

Study on Digital Health implementation in the EU

Presentation of Digital Health benchmark
results

Mai 12th, 2022

■ ■ ■
The better the question. The better the answer.
The better the world works.



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

Executive 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

DNS PFUE – Study on Digital Health implementation in the EU – eHealth Network



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.

- | | | | |
|----------|-----------|----------------|----------|
| Austria | France | Luxembourg | Scotland |
| Belgium | Germany | Malta | Slovakia |
| Bulgaria | Greece | Netherlands | Slovenia |
| Croatia | Hungary | Norway | Spain |
| Cyprus | Ireland | Poland | Sweden |
| Denmark | Italy | Portugal | |
| Estonia | Latvia | Czech Republic | |
| Finland | Lithuania | Romania | |



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.

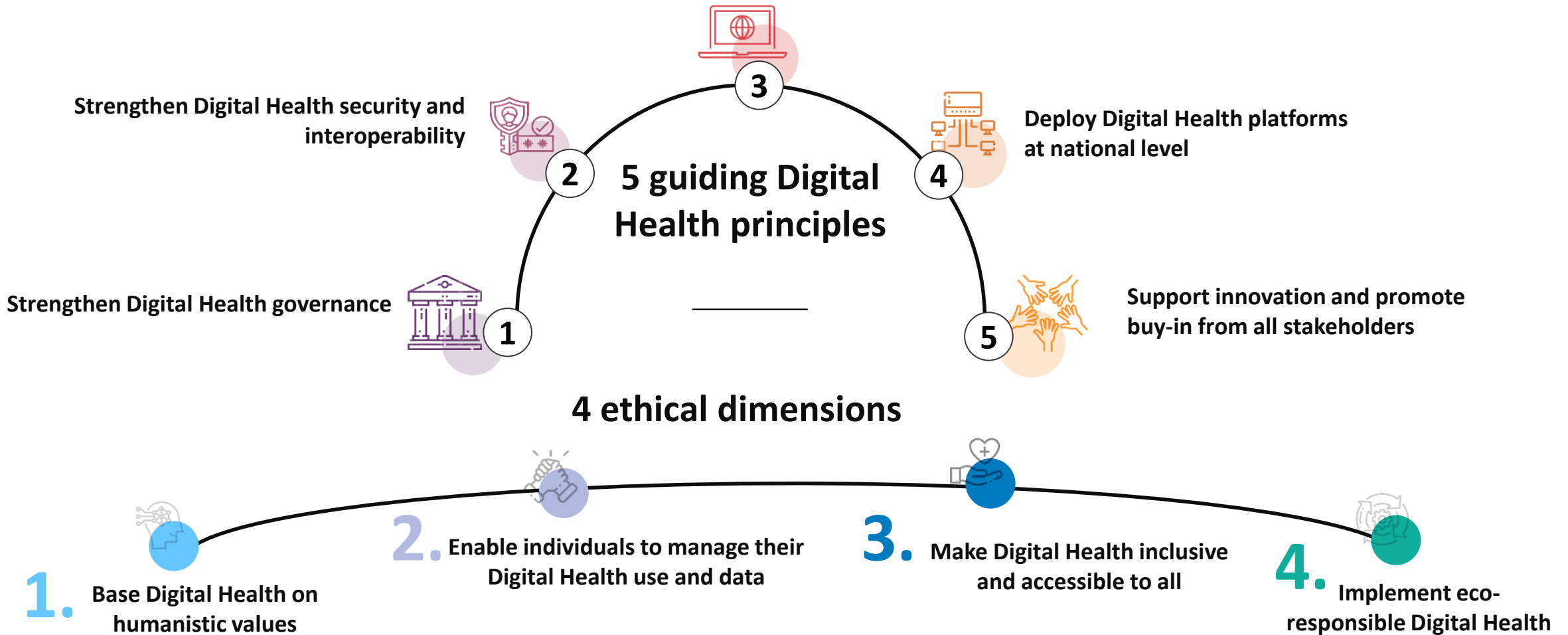
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Desk research covering 29 countries

