designed its own digital health roadmap and is rolling it out at its own pace. As already pointed out, it is not a benchmark and the point here is not to compare the merits of the various national agendas, but to take a snapshot of the current state of digital health deployment, putting it into perspective and analyzing it through the filter of the various guiding principles and criteria mentioned above.

The key findings and main trends are presented and analyzed in our final report. In this summary, we will limit ourselves to giving the most relevant "macro" insights:

- Almost all countries (25 of the 29 countries surveyed) have established an explicit national Digital Health strategy associated with a roadmap to deploy solutions. Almost two-thirds have appointed a dedicated agency in charge of implementing Digital Health projects.
- Nevertheless, not all involve health professionals’ representatives and only a few include users’ representatives in their governance bodies.
- The objectives pursued are quite similar: (1) Deployment of core services to the general public, either through digital services or by giving access to platforms where health data are stored, (2) Improving patients’ empowerment.
- The main focus is on basic features, such as the National Patient Record, which is the priority service for the majority of European countries and is the core building block and driving force of the digital health strategy. Other priorities are e-prescribing (already mandatory in 5 countries), secure identification of professionals, and secure messaging systems between patients and professionals.
- The deployment of digital health platforms at the national level is a widespread practice: 20 countries have already deployed a national portal allowing citizens to access their data. To achieve this purpose, securing the identification and authentication of patients and professionals is a prerequisite and a top priority. The portal can provide a large range of services, for example, e-prescription services, pharmaceutical databases, patient data repositories, patient records, services to register as organ donors, etc.

Executive Summary (5/8)

Overall state of play (2/2)

- Nonetheless, the scope and features of these platforms greatly differ between countries. Some countries only provide a health data viewer, when others provide a comprehensive platform allowing the citizens to take actions on their health. In this regard, areas of improvement remain with respect to the platforms' scope of services and the portability of health data
- It must also be noted that a majority of European countries have established a regulation on the secondary use of health data and many have already set up a national platform dedicated to this purpose.
- Interoperability frameworks based on widespread international standards (such as SNOMED-CT, HL7 FHIR or HL7 CDA R2) are already implemented in 22 countries. Likewise, 25 have developed a Digital Health security framework. Although these frameworks do exist, it must be noted that the extent of their deployment is quite uneven and that only 45% of countries have made all or some of these frameworks enforceable with a compliance obligation. In other words, several countries are not yet able to ensure that the digital health solutions comply with the security and interoperability frameworks. Therefore, interoperability remains a clear issue throughout Europe which is illustrated in some projects, such as MyHealth@EU which aims to allow cross-border health data exchanges.
- Although regulation and reimbursement remain the priority levers to accelerate the deployment of Digital Health innovations, many national and European programs financially support Innovation. Specifically, 21 countries offer funding dedicated to digital innovation in health and 18 countries participate directly in its development through public research programs.
- As a result, innovation is today at the core of the Digital Health ecosystem and many businesses and players are framing and implementing solutions based on new technologies such as connected devices and AI.
- The current state of play is a mixed bag of various types of initiatives, which underlines that a lot of work has yet to be done to deploy and use Digital Health innovations. One of the issues is that regulation must keep pace with innovation. Innovation is potentially limited by a lack of enforceable regulations, specifically in innovative areas such as mobile health, digital therapies and technologies such as big data or AI. But States must first understand their impacts before regulating them and invent innovative reimbursement models appropriate for these technologies.

Beyond these macro insights, **there is enormous potential for cross-fertilization between all the experiments and initiatives of the Member States**, through the dissemination of best practices, and potentially the adoption of turnkey solutions.

Executive Summary (6/8)

Focus on ethics (1/2)

To go directly to the point, for now, few countries are explicitly and systematically addressing issues related to ethics. Less than half show a strategic ambition concerning ethics in Digital Health, associated with operational objectives for national initiatives.

Regarding the first dimension which is to "**Base Digital Health on humanistic values**", we note a real willingness to better involve citizens in the definition of Digital Health solutions or to ensure that data are processed with respect for ethics and citizens' privacy. However, this willingness is yet to be operationalized into tangible actions in many countries.

Indeed, there are disparate approaches to the consideration of humanistic values in digital health. While a majority of countries have already implemented a national portal to store and share health data, few have relied on ethical frameworks for its design and established rules of use that are fully consistent with humanistic values. Likewise, only a minority of countries have set up ethics committees dedicated to digital health, mainly focusing on innovative developments.

The second dimension of ethics is to **enable individuals to manage their Digital Health tools and to control the use of their health data**.

Involving end-users – both professionals and citizens – in the design of digital solutions is the best way to prepare the ground and meet their expectations and needs. While a majority of countries are already getting health professionals advocacy groups involved in shaping digital health, only a few are including representatives of citizens.

Moreover, although most countries have deployed national platforms, the depth of features differs from country to country. For example, downloading data from the platform is not possible everywhere, and adding patient-generated documents is a feature available only in a few countries.

Finally, to have full control over their data and manage them according to their needs, citizens must be able to access and share them in a reliable and secure way. Interoperability is therefore a sine qua non condition. But, as already mentioned, interoperability remains an issue in many countries, which limits the availability of citizens' data.

Executive Summary (7/8)

Focus on ethics (2/2)

Accessibility and inclusiveness emerged relatively recently as a topic of interest but the level of maturity is quite good. Indeed, countries and the EU have historically established general accessibility frameworks, regulations and guidelines that apply to Digital Health, though without encompassing all its aspects (in particular, new innovative solutions such as mobile applications or AI-based solutions).

The initiatives underway in the Member States fall mainly into two main categories: (1) Providing an multichannel access to their Health Data to citizens with no possibility to use Digital Health by themselves, usually through a physical point of contact in which they can access a computer and be helped (2) Improving digital literacy by training and education.

A few countries are resorting to new digital technologies to close the digital divide. The assumption is that the more automation is provided, the less digital literacy is required from the end-users. Tangible use-cases have been developed, such as, for instance, tele-monitoring devices.

However, there is still a long way to go.

Finally, the fourth dimension is the **eco-responsibility of digital health** so as to comply with the overall European effort to reduce carbon emissions and mitigate climate change.

European direct initiatives on Digital Health sustainability are rather new and scattered. There is in fact very little scientific basis for addressing this topic.

However, it is fair to underline that the indirect impact of Digital Health on the overall carbon emission related to the health sector is significant. Indeed, telehealth reduces transportation carbon emissions. Early diagnosis, optimization of care pathways, reduction of the number of medical procedures, etc., all contribute to global sustainability.

To conclude this “focus-on-ethics”, we emphasize that the Member States have developed a lot of transposable best practices. This portfolio of best practices could serve as a basis for a proactive action at a national or European level.

Executive Summary (8/8)

The way forward

As this study shows, there is a tremendous momentum in Europe to accelerate the deployment and use of Digital Health.

What are the main avenues to foster this momentum?

- Firstly, all countries are facing the same challenge: getting citizens involved in digital health. To do this, they must involve all categories of citizens in the development of services, strengthen communication and training to enhance the digital literacy of the population, promote practices, and reduce the digital divide. And there are unavoidable ethical prerequisites to gain the trust of citizens. Each country has its own roadmap. However, unique opportunities do exist to dialogue on best practices, cross-fertilize ideas and build-upon the successes of other countries.
- Secondly, a common challenge is to develop semantic and technical standards at European level that will facilitate the exchanges of health data. “My Health@EU” and the future “European Health Data Space” are the frameworks structuring the European Digital Health policies and are the right vehicles to conduct such initiatives.
- Finally, the development of a more sustainable and responsible digital health system is a field still largely unexplored and undocumented. Some lines of action have been identified in this study. Again, these prospective and medium-term initiatives should be led at the European level.

Summary

Context of this study

Context

The French Presidency of the Council of the EU wishes to promote an ambitious agenda on Europe-wide Digital Health issues

Ethics is a prerequisite for building and implementing a strategy

European initiatives in the field of ethics in Digital Health must be leveraged

Main objectives of the study

A comprehensive overview of Digital Health in Europe, with a focus on ethics, to highlight best practices through 3 levers:

State of play on regulatory issues through an in-depth analysis of existing documentation and grey literature

... to better identify the scope of existing regulatory texts, their cross-references, and to provide recommendations

Assessment of countries around 5 guiding principles and 4 ethical dimensions, highlighting findings, best practices and key trends

... to perform an exhaustive analysis of quantitative and qualitative feedback by topic and by country

Feedback collection from EU countries on implemented initiatives and identification of priority areas for improvement at the EU level

...to identify strategic issues which require to establish targets and relevant actions must be carried out at the EU level

Study's scope

1 Desk research and EY network feedback

The development of Digital Health has been studied in 29 European countries -the 27 Member States, Scotland and Norway – to provide a comprehensive overview in Europe.

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Desk research covering 29 countries

2 National representatives consultation

National Digital Health representatives from 15 countries have been interviewed to build a first overview of current practices regarding ethics in Digital Health.

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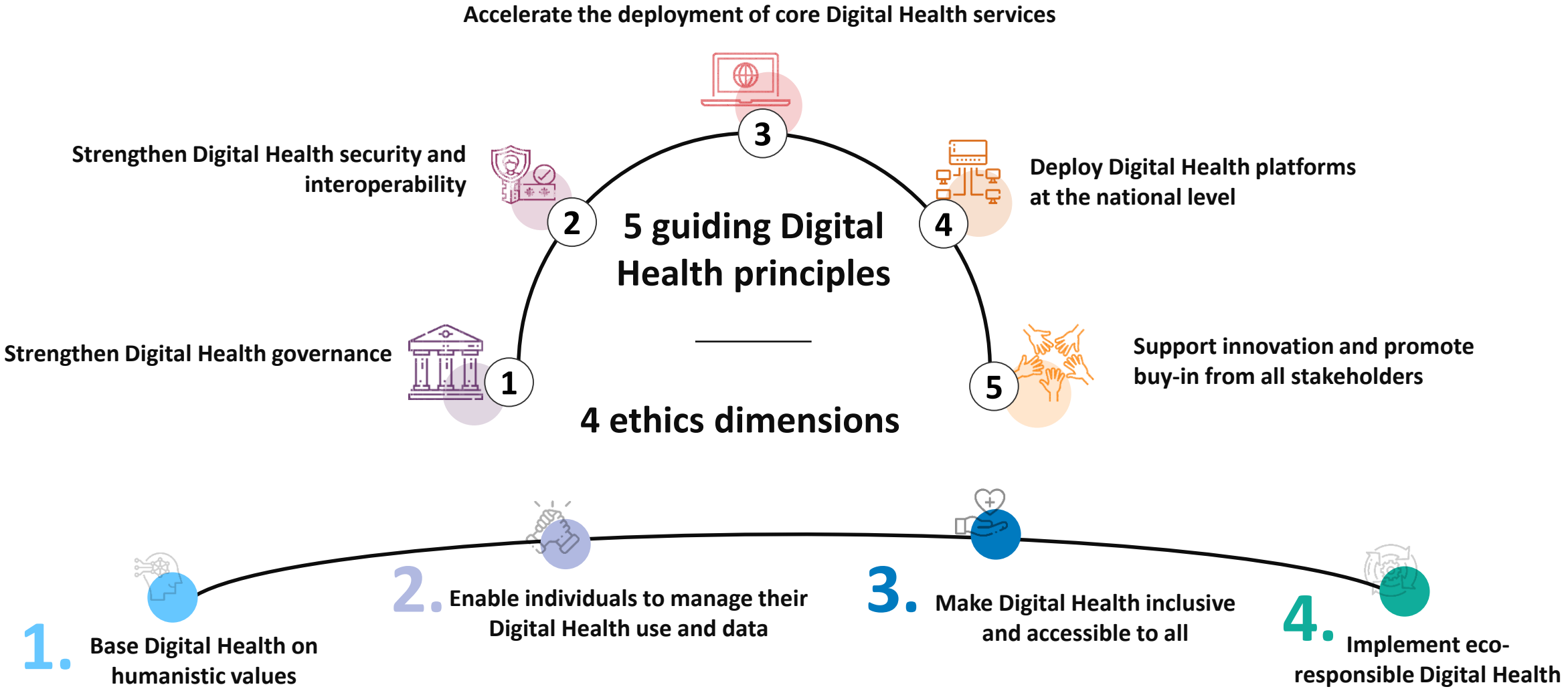
Consultation with delegates from 15 countries

5 guiding principles and 4 ethics dimensions



Summary

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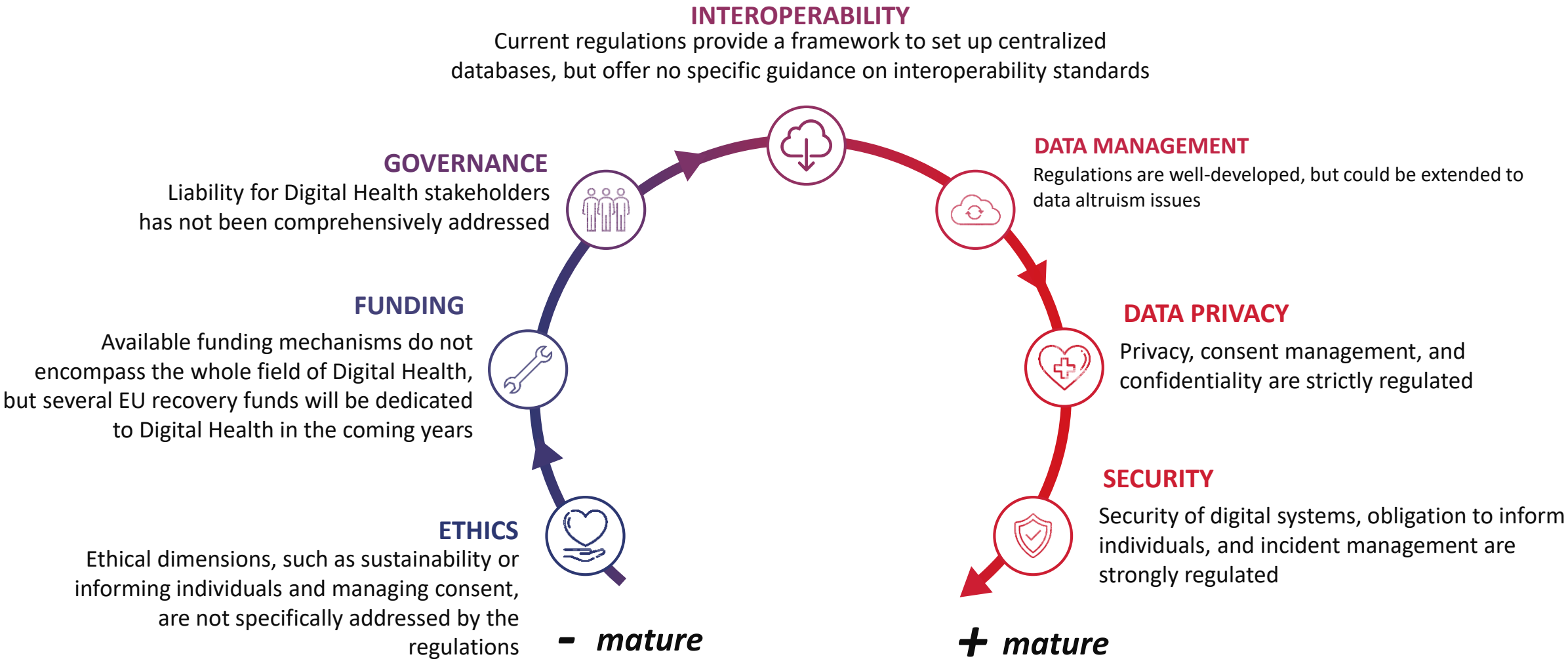
Desk research covering 29 countries

State of play of European regulation in the field of Digital Health



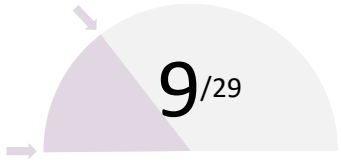
Guiding principles: key findings and main trends (1/5)

Desk research covering 29 countries

Strengthen Digital Health governance

Digital Health governance is **taking shape through legislation and dedicated organizations**, but individuals are not yet fully involved

have defined a national Digital Health strategy



include user representatives in their governance

Strategies and governance bodies of European countries are mainly focusing on the deployment of core national services. Such deployment also requires the implementation of security and interoperability frameworks regarding the data stored and shared. More recently following the COVID crisis, the deployment of telemedicine has been included in these roadmaps.

To do so, almost 2/3 of the countries have a dedicated agency in charge of implementing Digital Health projects.

Some EU countries have set up committees including health professionals and/or patient representatives, and providing practical advices on the use and/or assessments of Digital Health solutions.

National digital health strategies focus on developing portals and solutions to **put patient empowerment first**

have a strategic roadmap setting national Digital Health targets

propose tools to strengthen individuals' participation in the health decisions which impact them

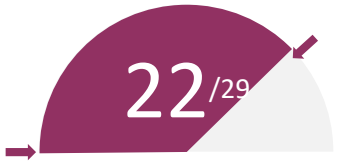
Patient empowerment has been placed at the center of several strategies. To support this ambition, countries head towards the creation of patient-centered health systems. As an example in some countries, there is an electronic health card that allows the patient to decide which medical data they want to store.

Guiding principles: key findings and main trends (2/5)

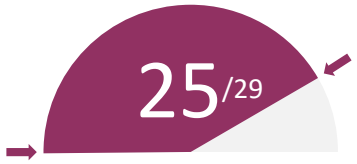
Desk research covering 29 countries

Strengthen Digital Health security and interoperability

Most countries are committed to adopting **security and interoperability frameworks** based on international standards

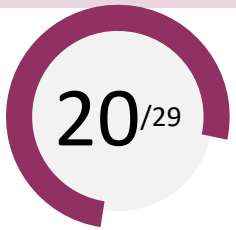


have created an interoperability framework (mainly based on SNOMED-CT, HL7 FHIR or IHE profiles)



have developed a Digital Health security framework, 56% of which have made it mandatory

Although regulations have been published, projects and organizations **allowing the secondary use of data are not yet implemented**



provide dedicated regulation on secondary use of health data

have a national infrastructure to collect and host data for secondary uses

Two-thirds of the countries have already implemented national interoperability frameworks for their digital solutions, which are mainly based on SNOMED-CT, HL7-FHIR, and IHE profiles. However, the extent of deployment is quite heterogeneous and only 45% of countries have made all or some of them mandatory.

Most countries have implemented a national security framework, but less than half of them apply financial coercive and/or incentive means to ensure compliance of information systems.

Most countries also rely on European projects to implement their frameworks in a consistent way with the European level – especially for the NCPeH project.

Less than half of the countries already provide a national structure dedicated to hosting and managing health data.

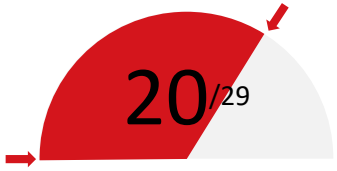
In some of these countries, a national agency is responsible for issuing data permits for the secondary use of health and social data in a centralized manner. This agency is responsible for processing data requests and providing the data.

Guiding principles: key findings and main trends (3/5)

Desk research covering 29 countries

Accelerate the deployment of core Digital Health services

Countries are engaged in providing **national public services to support** secure, structured **data exchanges**



rolled out a nationwide Digital Health secure messaging service

rolled out a national healthcare provider identification service

National Digital Health roadmap prioritize the deployment of **national portals to improve data sharing**

deployed a national Digital Health portal allowing individuals to access their data

rolled out a national platform dedicated to secondary use of health data

The e-prescription service is mostly deployed in European countries and even mandatory in 5 EU countries. Secure health messaging service for healthcare professionals is widely implemented in Europe, although it is not as important as the e-prescription service.

Secure health messaging service for individuals is not well-developed in Europe. However, some initiatives have been implemented, such as mobile applications allowing patients to securely exchange messages with their general practitioner, attend teleconsultations, and easily access their health documents.

Even though most of EU countries set up a national EHR, some countries have built a decentralized health system. Consequently, some services are managed independently and could be deployed in a heterogeneous way between the regions.

Implementation of a National Patient Record is a priority for most countries; however, disparities still appear. Some countries are still at a planning stage, others just started implementation, whereas strong deployment is observed in some Member States which stand out with many documents already gathered in their patient record.

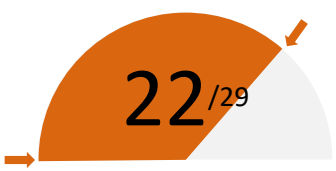
Whether Digital Health is governed at the regional or the national level, many countries have implemented Digital Health platforms which are widely used and provide a large range of services. They include, for example, e-prescription services, pharmaceutical databases, patient data repositories, patient records (consultations, references, test results), services to register as organ donors, a proxy service, and a screening service.

Guiding principles: key findings and main trends (4/5)

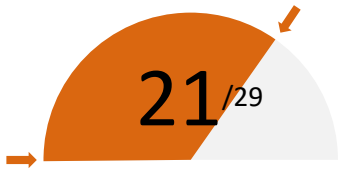
Desk research covering 29 countries

Deploy Digital Health platforms at the national level

Frameworks have been defined and services are provided to secure the **identification and authentication** of patients and healthcare providers



enforce a minimum guarantee for electronic identification to Digital Health services



provide means to identify healthcare professionals

Countries are engaged in providing individuals portals to **access and manage their health data**

provide patients with effective access to their health data

give access to a service allowing individuals to download their health data

To ensure secure access to national digital platforms, most countries use a centralized electronic identification system for individuals to connect. All but 1 of the Member States provide a unique individuals health identifier.

Healthcare professionals and legal entities index in centralized directories are quite well-implemented at national level and allow individuals to easily find the service they are looking for.

Even though the GDPR has supported significant progress on access to data, a significant number of countries is not complying with the regulation. Indeed, data portability is far from being assured with less than half of the Member States allowing individuals to download their data.

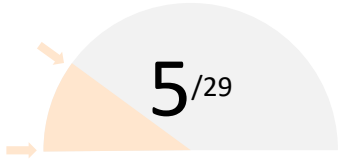
Guiding principles: key findings and main trends (5/5)

Desk research covering 29 countries

Support innovation and promote buy-in from all stakeholders

Telehealth is now widely reimbursed and financed but **regulations do not comprehensively address** AI and mHealth

reimburse telemedicine appointments, and 38% reimburse mHealth services



have enforced regulations on the use of AI for health

Innovation is supported through **national and European funding programs**

offer specific funds and financing for innovation in Digital Health

support the expansion of Digital Health through public research programs

Telemedicine implementation and related regulation have been quickly established during the Covid crisis. Regulations on new technologies such as mobile health applications, digital therapies, or Artificial Intelligence could be fostered.

Several countries enforced a regulation allowing the reimbursement of mobile health and several countries enforced a regulation allowing the reimbursement of digital therapies.

The vast majority of EU countries support and encourage health innovation in various ways. Some countries already have very strong training and acculturation to innovation, others are developing programs and projects to foster innovation.

For example, some countries have created incubators or launched programs with the aim of fostering innovation in the field of Digital Health with a focus on the development of new digital therapy applications or artificial intelligence.

Key findings regarding the overarching ethics dimensions

1. Base Digital Health on humanistic values

13/29

show a strategic ambition concerning ethics in Digital Health, associated with operational objectives for national initiatives

2. Enable individuals to manage their Digital Health use and data

7/29

offer a unified data collection system for research and care consent as well as dedicated regulation on the topic

3. Make Digital Health inclusive and accessible to all

11/29

provide communication or specific supporting actions to bridge the digital divide

4. Implement eco-responsible Digital Health

5/29

include sustainable development in their Digital Health strategy

Summary

Study's scope

2 National representatives consultation

National Digital Health representatives from 15 countries have been interviewed to build a first overview of current practices regarding ethics in Digital Health and to supplement the comprehensive overview led during the first phase.

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Scope of study: Consulting national representatives

2 Consulting national representatives

National Digital Health representatives from 15 countries have been interviewed to get a more thorough view of current practices regarding ethics in Digital Health.

The objective was to refine the comprehensive overview of the first phase, to detail and illustrate the observations made with a sample of practices or situations encompassing the 4 ethical dimensions analyzed.

3 main reasons have driven this selection:

Restrict the scope to meet the deadlines but with enough diversity to capture patterns representative of the topic

The ambitious agenda of the French Presidency resulted in tight deadlines between the first phase and the presentation to the European representatives. Therefore, it was necessary to select only a few countries reflecting European diversity regarding their size, their geographical situation, their centralized/decentralized organization, etc. Obviously, the approach was not to exclude countries, but rather simply to be representative of the diversity of EU countries.

Collect as many as possible relevant best practices in an efficient way

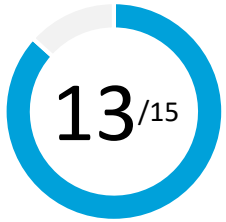
The countries have been selected according to how easy it was to get in touch with them as well as our prior knowledge of initiatives and best practices already carried out on the field of ethics. An initial scope of 5 countries has been gradually extended to 15 countries (the maximum scope possible for the study) to grasp as many best practices as possible in this field.

Provide a preliminary analysis to be supplemented later

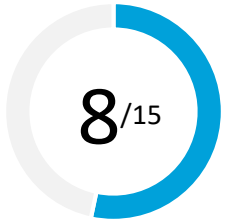
This analysis remains preliminary, without intending to be a basis for decision-making. Rather, it aims to uncover possible ways forward for further study, and to assess Member State-level initiatives and actions carried out involving the 4 ethical dimensions. An exhaustive analysis will be performed prior to monitoring the implementation of European ethical principles for Digital Health.

Base Digital Health on humanistic values (1/2)

Countries have deployed Digital Health platforms to support data exchanges, however not fully designed according to ethical guidelines

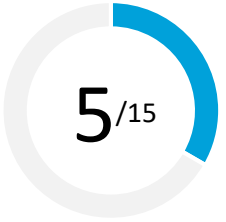


have implemented a centralized portal/system to make it easier to exchange and gather data and provide information to citizens

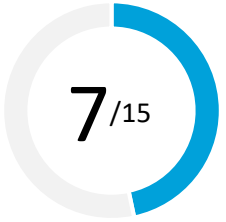


have implemented guidelines/frameworks regarding ethics in Digital Health

Several countries have implemented ethics committees dedicated to Digital Health and more especially to innovative solutions



have implemented ethics committees specifically addressing challenges involving AI development



have implemented ethics committees addressing challenges involving data and/or information systems in health

EU REGULATION LANDSCAPE

- Minimal and reasonable use of health data is a subject that has not yet been addressed at European level (beyond the minimization principle of the GDPR)
- Transparency regarding the collection and use of data is addressed by several documents. However, implementation methods (particularly in terms of standards and control) have yet to be defined.
- Criteria have been set for fundamental rights in the use of health-related technologies, but no regulatory obligations are in place.
- To date, the confidentiality of user data is regulated by a general framework at the EU level, but not one specific to the field of health, where national regulations prevail.
- The issue of civil, governmental and corporate liability is not being addressed in a comprehensive manner (and in particular with regard to the development of AI or DTx
- Educating and informing citizens about risks associated with the use of their personal health data is a sensitive issue that has been identified by the European Union.

Base Digital Health on humanistic values (2/2)

Consultation with 15 countries

Base Digital Health on humanistic values

Member States level initiatives

Health portals to provide services improving the overall efficiency of care

- Health portal include information and advices allowing individuals to better understand their health and data (e.g. explanation of blood test results)
- Individuals can electronically ask for the renewal of their prescription
- Individuals to healthcare providers secure messaging services are provided to support exchanges between appointments

National platforms to share pseudonymized data for research and AI development while ensuring individuals' privacy

Ethical guidelines shared with Digital Health solutions providers

Ethical guidelines implemented to promote:

- Data transparency, procedures, and decision processes
- Supervision and traceability of algorithms and data
- Respect for fundamental rights when using AI
- Fair and responsible collection of data

Key areas for improvement

No European mandatory framework containing ethical principles for the design and use of Digital Health solutions and services

Health professionals may not always have an active interest in recording and sharing patient data in national systems

Possible ways forward

Creating certifications for Digital Health providers to ensure ethical processing of personal data

Allowing individuals to share their own data, maybe even by including them in a European Digital Identity Wallet

Legend

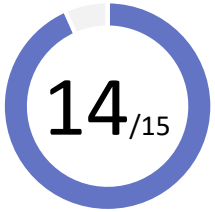
High priority *Medium priority* *Low priority*

Enable individuals to manage their Digital Health use and data (1/2)

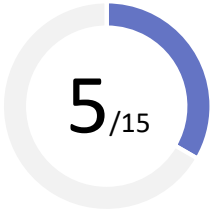
Consultation with 15 countries

Enable individuals to manage their Digital Health use and data

The majority of countries studied have implemented a platform for individuals to access their health data and Digital Health services

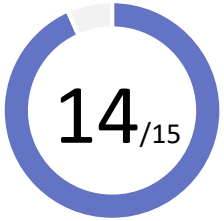


include health professionals in the definition of Digital Health (e.g., groups, associations, etc.)

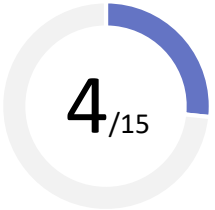


include individuals in the definition of Digital Health (e.g., groups, associations, etc.)

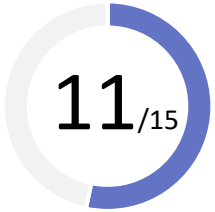
Although strong work has been observed regarding the implementation of national interoperability standards, there are progress margins to improve individuals ownership over their health data



have implemented (6) or are currently implementing (8) a national interoperability framework for Digital Health



allow the addition of patient-generated health data through their national platform



allow the downloading of health documents through their national platform

EU REGULATION LANDSCAPE

- Secondary use of data is a subject governed by European Union regulation. The future directive defining the European Health Data Space will provide a dedicated regulation for health data.
- There is a real ambition to define interoperability standards at the European level. While standards do exist, regulations setting out norms to be applied by all States and the industry have not been proposed.
- Regulations on health data sharing are well-defined in the European Union. However, data altruism is poorly addressed or regulated and could be an important challenge to address.
- Data portability, i.e. the ability to retrieve one's data in an open and readable format, is regulated in clear terms.
- The notion of technology assessment is addressed in several documents, some of which are specific to Digital Health.

Enable individuals to manage their Digital Health use and data (2/2)

Consultation with 15 countries

Enable individuals to manage their Digital Health use and data

Member States level initiatives

Patient advisory board co-designing the national health portal's features

Some Digital Health platforms include in their governance an advisory board:

- involving all health stakeholders
- helping design the portal's features

Individuals can prevent healthcare providers from accessing sensitive documents

Access to health records or portals often managed by individuals, with ability to:

- Prohibit access to particularly sensitive or chosen data
- Add data themselves
- Control data access based on a "therapeutic relationship"

Decentralized data exchange system built upon a national index of health data

Some countries provide a national single access point associated with a national health data index. It allows individuals to access all their data while preventing data redundancy by hosting data at the point of care.

Key areas for improvement

Lack of common standardization across the European Union

No European e-ID that supports cross-border data exchanges

No real process to listen to individuals and report their wishes

A lack of representation of the overall population (e.g., youth, healthy individuals)

Possible ways forward

Supporting Member States in deploying shared semantic standards and support the use of common technical standards for structured data exchanges

Creating and fostering a single European e-ID

Ensuring that all individuals are represented when building a Digital Health service

Legend

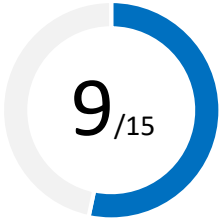
High priority *Medium priority* *Low priority*

Make Digital Health inclusive and accessible to all (1/2)

Consultation with 15 countries

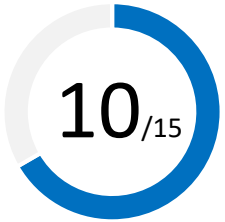
Make Digital Health inclusive and accessible to all

Most of the countries studied have implemented mandatory accessibility regulatory frameworks

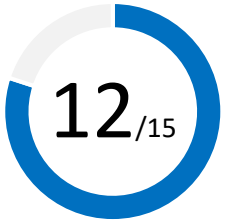


have implemented mandatory regulatory frameworks for individuals' accessibility to digital services

Overall, a large number of European countries have engaged several initiatives to get individuals and healthcare professionals onboard regarding Digital Health



provide physical services to ensure support for the access and management of health data



provide digital literacy, trainings and information points regarding Digital Health for individuals and healthcare professionals

EU REGULATION LANDSCAPE

The issues of fair and equitable access to health technologies by all citizens are largely addressed in EU regulation. These particularly include the regulations addressing access to (i) mobile health applications, (ii) data sharing portals, and (iii) future AI solutions.

Regulations set out requirements for access to solutions by people with disabilities, elderly people, or those with less education in the field.

