Collective statement to European decisionmakers calling for a pragmatic, convergent European evaluation framework for Digital Medical Devices (DMDs) starting in 2026

A huge digital health potential in Europe endangered by local fragmentation

With its 450 million citizens, the European Union (EU) faces numerous **healthcare challenges,** including an aging population, an increase in the prevalence of chronic illnesses, and a growing shortage of healthcare professionals[1].

A new generation of European digital health startups has already demonstrated its potential to address these challenges through **robust clinical studies** and **technical certifications** in their home markets. The **adoption** of their solutions is **well-established** among patients and healthcare professionals (HCPs). Hundreds of thousands of patients have already used remote patient monitoring (RPM) or remote therapeutic monitoring (RTM) in France, or digital therapeutics (DTx) in Germany, following a medical prescription. However, diverging evaluation frameworks across EU member states prevent these solutions from scaling from one country to another and from accessing sustainable economic models.

In the context of **intense global competition** and **rapid technological advancement**, this fragmentation threatens the survival of the European digital health industry and undermines the EU's technological sovereignty. It also leads to unequal access for patients, healthcare professionals, and payers across Europe.

The urgent need for a convergent EU evaluation framework with common clinical and technical criteria

There is now an **urgent need** to establish a **unified European evaluation framework** based on **pragmatic common clinical and technical criteria**. Such convergence would not only enable the emergence of strong European players capable of competing globally but also safeguard Europe's technological sovereignty.

This framework would also support the integration of digital health solutions into the upcoming **European Health Data Space (EHDS)**. Without the widespread adoption of these solutions across the EU, the EHDS risks remaining as a theoretical construct with limited operational impact.

Bridging political vision and practical implementation

Encouraging steps have been taken at the political level to lay the groundwork for a common evaluation framework[2], strengthen cross-border collaboration[3], and support the scaling of EU startups across the continent[4]. These initiatives reflect a **strong political commitment** to advancing healthcare innovation in Europe.

The next crucial step is to translate this momentum into **concrete outcomes** - within timelines that are realistic and workable for European startups.

So far, early cross-border evaluations have revealed **divergences** in **reimbursement decisions** on digital medical devices (DMDs), even when based on **identical clinical data.** Differences in technical requirements across countries have also been observed. Both contribute to increasing delays and costs to reach European market access. There is a strong hope - and a clear need - for this situation to evolve quickly.

<u>Our call as European Digital Health Innovators :</u>

As a coalition of EU startups driving innovation in digital health, we call for the establishment of a pragmatic and convergent European evaluation framework - based on common clinical and technical criteria - starting in 2026.

Such a framework would enable the swift and efficient cross-border diffusion of healthcare innovations, drive massive investments within the digital health sector in Europe, while matching the pace of technological development.

The race for European Technological Sovereignty is happening now. We need access to a unified European digital health market - now.

[1]Health at a Glance: Europe 2024 report, the European Commission: https://health.ec.europa.eu/state-health-eu/health-glance-europe/health-glance-europe-2024_en
[2]Classification grid and evidence matrix for evaluating digital medical devices under the European union landscape : https://doi.org/10.1038/s41746-025-01697-w
[3]Signature d'un accord franco-allemand pour renforcer la coopération sur l'évaluation des dispositifs médicaux numériques : https://sante.gouv.fr/actualites/presse/communiques-de-presse/article/signature-d-un-accord-franco-allemand-pour-renforcer-la-cooperation-sur-l
[4]EU Startup and Scaleup Strategy, the European Commission : https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/eu-startup-and-scaleup-strategy_en

Summary

- A new generation of European digital health startups has already proven its ability to address healthcare challenges with validated clinical outcomes, certified technologies and adoption by patients and HCPs.
- However, fragmented evaluation frameworks across EU member states hinder cross-border scaling.
- **This fragmentation threatens the short-term viability of Europe's digital health ecosystem and the EU's technological sovereignty.**
- Recent political initiatives have demonstrated an intention to converge on evaluation frameworks.
- Yet in 2025, real-world assessments of DMDs show that such convergence has not been achieved in practice.
- A pragmatic, unified EU evaluation framework must be implemented in 2026 to support the growth of European digital health startups and safeguard European technological sovereignty.