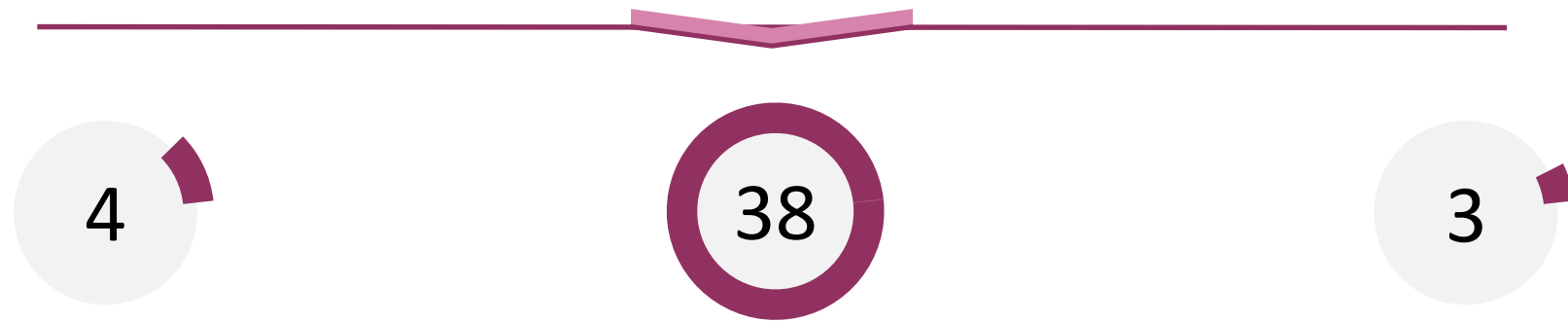
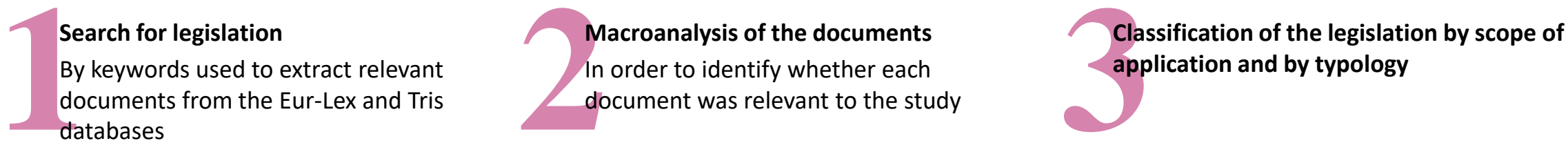
Consultation with delegates from 15 countries

5 guiding principles and 4 ethical dimensions

Accelerate the deployment of core Digital Health services



First approach to identify regulatory areas



Regulatory areas

Ethics, Marketing, Information Technology, Data

Regulatory documents

Distributed amongst the 4 areas

Fields of application

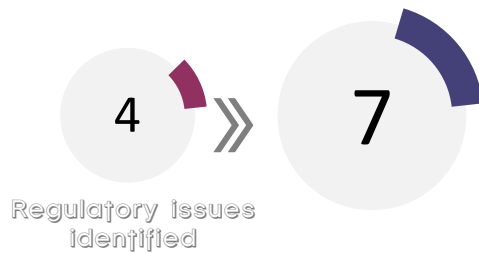
- Documents governing the healthcare sector and applicable to Digital Health
- Documents specific to Digital Health
- Cross-disciplinary documents with an impact on Digital Health

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, good practices, and compulsory requirements

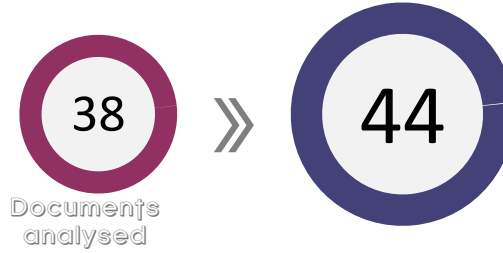
5 In-depth analysis of the different documents
Comprehensive analysis of the documents and identification of the theme discussed (i.e. with regards to the classification)

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 detail the analysis.
Cross-analysis of documents discussing multiple themes.



