



# SHAIPED

## Welcome to the 2nd volume of the SHAIPED Newsletter!

Dear colleagues and stakeholders,

Welcome to the second edition of the SHAIPED Newsletter! After a well-deserved summer break, the project has already entered a new phase of activity and we are pleased to share some of the latest highlights with you. In this issue, we present the launch of our External Advisory Board (EAB) – a group of experts ensuring that SHAIPED stays aligned with Europe’s fast-evolving regulatory and ethical landscape. You will also find updates on our work mapping AI medical device certification pathways across Europe, as well as progress in advancing the user journey for AI as Medical Devices (AIaMDs). Our activities further encompass the evolving European legal framework for health technologies and medical devices. Finally, we point you to upcoming events of interest for the SHAIPED community.

## Main event:

### Kick-Off of External Advisory Board

On 16 September 2025, the SHAIPEd consortium successfully held the Kick-off meeting of its EAB, marking an important milestone in the project's governance and stakeholder engagement. The EAB is composed of a diverse set of independent experts – from universities, healthcare institutions, industry, public authorities, and the legal/regulatory domain – all selected to provide high-level expertise and ensure SHAIPEd's objectives remain aligned with Europe's evolving health and AI landscape.

### Why an EAB?

SHAIPEd operates at the intersection of the EHDS Regulation and the AI Act, with direct relevance also to the Medical Devices Regulation (MDR) and the Health Technology Assessment Regulation (HTAR). This positioning means that the project's success depends not only on technical innovation but also on the ability to navigate a rapidly shifting regulatory, ethical and legal environment.

The EAB was therefore established to:

- Review and milestones and deliverables
- Provide strategic and regulatory guidance
- Offer targeted expertise to ensure SHAIPEd contributes meaningfully to the European framework for AIaMD

The Kick-off concluded with a roadmap for the EAB's involvement in SHAIPEd's work packages, particularly WP3, WP4 and WP5. Experts will be called upon to review upcoming documents, provide feedback through meetings and written reports and help guide the project toward meaningful and sustainable impact. With its EAB now in place, SHAIPEd is equipped with a strong governance mechanism to ensure that its technical innovations are matched with legal soundness, regulatory readiness and patient-centered values.

# The Four Expert Groups within the EAB

To ensure targeted expertise and efficient contributions, the EAB has been divided into four thematic groups, each tackling a specific dimension of SHAIPEd's work

## Legal Group

Focused on EU legislation relevant for AIaMD (AI Act, EHDS, MDR, HTAR), data protection, and the interplay of legal frameworks across Member States.

## Regulatory Group

Bringing expertise on certification processes, post-market surveillance, vigilance and health technology assessment pathways.

## Technical / Data Group

Advising on AI development challenges, including computing and storage needs, synthetic data generation, data discovery and interoperability.

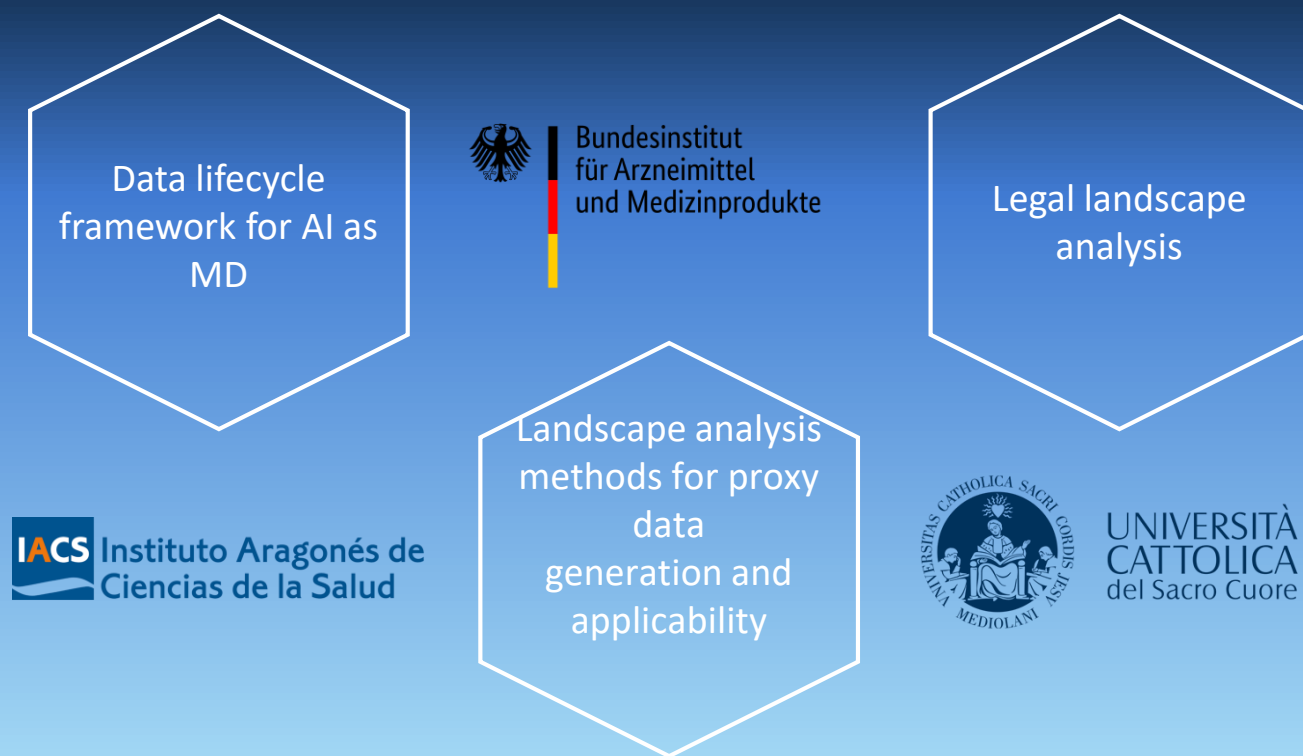
## EHDS & HDABs Group

Providing perspectives from HDABs, ensuring that outputs are fully compatible with EHDS infrastructures and add value to national and European health data ecosystems.



