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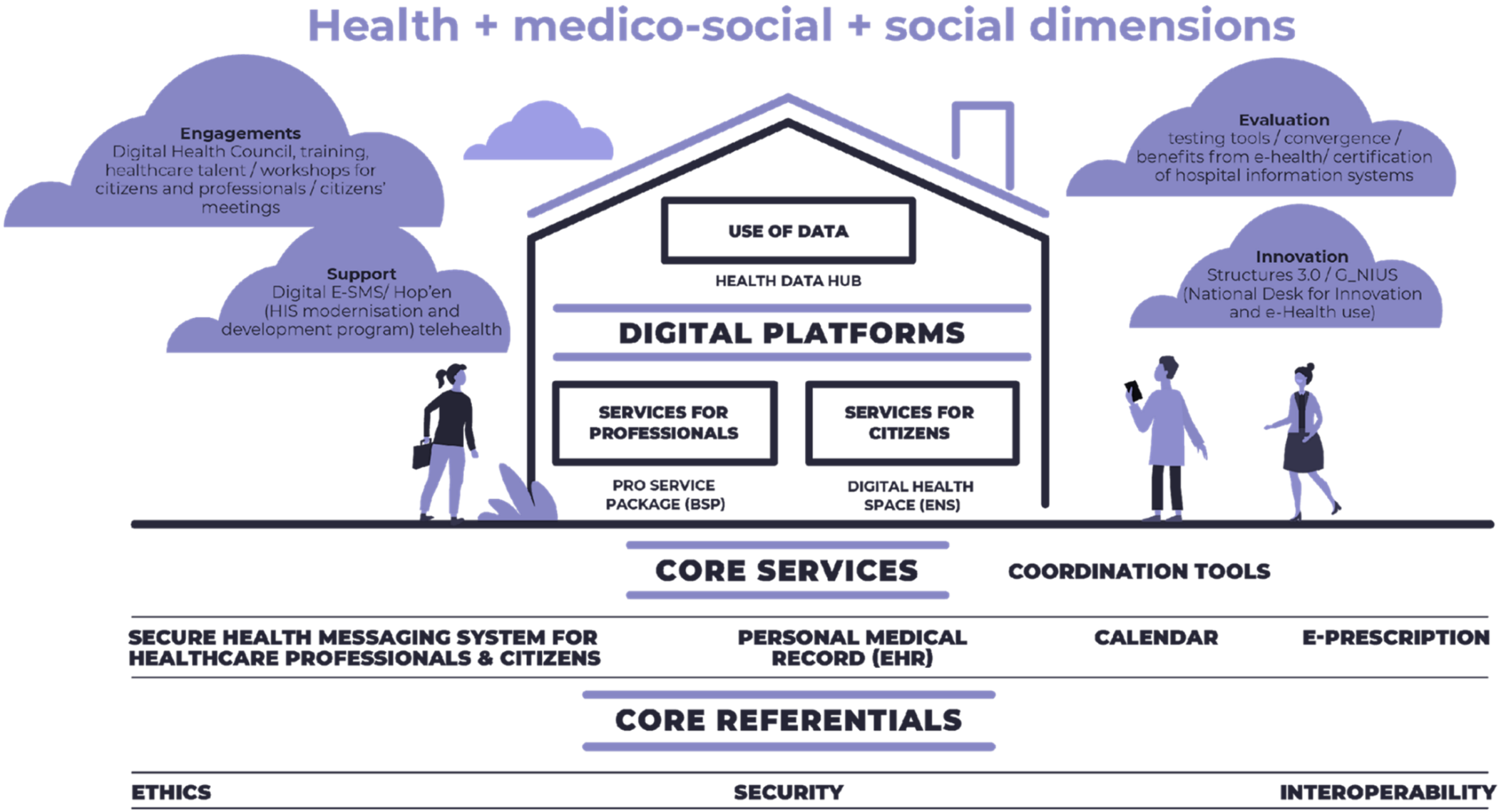
Presentation of the Digital Health Acceleration Strategy / Expected Fast Track for Digital Medical Devices

October 19, 2022

Louisa Stüwe
Ministerial Digital Health Delegation

L

French digital health implementation roadmap



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

Feuille de route ministérielle du numérique en santé (MSS – DNS)
2018 – 2022
5 orientations, 30 actions
Accélérer le virage numérique

