



**MINISTÈRE  
DE LA SANTÉ  
ET DE LA PRÉVENTION**

*Liberté  
Égalité  
Fraternité*

Délégation ministérielle  
au numérique en santé

# ***FRENCH DIGITAL HEALTH ROADMAP DIGITAL HEALTH EU PRIORITIES AND CONTRIBUTIONS***

***NOVEMBER 22, 2022***

***MINISTERIAL EHEALTH DELEGATION***

***FRENCH MINISTRY OF SOLIDARITY AND HEALTH***

# The French eHealth landscape at a glance



Ministerial eHealth  
Delegation, Ministry of  
Health



MINISTÈRE  
DES SOLIDARITÉS  
ET DE LA SANTÉ

*Liberté  
Égalité  
Fraternité*

National Digital Health  
Agency - ANS



AGENCE  
DU NUMÉRIQUE  
EN SANTÉ

Health Insurance  
CNAM



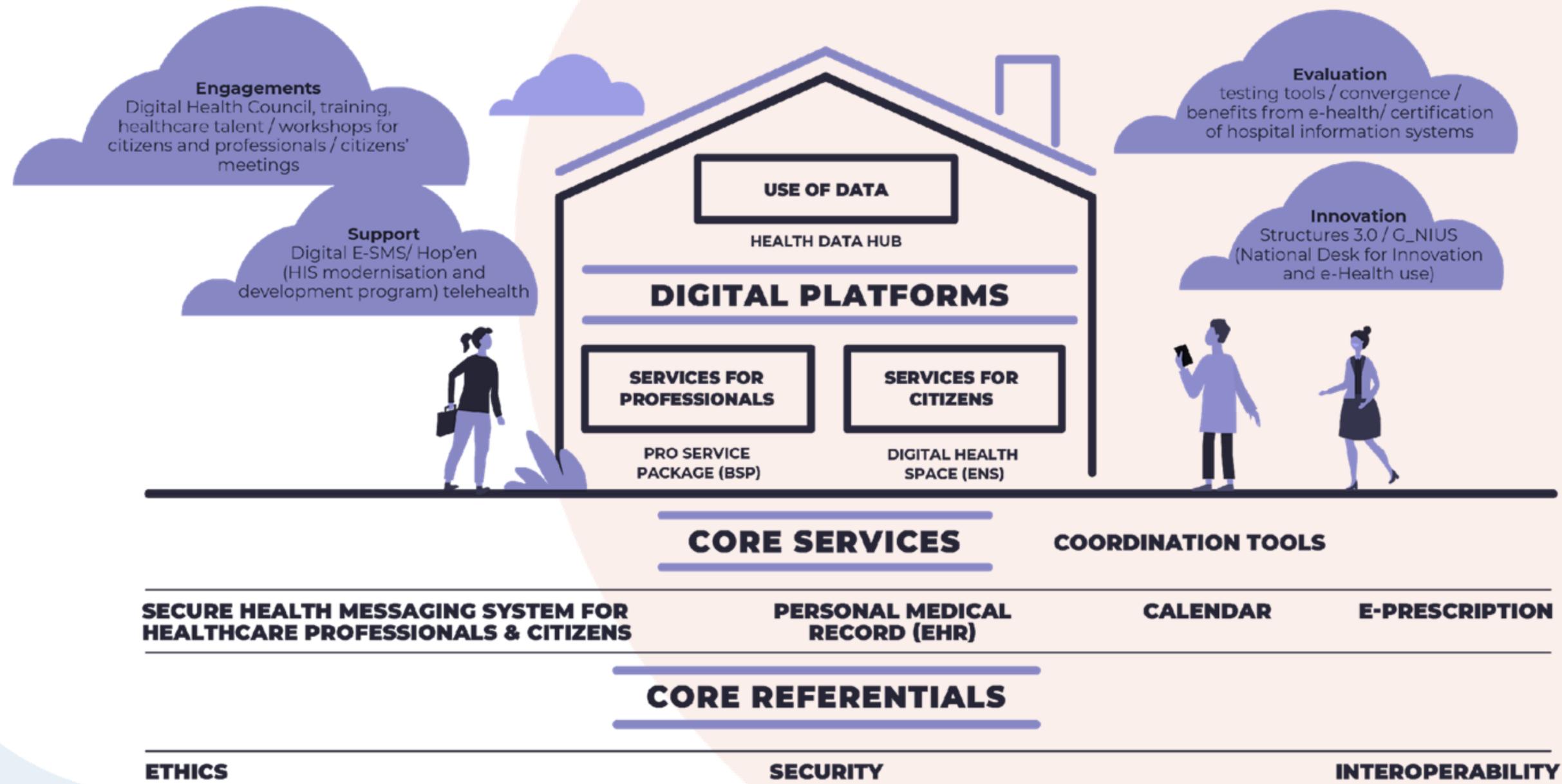
Health Data Hub



Regional/ local actors: ARS, GRADeS, hospitals, all actors of the digital health ecosystem...

# A comprehensive strategy to implement and transform the delivery of digital Health in France 2019 – 2022 (new one under revision)

## Health + medico-social + social dimensions



# Former French digital health roadmap: Five strategic focus areas for accelerating digital transformation

## 1st Orientation

- **STRENGTHENING THE GOVERNANCE OF DIGITAL HEALTH**

## 2nd Orientation

- **INCREASING THE SECURITY AND INTEROPERABILITY OF HEALTH INFORMATION SYSTEMS**

## 3rd Orientation

- **ACCELERATING THE DEPLOYMENT OF CORE DIGITAL SERVICES**

## 4th Orientation

- **DEPLOYING DIGITAL HEALTH PLATFORMS NATIONALLY**

## 5th Orientation

- **SUPPORTING INNOVATION AND PROMOTING STAKEHOLDER ENGAGEMENT**



# Strengthening Digital Health governance - major national Milestones



Implementation of the Digital Health roadmap



French Digital Health Roadmap acceleration

2019

2020

2021

2022

2023

#MaSanté2022  
#MyHealth2022  
ehealth roadmap  
Technical Doctrine



DOSSIER D'INFORMATION

Conférence ministère - Paris, le jeudi 25 avril 2019

Feuille de route  
« Accélérer le virage numérique »