Make Digital Health inclusive and accessible to all (2/2)

Consultation with 15 countries

Make Digital Health inclusive and accessible to all

Member States level initiatives

Trusted parties can be appointed by individuals to manage their health data

Several Member States offer an alternative to individuals, who can appoint trusted third parties to access and manage their health data

Innovations to improve Digital Health accessibility

Few countries include innovative services in their patient portals to facilitate their use, for instance:

- audio description
- sign language interpreting
- multilingual translation in teleconsultation

Public helpdesks

Many countries use public locations (post offices, library, etc.) as help points for the digitally excluded, offering advice or training

Key areas for improvement

Issues raised on improving patients' access to their health data and their ability to understand it or take action

No accessibility guidelines for mHealth applications

Possible ways forward

Improving and supporting Digital Health literacy by funding specific programs

Tackling the digital divide by accelerating the deployment and appropriation of innovative digital solutions

Legend

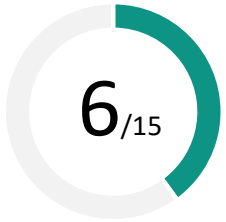
High priority *Medium priority* *Low priority*

Implement eco-responsible Digital Health (1/2)

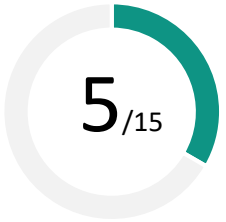
Consultation with 15 countries

Implement eco-responsible Digital Health

Although some improvements have been observed in the past few years, very few initiatives exist regarding the reduction of the environmental impact of Digital Health



have implemented sustainability guidelines or principles for the design of Digital Health solutions



are requiring the reuse of data through unified collection and storage of health data

None of the countries studied has put an "eco-score" in place to evaluate the environmental impact of Digital Health services

EU REGULATION LANDSCAPE

- Sustainable development in the creation of digital solutions is only addressed in non-binding opinions or recommendations.
  Details have been provided concerning the development of AI.
- Although digital solutions are generally affected, the regulations remains very cross-cutting since they are dealt with from the point of view of how companies contribute to sustainable development.
- None of the documents regarding digital sustainability are specific to health.

Implement eco-responsible Digital Health (2/2)

Consultation with 15 countries

Implement eco-responsible Digital Health

Member States level initiatives

Digital sobriety criteria applied to Digital Health solutions exchanging data with national portals

Digital Health solutions are registered and can exchange data with national platforms provided they meet a set of sustainability criteria. These include environmental criteria such as energy consumption, volume of data stored, and retention time

Mandatory reuse of existing and available digital public components and services

Some of the countries have implemented measures to reduce the energy consumption of digital services:

- Regulations stating that companies that develop digital tools must use existing data centers and/or servers or components
- The principle of data minimization, supporting the unified collection and storage of data
- Mandatory re-use of public services to avoid wasting resources on developing competing services with the same functionality

Key areas for improvement

Perceived lack of research to support best practices for reducing the overall energy consumption of the Digital Health ecosystem

Obstacles to environmental-friendly measures, given (i) the broader scope of digital sobriety beyond Digital Health, and (ii) the strength of the measures that need to be implemented to meet EU sustainability commitments

Possible ways forward

Conducting research to find the best ways to reduce the energy consumption of Digital Health

Taking inspiration from the European draft declaration "Making the green transition more digital and the digital transition greener" and adapting it for Digital Health

Legend

High priority *Medium priority* *Low priority*

Summary

1 Context and methodology

2 State of play of Digital Health in Europe

3 Best practices for ethics in Digital Health observed at a national level

4 In a nutshell…

Summary of the main trends observed throughout Europe

Digital Health is a top priority

All countries have established a strategy dedicated to Digital Health, mainly focusing on core national services deployment, telemedicine, and improving the ecosystem's interoperability and security.

Regulation must keep pace with innovation

Digital Health deployment and efficiency may be limited by a lack of coercive regulative frameworks: Few regulations are currently enforced, especially in innovative areas such as mHealth, digital therapies, or AI-based solutions.

Interoperability standards but limited enforceability

Strengthening the implementation and enforceability of interoperability standards is key to improving health data transfers, which would benefit from agreed European standards and could rely on a European e-ID, or even a future e-Wallet.

Ethics is not sufficiently being addressed in Digital Health

Most countries are aware of the challenges regarding ethics but few are directly and comprehensively addressing them. Giving individuals power over their health data and developing innovative solutions (such as AI) still have to be tackled.

Ethics by design is a lever for acceptability

For Digital Health to be actually used, it must be acceptable to healthcare providers and individuals, which relies on their trust in the solutions. Developing ethics-by-design approaches (including all four ethics dimensions) is a lever to improve trust and Digital Health use.

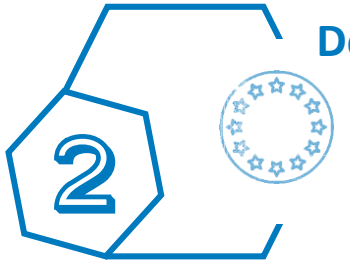
Eco-responsible Digital Health is still largely unexplored

Digital Health sustainability is an emerging matter that EU countries are starting to tackle: Overall, work must be conducted to highlight best practices and strategies focused towards reducing Digital Health energy consumption.

What are the main avenues for speeding up the development of digital health?

National roadmaps with a common challenge: Getting individuals more involved in digital health

- Ensure that all categories of individuals are represented in the development of services
- Develop communication and training, promote practices
- Reduce the digital divide
- Implement ethical prerequisites to earn trust



Develop cross-border data transfers, within the framework of EU

- Deploy semantic and technical standards to exchange health data
- Create a single European e-ID
- Include health data in the European Digital Identity Wallet

Foster a more sustainable, responsible digital health system

- Conduct research on eco-responsibility of Digital Health
- Create certifications for Digital Health

Appendix 1/3

Summary of the regulatory analysis

First approach to identify regulatory areas

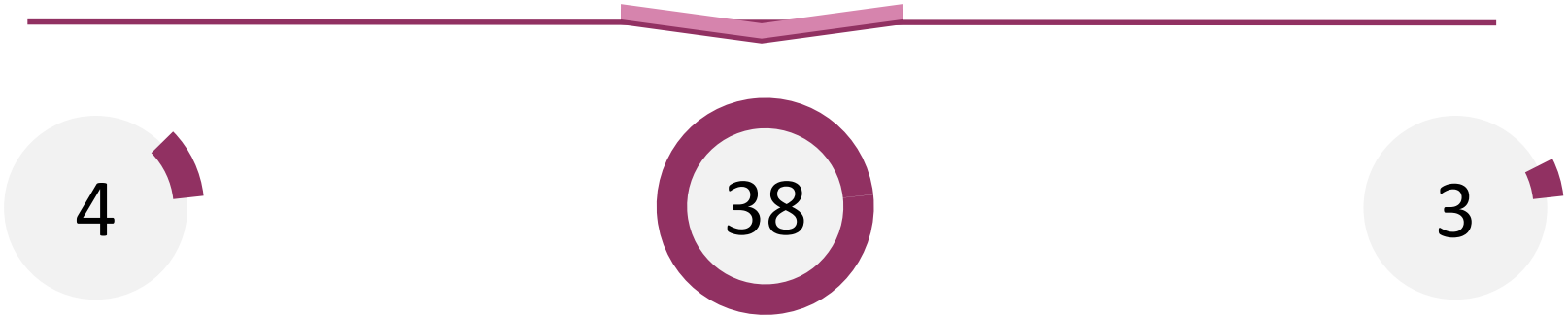
1 Search for legislation

By keywords used to extract relevant documents from the Eur-Lex and Tris databases

2 Macroanalysis of the documents

In order to identify whether each document was relevant to the study

3 Classification of the legislation by scope of application and by typology



Regulatory areas

Ethics, Marketing, Information Technology, Data

Regulatory documents

Distributed amongst the 4 areas

Scope of application

- Documents governing the healthcare sector and applicable to Digital Health
- Documents specific to Digital Health
- Cross-disciplinary documents with an impact on Digital Health

Approach to the in-depth regulatory analysis

4 **Revision of the regulatory scope**

Overview of the theme involved within the scope of analyzed documents.
Distinguishing between analysis reports, best practices, and compulsory requirements

5 **In-depth analysis of the different documents**

Comprehensive analysis of the documents and identification of the theme discussed (i.e. with regards to the classification)

6 **Analysis of the overlaps between the documents according to each theme**

In-depth analysis of the themes to highlight sub-themes in order to add detail to the analysis.
Cross-analysis of documents discussing multiple themes.

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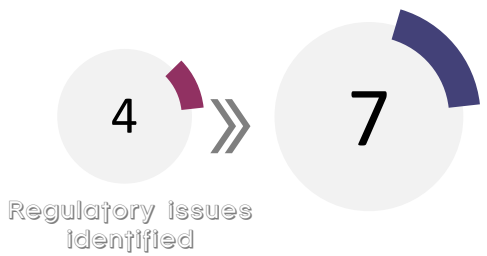
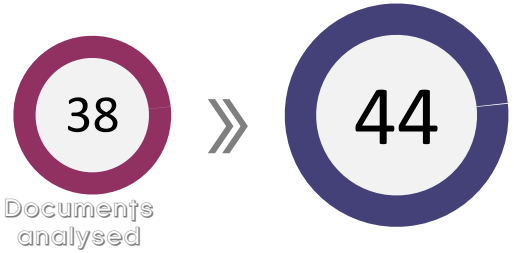
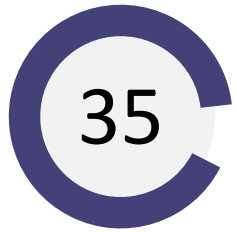






Defined themes

Added 3 themes following the detailed analysis of the documents to clarify their categorization

Regulatory documents

Added of 6 documents in the scope of analysis

Thematic overlaps

Intersecting references of documents dealing with the same key themes

Classification of the documents analised

Decrease in coerciveness level

Binding legislation

The **legislation** must be implemented by Member States. They specify both the objectives to be achieved and the possible means or tools to achieve them.

10 documents

Binding acts

Binding acts include two types of documents that set objectives to be achieved by Member States, without specifying the means or actions to be taken. A distinction is made between (i) **directives**, which set objectives and a time period to achieve them, and (ii) **decisions**, which are similar to directives but apply to specific situations or to a restricted area.

10 documents

Non-binding frameworks

These documents act as reference frameworks but are not made mandatory for the Member States and the ecosystem players. For example, **proposals for regulations** (which by their nature are not yet in force), **standards**, **frameworks** and **codes of conduct** or **conclusions** are considered to be non-binding.

8 documents

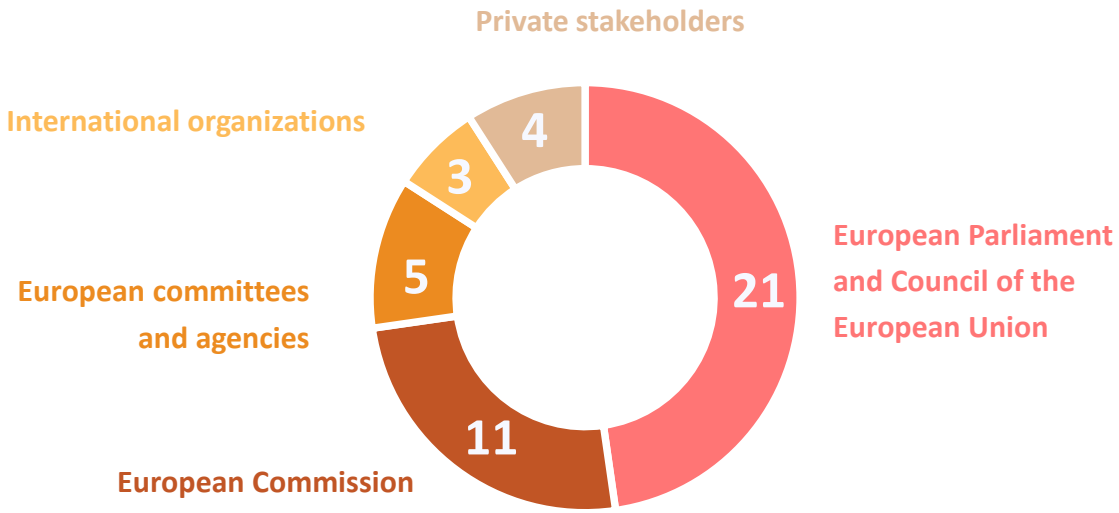
Advisory and information documents

Numerous documents are published by European stakeholders and provide specific information or guidelines to the ecosystem. Therefore, they are for information purposes only and do not entail any obligation for stakeholders. This category of documents include (i) **notices** and **recommendations** guiding legislative work, (ii) **resolutions** that set out the Commission's work streams, and (iii) **green papers** and **reports**.

16 documents

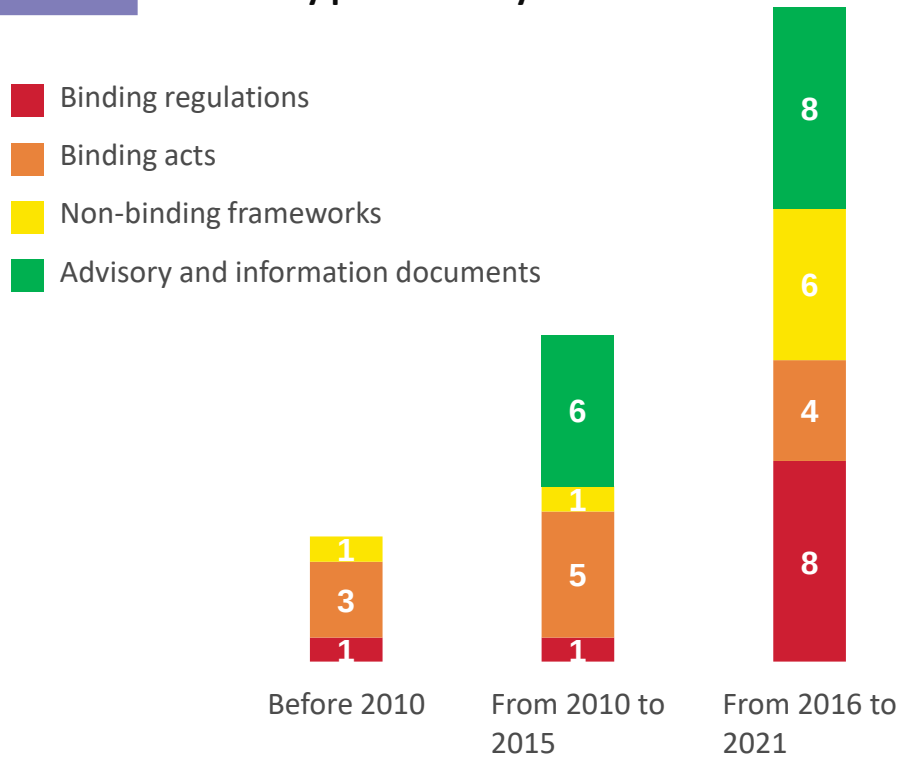
Distribution of documents

Breakdown of documents by author



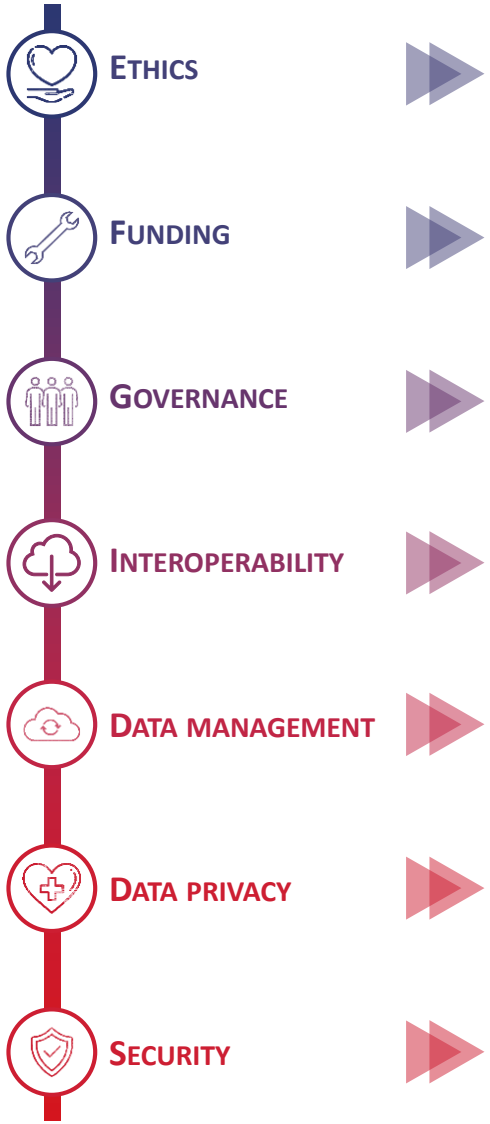
The stakeholders most represented as authors of the documents are: the **European Parliament**, the **Council of the European Union** and the **European Commission** (i.e. public European institutions).

Breakdown of documents by publication year



Most of the studied documents were published during the **last five years**, which reflects the recent increased involvement of the European authorities in the field of Digital Health. This highlights the fact that the results of the analysis widely reflect the present state of affairs, which is expected to evolve in the face of upcoming legislation.

Our research highlights 7 main topics



ETHICS

Inclusion and equity, sustainable development, respect for human rights, responsible data handling, data transparency, recognition of healthcare professionals' qualifications, patient participation

FUNDING

Costs and reimbursement, promotion of Digital Health in Europe

GOVERNANCE

Cooperation, representative entities, civil, corporate and government liability

INTEROPERABILITY

European database, European portal, promotion and implementation of standardized interoperability frameworks

DATA MANAGEMENT

Secondary use, sharing, altruism, portability and traceability of data

DATA PRIVACY

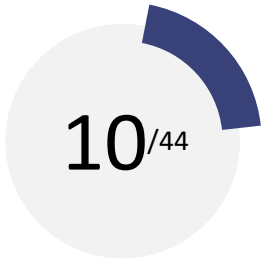
Information reliability, privacy, consent, legal protection of users, confidentiality

SECURITY

Users communication on data security, protection of data and associated infrastructure, technology assessment, incident management, implementation of security standards

Results by topic – Ethics (1/3)

ETHICS



documents identified on the topic

Base Digital Health on humanistic values	4 Intersecting references
Enable individuals to manage their Digital Health use and data	4 Intersecting references
Make Digital Health inclusive and accessible to all	8 Intersecting references
Implement eco-responsible Digital Health	2 Intersecting references

SUMMARY OF OUR ANALYSIS

1

Transparency regarding the collection and use of data is addressed by several documents, including a **proposal for a code of conduct dedicated to Digital Health**.

However, the implementation methods (particularly in terms of standards and control) have yet to be defined.

2

Respect for fundamental rights in the use of health-related technologies is covered by the definition of criteria but is not mandatory. The criteria does not cover all ethical aspects related to the respect of human rights in its broader sense.

Results by topic – Ethics (2/3)

ETHICS

3 **The minimal, judicious use of health data** is a subject that is yet to be addressed at European level. Its aim is to limit the processing of data with regard to the desired final outcomes (this goes beyond the GDPR data collection minimization principle). **Only one study by the EDPS** (European Data Protection Supervisor) addresses the notion of minimal use of data from an ethical perspective.

4 The involvement of citizens' representatives in the governance and defining of European Digital Health strategies is **mentioned but not yet regulated.** This ambition is limited to public policy matters and **does not encompass the design of services.**

5 The issues related to a **fair and equitable access to health technologies** by all citizens are widely addressed. The legislation specifically addresses issues of access to (i) mobile health applications, (ii) data sharing portals, and (iii) future AI solutions.

The legislation sets out requirements for access to solutions by people with disabilities, the elderly, or those with low digital skills.

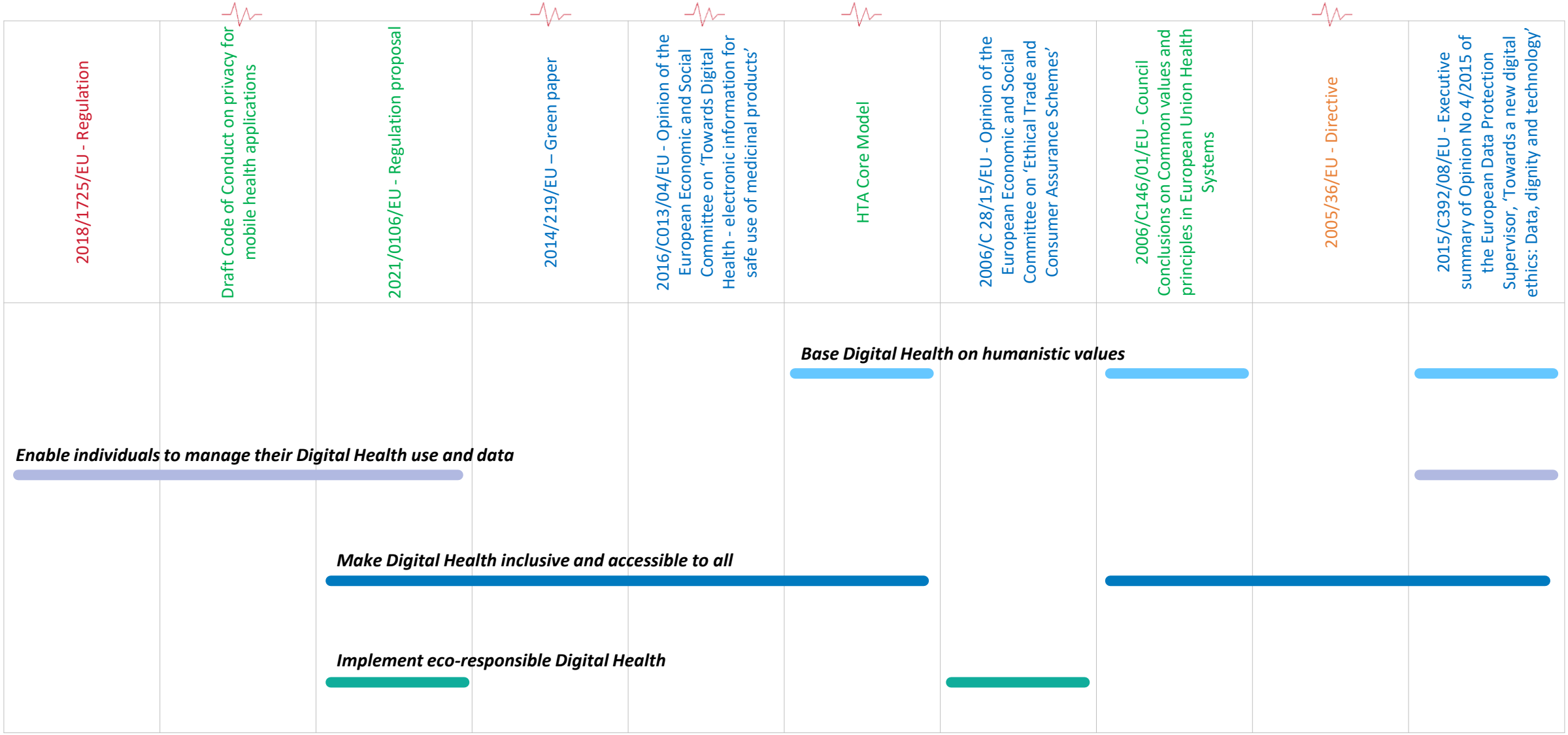
6 The **recognition of health professionals' qualifications** is addressed exclusively from a general point of view. **At this stage, the training of health professionals in the use of Digital Health is not regulated nor fully recognized.**

7 **Sustainability in developing and using digital solutions** is only addressed through non-binding opinion papers or recommendations. Details have been provided regarding the development of AI-based solution.

These recommendations are cross-cutting to all sectors and are intended for private companies to improve their carbon balance. **Digital Health is not specifically addressed.**

Results by topic – Ethics (3/3)

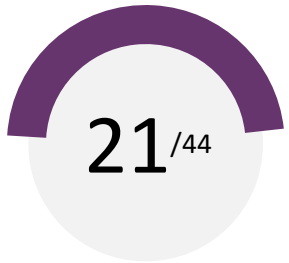
ETHICS



Specific health-related documents BINDING REGULATIONS BINDING ACTS NON-BINDING FRAMEWORKS ADVISORY AND INFORMATION DOCUMENTS

Results by topic – Governance (1/2)

GOVERNANCE



documents identified on the topic

European representatives entities	5 Intersecting references
Cooperation	13 Intersecting references
Civil, corporate and government liability	5 Intersecting references
Setting up of expert groups	2 Intersecting references

SUMMARY OF OUR ANALYSIS

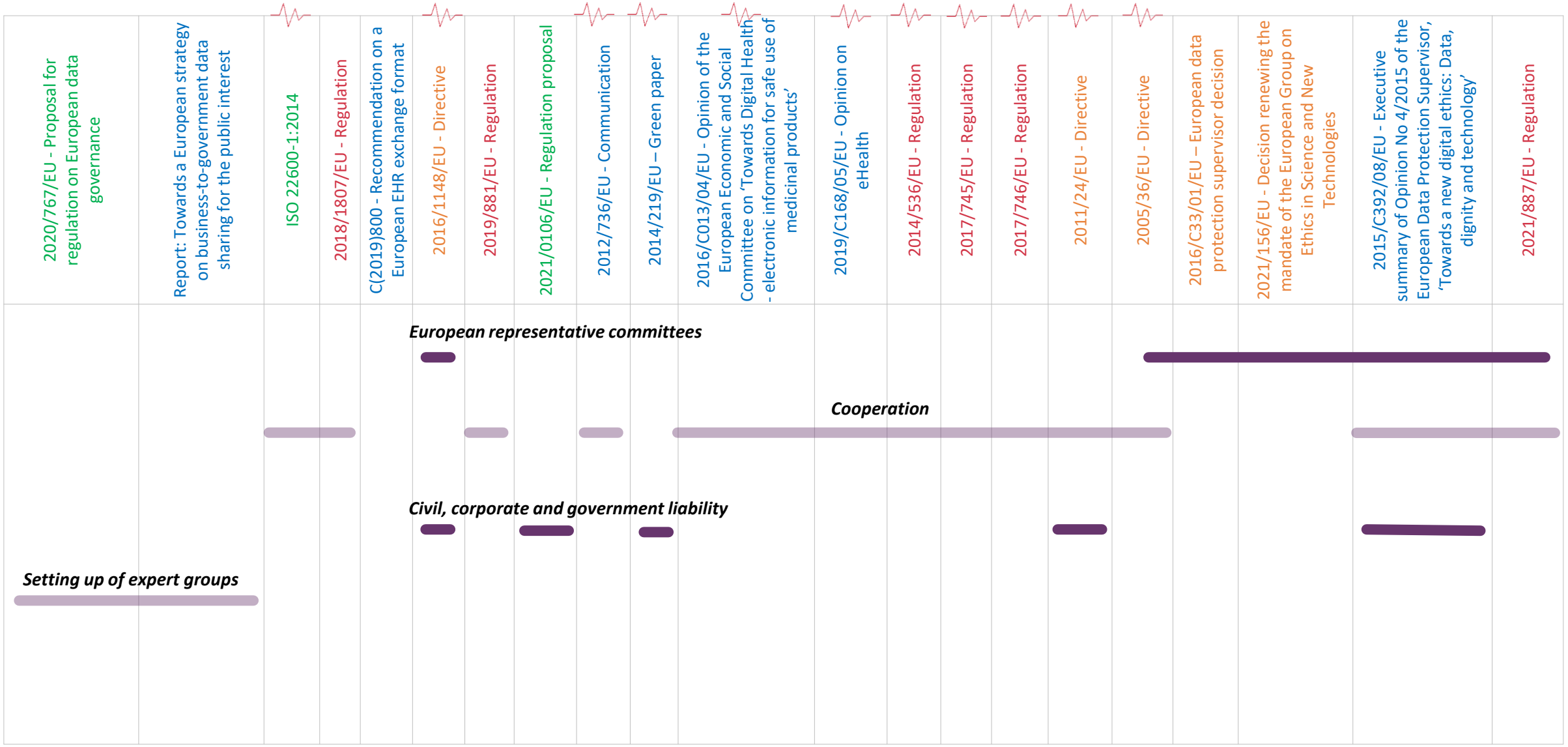
1 **While there is currently no national or European representative body dedicated to ethics in Digital Health, cross-cutting bodies address this matter**. Indeed, Digital Health ethical challenges have been identified but are not yet specifically addressed.

2 The implementation of **public-private and cross-border** cooperation in the fields of data sharing and data centralization is extensively addressed by the legislation. This cooperation is in the interest of the entire ecosystem (i.e. public authorities, research institutes, digital solution providers, laboratories, and biotech and medtech firms).

3 **Civil, governmental and corporate liability in Digital Health is not addressed in a comprehensive manner,** in particular with regards to the development of AI or Digital Therapeutics. Binding requirements are identified in numerous laws. Therefore, a deeper analysis could be conducted to assess the coherence and the exact scope of the overall legislation.

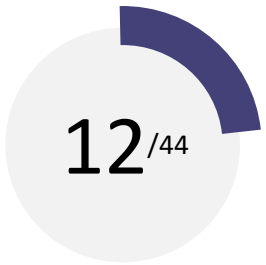
Results by topic – Governance (2/2)

GOVERNANCE



Results by topic – Funding (1/2)

FUNDING



documents identified on the topic

- Promotion of Digital Health in Europe — 6 Intersecting references
- Cost and reimbursement — 5 Intersecting references
- E-commerce — 3 Intersecting references

SUMMARY OF OUR ANALYSIS

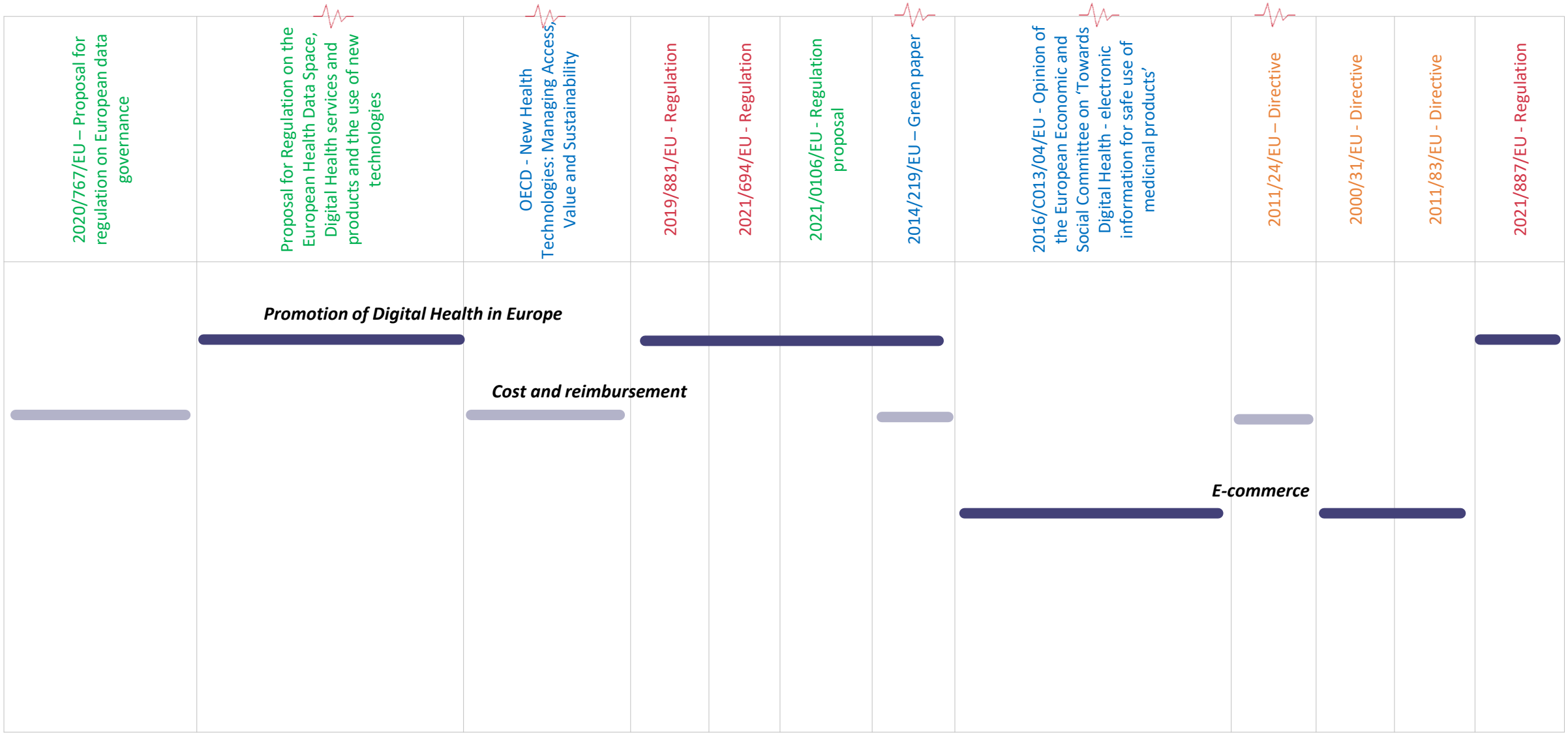
1 **Numerous funding programs,** such as Digital Europe and Horizon Europe, support the development of Digital Health companies and the solutions improvement. Nevertheless, most of theses programs **do not cover Digital Health in all its dimensions** as they focus on cybersecurity and Artificial Intelligence matters**.**

2 **Research and innovation in Digital Health** are supported through programs dedicated on cybersecurity and mobile health issues. **No dedicated program are observed regarding other challenges** such as pseudonymization or sustainable solutions.

3 **Electronic commerce** (e-commerce) is widely regulated by numerous documents. Some apply to the marketing of mobile health applications with an emphasis on communicating to the users regarding their rights and the aims and limits of the application. However, this legislation was not drafted specifically for Digital Health and has a broader scope of application.

Results by topic – Funding (2/2)

FUNDING

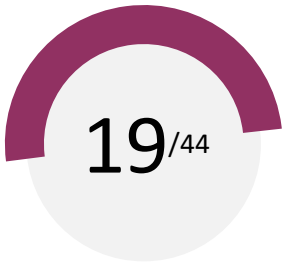


Specific health-related documents

BINDING REGULATIONS | BINDING ACTS | NON-BINDING FRAMEWORKS | ADVISORY AND INFORMATION DOCUMENTS

Results by topic – Interoperability (1/2)

INTEROPERABILITY



documents identified on the topic

Establishment of a European database	6 Intersecting references
Creation of a European health data consultation portal	6 Intersecting references
Promoting interoperability of health technologies in Europe	8 Intersecting references
Definition of procedures and standards on interoperability	5 Intersecting references

SUMMARY OF OUR ANALYSIS

1

The **creation of centralized databases** consolidating Member States data and supporting data sharing and access is mentioned in several European legislation. The legislation aims to improve patients pathways and treatments, and to develop data secondary uses.

