

Press release

Launch of Innovative Health Initiative project

MedTechLabel: Unified Digital Labelling for Medical Technology Products

April 20 2026

The Innovative Health Initiative (IHI) funded research project **MedTechLabel** is launched as a public-private partnership that aims to unify, standardize and harmonize Medical Devices (MD) and In Vitro Diagnostic (IVD) labelling. Our goal is to specify and test a framework for a unified digital labelling system for Medical Devices and IVDs. This unique public-private partnership is co-led by the University of Oslo (scientific coordinator) and Arthrex GmbH (industry lead) and has 20 consortium partners from 11 countries across Europe and the US.

The project

MedTechLabel's mission is to create and verify a unified digital labelling framework for medical technology products (MD/IVD). The project will develop the MedTechLabel framework specification that covers all categories and classes of MDs and IVDs. The framework will harmonize and standardize digital labelling processes in compliance with EU regulations, while being adaptable to national variations, future legislation, and global development.

Prof. Anne Moen, University of Oslo, MedTechLabel Scientific Coordinator

With the MedTechLabel public-private partnership, we set out to deliver a consensus-based digital labelling framework specification with required information for digital labelling of MDs and IVDs of all categories and classes. Our ambition is to reshape MD and IVD labelling practices, improve user experience and add value by addressing pressing needs for consistent and comprehensive digital labelling information.

MedTechLabel will address two key challenges: **i)** scalability and efficiency by more digitalization of labelling information, and **ii)** more accessible information for diverse users, with curated displays that support different roles and needs. MedTechLabel digital labelling framework specification seeks for consensus among all involved stakeholders: from manufacturers, notified bodies (NB), regulators, health authorities, to healthcare professionals, patients, and more.

Roger Peterson, Arthrex GmbH, MedTechLabel Industry Lead

From the industry perspective, there is an urgent need to harmonize and standardize digital labelling to significantly enhance operational efficiency and regulatory compliance. The collaboration in MedTechLabel promises strong and unique results that will progress much-needed evolution; harmonization and standardization of the medical technology products (MD/IVD) labelling practices.

This project will specify, test and assess the usefulness of the framework specification in a set of use cases with MD/IVD digital content, and demonstrate the added value of our approach for digital labelling to manufacturers, label users, NBs, regulators, and other stakeholders. We will progress to an International Workshop Agreement (IWA) for further consensus on ISO standards and policy recommendations, offering a foundation for further progress. Digital labelling can also reduce carbon footprint and water waste of physical labels, aligning with the EU Green Deal goals.

Supported by a grant from IHI

The MedTechLabel project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU), under grant agreement No 101251320. The JU receives support from the European Union's

Horizon Europe research and innovation programme and COCIR, EFPIA, Europa Bío, MedTech Europe, and Vaccines Europe.

Project Facts

Name: MedTechLabel: Unified Digital Labelling for Medical Technology Products

Grant Agreement Number: 101251320

Start date: 01/04/2026

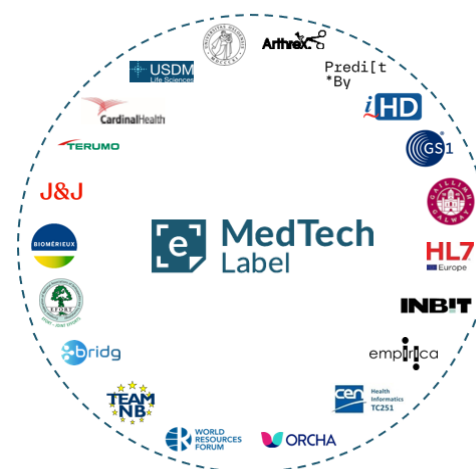
Duration: 36 months

Budget: 11 704 133 Euro (Horizon Europe and IHI Private members)

A robust public-private partnership

MedTechLabel brings together 14 public and 6 private partners from 11 countries, including University and Research Institutes, Notified Bodies (NBs), Standard Development Organisations (SDOs), SMEs, health authorities and procurers, and IHI private members representing MD/IVD manufacturers.

This positions the consortium with its diverse expertise and broad network to address challenges and leverage opportunities in the MD/IVD digital labelling landscape to ensure real-world relevance of the MedTechLabel framework specifications.



Partnership – consortium members

Norway	Universitet i Oslo (Scientific coordinator and Grant administrator)
Germany	Arthrex GmbH (Industry Lead) empirica Gesellschaft für Kommunikations- und Technologieforschung GmbH
Spain	PredictBy Research and Consulting S.L.
Belgium	The European Institute for Innovation Through Health Data GS1 AISBL HL7 Europe The European Association of Medical Devices-Notified Bodies Janssen Pharmaceutica NV Terumo Europe
Ireland	University of Galway Cardinal Health Ireland Manufacturing Ltd

Greece	Institoyto Bioiatrikis Texnologias
Netherlands	Better Standards for E-Health B.V. Orcha Health B.V.
Switzerland	World Resources Forum Association European Federation of National Associations of Orthopaedics and Traumatology
Estonia	Bridg OÜ
France	bioMérieux SA
USA	US Data Management, LLC

About IHI

The Innovative Health Initiative (IHI) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT, and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry). The goals are to translate health research and innovation into tangible benefits for patients and society and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. By supporting projects that bring diverse sectors together, IHI will pave the way for a more integrated approach to healthcare, covering prevention, diagnosis, treatment, and disease management.

Contact Information

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YouTube: [MedTechLabel](#)

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