Ségur du numérique en santé (MSS – DNS)
Juillet 2020 – Juillet 2025
2 Mds€ dont 600M€ pour le medico-social
Favoriser l'échange sécurisé de données entre les professionnels autour du patient

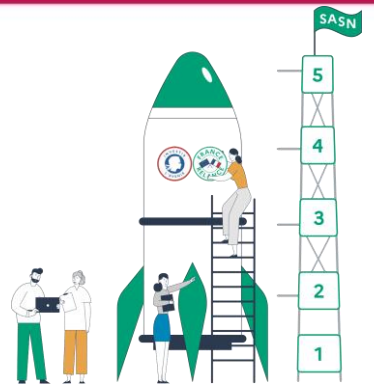
SÉGUR DE LA SANTÉ

PariSanté Campus
2020 – 2028
400 M€
Structurer et fédérer une filière en santé numérique de rayonnement mondial

PariSanté campus

2018 2019 2020 **2021** 2022 2023 2024 2025 2026 2027 2028

Grand Défi IA & Santé
2019
Améliorer les diagnostics médicaux grâce à l'IA



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INVESTIR L'AVENIR

Stratégie d'accélération Santé numérique (PIA 4 – France Relance)
2021 – 2025
Positionner la France en leader mondial de la santé numérique

Health Innovation Plan 2030: making France the leading European health industry

→ + EUR 7.5 bio.

A EUR 670 MILLION STRATEGY LAUNCHED ON 18 OCTOBER 2021

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Digital Health Acceleration Strategy

SUPPORTING DIGITAL HEALTH FOR THE ENTIRE INNOVATION PROCESS
A EUR 670 MILLION STRATEGY LAUNCHED ON 18 OCTOBER 2021

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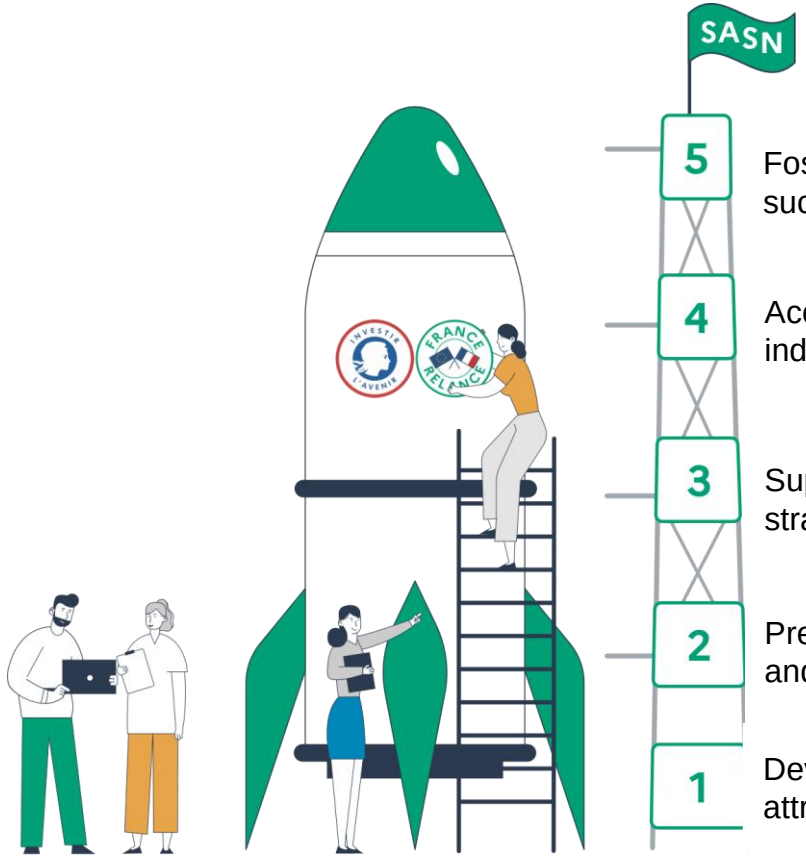

5 — Fostering the conditions for the large-scale **deployment** of successful projects
35 M € — 9 actions

4 — Accompany the implementation of real-life **experiments** and first industrial stages
168 M € — 4 actions

3 — Support the **development** of structural projects to strengthen strategic advantages
202 M € — 8 actions

