



SHAIPED

Welcome to the 5th volume of the SHAIPED Newsletter!

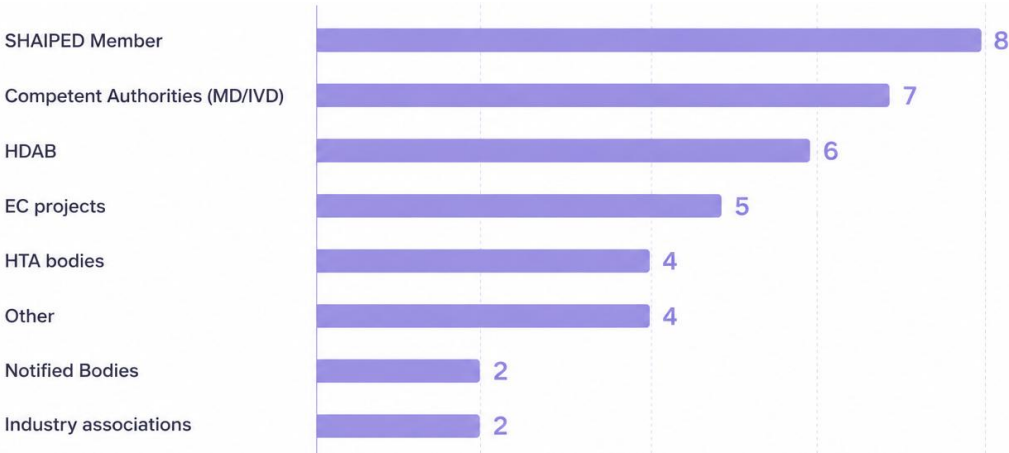
Dear colleagues and stakeholders,

The past few months have marked another important step forward for the SHAIPED project! Following our successful first SHAIPED Stakeholder Engagement Workshop on the Medical Device Artificial Intelligence (MDAI) lifecycle and the European Health Data Space (EHDS) integration, your feedback is already directly informing our next deliverables. In this issue, we highlight key contributions from consortium partners **INT** and **Erasmus MC**, and share what to expect at our upcoming SHAIPED Stakeholder Forum: *"Advancing AI Medical Devices in the EHDS"*. Happy reading!

Stakeholder Dialogue on AI Medical Devices and EHDS

Bringing together experts from across the European AI and health data ecosystem, the SHAIPEd Stakeholder Engagement Workshop took place online on 22 April 2026. The workshop served as an opportunity to present the project's proposed MDAI lifecycle while gathering feedback from stakeholders who will play a key role in implementing the EHDS. Discussions followed the four proposed phases of the MDAI lifecycle: from AI development and CE marking to adoption, reimbursement, and post-market monitoring. Rather than focusing solely on the proposed pathways, participants explored how these concepts could work in practice and identified the regulatory, technical, and organisational challenges that would need to be addressed to enable trustworthy AI across Europe.

Overview of stakeholder categories represented



Stakeholders highlighted the need for high-quality and harmonised datasets, clearer governance for the secondary use of health data, secure access through HDABs and SPE, and stronger interoperability between the EHDS, AI Act, and MDR/IVDR. Participants also emphasised the importance of reproducibility, data quality, long-term evidence generation, and practical mechanisms for supporting post-market surveillance, model drift monitoring, and regulatory oversight. Although several implementation challenges were identified, the discussion also demonstrated broad support for developing a harmonised European approach that simplifies access to high-quality health data while maintaining strong standards for privacy, security, and regulatory compliance. The insights collected will contribute to refining the proposed MDAI lifecycle, strengthening future project deliverables, and ensuring that SHAIPEd recommendations are grounded in real-world experience and the needs of the organisations that will ultimately implement them.

Partner perspectives in SHAIPEd: Insights from the project consortium



FONDAZIONE IRCCS
ISTITUTO NAZIONALE
DEI TUMORI

The Fondazione IRCCS Istituto Nazionale dei Tumori (INT) in Milan is one of Italy's leading comprehensive cancer centres, combining patient care, clinical research, and innovation in cancer prevention, diagnosis, and treatment. Its multidisciplinary approach brings together clinicians, radiologists, data scientists, bioengineers, and translational researchers to develop solutions that can be effectively implemented in clinical practice. Within SHAIPEd, INT contributes expertise in breast and thoracic oncology, supported by access to large-scale real-world imaging data. The organisation's contribution is further strengthened through **AI ON LAB**, an interdisciplinary laboratory focused on developing clinically applicable AI solutions in oncology. As part of the oncology use case in WP5, INT is providing mammography and chest CT datasets and supporting the creation of high-quality reference information through expert lesion annotation and clinical validation, helping evaluate AI tools designed for cancer detection in real-world settings. For INT, SHAIPEd addresses one of the key challenges in healthcare AI: access to high-quality, harmonised data and reliable evaluation pathways. By connecting clinical expertise, data infrastructures, and governance frameworks, the project supports the development of AI tools that are not only innovative but also trustworthy, reproducible, and ready for real-world use.