Ministerial eHealth  
Delegation  
Ethics Council



Dominique Pon  
& Laura Létourneau

Ministerial Digital Health Delegation



MyHealthSpace



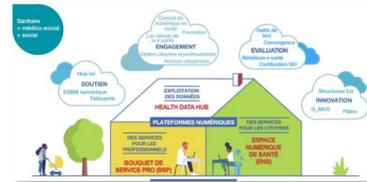
# Political will underpinned by funding - The Digital Health Acceleration Strategy aligned with other national digital health funding strategies

## NATIONAL DIGITAL HEALTH PROGRAMS

### Ministerial digital health roadmap

2018 – 2022

5 orientations, 25 actions  
Accelerate the digital shift



### Sécur de la santé – digital component

July 2020 – July 2025

€ 2 billion, including € 600 mio. medico-social sector  
Modernization, interoperability, security of health information systems, etc.



### PariSanté Campus

2020 – 2028

€ 400 mio.  
Birthplace of tomorrow's digital health



2018

2019

2020

2021

2022

2023

2024

2025

2026

2027

2028

### « Grand Défi » AI & Health

2019 - 2023

€ 30 mio. to improve medical diagnostics using artificial intelligence



### Medical Device Plan

2022 - 2026

€ 400 mio. to develop and produce innovative medical devices and digital and disruptive healthcare solutions



### Digital Health Acceleration Strategy

2021 – 2025

€ 718 mio. to make France a leader in digital health



# Digital Health Acceleration Strategy

A STRATEGY DESIGNED AND IMPLEMENTED IN COLLABORATION WITH REPRESENTATIVES OF THE ECOSYSTEM

## 2021

A large public consultation to build the strategy

50

Qualitative interviews

429

reponses

6

months of interministerial working groups

Une **préparation collective** aux appels à projets et à manifestation d'intérêt

12

webinars

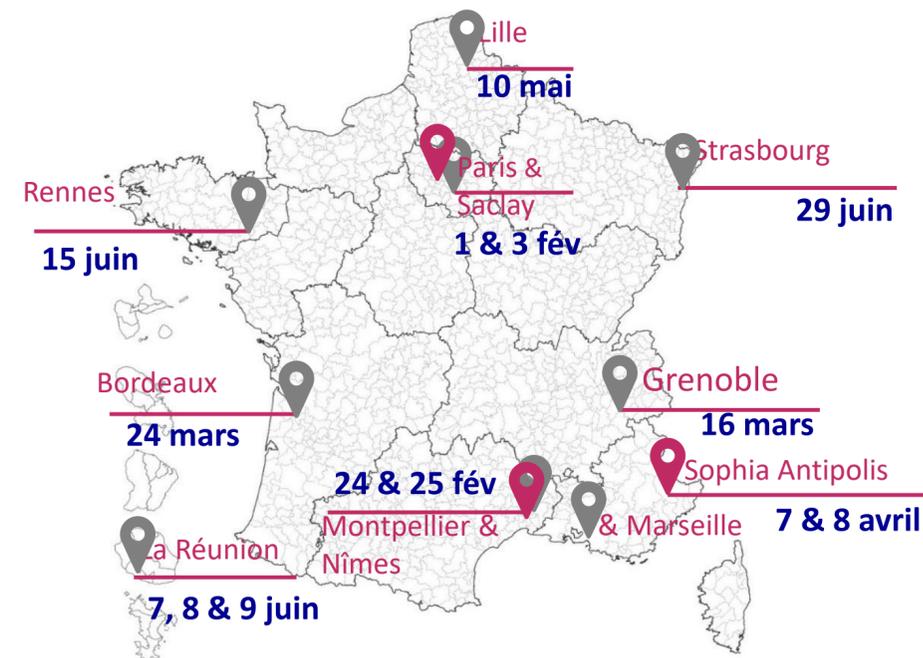
More than

120

meetings

## First semester of 2022

A « **Tour de France** » to meet the actors who are making digital health happen in the regions



