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ET DE LA SANTÉ

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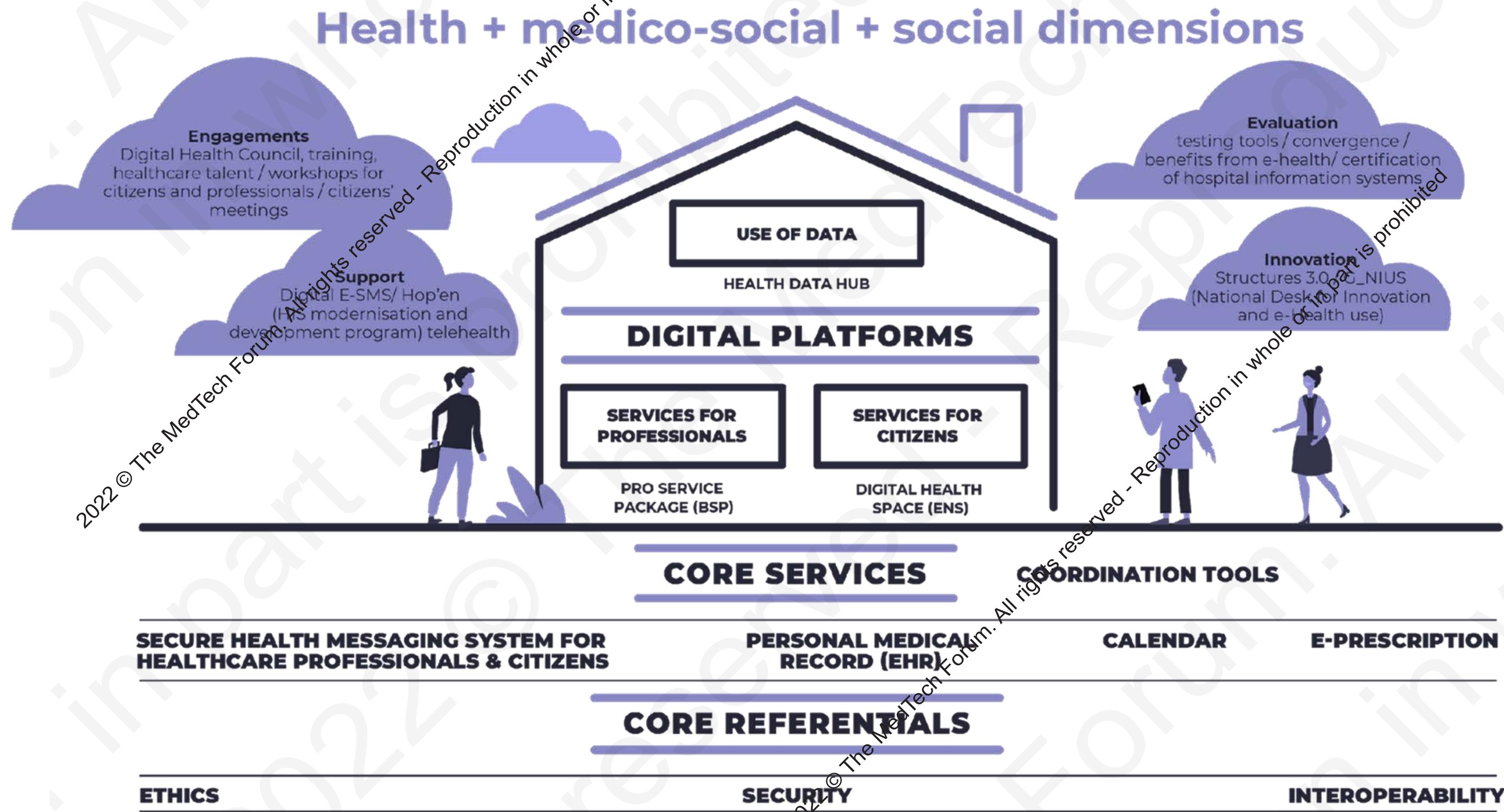
EUROPEAN ALIGNMENT OF DIGITAL HEALTH ASSESSMENT