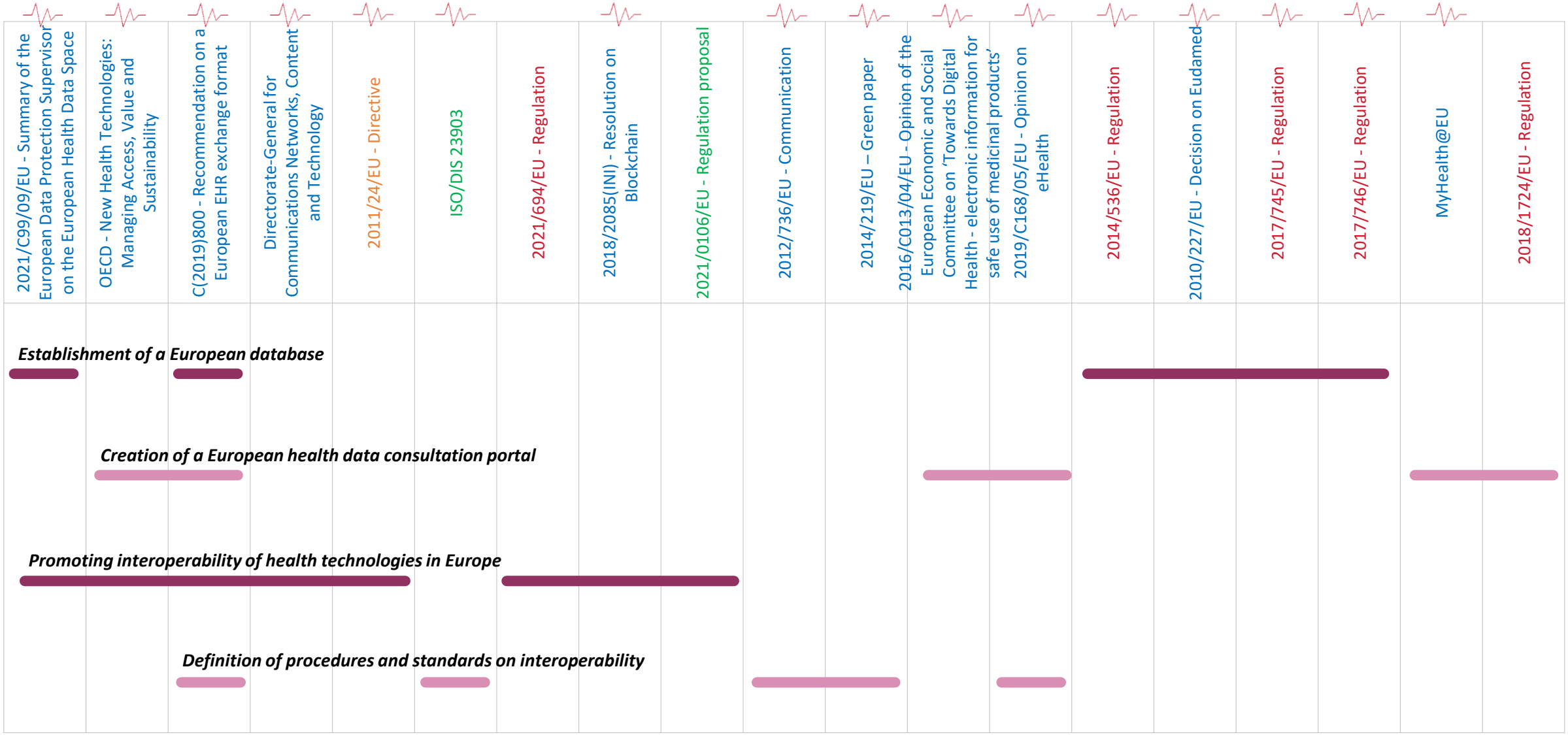
The forthcoming legislation on the European Health Data Hub will be key and have a major impact.

2

Beyond the promotion of interoperability in Digital Health, an ambition to develop interoperability standards at the European level is observed. While standards do exist (e.g. for European services such as the NCPeH), **legislation setting out norms and standards to be applied by all Member States and private companies has not been proposed or published.**

Results by topic – Interoperability (2/2)

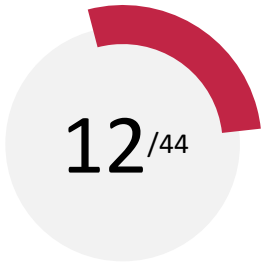
INTEROPERABILITY



Specific health-related documents BINDING REGULATIONS BINDING ACTS NON-BINDING FRAMEWORKS ADVISORY AND INFORMATION DOCUMENTS

Results by topic – Data management (1/2)

DATA MANAGEMENT



documents identified on the topic

Health data secondary use	4 Intersecting references
Health data sharing	5 Intersecting references
Health data altruism	2 Intersecting references
Health data portability	5 Intersecting references
Health data traceability	2 Intersecting references

SUMMARY OF OUR ANALYSIS

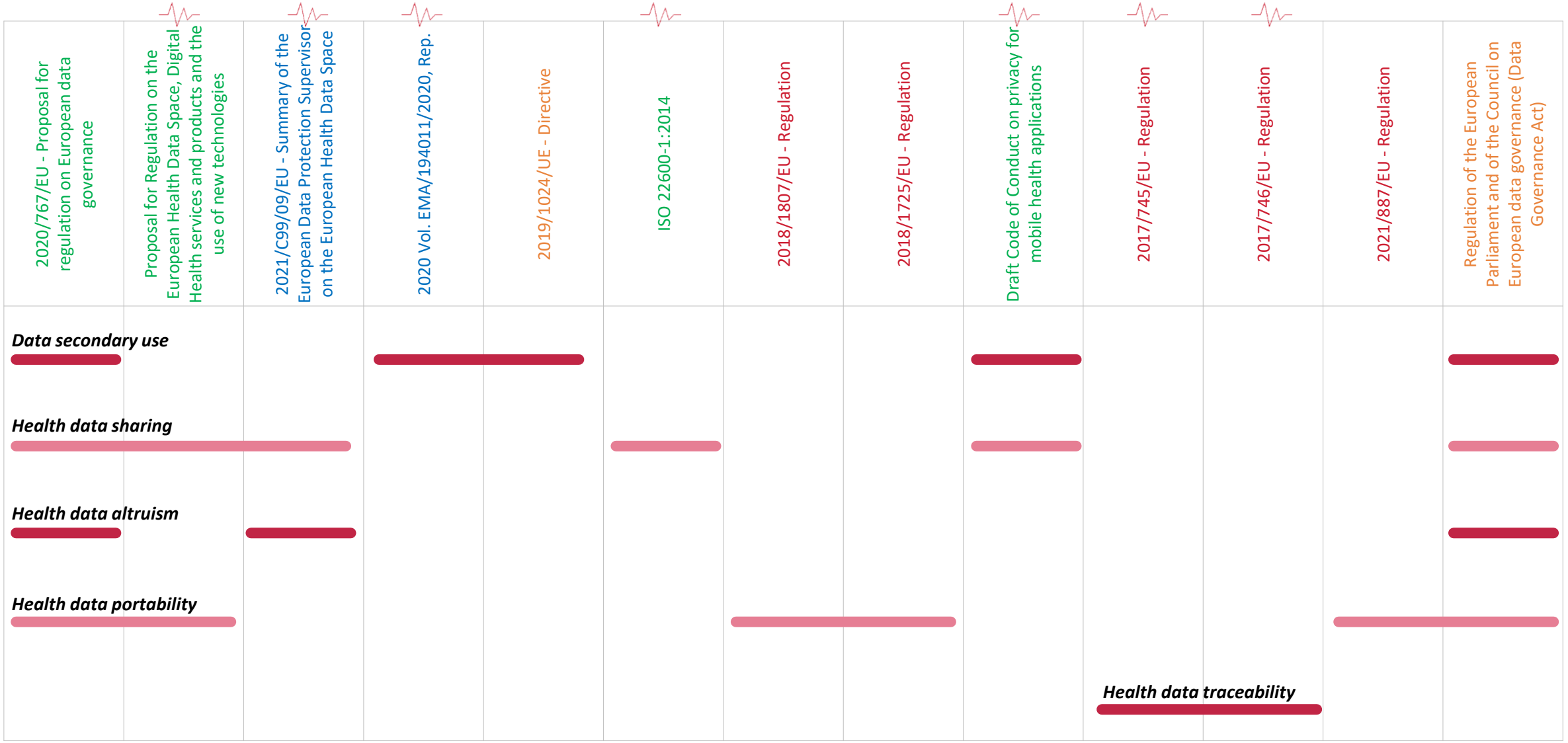
1 The **legislation defines numerous rules** to ensure the respect of citizens' privacy when collecting or processing their personal data. The GDPR obviously applies and is supplemented by some documents specific to Digital Health.

2 Legislation on health data sharing is well defined in the European Union. However, **data altruism** (i.e. voluntary provision of data by public or private producers) is **barely addressed, unregulated** and can be a real challenge. A proposal for an act on data governance is expected in the coming months.

3 **Data portability** (i.e. the possibility to retrieve one's data in an open and readable format) is clearly regulated. However, the portability is not associated with requirements in terms of data structures or interoperability standards (e.g. sending a CD-ROM can meet a request for data portability)

Results by topic – Data management (2/2)

DATA MANAGEMENT

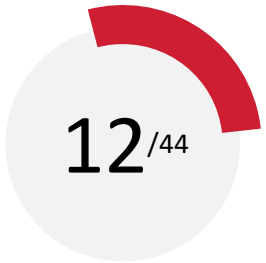


Specific health-related documents

BINDING REGULATIONS | BINDING ACTS | NON-BINDING FRAMEWORKS | ADVISORY AND INFORMATION DOCUMENTS

Results by topic – Data privacy (1/2)

DATA PRIVACY



documents identified on the topic

Privacy protection	4 Intersecting references
Reliability of information	6 Intersecting references
Consent	4 Intersecting references
Legal protection of users	5 Intersecting references
Data confidentiality	4 Intersecting references

SUMMARY OF OUR ANALYSIS

1 The **legislation defines numerous rules** to ensure the respect of citizens' privacy when collecting or processing their personal data. The GDPR obviously applies and is supplemented by some documents specific to Digital Health.

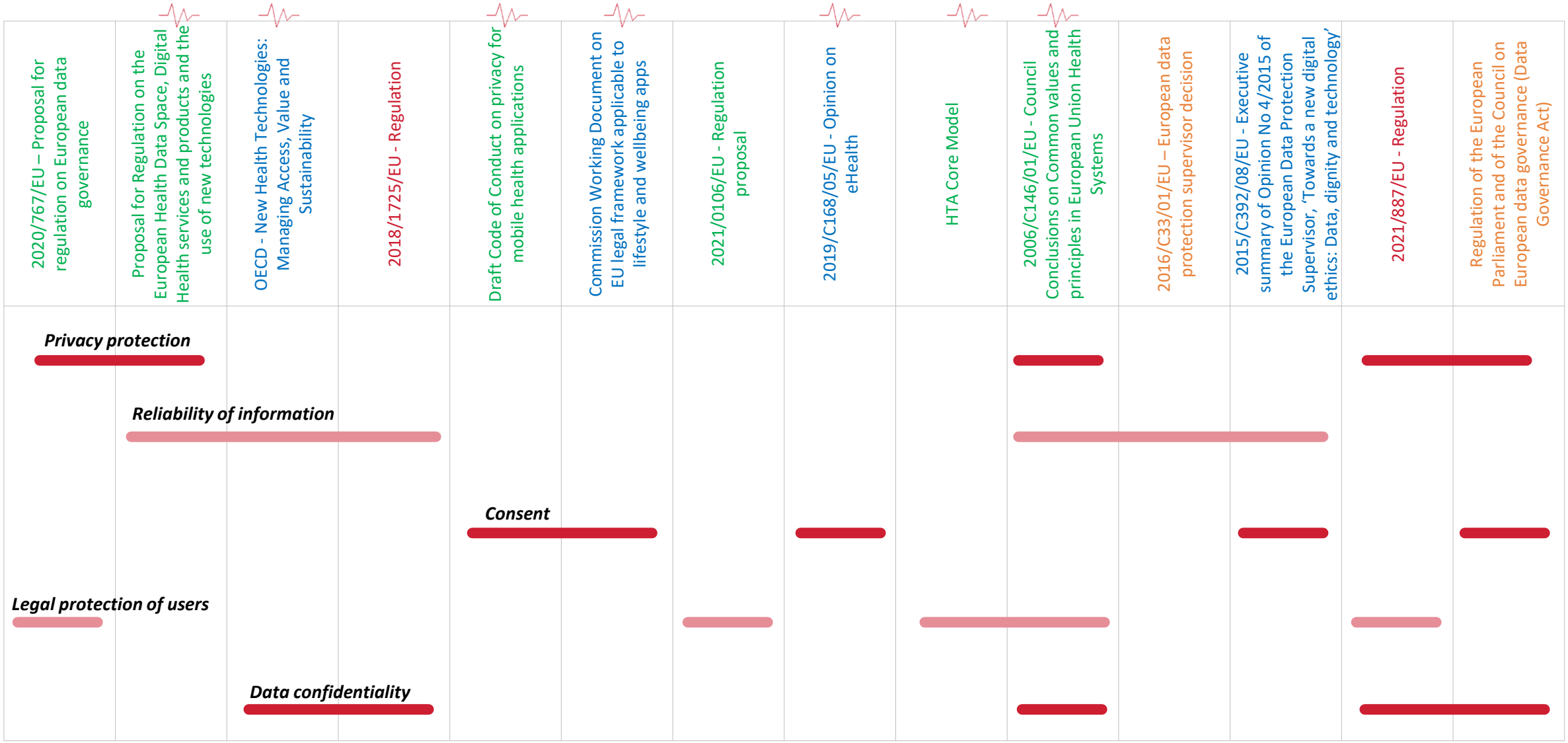
2 **Collecting consent is not systematically addressed** in European legislation. Implementing Digital Health comes with questions regarding consent when public health purposes require data collection. Thus, **the current legislation mainly defines the notion of "authorization" rather than "informed consent"**.

3 To date, legislation ensuring the **confidentiality and security** of users' data are defined through a transversal framework. In the field of Digital Health, national legislation prevails regarding data security and data access. Thus, a patchwork of practices is observed at the EU level.

4 The legal protection of consumers is defined by cross-cutting regulations. Specific Digital Health-related aspects are tackled through optional frameworks or guidelines that are not mandatory.

Results by topic – Data privacy (2/2)

DATA PRIVACY

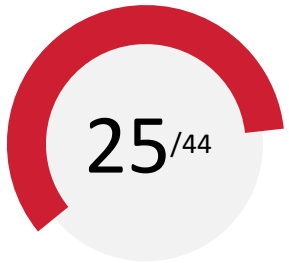


Specific health-related documents

BINDING REGULATIONS | BINDING ACTS | NON-BINDING FRAMEWORKS | ADVISORY AND INFORMATION DOCUMENTS

Results by topic – Security (1/2)

SECURITY



documents identified on the topic

Protection of data and associated infrastructure	21 Intersecting references
Implementation of security standards	10 Intersecting references
Users communication campaigns on data security	6 Intersecting references
Technology assessment criteria and frameworks	4 Intersecting references
Incident management (hacking, data leakage, etc.)	4 Intersecting references

SUMMARY OF OUR ANALYSIS

1 There is a strong desire to set-up **legislation with regard to the protection of personal data and metadata**. This matter is being addressed in a cross-cutting manner and appears to be already covered by legislation that is not dedicated to Digital Health.

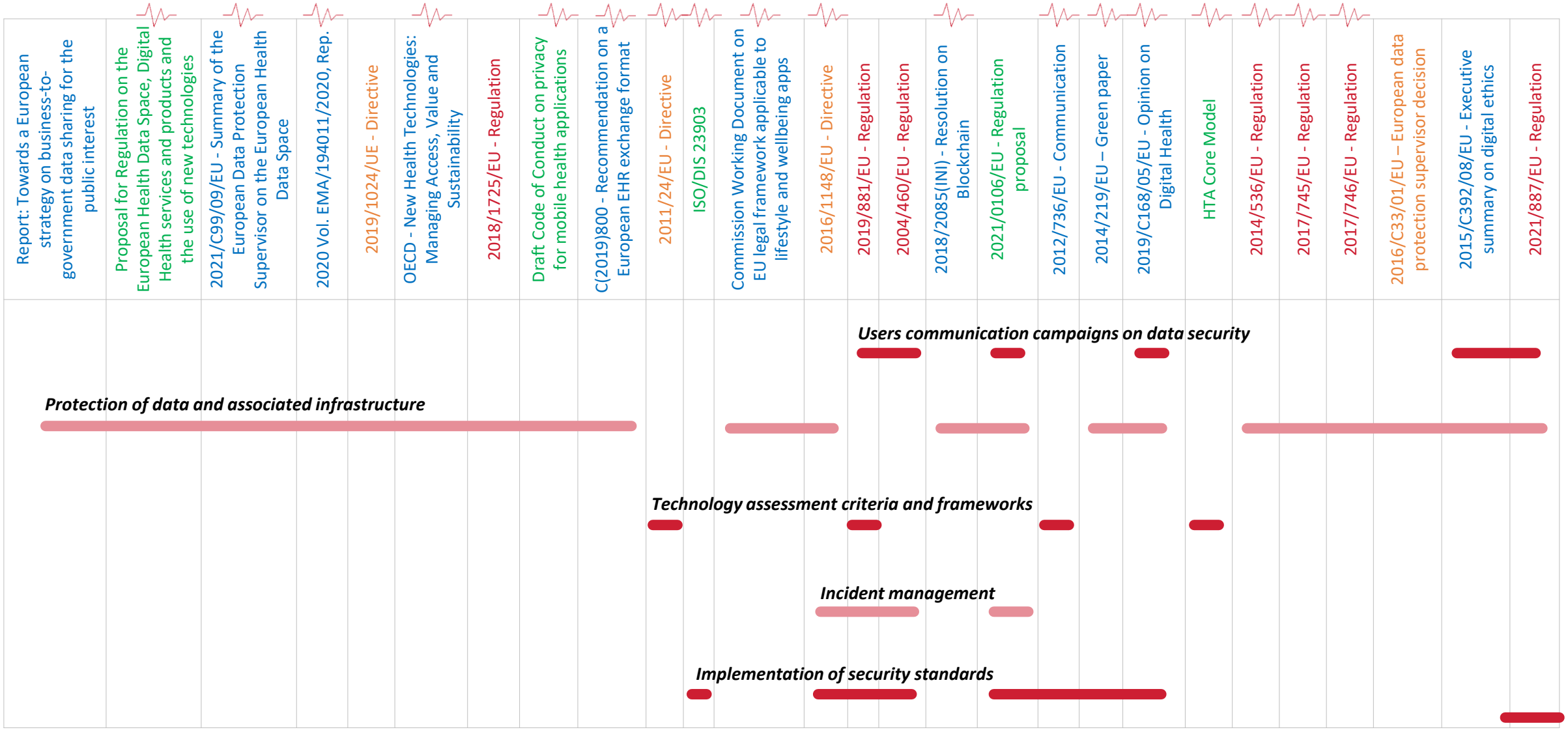
2 **Educating and informing citizens** about the risks associated with health data uses is a **sensitive issue strongly identified** at the EU level. The operationalization of these actions by the Member States could be subject to further study.

3 Technology assessment is addressed in several laws, including some that are specific to Digital Health. **The expectations are therefore defined** but have been published lately (from the early 2010s) and may require a future update.

4 The **management of security incidents** (e.g. hacking or data leakage) is dealt with in 3 documents, including a regulation proposal dedicated to AI. The various laws could be updated and improved with regards to the increased risks of cyber threats.

Results by topic – Security (2/2)

SECURITY



Specific health-related documents

BINDING REGULATIONS

BINDING ACTS

NON-BINDING FRAMEWORKS

ADVISORY AND INFORMATION DOCUMENTS

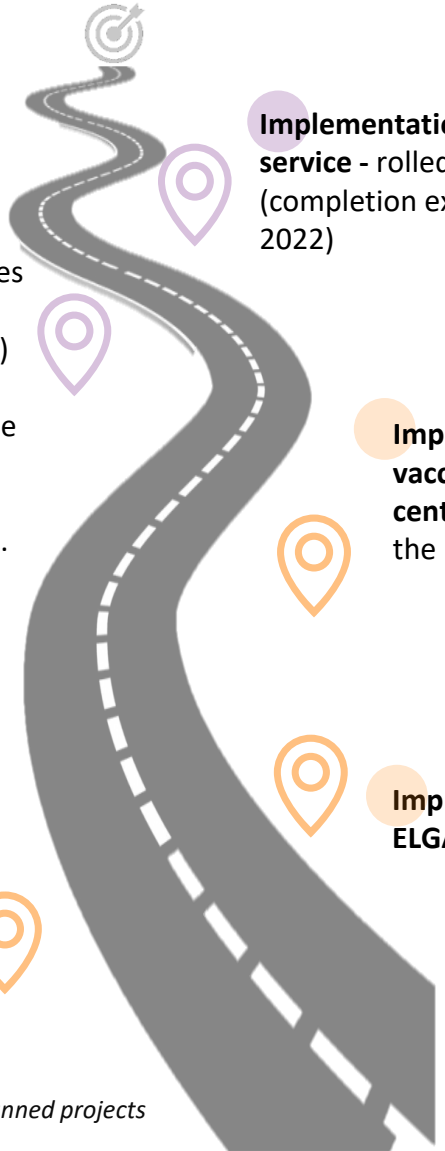
Appendix 2/3

Detailed analysis by country

Country Profile: Austria (1/4)

Austria

Summary of the Digital Health roadmap



Implementation of e-prescription service - rolled-out nationwide (completion expected by June 2022)

Telemedicine – numerous services (mostly in the areas of telemedicine and telemonitoring) are available. The corona pandemic acted as a driver for the implementation and use of telemedicine, following public efforts to set up prerequisite (inc. regulation) and promote its use.

Implementation of an e-vaccination certificate and a central vaccination register in the ELGA infrastructure (2019)

Implementation of the ELGA infrastructure in 2012

Implementing a centralized authentication system– for individuals and healthcare professionals

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓ *state level*
Assessment mechanisms	✓ *state level*

Sources

Country Profile: Austria (2/4)

Austria

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Austria did not build a dedicated strategy for ethics in Digital Health. However, the Austrian Patient Ombudsman is regularly involved in health-related initiatives including all public review procedures of relevant health laws.
- Universities seeking access to data for secondary use must make a request to university or hospital ethics committees

2. Enable individuals to manage their Digital Health use and data

- Data portability is ensured at national level
- Three different opt-out levels are defined: (i) the general opt-out, where the patient is completely disconnected from the system, (ii) the partial opt-out, i.e. the opt-out of only one of the services offered and (iii) the situational opt-out, where sensitive data are concerned
- Full transparency and traceability in ELGA
- EHR Participants are allowed to (i) hide or show electronic references and ELGA health data for ELGA healthcare providers, as well as delete electronic references to ELGA (so that the data remain only stored locally in the respective healthcare provider's system); (ii) shorten periods

3. Make Digital Health inclusive and accessible to all

- Legal framework requiring the accessibility of tools to all citizens (in case of disabilities)
- Physical access to the electronic health record through several ombudsman offices where citizens with difficulties in accessing digital tools can exercise their rights (citizens can contact the offices through writing or visit them in person)

4. Implement eco-responsible Digital Health

- A new fifth chapter of the Austrian Health Telematics Act allowing the use of the ELGA core components that cover all citizens takes advantage of not only the economic but also environmental added value of the investments already made by preventing the building of new software and hardware, thus avoiding the creation of costly as well as environmentally harmful parallel systems.

Country Profile: Austria (3/4)

Austria

Strengthen Digital Health Governance

- The ELGA system aims at facilitating the implementation of Digital Health solutions and supporting a common infrastructure for the health IT system
- National infrastructure (although not dedicated to healthcare) for data collection for research and scientific teaching purposes

Strengthen Digital Health security and interoperability

- High implementation level of ICD10 semantic standard, SNOMED-CT, LOINC and DICOM

  HL7-CDA has been largely implemented, HL7-FHIR is not yet implement.
- Systems regulated through specific regulation (Health Telematics Act 2012), with data security measures when using health and genetic data. Only one recent provision in the HTA 2012 allows statistical evaluations of vaccination data only. For all other health data and especially those in the ELGA system, there are clear provisions forbidding any secondary use of EHR data.

Accelerate the deployment of core Digital Health services

- In 2012, implementation of a decentralized electronic Health Record system with two main services: e-medication (central storage) and e-reports (local storage). There is an e-vaccination certificate and a central vaccination register (based on ELGA technical core components but with other legal rules than those applicable to ELGA)
- Ongoing deployment of an e-prescription service
- Telemonitoring reports have recently be added to ELGA and work is ongoing on adding living wills
- A telehealth commission has advised the government: telehealth is being deployed although it is not reimbursed at the national level (only a temporary reimbursement was deployed deployed during the covid-19 pandemic). Nonetheless, reimbursement regulations have been defined at state level (either project-related or partly in regular funding).

Country Profile: Austria (4/4)

Austria

Deploy Digital Health platforms at national level

- Data centrally accessible to all citizens in ELGA through a system of pointers
- ELGA system supporting a common infrastructure for the health IT system
- 5 technical core components: central patient register, register of healthcare providers, access control center, protocol system for access monitoring and online Digital Health access point (ELGA portal)

Support innovation and promote buy-in from all stakeholders

- Two government agencies, the Austrian Research Promotion Agency (Österreichische Forschungsförderungs GmbH, FFG) and Austria Wirtschaftsservice (AWS), are in charge of allocating funds to promote innovation (not only health related).

Focus on the enforceability of national reference systems

- There is a legal obligation for healthcare professionals to save patients' documents in ELGA
- There are financial coercive and/or incentive means to secure compliance with the regulatory framework on health data hosting

Country Profile: Belgium (1/4)

Belgium

Summary of the Digital Health roadmap

Accelerate the accessibility of Digital Health solutions - for individuals and healthcare professionals by supporting Digital Health innovation and entrepreneurship

Improve the ownerships of individuals over their health data - by developing Digital Health literacy and provide explanations on health data within the national Health platform

Promote health data sharing - by expanding the use of electronic health records and the infrastructures interoperability

Implement a national Digital Health platform - created for individuals and healthcare professionals, funded by the Ministry of Health and the Health and Disability Insurance with an €80M investment

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Belgium (2/4)

Belgium

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- There are national bodies and frameworks to ensure the interoperability (prerequisite to the individuals' ownership over their health data) and the security of Digital Health – projects regarding the improvement of individuals access to their health data are undergoing
- There is an initiative revolving around the creation of personal safes through "Solid" technology, where the storage is controlled by individuals and not by healthcare providers
- There are health expert groups within the Data Protection Authority

2. Enable individuals to manage their Digital Health use and data

- There are dedicated tools for the collection of citizens' consent for the use of their health data in the context of care (but not in the context of research)
- The Digital Health Platform includes in its governance a User Consultation Committee which assists the Management Committee by proposing initiatives or security measures to implement
- A national survey is sent to representatives of patient organizations and healthcare providers to gather their feedbacks on Digital Health

3. Make Digital Health inclusive and accessible to all

- Planned project "Empowerment of citizens" which aims at ensuring that every citizen can understand and use their own data, with two lines of work: Digital Health literacy and specific offices for people affected by the digital divide (e.g., in post offices)
- Since 2018, Belgian public websites must comply with an established framework for digital accessibility according to European directive 2016/2102
- Dedicated communication towards citizens on Digital Health and their rights

4. Implement eco-responsible Digital Health

- *No specific plans regarding the environmental impact of Digital Health*

Country Profile: Belgium (3/4)

Belgium

Strengthen Digital Health Governance

- Shared strategic and operational governance between the federal level and regions. The Telematics Commission, a body of the Ministry of Health, was responsible for Digital Health until 2008, the "Digital Health" platform has now taken over its entire role.
- Involvement of the ecosystem players in the construction of the Digital Health strategy (professionals, software publishers e.g. *Agoria*, patients' associations, etc.)
- There is a governance body between institutions and private publishers (example of *mHealth Belgium* vs *Agoria*)
- Public-private collaboration still needs to be improved as highlighted by the disparity of software implementation in hospitals (only 50% of hospitals)

Strengthen Digital Health security and interoperability

- National interoperability framework deployed in more than 50% of healthcare organizations
- Draft regulation on progress regarding secondary use of data - however, a *Healthdata.be* platform is already implemented to facilitate and standardize the registration of data for secondary use (research context)
- No mechanisms to ensure the enforceability of all national frameworks (controls are conducted by the eHealth platform for specific use-cases such as messaging systems and medication record).
- Data portability is only addressed at a regional level

Accelerate the deployment of core Digital Health services

- An assessment and reimbursement system for mobile health applications was published in May 2021. There is a website listing reliable mobile health applications and their level of trust: *mhealthbelgium.be*
- No authorisation or regulation of telemedicine - however, there is an evaluation system. *Note: Reimbursement of teleconsultations was only possible during the Covid crisis and reports have been published to envision its permanent reimbursement.*

Country Profile: Belgium (4/4)

Belgium

Deploy Digital Health platforms at national level

- "MaSanté"(Digital Health.fgov.be) is the national portal where individuals can access their health data including information saved and shared by healthcare providers, health insurance fund or other federal institutions and supported by digital tools deployed at a regional level - about 80% of use rate
- Patient identification with the electronic ID card (100% of the population); identification and authentication service for healthcare professionals (80% use rate)
- There are regional services dedicated to document management (80% effective use rate) and secure messaging (10% effective use rate) for individuals
- e-prescription service (Recip-e), mandatory since 2020 and used by 50% of healthcare infrastructures

  e-signature used in 35% of all health documents

Support innovation and promote buy-in from all stakeholders

- Absence of initial training in innovation and Digital Health for healthcare professionals - however, specialisations are possible (master's degree, double degree, etc.)
- *Digital Health Box* to collect individuals' initiatives about health innovation

Focus on the enforceability of national reference systems

- The Digital Health platform is used to validate the compliance of Digital Health services with the national architecture standards

Country Profile: Bulgaria (1/4)

Bulgaria

Summary of the Digital Health roadmap

Implementing academic and professional curricula for the development of Digital Health skills

Development of telemedicine, big data, innovation and new health technologies

Transparency in the access to health data - for the entire healthcare ecosystem and requiring tools interoperability

Regulation and standardization of the cybersecurity of health systems and the confidentiality of health data - introduction, development and upgrade of the National Health Information System (NHIS)

Implementing a Digital Health regulatory framework

Implementing Digital Health organisational model – reinforcement of stakeholders' capabilities

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✗
Is it enforceable?	✗
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✗

Sources

Country Profile: Bulgaria (2/4)

Bulgaria

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Strong desire to use the "Ethics by design" approach to data hosting and security in their National Digital Health Strategic Plan 2021-2027

2. Enable individuals to manage their Digital Health use and data

- Willingness to set up a guarantee system for citizens regarding the management of their health data (Digital Health regulations)

3. Make Digital Health inclusive and accessible to all

- There are tools to strengthen the involvement of citizens in decisions regarding their health (through patient organizations)

4. Implement eco-responsible Digital Health

- Stated desire to minimize the environmental impact of new solutions implemented in their National Digital Health Strategic Plan 2021-2027
- Program aiming at improving real-time connectivity of health facilities and digitizing key health services in order to achieve a more limited consumption of health resources

Country Profile: Bulgaria (3/4)

Bulgaria

Strengthen Digital Health Governance

- There is a national strategy (National Digital Health Strategy 2021-2027) and an operational roadmap (Action Plan 2021-2023)
- Low involvement and/or collaboration from public and private actors
- The Council of Ministers validates the Digital Health strategy and then the Ministry of Health is in charge of its implementation and its management, in consultation with the National Health Insurance Fund, the Union of Doctors and Dentists, the Patients' Associations, the Agency for e-Governance, and the High Council for Public Health

Strengthen Digital Health security and interoperability

- No national interoperability framework - however, the SNOMED-CT semantic standard is being deployed
- Beyond GDPR, a National Agency for e-Governance (SEGA) has been set up to deal with regulations, good practices and certifications of information systems
- No centralized health database for research or regulation on secondary use of data is underway

Accelerate the deployment of core Digital Health services

- A free national e-learning platform is being developed for healthcare professionals
- No regulation, procedure, or evaluation system on the management of telemedicine; no regulation or evaluation system to support mobile health applications
- To date, there is no Digital Health training for healthcare professionals - however, it is being integrated into higher education courses, particularly with regard to security issues and the operationalization of existing technologies

Country Profile: Bulgaria (4/4)

Bulgaria

Deploy Digital Health platforms at national level

- No project planned or underway for the creation of a personal health space for patients (authentication, document management, agenda, secure messaging, etc.)
- e-prescription currently in test phase and National Patient Record under development
- There is a patient identification system - however, it remains underdeveloped and not universal to all citizens; there is an identification and authentication system for healthcare professionals – but, not universal yet
- Absence of a secure health messaging between healthcare professionals

Support innovation and promote buy-in from all stakeholders

- Few national coordination and funding for companies or research laboratories in the health innovation sector (€25M): Digital Health is not a priority for the government and validation processes are long and complex

