Unified Digital Labelling for MD/IVD

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FACTS & FIGURES

Start date:	01.04.2026
End date:	31.03.2029
IHI funding:	3 806 900 €
Industry contribution:	8 189 233 €
Total Cost:	11 996 133 €
Coordinator:	University of Oslo
Industry lead:	Arthrex GmbH
Project website:	medtechlabel-ihi.eu
Social media:	@MedTechLabel IHI

CHALLENGE

Medical device and IVD Labelling: Navigating the transition to digital information.

Key challenges:

- **Disconnected sources** of information and standards
- Regulatory **complexity**
- Diverse **user needs**
- Lack of **harmonization**

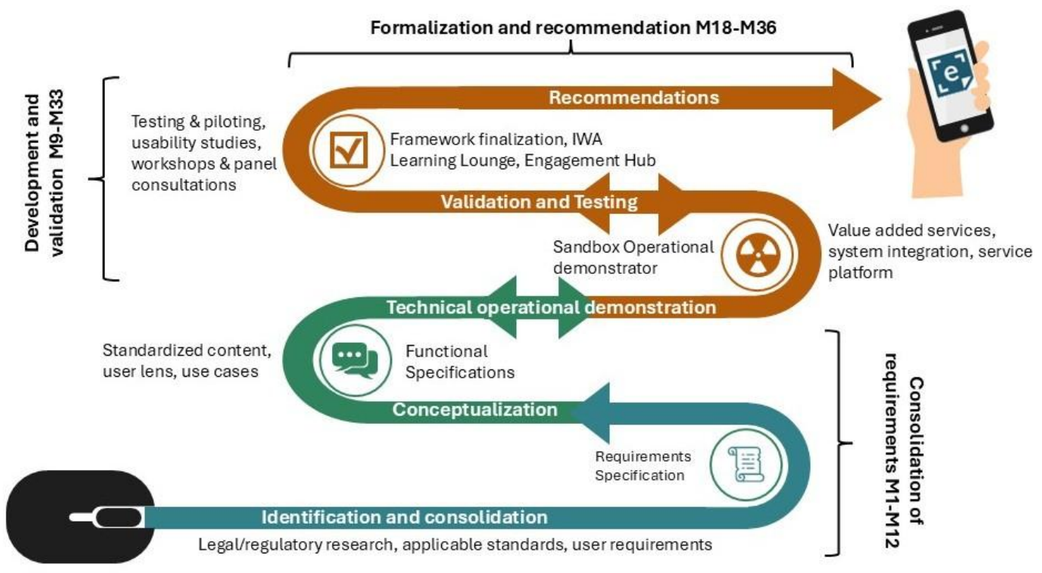
We develop a stakeholder-centered Digital Labelling Framework Specification.

My contribution focuses on stakeholder requirements, user lens development and framework validation.

APPROACH & METHODOLOGY

From identification to harmonization: Building the MedTechLabel Framework Specification

Regulatory requirements, standards, current practices and stakeholder needs are identified and consolidated into a common evidence base.



Through conceptualization, technical demonstration, testing and validation, the framework will be refined to support harmonization and future standardization through an International Workshop Agreement (IWA).

RESULTS

In the WP I am co-leading, we are building the foundation for the MedTechLabel Framework Specification.

Expected outputs include:

- Consolidated regulatory and standards requirements
- Mapping and analysis of current practices
- Stakeholder-informed use scenarios



VALUE OF IHI COLLABORATION

The IHI public-private partnership enables international, multi-stakeholder collaboration that would be difficult to achieve through individual organizations or national initiatives alone.

Through MedTechLabel, I work in an ecosystem that combines regulatory expertise, standards development, digital infrastructure and stakeholder engagement capacities needed to develop and validate the MedTechLabel Framework Specification.



This enables me to contribute to consensus-building, service innovation and future harmonization across regulatory, technical and user communities.

CAREER IMPACT

Participation in public-private projects has:

- Expanded my experience in international public-private, multi-stakeholder and trans-disciplinary collaboration across diverse communities
- Strengthened my leadership capacity and accelerated my development as an independent researcher
- Opened new opportunities for service innovation and future European research collaboration.

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