MAY 5, 2022
MEDTECH FORUM

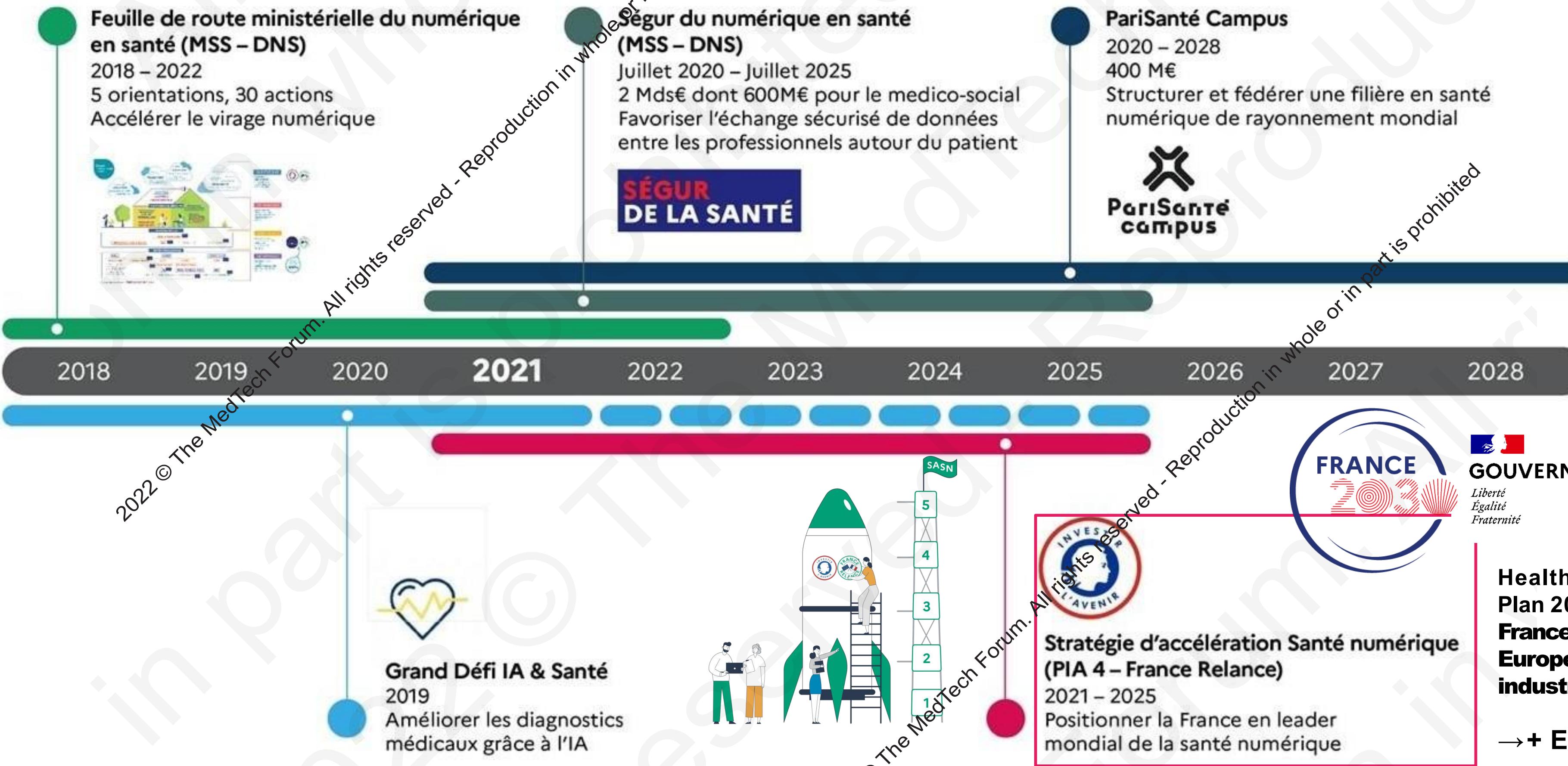
LOUISA STÜWE
MINISTERIAL EHEALTH DELEGATION
FRENCH MINISTRY OF SOLIDARITY AND HEALTH

