<u>IHE-Europe statement on the proposal for a European Health Data Space (EHDS)</u>

IHE-Europe welcomes the initiative of the European Health Data Space (EHDS) regulation, recognizing its significance in advancing the accessibility and exchange of health data across the European Union. IHE–Europe has been supporting the creation of the European eHealth Digital Services Infrastructure (eHDSI) from the beginning. IHE Profiles for the exchange of documents are at the core of the eHDSI, and the IHE Gazelle platform supports the execution of tests. IHE-Europe continues to support this initiative through engagement in current European Commission projects like XpanDH and xShare, contributing expertise to foster a more integrated and efficient healthcare ecosystem.

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

IHE facilitates healthcare information technology (HIT) interoperability through a four-step process which is an established ISO standard (the IHE Methodology): defining use cases, creating specifications on base of international standards, implementing in HIT systems, and testing at Connectathons. Over 200 global organisations contribute, and domain committees address interoperability in various clinical domains. The developed specifications are regrouped in Integration Profiles that provide a standards-based framework, tested at Connectathons involving 250+ vendors.

This process is extremely valuable for the vendors to assess the conformity of their products against IHE Profiles ensuring successful implementation of digital health solutions.

What is being proposed by the regulation is a complex and challenging project, and goes beyond what most countries in Europe have achieved so far in their national infrastructure.

We complement to base the EHDS on the proven concepts of the eHDSI and EEHRxF and recommend to continue to build out the specifications by profiling established international standards.

We believe that in the work related to the adoption of the regulation a broad community of stakeholders needs to be involved.

IHE-Europe and the National IHE Deployment Committees in Europe remain committed to support the European Commission and the digital health authorities in implementing the European Health Data Space throughout Europe by engaging in projects for defining the technical specifications, organising IHE Connectathons and Projectathons, and providing test infrastructure. IHE-Europe also offers to participate in the Advisory Forum to the EHDS board, which has been proposed by the European Parliament.

Sincerely,

Co-chairs of IHE-Europe

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About IHE-Europe: The mission of IHE-Europe is to improve patient care by advancing the interoperability of healthcare IT systems and the appropriate sharing of relevant information. Towards that end, IHE-Europe conducts education, testing, demonstrations and other activities promoting the deployment within Europe of systems compliant with the IHE Technical Frameworks developed by IHE International. IHE-Europe interacts with relevant governmental and non-governmental organisations in Europe. It also maintains close contacts with similar initiatives around the world.