9

stages

14

field visits

More than

600

meetings with actors of the ecosystem

27

roundtables and workshops

More than

1 700

participants

# Digital Health Acceleration Strategy

A STRATEGY ALREADY WELL UNDERWAY WITH ANNOUNCED AMBITIONS FOR 2025 AND BEYOND

## Today

Around **150 M €**  
committed at date

More than **60** projet  
laureates rewarded

**31 launched actions** including 9 calls for projets/ for  
expression of interest (AMI)

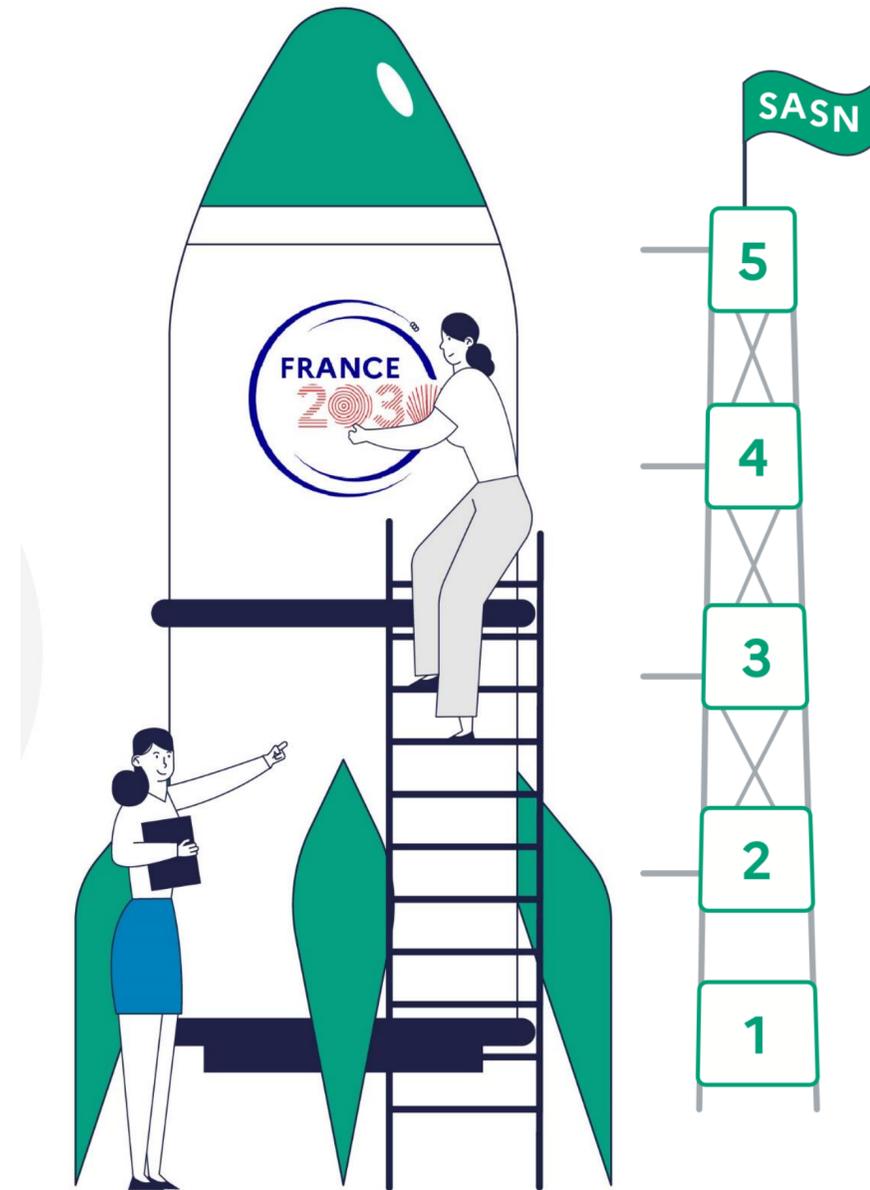
More than **500** candidates  
to all digital health calls

## Within the next 5 years

- **500 000 health apprentices and trainees** obtained digital health capacity building
- 30 structures selected as third-party experimentation sites, **100 experimented solutions**
- **2 new sustainable pathways to reimbursement** for digital solutions
- **70 clinical evaluations** of digital medical devices funded
- **1 national gateway** to facilitate the life of digital health entrepreneurs
- Achieve scientific breakthroughs and bring out **disruptive technologies**

# Digital Health Acceleration Strategy

A €718 MILLION STRATEGY LAUNCHED ON OCTOBER 18, 2021



Fostering the conditions for the **large-scale deployment** of successful projects

Accompany the implementation of **real-life experimentations** and **first industrial stages**

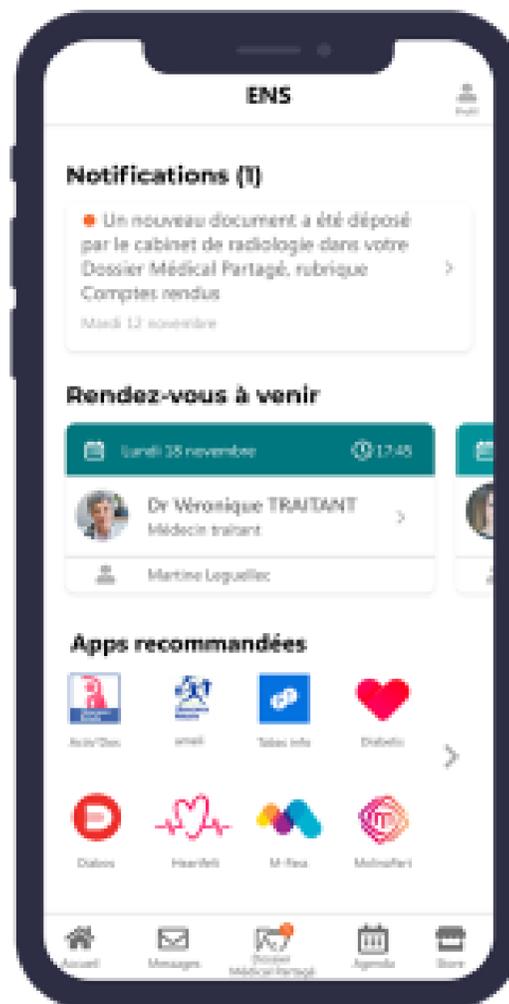
Support the **development** of structural projects to strengthen strategic advantages

Prepare the future generation of key digital health technologies and facilitate **rapid transfer mechanisms of research results**

Develop **stakeholder training**, stakeholder trust and professional attractiveness of the sector

Call for expression of interest for digital health (AMI)