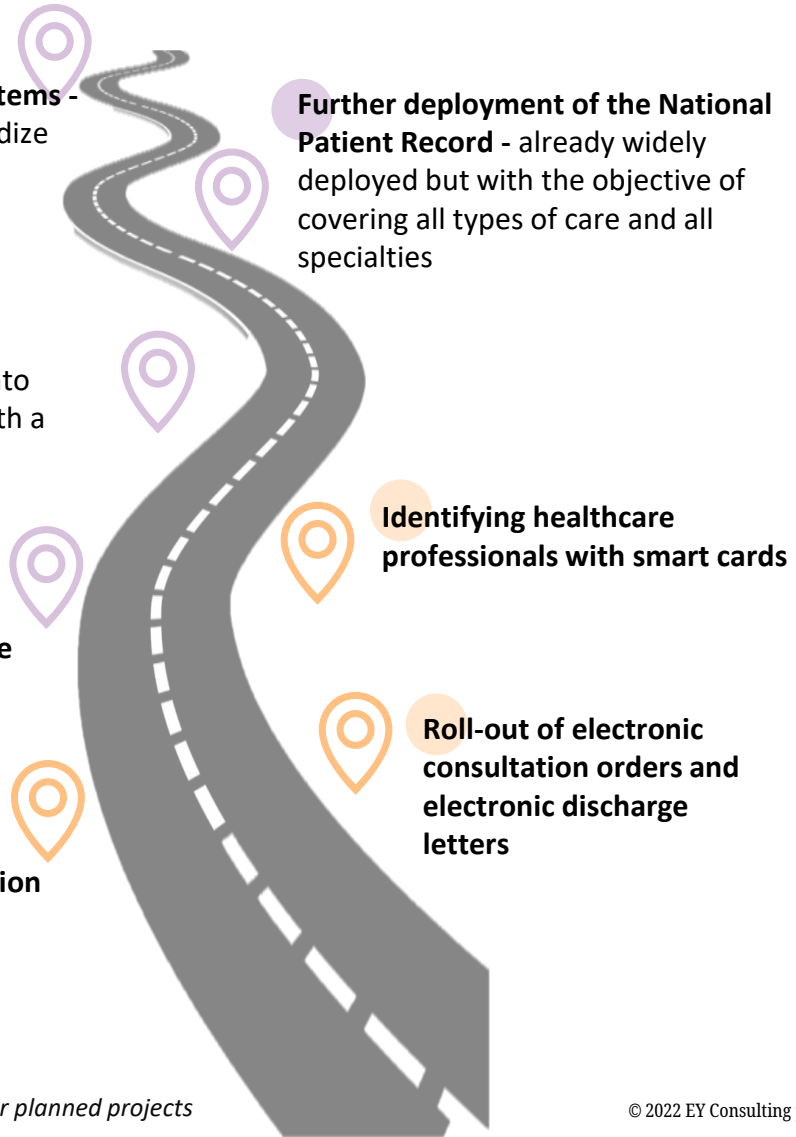
Focus on the enforceability of national reference systems

- To date, no control on compliance of digital solutions - however, their implementation is being considered
- Once implemented, they will be carried out before digital solutions are brought to market

Country Profile: Croatia (1/4)

Croatia

Summary of the Digital Health roadmap



Redesigning information systems - with the objective to standardize and harmonize health data

Further deployment of the National Patient Record - already widely deployed but with the objective of covering all types of care and all specialties

Integrating telemedicine - into traditional care pathways, with a key focus on emergency care

Identifying healthcare professionals with smart cards

Implementing an enforceable framework for information systems certification

Roll-out of electronic consultation orders and electronic discharge letters

Implementing an e-prescription service *(2021)*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Croatia (2/4)

Croatia

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National system centralizing patients' consent collection (Information Security Act) and enforcement of regulations supplementing GDPR on data protection (Information Access Act)
- According to the national digital strategy, the e-Citizens service provides users with important information on available services (for all sectors) and on their rights as to collecting and accessing their data (including health)

2. Enable individuals to manage their Digital Health use and data

- National security framework dedicated to health systems: A 3-factor authentication service is required to access national services

3. Make Digital Health inclusive and accessible to all

- *No specific political ambition identified on accessibility apart from general compliance of websites with the Accessibility Act*

4. Implement eco-responsible Digital Health

- *No specific political ambition identified on this subject*

Country Profile: Croatia (3/4)

Croatia

Strengthen Digital Health Governance

- Digital Health governance led by the Ministry of Health (MoH) and the Croatian Health Insurance Institute, defining a Competitive Industries and Innovation Program targeting Digital Health
- Digital Health defined as Priority 1 of the National Health Care Strategy 2012-2020 of Croatia, with long-term national Digital Health strategy 2021- 2027 and short-term Digital Health action plan 2021-22
- Important work undertaken on increasing funding and regulations to harmonize practices and improve data management

Strengthen Digital Health security and interoperability

- National interoperability frameworks to facilitate information-sharing between all state services
- International standards defined as references for software publishers
- For several years, the Croatian government has launched an Open Data initiative with the aim to facilitate data sharing and secondary use.
- Since 2020, Croatian physicians can access Maltese, Portuguese and Czech health data, and Croatian health data can be accessed by these countries. Croatian e-prescription can be collected in Finnish and Portuguese pharmacies, and Croatian pharmacists can provide medicines from Estonian, Finnish and Portuguese e-prescriptions.

Accelerate the deployment of core Digital Health services

- Secure health messaging solution for exchanges between healthcare professionals
- Prescription management service (drugs and consultations), and communication services with healthcare professionals, with e-prescription service widely deployed (used for 98% of prescriptions)
- Telehealth regulated by law and covered by health insurance (only if the healthcare provider is part of the telemedicine centres' network)
- Mobile health regulated and provided with a data collection authorisation, mainly based on the medical devices requirements

Country Profile: Croatia (4/4)

Croatia

Deploy Digital Health platforms at national level

- 4 core services implemented: (i) a directory of primary care professionals, (ii) a service for tracking past prescriptions, (iii) a service for online appointments with healthcare professionals, and (iv) a national portal for patients to manage their recorded health data and the associated access rights
- Individuals' identification systems to access health services (MBO ID) and healthcare professional identification card required to access all health services (PKI card)

Support innovation and promote buy-in from all stakeholders

- Training of healthcare professionals to use digital services and tools defined as a governmental priority
- Innovation projects mainly funded by the Croatian Health Insurance Fund with occasional support from European funds

Focus on the enforceability of national reference systems

- Croatia is implementing a certification process for information systems on data security and interoperability, especially for core services such as the national patient record.
- Croatia plans to define certification criteria regarding: certificates validity periods, certificate renewal conditions, or organizations' obligations and engagements.

Country Profile: Cyprus (1/4)

Cyprus

Summary of the Digital Health roadmap

Improvement of services and infrastructures - codification and classification of diagnoses and medical procedures, standardization of medical terminologies, deployment of health information systems throughout the country

National EHR – including numerous data (registries, medical history, lab results, medications, prescriptions, X-rays, etc.) developed and deployed within the country

Digitisation of the country - launch of a national Digital Health strategy (2007), creation of the Information System with the 2 main hospitals (2008)

Telemedicine deployment - setting up a regulatory framework and making infrastructures reliable

Digital Health litteracy - courses for healthcare professionals in digital technology (EHR, e-prescription, interoperability standards), citizens' information and empowerment (National Information Portal)

Deployment of e-prescription 2008-2013 – following a first experimentation, e-prescription was fully generalized. Mandatory trainings have been developed to support its use.

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Cyprus (2/4)

Cyprus

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National policy for the security of health information systems – *it is supported by the Information Technology Unit of the Ministry of Health, which is also responsible for supporting its implementation*
- National Committee for Bioethics
- The national Digital Health strategy stresses exhaustive communication regarding the rights of individuals and the use-cases of Digital Health

2. Enable individuals to manage their Digital Health use and data

- Unified system for collecting consent from citizens for the use of their health data in the context of care - this may still be done in paper form on arrival at the hospital

3. Make Digital Health inclusive and accessible to all

- Certifications regarding accessibility of digital tools for citizens (inclusion and disability)

4. Implement eco-responsible Digital Health

- *No defined ambition regarding environmental challenges*

Country Profile: Cyprus (3/4)

Cyprus

Strengthen Digital Health Governance

- National strategy drafted and its operational roadmap for Digital Health (NSRF 2007 - 2013) established and validated by the Ministry of Health and the Planning Bureau, and financed by the Cypriot Structural and Cohesion Funds
- Government entity dedicated to the organization of Digital Health and its implementation: the Information Technology Unit of the Ministry of Health

Strengthen Digital Health security and interoperability

- No national interoperability framework implemented - however, SNOMED-CT, IHE profiles and ICD10 standards widely deployed in the country (in 2009, Cyprus became a member of the IHTSDO)
- Data portability is not yet fully addressed.
- No regulation on secondary use of health data

Accelerate the deployment of core Digital Health services

- e-prescription widely deployed since 2008 with a high level of satisfaction
- No regulation or evaluation system to support mobile health applications

Country Profile: Cyprus (4/4)

Cyprus

Deploy Digital Health platforms at national level

- Creation in 2008 of the Information System of the 2 main hospitals of the country (Nicosia and Famagusta) followed by the implementation and use of the National Patient Record in 2013 in these 2 hospitals – but there is no personal health space for patients
- Undergoing project to develop a national system to exchange health data (i.e. decentralized EHR) but no patient portal are planned for the moment.
- Health identifier for citizens widely deployed since 2007; Identification of healthcare professionals in place since 2000 - associated authentication system eCard in planning

Support innovation and promote buy-in from all stakeholders

- Support for innovation projects – as with the two *initiatives Ambulance HC1001* and *Emergency-112 HC4027* set up by the University of Cyprus and the Nicosia Hospital for the creation of a portable medical device for emergency telemedicine, initially financed by the EU and then supported and deployed by the Cypriot government throughout the territory
- No regulation or control on the use of AI in the Digital Health sector
- Existing regulation and evaluation process for telemedicine but mHealth applications are not yet covered

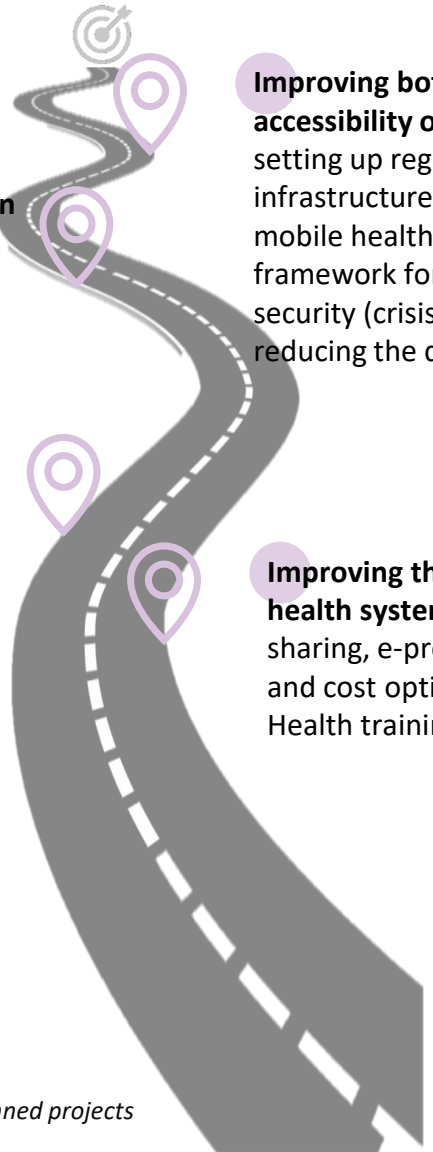
Focus on the enforceability of national reference systems

- *No regulation regarding the enforceability of national reference systems*

Country Profile: Czech Republic (1/4)

Czech Republic

Summary of the Digital Health roadmap



Increasing citizens' involvement in managing their health – e-appointment, teleconsultation, access to health data

Setting up and organising health infrastructures - creating centralized and mandatory health registers and databases, identifying professionals and citizens, access management, setting up and deploying interoperability standards and a National Health Record, implementing a legislative framework for Digital Health (privacy, security), European collaboration

Improving both quality and accessibility of health services - setting up regulation and infrastructure for telemedicine and mobile health services, setting a framework for data portability and security (crisis management), reducing the digital divide

Improving the efficiency of the health system – secure health data sharing, e-prescription, tracking and cost optimization, Digital Health training for professionals

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Czech Republic (2/4)

Czech Republic

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- The National Cyber and Information Security Agency issued Security standard for video conferencing in 2020.
- National eHealth Centre of the Ministry of Health has elaborated Strategy of cybersecurity, policies and Methodologies addressing cybersecurity issues in healthcare.
- National ethics committee and ethics committees in larger hospitals provide assessments of the scope of projects, studies and the use of collected research data

2. Enable individuals to manage their Digital Health use and data

- No national portal for citizens to access their health data exists. A few partial and experimental projects enable patients to access certain health data.
- Czech citizens have currently in 2022 access to (i) their COVID-19 vaccination record, and (ii) a national e-prescription service
- Participation of patients' representatives in strategic decisions and concepts of digital services, for example: Patients' Board within the Minister of Health

3. Make Digital Health inclusive and accessible to all

- The implementation of international (UN) guidelines on accessibility and EU Directive on the accessibility of websites and mobile applications are mandatorily applied to public health digital services
- Citizens have also the right to delegate the management of their data to a third party
- Czech Republic has a national information portal dedicated to health, which therefore also aims to provide explanatory/educational content so that citizens can learn how to use Digital Health solutions.
- This portal will soon be supplemented by "physical locations" to provide human support to citizens

4. Implement eco-responsible Digital Health

- The environmental issues are currently addressed at a general level, no specific initiative regarding this topic is in force yet in 2022
- Czech Republic co-signed a declaration of DigitalD9+ (D9+) of digitally advanced EU countries called "Making the green transition more digital and the digital transition greener" which identifies 7 axes for the development of a more responsible digital services

Country Profile: Czech Republic (3/4)

Czech Republic

Strengthen Digital Health Governance

- Strategic Digital Health roadmap validated by the Ministry of Health in 2016 and operational action plan validated in 2017
- National eHealth centre was established as part of Ministry of Health of the Czech Republic
- €10M invested for e-safety and €23M invested by the Operational Programme for Employment (OPE) with impact on Digital Health.
- €62M invested from 2017 to 2020 by the European investment fund IROP for the development of Digital Health

Strengthen Digital Health security and interoperability

- DASTA (Data standard for health care information exchange) is a Czech national standard for health care data exchange. It was established by a group of IT and scientific (medical) experts.
- No national interoperability framework to date, but it is under development - IHE profiles and HL7-FHIR standards are already deployed.
- There is a framework for national standards for the management of health documents and care procedures.
- MyHealth@EU: since 2020, There is technical infrastructure enabling Czech physicians to access Croatian health data. Czech health data, when available, can be consulted by Croatian and Luxembourg physicians since 2019, other counties will follow

Accelerate the deployment of core Digital Health services

- Mandatory e-prescription service since 2018 – effective use above 90%
- e-signature service for healthcare professionals is implemented
- Citizen electronic identification system is used for e-prescription and COVID-19 testing and vaccination
- National health information portal (nzip.cz) includes a directory of public healthcare providers

Country Profile: Czech Republic (4/4)

Czech Republic

Deploy Digital Health platforms at national level

- Besides national health portal, dedicated e-Prescription a COVID-19 vaccination record platforms and identification systems there is no nationwide platform. Concepts of nationwide access to EHR and telemedicine platforms are under study in 2022
- Making a healthcare professional identification system universal, individual identification system widely implemented (e-Identity)
- Dedicated portals for e-prescription and vaccination

Support innovation and promote buy-in from all stakeholders

- No specific regulation or assessment system for telehealth and mobile health apps is in use. Both are in preparation within the scope of a new Project from Recovery and Resilience Facility (RRF) “Telemedicine”, which should start in 2022
- Training opportunities in innovation and Digital Health for healthcare and other professionals
- No specific regulation on AI in Digital Health
- AKORD programme subsidizing doctors who equip themselves with a tool or service enabling them to practice telehealth that is offered by the GMIC

Focus on the enforceability of national reference systems

- No measures regarding the enforceability of national reference frameworks (EHR or interoperability).
- However, work in progress by the Ministry of Health (MoH) to establish control and sanction mechanisms for non-compliance with the future interoperability framework

Country Profile: Denmark (1/4)

Denmark

Summary of the Digital Health roadmap

Funding - €5.8B allocated by the government to build hospitals and IT infrastructure, as well as to support medical device development

Digital assistance tool - cancer patients (treatment adaptation) and pregnant women (2022)

Prevention Tools - medication administration errors, patients with chronic diseases, telemedicine reinforcement

System security - traceability of HCPs access to one's data in hospitals, prevention of cyber attacks, modernisation of IT infrastructure

Standardization - strengthening of the interoperability standards within the country

January 2021: Law on disclosure of Data Ethics Policy - first law in the world in this field

2018: "Min Læge" application - Secure messaging service between patient and GP, teleconsultation and access to health documents

2020: PRO (Patient Reported Outcome) - health questionnaire to enable better care

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Denmark (2/4)

Denmark

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- In 2019, an independent Data Ethics Council was launched by the government whose mission is to provide a perspective on the responsible use of data and promote new solutions that benefit society (and to implement a data ethical toolkit for businesses)
- In March 2019, the Danish government passed the Data Ethics Policy Disclosure Act
- Publication of a white paper (June 2021) named “Towards a better social contract with big tech” establishing 9 key principles regarding ethics in big tech

2. Enable individuals to manage their Digital Health use and data

- During the development of the Patient-Reported Outcome (PRO) service, many users were involved by participating in workshops: Health professionals from regions, municipalities and primary care, medical scientific institutions and patient unions
- A national strategy for health information security is being established (2019-2022)
- Individuals can appoint a “third party” to manage their health data

3. Make Digital Health inclusive and accessible to all

- Columna Cura: an electronic care and social record system that has been implemented in Danish municipalities, it enables elderly and chronically ill people to register and share information about their current care and treatment with health professionals.
- Interactive map showing the deployment of telemedicine and the projects in progress for each region (*https://telemedicinsk-landkort.dk/?locale=en*)

4. Implement eco-responsible Digital Health

- Denmark launched an online self-evaluation tool urging companies from every sector to be more self-conscious about their data responsibility – a flexible tool adapting to a wide range of company sizes and digital maturities, it tackles all sustainable, security and privacy criteria, aiming at a stronger digital Denmark while creating wider digital trust

Country Profile: Denmark (3/4)

Denmark

Strengthen Digital Health Governance

- There is a national strategic and operational roadmap dedicated to Digital Health, built by government authorities. Twice a year, the National Digital Health Council evaluates the progress made in implementing the strategy (each region/municipality has its own health services)
- Willingness to strengthen cooperation between public and private players in order to promote innovation in Digital Health (see roadmap)
- The Danish Health Data Authority is responsible for managing the national health data registry and Digital Health-related projects. It is also responsible for cybersecurity as well as the management of the healthcare reimbursement system.
- Medcom: public organisation belonging to the Ministry of Health in charge of the deployment of Digital Health services and the cooperation between actors in the health sector

Strengthen Digital Health security and interoperability

- There are national interoperability frameworks. In 2019, SNOMED-CT, COM-10 and the technical standard supported by IHE profiles were used. The HL7-FHIR standard is being implemented on all health systems.
- In addition to the GDPR, several regulations regarding data have been enforced: among others, the "Data Protection Act" and the "Health Act"
- "e-Journal": digital access to all the information of hospitals' EHR (for individuals and healthcare professionals)
- All patients' data is pseudonymized/anonymized in various (more than 15) health registries, which enable secondary use without collecting a dedicated consent: the data is accessible through a national platform associated to a search engine (*danishhealthdata.com*)

Accelerate the deployment of core Digital Health services

- Implementation of guidelines for the evaluation of mobile health applications
- Implementation of the "Joint public digitalisation strategy" (2016-2020) for the IT infrastructure modernisation

Country Profile: Denmark (4/4)

Denmark

Deploy Digital Health platforms at national level

- "Sundhed" (health) platform allowing citizens and healthcare providers to access data stored at the point of care, providing health literacy (e.g., regarding side effects of treatments) and is accessible through a dedicated application: "My Health" (data is accessible to patients through the Sundhed platform and to healthcare providers through their own software)
- "My Doctor" application that has been developed to enable communication between patients and general practitioners.
- Registry of all Danish healthcare professionals (managed by the Danish Patient Safety Authority)
- To connect to Digital Health services, a digital signature which includes (i) a unique ID, (ii) a password and (iii) a one-time password is used
- The shared medication record application (and the related national record) provides the history of past and current prescriptions. Citizens can request a prescription refill through the application and are able to access their children's data.

Support innovation and promote buy-in from all stakeholders

- Establishment of a research centre dedicated to artificial intelligence in healthcare (CAI-X) with dozens of projects underway
- There is a project called "Nordic Interoperability" to implement a platform ("Nordic Digital Health and Medication Platform") for the evaluation and the use of mobile health apps

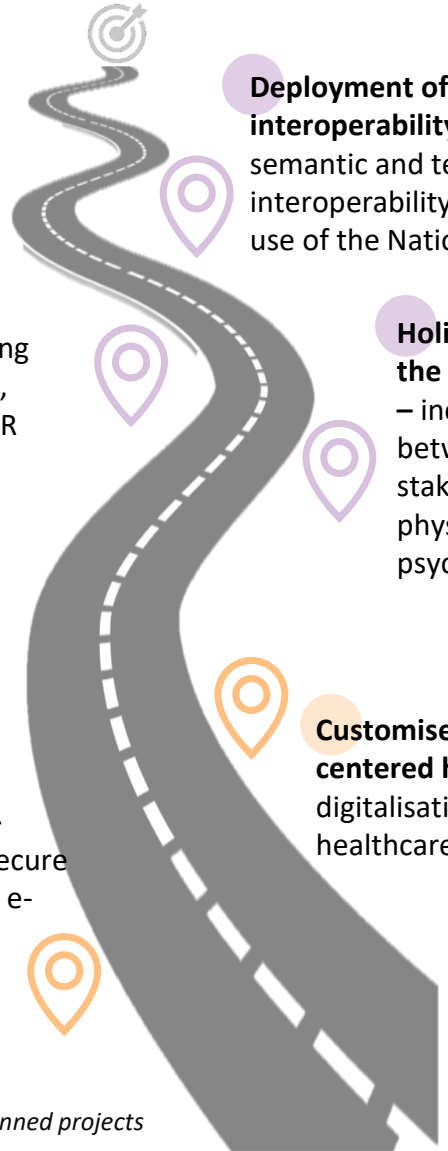
Focus on the enforceability of national reference systems

- The public institution Medcom is responsible for developing, documenting, testing and certifying the use of interoperability standards for health information systems.

Country Profile: Estonia (1/4)

Estonia

Summary of the Digital Health roadmap



Deployment of telemedicine and interoperability - teleconsultation, semantic and technical interoperability standards, mHealth, use of the National Patient Portal

Improvement of results and healthcare quality – strengthening the implemented infrastructures, especially with regards to the EHR and the HIS (national health database)

Holistic management of the healthcare process – increase cooperation between healthcare stakeholders (hospitals, physicians, psychologists, etc.)

Customised and patient-centered healthcare process – digitalisation of the patient healthcare process

Deployment of infrastructures – national Portal for health data, secure messaging service, national EHR, e-prescription and e-signature

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Sources

Country Profile: Estonia (2/4)

Estonia

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National Authority of Information Systems ensuring the cybersecurity of public-owned Digital Health systems, providing recommendations on data protection and security
- Several ethics committees such as Tallinn Medical Research Ethics Committee, Ethics Review Committee on Human Research of the University of Tartu, or Ethics Committee for health information, or ethics subgroups set up for dedicated projects

2. Enable individuals to manage their Digital Health use and data

- Estonian citizens are able to manage access to their data and to see which professionals have consulted their data or requested access to it.
- Citizens can download their data, but they cannot edit nor erase it. If they deem that a document is too sensitive, the citizen can “close” it.
- Many tools developed by Estonian e-state for data protection and transparency for individuals - among them, use of blockchain to ensure the integrity of people's data as well as a data embassy whose objective is to secure the most sensitive data
- When designing services, Estonia involves end-users in the design (identification of needs) and testing of its digital services

3. Make Digital Health inclusive and accessible to all

- Estonia applies the European Accessibility Guidelines.
- Citizens can appoint trustees for the management of their electronic patient records, possibility to go to a physical location (e.g., a library) Citizens also can go to a physical location (e.g., a library) to get help logging in to or using the portal

4. Implement eco-responsible Digital Health

- The Ministry of Economic Affairs and Communications has implemented a digital plan which includes objectives to reduce the carbon footprint of digital technology and to design more environmentally friendly solutions

Country Profile: Estonia (3/4)

Estonia

Strengthen Digital Health Governance

- Strategic roadmap implemented by the Ministry of Social Affairs and other stakeholders (governmental institutions, health insurance, physicians' associations, universities)
- Organisation dedicated to the Digital Health strategy (tehik.ee)
- €26M annual costs for both central services and HCP services
- A normative institution (TEHIK) is in charge of defining technical and semantical standards. A financial incentive is provided, by the authority in charge of health IS, contingent on proper implementation of national interoperability standards.

Strengthen Digital Health security and interoperability

- Regulation on the secondary use of health data (Public Information Act et Central HIS Statute) with a linked database: en.tai.ee
- National interoperability framework: (i) HL7-FHIR partially implemented (ii) limited implementation of SNOMED-CT due to Estonian particularities and (iii) limited implementation of OMOP.
- MyHealth@EU: since 2020, Estonian e-prescriptions can be collected in Finnish and Croatian pharmacies. Estonian pharmacists can provide medicines with Croatian, Finnish and Portuguese e-prescriptions.
- The Ministry of Economic Affairs has developed a solution allowing individuals to give their consent for the secondary use of their data. This solution would support the individuals in understanding what value could bring secondary uses of their data and give an informed consent.

Accelerate the deployment of core Digital Health services

- Several services: patient summary, e-prescription, referral letters, Covid certificates, health appointment booking, etc.
- e-prescription and secure messaging service used by all healthcare professionals with a high satisfaction level
- Reimbursement of teleconsultations aligned with the reimbursement of in-person consultations since 2021
- No regulation for the reimbursement mHealth applications or digital therapies (assessment system for mHealth applications from Taltech and Tartu universities not mandatory)

Country Profile: Estonia (4/4)

Estonia

Deploy Digital Health platforms at national level

- National patient portal to access health data and additional services: *eesti.ee* and *digilugu.ee* – 62% of Estonians connected in 2020 and wide use
- Access by individuals to their health information (e.g., patient summary, prescription, referral letters, etc.) and Digital Health services. Currently, the national health record on which is built the Patient Portal does not store patient generated data
- e-ID service allowing the authentication to the national portal
- National directories to index HCPs and health and social structures

Support innovation and promote buy-in from all stakeholders

- AI-based personalised medicine project revolving around the analysis of the genome to tailor medications with a dedicated ethics group, potentially supporting the development of a framework on the development of “ethic by design” Digital Health solutions
- Training program created by the Ministry of Social Affairs and dedicated to improving healthcare professionals’ use of digital services. Objectives: between 2020 and 2022, 500 HCPs will attend this training in addition to their initial cursus
- National infrastructure for the Digital Health innovation: haigekassa.ee

Focus on the enforceability of national reference systems

- The use of the EHR and its interoperability standards is required by the law.
- Functional and security inspections are carried out before the implementation of national tools. For private services, controls are done after the market launch.

Country Profile: Finland (1/4)

Finland

Summary of the Digital Health roadmap

Smart hospitals - project for hospital digitalization and health system sustainability

Inclusion of e-prescriptions into the National EHR - project started in 2007 and now completed

Implementing e-prescriptions - started in 2002 and completed in 2007

Implementing a national identification system - for patients (FINUID)

Implementing telemedicine (2010) - teleconsultation, telediagnosis, telemonitoring, telelaboratory services, video conferences

Funding - €33M from the government for the development of national Digital Health services (between 2006 and 2010)

€55M for the implementation of Digital Health systems (between 2011 and 2014)

Digital Health courses for healthcare professionals

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Finland (2/4)

Finland

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Health expertise within the national data protection authority, appointed by the Minister of Justice (TELLU)
- THL (Finnish Institute of Health and Welfare) Ethics Committee provides assessments of the use of collected research data
- Finnish government has established an AI ethics committee to better support ethical principles and to ensure that AI development in Finland is human-centred and based on trust
- An ethical handbook is currently being developed and will be shared with the ecosystem

2. Enable individuals to manage their Digital Health use and data

- Opinions and recommendations of EHR users constantly taken into account through satisfaction surveys
- Several health data protection laws have been passed in addition to the GDPR: "Data Protection Act", "Act on Patient's Status and Right", "Decree on Patient Record". The "Act on secondary Use of Health and Social data" was codeveloped with the ecosystem to prevent any security or ethical breach while developing health data secondary use.
- Individuals can fully manage the data they upload on their "personal health record" within the Kanta infrastructure.

3. Make Digital Health inclusive and accessible to all

- Design principles defined in the national regulation, stating that all digital services must ensure the usability, accessibility, and continuity of services
- Some NGOs representing several groups of individuals (e.g., elderly, immigrants) have set up training courses to improve their digital skills at local/regional level
- Mandatory accessibility guide set up to define the requirements for connecting new digital services to the Kanta portal

4. Implement eco-responsible Digital Health

- *The environmental issue is typically more addressed at a widest level*

Country Profile: Finland (3/4)

Finland

Strengthen Digital Health Governance

- Finnish health system is managed regionally, however, a national strategic roadmap has been built.
  Findata (secondary use of data) and Kanta (national patient portal) are managed at the national level.
- The Finnish Institute of Health and Welfare (THL) is responsible for managing health data registries. Since 201, Findata is the national body responsible for collecting health data, combining it and issuing permits for secondary uses.

Strengthen Digital Health security and interoperability

- Managed data is divided into two types: patient-generated data (editable and erasable), and health professional-generated data (neither editable nor erasable)
- MyHealth@EU: Finnish e-prescriptions can be collected in Croatian (2019), Estonian (2019) and Portuguese (2020) pharmacies. Finnish pharmacies can also provide medicines from Croatian, Estonian and Portuguese e-prescriptions
- Data stored in Kanta personal health record using HL7-FHIR interoperability standard

Accelerate the deployment of core Digital Health services

- Kanta is the national centralised infrastructure supporting the exchange of health data thank to an integrated approach and common interoperability standards. Regional/local systems are connected to the infrastructure and provide / retrieve data stored within the national infrastructure. This infrastructure include numerous national databases (pharmaceutical, imaging, patient record, etc.).
- Telehealth has existed since 1995 and is regulated and covered as a standard health care procedure. Mobile health is highly developed in Finland, with over 100,000 health apps available in the country
- Electronic identification services are provided to both individuals and healthcare providers to access Digital Health services.

Country Profile: Finland (4/4)

Finland

Deploy Digital Health platforms at national level

- MyKanta Pages that is the national platform for individuals to access their own health data, e.g., diagnoses, procedures, lab results, vaccination data and risk information. It is connected to the Kanta infrastructure.
- Individuals can upload their own data through MyKanta Pages and manage a personal health record (PHR). They can allow mHealth and IoT to share data with their PHR.
- MyKanta Pages includes e-prescription service with digital renewals of prescriptions, as well as the sharing of medical certificates and possibilities for individuals to state and manage their consents and living wills

Support innovation and promote buy-in from all stakeholders

- The "AI Innovation Ecosystem for Competitiveness of SMEs (AI-TIE)" programme (2021-2023) promotes innovation via artificial intelligence in SMEs, particularly in the health sector. The government is setting up a Centre of Excellence for AI and Masters programs in AI.
- Project "Nordic Interoperability“ implementing a platform ("Nordic Digital Health and Medication Platform") for the evaluation and use of mobile health applications
- SITRA is a Finnish Innovation Fund who has initiated the “Health Data 2030” project, aiming at implementing strategic objectives of Fair data economy (from the perspective of the use of health data)
- Finnish commitment (2019) is intended to implement digital training in health professionals' curricula

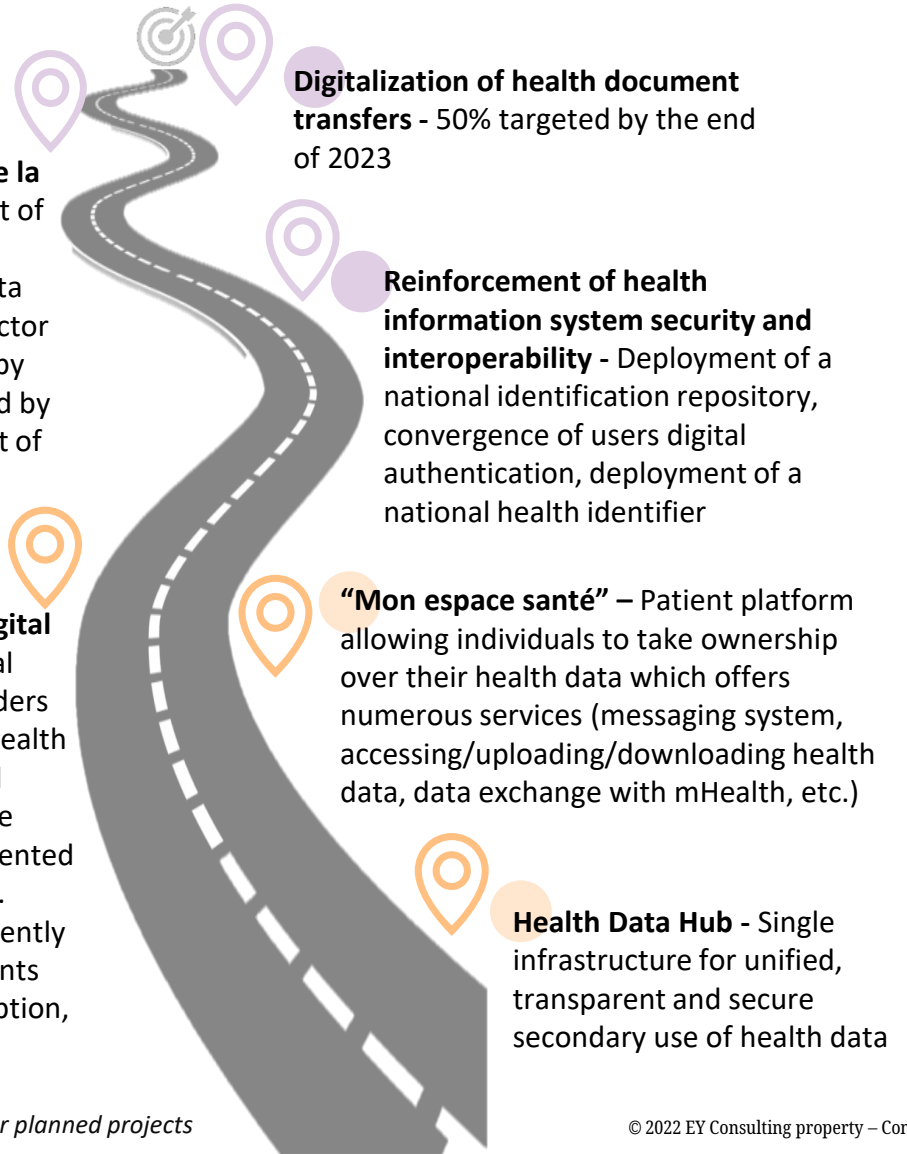
Focus on the enforceability of national reference systems

- Findata is responsible for processing and adjudicating applications for a data permit for (i) data from several different public controllers combined, (ii) data that originate from one or more private social or health care providers and (iii) data stored in Kanta services.