The team also sees strong potential in establishing common evaluation methodologies and secure pathways for testing AI-enabled medical devices across Europe. Beyond SHAIPEd, INT contributes to several national and international initiatives, including **APOLLO11**, **I3LUNG**, and **Cancer Core Europe**, all focused on leveraging diverse oncology data sources to support better clinical decision-making and advance innovation in cancer care.

“For patients and citizens, the most important benefit is the prospect of receiving care supported by AI tools that have been evaluated on diverse, real-world data rather than only on narrow development datasets.”

– INT team

Partner perspectives in SHAIPEd: Insights from the project consortium



Erasmus MC, the Imaging Office of the Department of Radiology & Nuclear Medicine supports a wide range of imaging-related activities, from data management and storage to automated image analysis and clinical implementation. By serving as a gateway to the department's expertise and technological capabilities, the team helps bridge the gap between research, clinical practice, and innovation. Its role as the **Population Imaging Flagship** node and connection to **Euro-BiolImaging** further extend these activities to the European level. A multidisciplinary team of radiologists, AI researchers, data stewards, and research software engineers contributes this expertise. As part of the project's oncology use case in WP5, Erasmus MC is currently providing mammography and lung CT datasets, supporting the development and validation of AI-enabled medical devices in a real-world setting. Through this work, the team is gaining valuable experience with the tools, methodologies, and governance models that will underpin future EHDS-compliant access to health data. Preparing healthcare organisations for the EHDS is one of the key motivations behind Erasmus MC's involvement in SHAIPEd. The team views data standardisation as one of the main challenges on the path towards interoperability and large-scale secondary use of health data and is actively promoting harmonized data structures and FAIR metadata practices. At the same time, the project offers a unique opportunity to test EHDS-compliant approaches to sharing imaging data and to align these efforts with broader national initiatives in the Netherlands. They are active contributor to **EUCAIM**, the **European Cancer Imaging Initiative**, which is currently evolving into a **European Digital Infrastructure Consortium (EDIC)**. Through this engagement, Erasmus MC is helping shape future frameworks, tools, and best practices that will support EHDS implementation and facilitate secure cross-border use of health data.

"EHDS-compliant access to imaging data can accelerate the development and validation of AI tools that have positive health benefits for patients and reduce the workload of researchers and healthcare professionals."
- Erasmus MC team

STAKEHOLDER FORUM

Shaping the future of AI Medical Devices in Europe



5 OCTOBER 2026



PARIS, FRANCE
& ONLINE



REGISTRATION OPEN!



The forum will bring together representatives from regulatory authorities, HDABs, HTA organisations, Notified Bodies, healthcare providers, industry, academia and European initiatives to discuss one central question:

How can Europe create a more effective ecosystem for developing, validating and deploying AI Medical Devices?

Session 1 – Ecosystem Dialogue: Making Europe Developer-Friendly for Medical AI. An interactive discussion exploring regulatory pathways, access to health data, evidence generation and practical barriers to bringing AI Medical Devices to the European market.

Session 2 – Data Readiness Reality Check: Is the Data Actually AI-Ready? Implementation-focused case studies and a multi-stakeholder discussion on data quality, secondary use of health data and real-world evidence for AI.

Rather than traditional presentations, the forum is designed to encourage practical discussions, exchange experiences across stakeholder groups and identify actionable recommendations that will contribute to the ongoing work of the SHAIPEd.

[Register here!](#)

Events of Interest for the SHAIPEd Community



EHFG 2026



29 September – 2 October 2026



Bad Hofgastein, Austria



[Event Details](#)



Building Commons for Clinical LLMs



1 – 2 October 2026



Paris, France



[Event Details](#)



International AI Summit 2026



14 October 2026



Dublin, Ireland



[Event Details](#)



European Health Data and Innovation Congress (EHDPC) 2026



14 – 16 October 2026



Paris, France



[Event Details](#)



HTA Stakeholder Network



23 October 2026



TBD



[Event Details](#)



EPHC 2026



10 – 13 November 2026



Bilbao, Spain



[Event Details](#)



Apply AI Summit



17 November 2026



Brussels, Belgium & Online



[Event Details](#)

As we take a short break for the summer, we would like to thank you for being part of the SHAIPEd community and for your continued support throughout the project. We wish you a relaxing summer, time to recharge, and we look forward to seeing you again this autumn!