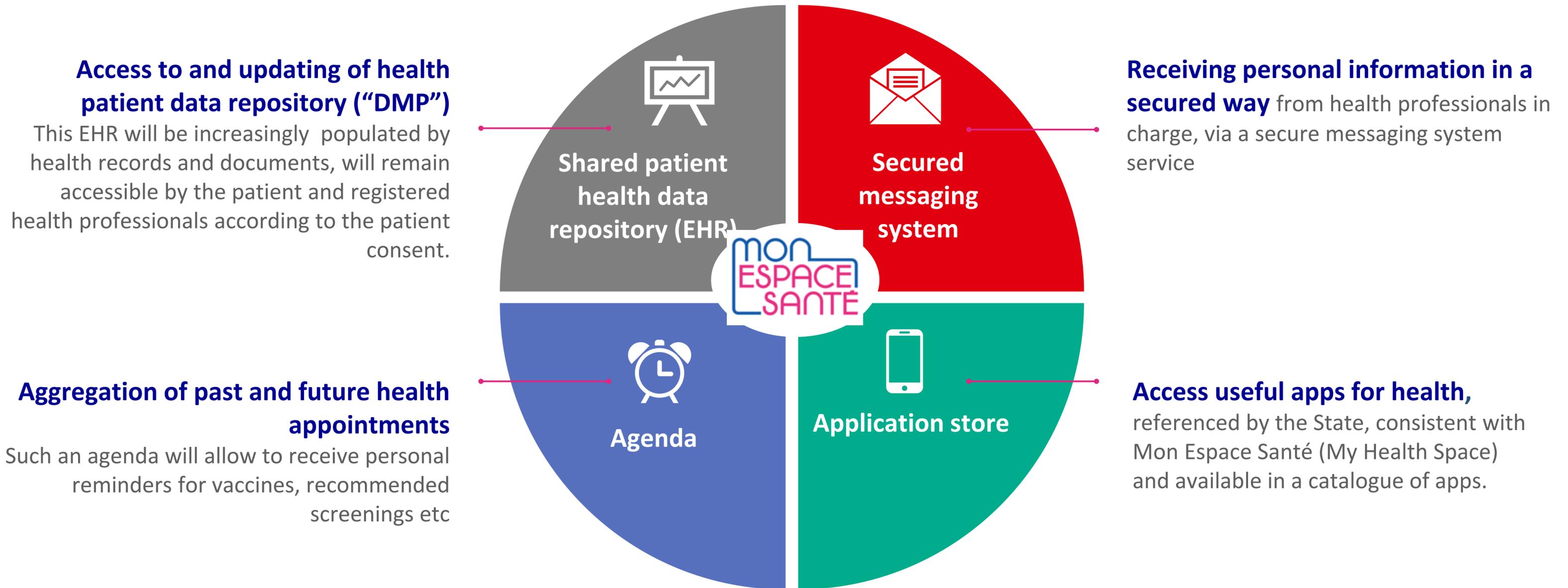
# MonEspaceSanté to foster patient access to health data



mon  
ESPACE  
SANTÉ



# MonEspaceSanté to foster patient access to health data



## STRATEGY FOR DIGITAL HEALTH

Move towards the construction of a single market, prepare the European Health Data Space

Establish the ethical prerequisites necessary for European citizens to trust digital health

Develop uses by moving towards the construction of a European single market

Towards a progressive harmonisation of technical standards

Towards a progressive harmonisation of market access

APPARTENANCE  
EUROPEAN  
BELONGING

PUISSANCE  
STRENGTH

Inscrire le numérique en santé dans un cadre de valeurs humanistes Base Digital Health on humanistic values
1. Le numérique en santé complète et optimise les pratiques de santé effectuées en présentiel <i>Digital Health complements and optimizes face-to-face healthcare</i>
2. Les personnes sont informées des bénéfices et des limites du numérique en santé <i>Individuals are informed about the benefits and limits of Digital Health</i>
3. Les personnes sont informées des modalités de fonctionnement des services numériques en santé et peuvent facilement paramétrer leurs interactions avec ces outils <i>Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them</i>
4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire <i>When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias</i>
Donner la main aux personnes sur le numérique et sur leurs données de santé Enable individuals to manage their Digital Health and data
5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé <i>Individuals are actively involved in shaping the European and national frameworks of Digital Health and data</i>
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé <i>Individuals can easily and reliably retrieve their health data in a commonly used format</i>
7. Les personnes peuvent facilement obtenir des informations sur la manière dont leurs données de santé ont été ou peuvent être consultées et dans quel but <i>Individuals can easily get information on how their health data have been or may be accessed and for which purpose</i>
8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable <i>Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable</i>
Développer un numérique en santé inclusif Make Digital Health inclusive
9. Les services numériques en santé sont accessibles à tous, y compris aux personnes en situation de handicap ou avec un faible niveau de littératie <i>Digital Health services are accessible by all, including by people with disabilities or low levels of literacy</i>
10. Les services du numérique en santé sont intuitifs et faciles à utiliser <i>Digital Health services are intuitive and easy to use</i>
11. Les personnes ont accès à des formations sur le numérique en santé <i>Individuals have access to Digital Health training</i>
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire <i>Digital Health services include support through human communication when needed</i>
Mettre en œuvre un numérique en santé éco-responsable Implement eco-responsible Digital Health
13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés <i>Environmental impacts of Digital Health are identified and measured</i>
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception <i>Digital Health services are developed in compliance with eco-design best practices</i>
15. La réutilisation et le recyclage des équipements informatiques en santé sont prévus <i>Re-use and recycling of Digital Health equipment is ensured</i>
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique <i>Digital Health stakeholders are committed to reducing their ecological footprint</i>



RELANCE  
RELAUNCH

PUISSANCE  
STRENGTH



RELANCE  
RELAUNCH

PUISSANCE  
STRENGTH



# #PFUE2022: An opportunity for digital health

A European way  
of using Digital  
health

## *Mission*

To implement ethics by design Digital Health globally and report transparently to the citizen

## *Vision*

To ensure progress in digital health follows humanistic values assets and tradition, and make it an enabler of success.