# Advancing the User Journey for AI as a Medical Device

– WP3



Work within SHAIPEd’s WP3 is progressing steadily, mapping how AI systems intended for medical purposes, known as AIaMD, interact with healthcare and regulatory ecosystems. AIaMDs, which operate with varying levels of autonomy and generate outputs that influence clinical decisions, fall under the MDR, the In Vitro Diagnostic Regulation (IVDR) and are generally classified as high risk under the AI Act when subject to third party conformity assessments.

The project examines scenarios where manufacturers, acting as Health Data Users, either fine-tune pre-trained models or develop AIaMDs from scratch using health data made accessible by HDABs under the EHDS. It also explores testing and certification pathways, ranging from clinical or performance evaluations for lower risk devices to full clinical investigations for higher risk devices and the subsequent evidence generation for Health Technology Assessments and reimbursement decisions at EU, national or payer initiated levels.

By integrating real world data from clinical deployment, HDABs can facilitate continuous monitoring, safety reporting and iterative model improvements, ensuring AIaMDs are both effective and aligned with the complex web of European regulatory requirements.

# Mapping Europe's AI Medical Device Certification – WP4

SHAIPED's WP4 is producing the first detailed map of Europe's certification pathways for AI enabled medical devices. Drawing on stakeholder meetings, cross WP collaboration and case studies, the team is benchmarking best practices and bottlenecks across the full digital health innovation lifecycle — from risk classification and CE marking to reimbursement and post-market follow-up. Special focus is given to how HDABs and SPEs can support validation and certification under the EHDS and the AI Act and how new infrastructures like testing facilities, regulatory sandboxes and AI factories could streamline approval. This evidence base is already informing SHAIPED proposals to simplify EU certification of AIaMD and accelerate patient access to trustworthy next generation technologies.



Fig. 1: Flowchart Steps of the CE Marking Process. Source CliniExperts International.

# The legal backbone of AI in healthcare:

## What you need to know about



- Medical Devices Regulation (MDR)


The Medical Devices Regulation (EU) 2017/745 is the central legal framework in the EU for ensuring the safety, performance and traceability of medical devices placed on the EU market. Under MDR, manufacturers must provide robust clinical evidence (or equivalent data) to support safety and effectiveness, maintain a quality management system and monitor devices after they are on the market. A key component is EUDAMED, the centralized database designed to increase transparency: it tracks device registrations, certificates, vigilance reports and more. In recent years, MDR has been amended to ease certain transitional burdens and adapt to practical realities. For example, Regulation (EU) 2024/1860 introduces phased roll-outs of EUDAMED and modifies transitional provisions. Meanwhile, the European Parliament has called for a broader revision of MDR and IVDR to address bottlenecks, capacity constraints in notified bodies and the urgent need for innovation pathways. Despite challenges, MDR marks a significant upgrade over earlier Directives (MDD/AIMDD). It strengthens patient safety, enforces post-market surveillance and demands that manufacturers align with the “state of the art.”



## Health Technology Assessment Regulation (HTAR)

The Health Technology Assessment Regulation (EU) 2021/2282 establishes a harmonized, EU-wide framework for evaluating the relative clinical effectiveness, safety and value of health technologies (primarily medicines, with potential future extensions) across Member States. Its purpose is to reduce redundant national assessments, speed access to innovation, and improve consistency in decision-making. HTAR entered into force on 11 January 2022 and becomes applicable from 12 January 2025. From that date, new assessments in certain therapeutic areas (like oncology or advanced therapies) must follow joint clinical assessment (JCA) procedures established under HTAR. In addition, HTAR institutes joint scientific consultations, whereby developers can seek early feedback on clinical evidence plans, and strengthens cooperation and data exchange across EU regulatory and health bodies. In sum, HTAR aims to streamline the pathway from innovation to patient access, reduce fragmentation in assessments and equip policymakers with more coherent evidence across Europe.

# Events of Interest for the SHAIPEd Community

 Patients and Citizen Forum Session 4 – The European Health Data Space: Progress, News and What’s Next For Patients

 Location: Online

 Date: 8 October 2025

 [Event Details](#)


 CSMD-Horizon MedTech AI / Digital Health Regulation Conference

 Location: Brussels, Belgium

 Date: 4–5 November 2025

 [Event Details](#)

 Health Data Policy into Practice – A TEHDAS2 and HL7 Vulcan Stakeholder Forum

 Location: Copenhagen, Denmark & Online

 Date: 9 October 2025

 [Event Details](#)

 5th Medical Devices & SaMD: AI, Regulatory & Compliance Summit

 Location: Berlin, Germany

 Date: 20–21 November 2025

 [Event Details](#)

 3rd European Health Data Protection Congress

 Location: Paris, France

 Date: 15–17 October 2025

 [Event Details](#)

 AI Healthcare Conference / Artificial Intelligence Summit

 Location: Berlin, Germany

 Date: 25–26 November 2025

 [Event Details](#)

As we move forward, we are excited to continue building on this momentum together with all our partners and stakeholders. Just as autumn leaves carried by the wind spread far and wide, we continue to share the word about SHAIPEd across networks, and look forward to keeping you updated on our progress.