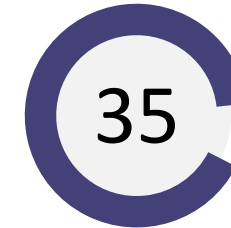
Defined themes

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

Summary

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1

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- | | | | |
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|  Belgium |  Germany |  Malta |  Slovakia |
|  Bulgaria |  Greece |  Netherlands |  Slovenia |
|  Croatia |  Hungary |  Norway |  Spain |
|  Cyprus |  Ireland |  Poland |  Sweden |
|  Denmark |  Italy |  Portugal | |
|  Estonia |  Latvia |  Czech Republic | |
|  Finland |  Lithuania |  Romania | |

 Desk research covering 29 countries



Summary of the Digital Health roadmap

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

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

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

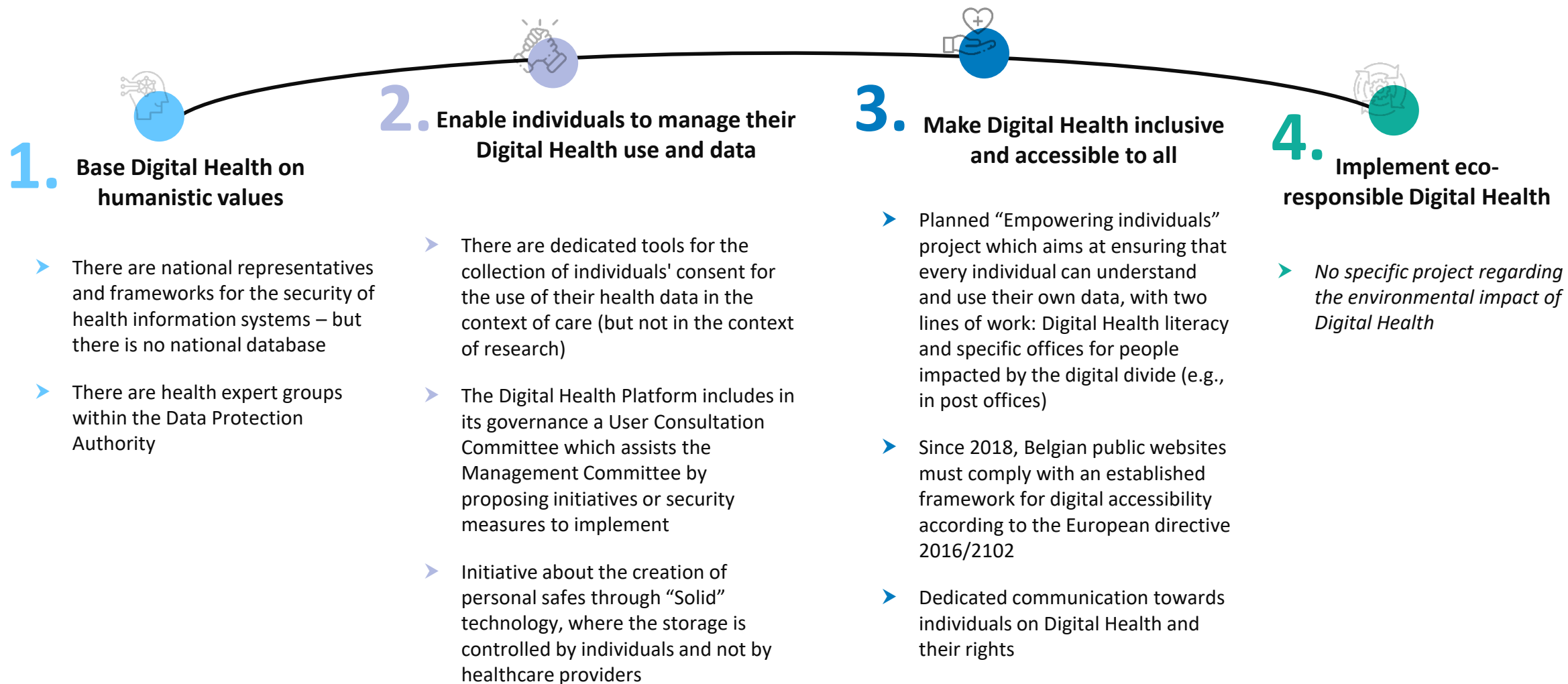


Key indicators

| | |
|---|---|
| ▶ 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 | ✓ |



Focus on ethics in Digital Health





Strengthen Digital Health Governance

- Shared strategic and operational governance between 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.
- Actors / stakeholders of the ecosystem involved in the construction of the Digital Health strategy (professionals, software publishers e.g. *Agoria*, patients associations, etc.)