**STRATEGY FOR DIGITAL HEALTH in EUROPE**  
A single market approach empowered by the European Health Data Space

European ethical principles for digital health

Develop European use cases

Technical standards

Market access



# #PFUE2022: The official program included 25 PFUE supported events representing the entire digital health ecosystem

AN UNPRECEDENTED MOBILIZATION FOR DIGITAL HEALTH IN EUROPE

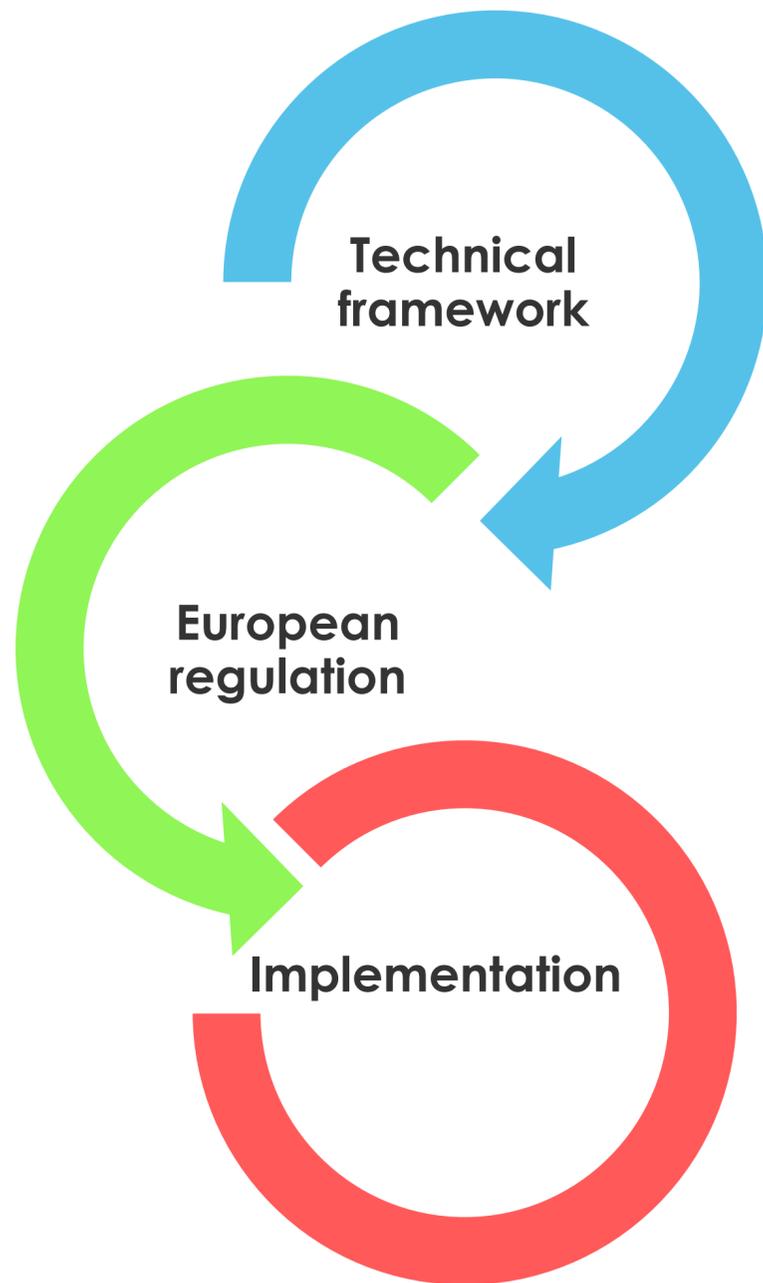


UNDER CONFIRMATION



# Lessons learned from the Covid pandemic

## A 12-week historical journey for Digital Health in Europe



- Decision from the Council of the European Union
- 27 countries
- A voluntary Digital Health experts Network, the eHealth Network
- Based on ethics
- Pragmatic



# Lessons learned from the Covid pandemic



# What is the promise of Europe to European citizens in terms of digital health ?

## Towards a European Health Data Space (EHDS)

- 27 countries, 27 health systems
- A European regulation – the Cross-border healthcare directive
- Services expected from citizens and health professionals

Access and provide access to their health data in digital format

Share interoperable health data

Ensure tools and infrastructure are in place

- **Empowered by Digital Health**



# What is the promise of Europe to European citizens in terms of digital health ?

## Towards a European Health Data Space (EHDS)



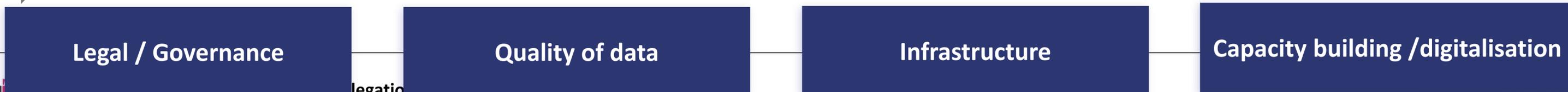
### OBJECTIVES

Timely and simplified exchange of and access to health data within the EU

### SCOPE & EXPECTED IMPACT



### MEANS



# What is the promise of Europe to European citizens in terms of digital health ?

European Health Data Space is already partly live with the creation of a European trusted zone and use-cases: MyHealth@EU