2 — Prepare the future generation of key digital health technologies and facilitate rapid transfer mechanisms of **research** results
60 M € — 2 actions

1 — Develop stakeholder **training**, stakeholder trust and professional attractiveness of the sector
81 M € — 12 actions

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Public consultation:
429 responses — 50 qualitative interviews — 6 months of interdepartmental work

Calls for expression of interest

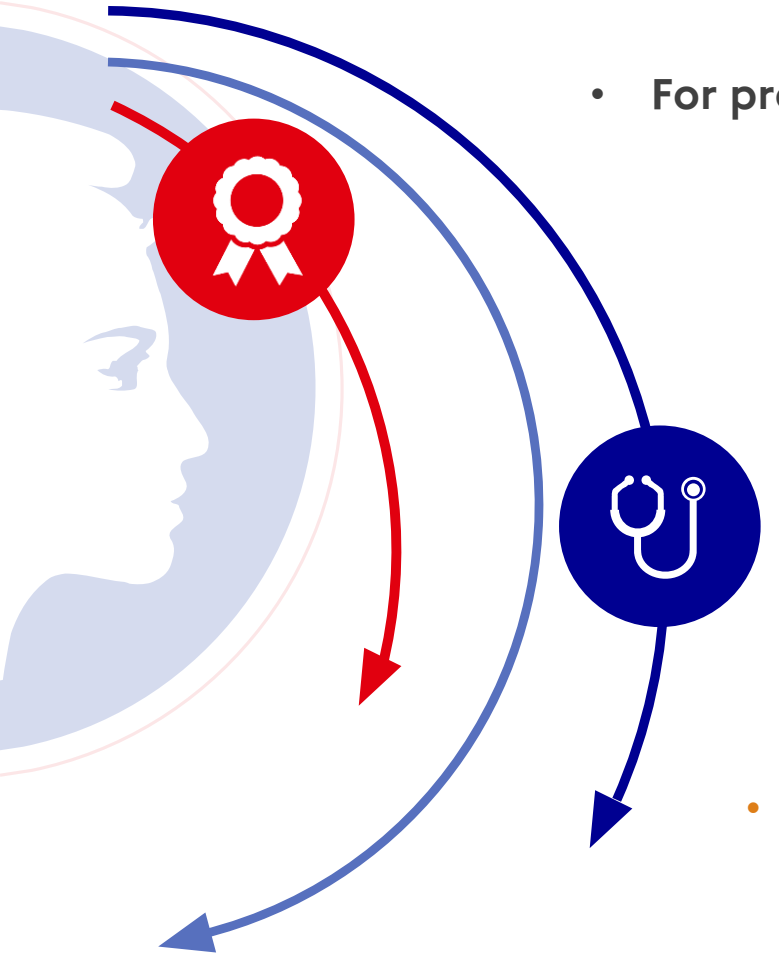
Paving the way to a fast-track DMD access in France

PRIOR EXPERIMENTATIONS TO A NATIONAL TRANSITIONAL AND TEMPORARY ONE-YEAR REIMBURSEMENT ACCESS SCHEME FOR DIGITAL MEDICAL DEVICES AND TELEMONITORING IN FRANCE

- France has been looking at improving care pathways since 2018 by experimenting telemonitoring prior to reimbursement (ETAPES program - Telemedicine Experimentation for the Improvement of Healthcare Pathways)
- The health technology assessment of the program was coordinated by the French National Authority for Health (Haute Autorité de Santé, HAS)
- Transitioning from ETAPES, the French government paved the way to implement a fast track reimbursement for DMDs by 2022 in its 2022 Social Security Funding Bill of December 2021. *Ministerial order to implement the article is pending as of October 19, 2022*
- More information on G_NIUS

Paving the way to a fast-track DMD access in France

IMPLEMENT EARLY ACCESS FOR CE-MARKED DIGITAL DEVICES FOR INDIVIDUAL USE THAT MEET THE CRITERIA FOR INCLUSION ON THE LIST OF PRODUCTS AND SERVICES AND FOR REMOTE MONITORING DEVICES