Country Profile: France (1/4)

France

Summary of the Digital Health roadmap



Digitalization of health document transfers - 50% targeted by the end of 2023

Digital part of the "Ségur de la Santé" - Massive investment of €2B in digital technology to universalize easy, secure data sharing within the health sector by upgrading the EHR used by the healthcare providers and by supporting the development of innovative solutions

Reinforcement of health information system security and interoperability - Deployment of a national identification repository, convergence of users digital authentication, deployment of a national health identifier

Implementation of core digital services – such as a national identifier, healthcare providers identity providers, secure health messaging service, national patient health record. These services have been implemented and are currently deployed. Additional services are currently being developed (e.g. patients identity provider, e-prescription, etc.)

"Mon espace santé" – Patient platform allowing individuals to take ownership over their health data which offers numerous services (messaging system, accessing/uploading/downloading health data, data exchange with mHealth, etc.)

Health Data Hub - Single infrastructure for unified, transparent and secure secondary use of health data

Key indicators

Patient health record	✓
E-prescription service	✗
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: France (2/4)

France

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Specific certification on health data hosting and dedicated security and interoperability frameworks ensuring that data are exchanged securely and are accessible to individuals
- "GT éthiques": working groups on Digital Health ethical issues
- Funding provided to conduct experiments with AI-based solutions and identify best practices to deploy them later

2. Enable individuals to manage their Digital Health use and data

- Digital Health France Tour carried out (Sept. 2019 to Feb. 2020) to introduce the national Digital Health policy and discuss its practical implementation with all Digital Health players (software vendors, healthcare providers, patients representative) involved in all regions
- Advisory boards created, representing the individuals in Digital Health projects governance (such as the Health Data Hub) and when framing new solutions (such as "Mon Espace Santé")
- Ability of individuals to fully manage their health data, choose who can access it and give their consent for health data exchanges through "Mon espace santé"

3. Make Digital Health inclusive and accessible to all

- Strong emphasis on individual participation through regular consultations (e.g. CNS)
- Willingness to frame the ethical dimension in Digital Health to overcome the digital divide and promote inclusion
- Ambassadors appointed in Regional Health Insurance Funds and in local offices to support the use of new solutions (especially Mon espace santé)
- Mandatory compliance to "RG2A" (General Accessibility Improvement Framework)

4. Implement eco-responsible Digital Health

- Strong willingness to include the environmental dimension into the design and the use of digital services
- Creation of an ecoscore for mHealth: each app referenced in the "Mon Espace Santé" app store must obtain a minimum score following a code review
- Creation of an ecoscore for hospital information systems which will be integrated into the hospital audit and certification process conducted by the national health authority

Country Profile: France (3/4)

France

Strengthen Digital Health Governance

- Clearly defined strategic and operational governance of Digital Health (Digital Health delegation of the French Ministry of Solidarity and Health, Digital Health National Agency, Digital Health doctrine, Ma Santé 2022 strategy, Segur Numérique roadamap, etc.)
- Regulatory framework for Digital Health defined (e.g. secondary use of health data, use of the national identifier, health data hosting, etc.) associated with ongoing reflections on the future use of AI

Strengthen Digital Health security and interoperability

- National implementation of international interoperability frameworks (HL7-FHIR, HL7 CDA and IHE profiles) with ongoing challenges to fully deploy them
- Active participation in interoperability projects at European level (epSOS, Digital Health network, eHAction, MH@EU, THEDAS, EHDS)
- Beyond the GDPR, regulation on secondary use of data and establishment of a national and centralized database of health data (HealthDataHub)
- Enforceable national security and interoperability frameworks for Health IS (a certification process has been deployed to assess and certify the solutions compliance)

Accelerate the deployment of core Digital Health services

- Numerous core services implemented: shared medical record (DMP), secure health messaging (MSS), e-prescription, national health identifier (INS), healthcare professionals identity provider (ProSanté Connect), regional services, etc.
- e-prescription service and e-signature for health documents (via e-CPS) currently being deployed
- secure messaging service between healthcare professionals is already deployed (effective use around 25%) and now support secure exchanges with individuals
- Investment of €2B to support the deployment and use of the “core Digital Health services” and data exchanges

Country Profile: France (4/4)

France

Deploy Digital Health platforms at national level

- National patient portal deployed (Mon Espace Santé) to empower individuals in their health and gave them ownership of their data, offering numerous services (record, advices, messaging services, etc.)
- Health Data Hub (HDH) platform deployed to gather data and enable large scale secondary use
- Regional coordination tools, including data exchanges solutions and telemedicine platforms provided at the regional level
- Electronic identification and authentication solutions for individuals (“Carte Vitale” app) currently under development
- Electronic health identification for all individuals through the “INS”
- New platform including various digital services dedicated to healthcare providers being framed to be provided in the coming years

Support innovation and promote buy-in from all stakeholders

- Specific funding for innovation in Digital Health (Ségur, PIA4, Innovation Santé 2030) with a clear focus on AI-based solutions and the support of various experimentations
- Development of the management and prescription of digital therapies, ongoing deployment (particularly remote monitoring)
- Development of training in innovation and Digital Health and creation of PariSanté Campus (a national campus to support innovation and collaboration between the public and private sectors)
- Reimbursement of telehealth (teleconsultation since 2018, tele-expertise since 2019, and telemonitoring starting in 2022)

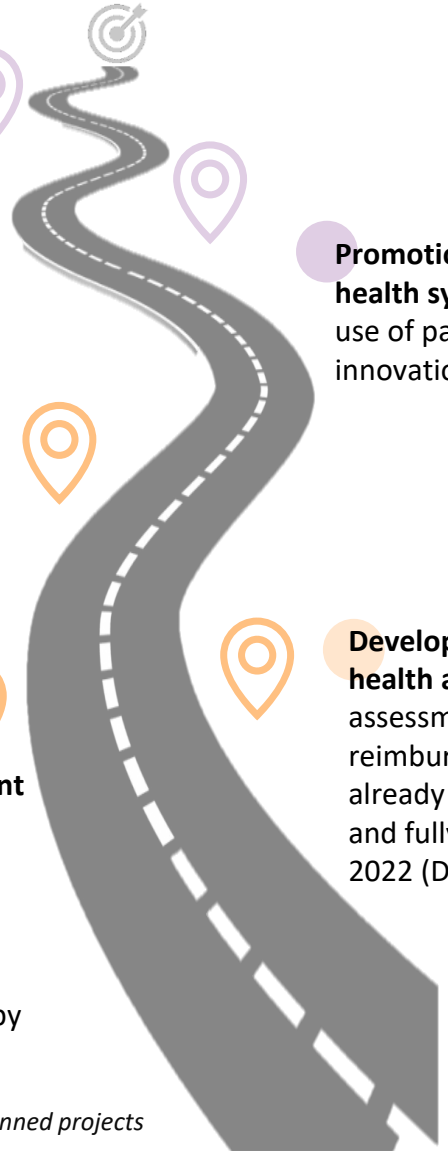
Focus on the enforceability of national reference systems

- National frameworks established for the interoperability and security of health information systems, but also for the secure hosting of health data
- The CNDA is responsible for carrying out tests prior to the use of a national component by a software publisher

Country Profile: Germany (1/4)

Germany

Summary of the Digital Health roadmap



Ramp-up of telemedicine - with telediagnosis, teleconsultation, teleexpertise, teletherapy or remote monitoring (legal framework defined since 2016)

Promotion of Big Data in the health system - integration and use of patient data for research, innovation and public health

Security and interoperability of health information systems - enforcement of regulations and deployment of standards for data sharing and protection

Development of mobile health applications - assessment and reimbursement system already widely implemented and fully implemented by 2022 (DiGA, BfarM scheme)

Deployment of a unified Patient Medical Record - launched on 1st January 2021 and available for Patients through mobile.(each insurance fund is providing a portal compliant to the national guidelines issued by the Ministry of Health)

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Germany (2/4)

Germany

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Report on big data and health published by the German Ethics Council (2017), giving rise to much reflection and discussion in public and research areas
- Standardization roadmap on AI In 2021 published by the German standardization institution (DIN), covering, among other things, ethical issues
- Health insurance companies legally obliged to provide patients with comprehensive information on the processing of medical data upon request

2. Enable individuals to manage their Digital Health use and data

- Ability of every individual to decide which medical data is shared and with whom healthcare providers thanks to the electronic health card (eGK) and the newly launched patient portals
- Health data portability ensured through all patient portals relying on the same technical and interoperability standards (that are certified by the gematik)

3. Make Digital Health inclusive and accessible to all

- Dedicated support and communication for patients and healthcare professionals currently being deployed to highlight the advantages of using electronic health records, as well as providing support
- German Care Modernisation Act: tackling the issue of the digital divide (for instance, dedicated offices created, where individuals can be supported when using Digital Health solutions)
- Germany is planning a study to investigate the use of digital technologies and robotics in long-term care to find out under which conditions their use is appropriate and creates real added value for those in need of care.

4. Implement eco-responsible Digital Health

- KLIK GREEN: project involving health stakeholders to avoid at least 100,000 tons of CO_2 equivalents emissions within the project period
- Framework for climate-smart health facilities published by KLUG
- Handbook of green practices published: information to help healthcare providers achieve climate protection
- Report of the Health System Advisory Council of 2021, addressing the issue of equal responsibilities which have to be observed in the development of Digital Health

Country Profile: Germany (3/4)

Germany

Strengthen Digital Health Governance

- Shared governance between the national level (insurance & reimbursement) and the federal level (finance & education)
- €5B invested in the development of artificial intelligence by the German Federal Government by 2025 with strong commitment for the health sector
- Private sector consulted when drafting the Digital Health Agenda
- €3B invested in the development of hospitals' modern emergency capacities, digitization and IT security by the KHZF fund (70%), and federal states and hospital operators (30%) by 2023

Strengthen Digital Health security and interoperability

- Implementation of the Telematic infrastructure to ensure improved medical care and high data security of the Digital Health thanks to common technical standards and security measures (e.g. the healthcare providers identification is conducted in the Telematik infrastructure)
- National interoperability framework (HL7-FHIR and IHE profiles): about 25% of health infrastructures use these standards
- Based on the GDPR, regulation on secondary use of data and implementation of centralized health databases for research (e.g., Health Data Lab at BfArM for research and health care planning)

Accelerate the deployment of core Digital Health services

- Identification and authentication of individuals through the electronic health card (eGK) launched on 1st January 2015
- secure health messaging service being deployed to secure and support exchanges between healthcare providers
- Healthcare providers able to identify and authentify themselves electronically through the Telematik infrastructure
- e-prescription and e-signature of health documents currently being deployed according to the law

Country Profile: Germany (4/4)

Germany

Deploy Digital Health platforms at national level

- Patient health record offered by insurance companies
- January 2021: first technical elements and start of electronic health record roll-out, focusing on: (i) the doctor's letter, (ii) diagnosis results, (iii) electronic medication plan, (iv) electronic emergency data and (v) vaccination records
- “Health Data Lab” gathering data from different sources for secondary use. Starting 2023, the individuals will be able to share their electronic health record with this national database

Support innovation and promote buy-in from all stakeholders

- Support to Digital Health research projects through several funding programs: Digital Agenda 2014-2017, Reinforcement Act (€75M), New High-Tech Strategy and Research Framework Programme
- Creation of training sessions in innovation and Digital Health for healthcare professionals (example of the INVITE platform)
- Support to 22 projects from 2020 to 2023 by the government under the programme "Digital innovations for the improvement of patient-centred care in the health care system" (€50M)
- Telemedicine and mHealth reimbursed, with €225M invested from 2016 to 2019 to support Digital Health innovation and an emphasis on telemedicine

Focus on the enforceability of national reference systems

- Digital Health Application: BfarM's mechanism to assess and reference authorized mobile apps
- The evaluation is carried out according to 5 main themes: device security, data protection and information security, interoperability, quality (ease of use, quality of medical content) and medical impact

Country Profile: Greece (1/4)

Greece

Summary of the Digital Health roadmap

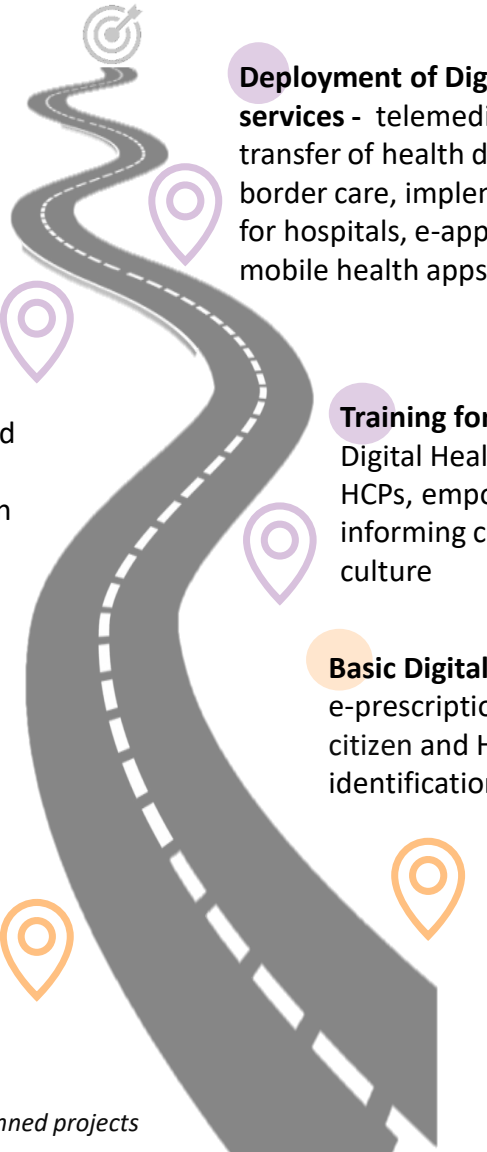
Harmonize health exchanges and the health data process – deployment of European interoperability standards, implementation of the National Electronic Healthcare Record, codification of health documents, improvement of services dedicated to the access of health data for citizens and professionals, creation of patient directories

Deployment of Digital Health services - telemedicine, digital transfer of health data for cross-border care, implementation of IS for hospitals, e-appointment, mobile health apps

Training for better care – Digital Health training for HCPs, empowering and informing citizens, innovation culture

Basic Digital Health services – e-prescription, e-signature, citizen and HCP electronic identification

Trustful environment established – collection of consent for the use and share of health data, support to innovation, regulation for protection and hosting of health data



Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Greece (2/4)

Greece

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Communication towards individuals regarding their rights and Digital Health matters (through newsletters and television), however, no involvement in the drafting of Digital Health strategy
- National policy regarding the security of health IS (managed by institutions not dedicated to Digital Health)
- Hosting services for healthcare organizations provided by Greek Research and Technology Network and the e-Government Centre for Social Security

2. Enable individuals to manage their Digital Health use and data

- Unified system to collect consent of individuals regarding the use of their health data for care or research
- Additional regulations enforced apart from GDPR (L. 4624/2019) related to security, confidentiality and data protection

3. Make Digital Health inclusive and accessible to all

- Application of Accessibility Act

4. Implement eco-responsible Digital Health

- Stated ambition to reduce the environmental impact of Digital Health, but not defined

Country Profile: Greece (3/4)

Greece

Strengthen Digital Health Governance

- National strategic and operational roadmap for Digital Health established by the Health Ministry, the Ministry of digital governance, IDIKA, EOPYY, the national network of telemedicine and EOF
- Governmental agency dedicated to the Digital Health organisation, National Council for Digital Health governance within the Ministry of Health, where HCPs are represented
- €891M in grants and €646M in loans injected through Recovery and Resilience Facility
- €10M invested each year for the digitalization of health – however, large-scale deployment of Digital Health solutions still complex

Strengthen Digital Health security and interoperability

- No national interoperability framework – however, thanks to the launch of the e-prescription service, a deployment procedure is currently being considered
- Normative institution for technical and semantic interoperability

Accelerate the deployment of core Digital Health services

- secure messaging service for HCPs (still low use rate)
- Mandatory use of e-prescription since 2013 (high satisfaction level, 90% of prescriptions renewed electronically)
- e-appointment service used by 38% of individuals since 2020, e-signature service used for 100% of documents
- No regulation nor assessment system for mobile health applications – however national application (MyHealth) provided for a secure access to health data (eIDAS compliant)
- No regulation nor assessment system for telemedicine services – however, deep interest regarding its implementation - telehealth certification for HCPs attributed by the EDIT

Country Profile: Greece (4/4)

Greece

Deploy Digital Health platforms at national level

- Centralised Digital Health record for individuals (authentication, document management, calendar, secure messaging service, etc.) announced but not deployed yet
- Identification system for citizens (used by 50% of the population) and unique identification number for HCPs (used by 96% of them)

Support innovation and promote buy-in from all stakeholders

- National Research Institute and Greek Research and Technology Network leading Digital Health research
- Greek Research and Technology Network and e-Government Centre for Social Security supporting Digital Health project leaders
- National documentation centre (EKT) in charge of Digital Health innovation - *In 2019, more than 20 start-ups participated to EIT Health (European Institute of Innovation Technologies in Health) programs thanks to EKT*

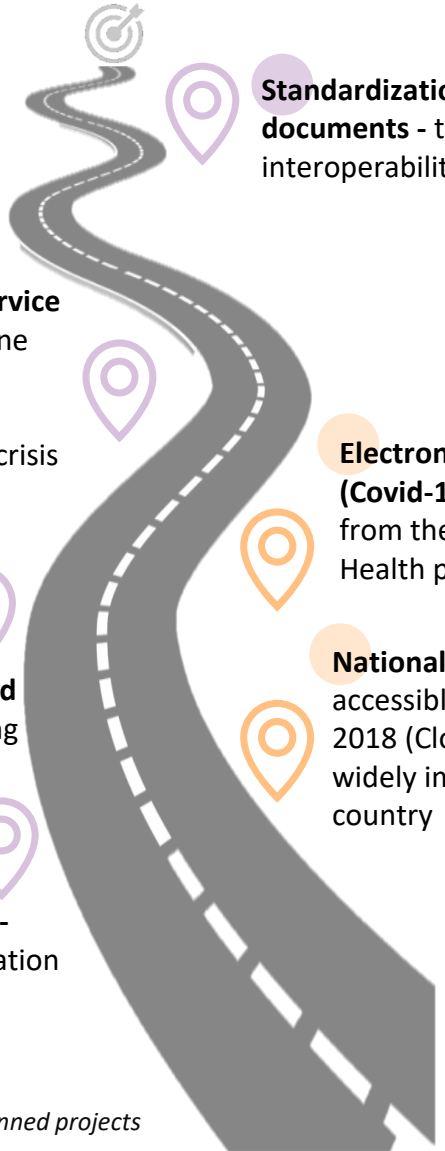
Focus on the enforceability of national reference systems

- There is a legal framework for the implementation of interoperability standards: NeHIF. No financing or controls are forecast for its establishment.
- This framework has been elaborated by the Greek government and the IDIKA.

Country Profile: Hungary (1/4)

Hungary

Summary of the Digital Health roadmap



Standardization of Digital Health documents - to ensure interoperability across the country

Implementing a telemedicine service - regulation regarding telemedicine including e-appointments and teleconsultations, implemented temporarily due to the Covid-19 crisis until June 2020

Electronic vaccination record (Covid-19) - downloadable from the national Digital Health portal

National e-prescription service - accessible by all pharmacists since 2018 (Cloud-based) and currently widely implemented across the country

Allowing individuals to download their health documents – ongoing through the national platform EESZT

Recovery and Resilience Facility - €308M allocated for the digitalisation of the health system

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Hungary (2/4)

Hungary

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Health Data Act (1997) implemented regarding the protection of personal health data
- Data protection included in all the Digital Health infrastructures with an Ethics-by-Design approach

2. Enable individuals to manage their Digital Health use and data

- Individuals can manage their consent through the national Digital Health platform EESZT thanks to the « self-determination » service

3. Make Digital Health inclusive and accessible to all

- *No specific initiative regarding this topic*

4. Implement eco-responsible Digital Health

- *No specific initiative regarding this topic*

Country Profile: Hungary (3/4)

Hungary

Strengthen Digital Health Governance

- National Digital Health Infrastructure and its specialised modules established within the framework of 2 projects under the social infrastructure operating program with support from the EU and funds of the Hungarian State (total investment of €13M and close cooperation between the Hungarian State and the EU)
- Strategic roadmap drafted for the digitalisation of health, but no operational roadmap

Strengthen Digital Health security and interoperability

- Mandatory national interoperability framework for all Digital Health stakeholders
- Informational self-determination and freedom granted through the Information Act (2011)
- The National Cybersecurity Centre is in charge of cybersecurity matters. A national authority for data protection and freedom of information exists, but it is not dedicated to Digital Health.
- A regulation regarding the secondary use of health data is implemented and a national platform to access this data is currently available.

Accelerate the deployment of core Digital Health services

- National Institute of Pharmacy and Nutrition (OGYEI) in charge of assessing mobile health applications
- Secure messaging service to exchange with healthcare professionals and secure messaging service dedicated to healthcare professionals
- Telemedicine regulated through Directive 2020/559/HU (Ministry of Health) – covering reimbursement of e-prescriptions, treatments and therapies (mandatory prerequisites: identification, data protection and suitable equipment)
- National mandatory e-prescription service, e-signature service

Country Profile: Hungary (4/4)

Hungary

Deploy Digital Health platforms at national level

- National patient record accessible through to the platform EESZT (70% of effective use by individuals)
- Electronic identification system for individuals (with an effective use of 60%) and electronic identification system for HCPs (100% use)

Support innovation and promote buy-in from all stakeholders

- Since 2018, the training for the use of the national platform EESZT incorporated into HCPs' curriculum, HCPs have access to e-Learnings (with final exam) through this platform.
- National Institute of Health Services in charge of managing and executing Digital Health projects.
- Among other projects, the National Research Development and Innovation Office is in charge of Digital Health research projects.

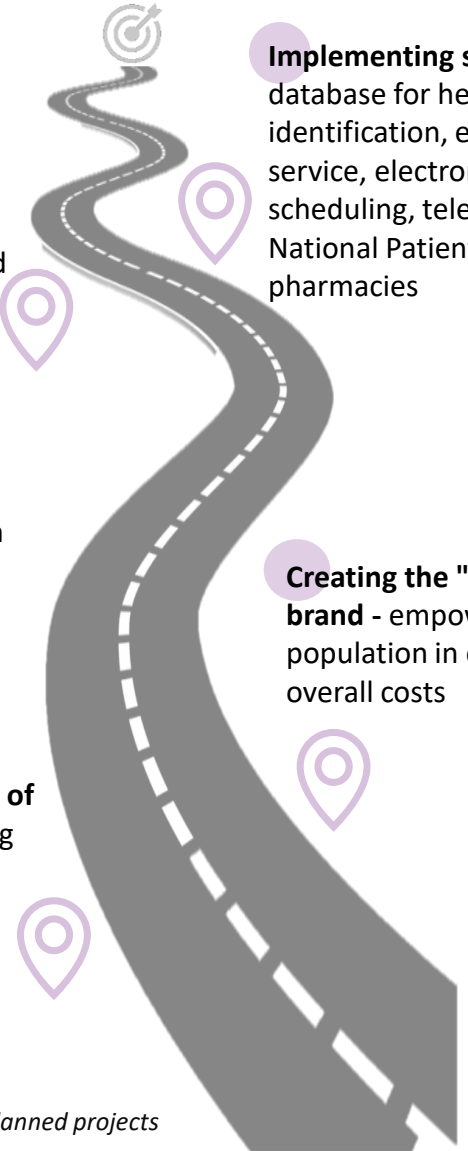
Focus on the enforceability of national reference systems

- The interoperability framework set at a national level is enforceable
- Legal framework for publishers as a compulsory accreditation to access the national Digital Health infrastructure

Country Profile: Ireland (1/4)

Ireland

Summary of the Digital Health roadmap



Implementing solutions - national database for healthcare providers identification, e-prescription service, electronic appointment scheduling, telemedicine, EHR, National Patient Portal, e-pharmacies

Creating an ecosystem - tailored funding programs, change management, training and resources on Digital Health, regulation on interoperability standards, regulation on privacy and user data protection, communication and information to the public, public/private cooperation

Creating the "Irish Digital Health" brand - empowering the population in order to reduce overall costs

Putting the patient at the heart of the health care system - creating reliable sources of information, facilitating participation in the care process, encouraging individual engagement with specialised programs

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✗
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Ireland (2/4)

Ireland

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National policy for health information systems security established (data protection and cybersecurity) – this policy is not supported by specific Digital Health bodies
- Strong willingness to empower individuals to manage their health by informing them about existing solutions and their use

2. Enable individuals to manage their Digital Health use and data

- *No defined ambition on the subject*

3. Make Digital Health inclusive and accessible to all

- *No defined ambition on the subject*

4. Implement eco-responsible Digital Health

- *No defined ambition on the subject*

Country Profile: Ireland (3/4)

Ireland

Strengthen Digital Health Governance

- National strategy drafted (Digital Health Strategy for Ireland) and its operational roadmap - however, complex implementation of digital solutions resulting in slow progress towards the objectives
- Public and private cooperation on the whole care pathway still weak, however co-development workshops set up between government, companies, schools and universities, research, associations
- Government entity dedicated to the organisation of Digital Health (Digital Health Ireland) but no dedicated agency for its implementation, directly managed by the Health, Safety and Environment ISD

Strengthen Digital Health security and interoperability

- No national interoperability framework - nevertheless, HL7-FHIR and SNOMED-CT standards used by some hospitals, especially for birth and maternity, or by general practitioners for patient follow-up
- No regulation on secondary use of data
- Low maturity on cybersecurity and data protection (e.g., May 2021 cyberattack), however measures rapidly being put in place to address this issue, including moving Digital Health services and data to more secure cloud infrastructures
- Data portability not always addressed

Accelerate the deployment of core Digital Health services

- e-prescription used for prescription renewal by general practitioners
- No National Patient Record - some hospitals have developed their own EHR, however, the majority are still working with paper documents
- No regulation, procedure or evaluation system regarding mobile health applications management
- No regulation, procedure or evaluation system regarding telemedicine acts management

Country Profile: Ireland (4/4)

Ireland

Deploy Digital Health platforms at national level

- No plan to create a centralized personal health space for patients (authentication, document management, calendar, secure messaging, etc.) - however, messaging and electronic calendar for blood tests provided through HealthLink website
- HealthLink: secure messaging system for GPs to communicate with each other and with hospitals (30% effective use rate)
- Patient identification system developed - accelerated thanks to Covid pandemic but not yet finalized
- No identification system for healthcare professionals

Support innovation and promote buy-in from all stakeholders

- €225M invested by the European Investment Bank in the Digital Health sector – however, this amount remains unused to date
- No funding or training in Digital Health for healthcare professionals

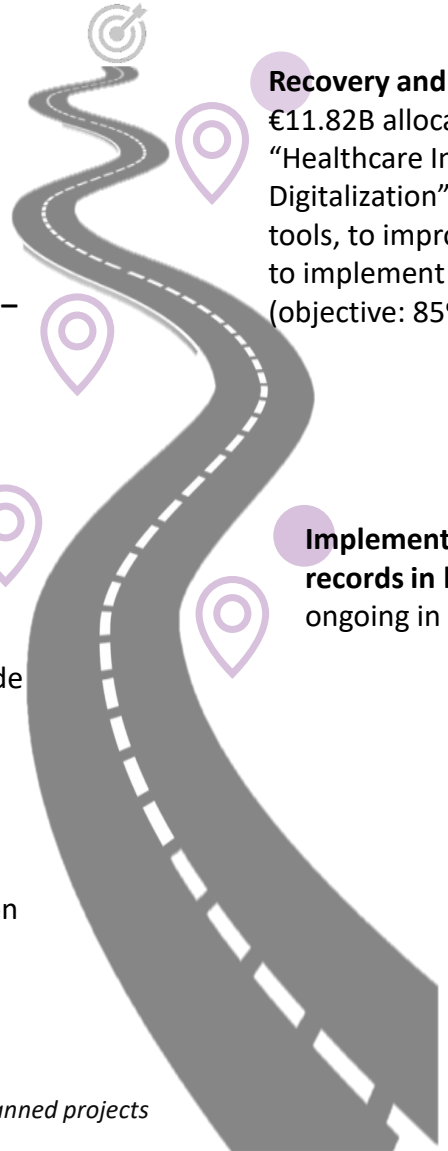
Focus on the enforceability of national reference systems

- Financial incentives with hospitals and general practitioners for the use of Digital Health services such as HealthLink
- Cybersecurity and privacy standards tested before solutions are released to the market: each test independently performed on each specification

Country Profile: Italy (1/4)

Italy

Summary of the Digital Health roadmap



Recovery and Resilience Facility – €11.82B allocated for the project "Healthcare Innovation, Research and Digitalization" to implement telemedicine tools, to improve Digital Health tools and to implement a national patient record (objective: 85% of use by 2026)

Recovery and Resilience Facility – €7.9B allocated for the project "Proximity assistance and telemedicine" to standardize the health system

Implementing Digital Health records in hospitals – currently ongoing in hospitals

Implementing a national Digital Health record – which is the number one priority. It will include other services such as electronic identification for individuals, administrative data, first aid reports, letters of discharge, a medicine record, a patient summary and a consent collection system for organ donations

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✗
Is it enforceable?	
Individuals' access to their health data	✓
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Italy (2/4)

Italy

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Dichiarazione dei diritti in Internet: Declaration of rights related to the use of Internet (2015) that specifies rights regarding social impact of technologies which are applicable to Digital Health platforms: the right to equal access to Internet and its data for all, as well as the right to receive clear and accessible information on the use of digital platforms

2. Enable individuals to manage their Digital Health use and data

- Communication campaigns planned to inform individuals regarding the implementation of the national patient record
- National entity dedicated to data protection ("Garante per la privacy") responsible for the application of the GDPR and consulted to frame new projects
- Open Innovation: collaborative digital platform developed in 2015 to foster the growth of Lombardy's innovation and research ecosystem, allowing users to participate in various discussions and provides news on innovative topics

3. Make Digital Health inclusive and accessible to all

- Tech2Doc platform implemented, built to provide training and information on innovation and new technologies to support medical practices

4. Implement eco-responsible Digital Health

- *No information or project identified on this matter*

Country Profile: Italy (3/4)

Italy

Strengthen Digital Health Governance

- National strategy drafted (through the Recovery and Resilience Facility) with its operational roadmap – however, implementation quite complex led at regional level
- Digitalization of the health sector managed by the Ministry for Technological Innovation and Digitization, Digital Health mostly addressed at a regional level
- Private stakeholders involved in the drafting of the Digital Health strategy

Strengthen Digital Health security and interoperability

- National interoperability framework (use of HL7-FHIR) – however, its implementation remains to be improved
- Commitment to participate in the European NCPeH project by 2022
- No regulation on secondary use of data beyond the GDPR
- Regional cybersecurity systems regarding health data

Accelerate the deployment of core Digital Health services

- e-prescription service already deployed and widely used across Italy
- Implementing an EHR within hospitals currently in project phase - however, differences of maturity between the regions
- No secure messaging service between healthcare professionals
- No centralized identification system for healthcare professionals. Individuals are electronically identified thanks to the “SPID” service (which is used for all public services)

Country Profile: Italy (4/4)

Italy

Deploy Digital Health platforms at national level

- National patient record implemented in most Italian regions, each region having its own Digital Health portal - *As part of its recovery plan, Italy plans to deploy a national patient portal in the coming years*
- No secure messaging service for individuals to communicate with healthcare professionals

Support innovation and promote buy-in from all stakeholders

- Willingness to include digital therapeutics in the treatment of patients, *the white paper 'Digital Therapeutics, an Opportunity for Italy' (2021) contains recommendations for the Italian ecosystem to advance in DTx*
- Funding and trainings to improve healthcare providers Digital Health skills identified but to be reinforced
- Legal definition of telemedicine in the public health code (exclusions of certain services) and coverage
- No regulation, procedure or evaluation system regarding the management of mobile health apps

Focus on the enforceability of national reference systems

- The Ministry of digital innovation is in charge of the assessment and the approval of the use of national reference frameworks.