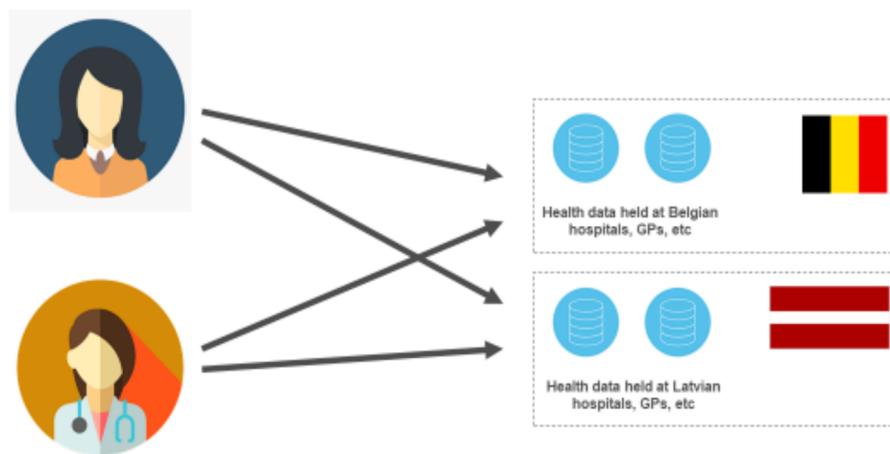
## Use cases integration



**MyHealth@EU : national contact points allow for a secured access to health data**

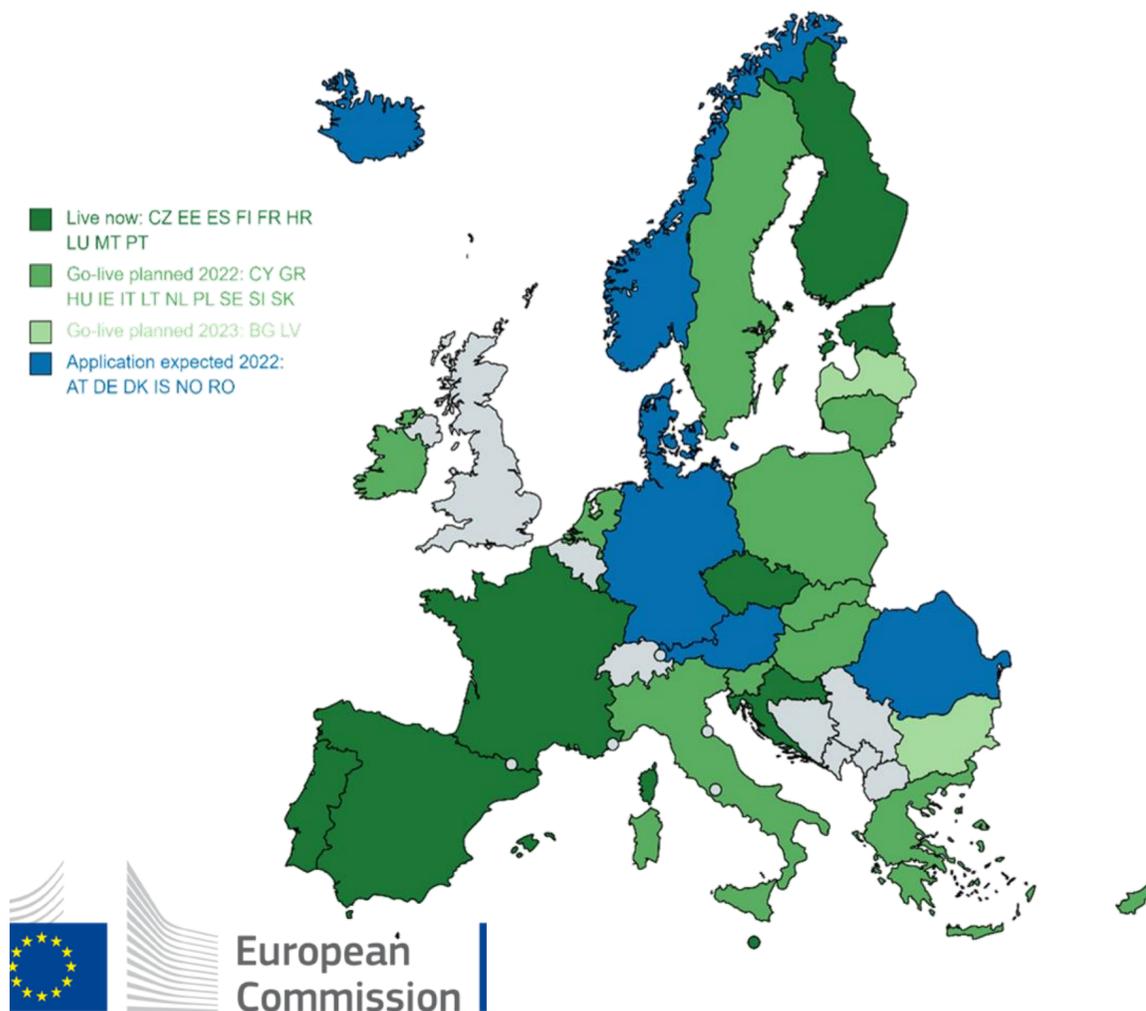
Patient summaries and ePrescriptions: 10 EU Member States live

> 2022: images, imaging report, laboratory results, discharge reports; rare diseases, original clinical documents, and access of patients to their health data in Europe



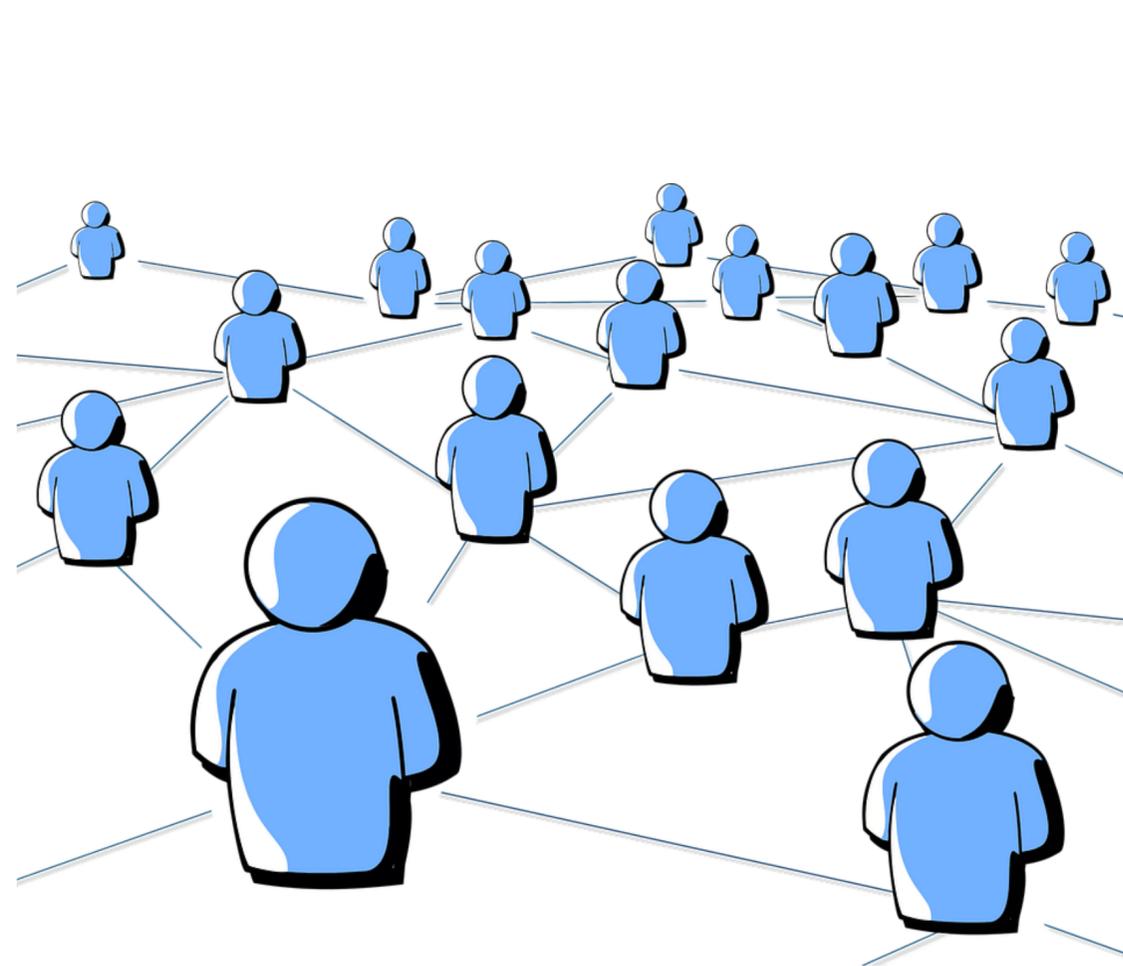
Granting citizens and healthcare professionals access to health data across borders in an interoperable, digital format