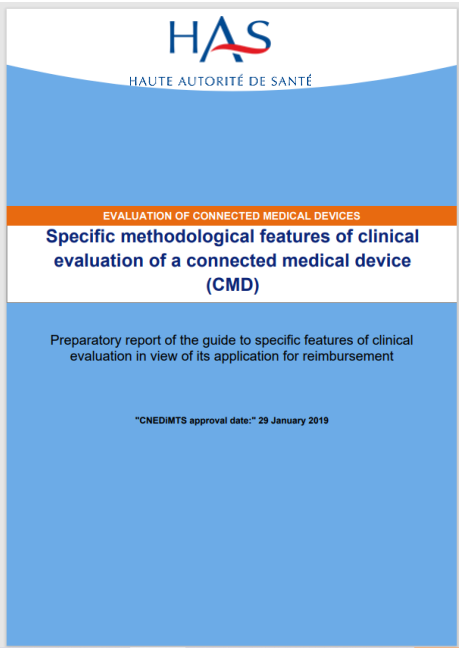
- For products already CE marked
- For Ditigal Therapeutics and innovative telemonitoring solutions with clinical evidence
- Data interoperability and security standards requirement

A Fast Track preliminary access

- Accelerated access to reimbursement
- 1 year to apply for normal reimbursement pathway
- Initial fixed price, tailored after 1 year

Guidelines in France

IN FRANCE, THE NATIONAL HEALTH AUTHORITY HAS PUBLISHED A CLASSIFICATION OF DMDS ACCORDING TO THEIR FUNCTIONALITIES, INTENDED USER AND AUTONOMY



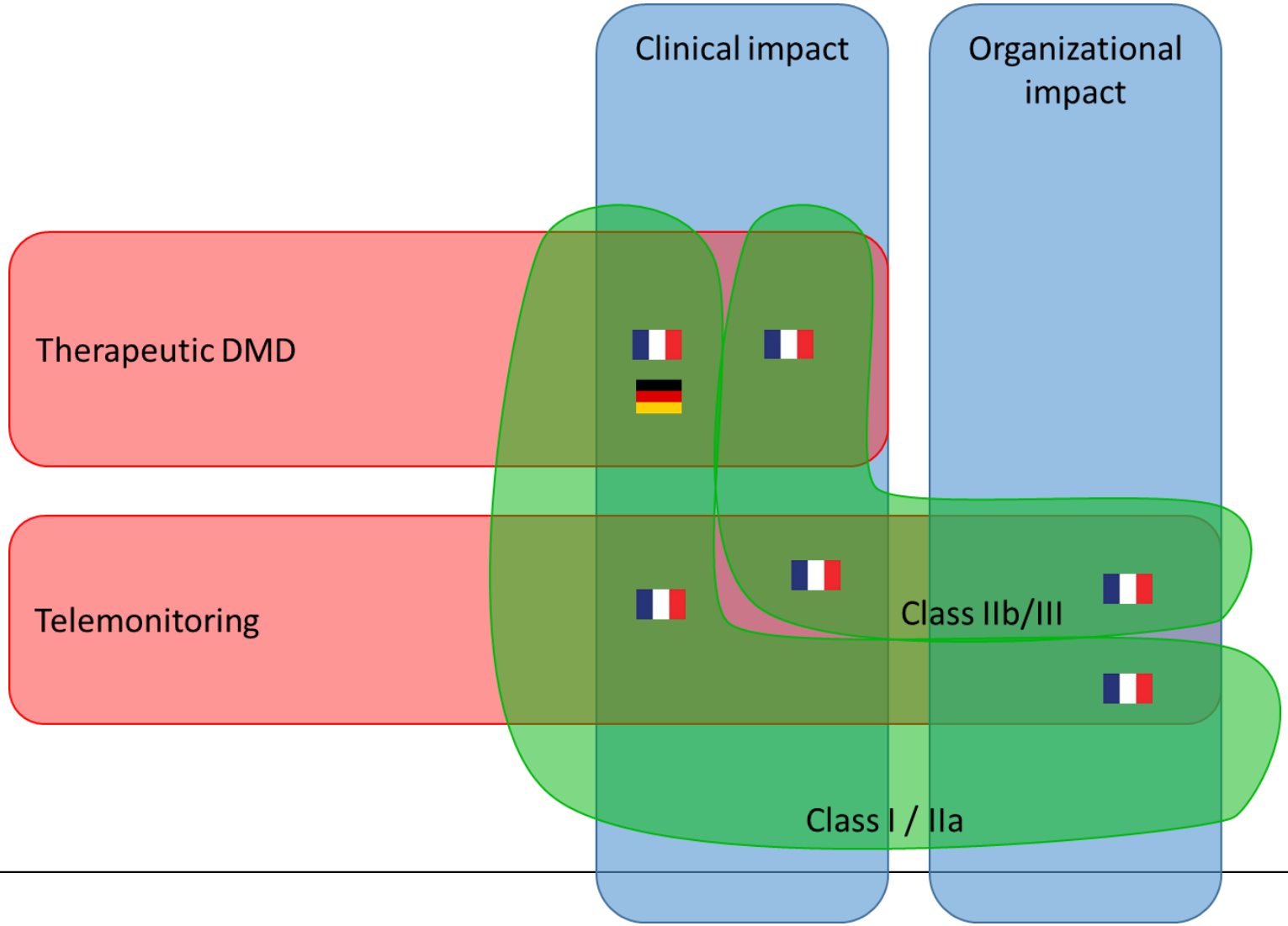
Guidelines by the National Health Authority (HAS):