Country Profile: Latvia (1/4)

Latvia

Summary of the Digital Health roadmap

Extension to European countries: access to national e-health portal (2022), patient summary and e-prescription (2023)

Empowering patients in their care pathway - giving patients ownership of their health data and enabling proactive prevention and health management, including through the deployment of a patient file

Further digitalization of the health system - digitalization of hospitals and primary care is fairly advanced and should be continued

Data framework implemented for patient records and cross-border data sharing

e-prescription service deployed - nationwide implementation

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Latvia (2/4)

Latvia

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Security-by-design for information systems, mandatory implementation of security governance and intrusion tests for all IS
- Communications from the Ministry regarding the patient portal, patient data management and patient data security, information available on the patient portal
- All data stored in the Digital Health system regulated by the Ministry, with data minimization principles when adding data into the system
- Open data portal where all government institutions collecting data must store data for everyone's use

2. Enable individuals to manage their Digital Health use and data

- Regulatory texts supplemental to the GDPR allowing data collection without requesting consent
- Data view history on national e-health portal, a service to manage professionals' access to data
- Downloadable health data
- Two-factor authentication system to access the portals

3. Make Digital Health inclusive and accessible to all

- Pilot projects carried out to facilitate access to health data for individuals with limited access to Internet, people without electronic identification tools and people lacking digital literacy
- Single contact points (i.e., offices) supporting citizens to get their eID and authorizations for third parties to get the access for people who do not have access to identification means
- Tutors can be appointed to access health data of minor children, elderly, and dependent people

4. Implement eco-responsible Digital Health

- Mandatory use of green procurement for every public institution – when implementing a new digital service, using the existing data centers is mandatory, since centralized systems can be a key to reduce energy consumption
- National federated cloud program set up by the Ministry of the Environment, aiming to migrate government systems from the traditional architecture to micro service-based architecture that lowers the energy consumption and therefore the environmental footprint generated by information systems

Country Profile: Latvia (3/4)

Latvia

Strengthen Digital Health Governance

- Strategic and operational governance implemented but with complexity for Digital Health deployment and development
- Governance set-up between institutions and private solution providers
- Political will to implement a patient-centred healthcare delivery model
- Main challenges: fragmentation of ICT architectures, and changes in the regulatory framework

Strengthen Digital Health security and interoperability

- Challenge to foster a complete interoperability of services (many standards currently in place except for SNOMED-CT)
- Two-factor authentication system to access 3 Digital Health portals
- Between 50 and 100 projects annually benefitting from secondary use of collected data

Accelerate the deployment of core Digital Health services

- Strong development of telehealth covered by common law
- Use of e-prescriptions raised through state budget fund, then mandatory
- Local mHealth applications developed (mobile app from State Emergency Medical Service)
- 2 services currently in an implementation phase (since 1st January 2022): organ donation consent and biological diagnosis consent

Country Profile: Latvia (4/4)

Latvia

Deploy Digital Health platforms at national level

- Different portals provided to access health data, with a centralized approach
- National Digital Health portal (eveseliba.gov.lv) centralizing citizens' health data: personal data, e-records, referrals and results, basic health data, e-prescription, e-sick leaves, immunization passports (currently only for Covid vaccinations), information on family doctor, and e-consultation
- Data view history, a service to manage professionals' access to data and a system enabling the management of health data on one's behalf are also available through this portal
- Information to individuals about disability services, medical services, medicines, and registers through latvija.lv portal
- During the pandemic, implementation of an additional portal dedicated to Covid Certificates, allowing citizens to generate verified Covid certificates as well as to access Covid test results

Support innovation and promote buy-in from all stakeholders

- Financial incentives set up (through funding for ICT equipment and computers) to support the use of Digital Health services on the healthcare professionals' side

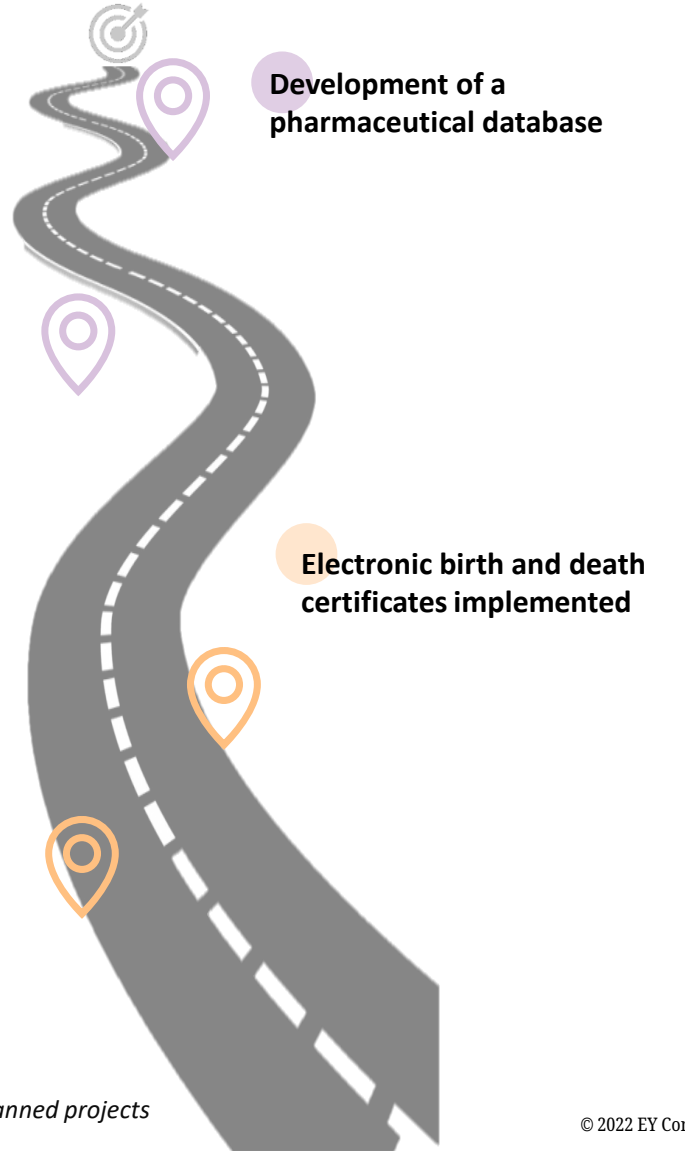
Focus on the enforceability of national reference systems

- National interoperability framework and requirements on data hosting
- No specific control or enforcement mechanisms identified

Country Profile: Lithuania (1/4)

Lithuania

Summary of the Digital Health roadmap



Development of a pharmaceutical database

Development of a secure health messaging service

Electronic birth and death certificates implemented

2015: Launch of a national Digital Health platform (ESPBI IS) - includes e-prescription and health document management services, deployed to all healthcare professionals in 2018

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✗
Is it enforceable?	
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Sources

Country Profile: Lithuania (2/4)

Lithuania

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Legal framework for data hosting, but not dedicated to health
- Draft law on secondary use of health data in progress

2. Enable individuals to manage their Digital Health use and data

- Ability to choose which healthcare professional has access to one's data

3. Make Digital Health inclusive and accessible to all

- Willingness to inform the public about data protection (in general)

4. Implement eco-responsible Digital Health

- *No defined ambition on the subject*

Country Profile: Lithuania (3/4)

Lithuania

Strengthen Digital Health Governance

- Strategic Digital Health roadmap (2018-2025)
- Ministry of Health leading Digital Health projects management without dedicated agency
- No Digital Health training in healthcare professionals curricula

Strengthen Digital Health security and interoperability

- Use of HL7-FHIR standard and willingness to deploy SNOMED-CT standard
- National entity for data protection (State Data Protection Inspectorate), but no dedicated body in healthcare
- National Center of Registers ("Registru Centras") responsible for public sector databases development and management, planned to become administrator of the national EHR (2021-2024 strategy: modernisation of the infrastructure, strengthening of security)

Accelerate the deployment of core Digital Health services

- National patient record used by healthcare professionals
- e-prescription service deployed
- No secure messaging service for citizens to communicate with healthcare professionals
- Core services on ESPBI IS platform: diagnoses, treatment information, electronic prescriptions, laboratory test referrals and results, referrals for consultations, medical images, vaccination information, health certificates

Country Profile: Lithuania (4/4)

Lithuania

Deploy Digital Health platforms at national level

- National health platform for citizens, including: laboratory tests, test referrals and test results, vaccination information, health certificates
- Pharmacists able to use the national platform to dispense electronically prescribed medicines

Support innovation and promote buy-in from all stakeholders

- Digital Health innovation not considered a priority in the national roadmap, however, willingness to participate in the EU project "Guidelines on FAIR Data Management in Horizon 2020" regarding solutions using artificial intelligence
- No regulation or reimbursement for mobile health applications

Focus on the enforceability of national reference systems

➢ *No measure implemented regarding the enforceability of national reference frameworks.*

Country Profile: Luxembourg (1/4)

Luxembourg

Summary of the Digital Health roadmap

Improvement of existing services and creation of new services – shared health record (DSP), secure messaging, patient Index (MPI), e-prescription, e-invoicing

Interoperability and cross-border exchanges - improving interoperability within the nation (technical then semantic), creating nomenclatures of similarities to build bridges between standards

Secure and trust information systems - ISO 27001 certification of the Digital Health Agency, implementation of procedures and methodologies to secure health information systems, assistance to health stakeholders to improve their security level

Deployment of the Shared Health Record (DSP) - clarification of the regulatory framework, deployment of the DSP to all individuals, feedback and improvements, extension of services to cross-border countries (interoperability, security)

Governance and management tools - clarification of decision-making and arbitration processes, creation of management tools and monitoring indicators

Finalized projects *Ongoing or planned projects*

Key indicators

- Patient health record ✓
- E-prescription service ✓
- Patient identification system ✓
- Interoperability framework ✓
  - Is it enforceable? ✓
- Security framework ✓
  - Is it enforceable? ✓
- Individuals' access to their health data ✓
  - HP's access management ✓
- National infrastructure for data collection ✓
- Regulation on secondary use of data ✓
- Regulation for telemedicine reimbursement ✓
  - Assessment mechanisms ✓

Sources

Country Profile: Luxembourg (2/4)

Luxembourg

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Communication and information to individuals about their rights in terms of Digital Health, website: *cns.public.lu*
- Advisory committee dealing with ethical issues of health data involved in the development of the patient record
- Additional regulations beyond the GDPR for the protection of individuals

2. Enable individuals to manage their Digital Health use and data

- Unified system to collect consent for healthcare and research use (possible through the DSP)
- During DSP's implementation, trainings conducted throughout the territory via representatives
- Access matrix: each patient can limit access to his/her data by health professionals and by type of document

3. Make Digital Health inclusive and accessible to all

- DSP available in 5 different languages
- In health institutions, appointed people to help individuals who have difficulties using digital services
- Specific help lines ("healthlines") set up at the Ministry of Health, the Digital Health Agency and the Health Insurance Fund
- During the pandemic, access offered by associations to tablets and computers for people affected by the digital divide
- Possibility to keep paper versions of health documents

4. Implement eco-responsible Digital Health

- Political willingness to include the environmental aspect in the design and use of digital services

Country Profile: Luxembourg (3/4)

Luxembourg

Strengthen Digital Health Governance

- Digital Health agency dedicated to drafting and implementing Digital Health strategy, supported by the Ministry of Health and cooperating with all the ecosystem's stakeholders: National Health Fund, individuals' representatives, IGSS, FHL, etc.
- By 2022, objective of the Digital Health agency's Scientific and Medical Commission to build a tool via existing documents and other specifications to summarize existing structured data (e.g. from patient summary or vaccination record) in a simple way

Strengthen Digital Health security and interoperability

- National interoperability framework - IHE and CIM10 profile standards deployed in only 5% of infrastructures - but no legislation in place to establish common standards
- MyHealth@EU: since 2019, access to Maltese and Czech health data by Luxembourgers physicians
- Regulatory framework and infrastructure for secondary use of health data (mandatory written consent) and ongoing project on health data anonymisation and pseudonymization

Accelerate the deployment of core Digital Health services

- Existing reimbursement and evaluation mechanism for mobile health devices: digital therapies, analyses underway by the health insurance (to provide a model meeting safety and performance criteria) but no reimbursement system set up yet
- Monitoring and evaluation of telemedicine devices: teleconsultation adoption in progress following the Covid crisis
- secure messaging service for healthcare professionals, used daily by 100% of HCPs
- Deployment of e-prescription service since 2019, electronic service implemented for e-prescriptions renewal
- Electronic vaccination record currently being tested

Country Profile: Luxembourg (4/4)

Luxembourg

Deploy Digital Health platforms at national level

- Centralized data and core services through the DSP (national Digital Health record, fully implemented in January 2020), the patient's digital identity and a health insurance affiliation verification service
- Data available in DSP include: biology reports, medical imaging and its report (since June 2021), patient summary, healthcare service summary and soon an electronic vaccination record
- 4 largest hospitals securely connected to the platform, along with specialized institutions, private doctors, pharmacies and analysis laboratories
- Electronic identification and authentication of individuals, healthcare professionals, legal health entities, and associated directories
- Regulations requiring compliance with the national identification system: quality assessment and monitoring via the “Identito-vigilance” tool

Support innovation and promote buy-in from all stakeholders

- Specific funds allocated to finance health research and innovation - example: *luxinnovation.lu*
- Training in innovation and Digital Health for professionals: e-learning, conferences (Vivalia), lectures
- General regulatory framework for the use of AI in the health sector (ISO/IEC TR2430 published in May 2021 and ISO/IEC 24368)
- Ongoing discussions on the implementation of financial means to support the use of digital services, to be managed by the health insurance system, as a compensation for each document uploaded

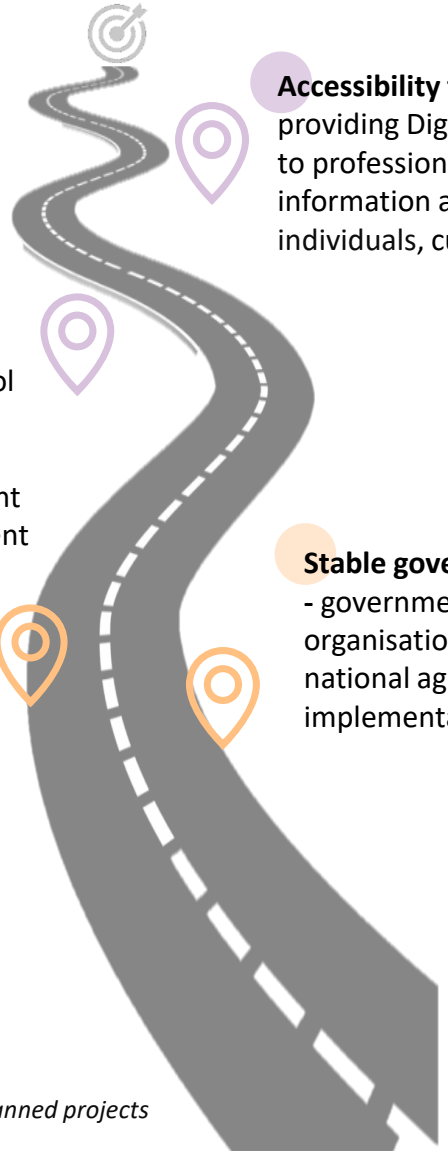
Focus on the enforceability of national reference systems

- Security checks by general administration on the compliance of Digital Health tools, for example regarding interoperability standards

Country Profile: Malta (1/4)

Malta

Summary of the Digital Health roadmap



Accessibility to Digital Health - providing Digital Health trainings to professionals and individuals, information and empowering individuals, culture of innovation

Investing in the creation of new Digital Health systems - implementation of a stock control and management system, digitalisation of medical records, development of a National Patient Summary and an Electronic Patient Record

Stable governance and environment - government entity dedicated to the organisation of Digital Health and national agency dedicated to its implementation (MITA)

Improving existing Digital Health services and systems - improvement and development of "myHealth" service, e-prescription, teleservice

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Sources

Country Profile: Malta (2/4)

Malta

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Explicit willingness to communicate with individuals about their rights and the challenges of Digital Health
- Social media supporting the Ministry of Health communication towards all citizens

2. Enable individuals to manage their Digital Health use and data

- National regulations and framework defined to ensure Digital health security and health data protection
- Individuals' consent always collected for health data exchanges, but no unified electronic system built so far
- Ability for individuals to access to their health data

3. Make Digital Health inclusive and accessible to all

- *No specific ambition defined on the subject*

4. Implement eco-responsible Digital Health

- *No defined ambition on the subject*

Country Profile: Malta (3/4)

Malta

Strengthen Digital Health Governance

- National strategy and operational roadmap for Digital Health established by the Parliamentary Secretariat for Health and the Ministry of Energy and Health
- Government entity dedicated to the organisation of Digital Health and agency dedicated to its implementation (MITA)
- CONVErGE project, partly financed by the European Regional Development Fund, supported the deployment of electronic health records (EHR) ins hospitals. The deployment in now finalised in almost all 11 Maltese hospitals.

Strengthen Digital Health security and interoperability

- No published national interoperability framework but international standards used by private vendors (ex : IHE Profiles), and general willingness to improve data standardization
- No regulation on secondary use of data beyond the GDPR
- MyHealth@EU : Since 2020, (1) access to Croatian and Portuguese health data by Maltese physicians and (2) consultation of Maltese health data by Croatian, Luxembourgish and Portuguese physicians

Accelerate the deployment of core Digital Health services

- e-prescription service (POYC), not fully deployed yet
- National directory for HCPs – however, no electronic authentication service
- No e-signature for health documents and no messaging for healthcare professionals
- National electronic identification service provided to all individuals

Country Profile: Malta (4/4)

Malta

Deploy Digital Health platforms at national level

- National health portal (MyHealth) implemented since 2012 and accessible to individuals and healthcare providers, providing additional services to individuals (management of their health data, health agenda) and healthcare providers (e-prescription, hospital referral)
- EHR developed and deployed in hospitals
- National infrastructure currently being developed to improve data exchanges within the ecosystem

Support innovation and promote buy-in from all stakeholders

- No regulation or control on the use of AI in Digital Health
- No regulation or assessment system to support or reimburse mHealth applications - however, list of recommended mobile health applications created (see here)
- No regulations on the overall reimbursement of telemedicine, however service provided and covered by Primary HealthCare
- Willingness to offer Digital Health training to healthcare providers and individuals as part of the national strategy

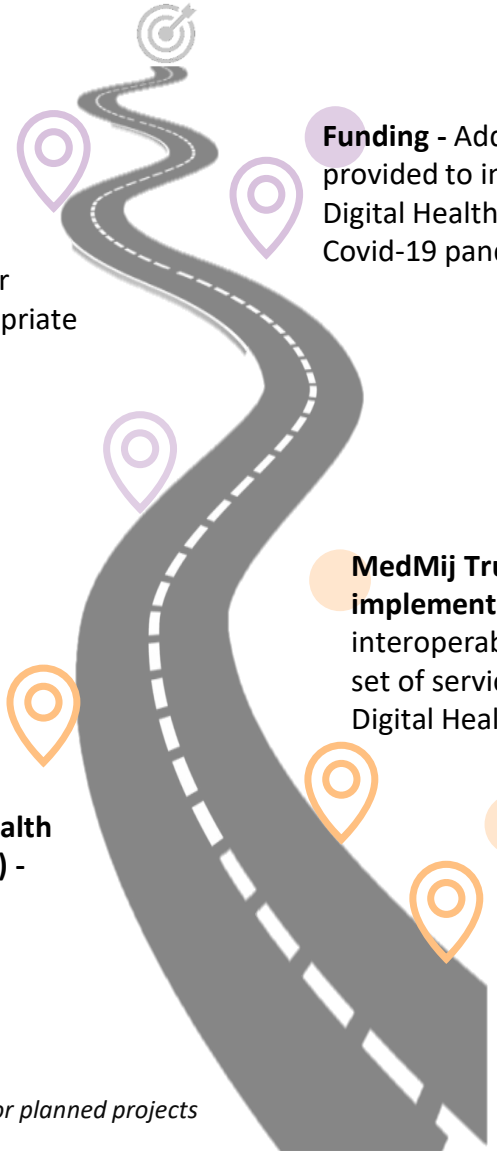
Focus on the enforceability of national reference systems

- Existing framework on interoperability standards: NeHIF – but no financial compensation or controls currently foreseen for its implementation
- This framework was set up by the Greek government and IDIKA.

Country Profile: Netherlands (1/4)

Netherlands

Summary of the Digital Health roadmap



Monitoring of Digital Health indicators - Establishment of recommendations to monitor Digital Health thank to appropriate KPIs

Expertise in Digital Health - Digital Health trainings for healthcare professionals and information portals for the population

Telemedicine and mobile health services implemented (2021) - Within an appropriate reimbursement scheme

Funding - Additional funding provided to improve access to Digital Health following the Covid-19 pandemic

MedMij Trust Framework implemented (2016) – Ensures the interoperability, security and minimal set of services of patient-centred Digital Health applications and portals

Numerous solutions and services locally developed – Until 2020, the government could not develop a national Digital Health infrastructure

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✗
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Sources

Country Profile: Netherlands (2/4)

Netherlands

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Information Board whose objective is to develop a sustainable healthcare information system with standardized data and a secure data exchange
- "MedMij trust program" created in 2016 with the objective of supporting data sharing, between patients and professionals, in a secure and interoperable framework (label being implemented gradually as it involves a very strict certification) – initiative supported by the government through a €0.5 billion grant

2. Enable individuals to manage their Digital Health use and data

- Managing individuals' consent to share their data is especially challenging, given the decentralized model - a target solution could not yet be defined
- Ability for individuals to access their data using a MedMij certified application: data management (add, edit or erase) and decide who can access it

3. Make Digital Health inclusive and accessible to all

- Netherlands motto: “The right information at the right place at the right time”
- The Ministry of Health, Welfare and Sport intends to raise awareness of Digital Health solutions through a national informative website
- Netherlands has launched a number of cross-cutting programs aimed at reducing the digital divide, in particular by setting up computer workstations and providing human support in several places (workplaces, libraries, etc.). These initiatives remain limited, particularly because of the decentralization of the health system and the development of Digital Health by the private ecosystem.

4. Implement eco-responsible Digital Health

- Netherlands has not launched a project on this dimension, although the national strategy mentions the ambition to move towards "greener" digital tools. Overall, hospitals have agreed to reduce their carbon footprint by 49% by 2023.

Country Profile: Netherlands (3/4)

Netherlands

Strengthen Digital Health Governance

- National Digital Health strategy set-up by the Ministry of Health, Welfare and Sport and the RIVM, in a decentralized Digital Health infrastructure involving many stakeholders at national, regional (12 provinces) and local (around 500 municipalities) level
- Digital Health in the Netherlands mainly developed by private organizations that must comply to national framework and standards
- Since 2021, increasing Digital Health funding from Netherlands Healthcare Authority (NZa), such as by fully reimbursing telehealth expenses

Strengthen Digital Health security and interoperability

- National framework to ensure health systems' interoperability
- MedMij certification program (with security, functional and interoperability assessments) for private-built patient-centred services, prerequisite to exchange data with the national services (EHR, e-prescription, etc.)
- Law issued on Digital Health data exchange (in process) and regulation on secondary health data use. National data collection infrastructure for secondary use created by two private companies: VEVZ and NICTIZ
- Participation in NCPEH European project since 2020, national toucHCPoint for European digital data exchange such as cross-border document exchanges

Accelerate the deployment of core Digital Health services

- Secure messaging service for professionals to professionals
- EHR used by healthcare professionals
- e-signature and e-authentication (for both healthcare providers and individuals) services currently being developed
- e-prescription service (EVS) and e-consultation service extensively deployed

Country Profile: Netherlands (4/4)

Netherlands

Deploy Digital Health platforms at national level

- EHR available but not as an unified system. The service is offered by several private software developers. Healthcare providers can access to individuals health record thank to the national AORTA platfrom.
- No secure messaging solution for patients to professionals. But special programs (VIPP) are set-up to speed-up information exchanges between individuals and professionals from various sector
- No national unique patient portal but several applications are already MedMij certified. This certification is a hardship and the government is providing funding to support the private stakeholders in obtaining it.

Support innovation and promote buy-in from all stakeholders

- Innovation emphasized by the Ministry of Health, Welfare and Sports within its Digital Health strategy: Events such as “Digital Health rallies“ created to focus on health innovation
- “Valuable AI for health” program set up by the Ministry of Health, Welfare and Sports to help Digital Health stakeholders to convert AI potential into value for patients, healthcare providers and individuals
- Telehealth and mobile health available with a reimbursement system

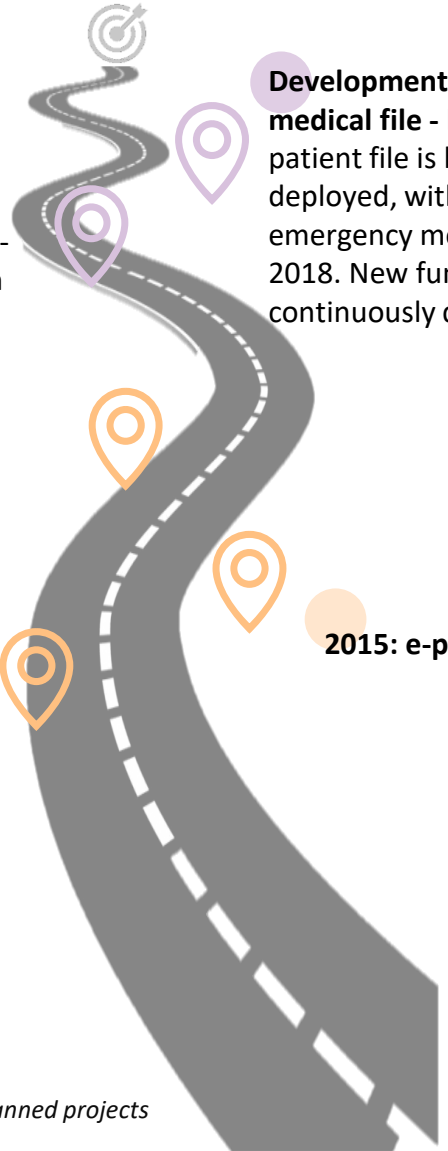
Focus on the enforceability of national reference systems

- The MedMij label is the Dutch standard for the secure health data sharing between healthcare professionals and patients

Country Profile: Norway (1/4)

Norway

Summary of the Digital Health roadmap



Development of the patient medical file - launched in 2012, the patient file is being gradually deployed, with an integration into emergency medicine pathway in 2018. New functionalities are continuously developed

Health data management – the new Digital Health strategy 2017-2022 focuses on access to health data in a reliable and secure way for healthcare providers and searchers

2016: National e-health council created

2015: e-prescription deployed

2012: National portfolio of Digital Health projects created - and projects prioritization to obtain “quick-wins” and long-term value

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals’ access to their health data	✓
HP’s access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✓

Sources

Country Profile: Norway (2/4)

Norway

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National coordination approach implemented to ensure privacy, regulation and ethics of AI solutions in health, involving hospitals, health professionals and end-users
- Several works and committees set up on ethics, applied to big data and AI
- Guidelines defined as more protective than the GDPR - to ensure transparency on data processing

2. Enable individuals to manage their Digital Health use and data

- Helsenorge portal launched in the early 2010s to improve individuals' access to their health data in a mainly decentralized system, with a wide range of digital services offered by local authorities
- Helsenorge portal and public Digital Health services designed alongside individuals' and healthcare providers representatives: 3 national advisory boards created and public hearings regularly set up

3. Make Digital Health inclusive and accessible to all

- European accessibility standards applied to design digital solutions and take into account the needs of users who are far from digital.
- Trainings and support services (including by providing physical support) offred to help individuals using Digital Health solution
- An individual can systematically appoint a third-party (e.g. friend, family) to manage his/her health data in his/her behalf
- Norway is conducting several projects to improve Digital Health literacy in order to better inform individuals about their rights and their health and to support them in using the solutions provided

4. Implement eco-responsible Digital Health

- Reducing the carbon footprint is a relatively recent initiative and could be included in the next Digital Health strategy
- Norway has launched an initiative to develop more frugal digital tools that require less energy and hardware to

Country Profile: Norway (3/4)

Norway

Strengthen Digital Health Governance

- Strategic and operational governance well-established, with a Digital Health council to bring together various stakeholders to define a strategy and manage projects
- NUFA: User representatives committee (healthcare providers, individuals and IT professionals) involved in the governance of Digital Health and the assessment of the different services
- The NUFA is supported by the NUIT, a prioritisation committee setting annual priorities for the national Digital Health portfolio

Strengthen Digital Health security and interoperability

- National interoperability framework published based on international standards (HL7-FHIR, SNOMED-CT and ICD 10)
- No funding provided to comply to the interoperability standards (considering the added-value when using Helsenorge)
- Dedicated regulation established on secondary use of data and national infrastructure being developed
- Security and data protection requirements (including for the hosting of health data) published and enforced

Accelerate the deployment of core Digital Health services

- e-prescription service widely deployed (used for more than 90% of Norwegian prescriptions)
- secure health messaging system provided to healthcare providers, e-signature service also available
- National databases and services deployed to support health data exchange (e.g. medication database, patient record, etc.)

Country Profile: Norway (4/4)

Norway

Deploy Digital Health platforms at national level

- helsenorge.no: national service offering health information and giving back individuals the ownership owner their health data (e.g. to download, upload, modify, manage or erase data)
- Growing number of system interconnected to Helsenorge (social care, student health centres, etc.), increasing diversity of accessible health data
- Access to additional services in Helsenorge: prescription renewal, test results (including Covid), Covid-19 dedicated chatbot, etc.

Support innovation and promote buy-in from all stakeholders

- Telehealth regulated and reimbursed but no technical assessment of the systems (no referencing nor certification)
- mHealth applications regulated and reimbursed: process currently being defined to fully assess mHealth (for instance, to grant data exchanges with Helsenorge based on technical and security requirements)

Focus on the enforceability of national reference systems

- Set of mandatory standards used as reference
- Financial penalties regarding the reimbursement of healthcare professionals who do not use the mandatory standards

Country Profile: Poland (1/4)

Poland

Summary of the Digital Health roadmap

Deployment of the medical file (from January 2021)

Development of national databases - by the Ministry of Health and specialized by pathology

Development of the P1 platform: digital platform for data collection, analysis and sharing - project financially supported by the EU for individuals, administrations and health professionals: deploying a national medical IS for monitoring care, a patient space (with medical record and diary) and e-prescription

Supervising the development of telemedicine following the health crisis

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Poland (2/4)

Poland

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- National regulations supplemental to the GDPR enforced on the collection and protection of individuals ' data - however consent is not required for the use of data in a research context
- Communications made towards users regarding their rights through the P1 platform and through communications on the Ministry of Health website

2. Enable individuals to manage their Digital Health use and data

- Scattered public databases and limited data exchanges

3. Make Digital Health inclusive and accessible to all

- *No specific ambition or project announced on Digital Health accessibility*

4. Implement eco-responsible Digital Health

- *No specific ambition or project announced to measure or reduce the environmental impact of Digital Health projects*

Country Profile: Poland (3/4)

Poland

Strengthen Digital Health Governance

- Clearly defined Digital Health governance and strategy at national level, with an agency dedicated to health technology assessment
- Existing government-sponsored project for a unified health information system accessible to patients and healthcare professionals
- Electronic platform for digital medical records implemented, including: medical information system, Internet patient account, e-prescription service and e-referencing partly financed by the EU using FEDER funding

Strengthen Digital Health security and interoperability

- No national interoperability framework
- Lack of deployment of SNOMED-CT and ICD10 standards, low deployment of HL7 standards (only 30% of institutions use the CDA HL7 standard)
- Law issued on Digital Health data exchange (in process) (WEGIZ)
- Strategic ambition to provide a framework for sharing health data with public and private stakeholders in order to develop research
- Participation in NCPEH European project since 2020
- National toucHCPoint for European digital data exchange such as document cross-border exchanges

Accelerate the deployment of core Digital Health services

- Telemedicine and mobile health services developed and supported
- Management of referrals to examinations and treatments
- No e-signature service but under development by NICTIZ
- e-prescription service (EVS) and e-consultation service in place

Country Profile: Poland (4/4)

Poland

Deploy Digital Health platforms at national level

- Electronic patient record for 100% of individuals since January 2021
- Development of a medical data IS which centralizes all care
- Development of a patient space gathering information on treatments and the patient file

Support innovation and promote buy-in from all stakeholders

- Important development of telemedicine following the COVID crisis, practices are supervised and procedures are covered
- Training for practitioners in new technologies is included in their curriculum
- Development of mobile health and its monitoring
- Strategic work in progress on new technologies management, especially AI

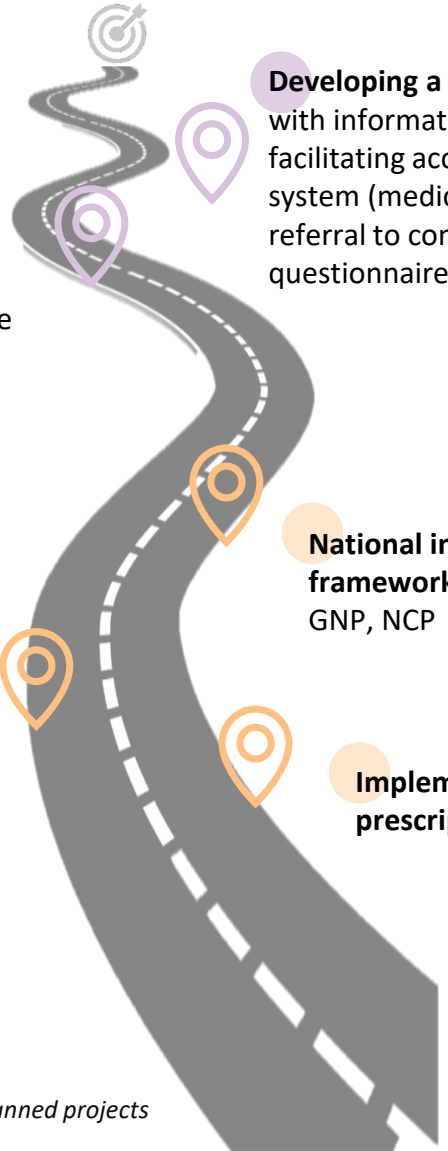
Focus on the enforceability of national reference systems

- *No service or reference frame is made enforceable*

Country Profile: Portugal (1/4)

Portugal

Summary of the Digital Health roadmap



Developing a national patient record – with information and services facilitating access to the health care system (medication information, referral to consultations, pre-diagnosis questionnaire, etc.)