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French digital health implementation roadmap



The Digital Health Acceleration aligned with other national digital health funding strategies



A EUR 650 MILLION STRATEGY LAUNCHED ON 18 OCTOBER 2021



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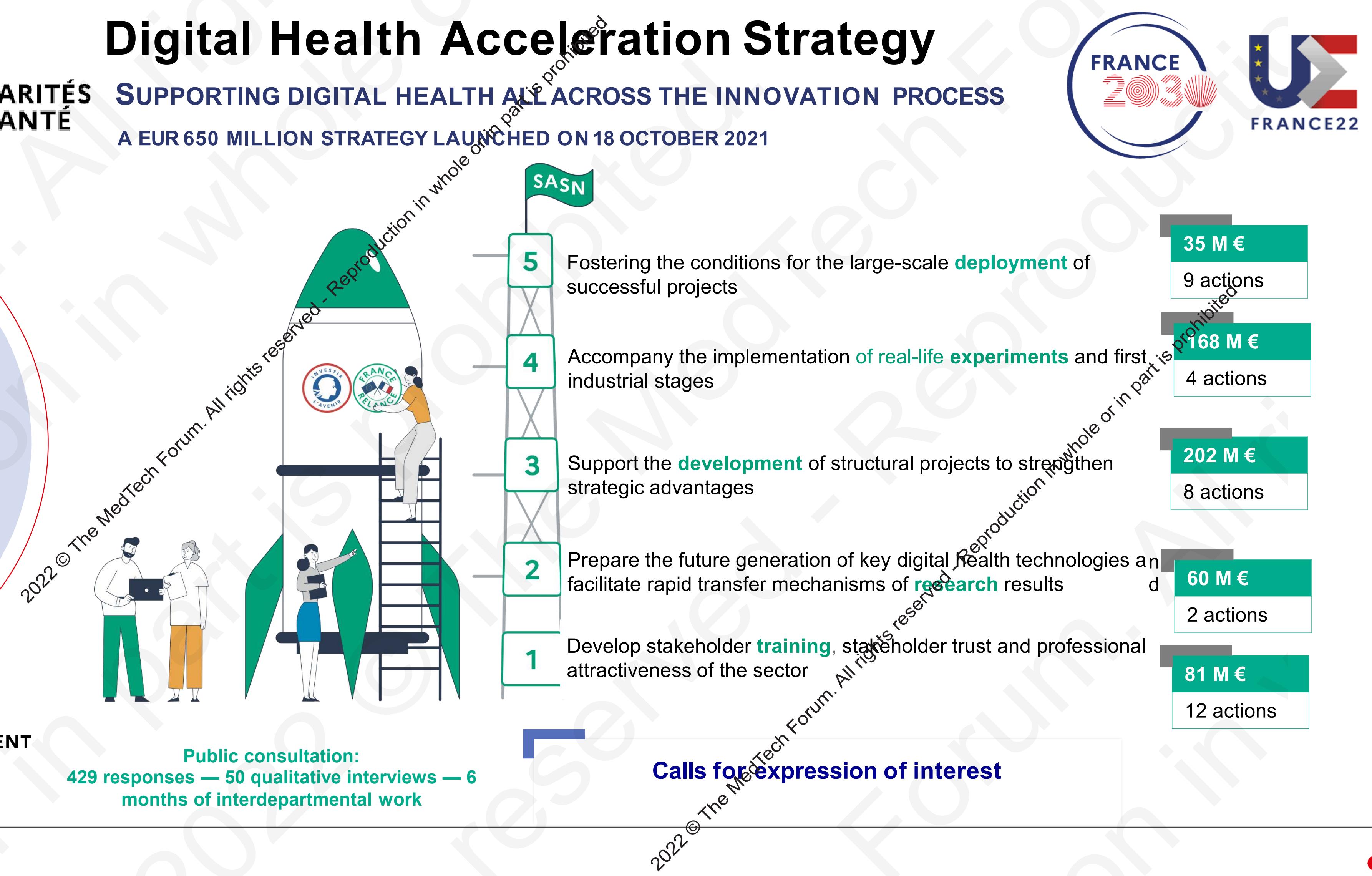
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Digital Health Acceleration Strategy