- Medical device evaluation by the CNEDiMTS (Medical Device and Health Technology Evaluation Committee): Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement Link
- Methodology for the clinical development of medical devices Link
- Analysis grid for the AI component in medical devices Link
- Real-world studies for the assessment of medicinal products and medical devices Link
- Guidelines for telemonitoring on 5 chronic diseases Link (In French)
- Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care Link

Guidelines by the National eHealth Agency (ANS): to be published by the end of 2022

Fast track access for DMDs access in the EU

BOTH GERMAN AND FRENCH NATIONAL REGULATIONS SUPPORT BROADER PATIENT ACCESS TO INNOVATIVE DMDS, USING DIFFERENT SCOPES



Launch of a European Taskforce

ACCELERATE EUROPEAN MARKET ACCESS THROUGH CLINICAL EVALUATION CRITERIA HARMONISATION FOR DIGITAL MEDICAL DEVICES (DMDS)

In April 2022 under the digital health agenda of the French presidency of the Council of the European Union, a new **European taskforce** has been launched based on several conferences organized by EIT Health with input from both **France and Germany**.

Mission:

- To **harmonize the innovative health technology assessment procedures** with the overall goal to enable a harmonised approach for European assessment supporting national appraisal and reimbursement by statutory health insurance organisations for distinct subclasses of DMDs.

- The taskforce seeks to advise the HTA Coordination Group (HTAR) of EunetHTA, national responsible authorities and agencies, innovators and policy makers – aligned with EU medical device regulators – on the development of a joint DMD assessment procedure, including the definition of DMDs based on their application purpose and evaluation categories.

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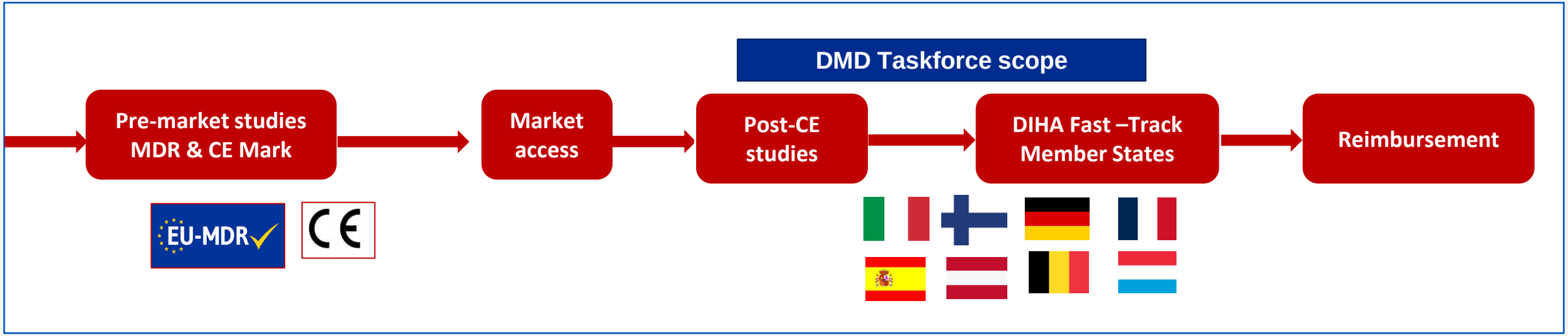
European Taskforce Rationale

TOWARDS A COMMON EUROPEAN MARKET FOR DIGITAL HEALTH

Framework of the **Regulation on Health Technology Assessment (HTA) regulation,** a deliverable of the EU Pharmaceutical Strategy, applicable from January 2025.