Next Steps

Starting in **2026**, particularly in France and Germany, the 2 largest healthcare markets in Europe, we urge **alignment** on:

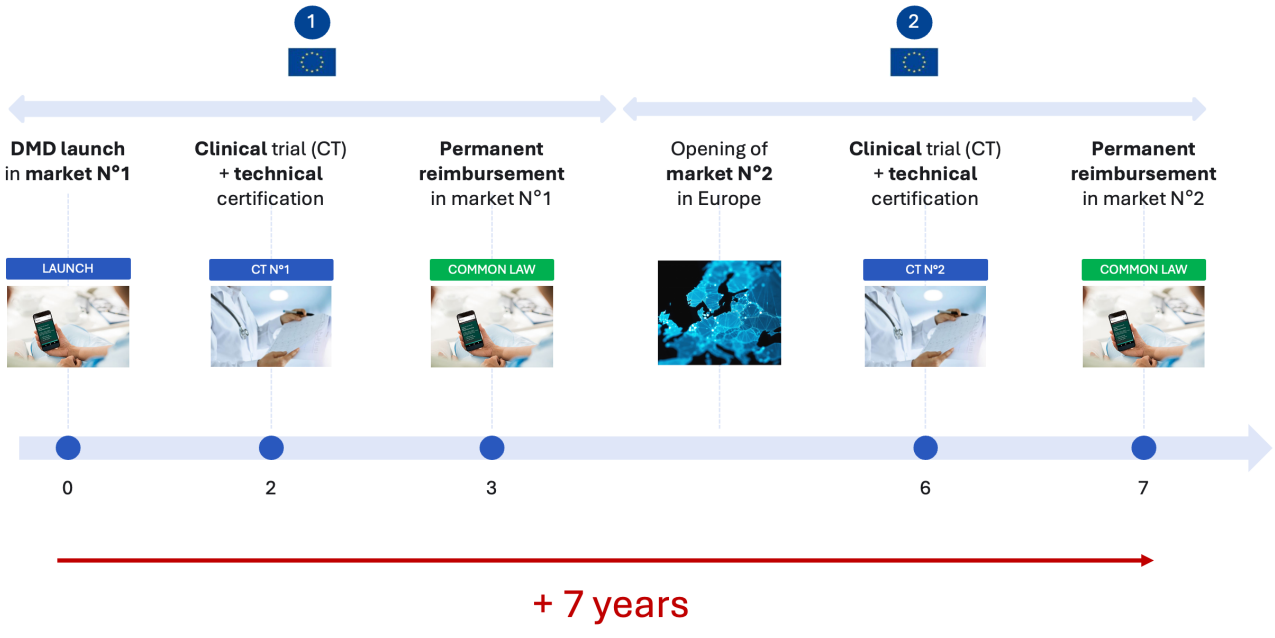
- Technical requirements for DMDs certification
- Clinical evaluation criteria for Digital Therapeutics (DTx), Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM) and AI-powered health solutions
- Operational procedures and methodologies for DMDs reimbursement pathways

We also call for the future European evaluation framework to be **truly pragmatic**, ensuring that healthcare innovations can access the **EU-wide market** within a reasonable timeframe (**2 to 3 years maximum**) after their launch in their home country. Beyond this timeframe, such technologies risk becoming **obsolete**.

To achieve this short-term goal by **2026**, we encourage European policymakers to adopt a **pragmatic and results-oriented approach**. The lessons learned from HTA initiatives to harmonize the evaluation of other health products, which have led to a ratcheting up of requirements and delays in patient access, should be carefully considered.

The goal is to ensure that safe DMDs reach patients as soon as possible.

Figure 1: Average theoretical delay to obtain DMD permanent coverage in 2 EU member states with fragmented evaluation frameworks



=> To sign our collective statement, please click on this link

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