SUPPORTING DIGITAL HEALTH ALL ACROSS THE INNOVATION PROCESS

A EUR 650 MILLION STRATEGY LAUNCHED ON 18 OCTOBER 2021



G_NIUS

SINGLE GATEWAY TO SUPPORT DIGITAL HEALTH ENTREPRENEURS SAVE TIME AND ACCELERATE MARKETING AUTHORISATIONS OF THEIR SOLUTIONS

G_NIUS services

Entrepreneurs are oriented towards the right contact person and gain access to the relevant information in order to follow the smoothest development of their product.



Decrypt regulation



Follow your healthcare pathway **Mon espace santé, Sécur numérique, National Health Identity (INS)**



Identify actors of the digital health ecosystem



Decipher funding keys and trends



A podcast 100 days to succeed



Commercialize a digital medical device



Identify e-health events



Discover eHealth news



in numbers

2,400

community members

9

institutional partners



12

competitiveness and partner clusters



THE FRENCH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION

#PFUE22 TO BUILD THE EUROPEAN AMBITION ON SHARED VALUES



- **« A strong Europe in the world
fully sovereign »**
 - **« A stronger, more sovereign,
more united Europe »**
 - **Making Europe a digital leader**
 - **Europeanise all strategies to
support the "innovation and
growth of start-ups"**
 - **A « Europe of public health »**

01

RELAUNCH

and economic strengthening to enable Europe to accompany the ecological and digital transitions

02

STRENGTH

To defend and promote our values and interests

03

SENSE OF EUROPEAN BELONGING

To build and develop a common European imagination: through culture, our shared values, our common history

#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: AN OPPORTUNITY FOR DIGITAL HEALTH



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

PRINCIPES EUROPÉENS POUR L'ÉTHIQUE DU NUMÉRIQUE EN SANTÉ EUROPEAN ETHICAL PRINCIPLES FOR DIGITAL HEALTH

Inscrire le numérique en santé dans un cadre de valeurs humanistes <i>Base Digital Health on humanistic values</i>
1. Le numérique en santé complète et optimise les pratiques de santé en 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 explicative et sans biais discriminatoires <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 <i>Enable individuals to manage their Digital Health and data</i>
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 <i>Make Digital Health inclusive</i>
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 <i>Implement eco-responsible Digital Health</i>
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>

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EU BELONGING

STRENGTH



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

Towards a progressive harmonisation of technical standards

RELAUNCH

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EU companies



Leading healthcare terminology, worldwide

Strengthen the governance

ACCELERATE
market access



RELAUNCH

STRENGTH

- 27 countries, 27 health systems
 - A new harmonised regulation on Health Technology Assessment (HTA), a deliverable of the EU Pharmaceutical Strategy, has been adopted late 2021.
 - Objectives:
 - Efficient use of resources
 - Strengthen the quality of HTA in the EU
 - Avoid duplication of efforts by HTA organisations and private companies at national level
 - Early 2021 : Germany paved the way for the assessment and reimbursement of Digital Health Applications with the introduction of DiGA in the national register of "applications for prescription"
 - Other European countries, including France, are following these developments. In France, an adapted transposition of the this model has been enacted with the Social Security Funding Law of 2022.



