



SHAIPED

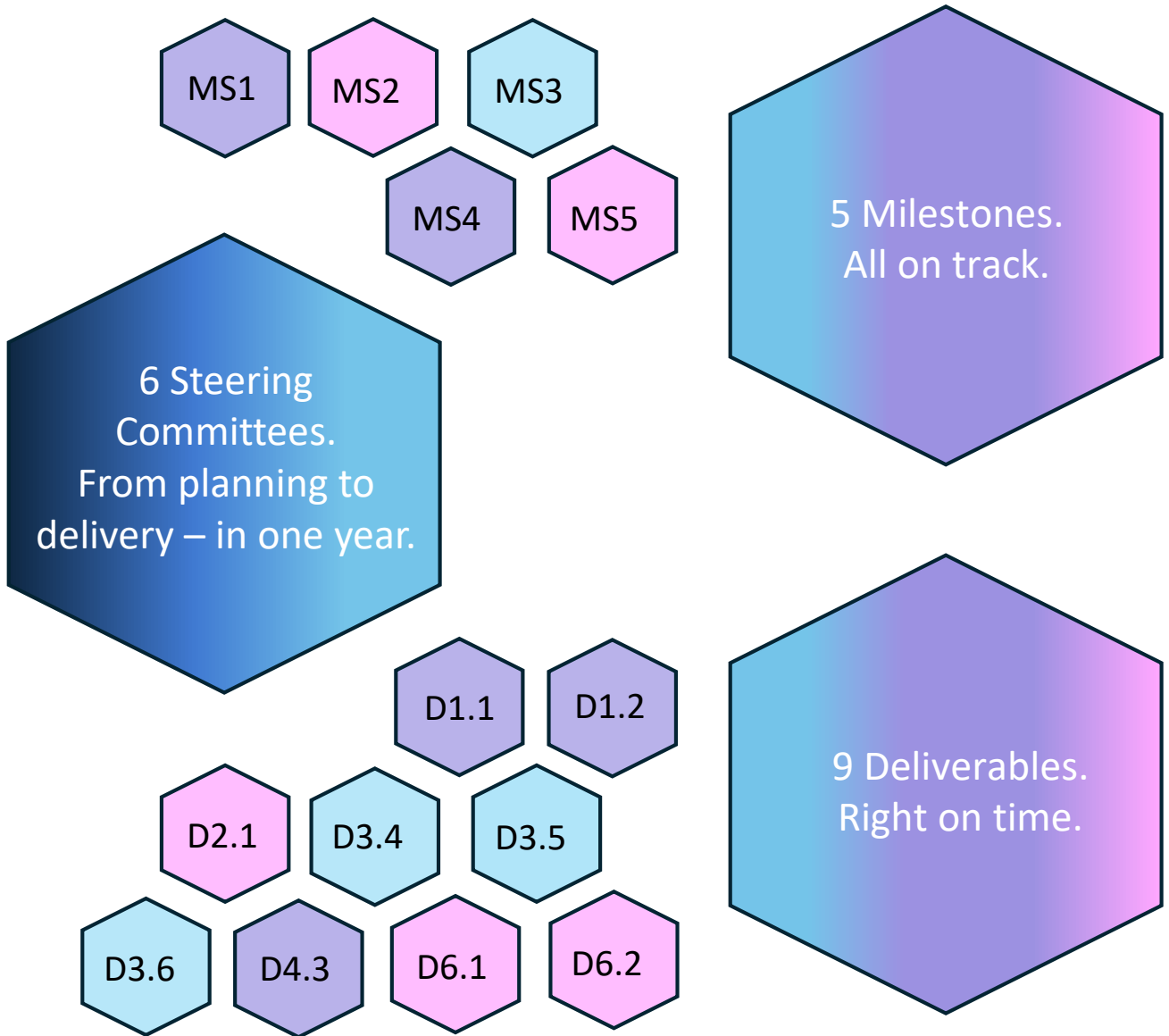
Welcome to the 3rd volume of the SHAIPED Newsletter!

Dear colleagues and stakeholders,

We are pleased to welcome you to third edition of the SHAIPED Newsletter, as the project continues to advance its work. This edition opens with SHAIPED Wrapped, offering a retrospective look at the project's first year. We then turn the spotlight to the people and institutions driving SHAIPED forward. We are delighted to feature interviews with two project partners — IACS and Sciansano — who share insights from their respective roles within the project. In addition, this newsletter highlights two key contributions developed by SHAIPED partners; the legal landscape analysis and the analysis of proxy data generation and applicability. Finally, we conclude with a selection of events of interest for the SHAIPED community, offering opportunities to stay engaged with relevant discussions, initiatives and upcoming activities in the field.

SHAIPED Wrapped: Year in Review

As 2025 came to a close, we took a moment to reflect on what was achieved within the SHAIPED project. Much like a “year in review”, this snapshot highlights the key milestones, deliverables, outputs, and collaborative efforts that shaped the project’s first phase, focused on establishing the foundations and developing a shared understanding of the current landscape. With this initial phase now completed, the project is moving into its next stage, shifting the focus towards pathway development and the realisation of concrete use cases.



Partner perspectives in SHAIPEd: Insights from the project consortium



Within SHAIPEd, **Sciensano – the Belgian Institute of Public Health** – contributes through its Innovation in Health Information Systems unit, which leads WP3. The team focuses on identifying concrete pathways to support the development, testing, and deployment of AI as a medical device, with particular attention to the interaction between real-world health data and regulatory processes. A key contribution of Sciensano to the project builds on its work on the **HealthDCAT metadata standard**, developed to support interoperability and secondary use of health data within the EHDS. By establishing a standardised way to describe health datasets, HealthDCAT improves the interoperability and findability of data across the **HealthData@EU** infrastructure, connecting HDABs, authorised participants, and the EU Datasets Catalogue.