## Country-level integration



# Lessons learned from the Covid pandemic

The European Health Data Space soon a reality also for the secondary use of data



Single access authorization



Catalog of data



Business model



3 pillars  
for the citizen

1. Ethics



2. Interoperability



3. Security



# European ethical principles for digital health

Digital health must be used to protect the health and well-being of all humanity and the biosphere

**Digital health does improve the whole life cycle of health issues**

*It allows for better care and individuals' empowerment through better control of their health data*

**Digital health also comes with questions and concerns**

*Who accessed my health data, and why? Is it possible to see my doctor despite the deployment of teleconsultation? Can I trust AI?*

**Building trust is key**

**Ethics are at the core of the French digital health roadmap**

Building on the French experience of digital health ethics and with the strong support of DG Santé and Member states teams, **European ethical principles** for digital health were adopted by the **eHealth network in a record time**

# European ethical principles for digital health

EUROPEAN ETHICAL PRINCIPLES FOR DIGITAL HEALTH WERE UNVEILED ON FEBRUARY 2, 2022, DURING THE MINISTERIAL CONFERENCE “CITIZENSHIP, ETHICS AND HEALTH DATA”

## Inscrire le numérique en santé dans un cadre de valeurs humanistes

### Base Digital Health on humanistic values

1. Le numérique en santé complète et optimise les pratiques de santé effectuées en présentiel  
*Digital Health complements and optimizes face-to-face healthcare*
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4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire  
*When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias*

## Donner la main aux personnes sur le numérique et sur leurs données de santé

### Enable Individuals to manage their Digital Health and data

5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé  
*Individuals are actively involved in shaping the European and national frameworks of Digital Health and data*
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé  
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8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable  
*Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable*



# European ethical principles for digital health

## Développer un numérique en santé inclusif *Make Digital Health Inclusive*

9. Les services numériques en santé sont accessibles à tous, y compris aux personnes en situation de handicap ou avec un faible niveau de littéracie  
*Digital Health services are accessible by all, including by people with disabilities or low levels of literacy*
10. Les services du numérique en santé sont intuitifs et faciles à utiliser  
*Digital Health services are intuitive and easy to use*
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*Individuals have access to Digital Health training*
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire  
*Digital Health services include support through human communication when needed*

## Mettre en œuvre un numérique en santé éco-responsable *Implement eco-responsible Digital Health*

13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés  
*Environmental impacts of Digital Health are identified and measured*
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception  
*Digital Health services are developed in compliance with eco-design best practices*
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*Re-use and recycling of Digital Health equipment is ensured*
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique  
*Digital Health stakeholders are committed to reducing their ecological footprint*



# European ethical principles for digital health

The Commission integrated most principles in the proposal for a regulation for a European health data space, a strong sign of engagement in the implementation process

Member States underlined the importance of the adoption of European ethical principles to prepare the EHDS, EPSCO, June 14

## Actions already implemented

- Adoption of a supportive document to clarify the principles, promote their appropriation and establish compliance in an unequivocal manner

- Adoption of a self evaluation grid to help Member States assess the ethics maturity of Digital health in their country



### 1. Dimension 1 - Base Digital Health on humanistic values

Dimension 1 extends the fundamental principles of healthcare to digital health, namely the fact that each person's will needs to be taken into consideration and that each person needs to be kept informed. This dimension is about respecting the right for individuals to have their digital health managed based on humanistic values such as choosing options corresponding to their preferences, values or life projects.

#### 1) Digital Health complements and optimizes face-to-face healthcare

Detailed explanation and underlying philosophical concepts

Digital health services are a complement to, and not a replacement for, analogue health services. The use of digital health services should not be compulsory for patients if "face-to-face" exist (e.g., for certain digital health new services such as telemonitoring, there is no in-person equivalent). Digital health services ought to be an alternative. Using digital health services can optimize face-to-face healthcare.

For example, individuals should have access both to face-to-face consultation and teleconsultation and they should be given the opportunity to choose to use one or the other. Face-to-face consultation should never be imposed.

For this principle, digital health mainly consists of telehealth and teleconsultation. In order for teleconsultation to be ethical, the choice between teleconsultation or face-to-face consultation should always be offered to patients, with no counterpart or negative impact on the patient care (no additional delay to get the appointment, with the same health professional, and at no extra cost for the patient).

The concepts of autonomy and freedom are the basis of this principle.

