



SHAIPED

Welcome to the 4th volume of the SHAIPED Newsletter!

Dear colleagues and stakeholders,

We are pleased to welcome you to a new edition of the SHAIPED Newsletter. This edition begins with the launch of our stakeholder survey, inviting experts to contribute insights on the use of Real-World Data (RWD) in shaping the future of Medical Device AI (MDAI) across Europe. We also introduce the evolving Omnibus approach, aimed at simplifying and better aligning regulatory frameworks. In addition, this issue highlights partner perspectives from the Belgian Health Data Agency (HDA) and Implicity, offering both public sector and industry viewpoints. Finally, we look ahead to a series of upcoming events and conferences, providing opportunities to connect and stay engaged with the European digital health community.

Shaping what comes next: Help shape how AI will be evaluated in Europe

The SHAIPEd consortium is launching a comprehensive **stakeholder survey** designed to gather targeted insights on the use of RWD in the evaluation, certification, and lifecycle management of MDAI across Europe. Aligned with the EHDS, this initiative explores how future HDABs can support key processes such as market certification, post-market surveillance, clinical follow-up, Health Technology Assessment (HTA), and reimbursement. To ensure relevance and depth, the survey is tailored to distinct stakeholder groups, with estimated completion times ranging from approximately **15 to 45 minutes** depending on the group. Participants are invited to **share their expertise** on topics such as RWD usage across the MDAI lifecycle, regulatory alignment, adaptive versus static AI systems, data quality, and cross-border access challenges. By contributing, stakeholders will play a direct role in **shaping actionable recommendations** and project deliverables, ultimately supporting more efficient, transparent, and harmonised pathways for integrating AI-driven medical technologies into healthcare systems across Europe.

SHAIPEd - Survey

Shared AI² Platform for European Digital Health

Help us understand how Real-World Data and AI²-based medical devices are governed across Europe.

Select your stakeholder group

Health Data Access Bodies

HDABs designated under the EHDS²

~3 min

Competent Authorities

Medical device regulatory authorities

~15 min

Notified Bodies

Conformity assessment organisations

~15 min

MDAI Providers

Developers of AI²-based medical devices

~15 min

Health Technology Assessment Bodies

National and regional HTA² organisations

~20 min

EC Groups & Committees

European Commission advisory bodies

~15 min

What is Omnibus proposal?

Released in late 2025, the Digital Omnibus and the subsequent **MDR/IVDR** Simplification proposal aim to reduce the administrative burden on innovators by tackling "double regulation." A key change for our community is the proposed relocation of medical devices within the **AI Act** framework. Rather than being subject to overlapping requirements from both the **AI Act** and the **MDR/IVDR**, the proposal suggests a more integrated approach where the **MDR/IVDR** takes the lead. This includes eliminating the automatic "high-risk" categorization for all **MDAI**, potentially accelerating development for lower-risk tools like monitoring applications.



The shift toward Data-Driven Regulation?

One of the most significant impacts for SHAIPEd is the strengthened role of **RWD** and **RWE**. The proposals envision a move from periodic, document-based oversight to a continuous, data-driven lifecycle process. In this new logic, **RWD** becomes a core regulatory trigger for actions such as **Post-Market Surveillance** and clinical evaluations. This aligns perfectly with SHAIPEd's mission to leverage the **EHDS** to provide the robust datasets needed for the training and validation of AI tools.

How SHAIPEd is adapting?

While the core safety and performance requirements remain unchanged, SHAIPEd is proactively updating its roadmap to reflect these procedural shifts. We are currently revising key deliverables to acknowledge the proposal draft and its potential influence on **HDABs**. SHAIPEd is continuing with our planned roadmap activities while actively taking into account the **European Commission's** simplification proposal to ensure our regulatory mappings reflect the latest shifts toward data-driven oversight.