In SHAIPEd, this expertise helps translate regulatory and technical requirements into practical guidance for HDABs, clarifying what capacities, tools, and services are needed to effectively support AI development while ensuring secure and trustworthy data use. Through this work, Sciensano contributes to strengthening the foundations for scalable, interoperable, and regulation-ready AI innovation in European healthcare.

„SHAIPEd is an exciting context to introduce a generative AI-driven demonstrator that combines synthetic proxy data, a semantic layer and retrieval-augmented generation. By improving data discoverability while avoiding the exposure of sensitive health data, the demonstrator illustrates how innovative AI solutions can support the EHDS.” – Sciensano team

Partner perspectives in SHAIPEd: Insights from the project consortium



The Aragon Health Sciences Institute (IACS) is a public research organisation of the Government of Aragón, Spain, dedicated to advancing research, innovation and knowledge transfer in biomedicine and health sciences. With strong expertise in health data science, medical informatics and artificial intelligence in healthcare, IACS operates at the intersection of research, policy and real-world health systems. Within SHAIPEd, IACS plays a central role in shaping how health data can be accessed, governed and reused to support the development and evaluation of AI-based medical devices. The team leads the definition of data flows and governance frameworks in the context of the EHDS and contributes methodological approaches to inform the adoption and reimbursement of AI technologies across European health systems. A key asset underpinning this work is **BIGAN**, the Aragón regional health data hub, providing access to high-quality data covering around 1.3 million individuals.

Building on long-standing experience in European health data initiatives, IACS helps translate EHDS secondary-use provisions into practical, operational solutions. At the same time, IACS highlights that a key challenge lies in aligning the perspectives of diverse stakeholders — from data providers and AI developers to regulators and health authorities. Achieving a shared understanding across technical, regulatory and clinical domains is essential to fully unlock the potential of AI-based medical devices within the EHDS.

“SHAIPEd represents the first EU-funded project in which an industrial community is challenged to explore the full potential of the EHDS. Defining a clear framework for the lifecycle of AI-based medical devices is both an opportunity and a responsibility for all partners involved.”
— IACS team

Legal landscape analysis – WP3

A joint analysis by SHAIPEP partners examines the European legal landscape relevant to AI as a medical device. Building on regulatory elements already introduced in previous newsletter editions, the analysis brings

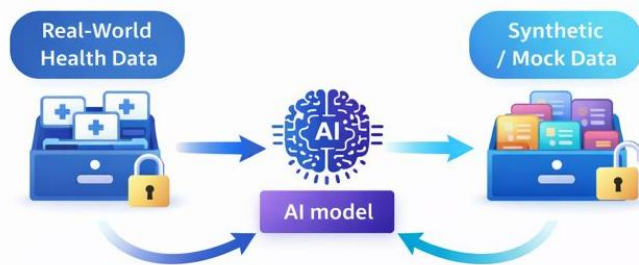
together and deepens the review of key frameworks such as the EHDS, the AI Act, MDR/IVDR and HTA, focusing on how these legislations interact and jointly shape the AI lifecycle in healthcare. It clarifies the roles and responsibilities of manufacturers, data users, notified bodies and HDABs, while recognising the evolving nature of the regulatory environment. The analysis further connects regulatory requirements to the different phases of the MDAI lifecycle, from early development and testing to certification, clinical adoption and post-market monitoring. By aligning legal obligations with practical development stages, the partners provide a shared reference to support regulatory readiness, cross-work package coordination and informed decision-making, helping to translate complex legislation into actionable and compliant innovation AI pathways in Europe.







Landscape analysis methods for proxy data generation and applicability – WP3



This work captures the collaborative efforts of SHAIPEP partners to map current methods for generating and using proxy data, with a focus on mockup and synthetic data for healthcare AI development. It reviews data modalities, generation techniques and available tools, highlighting how proxy data can support early experimentation, model development and testing when access to real-world health data is limited or delayed.

In parallel, the partners examine how proxy data can be evaluated in terms of quality, privacy and fitness for purpose, and how these practices align with EHDS principles. The work also explores how proxy data can complement regulated data access pathways, offering practical insights into the responsible use of synthetic and mock data to support innovation while remaining consistent with European legal, ethical and technical requirements.



Events of Interest for the SHAIPEd Community

 EHTEL Thought Leader
Symposium – “The EHDS is coming:
Let’s get people and data ready”
 Location: Helsinki, Finland
 Date: 19-21 January 2026
 [Event Details](#)

 Athens Digital Health Week 2026
 Location: Athens, Greece
 Date: 16-20 February 2026
 [Event Details](#)

 ICT&health World Conference
2026
 Location: Maastricht, Netherlands
 Date: 27-29 January 2026
 [Event Details](#)

 CoP SGs meeting and General
Assembly
 Location: Brussels, Belgium
 Date: 3-4 March 2026
 [Event Details](#)

 Data Privacy for Health Summit
2026
 Location: Brussels, Belgium
 Date: 29 January 2026
 [Event Details](#)

 European Digital Healthtech
Conference 2026
 Location: Luxembourg City,
Luxembourg
 Date: 26-27 March 2026
 [Event Details](#)

While winter may seem like a quieter season, it is often a time when foundations are strengthened and plans take shape. Within SHAIPEd, this period reflects steady progress behind the scenes, as regulatory, technical, and organisational work continues to mature. We are grateful for the ongoing collaboration and engagement of our partners and stakeholders, and we look forward to continuing this journey together in the months ahead.