« Machines that work take the place of man and lead to the end of humanity. Is it the same today with digital and AI? Are we facing the end of the physician? This is one of the questions we must answer. »<sup>1</sup>

Jean Gabriel Ganascia  
Professor at Sorbonne University, former President of the ethics committee of the French National Centre for Scientific Research (CNRS), France

Member states use cases

In Norway, citizens can choose between teleconsultations and face-to-face consultations, if the general practitioner office provides such a service. Not all general practitioners offer

teleconsultations, but the pandemic helped speed up the process of giving citizens access to teleconsultations. The price of the consultation is the same. You can only choose the option of teleconsultation if physical consultation is not required. Typically physical consultation is required for the first visit, and teleconsultation for follow-up consultations. It is also possible to book and perform teleconsultations through the national health portal Helsenorge.no.

Spain is a decentralized state for healthcare competences, the deployment depends on the Regional Healthcare services. In the Community of Madrid, for example, there is already a project to implement it. Today, there are telematics appointments wherein health professionals perform consultations with citizens via telephone. This approach began to be used with the pandemic and is being maintained. Likewise, in Madrid's Health Service, there is an application called "Mi carpeta de salud" where patients can contact their medical centre for online consultations. In those two examples, the use of teleconsultation is a choice of the patient.

In Finland, provisions on electronic transactions are (i.e. tele-consultation), as a general rule, per-missible and not mandatory, and various alternatives must be offered to a customer. Authorities must provide the opportunity for electronic transactions, but an individual cannot be forced to use exclusively electronic channels. Regarding administrative matters, they involve special requirements for the implementation of the electronic transaction service, such as the customer's right to appeal against an administrative matter.

In Italy, The National Health Service includes the provision of healthcare services in telemedicine. The national guidelines for the provision of telemedicine services adopted in December 2020 establish that tele visit should be limited to follow-up visits for patients who have already been diagnosed in the face-to-face visit.  
<https://www.salute.gov/pt/portale/e-health/dettaglioContenuti/EHealth.jsp?lingua=italiano&id=5525&area=Health&menu=telemedicina>  
<https://www.salute.gov/pt/portale/e-Health/dettaglioContenuti/EHealth.jsp?lingua=italiano&id=5525&area=Health&menu=telemedicina>

In France, the national health insurance regulates the use of teleconsultation. Health professional using teleconsultation must be located near the patient's home.  
• This location aims to make it possible to ensure regular monitoring of the patient's health and to organize a face-to-face consultation if needed.  
• Teleconsultation and face-to-face consultations should also be carried out alternately in order to ensure best quality and safety of care.  
<https://www.ameli.fr/assure/remboursements/rembourse/telemedecine/teleconsultation>

In Germany, citizens are entitled to use digital health applications. This is not mandatory, so they can choose between teleconsultations and face-to-face consultations. Both options are possible.

### SELF ASSESSMENT GRID

### Statements

#### Base Digital Health on humanistic values

#### 1 Digital Health complements and optimizes face-to-face healthcare

Telehealth services are available as part of a national or local strategy.

When new telehealth services are implemented instead of face to face alternatives, the face to face alternative remains possible.

When medically relevant, the choice between the digital health service and its face-to-face alternative is always up to the patient.

The national or local telehealth strategy provides for the same service and quality of care whether the patient chooses the face to face solution its telehealth alternative.

There are national or local good practices for ethical telehealth implementation.

# Towards a progressive harmonisation of market access



*Accelerate European market access through clinical evaluation criteria harmonisation for Digital Medical Devices (DMDs)*



*Initial steps*



*More to come*

*Connecting Digital Health innovation hubs via G\_NIUS  
Support European digital health entrepreneurs to navigate through the digital health ecosystem and accelerate market access in the EU*

Support the European digital health entrepreneurs to navigate through the digital health ecosystem and accelerate market access in the EU

G\_NIUS is a French initiative, part of the 2021-2025 Digital Health Acceleration Strategy (670 B€) willing to connect to European colleagues. A single gateway to support digital health entrepreneurs navigating through the ecosystem, save time and accelerate access to the market of their solutions

### G\_NIUS services



**Decrypt national digital health regulation**



**Follow your healthcare pathway**  
(MonEspaceSanté, Ségur numérique, National Health Identity (INS)...)



**Identify e-health events**



**Identify actors of the digital health ecosystem**



**Decipher funding keys and trends**



**Discover eHealth news**



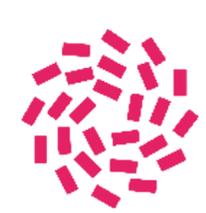
**A podcast**  
100 days to succeed



**Commercialize a digital medical device**



**New:** map of EU-level markets and hubs



# G\_NIUS Key figures

# G\_NIUS



## + 235 000

page views since its opening

## + 90 000

visitors since its opening

## 51%

of repeat visitors

## 2 800

community members



## 9

 institutional partners...

## The 6

 health competitiveness clusters, accompanied by clusters and living labs

## International Service: Decoding digital health abroad

### One «home page »

#### Decoding e-health abroad

If you want to develop internationally, take a look at our country fact sheets



#### Germany

Access to the country sheet

#### Pioneering reimbursement of digital innovation and health applications

- The German healthcare system is financed through a system of compulsory public and private insurance. The health insurance funds are the key players, although they operate within a legal framework set by the federal state and implemented by the 16 regions (Länder).
- It is the first country to have implemented a "fast track" for reimbursement of mobile applications (DIGA)

#### Belgium

Access to the country sheet

#### Several initiatives to drive the digital transformation of healthcare

- At the European level, the country is very actively involved in major health information projects
- Healthdata.be is the platform to facilitate and standardise the registration of health data



### Country fact sheets

Helping entrepreneurs discover international e-health ecosystems and understand all steps to access the market there

#### eHealth in Germany

##### Key figures

83M  
people

2nd  
a global player in MedTech

13.1%  
health expenditure as a share of GDP in 2020

Decision-making powers are divided between the 16 Länder, the federal government, and the statutory professional organizations

The federal government proposes draft laws, regulations and administrative provisions and the Länder are responsible for implementing them. The health system is financed by a compulsory insurance system, 87.7% public and 10.5% private, organised around public health insurance funds. Physicians bill health insurance companies directly, not patients.

Germany has the second-largest industry in terms of medical technology after the United States.



Scan to access the service!