Development of a telemedicine platform – objectives: support telehealth strategy, create new models of care delivery, integrate telehealth into patient pathways

National interoperability framework established – LIGHt, GNP, NCP

Digital Health services purchasing catalog implemented - creation of a platform to digitalize procedures and ensure a consistent purchasing system

Implementation of the e-prescription service

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Portugal (2/4)

Portugal

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Approval of the law “charter on human rights in a digital era” (Law No. 27/2021), promoting, among other things, the rights to protection against misinformation, to privacy in the digital environment, to digital will and to protection of personal profiles in digital platforms
- Process initiated around the development of services with humanistic values: national texts/frameworks shared
- Portuguese Presidency of the EU Council led to the publication of the "Lisbon Declaration - Digital Democracy with a Purpose"

2. Enable individuals to manage their Digital Health use and data

- No national electronic system to collect consents, however, GDPR enforced and implemented at national level for all individuals
- Communications carried out towards users and strategic Digital Health projects built through individual consultations
- National single entry point to access health data: SNS 24 (within the portal, individuals can manage some of their health data, decide to share it or not; they are always informed when their data are viewed)

3. Make Digital Health inclusive and accessible to all

- SNS 24 accessible 24 hours a day through an omnichannel approach based on 4 access modalities: (i) a web portal, (ii) a mobile application, (iii) a telephone switchboard and (iv) physical "counters" implemented locally by the public authorities ("physical counters" providing access to SNS 24 as part of a broader governmental strategy to support access to public digital services)
- Communication and trainings offered to individuals and healthcare providers, "Digital Health litteracy" developed during the covid-19 pandemic

4. Implement eco-responsible Digital Health

- EcoSaudé (ecohealth) program, supported by the Ministry of Health - one of the objectives of which is the reduction of energy consumption in the health sector (numerous themes addressed such as carbon footprint reduction, waste, water consumption, etc.)
- Digital sobriety approach developed, mostly based on the design of efficient and reusable digital components

Country Profile: Portugal (3/4)

Portugal

Strengthen Digital Health Governance

- Shared Services (SPMS) of the Ministry of Health in charge of defining Digital Health strategies and implementing key projects
- 2 main Digital Health services strategies: Big data and telehealth
- ENESIS 2020-2022: national strategy for the Digital Health ecosystem, focusing on three main dimensions: (1) promoting innovation in health through the engagement of individuals, health professionals and institutions, (2) implementing regulations and ethics frameworks regarding health data management, and (3) strengthening national data management in order to provide a global vision of the health system.

Strengthen Digital Health security and interoperability

- Mandatory national interoperability framework drafted based on international standards, currently being implemented by regional institutions
- National regulation on secondary use of health data, but data collection infrastructure only deployed at regional level
- MyHealth@EU: since 2020, (1) access to Croatian and Maltese health data by Portuguese physicians, (2) access to Portuguese health data by Croatian, Luxembourgish and Maltese physicians, (3) Portuguese e-prescriptions collected in Croatian, Estonian and Finnish pharmacies, and (4) provision of medicines from Croatian and Finnish e-prescriptions by Portuguese pharmacists

Accelerate the deployment of core Digital Health services

- e-prescription service widely deployed and associated to a national database
- Secure health messaging service between healthcare providers
- Online platform for healthcare providers including services (e-prescription, access to the patient summary, training sessions on Digital Health, etc.)
- Public identification services (for individuals and providers), not dedicated to the healthcare system

Country Profile: Portugal (4/4)

Portugal

Deploy Digital Health platforms at national level

- National Health Portal SNS24 (associated to a mobile app) offering access to health data (prescription, vaccination, registries, patient summary, etc.) and data management
- SNS24 infrastructure currently being deployed by regional and local stakeholders (data management improvement as one of the priorities)
- Additional services are offered through SN 24, such as a national teleconsultation service associated with automated translation (for foreign individuals and also deaf/dumb individuals). Portugal wishes to leverage on technology to improve Digital Health accessibility.

Support innovation and promote buy-in from all stakeholders

- National strategy on teleconsultation set up in 2013, teleconsultation reimbursed by common law and several services provided (with a mixed impact) - *Covid-19 pandemic has been a tremendous catalyst for teleconsultation use, which rose sixfold between 2020 and 2021 with nearly 200,000 teleconsultations*
- Mobile health underdeveloped, no reimbursement provided to date
- Numerous initiatives on innovation carried out, especially regarding AI

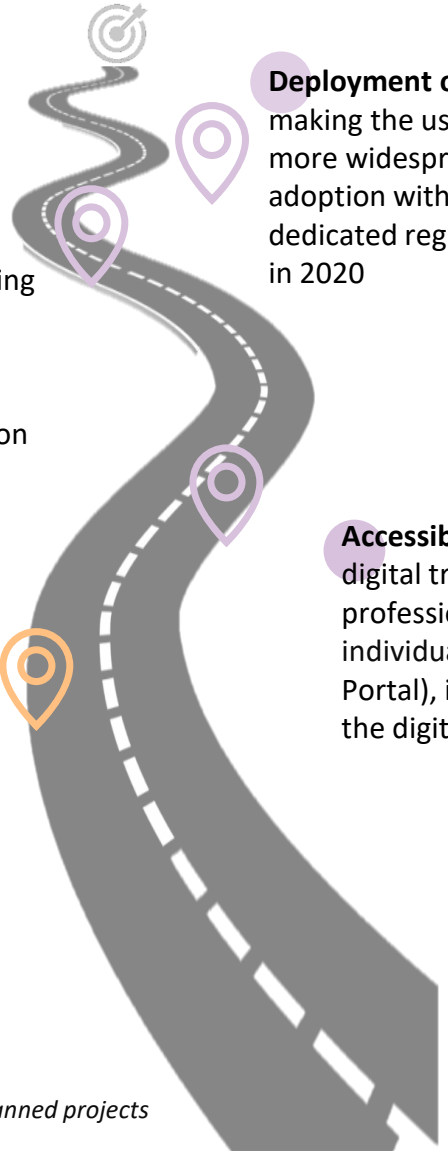
Focus on the enforceability of national reference systems

- The Digital Services Agency has established a compliance verification process for a set of health software.
- It specifies assessment criteria, implementation guidelines for IS compliance, and applications references (listing compliant and non-compliant applications).

Country Profile: Romania (1/4)

Romania

Summary of the Digital Health roadmap



Deployment of telemedicine - making the use of telemedicine more widespread and its adoption with respect to the dedicated regulation published in 2020

Improved services and infrastructure - e-prescription, EHR, National eCard 2021 including the Digital Health Card, National Health Data Base, health data protection regulation and transparency in health information reporting

Accessibility to Digital Health - digital training for health professionals, information for individuals (e.g. National Health Portal), inclusion and reduction of the digital divide

Digital Health services implemented - regulatory framework and support for the deployment of interoperability standards (2005), Digital Health Card for individual identification (2007), National Patient File (2008), e-prescription (2012)

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✗
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✗
HP's access management	✗
National infrastructure for data collection	✗
Regulation on secondary use of data	✗
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Romania (2/4)

Romania

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Additional regulations beyond the GDPR for security and data protection (not specific to health) established by the ANSPDCP
- Incident management protocol with feedbacks to NAMMD
- National Health Portal launched in 2005 by the Ministry of Communications and Information Technology in collaboration with the Ministry of Health to communicate with the Romanians and provided trainings and advices regarding their health

2. Enable individuals to manage their Digital Health use and data

- Unified system to collect individuals' consent for the use of their health data in health care and research (Law 46/2003)
- Individuals can access their data but are not yet able to fully manage to whom it is shared with

3. Make Digital Health inclusive and accessible to all

- Regulation on the transparency of communications to individuals on medical devices (GEO no. 46/2021)
- Existing projects and tools for inclusion and reduction of the digital divide (elderly, poor or disabled people) - however, their use remains low

4. Implement eco-responsible Digital Health

- Although health is presented in the 2030 Strategic Plan for Sustainable Development as an issue, Digital Health is only briefly mentioned.

Country Profile: Romania (3/4)

Romania

Strengthen Digital Health Governance

- National strategy and operational roadmap for health integrating Digital Health axes, established and validated by the Ministry of Health, then implemented by the National Agency for Health Programs (new strategy announced but not yet approved and implemented)
- Health information systems privately managed, maintained and funded

Strengthen Digital Health security and interoperability

- National interoperability framework with high deployment of European standards SNOMED-CT, HL7-FHIR, IHE and ICD10 profiles - strong involvement of NCOEHIS, HL7 Romania, Romanian Society for Health Informatics or the IT Developers Organisation in defining and supporting the implementation of regulations
- The issue of data portability is not dealt with
- No regulation or associated infrastructure beyond GDPR on secondary use of data, but willingness to define a National Health Data Analytics Master Plan which will support further initiatives or investments

Accelerate the deployment of core Digital Health services

- e-prescription deployed since 2012 (service currently not widely used)
- Non-legalised e-signature for the health sector and no secure messaging service between healthcare professionals
- National electronic identification of healthcare providers

Country Profile: Romania (4/4)

Romania

Deploy Digital Health platforms at national level

- Health identifier and associated authentication system: national Digital Health Card (eCard) launched in 2007 for the whole population, combining a passport and health information (insurance and patient records)
- National Health Record launched in 2008 in hospitals for individuals to access their health data through the Digital Health Card / eCard. However, no additional service is provided (e.g. prescription renewal, secure messaging services, management of health data)

Support innovation and promote buy-in from all stakeholders

- No regulation on the use of AI in the health sector - national strategy under development, academic publications and recommendations (Politehnica University of Bucharest and Technical University of Cluj-Napoca)
- Public training sessions and non-compulsory specialized courses on information technology for healthcare professionals
- Regulatory framework and evaluation system for the management of telemedicine procedures (Order n°196/2020 of law 95/2006):
  - Interoperability projects led in telemedicine (TELMES) in partnership with the INSCC and medical research centres
  - Projects led for the development of emergency telemedicine, telemonitoring of the elderly at home, etc.

  To date, no project addressing mHealth application

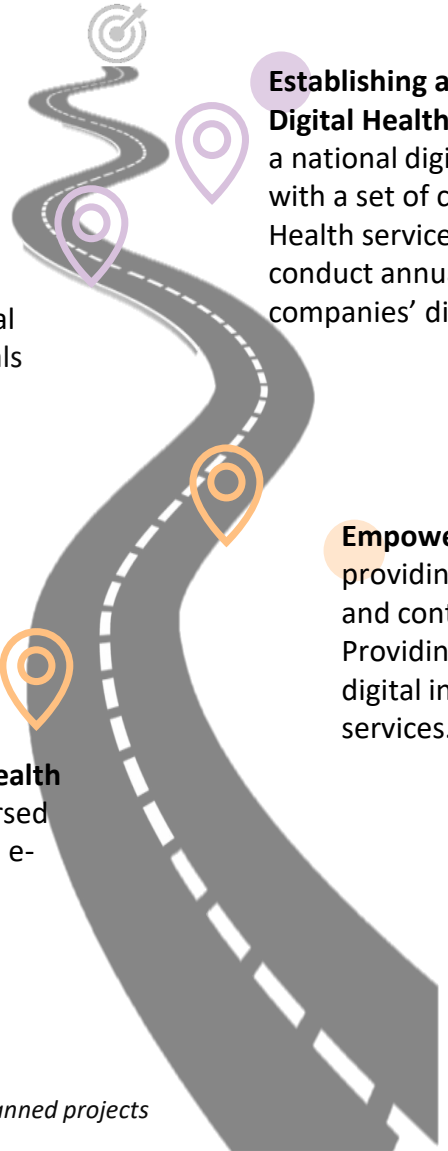
Focus on the enforceability of national reference systems

➢ *No measure implemented regarding the enforceability of national reference frameworks*

Country Profile: Scotland (1/4)

Scotland

Summary of the Digital Health roadmap



Establishing a reliable and secure Digital Health system - enhancing a national digital platform (NDP) with a set of cloud-based Digital Health services. Continuing to conduct annual assessments of the companies' digital maturity.

Building trust - involving people and staff in the tools' design, technologies and services supporting them - Ensuring digital access for all - Enabling individuals to control their health data

Empowering individuals - providing individuals with access and control over their health data. Providing simplified access to digital information, tools and services.

Building an innovative Digital Health environment - access to reimbursed telehealth and mHealth services, e-prescription, NHS

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✗
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✗
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✓

Sources

Country Profile: Scotland (2/4)

Scotland

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- UK Data Protection Act 2018 supplementing the GDPR on the collection and hosting of health data
- Willingness to integrate an ethical dimension in Digital Health use by setting up projects such as the Women's Health Plan
- National platform provided to access Digital Health services and to inform users about the use of these tools: scot.nhs.uk

2. Enable individuals to manage their Digital Health use and data

- "Safe Harbor Charter" allowing the use of health data for research purposes when individual patient consent isn't collected

3. Make Digital Health inclusive and accessible to all

- *No specific ambition announced on Digital Health accessibility*
- *Between 2014 and 2017, £30M initiative benefitting 62,000 people driven by SCTT for the government's Technology Enabled Care (TEC) project to equip Scottish citizens with telehealth technologies*

4. Implement eco-responsible Digital Health

- Political willingness to integrate an ethical dimension to the use of Digital Health – no specific objective on reducing the environmental impact of Digital Health projects

Country Profile: Scotland (3/4)

Scotland

Strengthen Digital Health Governance

- Regional approach regarding Digital Health strategy, with a governance set up following the failure of the National Programme for IT, launched in 2002 and abandoned in 2011 after more than €8.6B invested
- Training sessions for healthcare professionals combining digital and health, but with scope for further improvement
- Health Information Systems mainly privately managed, maintained and funded

Strengthen Digital Health security and interoperability

- National interoperability framework, however complex: many standards implemented but non-interoperable, uses vary according to healthcare professionals
- Regulatory framework and IT infrastructure dedicated to the secondary use of health data, especially for cancer research
- No participation in the European NCPeH project
- Collection and analysis of health data by ISD to improve NHS services for over 50 years.

  Health databases indexed on the CHI number (Community Health Index) have existed for over 30 years

Accelerate the deployment of core Digital Health services

- Secure health messaging service for healthcare professionals, telehealth, mHealth and e-prescription services available
- Digital Health trainings sessions for healthcare professionals
- eNMAHCP initiative created, aiming at obtaining feedbacks from healthcare professionals on Digital Health services to improve them

Country Profile: Scotland (4/4)

Scotland

Deploy Digital Health platforms at national level

- National electronic patient identification: CHI (Community Health Index)

Support innovation and promote buy-in from all stakeholders

- Strong support for innovation with centres dedicated to supporting and funding projects such as the Digital Health and Care Institute in Edinburgh and Glasgow
- No specific regulation on the use of AI in health, but evaluation criteria used via the 2002 Medical Device Regulation
- No specific regulation of mobile health applications
- Regulatory frameworks and national standards on telehealth

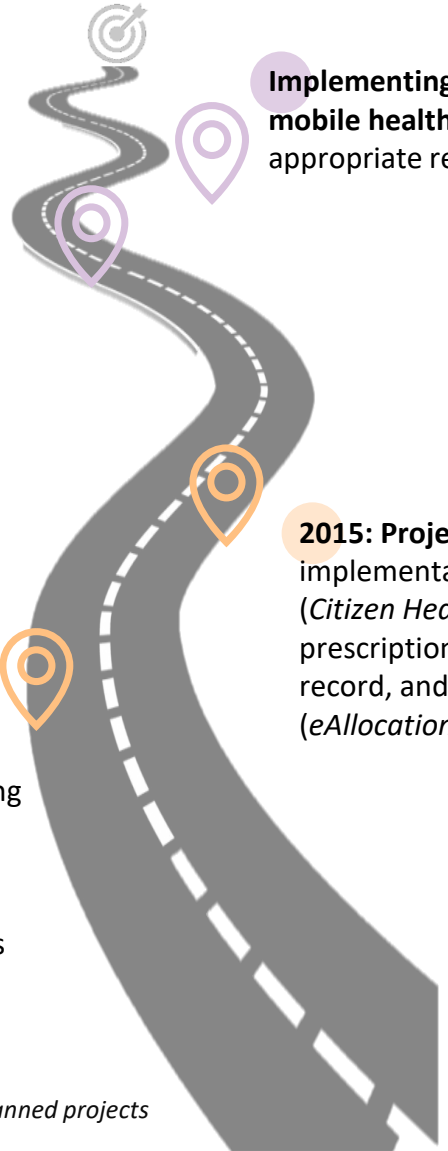
Focus on the enforceability of national reference systems

- Mandatory national interoperability framework implemented

Country Profile: Slovakia (1/4)

Slovakia

Summary of the Digital Health roadmap



Implementing telemedicine and mobile health - with an appropriate reimbursement service

Recovery and Resilience - €1.163M investment to improve hospital information networks, telemedicine and health sector digitalization

2015: Project eSO1 - implementation of a patient record (*Citizen Health eBook*), e-prescription, electronic drug record, and e-reimbursement (*eAllocation*)

2015: "National Digital Health Extension of Functionality and Services" - national project aiming at consolidating databases (especially on drugs), digitalizing administration, increasing the number of Digital Health services and improving data protection

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✗
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✗

Sources

Country Profile: Slovakia (2/4)

Slovakia

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Adoption of the Acts 576/2004 and 153/2013 regulating health data storage and the security of health information systems
- Implementing a national platform that informs users on how to use these tools

2. Enable individuals to manage their Digital Health use and data

- According to the provisions of the Health Care Act (576/2004), a person for whom medical records are kept is entitled to prohibit the provision and disclosure of his medical records data.
- Access to Digital Health services provided through the national platform

3. Make Digital Health inclusive and accessible to all

- Ongoing study by the NHIC entitled "Extending Health to Telemedicine Services", to assess the feasibility of supporting tools for assisted living and telemedicine

4. Implement eco-responsible Digital Health

- *No ambition clearly defined on the sustainability of health digital services*

Country Profile: Slovakia (3/4)

Slovakia

Strengthen Digital Health Governance

- National Digital Health Strategy defined and implemented by the Ministry of Health, the Ministry of Finance, Regional Development and Digitalisation, and the National Health Information Centre (NHIC)
- The NHIC is an entity dedicated to the digitisation of the health system. It is a separate Government Body state-founded by the Ministry of Health.
- The Institute of Research and Development (Inštitút výskumu a vývoja) is responsible for research related to the health agenda.

  Associated event: the “Innovations & Digital Trends in Healthcare” Conference which took place in Bratislava on October 14, 2021.

Strengthen Digital Health security and interoperability

- National interoperability framework - moderate deployment of SNOMED-CT semantic standard and high deployment of IHE profiles technical standard
- Regulatory framework dedicated to the secondary use of health data (“GDPR and Healthcare Act”) established
- Participation in the European NCPeH project with 18 516 estimated connections per year
- National agency dedicated to data protection ("Office for Personal Data Protection“) - although not dedicated to healthcare, consulted on Digital Health programs
- No national infrastructure to collect health data (especially for secondary use)

Accelerate the deployment of core Digital Health services

- Electronic patient review system: national electronic record storing completed reports and health information
- e-prescription service deployed at a national level
- e-signature system certifying the medical documents provided by healthcare professionals
- Electronic identification and authentication solutions for patients and healthcare professionals deployed nationwide

Country Profile: Slovakia (4/4)

Slovakia

Deploy Digital Health platforms at national level

- Individuals access their data through the national patient record - the ID card is used for identification (eiDAS compliant) in accordance with the Act 153/2013.
- Patients electronic vaccination record already set-up at national level
- Individuals can access and manage their health data stored in the national record through a dedicated portal.

Support innovation and promote buy-in from all stakeholders

- Use of European funds for the implementation of a "National strategy for AI in healthcare"
- Telemedicine and mobile health are not yet implemented
- Regulatory frameworks and national standards on telehealth

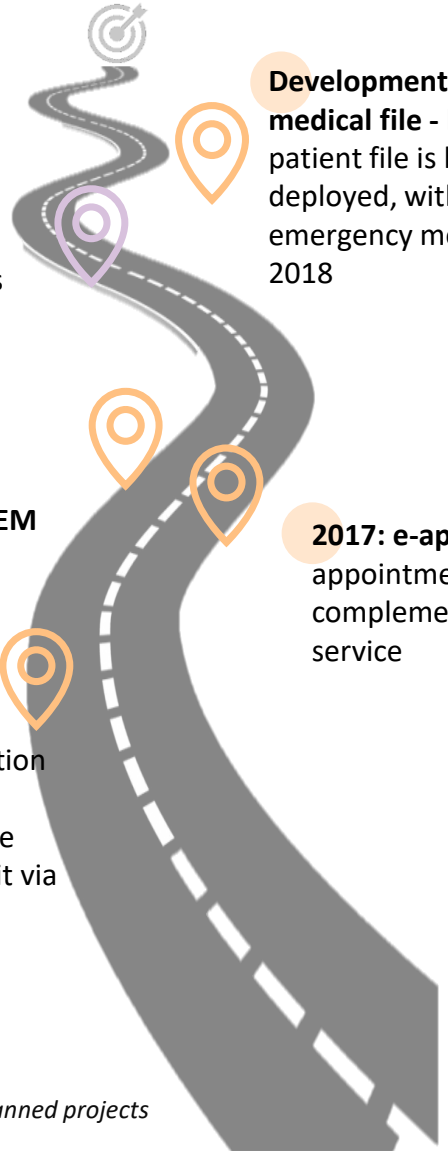
Focus on the enforceability of national reference systems

- The normative institution for technical and semantic interoperability subjects is the Ministry of Investments, Regional Development and Informatisation
- Enforceability of the interoperability framework is ensured by: Act 275/2006 on public administration information systems, Act 95/2019 on information technologies in public administration, MFSR Decree on Standards for ISVS. Theoretically, compliance mechanisms exist but they are not consistently implemented and applied. Incentive mechanisms also exist (Act 69/2018).

Country Profile: Slovenia (1/4)

Slovenia

Summary of the Digital Health roadmap



Development of the patient medical file - launched in 2012, the patient file is being gradually deployed, with an integration into emergency medicine pathway in 2018

Recovery and Resilience – €83M investment in the digital transformation of health systems (including wider deployment of telehealth)

2017: implementation of the zVEM patient portal

2017: e-appointment – online appointment booking service complemented by an e-referrals service

2016: e-prescription – implementation of an e-prescription service, currently used by all healthcare professionals, with the possibility for patients to access it via the zVEM portal

Finalized projects *Ongoing or planned projects*

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✗
Is it enforceable?	
Security framework	✓
Is it enforceable?	✗
Individuals' access to their health data	✓
HP's access management	✗
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Sources

Country Profile: Slovenia (2/4)

Slovenia

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- General rules applicable to healthcare and artificial intelligence
- Existing Health Ethics Committee not dedicated to Digital Health that conducts work on the use of AI, responsible for analyzing requests for secondary processing of data and authorizing them
- No specific involvement of users, no single patient association (or representative organization of patient associations)

2. Enable individuals to manage their Digital Health use and data

- Unstructured data shared on the zVEM portal (mostly documents), with data portability not fully ensured for patients
- No legal right for patients to delete data in the zVEM portal (in order not to degrade the quality of care): a correction can be required
- Patients informed about data access
- Ability to disallow access of a health professional to their data or to hide a document from all health professionals

3. Make Digital Health inclusive and accessible to all

- National zVEM portal complies with European regulation on website accessibility
- Willingness to set up physical locations to assist individuals in obtaining their electronic identity or to gain initial access to the portal, but lack of resources
- Ongoing work from public authorities on two accessibility-related initiatives: (i) a "digital voucher" financing the elderly and young people and (ii) the creation of a delegation system within the zVEM portal that would allow a relative/carer to manage the portal on behalf of a person who is not digitally aware

4. Implement eco-responsible Digital Health

- Not considered a top priority in Slovenia, although the infrastructure is regularly updated to follow European regulation on energy consumption reduction

Country Profile: Slovenia (3/4)

Slovenia

Strengthen Digital Health Governance

- No entity within the government responsible for setting up a strategic and operational roadmap for Digital Health
- Slovenian National Institute of Public Health responsible for implementing projects related to Digital Health, especially the central registry of patients
- Private stakeholders are part of the drafting of the Digital Health strategy

Strengthen Digital Health security and interoperability

- OpenEHR adopted for national healthcare system
- Specific regulation and national infrastructure dedicated to health data collection and secondary use
- Integration into the NCPeH project by 2022
- Health Database Act implemented
- Regulatory framework implemented regarding the use of health data

Accelerate the deployment of core Digital Health services

- Secure messaging service between health professionals
- e-prescription, e-appointment, e-referrals, e-signature and patient summary implemented
- Mobile application provided to access national digital services
- No secure messaging service between patients and health professionals

Country Profile: Slovenia (4/4)

Slovenia

Deploy Digital Health platforms at national level

- Patient portal “zVEM” gathering digital services available
- Patients informed about data access, however not able to manage consent

Support innovation and promote buy-in from all stakeholders

- No national project to promote innovation in the field of Digital Health
- Mobile health still under development
- Telehealth currently being deployed, reimbursement and evaluation mechanism (EUNETHTA 3) implemented for telehealth solutions
- No specific guideline related to AI in healthcare

Focus on the enforceability of national reference systems

- *No regulation regarding the enforceability of national standards*

Country Profile: Spain (1/4)

Spain

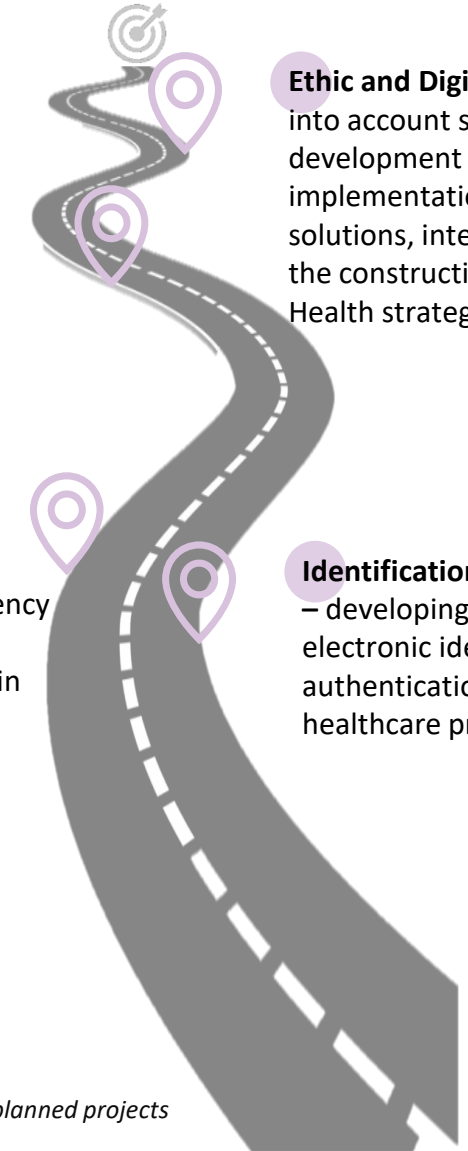
Summary of the Digital Health roadmap

Telemedicine deployment - building and implementing the regulation and reimbursement frameworks for telemedicine

Ethic and Digital Health - taking into account sustainable development in the implementation of Digital Health solutions, integrating patients in the construction of the Digital Health strategy

Supporting the digitisation of practices - improving the efficiency of healthcare professionals by investing in digital technology (in 2021, €400M were invested in hospital equipment)

Identification and authentication – developing the infrastructure for electronic identification and authentication of individuals and healthcare professionals



Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✗
Is it enforceable?	
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✗
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✗
Assessment mechanisms	✗

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Spain (2/4)

Spain

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- Charter on individuals' digital rights (July 2021) with a specific section about security within Digital Health : information systems must be interoperable, access to and portability of patient information, use of Digital Health for clinical assistance (especially AI) is allowed upon clinical judgement of HCPs without any restriction
- Training for citizens performed, communication programs on digital services

2. Enable individuals to manage their Digital Health use and data

- No dedicated system for collecting consent, however existing national regulation that supplements GDPR on data protection
- HCDSNS allowing data to be viewed by patients and health professionals
- Ability for citizens to monitor and control the access to their health data
- Ability to consult and download data, however impossible for the individuals to delete or edit data

3. Make Digital Health inclusive and accessible to all

- Public authorities responsible for digital inclusion: specific section in the charter of individuals' digital rights (July 2021) dedicated to the social impact of Digital Health, promoting universal access to Digital Health services
- Spanish decree stipulating that all applications developed by public administrations for individuals must follow accessibility standards - several initiatives carried out at regional level to reduce digital divide (communication, training, human support, etc.)
- Possibility to provide records in a paper-based format upon request
- Initiatives carried out to increase digital literacy (school, universities, elderly)
- Strategic plans to provide high bandwith connections to 100% of Spain

4. Implement eco-responsible Digital Health

- Specific regulation stating that applications developed by public bodies must be systematically reusable
- Promoting the reuse of data by the public technology transfer center (CTT) to reduce energy resources needed when creating new services
- National regulation including some "green clauses", requirement for public authorities to acquire less energy-intensive digital solutions

Country Profile: Spain (3/4)

Spain

Strengthen Digital Health Governance

- No national governance of Digital Health projects apart from the Spanish Public Healthcare System, regions have their own authority and budget
- Specific funds allocated to finance health research and innovation: public research programs CDTI and red.es
- Private stakeholders involved in drafting Digital Health strategy but without access to data unless they are subcontractors of a regional healthcare service

Strengthen Digital Health security and interoperability

- High deployment of international interoperability standards (HL7-FHIR and ICD10), obligation to provide interoperability
- Regulatory framework dedicated to the secondary use of health data
- Legal frameworks to assess digital technologies safety, effectiveness and efficiency (applicable to health)
- 2-factor authentication mechanism to access National healthcare System, level 3 (IPSEeC) and level 4 (TLS) encryption
- No post-commercialisation controls to check the enforceability of national information systems
- Spain participates in European interoperability and data sharing projects (NCPeH and FAIR4Health)

Accelerate the deployment of core Digital Health services

- 3 national/regional core services: e-prescription (RESNS), general patient registry (TSI-SNS), online appointment booking
- Electronic prescriptions renewal
- Secure health messaging service only between patients and healthcare professionals

Country Profile: Spain (4/4)

Spain

Deploy Digital Health platforms at national level

- TSI-SNS: centralized database with federated instances in the regions, clinical data is stored in the regions (except for patient registry, in the Ministry of Health), access through regional digital health portals
  Included: administrative and health coverage information (96% of the population)
- HCDSNS: exchange of clinical reports between regions
  RESNS: national e-prescription/e-dispensing service
- Strong effort made to standardize identification: electronic identification and authentication for patients and healthcare professionals deployed nationwide (eiDAS compliant)

Support innovation and promote buy-in from all stakeholders

- Strong development of mHealth solutions for monitoring chronic diseases
- Reimbursement of teleconsultations unevenly regulated at regional level
- No courses in innovation and Digital Health in the curriculum of healthcare professionals

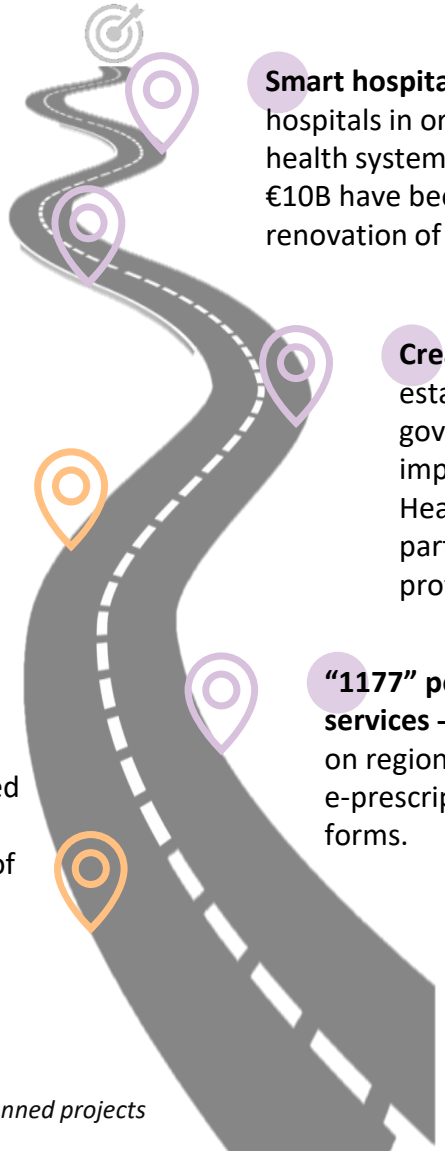
Focus on the enforceability of national reference systems

- Defined semantic and technical interoperability standards at national level with a catalog of SNOMED-CT, OID and HL7 references
- Use of standards to structure the national patient record
- EHR is added to by interfacing with the tools of the different autonomous regions of Spain: not mandatory to use national standards, but they must be compatible

Country Profile: Sweden (1/4)

Sweden

Summary of the Digital Health roadmap



May 2023: National Drug List - service allowing HCPs to view information on patient prescriptions. System directly implemented in the HCP's care information system

Digital Health training for healthcare professionals

May 2021: Prescription monitoring service- service allowing access to patients' information regarding their prescriptions and drugs purchased in a pharmacy. This service is a complement to the national list of medicines (as long as it is not implemented in the HCP information systems)

Smart hospitals - digitalization of hospitals in order to make the health system sustainable. Already €10B have been allocated for the renovation of hospitals.