Strengthen Digital Health security and interoperability

- National interoperability framework deployed in 50% of healthcare organizations
- Draft regulation on progress regarding secondary use of data - however, a *Healthdata.be* platform is already implemented to facilitate and standardise the registration of data for secondary use (research context)



Accelerate the deployment of core Digital Health services

- Mobile health application assessment and reimbursement system published in May 2021. There is a website listing reliable mobile health applications and their level of trust: *mhealthbelgium.be*

- There is a governance body between institutions and private software 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)
- No post-control mechanisms to ensure the enforceability of national reference systems
- Data portability is only addressed at a regional level
- No authorisation or regulation of telemedicine - however, there is an evaluation system. *Note: Teleconsultations could only be reimbursed during the Covid crisis.*



Deploy Digital Health platforms at national level



“MaSanté”(Digital Health.fgov.be), national portal where individuals can access their health data, including information saved and shared by healthcare providers, the health insurance fund, or other federal institutions and supported by digital tools deployed at a regional level - about 80% use rate



Patient identification with the electronic ID card (100% of the population); identification and authentication service for healthcare professionals (80% use rate)



Support innovation and promote buy-in from all stakeholders



No initial training in innovation and Digital Health for healthcare professionals - however, specialisations are possible (master's degree, double degree, etc.)



Existence of regional services dedicated to document management (80% effective use rate) and secure messaging (10% effective use rate) for patients



e-prescription service (Recip-e), mandatory since 2020 and used by 50% of healthcare infrastructures
e-signatures used in 35% of all health documents



Digital Health Box to collect individuals initiatives about health innovation

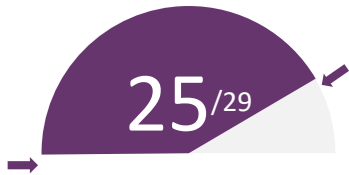


Spotlight on the enforceability of national reference systems

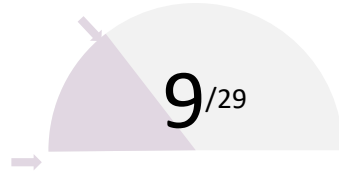
- The Digital Health platform is used to validate the compliance of Digital Health services with the national architecture standards

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

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

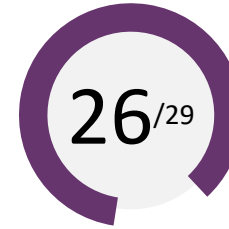


have defined a national Digital Health strategy



include users representatives in their governance

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



Strategies and governance bodies are mainly focusing on the **deployment of core national services**.

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.



Countries head towards the creation of a **patient-centered health system**.

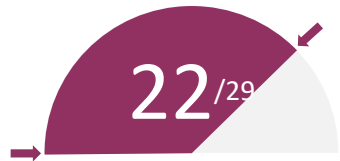
In some countries, an **electronic health card** allows the patient to decide which medical data they want to store.

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 (based on SNOMED-CT, HL7 FHIR or IHE profiles)



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

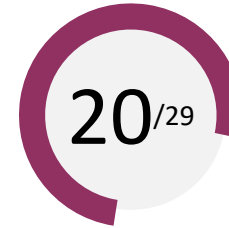


The **interoperability frameworks deployment extent is quite heterogeneous** and **only 45% of countries** have made all or some of them **mandatory**.

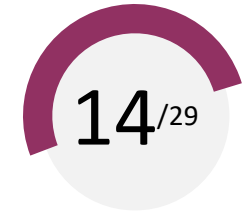


Most countries also **rely on European projects to implement their frameworks** in a consistent European way – especially for the NCPeH project.

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



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 processing data requests** and issuing data permits.

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** secured, structured **data exchanges**



rolled out a nationwide Digital Health secured messaging service

rolled out a national healthcare provider identification service



E-prescription is mostly deployed in European countries and even mandatory in 5 EU countries.

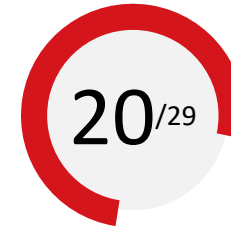


Secured **individuals health messaging services are not well-developed** in Europe. However, **mobile applications have been implemented** and offer numerous services to individuals.

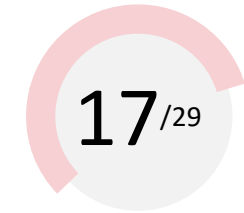


Some countries have built a decentralized health system, in which some services could be **deployed in heterogeneous ways** between the regions.