How to harmonise clinical evaluation criteria & methodologies in Europe for the evaluation of the digital medical devices (DMD)?

EUROPEAN TASKFORCE: HARMONISATION OF CLINICAL CRITERIA AND METHODOLOGY FOR EVALUATING DIGITAL MEDICAL DEVICES

The Taskforce is composed of leading institutional, HTA and clinical researchers:

- EUnetHTA
- BfArM in Germany
- HTA body HAS in France
- Innovative methodology experts
- Major scientific experts and European scientific communities (Digital Medicine Society (DiMe), Biomedical Alliance)
- Patient associations
- European Observatory on Health Systems and Policies
- Representatives from TEHDaS/E EHDS

Objectives

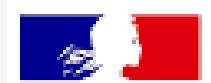
1. Combine and lead efforts to facilitate the access to the European market for digital medical devices at Member States level.
2. Reach consensus how to harmonise clinical trial criteria for the evaluation of DMDs in the EU
3. Drive other European countries to join the discussion



France, Germany and Luxembourg have already started implementing a methodology to assess digital medical devices. Belgium, Austria, Ireland and Spain have expressed strong interest.

The project is coordinated by EIT health, chaired by France and cochaired by EUNeHTA:

- To drive the reflection
- Guarantee the neutrality of the exchanges
- Disseminate at European scale
- Provide network



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BUILDING THE PAN-EUROPEAN CONSENSUS



- Testimonies, use case and pilots from large and middle-sized companies and start-ups
- Review of the conclusions of the Taskforce



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Délégation ministérielle
au numérique en santé
DNS

DMD TASKFORCE COMMUNICATION PLAN



EUnetHTA, HASevent in
Paris
7 & 8 March



EIT Health Summit
Stockholm
24 & 25 May



The State of Digital
Therapeutics 2022
Brussels
S1 of June



HIMSS22
PFUE
Helsinki
16 June



HTA2022
Netherlands
Utrecht
25-29 June



Digital Medicine
Conference
Luxembourg
26 & 27 October

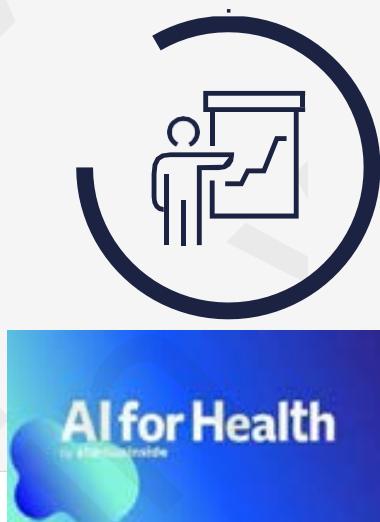
Digital Health Scaleup 2025
BPI, French Healthcare
Ministry of Foreign Affairs
07 April



Commission e-santé
France Biotech
PariSanté Campus
15 April



Start-up Day
Paris Cité des Sciences
10 May



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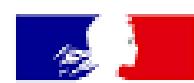
THANK YOU AND LOOKING FORWARD TO YOUR INPUTS AND COLLABORATIVE WORK FOR THE EU



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FRANCE 22
PRÉSIDENCE FRANÇAISE
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FRENCH EU PRESIDENCY DOSSIER DE PRESSE

DIGITAL HEALTH ACCELERATION STRATEGY DOSSIER DE PRESSE

G_NIUS WEBSITE : [HTTPS://GNIUS.ESANTE.GOUV.FR/](https://gnius.esante.gouv.fr/)

NATIONAL DIGITAL HEALTH AGENCY FRENCH EU PRESIDENCY

WEBSITE WITH ALL ECOSYSTEM EVENTS:

French Presidency of the Council of the European Union | Europe International (esante.gouv.fr)

FRENCH EU PRESIDENCY OFFICIAL EVENT PAGE:

<https://presidence-francaise.consilium.europa.eu/fr/evenements/conference-ministerielle-citoyennete-ethique-et-donnees-de-sante/>