Creating a governance - establishment of a new governance for the implementation of the Digital Health strategy, including the participation of healthcare professionals

"1177" portal for Digital Health services - services available depend on region of residence and include: e-prescription, e-medication, e-forms.

Key indicators

Patient health record	✓
E-prescription service	✓
Patient identification system	✓
Interoperability framework	✓
Is it enforceable?	✓
Security framework	✓
Is it enforceable?	✓
Individuals' access to their health data	✓
HP's access management	✓
National infrastructure for data collection	✓
Regulation on secondary use of data	✓
Regulation for telemedicine reimbursement	✓
Assessment mechanisms	✓

Finalized projects *Ongoing or planned projects*

Sources

Country Profile: Sweden (2/4)

Sweden

Focus on ethics in Digital Health

1. Base Digital Health on humanistic values

- 1177 health guide to inform individuals about available Digital Health services in their region (in 2019, 50 million connections were recorded in this system)
- 3 committees responsible for ethics in Sweden, not dedicated to Digital Health: Swedish Ethical Review Authority, Swedish National Council on Medical Ethics and Special Committee for Technological Innovation and Ethics
- Consideration of ethical issues anchored in the country's approach to the creation of new services (Swedish Patient Data Act implemented before GDPR)

2. Enable individuals to manage their Digital Health use and data

- 2 services to access health data: 1177 portal for individuals and (ii) the National Patient Overview for health professionals
- Decentralized health system with data remaining stored at local level: national services based on a local data indexing system
- Ability to access their data and choose which health professionals can consult them
- System decentralization which implies regional disparities: Not all regions offer the same depth of data indexing

3. Make Digital Health inclusive and accessible to all

- Dedicated physical "citizens' offices" set up to support the population in (i) creating a digital identity and (ii) using digital tools
- “Citizens' offices" also financing non-governmental associations responsible for improving "health digital literacy"

4. Implement eco-responsible Digital Health

- Sustainability and digital sobriety not considered top priority objectives for the moment in the field of Digital Health
- Swedish system based on data indexing: data is stored only once at local level (no duplication for national sharing or secondary uses) - Digital Health architecture in line with national policy to prevent duplication of data to limit the ecological impact of digital technology

Country Profile: Sweden (3/4)

Sweden

Strengthen Digital Health Governance

- National strategic and operational roadmap, governance distributed among regions and municipalities
- Dedicated Digital Health agency (Swedish Digital Health Agency) and National Board of Health and Welfare in charge of health data management
- Swedish commitment (2019) introducing digital training in the curricula of health professionals
- SALAR (Swedish Association of Local Authorities and Regions) enabling governance at regional and local level
- INERA company in charge of national platform management

Strengthen Digital Health security and interoperability

- National interoperability framework - In 2019, the HL7-V3 Green CDA standard is nationally implemented, as well as ICD10 standard and technical standards supported by IHE profiles.
- Health data protection laws implemented (in addition to GDPR): Patient Data Act, Health Data Register Act, Public Access to Information and Secrecy Act
- Participation in the European NCPeH project in 2022
- HL7-FHIR standard expected to be deployed more widely over the next years
- Existing project "Nordic Interoperability" to set up a platform ("Nordic Digital Health and Medication Platform") for the evaluation and use of mobile health applications. More than 100,000 health applications available, e.g. remote health check for the elderly

Accelerate the deployment of core Digital Health services

- Mandatory e-prescription service, statistics service regarding prescriptions (especially for liberal HP)
- Application services for a license allowing to prescribe medicines which are not approved in Sweden (KLAS)
- Services to order recovery certificates from Covid-19
- Electronic proxy service allowing to pick up medicines in the pharmacy
- Service implemented to receive medication at home
- Service providing access to prescriptions and history of drugs purchased in a pharmacy

Country Profile: Sweden (4/4)

Sweden

Deploy Digital Health platforms at national level

- 2 main platforms: 1177 portal for patients and National patient Overview for healthcare providers
- Sjunet: dedicated IP-based network that enables electronic communication between Swedish hospitals
- Electronic forms for various requests (extract of medicine register, vaccination certificates)
- SITHS: national electronic security solution for healthcare professionals identification
- VARA directory listing all medicines and their effects, routes of administration, types of prescription, etc.

Support innovation and promote buy-in from all stakeholders

- Strong development of mHealth solutions to monitor chronic diseases
- Reimbursement of teleconsultations heterogeneously regulated at regional level
- No specific training in innovation and Digital Health in the curriculum of healthcare professionals

Focus on the enforceability of national reference systems

- *No information collected on national reference systems enforceability*

Appendix 3/3
Sources

Introduction

In the next pages are gathered the main sources used to build the country profiles, supporting the detailed analysis by country

The sources have been identified (i) from an extensive desk research, (ii) from suggestions by the European network of EY correspondents (which have provided additional references) and (iii) from national Digital Health representatives of the 15 countries that participated in the field of play's interviews.

However, some information in the country profiles are related to direct information from the EY correspondents and/or the national e-health representatives without being related to a specific source, thus these next pages do not represent the entire scope of information they were able to share.

General (1/3)

All countries

Title of the document	Type	Date	Author	Main topics	Link	Scope
Digital Health across the Nordics	Market report	2021	Nordic Interoperability Project	Mobile health	Link here	Nordic countries
D4.1 - Policy Framework on People Empowerment	Policy framework	2019	eHAction – European Commission	Telehealth and mobile health	Link here	EU countries
D4.2 - Policy Proposal on People Empowerment	Policy proposal	2020	eHAction – European Commission	Telehealth and mobile health	Link here	EU countries
e-health Standardisation in the Nordic Countries	Publication	2019	Nordic Council of Ministers	Interoperability standards	Link here	Nordic countries
Empowering the health workforce to make the most of the digital revolution	Working paper	2021	OECD	Digital transformation focus on healthcare professionals	Link here	European countries
Survey results: National health data infrastructure and governance	Working paper	2021	OECD	National health data infrastructure and governance	Link here	European countries
Why sustainable healthcare is set to be next growth area for Sweden and Finland	Article	2021	Business Finland	Smart hospitals	Link here	Nordic countries
How well is your country doing on policy for secondary use of health data ?	Report	2021	Open Data Institute	Secondary use of health data	Link here	European countries
The European Health Data & Evidence Network Sharing the OHDSI Journey and a Vision of Evidence 'Today, Not in Several tomorrows'	Report	2021	OHDSI	OMOP deployment	Link here	European countries
University Free Apply website	Website	2021	Free Apply	Bachelor, Master and PhD in e-health	Link here	European countries
Innovation Day 2021	Presentation	2021	X-e-health	EHR	Link here	EU countries

General (2/3)

All countries

Title of the document	Type	Date	Author	Main topics	Link	Scope
Telehealth around the world : a global guide	Publication	2020	DLA Piper	Telehealth	Link here	European countries
Health at a Glance 2021: OECD indicators	Report	2021	OECD	Health in Europe	Link here	Austria, France, Germany, Italy, Spain, UK
#SmartHealthSystems - international comparison of digital strategies	Report	2018	Bertelsmann Stiftung Empirica	e-health strategy	Link here	Denmark, France, Netherlands
ISO TC 215 Health informatics	List	2021	ISO	Working groups ISO TC 215	Link here	European countries
MyHealth@EU	Article	2021	European Commission	MyHealth@EU	Link here	EU countries
CEN/TC 251	Report	2021	CEN	Working groups CEN TC 251	Link here	France, Germany, Italy, Netherlands, Slovenia, Spain, Sweden, UK
Security and Resilience in e-health	Report	2015	ENISA	MyHealth@EU	Link here	European countries
e-health, Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU	Report	2019	European Commission	e-health, Interoperability and Artificial Intelligence	Link here	EU countries
Deployment of telemedicine and telehealth in Europe	Report	2021	EY	Telemedicine and telehealth in Europe	Internal document	European countries
Study on health data, Digital Health and artificial intelligence in healthcare	Report	2021	EY	Health data, Digital Health and artificial intelligence	Internal document	European countries

General (3/3)

All countries

Title of the document	Type	Date	Author	Main topics	Link	Scope
Matrix on e-health strategies and models overview in selected EU Member States	Report	2020	EY	EU e-health strategies	Internal document	Austria, Czech Republic, Denmark, Estonia, Lithuania, Netherlands, Norway, Portugal, Spain (Catalonia)
Overview analysis of e-health strategies and models in selected EU Member States	Report	2020	EY	EU e-health strategies	Internal document	Austria, Czech Republic, Denmark, Estonia, Lithuania, Netherlands, Norway, Portugal, Spain (Catalonia)
Summary of virtual study visits: Best practices in e-health - Estonia, Lithuania, Netherlands, Portugal, Spain (Catalonia)	Report	2019	EY	Best practices for Bulgarian e-health strategy	Internal document	Estonia, Lithuania, Netherlands, Portugal, Spain (Catalonia)

Austria

Austria

Title of the document	Type	Date	Author	Main topics	Link
COVID-19 : An opportunity for healthcare in Austria	Report	2020	Health Hub Vienna	e-health strategy	Link here
Digital Roadmap Austria	Report	2016	Gouvernement Autrichien	Digital strategic roadmap	Link here
ICD-Klassifikation	Article	2021	Statistik Austria	ICD-10	Link here
Integrating the Healthcare Enterprise	Presentation	2010	IHE Austria	IHE profiles	Link here
Bundesrecht konsolidiert: Gesamte Rechtsvorschrift für Gesundheitstelematikgesetz 2012, Fassung vom 20.12.2021	Law	2021	Rechtsinformationssystem des Bundes	Regulation on the secondary use of data, health information systems security, health data hosting	Link here
Telegesundheitsdienste-Kommission gemäß § 8 BMG	Article	2019	Ministry of health	Telehealth services commission	Link here
E-Health	Article	2019	Ministry of health	e-health stakeholders	Link here
SNOMED CT	Article	2021	ELGA	SNOMED-CT	Link here
Datenschutz und Datensicherheit bei ELGA	Article	2021	ELGA	Health data protection	Link here

Belgium

Belgium

Title of the document	Type	Date	Author	Main topics	Link
Plan d'actions e-santé 2019-2021	Report	2019	Gouvernements régions belges	e-health action plan	Link here
Country Brief - Belgium	Report	2010	European Commission e-Health Strategies	e-health strategy	Link here
The future directions and evolutions of e-health in Belgium	Report	2021	EY pour la Commission Européenne	e-health strategy	Internal document
Plateforme e-health - Indicateurs de performance pour le 1er et 2ème trimestre 2020	Report	2020	e-health	Use of the e-health platform	Internal document
Le contexte de l'e-santé en Belgique : de la santé vers l'e-santé	Article	2021	Brussels health network	e-health context in Belgium	Link here
Roadmap 3.0	Article	2019	eSanté	e-prescription use	Link here
e-Santé Wallonie inaugure un module d'e-learning pour les professionnels de première ligne	Article	2020	Patient Numérique	e-health e-learning for HCPs	Link here
Votre santé au centre de nos préoccupations Guide du consentement éclairé pour le partage électronique des données de santé	Guide	2016	Federal public service	Informed consent	Link here

Bulgaria

Bulgaria

Title of the document	Type	Date	Author	Main subject	Link
e-health innovation trainings	Website	2021	Free Apply	e-health innovation trainings	Link here

Croatia

Croatia

Title of the document	Type	Date	Author	Main topics	Link
Croatia	Country summary	2016	World Health Organization	e-health legal frameworks, telehealth, mHealth, EHR, big data	Link here
AUTOMATIC PROCESSING OF PERSONAL DATA COMPILATION OF REPLIES ON MEDICAL TECHNOLOGIES AND DATA PROTECTION ISSUES	Questionnaire	2015	Council of Europe - Directorate General Human Rights and Rule of Law	Health data hosting	Link here
Implementation of e-health in Croatia	Presentation	2015	Ministry of Health	Messaging between patients and HCPs	Link here
Farmacia	Website		Farmacia	Pharmacies' directory	Link here
Domovi zdravlja	Website		Ministry of health	Health centers' directory	Link here

Cyprus

Cyprus

Title of the document	Type	Date	Author	Main topics	Link
Country Brief - Cyprus	Report	2010	European Commission e-Health Strategies	e-health strategy	Link here
e-health strategies and implementation activities in Cyprus	Report	2007	e-health ERA	e-health strategy	Link here
Digital Government Factsheet 2019 Cyprus	Report	2019	European Commission	e-health strategy	Link here
Overview of the national laws on the electronic Health records in the EU member states - National report for Cyprus	Report	2014	Time.lex Milieu Ltd	Laws on EHR Secondary use of data regulation	Link here
e-health Lab	Website	2021	e-health Lab – University of Cyprus	e-health public research programs	Link here
Clinical Trials	Article		Pharmaceutical services – Ministry of Health	Clinical studies on medical devices	Link here
Medical Card application	Website		Ministry of Health	Medical card	Link here
Know your doctor	Website	2021	Know your doctor	Legal Entity directory	Link here
Department of social inclusion of persons with disabilities	Website	2021	Department of social inclusion of persons with disabilities	Accessibility regulation	Link here
IT Unit	Website	2021	Ministry of Health	Agency for the implementation of e-health projects	Link here
CovTracer	Website	2021	mHealth Hub	mHealth	Link here
Finance for research for health	Article		Health research web	Health research	Link here
The 2019 introduction of the new National Healthcare System in Cyprus	Publication	2021	Panagiotis Petrou	National healthcare system	Link here

Czech Republic

Czech Republic

Title of the document	Type	Date	Author	Main topics	Link
National e-health Centre - Home	Website	2021	National e-health centre	e-health services	Link here
eHealth platform	Website	2021	NIX-ZD	Unique identification number	Link here
Nzip	Website	2021	Ministry of health	Additional services for patients - information portal for health	Link here
Statistika elecktroniké prekcripce – rok 2021	Report	2021	eRecept	A-prescription statistics (use, level of satisfaction)	Link here
IMPROVING THE CZECH HEALTH CARE SYSTEM ECONOMICS DEPARTMENT WORKING PAPERS No. 1522	Working paper	2018	OECD	Number of infrastructures using e-prescription	Link here
Ulékare	Website	2021	Ulékare	Messaging service for patients	Link here
IHE Czech Republic	Website	2021	IHE	Implementation of IHE profiles	Link here
Introducing the FREOPP World Index of Healthcare Innovation	Article	2020	Freopp	Innovation in the e-health sector	Link here
Sbíráme a zpracováváme statistická data pro zkvalitnění našeho zdravotnictví	Website	2021	UZIS	Health data	Link here
The national e-health strategy of the Czech Republic 2016-2020	Report	2016	Ministry of health	e-health strategy	Link here
Action plan for national e-health strategy 2016-2020	Report	2017	Ministry of health	Operational roadmap	Link here

Denmark

Denmark

Title of the document	Type	Date	Author	Main topics	Link
Digital Health Strategy 2018-2022	Report	2018	Government	e-health strategy	Link here
e-health platform Sundhed	Website	2021	Sundhed	Core services	Link here
Toward a better social contract with big tech	White paper	2021	Government	Charter on citizens' rights in the digital field	Link here
Research projects within Digital Health	Article	2020	SDU (University of Southern Denmark)	e-health research	Link here
Denmark AI Strategy Report	Report	2021	European Commission	Evaluation criteria – data ethics AI	Link here
Use of IT across the population	Article	2020	Danmark Statistik	Statistics – national use of digital services	Link here
e-health in Denmark e-health as part of a coherent Danish healthcare system	Report	2012	Danish Ministry of Health	e-health system	Link here
Denmark: an independent council and a labelling scheme to promote the ethical use of data	Article	2020	OECD AI Danish Business Authority	Data ethics in AI	Link here

Estonia

Estonia

Title of the document	Type	Date	Author	Main topics	Link
Health and well-being information centre website	Website	2021	Health and well-being information centre	e-health services	Link here
Patient Portal	Website	2021	Patient portal	Immunisation certificates, health declarations	Link here
Citizens' satisfaction with the services provided by the state - public e-services	Presentation	2014	TNS Emor (private company)	Satisfaction rate e-prescription	Link here
e-health Factsheet	Communication	2021	Digilugu.ee	e-prescription use	Link here
Health Services Organisation Act	Act	2001	Estonia Parliament	Mandatory use of health IS	Link here
National institute for health development	Website	2021	Tervise Arengu Instituut	Secondary use of health data	Link here
Health Statistics and Health research database	Website	2021	Health Statistics and Health research database	Secondary use of health data	Link here
MSc Digital Health	Website	2021	TalTech	MSc Digital Health	Link here
Health system development projects	Communication		Eesti Haigekassa	Innovation funding	Link here
Three-level IT Baseline Security System ISKE	Article	2021	Republic of Estonia – Information System Authority	Regulation on health IS security Health data hosting	Link here

Finland

Finland

Title of the document	Type	Date	Author	Main topics	Link
Country Brief: Finland	Report	2010	e-health Strategies Commission Européenne	e-health strategy	Link here
Kanta website	Website	2021	Kanta	Core services	Link here
e-health and eSocial in Finland - today and 2020	Report	2015	Ministry of Social Affairs and Health Finland	e-prescriptions statistics and e-health strategy	Link here
e-health and eWelfare of Finland	Report	2018	National Institute for Health and Welfare	EHR and sharing of health data	Link here
Top mHealth (Mobile Health) Companies and Startups in Finland (2021)	Article	2021	Leap Droid	Mobile health	Link here

France

France

Title of the document	Type	Date	Author	Main topics	Link
LPPR : Dépôt d'un dossier auprès de la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé	Guide	2016	HAS	DTx processing	Link here
Règlement intérieur de la CNEDiMTS (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé)	Regulation	2021	HAS	DTx processing	Link here
Les programmes financés par le ministère et leurs appels à projets : PHRC, PRT, PRME, PREPS, PHRIP et ReSP-Ir !	Article	2021	Ministère de la Santé	Public research programs on Digital Health	Link here
I am a health professional in France and I want to access the medical records of a European patient	Communication	2021	Le Cleiss	MyHealth@EU	Link here
Quelle est la stratégie gouvernementale pour faire de la France un leader en santé numérique ?	Article	2021	L'Usine Digitiale	e-health fundings	Link here

Germany (1/2)

Germany

Title of the document	Type	Date	Author	Main topics	Link
The German healthcare system	Report	2020	Federal Ministry of Health	Users representatives in the e-health governance	Link here
e-health in Germany – Market study	Market study	2019	Task Force Health Care	Implication of private stakeholders in the e-health strategy	Link here
National policy in interoperability in Germany	Presentation	2021	IHE Europe	IHE profiles and HL7-FHIR implementation	Link here
A Consensus German Reporting Standard for Secondary Data Analyses, Version 2	Publication	2016	Swart E, Bitzer EM, Gothe H, et al	Secondary use of data regulation	Link here
The German Pharmacoepidemiological Research Database (GePaRD)	Communication	2021	Leibniz Institute for Prevention Research and Epidemiology - BIPS GmbH	National infrastructure for health data	Link here
Data Ethics Commission	Article	2021	Federal Ministry of Justice and Consumer Protection	National framework for health systems security	Link here
Country Brief: Germany	Report	2010	Empirica – e-health Strategies – European Commission	Use of e-prescription, Centralised authentification for HCPs	Link here

Germany (2/2)

Germany

Title of the document	Type	Date	Author	Main topics	Link
eSignature legality in Germany	Article	2021	DocuSign	e-signature	Link here
The German healthcare system	Article	2021	Expatica	Involvement of users in e-health	Link here
En Allemagne, privé et public font recherche commune	Article	2021	L'Usine Nouvelle	Trainings innovation	Link here
Germany AI strategy report	Report	2021	European Commission	AI regulations and evaluation criteria	Link here
German hospitals to get €3 billion funding boost for digitalisation	Article	2020	Healthcare IT News	Fundings for e-health	Link here
Germany Approves New Forms for Patient Consents	Article	2020	Morgan, Lewis & Bockius LLP	Collection of consent	Link here
L'e-santé en Allemagne	Report	2016	French Ambassy in Germany	Public policies for e-health	Link here
DIGA Background	Report	2021	EY	German health system	Internal document

Greece

Greece

Title of the document	Type	Date	Author	Main topics	Link
The Healthcare System in Greece and the reforming & investment opportunities	Report	2021	EY	Healthcare system, Investments	Internal document
EIT Health	Website	2020	EKT	Innovation fund for e-health	Link here
MyHealthapp	Article	2021	Government	Messaging service	Link here

Hungary

Hungary

Title of the document	Type	Date	Author	Main topics	Link
Main focus areas of the office	Website	2021	National Research Development and Innovation Office	Research programs related to e-health	Link here
EESZT Information Portal	Website	2021	Government	e-health portal	Link here
Creating an enabling regulation for telemedicine	Article	2021	World Health Organization	Telemedicine regulations	Link here

Ireland

Ireland

Title of the document	Type	Date	Author	Main topics	Link
e-health Ireland	Website	2021	The health service executive	e-health strategy	Link here
e-health Strategy for Ireland	Report		Health service executive Patient safety First	e-health strategy	Link here

Italy

Italy

Title of the document	Type	Date	Author	Main topics	Link
Dichiarazione dei diritti in Internet	Declaration	2015	Government	Declaration of rights regarding the internet	Link here

Latvia

Latvia

Title of the document	Type	Date	Author	Main topics	Link
Law project 2021-2027 public health (with a part on ethics in e-health)	Law project	2021	Government	Public health (with a part on ethics in e-health)	Link here
Patient right defense law	Regulation	2010	Saeima (Parliament)	Patient right defense law	Link here
Procedures for ensuring compliance of information and communication technology systems	Regulation	2015	Cabinet of ministers	Compliance of information and communication technology systems	Link here
Law on information systems	Regulation	2002	Saeima (Parliament)	Information systems	Link here
Information technology security law	Regulation	2010	Saeima (Parliament)	Security of information technology	Link here

Lithuania

Lithuania

Title of the document	Type	Date	Author	Main topics	Link
Case study - Lithuania: Better care through national health record	Website	2021	Nortal	National health record	Link here
Overview of the national laws on EHR in the EU Member States - National Report for Lithuania	Report	2014	time.lex Milieu	National laws on EHR	Link here
e-health recovery and resilience facility	Report	2021	Recovery and resilience facility	e-health recovery and resilience facility	Link here
Lithuania Is Becoming a Growth Hotspot for Digital Health	Website	2019	ECHAlliance	Public Research Digital Health	Link here
International Comparison eID Means		2015	PBLQ	eID in health	Link here
Hospitals world guide	Guide	2021	Hospitals world guide	Hospitals Directory	Link here
HEALTH CARE SPECIALISTS	Website	2021	VASPVT	Healthcare specialists directory	Link here

Luxembourg

Luxembourg

Title of the document	Type	Date	Author	Main topics	Link
Présentation du Dossier de soins partagé et de sa campagne de communication «MyDSP»	Communication	2020	Government	Statistics – national e-health portal	Link here
La téléconsultation - Comment ça marche	Article	2021	Government - CNS	e-prescription renewal	Link here
Intelligence artificielle : publication d'un nouveau rapport technique pour présenter les cas d'utilisation	Article	2021	Government	Evaluation criteria in AI	Link here
Une intelligence artificielle de confiance au service du système de santé	Article	2021	Journal du droit de la santé et de l'Assurance Maladie / Numéro 28	Artificial Intelligence in health	Link here
Elaboration SDSI Santé national Version 2 au Luxembourg - Feuille de route 2016-1019	Report	2016	e-health agency Luxembourg	e-health roadmap	Link here

Malta (1/2)

Malta

Title of the document	Type	Date	Author	Main topics	Link
A national health systems strategy for Malta (2014-2020)	Report	2014	Parliamentry secretariat for health	e-health strategy	Link here
Healthcare profession act - medical council	Report	2021	Medical Council	Medical register - principal list	Link here
Telemedicine services	Article	2021	Ministry of health	Telemedicine regulation	Link here
Mobile Health Apps	Guide list	2021	Ministry of health	Recommended mHealth apps	Link here
Academy for Patient Centred Excellence and Innovation in Regulatory Sciences	Website	2021	Malta Medicines Authority	Innovation in health Public research programs Digital Health	Link here
Clinical trials	Website	2021	Malta Medicines Authority	Clinical trials	Link here

Malta (2/2)

Malta

Title of the document	Type	Date	Author	Main topics	Link
National eSkills Strategy 2019-2021	Report	2019	eSkills Malta Foundation	Digital skills diagnostic	Link here
myHealth – User guide for patients	Guide	2019	Information Management Unit	Centralised identification number for citizens	Link here
Medical Practitioners and Consultants	Website	2021	Pharmacy.com	Legal entity directory	Link here
myHealth	Website	2021	Ministry of Health	Health document management for citizens	Link here
The Computer Generated Prescription - Patients' Electronic Treatment Records real-time Update	Article	2021	Ministry of Health	e-prescription service	Link here
LEĠIŻLAZZJONI MALTA	Website		LEĠIŻLAZZJONI MALTA	Secondary use of data regulation	Link here
About Digital Inclusion	Website		Malta Communications Authority	Digital inclusion	Link here

Netherlands

Netherlands

Title of the document	Type	Date	Author	Main topics	Link
Government encouraging the use of e-health (telehealth)	Article	2021	Netherlands government	Tele-health	Link here
Over de Slimme Zorg Estafette	Website	2021	Slimme Zorg Estafette	e-health relay 2022	Link here
Keeping and sharing medical records	Article		Netherlands Enterprise Agency, RVO	Centralised authentification system for HCPs	Link here
Wegwijs in zorgtechnologie, e-health en digitale zorg	Website		Ministry of Health	Information e-health to users	Link here
VWS Valuable AI for health program	Article		Ministry of Health	VWS Valuable AI for health program	Link here
Health Informatics Degrees	Website	2021	StudyPortals	Health informatics trainings	Link here
Zorg voor innoveren	Article		Government	Innovation funds in health	Link here

Norway

Norway

Title of the document	Type	Date	Author	Main topics	Link
National governance model	Communication	2021	e-health Directorate	e-health governance management, Fundings	Link here
Norms	Communication	2021	E-Health Directorate	Security of Health Systems	Link here
Norvegian Centre for e-health research	Website	2021	Norvegian Centre for e-health research	e-health research	Link here
National e-health platform	Website	2021	Helse Norge	Core services	Link here

Poland

Poland

Title of the document	Type	Date	Author	Main topics	Link
Digital healthcare 2021	Article	2021	Chambers and Partners	Telehealth reimbursement regulation, Health data hosting	Link here
Programme agreement signed for the Health programme in Poland	Article	2019	EEA Grants	e-health innovation projects	Link here
Poland - Broad Alliance for Digital Skills	Article	2021	Digital Skills and Jobs Platform – European Union	Digital trainings by NGO	Link here
List of medical facilities in Poland	List	2020	UK Government	Medical facilities in Poland	Link here
Number of individuals using Patient's Internet Account in Poland from March 2020 to July 2021	Report	2021	Statista	Citizens' access to their health documents	Link here
ICT, DIGITAL LITERACY, DIGITAL INCLUSION AND MEDIA EDUCATION IN POLAND	Publication	2020	Pedagogical University of Cracow	Digital literacy, Digital Inclusion	Link here

Portugal

Title of the document	Type	Date	Author	Main topics	Link
Carta portuguesa de direitos humanos na era digital	Charter	2021	Government	Human rights regarding digital tools	Link here
National strategic telehealth plan 2019-2022	Report	2019	SNS, SPMS, CNTS (national center of telehealth)	e-health strategy	Link here
From big data to smart health Putting data to work for the public's health Data Strategy for Next Generation Portuguese National Health Service	Report	2019	Advanced Analytics and Intelligence Unit Information Systems Department Shared Services of the Ministry of Health	big data in e-health - data strategy	Link here

Romania (1/2)

Romania

Title of the document	Type	Date	Author	Main topics	Link
New ID Cards To Serve Also As Health Cards	Article	2020	Romania Journal	Identification	Link here
Romania: Romania Sets Out New Rules On Medical Devices	Article	2021	Mădălina Anghenie Alexandra-Ioana Popescu	Transparency communication health	Link here
Romania makes first step on e-health path by turning on electronic prescription system	Article	2018	Romania Insider	e-prescription and fundings	Link here
National E-Health Record – Romanian National Health Insurance House	Website	2021	UTI	EHR	Link here
La e-santé - télémédecine, santé numérique ou santé connectée	Guide	2021	IRDES	Telehealth	Link here
Romania permanently regulates telemedicine	Report	2020	CMS Law Now	Telemedicine	Link here
AI In Romania	Article	2021	OECD AI	AI	Link here
'Big data analytics' and processing of health data for scientific research purposes : the Romanian legal framework	Report	2018	AEGLE	Consent	Link here

Romania (2/2)

Romania

Title of the document	Type	Date	Author	Main topics	Link
Description of the National Health Information System in Romania	Report	2003	World Health Organization	Consent	Link here
The National Supervisory Authority For Personal Data Processing	Website	2021	The National Supervisory Authority For Personal Data Processing	Data protection	Link here
Initiatives in the Romanian e-health Landscape	Research paper	2011	Babeş-Bolyai Universit, Cluj-Napoca, Romania University of Medicine and Pharmacy, Cluj-Napoca, Romania	e-health in Romania	Link here
e-health strategy and implementation activities in Romania	Report	2007	e-health ERA	e-health strategy	Link here
Romania's sustainable development strategy 2030	Report	2018	Department of Sustainable Development	Sustainable development in digital tools	Link here
Building e-health National Strategies - The Romanian Experience	Research paper	2009	Department of Medical Informatics, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania bNational Center for Health Statistics and Informatics, Bucharest, Romania	e-health national strategy	Link here

Scotland

Scotland

Title of the document	Type	Date	Author	Main topics	Link
Why does the NHS struggle to adopt e-health innovations? A review of macro, meso and micro factors	Publication	2019	BMC Health services research	e-prescription renewal and investments for e-health	Link here
UK: Digital Health Laws and Regulations	Article	2021	ICLG	Regulations e-health Scotland and UK	Link here
Protecting Scotland's Health	Website		Health Protection Scotland	e-health projects accompanying National framework for health systems security	Link here
Charter for Safe Havens in Scotland: Handling Unconsented Data from National Health Service Patient Records to Support Research and Statistics	Charter	2015	Scottish Government	National regulation to free from collect of consent	Link here
Electronic Health Records	Article		NHS Research Scotland	Unique identification number for the health sector	Link here
Digital Health and Care Strategy	Publication	2021	Cabinet Secretary for Health and Social Care	e-health roadmap	Link here
Digital Health and Care Scotland - About	Website	2021	Digital Health and Care Scotland	Organisation for the e-health strategy management	Link here
About NHS Scotland	Article		NHS Scotland	e-health Agency	Link here

Slovakia

Slovakia

Title of the document	Type	Date	Author	Main topics	Link
Elektronické zdravotníctvo	Article	2021	eZdravie	e-health functionalities launched on an ongoing basis	Link here
Elektronické zdravotníctvo	Article	2021	eZdravie	Centralized electronic authentication system of citizens	Link here
MFSR Decree on Standards for ISVS	Regulation	2021	Ministry of Investments, Regional Development and Informatization of the Slovak Republic	Enforceability (mandatory of use) of the interoperability framework which also contain standards and models for project management of information systems implementation	Link here
Act no. 95/2019 Coll. on information technologies in public administration	Act	2019	Ministry of Investments, Regional Development and Informatization of the Slovak Republic	Enforceability (mandatory of use) of the interoperability framework which also contain standards and models for project management of information systems implementation	Link here
Act no. 275/2006 Coll. on public administration information systems	Act	2006	Ministry of Investments, Regional Development and Informatization of the Slovak Republic	Enforceability (mandatory of use) of the interoperability framework which also contain standards and models for project management of information systems implementation	Link here
Ministry of Investments, Regional Development and Informatization of the Slovak Republic	Article	2021	Ministry of Investments, Regional Development and Informatization of the Slovak Republic	Existence of a normative institution for technical and semantic interoperability subjects	Link here

Slovenia

Slovenia

Title of the document	Type	Date	Author	Main topics	Link
Analysis of e-Health solutions in Slovenia: A usage perspective	Report	2019	UPORABNA INFORMATIKA	e-health strategy	Link here
Svit	Website	2021	Svit	e-health projects	Link here

Spain

Spain

Title of the document	Type	Date	Author	Main topics	Link
Carta derechos digitales	Charter	2021	Gouvernement	Charter on citizens' rights in the digital field	Link here

Sweden

Sweden

Title of the document	Type	Date	Author	Main topics	Link
A strategy for implementing e-health vision 2025	Report	2020	Ministry of health and social affairs	e-health strategy	Link here
1177 Vardguiden	Website		1177 Vardguiden	information on e-health services	Link here
Linneuniversitetet	Website		Linneuniversitetet	e-health institute	Link here
VISMA Sign	Website		VISMA Sign	e-signature	Link here