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



Implementation of a **National Patient Record is a priority** for most countries. However, **disparities still appear regarding the maturity of these projects**



Many countries have implemented **Digital Health platforms, widely used** and providing a **large range of services and health data** (*e-prescription, pharmaceutical databases, patient data repositories, patient records, teleconsultation etc.*)

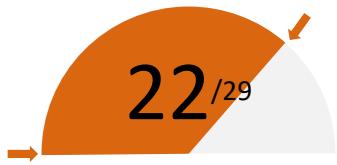
Guiding principles: key findings and main trends (4/5)



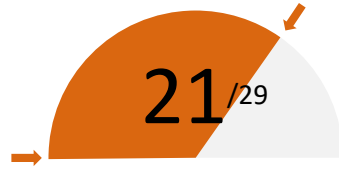
Desk research covering 29 countries

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 a means to identify healthcare professionals

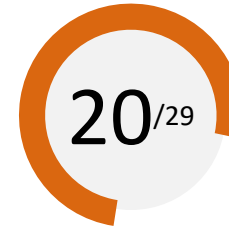


To ensure secure access to national digital platforms, **most countries use a centralized electronic identification system**. All but 1 of the Member States **provide a unique individual health identifier**.



Healthcare professionals and **legal entities index are quite well-implemented** at national levels and allow individuals to easily find the services they are looking for.

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



Even though **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 ensured** and less than half of the countries **allow individuals to download their data**.

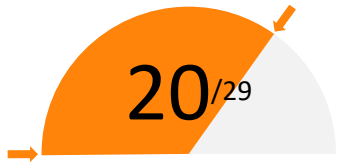
Guiding principles: key findings and main trends (5/5)



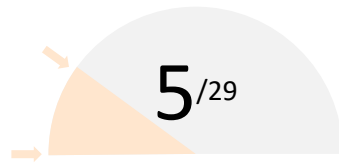
Desk research covering 29 countries

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

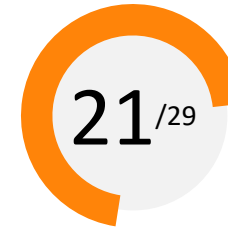


reimburse telemedicine appointments, and 38% reimburse mHealth services

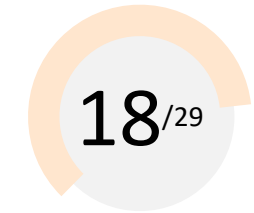


have enforced regulations on the use of AI for health

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 regulations have been quickly established during the Covid crisis. Regulations on new technologies such as mobile health applications, digital therapies, or Artificial Intelligence could be developed.



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



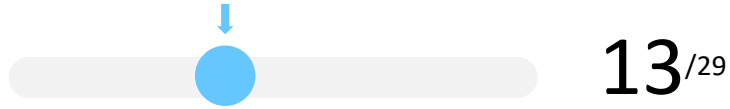
The vast majority of EU countries support and encourage health innovation in various ways.

Some countries already have very strong training and acculturation to innovation, others are developing programs and projects to foster innovation (such as incubators or programs with a focus on digital therapy applications or artificial intelligence).

Key findings regarding the overarching ethical dimensions



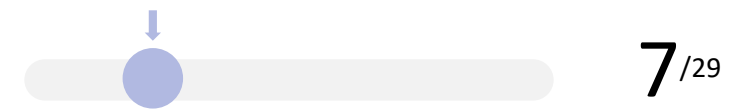
Base Digital Health on humanistic values



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

1.

Enable individuals to manage their Digital Health use and data

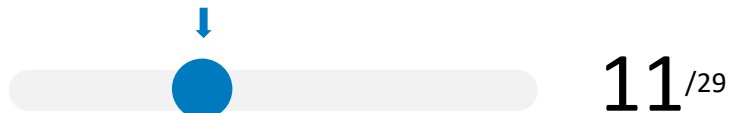


offer a unified data collection system for research and care consent as well as dedicated regulation on the topic

2.



Make Digital Health inclusive and accessible to all

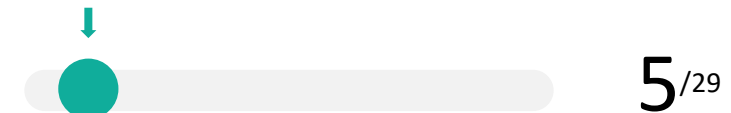


provide communication or specific supporting actions to bridge the digital divide

3.