➔ By developing a **joint approach** producing concrete outputs that can be used in the Member States, duplication of assessments can be avoided, patient access to innovative and proven digital health solutions can be accelerated, and health systems improved.

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European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)

- The final recommendations for harmonizing clinical criteria and methodologies for evaluating DMDs results from three work packages.

Work package 1

- Harmonize the taxonomy of DMDs based on their application scope and evaluation categories

Work package 2

- Consensus on determining quantity, quality and the type of evidence that is needed for assessing DMDs

Work package 3 & 4

- Propose a social health evaluation framework based on pre-requirements (technical, technological, ethical)

Definition/Selection of the DMDs

- Compare definition by national HTA-R (Germany/France/other)
- Harmonize with MDR
- Extract similarities

<u>Propose a joint definition/taxonomy</u>

- Therapeutic Application purpose
- Diagnostic Application purpose

linked to WP2 evaluation criteria

Joint Evaluation Criteria

- Analyse existing Evaluation Criteria
  - Clinical evidence categories
  - Outcome/ study methods + design
- Compare to international evaluation concepts (e.g. EU, UK, USA, etc.)

<u>Recommend Joint Evaluation Concepts</u>

- Patient-centric effects
- Service-relevant measures

for the different DMD types (WP1)

Socio-Economic Acceptance

- Assess social acceptance criteria (patient engagement, HCP integration, health economic evaluation)
- Ethical, Legal and Social evaluation
- regional integration into healthcare services

<u>Suggest socio-economic evaluation tailored to DMDs</u>

External Advisory group

Contribute to the final suggestions by sharing perspectives of different stakeholders and experiences from real-world examples

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Taskforce Member Institutions

- **Austrian Institute for Health Technology Assessment, AIHTA** (Austria)
- **Belgian Health Care Knowledge Centre, KCE** (Belgium)
- **BioMed Alliance**
- **Bocconi University** (Italy)
- **Catalan Agency for Health Quality and Assessment AQuAS** (Spain)
- **EIT Health** (France)
- **EUnetHTA**
- **European Observatory on Health Systems and Policies**
- **European Patients' Forum, EPF**
- **Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM** (Germany)
- **FinCCHTA** (Finland)
- **Finnish Innovation Fund Sitra** (Finland)
- **French Ministry of Solidarity and Health** (France)
- **Luxembourg Health Directorate** (Luxembourg)
- **Medical University of Vienna** (Austria)
- **National Health Authority, HAS** (France)
- **University of Liège** (Belgium)
- **Universtiy of Luxemburg** (Luxemburg)

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European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)

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WP1 Taxonomy of DMDs

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WP2 Clinical Evidence Model

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Aude Rochereau
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Dimitra Panteli
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Reinhard Jeindl
Magali Boers

WP3&4 Socio-Economic aspects data and study designs

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Johannes Ahlqvist
Barbara Hoefgen
Ramon Maspons
Dimitra Panteli
Hannah-Marie Weller
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Calendar: Achievements & Milestones

6th May 2022 :
First Taskforce Meeting

14th June 2022 :
Agreement on goals and mission statement of Taskforce. Panel discussion at **HIMSS Europe Helsinki**

1st August 2021 :
Scientific manuscript on vision, mission and working methods of the Taskforce finished (to be published)

September 2022:
Preparations for **Horizon Europe 2023 & Joint Action Calls** to obtain funding for the implementation of the recommendations

26-27th October 2022:
First results of work packages will be presented to the public at **Digital Medicine Conference Luxemburg**

15th November 2022:
Work starts with the **External Advisory Group** to validate recommendations of the Taskforce

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Links

French EU Presidency digital Health – Press kit

Overview of achievements of the national Digital Health Strategy 2019 - 2022 - Link

Study on digital health in the EU - Link

Digital Health Acceleration Strategy press kit

G_NIUS Website : https://gnius.esante.gouv.fr/