Partner perspectives in SHAIPEd: Insights from the project consortium



The **Belgian Health Data Agency (HDA)** is the national authority responsible for enabling the secondary use of health data in Belgium, in alignment with the **EHDS**. As a future **HDAB**, **HDA** is actively working to ensure that health data are accessible, interoperable, and used in a secure and trustworthy way to support innovation and better healthcare outcomes. Drawing on its experience with the implementation of the **EHDS** secondary-use framework and involvement in EU initiatives such as **TEHDAS2**, the team is closely engaged in translating regulatory requirements into practical, operational solutions — particularly in areas such as secure processing environments and data governance. The rapid evolution of regulatory frameworks such as the **AI Act** represents both an opportunity and a challenge. While these frameworks are essential to ensure safety, trust, and accountability, their real impact will depend on how effectively they are operationalised in practice. Ensuring that regulation enables and empowers innovation — rather than unintentionally constraining it — is seen as a key priority. **HDA** emphasises the need for clearer and

more harmonised approaches to implementing legal frameworks across Europe, alongside more practical guidance for stakeholders working with health data and AI. Improving decision-making processes for AI-related data access — particularly from the perspective of **HDAB** — is critical to making these frameworks truly functional and impactful. By addressing these challenges, SHAIPEd contributes to building a more coherent and operational European landscape for AI in healthcare, supporting both innovation and regulatory compliance.

SHAIPEd has a role of a pioneering project that helps translate high-level regulatory principles into practical and operational frameworks. In particular, it is among the first initiatives to explore how AI development and testing — in compliance with the AI Act — can be effectively carried out within the emerging European data spaces. — HDA team









Partner perspectives in SHAIPEd: Insights from the project consortium



Implicity is a digital **MedTech** company specialised in cardiac remote monitoring and data-driven care management, developing solutions that combine real-world clinical data with AI to improve patient follow-up and anticipate clinical events. Within SHAIPEd, the company leads **Use Case 3**, focused on evaluating the real-world impact of remote heart failure management solutions across France and Germany. Drawing on strong expertise at the intersection of digital health, **RWE**, and market access, **Implicity** brings a practical perspective on how AI-based medical devices can be validated and adopted across different **European health systems**. Their work highlights the importance of combining clinical data with national health databases to generate robust evidence on outcomes such as hospitalisations, mortality, and healthcare system impact. From **Implicity's** perspective, one of the main challenges in the **European health ecosystem** remains the fragmentation of data infrastructures and the difficulty of generating comparable, cross-country evidence. Addressing these gaps is essential not only for innovation, but also for supporting reimbursement decisions and broader adoption of digital health solutions. SHAIPEd is as a key opportunity to move from theory to practice — testing how **RWD** can be effectively accessed, linked, and used across countries. The project also provides a framework to better align evidence requirements and support more transparent and efficient data access processes. **Implicity** emphasises that unlocking the full potential of health data in Europe requires alignment between stakeholders, regulatory frameworks, and evidence expectations.

“Through large-scale real-world evidence studies based on national health databases, Implicity has demonstrated the clinical and organisational benefits of remote monitoring solutions, while building a strong foundation for contributing to SHAIPEd and the wider European health data ecosystem.” – Implicity team

Events of Interest for the SHAIPEd Community

- TEHDAS2 Stakeholder Forum 2026
 29 – 30 April 2026
 Limassol, Cyprus & Online
 [Event Details](#)
- Rise of AI Conference
 5 – 6 May 2026
 Berlin, Germany & Online
 [Event Details](#)
- Data Innovation Summit 2026
 6 - 8 May 2026
 Stockholm, Sweden & Online
 [Event Details](#)

-  DSC Next – 2nd International Data Science Conference
 7 - 8 May 2026
 Amsterdam, Netherlands
 [Event Details](#)

-  AI WEEK - AI HEALTHCARE SUMMIT
 19 - 20 May 2026
 Milan, Italy
 [Event Details](#)

-  HIMSS26 Europe — European Health Conference & Exhibition
 19 – 21 May 2026
 Copenhagen, Denmark
 [Event Details](#)

-  Data Week Leipzig 2026
 1 - 5 June 2026
 Leipzig, Germany & Online
 [Event Details](#)

As spring unfolds, it brings a sense of renewal and fresh momentum across the SHAIPEd community. This season reflects a time of new ideas, growing collaboration, and continued progress towards a more connected and innovative European health data ecosystem. We look forward to the months ahead and to sharing further developments with you.