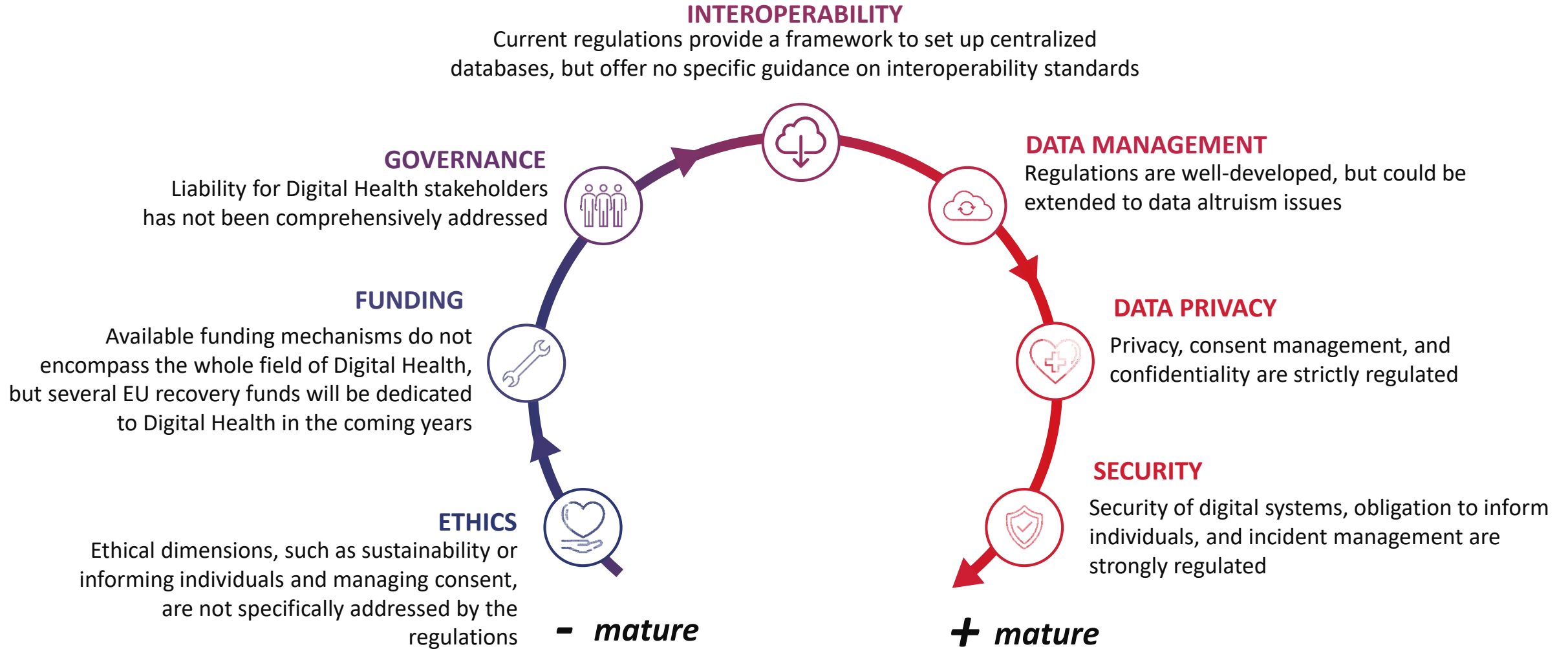
4.

Implement eco-responsible Digital Health



include sustainable development in their Digital Health strategy

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



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Study's scope



National representatives consultation

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



Austria



France



Luxembourg



Scotland



Belgium



Germany



Malta



Slovakia



Bulgaria



Greece



Netherlands



Slovenia



Croatia



Hungary



Norway



Spain



Cyprus



Ireland



Poland



Sweden



Denmark



Italy



Portugal



Estonia



Latvia



Czech Republic



Finland



Lithuania



Romania

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 the 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)

Consultation with 15 countries
 Base Digital Health on humanistic values



Countries have deployed Digital Health platforms to support data transfers, but they have not been fully designed to meet ethical guidelines

13/15

have implemented a centralized portal/system to make it easier to exchange and gather data and inform citizens about services

- AT
- DE
- LV
- PT
- BE
- EE
- LU
- SE
- ES
- SI
- DK
- FI
- NO



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

5/15

have implemented ethics committees specifically addressing challenges involving AI development

- AT
- PT
- SE
- FI
- NO

8/15

have implemented guidelines/frameworks regarding ethics in Digital Health

- PT
- LU
- SE
- CZ
- ES
- DK
- FI
- NO

7/15

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

- DE
- PT
- SE
- BE
- EE
- DK
- NO

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

- The health portal includes information and advice allowing individuals to better understand their health and data (e.g. explanation of blood test results)
- Individuals can electronically ask for prescription refills
- Secure messaging services are provided so that individuals and healthcare providers can maintain a dialogue 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

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



Countries are committed to involve users when defining Digital Health, but there is still room for improvement in order to include all individuals

14/15

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

- AT
- DE
- LV
- PT
- BE
- EE
- LU
- SE
- CZ
- ES
- NL
- SI
- DK
- NO

5/15

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

- AT
- EE
- LU
- ES
- NO



Although strong work has been observed regarding the implementation of national interoperability standards, there is room to improve individuals' ownership over their health data

14/15

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

- AT
- DE
- PT
- BE
- EE
- LU
- SE
- CZ
- ES
- NL
- SI
- DK
- FI
- NO

4/15

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

- PT
- ES
- NL
- NO

11/15

allow the downloading of health documents through their national platform

- AT
- DE
- LV
- PT
- EE
- LU
- SE
- ES
- NL
- DK
- FI

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 that:

- involves all health stakeholders
- assists in designing 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 common technical standards for 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



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

9 /15

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

-  AT
-  DE
-  BE
-  EE
-  CZ
-  ES
-  NL
-  FI
-  NO

10 /15

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


-  AT
-  DE
-  LV
-  PT
-  BE
-  EE
-  LU
-  SE
-  ES
-  DK


12 /15

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

-  AT
-  LV
-  PT
-  EE
-  LU
-  SE
-  CZ
-  ES
-  NL
-  SI
-  FI
-  NO

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



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

6 /15

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



5 /15

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



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



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 developing digital tools must use existing public components and e-services
- Principle of data minimization supporting the unified collection and storage of data



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 respect EU sustainability commitments



Possible ways forward

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

Taking inspiration and adapting the European draft declaration “Making the green transition more digital and the digital transition greener” 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

Executive summary



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

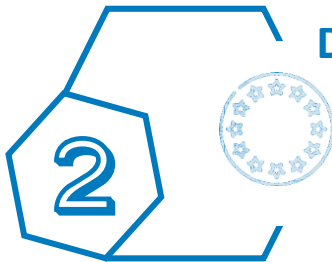
Digital Health sustainability is an emerging matter that EU countries are starting to tackle: Overall, work must be conducted to highlight best practices and strategies focused towards reducing Digital Health energy consumption.

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



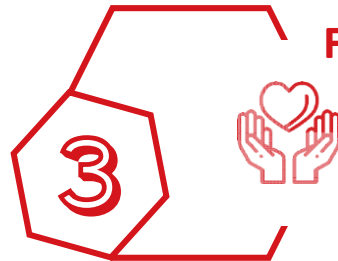
National roadmaps with a common challenge: Getting individuals more involved in digital health

- 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

The image shows three European Union flags flying on tall, silver poles against a clear, light blue sky. The flags are blue with twelve yellow stars arranged in a circle. The largest flag is in the foreground, and two smaller ones are behind it to the right. The text 'Appendix' is overlaid on the left side of the largest flag.

Appendix

European ethical principles for digital health



BASE DIGITAL HEALTH ON HUMANISTIC VALUES

1. Digital Health complements and optimizes face-to-face healthcare
2. Individuals are informed about the benefits and limits of Digital Health
3. Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them
4. When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias



ENABLE INDIVIDUALS TO MANAGE THEIR DIGITAL HEALTH AND DATA

5. Individuals are actively involved in shaping the European and national frameworks of Digital Health and data
6. Individuals can easily and reliably retrieve their health data in a commonly-used format
7. Individuals can easily get information on how their health data have been or may be accessed and for which purpose
8. Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable



MAKE DIGITAL HEALTH INCLUSIVE

9. Digital Health services are accessible by all, including by people with disabilities or low levels of literacy
10. Digital Health services are intuitive and easy to use
11. Individuals have access to Digital Health training
12. Digital Health services include support through human communication when needed



IMPLEMENT ECO-RESPONSIBLE DIGITAL HEALTH

13. Environmental impacts of Digital Health are identified and measured
14. Digital Health services are developed in compliance with eco-design best practices
15. Re-use and recycling of Digital Health equipment is ensured
16. Digital Health stakeholders are committed to reducing their ecological footprint